

**Programmatic Environmental Assessment for Exemption Requests by R.J.
Reynolds Tobacco Company for “Pall Mall Menthol Green Filter and Pall
Mall Menthol Green Filter 100”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

April 26, 2018

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This programmatic environmental assessment (PEA) is for two Exemption Requests for combusted, filtered cigarettes manufactured by R.J. Reynold 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 with 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

R.J. Reynolds Tobacco Company

2. Address of Applicant

401 N. Main Street
Winston-Salem, NC 27101

3. Manufacturer

R.J. Reynolds Tobacco Company

4. Description of the Proposed Actions

The proposed actions are for FDA to issue exemptions under section 905(j)(3) from the requirement of demonstrating that a tobacco product is substantially equivalent within the meaning of section 910 of the FD&C Act for the introduction of two combusted, filtered cigarettes into interstate commerce for commercial distribution in the United States. This authorization is based on the finding that the modifications in the new products are 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 the marketing of the modified tobacco products would be appropriate for the protection of the public health, and an exemption is otherwise applicable. The applicant stated that they intend to discontinue production and marketing of the corresponding original products if a marketing order is granted for the new products. The original products for EX0000213 and EX0000214 are grandfathered products GF1501198 and GF1501484, which received confirmation of grandfathered status on March 31, 2016 and June 15, 2016, respectively.

4.1. Requested Actions

The applicant, R.J. Reynolds Tobacco Company, submitted two requests to FDA to exempt from the requirement of demonstrating substantial equivalence for two new combusted, filtered cigarette products.

4.2. Need for Actions

R.J. Reynolds Tobacco Company wishes to introduce the new tobacco products, as described, into interstate commerce for commercial distribution in the United States. The applicant claims that the differences in the new products and the corresponding original products are minor modifications. 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 products an exemption from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated reports, 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 Product that is Subject of the Proposed Actions

4.3.1. Type of Tobacco Product

Combusted, filtered cigarettes

4.3.2. Product Names and the Submission Tracking Numbers (STN)

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

STN	New Product	Original STN	Original Product
EX0000213	Pall Mall Menthol Green Filter	GF1501198	Pall Mall Light Menthol King Box
EX0000214	Pall Mall Menthol Green Filter 100	GF1501484	Pall Mall Light Menthol 100s Box

4.3.3. Description of the Product Packages

The new products' packaging consists of a foil inner liner, inner frame, box, film overlap, and carton.

4.3.4. Location of Manufacturing

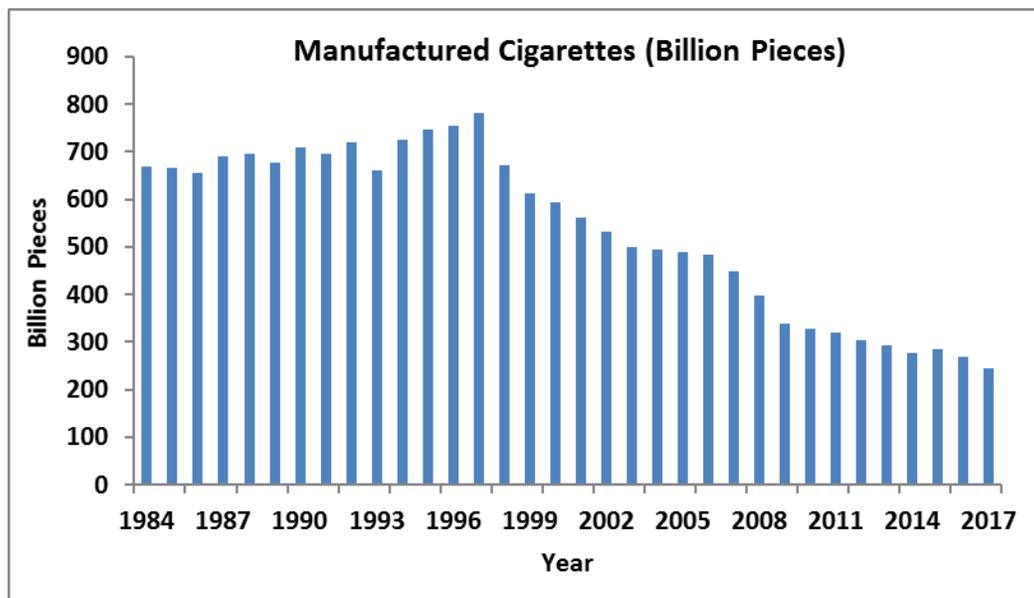
The manufacturer, R.J. Reynold Tobacco Company (RJR), is located at 7855 King-Tobacoville Road in Tobacoville, North Carolina in the United States (Figure 1). The facility is surrounded by woodlands, bounded by the city of King, NC to the north, US 52 (a four-lane divided highway) to the east, and mixed use residential, commercial, and agricultural land to the south and west.

5. Potential Environmental Impacts Due to the Proposed Actions

5.1. Potential Environmental Impacts Due to Manufacturing the New Products

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, 245.63 billion cigarettes (12.282 billion packs of 20 cigarettes each) have been manufactured in 2017 (Figure 2) with cigarette manufacturing declining since 1997.^{2 3} As of November 2017, 30 different tobacco manufacturers were registered in the state of North Carolina, including R.J. Reynolds Tobacco Company, as a "participating manufacturer" under the Master Settlement Agreement and 13 were registered as a "non-participating manufacturer".⁴

Figure 2. Total Cigarettes Manufactured in the United States, 1984-2017



The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.⁵ Only 14 tobacco manufacturers that are registered in

² U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 7, 2018.

³ Million pound of cigarettes value is calculated based on the assumption that approximately 0.9 grams of tobacco is used per cigarette. Million pound cigarettes =
$$\frac{(X \text{ billion cigarette pieces} \times 10^9) \times \left(\frac{0.9 \text{ g}}{453.59 \text{ g}}\right)}{10^6}$$

⁴ Tobacco manufacturers who wish to sell their product in North Carolina are subject to: (1) Tobacco Escrow Statute, where tobacco manufacturers must either become a party to the Mass Settlement Agreement and comply with its terms, or establish an escrow account and pay into it in accordance with N. C. Gen. Stat. § 66-291 as a "non-participating manufacturer", and (2) Brand Listing Statute, where tobacco manufacturers who wish to sell their product in North Carolina must first qualify to be included on the Approved Tobacco List issued by the Attorney General. "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 December 7, 2017."

⁵ 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

North Carolina under MSA as a “participating manufacturer”, including R.J. Reynold Tobaccoville facility, report emissions to EPA. In 2016, United States tobacco manufacturers released ammonia, nicotine and nicotine salts to the environment and nicotine and nicotine salts were also transferred to publicly owned treatment works (POTWs) or an off-site location (Table 1).⁶ The TRI database search also did not show that the Tobaccoville manufacturing facility disposed of, treated, or released into the environment any other toxicants associated with manufacturing tobacco products.

Table 1 Emissions Associated with Manufacturing Tobacco Products

Emissions Associated with All Tobacco Product Manufacturers in the United States				
Chemical Name	Air Release (Pound)	Land Release (Pound)	Water Release (Pound)	POTW Transfer (Pound)
Ammonia	406,454	1	186	18,056
Nicotine & Nicotine Salts	253,436	74,322	30	108,051
Emissions Associated with Tobacco Product Manufacturing at RJR Facility in Tobaccoville, NC				
Ammonia	20,003	1	0	4,785
Nicotine & Nicotine Salts	18,909	3	0	277

The Agency anticipates the waste generated due to manufacturing the new products will be released to the environment, transferred to POTW, and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility and in a similar manner to other combusted, filtered cigarettes manufactured in the United States. The applicant stated that the new products will compete with other currently marketed combusted, filtered cigarettes. The applicant also stated that production and marketing of the original products will cease if a marketing order is granted for the new products. 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 the information in the two Exemption Requests, the new products and the original products will be manufactured in a similar manner and the changes related in the deletion of a tobacco additive, in the tipping paper, and the addition of a tobacco additive, in the tipping paper are minor changes that would not be expected to release new air emissions. Consequently, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of

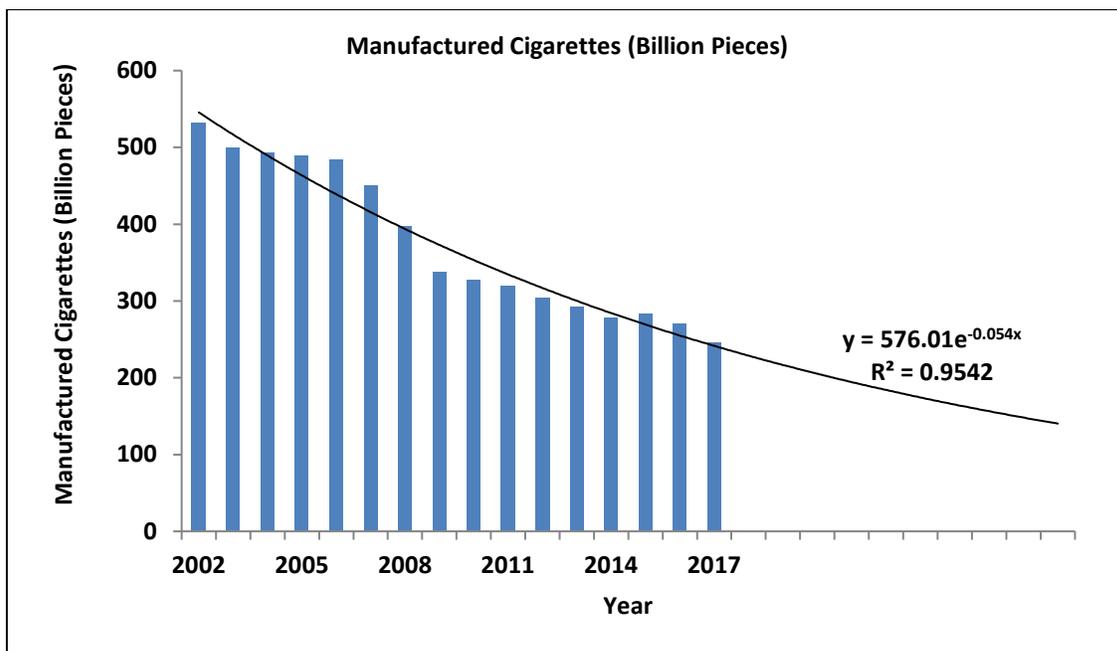
facilities across the United States, including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes 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.

⁶ U.S. Environmental Protection Agency (EPA). *TRI Data Form R & A Download*. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched on December 7, 2017.

manufacturing the new product.

The applicant provided the first- and fifth-year market volumes for the new products (Confidential Appendix 2). 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 United States from 2002 to 2017 was used to forecast the manufacture of cigarettes. This was achieved by using one best-fit power trend line with the R2 value of 0.9542. Accordingly, the forecasted number of all cigarettes to be manufactured in the United States is estimated to be 230.01 billion pieces in 2018 and 185.33 billion pieces in 2022 (Figure 3).⁷

Figure 3. Forecast of Cigarettes' Manufacturing in the United States, 2002-2017



The projected market volume of the new products is a small fraction of the forecasted manufacture of all cigarettes in the United States in 2018 and 2022 (Confidential Appendix 2). Additionally, the applicant stated that manufacturing the new products will not require any new equipment or expansion of the current manufacturing.

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations and provided information on the facility's air, storm water and wastewater permits. The applicant's air permit expired in November 2012 but they reapplied in 2012 and are 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 EPA under the GHG reporting rule 40 CFR 98, submitting EPA Tier 2,

⁷ Projected first-year and fifth-year billion pieces of cigarettes = $576.01 \times e^{(-0.052 \times (Year - 2002))}$

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. Therefore, introduction of materials released into the environment is not expected to exceed the allowed amount to be released to the environment under relevant environmental laws.

The applicant noted that the facility complies with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). The applicant consulted with the U.S. Fish and Wildlife Services and confirmed that the location of the manufacturing facility is not within or near a habitat, critical or otherwise, of a threatened or endangered species, per habitat maps.⁸ According to the Exemption Request, the requested actions will neither jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species identified under the ESA.

The applicant also stated that their facility complies with other environmental regulations including maintaining EPA Spill Prevention Control and Countermeasure plans, reporting GHG emissions to 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. Therefore, introduction of materials released into the environment is not expected to exceed the allowed amount to be introduced to the environment under relevant environmental laws.

5.2. Potential Environmental Impacts Due to Use of the New Products

According to the U.S. TTB statistical data, the use of cigarettes in the United States decreased from 512.02 billion cigarettes (512,020 tons) in 1997 to 247.19 billion cigarettes (247,191 tons) in 2017 (Figure 4).^{9 10}

⁸ Habitat maps are located at:

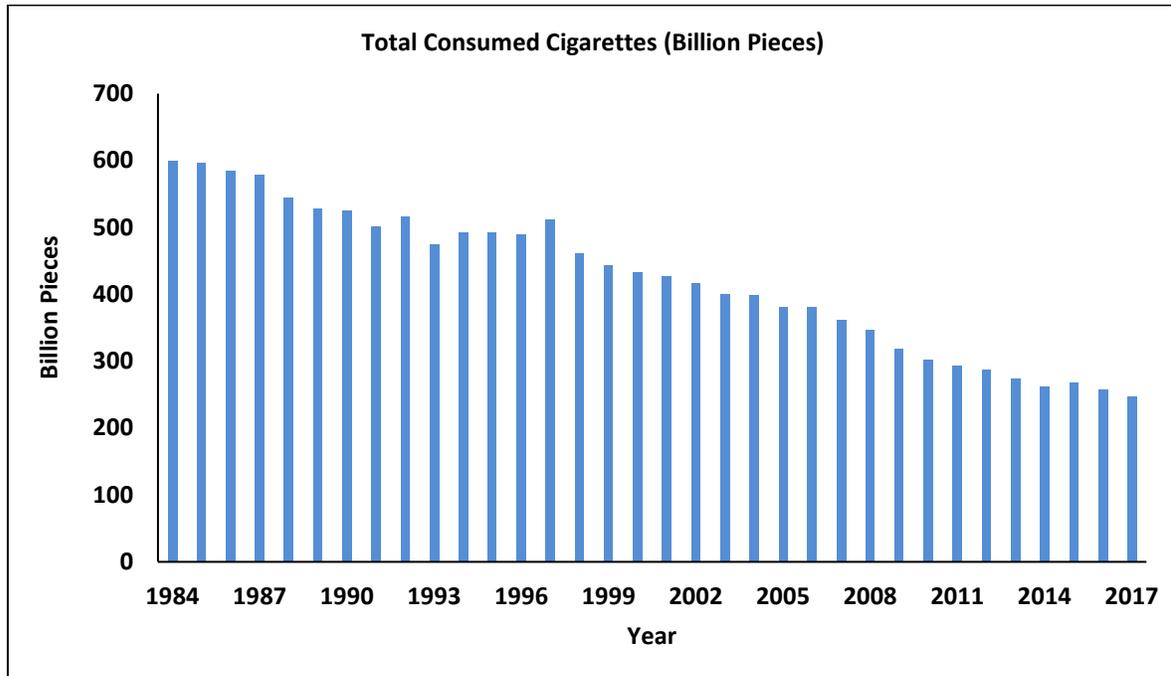
<http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>. Accessed on December 7, 2017.

⁹ OECD Health Statistics 2017, Definitions, Sources and Methods; Tobacco consumption in grams per capita (ages 15+). Available at:

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKewi_tLXjt_jXAhUNkeAKH_TJNCzQQFggrMAE&url=http%3A%2F%2Fstats.oecd.org%2Ffileview2.aspx%3FIDFile%3D8e59b835-8196-426e-9297-15bc1dab652c&usg=AOvVaw2CgYitJQhppHiy96iSnS-r. Accessed December 7, 2017.

¹⁰ Million tons of cigarettes value is calculated based on the assumption that approximately 1.0 grams of tobacco is used per cigarette Million pound cigarettes = $\frac{(X \text{ billion cigarette pieces} \times 10^9) \times (\frac{1.0 \text{ g}}{453.59 \text{ g}})}{10^6}$

Figure 4. Use of Cigarettes in the United States, 1984 – 2017



Based on the changes between the new and original products outlined in section 4.4, 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. The combustion products from the new products will be released in the same manner to the combustion products of the original products and other marketed cigarettes.

When burned, cigarettes produce environmental tobacco smoke (ETS) or secondhand smoke (SHS). There is no safe level of exposure to SHS [1, 2]. Even low levels of SHS can harm children and adults in many ways, including the following:

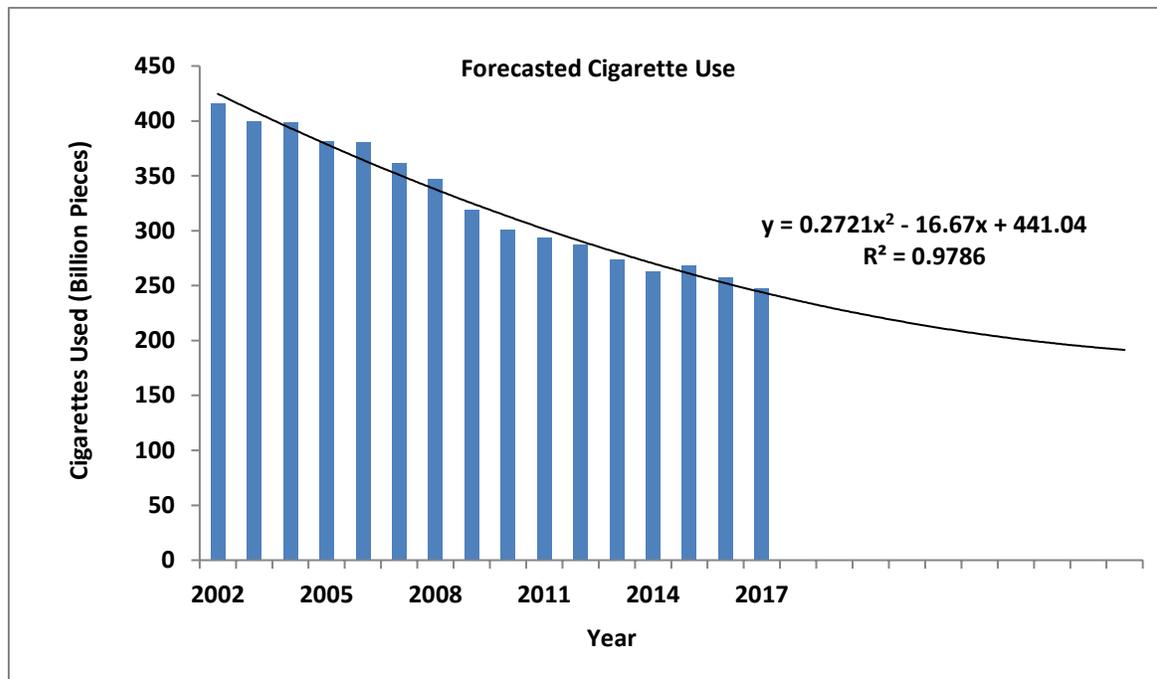
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% [3].
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness [1, 2].
- SHS causes more than 40,000 deaths a year [3].

To evaluate the environmental impact of the proposed action due to use of the new product, historical data regarding total use of cigarettes from 2002 to 2017 was employed to mathematically estimate the forecast of the total amount of cigarettes used in the United States.¹¹ Using the best-fit trend line with

¹¹ The forecast trend line is extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed December 7, 2017.

an R² value of 0.9786, the forecasted number of cigarettes that will be used in the United States is estimated at 236.26 billion cigarettes and 210.92 billion cigarettes are forecasted to be used in the first year and fifth year of marketing the new products, respectively (Figure 5).¹²

Figure 5. Forecasted Use of Cigarettes in the United States, 2002-2017



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 corresponding original products, and other cigarettes already on the market. As noted, the difference between the new products and the original products are minor changes in ingredients; the weight of packaging material is the same. Additionally, because (1) the new products will replace the original products and compete with other currently marketed cigarettes; and (2) the projected market volumes of the new products in the first and fifth year of its marketing occupy a negligible fraction of the total projected estimate of use of cigarettes in the United States (Confidential Appendix 3), no net addition of GHG emissions is anticipated.

¹² Projected first-year and fifth-year billion pieces of cigarettes = $0.2721 \times ((Year - 2002)^2) - (16.67 \times (Year - 2002)) + 441.04$

5.3. Potential Environmental Impacts Due to Disposal of the New Products

5.3.1 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 United States, including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packaging materials. Specifically, according to the U.S. Environmental Protection Agency (U.S. EPA), approximately 258.46 million tons of waste was generated in the United States in 2014, and approximately 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 6 and 7).¹³ Paper and paperboard accounted 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%), of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW, 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. On average, 4.4 pounds of waste was generated per person in the United States, of which 2.1 pounds was recycled, composted, or combusted for energy recovery [4].

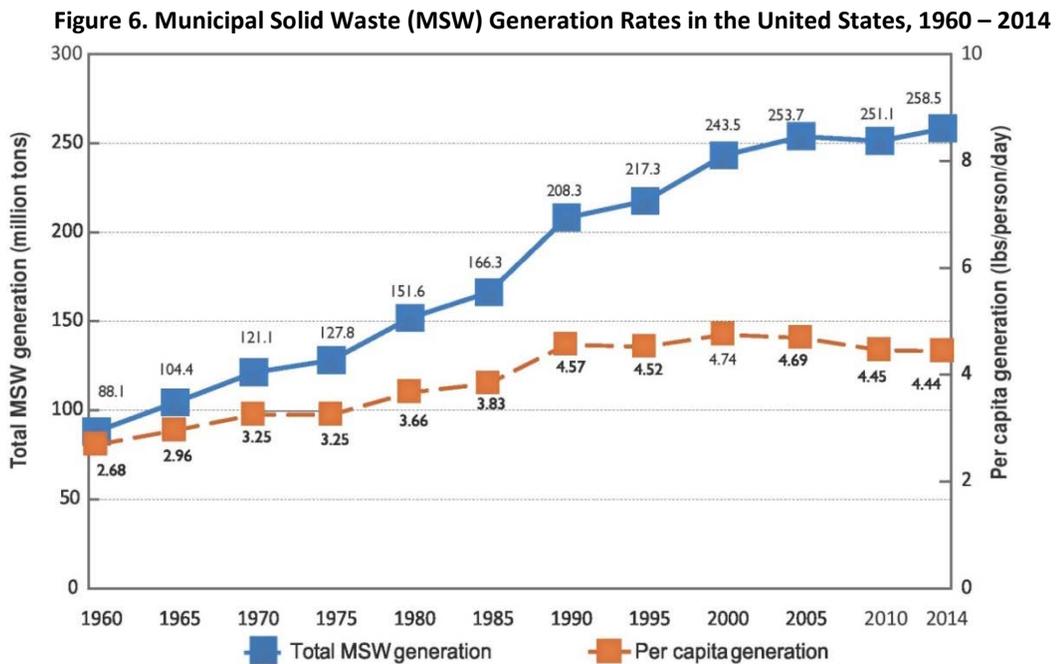


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

¹³ The "ton" unit in section 5.3.1 is U.S. short ton, unless specified otherwise

Figure 7. MSW Recycling Rates in the U.S., 1960 – 2014

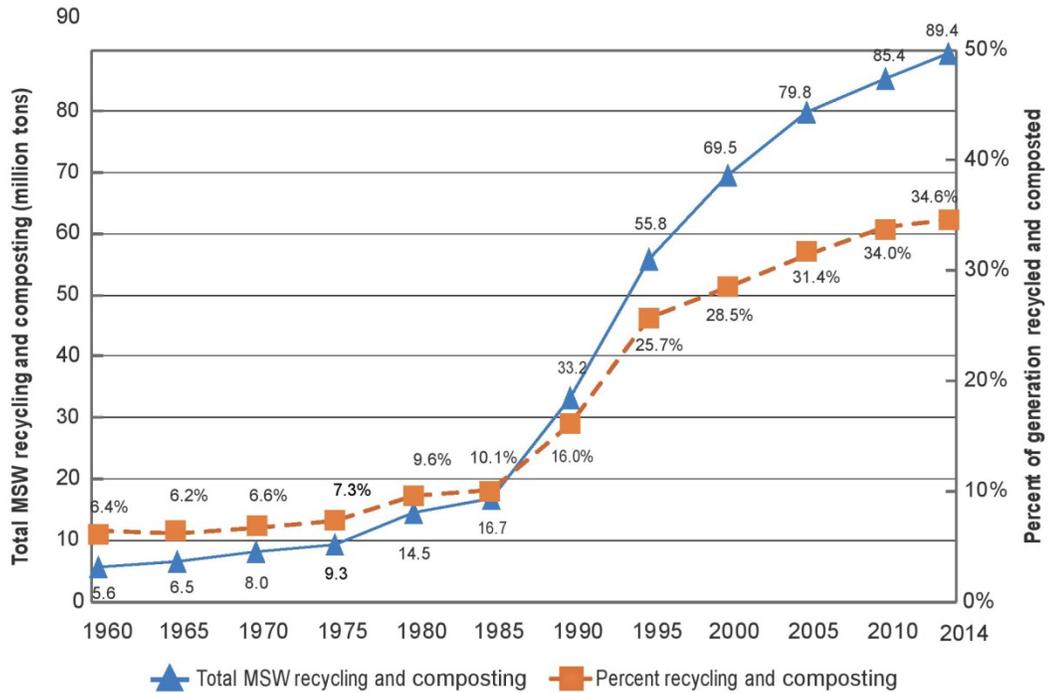


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the new products will be the same as the disposal conditions of other cigarettes 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 calculate the amount of waste from disposal of the packaging material and product material, the Agency used the first- and fifth-year projected volumes of marketing the new products after issuance of the marketing orders for the new products (Confidential Appendix 4). The calculated cumulative waste of the packaging material is a minuscule fraction of the forecasted MSW that would be generated in the United States. In addition, because paper components and plastic wrap are more likely to be recycled, at least a portion of the packaging waste is likely to be recycled.

Construction of new POTWs or landfills is not anticipated due to the proposed actions. The Agency has reached this determination because (1) the applicant stated that the new products will compete with other similar products on the market, (2) the original products will be discontinued, and (3) the waste generated will be a minuscule fraction of the total MSW generated in the United States.

The Agency does not anticipate the proposed actions to lead to the release of new chemicals into the environment due to use of the new products. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes manufactured in the facility.

5.3.2 Disposal of Cigarettes Following Use

Used cigarettes are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent products are likely to move by run-off to the ocean. When discarded as MSW, the products would enter landfills.

A major existing environmental consequence of the use of combusted filtered cigarettes is the waste disposal of the cigarette butts. Evidence has shown that cigarette butts are the most prevalent items discarded into roads and streets in urban areas. Once dumped onto city streets, they move through the storm drains to streams, into the ocean, and back onto the beaches, while leaching toxicants, including arsenic, lead, nicotine and ethyl phenol, into the aquatic environment and soil along the way. Discarded filters are found to be the most collected item in beach clean-ups and litter surveys. An estimated 30% of the total waste (by count) on U.S. shorelines, waterways, and land is cigarette butt waste [5].

5.3.3 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 to install landfill gas collection-and-control systems if they will have a waste capacity of 2.5 million metric tons or more. Additionally, all landfills must report GHG emissions to the U.S. EPA under 40 CFR 98.

Methane (CH₄) is a potent GHG that has a global warming potential of 28-36 times greater than carbon dioxide (CO₂), and has an atmospheric life of about 12 years. Landfills are the third largest source of human-related CH₄ emissions in the United States, releasing an estimated 133.1 million metric tons of CO₂-equivalent, accounting for approximately 15.4% of these emissions in 2015 [6]. The decomposition of landfill waste produces approximately 50% biogenic CO₂ and 50% CH₄, by volume, as well as trace amounts of non-CH₄ organic compounds and volatile organic compounds. However, only CH₄ generation and emissions are estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines [7].

Because the waste generated from the new products comprises a negligible fraction of the total MSW, the GHG emitted from waste associated with the new products is negligible according to quantified GHG emissions from disposal of the new products in this EA (Confidential Appendix 5). No additional control of GHG emissions is anticipated in the landfills.

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment due to disposal of the new products. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes. No new types of material are anticipated to be emitted to the environment due to disposal after use.

6. 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 products 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. When comparing the market volume projections with the forecasted total cigarette volumes in the United States, the Agency found that the projected market volumes of the new products are a small portion of the total forecasted cigarette market volumes in 2018 and 2022. Because the applicant stated that the new products will compete with other similar cigarettes and that the original products will be discontinued, 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.

7. 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 were developed.

8. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco product in the United States. 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 action): 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.

9. List of Preparers:

The following individuals were primarily responsible for preparing and reviewing this environmental assessment:

Preparer:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: 4 years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

Hoshing Chang, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biochemistry and M.S. in Environmental Science

Experience: 9 years in NEPA practice

Expertise: Waste water treatment, environmental impact analysis

10. List of Agencies and Persons Consulted

Not applicable.

11. 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)

12. Confidential Appendix

Confidential Appendix 1: Proposed Minor Modification to the Corresponding Original Products

Confidential Appendix 2: First- and Fifth-Year Market Volume Projections of the New Products and Projected Percentage of Future Cigarette Manufacturing in the United States Occupied by the New Products

Confidential Appendix 3: First- and Fifth-Year Market Volume Projections of the New Products and Projected Percentage of Future Cigarette Use in the United States Occupied by the New Products

Confidential Appendix 4: Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products

Confidential Appendix 5: The Agency's Estimated GHG Emissions in the First and Fifth Year of Marketing the New Products

13. References

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APPENDIX 1

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

STN	New Products	Amendments
EX0000213	Pall Mall Menthol Green Filter	No Amendments
EX0000214	Pall Mall Menthol Green Filter 100	

CONFIDENTIAL APPENDIX 1

Proposed Minor Modifications to the Corresponding Original Products

STN	Modification
EX0000213	Deletion of White Tipping Paper Ink
EX0000214	Addition of Cork-on-White Tipping Paper Ink

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections of the New Products and Projected Percentage of Future Cigarette Manufacturing in the United States Occupied by the New Products

STN	First-Year Projected Market Volume (Pieces)	Fifth-Year Projected Market Volume (Pieces)
EX0000213	(b) (4)	(b) (4)
EX0000214	(b) (4)	(b) (4)
Projected Manufacture of Cigarettes in United States ¹⁴	230.011 Billion	185.328 Billion
Projected Market Occupation of the New Product Based on Total Cigarettes Manufactured in the United States (%) ¹⁵	(b) (4)	(b) (4)

The projected market volumes of the new products in the first and fifth year of marketing comprise a small fraction of the estimated future cigarette manufacturing in the United States.

¹⁴ See section 5.1

¹⁵ *Projected Market Occupation of New Product in the United States (%) =*

$$\frac{\text{Projected Market Volume of the New Product (cigarette pieces)}}{\text{Projected Manufacture of Cigarettes in United States (cigarette pieces)}} \times 100\%$$

CONFIDENTIAL APPENDIX 3

First- and Fifth-Year Market Volume Projections of the New Products and Projected Percentage of Future Cigarette Use in the United States Occupied by the New Products

STN	First-Year Projected Volume (Pieces)	Fifth-Year Projected Volume (Pieces)
EX0000213	(b) (4)	(b) (4)
EX0000214	(b) (4)	(b) (4)
Projected Use of Cigarettes in United States ¹⁶	236.258 Billion	210.922 Billion
Projected Market Occupation of the New Products Based on Total Cigarettes Used in the United States (%) ¹⁷	(b) (4)	(b) (4)

The projected market volumes of the new products in the first and fifth year of marketing comprise a small percent of the estimated future use of cigarettes in the United States.

¹⁶ See section 5.2

¹⁷ $\text{Projected Market Volume of Use of New Product in the United States (\%)} = \frac{\text{Projected Market Volume of the New Product (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100\%$

CONFIDENTIAL APPENDIX 4

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 2018 and 2022. Projected waste generation is a summation of the projected waste of packaging components (i.e. waste of cardboard carton, and paper soft pack label, closure, foil inner liner, and plastic wrap of the retail box) and cigarette butts of the new product:

$\sum_{i=1}^2 A_i = \sum_{i=1}^2 (B_i + C_i + D_i + E_i + F_i)$ $B = \frac{G}{H} \times (I) \times S$ $C = \frac{G}{H} \times K \times S$ $D = \frac{G}{H} \times L \times S$ $E = \frac{G}{H \times M} \times N \times S$ $F = G \times O \times P \times S$ $P = \frac{Q}{R}$	<p><i>A</i>: Projected total waste generation of the product (metric tons) <i>B</i>: Projected waste generation of the retail pack paper label and closure of the new product (metric tons) <i>C</i>: Projected waste generation of the foil inner liner of the new product (metric tons) <i>D</i>: Projected waste generation of the plastic wrap of the new product (metric tons) <i>E</i>: Projected waste generation of the cardboard carton of the new product (metric tons) <i>F</i>: Projected waste generation of cigarette butts of the new product (metric tons) <i>G</i>: Projected market volume of the new product (number of individual cigarettes; also see Confidential Appendix 2) <i>H</i>: Number of cigarettes per soft pack = 20 <i>I</i>: Weight of the retail pack label paper (grams) <i>K</i>: Weight of the foil inner liner (grams) <i>L</i>: Weight of the plastic wrap (grams) <i>M</i>: Number of packs per carton = 10 <i>N</i>: Weight of empty cardboard carton (grams) <i>O</i>: Weight of cigarette (gram) <i>P</i>: Cigarette butt ratio <i>Q</i>: Cigarette butt length¹⁸ <i>R</i>: Length of cigarette (millimeter) <i>S</i>: 1.0 x 10⁻⁶ metric tons/gram</p>
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¹⁸ 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 of as solid waste following use.

a) Projected Waste of Packaging Material

Projected packaging waste is calculated as below:

Projected Year	STN	Projected market volume G	# of Cigarettes per box H	Weight of Retail pack paper label I	Retail pack paper waste B	# of packs per carton M	Weight of carton N	Cardboard Carton Waste E	Weight of foil K	Foil waste C	Weight of Plastic L _i	Plastic waste D
First-Year	EX0000213	(b) (4)	20	5.11	(b) (4)	10	19.73	(b) (4)	1.07	(b) (4)	0.36	(b) (4)
	EX0000214	(b) (4)	20	5.67	(b) (4)	10	21.94	(b) (4)	1.21	(b) (4)	0.39	(b) (4)
	Totals	(b) (4)			(b) (4)			(b) (4)		(b) (4)		(b) (4)
Fifth-Year	EX0000213	(b) (4)	20	5.11	(b) (4)	10	19.73	(b) (4)	1.07	(b) (4)	0.36	(b) (4)
	EX0000214	(b) (4)	20	5.67	(b) (4)	10	21.94	(b) (4)	1.21	(b) (4)	0.39	(b) (4)
	Totals	(b) (4)			(b) (4)			(b) (4)		(b) (4)		(b) (4)

If all the projected packaging waste generated from use of the new products is disposed of in landfills, the projected cumulative paper waste generated in the first and fifth years of marketing the new products would be (b) (4)) metric tons in 2018 and (b) (4)) metric tons in 2022. This is a negligible fraction of the 258.46 million tons (equivalent to 234.47 million metric tons) of total waste reported in the United States in 2014.¹⁹ Likewise, the projected plastic waste of (b) (4) metric tons in 2018 and (b) (4) metric tons in 2022 is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States 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 United States. If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed of in landfills (variable B and E 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.

¹⁹ 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 October 24, 2017).

b) Projected Waste of Cigarette Butts

Projected waste of disposed cigarette butts is calculated as below:

Projected Year	STN	Market volume G_i	Length of Cigarette R	Weight of Cigarette O	Waste of Cigarette Butt F
First-Year	EX0000213	(b) (4)	83	0.9621	(b) (4)
	EX0000214	(b) (4)	98	1.1441	(b) (4)
	Totals	(b) (4)			(b) (4)
Fifth-Year	EX0000213	(b) (4)	83	0.9621	(b) (4)
	EX0000214	(b) (4)	98	1.1441	(b) (4)
	Totals	(b) (4)			(b) (4)

If all the projected cigarette butt waste generated from use of the new product is disposed of in landfills, the projected waste of (b) (4) metric tons in 2018 and (b) (4) metric tons in 2022 will be a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.

CONFIDENTIAL APPENDIX 5

The Agency’s Estimated GHG Emissions in the First and Fifth Year of Marketing the New Product

a) GHG Emissions from Use of Product:

The amount of CO₂-equivalent (CO₂-eq) gases emitted from the use of one cigarette is estimated at 45-65 mg [8]. As a conservative approach, the Agency used the upper limit of CO₂ emitted per cigarette to calculate the GHG emissions from use of the new product.

GHG Emissions from Use of Product (metric tons of CO₂-eq) =

$$\text{Projected Market Volume of Product (cigarette)} \times 0.065 \text{gCO}_2 \text{ - eq/cigarette} \times 0.000001 \text{ metric tons/g}$$

Metric Tons of CO ₂ -eq		
STN	First-Year	Fifth-Year
EX0000213	(b) (4)	
EX0000214		

The estimated total GHG emission associated with marketing the new product is (b) (4) metric tons CO₂-eq in the first year and (b) (4) metric tons CO₂-eq in the fifth year after marketing the new product. This is a negligible fraction of the 6.87 billion metric tons of CO₂-eq reported in the United States in 2014 [6].

b) GHG Emissions from Disposal of New Product Following Use:

GHG emissions from the disposal of packaging and spent new product following use of the new product were calculated using the Waste Reduction Model (WARM), version 14 [9]. WARM is a calculation tool that estimates GHG emissions across different material types commonly found in municipal solid waste (MSW).

Metric Tons of CO ₂ -eq		
STN	First-Year	Fifth-Year
EX0000213	(b) (4)	
EX0000214		

Taking into account the rates for recycling and landfill disposal of various material types, the amount of GHG emissions from the disposal of packaging and products for the new product following use is a negligible fraction of the 115.7 million metric tons of CO₂-eq reported in the United States in 2015 [6].