Environmental Assessment for Marketing Orders for Eleven New Smokeless Tobacco Products Manufactured by U.S. Smokeless Tobacco Company LLC

Prepared by Center for Tobacco Products
U.S. Food and Drug Administration

September 11, 2019

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1. Applicant and Manufacturer Information

Applicant Name	Altria Client Services LLC
Applicant Address	2325 Bells Road Richmond, VA 23234
Manufacturer Name	U.S. Smokeless Tobacco Company LLC
Product Manufacturing Address	800 Harrison Street Nashville, TN 37203 2303 Bells Road Richmond, VA 23234

2. Product Information

New Product	STN	Predicate Product
Red Seal Fine Cut Wintergreen	SE0004825	Red Seal Fine Cut Wintergreen (2007)
Red Seal Long Cut Mint	SE0004826	Red Seal Long Cut Mint (2007)
Red Seal Long Cut Natural	SE0004827	Red Seal Long Cut Natural (2007)
Red Seal Long Cut Straight	SE0004828	Red Seal Long Cut Straight (2007)
Red Seal Long Cut Wintergreen	SE0004829	Red Seal Long Cut Wintergreen (2007)
Husky Fine Cut Natural	SE0004875	Husky Fine Cut Natural (2007)
Husky Fine Cut Wintergreen	SE0004876	Husky Fine Cut Wintergreen (2007)
Husky Long Cut Mint	SE0004877	Husky Long Cut Mint (2007)
Husky Long Cut Natural	SE0004878	Husky Long Cut Natural (2007)
Husky Long Cut Straight	SE0004879	Husky Long Cut Straight (2007)
Husky Long Cut Wintergreen	SE0004880	Husky Long Cut Wintergreen (2007)

Product Category	Smokeless
Product Subcategory	Loose moist snuff
Product Packages	42.53 g loose moist snuff per can for SE0004825-SE0004829 34.02 g loose moist snuff per can for SE0004875-SE0004880

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States.

The Agency shall issue marketing orders if, after considering the substantial equivalence reports and amendments submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products. The predicate products are grandfathered products and were on the market as of February 15, 2007.

The new products differ from the corresponding predicate products in changes in types of tobacco used, ingredients in the tobacco, replacing the plastic can lid with a metal can lid, and addition of indirect

additives that are processing aides used during production of the metal can lids (Confidential Appendix 1).

The applicant provided first- and fifth-year market volume projections for the new products (Confidential Appendix 2).

4. Alternatives to the Proposed Actions

The no-action alternative is the Agency does not issue marketing orders for the new tobacco products in the United States.

5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the New Products

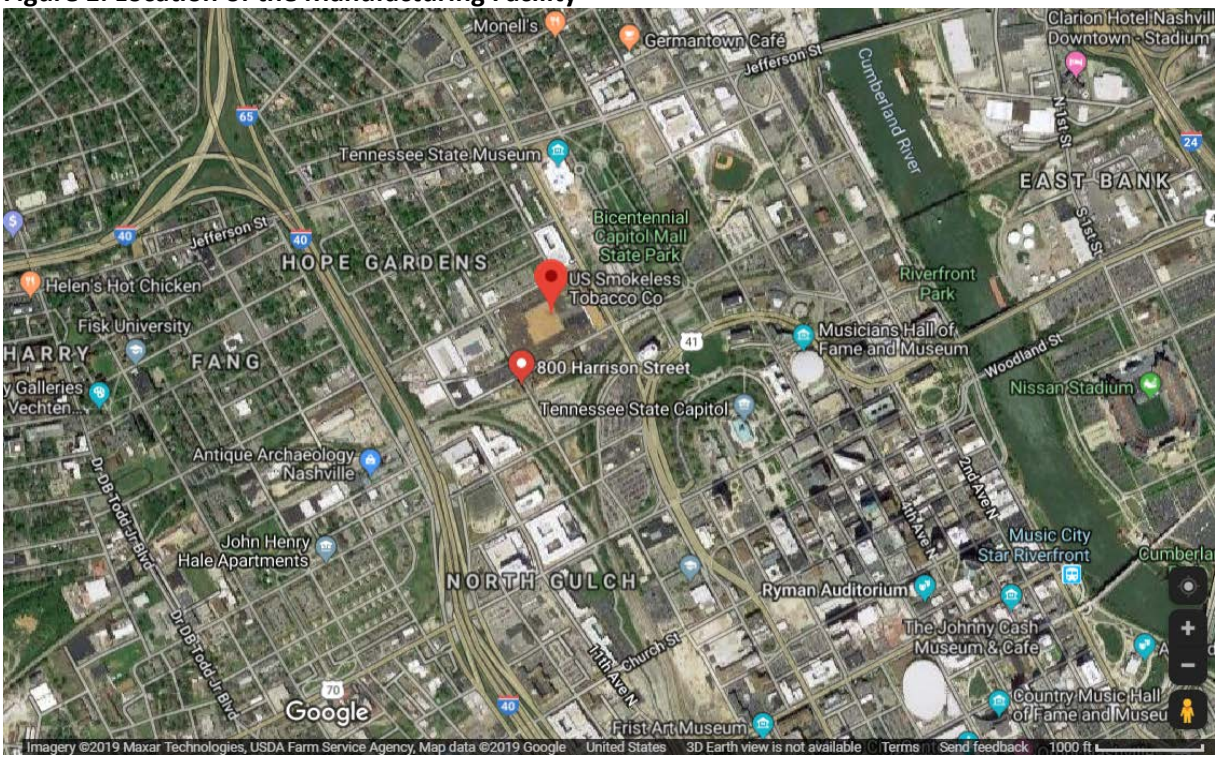
The Agency evaluated potential environmental impacts that may be caused by manufacturing the new products and found no significant impacts.

5.1 Affected Environment

The new products would be manufactured at U.S. Smokeless Tobacco Company LLC, 800 Harrison Street, Nashville, TN 37203 (Figure 1) and 2303 Bells Road, Richmond, VA 23234 (Figure 2). The Nashville, TN facility is within an industrial park in downtown Nashville, with a railroad spur along its southern perimeter, offices and parking lots to the north, a six-lane highway to the west, a residential neighborhood to the north, and Cumberland River to the east. [1]

[1] Google. 2019. Map of 800 Harrison Street, Nashville, TN 37203. Retrieved from Google Maps: www.google.com/maps. August 2, 2019.

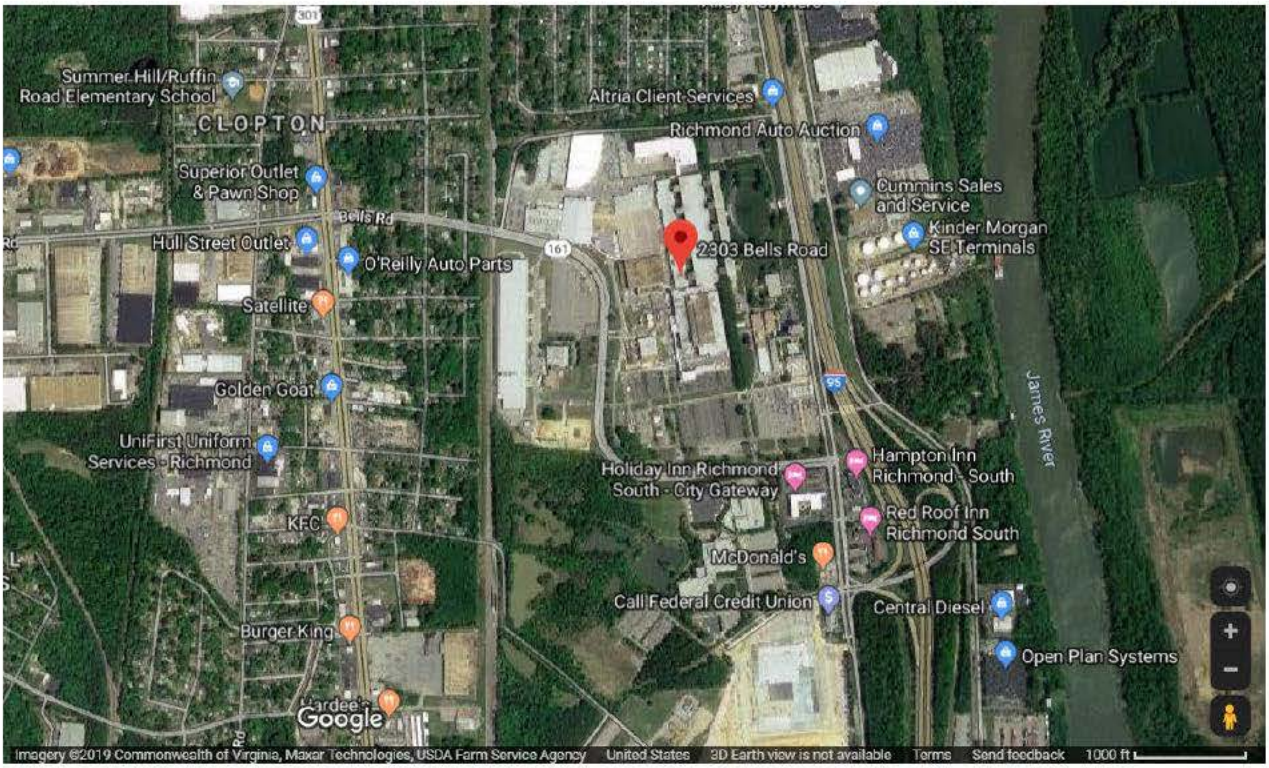
Figure 1. Location of the Manufacturing Facility



The Richmond, VA manufacturing facility is surrounded by a residential development across a road to the north; a two-lane divided road and an interstate freeway (I-95) to the east; two hotels, a fast food restaurant, and a gas station at the southeast corner; undeveloped forested land and a petroleum product pumping station and delivery terminal to the south; and a railroad to the west with a spur into the manufacturing facility.[2]

[2] Google. 2019. Map of 2303 Bells Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. August 2, 2019.

Figure 2. Location of the Manufacturing Facility



5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the new products based on information gathered by the Agency and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products is not expected to result in changes in air emissions from the manufacturing facilities and would not require new or revised permits.
Water resources	The applicant stated that manufacturing the new products is not expected to result in changes in water discharges from the manufacturing facilities and would not require new or revised permits.
Land use and zoning	The applicant stated that there would be no facility expansion due to the new products. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed actions.
Biological resources	The applicant stated that there would be no facility expansion due to the new products and that manufacturing the new products would not result in changes in emissions or water discharges. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new products.

Environmental Resource	Analysis of Potential Impacts
Soils	The applicant stated that there would be no facility expansion due to the new products. Therefore, no effects on soils would occur as a direct impact from manufacturing the new products.
Socioeconomic conditions	The applicant stated that there would be no facility expansion or changes in air emissions or water discharges at the facilities. Therefore, no socioeconomic effects (beneficial or adverse) would occur as a direct impact from manufacturing the new products.
Solid waste and hazardous materials	The applicant stated that manufacturing the new products would lead to the same or similar substances and types of emissions as those associated with current smokeless tobacco product manufacturing at the facilities. Additionally, the applicant stated that no material changes in solid waste generation are expected to result from manufacturing the new products. Therefore, the Agency does not anticipate that manufacturing the new products would lead to the presence of new chemicals in the manufacturing waste stream.
Floodplains, wetlands, and coastal zones	The applicant stated that there would be no facility expansion due to the new products. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact of manufacturing the new products.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations that live near the manufacturing facilities.
Regulatory compliance	The applicant provided manufacturing permits for both the Nashville, TN (Synthetic Minor Air Pollutant Source Operating Permits: Permit Numbers 81-2 through 81-4, 81-6, 81-8, and 81-9) and the Richmond, VA (Stationary Source Permit to Construct and Operate (Registration No.: 52609) manufacturing facilities. The applicant also stated that their manufacturing facilities are in compliance with all relevant federal, state, and local environmental regulations. The Agency's search for the manufacturing facilities in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of environmental laws and regulations.

5.3 Cumulative Impacts

The Agency does not anticipate the proposed actions to incrementally increase or change the chemicals released to the environment from the facilities' tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017, the U.S. Smokeless Tobacco's manufacturing facility in Nashville, Tennessee released 17,153 pounds of ammonia and 235 pounds of nicotine and nicotine salts to air (totaling 17,388 pounds) and transferred 40,409 pounds of ammonia and nicotine and nicotine salts to Central Wastewater Treatment Plant (Table 1),[3] constituting 14% of TRI releases in Davidson County.[4] No other hazardous air pollutants were reported. The Richmond facility was not

[3] U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched December 20, 2018.

[4] U.S. EPA. https://myrtk.epa.gov/info/report.jsp?IDT=TRI&ID=37203STBCC800HA. The site allows for searching the industrial facilities that manage toxic waste chemicals. Accessed December 20, 2018.

found in the ECHO database under the address provided, however, the Philip Morris USA facility occupies the same space but has a different address, 3601 Commerce Road, Richmond, VA 23234. Philip Morris and USSTC are corporate entities under the parent company, Altria. A search in the EPA's TRI database showed that in 2017, Philip Morris USA manufacturing facility in Richmond, Virginia released 18,713 pounds of ammonia and 10,683 pounds of nicotine and nicotine salts to air (totaling 29,396 pounds), but released no other hazardous air pollutants at reportable levels (Table 2).[5] Ammonia adversely affects ocular and respiratory systems; nicotine and nicotine salts have known adverse developmental effects.[6] The TRI database search did not show that the U.S. Smokeless Tobacco manufacturing facilities disposed of, treated, or released into the environment any other toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facilities released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at Nashville U.S. Smokeless Tobacco Facility in 2017

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			17,970
Energy Recovery			0
Treated			102,420
Subtotal Waste Managed			*120,390*
On-Site Release	Air	Ammonia	17,153
		Nicotine and Salts	235
	Water	Ammonia	0
		Nicotine and Salts	0
	Land	Ammonia	0
		Nicotine and Salts	0
Off-Site Disposal/Release			40,409
Subtotal Waste Released			*57,797*
Total Production-Related Waste			**178,187**

Table 2 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Richmond Philip Morris USA Facility in 2017

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			126,020
Energy Recovery			0
Treated			104,427
Subtotal Waste Managed			*230,447*
On-site Release	Air	Ammonia	18,713
		Nicotine and Salts	10,683

[5] 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 July 18, 2019.

[6] Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
	Water	Ammonia	0
		Nicotine and Salts	0
	Land	Ammonia	0
		Nicotine and Salts	0
Off-site Release			60,822
Subtotal Waste Released			*90,218*
Total Production-Related Waste			**320,665**

5.4 Impacts from No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing conditions of manufacturing smokeless tobacco products, as many similar tobacco products would continue to be manufactured at the listed facilities.

6. Potential Environmental Impacts of the Proposed Actions and Alternatives - Use of the New Products

The Agency evaluated potential environmental impacts that may be caused by use of the new products and found no significant impacts.

6.1 Affected Environment

The affected environment is the entire United States because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

6.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from use of the new products based on Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new products are likely to be used by the same consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no change in impacts to environmental justice populations is expected.

6.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with the new products' use under the proposed actions, would lead to cumulative impacts.

6.4 Impacts from No-Action Alternative

The no-action alternative would not change the existing use of other smokeless tobacco products in the United States, as many similar smokeless tobacco products would continue to be marketed and therefore used.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives - Disposal of the New Products

The Agency evaluated potential environmental impacts that may be caused by disposal of the new products and found no significant impacts.

7.1 Affected Environment

The affected environment is the entire United States because the marketing orders would allow the new tobacco products to be sold to consumers nationwide who would dispose of the used new products and packaging as municipal solid waste, recycled material, or litter.

7.2 Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from disposal based on Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of the used new products could lead to terrestrial wildlife having direct exposure to the used product and hazardous substances leaching to aquatic environments and soil. However, no net increase in littering is expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations from disposal of the used new products and packaging waste.
Water resources	Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of the used new products could result in hazardous substances leaching to water systems. However, no net increase in littering is expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.

Environmental Resource	Analysis of Potential Impacts
Solid Waste	The distribution of waste generated due to disposal of the new products and packaging is expected to correspond to the pattern of product use in the United States. The total solid waste generated was calculated based on the applicant provided first- and fifth-year marketing projections for the new products (Confidential Appendix 2). No significant environmental impacts were identified due to the waste disposal as it is a negligible fraction of the total waste reported in the United States (Confidential Appendix 3).
Regulatory compliance	The new products have no features that would lead to a different rate of used product littering compared to currently marketed smokeless tobacco products. Despite state and local ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new products as for currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.

7.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with the new products' disposal under the proposed actions, would lead to cumulative impacts.

7.4 Impacts from No-Action Alternative

The no-action alternative would not change the existing disposal of other smokeless tobacco products in the United States, as many similar smokeless tobacco products would continue to be marketed and therefore disposed of.

8. List of Preparers

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

Preparers:

Shannon K. Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management
Experience: Four years in environmental science, three years in toxicology
Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

Reviewer:

Gregory G. Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science
Experience: Thirty-seven years in environmental compliance and analysis
Expertise: Environmental toxicology, risk assessment, regulatory compliance, NEPA analysis

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1: Comparison of the New Products to the Predicate Products

SE Report	Component	Change
SE0004825 SE0004826 SE0004827 SE0004828 SE0004829 SE0004875 SE0004876 SE0004877 SE0004878 SE0004879 SE0004880	Tobacco	The new products contain (b) (4) and adjustments in the amounts of (b) (4), and (b) (4) tobacco.
	Ingredients	The new products contain minor modifications in ingredients including (b) (4) compared to the predicate products.
	Container	The new products are packaged with metal can lids compared to plastic can lids for the predicate products.
	Indirect additives	Processing aides related to the metal can lid are included as trace possible in the new products including enamel coating, gold R/C enamel, and white protopet 1s petrolatum

Confidential Appendix 2: Market Volume Projections for the New Product

STN	Name	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0004825	Red Seal Fine Cut Wintergreen	Can	(b) (4)	
SE0004826	Red Seal Long Cut Mint	Can		
SE0004827	Red Seal Long Cut Natural	Can		
SE0004828	Red Seal Long Cut Straight	Can		
SE0004829	Red Seal Long Cut Wintergreen	Can		
SE0004875	Husky Fine Cut Natural	Can		
SE0004876	Husky Fine Cut Wintergreen	Can		
SE0004877	Husky Long Cut Mint	Can		
SE0004878	Husky Long Cut Natural	Can		
SE0004879	Husky Long Cut Straight	Can		
SE0004880	Husky Long Cut Wintergreen	Can		

The applicant stated that the predicate products would not be simultaneously marketed with the new products.

Confidential Appendix 3: The First- and Fifth-Year Projection of Waste of Packaging Materials 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 after use of the new products. Projected total waste is the summation of the projected paper, plastic, and metal waste generation of the products. Projected total paper waste is the summation of the projected recyclable (shipping case) and non-recyclable (coated paper side label) paper waste generation of the product. Projected total plastic waste is the summation of the projected recyclable (can bottom) and non-recyclable (shrink wrap) plastic waste generation of the product.

$$\sum_{i=1}^{11} A_i = \sum_{i=1}^{11} (B_i + C_i + D_i)$$

$$B_i = \sum_{i=1}^{11} (G_i + H_i)$$

$$C_i = \sum_{i=1}^{11} (E_i + F_i)$$

$$D_i = J_i \times M \times Z$$

$$E_i = J_i \times N \times Z$$

$$F_i = \frac{J_i}{K} \times P \times Z$$

$$G_i = \frac{J_i \times Q \times Z}{Li \times Ki}$$

$$H_i = J_i \times O \times Z$$

A_i: Projected total waste generation of the product (metric tons)
B_i: Projected paper waste generation of the product (metric tons)
C_i: Projected plastic waste generation of the product (metric tons)
D_i: Projected metal waste of the product (metric tons)
E_i: Projected recyclable plastic waste generation of the product (metric tons)
F_i: Projected non-recyclable plastic waste generation of the product (metric tons)
G_i: Projected recyclable paper waste generation of the product (metric tons)
H_i: Projected non-recyclable paper waste generation of the product (metric tons)
I_i: Projected market volume of the product (pounds)
J_i: Projected market volume (number of individual units; each unit comprises of one can bottom, one can lid, and one coated side label)
K: Number of individual units per log roll
L: Number of log rolls per shipping case
M: Weight of metal (tin-plated steel) can lid (grams)
N: Weight of plastic (polypropylene) can bottom (grams)
O: Weight of coated paper side label (grams)
P: Weight of plastic shrink wrap (grams)
Q: Weight of shipping case (grams)
Z: 1.0×10^{-6} metric tons/gram

STN	Year	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
SE0004825	First	(b) (4)																
	Fifth																	
SE0004826	First																	
	Fifth																	
SE0004827	First																	
	Fifth																	
SE0004828	First																	
	Fifth																	
SE0004829	First																	
	Fifth																	
SE0004875	First																	
	Fifth																	
SE0004876	First																	
	Fifth																	
SE0004877	First																	
	Fifth																	
SE0004878	First																	
	Fifth																	
SE0004879	First																	
	Fifth																	
SE0004880	First																	
	Fifth																	

Total Waste

If the entire packaging paper, plastic, and metal components are disposed of as waste, which is a conservative approach, the projected cumulative paper, plastic, and metal waste in the first and fifth years of marketing the new products are (b) (4) metric tons and (b) (4) metric tons, respectively. This is a negligible fraction of the 262.4 million metric tons of total waste reported in the United States in 2015 (U.S. EPA, 2018).