



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
Office of Science
Silver Spring MD 20993

MEMORANDUM

Date: June 20, 2017

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Through: Hoshing Chang, Ph.D. For
Environmental Science Branch Chief
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To: File

Subject: Environmental assessment for SE Reports submitted by Republic Tobacco, LP. SE0012908, SE0012912-SE0012936, SE0012938, SE0012946-SE0012952

Purpose

The purpose of this memo is to correct three issues found in the Agency-prepared Environmental Assessment (EA) for SE Reports submitted by Republic Tobacco, LP.

1. On the fifth page of the EA, a table under section 4.3.2 identifies the SE Reports covered by the EA. The names of the predicate products are incorrect. The incorrect predicate names are highlighted in bold in the following table (the table was copied from the EA). Additionally, one STN (SE0012926) is incorrectly listed under "previously found SE".

STN	New Product	Predicate Product (Grandfathered Product)
SE0012908	Abadie 1-1/2 Size	Abadie 1-1/2 Size
SE0012912	JOB 1.5 Gold	JOB 1.5 Gold
SE0012913	TOP Standard	TOP Standard
SE0012914	Zig-Zag 1¼ Size French Orange	Zig-Zag 1¼ Size French Orange
SE0012915	Rolling Standard	Rolling Standard
SE0012916	Zig-Zag King Size	Zig-Zag King Size
SE0012917	Ventura Whites	Ventura Whites
SE0012918	Zig-Zag Kutcorners Slow Burning	Zig-Zag Kutcorners Slow Burning
SE0012919	JOB 1.0 Silver	JOB 1.0 Silver
SE0012920	TOP 1-1/2 Size	TOP 1-1/2 Size
SE0012922	OCB Ungummed	OCB Ungummed
SE0012923	OCB Yellow Cigarette Papers with Tips	OCB Yellow Cigarette Papers with Tips
SE0012924	Zig-Zag White	Zig-Zag White
SE0012925	JOB 1.0 Gold	JOB 1.0 Gold
SE0012928	OCB Slim Long Cigarette Papers with Tips	OCB Slim Long Cigarette Papers with Tips
SE0012929	JOB Single Wide (White)	JOB Single Wide (White)
SE0012930	Abadie 1-1/4 Size	Abadie 1-1/4 Size
SE0012931	JOB Brown Double Wide	JOB Brown Double Wide
SE0012932	Abadie Single Width	Abadie Single Width
SE0012934	JOB Brown 1-1/4	JOB Brown 1-1/4
SE0012935	JOB Brown 1-1/2	JOB Brown 1-1/2
SE0012936	JOB French White	JOB French White
SE0012938	JOB Double Wide Gold	JOB Double Wide Gold
SE0012946	JOB Cutcorners (White)	JOB Cutcorners (White)
SE0012947	JOB 1-1/4 (Orange)	JOB 1-1/4 (Orange)
SE0012948	JOB 1-1/2 (White) 99¢	JOB 1-1/2 (White) 99¢
SE0012949	JOB 1.5 Slim Gold	JOB 1.5 Slim Gold
SE0012950	JOB 1.5 Silver	JOB 1.5 Silver
SE0012951	JOB 1.25 Silver	JOB 1.25 Silver
SE0012952	JOB 1.25 Gold	JOB 1.25 Gold
STN	New Product	Predicate Product (Previously found SE)
SE0012921	OCB Organic Hemp King Size Slim	OCB Organic Hemp King Size Slim
SE0012926	JOB Tribal King Size	JOB Tribal King Size
SE0012927	OCB Organic Hemp Single Wide	OCB Organic Hemp Single Wide
SE0012933	OCB Organic Hemp 1-1/4 Size	OCB Organic Hemp 1-1/4 Size

The correct names for the predicate products are highlighted in bold in the following table. Additionally, SE0012926 is now listed under “grandfathered product” and highlighted in italics.

STN	New Product	Predicate Product (Grandfathered Product)
SE0012908	Abadie 1-1/2 Size	Abadie 1-1/2 Width
SE0012912	JOB 1.5 Gold	J<>B 1.5 Gold 24's
SE0012913	TOP Standard	TOP Cig Paper 24's
SE0012914	Zig-Zag 1¼ Size French Orange	French Orange
SE0012915	Rolling Standard	Rolling Cigarette Paper 40's
SE0012916	Zig-Zag King Size	King Size
SE0012917	Ventura Whites	Ventura Whites 24 CT
SE0012918	Zig-Zag Kutcorners Slow Burning	KC Slow Burning
SE0012919	JOB 1.0 Silver	J<>B 1.0 Silver 24's
SE0012920	TOP 1-1/2 Size	TOP 1-1/2 24's
SE0012922	OCB Ungummed	OCB Cig Paper 24's
SE0012923	OCB Yellow Cigarette Papers with Tips	OCB Yellow Cig Paper
SE0012924	Zig-Zag White	White
SE0012925	JOB 1.0 Gold	J<>B 1.0 Gold 24's
SE0012926	JOB Tribal King Size	JOB Tribal King Size
SE0012928	OCB Slim Long Cigarette Papers with Tips	OCB Slim Long
SE0012929	JOB Single Wide (White)	J<>B Single Wide White 24's
SE0012930	Abadie 1-1/4 Size	Abadie 1-1/4 Width
SE0012931	JOB Brown Double Wide	J<>B DBL Wide Brown 24's
SE0012932	Abadie Single Width	Abadie Single Width
SE0012934	JOB Brown 1-1/4	J<>B 1-1/4 Brown 24's
SE0012935	JOB Brown 1-1/2	J<>B 1-1/2 Brown 24's
SE0012936	JOB French White	J<>B French Light 24's
SE0012938	JOB Double Wide Gold	J<>B Double Wide Gold 24's
SE0012946	JOB Cutcorners (White)	J<>B Cutcorner Slow 24's
SE0012947	JOB 1-1/4 (Orange)	J<>B 1-1/4 Orange 24's
SE0012948	JOB 1-1/2 (White) 99¢	J<>B 1-1/2 White \$.99
SE0012949	JOB 1.5 Slim Gold	J<>B 1.5 Slim Gold 24's
SE0012950	JOB 1.5 Silver	J<>B 1.5 Silver 24's
SE0012951	JOB 1.25 Silver	J<>B 1.25 Silver 24's
SE0012952	JOB 1.25 Gold	J<>B 1.25 Gold 24's
STN	New Product	Predicate Product (Previously found SE)
SE0012921	OCB Organic Hemp King Size Slim	OCB Organic Hemp King Size Slim
SE0012927	OCB Organic Hemp Single Wide	OCB Organic Hemp Single Wide
SE0012933	OCB Organic Hemp 1-1/4 Size	OCB Organic Hemp 1-1/4 Size

2. On pages 33 through 34 of the EA, there was a calculation error in one column of a table in confidential appendix 4. This table compares the current-year market volume for the predicate products with total roll-your-own (RYO) tobacco products used in the U.S. The numbers in the last column of the table designated "Market Occupation of Predicate Product in the U.S. (%)" are incorrect. The table from the EA is copied below, with the incorrect numbers highlighted in bold.

STN	Year	Import of Total Tobacco Products from France (Metric Tons)	Use of Total RYO Tobacco in the U.S. (Metric Tons)	Market Volume of Predicate Product (Metric Tons)	Market Occupation of Predicate Product in the U.S. (%)
SE0012908	2016	(b) (4)			
SE0012912	2016				
SE0012913	2016				
SE0012914	2016				
SE0012915	2016				
SE0012916	2016				
SE0012917	2016				
SE0012918	2016				
SE0012919	2016				
SE0012920	2016				
SE0012921	2016				
SE0012922	2016				
SE0012923	2016				
SE0012924	2016				
SE0012925	2016				
SE0012926	2016				
SE0012927	2016				
SE0012928	2016				
SE0012929	2016				
SE0012930	2016				
SE0012931	2016				
SE0012932	2016				
SE0012933	2016				
SE0012934	2016				
SE0012935	2016				
SE0012936	2016				
SE0012938	2016				
SE0012946	2016				
SE0012947	2016				
SE0012948	2016				
SE0012949	2016				
SE0012950	2016				
SE0012951	2016				
SE0012952	2016				

This table should read as follows, with the correct numbers for the market occupation of the predicate products in the U.S. highlighted in bold.

STN	Year	Import of Total Tobacco Products from France (Metric Tons)	Use of Total RYO Tobacco in the U.S. (Metric Tons)	Market Volume of Predicate Product (Metric Tons)	Market Occupation of Predicate Product in the U.S. (%)
SE0012908	2016	(b) (4)			
SE0012912	2016				
SE0012913	2016				
SE0012914	2016				
SE0012915	2016				

STN	Year	Import of Total Tobacco Products from France (Metric Tons)	Use of Total RYO Tobacco in the U.S. (Metric Tons)	Market Volume of Predicate Product (Metric Tons)	Market Occupation of Predicate Product in the U.S. (%)
SE0012916	2016	(b) (4)			
SE0012917	2016				
SE0012918	2016				
SE0012919	2016				
SE0012920	2016				
SE0012921	2016				
SE0012922	2016				
SE0012923	2016				
SE0012924	2016				
SE0012925	2016				
SE0012926	2016				
SE0012927	2016				
SE0012928	2016				
SE0012929	2016				
SE0012930	2016				
SE0012931	2016				
SE0012932	2016				
SE0012933	2016				
SE0012934	2016				
SE0012935	2016				
SE0012936	2016				
SE0012938	2016				
SE0012946	2016				
SE0012947	2016				
SE0012948	2016				
SE0012949	2016				
SE0012950	2016				
SE0012951	2016				
SE0012952	2016				

Based on these updated numbers, the cumulative market occupation of the predicate products for these 34 STNs is (b) (4) % of the total RYO products in the U.S. in 2016.

- On pages 35 through 36 of the EA there was a calculation error in one column of a table in confidential appendix 5. This table compares the first- and fifth-year market volume projections for the new products with total RYO tobacco products used in the U.S. The numbers in the last column of the table designated "Projected Market Occupation of New Product in the U.S. (%)" are incorrect. The table from the EA is copied below, with the incorrect numbers highlighted in bold.

STN	Year	Forecasted Import of Total Tobacco Products from France (Metric Tons)	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)	Projected Market Volume of New Product (Metric Tons)	Projected Market Occupation of New Product in the U.S. (%)
SE0012908	First-Year	(b) (4)			

STN	Year	Forecasted Import of Total Tobacco Products from France (Metric Tons)	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)	Projected Market Volume of New Product (Metric Tons)	Projected Market Occupation of New Product in the U.S. (%)
	Fifth Year	(b) (4)			
SE0012912	First-Year				
	Fifth Year				
SE0012913	First-Year				
	Fifth Year				
SE0012914	First-Year				
	Fifth Year				
SE0012915	First-Year				
	Fifth Year				
SE0012916	First-Year				
	Fifth Year				
SE0012917	First-Year				
	Fifth Year				
SE0012918	First-Year				
	Fifth Year				
SE0012919	First-Year				
	Fifth Year				
SE0012920	First-Year				
	Fifth Year				
SE0012921	First-Year				
	Fifth Year				
SE0012922	First-Year				
	Fifth Year				
SE0012923	First-Year				
	Fifth Year				
SE0012924	First-Year				
	Fifth Year				
SE0012925	First-Year				
	Fifth Year				
SE0012926	First-Year				
	Fifth Year				
SE0012927	First-Year				
	Fifth Year				
SE0012928	First-Year				
	Fifth Year				
SE0012929	First-Year				
	Fifth Year				
SE0012930	First-Year				
	Fifth Year				
SE0012931	First-Year				
	Fifth Year				
SE0012932	First-Year				
	Fifth Year				
SE0012933	First-Year				
	Fifth Year				
SE0012934	First-Year				
	Fifth Year				
SE0012935	First-Year				

STN	Year	Forecasted Import of Total Tobacco Products from France (Metric Tons)	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)	Projected Market Volume of New Product (Metric Tons)	Projected Market Occupation of New Product in the U.S. (%)
	Fifth Year	(b) (4)			
SE0012936	First-Year				
	Fifth Year				
SE0012938	First-Year				
	Fifth Year				
SE0012946	First-Year				
	Fifth Year				
SE0012947	First-Year				
	Fifth Year				
SE0012948	First-Year				
	Fifth Year				
SE0012949	First-Year				
	Fifth Year				
SE0012950	First-Year				
	Fifth Year				
SE0012951	First-Year				
	Fifth Year				
SE0012952	First-Year				
	Fifth Year				

The table should read as follows, with the correct numbers for the projected market occupation of new product in the U.S. highlighted in bold.

STN	Year	Forecasted Import of Total Tobacco Products from France (Metric Tons)	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)	Projected Market Volume of New Product (Metric Tons)	Projected Market Occupation of New Product in the U.S. (%)
SE0012908	First-Year	(b) (4)			
	Fifth Year				
SE0012912	First-Year				
	Fifth Year				
SE0012913	First-Year				
	Fifth Year				
SE0012914	First-Year				
	Fifth Year				
SE0012915	First-Year				
	Fifth Year				
SE0012916	First-Year				
	Fifth Year				
SE0012917	First-Year				
	Fifth Year				
SE0012918	First-Year				
	Fifth Year				
SE0012919	First-Year				

STN	Year	Forecasted Import of Total Tobacco Products from France (Metric Tons)	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)	Projected Market Volume of New Product (Metric Tons)	Projected Market Occupation of New Product in the U.S. (%)
	Fifth Year	(b) (4)			
SE0012920	First-Year				
	Fifth Year				
SE0012921	First-Year				
	Fifth Year				
SE0012922	First-Year				
	Fifth Year				
SE0012923	First-Year				
	Fifth Year				
SE0012924	First-Year				
	Fifth Year				
SE0012925	First-Year				
	Fifth Year				
SE0012926	First-Year				
	Fifth Year				
SE0012927	First-Year				
	Fifth Year				
SE0012928	First-Year				
	Fifth Year				
SE0012929	First-Year				
	Fifth Year				
SE0012930	First-Year				
	Fifth Year				
SE0012931	First-Year				
	Fifth Year				
SE0012932	First-Year				
	Fifth Year				
SE0012933	First-Year				
	Fifth Year				
SE0012934	First-Year				
	Fifth Year				
SE0012935	First-Year				
	Fifth Year				
SE0012936	First-Year				
	Fifth Year				
SE0012938	First-Year				
	Fifth Year				
SE0012946	First-Year				
	Fifth Year				
SE0012947	First-Year				
	Fifth Year				
SE0012948	First-Year				
	Fifth Year				
SE0012949	First-Year				
	Fifth Year				
SE0012950	First-Year				
	Fifth Year				
SE0012951	First-Year				

STN	Year	Forecasted Import of Total Tobacco Products from France (Metric Tons)	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)	Projected Market Volume of New Product (Metric Tons)	Projected Market Occupation of New Product in the U.S. (%)
	Fifth Year	(b) (4)			
SE0012952	First-Year				
	Fifth Year				

Based on these updated numbers, the cumulative projected market occupation of the new products for these 34 STNs in the first- and fifth-year of marketing is (b) (4) and (b) (4), respectively, of the total forecasted RYO products in the U.S. in 2017 and 2021.

The results from the updated calculations do not negate the conclusions in the EA. The following discussion supports the Agency’s conclusions in the EA to support the “finding of no significant impact” (FONSI). The FONSI is for the purpose of the market authorization of the new products. The trend of RYO manufacture in the U.S. has declined from 2008 to 2016 and the Agency has no reason to expect that this trend will not continue. For rolling papers, however, the true market for RYO tobacco is difficult to estimate due to cigarette papers being diverted from tobacco to marijuana. While RYO tobacco usage in the U.S. has decreased, the use of marijuana has increased 1.5% between 2007 and 2013 according to a 2014 U.S. Health and Human Services survey¹. However, the survey only covered illicit use of marijuana so that further increases in marijuana use due to legalization in Washington, Oregon and Colorado as well as legal medical marijuana use, were not represented.

Currently there are no economic data available that quantify how rolling papers are used, i.e. – tobacco or marijuana. Qualitatively, therefore, the applicant’s market estimates for cigarette papers may not only reflect use for RYO tobacco, but may also be influenced by consumers purchasing papers for legal and illegal use of marijuana. This could result in an overestimate when comparing market projections to projected RYO product usage. Based solely on waste generated from the sale and use of the rolling papers, regardless of market, the environmental impact will be negligible from the introduction and use of the new and predicate products presented in the EA.

¹ National Survey on Drug Use and Health: Summary of National Findings, 2014. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Service Administration, Center for Behavioral Health Statistics and Quality.