Programmatic Environmental Assessment for Market Authorizations for Japan Tobacco International, Inc. "Wave Menthol King Size" and "Wave Full Flavor King Size"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

August 2, 2017

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This programmatic environmental assessment (PEA) is for the market authorizations for two roll-your-own (RYO) cigarette papers manufactured by Japan Tobacco International U.S.A., Inc." (JTI USA). Information presented in the PEA is based on the submissions referenced in Table 1 unless noted 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

Japan Tobacco International U.S.A., Inc.

2. Address

500 Frank W. Burr Blvd., Suite 1601, Teaneck, NJ 07666, USA

3. Manufacturer

Japan Tobacco International
Tutlin Urunleri Sanayi, A.S.
Copak Mahalles; No. 12
Torbali Izmir, Turkey

4. Description of Proposed Actions

These proposed actions are for FDA to issue a market authorization under section 910(a)(2) of the FD&C Act for the introduction of Wave Menthol King Size and Wave Full Flavor King Size into interstate commercial distribution in the U.S. The authorizations are based on the finding that these new products are substantially equivalent to the corresponding predicate products that were on the market as of February 15, 2007. The applicant intends to market the new products and discontinue the predicate products after receiving market authorizations for the new products.

4.1 Requested Action

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

4.2 Need for Action

JTI USA wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the U.S. The applicant claims that the new products are substantially equivalent to the corresponding predicate products (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) reports (SE0013536-SE0013537), 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 their corresponding predicate products, Wave Menthol King Size and Wave Full Flavor King Size, which were commercially marketed in the United States on February15, 2007.

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

4.3.1 Type of Tobacco Products

The new products are filtered cigarettes.

4.3.2 Product Names and Their Original STNs

The names of the new products are listed in the table below, along with the original submission tracking numbers (STNs) and the names of the corresponding predicate products.

STN	New Product	Predicate Product (Grandfathered Product)
SE0013536	Wave Menthol King Size	Wave Menthol King Size
SE0013537	Wave Full Flavor King Size	Wave Full Flavor King Size

4.3.3 Description of the Product Package

The unit sale packaging for the products is the same for the new and corresponding predicate products. The filtered cigarettes are sold to the consumer (point of sale) in packs of 20 cigarettes each. The retail box unit is a carton of 10 packs. The cartons are shipped to retailers in boxes of 30 cartons. The packs are comprised of cardboard and aluminum foil with a polypropylene outer wrap and tear tape. Details of the package components and weights of each package component for the new products are described in Confidential Appendix 1.

4.3.4 Location of Manufacturing

Japan Tobacco International,
Tutlin Urunleri Sanayi, A.S.
Copak Mahalles; No. 12,
Torbali Izmir, Turkey.

4.3.5 Location of Use

JTI USA intends to sell the new tobacco products to consumers in the U.S.

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 products and any other combusted cigarette products. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates the distribution of waste from disposal after use will correspond to the pattern of the product use. This disposal pattern will be the same as the predicate products, (b) (4) .

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

The new products differ from the corresponding predicate products only in location of the monogram ink. For the new products, the monogram ink is on the tipping paper and for the predicate products the monogram ink is on the rod paper. In the new products, the monogram ink is not burned. The applicant stated that the (b) (4) are expected to (b) (4) the corresponding (b) (4) (b) (4)

5. Environmental Introduction Due to the Proposed Actions

5.1 Introduction as a Result of Manufacturing the New Tobacco Products

5.1.1 Tobacco Products Imported from Turkey

Tobacco Import and Tobacco Market Volumes. According to the U.S. International Trade Commission (USITC), the import of total tobacco products to the U.S. from Turkey has averaged 847.6 metric tons from 2006 to 2016 (Figure 1)[i] [1]. The mass of cigarettes used in the Unites States is projected to decline from 368.072 thousand metric tons in 2004 to 184.072 thousand metric tons in 2021 (Figure 2). Data from 2016 regarding total cigarette use in the U.S. were used to examine the percent of the total cigarettes used that would have been imported from Turkey. The average metric tons of cigarettes imported each year from Turkey, 847.6, is only 0.46 % of cigarettes used in the US in 2016 (Figure 2). JTI USA likely imports only a portion of the total number of cigarettes imported from Turkey, therefore the JTI USA cigarette products used in the US would be (b) (4) of cigarettes used in the US, based on the 2016 tobacco import and market volume data (Confidential Appendix 2).

[i] The average value for the years 2006 to 2016 was used because there was no projected value for Turkish imports in 2021.

Figure 1. Total Tobacco Products Imported from Turkey into the U.S. 2005-2016[1]

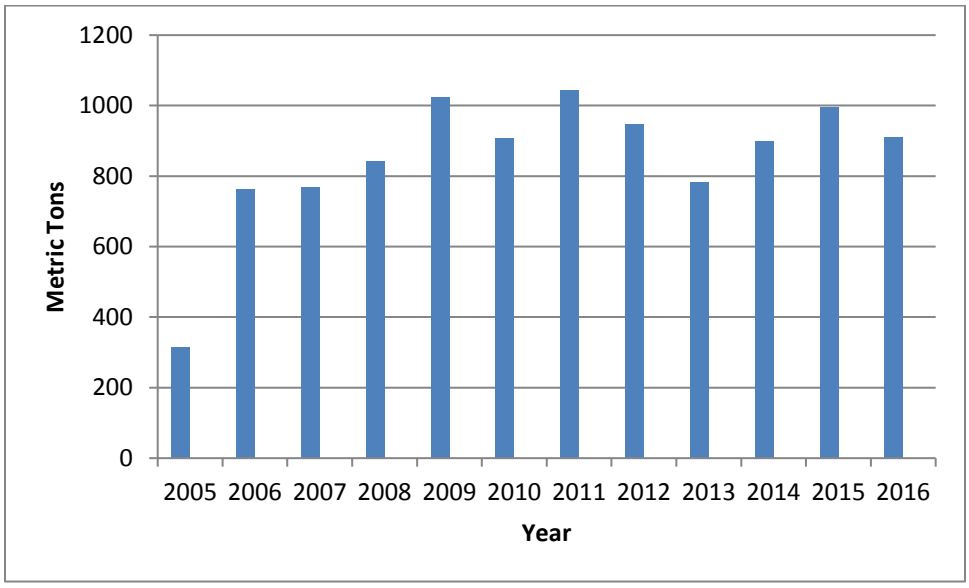
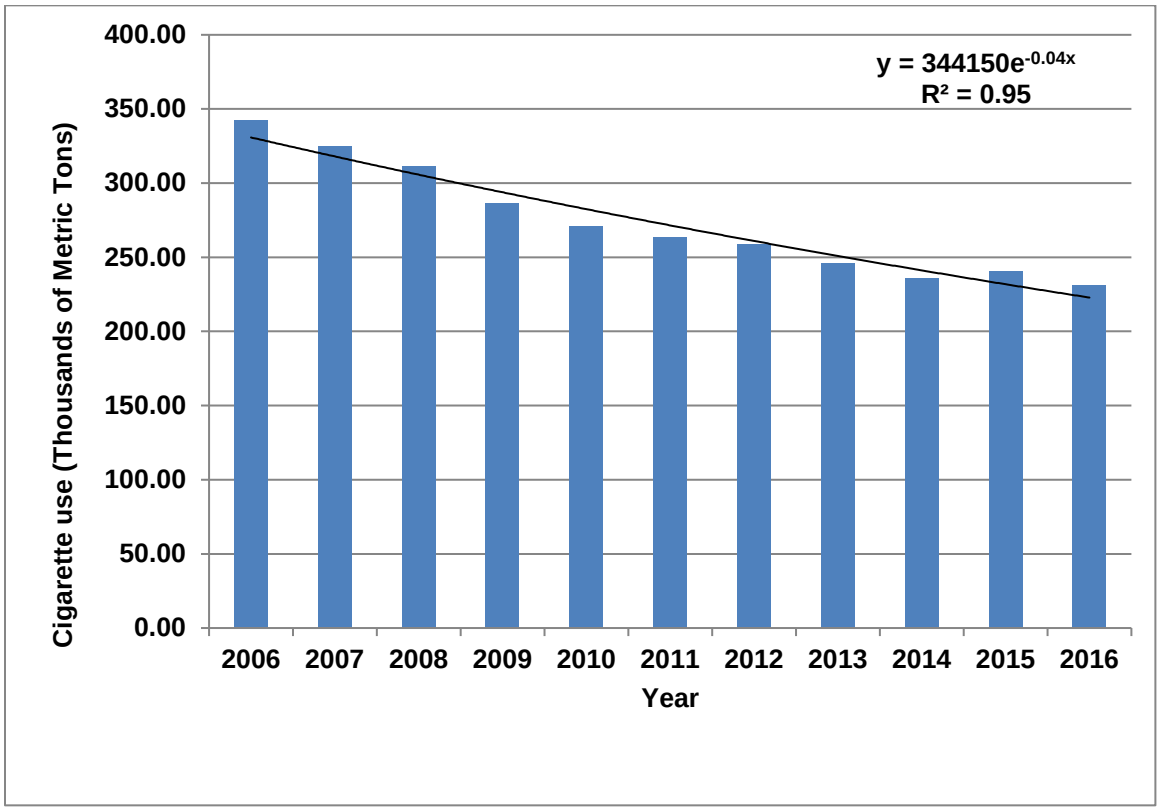


Figure 2. Cigarettes used (thousands of metric tons) in the U.S. 2006 to 2016[2]



5.1.2 Environmental Introduction from Manufacturing the New Tobacco Products

The Agency anticipates the waste generated as a result of manufacturing the new combusted cigarette products will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from the predicate products or any other products manufactured in the same facility and in a similar manner to other combusted cigarette products manufactured in Turkey. The (b) (4) Therefore, neither expansion of the manufacturing facility nor increases of the waste disposal requirements are anticipated for manufacturing the new products.

Based on information in the SE Reports, the new products differ from the corresponding predicate products in placement of the monographic ink on the tipping paper versus the rod paper. The ink placement change would not result in the release of any new substances or emissions into the environment. The Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products. Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed at the manufacturing facility.

The manufacturing facility is located in Turkey and the applicant states that the facility is in compliance with applicable federal and local Turkish environmental laws and regulations as well as being certified under ISO 9001 (Quality Management Systems) and ISO 114001 (Environmental Management Systems). Certification for environmental laws and ISO certifications are provided in Confidential Appendix 4 of this EA. The applicant also states that the cigarettes are produced from renewable and sustainable sources. The materials (cigarette paper, filter tow, plug wrap, tipping paper, base paper) are sourced from suppliers that have attested that they are either developing products that are the highest possible utilization of renewable raw materials, utilizing resources in a sustainable way, or utilizing best available technology (BAT) focused on reduction of emissions to water and air as well as the reductions and maximum reuse or recycling of solid wastes. The applicant states that the papers used in production of the new and corresponding predicate products are derived from sustainable sources and their manufacture does not appear to endanger any species or critical habitat.

Because the (b) (4) no increase in greenhouse gas (GHG) emissions is anticipated from the proposed actions. In addition, the applicant states that the manufacturing facility abides by all applicable Turkish emissions regulations and requirements.

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

5.2.1 Use of the Combusted Cigarette Tobacco Products in the U.S.

As discussed above, the proportion of total cigarette usage in the U.S. represented by imports from Turkey is a low 0.46% and the projected market weight for the new

products are even (b) (4) yielding negligible fractions of the total U.S. consumption of cigarettes.

5.2.2 Environmental Introduction from Use of the New Products

During use, the new products are usually burned to ash, carbon dioxide and water vapor as well as products of incomplete combustion (e.g., carbon monoxide). These combustion products from the new products are released into the environment in a similar manner to the predicate products and other cigarette products. The substances released during use of the new products are less than those released from the predicate products because the ink is on the tipping paper and is not burned during use, whereas the ink is on the rod paper of the predicate products and is burned during use. Therefore, no new substances are expected to be released to the environment as result of use of the new products. (b) (4) and no new GHGs are anticipated to be released.

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

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

5.3.1 Disposal Following Use of Combusted Cigarette Products

a) Disposal of Packaging Material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. To address the environmental effects of disposal of the packaging materials, information on total trash as well as paper and paperboard trash generated in the U.S can be used.

In 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the U.S., and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 3 and 4). 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. 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 U.S. in 2014[3].

Figure 3. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2014

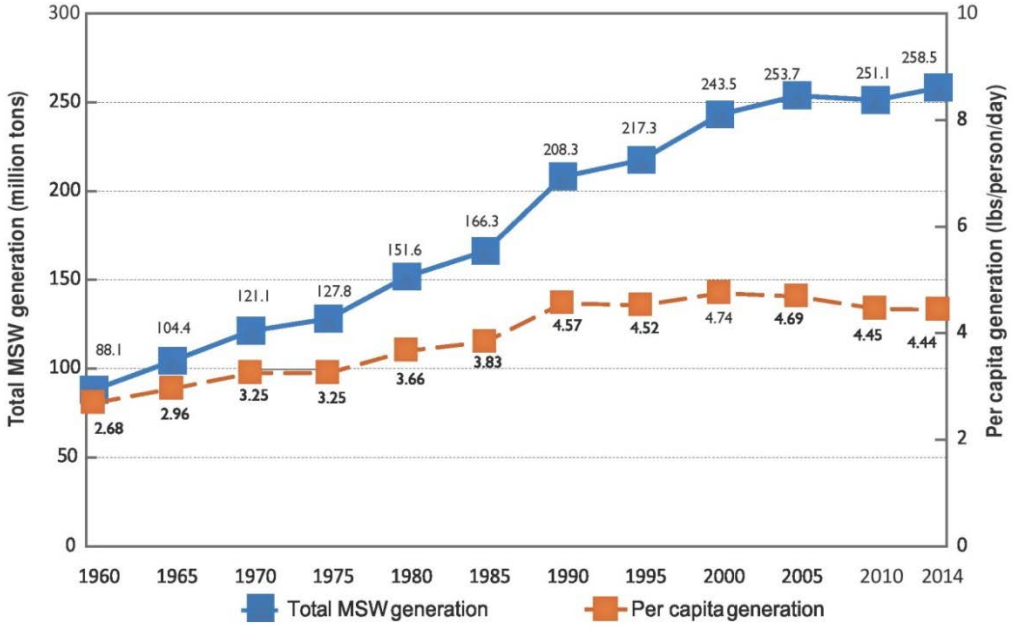
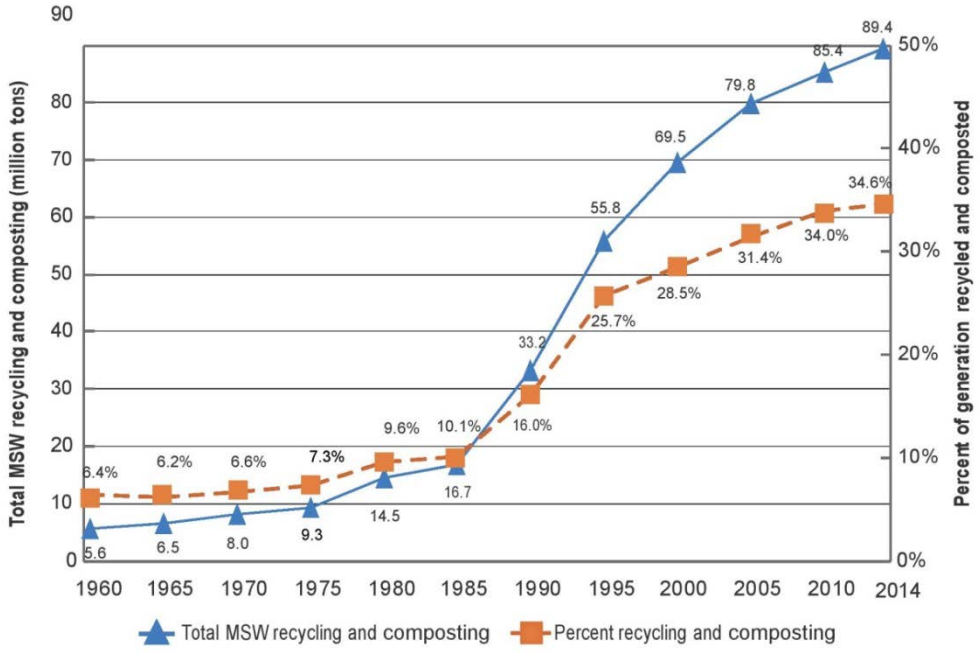


Figure 4. MSW Recycling Rates in the U.S., 1960-2014



b) Disposal of Used Cigarettes Following Use

Used combusted cigarette tobacco products are usually disposed of in MSW landfills or as litter. When discarded as MSW, the products would enter landfills. Assuming that all used cigarette products will be disposed of as MSW, the estimated waste of used

cigarette tobacco products is a fraction of a percent of the total 258.46 million tons (234.47 million metric tons) of projected MSW to be generated in the U.S

When discarded as litter, the spent products (specifically filters) are likely to move through runoff down storm drains into streams and rivers and enter the oceans where they wash up on beaches. Waste products of cigarette consumption consist of cigarette butts. Discarded cigarette filters are found to be the most collected item in beach cleanup and litter surveys. An estimated 30 percent of the total waste (by count) on U.S. shorelines, waterways, and land is cigarette waste [5].

c) Air Emissions from Disposal

The used combusted cigarette tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. However, the Clean Air Act requires that all landfills constructed or modified after July 17, 2014 that have a waste capacity of 2.5 million metric tons or more to have landfill gas collection-and-control systems installed. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98. Some landfills are permitted and capture the emitted methane as a source of energy [6].

5.3.2 Environmental Introduction from Disposal Following Use of the New Products

The Agency believes that the disposal of the new products will be similar to the disposal conditions of the predicate products and any other cigarette products that are currently being marketed. After using the new products, the users may dispose of or recycle the packaging material. Users may also discard what remains of the product after smoking, such as remaining combusted tobacco and cigarette, as discussed above, as MSW or litter.

To determine the amount of waste due to disposal of packaging material and product material, the Agency uses the projected market volumes in the first- and fifth-years after issuance of authorization orders for the new products. However, the weight of packaging materials (Confidential Appendix 2) for the new products and the corresponding predicate products are the same and the projected first-year market volumes for the new products (Confidential Appendix 3) and the current market volumes for the corresponding predicate products are the same. Therefore, no change in the amount of waste is expected. The input to the environment would be the same for both new and predicate products.

As previously discussed, (b) (4) , construction of new POTWs or landfills are not anticipated due to the proposed actions. Because the new products are expected to compete with and (b) (4) , no net increase of the GHG emitted from the waste associated with the new products is anticipated. Furthermore, the GHG emissions from the disposal of the used products and packaging associated with the new and predicate products are the same because the new and predicate products are identical except for the (b) (4) of the new product.

Because the new products will [redacted] no additional environmental burden is expected from use of the new products. Finally, the projected market volumes of the new products are minuscule compared to the total yearly use of cigarettes in the U.S.

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

The only change in the materials released in the environment is related to the monogram ink which is not on the rod paper and is therefore not burned. Monogram ink is present on the tipping paper and would accompany the cigarette butt into disposal or as litter. However, the components of the ink are present in such minimal levels that no further discussion is needed.

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

The applicant stated that the manufacturing operation is in compliance with all federal and local Turkish environmental laws and ISO standards. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what is allowed to be introduced to the environment under current and relevant environmental laws and ISO standards (Confidential Appendix 4).

As discussed above, the amount of materials anticipated to enter the environment due to the use of the new products are small fractions when compared to that of the projected cigarette products imported from Turkey and used in the U.S. The Agency [redacted] are issued. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new substances or new type of emissions are expected to be released, and therefore no new environmental controls are needed. No new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The [redacted] cigarette products that are substantially equivalent to the new products; the difference being a change in the placement of the monogram ink. The applicant also states that the proposed actions will not require an expansion of the manufacturing facility. Because the [redacted] noted earlier, no increase of overall cigarette tobacco product market volume and no net increase of energy use will be expected from the proposed actions. Additionally, the applicant stated that all ingredients used to manufacture the new products, as well as the predicate products, are from renewable and sustainable resources. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new products and their proposed use.

10. Alternatives to the Proposed Actions

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

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

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

11. List of Preparers

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

Preparer:

James F. Hobson, Ph.D., DABT
- Education: M.S. in Toxicology, Ph.D. in Biology and Environmental Toxicology
- Experience: 36 years in Regulatory and Environmental Toxicology
- Expertise: NEPA analysis, risk assessment, toxicology and ecotoxicology,

Reviewer

Gregory G. Gagliano, M.S., Center for Tobacco Products
- Education: M.S. in Environmental Science
- Experience: 34 years in Environmental Toxicology and Risk Assessment
- Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

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

14. Confidential Appendix List

Confidential Appendix 1: Proportion of Total Turkish Imports Imported by JTI
Confidential Appendix 2: Packaging Materials for the New and Predicate Products
Confidential Appendix 3: First- and Fifth-Year Market Volume Projections of the New and Corresponding Predicate Products if the Proposed Actions are Taken
Confidential Appendix 4: Certification of Compliance with Environmental Laws and ISO Standards

15. References

1 United States International Trade Commission, available at: http://dataweb.usitc.gov/ Accessed June 20, 2017

2 U.S. Department of Treasury, Alcohol and Tobacco Tax and Trade Bureau (TTB).Tobacco Statistics. Available at: http://www.ttb.gov/tobacco-stats.shtm. Accessed June 20, 2017.

3 U.S. EPA. Materials and Waste Management in the United States Key Facts and figures. Available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures. Accessed June 17, 2017

4 Novotny, T and F. Zhao. Consumption and Production Waste: Another Externality of Tobacco Use. Tobacco Control 1999:75-80

5 Tobacco Control Legal Consortium. Policy Tools for Minimizing Public Health and Environmental Effects of Cigarette Waste. March 2014. Available at: http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-cigarette-waste-2014.pdf. Accessed July 11, 2017.

6 U.S. EPA. Landfill Methane Outreach Program (LMOP). Basic Information about Landfill Gas. Available at: https://www.epa.gov/lmop/basic-information-about-landfill-gas. Accessed July 11, 2017.

APPENDIX 1

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

STN	New Product	Predicate Product	Amendments
SE0013536	Wave Menthol King Size	Wave Menthol King Size	SE0013553 SE0013773 SE0013797 SE0014124
SE0013537	Wave Full Flavor King Size	Wave Full Flavor King Size	SE0013773 SE0013797 SE0014124

(b) (4)

Confidential Appendix 2
The Packaging Materials for the New and Predicate Products

(b) (4)

Confidential Appendix 3

First- and Fifth-Year Market Volume Projections of the
New and Corresponding Predicate Products if the Proposed Actions are Taken

STN	Measure	First-Year Market Volume		Fifth-Year Market Volume	
		New Product	Predicate Product	New Product	Predicate Product
SE0013536	Units (millions)	(b) (4) [redacted]			
	Metric Tons				
SE0013537	Units (millions)				
	Metric Tons				

The first-and fifth-year market volumes of the new and predicate products projected to occupy the U.S. market were determined by comparing the projected market volume of the new products to the forecasted use of cigarettes in the U.S. (Figure 2 of the PEA). The first- and fifth-year marketing of the new products were calculated using the equations below:

Example calculations:

First-year market occupation of new products (%)

$$\frac{First\text{-}Year\ Volume\ Projection\ (metric\ tons)}{Forcasted\ Use\ of\ Cigarettes\ in\ the\ U.S.\ for\ 2017\ (Metric\ Tons)}\ x\ 100 = \%$$

Fifth-year market occupation of new products (%)

$$\frac{Fifth\text{-}Year\ Volume\ Projection\ \ (Metric\ Tons)}{Forcsted\ Use\ of\ Cigarettes\ in\ the\ U.S.\ for\ 2021\ (Metric\ Tons)}\ x\ 100 = \%$$

Percent of Total Cigarette Usage in the U.S. Occupied by
JTI Products in SE0013536 and SE0013537.

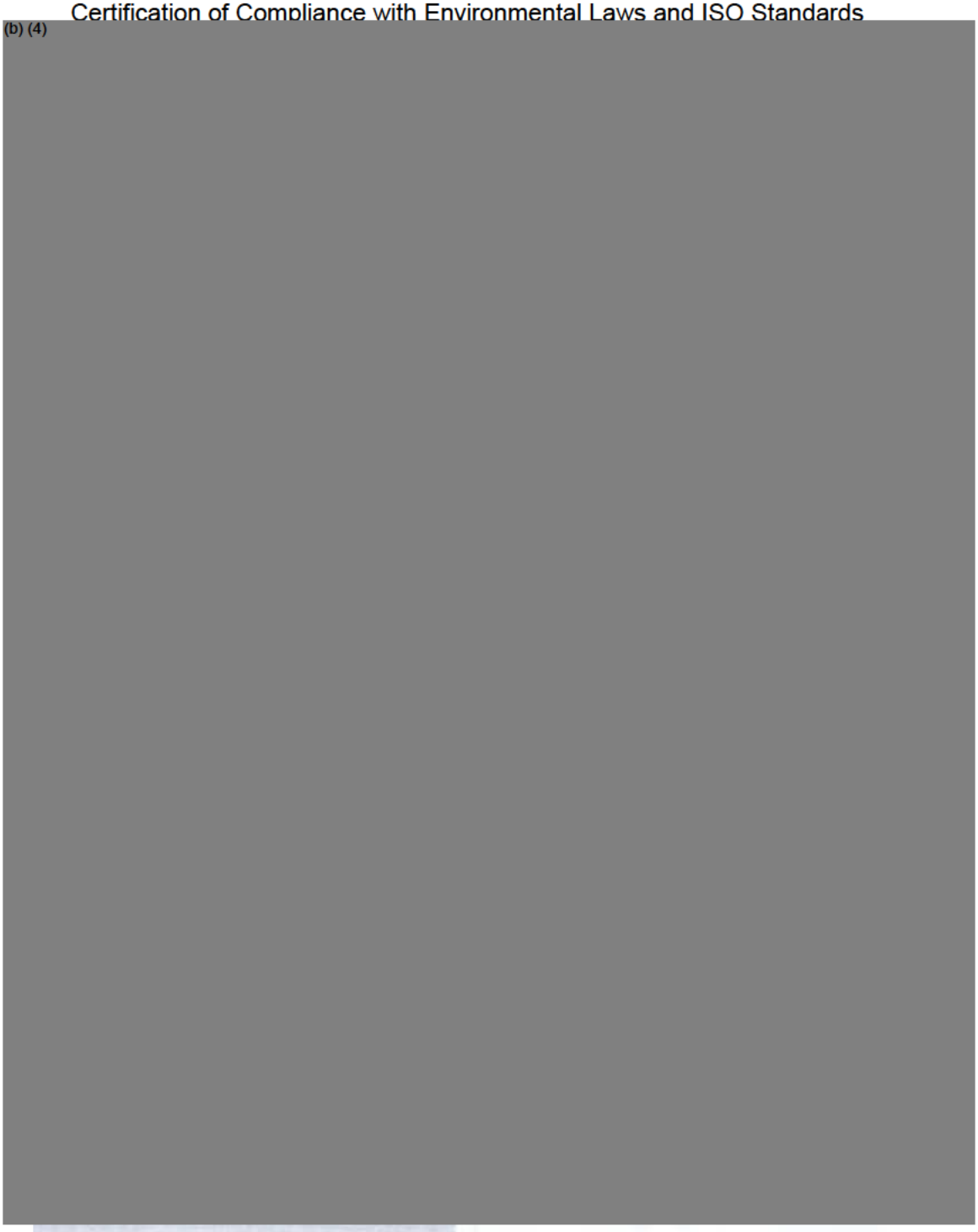
STN	Product	Year	Forecasted Use of Cigarettes in Metric Tons[2]	Projected Market Volume of New Product (Metric Tons)	Projected Market Occupation of New Product in the U.S. (%)
SE0013536	New	2017	(b) (4) [redacted]		
	New	2021			
SE0013537	New	2017			
	New	2021			

As discussed, the applicant states that the pre
Agency action occurs. If the agency action does not occur, then the predicate products will continue to be marketed in 2017 and 2021.

Confidential Appendix 2

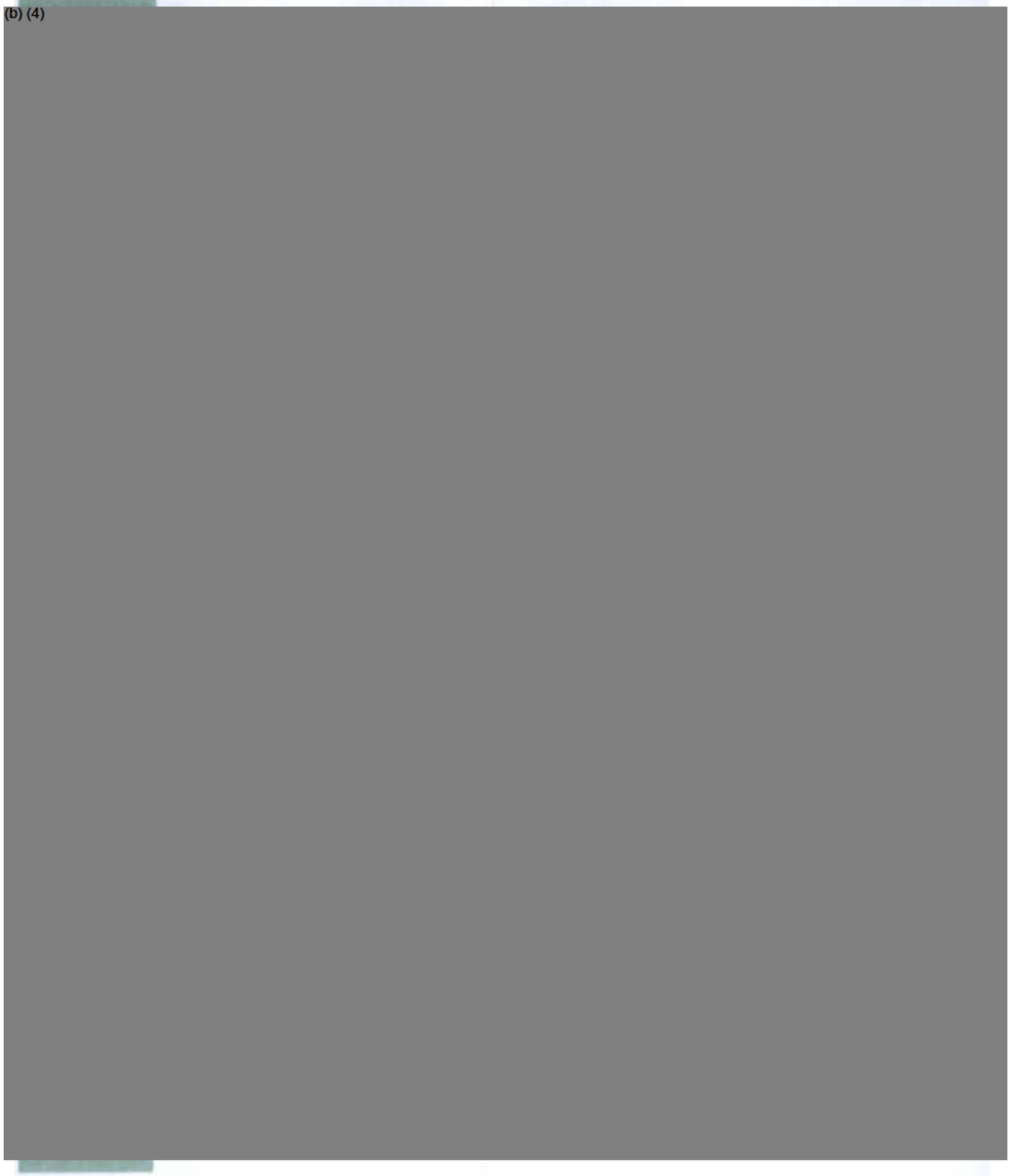
Certification of Compliance with Environmental Laws and ISO Standards

(b) (4)



ISO 14001

(b) (4)



Türkiye

JTI

CERTIFICATION

OF

(b) (4)