

**Programmatic Environmental Assessment for
Exemption Requests by R.J. Reynolds Tobacco
Company for Six New Products, Two of Each Named
“Newport Box, Newport Box 100s and Newport Kings”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

September 8, 2017

Table of Contents

1.	Name of Applicant	4
2.	Address	4
3.	Manufacturer	4
4.	Description of Proposed Actions	4
4.1	Requested Action	4
4.2	Need for Action	4
4.3	Identification of the New Tobacco Products that is the Subject of the Proposed Actions	5
4.3.1	Type of Tobacco Products	5
4.3.2	Product Names and Their Original STNs	5
4.3.3	Description of the Product Package	5
4.3.4	Location of Manufacturing	5
4.3.5	Location of Use	6
4.3.6	Location of Disposal	6
4.4	Modification(s) Identified as Compared to the Original Product	7
5.	Environmental Introduction Due to the Proposed Actions	7
5.1.	Introduction as a Result of Manufacturing the New Tobacco Products	7
5.1.1.	Tobacco Manufacture in the U.S. and Environmental Conditions near R.J. Reynolds' Tobaccoville Facility	7
5.1.2.	Environmental Introduction from Manufacturing the New Tobacco Products	9
5.2.	Environmental Introduction as a Result of Use of the New Tobacco Products	10
5.3.	Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Products	12
5.3.1.	Disposal Following Use of Cigarettes	12
a)	Disposal of Packaging Material	12
b)	Disposal of Used Cigarettes Following Use	13
c)	Air Emissions	16
5.3.2	Environmental Introduction from Disposal Following Use of the New Products	17
6.	Fate of Materials Released into the Environment Due to the Proposed Actions	17
7.	Environmental Effects of New Materials Released into the Environment due to the Proposed Actions	18
8.	Use of Resources and Energy	18
9.	Mitigation	18
10.	Alternatives to the Proposed Actions	18
11.	List of Preparers	19

12. List of Agencies and Persons Consulted	19
13. Appendix List.....	19
14. Confidential Appendix List.....	19
15. References	20
APPENDIX 1	21
Submission Tracking Numbers for the EX Requests for the New Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)	21
APPENDIX 2	22
Forecast of Cigarettes Manufactured in the U.S.....	22
APPENDIX 3	23
Projected Use of Cigarettes in the U.S. in the First and Fifth Year of Marketing the New Products	23
CONFIDENTIAL APPENDIX 1.....	24
Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products.....	24
CONFIDENTIAL APPENDIX 2.....	27
The Current Market Volumes of the Original Products and Provisional Products with Identical Names as the New Products and First- and Fifth-Year Market Volume Projections of the New Products.....	27
CONFIDENTIAL APPENDIX 3.....	28
Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the U.S.	28

This programmatic environmental assessment (PEA) is for the Exemption Requests for six combusted, filtered cigarettes manufactured by "R.J. Reynolds Tobacco Company". Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 905(j)(3) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

RAI Services Company on behalf of R.J. Reynolds Tobacco Company

2. Address

401 N. Main Street
Winston-Salem, NC 27101

3. Manufacturer

R.J. Reynolds Tobacco Company
7855 King-Tobaccoville Road
Tobaccoville, NC 27050

4. Description of Proposed Actions

These proposed actions are for FDA to issue exemptions from SE Reports for the market authorization under section 905(j)(3) of the FD&C Act for the introduction of combusted, filtered cigarettes into interstate commercial distribution in the U.S. This authorization is based on the finding that the modifications would be minor modifications of a tobacco product that can be sold under the FD&C Act, an SE Report is not necessary to ensure that permitting marketing of the modified tobacco product would be appropriate for the protection of the public health, and an exemption is otherwise applicable. The proposed actions are for six combusted products, EX0000182-185 and EX0000188. The original product for EX0000182 and EX0000185 is a grandfathered product, GF1200323, which received confirmation of grandfathered status on April 10, 2013. The original product for EX0000183-EX0000184 is a grandfathered product, GF1200467, which received confirmation of grandfathered status on May 14, 2013. The original product for EX0000186 and EX0000188 is grandfathered product GF1200321, which received confirmation of grandfathered status on November 20, 2012.

4.1 Requested Action

The applicant, RAI Services on behalf of R.J. Reynolds Tobacco Company, submitted requests to FDA to exempt from SE requirements six new products, two named Newport Box, two named Newport Box 100s, and the remaining two named Newport Kings, all of which are combusted, filtered cigarettes.

4.2 Need for Action

RAI Services Company on behalf of R.J. Reynolds Tobacco Company wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the U.S. The applicant states that the difference between the new and original products is

the replacement of non-fire standard compliant (FSC) cigarette paper with FSC cigarette paper. In addition, the applicant claimed that the new and original products have identical packaging composition. The applicant must obtain a written notification that FDA has granted the product an exemption from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained the exemption from substantial equivalence.

4.3 Identification of the New Tobacco Products that is the Subject of the Proposed Actions

4.3.1 Type of Tobacco Products

Combusted, filtered cigarettes

4.3.2 Product Names and Their Original STNs

The names of the new products are listed below, along with the original submission tracking numbers (STNs) and the names and STNs of the original products. See Appendix 1 for additional STNs associated with the new products and the corresponding original products.

STN	New Product	STN	Original Product
EX0000182	Newport Box	GF1200323	Newport Menthol Box
EX0000185	Newport Box		
EX0000183	Newport Box 100s	GF1200467	Newport Menthol Box 100s
EX0000184	Newport Box 100s		
EX0000186	Newport Kings	GF1200321	Newport Menthol Kings
EX0000188	Newport Kings		

4.3.3 Description of the Product Package

The packaging materials of the finished new products are identical in materials and composition to those of the corresponding original products. The new product packaging consists of a foil inner liner, inner frame, box, film overlap, and carton. Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 1.

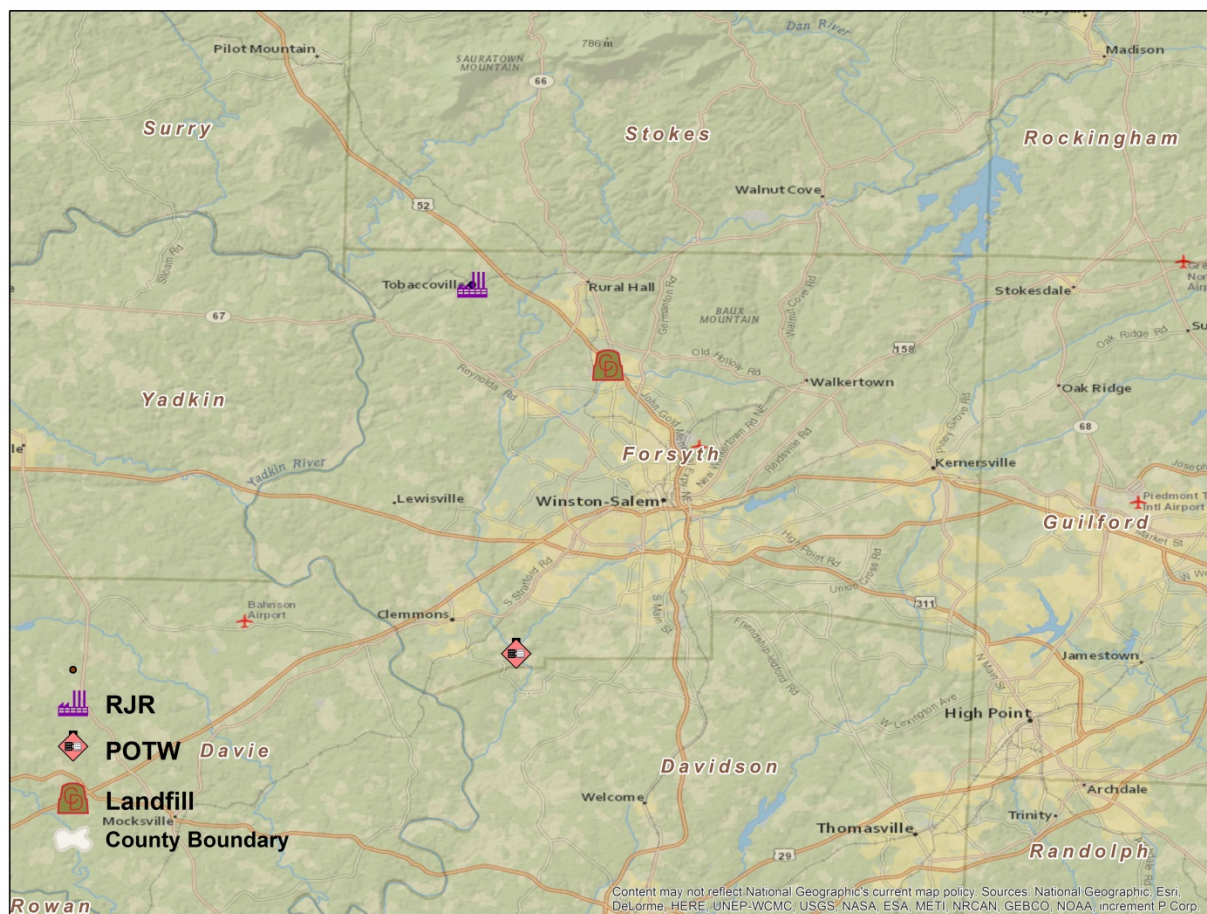
4.3.4 Location of Manufacturing

R.J. Reynolds Tobacco Company
7855 King-Tobaccoville Road
Tobaccoville, NC 27050

The facility is located in the Upper Yadkin River Basin with 8-digit hydrologic unit code (HUC): 03040101. This basin covers approximately 2,336 square miles and constitutes the Yadkin River headwaters. Major municipalities within this HUC include towns of

Wilkesboro, Elkin, Mount Airy and Yadkinville, and the city of Winston-Salem. Overall land cover breakdown across the HUC accounts for approximately 57% forested, 24% agricultural, 13% developed and 6% other categories. Administratively, the facility is based in Forsyth County with a population of 350,670 (Census 2010) and a land area of 408 square miles.

Figure 1. Location of the Manufacturer, POTW¹ and Landfill²



4.3.5 Location of Use

R.J. Reynolds Tobacco Company intends to distribute and sell the new tobacco products to consumers in the U.S.

4.3.6 Location of Disposal

¹ Publicly Owned Treatment Works

² Manufacturer address via Google Map. Accessed June 2, 2017.

Once used, the new tobacco products will be disposed of in landfills as municipal solid waste (MSW) or as litter in the same manner as the original products and any other combusted, filtered cigarettes. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates the distribution of waste from disposal after use will correspond to the pattern of the product use.

4.4 Modification(s) Identified as Compared to the Original Product

The applicant states that the difference between the new and original products is the replacement of non-FSC cigarette paper with FSC cigarette paper.

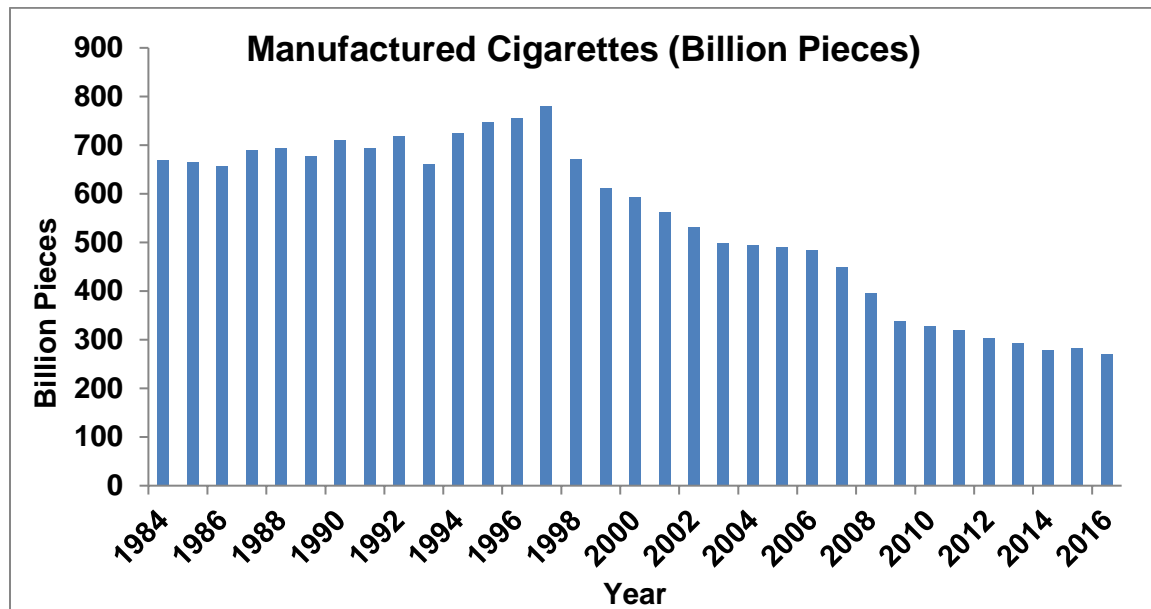
5. Environmental Introduction Due to the Proposed Actions

5.1. Introduction as a Result of Manufacturing the New Tobacco Products

5.1.1. *Tobacco Manufacture in the U.S. and Environmental Conditions near R.J. Reynolds' Tobaccoville Facility*

Tobacco Manufacturing in the U.S. As of August 15, 2017, a total of 1,264 tobacco production establishments (e.g., e-cigarette, hookah, dissolvable, cigar, and cigarette) are registered under 915(c) of the FD&C Act. A number of these manufacturers produced 270 billion cigarettes (13.5 billion packs of 20 cigarettes each) in 2016 with a decline seen in cigarette production starting in 1997 (Figure 2) [1]. As of June 2017, under the Master Settlement Agreement the state of North Carolina had 29 different tobacco manufacturers registered as a “non-participating manufacturer” and 128 registered as a “participating manufacturer”, including R.J. Reynolds Tobacco Company [2].

Figure 2. Total Cigarettes Manufactured in the U.S. 1984-2016



Ammonia and Nicotine, Including Nicotine Salts from Tobacco Manufacturing Facilities and Tobaccoville facility.

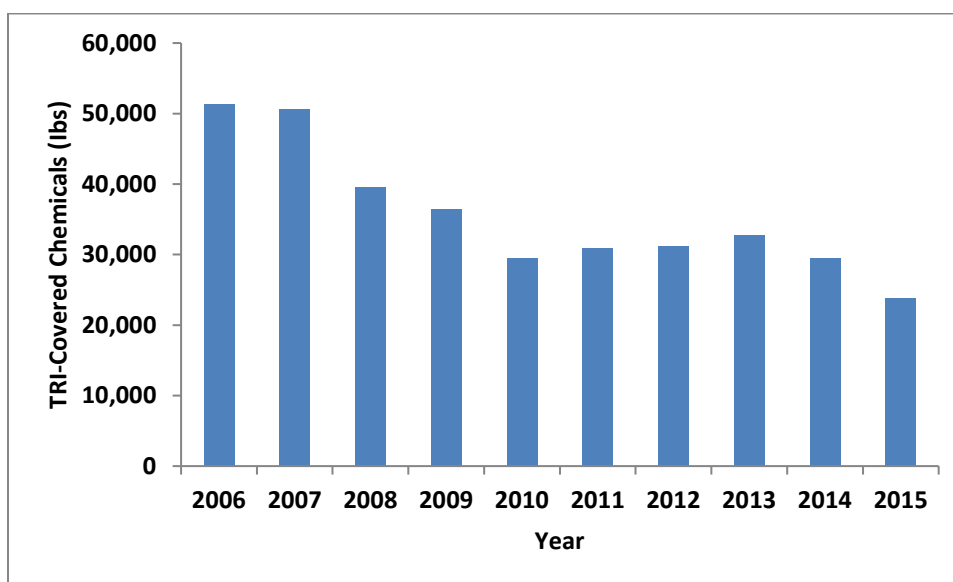
The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.³ In 2015, U.S. tobacco manufacturers released 475,000 pounds of ammonia and 280,000 pounds of nicotine and nicotine salts to the air; 9,564 pounds of ammonia and 313,765 pounds of nicotine and nicotine salts to landfill; 220 pounds of ammonia and 279 pounds of nicotine and nicotine salts to the surface water; and 19,550 pounds of ammonia and 83,384 pounds of nicotine and nicotine salts transferred to POTWs or an off-site location. A search in the TRI database indicates that the R.J. Reynolds Tobaccoville facility ranks 363 out of 1,041 TRI facilities for waste release in the food/beverages/tobacco industry category in 2015.

The Tobaccoville facility transferred 1,627 pounds of nicotine and nicotine salts and 499 pounds of ammonia to Hanes Landfill located at Winston-Salem, NC. The facility also released 13,865 pounds of nicotine and nicotine salts and 9,899 pounds of ammonia to the air. According to EPA, release of the chemicals to air from the facility decreased from 51,362 pounds in 2006 to 23,764 pounds in 2015 (figure 3).

The facility also transferred 938 pounds of nicotine and nicotine salts and 4,088 pounds of ammonia to the Muddy Creek POTW for treatment and release of the chemicals in 2015. The POTW is located on the southern border of Forsyth County and is permitted for 21 million gallons per day of residential and industrial wastewater. The POTW discharges its treated effluent into the Muddy Creek. The Muddy Creek is reported impaired by North Carolina Department of Environmental Quality (DEQ) due to turbidity and fecal coliform [3].

³ The estimation is done by using the Toxics Release Inventory (TRI), a dataset (<http://www.epa.gov/tri/>) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the U.S., including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Not all toxic release data of tobacco manufacturers are included in the database. The database includes information from any facility that (1) falls within a TRI-reportable industry sector or is federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (3) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical (<https://www.epa.gov/sites/production/files/documents/TRIListChangesUpdate11282011.pdf>) in an amount above the TRI reporting threshold during a calendar year.

Figure 3. TRI-covered Chemical Emission to Air from the Facility 2006-2015



Endangered and Threatened Species near the Manufacturing Facility

According to North Carolina's Fish and Wildlife Service, as of August 2017, 61 federally threatened and endangered species⁴ exist in North Carolina. Of these species, three endangered species (Red-cockaded woodpecker, Roanoke logperch, and Small-anthered bittercress) are observed in Forsyth County. However, the applicant claimed that in consultation with U.S. Fish & Wildlife Services, they have confirmed that the location of the manufacturing facility, 7855 King-Tobaccolville Road, Tobaccolville, NC 27050, is not within or in close proximity to a habitat of a threatened or endangered species. This assessment was conducted with the use of habitat maps made available by the U.S. Fish and Wildlife Service. Therefore, the agency does not anticipate any adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act ("ESA") due to the manufacture and commercial introduction of the new products.

5.1.2. Environmental Introduction from Manufacturing the New Tobacco Products

⁴ The Endangered Species Act of 1973 (ESA) protects species of plants and animals that are in danger of extinction. The purpose of the ESA is to protect and recover jeopardized species and their habitats. The ESA is administered by the U.S. Fish and Wildlife Service (USFWS) and the Commerce Department's National Marine Fisheries Service (NMFS). The ESA allows the USFWS and the NMFS to list species of plants and animals as threatened or endangered. "Endangered" means a species is in danger of extinction throughout all or a significant portion of its range. "Threatened" means a species is likely to become endangered within the foreseeable future [FWS].

Introduction from Manufacturing the New Products in the Proposed Actions. The waste emissions to air, land and water have been discussed in the previous section. The Agency anticipates the waste generated as a result of manufacturing the new combusted, filtered cigarettes will be released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other combusted, filtered cigarettes manufactured in the U.S. The applicant stated that the new products will also compete with other currently marketed combusted, filtered cigarettes. No expansion of the manufacturing facility is anticipated for manufacturing the new products. Therefore, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the production of all combusted, filtered cigarettes.

Based on information in the exemption requests, the only differences between the new products and the corresponding original products are the replacement of non-FSC cigarette paper with FSC cigarette paper. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

The applicant provided (1) the first- and fifth-year market volumes for the new products (2) the current market volumes of the original products and (3) the current market volumes of provisional products with identical names as the new products. The applicant stated that the new products are intended to replace the identically-named provisional products when the Agency issues the market authorizations for the new products (Confidential Appendix 2). According to the applicant, no increase of market volumes is anticipated. Additionally, the applicant stated that manufacturing the new products will not require any new equipment or expansion of the current manufacturing facility. Therefore, no new control practices of air emission, water discharge, or solid waste disposal are needed.

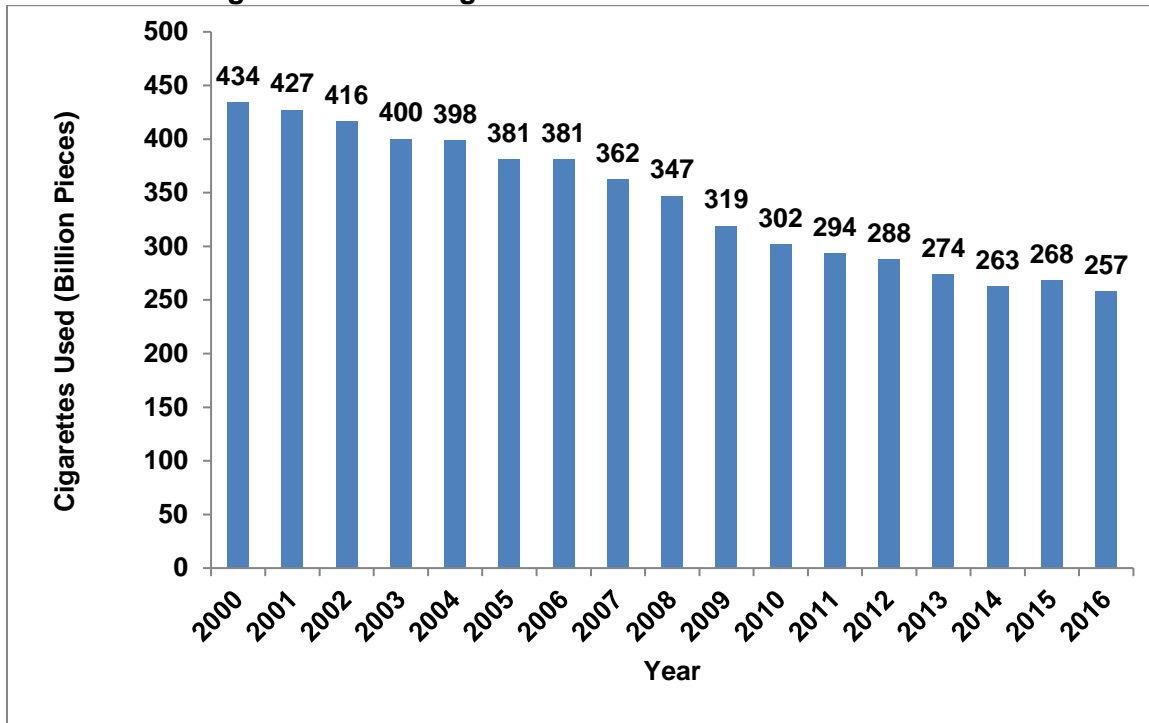
The applicant stated that they are in compliance with all federal, state, and local environmental regulations and provided information on the manufacturer's air, storm water and wastewater permits. The applicant's air permit expired in November 2012 but the applicant reapplied in 2012 and is waiting for the renewed permit. The applicant also stated that their facility complies with other environmental regulations including maintaining EPA Spill Prevention Control and Countermeasure plans, reporting greenhouse gas (GHG) emissions to the EPA under the GHG reporting rule 40 CFR 98, submitting EPA Tier 2, EPA TRI, and North Carolina Right-to-Know reports, complying with the DHS Chemical Antiterrorism Standards, and complying with applicable solid and hazardous waste regulations.

5.2. Environmental Introduction as a Result of Use of the New Tobacco Products

5.2.1. Use of Cigarettes in the U.S.

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of cigarettes in the U.S. decreased from 434 billion in 2000 to 257 billion in 2016 (Figure 3) [1].

Figure 3. Use of Cigarettes in the U.S. in 2000-2016⁴



When using cigarettes, the users produce environmental tobacco smoke (ETS) or secondhand smoke. The ETS composed of sidestream smoke (SS), emitted from the smoldering tobacco between puffs, and exhaled mainstream smoke (MS) from the smoker.

ETS contains many of the toxic agents and carcinogens that are present in MS, but in diluted form. The major source of ETS is SS, which contains higher amounts of some toxic and carcinogenic agents than MS when it is obtained in its undiluted form. The primary reason that undiluted SS and MS have different concentrations of toxic and carcinogenic agents is that peak temperatures in the burning cone of a cigarette reach 800° to 900°C during puffing, but only 600°C between puffs, resulting in less complete combustion of tobacco during generation of SS. In addition, most of the burning cone is oxygen deficient during smoldering and produces a strongly reducing environment

There is no safe level of exposure to secondhand smoke [4, 5]. Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30%[6].
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness [4, 5].

- Secondhand smoke causes more than 40,000 deaths a year [6].

5.2.2. *Environmental Introduction from Use of the New Products*

The Agency does not anticipate new substances to be released into the environment as a result of use of the new cigarettes, relative to the substances released by the original products, and other cigarettes already on the market. As noted, the only difference between the new products and the corresponding original products is the replacement of non-FSC cigarette paper with FSC cigarette paper

5.3. Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Products

The environmental consequences resulting from disposal following use of cigarettes are a) disposal of packaging, b) discarding of the used cigarettes, and c) air emissions.

5.3.1. *Disposal Following Use of Cigarettes*

a) Disposal of Packaging Material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the U.S., including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packing materials. Specifically, in 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the U.S., and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 4 and 5) [7]. Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery [7].

Figure 4. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2014

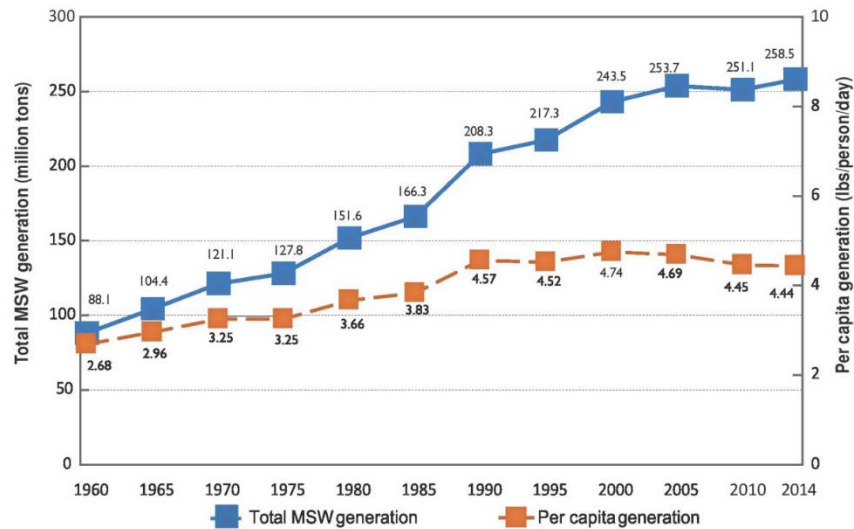


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 5. MSW Recycling Rates in the U.S., 1960-2014

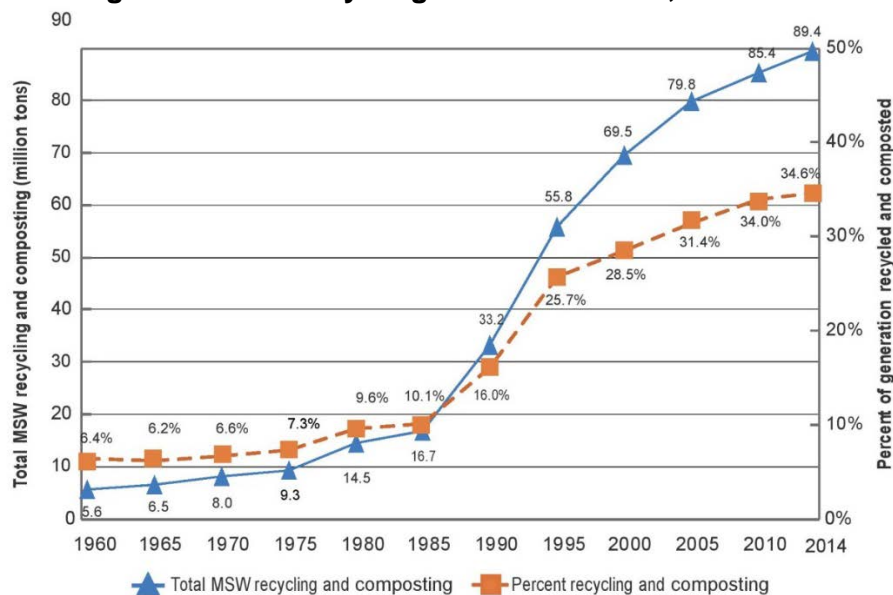


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

b) Disposal of Used Cigarettes Following Use

At the end of life, cigarette butt waste usually undergoes a series of scenarios for both managed and unmanaged waste (Figure 7). The managed waste is the waste that is handled by an organized solid waste collection and management system. The managed waste is treated as municipal solid waste (MSW) and either incinerated with energy recovery or landfilled. The unmanaged waste is the result of users littering cigarettes. According to a report published by "Keep America Beautiful", a study of 767 smokers showed 35% of used cigarettes were disposed of properly (with MSW) with a resulting

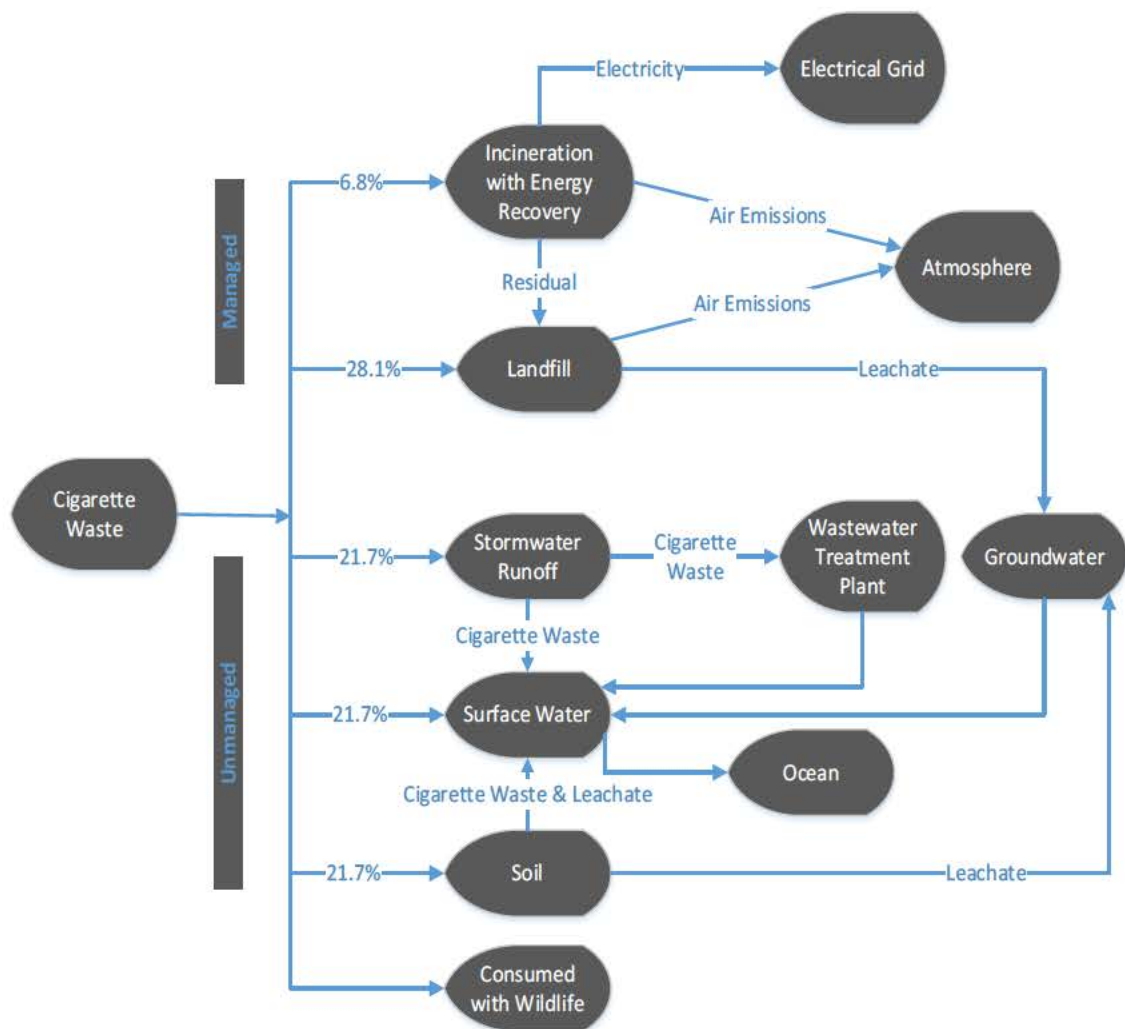
65% littering rate for cigarette butts[5]. This study is done by observing the cigarettes users' behavior in 44 locations.⁵

For the managed waste, 80.4% by-weight of the managed waste enters landfills, and the remaining 19.6% by-weight is incinerated for energy recovery [6]; that is, approximately 28.1% by-weight ($80.4\% \times 35\%$) of the total cigarette waste enters the landfills and 6.8% by-weight ($19.6\% \times 35\%$) of the total cigarette waste enters the incinerators. For the unmanaged waste, the Agency assumes that cigarette butt waste enters the storm water runoff, surface water, and soil in equal amounts; that is, 21.7% each by-count of total cigarette butt waste (Figure 7).

Majority of unmanaged cigarette waste ends up to oceans and beaches across the U.S. and globe. The annual Ocean Conservancy's International Coastal Cleanup (ICC) reports that cigarette waste has been the single most collected item since a day long collection began. Using the data from ICC, the Agency produced a map displaying the average collected cigarette waste (2010-2015) from coastal states (excluding Great Lakes coast) on the international coastal cleanup day (Figure 8).

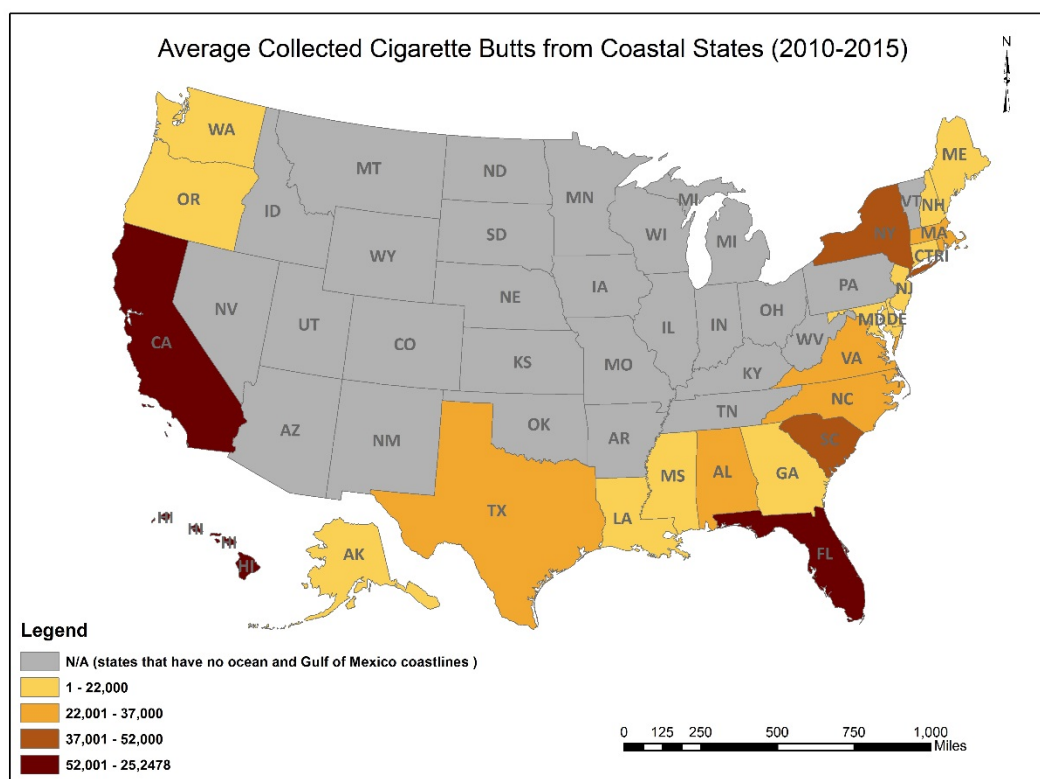
Figure 7. End of life pathways for cigarette waste

⁵ Including city center, retail, medical/hospital, gas station, bar/restaurant, recreational, and rest area settings.



Note that the percentages indicate the likelihood of a cigarette butt following each end of life pathway.

Figure 8. Collected Cigarette Waste from Coastal States (2010-2015)



c) Air Emissions

The used tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. The Clean Air Act requires that all landfills constructed or modified after July 17, 2014 that have a waste capacity of 2.5 million metric tons or more to have landfill gas collection-and-control systems installed. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98. As of June 2017, there are 634 operational landfill gas energy projects in the U.S. and approximately 400 landfills that are good candidates for projects [8].

The primary GHG emitted as a result of human activities in the U.S. is CO₂, representing 82% followed by methane 10%, nitrous oxide 5% and fluorinated gases 3%. Landfills are the third largest anthropogenic source of methane emissions in the United States (115.7 MMT CO₂-eq.), accounting for 17.6% of total methane emissions in 2015. From 1990 to 2015, methane emissions from landfills decreased by 63.8 MMT CO₂-eq. (35.6%), with small increases occurring in some interim years. This downward trend in emissions coincided with increased landfill gas collection and control systems, and a reduction of decomposable materials (i.e., paper and paperboard, food scraps, and yard trimmings) discarded in MSW landfills over the time period, which has more

than offset the additional methane emissions that would have resulted from an increase in the amount of municipal solid waste landfilled.

5.3.2 *Environmental Introduction from Disposal Following Use of the New Products*

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other cigarettes and other tobacco products that are currently being marketed. After using the new products, the users may dispose of or recycle the packaging material. Users may also discard the combusted cigarettes and filters, as discussed above, as MSW or litter.

To determine the amount of waste due to disposal of packaging material and product material, the Agency used the projected market volumes in the first and fifth years after issuance of an authorization order for the new products. The calculated waste of the packaging materials and product materials of the new products were determined to be miniscule compared to the forecasted MSW to be generated in the U.S. (Confidential Appendix 3). In addition, paper components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

As previously discussed, because the applicant stated that the new products will compete with other similar products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated due to the proposed actions.

The applicant stated that new products are anticipated to replace the currently marketed provisional products with the same names, the GHG emitted from waste associated with the new products is not anticipated to increase when the new products are authorized to be marketed. Also, the landfill sites are already equipped with mitigation plans (installed landfill gas collection and control systems, and a reduction of decomposable materials) when needed. No additional control of GHG emissions is anticipated in the landfills.

6. Fate of Materials Released into the Environment Due to the Proposed Actions

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the new products are anticipated to be manufactured, used, and disposed of in the same way as other cigarettes. Additionally, the inclusion of FSC paper in the new products is based on regulation that requires all cigarettes sold in the U.S. to be fire safety compliant. As of July 1, 2011 all 50 states and the District of Columbia require cigarettes sold to be FSC⁶. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use.

⁶ National Fire Protection Association: <http://www.nfpa.org/public-education/by-topic/top-causes-of-fire/smoking/coalition-for-fire-safe-cigarettes/states-that-have-passed-fire-safe-cigarette-laws>

7. Environmental Effects of New Materials Released into the Environment due to the Proposed Actions

The applicant stated that the manufacturing operation is in compliance with all local, state, and federal environmental laws. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

As discussed above, the quantity of materials anticipated to enter the environment due to the manufacturing and use of the new products are small fractions when compared to that of the projected manufacture and use of cigarettes in the U.S. The Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all cigarettes. In addition, the quantity of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new substances or new type of emissions are expected to be released, and therefore no new environmental controls are needed. No new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The applicant stated that there will be no change in how the new products are manufactured compared to the corresponding original products. The same raw materials and energy will be used to manufacture the new products compared to the original product and the applicant does not anticipate any increased energy or resource needs to manufacture the new products. The applicant stated that the proposed actions will not require an expansion of the manufacturing facility. Because the applicant stated that the new products will compete with other similar cigarettes and replace identically-named provisional products, no increase of overall cigarette market volume and no net increase of energy use will be expected from the proposed actions. The applicant stated that no adverse effects to endangered or threatened species or critical habitat are expected from manufacturing the new products. Additionally, the applicant stated that the manufacturing facility has a goal to minimize GHG emissions by 20%, reduce energy use by 25%, reduce water use by 30%, and increase recycling to at least 60% of the waste at the facility by 2020.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new products. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Actions

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco products in the U.S. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as many similar tobacco products would continue to be marketed.

Alternative B (Proposed actions): There is no substantial environmental effect due to the proposed actions of authorizing the new products and associated manufacture, use, and disposal following use of the new tobacco products (Confidential Appendices 2-5).

Therefore, the difference between the environmental impacts of these two alternatives is negligible, or non-existent.

11. List of Preparers

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

Preparer:

Mehran Niazi, PhD, Center for Tobacco Products

Education: M. Sc. in Environmental Planning; PhD in Environmental Science

Experience: 12 years in environmental fate and transport and environmental modeling

Expertise: Water quality modeling, environmental fate and transport

Reviewer:

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: M. Sc. in Environmental Science; PhD in Biochemistry

Experience: 9 years in NEPA practice

Expertise: NEPA analysis, wastewater treatment

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

Appendix 1: Submission Tracking Numbers for the EX Requests for the New Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

Appendix 2: Forecast of Cigarettes Manufactured in the U.S.

Appendix 3: Projected Use of Cigarettes in the U.S. in the First and Fifth Year of Marketing the New Products

14. Confidential Appendix List

Confidential Appendix 1: Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products

Confidential Appendix 2: The Current Market Volumes of the Original Products and Provisional Products with Identical Names as the New Products and First- and Fifth-Year Market Volume

Confidential Appendix 3:	Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the U.S.
Confidential Appendix 4:	The Agency's Estimated GHG in the First and Fifth Year of Marketing the New Products

15. References

1. U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 15, 2017.
2. North Carolina Department of Justice. *Tobacco Lists*. 2017. Available at <http://www.ncdoj.gov/getdoc/3b96da5a-6384-4bfc-bd2f-3636a5bb8711/2-6-4-3-6-Tobacco-Lists.aspx>. Accessed June 27, 2017.
3. Centers for Disease Control and Prevention (CDC). Economic Facts about Tobacco Production and Use. Available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/. Accessed January 16, 2015.
4. U.S. Department of Health and Human Services (HHS). 2006. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.
5. U.S. Department of Health and Human Services (HHS). 2006. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.
6. U.S. Department of Health and Human Services (HHS). 2014. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA.
7. Environmental Protection Agency (EPA). Materials and Waste Management in the United States Key Facts and Figures. Available at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures>. Accessed June 27, 2016.
8. Environmental Protection Agency (EPA). *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015*. 2017(EPA 430-P-17-001).

APPENDIX 1

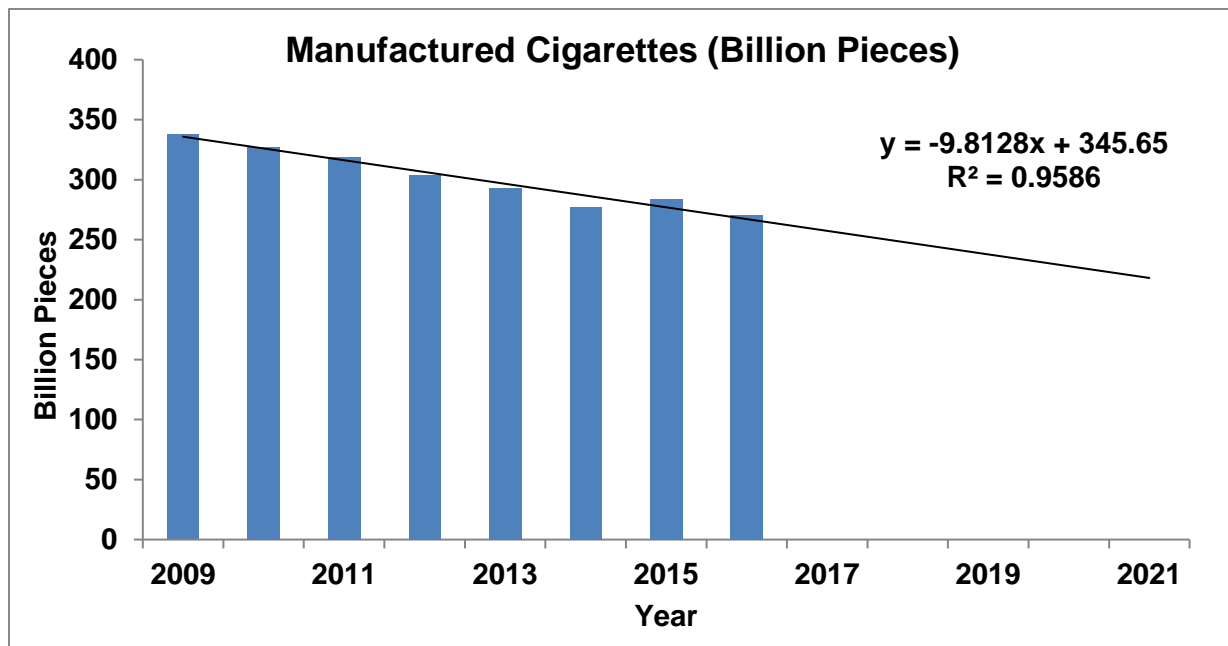
Submission Tracking Numbers for the EX Requests for the New Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

STN	Product Name	Amendments
EX0000182	Newport Box	EX0000192
EX0000185	Newport Box	
EX0000183	Newport Box 100s	
EX0000184	Newport Box 100s	
EX0000186	Newport Kings	
EX0000188	Newport Kings	

APPENDIX 2

Forecast of Cigarettes Manufactured in the U.S.

To evaluate the environmental impact of the proposed actions due to manufacturing of the new products, historical data regarding the manufacture of cigarettes in the U.S. from 2009 to 2016 was used to forecast the manufacture of cigarettes⁷. This was achieved by using one best-fit linear trend line with the R^2 value of 0.9586. Accordingly, the forecasted quantity of all cigarettes to be manufactured in the U.S. is estimated to be 257 billion pieces in 2017 and 218 billion pieces in 2021. The quantity of all cigarettes manufactured in the U.S. was 270 billion pieces in 2016.



⁷ Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau: Statistical Report – Tobacco for December 2016. Reported on February 16, 2017. Available at: <https://www.ttb.gov/statistics/2016/201612tobacco.pdf>. Accessed on June 27, 2017.

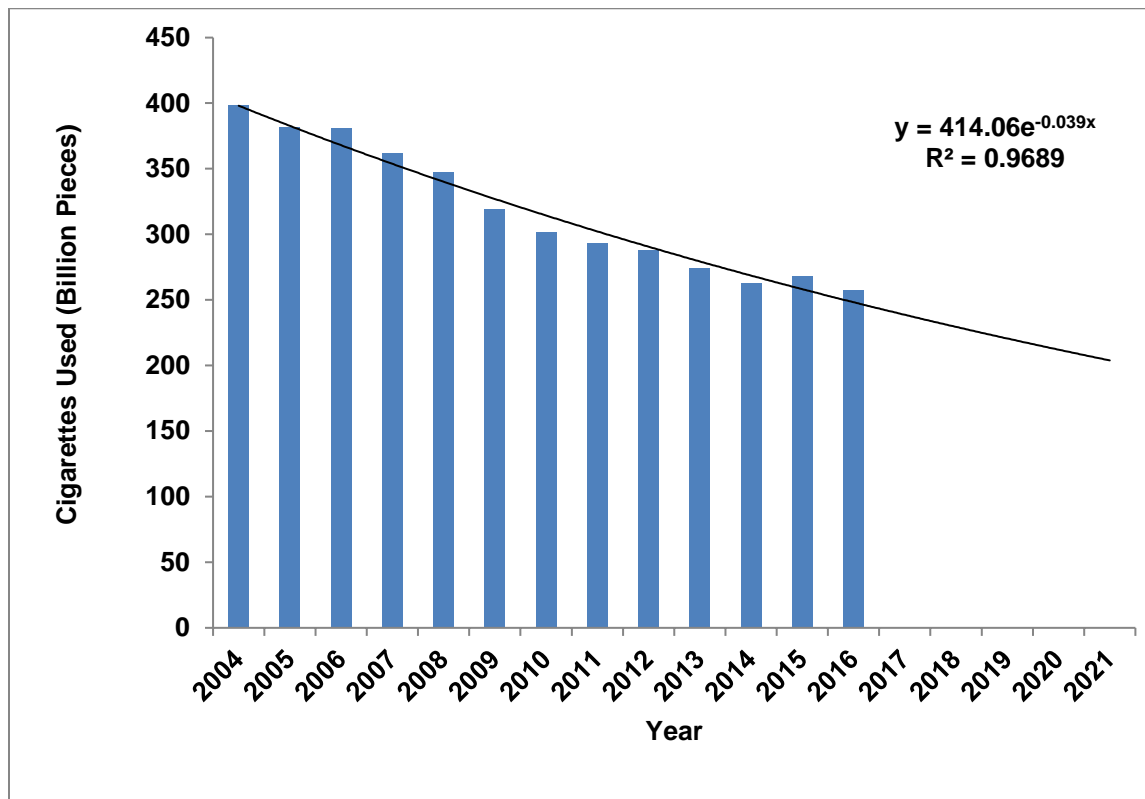
APPENDIX 3

Projected Use of Cigarettes in the U.S. in the First and Fifth Year of Marketing the New Products

To evaluate the environmental impact of the proposed actions due to use of the new products, historical data regarding total use of cigarettes from 2004 to 2016 was employed to mathematically estimate the forecast of the total quantity of cigarettes used in the U.S.⁸ This was achieved by using the one best-fit trend line with R^2 value above 0.9.

Projected Use of Cigarettes in the U.S.:

Using the best-fit power trend line with the R^2 value of 0.9689, the forecasted number of cigarettes that will be used in the U.S. is estimated to be 239.85 billion in 2017 and 205.21 billion in 2021.



⁸ Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 15, 2017.

CONFIDENTIAL APPENDIX 1

Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products

To analyze the environmental effects from total waste due to the proposed actions, the Agency estimated the first- and fifth-year projected weight of the packaging and product materials waste (in metric tons) that would be generated from disposal after use of the new products in 2017 and 2021. Projected waste generation is the summation of the projected cardboard retail boxes, cardboard of the cartons, foil inner liner, plastic wrap of retail boxes, and cigarettes butts of the new products:

$\sum_{i=1}^6 A_i = \sum_{i=1}^6 (B_i + C_i + D_i + E_i + F_i)$ $B_i = \frac{G_i}{H_i} \times I_i \times S$ $C_i = \frac{G_i}{H_i \times J_i} \times K_i \times S$ $D_i = \frac{G_i}{H_i} \times L_i \times S$ $E_i = \frac{G_i}{H_i} \times M_i \times S$ $F_i = \frac{G_i \times O_i \times P_i}{100} \times S$ $P_i = \frac{Q_i}{R_i} \times 100$	<p>A_i: Projected total waste generation of the product (metric tons)</p> <p>B_i: Projected waste generation of retail cardboard boxes of the new products (metric tons)</p> <p>C_i: Projected waste generation of the retail cardboard cartons of the new products (metric tons)</p> <p>D_i: Projected waste generation of the foil inner liner (metric tons)</p> <p>E_i: Projected waste generation of retail box plastic of the new products (metric tons)</p> <p>F_i: Projected waste generation of cigarette butts of the new products (metric tons)</p> <p>G_i: Total Projected market volume of the new products (total number of individual cigarettes)</p> <p>H_i: Number of cigarettes per retail box</p> <p>I_i: Weight of empty retail cardboard box (grams)</p> <p>J_i: Number of retail boxes per carton</p> <p>K_i: Weight of empty retail carton (grams)</p> <p>L_i: Weight of foil inner liner (grams)</p> <p>M_i: Weight of plastic wrap per retail box (grams)</p> <p>O_i: Weight of cigarette (gram)</p> <p>P_i: Cigarette butt ratio (%)</p> <p>Q_i: Cigarette butt length⁹</p> <p>R_i: Length of cigarette (millimeter)</p> <p>S: 1.0×10^{-6} metric tons/gram</p>
--	---

⁹ ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed as solid waste following use.

a) Projected Waste of Packaging Material

Projected packaging waste is calculated as below:

Projected Year	STN	Market volume G_i	# cigarettes per box H_i	Weight of retail box I_i	Retail box waste B_i	# boxes per carton J_i	Weight of carton K_i	Carton waste C_i	Weight of foil L_i	Foil waste D_i	Weight of plastic M_i	Plastic waste E_i
First-Year Projected Volume	EX0000182	(b) (4)	20	4.37	(b) (4)	10	20.5	(b) (4)	1.04	(b) (4)		
	EX0000185	(b) (4)	20	4.37	(b) (4)	10	20.5	(b) (4)	1.04	(b) (4)		
	EX0000183	(b) (4)	20	5.1	(b) (4)	10	23.29	(b) (4)	1.21	(b) (4)		
	EX0000184	(b) (4)	20	5.1	(b) (4)	10	23.29	(b) (4)	1.21	(b) (4)		
	EX0000186	(b) (4)	20	1.47	(b) (4)	10	19.44	(b) (4)	1.04	(b) (4)		
	EX0000188	(b) (4)	20	1.47	(b) (4)	10	19.44	(b) (4)	1.04	(b) (4)		
	Total	(b) (4)			(b) (4)			(b) (4)		(b) (4)		
Fifth-Year Projected Volume	EX0000182	(b) (4)	20	4.37	(b) (4)	10	20.5	(b) (4)	1.04	(b) (4)		
	EX0000185	(b) (4)	20	4.37	(b) (4)	10	20.5	(b) (4)	1.04	(b) (4)		
	EX0000183	(b) (4)	20	5.1	(b) (4)	10	23.29	(b) (4)	1.21	(b) (4)		
	EX0000184	(b) (4)	20	5.1	(b) (4)	10	23.29	(b) (4)	1.21	(b) (4)		
	EX0000186	(b) (4)	20	1.47	(b) (4)	10	19.44	(b) (4)	1.04	(b) (4)		
	EX0000188	(b) (4)	20	1.47	(b) (4)	10	19.44	(b) (4)	1.04	(b) (4)		
	Total	(b) (4)			(b) (4)			(b) (4)		(b) (4)		

If all the projected packaging waste generated from use of the products is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new products would be (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014. Likewise, the projected plastic waste of (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021 is a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014.

A portion of the generated cardboard waste is likely to be recycled, with an overall recycling rate for paper and paperboard products of 64.7% in the U.S.¹⁰ If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed in landfills (Variable B and C above) would be decreased to (b) (4) metric tons (b) (4) metric tons) in the first year and (b) (4) metric tons (b) (4) metric tons) in the fifth year of marketing the new products.

¹⁰ EPA. Advancing Sustainable Materials Management: Facts and Figures Report. Available at: <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report> (accessed April 4, 2017).

b) Projected Waste of the Cigarette Butts in the First and Fifth Year of Marketing the New Product

Projected cigarette butt waste generated is calculated as below:

Projected Year	STN	Market volume G_i	Cigarette length R_i	Cigarette weight O_i	Cigarette butt waste F_i
First-Year Projected Volume	EX0000182	(b) (4)	80	0.8967	(b) (4)
	EX0000185	(b) (4)	80	0.8959	
	EX0000183	(b) (4)	99	1.1141	
	EX0000184	(b) (4)	99	1.1151	
	EX0000186	(b) (4)	84	0.9449	
	EX0000188	(b) (4)	84	0.9458	
	Total	(b) (4)			
Fifth-Year Projected Volume	EX0000182	(b) (4)	80	0.8967	(b) (4)
	EX0000185	(b) (4)	80	0.8959	
	EX0000183	(b) (4)	99	1.1141	
	EX0000184	(b) (4)	99	1.1151	
	EX0000186	(b) (4)	84	0.9449	
	EX0000188	(b) (4)	84	0.9458	
	Total	(b) (4)			

If all the projected filter waste generated from use of the products is disposed in landfills, the projected waste of (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021 will be a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014.

CONFIDENTIAL APPENDIX 2

**The Current Market Volumes of the Original Products and Provisional Products with
Identical Names as the New Products and First- and Fifth-Year Market Volume
Projections of the New Products**

STN	Unit	First-Year Market Volume	Fifth-Year Market Volume	The Current Market Volume for the Original Products	The Current Market Volume for the provisional Products
EX0000182	# of cigarettes	(b) (4)			
EX0000183	# of cigarettes				
EX0000184	# of cigarettes				
EX0000185	# of cigarettes				
EX0000186	# of cigarettes				
EX0000188	# of cigarettes				

CONFIDENTIAL APPENDIX 3

Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the U.S.

The first- and fifth-year market volumes of the new products projected to occupy the U.S. market were determined by comparing the projected market volume of the new products to the forecasted use of cigarettes in the U.S. (Appendices 2 and 3, and Confidential Appendix 2). The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new products was calculated using the equations below:

$$\text{First Year Market Occupation of New Products (\%)} = \frac{\text{First-Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of cigarettes in the U.S. for 2017 (metric tons)}} \times 100\%$$

$$\text{Fifth Year Market Occupation of New Products (\%)} = \frac{\text{Fifth-Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of cigarettes in the U.S. for 2021 (metric tons)}} \times 100\%$$

STN	Year	Forecasted Use of Total Cigarettes in the U.S. (billion cigarettes) ¹¹	Projected Market Volume of New Product (billion cigarettes) ¹²	Projected Market Occupation of New Product in the U.S. (%)
EX0000182	2017	239.85	(b) (4)	
	2021	205.21		
EX0000185	2017	239.85		
	2021	205.21		
EX0000183	2017	239.85		
	2021	205.21		
EX0000184	2017	239.85		
	2021	205.21		
EX0000186	2017	239.85		
	2021	205.21		
EX0000188	2017	239.85		
	2021	205.21		

Comparing the projected market volume of the new products with the projected use of all cigarettes produced in the U.S. in 2017 and 2021, the cumulative projected market volumes of the new products are approximately (b) (4) of the total projected cigarette use in 2017 and (b) (4) of that projected use for 2021.

¹¹ See Appendix 3.

¹² See Confidential Appendix 3.