

FINDING OF NO SIGNIFICANT IMPACT

for

Product Market Authorization Order for

TOP King Size

Manufactured by Republic Tobacco, LP

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement is not required.

Republic Tobacco, LP, wishes to introduce one new roll-your-own (RYO) tobacco product into interstate commerce for commercial distribution in the United States (U.S.) and submitted to FDA substantial equivalence (SE) reports to obtain market authorizations under the provisions of section 910 and 905(j) of the FD&C Act.

The Agency prepared the environmental assessment (EA), dated August 15, 2017, under the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act and in accordance with 21 CFR 25.41 to support the finding of no significant impact (FONSI). The evidence supporting this finding is contained in the attached EA, which is available to the public upon request.

The EA provides an environmental effect assessment due to manufacturing, use, and disposal after use of the new product. The EA also provides analysis on energy and resource use as a result of marketing the new product. The new product is manufactured in Spain, and used and disposed of in the U.S.

To evaluate the environmental introduction for the proposed action due to the manufacturing of the new product, the Agency used historical data from 2000 to 2016 from the U.S. International Trade Commission (USITC) to forecast the amount of RYO tobacco products imported to the U.S. from Spain. No new types of emissions due to manufacturing are anticipated, and no new pollution control practices are anticipated.

To evaluate the environmental introduction for the proposed action due to the use of the new product, the Agency utilized historical data of the use of RYO tobacco products from 2008 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports to forecast the number of RYO tobacco products consumed and found the projection for use of RYO tobacco products is declining. Also, the Agency does not foresee that any new substances or emissions will be released into the environment as a result of use of the new product.

The Agency believes that the disposal of the new product resembles the disposal conditions of RYO tobacco products that are currently marketed. The waste generated as a result of use of the new product 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

other RYO tobacco products used in the U.S. The amount of projected total waste due to use and disposal of the new product is a minute fraction of the forecasted tobacco product waste generated in the U.S., based on information presented in the U.S. Environmental Protection Agency's report "*Advancing Sustainable Materials Management: Facts and Figures 2014*". Therefore, construction of new POTWs and landfills are not anticipated as a result of the proposed action.

The Agency does not anticipate the market volume for RYO tobacco products to be noticeably changed based on the provided information because the new product will compete with the same types of products on the market. Consequently, no additional use of resources and energy due to marketing the new product is anticipated.

No significant environmental impacts are expected from marketing the new product because no new control practices of air emission, water discharge, or solid waste disposal are foreseen; no additional use of resources and energy due to marketing the new product is anticipated.

The applicant also stated their compliance with the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES) along with abiding by all applicable Spanish regional and federal emissions, regulations and requirements.

Approved by Digitally signed by Kimberly A. Benson -S
Date: 2017.08.15 15:50:00 -04'00'
Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
Food and Drug Administration