

**Programmatic Environmental Assessment for Marketing
Orders for R.J. Reynolds Tobacco Company's "Camel Crush
Classic" and "Camel Crush Blue"**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

June 28, 2018

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This programmatic environmental assessment (PEA) is for the marketing orders for 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 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

R.J. Reynolds Tobacco Company

2. Address

2325 Bells Road
Richmond, VA 23235

3. Manufacturer

R.J. Reynolds Tobacco Company

4. Description of Proposed Actions

These proposed actions are for FDA to issue marketing orders under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of the combusted, filtered cigarettes, Camel Crush Classic and Camel Crush Blue, into interstate commercial distribution in the United States. The authorizations are based on the findings that these new products are substantially equivalent to the single predicate product that was on the market as of February 15, 2007. The applicant does not intend to market the new and predicate products simultaneously after receiving marketing orders for the new products.

4.1 Requested Actions

Orders finding the listed tobacco products are substantially equivalent to the predicate product.

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 claimed that the new products differ from the predicate product in product component (sec 910(a)(3)(A)(ii) of the FD&C Act) (Confidential Appendix 1). After considering the substantial equivalence (SE) reports (SE0014068 and SE0014069), the Agency shall issue orders pursuant to section 910(a)(2) of the FD&C Act when finding the new products to be substantially equivalent to the predicate product.

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

4.3.1 Type of Tobacco Products

Combusted, filtered cigarettes

4.3.2 Product Names and the Submission Tracking Numbers (STNs)

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

STN	New Product	Predicate Product
SE0014068	Camel Crush Classic	Camel Light Box with Menthol Capsule
SE0014069	Camel Crush Blue	Camel Light Box with Menthol Capsule

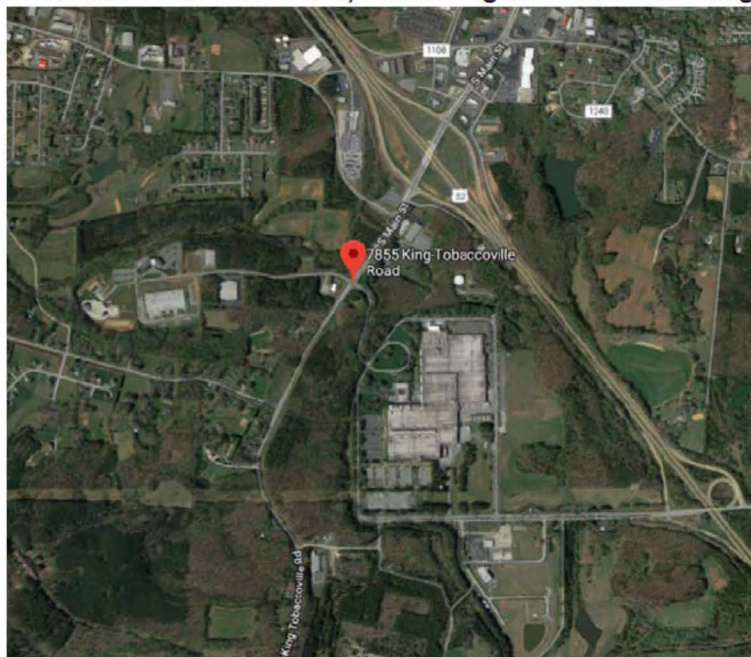
4.3.3 Description of the Product Package

The new products are packaged 20 cigarettes in each pack. The cigarettes are wrapped in a foil inner liner and surrounded by a pack paper board. The packs are enclosed in polypropylene film overwrap with a piece of tear tape attached. 10 finished packs are inserted into each carton, which is composed of bleached sulphate board. 60 cartons are placed into each shipping case, which is composed of unbleached kraft paper.

4.3.4 Location of Manufacturing

The manufacturer of the combusted, filtered cigarettes is located at 7855 King-Tobaccoville Road, Tobaccoville, NC 27050 (Figure 1).

Figure 1. Location of the Combusted, Filtered Cigarette Manufacturing Facility¹



¹ Manufacturer address via Google Map. Accessed January 16, 2018.

4.3.5 Location of Use

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

4.3.6 Location of Disposal

Once used, the new tobacco products will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the predicate product and any other combusted, filtered cigarettes. Disposal of the packaging materials will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates that 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 Predicate Product

The applicant claims that the new products differ from the predicate product in product component. Details of product changes are described in Confidential Appendix 1.

5. Potential Environmental Impacts Due to the Proposed Actions

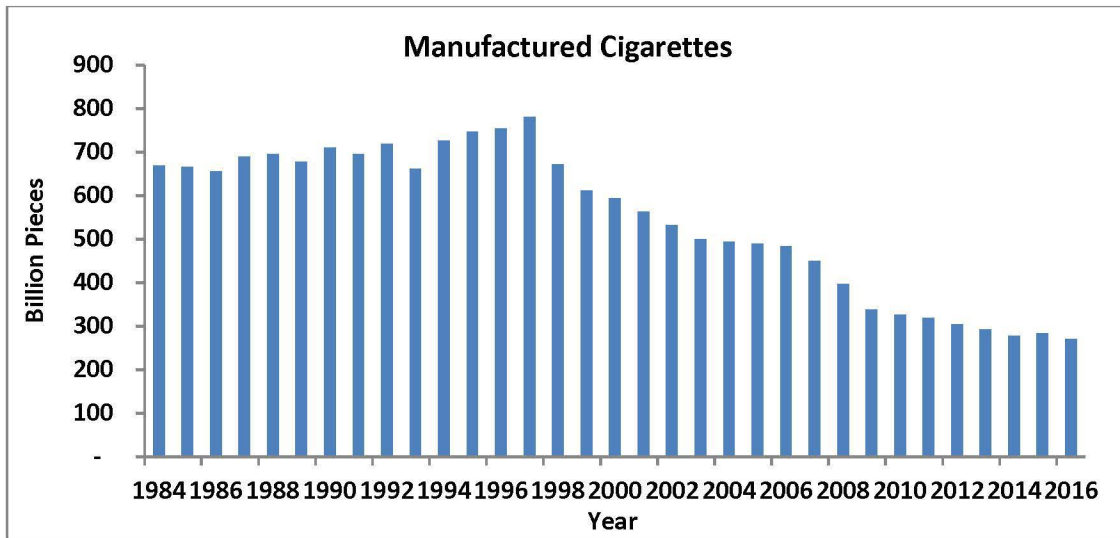
5.1 Potential Environmental Impacts Due to Manufacturing the New Products

According to the Tobacco Statistical Release reports of the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), the production of cigarettes decreased from 669 billion pieces in 1984 to 270 billion pieces in 2016 (Figure 2).² As of January 2018, a total of 2,524 tobacco establishments are registered under 915(c) of the FD&C Act.³ As of January 2018, there are 31 different tobacco manufacturers, including R.J. Reynolds Tobacco Company, registered as a participating manufacturer under the Master Settlement Agreement in the State of North Carolina (North Carolina Department of Justice, 2018) and 14 were registered as a non-participating manufacturer.

² U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed January 9, 2018.

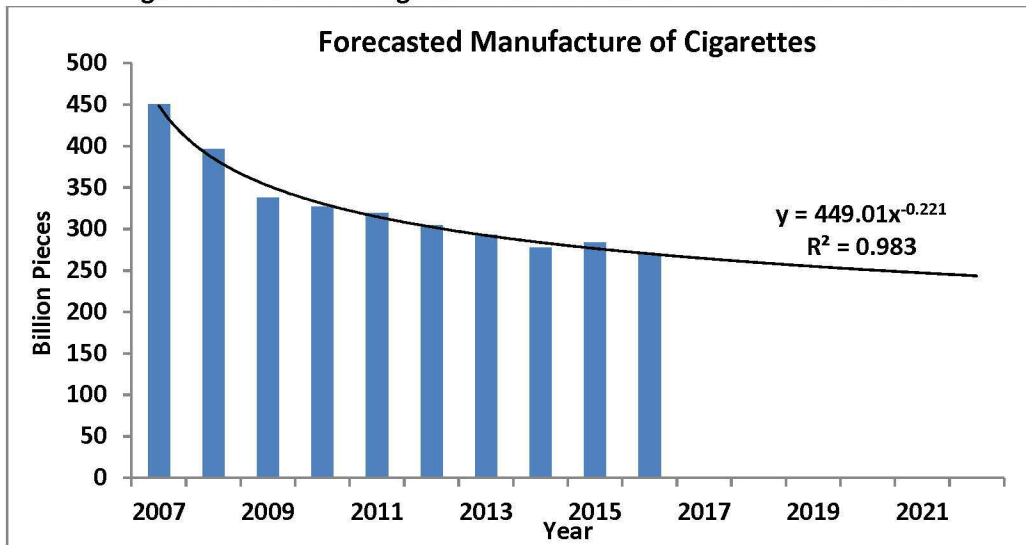
³ Based on FDA's Establishment Registration & Tobacco Product Listing Database. Available at <https://www.accessdata.fda.gov/scripts/ctpocerl/index.cfm?action=main.home>. Accessed January 8, 2018.

Figure 2. Total Manufactured Cigarettes in the United States in 1984-2016



The applicant provided the first- and fifth-year market volume projections for the new products (Confidential Appendix 2). To evaluate the environmental impact of the proposed actions due to manufacturing the new products, historical data regarding the manufacture of cigarettes in the United States from 2007 to 2016 was used to forecast the manufacture of cigarettes. This was achieved by using one best-fit power trend line with the R^2 value of 0.983.⁴ Accordingly, the forecasted number of cigarettes to be manufactured in the United States is estimated to be 264 billion pieces in 2018 and 247 billion pieces in 2022 (Figure 3).

Figure 3. Forecast of Cigarettes Manufactured in the United States



Comparing the projected market volumes of the new products with the forecasted market volume of cigarettes in 2018 and 2022, the cumulative projected market volumes of the new products are small

⁴ Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed on January 9, 2018. Note: 2017 annual TTB values have not been released. Since the SE Reports were received in 2017, the first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

fractions of the total forecasted market volume in 2018 and 2022 (Figure 3 and Confidential Appendices 2 and 3). Additionally, the applicant stated that manufacturing the new products would not require any new equipment at the manufacturing facility and no expansion of the manufacturing facility is anticipated for manufacturing the new products.

The applicant stated that the new products will be manufactured in the same manner as the predicate product and additional resources (e.g., landfills, recycling centers) will not be required for the disposal of waste generated from manufacturing the new products. The applicant also stated that the waste generated from manufacturing the new products will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as other products manufactured in the same manufacturing facility and other similar products.

The emission information associated with the U.S. manufacturing of all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available. The Agency uses TRI data to assess the environmental impacts from the emissions released by tobacco manufacturing facilities. In 2016, the R.J. Reynolds Tobaccoville facility released 10,030 pounds of ammonia and 18,909 pounds of nicotine and nicotine salts to the air and 1 pound of ammonia and 3 pounds of nicotine and nicotine salts to the land. In comparison, reporting facilities in the United States released 406,453 pounds of ammonia and 253,436 pounds of nicotine and nicotine salts to the air and 1 pound of ammonia and 74,323 pounds of nicotine and nicotine salts to the land. The R.J. Reynolds Tobaccoville facility also transferred 493 pounds of ammonia and 4,409 pounds of nicotine and nicotine salts off-site for landfill disposal and waste management. In comparison, U.S. reporting tobacco facilities transferred 35,063 pounds of ammonia and 463,441 pounds of nicotine and nicotine salts off-site.

The applicant stated that because the minor modifications are not expected to materially affect any other characteristics of the new products and because the proposed fire standard compliant cigarette paper is commonly used throughout the cigarette industry, manufacturing the new products will not result in emissions of new or additional compounds. The applicant also stated that manufacturing the new products will not require additional environmental controls for air emissions, water discharge, or solid waste disposal. Furthermore, the applicant stated compliance to all applicable federal, state, and local environmental regulations and maintenance of permits for air quality, storm water and wastewater discharges, and hazardous waste (Table 1).

Table 1. Environmental Permits Maintained by R.J. Reynolds Tobaccoville Facility

Permit	Permit Number	Issued by	Status
Title V Air Quality	00745-TV-38	Forsyth County, Office of Environmental Assistance and Protection, Winston-Salem, NC	Draft, October 31, 2017
National Pollutant Discharge Elimination System (NPDES)	NCG060079	North Carolina Department of Environmental Quality	Expires October 31, 2018
Resource Conservation and Recovery Act (RCRA)	NCD982076739	North Carolina Department of Environmental Quality	N/A

The applicant provided the annual energy used at the manufacturing facility (Confidential Appendix 2). The applicant stated that manufacturing the new products will not result in additional energy use because an expansion of the manufacturing facility or additional or new equipment is not expected. Additionally, the applicant stated that the energy used to manufacture the new products will not differ from that used to manufacture other combusted cigarette products at the manufacturing facility. The applicant also claimed that any potential incremental increase in energy used resulting from the manufacture of the new products will be offset to reduce overall energy use to align with the company's sustainability strategies. Furthermore, the applicant provided a sustainability report that summarized efforts to reduce energy intensity, water use, and greenhouse gas (GHG) emissions, and increase recycling of waste. Because the new products will compete with other currently marketed cigarettes, no different or increase in GHG emissions is anticipated from the proposed actions. Additionally, the estimated GHG emissions for manufacturing the new products, the GHG emitted associated with manufacturing the new products is miniscule compared to total GHG emissions reported in the United States (Confidential Appendix 2).

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

According to the TTB Statistical Release reports, the use of cigarettes in the United States decreased from 599 billion pieces in 1984 to 257 billion pieces in 2016 (Figure 4)⁵ (U.S. Dept of Treasury Alcohol and Tobacco Tax and Trade Bureau, 2018).

To evaluate the environmental impact of the proposed actions due to use of the new products, the Agency analyzed historical use data for 2004-2016 to forecast the future use of cigarettes in the United States. This was achieved by using one best-fit exponential trend line with the R^2 value of 0.9689.⁶ Accordingly, the forecasted number of cigarettes to be consumed in the United States is estimated to be 240 billion pieces in 2018 and 205 billion pieces in 2022 (Figure 5).

⁵ U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed January 9, 2018.

⁶ Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed on January 9, 2018. Note: 2017 annual TTB values have not been released. Since the SE Reports were received in 2017, the first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

Figure 4. Use of Cigarettes in the United States in 1984-2016

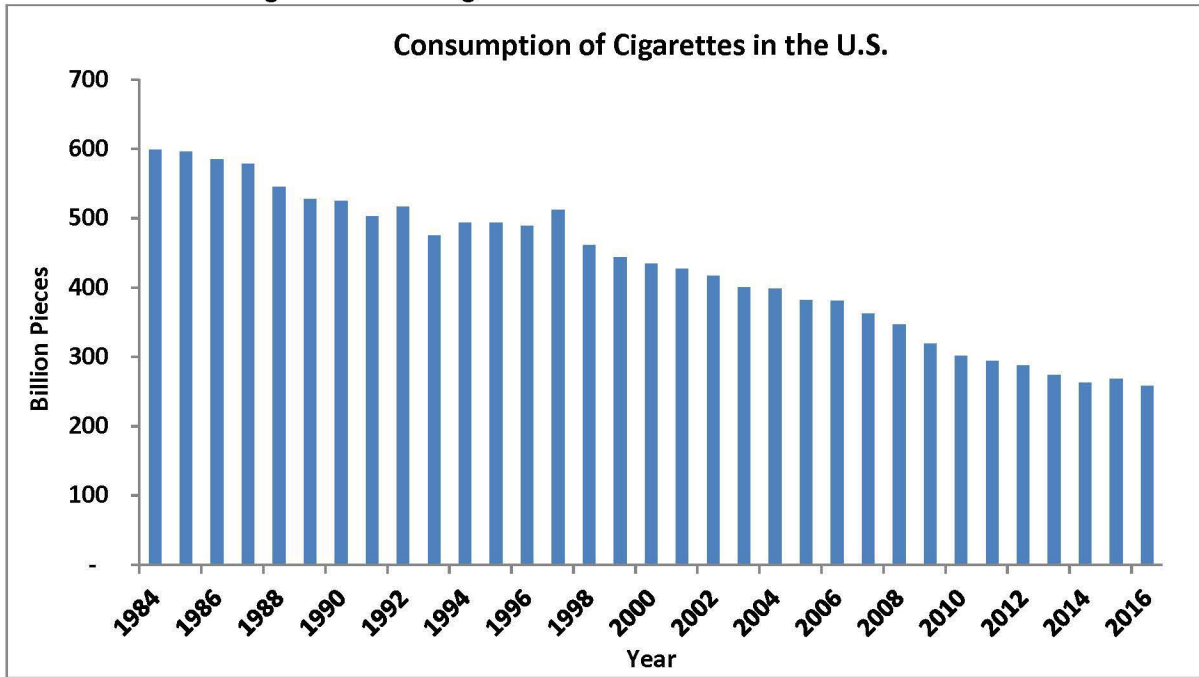
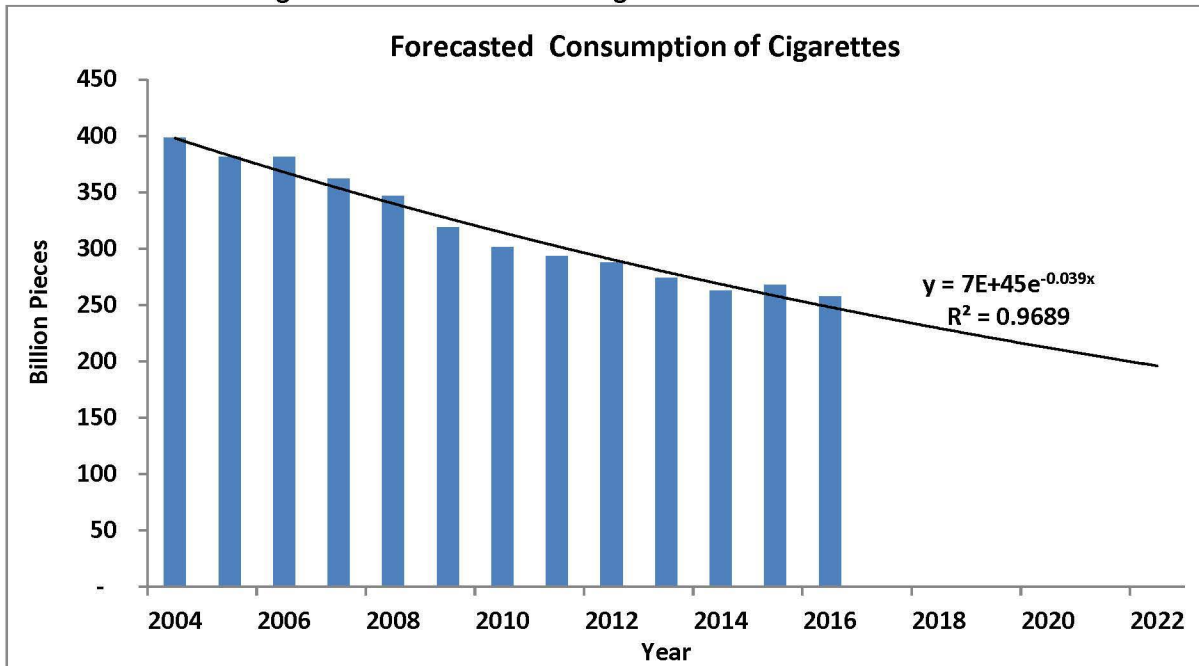


Figure 5. Forecasted Use of Cigarettes in the United States



Because the new products are expected to compete with other cigarettes on the market, the Agency anticipates minimal or no net increase in the use of all cigarettes (Confidential Appendix 4). Additionally, the new products are used in a similar manner to the predicate product and other cigarette products. Subsequently, the Agency does not anticipate new substances to be released into the environment from the use of the new cigarette products, relative to the substances released by other similar products already on the market.

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

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

5.3.1 Disposal of Packaging Material

Packaging materials 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 tobacco products, can be informative about the disposal of packaging materials associated with tobacco products. In 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 6 and 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. Of the total plastic MSW generated at 33.25 million tons, 3.17 million tons (9.5%) was recycled, 25.10 million tons (75.5%) was disposed of in landfills, and 4.98 million tons (15.0%) was combusted with energy recovery. On average, 4.4 pounds per person of waste was generated, of which 2.1 pounds was recycled, composted, or combusted for energy recovery in the United States in 2014 (U.S. Environmental Protection Agency, 2016).

Figure 6. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

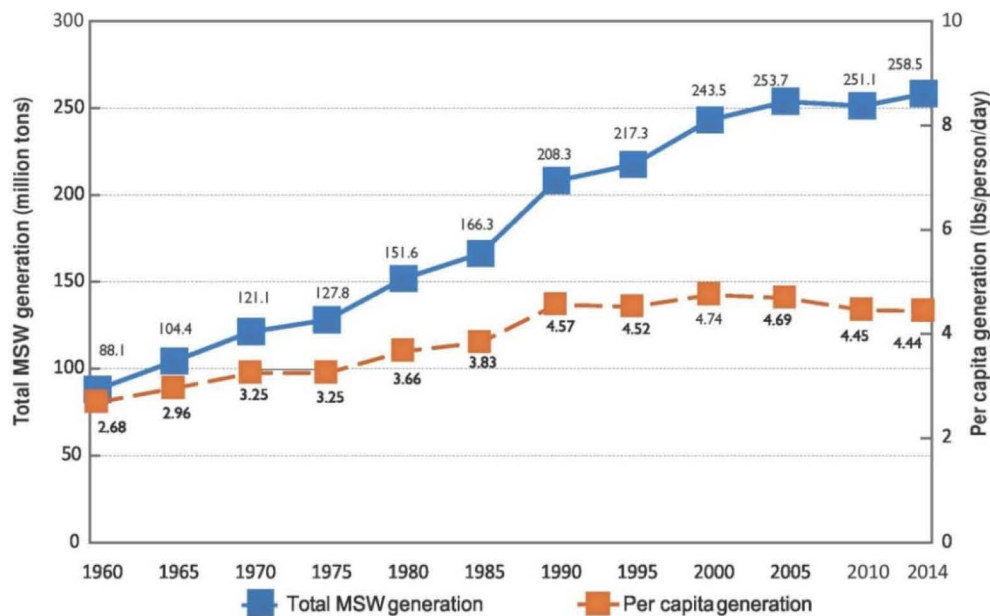


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 7. MSW Recycling Rates in the United States, 1960-2014

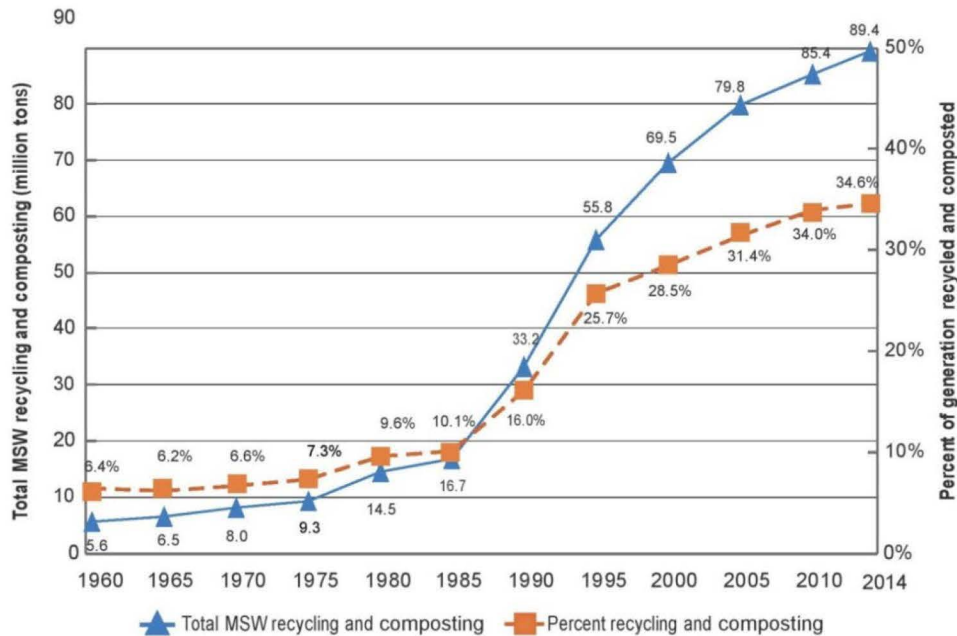


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the packaging materials associated with the new products will be to the same as the disposal conditions of similar cigarette products that are currently being marketed. After using the new product, users may recycle or dispose of the packaging material as MSW or litter.

To determine the amount of waste due to disposal of the packaging material, the Agency used the projected market volumes in the first and fifth years after issuance of marketing orders for the new products. The calculated waste of the packaging materials of the new products were determined to be miniscule compared to the forecasted MSW to be generated in the United States (Confidential Appendix 5).

As previously discussed, the new tobacco products will compete with similar cigarette products on the market. Based on that and the above-mentioned information regarding waste, construction of POTWs or landfills due to disposal of the new products' packaging material is not anticipated.

5.3.2 Discarding of the Used Cigarettes

Cigarette butt waste may have an end-of-life-cycle scenario as either managed or unmanaged waste. Managed waste is handled by an organized solid waste collection and management system. For the managed waste, 80.4% by weight enters landfills and the remaining 19.6% by weight is incinerated for energy recovery (U.S. Environmental Protection Agency, 2016). The Agency used the projected market volumes for the first and fifth years of marketing to estimate the waste from discarding used products (cigarette butts). The estimated waste from cigarette butt disposal as MSW would be miniscule compared to the total forecasted MSW in the United States (Confidential Appendix 5). As noted, the new combusted, filtered cigarette products will compete with similar combusted, filtered cigarette products on the market. The estimates described above and detailed in Confidential Appendix 5 indicate a negligible contribution to U.S. MSW. As such, construction of new solid waste landfills or incinerators is not anticipated due to the disposal of used products under the proposed actions.

Unmanaged waste consists of littered cigarette butts. The environmental effects of cigarette butt litter have been summarized as follows (Novotny, et al., 2015):

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide... The biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste... Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Introducing the new products into the U.S. market is not expected to increase the nationwide use of combusted, filtered cigarettes; instead, they would compete for market share with existing products. Therefore, authorizing of the new products is not expected to affect the overall level of cigarette butt litter in the United States.

5.3.3 Air Emissions

Landfill disposal or incineration of the used products and packaging materials will produce GHGs (U.S. Environment Protection Agency, 2017).

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. Global CH₄ emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related CH₄ emissions in the United States, releasing an estimated 115.7 million metric tons of CO₂-equivalents, accounting for approximately 15.4% of total CH₄ emissions in 2015 (Intergovernmental Panel On Climate Change (IPCC), 2017). The decomposition of landfill waste produces approximately 50% biogenic CO₂ and 50% CH₄, by volume, as well as trace amounts of non-methane 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 (Intergovernmental Panel On Climate Change (IPCC), 2017).

Noting again that the new products will compete with currently marketed cigarettes. Additionally, the waste generated from using the new products is expected to make up a negligible fraction of the total MSW (Confidential Appendix 5). Therefore, the GHG emitted from the waste associated with the new products is negligible, based on the estimation of GHG emissions from the disposal of the new products (Confidential Appendix 6) in this PEA. Furthermore, the Clean Air Act requires that all landfills constructed or modified after July 17, 2014 with 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. Therefore, no additional control of GHG emissions is anticipated in the landfills.

6. Use of Resources and Energy

The applicant provided the annual energy use at the manufacturing facility (Confidential Appendix 2). The applicant stated that manufacturing the new products will not result in additional energy used because neither an expansion of the manufacturing facility nor an addition of any new manufacturing equipment is expected. Additionally, the applicant stated that the energy used to manufacture the new

products will not differ from that used to manufacture other combusted cigarette products at the manufacturing facility. The applicant also claimed that any potential incremental increase in energy use resulting from the manufacture of the new products will be offset to reduce overall energy use to align with the company's sustainability strategies. Furthermore, because the new products will compete with other currently marketed cigarettes, no different or increase in GHG emissions is anticipated from the proposed actions.

The applicant conducted a review with U.S. Fish & Wildlife Services and Appendices I, II, and III of the Convention in International Trade in Endangered Species (CITES) and confirmed that the Tobaccoville manufacturing facility is not within or near a habitat, critical or otherwise, of a threatened or endangered species. The applicant also stated the materials used to manufacture the new products are in compliance with the Endangered Species Act (ESA) and CITES. Additionally, the applicant claimed has not identified any adverse effects specific to a species or the critical habitat of a species identified under ESA and CITES associated with the manufacture and commercial distribution of the predicate product.

7. Mitigation

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

8. 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 United States. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal of tobacco products as many other similar cigarette products will continue to be marketed.

Alternative B (Proposed actions): There is no substantial environmental effect due to the proposed actions of authorizing the new products (Confidential Appendices 2, 3, and 4) and associated manufacture, use, and disposal of the new tobacco products.

9. 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:⁷

Primary reviewer:

Catherine W. McCollum, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biochemistry and Cell Biology

Experience: 4 years in NEPA practice, 11 years in various scientific activities

⁷ The reviewer completed the final edits to the EA as the primary preparer had left the Agency before the document was finalized.

Expertise: NEPA analysis, environmental impact analysis, ecotoxicity, developmental toxicology

Reviewer:

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

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

Experience: 9 years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

10. List of Agencies and Persons Consulted

Not applicable.

11. Appendix List

Appendix 1: Submission Tracking Numbers and Related Amendments for the SE Reports and Package Sizes of the New and Predicate Products Covered Under this Programmatic Environmental Assessment (PEA)

12. Confidential Appendix List

Confidential Appendix 1: Modifications between the New Products and the Single Predicate Product

Confidential Appendix 2: The First- and Fifth-Year Market Volume Projections of the New Products and Energy Use

Confidential Appendix 3: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarette Products Used in the United States

Confidential Appendix 4: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarette Products Manufactured in the United States

Confidential Appendix 5: The First- and Fifth-Year Projection of Waste of Packaging Materials and Cigarette Butts Associated with Marketing the New Products

Confidential Appendix 6: Estimated Greenhouse Gas Emissions in the First and Fifth Years of Marketing the New Products

13. References

Action Research. (2009). *Littering Behavior in America: Results of a National Study*. Retrieved from Keep America Beautiful:
https://www.kab.org/sites/default/files/News%26Info_Research_LitteringBehaviorinAmerica_2009Report_Final.pdf

Geiss, O. D. (2007). Tobacco, Cigarettes and Cigarette Smoke: An Overview. *European Commission, Directorate-General Joint Research Centre, Institute for Health and Consumer Protection*.

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- North Carolina Department of Justice. (2018, January 17). *Tobacco Lists*. Retrieved from <http://www.ncdoj.gov/getdoc/e0a9feb0-7adc-48da-8e85-8107d8fd53b8/3-1-17-PMBrandsListbyManuf.aspx>
- Novotny, T., Aguinaga Bialous, S., Burt, L., Curtix, C., da Costa, V., Usman Iqtidar, S., . . . d'Espaignet, E. (2015). The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. *Bull World Health Organ*, 93(12), 877-880.
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- U.S. Environmental Protection Agency. (2016). *Advancing Sustainable Material Management: Facts and Figures*. Retrieved from https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf
- U.S. Environmental Protection Agency. (2017). *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015*. Retrieved from https://www.epa.gov/sites/production/files/2017-02/documents/2017_complete_report.pdf
- U.S. Environmental Protection Agency. (2018, January 23). Retrieved from Exposure Factors Handbook 2011 Edition (Final Report): <https://cfpub.epa.gov/ncea/risk/recorddisplay.cfm?deid=236252>
- U.S. Environmental Protection Agency. (2018, January 23). *Waste Reduction Model (WARM)*. Retrieved from <https://www.epa.gov/warm/versions-waste-reduction-model-warm#WARM%20Tool%20V14>

APPENDIX 1

Submission Tracking Numbers and Related Amendments for the SE Reports and Package Sizes of the New and Predicate Products Covered Under this Programmatic Environmental Assessment (PEA)

STN	New Product	Predicate Product	Packaging Size			Amendments
			Sticks/Pack	Packs/Carton	Cartons/ Shipping Case	
SE0014068	Camel Crush Classic	Camel Light Box with Menthol Capsule	20	10	60	SE0014322, SE0014447
SE0014069	Camel Crush Blue	Camel Light Box with Menthol Capsule	20	10	60	

CONFIDENTIAL APPENDIX 1

Modifications between the New Products and the Single Predicate Product

Component	Unit of Measure	New	Predicate
Cigarette Paper	mg/cig	Fire standard compliant (FSC); Target: (b) (4)	Non-fire standard compliant (non-FSC); (b) (4)
Monogram (Barrel) Ink, Gold	mg/cig	N/A	Target: (b) (4)
Tobacco Blend – (b) (4)	mg/cig	Target: (b) (4)	Target: (b) (4)
Tobacco Blend – (b) (4)	mg/cig	N/A	Target: (b) (4)

Due to the change from non-FSC paper in the predicate product to FSC paper in the new products, the table below lists the cigarette paper ingredient modifications.

Cigarette Paper Component	Function	New		Predicate	
		% of Formulation	mg/cig	% of Formulation	mg/cig
(b) (4)	Fiber	(b) (4)			
	Filler	(b) (4)			
	Combustion modifier	N/A	N/A	(b) (4)	(b) (4)
	Combustion modifier	N/A	N/A	(b) (4)	(b) (4)
	Combustion modifier	N/A	N/A	(b) (4)	
	Binder	N/A	N/A	(b) (4)	
	-	N/A	N/A	(b) (4)	
	Combustion modifier	(b) (4)		N/A	N/A
	Combustion modifier	(b) (4)		N/A	N/A
	Binding agent	(b) (4)		N/A	N/A
	Banding material	(b) (4)		N/A	N/A

CONFIDENTIAL APPENDIX 2

The First- and Fifth-Year Market Volume Projections of the New Products and Energy Use

STN	Number of Cigarettes	
	First-Year Market Volume	Fifth-Year Market Volume
SE0014068	(b) (4)	(b) (4)
SE0014069	(b) (4)	(b) (4)

The applicant stated that the energy used to manufacture the new products is expected to be the same as that for any other combusted cigarette product manufactured by R.J. Reynolds Tobacco Company. The applicant stated that the manufacturing facility does not meter energy use for each manufacturing process; however, the average energy used per one individual cigarette manufactured was approximated and scaled to further estimate the potential energy used to manufacture the new products (see table below). The applicant also stated that of the total estimated annual energy used to manufacture the new products (b) (4) is anticipated to be purchased electricity and (b) (4) used per new product. Purchased electricity is sourced from (b) (4) which reportedly produces 1% of their electricity from renewable sources (0.1% solar, 0.9% hydro), while natural gas is sourced from (b) (4).

Type of Energy	Supplier	Unit of Measure	Used in 2016	Estimated Average Energy Used Manufacturing One Individual Cigarette	Estimated Annual Energy Used Manufacturing the New Products		Metric Tons Carbon Dioxide-Equivalent of GHG Emissions for Manufacturing the New Products ⁹
					SE0014068	SE0014069	
Electricity	(b) (4)	Kilowatt-hours	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Natural Gas	(b) (4)	MCF (thousands of cubic feet)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Total GHG Emissions							(b) (4)

Using the EPA Greenhouse Gas Equivalencies Calculator⁸, manufacturing the new products would generate a total of (b) (4) metric tons carbon dioxide-equivalents (CO₂-eq) of GHG emissions. This is a negligible fraction (b) (4) of the total gross U.S. GHG emissions of 6.59 billion metric tons of CO₂-eq reported in 2015 (U.S. Environmental Protection Agency, 2017).

⁸ U.S. Environmental Protection Agency. Energy and the Environment. Greenhouse Gas Equivalencies Calculator. Available at <https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator>. Accessed January 17, 2018.

CONFIDENTIAL APPENDIX 3

Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarette Products Manufactured in the United States

The portion of cigarettes manufactured in the United States that will be accounted for by the new products in the first and fifth years after issuance of the marketing orders was determined by comparing the projected market volumes of the new products to the forecasted manufacture of total cigarettes in the United States (Figure 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.⁹

First Year Market Occupation of New Products (%)

$$= \frac{\text{First-Year Market Volume Projection}}{\text{Forecasted Manufacture of Cigarettes in the U.S. for 2018}} \times 100\%$$

Fifth Year Market Occupation of New Products (%)

$$= \frac{\text{Fifth-Year Market Volume Projection}}{\text{Forecasted Manufacture of Cigarettes in the U.S. for 2022}} \times 100\%$$

STN	Year	Forecasted Manufacture of Cigarettes in the United States ¹⁰ (# of cigarettes)	Projected Market Volume of New Products ¹¹ (# of cigarettes)	Projected Cigarette Market Occupation of New Products (%)
SE0014068	First	264,306,735,060	(b) (4)	
	Fifth	246,796,982,329		
SE0014069	First	264,306,735,060		
	Fifth	246,796,982,329		

⁹ 2017 annual TTB values have not been released. Since the SE Reports were received in 2017, the first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

¹⁰ See Figure 3.

¹¹ See Confidential Appendix 2.

CONFIDENTIAL APPENDIX 4

Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarette Products Used in the United States

The portion of cigarettes used in the United States that will be attributed to the new products was similarly determined by comparing the projected market volumes of the new products to the forecasted use of total cigarettes in the United States. (Figure 5, and Confidential Appendix 2). The percent of the total cigarette market occupied in the projected first and fifth years of marketing the new products was calculated using the equations below.¹²

First Year Market Occupation of New Products (%)

$$= \frac{\text{First-Year Market Volume Projection}}{\text{Forecasted Use of Cigarettes in the U.S. for 2018}} \times 100\%$$

Fifth Year Market Occupation of New Products (%)

$$= \frac{\text{Fifth-Year Market Volume Projection}}{\text{Forecasted Use of Cigarettes in the U.S. for 2022}} \times 100\%$$

STN	Year	Forecasted Use of Cigarettes in the United States ¹³ (# of cigarettes)	Projected Market Volume of New Products ¹⁴ (# of cigarettes)	Projected Cigarette Market Occupation of New Products (%)
SE0014068	First	239,849,319,526	(b) (4)	
	Fifth	205,205,289,624		
SE0014069	First	239,849,319,526		
	Fifth	205,205,289,624		

¹² 2017 annual TTB values have not been released. Since the SE Reports were received in 2017, the first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

¹³ See Figure 5.

¹⁴ See Confidential Appendix 2.

CONFIDENTIAL APPENDIX 5

The First- and Fifth-Year Projection of Waste of Packaging Materials and Cigarette Butts Associated with Marketing the New Products

To analyze the environmental effects from waste due to the proposed actions, the Agency estimated the first- and fifth-year weights of the projected packaging materials waste (in metric tons) that are generated from disposal of the products in 2018 and 2022. Projected total waste is the summation of the projected paper and plastic waste generation of the products. Projected total paper waste is the summation of the projected recyclable (shipping case, carton, cigarette pack innerframe, and outerframe) and non-recyclable (cigarette pack innerliner) paper waste generation of the products. Projected plastic waste is the non-recyclable cigarette pack film overwrap of the products.

$$\sum_{i=1}^2 A_i = \sum_{i=1}^2 (B_i + C_i)$$

$$B_i = \sum_{i=1}^2 (D_i + E_i)$$

$$C_i = \frac{F_i}{G} \times K_i \times Z$$

$$D_i = \left\{ \left[\frac{F_i}{G} \times (H_i + I_i) \right] + \left(\frac{F_i \times M_i}{G \times L} \right) + \left(\frac{F_i \times O_i}{G \times L \times N} \right) \right\} \times Z$$

$$E_i = \frac{F_i}{G} \times J_i \times Z$$

$$Q = \frac{S_i}{T_i} \times 100$$

$$P_i = F \times R_i \times \frac{Q}{100} \times Z$$

- A_i : Projected total waste generation of the products (metric tons)
- B_i : Projected paper waste generation of the products (metric tons)
- C_i : Projected plastic waste generation of the products (metric tons)
- D_i : Projected recyclable paper waste generation of the products (metric tons)
- E_i : Projected non-recyclable paper waste generation of the products (metric tons)
- F_i : Projected market volumes of the products
- G : Number of cigarettes per cigarette pack
- H_i : Weight of empty cigarette pack outerframe (grams)
- I_i : Weight of cigarette pack innerframe (grams)
- J_i : Weight of cigarette pack foil innerliner (grams)
- K_i : Weight of cigarette pack film overwrap (grams)
- L : Number of cigarette packs per empty carton
- M_i : Weight of empty carton (grams)
- N : Number of cartons per shipping case
- O_i : Weight of empty shipping case (grams)
- P_i : Projected cigarette butt waste (metric tons)
- Q : Cigarette butt ratio (%)
- R_i : Weight of cigarette (grams)
- S_i : Length of cigarette butt (millimeters)¹⁵
- T_i : Length of cigarette (millimeters)
- Z : 1.0×10^{-6} metric tons/gram

a) Projected Waste of Packaging Material

¹⁵ Cigarette butt length (mm): For filtered cigarettes: the greatest of 23mm, length of filter + 8mm, or length of overwrap + 3mm, from draft 2015 revisions to ISO 3308 intense smoking regimen (section 7.2.1).

Year	STN	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
First	SE0014068	671.5	60	18.8	10	0.37	1.07	0.79	4.84	20	(b) (4)					
	SE0014069	671.5	60	18.8	10	0.37	1.07	0.79	4.84	20						
Total First-Year												(b) (4)				
Fifth	SE0014068	671.5	60	18.8	10	0.37	1.07	0.79	4.84	20	(b) (4)					
	SE0014069	671.5	60	18.8	10	0.37	1.07	0.79	4.84	20						
Total Fifth-Year												(b) (4)				

The shipping case, carton, and cigarette pack innerframe and outerframe are disposed of, recycled, or both, as paper waste; the cigarette pack foil innerliner, which is machine glazed paper laminated to aluminum foil, is disposed of as waste or litter. Estimation of generated total paper waste for the new products is (b) (4) metric tons in the first year of marketing the new products and (b) (4) metric tons in the fifth year. A portion of the shipping case waste is likely to be recycled with an overall recycling rate for paper products at 64.7% in the United States, according to the EPA (U.S. Environmental Protection Agency, 2016). Therefore, if 100% of the cigarette pack foil innerliner and 35.3% of the recyclable paper waste are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative paper waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new products.¹⁶ The cigarette pack film overwrap is disposed of as waste or litter. Estimation of generated total plastic waste for the new products is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year.

With the conservative approach of assuming the entire packaging paper and plastic components are disposed of as waste the projected cumulative paper and plastic waste in the first and fifth years of marketing the new products are (b) (4) metric tons and (b) (4) metric tons, respectively. These are negligible fractions of the 234.47 million metric tons of total waste reported in the United States in 2014.

¹⁶ At 35.3% disposal rate as paper waste (on shipping cases, carton, and cigarette pack innerframe and outerframe) for the 1st Year, (b) (4) metric tons) + (b) (4) metric tons; 5th Year, (b) (4) metric tons) + (b) (4) metric tons.

b) Projected Waste of Cigarette Butts

Year	STN	T	S	R	F	Q	P
First	SE0014068	83	35	0.9618	(b) (4)	42	(b) (4)
	SE0014069	83	35	0.9601	(b) (4)	42	
Total First-Year							
Fifth	SE0014068	83	35	0.9618	(b) (4)	42	
	SE0014069	83	35	0.9601	(b) (4)	42	
Total Fifth-Year							

Cigarette butts are disposed of as litter or MSW. A littering rate of 34% was estimated for cigarettes based on human exposure factors and littering behavior (Action Research, 2009; U.S. Environmental Protection Agency, 2018). If 34% of the total cigarette butt waste was disposed of as litter, the projected littered cigarette butt waste is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year¹⁷, while the projected cigarette butt waste disposed of as MSW is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new products. If the entire projected cigarette butt waste generated from the use of the products is disposed of in landfills, the projected cigarette waste in the first year of marketing is (b) (4) metric tons and in the fifth year of marketing the new products (b) (4) metric tons. These are negligible fractions of the 234.47 million metric tons of total waste reported in the United States in 2014.

¹⁷ At 34% disposal rate as litter for the 1st Year, (b) (4) metric tons; 5th Year, (b) (4) metric tons.

CONFIDENTIAL APPENDIX 6

Estimated Greenhouse Gas Emissions in the First and Fifth Years of Marketing the New Products

a) Greenhouse Gas (GHG) Emissions from Use of the Products:

The amount of CO₂-equivalent (CO₂-eq) gases emitted from the use of one cigarette is estimated at 45-65 mg (Geiss, 2007). 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 products.

$$\begin{aligned} \text{GHG Emissions from Use of Product (metric tons of CO}_2\text{-eq.)} = \\ \text{Projected Market Volume of Product (cigarette)} \times 0.065 \text{ gCO}_2 \\ - \text{eq/cigarette} \times 0.000001 \text{ metric tons/g} \end{aligned}$$

Metric Tons of CO ₂ -eq		
STN	First Year	Fifth Year
SE0014068	(b) (4)	
SE0014069		
Total		

The estimated total GHG emissions generated from use of the new products are (b) (4) metric tons CO₂-eq in the first year and (b) (4) metric tons CO₂-eq in the fifth year. These are negligible fractions (b) (4) (%) of the total gross U.S. GHG emissions at 6.59 billion metric tons of CO₂-eq reported in 2015 (U.S. Environmental Protection Agency, 2017).

b) GHG Emissions from Disposal of the Products:

GHG emissions for the new products from the disposal of packaging and the used product were calculated using the Waste Reduction Model (WARM), version 14 (U.S. Environmental Protection Agency, 2018). WARM is a calculation tool that estimates GHG emissions across different material types commonly found in MSW.

Metric Tons of CO ₂ -eq		
STN	First Year	Fifth Year
SE0014068	(b) (4)	
SE0014069		
Total		

Considering the rates for recycling and MSW landfill disposal of various material types, the total amount of GHG emissions from the disposal of packaging and used product for the new products was estimated. The recycling rate of paper was considered for entries into the WARM model to reduce the landfill input; however, the metric tons recycled was not entered into the model because the intent is to determine the GHG emissions associated with MSW generation. The total amount of GHG emissions from the disposal of packaging and used product for the new products is estimated at (b) (4) metric tons of CO₂-eq for the first year and (b) (4) metric tons of CO₂-eq for the fifth year. These estimates are negligible fractions (b) (4) (%) of the 115.7 million metric tons of CO₂-eq of landfill CH₄ emissions reported in the United States in 2015 (U.S. Environmental Protection Agency, 2017).