

5 ENVIRONMENTAL ASSESSMENTS

5.1 Camel Snus Frost: Advertising Execution #1

This Environmental Assessment (EA) is required for authorization of Camel Snus Frost as a modified risk tobacco product as communicated per [Advertising Execution 1](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.1.1 Description of Proposed Action

5.1.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.1.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Frost as a modified risk tobacco product.

5.1.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Frost	0.6 gram	9.0 gram

Package Description

Camel Snus Frost is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.1.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Frost while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Frost. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 1](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.1-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 0.4% of current regular cigarette smokers. Apportionment to the Camel Snus Frost style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Frost represents 32.9% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Frost, due to introduction of the proposed modified risk advertising, is 0.13% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.13% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.1-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

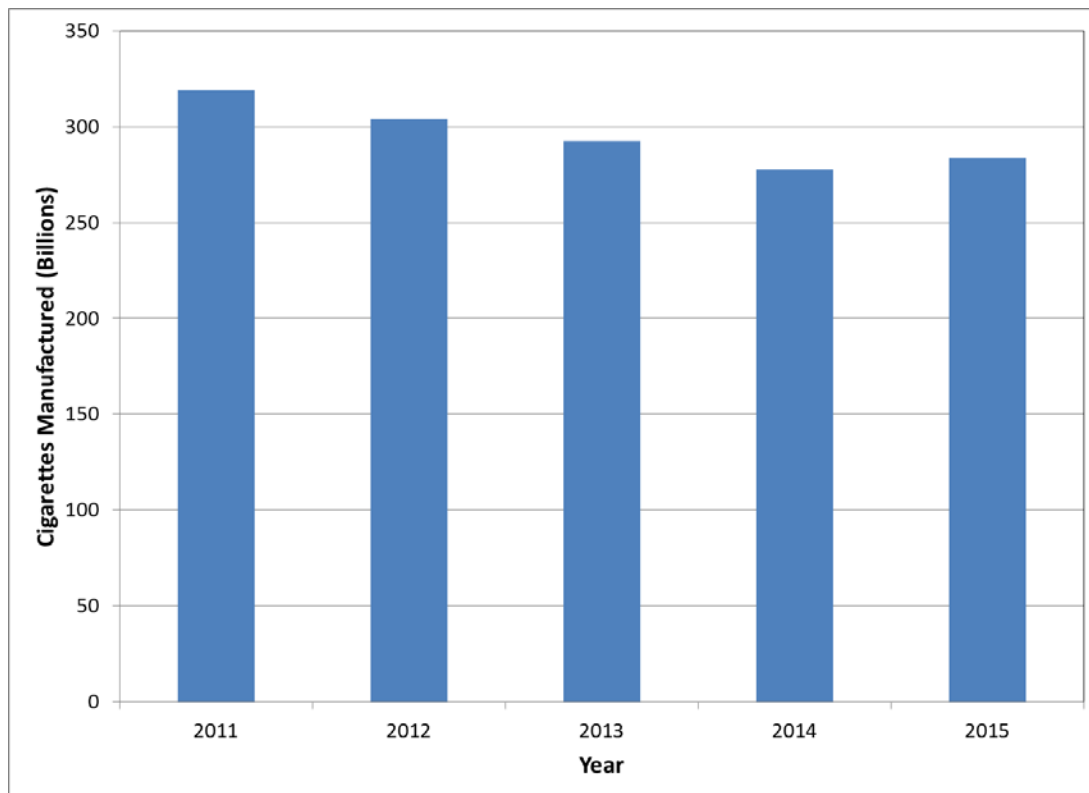
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	5.8%	2.1%	0.4%
Control (without proposed modified risk messaging)	5.4%	2.2%	0.4%
Net Impact of Test after correcting for Control	0.4%	-	-

5.1.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.1-1](#)).

Figure 5.1-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.1-2](#).

Table 5.1-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.13% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.1-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.1-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.13% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost. Total ammonia and nicotine emissions are expected to decrease by 33.9 and 51.6 pounds per year, respectively, based upon the proposed action.

Table 5.1-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	32.3
Ammonia (Total off-site release)	499	1,545	1,238	1.6
Ammonia (Total)	10,398	32,192	25,797	33.9
Nicotine (Total on-site release)	13,865	42,926	34,398	45.3
Nicotine (Total off-site release)	1,942	6,012	4,818	6.3
Nicotine (Total)	15,807	48,938	39,216	51.6

5.1.2.2 Environmental Consequences from Manufacturing Camel Snus Frost

Waste generated as a result of manufacturing Camel Snus Frost is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Frost releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Frost use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Frost. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Frost is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.1-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Frost due to the proposed order are summarized in [Table 5.1-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Frost (~ 1.5%); (c) the average rate of each emission type per pound of Camel Snus Frost tobacco manufactured in 2015 and (d) the number of smokers (~ 52,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Frost (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.13% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.1-2](#) and [Figure 5.1-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.1-4](#) and [Table 5.1-5](#), respectively.

Figure 5.1-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

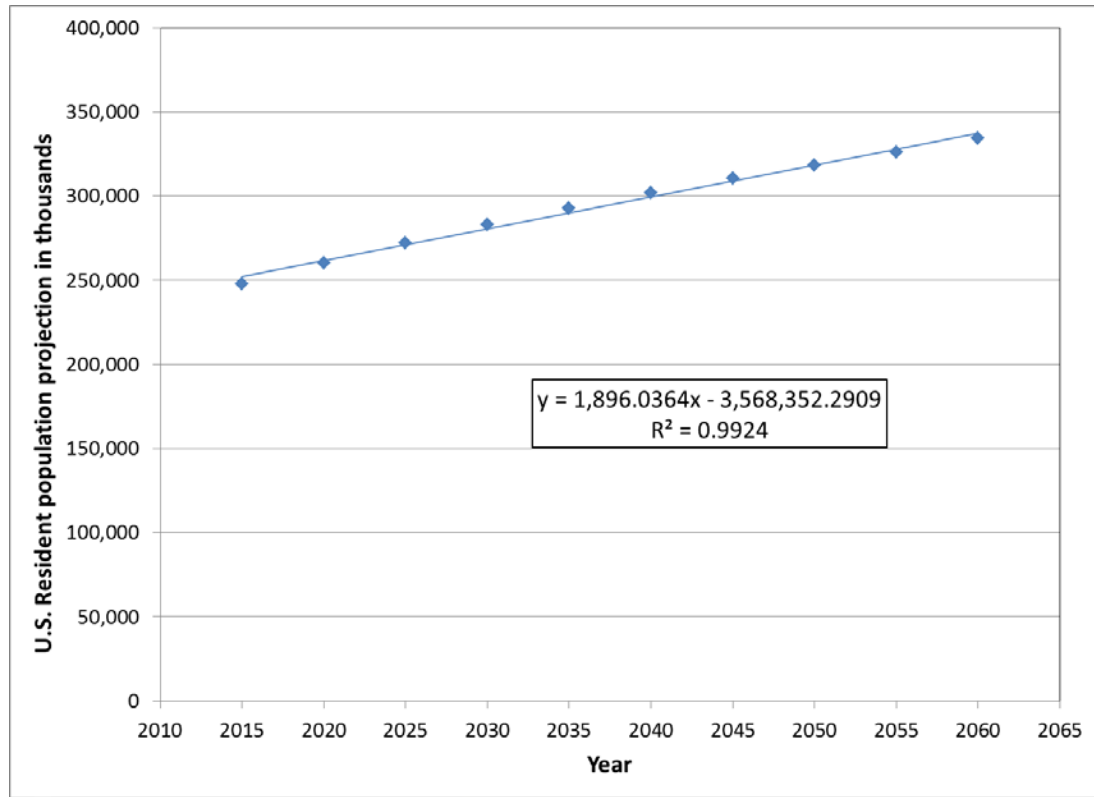


Table 5.1-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.1-3: Adult Smoking Incidence 2001 – 2014

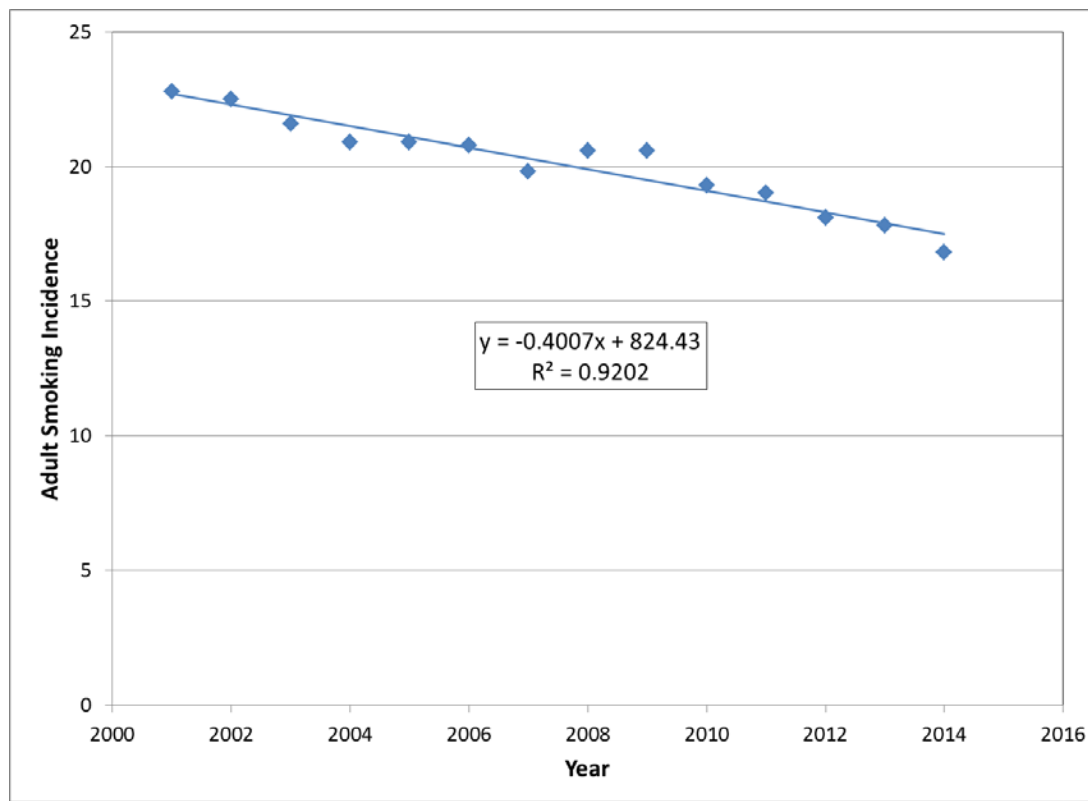


Table 5.1-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 ([Table 5.1-6](#)). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Frost production and associated manufacturing emissions. Based on 0.1316% of the projected smokers switching to the use of 5 pouches of Camel Snus Frost per day, an additional 124,767 pounds of Camel Snus Frost will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Frost will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Frost each day is greater than current Camel Snus Frost use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.1-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Frost production, total ammonia and nicotine emissions are expected to increase by 28 and 146 pounds per year, respectively, based upon the proposed action ([Table 5.1-7](#)).

Table 5.1-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Frost

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Frost Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Frost	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	31	0.111	14
Ammonia (Total off-site release)	2,123	33	0.116	14
Ammonia (Total)	4,159	64	-	28
Nicotine (Total on-site release)	11,293	174	0.615	77
Nicotine (Total off-site release)	10,168	157	0.553	69
Nicotine (Total)	21,461	331	-	146

5.1.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.1-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.09% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.1-8](#)).

Figure 5.1-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

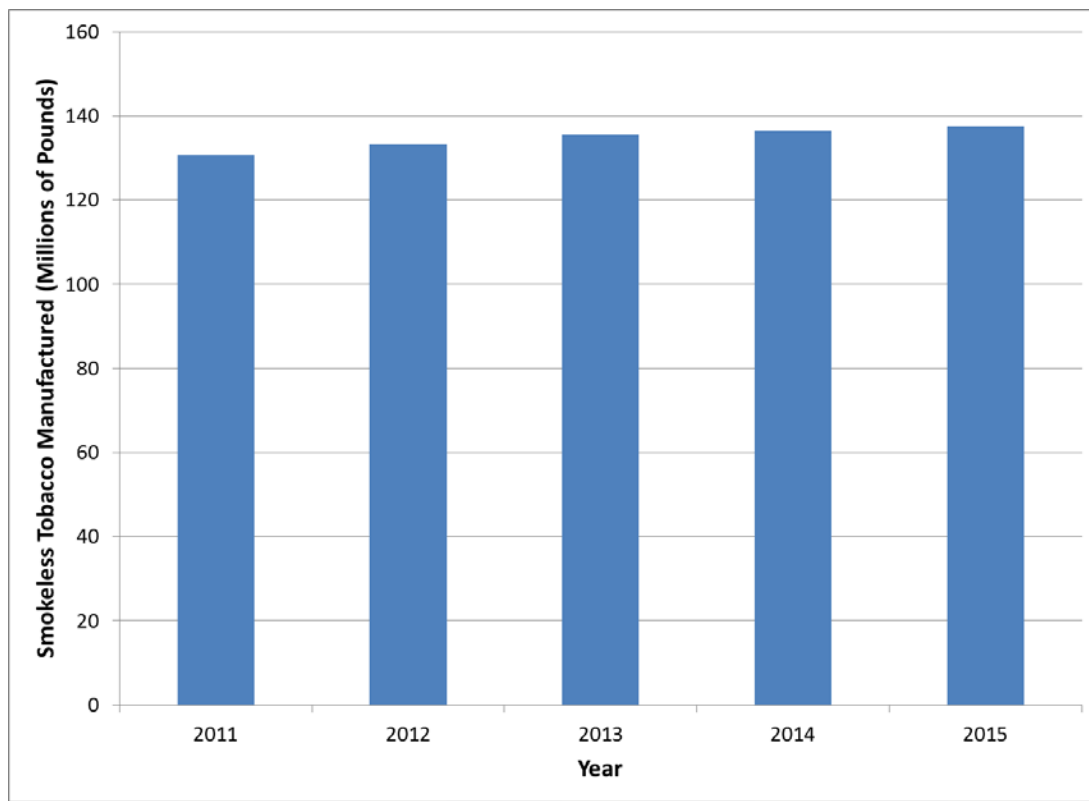


Table 5.1-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	14	15,233	0.09
Ammonia (Total off-site release)	0.116	14	15,884	0.09
Ammonia (Total)	-	28	31,117	0.09
Nicotine (Total on-site release)	0.615	77	84,492	0.09
Nicotine (Total off-site release)	0.553	69	76,075	0.09
Nicotine (Total)	-	146	160,567	0.09

5.1.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.1-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 6.6×10^{-06} percent decrease) and the increase in Camel Snus Frost production has a negligible impact (a 6.9×10^{-06} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.1-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.1-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	299.3 million cigarettes	23,309	10,918	34,226
Increases from Camel Snus Frost	124,767 pounds	8,593	27,224	35,817

5.1.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Frost and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.1.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Frost accounted for ~ 0.21% by weight of the smokeless tobacco manufactured in the United States and ~ 26% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 52,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, resulting in a decrease of ~ 300 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 124,767 pounds of Camel Snus Frost will be manufactured based upon those smokers using 5 pouches of Camel Snus Frost per day.

5.1.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Frost. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Frost. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 300 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.1.4 Environmental Introduction as a Result of Disposal after Product Use

5.1.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Frost in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Frost includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Frost consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.1-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.1-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Frost are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.1-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

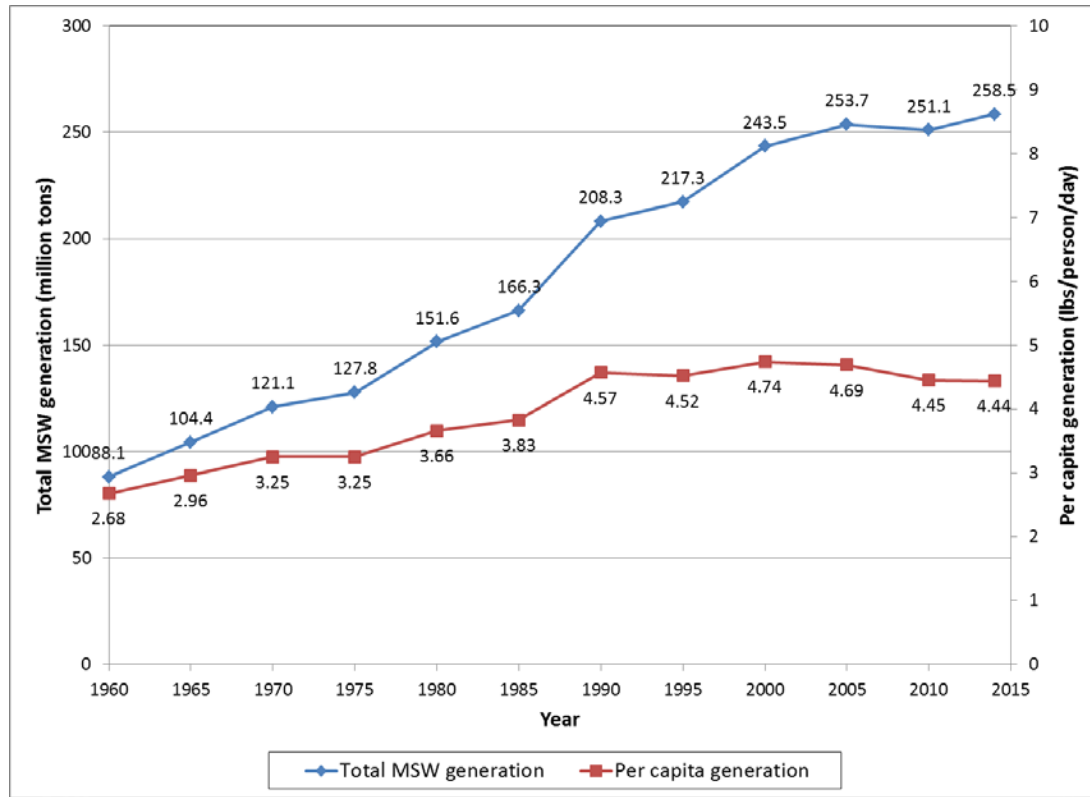
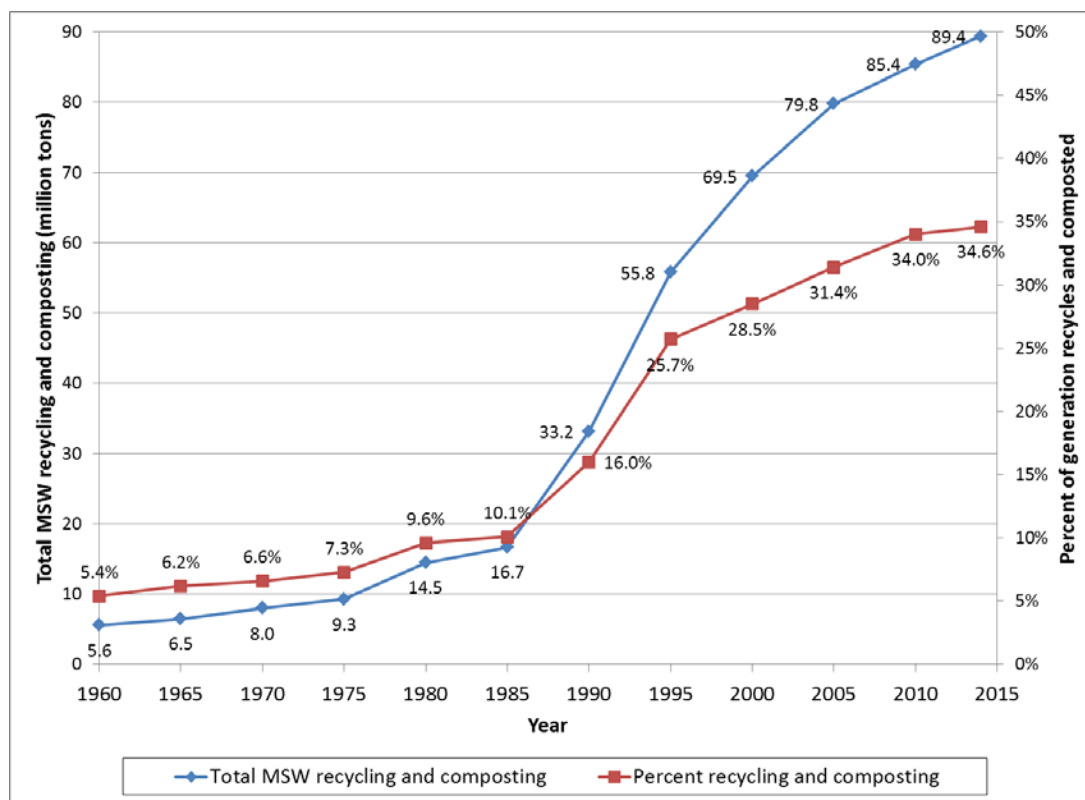


Figure 5.1-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.1.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.1.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Frost

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 52,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, resulting in a decrease of ~ 300 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 300 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.1-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 58 tons per year.

Table 5.1-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	173.9	64,439	32.2
“100 mm” (90 – 101 mm)	40.8	122.0	50,560	25.3
“120 mm” (118 – 120 mm)	1.1	3.4	1,356	0.7
Total (All styles)	100	299.3	116,355	58.2

Based on the proposed action resulting in ~ 52,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, it is estimated that an additional 124,767 pounds of Camel Snus Frost will be manufactured if those smokers use 5 pouches of Camel Snus Frost per day each day of the year. Waste generated due to Camel Snus Frost use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Frost tobacco will become waste for disposal after use, resulting in an increase of ~ 62 tons of used Camel Snus Frost pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 2.3×10^{-05} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Frost used pouch disposal has a negligible impact (a 2.4×10^{-05} percent increase) to the MSW stream, based on the same figures ([Table 5.1-11](#)).

Table 5.1-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	58	2.3×10^{-05}
Increase in used Camel Snus Frost pouches	62	2.4×10^{-05}

5.1.4.2.2 Disposal of Cigarette and Camel Snus Frost Packaging Material

Based on ~ 52,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 15 million fewer cigarette packs and approximately 1.5 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 6.3 million more Camel Snus Frost tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.1-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.1-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 151 tons per year ([Table 5.1-13](#)).

Camel Snus Frost Packaging weights are summarized in [Table 5.1-14](#). The Camel Snus Frost package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Frost use, it is estimated that packaging waste will increase by 154 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 5.9×10^{-05} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Frost packaging disposal will have a negligible impact (a 6.0×10^{-05} percent increase), based on the same figures ([Table 5.1-15](#)).

Table 5.1-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.1-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	869,393	173,327	86.7
"100 mm" (90 – 101 mm)	40.8	609,935	125,499	62.7
"120 mm" (118 – 120 mm)	1.1	17,148	3,880	1.9
Total (All styles)	100	1,496,476	302,706	151

Table 5.1-14: Camel Snus Frost Packaging Weights

Camel Snus Frost Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.1-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	151	5.9×10^{-05}
Increase in Camel Snus Frost packaging waste	154	6.0×10^{-05}

5.1.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Frost will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.1.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.1.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.1.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 52,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 300 million fewer cigarettes will be manufactured and that approximately 94 million more pouches of Camel Snus Frost will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.1-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.1-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost	Net Change Due to the Proposed Action
Electricity (thousand kWh)	567	63	-505
Water (ccf)	100,859	5,091	-95,767
Natural gas (ccf)	16,592	1,747	-14,845

5.1.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.1.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 52,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 300 million fewer cigarettes will be manufactured and that approximately 94 million more pouches of Camel Snus Frost will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.1-17](#) summarizes projected annual changes in GHG

emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.1-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	775	84	-691

5.1.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Frost manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps² made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals³ and plants⁴ and (b) the endangered and threatened species listed in Appendices I, II, and III⁵ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Frost manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Frost are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

² Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

³ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁴ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

⁵ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Frost are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Frost have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.1.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.1.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Frost as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Frost as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.1.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.2 Camel Snus Mint: Advertising Execution #1

This Environmental Assessment (EA) is required for authorization of Camel Snus Mint as a modified risk tobacco product as communicated per [Advertising Execution 1](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.2.1 Description of Proposed Action

5.2.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.2.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Mint as a modified risk tobacco product.

5.2.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Mint	0.6 gram	9.0 gram

Package Description

Camel Snus Mint is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.2.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Mint while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Mint. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 1](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.2-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 0.4% of current regular cigarette smokers. Apportionment to the Camel Snus Mint style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Mint represents 8.7% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Mint, due to introduction of the proposed modified risk advertising, is 0.03% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.03% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.2-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

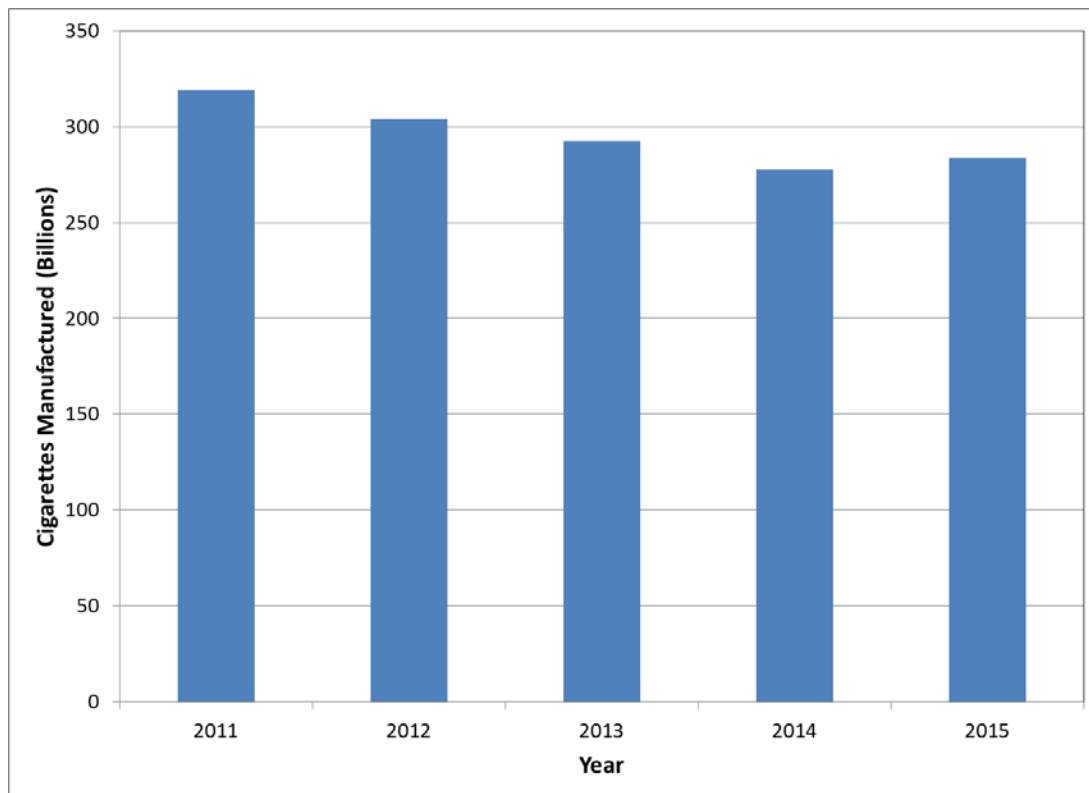
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	5.8%	2.1%	0.4%
Control (without proposed modified risk messaging)	5.4%	2.2%	0.4%
Net Impact of Test after correcting for Control	0.4%	-	-

5.2.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.2-1](#)).

Figure 5.2-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.2-2](#).

Table 5.2-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.03% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.2-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.2-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.03% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint. Total ammonia and nicotine emissions are expected to decrease by 9 and 14 pounds per year, respectively, based upon the proposed action.

Table 5.2-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	9
Ammonia (Total off-site release)	499	1,545	1,238	0.4
Ammonia (Total)	10,398	32,192	25,797	9
Nicotine (Total on-site release)	13,865	42,926	34,398	12
Nicotine (Total off-site release)	1,942	6,012	4,818	2
Nicotine (Total)	15,807	48,938	39,216	14

5.2.2.2 Environmental Consequences from Manufacturing Camel Snus Mint

Waste generated as a result of manufacturing Camel Snus Mint is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Mint releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Mint use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Mint. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Mint is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company.

The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.2-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Mint due to the proposed order are summarized in [Table 5.2-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Mint (~ 0.4%); (c) the average rate of each emission type per pound of Camel Snus Mint tobacco manufactured in 2015 and (d) the number of smokers (~ 14,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Mint (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.03% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.2-2](#) and [Figure 5.2-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.2-4](#) and [Table 5.2-5](#), respectively.

Figure 5.2-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

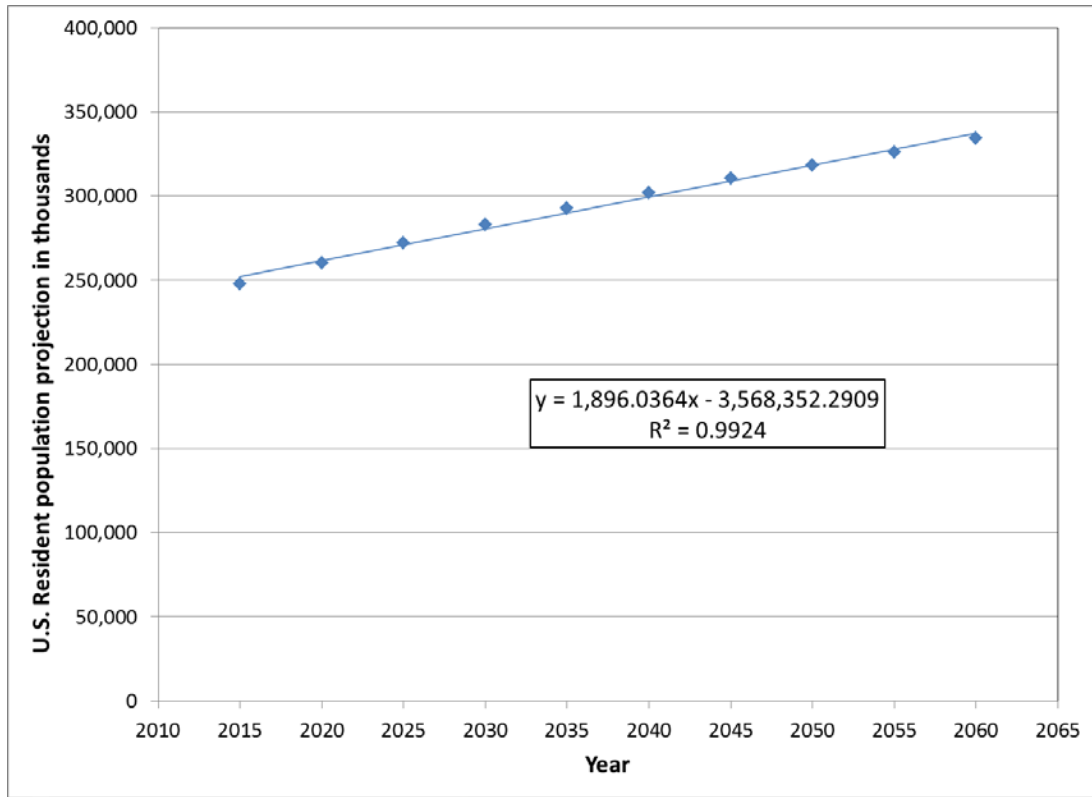


Table 5.2-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.2-3: Adult Smoking Incidence 2001 – 2014

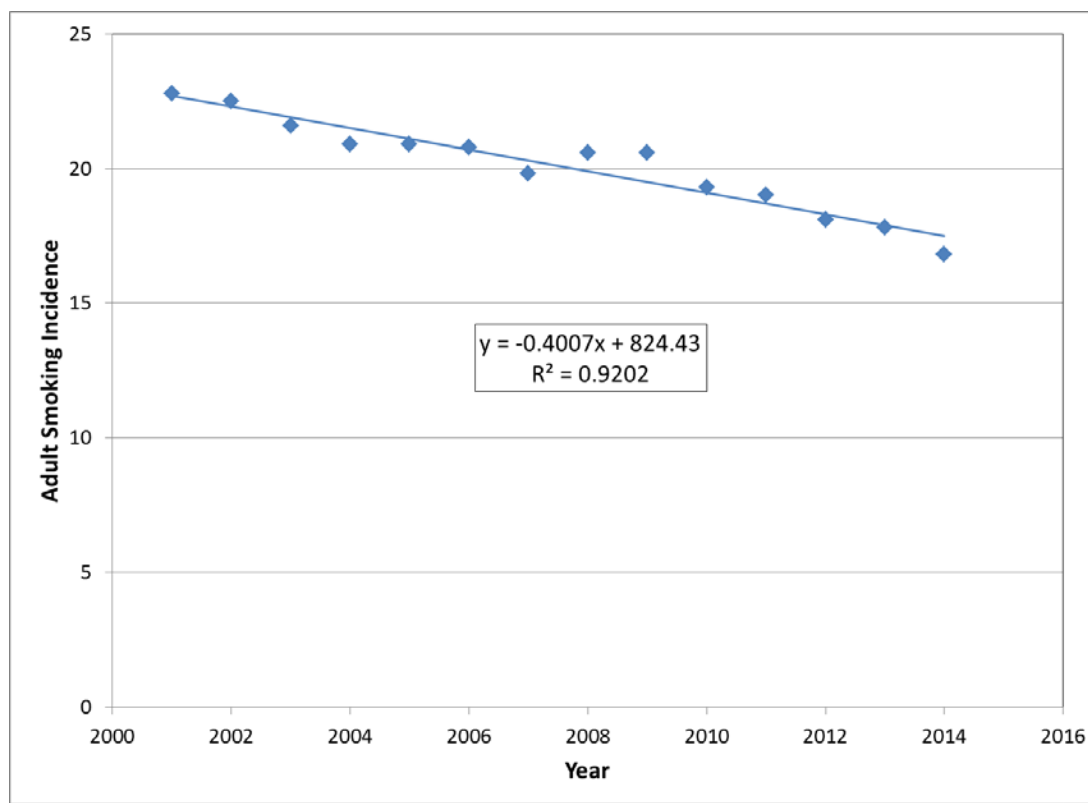


Table 5.2-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.2-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Mint production and associated manufacturing emissions. Based on 0.0348% of the projected smokers switching to the use of 5 pouches of Camel Snus Mint per day, an additional 32,993 pounds of Camel Snus Mint will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Mint will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Mint each day is greater than current Camel Snus Mint use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.2-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Mint production, total ammonia and nicotine emissions are expected to increase by 7 and 39 pounds per year, respectively, based upon the proposed action ([Table 5.2-7](#)).

Table 5.2-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Mint

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Mint Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Mint	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	8	0.111	4
Ammonia (Total off-site release)	2,123	9	0.116	4
Ammonia (Total)	4,159	17	-	7
Nicotine (Total on-site release)	11,293	46	0.615	20
Nicotine (Total off-site release)	10,168	41	0.553	18
Nicotine (Total)	21,461	87	-	39

5.2.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.2-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.02% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.2-8](#)).

Figure 5.2-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

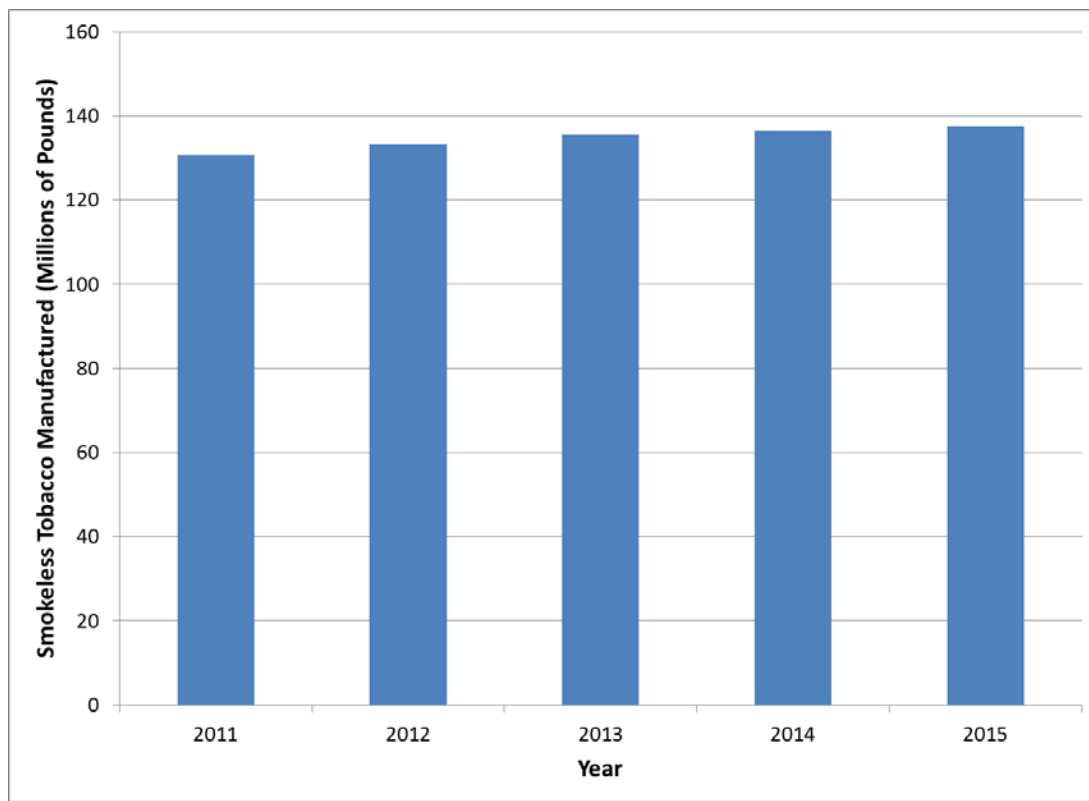


Table 5.2-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	4	15,233	0.02
Ammonia (Total off-site release)	0.116	4	15,884	0.02
Ammonia (Total)	-	7	31,117	0.02
Nicotine (Total on-site release)	0.615	20	84,492	0.02
Nicotine (Total off-site release)	0.553	18	76,075	0.02
Nicotine (Total)	-	39	160,567	0.02

5.2.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.2-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 1.75×10^{-6} percent decrease) and the increase in Camel Snus Mint production has a negligible impact (a 1.83×10^{-6} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.2-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.2-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	79.1 million cigarettes	6,164	2,887	9,051
Increases from Camel Snus Mint	32,993 pounds	2,272	7,199	9,471

5.2.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Mint and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.2.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Mint accounted for ~ 0.05% by weight of the smokeless tobacco manufactured in the United States and ~ 7% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 14,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, resulting in a decrease of ~ 79 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 32,993 pounds of Camel Snus Mint will be manufactured based upon those smokers using 5 pouches of Camel Snus Mint per day.

5.2.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Mint. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Mint. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 79 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.2.4 Environmental Introduction as a Result of Disposal after Product Use

5.2.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Mint in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Mint includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Mint consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.2-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.2-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Mint are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.2-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

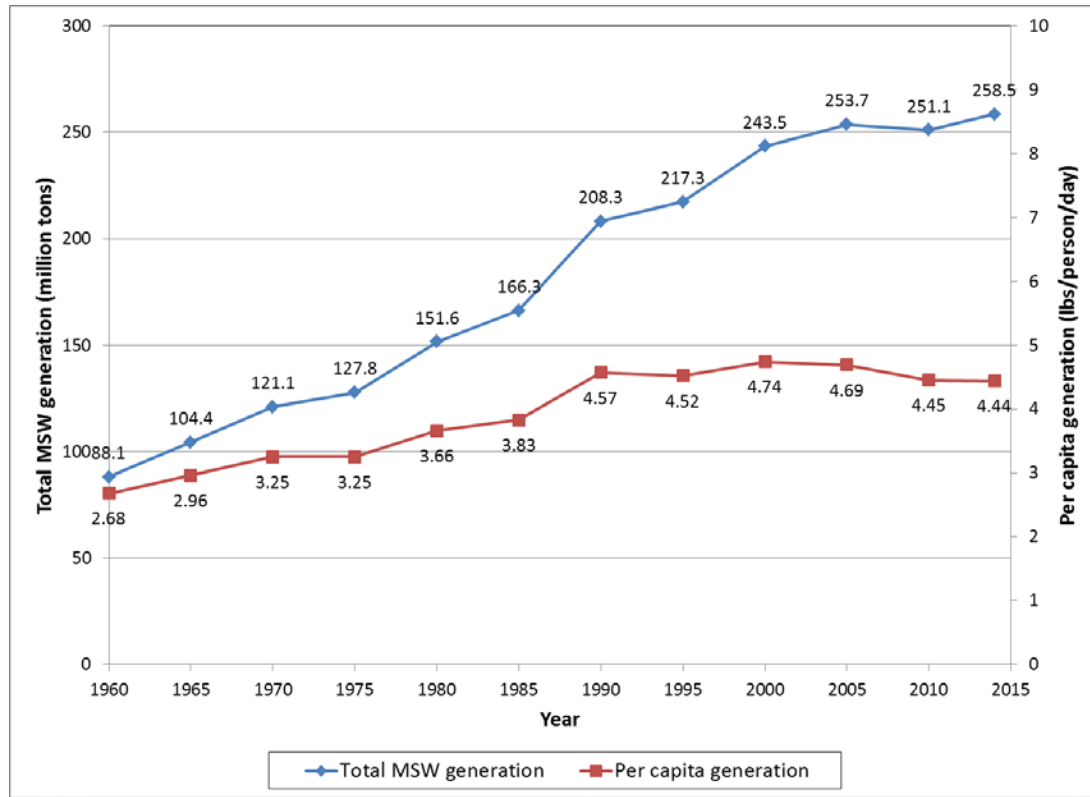
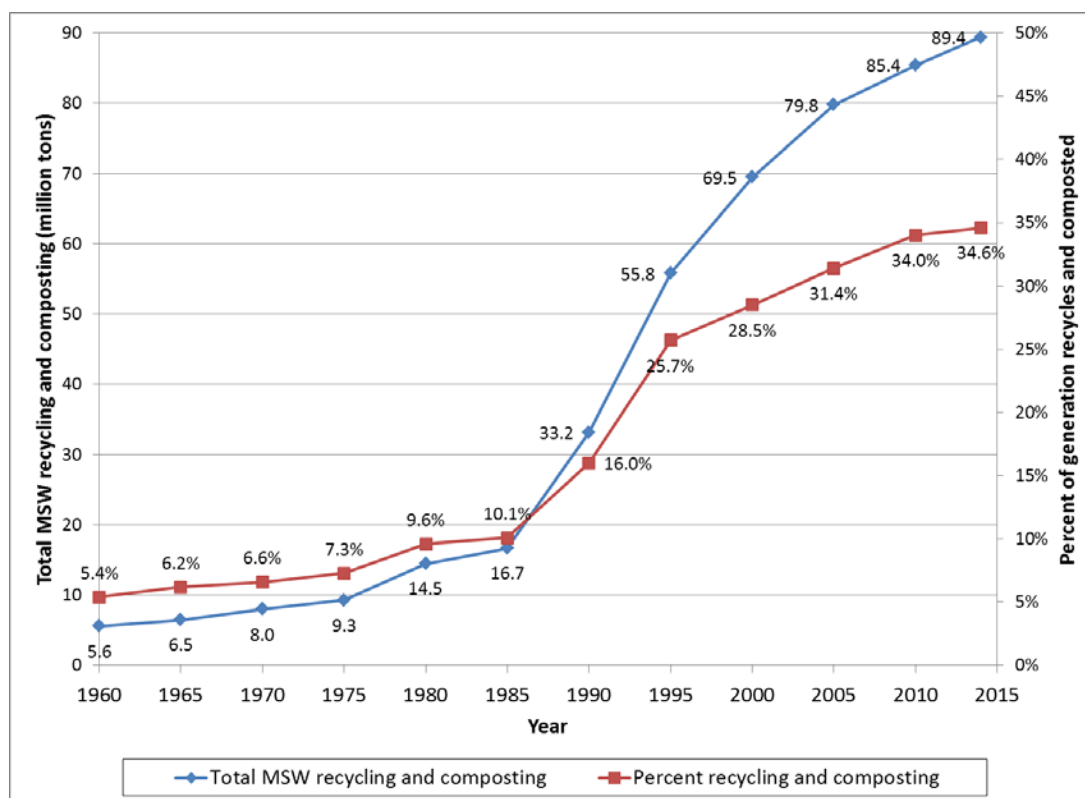


Figure 5.2-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.2.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.2.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Mint

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 14,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, resulting in a decrease of ~ 79 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 79 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.2-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 15 tons per year.

Table 5.2-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	46	17,040	9
“100 mm” (90 – 101 mm)	40.8	32	13,370	7
“120 mm” (118 – 120 mm)	1.1	1	358	0.2
Total (All styles)	100	79	30,769	15

Based on the proposed action resulting in ~ 14,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, it is estimated that an additional 32,993 pounds of Camel Snus Mint will be manufactured if those smokers use 5 pouches of Camel Snus Mint per day each day of the year. Waste generated due to Camel Snus Mint use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Mint tobacco will become waste for disposal after use, resulting in an increase of ~ 16 tons of used Camel Snus Mint pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 6.0×10^{-06} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Mint used pouch disposal has a negligible impact (a 6.4×10^{-06} percent increase) to the MSW stream, based on the same figures ([Table 5.2-11](#)).

Table 5.2-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	15	6.0×10^{-6}
Increase in used Camel Snus Mint pouches	16	6.4×10^{-6}

5.2.4.2.2 Disposal of Cigarette and Camel Snus Mint Packaging Material

Based on ~ 14,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 4 million fewer cigarette packs and approximately 0.4 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 1.7 million more Camel Snus Mint tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.2-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.2-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 40 tons per year ([Table 5.2-13](#)).

Camel Snus Mint Packaging weights are summarized in [Table 5.2-14](#). The Camel Snus Mint package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Mint use, it is estimated that packaging waste will increase by 41 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 1.5×10^{-5} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Mint packaging disposal will have a negligible impact (a 1.6×10^{-5} percent increase), based on the same figures ([Table 5.2-15](#)).

Table 5.2-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.2-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	299,900	45,834	23
"100 mm" (90 – 101 mm)	40.8	161,290	33,187	17
"120 mm" (118 – 120 mm)	1.1	4,535	1,026	1
Total (All styles)	100	395,725	80,047	40

Table 5.2-14: Camel Snus Mint Packaging Weights

Camel Snus Mint Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.2-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	40	1.5×10^{-05}
Increase in Camel Snus Mint packaging waste	41	1.6×10^{-05}

5.2.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Mint will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.2.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.2.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.2.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 14,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 79 million fewer cigarettes will be manufactured and that approximately 25 million more pouches of Camel Snus Mint will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.2-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.2-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mint	Net Change Due to the Proposed Action
Electricity (thousand kWh)	150	17	-133
Water (ccf)	26,671	1,346	-25,324
Natural gas (ccf)	4,388	462	-3,926

5.2.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.2.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 14,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 79 million fewer cigarettes will be manufactured and that approximately 25 million more pouches of Camel Snus Mint will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.2-17](#) summarizes projected annual changes in GHG

in Camel Snus Mint are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Mint have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.2.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.2.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Mint as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Mint as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.2.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.3 Camel Snus Mellow: Advertising Execution #1

This Environmental Assessment (EA) is required for authorization of Camel Snus Mellow as a modified risk tobacco product as communicated per [Advertising Execution 1](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).¹¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.3.1 Description of Proposed Action

5.3.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.3.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Mellow as a modified risk tobacco product.

5.3.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

¹¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Mellow	0.6 gram	9.0 gram

Package Description

Camel Snus Mellow is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.3.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Mellow while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Mellow. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA's MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 1](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.3-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 0.4% of current regular cigarette smokers. Apportionment to the Camel Snus Mellow style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Mellow represents 14.2% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Mellow, due to introduction of the proposed modified risk advertising, is 0.06% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.06% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.3-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

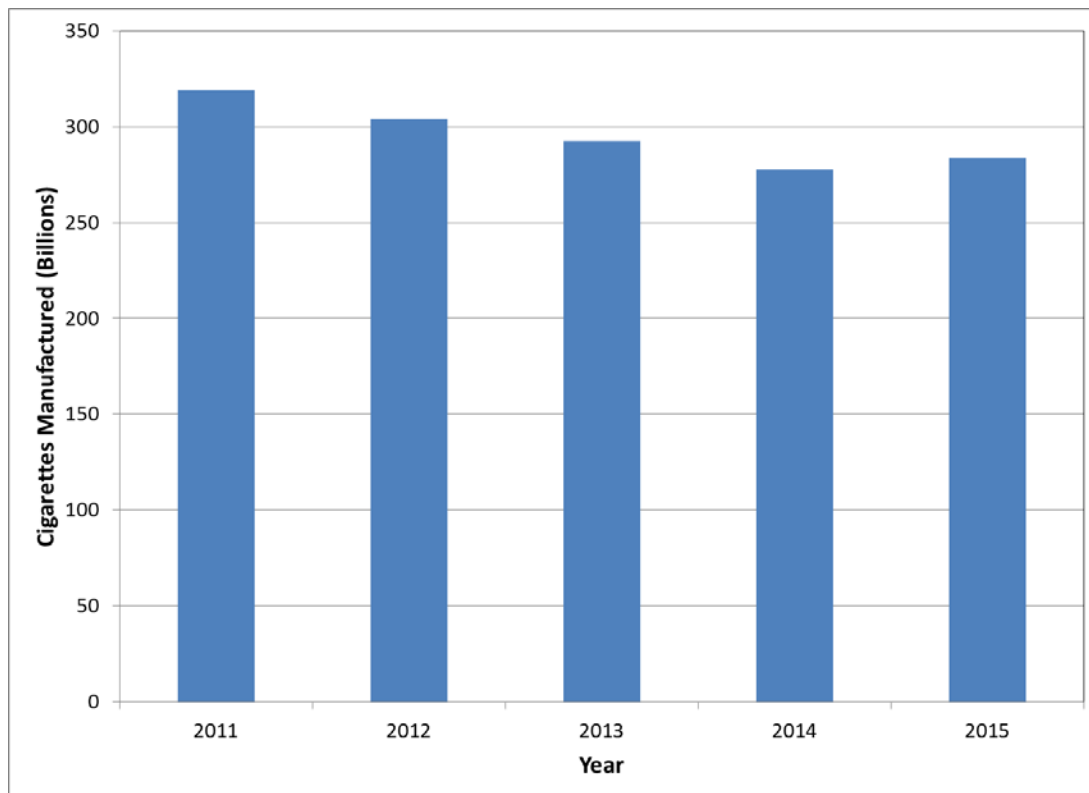
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	5.8%	2.1%	0.4%
Control (without proposed modified risk messaging)	5.4%	2.2%	0.4%
Net Impact of Test after correcting for Control	0.4%	-	-

5.3.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.3-1](#)).

Figure 5.3-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.3-2](#).

Table 5.3-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.06% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.1-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.3-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.06% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow. Total ammonia and nicotine emissions are expected to decrease by 14.7 and 22.3 pounds per year, respectively, based upon the proposed action.

Table 5.3-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	13.9
Ammonia (Total off-site release)	499	1,545	1,238	0.7
Ammonia (Total)	10,398	32,192	25,797	14.7
Nicotine (Total on-site release)	13,865	42,926	34,398	19.5
Nicotine (Total off-site release)	1,942	6,012	4,818	2.7
Nicotine (Total)	15,807	48,938	39,216	22.3

5.3.2.2 Environmental Consequences from Manufacturing Camel Snus Mellow

Waste generated as a result of manufacturing Camel Snus Mellow is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Mellow releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Mellow use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Mellow. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Mellow is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.3-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Mellow due to the proposed order are summarized in [Table 5.3-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Mellow (~ 0.7%); (c) the average rate of each emission type per pound of Camel Snus Mellow tobacco manufactured in 2015 and (d) the number of smokers (~ 22,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Mellow (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.06% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.3-2](#) and [Figure 5.3-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.3-4](#) and [Table 5.3-5](#), respectively.

Figure 5.3-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

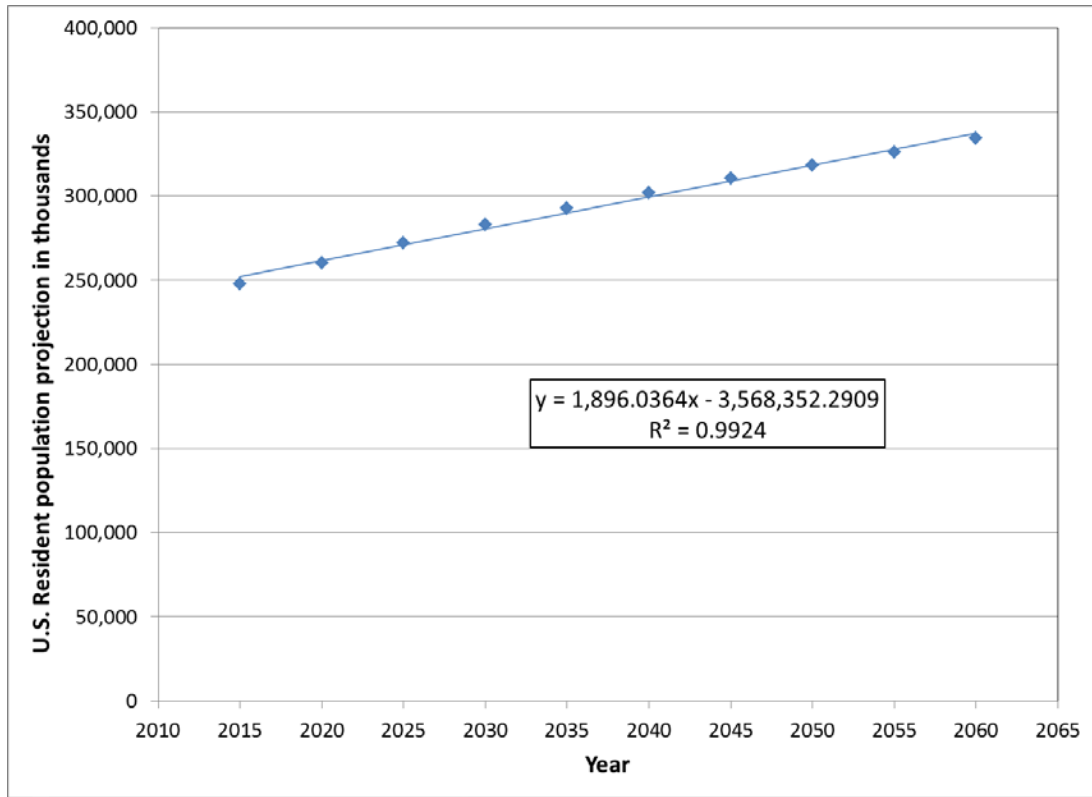


Table 5.3-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.3-3: Adult Smoking Incidence 2001 – 2014

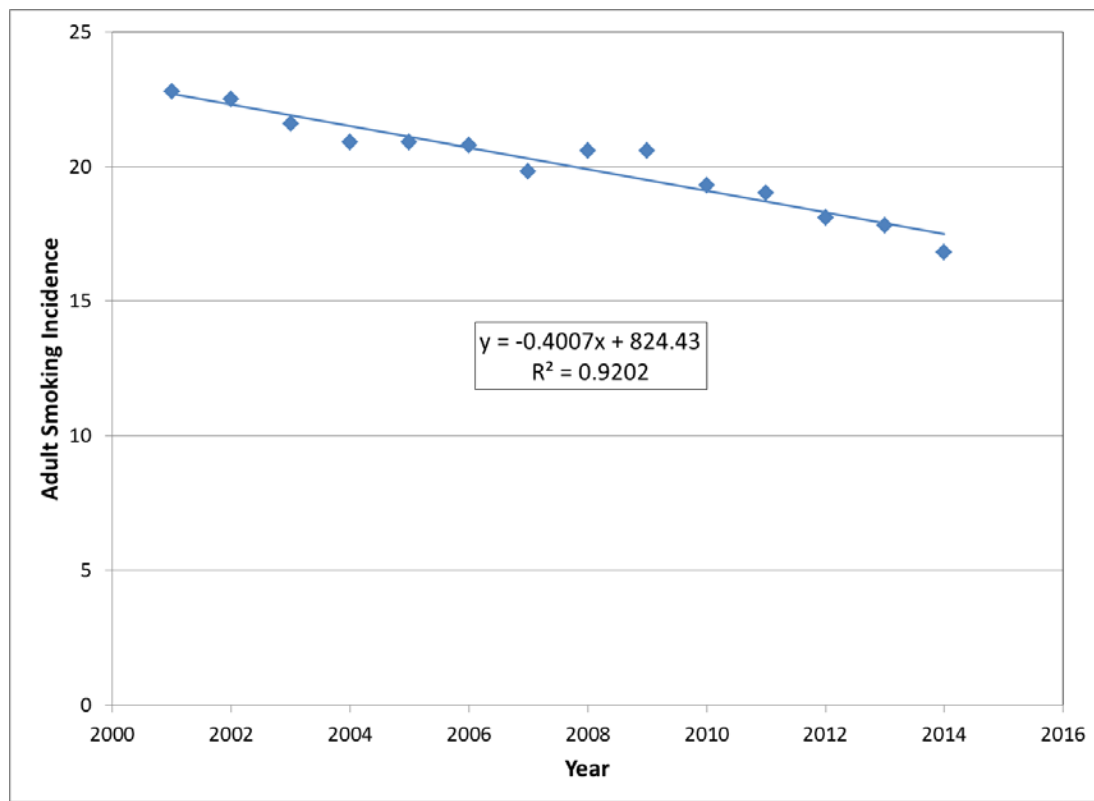


Table 5.3-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.3-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Mellow production and associated manufacturing emissions. Based on 0.0568% of the projected smokers switching to the use of 5 pouches of Camel Snus Mellow per day, an additional 53,851 pounds of Camel Snus Mellow will be manufactured. Of note, this estimate assumes that all of the projected switching from

smoking cigarettes to the use of Camel Snus Mellow will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Mellow each day is greater than current Camel Snus Mellow use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.3-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Mellow production, total ammonia and nicotine emissions are expected to increase by 12 and 63 pounds per year, respectively, based upon the proposed action ([Table 5.3-7](#)).

Table 5.3-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Mellow

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Mellow Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Mellow	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	14	0.111	6
Ammonia (Total off-site release)	2,123	14	0.116	6
Ammonia (Total)	4,159	28	-	12
Nicotine (Total on-site release)	11,293	75	0.615	33
Nicotine (Total off-site release)	10,168	67	0.553	30
Nicotine (Total)	21,461	142	-	63

5.3.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.3-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.04% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.3-8](#)).

Figure 5.3-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

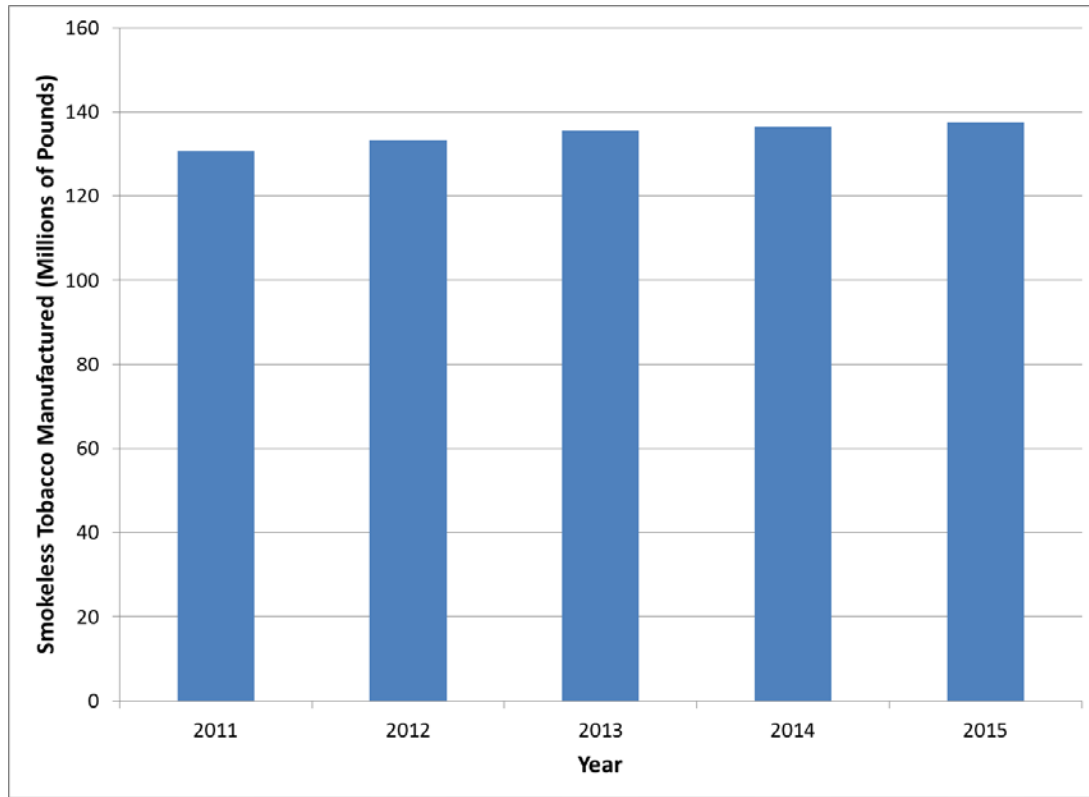


Table 5.3-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	6	15,233	0.04
Ammonia (Total off-site release)	0.116	6	15,884	0.04
Ammonia (Total)	-	12	31,117	0.04
Nicotine (Total on-site release)	0.615	33	84,492	0.04
Nicotine (Total off-site release)	0.553	30	76,075	0.04
Nicotine (Total)	-	63	160,567	0.04

5.3.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.3-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 2.9×10^{-06} percent decrease) and the increase in Camel Snus Mellow production has a negligible impact (a 3.0×10^{-06} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.3-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

Table 5.3-9: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	129.2 million cigarettes	10,060	4,712	14,772
Increases from Camel Snus Mellow	53,851 pounds	3,709	11,750	15,459

5.3.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Mellow and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.3.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Mellow accounted for ~ 0.09% by weight of the smokeless tobacco manufactured in the United States and ~ 11% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 22,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, resulting in a decrease of ~ 129 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 53,851 pounds of Camel Snus Mellow will be manufactured based upon those smokers using 5 pouches of Camel Snus Mellow per day.

5.3.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Mellow. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Mellow. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 129 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.3.4 Environmental Introduction as a Result of Disposal after Product Use

5.3.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Mellow in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Mellow includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Mellow consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.3-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.3-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Mellow are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.3-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

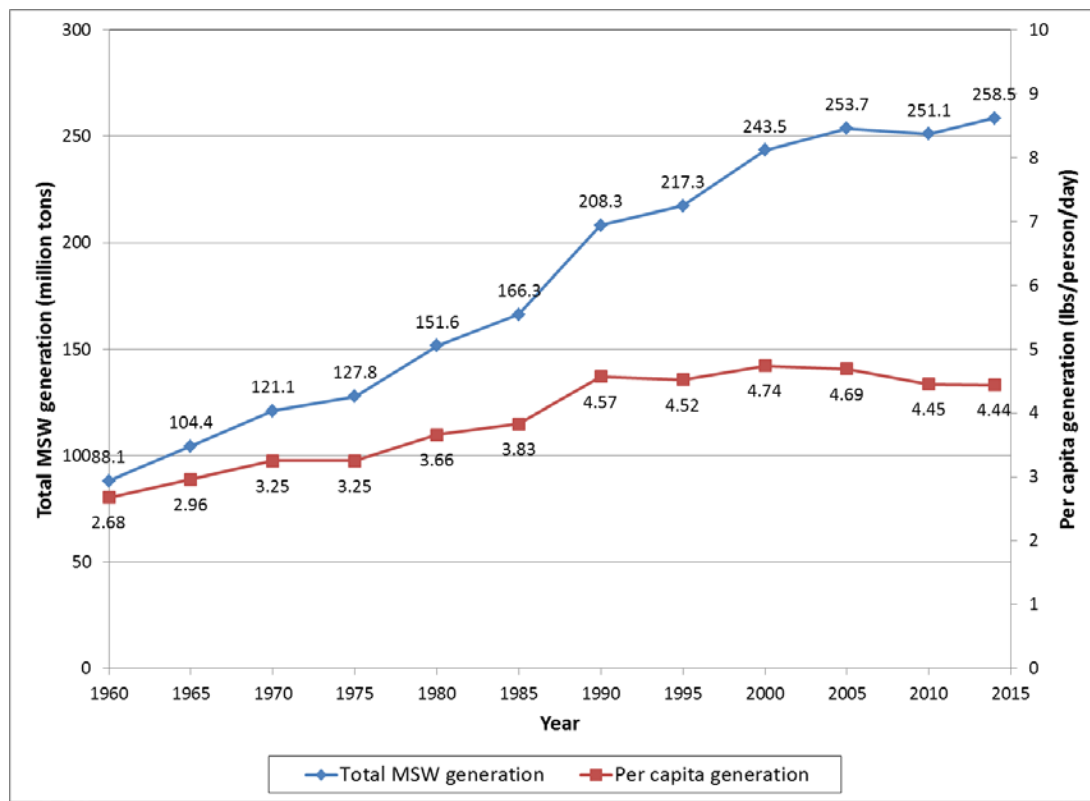
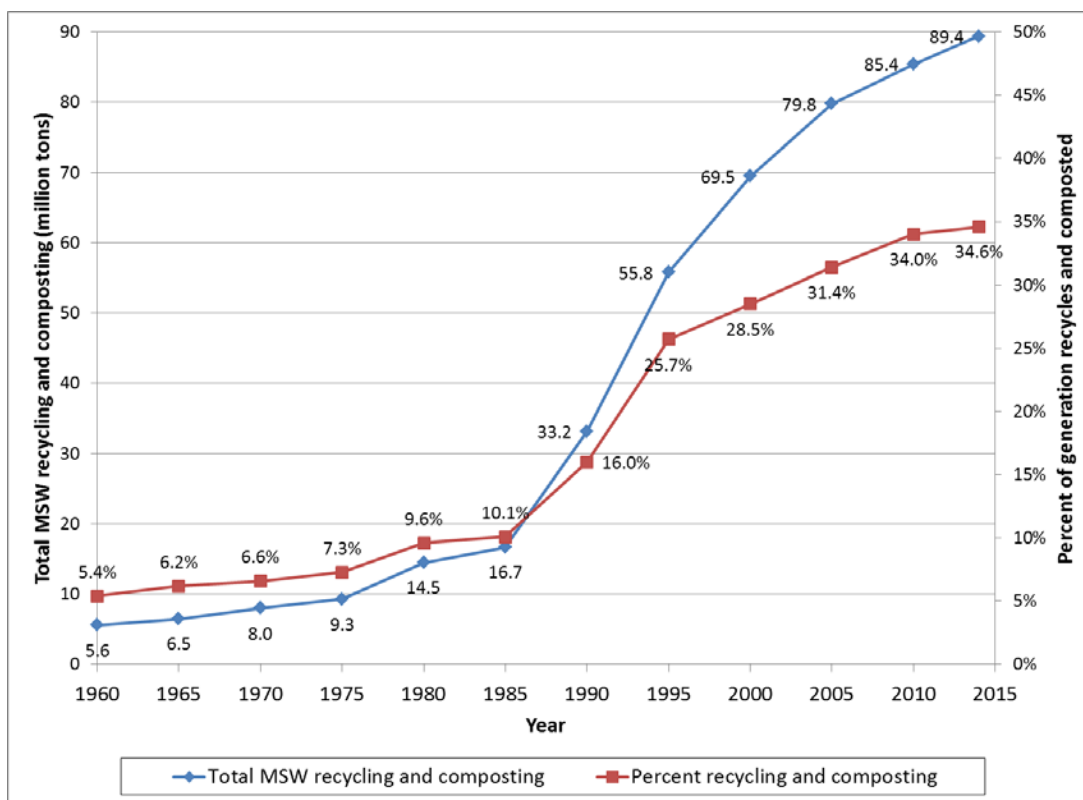


Figure 5.3-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.3.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.3.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Mellow

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 22,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, resulting in a decrease of ~ 129 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 129 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.3-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 25 tons per year.

Table 5.3-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	75	27,813	14
“100 mm” (90 – 101 mm)	40.8	53	21,822	11
“120 mm” (118 – 120 mm)	1.1	1	585	0.3
Total (All styles)	100	129	50,220	25

Based on the proposed action resulting in ~ 22,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, it is estimated that an additional 53,851 pounds of Camel Snus Mellow will be manufactured if those smokers use 5 pouches of Camel Snus Mellow per day each day of the year. Waste generated due to Camel Snus Mellow use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Mellow tobacco will become waste for disposal after use, resulting in an increase of ~ 27 tons of used Camel Snus Mellow pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 9.7×10^{-6} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Mellow used pouch disposal has a negligible impact (a 1.0×10^{-5} percent increase) to the MSW stream, based on the same figures ([Table 5.3-11](#)).

Table 5.3-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	25	9.7×10^{-6}
Increase in used Camel Snus Mellow pouches	27	1.0×10^{-5}

5.3.4.2.2 Disposal of Cigarette and Camel Snus Mellow Packaging Material

Based on ~ 22,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 6 million fewer cigarette packs and approximately 0.6 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 2.7 million more Camel Snus Mellow tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.3-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.3-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 65 tons per year ([Table 5.3-13](#)).

Camel Snus Mellow Packaging weights are summarized in [Table 5.3-14](#). The Camel Snus Mellow package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Mellow use, it is estimated that packaging waste will increase by 66 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 2.5×10^{-5} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Mellow packaging disposal will have a negligible impact (a 2.6×10^{-5} percent increase), based on the same figures ([Table 5.3-15](#)).

Table 5.3-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.3-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	375,240	74,810	37
"100 mm" (90 – 101 mm)	40.8	263,255	54,167	27
"120 mm" (118 – 120 mm)	1.1	7,401	1,675	1
Total (All styles)	100	645,896	130,651	65

Table 5.3-14: Camel Snus Mellow Packaging Weights

Camel Snus Mellow Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.3-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	65	2.5×10^{-05}
Increase in Camel Snus Mellow packaging waste	66	2.6×10^{-05}

5.3.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Mellow will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.3.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.3.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.3.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 22,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 129 million fewer cigarettes will be manufactured and that approximately 41 million more pouches of Camel Snus Mellow will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.3-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.3-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mellow	Net Change Due to the Proposed Action
Electricity (thousand kWh)	245	27	-218
Water (ccf)	43,532	2,198	-41,334
Natural gas (ccf)	7,161	754	-6,407

5.3.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.3.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 22,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 129 million fewer cigarettes will be manufactured and that approximately 41 million more pouches of Camel Snus Mellow will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.3-17](#) summarizes projected annual changes in

GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.3-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mellow	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	335	36	-298

5.3.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Mellow manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps¹² made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals¹³ and plants¹⁴ and (b) the endangered and threatened species listed in Appendices I, II, and III¹⁵ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Mellow manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Mellow are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

¹² Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

¹³ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

¹⁴ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&ffamily=on&header=Listed+Plants. Accessed on June 14, 2016.

¹⁵ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Mellow are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Mellow have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.3.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.3.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Mellow as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Mellow as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.3.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.4 Camel Snus Frost Large: Advertising Execution #1

This Environmental Assessment (EA) is required for authorization of Camel Snus Frost Large as a modified risk tobacco product as communicated per [Advertising Execution 1](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).¹⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.4.1 Description of Proposed Action

5.4.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.4.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Frost Large as a modified risk tobacco product.

5.4.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

¹⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Frost Large	1.0 gram	15.0 gram

Package Description

Camel Snus Frost Large is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.4.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Frost Large while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will switch from smoking cigarettes to exclusively using Camel Snus Frost Large. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA's MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 1](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.4-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 0.4% of current regular cigarette smokers. Apportionment to the Camel Snus Frost Large style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Frost Large represents 28.4% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Frost Large, due to introduction of the proposed modified risk advertising, is 0.11% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.11% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.4-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

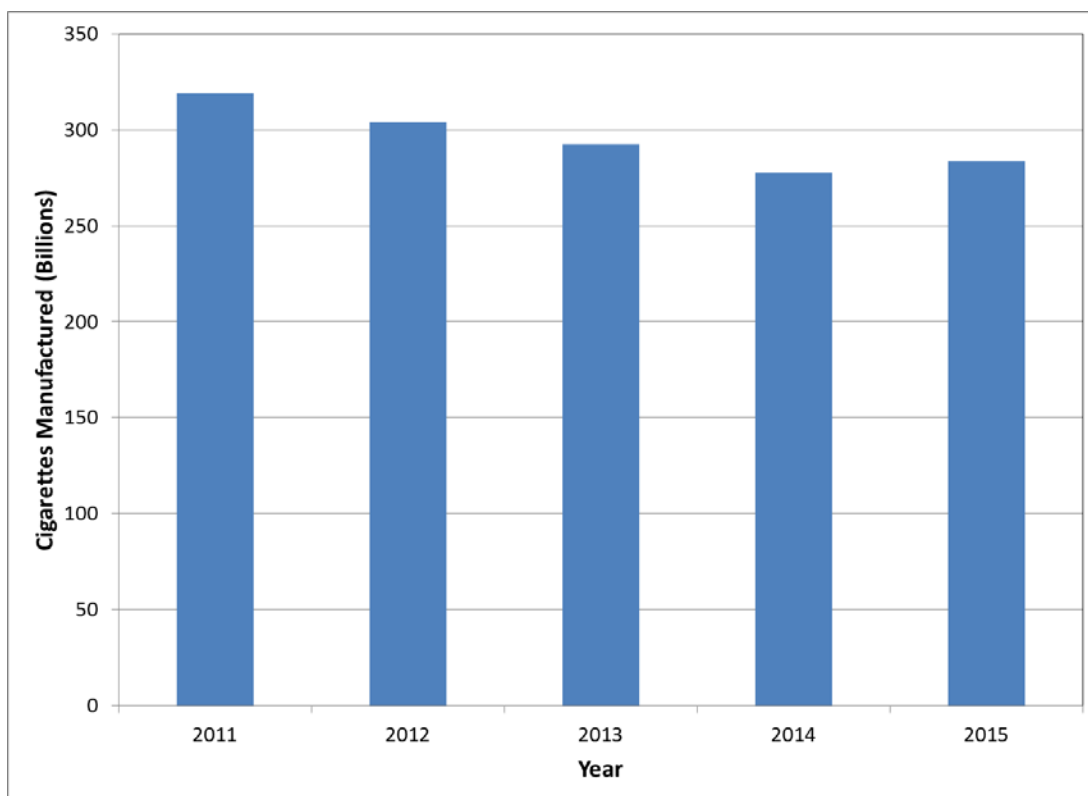
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	5.8%	2.1%	0.4%
Control (without proposed modified risk messaging)	5.4%	2.2%	0.4%
Net Impact of Test after correcting for Control	0.4%	-	-

5.4.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.4-1](#)).

Figure 5.4-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.4-2](#).

Table 5.4-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.11% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.4-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.4-3](#). Those values are estimated from: (a) current annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.11% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large. Total ammonia and nicotine emissions

are expected to decrease by 29 and 45 pounds per year, respectively, based upon the proposed action.

Table 5.4-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	28
Ammonia (Total off-site release)	499	1,545	1,238	1
Ammonia (Total)	10,398	32,192	25,797	29
Nicotine (Total on-site release)	13,865	42,926	34,398	39
Nicotine (Total off-site release)	1,942	6,012	4,818	5
Nicotine (Total)	15,807	48,938	39,216	45

5.4.2.2 Environmental Consequences from Manufacturing Camel Snus Frost Large

Waste generated as a result of manufacturing Camel Snus Frost Large is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Frost Large releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Frost Large use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Frost Large. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Frost Large is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts

on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.4-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Frost Large due to the proposed order are summarized in [Table 5.4-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Frost Large (~ 2.2%); (c) the average rate of each emission type per pound of Camel Snus Frost Large tobacco manufactured in 2015 and (d) the number of smokers (~ 45,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Frost Large (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.11% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.4-2](#) and [Figure 5.4-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.4-4](#) and [Table 5.4-5](#), respectively.

Figure 5.4-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

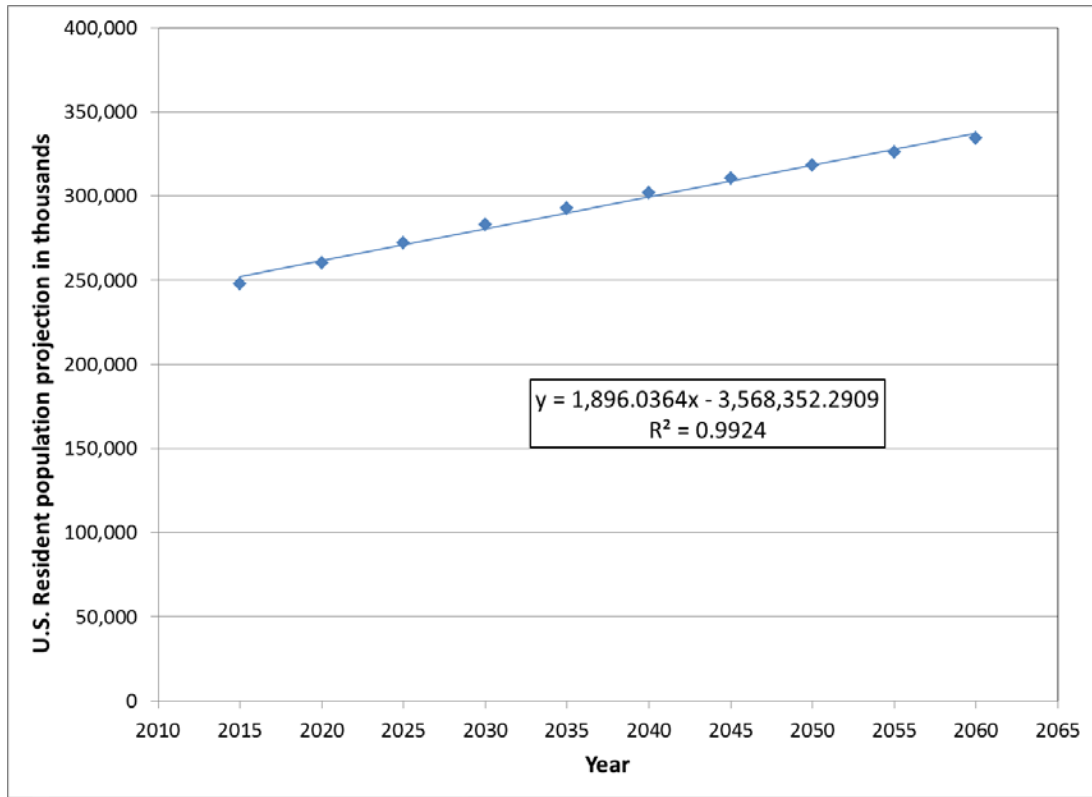


Table 5.4-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.4-3: Adult Smoking Incidence 2001 – 2014

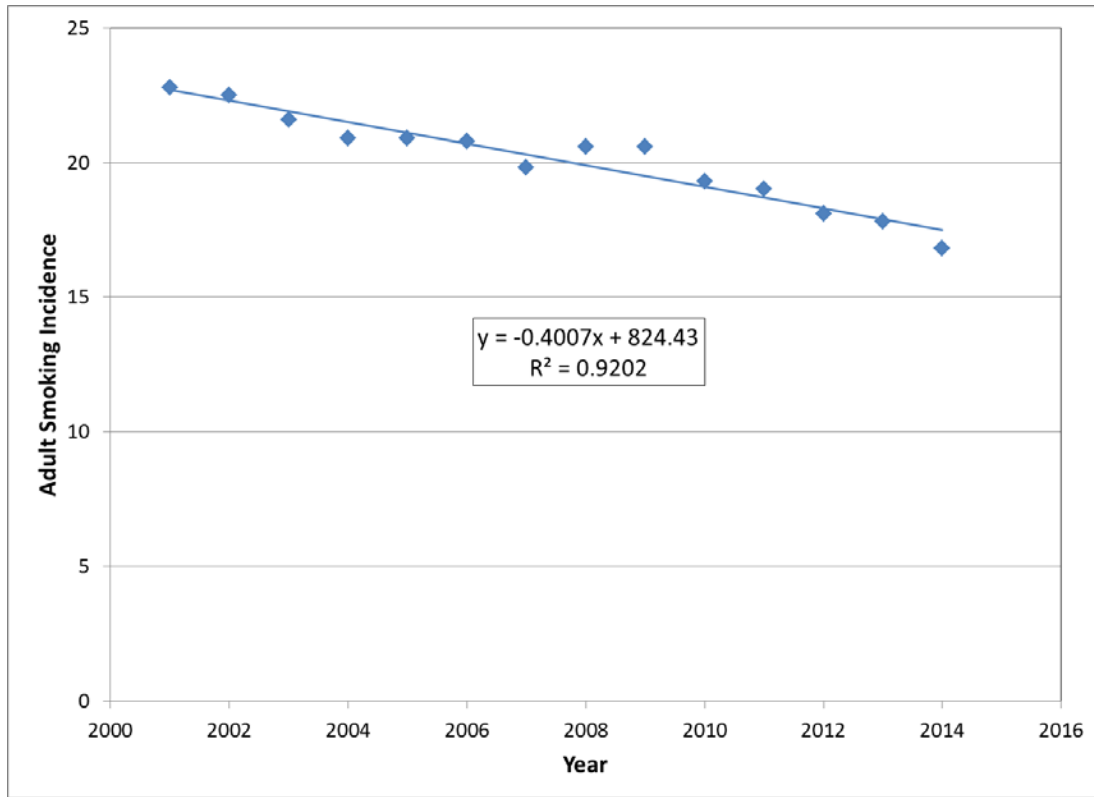


Table 5.4-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 ([Table 5.4-6](#)). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Frost Large production and associated manufacturing emissions. Based on 0.1136% of the projected smokers switching to the use of 5 pouches of Camel Snus Frost Large per day, an additional 179,502 pounds of Camel Snus Frost Large will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking cigarettes to the use of Camel Snus Frost Large will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Frost Large each day is greater than current Camel Snus Frost Large use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.4-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Frost Large production, total ammonia and nicotine emissions are expected to increase by 41 and 210 pounds per year, respectively, based upon the proposed action ([Table 5.4-7](#)).

Table 5.4-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Frost Large

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Frost Large Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Frost Large	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	45	0.111	20
Ammonia (Total off-site release)	2,123	47	0.116	21
Ammonia (Total)	4,159	92	-	41
Nicotine (Total on-site release)	11,293	250	0.615	110
Nicotine (Total off-site release)	10,168	225	0.553	99
Nicotine (Total)	21,461	476	-	210

5.4.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.4-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.13% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.4-8](#)).

Figure 5.4-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

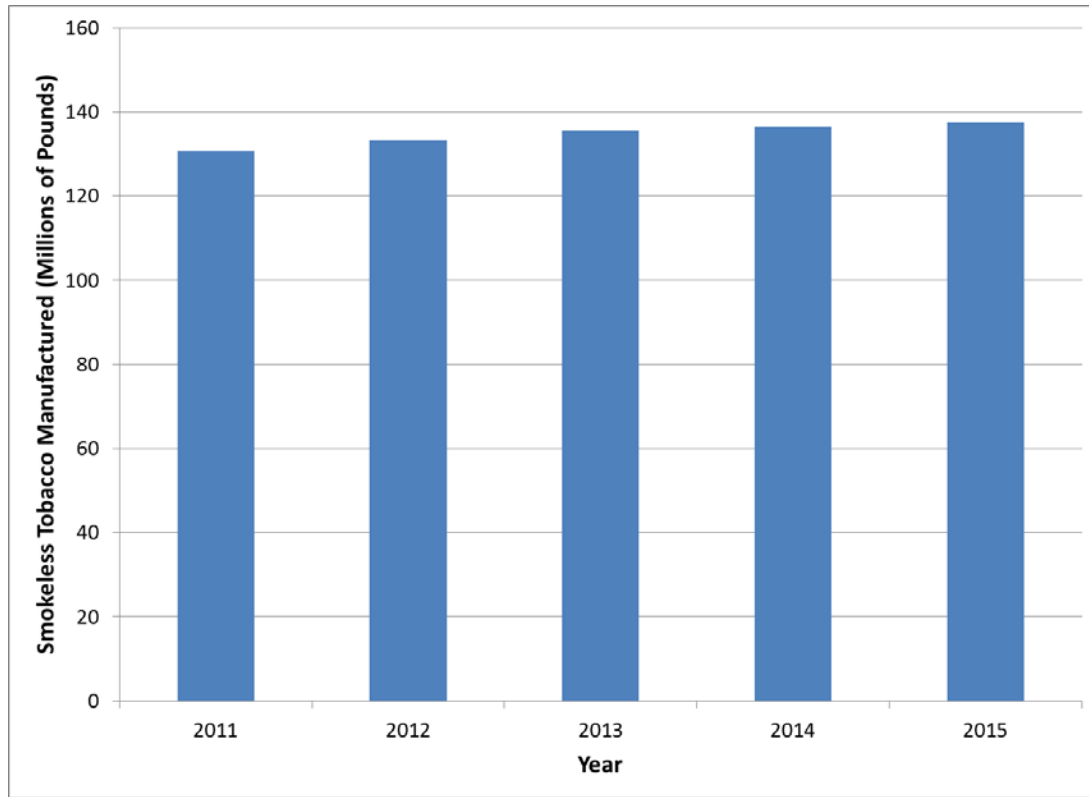


Table 5.4-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	20	15,233	0.13
Ammonia (Total off-site release)	0.116	21	15,884	0.13
Ammonia (Total)	-	41	31,117	0.13
Nicotine (Total on-site release)	0.615	110	84,492	0.13
Nicotine (Total off-site release)	0.553	99	76,075	0.13
Nicotine (Total)	-	210	160,567	0.13

5.4.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.4-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 5.7×10^{-06} percent decrease) and the increase in Camel Snus Frost Large production has a negligible impact (a 1.0×10^{-05} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.4-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

Table 5.4-9: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	258.4 million cigarettes	20,121	9,424	29,545
Increases from Camel Snus Frost Large	179,502 pounds	12,363	39,167	51,530

5.4.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Frost Large and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.4.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Frost Large accounted for ~ 0.30% by weight of the smokeless tobacco manufactured in the United States and ~ 23% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 45,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, resulting in a decrease of ~ 260 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 179,502 pounds of Camel Snus Frost Large will be manufactured based upon those smokers using 5 pouches of Camel Snus Frost Large per day.

5.4.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Frost Large. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Frost Large. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 260 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.4.4 Environmental Introduction as a Result of Disposal after Product Use

5.4.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Frost Large in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Frost Large includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Frost Large consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.4-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.4-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Frost Large are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.4-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

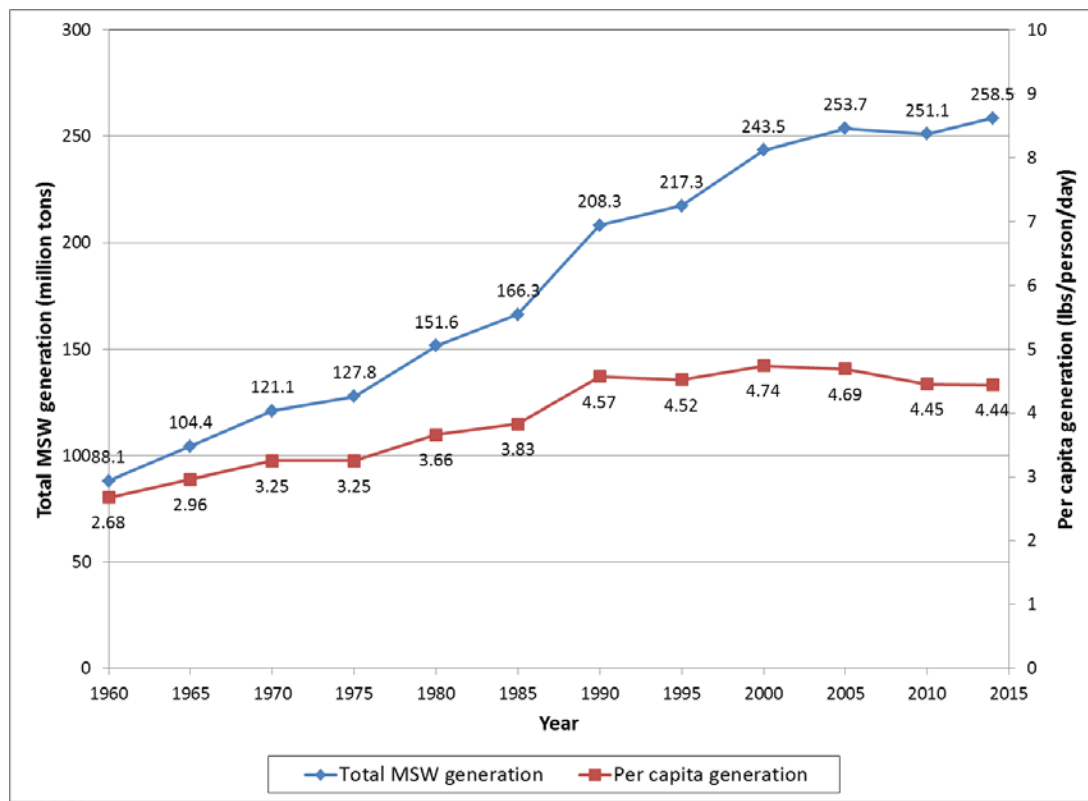
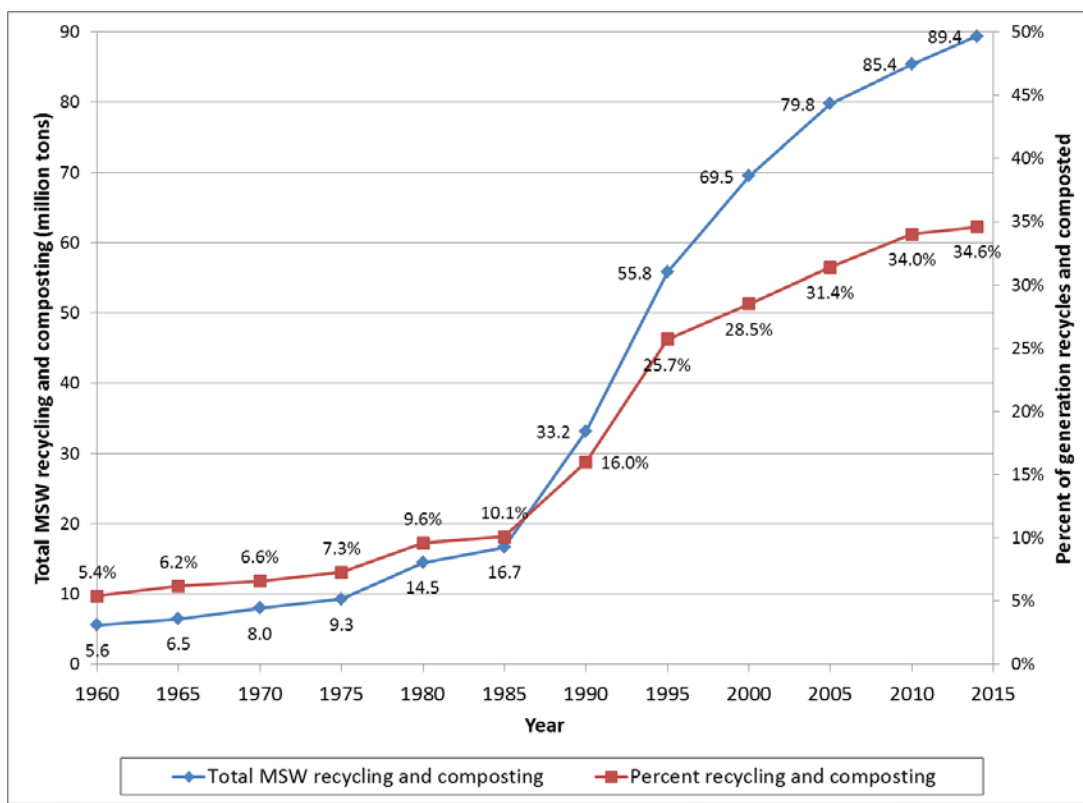


Figure 5.4-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.4.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.4.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Frost Large

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 45,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, resulting in a decrease of ~ 260 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 260 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.4-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 50 tons per year.

Table 5.4-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	150	55,625	28
“100 mm” (90 – 101 mm)	40.8	105	43,645	22
“120 mm” (118 – 120 mm)	1.1	3	1,170	1
Total (All styles)	100	258	100,440	50

Based on the proposed action resulting in ~ 45,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, it is estimated that an additional 179,502 pounds of Camel Snus Frost Large will be manufactured if those smokers use 5 pouches of Camel Snus Frost Large per day each day of the year. Waste generated due to Camel Snus Frost Large use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Frost Large tobacco will become waste for disposal after use, resulting in an increase of ~ 90 tons of used Camel Snus Frost Large pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 1.9×10^{-5} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Frost Large used pouch disposal has a negligible impact (a 3.5×10^{-5} percent increase) to the MSW stream, based on the same figures ([Table 5.4-11](#)).

Table 5.4-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	50	1.9×10^{-05}
Increase in used Camel Snus Frost Large pouches	90	3.5×10^{-05}

5.4.4.2.2 Disposal of Cigarette and Camel Snus Frost Large Packaging Material

Based on ~ 45,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 13 million fewer cigarette packs and approximately 1.3 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 5.4 million more Camel Snus Frost Large tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.4-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.4-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 131 tons per year ([Table 5.4-13](#)).

Camel Snus Frost Large Packaging weights are summarized in [Table 5.4-14](#). The Camel Snus Frost Large package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Frost Large use, it is estimated that packaging waste will increase by 133 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 5.05×10^{-05} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Frost Large packaging disposal will have a negligible impact (a 5.14×10^{-05} percent increase), based on the same figures ([Table 5.4-15](#)).

Table 5.4-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.4-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	750,479	149,619	75
"100 mm" (90 – 101 mm)	40.8	526,509	108,334	54
"120 mm" (118 – 120 mm)	1.1	14,803	3,349	2
Total (All styles)	100	1,291,791	261,302	131

Table 5.4-14: Camel Snus Frost Large Packaging Weights

Camel Snus Frost Large Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.4-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	131	5.05×10^{-05}
Increase in Camel Snus Frost Large packaging waste	133	5.14×10^{-05}

5.4.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Frost Large will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.4.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.4.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.4.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 45,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 260 million fewer cigarettes will be manufactured and that approximately 81 million more pouches of Camel Snus Frost Large will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.4-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.4-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost Large	Net Change Due to the Proposed Action
Electricity (thousand kWh)	490	90	-399
Water (ccf)	87,063	7,325	-79,738
Natural gas (ccf)	14,323	2,514	-11,809

5.4.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.4.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 45,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 260 million fewer cigarettes will be manufactured and that approximately 81 million more pouches of Camel Snus Frost Large will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. Table 5.4-17 summarizes projected annual changes in GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.4-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost Large	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	669	121	-549

5.4.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act ("ESA") (1973 Endangered Species Act) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora ("CITES") (Convention on International Trade in Endangered Species) are expected due to the proposed action. The location of Camel Snus Frost Large manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps¹⁷ made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals¹⁸ and plants¹⁹ and (b) the endangered and threatened species

¹⁷ Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

¹⁸ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

¹⁹ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

listed in Appendices I, II, and III²⁰ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Frost Large manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Frost Large are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used in Camel Snus Frost Large are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Frost Large have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.4.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers

²⁰ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.

- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.

- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.4.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Frost Large as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Frost Large as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.4.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.5 Camel Snus Winterchill: Advertising Execution #1

This Environmental Assessment (EA) is required for authorization of Camel Snus Winterchill as a modified risk tobacco product as communicated per [Advertising Execution 1](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).²¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.5.1 Description of Proposed Action

5.5.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.5.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Winterchill as a modified risk tobacco product.

5.5.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

²¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Winterchill	1.0 gram	15.0 gram

Package Description

Camel Snus Winterchill is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.5.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Winterchill while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will switch from smoking cigarettes to exclusively using Camel Snus Winterchill. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA's MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 1](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.5-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 0.4% of current regular cigarette smokers. Apportionment to the Camel Snus Winterchill style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Winterchill represents 13.6% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Winterchill, due to introduction of the proposed modified risk advertising, is 0.05% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.05% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.5-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

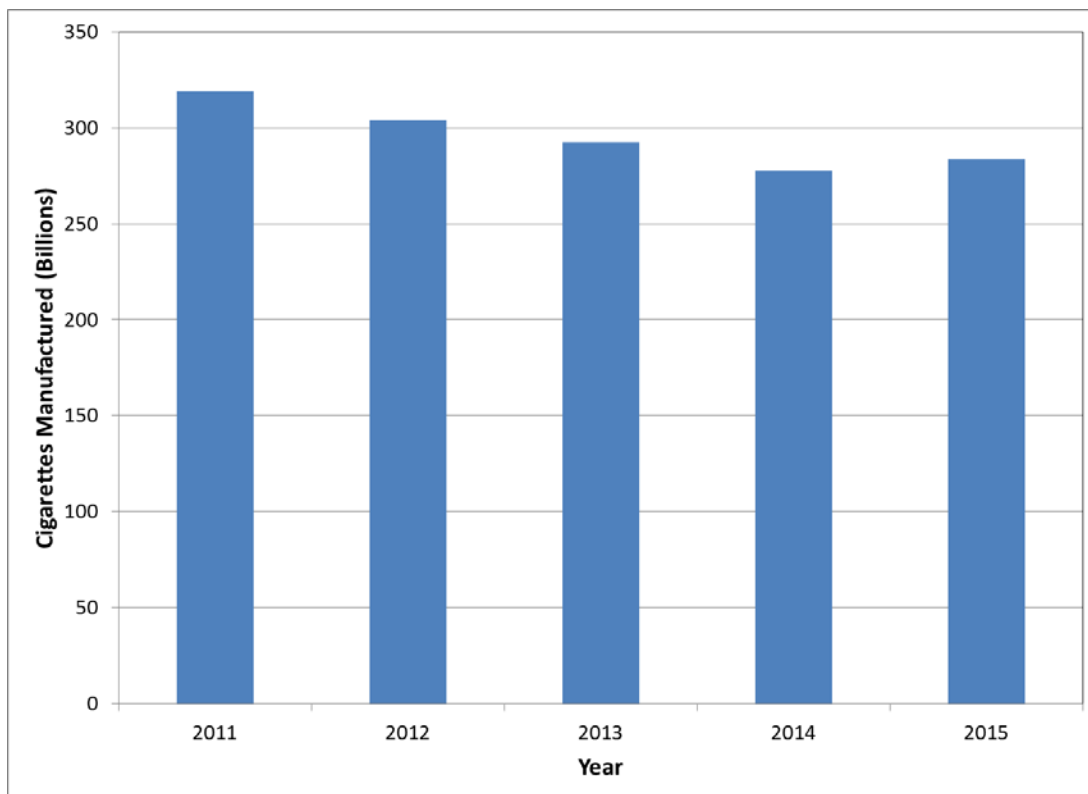
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	5.8%	2.1%	0.4%
Control (without proposed modified risk messaging)	5.4%	2.2%	0.4%
Net Impact of Test after correcting for Control	0.4%	-	-

5.5.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.5-1](#)).

Figure 5.5-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.5-2](#).

Table 5.5-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.05% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.5-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.5-3](#). Those values are estimated from: (a) current annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.05% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill. Total ammonia and nicotine emissions

are expected to decrease by 14.0 and 21.3 pounds per year, respectively, based upon the proposed action.

Table 5.5-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	13.4
Ammonia (Total off-site release)	499	1,545	1,238	0.7
Ammonia (Total)	10,398	32,192	25,797	14.0
Nicotine (Total on-site release)	13,865	42,926	34,398	18.7
Nicotine (Total off-site release)	1,942	6,012	4,818	2.6
Nicotine (Total)	15,807	48,938	39,216	21.3

5.5.2.2 Environmental Consequences from Manufacturing Camel Snus Winterchill

Waste generated as a result of manufacturing Camel Snus Winterchill is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Winterchill releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Winterchill use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Winterchill. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Winterchill is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts

on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.5-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Winterchill due to the proposed order are summarized in [Table 5.5-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (*see* column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Winterchill (~ 1.1%); (c) the average rate of each emission type per pound of Camel Snus Winterchill tobacco manufactured in 2015 and (d) the number of smokers (~ 21,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Winterchill (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.05% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.5-2](#) and [Figure 5.5-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.5-4](#) and [Table 5.5-5](#), respectively.

Figure 5.5-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

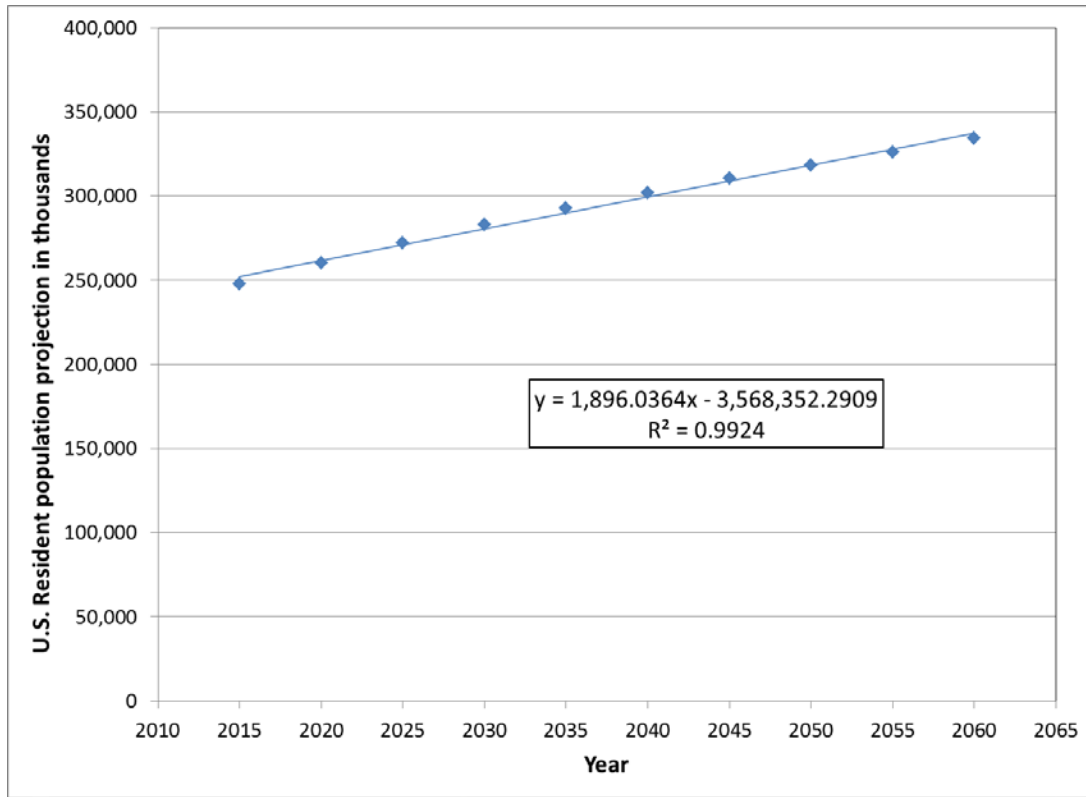


Table 5.5-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.5-3: Adult Smoking Incidence 2001 – 2014

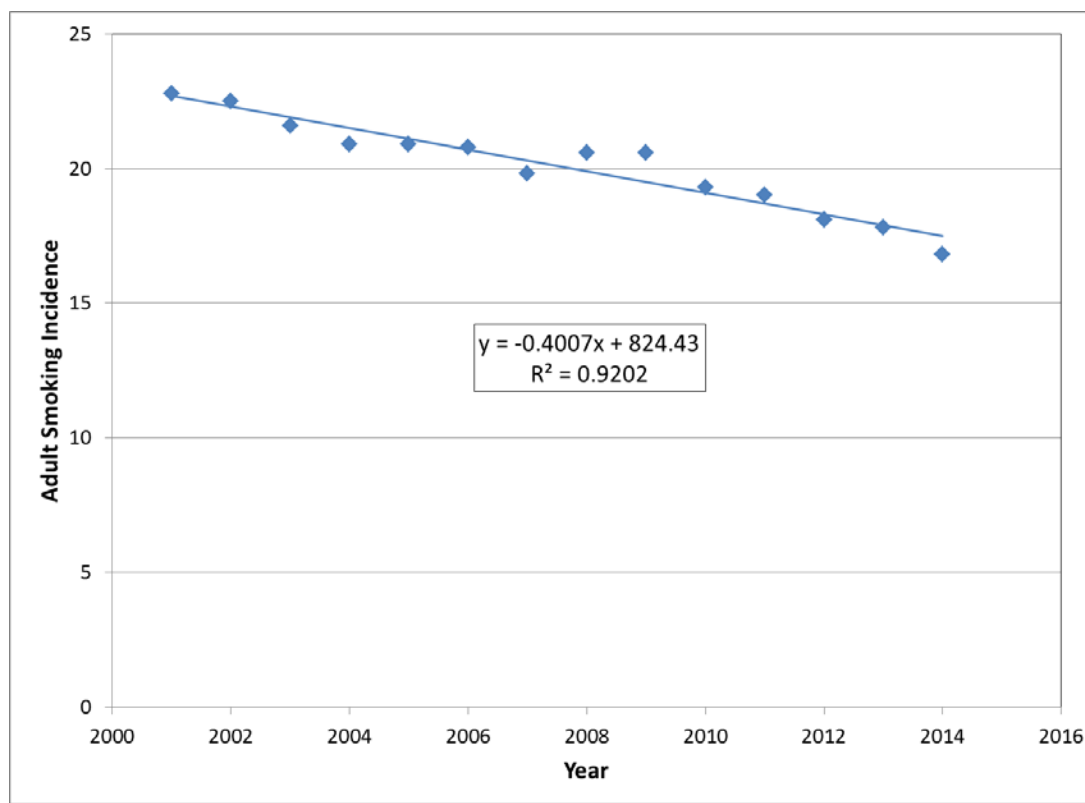


Table 5.5-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 ([Table 5.5-6](#)). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Winterchill production and associated manufacturing emissions. Based on 0.0544% of the projected smokers switching to the use of 5 pouches of Camel Snus Winterchill per day, an additional 85,959 pounds of Camel Snus Winterchill will be manufactured. Of note, this estimate assumes that all of the projected

switching from smoking cigarettes to the use of Camel Snus Winterchill will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Winterchill each day is greater than current Camel Snus Winterchill use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.5-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Winterchill production, total ammonia and nicotine emissions are expected to increase by 19 and 100 pounds per year, respectively, based upon the proposed action ([Table 5.5-7](#)).

Table 5.5-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Winterchill

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Winterchill Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Winterchill	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	22	0.111	10
Ammonia (Total off-site release)	2,123	22	0.116	10
Ammonia (Total)	4,159	44	-	19
Nicotine (Total on-site release)	11,293	120	0.615	53
Nicotine (Total off-site release)	10,168	108	0.553	48
Nicotine (Total)	21,461	227	-	100

5.5.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.5-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.06% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.5-8](#)).

Figure 5.5-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

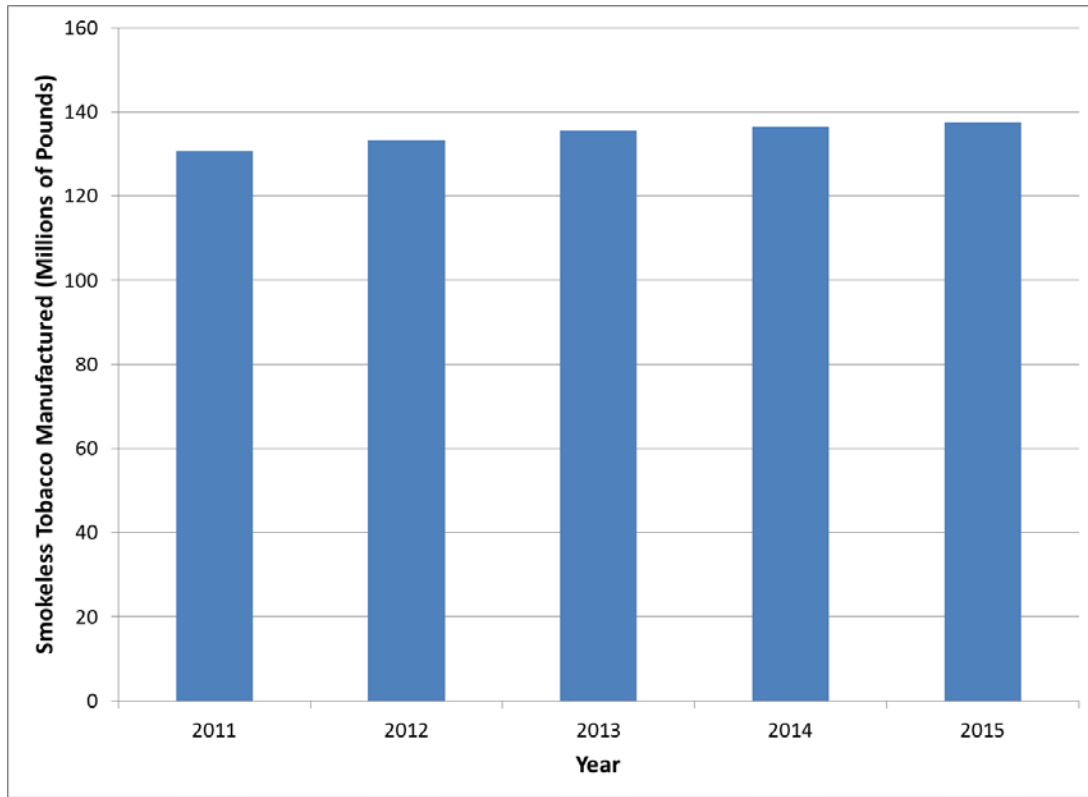


Table 5.5-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	10	15,233	0.06
Ammonia (Total off-site release)	0.116	10	15,884	0.06
Ammonia (Total)	-	19	31,117	0.06
Nicotine (Total on-site release)	0.615	53	84,492	0.06
Nicotine (Total off-site release)	0.553	48	76,075	0.06
Nicotine (Total)	-	100	160,567	0.06

5.5.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.5-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 2.7×10^{-6} percent decrease) and the increase in Camel Snus Winterchill production has a negligible impact (a 4.8×10^{-6} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.5-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

Table 5.5-9: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	123.7 million cigarettes	9,635	4,513	14,148
Increases from Camel Snus Winterchill	85,959 pounds	5,920	18,756	24,676

5.5.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Winterchill and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.5.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Winterchill accounted for ~ 0.14% by weight of the smokeless tobacco manufactured in the United States and ~ 11% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 21,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, resulting in a decrease of ~ 124 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 85,959 pounds of Camel Snus Winterchill will be manufactured based upon those smokers using 5 pouches of Camel Snus Winterchill per day.

5.5.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Winterchill. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Winterchill. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 124 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.5.4 Environmental Introduction as a Result of Disposal after Product Use

5.5.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Winterchill in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Winterchill includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Winterchill consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.5-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.5-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Winterchill are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.5-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

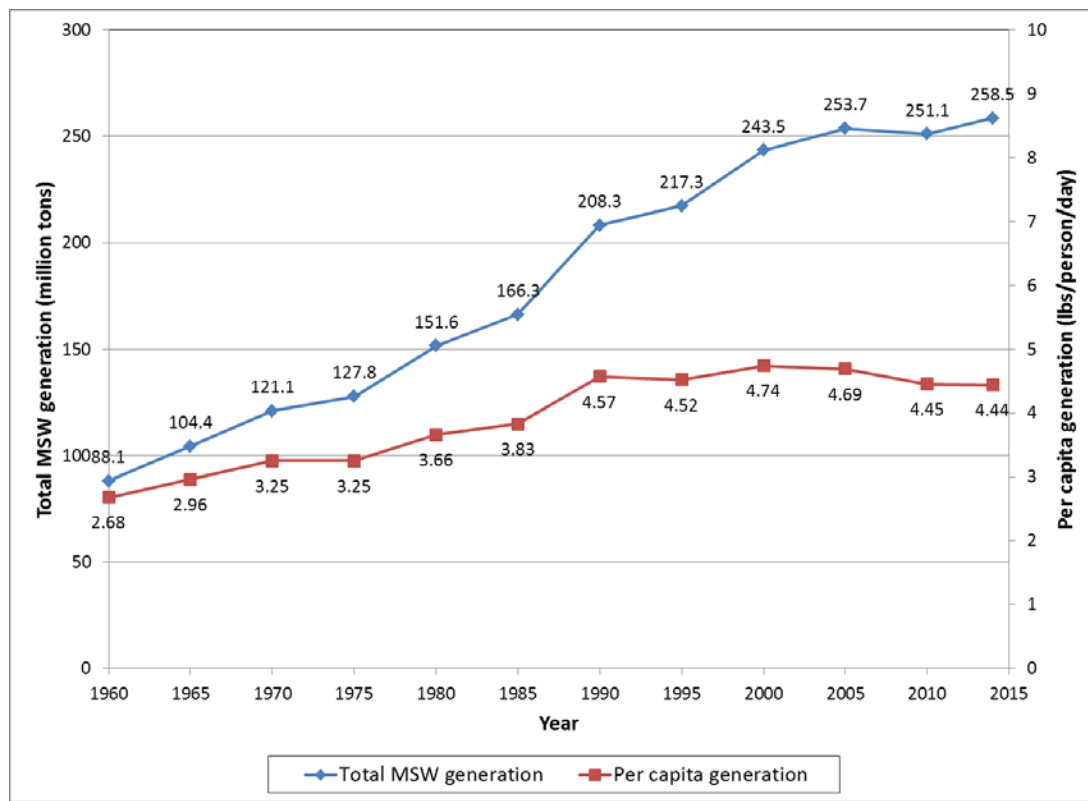
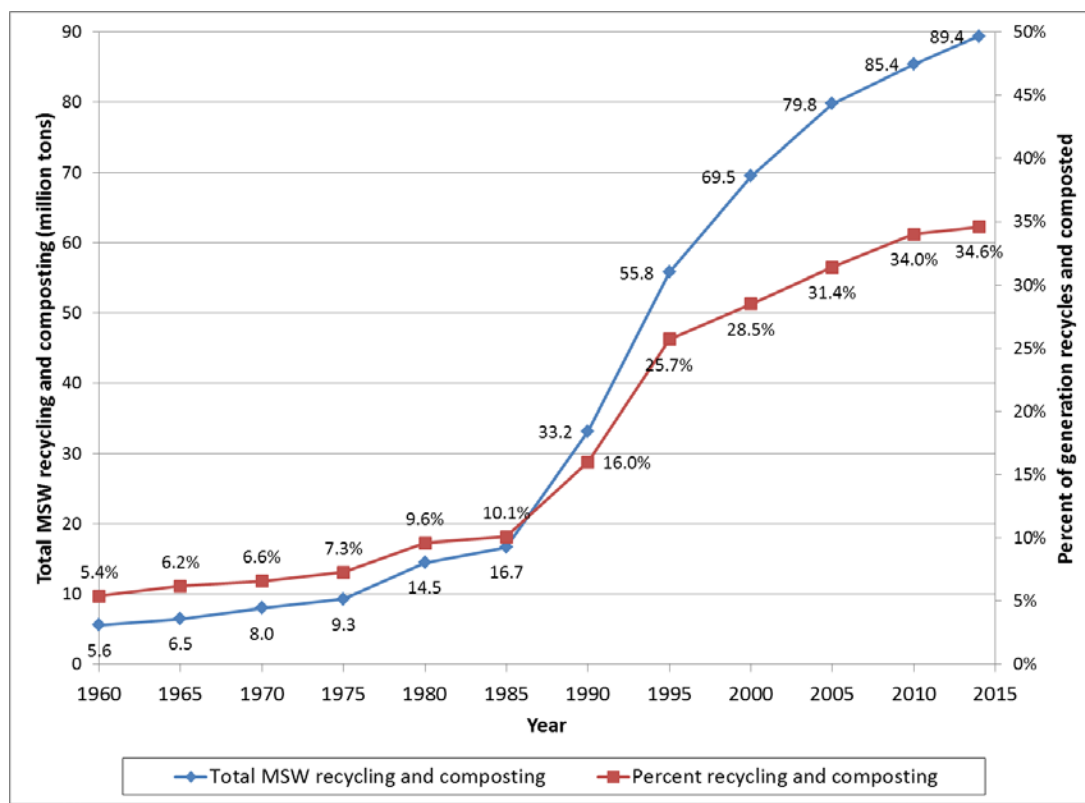


Figure 5.5-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.5.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.5.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Winterchill

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 21,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, resulting in a decrease of ~ 124 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 124 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.5-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 24 tons per year.

Table 5.5-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	72	26,638	13.3
“100 mm” (90 – 101 mm)	40.8	50	20,900	10.5
“120 mm” (118 – 120 mm)	1.1	1	560	0.3
Total (All styles)	100	124	48,098	24.0

Based on the proposed action resulting in ~ 21,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, it is estimated that an additional 85,959 pounds of Camel Snus Winterchill will be manufactured if those smokers use 5 pouches of Camel Snus Winterchill per day each day of the year. Waste generated due to Camel Snus Winterchill use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Winterchill tobacco will become waste for disposal after use, resulting in an increase of ~ 43 tons of used Camel Snus Winterchill pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 9.3×10^{-6} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Winterchill used pouch disposal has a negligible impact (a 1.7×10^{-5} percent increase) to the MSW stream, based on the same figures ([Table 5.5-11](#)).

Table 5.5-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	24	9.3×10^{-6}
Increase in used Camel Snus Winterchill pouches	43	1.7×10^{-5}

5.5.4.2.2 Disposal of Cigarette and Camel Snus Winterchill Packaging Material

Based on ~ 21,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 6 million fewer cigarette packs and approximately 0.6 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 2.6 million more Camel Snus Winterchill tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.5-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.5-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 63 tons per year ([Table 5.5-13](#)).

Camel Snus Winterchill Packaging weights are summarized in [Table 5.5-14](#). The Camel Snus Winterchill package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Winterchill use, it is estimated that packaging waste will increase by 64 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 2.4×10^{-5} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Winterchill packaging disposal will have a negligible impact (a 2.5×10^{-5} percent increase), based on the same figures ([Table 5.5-15](#)).

Table 5.5-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.5-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	359,385	71,649	35.8
"100 mm" (90 – 101 mm)	40.8	252,131	51,878	25.9
"120 mm" (118 – 120 mm)	1.1	7,089	1,604	0.8
Total (All styles)	100	618,604	125,131	63

Table 5.5-14: Camel Snus Winterchill Packaging Weights

Camel Snus Winterchill Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.5-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	63	2.4×10^{-05}
Increase in Camel Snus Winterchill packaging waste	64	2.5×10^{-05}

5.5.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Winterchill will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.5.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.5.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.5.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 21,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 124 million fewer cigarettes will be manufactured and that approximately 39 million more pouches of Camel Snus Winterchill will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.5-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.5-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Winterchill	Net Change Due to the Proposed Action
Electricity (thousand kWh)	234	43	-191
Water (ccf)	41,692	3,508	-38,184
Natural gas (ccf)	6,859	1,204	-5,655

5.5.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.5.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 21,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 124 million fewer cigarettes will be manufactured and that approximately 39 million more pouches of Camel Snus Winterchill will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.5-17](#) summarizes projected annual changes in GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.5-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Winterchill	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	321	58	-263

5.5.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act ("ESA") ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora ("CITES") ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Winterchill manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps²² made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals²³ and plants²⁴ and (b) the endangered and threatened species

²² Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

²³ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

²⁴ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

listed in Appendices I, II, and III²⁵ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Winterchill manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Winterchill are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used in Camel Snus Winterchill are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Winterchill have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.5.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers

²⁵ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.

- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.

- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.5.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Winterchill as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Winterchill as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.5.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.6 Camel Snus Robust: Advertising Execution #1

This Environmental Assessment (EA) is required for authorization of Camel Snus Robust as a modified risk tobacco product as communicated per [Advertising Execution 1](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).²⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.6.1 Description of Proposed Action

5.6.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.6.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Robust as a modified risk tobacco product.

5.6.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

²⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Robust	1.0 gram	15.0 gram

Package Description

Camel Snus Robust is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.6.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Robust while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Robust. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 1](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.6-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 0.4% of current regular cigarette smokers. Apportionment to the Camel Snus Robust style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Robust represents 2.2% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Robust, due to introduction of the proposed modified risk advertising, is 0.01% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.01% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.6-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

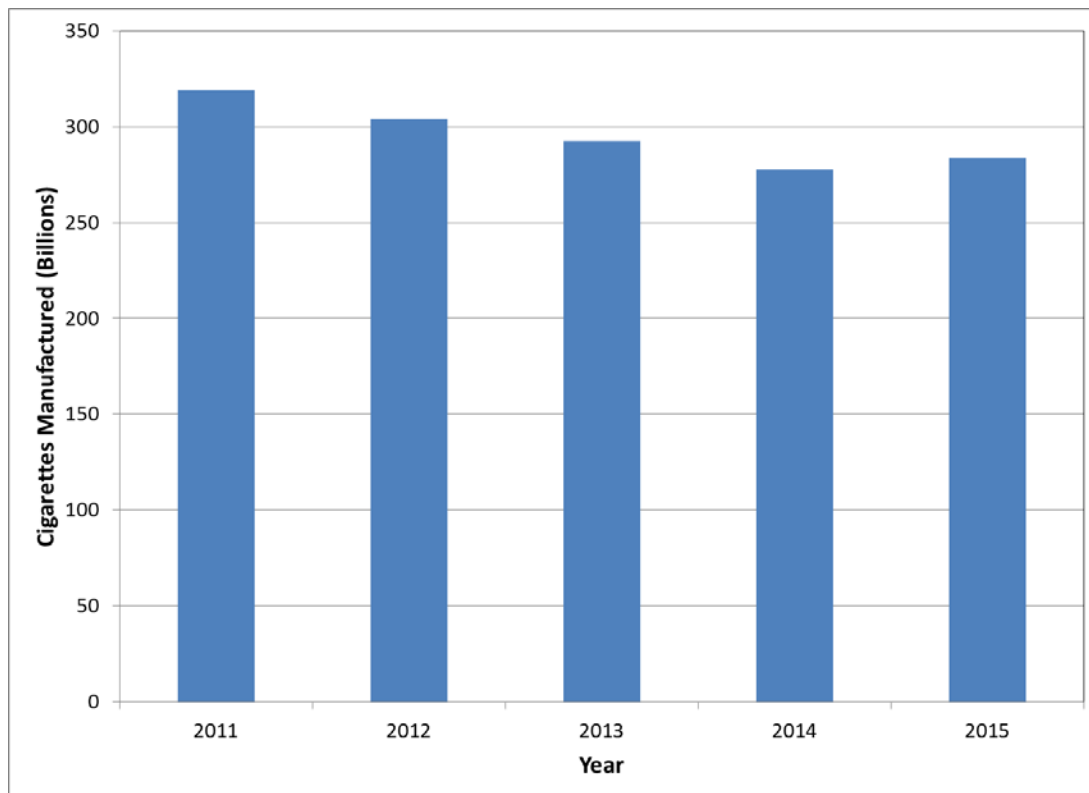
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	5.8%	2.1%	0.4%
Control (without proposed modified risk messaging)	5.4%	2.2%	0.4%
Net Impact of Test after correcting for Control	0.4%	-	-

5.6.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.6-1](#)).

Figure 5.6-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.6-2](#).

Table 5.6-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.01% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.6-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.6-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.01% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust. Total ammonia and nicotine emissions are expected to decrease by 2.3 and 3.5 pounds per year, respectively, based upon the proposed action.

Table 5.6-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	2.2
Ammonia (Total off-site release)	499	1,545	1,238	0.1
Ammonia (Total)	10,398	32,192	25,797	2.3
Nicotine (Total on-site release)	13,865	42,926	34,398	3.0
Nicotine (Total off-site release)	1,942	6,012	4,818	0.4
Nicotine (Total)	15,807	48,938	39,216	3.5

5.6.2.2 Environmental Consequences from Manufacturing Camel Snus Robust

Waste generated as a result of manufacturing Camel Snus Robust is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Robust releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Robust use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Robust. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Robust is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.6-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Robust due to the proposed order are summarized in [Table 5.6-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Robust (~ 0.2%); (c) the average rate of each emission type per pound of Camel Snus Robust tobacco manufactured in 2015 and (d) the number of smokers (~ 3,500) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Robust (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.01% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.6-2](#) and [Figure 5.6-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.6-4](#) and [Table 5.6-5](#), respectively.

Figure 5.6-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

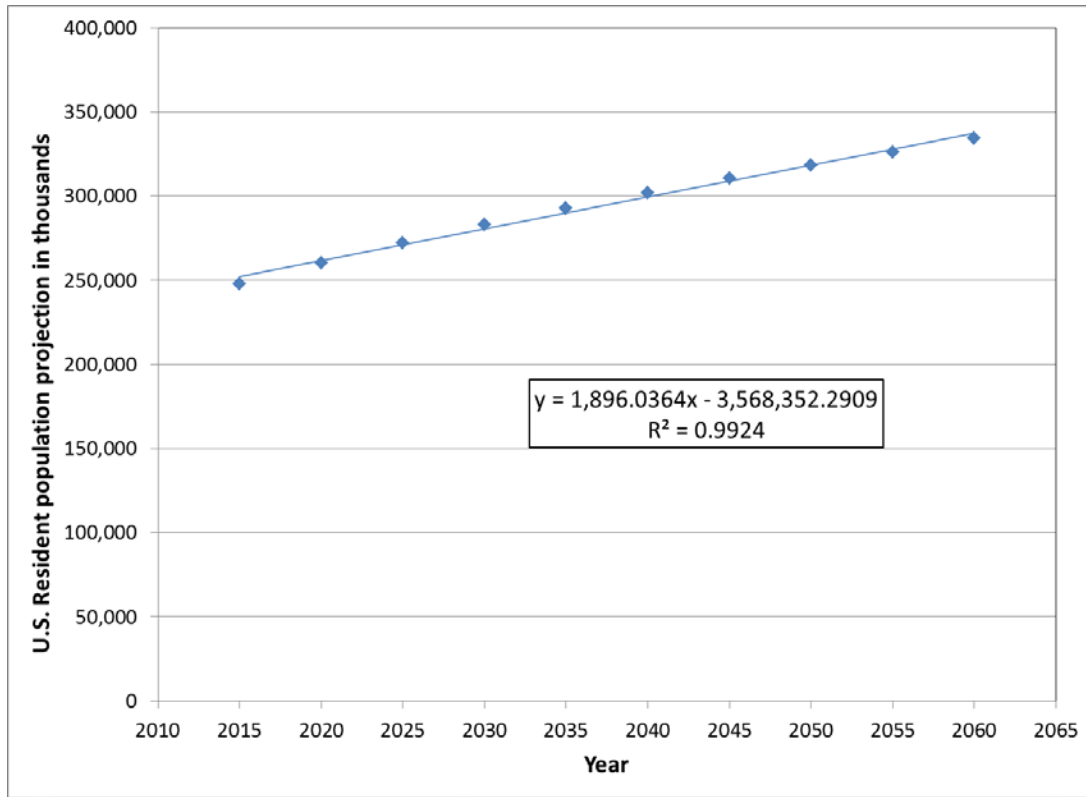


Table 5.6-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.6-3: Adult Smoking Incidence 2001 – 2014

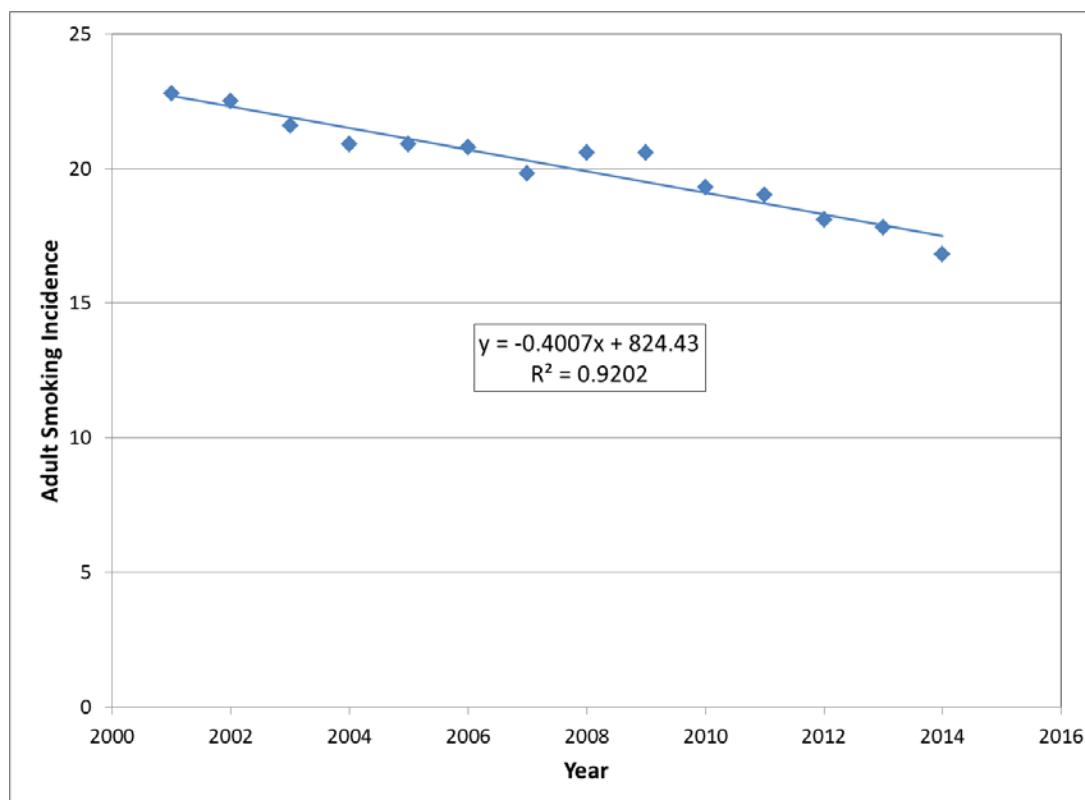


Table 5.6-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.6-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Robust production and associated manufacturing emissions. Based on 0.0088% of the projected smokers switching to the use of 5 pouches of Camel Snus Robust per day, an additional 13,905 pounds of Camel Snus Robust will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Robust will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Robust each day is greater than current Camel Snus Robust use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.6-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Robust production, total ammonia and nicotine emissions are expected to increase by 3 and 16 pounds per year, respectively, based upon the proposed action ([Table 5.6-7](#)).

Table 5.6-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Robust

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Robust Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Robust	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	4	0.111	2
Ammonia (Total off-site release)	2,123	4	0.116	2
Ammonia (Total)	4,159	7	-	3
Nicotine (Total on-site release)	11,293	20	0.615	9
Nicotine (Total off-site release)	10,168	18	0.553	8
Nicotine (Total)	21,461	37	-	16

5.6.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.6-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.01% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.6-8](#)).

Figure 5.6-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

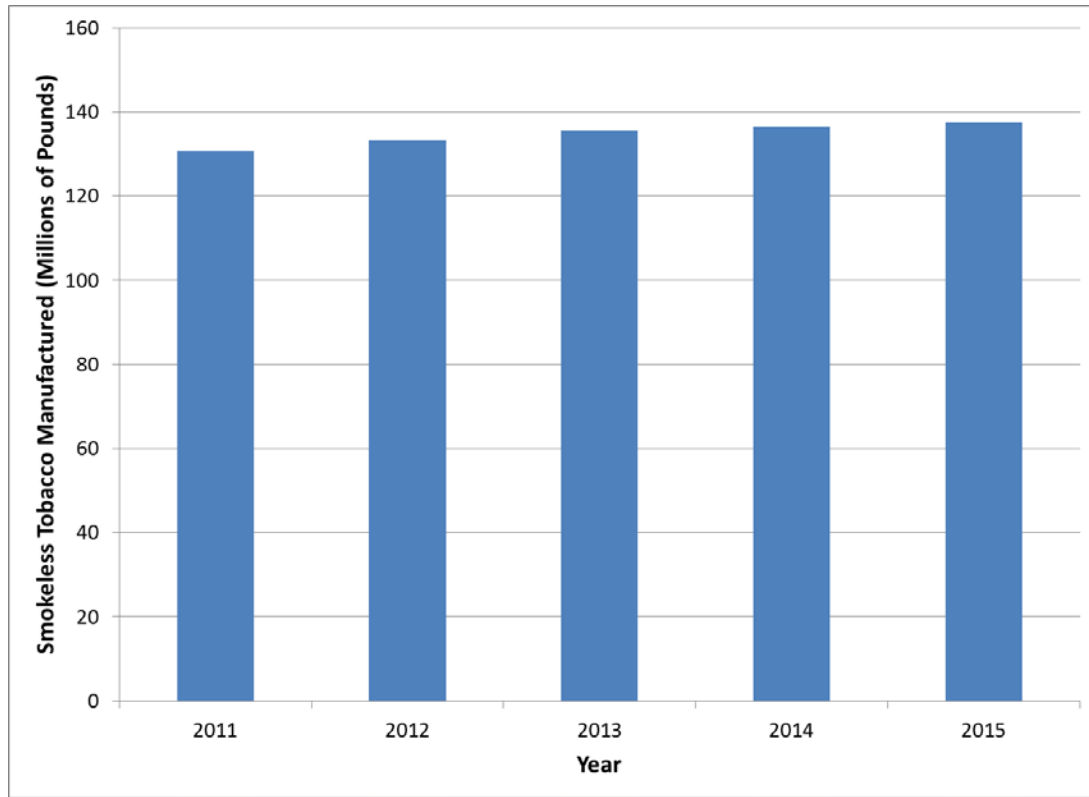


Table 5.6-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	2	15,233	0.01
Ammonia (Total off-site release)	0.116	2	15,884	0.01
Ammonia (Total)	-	3	31,117	0.01
Nicotine (Total on-site release)	0.615	9	84,492	0.01
Nicotine (Total off-site release)	0.553	8	76,075	0.01
Nicotine (Total)	-	16	160,567	0.01

5.6.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.6-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 4.4×10^{-07} percent decrease) and the increase in Camel Snus Robust production has a negligible impact (a 7.7×10^{-07} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.6-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

Table 5.6-9: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	20.0 million cigarettes	1,559	730	2,289
Increases from Camel Snus Robust	13,905 pounds	958	3,034	3,992

5.6.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Robust and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.6.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Robust accounted for ~ 0.02% by weight of the smokeless tobacco manufactured in the United States and ~ 2% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 3,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, resulting in a decrease of ~ 20 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 13,905 pounds of Camel Snus Robust will be manufactured based upon those smokers using 5 pouches of Camel Snus Robust per day.

5.6.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Robust. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Robust. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 20 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.6.4 Environmental Introduction as a Result of Disposal after Product Use

5.6.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Robust in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Robust includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Robust consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.6-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.6-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Robust are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.6-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

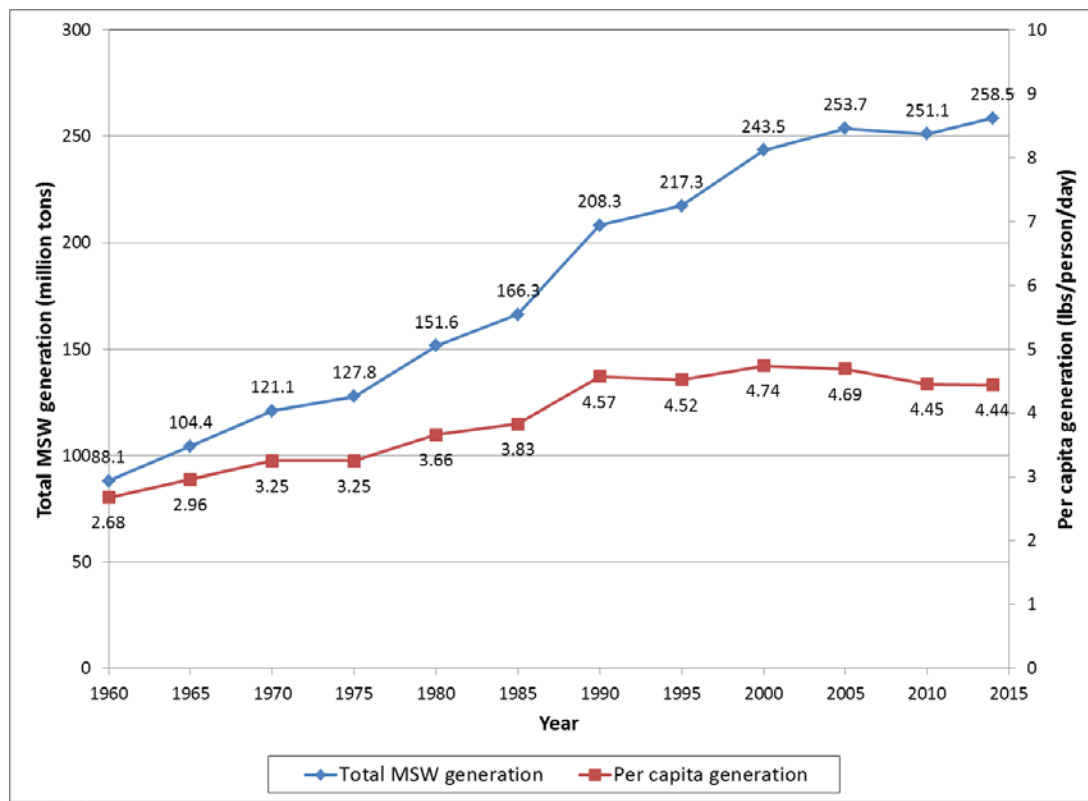
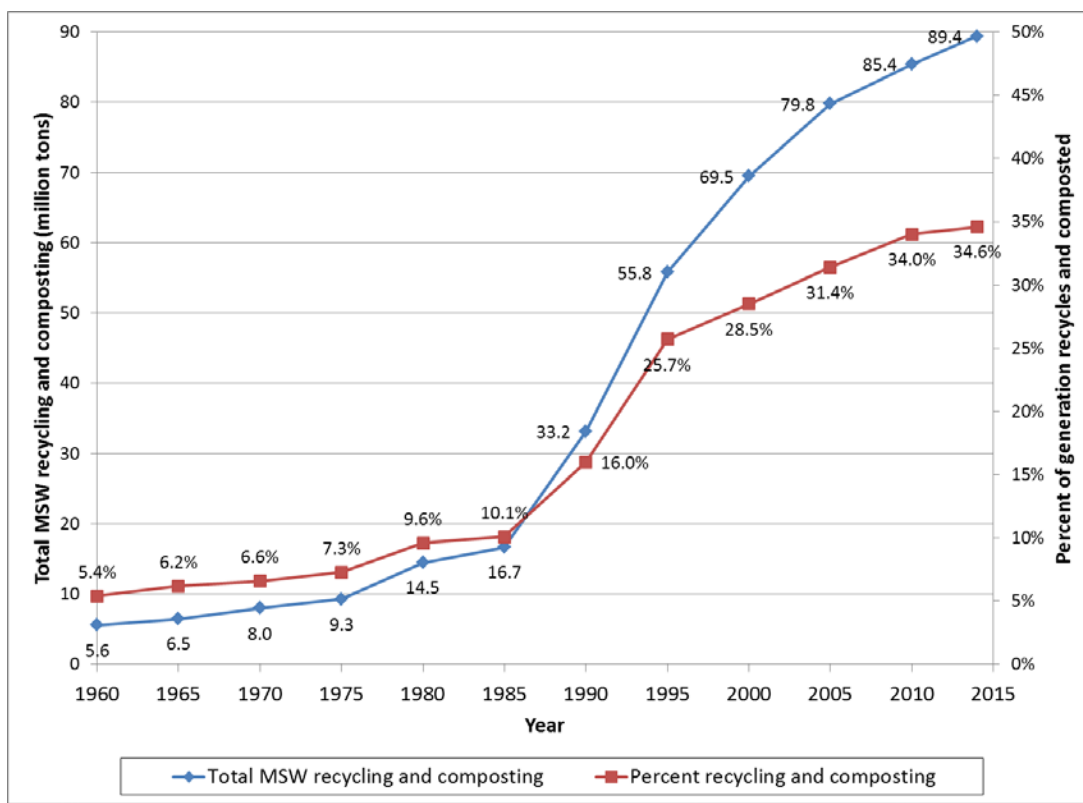


Figure 5.6-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.6.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.6.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Robust

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 3,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, resulting in a decrease of ~ 20 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 20 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.6-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 3.9 tons per year.

Table 5.6-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	11.6	4,309	2.2
“100 mm” (90 – 101 mm)	40.8	8.2	3,381	1.7
“120 mm” (118 – 120 mm)	1.1	0.2	91	0.05
Total (All styles)	100	20.0	7,781	3.9

Based on the proposed action resulting in ~ 3,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, it is estimated that an additional 13,905 pounds of Camel Snus Robust will be manufactured if those smokers use 5 pouches of Camel Snus Robust per day each day of the year. Waste generated due to Camel Snus Robust use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Robust tobacco will become waste for disposal after use, resulting in an increase of ~ 7 tons of used Camel Snus Robust pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 1.5×10^{-06} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Robust used pouch disposal has a negligible impact (a 2.7×10^{-06} percent increase) to the MSW stream, based on the same figures ([Table 5.6-11](#)).

Table 5.6-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	3.9	1.5×10^{-6}
Increase in used Camel Snus Robust pouches	7	2.7×10^{-6}

5.6.4.2.2 Disposal of Cigarette and Camel Snus Robust Packaging Material

Based on ~ 3,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 1 million fewer cigarette packs and approximately 100 thousand fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 420 thousand more Camel Snus Robust tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.6-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.6-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 10.1 tons per year ([Table 5.6-13](#)).

Camel Snus Robust Packaging weights are summarized in [Table 5.6-14](#). The Camel Snus Robust package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Robust use, it is estimated that packaging waste will increase by 10.3 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 3.9×10^{-6} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Robust packaging disposal will have a negligible impact (a 4.0×10^{-6} percent increase), based on the same figures ([Table 5.6-15](#)).

Table 5.6-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.6-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	58,136	11,590	5.8
"100 mm" (90 – 101 mm)	40.8	40,786	8,392	4.2
"120 mm" (118 – 120 mm)	1.1	1,147	259	0.1
Total (All styles)	100	100,068	20,242	10.1

Table 5.6-14: Camel Snus Robust Packaging Weights

Camel Snus Robust Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.6-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	10.1	3.9×10^{-6}
Increase in Camel Snus Robust packaging waste	10.3	4.0×10^{-6}

5.6.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Robust will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.6.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.6.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.6.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 3,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 20 million fewer cigarettes will be manufactured and that approximately 6 million more pouches of Camel Snus Robust will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.6-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.6-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Robust	Net Change Due to the Proposed Action
Electricity (thousand kWh)	38	7	-31
Water (ccf)	6,744	567	-6,177
Natural gas (ccf)	1,110	195	-915

5.6.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.6.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 3,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 20 million fewer cigarettes will be manufactured and that approximately 6 million more pouches of Camel Snus Robust will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.6-17](#) summarizes projected annual changes in

GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.6-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Robust	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	52	9	-42

5.6.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Robust manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps²⁷ made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals²⁸ and plants²⁹ and (b) the endangered and threatened species listed in Appendices I, II, and III³⁰ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Robust manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Robust are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

²⁷ Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

²⁸ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

²⁹ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

³⁰ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Robust are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Robust have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.6.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.6.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Robust as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Robust as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.6.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.7 Camel Snus Frost: Advertising Execution #2

This Environmental Assessment (EA) is required for authorization of Camel Snus Frost as a modified risk tobacco product as communicated per [Advertising Execution 2](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).³¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.7.1 Description of Proposed Action

5.7.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.7.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Frost as a modified risk tobacco product.

5.7.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

³¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Frost	0.6 gram	9.0 gram

Package Description

Camel Snus Frost is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.7.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Frost while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Frost. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 2](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.7-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.3% of current regular cigarette smokers. Apportionment to the Camel Snus Frost style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Frost represents 32.9% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Frost, due to introduction of the proposed modified risk advertising, is 0.43% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.43% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.7-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

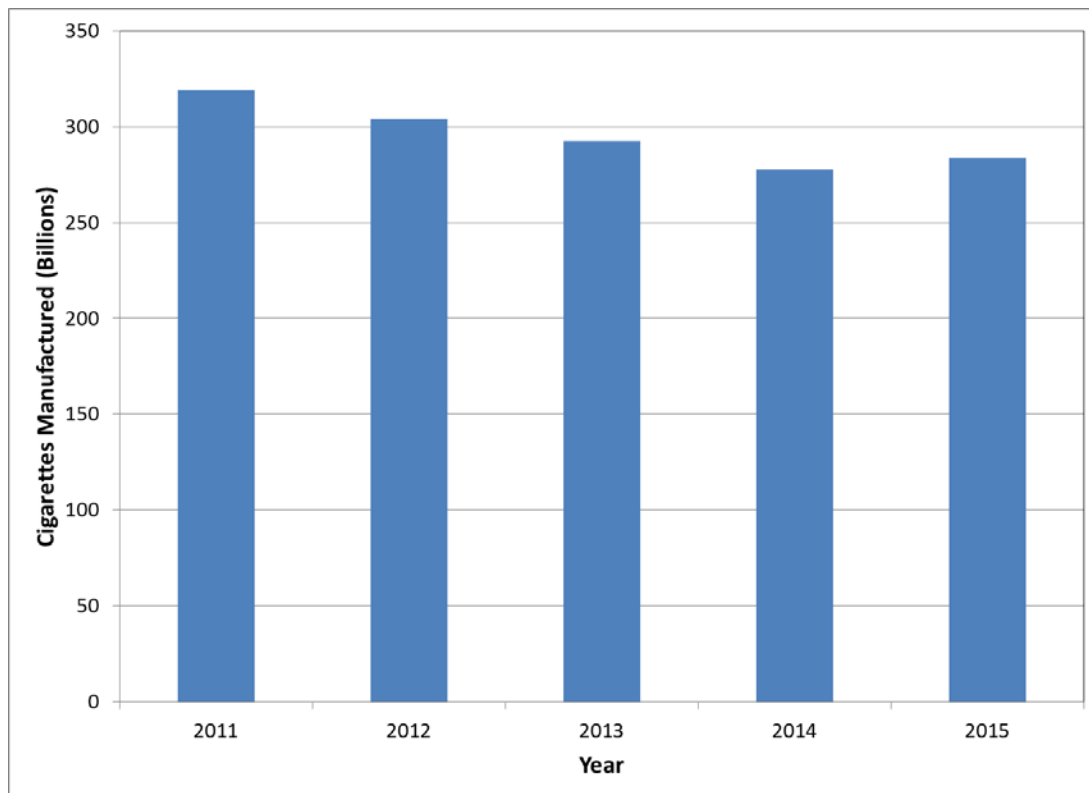
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.2%	1.9%	0.5%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.3%	-	-

5.7.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.7-1](#)).

Figure 5.7-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.7-2](#).

Table 5.7-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.43% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.7-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.7-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.43% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost. Total ammonia and nicotine emissions are expected to decrease by 110 and 168 pounds per year, respectively, based upon the proposed action.

Table 5.7-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	105
Ammonia (Total off-site release)	499	1,545	1,238	5
Ammonia (Total)	10,398	32,192	25,797	110
Nicotine (Total on-site release)	13,865	42,926	34,398	147
Nicotine (Total off-site release)	1,942	6,012	4,818	21
Nicotine (Total)	15,807	48,938	39,216	168

5.7.2.2 Environmental Consequences from Manufacturing Camel Snus Frost

Waste generated as a result of manufacturing Camel Snus Frost is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Frost releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Frost use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Frost. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Frost is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.7-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Frost due to the proposed order are summarized in [Table 5.7-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Frost (~ 1.5%); (c) the average rate of each emission type per pound of Camel Snus Frost tobacco manufactured in 2015 and (d) the number of smokers (~ 168,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Frost (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.43% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.7-2](#) and [Figure 5.7-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.7-4](#) and [Table 5.7-5](#), respectively.

Figure 5.7-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

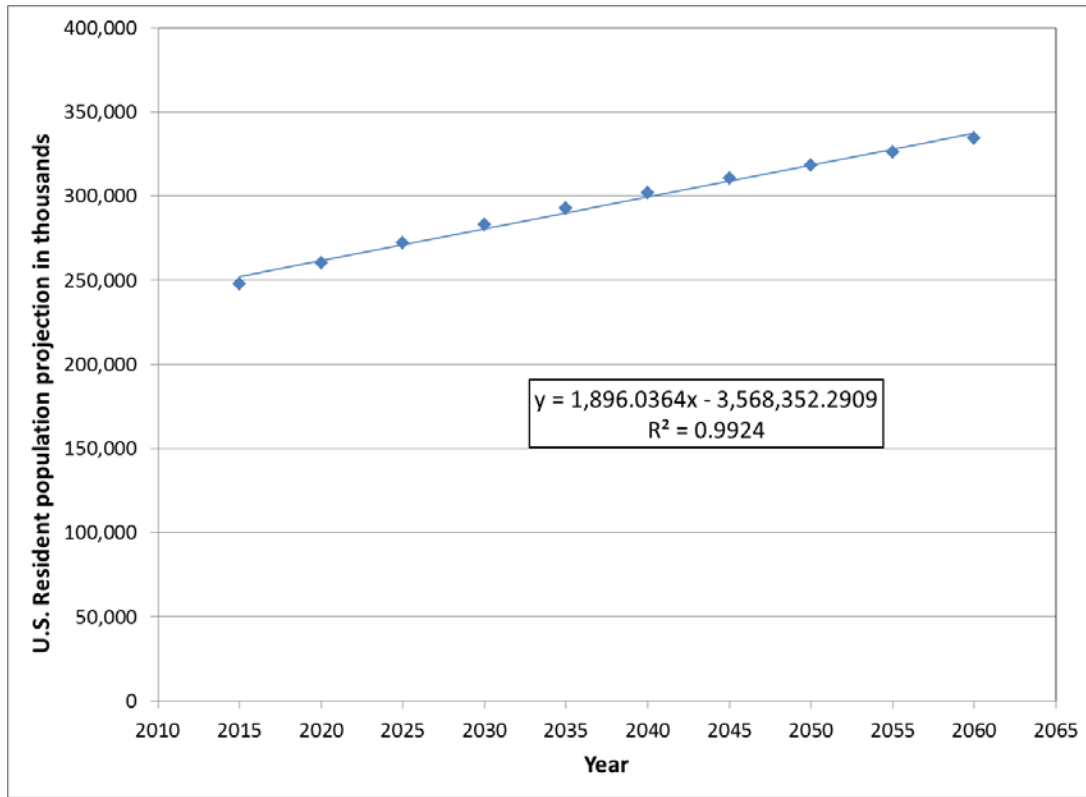


Table 5.7-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.7-3: Adult Smoking Incidence 2001 – 2014

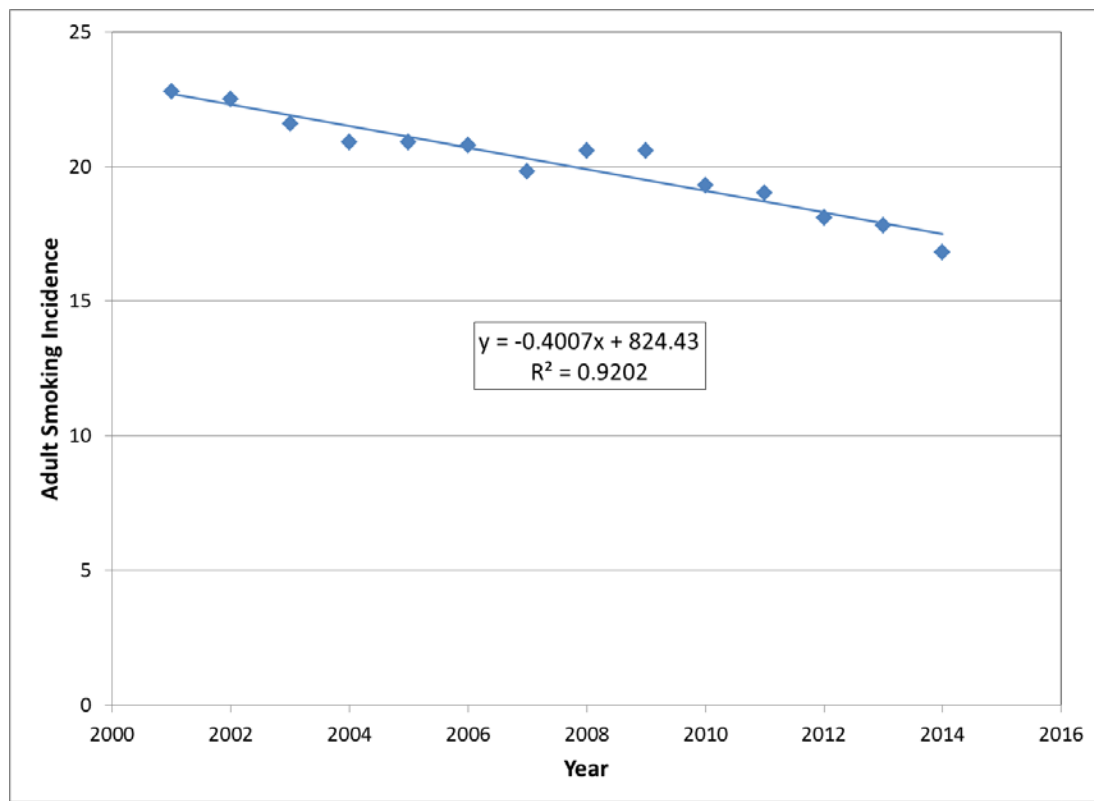


Table 5.7-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.7-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Frost production and associated manufacturing emissions. Based on 0.4277% of the projected smokers switching to the use of 5 pouches of Camel Snus Frost per day, an additional 405,492 pounds of Camel Snus Frost will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Frost will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Frost each day is greater than current Camel Snus Frost use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.7-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Frost production, total ammonia and nicotine emissions are expected to increase by 92 and 474 pounds per year, respectively, based upon the proposed action ([Table 5.7-7](#)).

Table 5.7-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Frost

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Frost Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Frost	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	31	0.111	45
Ammonia (Total off-site release)	2,123	33	0.116	47
Ammonia (Total)	4,159	64	-	92
Nicotine (Total on-site release)	11,293	174	0.615	249
Nicotine (Total off-site release)	10,168	157	0.553	224
Nicotine (Total)	21,461	331	-	474

5.7.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.7-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.29% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.7-8](#)).

Figure 5.7-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

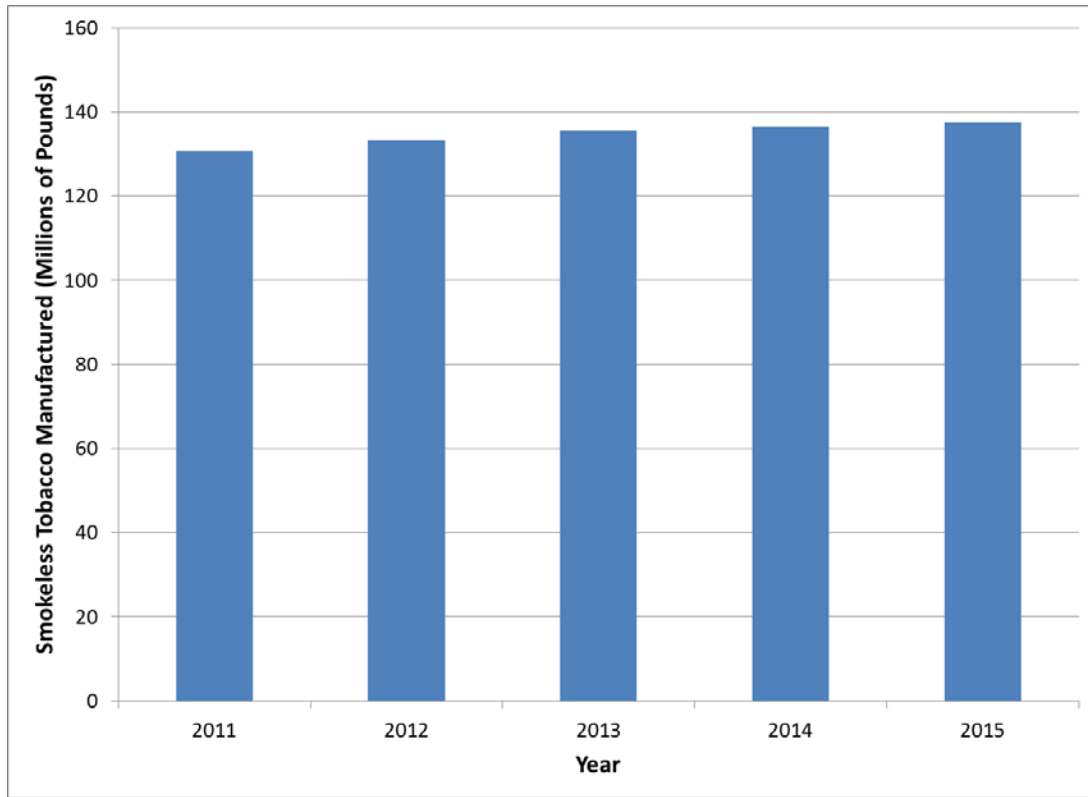


Table 5.7-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	45	15,233	0.29
Ammonia (Total off-site release)	0.116	47	15,884	0.29
Ammonia (Total)	-	92	31,117	0.29
Nicotine (Total on-site release)	0.615	249	84,492	0.29
Nicotine (Total off-site release)	0.553	224	76,075	0.29
Nicotine (Total)	-	474	160,567	0.29

5.7.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.7-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 2.15×10^{-05} percent decrease) and the increase in Camel Snus Frost production has a negligible impact (a 2.25×10^{-05} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.7-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

Table 5.7-9: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	972.7 million cigarettes	75,753	35,482	111,236
Increases from Camel Snus Frost	405,492 pounds	27,927	88,478	116,405

5.7.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Frost and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.7.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Frost accounted for ~ 0.21% by weight of the smokeless tobacco manufactured in the United States and ~ 26% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 168,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, resulting in a decrease of ~ 1 billion cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 405,492 pounds of Camel Snus Frost will be manufactured based upon those smokers using 5 pouches of Camel Snus Frost per day.

5.7.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Frost. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Frost. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 1 billion cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.7.4 Environmental Introduction as a Result of Disposal after Product Use

5.7.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Frost in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Frost includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Frost consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.7-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.7-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Frost are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.7-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

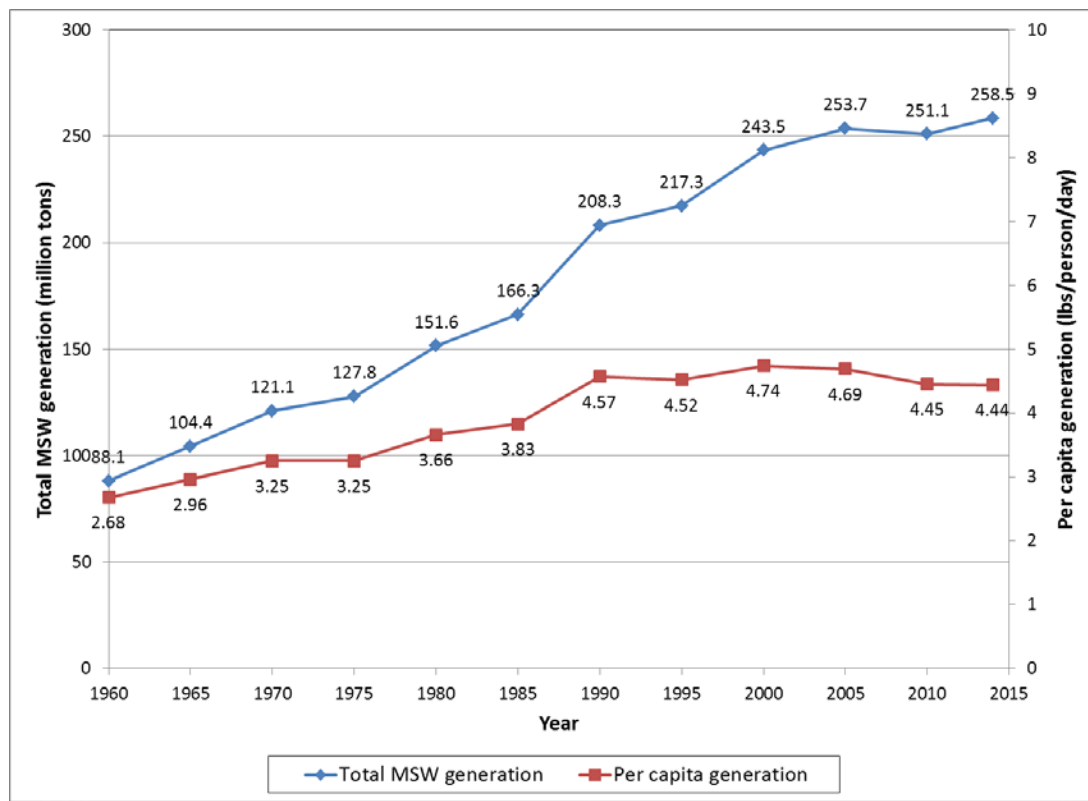
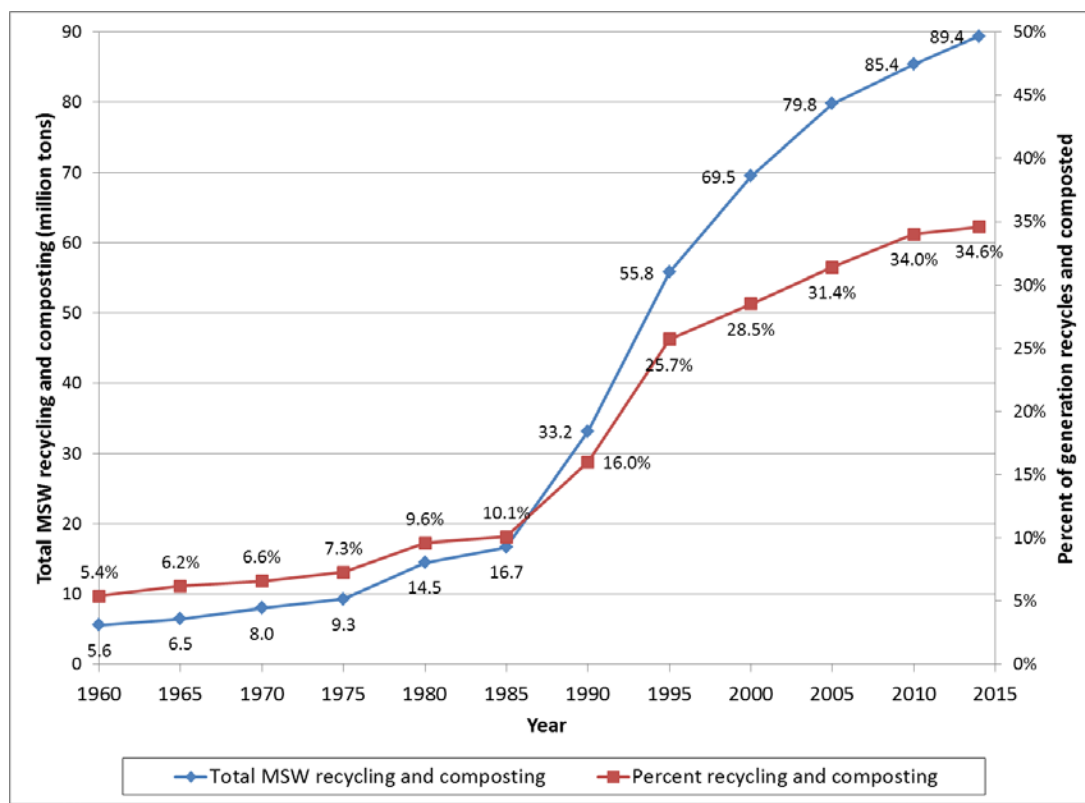


Figure 5.7-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.7.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.7.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Frost

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 168,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, resulting in a decrease of ~ 1 billion cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 1 billion cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.7-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 189 tons per year.

Table 5.7-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	565	209,428	105
“100 mm” (90 – 101 mm)	40.8	396	164,320	82
“120 mm” (118 – 120 mm)	1.1	11	4,406	2
Total (All styles)	100	973	378,154	189

Based on the proposed action resulting in ~ 168,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, it is estimated that an additional 405,492 pounds of Camel Snus Frost will be manufactured if those smokers use 5 pouches of Camel Snus Frost per day each day of the year. Waste generated due to Camel Snus Frost use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Frost tobacco will become waste for disposal after use, resulting in an increase of ~ 203 tons of used Camel Snus Frost pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 7.3×10^{-05} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Frost used pouch disposal has a negligible impact (a 7.8×10^{-05} percent increase) to the MSW stream, based on the same figures ([Table 5.7-11](#)).

Table 5.7-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	189	7.3×10^{-05}
Increase in used Camel Snus Frost pouches	203	7.8×10^{-05}

5.7.4.2.2 Disposal of Cigarette and Camel Snus Frost Packaging Material

Based on ~ 168,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 49 million fewer cigarette packs and approximately 4.9 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 20 million more Camel Snus Frost tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.7-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.7-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 492 tons per year ([Table 5.7-13](#)).

Camel Snus Frost Packaging weights are summarized in [Table 5.7-14](#). The Camel Snus Frost package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Frost use, it is estimated that packaging waste will increase by 501 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 1.90×10^{-04} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Frost packaging disposal will have a negligible impact (a 1.94×10^{-04} percent increase), based on the same figures ([Table 5.7-15](#)).

Table 5.7-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.7-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	2,825,529	563,312	282
"100 mm" (90 – 101 mm)	40.8	1,982,288	407,873	204
"120 mm" (118 – 120 mm)	1.1	55,731	12,610	6
Total (All styles)	100	4,863,548	983,794	492

Table 5.7-14: Camel Snus Frost Packaging Weights

Camel Snus Frost Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.7-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	492	1.90×10^{-04}
Increase in Camel Snus Frost packaging waste	501	1.94×10^{-04}

5.7.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Frost will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.7.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.7.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.7.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 168,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 1 billion fewer cigarettes will be manufactured and that approximately 307 million more pouches of Camel Snus Frost will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.7-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.7-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost	Net Change Due to the Proposed Action
Electricity (thousand kWh)	1,843	204	-1,640
Water (ccf)	327,790	16,547	-311,243
Natural gas (ccf)	53,926	5,679	-48,247

5.7.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.7.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 168,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 1 billion fewer cigarettes will be manufactured and that approximately 307 million more pouches of Camel Snus Frost will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.7-17](#) summarizes projected annual changes in GHG

in Camel Snus Frost are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Frost have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.7.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.7.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Frost as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Frost as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.7.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.8 Camel Snus Mint: Advertising Execution #2

This Environmental Assessment (EA) is required for authorization of Camel Snus Mint as a modified risk tobacco product as communicated per [Advertising Execution 2](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).³⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.8.1 Description of Proposed Action

5.8.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.8.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Mint as a modified risk tobacco product.

5.8.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

³⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Mint	0.6 gram	9.0 gram

Package Description

Camel Snus Mint is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.8.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Mint while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Mint. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 2](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.8-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.3% of current regular cigarette smokers. Apportionment to the Camel Snus Mint style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Mint represents 8.7% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Mint, due to introduction of the proposed modified risk advertising, is 0.11% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.11% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.8-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

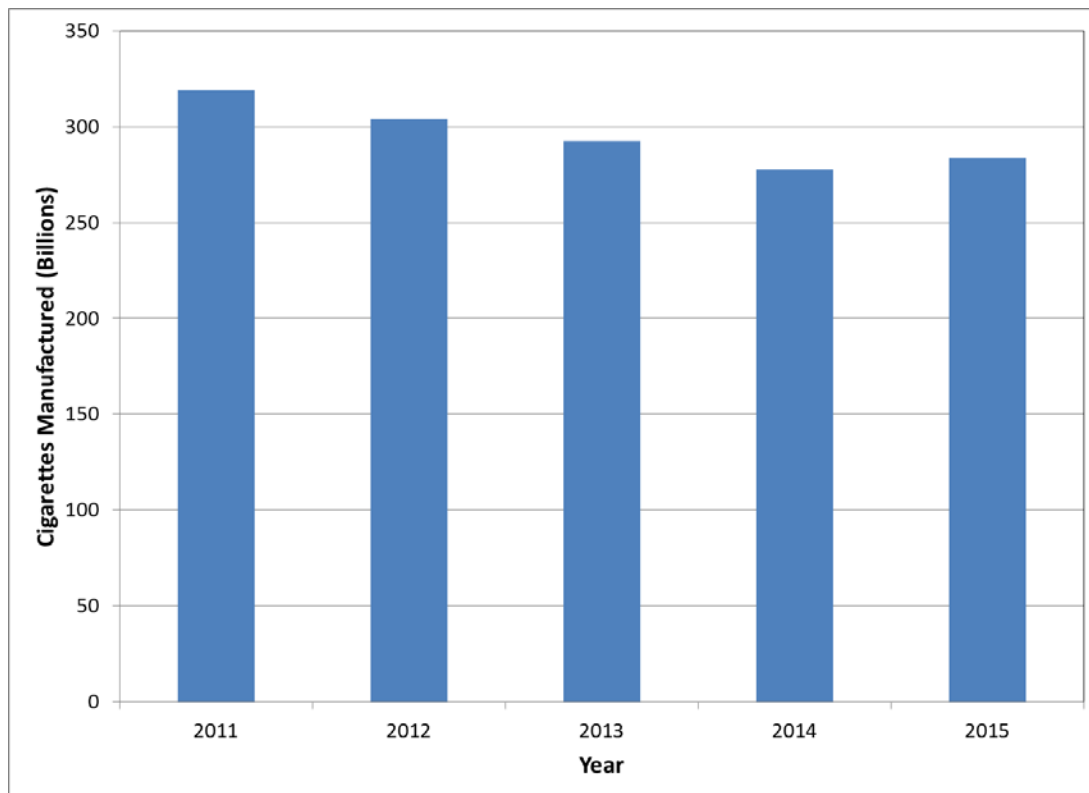
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.2%	1.9%	0.5%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.3%	-	-

5.8.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.8-1](#)).

Figure 5.8-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.8-2](#).

Table 5.8-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.11% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.8-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.8-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.11% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint. Total ammonia and nicotine emissions are expected to decrease by 29 and 44 pounds per year, respectively, based upon the proposed action.

Table 5.8-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	28
Ammonia (Total off-site release)	499	1,545	1,238	1
Ammonia (Total)	10,398	32,192	25,797	29
Nicotine (Total on-site release)	13,865	42,926	34,398	39
Nicotine (Total off-site release)	1,942	6,012	4,818	5
Nicotine (Total)	15,807	48,938	39,216	44

5.8.2.2 Environmental Consequences from Manufacturing Camel Snus Mint

Waste generated as a result of manufacturing Camel Snus Mint is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Mint releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Mint use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Mint. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Mint is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.8-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Mint due to the proposed order are summarized in [Table 5.8-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Mint (~ 0.4%); (c) the average rate of each emission type per pound of Camel Snus Mint tobacco manufactured in 2015 and (d) the number of smokers (~ 44,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Mint (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.11% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.8-2](#) and [Figure 5.8-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.8-4](#) and [Table 5.8-5](#), respectively.

Figure 5.8-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

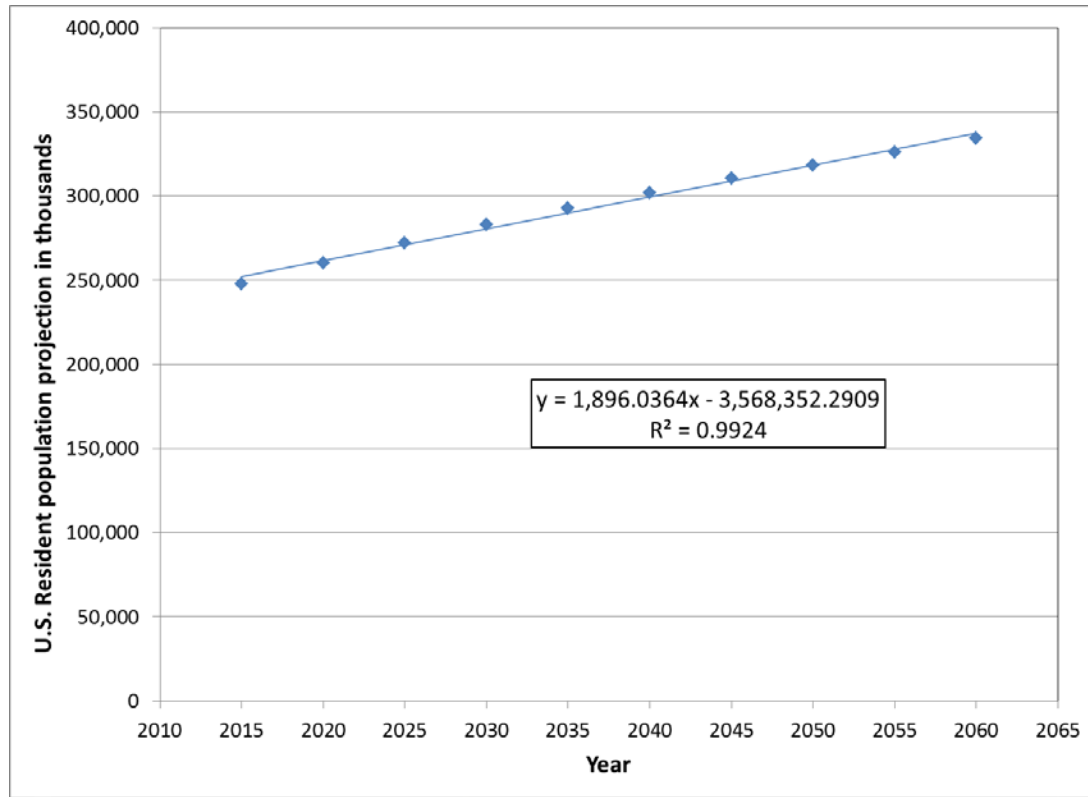


Table 5.8-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.8-3: Adult Smoking Incidence 2001 – 2014

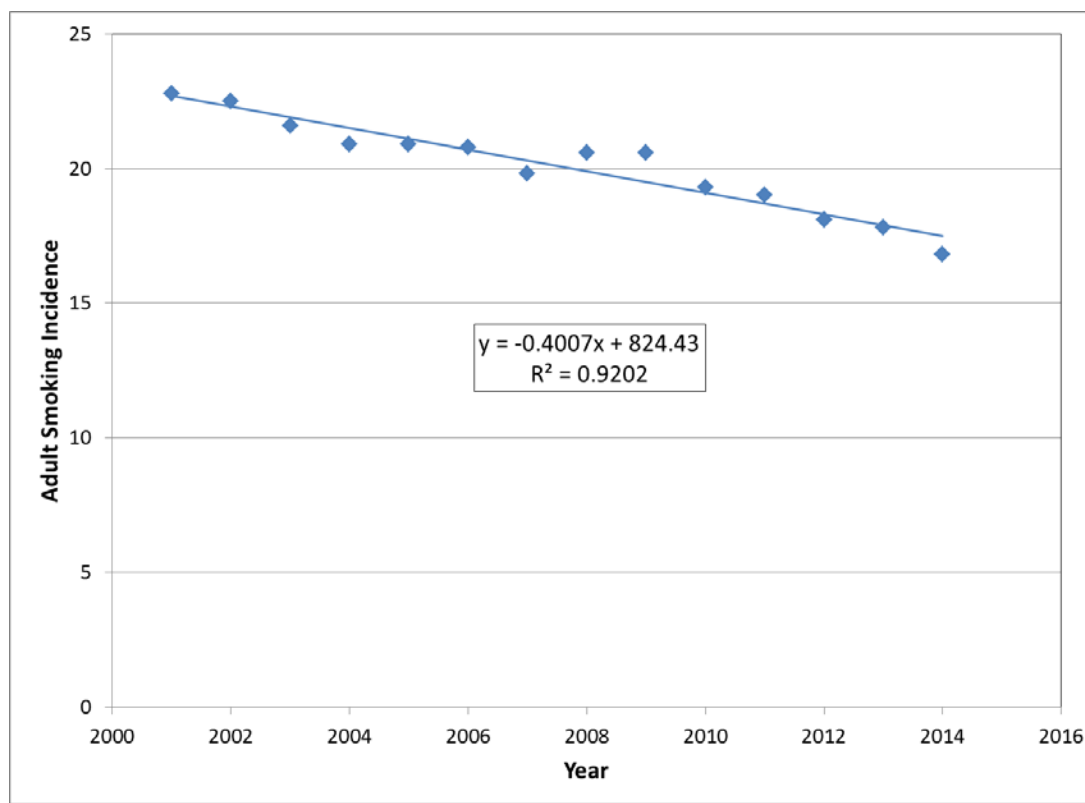


Table 5.8-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Figure 5.8-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Mint production and associated manufacturing emissions. Based on 0.1131% of the projected smokers switching to the use of 5 pouches of Camel Snus Mint per day, an additional 107,227 pounds of Camel Snus Mint will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Mint will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Mint each day is greater than current Camel Snus Mint use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.8-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Mint production, total ammonia and nicotine emissions are expected to increase by 24 and 125 pounds per year, respectively, based upon the proposed action ([Table 5.8-7](#)).

Table 5.8-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Mint

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Mint Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Mint	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	8	0.111	12
Ammonia (Total off-site release)	2,123	9	0.116	12
Ammonia (Total)	4,159	17	-	24
Nicotine (Total on-site release)	11,293	46	0.615	66
Nicotine (Total off-site release)	10,168	41	0.553	59
Nicotine (Total)	21,461	87	-	125

5.8.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.8-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.08% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.8-8](#)).

Figure 5.8-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

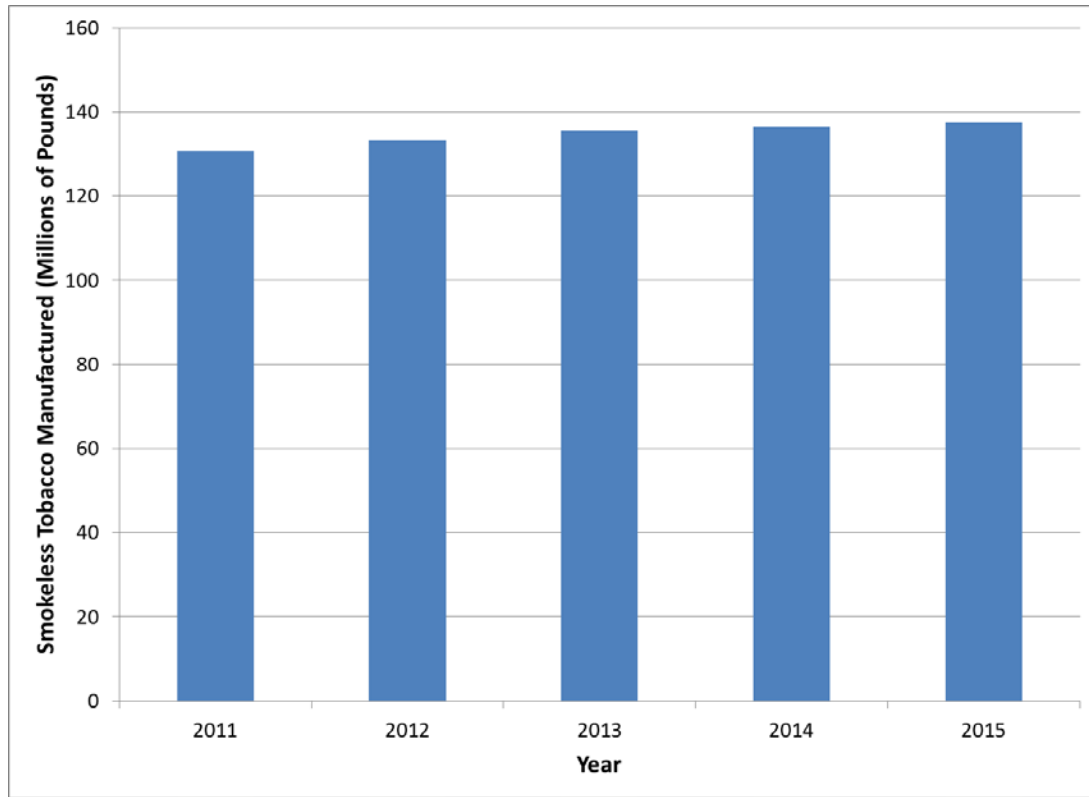


Table 5.8-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	12	15,233	0.08
Ammonia (Total off-site release)	0.116	12	15,884	0.08
Ammonia (Total)	-	24	31,117	0.08
Nicotine (Total on-site release)	0.615	66	84,492	0.08
Nicotine (Total off-site release)	0.553	59	76,075	0.08
Nicotine (Total)	-	125	160,567	0.08

5.8.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.8-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 5.7×10^{-06} percent decrease) and the increase in Camel Snus Mint production has a negligible impact (a 6.0×10^{-06} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.8-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

Table 5.8-9: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	257.2 million cigarettes	20,032	9,383	29,415
Increases from Camel Snus Mint	107,227 pounds	7,385	23,397	30,782

5.8.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Mint and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.8.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Mint accounted for ~ 0.05% by weight of the smokeless tobacco manufactured in the United States and ~ 7% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 44,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, resulting in a decrease of ~ 260 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 107,227 pounds of Camel Snus Mint will be manufactured based upon those smokers using 5 pouches of Camel Snus Mint per day.

5.8.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Mint. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Mint. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 260 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.8.4 Environmental Introduction as a Result of Disposal after Product Use

5.8.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Mint in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Mint includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Mint consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.8-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.8-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Mint are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.8-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

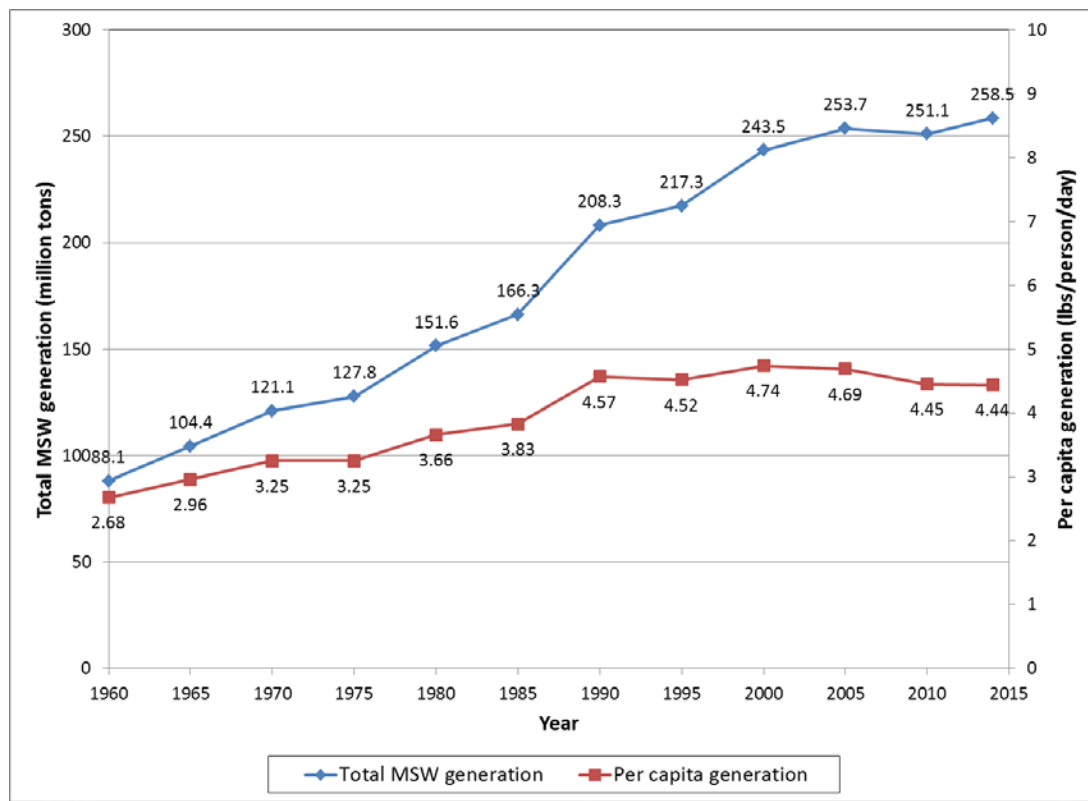
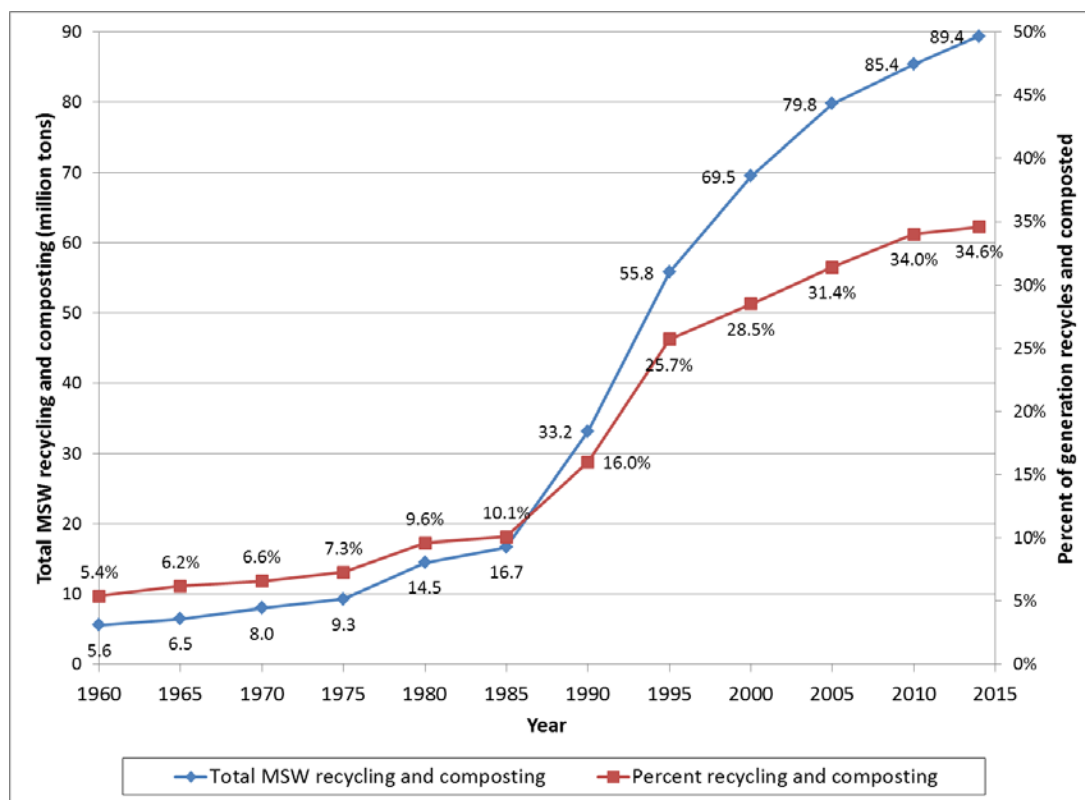


Figure 5.8-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.8.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.8.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Mint

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 44,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, resulting in a decrease of ~ 260 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 260 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.8-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 50 tons per year.

Table 5.8-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	149	55,381	28
“100 mm” (90 – 101 mm)	40.8	105	43,452	22
“120 mm” (118 – 120 mm)	1.1	3	1,165	1
Total (All styles)	100	257	99,998	50

Based on the proposed action resulting in ~ 44,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, it is estimated that an additional 107,227 pounds of Camel Snus Mint will be manufactured if those smokers use 5 pouches of Camel Snus Mint per day each day of the year. Waste generated due to Camel Snus Mint use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Mint tobacco will become waste for disposal after use, resulting in an increase of ~ 54 tons of used Camel Snus Mint pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 1.9×10^{-05} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Mint used pouch disposal has a negligible impact (a 2.1×10^{-05} percent increase) to the MSW stream, based on the same figures ([Table 5.8-11](#)).

Table 5.8-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	50	1.9×10^{-05}
Increase in used Camel Snus Mint pouches	54	2.1×10^{-05}

5.8.4.2.2 Disposal of Cigarette and Camel Snus Mint Packaging Material

Based on ~ 44,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 13 million fewer cigarette packs and approximately 1.3 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 5.4 million more Camel Snus Mint tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.8-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.8-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 130 tons per year ([Table 5.8-13](#)).

Camel Snus Mint Packaging weights are summarized in [Table 5.8-14](#). The Camel Snus Mint package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Mint use, it is estimated that packaging waste will increase by 132 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 5.0×10^{-05} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Mint packaging disposal will have a negligible impact (a 5.1×10^{-05} percent increase), based on the same figures ([Table 5.8-15](#)).

Table 5.8-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.8-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	747,176	148,961	74
"100 mm" (90 – 101 mm)	40.8	524,192	107,857	54
"120 mm" (118 – 120 mm)	1.1	14,737	3,335	2
Total (All styles)	100	1,286,105	260,152	130

Table 5.8-14: Camel Snus Mint Packaging Weights

Camel Snus Mint Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.8-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	130	5.0×10^{-05}
Increase in Camel Snus Mint packaging waste	132	5.1×10^{-05}

5.8.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Mint will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.8.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.8.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.8.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 44,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 260 million fewer cigarettes will be manufactured and that approximately 81 million more pouches of Camel Snus Mint will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.8-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.8-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mint	Net Change Due to the Proposed Action
Electricity (thousand kWh)	487	54	-434
Water (ccf)	86,680	4,376	-82,304
Natural gas (ccf)	14,260	1,502	-12,758

5.8.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.8.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 44,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 260 million fewer cigarettes will be manufactured and that approximately 81 million more pouches of Camel Snus Mint will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.8-17](#) summarizes projected annual changes in GHG

emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.8-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mint	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	666	72	-594

5.8.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Mint manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps³⁷ made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals³⁸ and plants³⁹ and (b) the endangered and threatened species listed in Appendices I, II, and III⁴⁰ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Mint manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Mint are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

³⁷ Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

³⁸ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

³⁹ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

⁴⁰ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Mint are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Mint have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.8.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.8.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Mint as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Mint as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.8.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.9 Camel Snus Mellow: Advertising Execution #2

This Environmental Assessment (EA) is required for authorization of Camel Snus Mellow as a modified risk tobacco product as communicated per [Advertising Execution 2](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁴¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.9.1 Description of Proposed Action

5.9.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.9.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Mellow as a modified risk tobacco product.

5.9.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁴¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Mellow	0.6 gram	9.0 gram

Package Description

Camel Snus Mellow is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.9.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Mellow while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Mellow. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 2](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.9-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.3% of current regular cigarette smokers. Apportionment to the Camel Snus Mellow style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Mellow represents 14.2% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Mellow, due to introduction of the proposed modified risk advertising, is 0.18% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.18% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.9-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

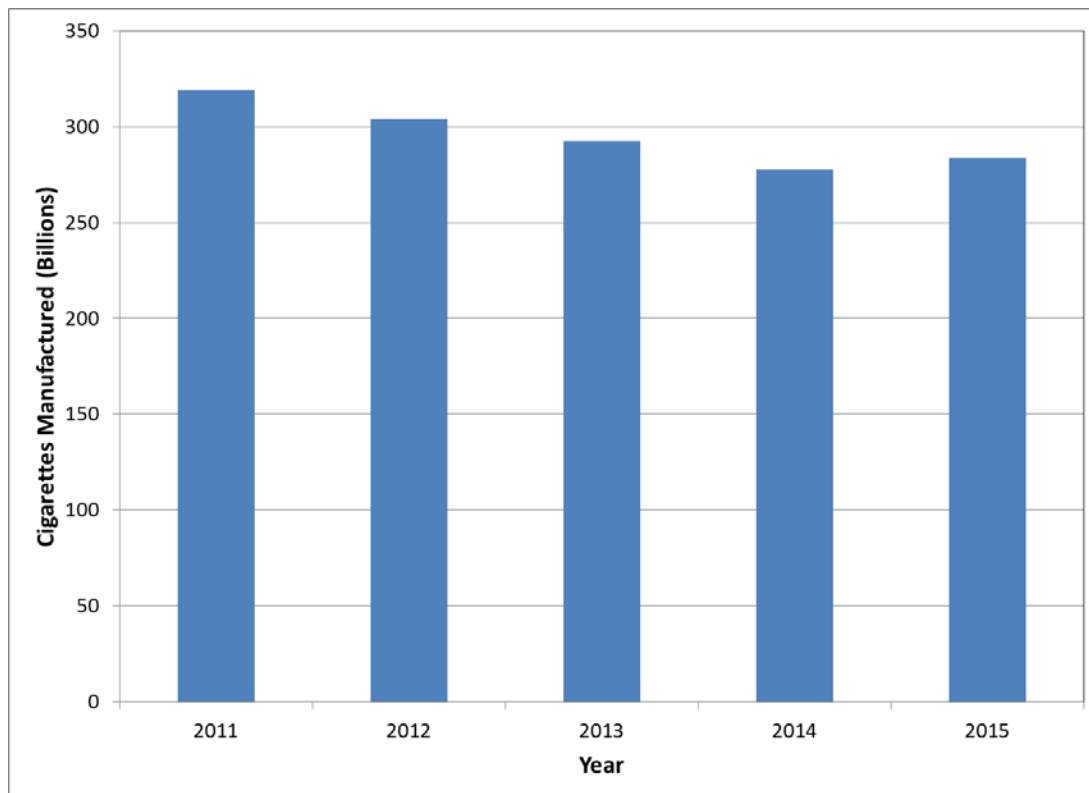
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.2%	1.9%	0.5%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.3%	-	-

5.9.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.9-1](#)).

Figure 5.9-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.9-2](#).

Table 5.9-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.18% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.9-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.9-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.18% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow. Total ammonia and nicotine emissions are expected to decrease by 48 and 72 pounds per year, respectively, based upon the proposed action.

Table 5.9-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	45
Ammonia (Total off-site release)	499	1,545	1,238	2
Ammonia (Total)	10,398	32,192	25,797	48
Nicotine (Total on-site release)	13,865	42,926	34,398	63
Nicotine (Total off-site release)	1,942	6,012	4,818	9
Nicotine (Total)	15,807	48,938	39,216	72

5.9.2.2 Environmental Consequences from Manufacturing Camel Snus Mellow

Waste generated as a result of manufacturing Camel Snus Mellow is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Mellow releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Mellow use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Mellow. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Mellow is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.9-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Mellow due to the proposed order are summarized in [Table 5.9-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Mellow (~ 0.7%); (c) the average rate of each emission type per pound of Camel Snus Mellow tobacco manufactured in 2015 and (d) the number of smokers (~ 72,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Mellow (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.18% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.9-2](#) and [Figure 5.9-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.9-4](#) and [Table 5.9-5](#), respectively.

Figure 5.9-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

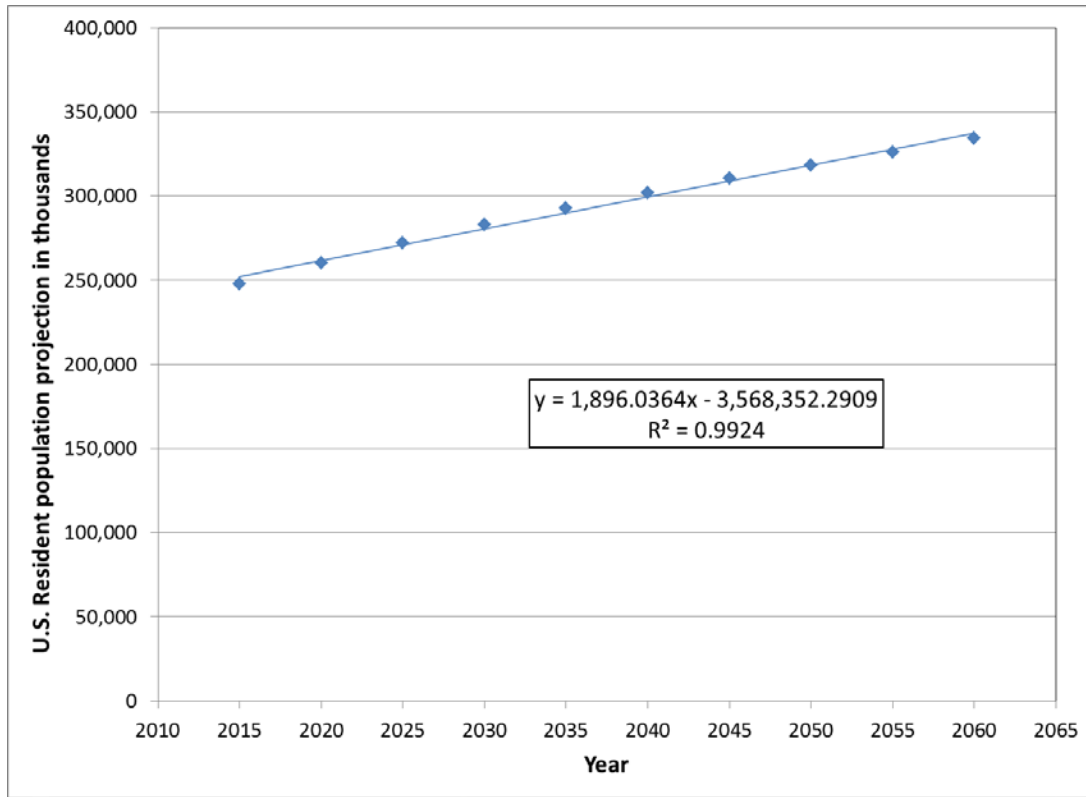


Table 5.9-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.9-3: Adult Smoking Incidence 2001 – 2014

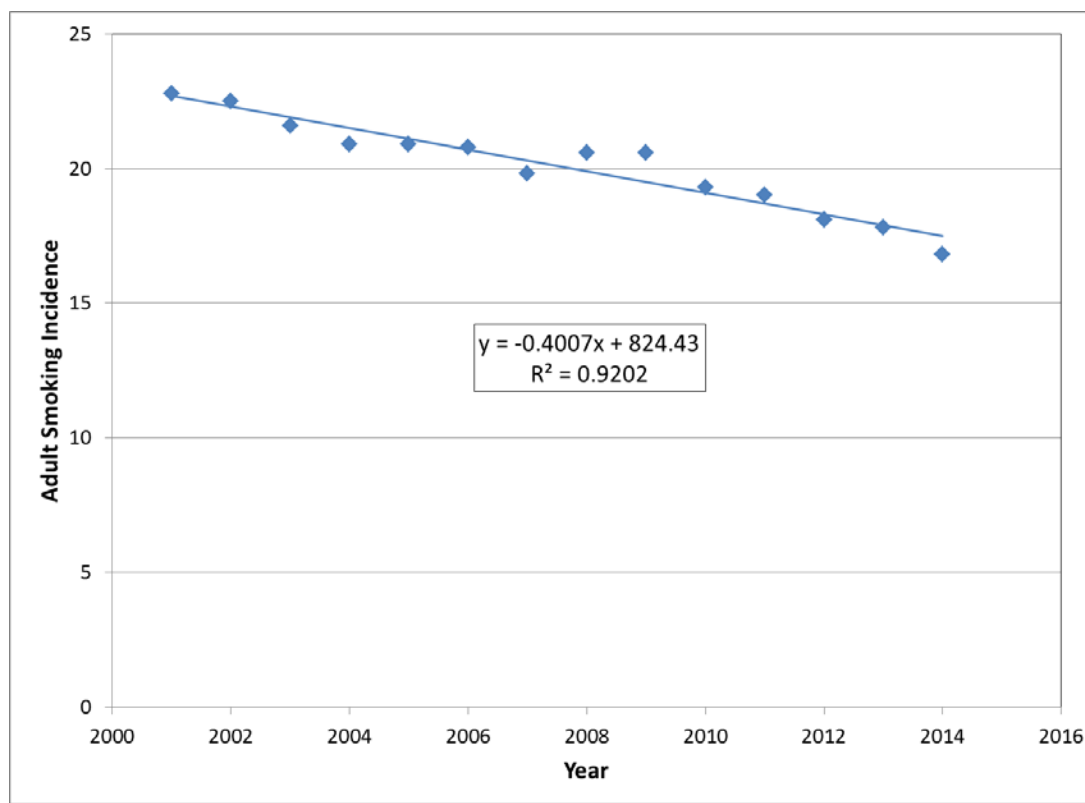


Table 5.9-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.9-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Mellow production and associated manufacturing emissions. Based on 0.1846% of the projected smokers switching to the use of 5 pouches of Camel Snus Mellow per day, an additional 175,015 pounds of Camel Snus Mellow will be manufactured. Of note, this estimate assumes that all of the projected switching from

smoking cigarettes to the use of Camel Snus Mellow will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Mellow each day is greater than current Camel Snus Mellow use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.9-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Mellow production, total ammonia and nicotine emissions are expected to increase by 40 and 204 pounds per year, respectively, based upon the proposed action ([Table 5.9-7](#)).

Table 5.9-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Mellow

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Mellow Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Mellow	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	14	0.111	19
Ammonia (Total off-site release)	2,123	14	0.116	20
Ammonia (Total)	4,159	28	-	40
Nicotine (Total on-site release)	11,293	75	0.615	108
Nicotine (Total off-site release)	10,168	67	0.553	97
Nicotine (Total)	21,461	142	-	204

5.9.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.9-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.13% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.9-8](#)).

Figure 5.9-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

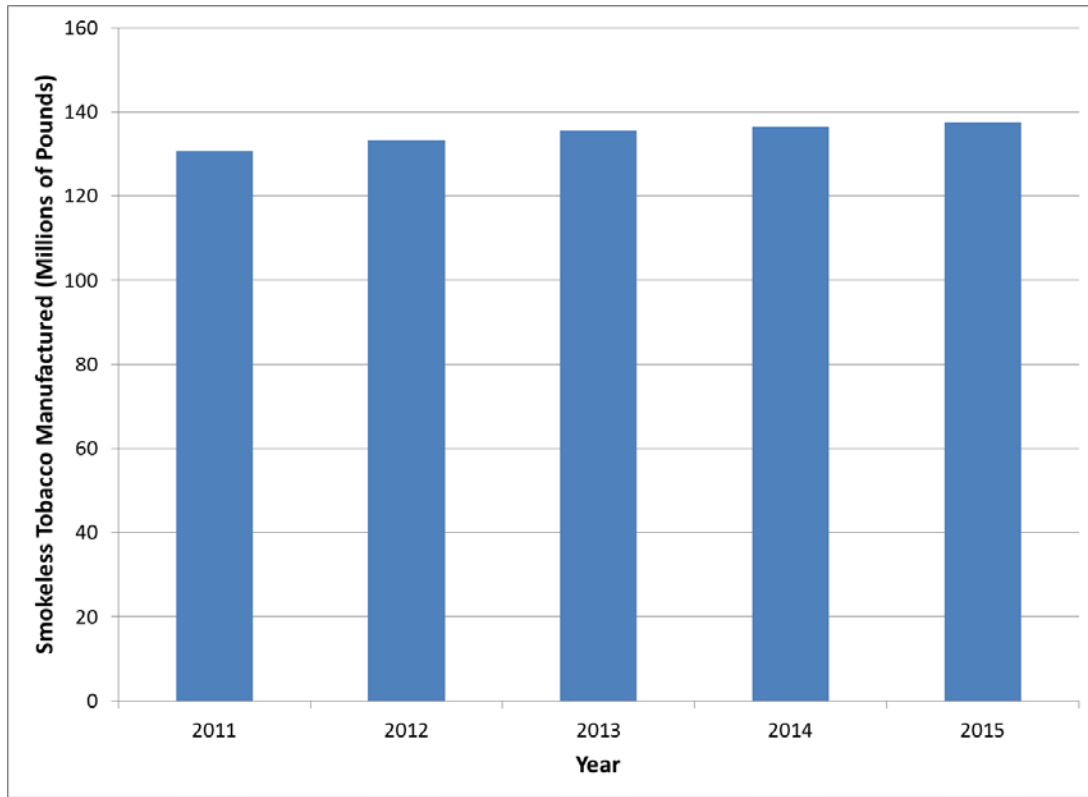


Table 5.9-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	19	15,233	0.13
Ammonia (Total off-site release)	0.116	20	15,884	0.13
Ammonia (Total)	-	40	31,117	0.13
Nicotine (Total on-site release)	0.615	108	84,492	0.13
Nicotine (Total off-site release)	0.553	97	76,075	0.13
Nicotine (Total)	-	204	160,567	0.13

5.9.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.9-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 9.3×10^{-6} percent decrease) and the increase in Camel Snus Mellow production has a negligible impact (a 9.7×10^{-6} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.9-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.9-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	419.8 million cigarettes	32,696	15,315	48,011
Increases from Camel Snus Mellow	175,015 pounds	12,054	38,188	50,242

5.9.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Mellow and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.9.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Mellow accounted for ~ 0.09% by weight of the smokeless tobacco manufactured in the United States and ~ 11% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 72,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, resulting in a decrease of ~ 420 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 175,015 pounds of Camel Snus Mellow will be manufactured based upon those smokers using 5 pouches of Camel Snus Mellow per day.

5.9.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Mellow. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Mellow. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 420 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.9.4 Environmental Introduction as a Result of Disposal after Product Use

5.9.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Mellow in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Mellow includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Mellow consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.9-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.9-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Mellow are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.9-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

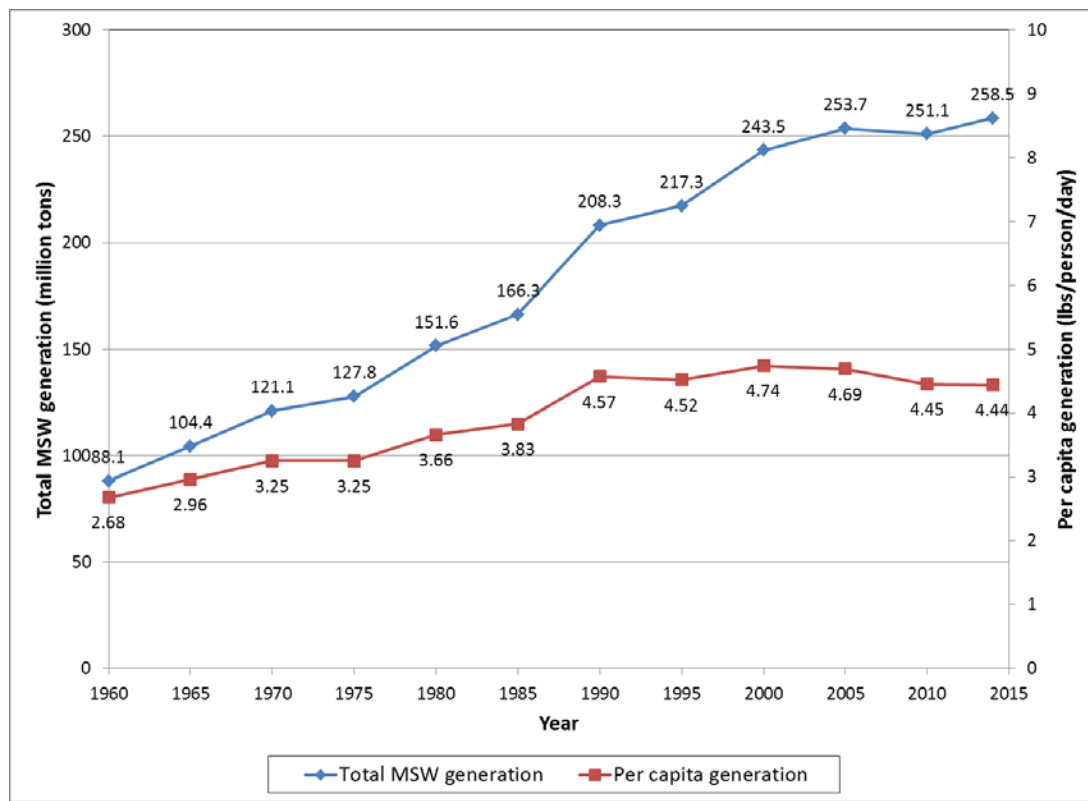
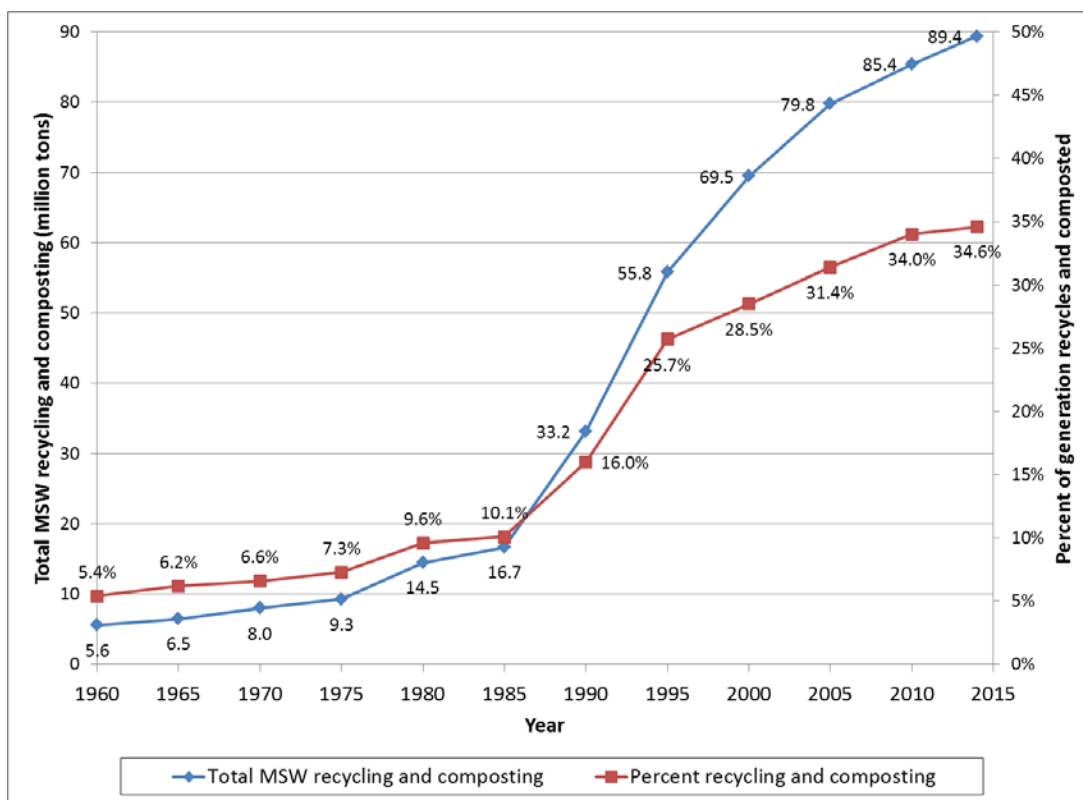


Figure 5.9-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.9.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.9.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Mellow

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 72,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, resulting in a decrease of ~ 420 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 420 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.9-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 82 tons per year.

Table 5.9-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	244	90,391	45
“100 mm” (90 – 101 mm)	40.8	171	70,922	35
“120 mm” (118 – 120 mm)	1.1	5	1,902	1
Total (All styles)	100	420	163,215	82

Based on the proposed action resulting in ~ 72,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, it is estimated that an additional 175,015 pounds of Camel Snus Mellow will be manufactured if those smokers use 5 pouches of Camel Snus Mellow per day each day of the year. Waste generated due to Camel Snus Mellow use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Mellow tobacco will become waste for disposal after use, resulting in an increase of ~ 88 tons of used Camel Snus Mellow pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 3.2×10^{-05} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Mellow used pouch disposal has a negligible impact (a 3.4×10^{-05} percent increase) to the MSW stream, based on the same figures ([Table 5.9-11](#)).

Table 5.9-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	82	3.2×10^{-05}
Increase in used Camel Snus Mellow pouches	88	3.4×10^{-05}

5.9.4.2.2 Disposal of Cigarette and Camel Snus Mellow Packaging Material

Based on ~ 72,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 21 million fewer cigarette packs and approximately 2.1 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 8.8 million more Camel Snus Mellow tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.9-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.9-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 212 tons per year ([Table 5.9-13](#)).

Camel Snus Mellow Packaging weights are summarized in [Table 5.9-14](#). The Camel Snus Mellow package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Mellow use, it is estimated that packaging waste will increase by 216 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 8.2×10^{-05} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Mellow packaging disposal will have a negligible impact (a 8.4×10^{-05} percent increase), based on the same figures ([Table 5.9-15](#)).

Table 5.9-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.9-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	1,219,529	243,131	122
"100 mm" (90 – 101 mm)	40.8	855,577	176,042	88
"120 mm" (118 – 120 mm)	1.1	24,054	5,443	3
Total (All styles)	100	2,099,160	424,616	212

Table 5.9-14: Camel Snus Mellow Packaging Weights

Camel Snus Mellow Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.9-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	212	8.2×10^{-05}
Increase in Camel Snus Mellow packaging waste	216	8.4×10^{-05}

5.9.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Mellow will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.9.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.9.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.9.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 72,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 420 million fewer cigarettes will be manufactured and that approximately 132 million more pouches of Camel Snus Mellow will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.9-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.9-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mellow	Net Change Due to the Proposed Action
Electricity (thousand kWh)	796	88	-708
Water (ccf)	141,478	7,142	-134,336
Natural gas (ccf)	23,275	2,451	-20,824

5.9.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.9.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 72,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 420 million fewer cigarettes will be manufactured and that approximately 132 million more pouches of Camel Snus Mellow will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.9-17](#) summarizes projected annual changes in

GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.9-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mellow	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	1,088	118	-970

5.9.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Mellow manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁴² made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁴³ and plants⁴⁴ and (b) the endangered and threatened species listed in Appendices I, II, and III⁴⁵ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Mellow manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Mellow are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

⁴² Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁴³ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁴⁴ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

⁴⁵ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Mellow are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Mellow have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.9.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.9.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Mellow as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Mellow as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.9.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.10 Camel Snus Frost Large: Advertising Execution #2

This Environmental Assessment (EA) is required for authorization of Camel Snus Frost Large as a modified risk tobacco product as communicated per [Advertising Execution 2](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁴⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.10.1 Description of Proposed Action

5.10.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.10.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Frost Large as a modified risk tobacco product.

5.10.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁴⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Frost Large	1.0 gram	15.0 gram

Package Description

Camel Snus Frost Large is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.10.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Frost Large while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will switch from smoking cigarettes to exclusively using Camel Snus Frost Large. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA's MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 2](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.10-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.3% of current regular cigarette smokers. Apportionment to the Camel Snus Frost Large style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Frost Large represents 28.4% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Frost Large, due to introduction of the proposed modified risk advertising, is 0.37% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.37% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.10-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

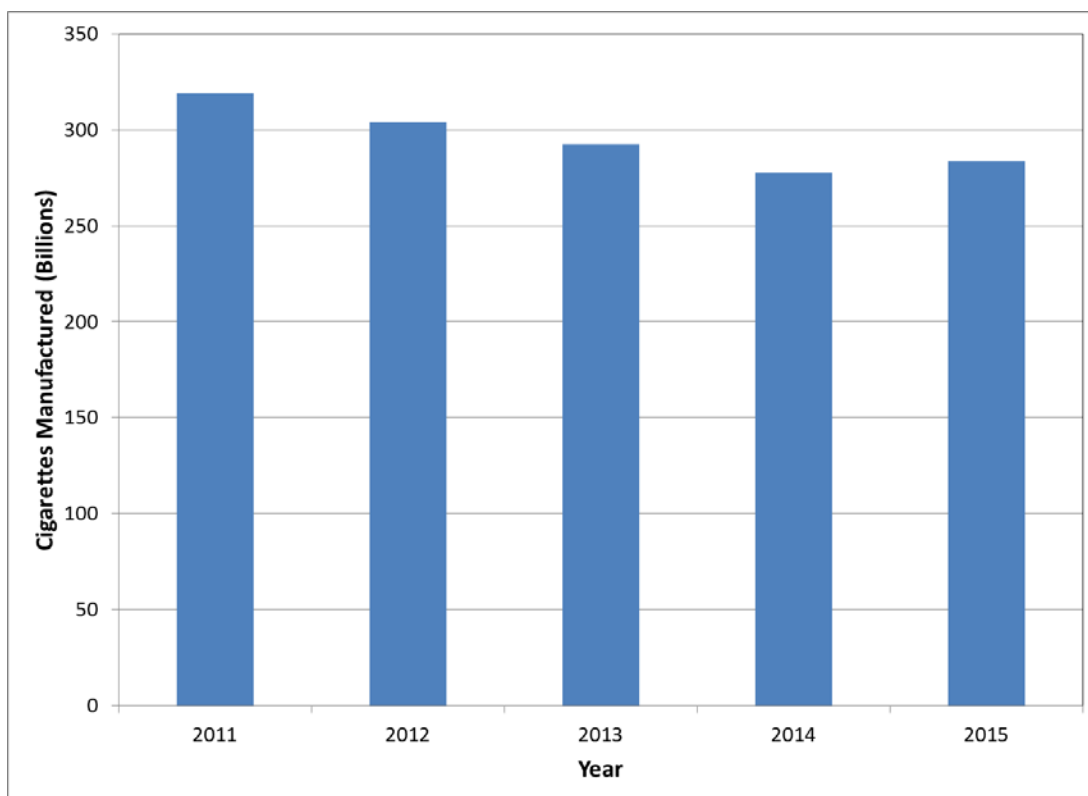
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.2%	1.9%	0.5%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.3%	-	-

5.10.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.10-1](#)).

Figure 5.10-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.10-2](#).

Table 5.10-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.37% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.10-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.10-3](#). Those values are estimated from: (a) current annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.37% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large. Total ammonia and nicotine emissions

are expected to decrease by 95 and 145 pounds per year, respectively, based upon the proposed action.

Table 5.10-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	91
Ammonia (Total off-site release)	499	1,545	1,238	5
Ammonia (Total)	10,398	32,192	25,797	95
Nicotine (Total on-site release)	13,865	42,926	34,398	127
Nicotine (Total off-site release)	1,942	6,012	4,818	18
Nicotine (Total)	15,807	48,938	39,216	145

5.10.2.2 Environmental Consequences from Manufacturing Camel Snus Frost Large

Waste generated as a result of manufacturing Camel Snus Frost Large is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Frost Large releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Frost Large use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Frost Large. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Frost Large is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table](#)

5.10-7). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Frost Large due to the proposed order are summarized in [Table 5.10-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Frost Large (~ 2.2%); (c) the average rate of each emission type per pound of Camel Snus Frost Large tobacco manufactured in 2015 and (d) the number of smokers (~ 145,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Frost Large (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.37% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.10-2](#) and [Figure 5.10-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.10-4](#) and [Table 5.10-5](#), respectively.

Figure 5.10-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

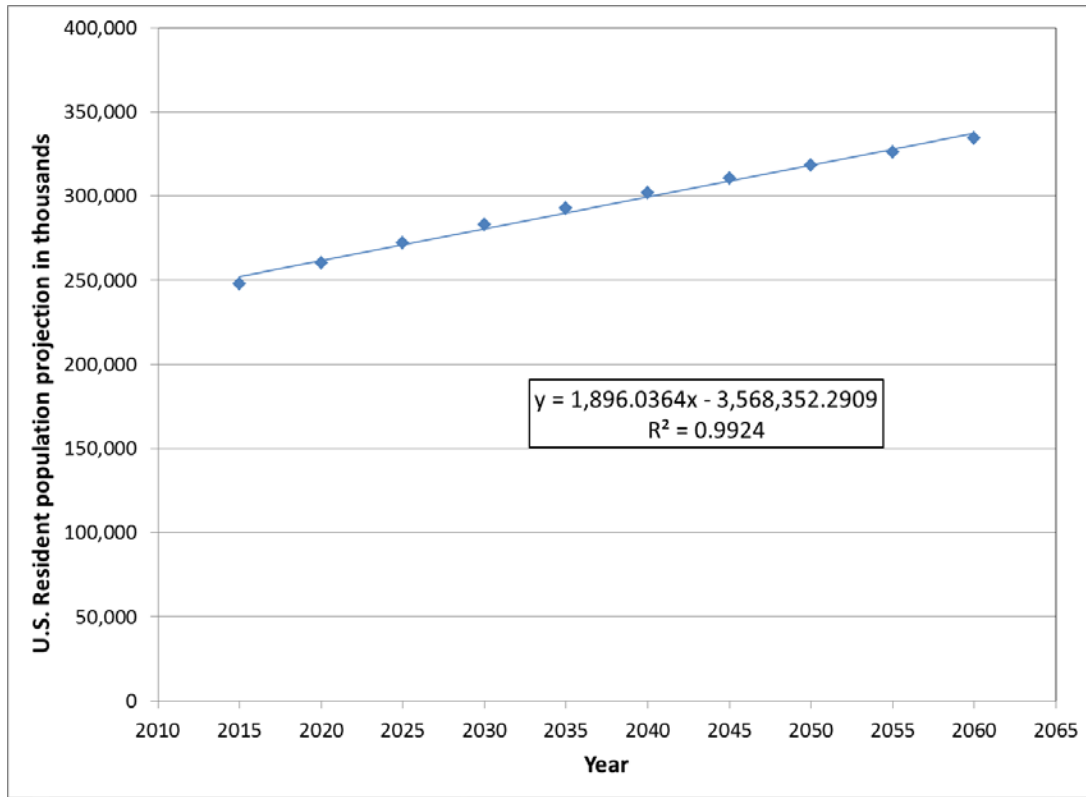


Table 5.10-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.10-3: Adult Smoking Incidence 2001 – 2014

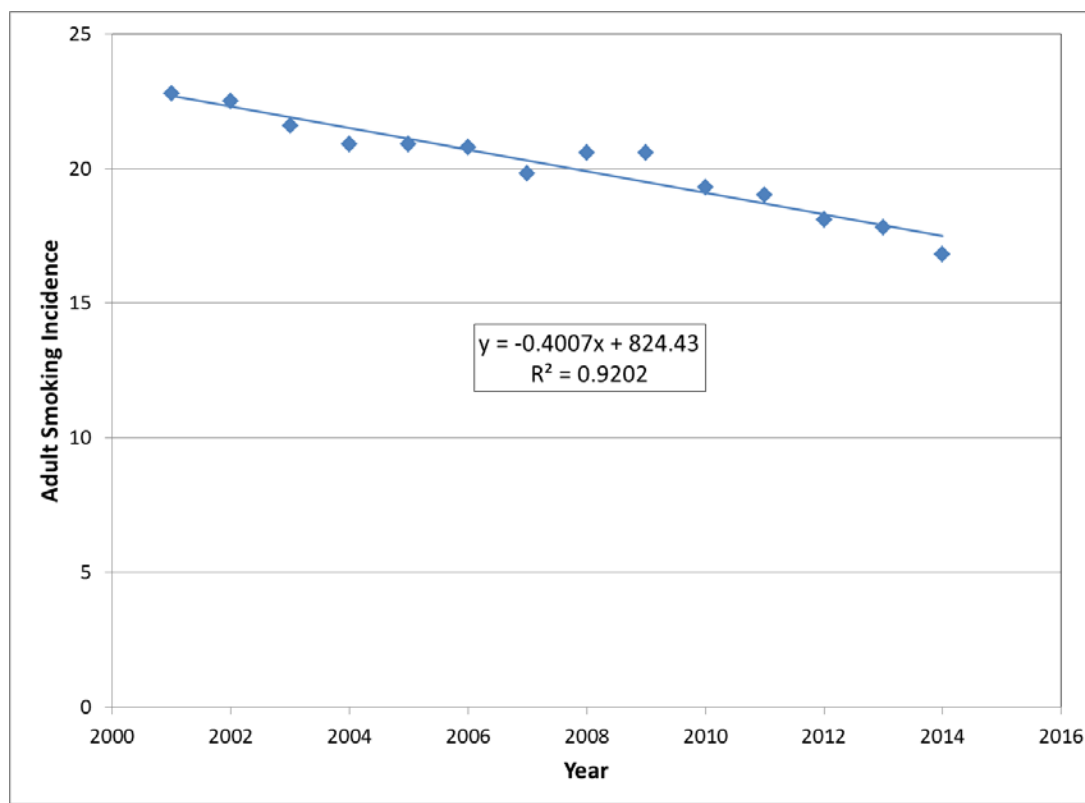


Table 5.10-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.10-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Frost Large production and associated manufacturing emissions. Based on 0.3692% of the projected smokers switching to the use of 5 pouches of Camel Snus Frost Large per day, an additional 583,383 pounds of Camel Snus Frost Large will be manufactured. Of note, this estimate assumes that all of the projected

switching from smoking cigarettes to the use of Camel Snus Frost Large will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Frost Large each day is greater than current Camel Snus Frost Large use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.10-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Frost Large production, total ammonia and nicotine emissions are expected to increase by 132 and 681 pounds per year, respectively, based upon the proposed action ([Table 5.10-7](#)).

Table 5.10-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Frost Large

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Frost Large Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Frost Large	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	45	0.111	65
Ammonia (Total off-site release)	2,123	47	0.116	67
Ammonia (Total)	4,159	92	-	132
Nicotine (Total on-site release)	11,293	250	0.615	359
Nicotine (Total off-site release)	10,168	225	0.553	323
Nicotine (Total)	21,461	476	-	681

5.10.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.10-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.42% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.10-8](#)).

Figure 5.10-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

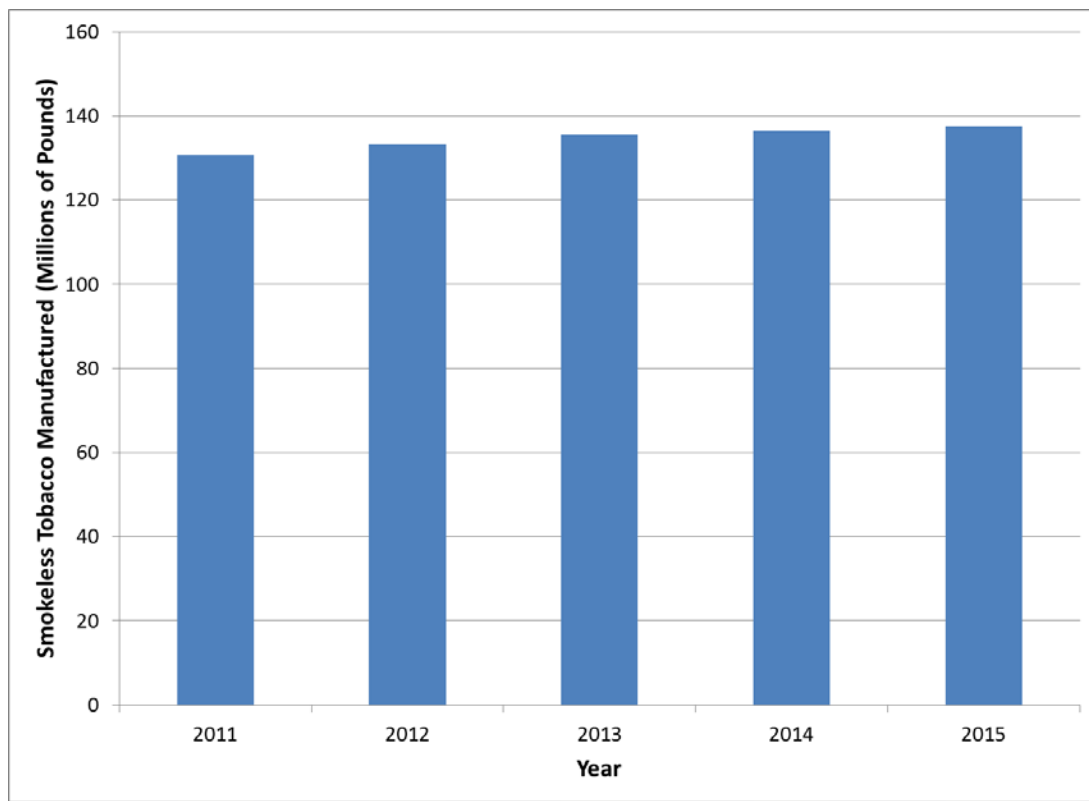


Table 5.10-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	65	15,233	0.42
Ammonia (Total off-site release)	0.116	67	15,884	0.42
Ammonia (Total)	-	132	31,117	0.42
Nicotine (Total on-site release)	0.615	359	84,492	0.42
Nicotine (Total off-site release)	0.553	323	76,075	0.42
Nicotine (Total)	-	681	160,567	0.42

5.10.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.10-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 1.9×10^{-05} percent decrease) and the increase in Camel Snus Frost Large production has a negligible impact (a 3.2×10^{-05} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.10-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.10-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	839.7 million cigarettes	65,392	30,629	96,021
Increases from Camel Snus Frost Large	583,383 pounds	40,179	127,294	167,472

5.10.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Frost Large and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.10.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Frost Large accounted for ~ 0.30% by weight of the smokeless tobacco manufactured in the United States and ~ 23% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 145,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, resulting in a decrease of ~ 840 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 583,383 pounds of Camel Snus Frost Large will be manufactured based upon those smokers using 5 pouches of Camel Snus Frost Large per day.

5.10.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Frost Large. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Frost Large. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 840 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.10.4 Environmental Introduction as a Result of Disposal after Product Use

5.10.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Frost Large in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Frost Large includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Frost Large consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.10-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.10-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Frost Large are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.10-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

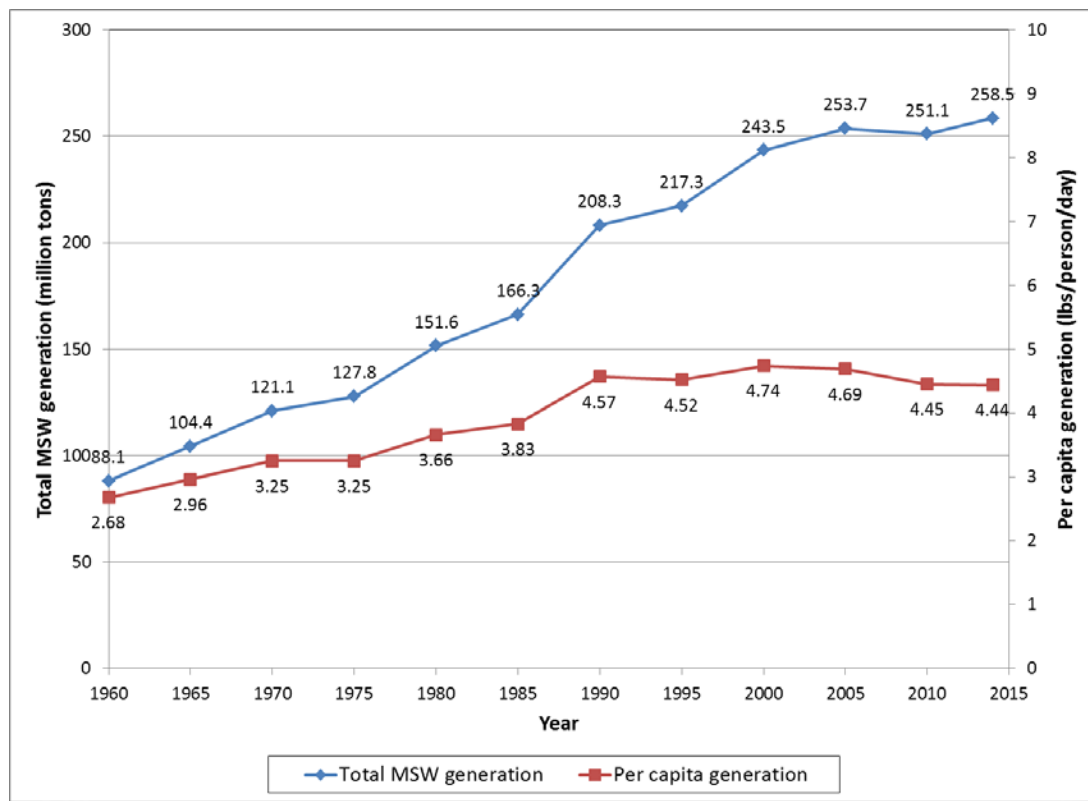
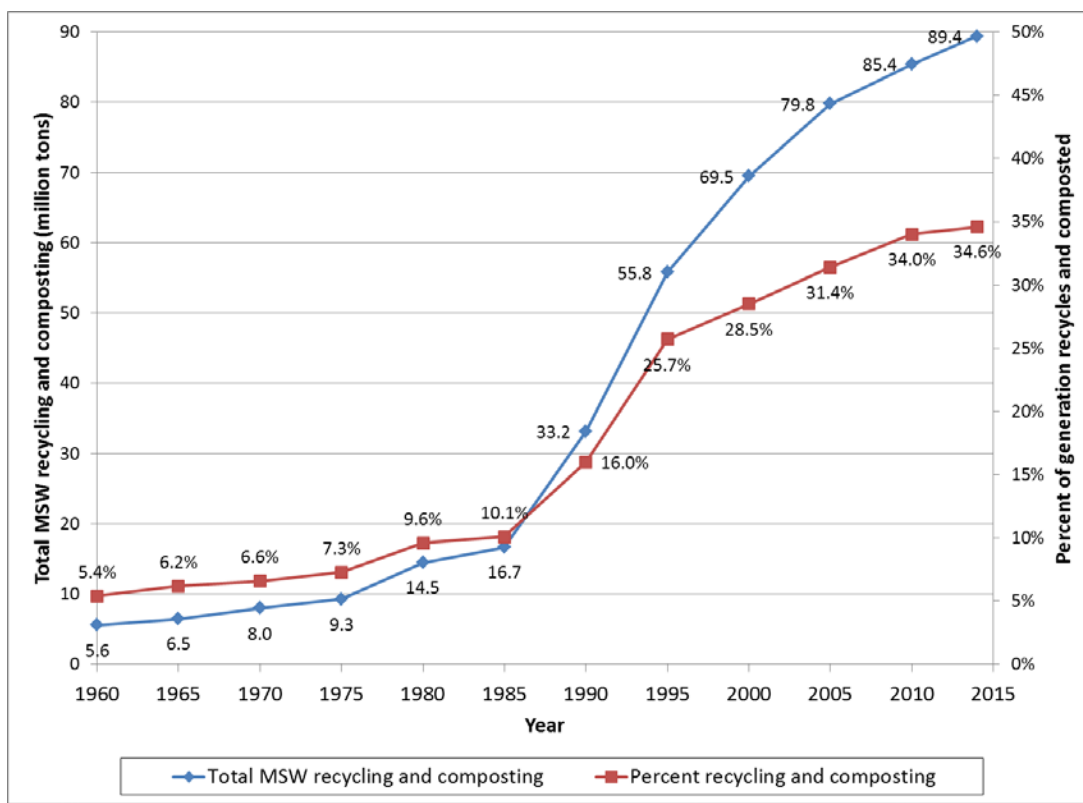


Figure 5.10-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.10.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.10.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Frost Large

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 145,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, resulting in a decrease of ~ 840 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 840 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.10-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 163 tons per year.

Table 5.10-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	488	180,782	90
“100 mm” (90 – 101 mm)	40.8	342	141,845	71
“120 mm” (118 – 120 mm)	1.1	10	3,803	2
Total (All styles)	100	840	326,431	163

Based on the proposed action resulting in ~ 145,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, it is estimated that an additional 583,383 pounds of Camel Snus Frost Large will be manufactured if those smokers use 5 pouches of Camel Snus Frost Large per day each day of the year. Waste generated due to Camel Snus Frost Large use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Frost Large tobacco will become waste for disposal after use, resulting in an increase of ~ 292 tons of used Camel Snus Frost Large pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 6.3×10^{-5} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Frost Large used pouch disposal has a negligible impact (a 1.1×10^{-4} percent increase) to the MSW stream, based on the same figures ([Table 5.10-11](#)).

Table 5.10-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	163	6.3×10^{-5}
Increase in used Camel Snus Frost Large pouches	292	1.1×10^{-4}

5.10.4.2.2 Disposal of Cigarette and Camel Snus Frost Large Packaging Material

Based on ~ 145,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 42 million fewer cigarette packs and approximately 4.2 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 17.6 million more Camel Snus Frost Large tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.10-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.10-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 425 tons per year ([Table 5.10-13](#)).

Camel Snus Frost Large Packaging weights are summarized in [Table 5.10-14](#). The Camel Snus Frost Large package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Frost Large use, it is estimated that packaging waste will increase by 432 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 1.6×10^{-4} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Frost Large packaging disposal will have a negligible impact (a 1.7×10^{-4} percent increase), based on the same figures ([Table 5.10-15](#)).

Table 5.10-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.10-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	2,439,058	486,263	243
"100 mm" (90 – 101 mm)	40.8	1,711,154	352,085	176
"120 mm" (118 – 120 mm)	1.1	48,108	10,885	5
Total (All styles)	100	4,198,321	849,233	425

Table 5.10-14: Camel Snus Frost Large Packaging Weights

Camel Snus Frost Large Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.10-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	425	1.6×10^{-04}
Increase in Camel Snus Frost Large packaging waste	432	1.7×10^{-04}

5.10.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Frost Large will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.10.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.10.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.10.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 145,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 840 million fewer cigarettes will be manufactured and that approximately 265 million more pouches of Camel Snus Frost Large will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.10-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.10-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost Large	Net Change Due to the Proposed Action
Electricity (thousand kWh)	1,591	293	-1,298
Water (ccf)	282,956	23,807	-259,149
Natural gas (ccf)	46,550	8,170	-38,380

5.10.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.10.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 145,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 840 million fewer cigarettes will be manufactured and that approximately 265 million more pouches of Camel Snus Frost Large will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.10-17](#) summarizes projected annual changes in GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.10-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost Large	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	2,175	392	-1,783

5.10.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act ("ESA") ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora ("CITES") ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Frost Large manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁴⁷ made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁴⁸ and plants⁴⁹ and (b) the endangered and threatened species

⁴⁷ Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁴⁸ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁴⁹ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

listed in Appendices I, II, and III⁵⁰ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Frost Large manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Frost Large are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used in Camel Snus Frost Large are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Frost Large have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.10.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers

⁵⁰ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.

- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.

- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.10.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Frost Large as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Frost Large as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.10.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.11 Camel Snus Winterchill: Advertising Execution #2

This Environmental Assessment (EA) is required for authorization of Camel Snus Winterchill as a modified risk tobacco product as communicated per [Advertising Execution 2](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁵¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.11.1 Description of Proposed Action

5.11.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.11.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Winterchill as a modified risk tobacco product.

5.11.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁵¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Winterchill	1.0 gram	15.0 gram

Package Description

Camel Snus Winterchill is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.11.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Winterchill while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will switch from smoking cigarettes to exclusively using Camel Snus Winterchill. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA's MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 2](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.11-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.3% of current regular cigarette smokers. Apportionment to the Camel Snus Winterchill style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Winterchill represents 13.6% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Winterchill, due to introduction of the proposed modified risk advertising, is 0.18% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.18% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.11-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

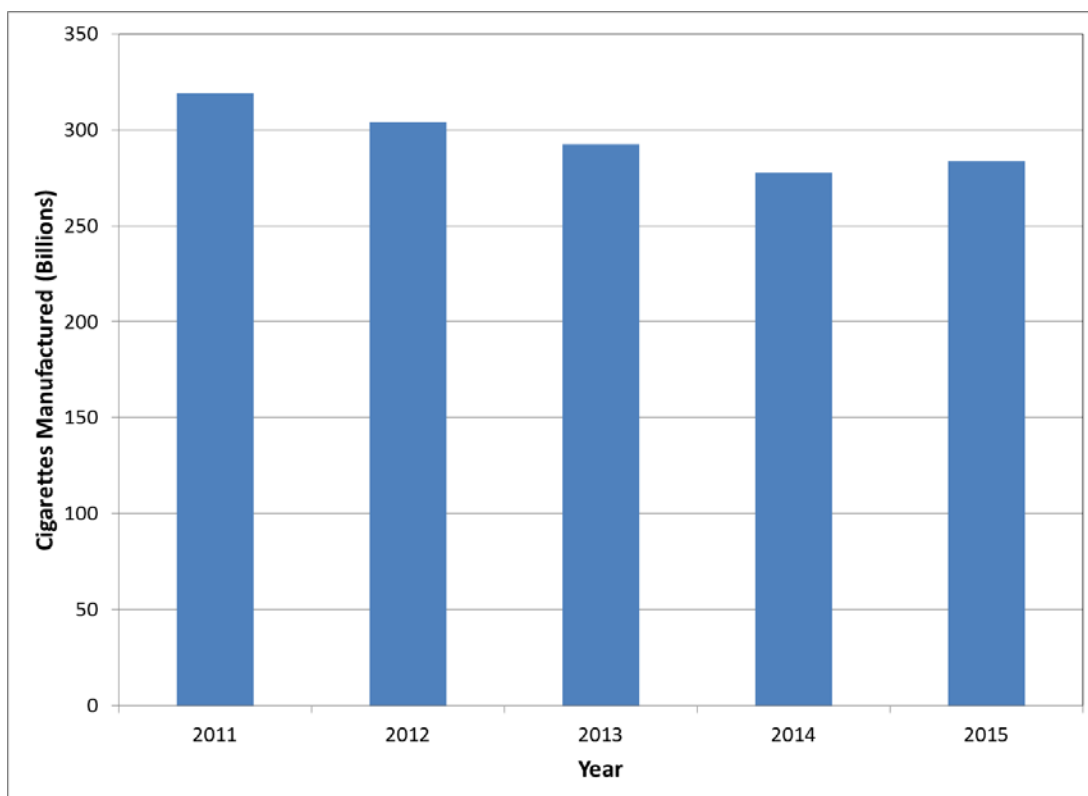
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.2%	1.9%	0.5%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.3%	-	-

5.11.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.11-1](#)).

Figure 5.11-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.11-2](#).

Table 5.11-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.18% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.11-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.11-3](#). Those values are estimated from: (a) current annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.18% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill. Total ammonia and nicotine emissions

are expected to decrease by 46 and 69 pounds per year, respectively, based upon the proposed action.

Table 5.11-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	43
Ammonia (Total off-site release)	499	1,545	1,238	2
Ammonia (Total)	10,398	32,192	25,797	46
Nicotine (Total on-site release)	13,865	42,926	34,398	61
Nicotine (Total off-site release)	1,942	6,012	4,818	9
Nicotine (Total)	15,807	48,938	39,216	69

5.11.2.2 Environmental Consequences from Manufacturing Camel Snus Winterchill

Waste generated as a result of manufacturing Camel Snus Winterchill is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Winterchill releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Winterchill use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Winterchill. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Winterchill is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table](#)

5.11-7). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Winterchill due to the proposed order are summarized in [Table 5.11-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Winterchill (~ 1.1%); (c) the average rate of each emission type per pound of Camel Snus Winterchill tobacco manufactured in 2015 and (d) the number of smokers (~ 69,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Winterchill (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.18% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.11-2](#) and [Figure 5.11-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.11-4](#) and [Table 5.11-5](#), respectively.

Figure 5.11-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

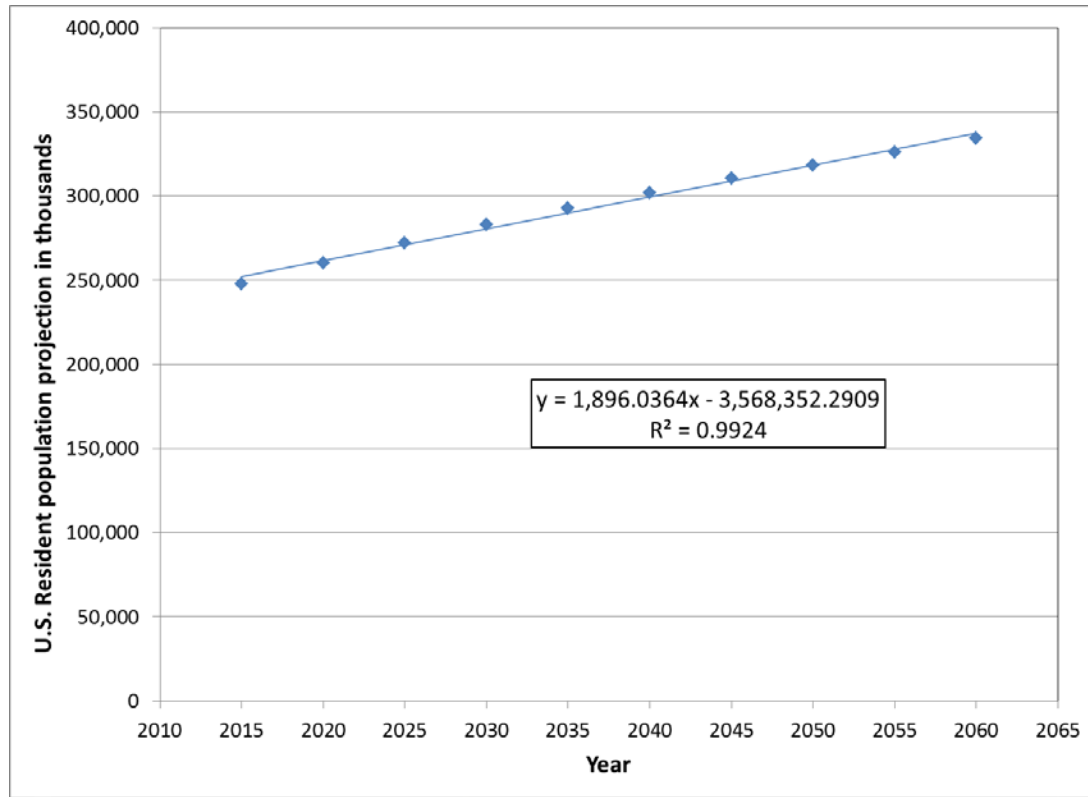


Table 5.11-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.11-3: Adult Smoking Incidence 2001 – 2014

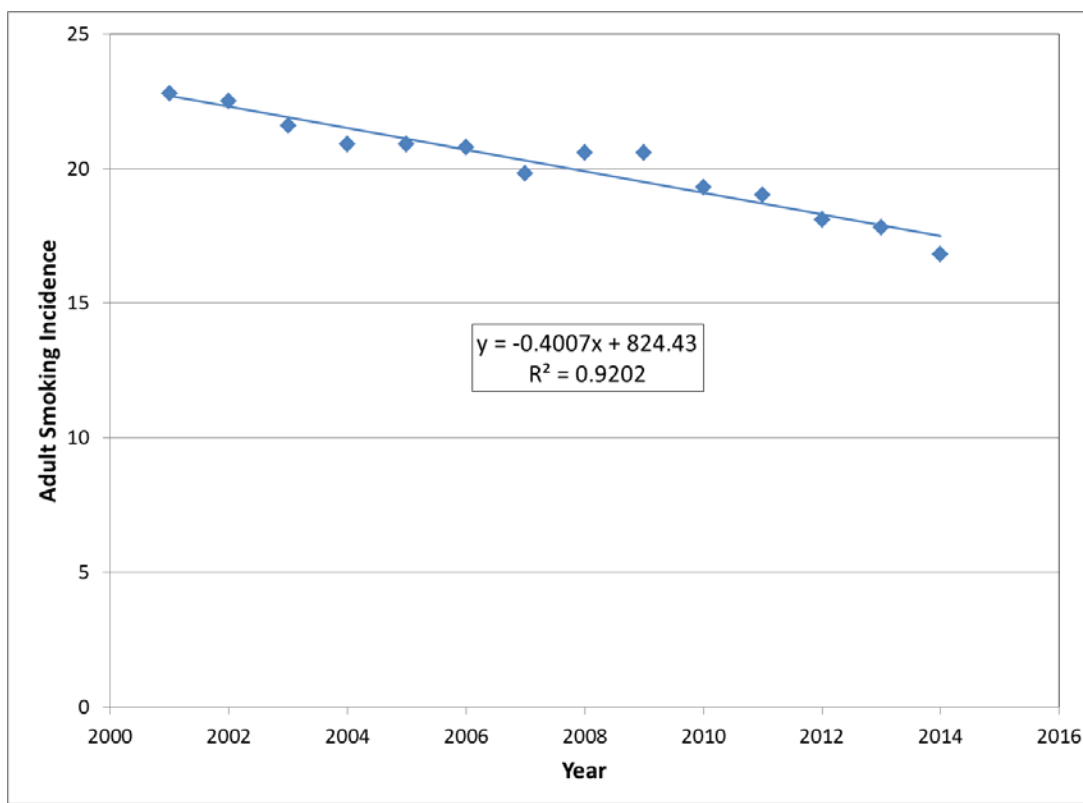


Table 5.11-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 ([Table 5.11-6](#)). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Winterchill production and associated manufacturing emissions. Based on 0.1768% of the projected smokers switching to the use of 5 pouches of Camel Snus Winterchill per day, an additional 279,366 pounds of Camel Snus Winterchill will be manufactured. Of note, this estimate assumes that all of the projected

switching from smoking cigarettes to the use of Camel Snus Winterchill will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Winterchill each day is greater than current Camel Snus Winterchill use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.11-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Winterchill production, total ammonia and nicotine emissions are expected to increase by 63 and 326 pounds per year, respectively, based upon the proposed action ([Table 5.11-7](#)).

Table 5.11-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Winterchill

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Winterchill Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Winterchill	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	22	0.111	31
Ammonia (Total off-site release)	2,123	22	0.116	32
Ammonia (Total)	4,159	44	-	63
Nicotine (Total on-site release)	11,293	120	0.615	172
Nicotine (Total off-site release)	10,168	108	0.553	155
Nicotine (Total)	21,461	227	-	326

5.11.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.11-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.20% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.11-8](#)).

Figure 5.11-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

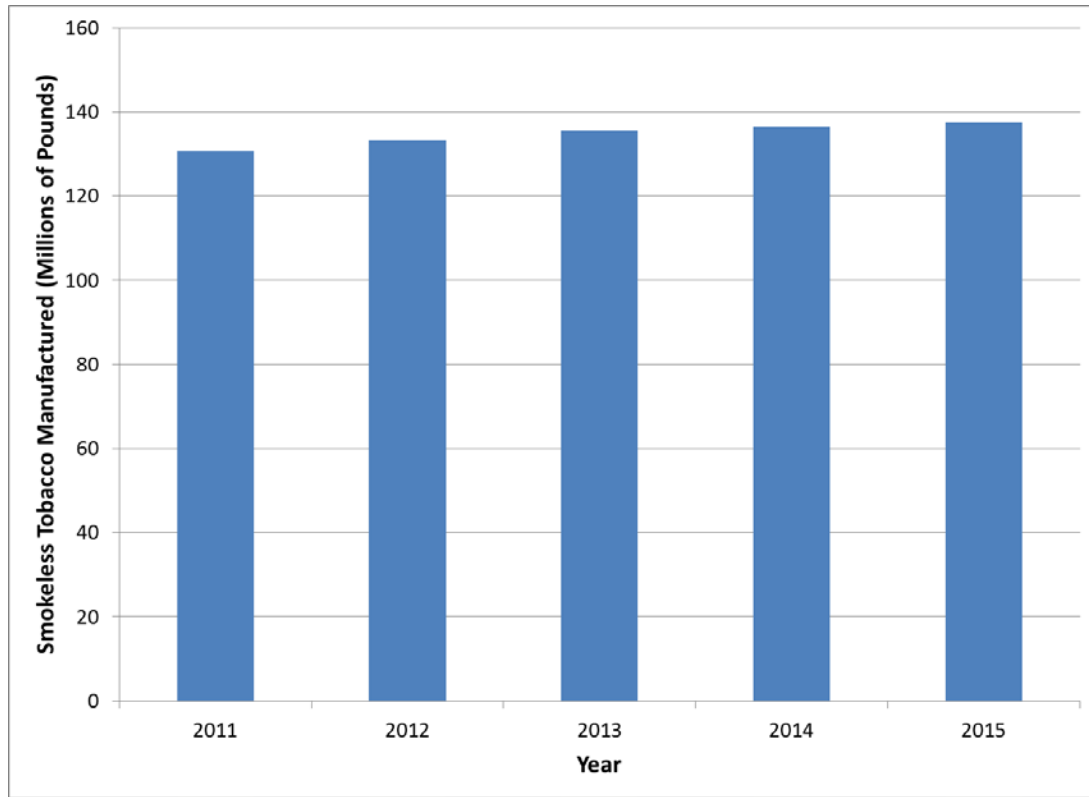


Table 5.11-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	31	15,233	0.20
Ammonia (Total off-site release)	0.116	32	15,884	0.20
Ammonia (Total)	-	63	31,117	0.20
Nicotine (Total on-site release)	0.615	172	84,492	0.20
Nicotine (Total off-site release)	0.553	155	76,075	0.20
Nicotine (Total)	-	326	160,567	0.20

5.11.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.11-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 8.9×10^{-06} percent decrease) and the increase in Camel Snus Winterchill production has a negligible impact (a 1.6×10^{-05} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.11-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.11-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	402.1 million cigarettes	31,314	14,667	45,982
Increases from Camel Snus Winterchill	279,366 pounds	19,240	60,958	80,198

5.11.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Winterchill and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.11.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Winterchill accounted for ~ 0.14% by weight of the smokeless tobacco manufactured in the United States and ~ 11% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 69,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, resulting in a decrease of ~ 402 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 279,366 pounds of Camel Snus Winterchill will be manufactured based upon those smokers using 5 pouches of Camel Snus Winterchill per day.

5.11.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Winterchill. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Winterchill. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 402 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.11.4 Environmental Introduction as a Result of Disposal after Product Use

5.11.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Winterchill in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Winterchill includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Winterchill consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.11-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.11-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Winterchill are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.11-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

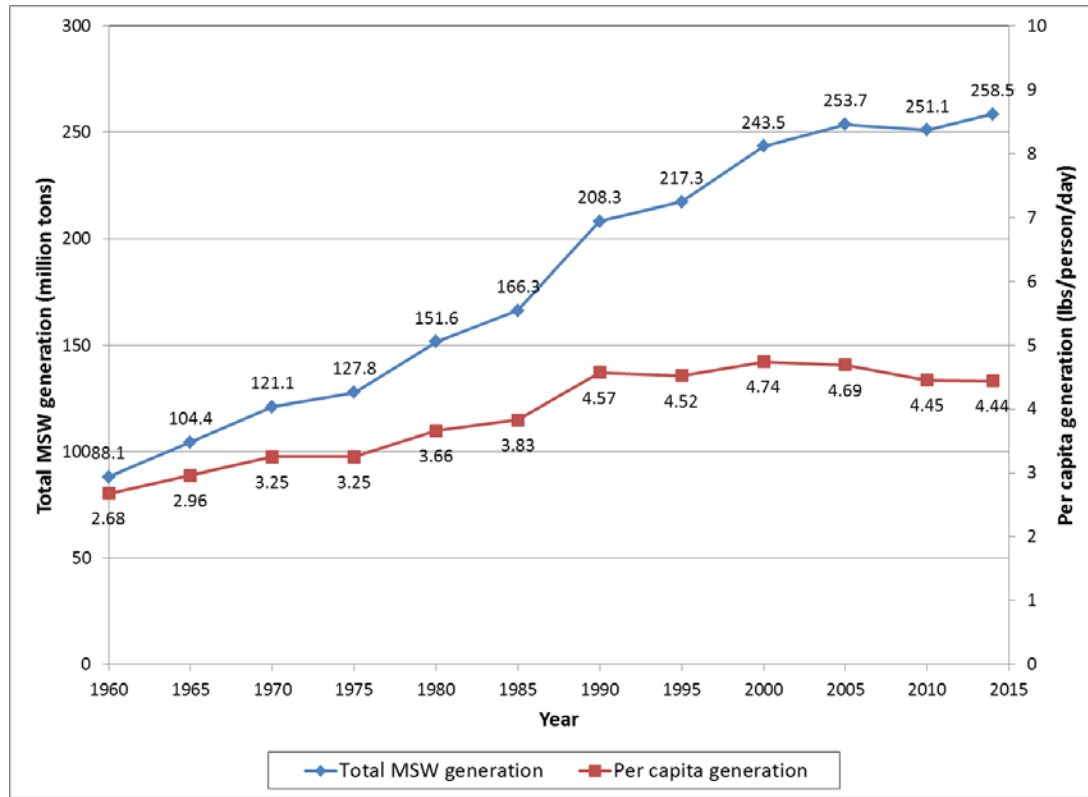
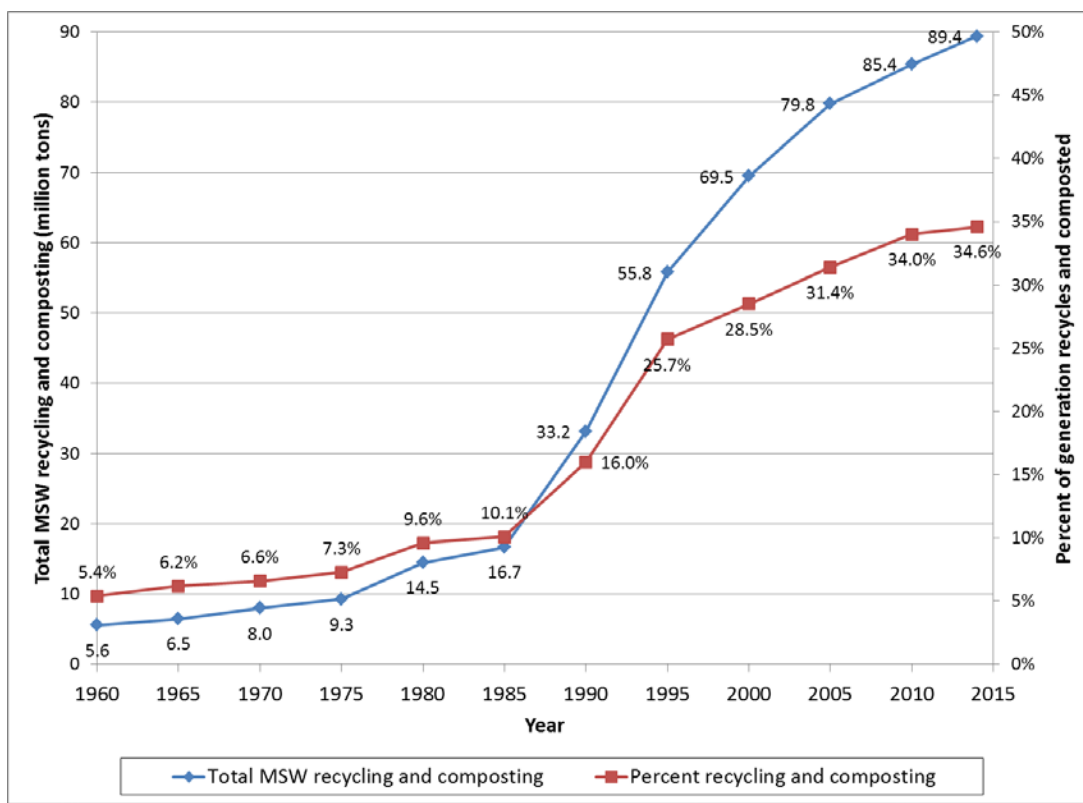


Figure 5.11-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.11.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.11.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Winterchill

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 69,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, resulting in a decrease of ~ 402 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 402 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.11-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 78 tons per year.

Table 5.11-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	234	86,572	43
“100 mm” (90 – 101 mm)	40.8	164	67,926	34
“120 mm” (118 – 120 mm)	1.1	5	1,821	1
Total (All styles)	100	402	156,319	78

Based on the proposed action resulting in ~ 69,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, it is estimated that an additional 279,366 pounds of Camel Snus Winterchill will be manufactured if those smokers use 5 pouches of Camel Snus Winterchill per day each day of the year. Waste generated due to Camel Snus Winterchill use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Winterchill tobacco will become waste for disposal after use, resulting in an increase of ~ 140 tons of used Camel Snus Winterchill pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 3.0×10^{-5} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Winterchill used pouch disposal has a negligible impact (a 5.4×10^{-5} percent increase) to the MSW stream, based on the same figures ([Table 5.11-11](#)).

Table 5.11-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	78	3.0×10^{-05}
Increase in used Camel Snus Winterchill pouches	140	5.4×10^{-05}

5.11.4.2.2 Disposal of Cigarette and Camel Snus Winterchill Packaging Material

Based on ~ 69,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 20 million fewer cigarette packs and approximately 2 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 8.4 million more Camel Snus Winterchill tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.11-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.11-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 203 tons per year ([Table 5.11-13](#)).

Camel Snus Winterchill Packaging weights are summarized in [Table 5.11-14](#). The Camel Snus Winterchill package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Winterchill use, it is estimated that packaging waste will increase by 207 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 7.9×10^{-05} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Winterchill packaging disposal will have a negligible impact (a 8.0×10^{-05} percent increase), based on the same figures ([Table 5.11-15](#)).

Table 5.11-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.11-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	1,168,000	232,858	116
"100 mm" (90 – 101 mm)	40.8	819,426	168,604	84
"120 mm" (118 – 120 mm)	1.1	23,038	5,213	3
Total (All styles)	100	2,010,464	406,675	203

Table 5.11-14: Camel Snus Winterchill Packaging Weights

Camel Snus Winterchill Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.11-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	203	7.9×10^{-05}
Increase in Camel Snus Winterchill packaging waste	207	8.0×10^{-05}

5.11.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Winterchill will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.11.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.11.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.11.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 69,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 402 million fewer cigarettes will be manufactured and that approximately 127 million more pouches of Camel Snus Winterchill will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.11-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.11-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Winterchill	Net Change Due to the Proposed Action
Electricity (thousand kWh)	762	140	-622
Water (ccf)	135,500	11,400	-124,100
Natural gas (ccf)	22,291	3,912	-18,379

5.11.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.11.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 69,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 402 million fewer cigarettes will be manufactured and that approximately 127 million more pouches of Camel Snus Winterchill will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT’s Tobaccoville manufacturing facility. [Table 5.11-17](#) summarizes projected annual changes in GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.11-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Winterchill	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	1,042	188	-854

5.11.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Winterchill manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁵² made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁵³ and plants⁵⁴ and (b) the endangered and threatened species

⁵² Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁵³ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁵⁴ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

listed in Appendices I, II, and III⁵⁵ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Winterchill manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Winterchill are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used in Camel Snus Winterchill are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Winterchill have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.11.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers

⁵⁵ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.

- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.

- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.11.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Winterchill as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Winterchill as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.11.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.12 Camel Snus Robust: Advertising Execution #2

This Environmental Assessment (EA) is required for authorization of Camel Snus Robust as a modified risk tobacco product as communicated per [Advertising Execution 2](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁵⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.12.1 Description of Proposed Action

5.12.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.12.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Robust as a modified risk tobacco product.

5.12.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁵⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Robust	1.0 gram	15.0 gram

Package Description

Camel Snus Robust is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.12.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Robust while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Robust. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 2](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.12-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.3% of current regular cigarette smokers. Apportionment to the Camel Snus Robust style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Robust represents 2.2% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Robust, due to introduction of the proposed modified risk advertising, is 0.03% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.03% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.12-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

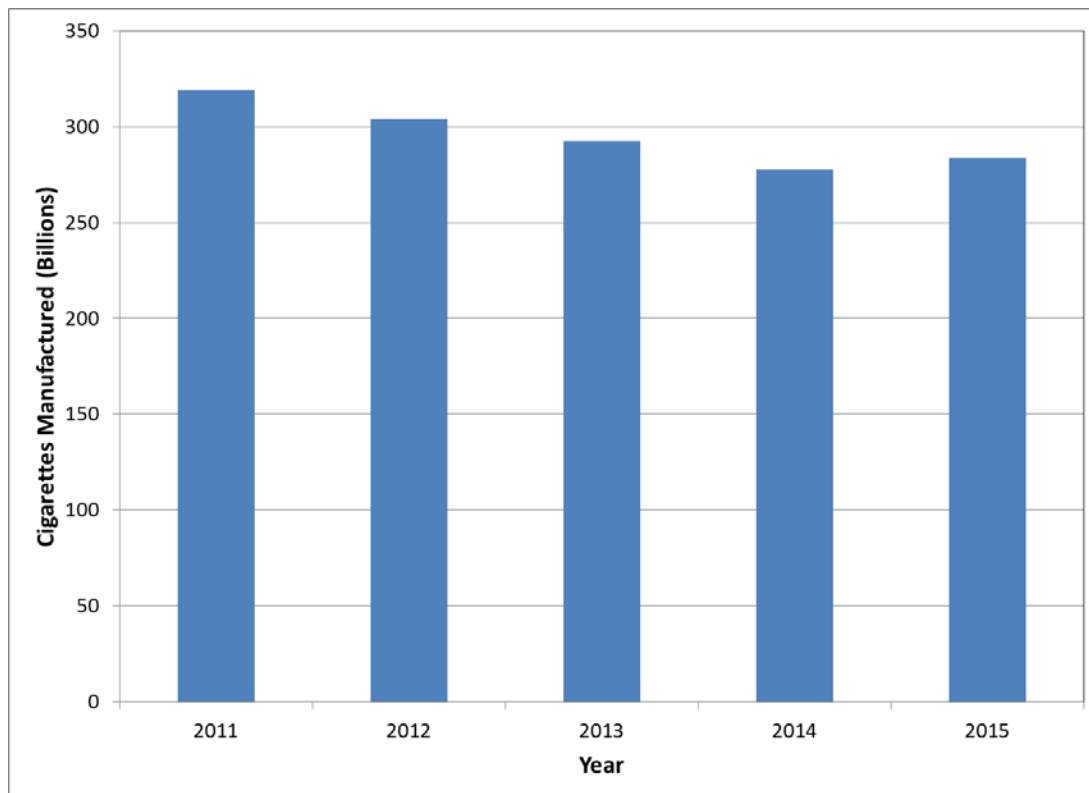
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.2%	1.9%	0.5%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.3%	-	-

5.12.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.12-1](#)).

Figure 5.12-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.12-2](#).

Table 5.12-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.03% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.12-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.12-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.03% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust. Total ammonia and nicotine emissions are expected to decrease by 7.4 and 11.2 pounds per year, respectively, based upon the proposed action.

Table 5.12-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	7.0
Ammonia (Total off-site release)	499	1,545	1,238	0.4
Ammonia (Total)	10,398	32,192	25,797	7.4
Nicotine (Total on-site release)	13,865	42,926	34,398	9.8
Nicotine (Total off-site release)	1,942	6,012	4,818	1.4
Nicotine (Total)	15,807	48,938	39,216	11.2

5.12.2.2 Environmental Consequences from Manufacturing Camel Snus Robust

Waste generated as a result of manufacturing Camel Snus Robust is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Robust releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Robust use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Robust. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Robust is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.12-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Robust due to the proposed order are summarized in [Table 5.12-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Robust (~ 0.2%); (c) the average rate of each emission type per pound of Camel Snus Robust tobacco manufactured in 2015 and (d) the number of smokers (~ 11,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Robust (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.03% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.12-2](#) and [Figure 5.12-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.12-4](#) and [Table 5.12-5](#), respectively.

Figure 5.12-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

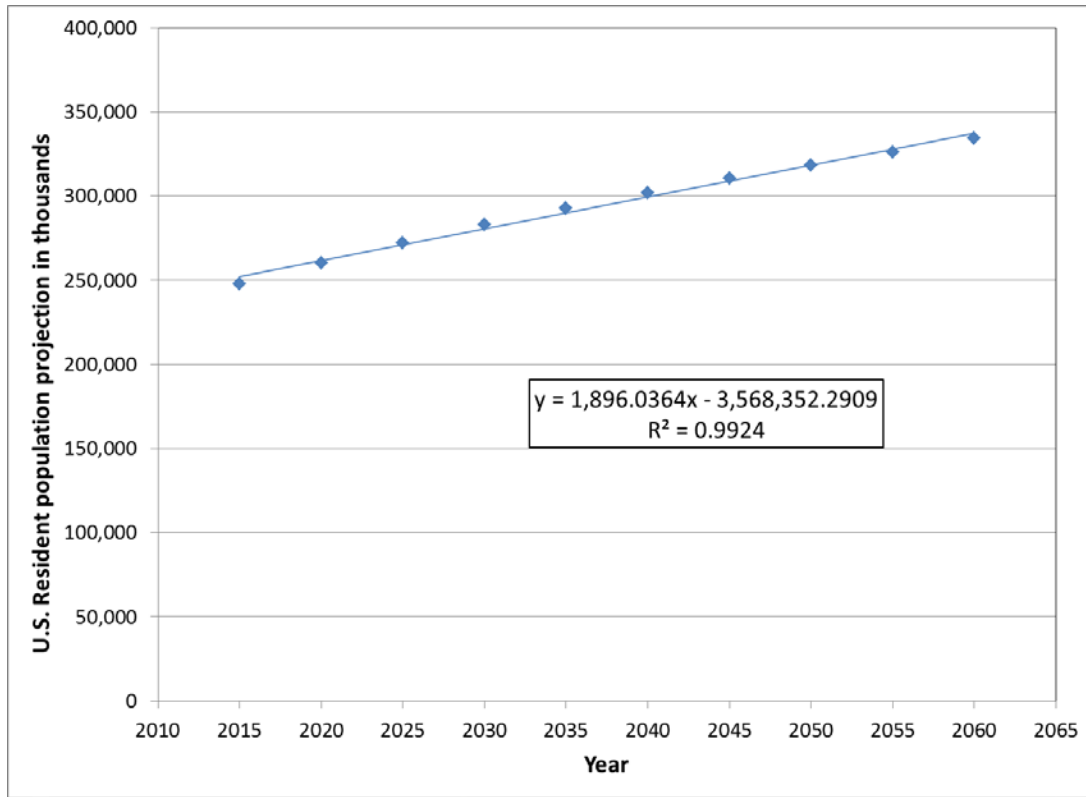


Table 5.12-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.12-3: Adult Smoking Incidence 2001 – 2014

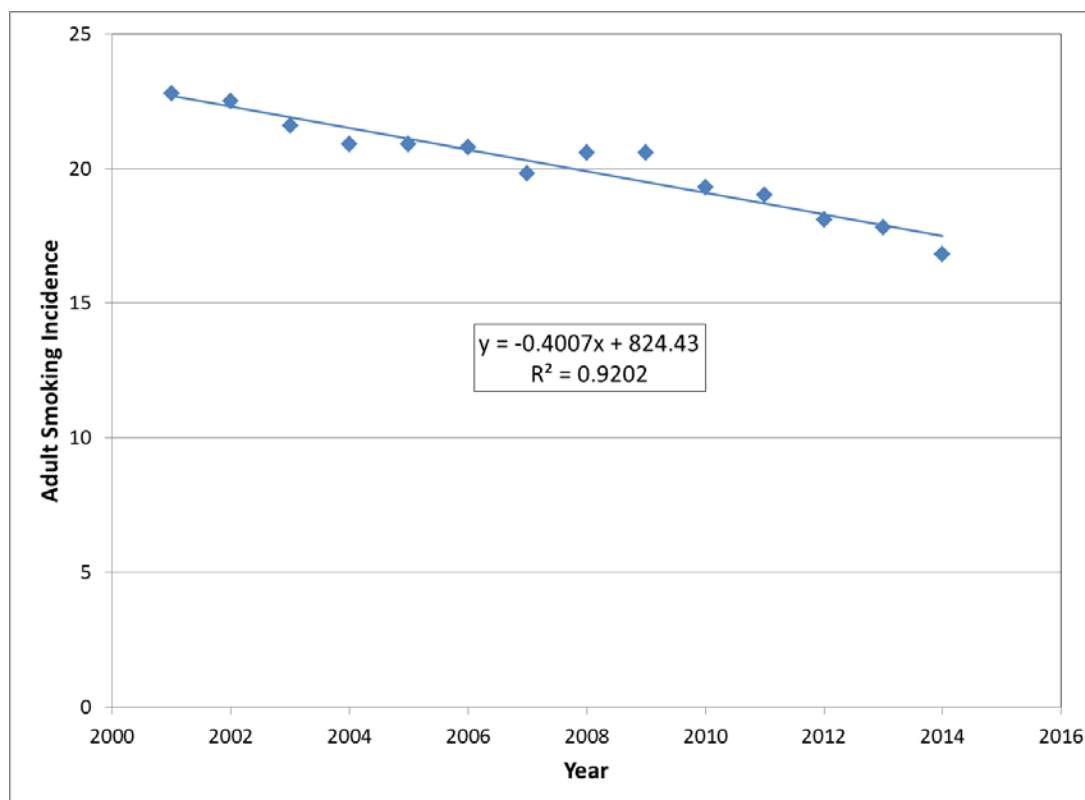


Table 5.12-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 ([Table 5.12-6](#)). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Robust production and associated manufacturing emissions. Based on 0.0286% of the projected smokers switching to the use of 5 pouches of Camel Snus Robust per day, an additional 45,192 pounds of Camel Snus Robust will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Robust will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Robust each day is greater than current Camel Snus Robust use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.12-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Robust production, total ammonia and nicotine emissions are expected to increase by 10 and 53 pounds per year, respectively, based upon the proposed action ([Table 5.12-7](#)).

Table 5.12-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Robust

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Robust Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Robust	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	4	0.111	5
Ammonia (Total off-site release)	2,123	4	0.116	5
Ammonia (Total)	4,159	7	-	10
Nicotine (Total on-site release)	11,293	20	0.615	28
Nicotine (Total off-site release)	10,168	18	0.553	25
Nicotine (Total)	21,461	37	-	53

5.12.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.12-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.03% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.12-8](#)).

Figure 5.12-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

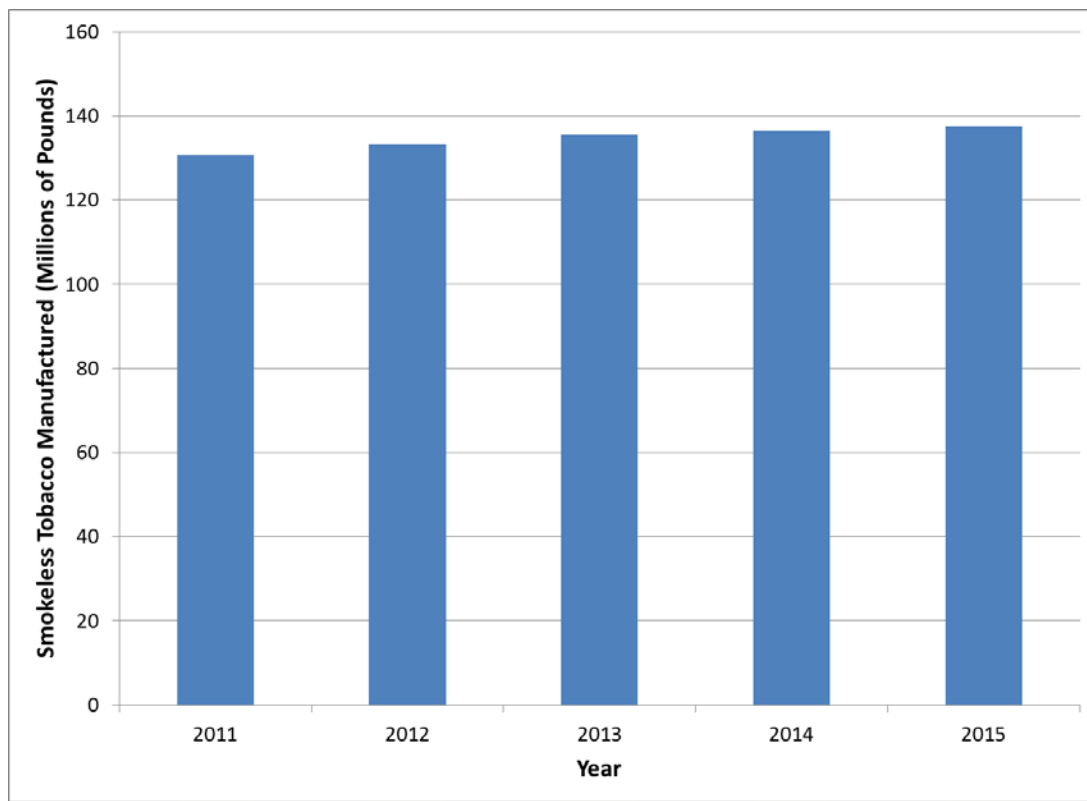


Table 5.12-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	5	15,233	0.03
Ammonia (Total off-site release)	0.116	5	15,884	0.03
Ammonia (Total)	-	10	31,117	0.03
Nicotine (Total on-site release)	0.615	28	84,492	0.03
Nicotine (Total off-site release)	0.553	25	76,075	0.03
Nicotine (Total)	-	53	160,567	0.03

5.12.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.12-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 1.4×10^{-06} percent decrease) and the increase in Camel Snus Robust production has a negligible impact (a 2.5×10^{-06} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.12-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.12-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	65.0 million cigarettes	5,066	2,373	7,438
Increases from Camel Snus Robust	45,192 pounds	3,112	9,861	12,973

5.12.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Robust and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.12.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Robust accounted for ~ 0.02% by weight of the smokeless tobacco manufactured in the United States and ~ 2% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 11,000 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, resulting in a decrease of ~ 65 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 45,192 pounds of Camel Snus Robust will be manufactured based upon those smokers using 5 pouches of Camel Snus Robust per day.

5.12.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Robust. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Robust. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 65 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.12.4 Environmental Introduction as a Result of Disposal after Product Use

5.12.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Robust in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Robust includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Robust consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.12-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.12-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Robust are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.12-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

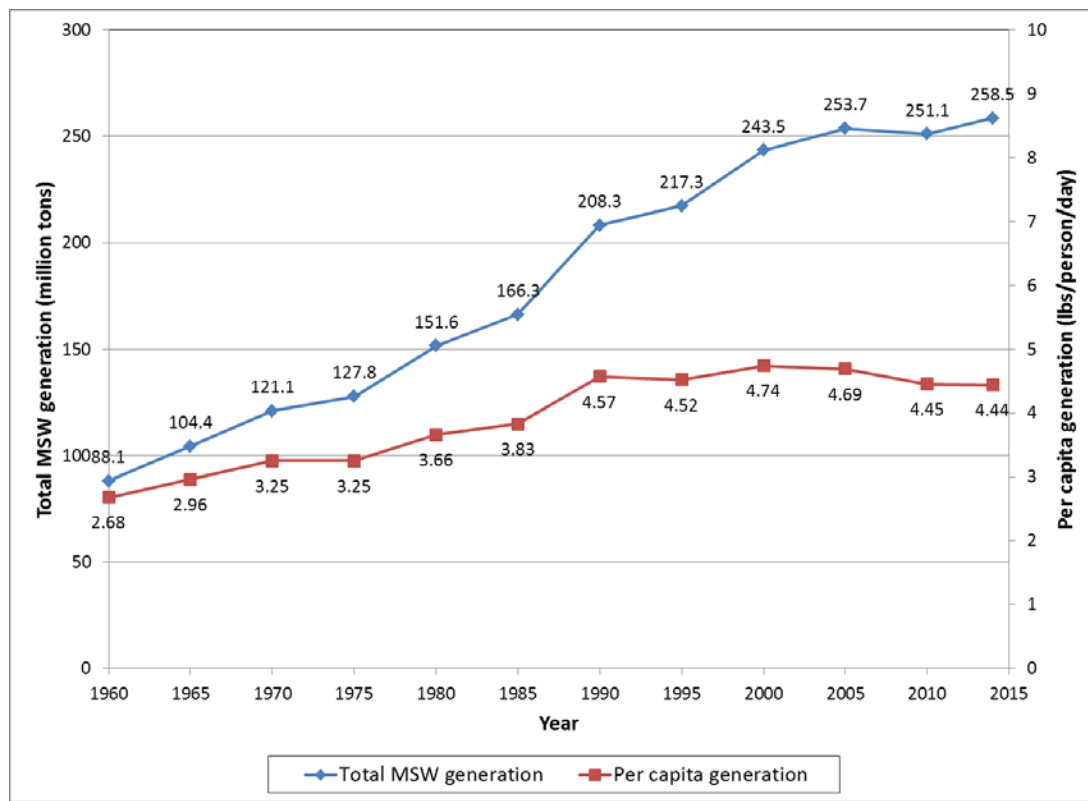
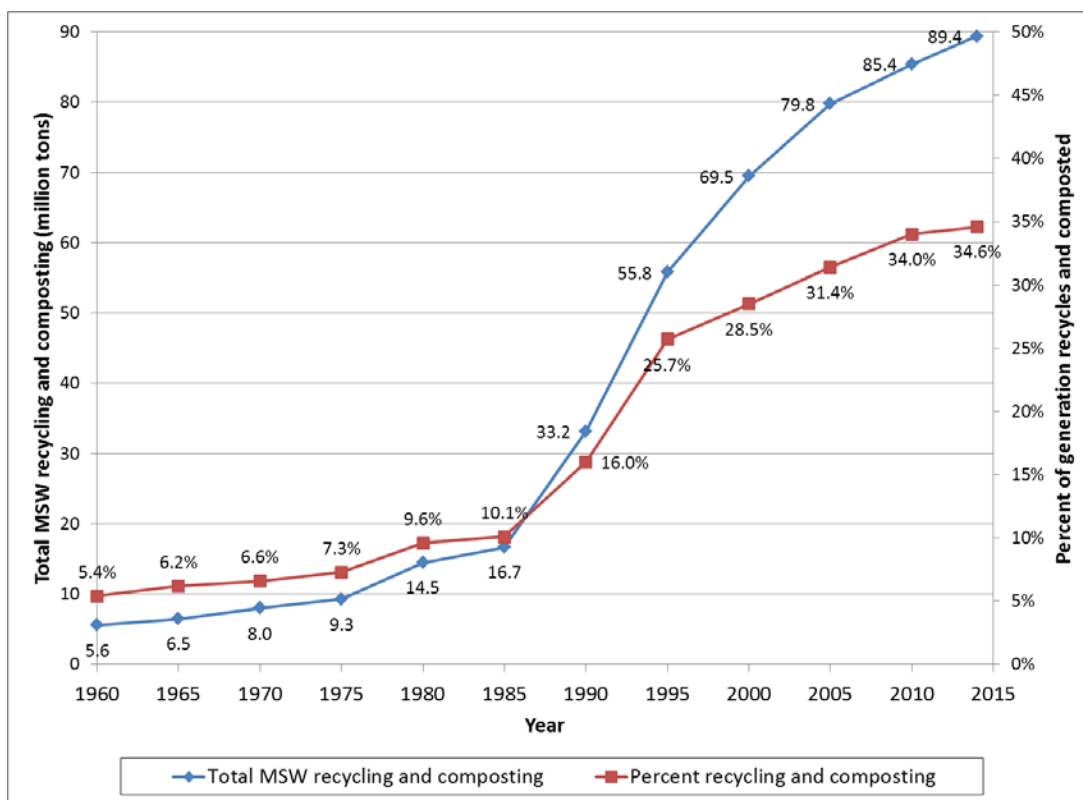


Figure 5.12-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.12.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.12.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Robust

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 11,000 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, resulting in a decrease of ~ 65 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 65 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.12-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 12.6 tons per year.

Table 5.12-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	37.8	14,004	7.0
“100 mm” (90 – 101 mm)	40.8	26.5	10,988	5.5
“120 mm” (118 – 120 mm)	1.1	0.7	295	0.1
Total (All styles)	100	65.0	25,287	12.6

Based on the proposed action resulting in ~ 11,000 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, it is estimated that an additional 45,192 pounds of Camel Snus Robust will be manufactured if those smokers use 5 pouches of Camel Snus Robust per day each day of the year. Waste generated due to Camel Snus Robust use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Robust tobacco will become waste for disposal after use, resulting in an increase of ~ 23 tons of used Camel Snus Robust pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 4.9×10^{-6} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Robust used pouch disposal has a negligible impact (a 8.7×10^{-6} percent increase) to the MSW stream, based on the same figures ([Table 5.12-11](#)).

Table 5.12-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	12.6	4.9×10^{-6}
Increase in used Camel Snus Robust pouches	23	8.7×10^{-6}

5.12.4.2.2 Disposal of Cigarette and Camel Snus Robust Packaging Material

Based on ~ 11,000 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 3.3 million fewer cigarette packs and approximately 330 thousand fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 1.4 million more Camel Snus Robust tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.12-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.12-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 32.9 tons per year ([Table 5.12-13](#)).

Camel Snus Robust Packaging weights are summarized in [Table 5.12-14](#). The Camel Snus Robust package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Robust use, it is estimated that packaging waste will increase by 33.5 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 1.27×10^{-5} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Robust packaging disposal will have a negligible impact (a 1.30×10^{-5} percent increase), based on the same figures ([Table 5.12-15](#)).

Table 5.12-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.12-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	188,941	37,668	19
"100 mm" (90 – 101 mm)	40.8	132,554	27,274	14
"120 mm" (118 – 120 mm)	1.1	3,727	843	0.4
Total (All styles)	100	325,222	65,786	32.9

Table 5.12-14: Camel Snus Robust Packaging Weights

Camel Snus Robust Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.12-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	32.9	1.27×10^{-05}
Increase in Camel Snus Robust packaging waste	33.5	1.30×10^{-05}

5.12.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Robust will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.12.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.12.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.12.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 11,000 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 65 million fewer cigarettes will be manufactured and that approximately 20 million more pouches of Camel Snus Robust will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.12-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.12-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Robust	Net Change Due to the Proposed Action
Electricity (thousand kWh)	123	23	-101
Water (ccf)	21,919	1,844	-20,075
Natural gas (ccf)	3,606	633	-2,973

5.12.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.12.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 11,000 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 65 million fewer cigarettes will be manufactured and that approximately 20 million more pouches of Camel Snus Robust will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.12-17](#) summarizes projected annual changes in

GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.12-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Robust	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	169	30	-138

5.12.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Robust manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁵⁷ made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁵⁸ and plants⁵⁹ and (b) the endangered and threatened species listed in Appendices I, II, and III⁶⁰ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Robust manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Robust are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

⁵⁷ Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁵⁸ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁵⁹ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

⁶⁰ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Robust are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Robust have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.12.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.12.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Robust as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Robust as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.12.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.13 Camel Snus Frost: Advertising Execution #3

This Environmental Assessment (EA) is required for authorization of Camel Snus Frost as a modified risk tobacco product as communicated per [Advertising Execution 3](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁶¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.13.1 Description of Proposed Action

5.13.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.13.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Frost as a modified risk tobacco product.

5.13.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁶¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Frost	0.6 gram	9.0 gram

Package Description

Camel Snus Frost is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.13.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Frost while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Frost. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 3](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.13-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.1% of current regular cigarette smokers. Apportionment to the Camel Snus Frost style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Frost represents 32.9% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Frost, due to introduction of the proposed modified risk advertising, is 0.36% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.36% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.13-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

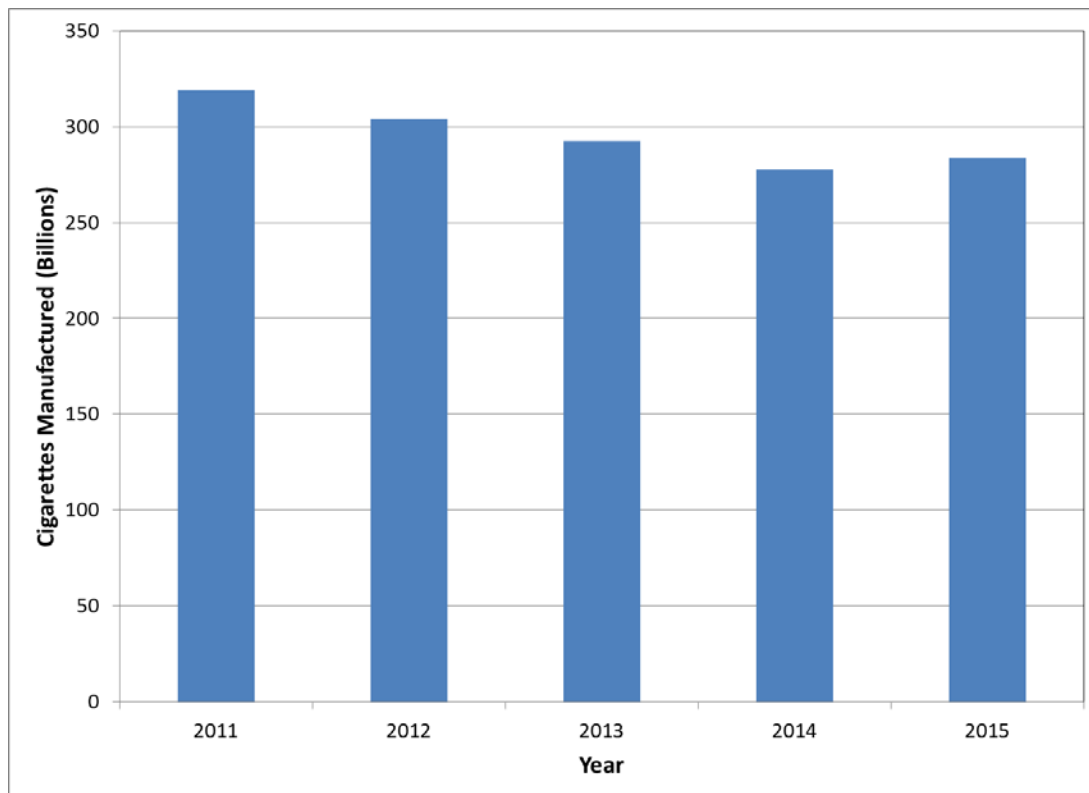
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.0%	2.0%	0.4%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.1%	-	-

5.13.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.13-1](#)).

Figure 5.13-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.13-2](#).

Table 5.13-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.36% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.13-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.13-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.36% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost. Total ammonia and nicotine emissions are expected to decrease by 93 and 142 pounds per year, respectively, based upon the proposed action.

Table 5.13-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	89
Ammonia (Total off-site release)	499	1,545	1,238	4
Ammonia (Total)	10,398	32,192	25,797	93
Nicotine (Total on-site release)	13,865	42,926	34,398	124
Nicotine (Total off-site release)	1,942	6,012	4,818	17
Nicotine (Total)	15,807	48,938	39,216	142

5.13.2.2 Environmental Consequences from Manufacturing Camel Snus Frost

Waste generated as a result of manufacturing Camel Snus Frost is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Frost releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Frost use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Frost. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Frost is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.13-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Frost due to the proposed order are summarized in [Table 5.13-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Frost (~ 1.5%); (c) the average rate of each emission type per pound of Camel Snus Frost tobacco manufactured in 2015 and (d) the number of smokers (~ 142,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Frost (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.36% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.13-2](#) and [Figure 5.13-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.13-4](#) and [Table 5.13-5](#), respectively.

Figure 5.13-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

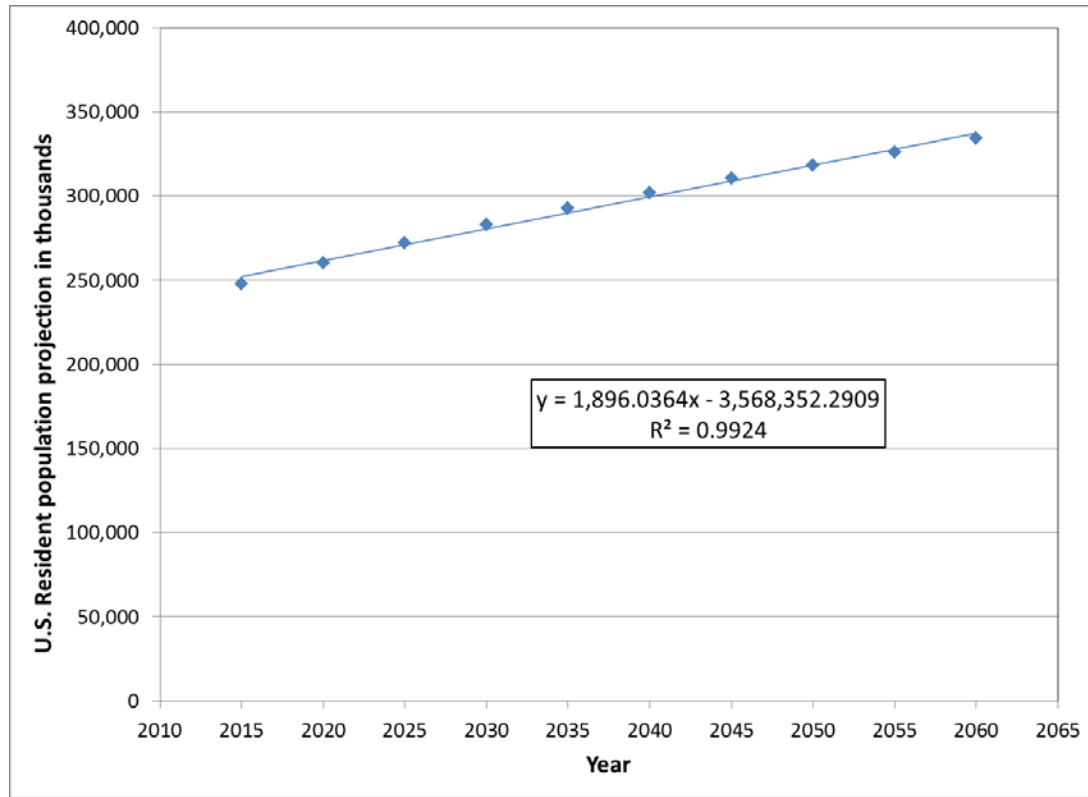


Table 5.13-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.13-3: Adult Smoking Incidence 2001 – 2014

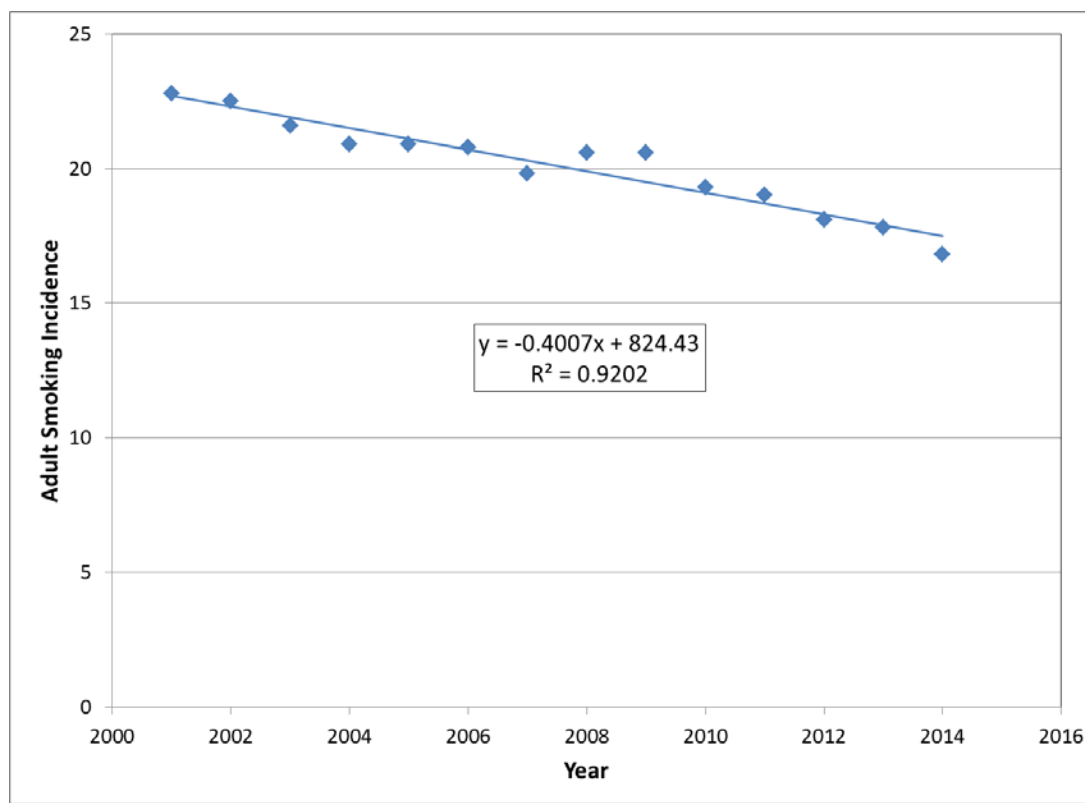


Table 5.13-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.13-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Frost production and associated manufacturing emissions. Based on 0.3619% of the projected smokers switching to the use of 5 pouches of Camel Snus Frost per day, an additional 343,109 pounds of Camel Snus Frost will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Frost will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Frost each day is greater than current Camel Snus Frost use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.13-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Frost production, total ammonia and nicotine emissions are expected to increase by 78 and 401 pounds per year, respectively, based upon the proposed action ([Table 5.13-7](#)).

Table 5.13-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Frost

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Frost Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Frost	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	31	0.111	38
Ammonia (Total off-site release)	2,123	33	0.116	40
Ammonia (Total)	4,159	64	-	78
Nicotine (Total on-site release)	11,293	174	0.615	211
Nicotine (Total off-site release)	10,168	157	0.553	190
Nicotine (Total)	21,461	331	-	401

5.13.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.13-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.25% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.13-8](#)).

Figure 5.13-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

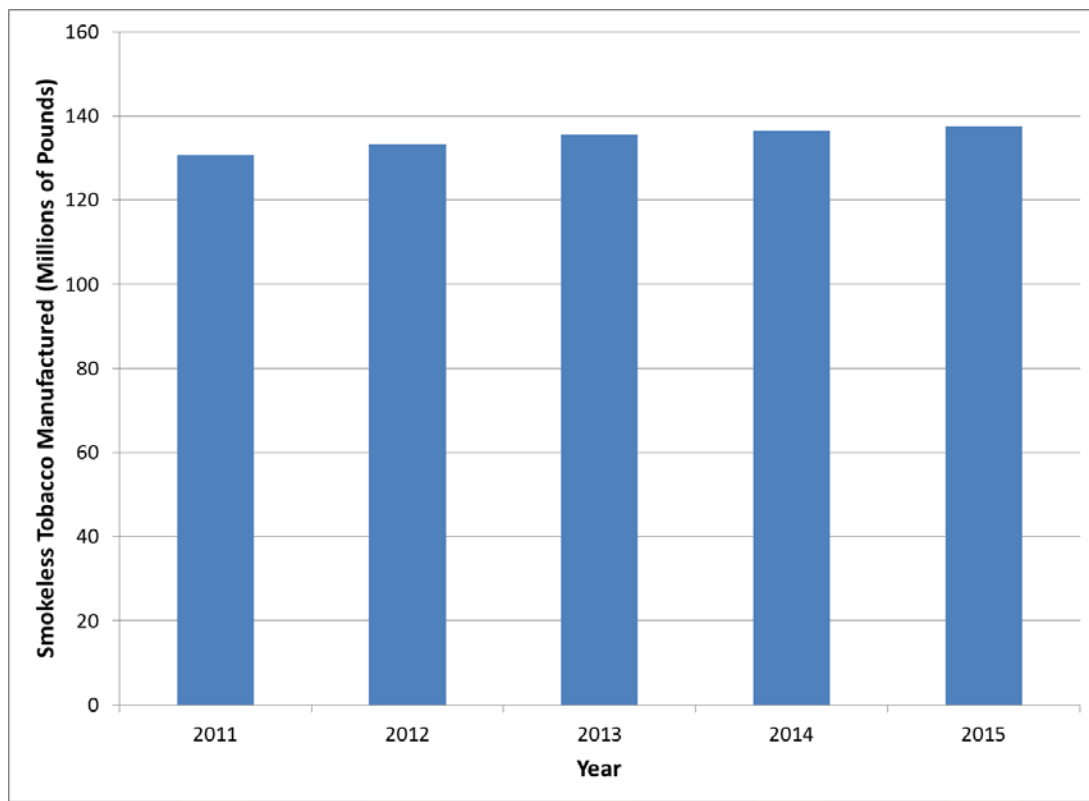


Table 5.13-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	38	15,233	0.25
Ammonia (Total off-site release)	0.116	40	15,884	0.25
Ammonia (Total)	-	78	31,117	0.25
Nicotine (Total on-site release)	0.615	211	84,492	0.25
Nicotine (Total off-site release)	0.553	190	76,075	0.25
Nicotine (Total)	-	401	160,567	0.25

5.13.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.13-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 1.8×10^{-05} percent decrease) and the increase in Camel Snus Frost production has a negligible impact (a 1.9×10^{-05} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.13-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.13-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	823.1 million cigarettes	64,099	30,024	94,123
Increases from Camel Snus Frost	343,109 pounds	23,631	74,866	98,497

5.13.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Frost and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.13.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Frost accounted for ~ 0.21% of the smokeless tobacco manufactured in the United States and ~ 26% of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 142,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, resulting in a decrease of ~ 800 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 343,109 pounds of Camel Snus Frost will be manufactured based upon those smokers using 5 pouches of Camel Snus Frost per day.

5.13.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Frost. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Frost. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 800 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.13.4 Environmental Introduction as a Result of Disposal after Product Use

5.13.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Frost in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Frost includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Frost consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.13-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.13-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Frost are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.13-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

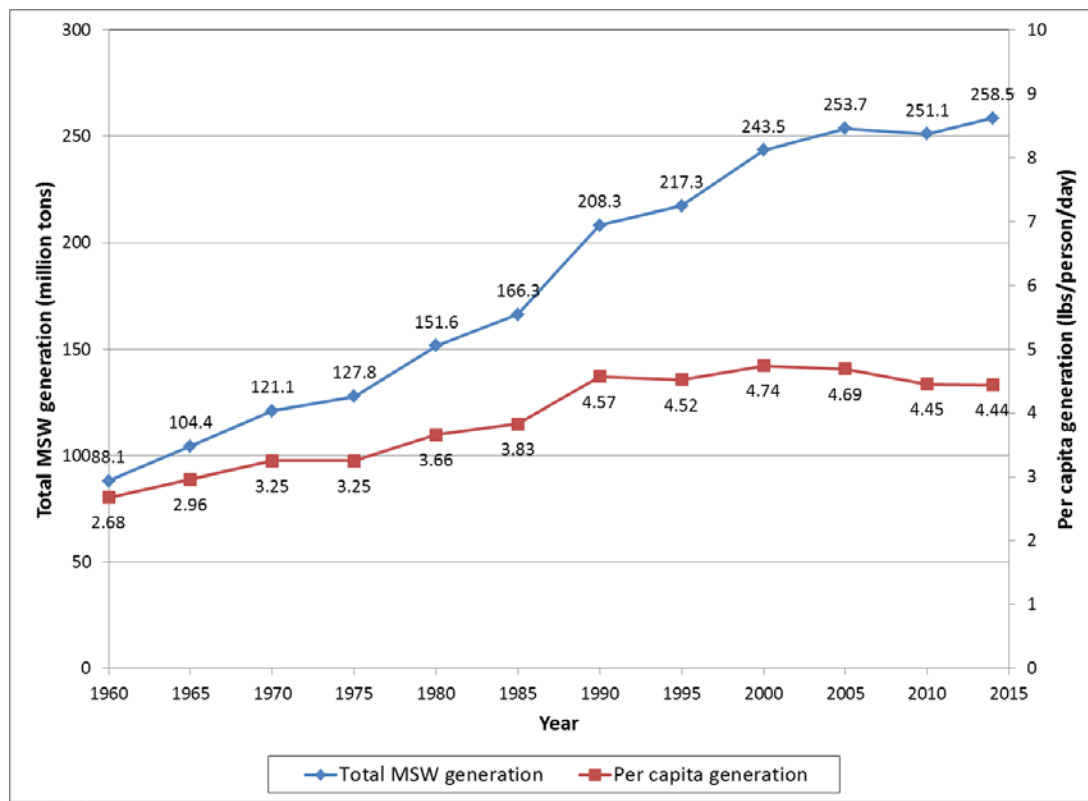
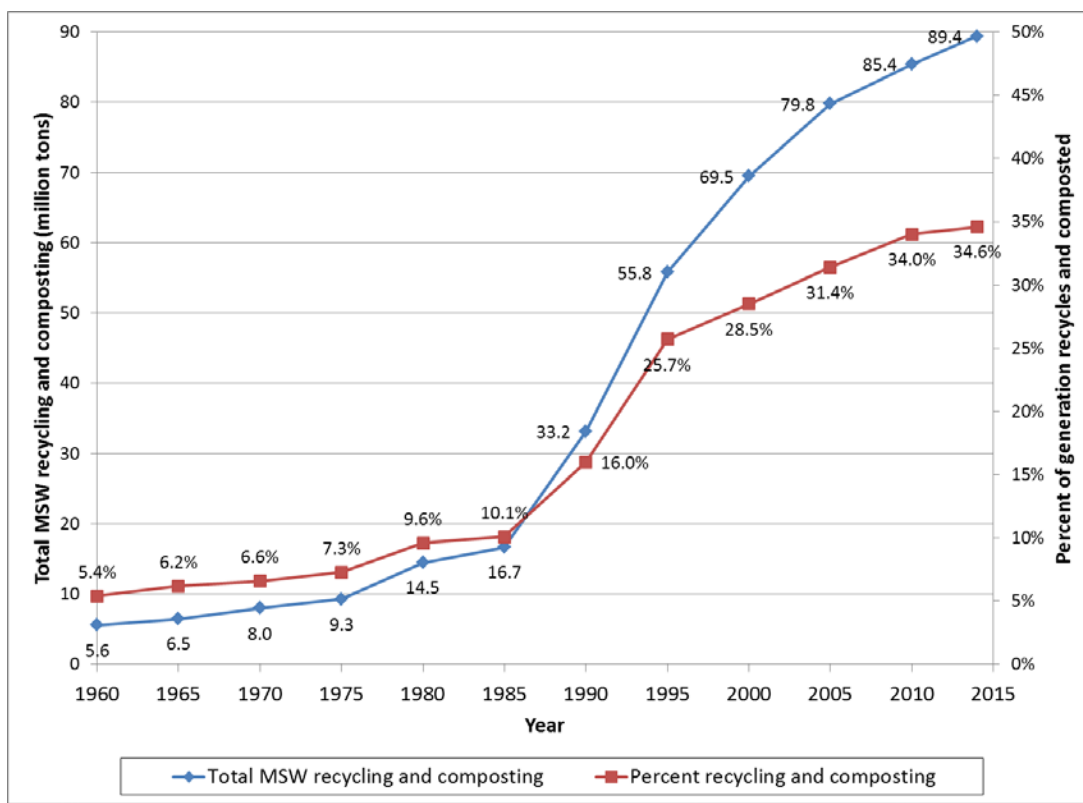


Figure 5.13-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.13.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.13.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Frost

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 142,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, resulting in a decrease of ~ 800 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 800 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.13-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 160 tons per year.

Table 5.13-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	478	117,208	89
“100 mm” (90 – 101 mm)	40.8	335	139,040	70
“120 mm” (118 – 120 mm)	1.1	9	3,728	2
Total (All styles)	100	823	319,976	160

Based on the proposed action resulting in ~ 142,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022, it is estimated that an additional 343,109 pounds of Camel Snus Frost will be manufactured if those smokers use 5 pouches of Camel Snus Frost per day each day of the year. Waste generated due to Camel Snus Frost use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Frost tobacco will become waste for disposal after use, resulting in an increase of ~ 172 tons of used Camel Snus Frost pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 6.2×10^{-05} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Frost used pouch disposal has a negligible impact (a 6.6×10^{-05} percent increase) to the MSW stream, based on the same figures ([Table 5.13-11](#)).

Table 5.13-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	160	6.2×10^{-05}
Increase in used Camel Snus Frost pouches	172	6.6×10^{-05}

5.13.4.2.2 Disposal of Cigarette and Camel Snus Frost Packaging Material

Based on ~ 142,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 41 million fewer cigarette packs and approximately 4.1 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 17 million more Camel Snus Frost tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Frost packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.13-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.13-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 416 tons per year ([Table 5.13-13](#)).

Camel Snus Frost Packaging weights are summarized in [Table 5.13-14](#). The Camel Snus Frost package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Frost use, it is estimated that packaging waste will increase by 424 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 1.61×10^{-04} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Frost packaging disposal will have a negligible impact (a 1.64×10^{-04} percent increase), based on the same figures ([Table 5.13-15](#)).

Table 5.13-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.13-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	2,390,832	476,648	238
"100 mm" (90 – 101 mm)	40.8	1,677,321	345,123	173
"120 mm" (118 – 120 mm)	1.1	47,157	10,670	5
Total (All styles)	100	4,115,310	832,441	416

Table 5.13-14: Camel Snus Frost Packaging Weights

Camel Snus Frost Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.13-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	416	1.61×10^{-04}
Increase in Camel Snus Frost packaging waste	424	1.64×10^{-04}

5.13.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Frost will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.13.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.13.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.13.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 142,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 800 million fewer cigarettes will be manufactured and that approximately 259 million more pouches of Camel Snus Frost will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.13-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.13-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost	Net Change Due to the Proposed Action
Electricity (thousand kWh)	1,560	172	-1,387
Water (ccf)	277,361	14,002	-263,359
Natural gas (ccf)	45,629	4,805	-40,824

5.13.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.13.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 142,000 smokers switching from smoking to exclusive use of Camel Snus Frost during 2018 – 2022 due to the proposed action, it is estimated that approximately 800 million fewer cigarettes will be manufactured and that approximately 259 million more pouches of Camel Snus Frost will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.13-17](#) summarizes projected annual changes in GHG

emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.13-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	2,132	231	-1,902

5.13.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) (1973 Endangered Species Act) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) (Convention on International Trade in Endangered Species) are expected due to the proposed action. The location of Camel Snus Frost manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁶² made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁶³ and plants⁶⁴ and (b) the endangered and threatened species listed in Appendices I, II, and III⁶⁵ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Frost manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Frost are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

⁶² Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁶³ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁶⁴ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&ffamily=on&header=Listed+Plants. Accessed on June 14, 2016.

⁶⁵ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Frost are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Frost have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.13.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.13.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Frost as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Frost as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.13.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.14 Camel Snus Mint: Advertising Execution #3

This Environmental Assessment (EA) is required for authorization of Camel Snus Mint as a modified risk tobacco product as communicated per [Advertising Execution 3](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁶⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.14.1 Description of Proposed Action

5.14.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.14.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Mint as a modified risk tobacco product.

5.14.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁶⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Mint	0.6 gram	9.0 gram

Package Description

Camel Snus Mint is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.14.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Mint while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Mint. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 3](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.14-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.1% of current regular cigarette smokers. Apportionment to the Camel Snus Mint style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Mint represents 8.7% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Mint, due to introduction of the proposed modified risk advertising, is 0.1% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.1% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.14-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

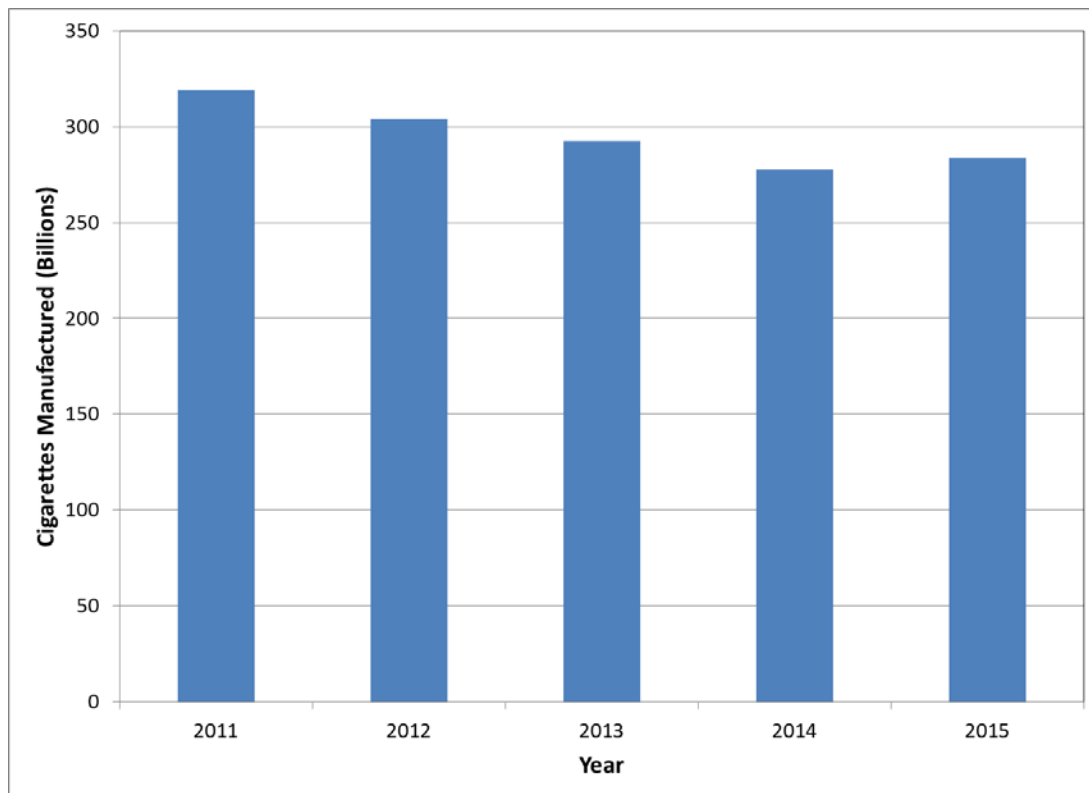
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.0%	2.0%	0.4%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.1%	-	-

5.14.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.14-1](#)).

Figure 5.14-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.14-2](#).

Table 5.14-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.1% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.14-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.14-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.1% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint. Total ammonia and nicotine emissions are expected to decrease by 25 and 38 pounds per year, respectively, based upon the proposed action.

Table 5.14-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	24
Ammonia (Total off-site release)	499	1,545	1,238	1
Ammonia (Total)	10,398	32,192	25,797	25
Nicotine (Total on-site release)	13,865	42,926	34,398	33
Nicotine (Total off-site release)	1,942	6,012	4,818	5
Nicotine (Total)	15,807	48,938	39,216	38

5.14.2.2 Environmental Consequences from Manufacturing Camel Snus Mint

Waste generated as a result of manufacturing Camel Snus Mint is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Mint releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Mint use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Mint. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Mint is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.14-6](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Mint due to the proposed order are summarized in [Table 5.14-6](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Mint (~ 0.4%); (c) the average rate of each emission type per pound of Camel Snus Mint tobacco manufactured in 2015 and (d) the number of smokers (~ 38,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Mint (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.1% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mint, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.14-2](#) and [Figure 5.14-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.14-4](#) and [Table 5.14-5](#), respectively.

Figure 5.14-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

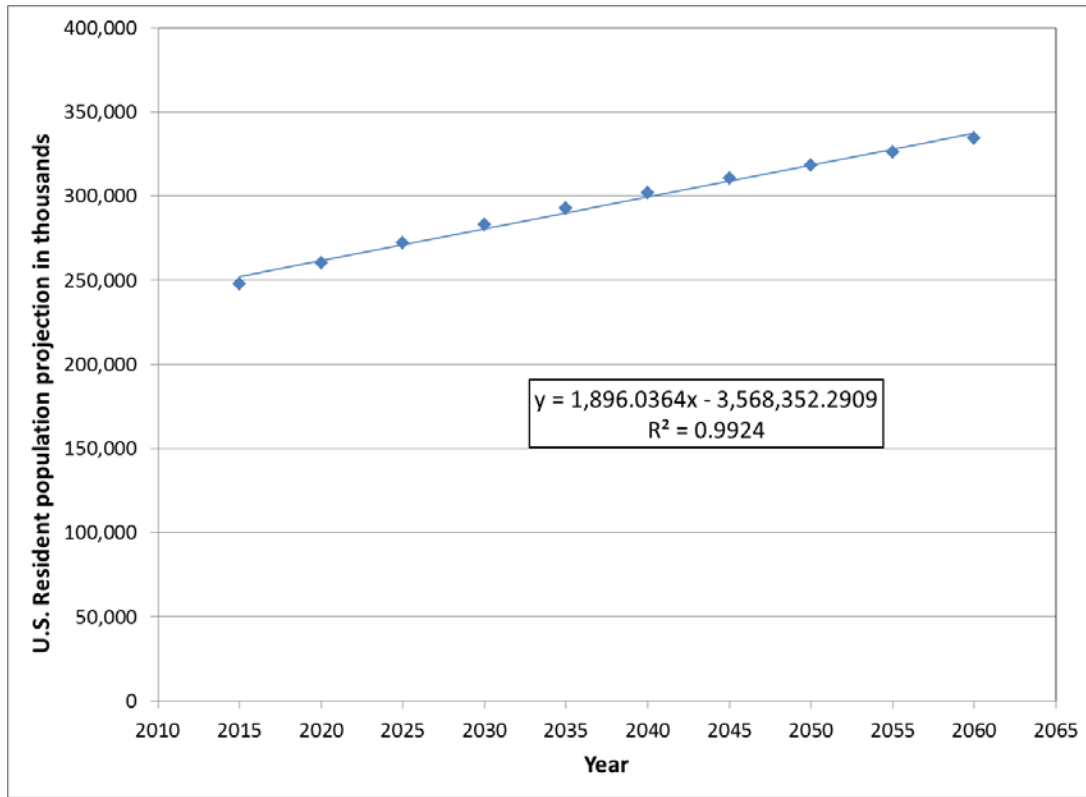


Table 5.14-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.14-3: Adult Smoking Incidence 2001 – 2014

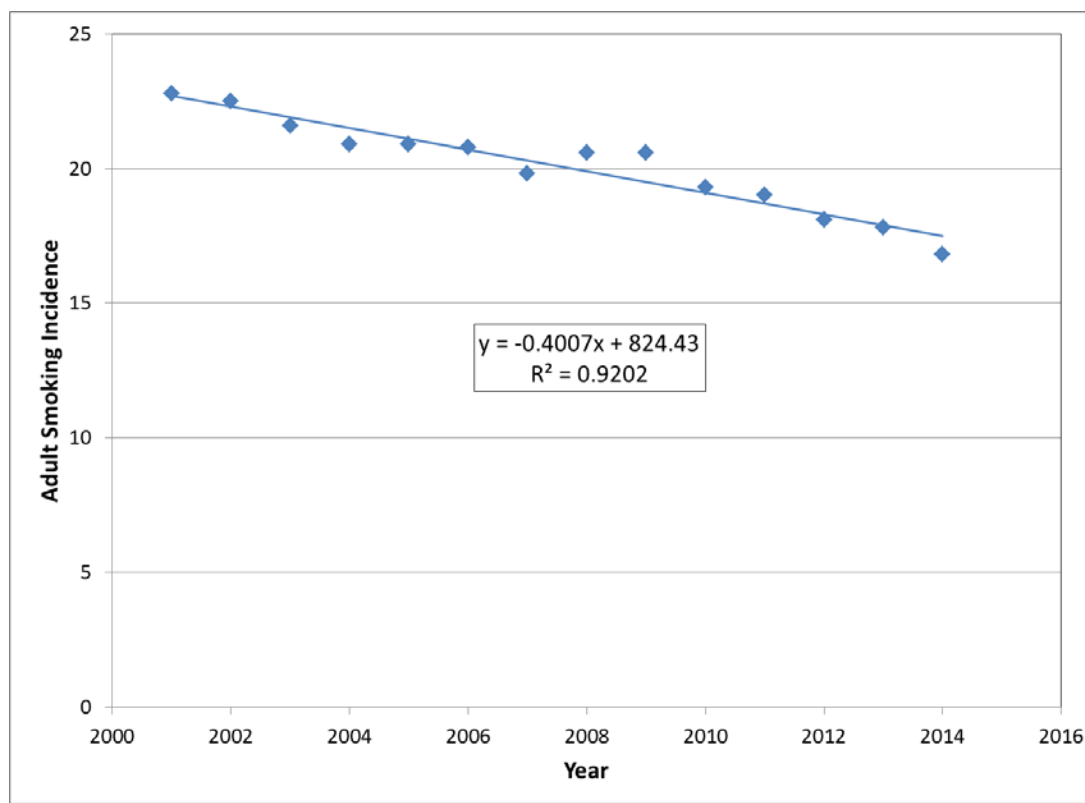


Table 5.14-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.14-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Mint production and associated manufacturing emissions. Based on 0.0957% of the projected smokers switching to the use of 5 pouches of Camel Snus Mint per day, an additional 90,731 pounds of Camel Snus Mint will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Mint will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Mint each day is greater than current Camel Snus Mint use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.14-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Mint production, total ammonia and nicotine emissions are expected to increase by 21 and 106 pounds per year, respectively, based upon the proposed action ([Table 5.14-7](#)).

Table 5.14-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Mint

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Mint Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Mint	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	8	0.111	10
Ammonia (Total off-site release)	2,123	9	0.116	10
Ammonia (Total)	4,159	17	-	21
Nicotine (Total on-site release)	11,293	46	0.615	56
Nicotine (Total off-site release)	10,168	41	0.553	50
Nicotine (Total)	21,461	87	-	106

5.14.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.14-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.07% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.14-8](#)).

Figure 5.14-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

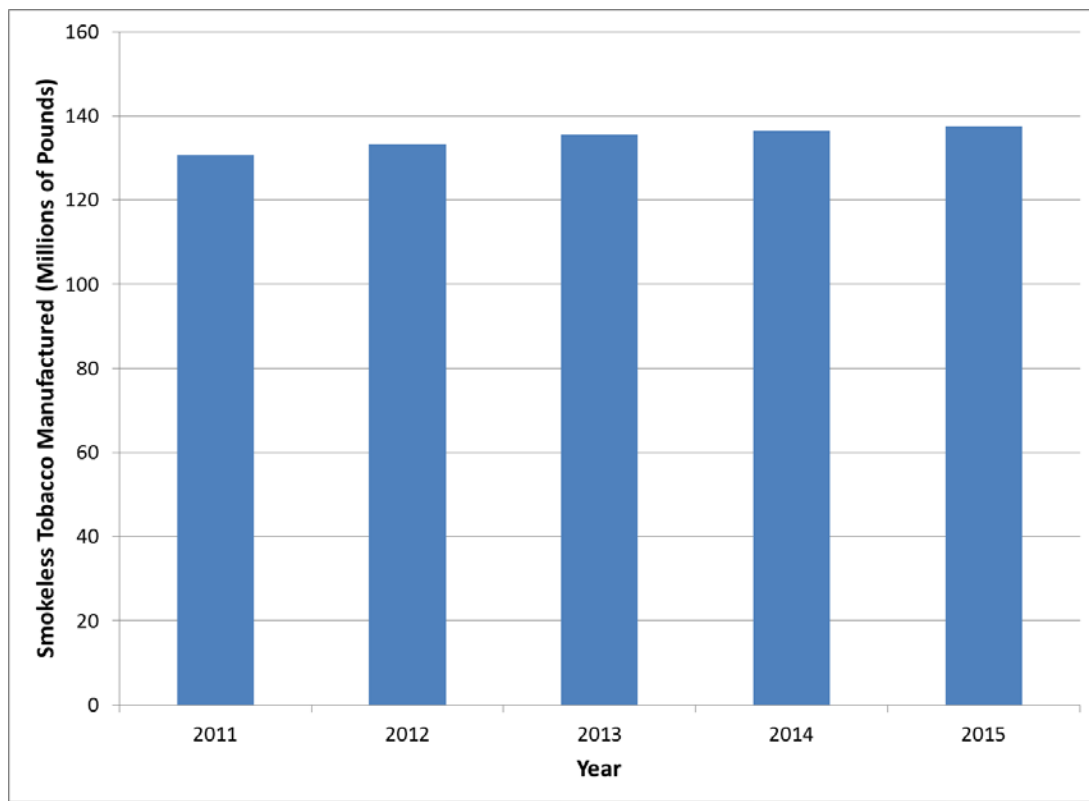


Table 5.14-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	10	15,233	0.07
Ammonia (Total off-site release)	0.116	10	15,884	0.07
Ammonia (Total)	-	21	31,117	0.07
Nicotine (Total on-site release)	0.615	56	84,492	0.07
Nicotine (Total off-site release)	0.553	50	76,075	0.07
Nicotine (Total)	-	106	160,567	0.07

5.14.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.14-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 4.8×10^{-06} percent decrease) and the increase in Camel Snus Mint production has a negligible impact (a 5.0×10^{-06} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.14-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

Table 5.14-9: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	217.6 million cigarettes	16,950	7,939	24,890
Increases from Camel Snus Mint	90,731 pounds	6,249	19,797	26,046

5.14.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Mint and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.14.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Mint accounted for ~ 0.05% by weight of the smokeless tobacco manufactured in the United States and ~ 7% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 38,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, resulting in a decrease of ~ 218 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 90,731 pounds of Camel Snus Mint will be manufactured based upon those smokers using 5 pouches of Camel Snus Mint per day.

5.14.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Mint. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Mint. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 218 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.14.4 Environmental Introduction as a Result of Disposal after Product Use

5.14.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Mint in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Mint includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Mint consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.14-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.14-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Mint are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.14-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

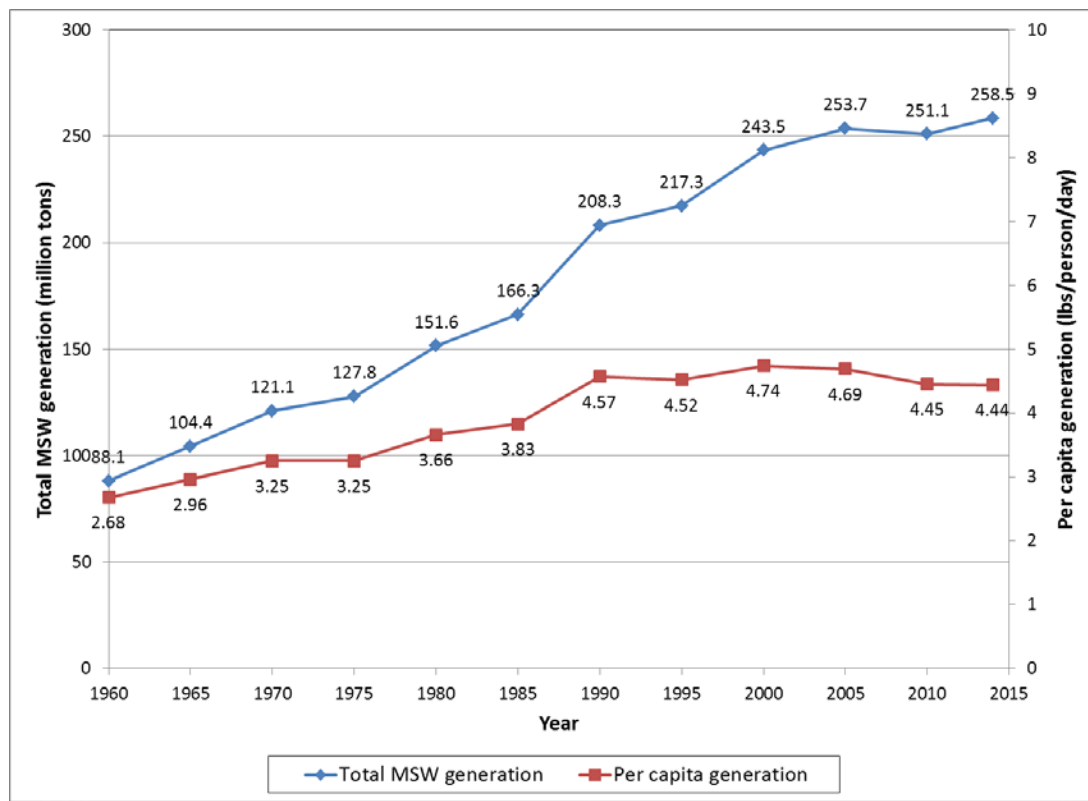
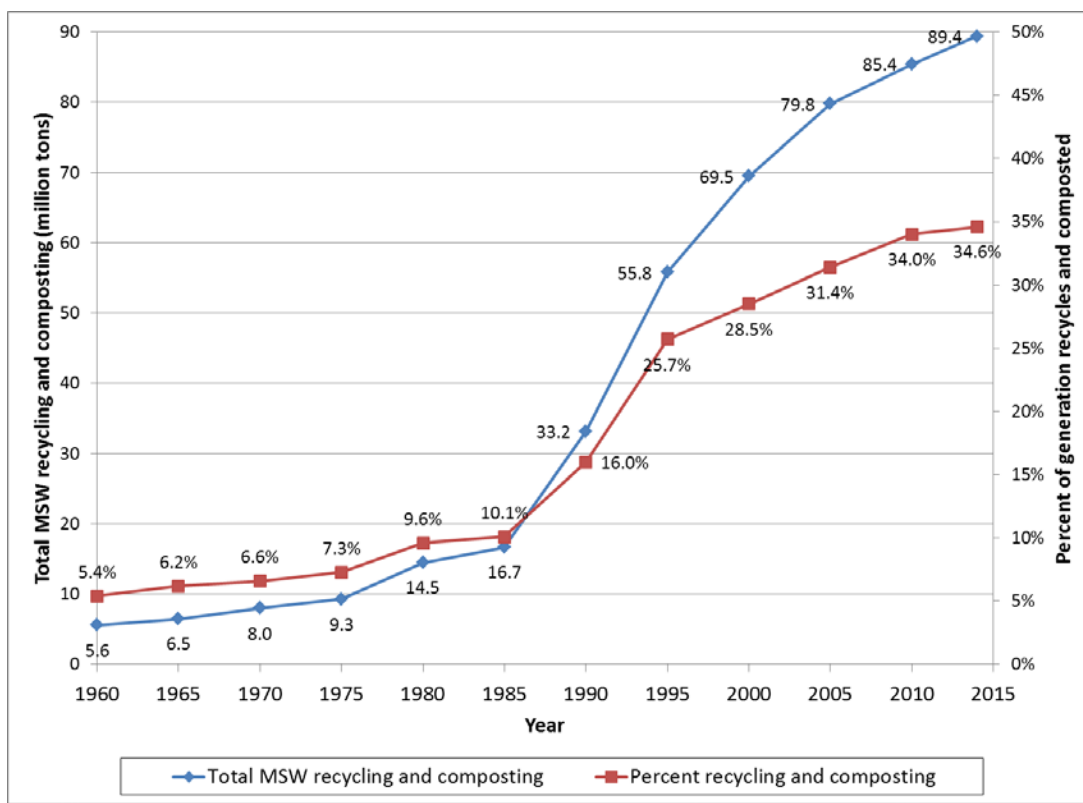


Figure 5.14-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.14.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.14.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Mint

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 38,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, resulting in a decrease of ~ 218 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 218 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.14-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 42 tons per year.

Table 5.14-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	126	46,860	23
“100 mm” (90 – 101 mm)	40.8	89	36,767	18
“120 mm” (118 – 120 mm)	1.1	2	986	0.5
Total (All styles)	100	218	84,614	42

Based on the proposed action resulting in ~ 38,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022, it is estimated that an additional 90,731 pounds of Camel Snus Mint will be manufactured if those smokers use 5 pouches of Camel Snus Mint per day each day of the year. Waste generated due to Camel Snus Mint use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Mint tobacco will become waste for disposal after use, resulting in an increase of ~ 45 tons of used Camel Snus Mint pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 1.6×10^{-05} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Mint used pouch disposal has a negligible impact (a 1.8×10^{-05} percent increase) to the MSW stream, based on the same figures ([Table 5.14-11](#)).

Table 5.14-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	42	1.6×10^{-05}
Increase in used Camel Snus Mint pouches	45	1.8×10^{-05}

5.14.4.2.2 Disposal of Cigarette and Camel Snus Mint Packaging Material

Based on ~ 38,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 11 million fewer cigarette packs and approximately 1.1 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 4.6 million more Camel Snus Mint tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Mint packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.14-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.14-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 110 tons per year ([Table 5.14-13](#)).

Camel Snus Mint Packaging weights are summarized in [Table 5.14-14](#). The Camel Snus Mint package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Mint use, it is estimated that packaging waste will increase by 112 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 4.26×10^{-05} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Mint packaging disposal will have a negligible impact (a 4.33×10^{-05} percent increase), based on the same figures ([Table 5.14-15](#)).

Table 5.14-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.14-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	632,226	126,044	63
"100 mm" (90 – 101 mm)	40.8	443,547	91,264	46
"120 mm" (118 – 120 mm)	1.1	12,470	2,822	1
Total (All styles)	100	1,088,243	220,129	110

Table 5.14-14: Camel Snus Mint Packaging Weights

Camel Snus Mint Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.14-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	110	4.26×10^{-05}
Increase in Camel Snus Mint packaging waste	112	4.33×10^{-05}

5.14.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Mint will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.14.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.14.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.14.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 38,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 218 million fewer cigarettes will be manufactured and that approximately 69 million more pouches of Camel Snus Mint will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.14-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.14-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mint	Net Change Due to the Proposed Action
Electricity (thousand kWh)	412	46	-367
Water (ccf)	73,345	3,703	-69,642
Natural gas (ccf)	12,066	1,271	-10,795

5.14.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.14.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 38,000 smokers switching from smoking to exclusive use of Camel Snus Mint during 2018 – 2022 due to the proposed action, it is estimated that approximately 218 million fewer cigarettes will be manufactured and that approximately 69 million more pouches of Camel Snus Mint will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.14-17](#) summarizes projected annual changes in GHG

emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.14-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mint	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	564	61	-503

5.14.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Mint manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁶⁷ made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁶⁸ and plants⁶⁹ and (b) the endangered and threatened species listed in Appendices I, II, and III⁷⁰ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Mint manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Mint are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

⁶⁷ Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁶⁸ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁶⁹ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

⁷⁰ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Mint are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Mint have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.14.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.14.12 Alternatives to the Proposed Action

- *Alternative A* (no-action alternative): an order authorizing Camel Snus Mint as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.
- *Alternative B* (proposed-action alternative): an order authorizing Camel Snus Mint as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.14.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.15 Camel Snus Mellow: Advertising Execution #3

This Environmental Assessment (EA) is required for authorization of Camel Snus Mellow as a modified risk tobacco product as communicated per [Advertising Execution 3](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁷¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.15.1 Description of Proposed Action

5.15.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.15.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Mellow as a modified risk tobacco product.

5.15.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁷¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Mellow	0.6 gram	9.0 gram

Package Description

Camel Snus Mellow is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.15.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Mellow while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Mellow. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 3](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.15-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.1% of current regular cigarette smokers. Apportionment to the Camel Snus Mellow style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Mellow represents 14.2% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Mellow, due to introduction of the proposed modified risk advertising, is 0.16% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.16% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.15-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

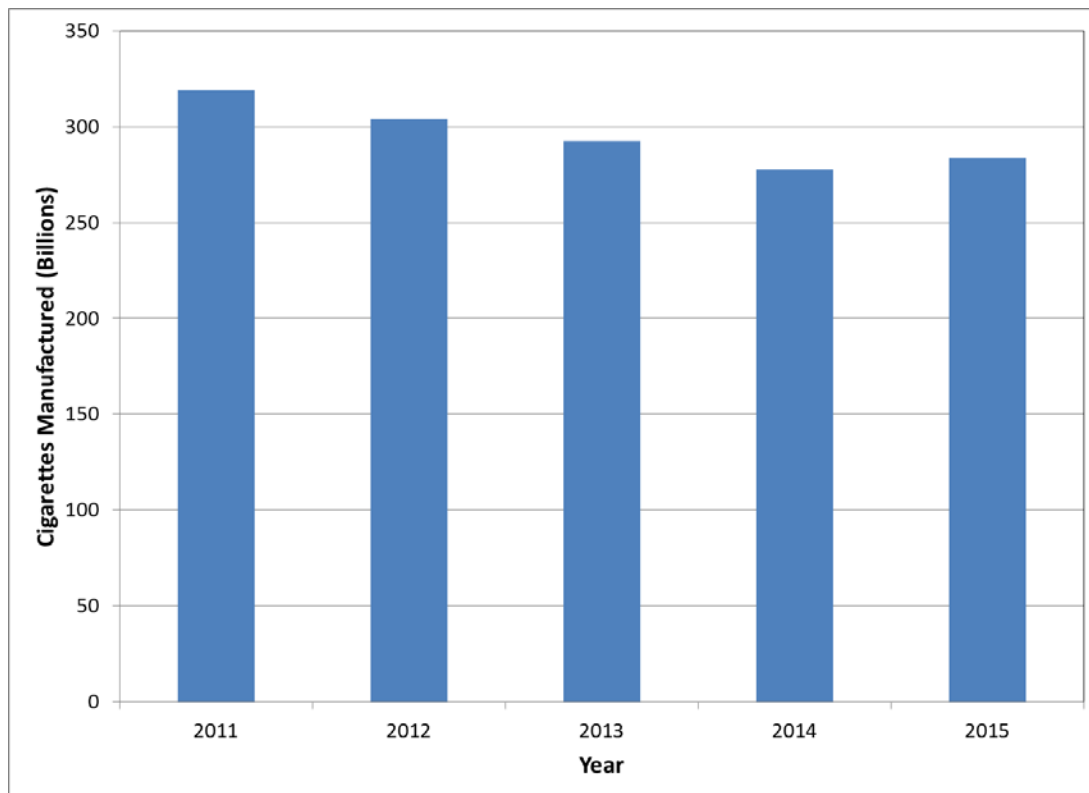
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.0%	2.0%	0.4%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.1%	-	-

5.15.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.15-1](#)).

Figure 5.15-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.15-2](#).

Table 5.15-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.16% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.15-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.15-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.16% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow. Total ammonia and nicotine emissions are expected to decrease by 40 and 61 pounds per year, respectively, based upon the proposed action.

Table 5.15-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	38
Ammonia (Total off-site release)	499	1,545	1,238	2
Ammonia (Total)	10,398	32,192	25,797	40
Nicotine (Total on-site release)	13,865	42,926	34,398	54
Nicotine (Total off-site release)	1,942	6,012	4,818	8
Nicotine (Total)	15,807	48,938	39,216	61

5.15.2.2 Environmental Consequences from Manufacturing Camel Snus Mellow

Waste generated as a result of manufacturing Camel Snus Mellow is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Mellow releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Mellow use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Mellow. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Mellow is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.15-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Mellow due to the proposed order are summarized in [Table 5.15-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Mellow (~ 0.7%); (c) the average rate of each emission type per pound of Camel Snus Mellow tobacco manufactured in 2015 and (d) the number of smokers (~ 61,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Mellow (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.16% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Mellow, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.15-2](#) and [Figure 5.15-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.15-4](#) and [Table 5.15-5](#), respectively.

Figure 5.15-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

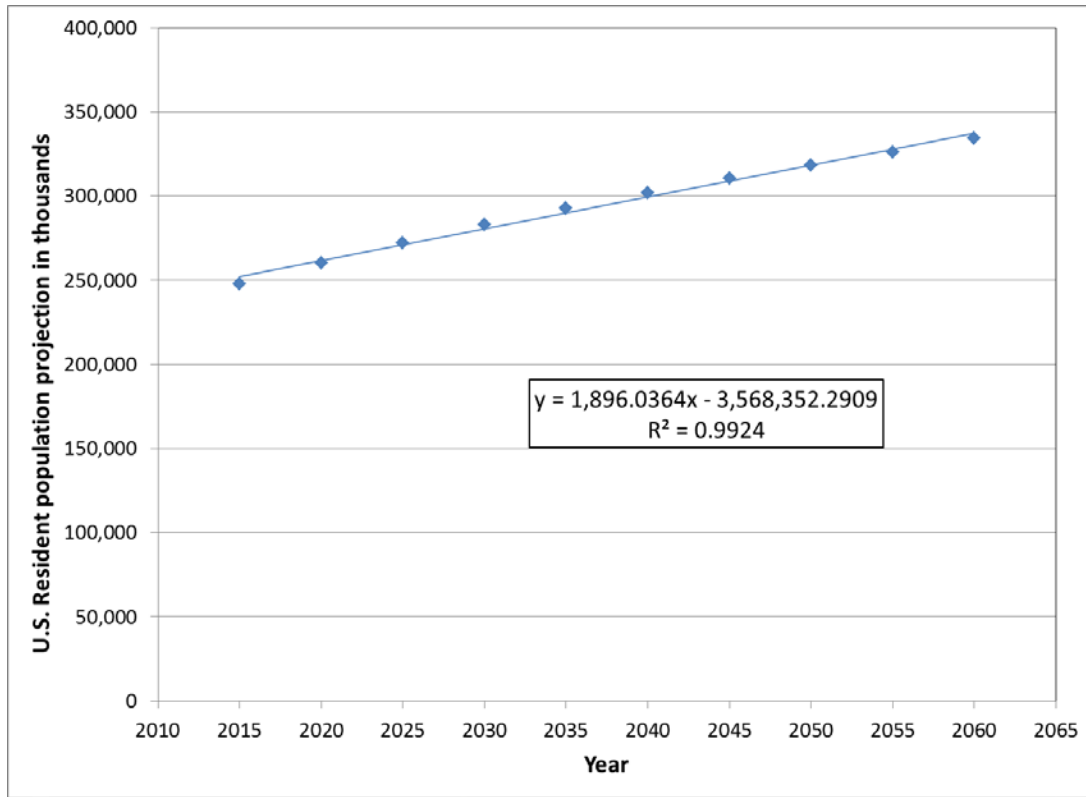


Table 5.15-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.15-3: Adult Smoking Incidence 2001 – 2014

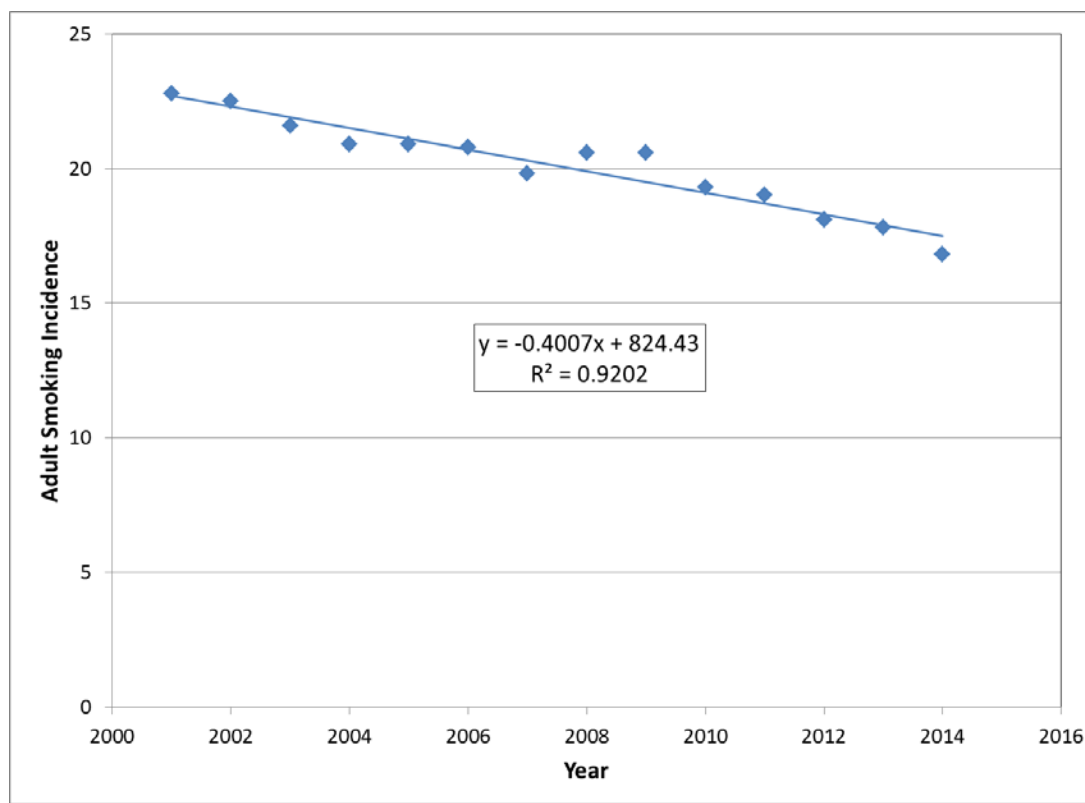


Table 5.15-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.15-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Mellow production and associated manufacturing emissions. Based on 0.1562% of the projected smokers switching to the use of 5 pouches of Camel Snus Mellow per day, an additional 148,089 pounds of Camel Snus Mellow will be manufactured. Of note, this estimate assumes that all of the projected switching from

smoking cigarettes to the use of Camel Snus Mellow will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Mellow each day is greater than current Camel Snus Mellow use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.15-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Mellow production, total ammonia and nicotine emissions are expected to increase by 34 and 173 pounds per year, respectively, based upon the proposed action ([Table 5.15-7](#)).

Table 5.15-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Mellow

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Mellow Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Mellow	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	14	0.111	16
Ammonia (Total off-site release)	2,123	14	0.116	17
Ammonia (Total)	4,159	28	-	34
Nicotine (Total on-site release)	11,293	75	0.615	91
Nicotine (Total off-site release)	10,168	67	0.553	82
Nicotine (Total)	21,461	142	-	173

5.15.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.14-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.11% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.15-8](#)).

Figure 5.15-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

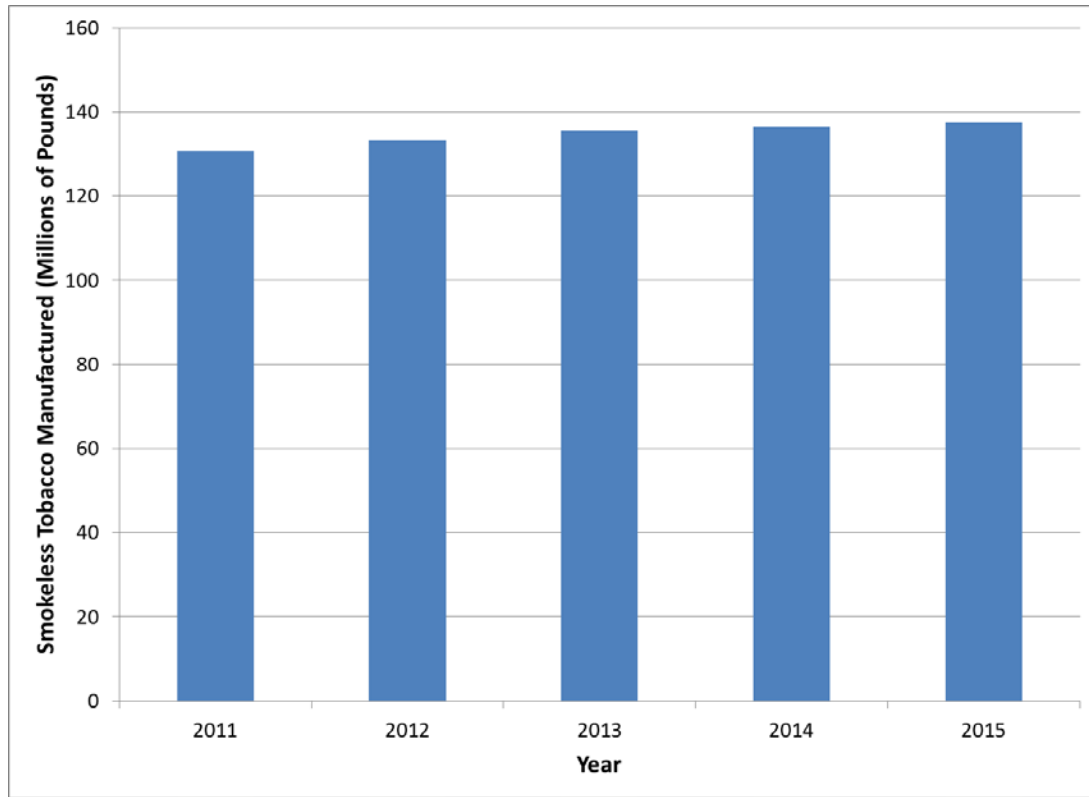


Table 5.15-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	16	15,233	0.11
Ammonia (Total off-site release)	0.116	17	15,884	0.11
Ammonia (Total)	-	34	31,117	0.11
Nicotine (Total on-site release)	0.615	91	84,492	0.11
Nicotine (Total off-site release)	0.553	82	76,075	0.11
Nicotine (Total)	-	173	160,567	0.11

5.15.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.15-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 7.9×10^{-06} percent decrease) and the increase in Camel Snus Mellow production has a negligible impact (a 8.2×10^{-06} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.15-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.15-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	355.2 million cigarettes	27,666	12,958	40,624
Increases from Camel Snus Mellow	148,089 pounds	10,199	32,313	42,519

5.15.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Mellow and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.15.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Mellow accounted for ~ 0.09% by weight of the smokeless tobacco manufactured in the United States and ~ 11% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 61,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, resulting in a decrease of ~ 355 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 148,089 pounds of Camel Snus Mellow will be manufactured based upon those smokers using 5 pouches of Camel Snus Mellow per day.

5.15.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Mellow. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Mellow. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 355 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.15.4 Environmental Introduction as a Result of Disposal after Product Use

5.15.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Mellow in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Mellow includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Mellow consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.15-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.15-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Mellow are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.15-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

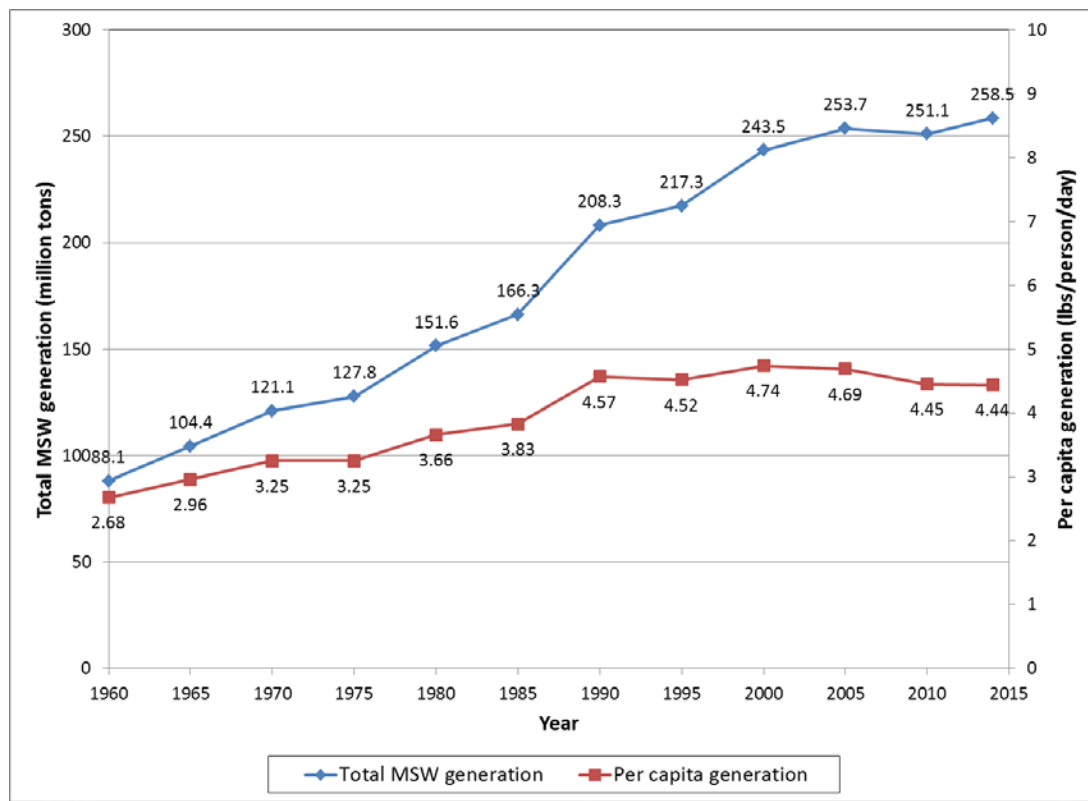
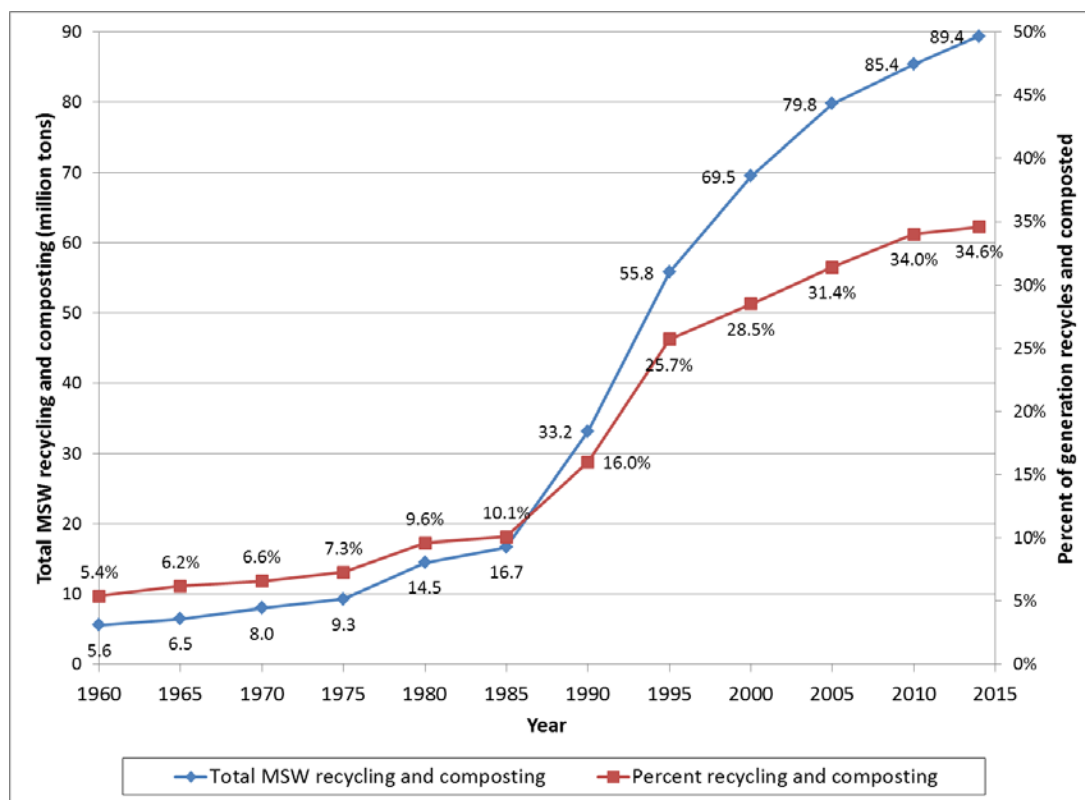


Figure 5.15-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.15.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.15.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Mellow

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 61,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, resulting in a decrease of ~ 355 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 355 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.15-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 69 tons per year.

Table 5.15-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	206	76,485	38
“100 mm” (90 – 101 mm)	40.8	145	60,011	30
“120 mm” (118 – 120 mm)	1.1	4	1,609	1
Total (All styles)	100	355	138,105	69

Based on the proposed action resulting in ~ 61,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022, it is estimated that an additional 148,089 pounds of Camel Snus Mellow will be manufactured if those smokers use 5 pouches of Camel Snus Mellow per day each day of the year. Waste generated due to Camel Snus Mellow use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Mellow tobacco will become waste for disposal after use, resulting in an increase of ~ 74 tons of used Camel Snus Mellow pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 2.7×10^{-05} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Mellow used pouch disposal has a negligible impact (a 2.9×10^{-05} percent increase) to the MSW stream, based on the same figures ([Table 5.15-11](#)).

Table 5.15-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	69	2.7×10^{-05}
Increase in used Camel Snus Mellow pouches	74	2.9×10^{-05}

5.15.4.2.2 Disposal of Cigarette and Camel Snus Mellow Packaging Material

Based on ~ 61,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 18 million fewer cigarette packs and approximately 1.8 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 7.5 million more Camel Snus Mellow tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Mellow packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.15-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.15-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 180 tons per year ([Table 5.15-13](#)).

Camel Snus Mellow Packaging weights are summarized in [Table 5.15-14](#). The Camel Snus Mellow package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Mellow use, it is estimated that packaging waste will increase by 183 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 7.0×10^{-05} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Mellow packaging disposal will have a negligible impact (a 7.1×10^{-05} percent increase), based on the same figures ([Table 5.15-15](#)).

Table 5.15-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.15-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	1,031,909	205,727	103
"100 mm" (90 – 101 mm)	40.8	723,950	148,959	74
"120 mm" (118 – 120 mm)	1.1	20,354	4,605	2
Total (All styles)	100	1,776,213	359,291	180

Table 5.15-14: Camel Snus Mellow Packaging Weights

Camel Snus Mellow Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.15-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	180	7.0×10^{-5}
Increase in Camel Snus Mellow packaging waste	183	7.1×10^{-5}

5.15.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Mellow will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.15.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.15.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.15.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 61,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 355 million fewer cigarettes will be manufactured and that approximately 112 million more pouches of Camel Snus Mellow will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.15-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.15-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mellow	Net Change Due to the Proposed Action
Electricity (thousand kWh)	673	74	-599
Water (ccf)	119,712	6,043	-113,669
Natural gas (ccf)	19,694	2,074	-17,620

5.15.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.15.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 61,000 smokers switching from smoking to exclusive use of Camel Snus Mellow during 2018 – 2022 due to the proposed action, it is estimated that approximately 355 million fewer cigarettes will be manufactured and that approximately 112 million more pouches of Camel Snus Mellow will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.15-17](#) summarizes projected annual changes in

GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.15-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Mellow	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	920	100	-821

5.15.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Mellow manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁷² made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁷³ and plants⁷⁴ and (b) the endangered and threatened species listed in Appendices I, II, and III⁷⁵ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Mellow manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Mellow are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

⁷² Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁷³ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁷⁴ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&ffamily=on&header=Listed+Plants. Accessed on June 14, 2016.

⁷⁵ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Mellow are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Mellow have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.15.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.15.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Mellow as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Mellow as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.15.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.16 Camel Snus Frost Large: Advertising Execution #3

This Environmental Assessment (EA) is required for authorization of Camel Snus Frost Large as a modified risk tobacco product as communicated per [Advertising Execution 3](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁷⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.16.1 Description of Proposed Action

5.16.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.16.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Frost Large as a modified risk tobacco product.

5.16.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁷⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Frost Large	1.0 gram	15.0 gram

Package Description

Camel Snus Frost Large is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.16.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Frost Large while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will switch from smoking cigarettes to exclusively using Camel Snus Frost Large. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA's MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 3](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.16-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.1% of current regular cigarette smokers. Apportionment to the Camel Snus Frost Large style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Frost Large represents 28.4% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Frost Large, due to introduction of the proposed modified risk advertising, is 0.31% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.31% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.16-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

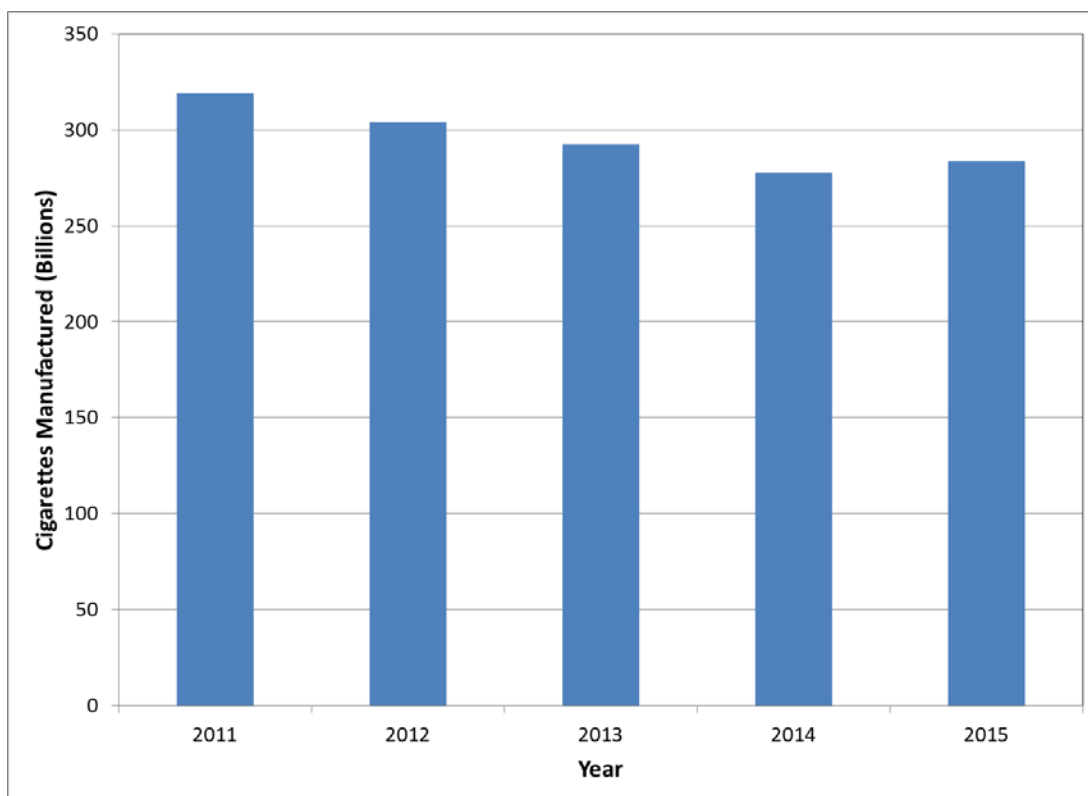
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.0%	2.0%	0.4%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.1%	-	-

5.16.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.16-1](#)).

Figure 5.16-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.16-2](#).

Table 5.16-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.31% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.16-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.16-3](#). Those values are estimated from: (a) current annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.31% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large. Total ammonia and nicotine emissions

are expected to decrease by 81 and 123 pounds per year, respectively, based upon the proposed action.

Table 5.16-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	77
Ammonia (Total off-site release)	499	1,545	1,238	4
Ammonia (Total)	10,398	32,192	25,797	81
Nicotine (Total on-site release)	13,865	42,926	34,398	107
Nicotine (Total off-site release)	1,942	6,012	4,818	15
Nicotine (Total)	15,807	48,938	39,216	123

5.16.2.2 Environmental Consequences from Manufacturing Camel Snus Frost Large

Waste generated as a result of manufacturing Camel Snus Frost Large is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Frost Large releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Frost Large use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Frost Large. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Frost Large is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table](#)

5.16-7). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Frost Large due to the proposed order are summarized in [Table 5.16-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Frost Large (~ 2.2%); (c) the average rate of each emission type per pound of Camel Snus Frost Large tobacco manufactured in 2015 and (d) the number of smokers (~ 123,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Frost Large (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.31% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Frost Large, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.16-2](#) and [Figure 5.16-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.16-4](#) and [Table 5.16-5](#), respectively.

Figure 5.16-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

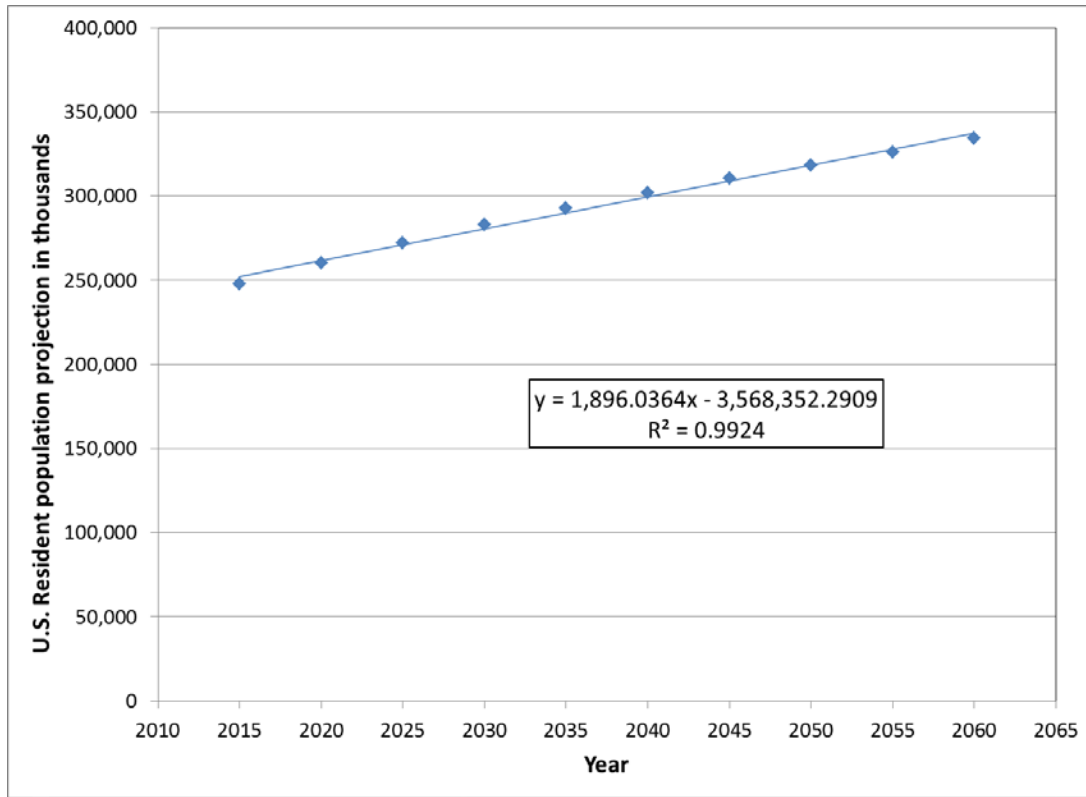


Table 5.16-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.16-3: Adult Smoking Incidence 2001 – 2014

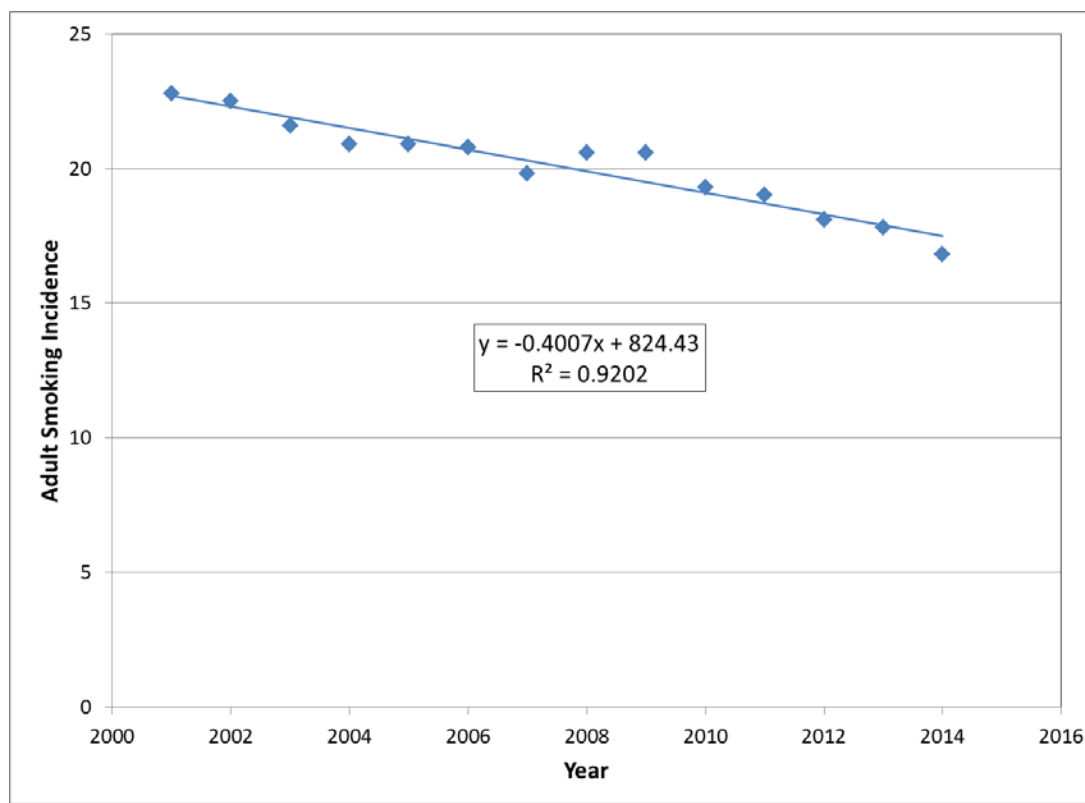


Table 5.16-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 ([Table 5.16-6](#)). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Frost Large production and associated manufacturing emissions. Based on 0.3124% of the projected smokers switching to the use of 5 pouches of Camel Snus Frost Large per day, an additional 493,632 pounds of Camel Snus Frost Large will be manufactured. Of note, this estimate assumes that all of the projected

switching from smoking cigarettes to the use of Camel Snus Frost Large will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Frost Large each day is greater than current Camel Snus Frost Large use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.16-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Frost Large production, total ammonia and nicotine emissions are expected to increase by 112 and 577 pounds per year, respectively, based upon the proposed action ([Table 5.16-7](#)).

Table 5.16-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Frost Large

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Frost Large Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Frost Large	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	45	0.111	55
Ammonia (Total off-site release)	2,123	47	0.116	57
Ammonia (Total)	4,159	92	-	112
Nicotine (Total on-site release)	11,293	250	0.615	303
Nicotine (Total off-site release)	10,168	225	0.553	273
Nicotine (Total)	21,461	476	-	577

5.16.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.16-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.36% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.16-8](#)).

Figure 5.16-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

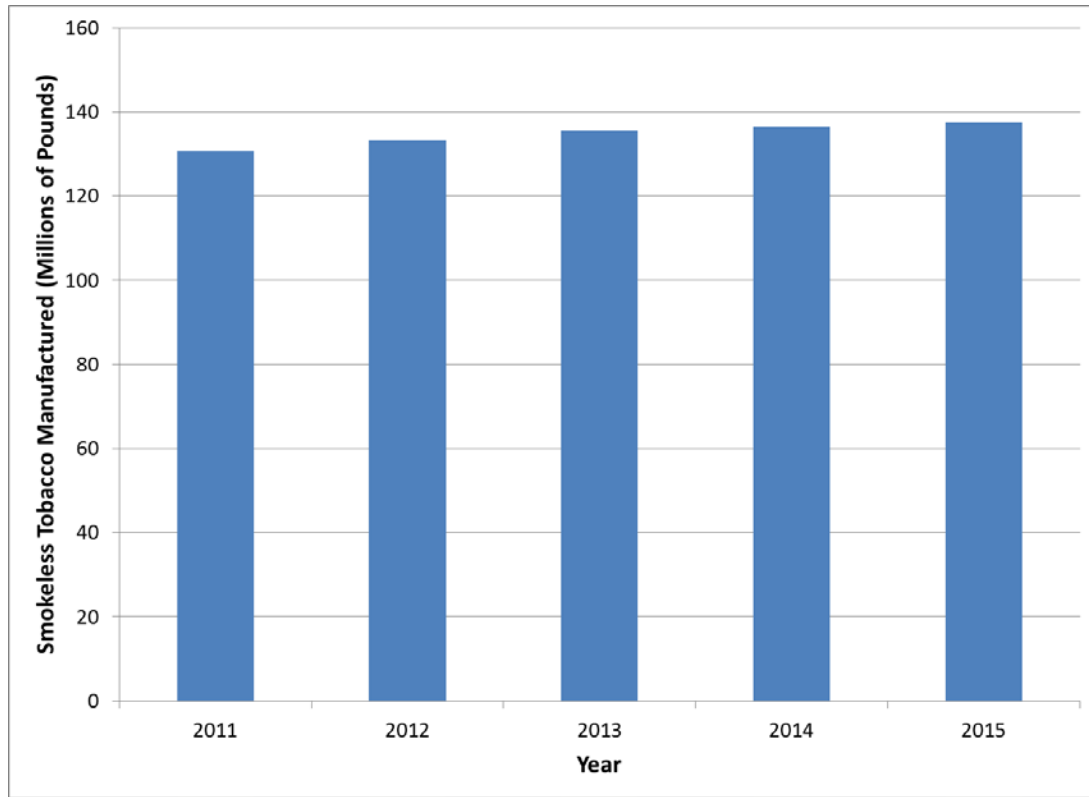


Table 5.16-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	55	15,233	0.36
Ammonia (Total off-site release)	0.116	57	15,884	0.36
Ammonia (Total)	-	112	31,117	0.36
Nicotine (Total on-site release)	0.615	303	84,492	0.36
Nicotine (Total off-site release)	0.553	273	76,075	0.36
Nicotine (Total)	-	577	160,567	0.36

5.16.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.16-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 1.6×10^{-05} percent decrease) and the increase in Camel Snus Frost Large production has a negligible impact (a 2.7×10^{-05} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.16-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.16-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	710.5 million cigarettes	55,332	25,917	81,249
Increases from Camel Snus Frost Large	493,632 pounds	33,997	107,710	141,707

5.16.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Frost Large and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.16.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Frost Large accounted for ~ 0.30% by weight of the smokeless tobacco manufactured in the United States and ~ 23% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 123,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, resulting in a decrease of ~ 710 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 493,632 pounds of Camel Snus Frost Large will be manufactured based upon those smokers using 5 pouches of Camel Snus Frost Large per day.

5.16.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Frost Large. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Frost Large. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 710 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.16.4 Environmental Introduction as a Result of Disposal after Product Use

5.16.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Frost Large in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Frost Large includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Frost Large consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.16-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.16-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Frost Large are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.16-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

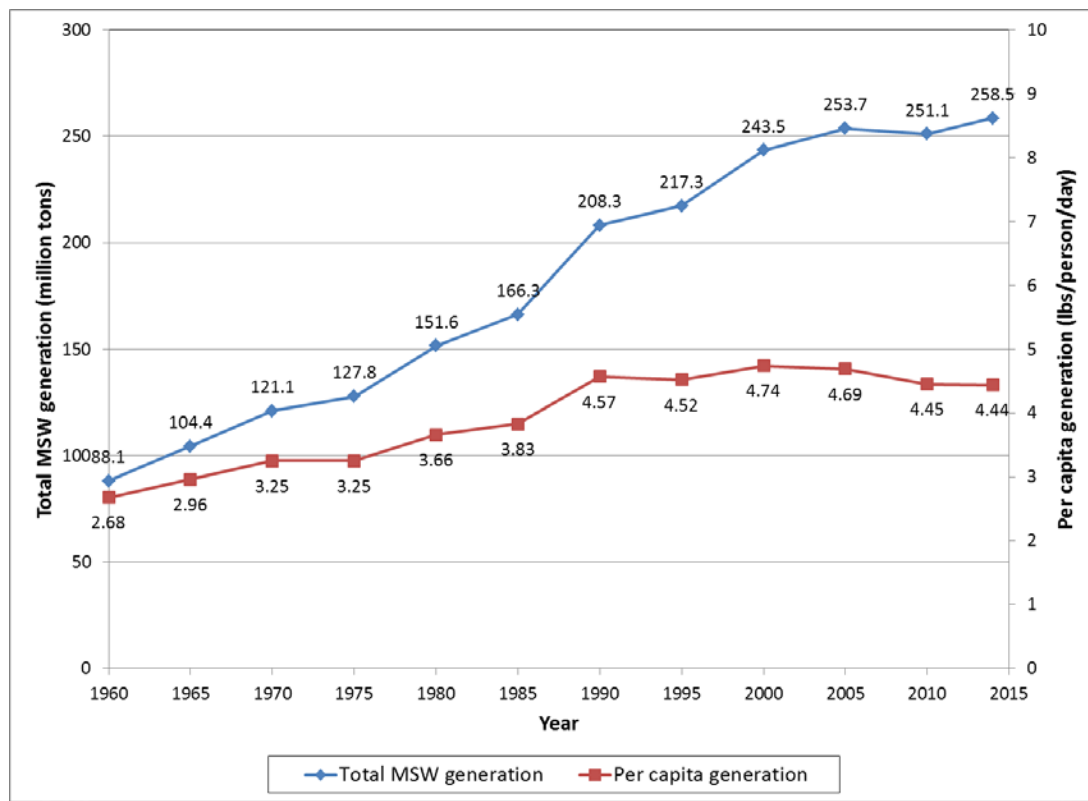
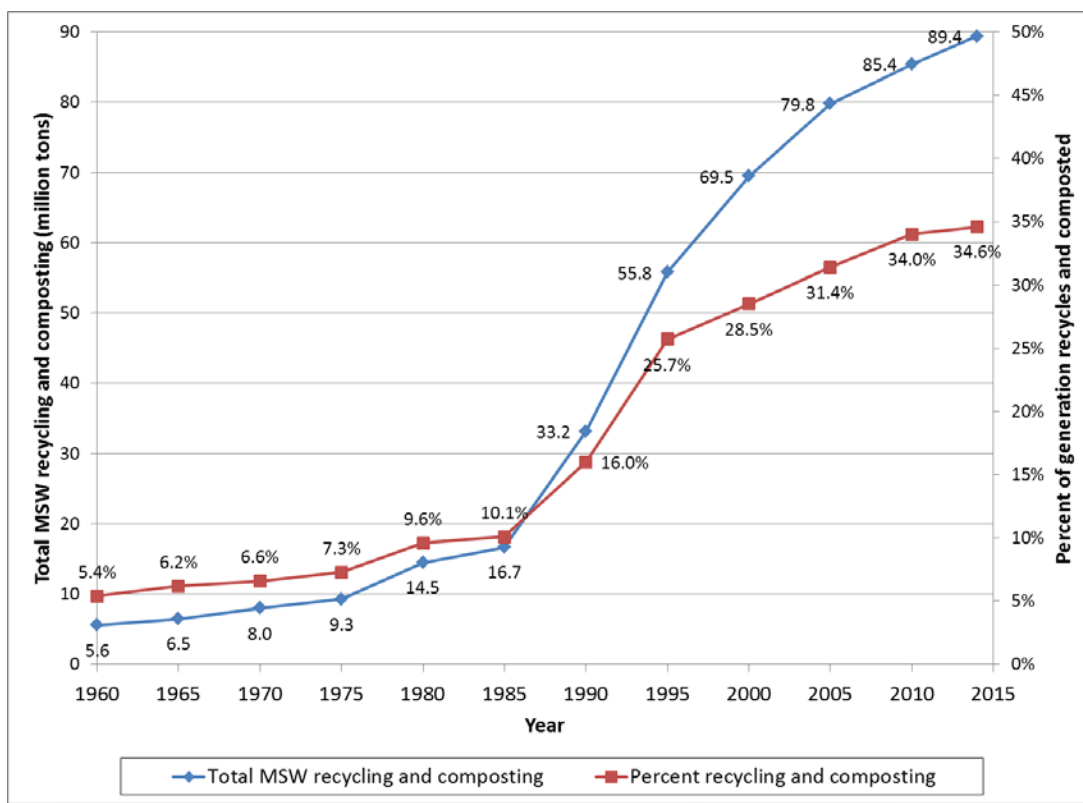


Figure 5.16-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.16.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.16.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Frost Large

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 123,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, resulting in a decrease of ~ 710 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 710 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.16-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 138 tons per year.

Table 5.16-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	413	152,970	76
“100 mm” (90 – 101 mm)	40.8	290	120,023	60
“120 mm” (118 – 120 mm)	1.1	8	3,218	2
Total (All styles)	100	710	276,211	138

Based on the proposed action resulting in ~ 123,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022, it is estimated that an additional 493,632 pounds of Camel Snus Frost Large will be manufactured if those smokers use 5 pouches of Camel Snus Frost Large per day each day of the year. Waste generated due to Camel Snus Frost Large use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Frost Large tobacco will become waste for disposal after use, resulting in an increase of ~ 247 tons of used Camel Snus Frost Large pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 5.3×10^{-05} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Frost Large used pouch disposal has a negligible impact (a 9.5×10^{-05} percent increase) to the MSW stream, based on the same figures ([Table 5.16-11](#)).

Table 5.16-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	138	5.3×10^{-5}
Increase in used Camel Snus Frost Large pouches	247	9.5×10^{-5}

5.16.4.2.2 Disposal of Cigarette and Camel Snus Frost Large Packaging Material

Based on ~ 123,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 36 million fewer cigarette packs and approximately 3.6 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 14.9 million more Camel Snus Frost Large tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Frost Large packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.16-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.16-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 359 tons per year ([Table 5.16-13](#)).

Camel Snus Frost Large Packaging weights are summarized in [Table 5.16-14](#). The Camel Snus Frost Large package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Frost Large use, it is estimated that packaging waste will increase by 366 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 1.39×10^{-4} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Frost Large packaging disposal will have a negligible impact (a 1.41×10^{-4} percent increase), based on the same figures ([Table 5.16-15](#)).

Table 5.16-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.16-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	2,063,818	411,453	206
"100 mm" (90 – 101 mm)	40.8	1,447,900	297,918	149
"120 mm" (118 – 120 mm)	1.1	40,707	9,210	5
Total (All styles)	100	3,552,425	718,581	359

Table 5.16-14: Camel Snus Frost Large Packaging Weights

Camel Snus Frost Large Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.16-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	359	1.39×10^{-04}
Increase in Camel Snus Frost Large packaging waste	366	1.41×10^{-04}

5.16.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Frost Large will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.16.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.16.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.16.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 123,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 710 million fewer cigarettes will be manufactured and that approximately 224 million more pouches of Camel Snus Frost Large will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.16-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.16-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost Large	Net Change Due to the Proposed Action
Electricity (thousand kWh)	1,346	248	-1,098
Water (ccf)	239,424	20,144	-219,280
Natural gas (ccf)	39,388	6,913	-32,475

5.16.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.16.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 123,000 smokers switching from smoking to exclusive use of Camel Snus Frost Large during 2018 – 2022 due to the proposed action, it is estimated that approximately 710 million fewer cigarettes will be manufactured and that approximately 224 million more pouches of Camel Snus Frost Large will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. Table 5.16-17 summarizes projected annual changes in GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.16-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Frost Large	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	1,841	332	-1,509

5.16.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act ("ESA") (1973 Endangered Species Act) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora ("CITES") (Convention on International Trade in Endangered Species) are expected due to the proposed action. The location of Camel Snus Frost Large manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁷⁷ made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁷⁸ and plants⁷⁹ and (b) the endangered and threatened species

⁷⁷ Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁷⁸ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁷⁹ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

listed in Appendices I, II, and III⁸⁰ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Frost Large manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Frost Large are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used in Camel Snus Frost Large are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Frost Large have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.16.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers

⁸⁰ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.

- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.

- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.16.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Frost Large as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Frost Large as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.16.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.17 Camel Snus Winterchill: Advertising Execution #3

This Environmental Assessment (EA) is required for authorization of Camel Snus Winterchill as a modified risk tobacco product as communicated per [Advertising Execution 3](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁸¹

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.17.1 Description of Proposed Action

5.17.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.17.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Winterchill as a modified risk tobacco product.

5.17.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁸¹ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Winterchill	1.0 gram	15.0 gram

Package Description

Camel Snus Winterchill is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.17.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Winterchill while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will switch from smoking cigarettes to exclusively using Camel Snus Winterchill. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA's MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 3](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.17-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.1% of current regular cigarette smokers. Apportionment to the Camel Snus Winterchill style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Winterchill represents 13.6% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Winterchill, due to introduction of the proposed modified risk advertising, is 0.15% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.15% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.17-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

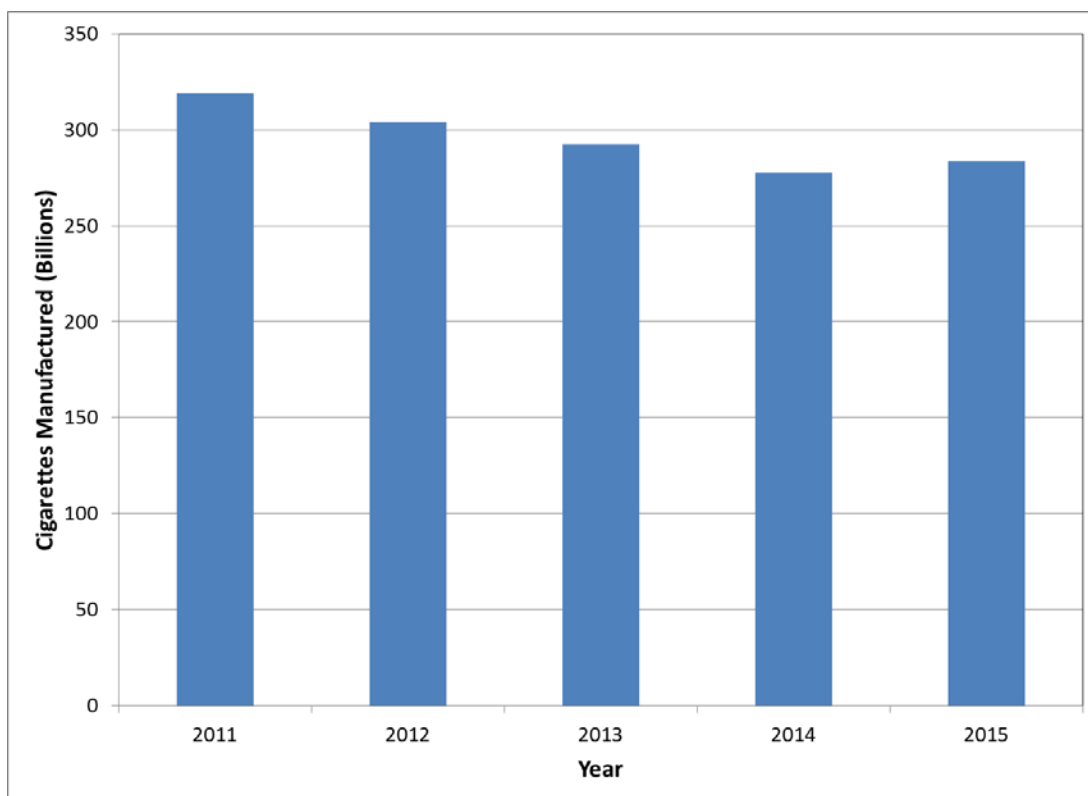
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.0%	2.0%	0.4%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.1%	-	-

5.17.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.17-1](#)).

Figure 5.17-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.17-2](#).

Table 5.17-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.15% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.17-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.17-3](#). Those values are estimated from: (a) current annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.15% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill. Total ammonia and nicotine emissions

are expected to decrease by 39 and 59 pounds per year, respectively, based upon the proposed action.

Table 5.17-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	37
Ammonia (Total off-site release)	499	1,545	1,238	2
Ammonia (Total)	10,398	32,192	25,797	39
Nicotine (Total on-site release)	13,865	42,926	34,398	51
Nicotine (Total off-site release)	1,942	6,012	4,818	7
Nicotine (Total)	15,807	48,938	39,216	59

5.17.2.2 Environmental Consequences from Manufacturing Camel Snus Winterchill

Waste generated as a result of manufacturing Camel Snus Winterchill is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Winterchill releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Winterchill use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Winterchill. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Winterchill is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table](#)

5.17-7). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Winterchill due to the proposed order are summarized in [Table 5.17-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Winterchill (~ 1.1%); (c) the average rate of each emission type per pound of Camel Snus Winterchill tobacco manufactured in 2015 and (d) the number of smokers (~ 59,000) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Winterchill (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.15% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Winterchill, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.17-2](#) and [Figure 5.17-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.17-4](#) and [Table 5.17-5](#), respectively.

Figure 5.17-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

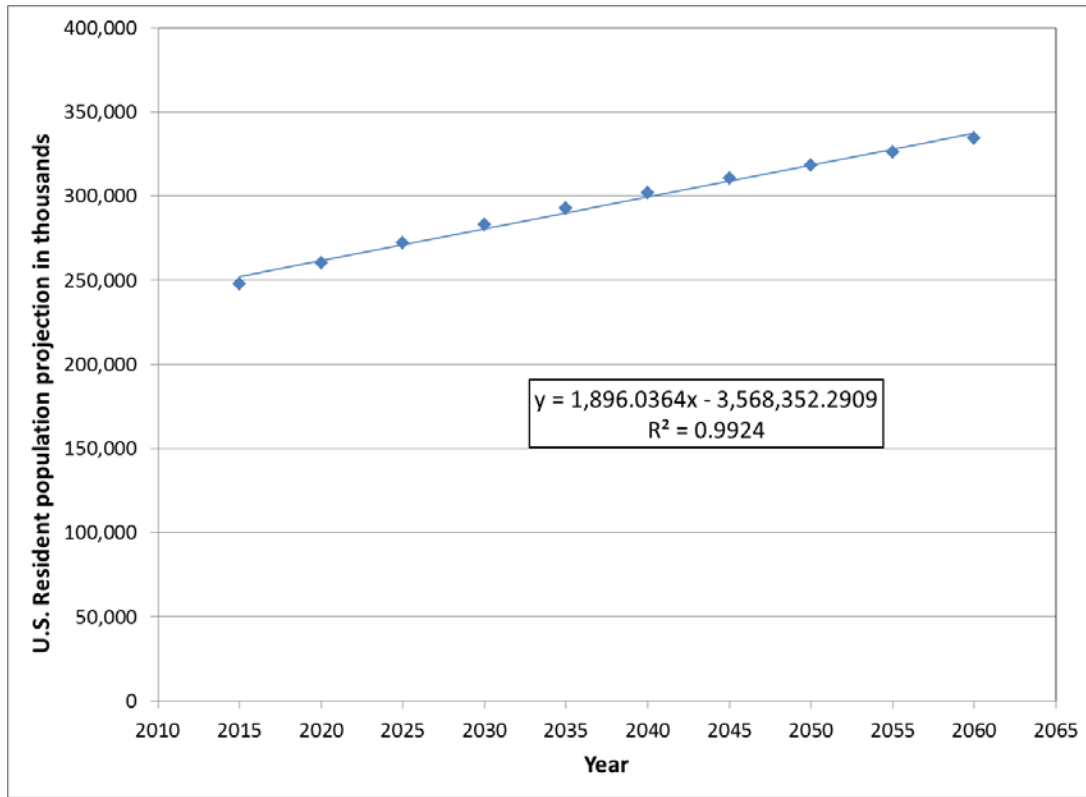


Table 5.17-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.17-3: Adult Smoking Incidence 2001 – 2014

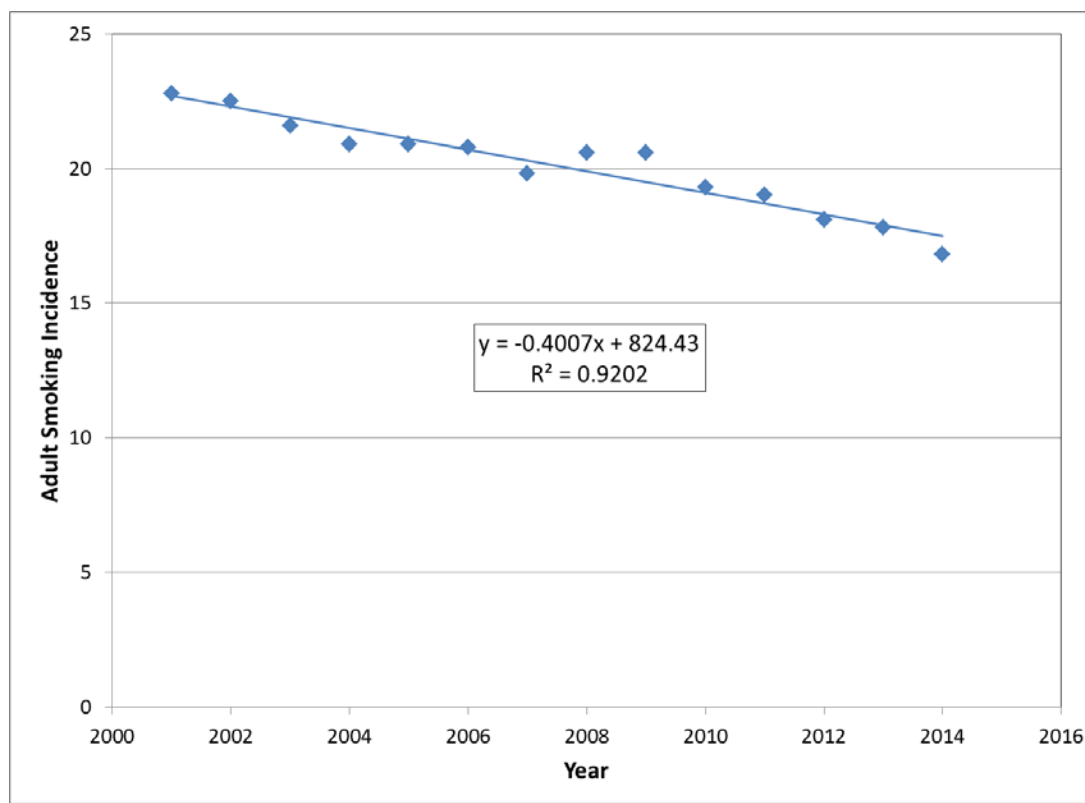


Table 5.17-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Table 5.17-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Winterchill production and associated manufacturing emissions. Based on 0.1496% of the projected smokers switching to the use of 5 pouches of Camel Snus Winterchill per day, an additional 236,387 pounds of Camel Snus Winterchill will be manufactured. Of note, this estimate assumes that all of the projected

switching from smoking cigarettes to the use of Camel Snus Winterchill will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Winterchill each day is greater than current Camel Snus Winterchill use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.17-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Winterchill production, total ammonia and nicotine emissions are expected to increase by 54 and 276 pounds per year, respectively, based upon the proposed action ([Table 5.17-7](#)).

Table 5.17-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Winterchill

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Winterchill Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Winterchill	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	22	0.111	26
Ammonia (Total off-site release)	2,123	22	0.116	27
Ammonia (Total)	4,159	44	-	54
Nicotine (Total on-site release)	11,293	120	0.615	145
Nicotine (Total off-site release)	10,168	108	0.553	131
Nicotine (Total)	21,461	227	-	276

5.17.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.17-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.17% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.17-8](#)).

Figure 5.17-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

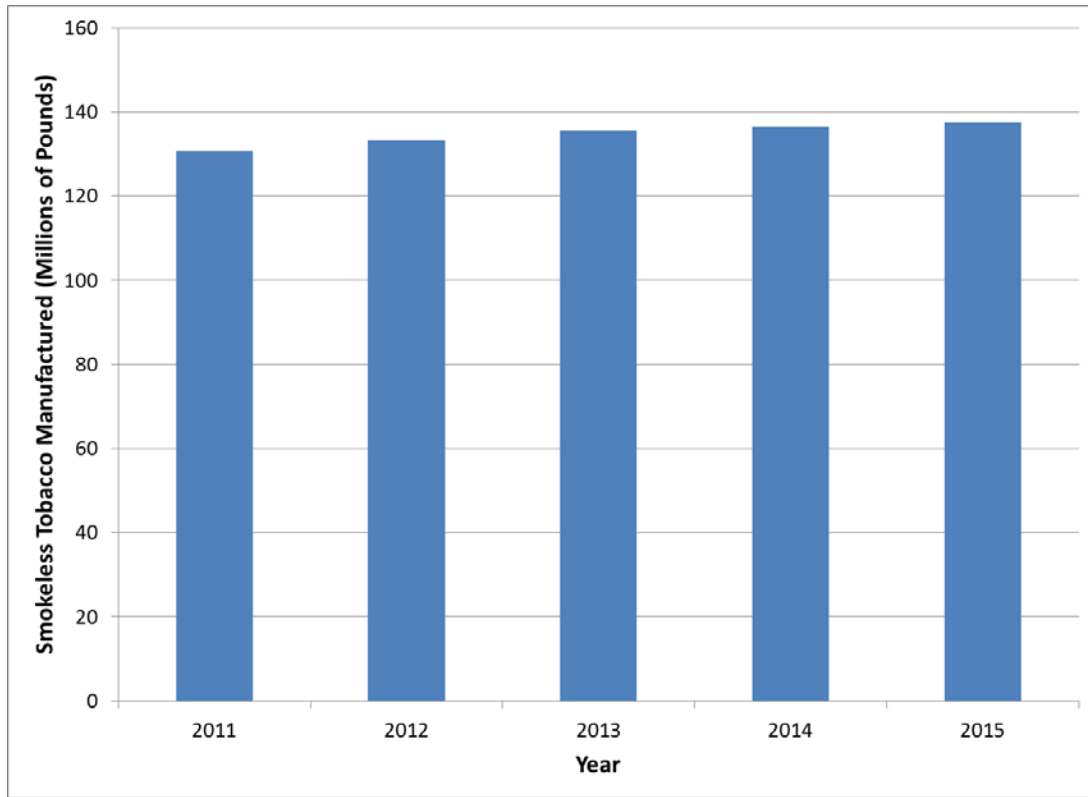


Table 5.17-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	26	15,233	0.17
Ammonia (Total off-site release)	0.116	27	15,884	0.17
Ammonia (Total)	-	54	31,117	0.17
Nicotine (Total on-site release)	0.615	145	84,492	0.17
Nicotine (Total off-site release)	0.553	131	76,075	0.17
Nicotine (Total)	-	276	160,567	0.17

5.17.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.17-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 7.5×10^{-06} percent decrease) and the increase in Camel Snus Winterchill production has a negligible impact (a 1.3×10^{-05} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.17-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.17-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	340.2 million cigarettes	26,497	12,411	38,908
Increases from Camel Snus Winterchill	236,387 pounds	16,280	51,580	67,860

5.17.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Winterchill and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.17.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Winterchill accounted for ~ 0.14% by weight of the smokeless tobacco manufactured in the United States and ~ 11% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 59,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, resulting in a decrease of ~ 340 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 236,387 pounds of Camel Snus Winterchill will be manufactured based upon those smokers using 5 pouches of Camel Snus Winterchill per day.

5.17.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Winterchill. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Winterchill. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 340 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.17.4 Environmental Introduction as a Result of Disposal after Product Use

5.17.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Winterchill in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Winterchill includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Winterchill consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.17-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.17-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Winterchill are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.17-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

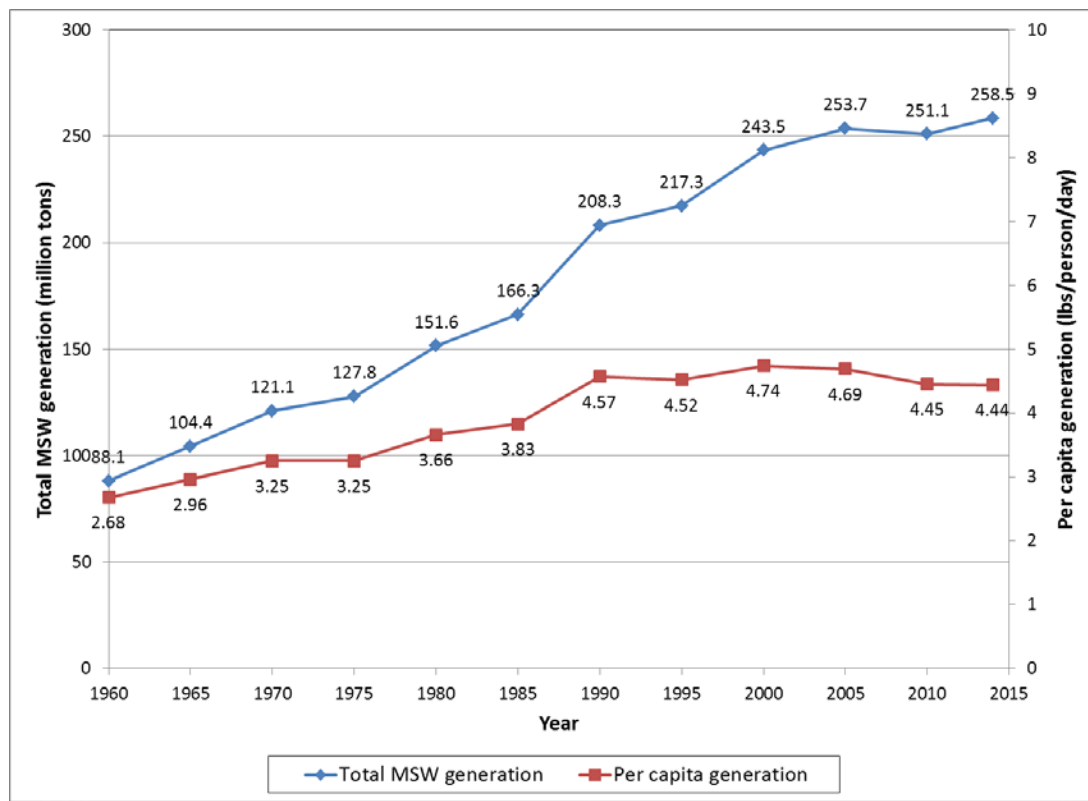
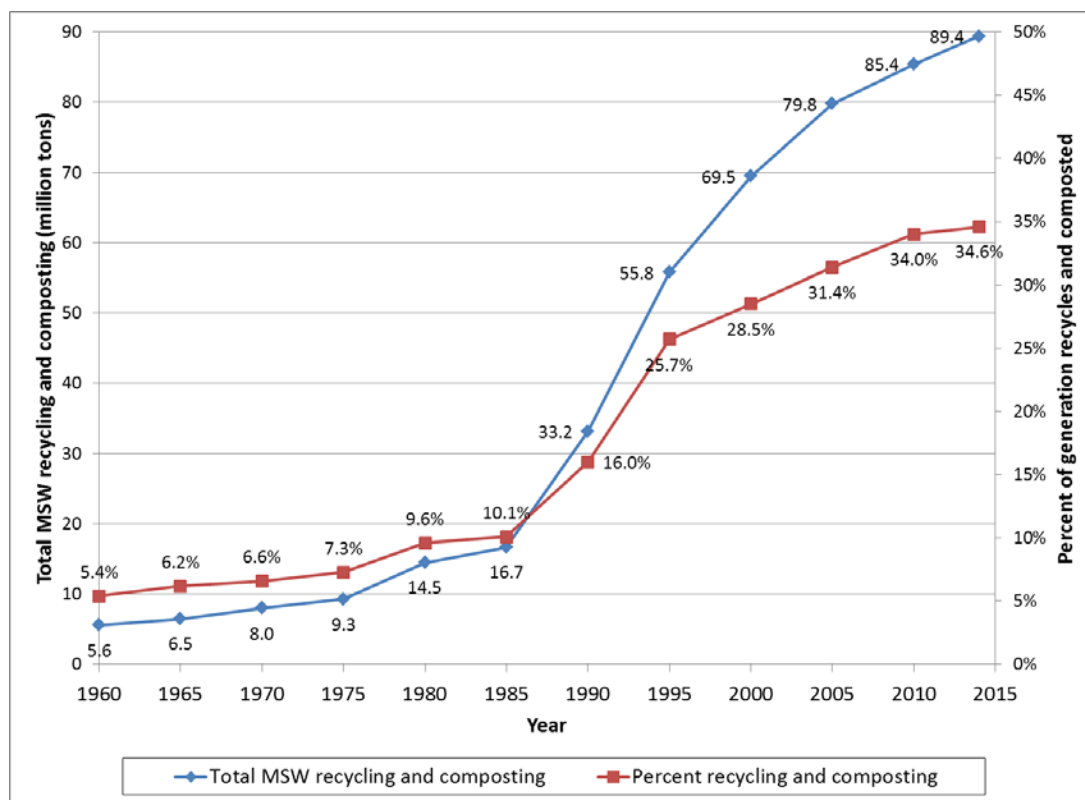


Figure 5.17-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.17.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.17.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Winterchill

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 59,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, resulting in a decrease of ~ 340 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 340 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.17-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 66 tons per year.

Table 5.17-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	198	73,253	37
“100 mm” (90 – 101 mm)	40.8	139	57,476	29
“120 mm” (118 – 120 mm)	1.1	4	1,541	1
Total (All styles)	100	340	132,270	66

Based on the proposed action resulting in ~ 59,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022, it is estimated that an additional 236,387 pounds of Camel Snus Winterchill will be manufactured if those smokers use 5 pouches of Camel Snus Winterchill per day each day of the year. Waste generated due to Camel Snus Winterchill use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Winterchill tobacco will become waste for disposal after use, resulting in an increase of ~ 118 tons of used Camel Snus Winterchill pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 2.6×10^{-5} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Winterchill used pouch disposal has a negligible impact (a 4.6×10^{-5} percent increase) to the MSW stream, based on the same figures ([Table 5.17-11](#)).

Table 5.17-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	66	2.6×10^{-05}
Increase in used Camel Snus Winterchill pouches	118	4.6×10^{-05}

5.17.4.2.2 Disposal of Cigarette and Camel Snus Winterchill Packaging Material

Based on ~ 59,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 17 million fewer cigarette packs and approximately 1.7 million fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 7.1 million more Camel Snus Winterchill tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Winterchill packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.17-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.17-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 172 tons per year ([Table 5.17-13](#)).

Camel Snus Winterchill Packaging weights are summarized in [Table 5.17-14](#). The Camel Snus Winterchill package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Winterchill use, it is estimated that packaging waste will increase by 175 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 6.7×10^{-05} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Winterchill packaging disposal will have a negligible impact (a 6.8×10^{-05} percent increase), based on the same figures ([Table 5.17-15](#)).

Table 5.17-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.17-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	988,307	197,034	99
"100 mm" (90 – 101 mm)	40.8	693,361	142,665	71
"120 mm" (118 – 120 mm)	1.1	19,494	4,411	2
Total (All styles)	100	1,701,161	344,109	172

Table 5.17-14: Camel Snus Winterchill Packaging Weights

Camel Snus Winterchill Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.17-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	172	6.7×10^{-05}
Increase in Camel Snus Winterchill packaging waste	175	6.8×10^{-05}

5.17.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Winterchill will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.17.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.17.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.17.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 59,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 340 million fewer cigarettes will be manufactured and that approximately 107 million more pouches of Camel Snus Winterchill will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.17-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.17-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Winterchill	Net Change Due to the Proposed Action
Electricity (thousand kWh)	645	119	-526
Water (ccf)	114,654	9,646	-105,007
Natural gas (ccf)	18,862	3,311	-15,551

5.17.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.17.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 59,000 smokers switching from smoking to exclusive use of Camel Snus Winterchill during 2018 – 2022 due to the proposed action, it is estimated that approximately 340 million fewer cigarettes will be manufactured and that approximately 107 million more pouches of Camel Snus Winterchill will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT’s Tobaccoville manufacturing facility. [Table 5.17-17](#) summarizes projected annual changes in GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.17-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Winterchill	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	881	159	-722

5.17.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Winterchill manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁸² made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁸³ and plants⁸⁴ and (b) the endangered and threatened species

⁸² Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁸³ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁸⁴ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&family=on&header=Listed+Plants. Accessed on June 14, 2016.

listed in Appendices I, II, and III⁸⁵ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Winterchill manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Winterchill are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used in Camel Snus Winterchill are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Winterchill have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.17.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers

⁸⁵ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.

- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.

- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.17.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Winterchill as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Winterchill as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.17.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.18 Camel Snus Robust: Advertising Execution #3

This Environmental Assessment (EA) is required for authorization of Camel Snus Robust as a modified risk tobacco product as communicated per [Advertising Execution 3](#). This EA has been prepared in accordance with [21 CFR 25.40](#) in support of a modified risk order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([TCA Section 911\(g\)\(1\)](#)).⁸⁶

Name of Applicant/Submitter

R.J. Reynolds Tobacco Company

Address

401 N. Main Street
Winston-Salem, NC 27101

Manufacturer

American Snuff Company, LLC, Taylor Brothers Division, under contract to R.J. Reynolds Tobacco Company

5.18.1 Description of Proposed Action

5.18.1.1 Requested Action

Issuance of a modified risk tobacco product order under [TCA Section 911\(g\)\(1\)](#)

5.18.1.2 Need for Action

R.J. Reynolds Tobacco Company proposes to market Camel Snus Robust as a modified risk tobacco product.

5.18.1.3 Identification of the Product that is Subject to the Proposed Action

Type of Tobacco Product

Portioned pouched smokeless tobacco product within the snus sub-category.

⁸⁶ In accordance with [40 CFR § 1502.17](#), the individuals primarily responsible for preparation of this environmental assessment were: Joy A. Bodnar, M.S. (Experience: 40 years in analytical chemistry and various other scientific and regulatory activities); Christie A. Young, Ph.D. (Experience: 6 years in immunology and various other scientific activities); Michael F. Borgerding, Ph.D. (Experience: 36 years in analytical chemistry and various other scientific and regulatory activities).

Name of Tobacco Product

NAME	PORTION SIZE	TIN AMOUNT
Camel Snus Robust	1.0 gram	15.0 gram

Package Description

Camel Snus Robust is packaged in a two-piece metal container fabricated out of tin plated steel. Five tins are combined in a “sleeve” by wrapping with shrink wrap film.

Location of Manufacturing

2415 South Stratford Rd
Winston-Salem, NC 27103

Location of Use

R.J. Reynolds Tobacco Company (“RJRT”) intends to sell the tobacco product to wholesale distributors for ultimate sale to adult consumers at retail in the United States.

Location of Disposal

Disposal of the tobacco product will be through deposit in municipal solid waste (MSW) landfills or as litter, in the same manner as any other commercially marketed smokeless tobacco product. Following use of the tobacco product, packaging materials either will enter the recycling stream or will be deposited in MSW landfills or as litter. The geographical distribution of waste from disposal after product use should correspond to current patterns of product use throughout the United States.

5.18.2 Environmental Introduction Due to Proposed Action

This section will address environmental introduction due to the proposed action in three categories, including environmental introduction as a result of (a) manufacturing tobacco products, (b) the use of products and (c) disposal of materials following use of products.

Following introduction of the proposed modified risk advertising of Camel Snus, it is expected that that some smokers will switch from smoking to exclusive use of Camel Snus. Such a change in product use behavior will increase environmental introduction of product and packaging materials related to Camel Snus Robust while also decreasing product and packaging materials from the use of cigarettes. The magnitudes of anticipated changes are summarized by product type in the following sections. A context for the changes is also provided in terms of comparison to environmental introduction from the manufacture, use and disposal of both cigarettes and smokeless tobacco currently sold in the United States.

A key input into calculations that estimate environmental introduction is the magnitude of change that will result from the proposed action in terms of the number of smokers that will

switch from smoking cigarettes to exclusively using Camel Snus Robust. For the purpose of this EA, that information was established by a likelihood of use study.

In accordance with FDA’s MRTPA Draft Guidance, RJRT conducted a likelihood of use study to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ likelihood to use Camel Snus ([FDA MRTPA Draft Guidance 2012](#)). Among those who were likely to use Camel Snus, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) was evaluated. Evaluation of likelihood of use among current tobacco users included assessment among current users who expected to quit tobacco. Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users.

The full study report for proposed [Advertising Execution 3](#) is included in this Application ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#)). Note that the study reports the likelihood of use for all Camel Snus styles collectively based upon the proposed advertising. Per [Table 5.18-1](#), likelihood of Camel Snus use is the net difference in projected current regular cigarette users purchase rates determined for the proposed modified risk advertising and the control advertising (which did not contain modified risk messaging). Therefore, the projected purchase rate for Camel Snus due to introduction of the proposed modified risk advertising is 1.1% of current regular cigarette smokers. Apportionment to the Camel Snus Robust style is based on the assumption that the market share of each Camel Snus style will remain constant relative to the total Camel Snus market share in 2015. Based on 2015 volumes, Camel Snus Robust represents 2.2% of the total Camel Snus market. Therefore, the projected purchase rate for Camel Snus Robust, due to introduction of the proposed modified risk advertising, is 0.02% of current regular cigarette smokers. For the purpose of this EA, it is assumed that 0.02% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust. Further, it is assumed that the period relevant for this EA is from 2018 to 2022, consistent with the stated duration of an MRTP order when all post-market surveillance requirements are fulfilled.

Table 5.18-1: Likelihood of Use Study Results: Projected Camel Snus Purchase Rates (%) by Current Cigarette Use Status

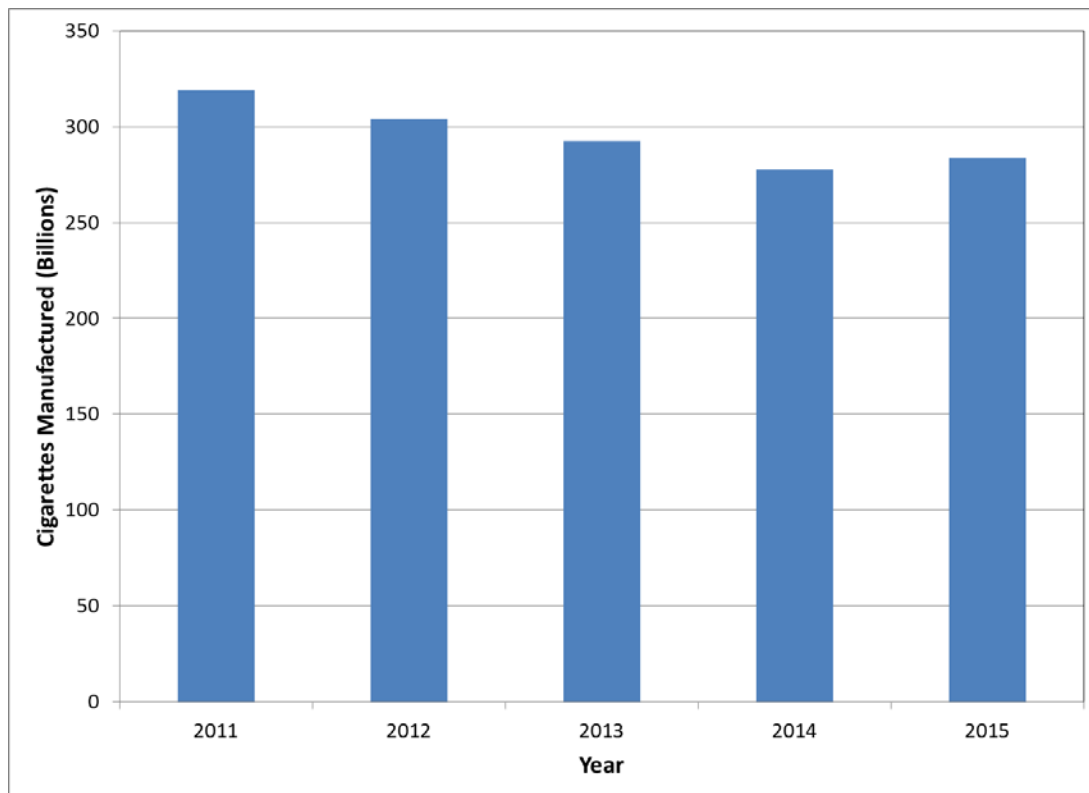
	Current Regular Cigarette Users	Former Regular Cigarette Users	Never Regular Cigarette Users
Test (with proposed modified risk messaging)	8.0%	2.0%	0.4%
Control (without proposed modified risk messaging)	6.9%	2.0%	0.4%
Net Impact of Test after correcting for Control	1.1%	-	-

5.18.2.1 Environmental Consequences from Manufacturing Cigarettes

Waste generated as a result of manufacturing cigarettes is released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed of in landfills in the same manner as other products manufactured by other industries. It is anticipated that, in general, such cigarette-related releases will decrease due to the proposed action in proportion to the anticipated decline in cigarette purchases. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. cigarette manufacturing totaled approximately 319 billion cigarettes in 2011, decreasing to 284 billion cigarettes in 2015 ([Figure 5.18-1](#)).

Figure 5.18-1: Cigarettes Manufactured in the United States 2011 – 2015



Estimation of Cigarettes Manufactured in 2018 – 2022

In order to assess environmental introduction from manufacturing cigarettes due to the proposed action, the changes in the number of cigarettes manufactured annually are projected

for 2018 – 2022. Regression analysis of the data from TTB Statistical Reports for 2011 – 2015 indicates that U.S. cigarette production is declining, on average, according to the equation: Cigarettes Manufactured (billions) = $-9.6686 * \text{Year} + 19758$ ($R^2 = 0.86$). Assuming this trend continues, manufactured cigarette projections for the years 2018 – 2022 are summarized in [Table 5.18-2](#).

Table 5.18-2: Projected Number of Cigarettes Manufactured in the United States Based on 2011 – 2015 Trend Data

Year	Projected Number of Cigarettes Manufactured in the U.S. (billions)
2018	246.8
2019	237.1
2020	227.4
2021	217.8
2022	208.1

The average projected number of cigarettes manufactured in 2018 – 2022 is 227.5 billion cigarettes, or 80.1% of the reported 2015 value ([U.S. Tobacco Manufacturing 2015](#)).

Estimated Change in Release of Toxicants Generated by the Cigarette Manufacturing Facilities Due to the Proposed Action

Projected changes in the amounts of toxicants released from cigarette manufacturing are based on combining several types of information, including: current release rates for the RJRT manufacturing facility; the U.S. cigarette market share currently held by RJRT; the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022; and the assumption that 0.02% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust.

RJRT has its major manufacturing facility in the Winston-Salem, NC area located at Tobaccoville, NC. The U.S. EPA compiles an annual Toxic Release Inventory (TRI) that includes toxic release information for the Tobaccoville cigarette manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the Tobaccoville manufacturing facility disposed of 9,899 pounds of ammonia and 13,865 pounds of nicotine and salts on-site, and 499 pounds of ammonia and 1,942 pounds of nicotine and salts off-site ([Table 5.18-3](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of cigarettes due to the proposed order are summarized in [Table 5.18-3](#). Those values are estimated from: (a) current

annual release rates for the RJRT manufacturing facility (see column 2 of the Table); (b) the U.S. cigarette market share currently held by RJRT (32.3%); (c) the projected change in the number of cigarettes manufactured in the U.S. between 2015 and the period 2018 – 2022 (a 19.9% decline); and (d) the assumption that 0.02% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust. Total ammonia and nicotine emissions are expected to decrease by 6.2 and 9.5 pounds per year, respectively, based upon the proposed action.

Table 5.18-3: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by U.S. Cigarette Manufacturing Facilities

Type of Release	RJRT 2015 Release (pounds)	Estimated 2015 Release for U.S. Cigarette Manufacturing (pounds)	Estimated 2018 – 2022 Average Release for U.S. Cigarette Manufacturing (pounds)	Estimated <u>Decrease</u> in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	9,899	30,647	24,559	5.9
Ammonia (Total off-site release)	499	1,545	1,238	0.3
Ammonia (Total)	10,398	32,192	25,797	6.2
Nicotine (Total on-site release)	13,865	42,926	34,398	8.3
Nicotine (Total off-site release)	1,942	6,012	4,818	1.2
Nicotine (Total)	15,807	48,938	39,216	9.5

5.18.2.2 Environmental Consequences from Manufacturing Camel Snus Robust

Waste generated as a result of manufacturing Camel Snus Robust is released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as other smokeless tobacco products and products manufactured by other industries. It is anticipated that, in general, such Camel Snus Robust releases will increase due to the proposed action as smokers stop smoking and switch to exclusive Camel Snus Robust use. The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured Camel Snus Robust. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed order.

Camel Snus Robust is manufactured by American Snuff Company, LLC, Taylor Brothers Division, (ASC Taylor Brothers) in Winston-Salem NC under contract to R.J. Reynolds Tobacco Company. The U.S. EPA compiles an annual TRI that includes toxic release information for the ASC Taylor Brothers manufacturing facility ([U.S. EPA Facility Release Report 2015](#)). Per that report, in 2015 the facility disposed of 2,036 pounds of ammonia and 11,293 pounds of nicotine and salts on-site, and 2,123 pounds of ammonia and 10,168 pounds of nicotine and salts off-site ([Table 5.18-7](#)). The materials reported on the TRI were byproducts of, or wastes from, processing tobacco.

The estimated changes in release of toxic substances from the manufacture of Camel Snus Robust due to the proposed order are summarized in [Table 5.18-7](#). Those values are estimated from: (a) current annual release rates for the ASC Taylor Brothers manufacturing facility (see column 2 of the Table); (b) the fraction of tobacco manufactured at the facility accounted for by Camel Snus Robust (~ 0.2%); (c) the average rate of each emission type per pound of Camel Snus Robust tobacco manufactured in 2015 and (d) the number of smokers (~ 9,500) projected to stop smoking during the period 2018 – 2022 and switch to exclusive use of Camel Snus Robust (5 pouches per day).

Calculation of the number of smokers that will stop smoking during the period 2018 – 2022 is based on the assumption that ~ 0.02% of current regular cigarette users will switch completely from smoking cigarettes to the use of Camel Snus Robust, together with projections of the adult population and adult smoking incidence during that time period. Adult population projections are based on U.S. Census Bureau data for the years 2015 – 2060 ([Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 \(NP2014-T3\)](#)) and adult smoking incidence projections are based on information provided by the U.S. Centers for Disease Control and Prevention for the years 2001 – 2014 ([CDC 2016e](#)). Regression analysis used for the projections are found in [Figure 5.18-2](#) and [Figure 5.18-3](#). The projected number of adults (18 years and older) and the adult smoking incidence for the years 2018 – 2022 are found in [Table 5.18-4](#) and [Table 5.18-5](#), respectively.

Figure 5.18-2: U.S. Resident Population (18 Years and Older) Projected Through 2060

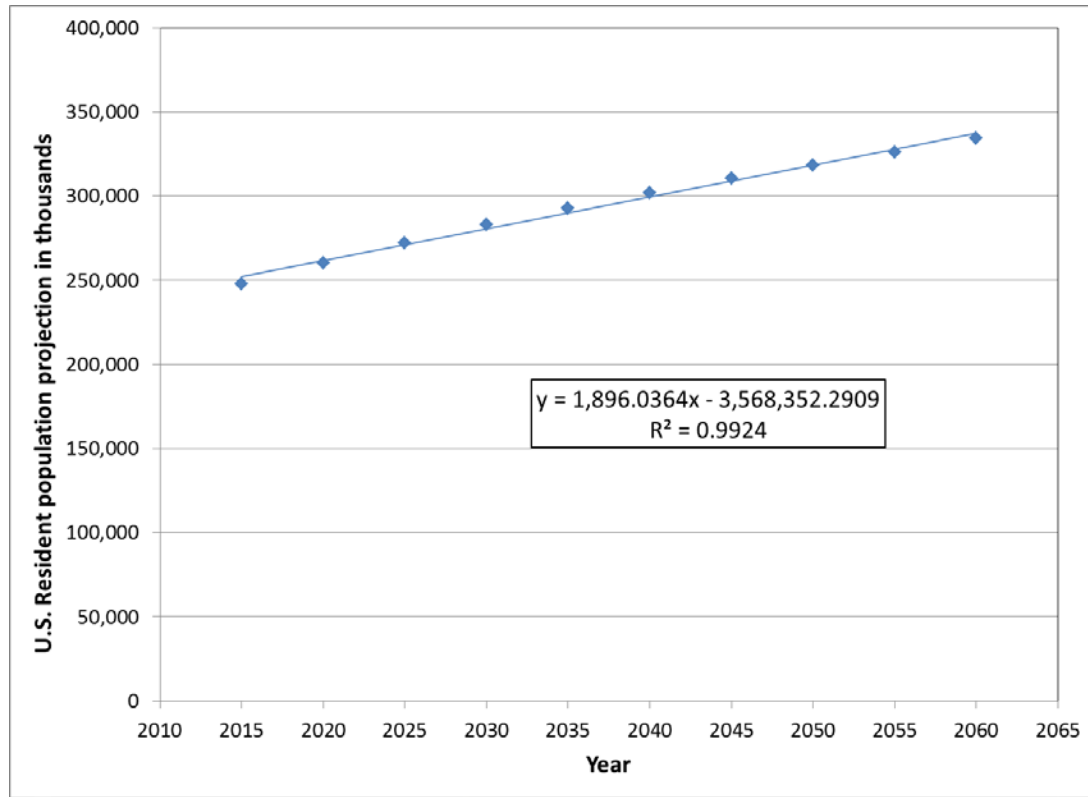


Table 5.18-4: Projected Number of Adults in the United States Based on 2015 – 2060 Trend Data

Year	Projected Number of Adults in the U.S. (thousands)
2018	257,849
2019	259,745
2020	261,641
2021	263,537
2022	265,433

Figure 5.18-3: Adult Smoking Incidence 2001 – 2014

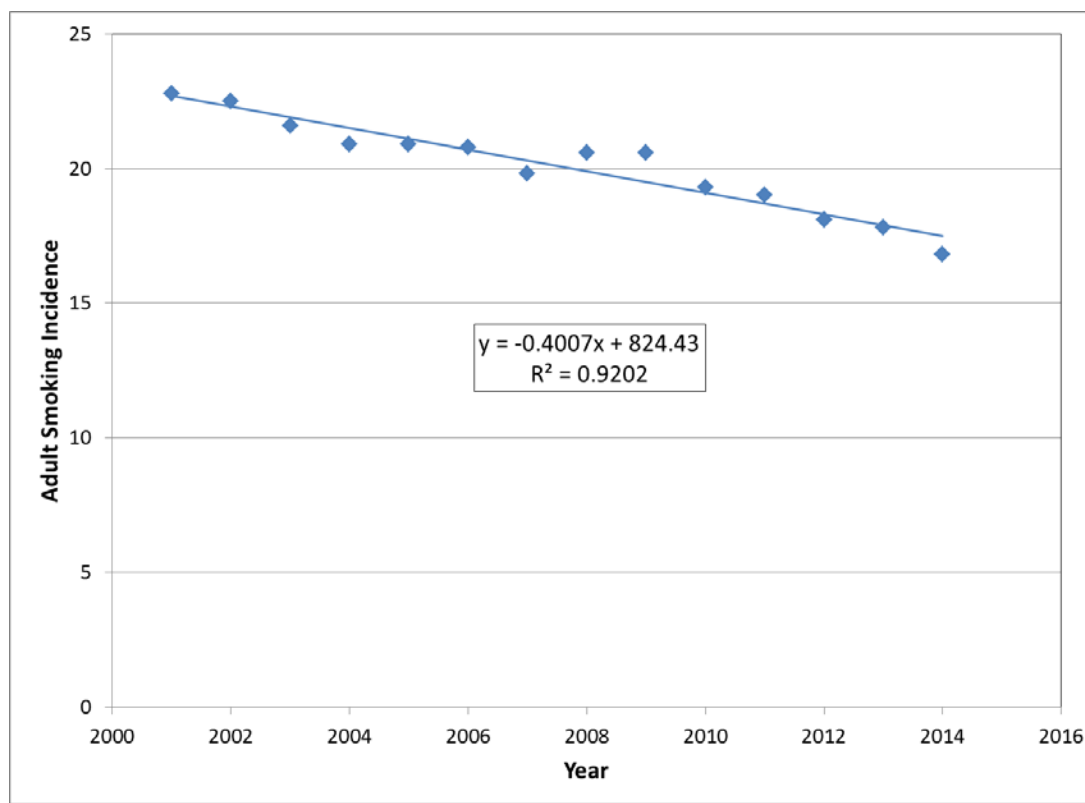


Table 5.18-5: Projected U.S. Adult Smoking Incidence Based on 2001 – 2014 Trend Data

Year	Projected Adult Smoking Incidence (%)
2018	15.8
2019	15.4
2020	15.0
2021	14.6
2022	14.2

The product of the projected number of adults in the U.S. together with the smoking incidence provides projected values for the number of smokers in 2018 – 2022 (Figure 5.17-6). For the purpose of this assessment, the average number of projected smokers for that time period (39.273 million) is used to calculate the increase in Camel Snus Robust production and associated manufacturing emissions. Based on 0.0242% of the projected smokers switching to the use of 5 pouches of Camel Snus Robust per day, an additional 38,239 pounds of Camel Snus Robust will be manufactured. Of note, this estimate assumes that all of the projected switching from smoking

cigarettes to the use of Camel Snus Robust will occur in the first year. Additionally, the use of 5 pouches of Camel Snus Robust each day is greater than current Camel Snus Robust use data, both in terms of pouches per day used, and days per week in which the product is used ([Camel Snus Product Use Report](#)).

Table 5.18-6: Projected Number of Smokers in the United States for the Years 2018 – 2022

Year	Projected Number of Smokers (millions)
2018	40.8
2019	40.0
2020	39.3
2021	38.5
2022	37.7

Based on the projected increase in Camel Snus Robust production, total ammonia and nicotine emissions are expected to increase by 9 and 45 pounds per year, respectively, based upon the proposed action ([Table 5.18-7](#)).

Table 5.18-7: Estimated Change in Release of EPA Toxic Release Inventory Substances Generated by the Manufacture of Camel Snus Robust

Type of Release	ASC Taylor Brothers 2015 Release (pounds)	ASC Taylor Brothers 2015 Camel Snus Robust Release (pounds)	Release Rate per 1000 Pounds of Camel Snus Robust	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)
Ammonia (Total on-site release)	2,036	4	0.111	4
Ammonia (Total off-site release)	2,123	4	0.116	4
Ammonia (Total)	4,159	7	-	9
Nicotine (Total on-site release)	11,293	20	0.615	24
Nicotine (Total off-site release)	10,168	18	0.553	21
Nicotine (Total)	21,461	37	-	45

5.18.2.3 Environmental Consequences Identified in Relation to the Manufacture of Smokeless Tobacco Currently Sold in the U.S.

According to the Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Reports from 2011 – 2015 ([U.S. Tobacco Manufacturing 2011](#); [U.S. Tobacco Manufacturing 2012](#); [U.S. Tobacco Manufacturing 2013](#); [U.S. Tobacco Manufacturing 2014](#); [U.S. Tobacco Manufacturing 2015](#)), U.S. smokeless tobacco manufacturing totaled approximately 130 million pounds of smokeless tobacco in 2011 and increased to approximately 140 million pounds in 2015 ([Figure 5.18-4](#)). Total smokeless tobacco is defined as the sum of reported values for “snuff” (defined by TTB as any finely cut, ground, or powdered tobacco that is not intended to be smoked) and “chewing tobacco” (defined by TTB as any leaf tobacco that is not intended to be smoked). Based on the amount of smokeless tobacco manufactured in 2015 and assuming comparable emission rates to those calculated based on ASC Taylor Brothers, total ammonia and nicotine emissions were 31,117 and 160,567 pounds per year, respectively. Thus, increased emissions due to the proposed action represent 0.03% of the emissions associated with 2015 smokeless tobacco manufacture ([Table 5.18-8](#)).

Figure 5.18-4: Smokeless Tobacco Manufactured in the United States 2011 – 2015

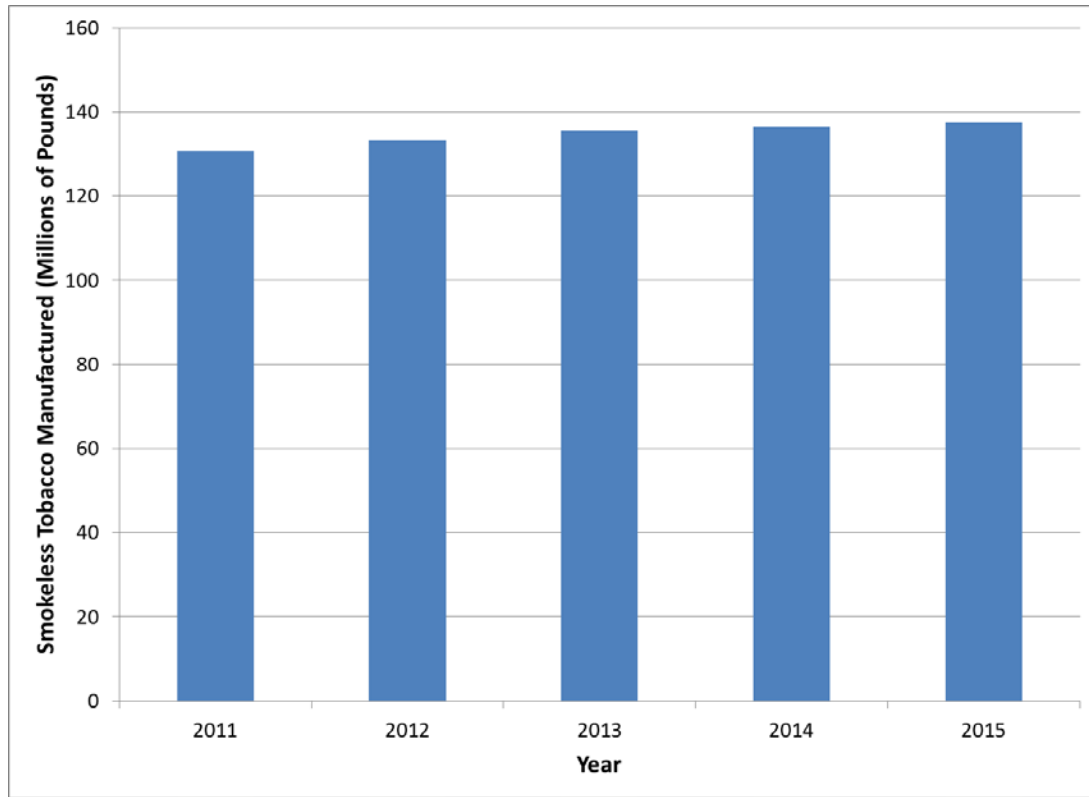


Table 5.18-8: Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production

Type of Release	Release Rate per 1000 Pounds of Tobacco	Estimated Increase in 2018 – 2022 Average Annual Release Due to the Proposed Action (pounds)	Estimated Release Based on 2015 Total Smokeless Tobacco Manufactured (pounds)	Estimated Increase Due to the Proposed Action Relative to 2015 Smokeless Tobacco Production (%)
Ammonia (Total on-site release)	0.111	4	15,233	0.03
Ammonia (Total off-site release)	0.116	4	15,884	0.03
Ammonia (Total)	-	9	31,117	0.03
Nicotine (Total on-site release)	0.615	24	84,492	0.03
Nicotine (Total off-site release)	0.553	21	76,075	0.03
Nicotine (Total)	-	45	160,567	0.03

5.18.2.4 Municipal Landfill and Recycling Waste from Manufacturing Tobacco Products Due to the Proposed Action

RJRT is committed to effectively managing the company's environmental footprint while delivering high quality products to adult tobacco consumers. RJRT employees work continuously to maximize efficiencies and minimize manufacturing operations' environmental impact, consistent with goals described in the [2015 Reynolds American Sustainability Report](#). RJRT actively works to limit material inputs and reuse process waste throughout the manufacturing process, consistent with the goal of recycling at least 60% of all facility waste by 2020. [Table 5.18-9](#) summarizes waste and recycling projected due to the proposed action. The decrease in cigarettes smoked has a negligible impact (a 1.2×10^{-06} percent decrease) and the increase in Camel Snus Robust production has a negligible impact (a 2.1×10^{-06} percent increase) to the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)). Municipal landfill waste and recycling values in [Table 5.18-9](#) are based on current manufacturing practices and do not include any improvements that may occur in the future.

**Table 5.18-9: Estimated Change in Release of EPA Toxic Release Inventory Substances
Generated by U.S. Cigarette Manufacturing Facilities**

Type of Change	Tobacco Product Change	Municipal Solid Waste (pounds)	Recycled Waste (pounds)	Total Waste (pounds)
Decreases from Cigarettes	55.0 million cigarettes	4,286	2,008	6,294
Increases from Camel Snus Robust	38,239 pounds	2,634	8,344	10,977

5.18.3 Environmental Introduction from Product Use

This section will consider (a) existing and projected conditions of product use for Camel Snus Robust and cigarettes in the United States, and (b) environmental introduction due to the proposed action from use of the product.

5.18.3.1 Existing and Projected Conditions of Product Use

As of 2015, there are approximately 42.9 million smokers in the United States or approximately 17% of the adult population. The number of cigarettes manufactured in 2015 was approximately 284 billion. In 2015, Camel Snus Robust accounted for ~ 0.02% by weight of the smokeless tobacco manufactured in the United States and ~ 2% share of all snus.

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 9,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, resulting in a decrease of ~ 55 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. An additional 38,239 pounds of Camel Snus Robust will be manufactured based upon those smokers using 5 pouches of Camel Snus Robust per day.

5.18.3.2 Environmental Introduction During Use of the Product

The proposed action is not intended, nor is it expected, to materially affect any characteristic (materials, ingredients, design, composition, heating source, or other features) of currently manufactured cigarettes or of Camel Snus Robust. Additionally, the proposed action is not intended, nor is it expected to materially affect the manner of use for cigarettes or Camel Snus Robust. Therefore, RJRT does not anticipate any new substances or new type of emissions to be released into the environment because of the proposed action. The proposed action is projected to decrease cigarette smoking by ~ 55 million cigarettes per year, thus reducing environmental tobacco smoke (“ETS”) emissions by that number of cigarettes.

5.18.4 Environmental Introduction as a Result of Disposal after Product Use

5.18.4.1 Existing Conditions of Disposal Following Use of Cigarettes and Camel Snus Robust in the U.S.

Environmental introduction that results from disposal of materials following the use of cigarettes and Camel Snus Robust includes disposal of: (a) the portion of the tobacco product that remains after use, (b) packaging materials, and (c) bodily excretions from the user of the product. The waste that is generated due to cigarette consumption consists of cigarette butts (filter, paper and, if present, tobacco), packaging materials and bodily excretions. Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. The waste that is generated due to Camel Snus Robust consumption consists of the used snus pouch (tobacco and fleece), packaging materials and bodily excretions. Although the tobacco and fleece components of the used pouch are biodegradable, the packaging tin can persist in the environment. Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

Consumers dispose of used tobacco products through deposit into MSW landfills or incinerators, or as litter. Consumers either place packaging materials from tobacco products in the recycling stream, deposit them in MSW landfills or incinerators, or dispose of them as litter. Disposal of any excreted materials occurs through sewage discharges to POTWs or septic systems for treatment.

Current Condition of MSW

MSW generation rates have increased in the U.S. from 1960 to 2014 ([Figure 5.18-5](#)). In 2014, the amount of waste generated in the U.S. was approximately 258 million tons. Approximately 89 million tons of the waste was recycled and composted, which is equivalent to a 34.6% recycling rate ([Figure 5.18-6](#)). The generation of MSW consists of paper (27%), food (15%), yard trimmings (13%), plastics (13%), rubber, leather and textiles (10%), metals (9%), wood (6%), and glass (4%). Paper and paperboard accounted for about 50% of all recycling. Yard trimmings contributed approximately 24%, and metals about 9%. On average, 4.44 pounds per person per day of municipal waste was generated in the U.S. in 2014 ([2014 Sustainable Materials Management Fact Sheet](#)).

Current Condition of Excreted Materials

Components (or metabolites of those components) present in tobacco or tobacco smoke are excreted by the user after use. Those materials may enter the sewer system as a component in human waste. The excreted waste is digested by microbial systems in the home’s septic system or treated in POTWs. Users of smokeless tobacco products such as Camel Snus Robust are not exposed to, and do not excrete, materials produced from the combustion of tobacco.

Figure 5.18-5: Municipal Solid Waste Generation Rates in the U.S., 1960 – 2014

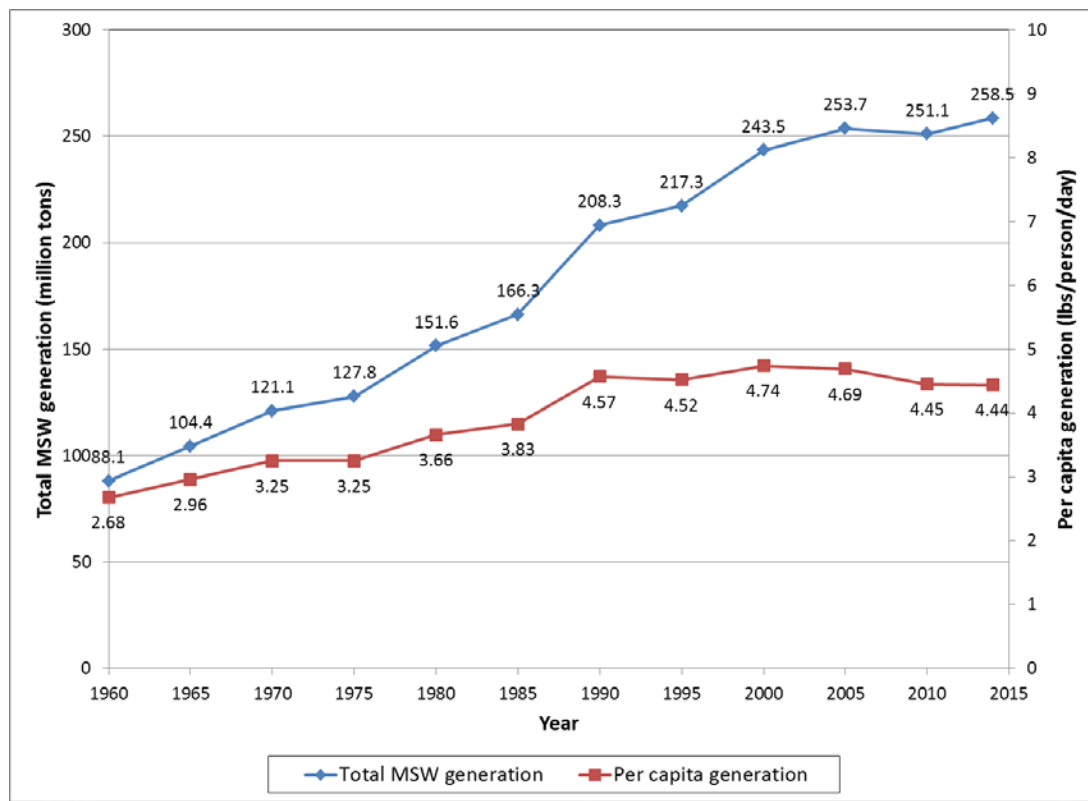
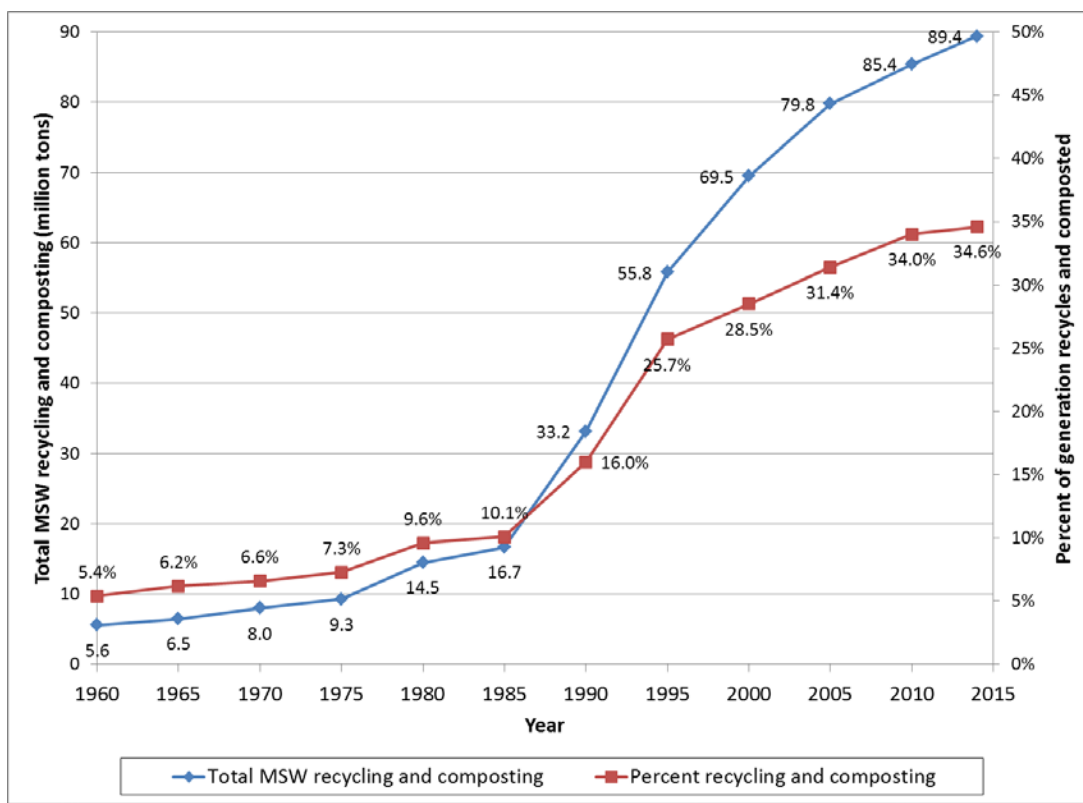


Figure 5.18-6: Municipal Solid Waste Recycling Rates in the U.S., 1960 – 2014



5.18.4.2 Change in Environmental Introduction from Material Disposed of After Product Use as a Result of the Proposed Action

5.18.4.2.1 Disposal of Cigarette Butts and Used Portion of Camel Snus Robust

As discussed in the preceding sections, it is estimated that the proposed action may result in ~ 9,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, resulting in a decrease of ~ 55 million cigarettes smoked per year, assuming an average use rate of ~ 16 cigarettes per day. The product waste that is generated due to cigarette use (and disposed of after product use) consists of cigarette butts (filter, paper and, if present, tobacco). Although the paper and tobacco components of the cigarette butts are biodegradable, the filter component of the cigarette butt and plastic wrappers from packaging can persist in the environment. Consumers dispose of cigarette butts through deposit into MSW landfills or incinerators, or as litter. Evidence has shown that cigarette butts are the most prevalent items discarded onto roads and streets in urban areas. Once dumped onto city streets, they can move through the storm drains to streams, into the ocean, and back onto the beaches. Discarded cigarette filters are found to be the most collected item in beach clean-ups, as an estimated 40% of the total waste (by count) on U.S. shorelines is cigarette waste ([Ocean Conservancy 2016 Annual Report](#)). The proposed action is estimated to reduce cigarette waste after product use by eliminating ~ 55 million cigarette butts.

The estimated decline in cigarette butt waste (both on a total cigarette and per style basis) is summarized in [Table 5.18-10](#). The cigarette butt waste is estimated by style because the amount of filter material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette butt waste is estimated for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of filter material per cigarette is assumed to be 0.1681 g, 0.1880 g, and 0.1793 g, respectively. Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette butt waste will decline by ~ 11 tons per year.

Table 5.18-10: Projected Annual Decline in Total Cigarette Butt Waste and Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (millions)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
“King Size” (70 – 85 mm)	58.1	32	11,850	6
“100 mm” (90 – 101 mm)	40.8	22	9,298	5
“120 mm” (118 – 120 mm)	1.1	0.6	249	0.1
Total (All styles)	100	55	21,397	11

Based on the proposed action resulting in ~ 9,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022, it is estimated that an additional 38,239 pounds of Camel Snus Robust will be manufactured if those smokers use 5 pouches of Camel Snus Robust per day each day of the year. Waste generated due to Camel Snus Robust use consists of the used snus pouch (tobacco and fleece). The tobacco and fleece components of the used pouch are biodegradable and the Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” ([Section 4](#)). For the purpose of this assessment, it is assumed that all of the additional Camel Snus Robust tobacco will become waste for disposal after use, resulting in an increase of ~ 19 tons of used Camel Snus Robust pouches per year. The projected decrease in disposal of cigarette butts has a negligible impact (a 4.1×10^{-6} percent decrease) on the MSW stream based on 2014 figures ([EPA Municipal Solid Waste](#)), assuming all cigarette butts are disposed of as MSW. Similarly, the projected increase in Camel Snus Robust used pouch disposal has a negligible impact (a 7.4×10^{-6} percent increase) to the MSW stream, based on the same figures ([Table 5.18-11](#)).

Table 5.18-11: Projected Annual Change in Material Disposed of After Product Use

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette butt waste	11	4.1×10^{-6}
Increase in used Camel Snus Robust pouches	19	7.4×10^{-6}

5.18.4.2.2 Disposal of Cigarette and Camel Snus Robust Packaging Material

Based on ~ 9,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 2.8 million fewer cigarette packs and approximately 280 thousand fewer cigarette cartons will be disposed of by either placing packaging materials in the recycling stream, depositing them in MSW landfills or incinerators, or disposing of them as litter. It is estimated that approximately 1.2 million more Camel Snus Robust tins will be disposed of from smokers switching to exclusive use of the product. Camel Snus Robust packaging tins include instructions to avoid littering, “Do Not Litter” and to recycle the tin after use, “This Container Is Recyclable” ([Section 4](#)).

The amount of cigarette packaging material depends on the overall cigarette length. For the purpose of this environmental assessment, cigarette packaging material waste assumptions are established for three categories: “King Size” (styles from 70 – 85 mm in length), “100 mm” (styles from 90 – 101 mm in length) and “120 mm” (styles from 118 – 120 mm in length). The amount of waste per pack of cigarettes is assumed to be 7.07 g, 7.36 g, and 8.29 g, respectively, for the three categories ([Table 5.18-12](#)). The amount of waste per carton of cigarettes (a carton containing 10 packs) is assumed to be 90.43 g, 93.33 g, and 102.63 g, respectively ([Table 5.18-12](#)). Based upon the projected decline in cigarette smoking due to the proposed action, it is estimated that cigarette packaging waste will decline by 27.8 tons per year ([Table 5.18-13](#)).

Camel Snus Robust Packaging weights are summarized in [Table 5.18-14](#). The Camel Snus Robust package weighs 22.0 g and a sleeve of 5 tins weighs 111.1 g. Based on the projected increase in Camel Snus Robust use, it is estimated that packaging waste will increase by 28.3 tons.

If all packaging is disposed of in the MSW stream, based on 2014 figures ([EPA Municipal Solid Waste](#)), the projected decrease in cigarette packaging waste will have a negligible impact (a 1.08×10^{-5} percent decrease) on the waste stream. Similarly, the projected increase in Camel Snus Robust packaging disposal will have a negligible impact (a 1.10×10^{-5} percent increase), based on the same figures ([Table 5.18-15](#)).

Table 5.18-12: Cigarette Packaging and Carton Weights Assumed for Different Cigarette Styles

Packaging		"King Size" (70 – 85 mm)	"100 mm" (90 – 101 mm)	"120 mm" (118 – 120 mm)
<u>Package Components</u>	<u>Material Type</u>	<u>Weight (g)</u>		
Empty Box	Solid bleached sulphate board	4.84	5.10	5.81
Foil innerliner of one cigarette box	Machine glazed paper laminated to aluminum foil	1.07	1.00	1.27
Innerframe of one cigarette box	Solid bleached sulphate board	0.79	0.84	0.77
Film overwrap of one cigarette box	Overwrap individual box with oriented polypropylene film	0.37	0.42	0.44
Total pack weight		7.07	7.36	8.29
Empty carton (accommodates 10 boxes)	Solid bleached sulphate board	19.73	19.73	19.73
Total packaging weight (per 200 cigarettes)	Carton plus 10 packs	90.43	93.33	102.63

Table 5.18-13: Projected Annual Decline in Total Cigarette Packaging Waste and Packaging Waste per Style Due to the Proposed Action

Cigarette Style	2015 U.S. Cigarette Market Share (%)	Projected Cigarette Decline (cartons)	Projected Decline in Cigarette Packaging Waste (pounds)	Projected Decline in Cigarette Packaging Waste (tons)
"King Size" (70 – 85 mm)	58.1	159,873	31,873	16
"100 mm" (90 – 101 mm)	40.8	112,161	23,078	12
"120 mm" (118 – 120 mm)	1.1	3,153	713	0.4
Total (All styles)	100	275,188	55,665	27.8

Table 5.18-14: Camel Snus Robust Packaging Weights

Camel Snus Robust Packaging	Weight (g)
Tin lid	8.6
Tin base	12.9
Shrink tape	0.5
Total per package	22.0
5 Tin sleeve overwrap	1.1
Total per 5 tins and sleeve overwrap	111.1

Table 5.18-15: Projected Annual Change in Packaging Waste

Change in Material Disposed of After Product Use	Annual Introduction (tons)	Percentage of 2014 Municipal Solid Waste in the U.S.
Decline in cigarette packaging waste	27.8	1.08×10^{-05}
Increase in Camel Snus Robust packaging waste	28.3	1.10×10^{-05}

5.18.4.2.3 Excretion of Substances in Cigarette Smoke and Tobacco

Components (or metabolites of those components) present in tobacco and tobacco smoke are excreted by smokers after smoking. Smokers that switch exclusively to Camel Snus Robust will not be exposed to mainstream cigarette smoke and, therefore, will not excrete materials produced from the combustion of tobacco to form mainstream cigarette smoke. Excreted materials will enter the sewer system as a component in human waste. Excreted waste will be digested by microbial systems in the home's septic system or treated in POTWs.

5.18.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Release of new chemicals into the environment is not anticipated due to the proposed action.

5.18.6 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

No environmental effects are anticipated as no new materials will be released into the environment due to the proposed action.

5.18.7 Changes in the Use of Resources and Energy Due to the Proposed Action

Based on ~ 9,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 55 million fewer cigarettes will be manufactured and that approximately 17 million more pouches of Camel Snus Robust will be produced. While the amounts of natural resources and energy used to produce cigarettes is expected to vary from one manufacturer to the next, for the purpose of this environmental assessment these quantities are assumed to be consistent with the amounts necessary to manufacture cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.18-16](#) summarizes projected annual changes in resource and energy use due to the proposed action.

Table 5.18-16: Projected Annual Change in Resource and Energy Use

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Robust	Net Change Due to the Proposed Action
Electricity (thousand kWh)	104	19	-85
Water (ccf)	18,547	1,560	-16,986
Natural gas (ccf)	3,051	536	-2,516

5.18.8 Mitigation Measures

No adverse environmental effects have been identified due to the proposed action.

5.18.9 Greenhouse Gas Emissions

Carbon dioxide (CO₂) is naturally present in the atmosphere as part of the Earth's carbon cycle (the natural circulation of carbon among the atmosphere, oceans, soil, plants, and animals). Carbon dioxide is also the primary greenhouse gas (GHG) emitted by human activities in the United States. In 2011, U.S. GHG net emissions—including land use, land-use change, and forestry (LULUCF)—were 5,797 teragrams (Tg) of CO₂ equivalents (CO₂e) ([2014 United States Climate Action Report](#)). CO₂ accounts for more than 80% of U.S. greenhouse gas emissions from human activities. The main human activity that emits CO₂ is the combustion of fossil fuels (coal, natural gas, and oil) for energy and transportation, although certain industrial processes and land-use changes also emit CO₂.

Based on ~ 9,500 smokers switching from smoking to exclusive use of Camel Snus Robust during 2018 – 2022 due to the proposed action, it is estimated that approximately 55 million fewer cigarettes will be manufactured and that approximately 17 million more pouches of Camel Snus Robust will be produced. While the amount of GHG generated to produce cigarettes may vary from one manufacturer to the next, for the purpose of this environmental assessment the quantity is assumed to be consistent with the GHG produced when manufacturing cigarettes at RJRT's Tobaccoville manufacturing facility. [Table 5.18-17](#) summarizes projected annual changes in

GHG emissions due to the proposed action. The projected changes are small compared to total GHG emissions from cigarette and smokeless tobacco manufacturing in the United States.

Table 5.18-17: Projected Annual Change in Greenhouse Gas Emissions

Change in Material Disposed of After Product Use	Decrease Due to Reduced Use of Cigarettes	Increase Due to Use of Camel Snus Robust	Net Change Due to the Proposed Action
GHG (metric tons CO ₂ equivalents)	143	26	-117

5.18.10 Compliance with Environmental Acts

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act (“ESA”) ([1973 Endangered Species Act](#)) or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (“CITES”) ([Convention on International Trade in Endangered Species](#)) are expected due to the proposed action. The location of Camel Snus Robust manufacturing (American Snuff Company, LLC, Taylor Brothers Division; 2415 South Stratford Road, Winston-Salem, NC 27103) is not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps⁸⁷ made available by the U.S. Fish and Wildlife Service.

RJRT has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals⁸⁸ and plants⁸⁹ and (b) the endangered and threatened species listed in Appendices I, II, and III⁹⁰ of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RJRT is not aware of any information to suggest that the projected increase in Camel Snus Robust manufacture due to the proposed action would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for that species.

None of the materials used in the manufacture of Camel Snus Robust are listed by either the U.S. Fish and Wildlife Service or the CITES. To the best of our knowledge, none of the materials used

⁸⁷ Habitat maps are located at:

<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed and reviewed on July 11, 2016.

⁸⁸ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcritab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. Accessed on June 14, 2016.

⁸⁹ http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&ffamily=on&header=Listed+Plants. Accessed on June 14, 2016.

⁹⁰ <https://cites.org/sites/default/files/eng/app/2016/E-Appendices-2016-03-10.pdf>. Listing valid from March 10, 2016, and accessed on June 14, 2016.

in Camel Snus Robust are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service or the CITES.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Camel Snus Robust have been identified and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the subject product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RJRT is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements ([40 CFR 1508.27\(b\)\(10\)](#)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

To the best of our knowledge, no situations such as these apply to the manufacture of the product.

5.18.11 Compliance with State, Federal and Local Environmental Regulations

ASC Taylor Brothers manufacturing operation is in compliance with all local, state and federal environmental laws. Examples include the following.

Air Quality

- ASC Taylor Brothers holds an air quality permit issued by the Forsyth County Office of Environmental Assistance and Protection (permit # 00553R12; expires May 29, 2018) for the Taylor Brothers manufacturing facility. American Snuff Company, LLC, Taylor Brothers Division are in compliance with the numerous requirements of the air quality permit which include the timely submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- ASC Taylor Brothers was last inspected August 6, 2015 by the Forsyth County Office of Environmental Assistance and Protection and nothing constituting a violation of their operating permit was found.

Storm water

- ASC Taylor Brothers applied for and obtained a No-Exposure Certification exclusion (NCGNE0671) for storm wastewater permitting from the North Carolina Department of Environmental and Natural Resources Division of Water on February 16, 2010 as provided for under 40 CFR 126.22(g) which is incorporated by reference in North Carolina regulations.
- Self-monitoring No Exposure Exclusion Re-Certification inspections are completed annually. The latest No Exposure Exclusion Self Re-Certification inspection at ASC Taylor Brothers was completed on January 11, 2017. No violations of the No Exposure Exclusion Certification were found.

Wastewater

- ASC Taylor Brothers has a wastewater permit issued by the North Carolina Environmental Management Commission Department of Environment and Natural Resources that is in effect from the date of issuance, November 6, 2007, until it is rescinded. Because ASC Taylor Brothers' wastewater is discharged into the city of Winston-Salem's wastewater treatment system, the city of Winston-Salem has conducted inspections of the wastewater system at Taylor Brothers and has found no non-compliance issues.
- ASC Taylor Brothers complies with the numerous requirements of the permit which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

In addition, there are other environmental regulation activities to which ASC Taylor Brothers complies:

- In 2012, ASC Taylor Brothers examined their need to comply with Spill Prevention, Control, and Countermeasure (SPCC) plan as determined by 40 CFR part 112 and have removed their 6,000 gallon above ground alcohol tank and 20,000 gallon fuel oil tank. Their inventory now consists of two 509 gallon transformers. They continue to monitor their container capacity. If their capacity reaches the threshold of 1,320 gallons, a SPPC plan will be developed and immediately implemented.
- ASC Taylor Brothers reports greenhouse gas emissions to the Environmental Protection Agency under the Greenhouse Gas reporting rule on an annual basis.
- ASC Taylor Brothers submits EPA Tier 2 and Form R reports annually as required.
- ASC Taylor Brothers is in compliance with applicable solid and hazardous waste regulations.

ASC Taylor Brothers does not currently have any Notices of Violation under any environmental regulations described above.

5.18.12 Alternatives to the Proposed Action

Alternative A (no-action alternative): an order authorizing Camel Snus Robust as a modified risk tobacco product is not issued under the no-action alternative. The environmental impact of this action would not change the existing condition.

Alternative B (proposed-action alternative): an order authorizing Camel Snus Robust as a modified risk tobacco product is issued under the proposed-action alternative. There is virtually no effect on manufacturing emissions and introduction of waste materials into the MSW stream due to the proposed action other than the fact that a much greater proportion of waste material is recyclable. The proposed action is anticipated to significantly reduce energy and natural resource consumption, as well as, reduce greenhouse gas emissions. In addition, this action will alter the biopersistence/biodegradability profile of tobacco products in a positive manner by reducing cigarette butt waste and it will significantly reduce environmental tobacco smoke (ETS) emissions.

5.18.13 Conclusion

There is no significant increase in environmental impact from this proposed action; however, there is a significant decrease in ETS emissions, energy and natural resource usage, GHG emissions and introduction of biopersistent material into MSW landfills and as litter.

5.19 List of Preparers

In accordance with [40 CFR § 1502.17](#), this section summarizes a list of names and qualifications (including position/title, education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing the environmental assessments in [Sections 5.1 – 5.18](#).

Joy A. Bodnar, M.S., RAI Services Company

Title: Master Scientist, Submissions & Engagement

Education: M.S. in Analytical Chemistry, B.S. in Chemistry

Experience: 40 years in analytical chemistry and various scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

Christie A. Young, Ph.D., M.B.A., RAI Services Company

Title: Senior Scientist, Submissions & Engagement

Education: Ph.D. in Microbiology & Immunology, B.S. in Biology

Experience: 6 years in various scientific activities

Expertise: Scientific and Regulatory Affairs

Denise Bowman, M.B.A., RAI Services Company

Title: Senior Staff Scientist, Submissions & Engagement

Education: B.A. in Biology

Experience: 24 years in various scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

Patrick Murphy, RAC (U.S.), M.A., RAI Services Company

Title: Director, Submissions & Engagement

Education: M.A in Communications, B.S. in Biology

Experience: 19 years in various scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

Michael F. Borgerding, Ph.D., RAI Services Company

Title: Senior Director, Submissions & Engagement

Education: Ph.D. in Analytical Chemistry, M.S. in Chemistry, B.S. in Biochemistry

Experience: 36 years in analytical chemistry and various scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

Michael W. Ogden, Ph.D., RAI Services Company

Title: Vice President, Scientific & Regulatory Affairs

Education: Ph.D. in Analytical Chemistry, B.S. degrees in both Chemistry and Applied Mathematics

Experience: 32 years in analytical and biological chemistry, toxicology, epidemiology, and regulatory activities

Expertise: Scientific and Regulatory Affairs

5.20 List of Agencies and Persons Consulted

In accordance with 40 CFR § 1508.9, this section summarizes the list of agencies and persons consulted in preparation of the environmental assessments in [Sections 5.1 – 5.18](#).

Agencies and Persons Consulted	Consultation
Jennifer Schmitz Regulatory Health Project Manager Center for Tobacco Products U.S. Food and Drug Administration	Sought clarity on electronic submissions of SE exemption requests and FDA expectations for listing of agencies and persons consulted in preparation of Environmental Assessments. That learning has been applied in the preparation of these Environmental Assessments.
U.S. Food & Drug Administration (www.FDA.gov)	Per FDA guidance, consulted examples of EAs prepared, accepted, and/or posted by FDA in accordance with 21 CFR 25.40 .
U.S. Fish & Wildlife Services Endangered Species Act (ESA) (1973 Endangered Species Act)	Consulted habitat maps ² to confirm location of RJRT facility was not within or in close proximity to a critical habitat or endangered animal ³ and plant ⁴ species.

Agencies and Persons Consulted	Consultation
<p>Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (Convention on International Trade in Endangered Species)</p>	<p>Consulted the endangered and threatened species in Appendices I, II, and III⁵ to confirm none of these materials are used to manufacture the new product.</p>
<p>National Environmental Policy Act (NEPA) https://www.epa.gov/nepa</p>	<p>Consulted on process and compliance with the Act.</p>
<p>Hugh McBride Lead Manager Environment Health & Safety (EHS) American Snuff Company, LLC, Taylor Brothers Division</p>	<p>Consulted to confirm compliance, no Notices of Violation, and all applicable ASC Taylor Brothers permits associated with federal, state, and local environmental regulations. EHS collaborates with the following external partners: Sutton-Kennerly and Associates, Morton Environmental Consulting, Golder Associates Engineering Consultants, Forsyth County Office of Environmental Assistance, North Carolina Department of Environmental Quality, Research & Analytical Laboratories, Inc. (for sampling).</p> <p>Consulted to confirm resource usage (electricity, water, and natural gas) at American Snuff Company, LLC, Taylor Brothers Division manufacturing facility.</p>
<p>Ronald (Ronnie) Rowe Master Engineer R.J. Reynolds Tobacco Company</p>	<p>Consulted to confirm resource usage (electricity, water, and natural gas) at R.J. Reynolds Tobacco Company manufacturing facility.</p>
<p>Timothy E. Tucker Plant Manager American Snuff Company, LLC, Taylor Brothers Division</p>	<p>Consulted to confirm Camel Snus production by Camel Snus style.</p>
<p>Bryan Hatchell Director Communications RAI Services Company</p>	<p>Consulted on RAI sustainability program. http://sustainability.reynoldsameric.com/</p>