Programmatic Environmental Assessment for Modified Risk Orders for Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks, Marlboro Fresh Menthol Heatsticks, and IQOS System Holder and Charger Manufactured by Philip Morris Products S.A.

Prepared by:
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1. Introduction

1.1 Background

On December 5, 2016, Philip Morris Products S.A. (PMP) submitted modified risk tobacco product applications (MRTPAs) for three flavors of Heatsticks and the IQOS Holder and Charger. In the MRTPAs, PMP requests that the U.S. Food & Drug Administration (FDA) issue risk modification orders for these proposed modified risk tobacco products under section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Public Law 111-31).

Issuing an exposure modification order for a tobacco product is a federal action for which FDA must consider environmental impacts before deciding to proceed, in accordance with the requirements of the National Environmental Policy Act (NEPA). FDA prepared this programmatic environmental assessment (PEA) to evaluate the potential for significant environmental impacts from the proposed modified risk orders for the proposed modified risk tobacco products. This PEA conforms to the Council on Environmental Quality's (CEQ's) NEPA regulations applicable to all agencies (40 Code of Federal Regulations [CFR] Part 1500) and FDA's agency-specific NEPA regulations (21 CFR Part 25). If a PEA concludes that proposed actions would not have significant environmental impacts, then an agency issues a finding of no significant impact (FONSI) to document this conclusion, completing the NEPA process. If a potentially significant impact is identified, then the agency proceeds to prepare an environmental impact statement.

Section 1 of this PEA describes the purpose of and need for the actions, identifies relevant laws and requirements, describes a related action, and summarizes the scope of this PEA. Section 2 identifies the proposed and alternatives actions. Section 3 presents the environmental impact analysis. Sections 4 and 5 present the preparers and the agencies and persons consulted.

1.2 Purpose of and Need for Action

Purpose: Upon receipt of an MRTPA, FDA considers the submission, using criteria detailed in section 911 of the FD&C Act, and issues an order that either allows or denies the claim(s) of modified risk for a commercially marketed tobacco product. The purpose of FDA's MRTPA review is to determine if a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies, and issuance of an order is expected to benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products (section 911(g)(2) of the FD&C Act).

Need: FDA is responsible for reviewing an MRTPA, making a finding as described in the previous paragraph, and subsequently determining whether or not to issue a marketing order for the proposed modified risk tobacco product.

1.3 Related Actions

On May 12, 2017, Philip Morris Products S.A. (PMP) submitted premarket tobacco product applications (PMTAs) for three flavors of Heatsticks and the IQOS Holder and Charger. In the PMTAs, PMP requested the FDA to permit marketing of these new tobacco products by issuing marketing orders under section 910 of the FD&C Act (Public Law 111-31). A PEA for the PMTAs was prepared as required by NEPA and marketing orders were granted on April 30, 2019.

1.4 Scope of Environmental Assessment

Scoping is the process for determining the scope of issues to be addressed in a NEPA document and for identifying the significant issues related to a proposed action. For this PEA, scoping methods consisted of (1) internal Agency scoping, in which environmental and other scientific staff within the FDA Center for Tobacco Products reviewed the products' manufacturing, use, and disposal information to identify potential areas of environmental impact for review in this PEA; and (2) reviewing public comment submissions posted to the docket FDA-2017-D-3001 (www.regulations.gov) for the MRTPAs for these proposed modified risk tobacco products. Internal Agency scoping served as the basis for the format and content of this PEA. The MRTPA docket did not contain any public comments that identified potential environmental concerns within the scope of this analysis in addition to those evaluated in this PEA.

The scope of a NEPA analysis is defined by the range of actions, alternatives, and impacts that are considered (40 CFR 1508.25). Using input from the scoping process described above, this PEA evaluates the following:

- The ***actions*** in this PEA are issuing marketing orders for four proposed modified risk tobacco products. The decision on whether to take these actions and issue the marketing orders is a result of FDA's reviews of the MRTPAs for the proposed modified risk tobacco products. FDA did not identify any connected actions.[1] FDA also did not identify any cumulative or similar actions, given that any future marketing orders for MRTPAs from this or other applicants for products that are similar or have similar environmental impacts would be speculative.
- The ***alternatives*** in this PEA are the courses of action available to FDA under Chapter IX of the FD&C Act, described in detail in Sections 2.1 and 2.2. As the proposed actions, FDA may issue marketing orders for one or more of the proposed modified risk tobacco products. The no-action alternative is FDA does not issue marketing orders for the proposed modified risk tobacco products.
- The ***impacts*** evaluated in this PEA, described in Section 3, include direct, indirect, and cumulative impacts to environmental resources.

2. Proposed Actions and Alternative

2.1 The Need for the Proposed Actions

Philip Morris Products S.A. submitted four MRTPAs for heated tobacco products (described in Table 1) on December 5, 2016 to FDA seeking marketing orders under section 911(g)(1) and 911(g)(2) of the FD&C Act.

[1] Actions are connected if they automatically trigger other actions, cannot or will not proceed unless other actions are taken previously or simultaneously, or are interdependent parts of a larger action and depend on the larger action for their justification (40 CFR 1508.25).

Table 1. Description of the Proposed Modified Risk Tobacco Products

STN*	Name	Description
MR0000059	Marlboro Heatsticks	• pack of 20 Heatsticks • carton of 10 packs
MR0000060	Marlboro Smooth Menthol Heatsticks	• pack of 20 Heatsticks • carton of 10 packs
MR0000061	Marlboro Fresh Menthol Heatsticks	• pack of 20 Heatsticks • carton of 10 packs
MR0000133	IQOS Holder and Charger	As packaged for sale to the consumer, the IQOS system is accompanied by the following accessories: AC adaptor, USB charging cable, cleaning brush, user guide.

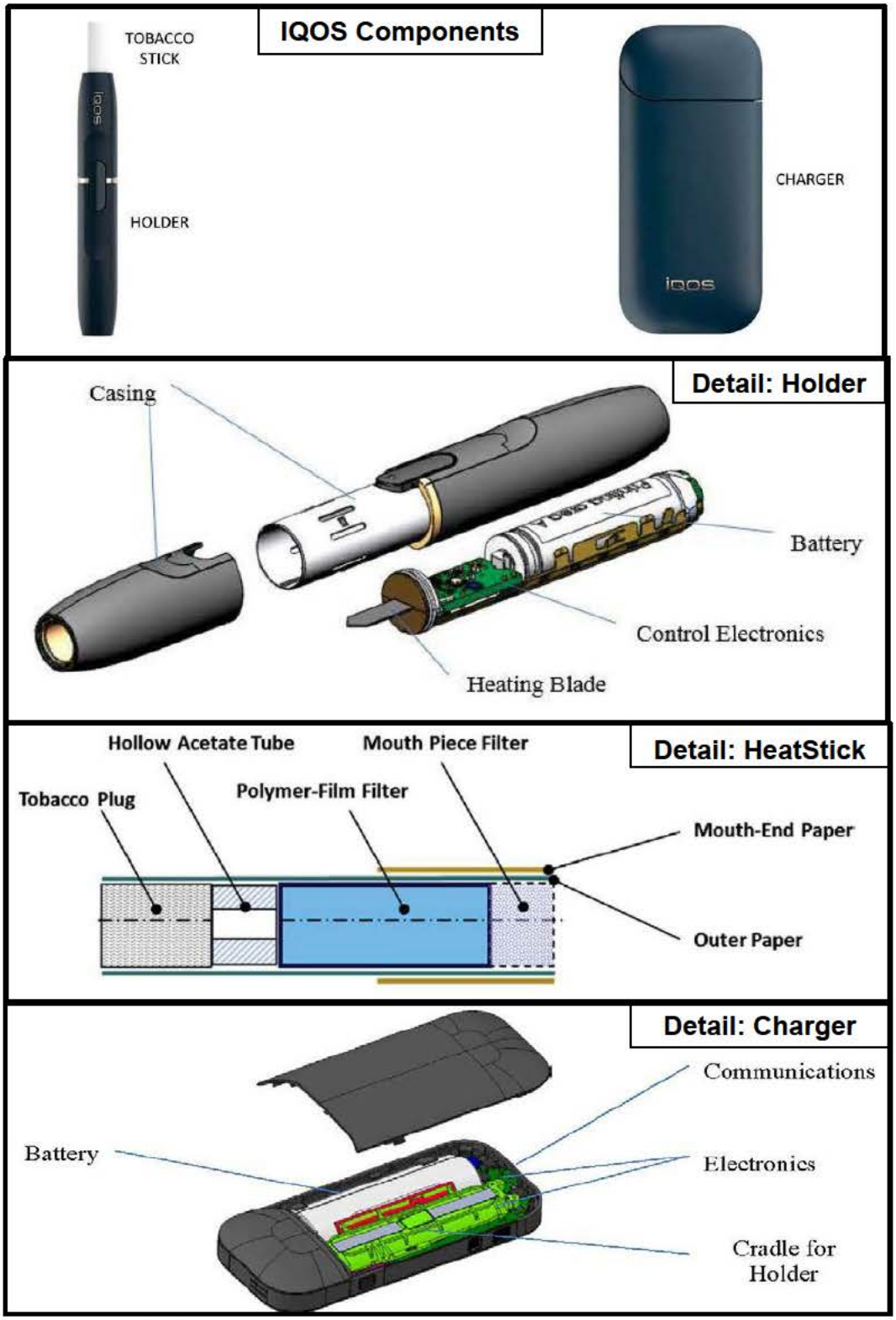
*STN = submission tracking number.

The products would be manufactured outside of the United States, as follows:

- The tobacco leaf is blended and ground at PMP, Quai Jeanrenaud, Neuchatel 2000, Switzerland.
- The Heatsticks are manufactured and packaged at Philip Morris Manufacturing and Technology Bologna S.p.A., Via Fratelli Rosselli 4, 40069 Zola Predosa, Bologna, Italy.
- The IQOS system and accessories are manufactured by a supplier on behalf of PMP.

Figure 1 depicts the IQOS system components and details of the Holder and Heatstick designs.

Figure 1. IQOS System Components



Source: PMP 2017.

The Heatstick, which resembles a short cigarette, contains tobacco that is ground and reconstituted into sheets (termed cast-leaf) following the addition of water, glycerin, guar gum, and cellulose fibers. The Heatstick contains two filters: a polymer-film filter to cool the aerosol and a low-density cellulose acetate mouthpiece filter that mimics a cigarette. When the user places the Heatstick in the open end of the Holder, a ceramic blade with a platinum heating element inserts into the tobacco plug. The user turns on a switch and the electronically controlled blade heats the tobacco to produce an aerosol, inhaled by the user through the mouthpiece filter. The blade heats the tobacco for a fixed period of approximately six minutes and allows up to fourteen puffs to be taken during that time. The tobacco does not ignite and the Heatstick is not consumed or decreased in size during use. Electronic controls prevent the temperature of the blade from exceeding 350˚C. The material inhaled from one Heatstick contains approximately 70 percent of the nicotine as the material inhaled from a combusted cigarette.

The Holder has sufficient electrical charge for use of a single Heatstick. After each Heatstick use, the Holder must be recharged by inserting it into the Charger. The Charger stores an amount of energy to recharge the holder approximately 20 times and is itself recharged using an included AC adaptor. (b) (4) .

2.2 No Action

The no-action alternative is for FDA to deny the MRTPAs. The proposed modified risk tobacco products would not be marketed with the reduced exposure claims in the United States and, for the purposes of the analysis in this PEA, it is assumed that the combusted cigarette market would retain its current and projected future user base.

3. Potential Environmental Impacts

Potential impacts of the proposed actions and no action, from product manufacturing, use, and disposal, are discussed in the PEA for the IQOS PMTAs (STNs PM0000424, PM0000425, PM0000426 and PM0000479). The PEA discussed the potential direct, indirect, and cumulative impacts on environmental resources from product use and disposal under the proposed actions and no action. The products in the MRTPAs are the same as in the PMTAs with the only difference being the modified risk claims under the MRTPAs. The Agency determined that, given the proposed claims are the only difference between the PMTAs and the MRTPAs, the environmental impacts of the products with the modified risk claims are considered in the PMTA PEA. Specifically, the Agency did not identify any significant environmental impacts from the proposed and alternative actions.

4. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this PEA:

Preparer:

Gregory G. Gagliano, 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

Reviewer:

Hoshing W. Chang, Center for Tobacco Products

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

Experience: Eleven years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

5. List of Agencies and Persons Consulted

No agencies or persons were consulted during preparation of this PEA. All information was obtained from the applicant or publicly available information sources.