

**Environmental Assessment
for Marketing Order for
IQOS 3 Holder and Charger
Manufactured by
Philip Morris Products S.A.**

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

October 6, 2020

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1. Introduction

1.1 Background

On March 30, 2020 Philip Morris Products S.A. (PMP) submitted a supplemental premarket tobacco product application (PMTA) for the IQOS 3 Holder and Charger. In the PMTAs, PMP requests that the U.S. Food & Drug Administration (FDA) issue a marketing order for this new tobacco product under section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Public Law 111-31).

Issuing a marketing order for a new 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 environmental assessment (EA) to evaluate the potential for significant environmental impacts from the proposed marketing order for the proposed new tobacco product. This EA 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 an EA concludes that a proposed action 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 EA describes the purpose of and need for the action, identifies relevant laws and requirements, describes a related action, and summarizes the scope of this EA. Section 2 identifies the proposed and alternative 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 a PMTA, FDA considers the submission, using criteria detailed in section 910 of the FD&C Act, and issues an order that either allows or denies the marketing order for a new tobacco product. The purpose of FDA's PMTA review is to determine if marketing the new tobacco product is appropriate for the protection of public health.

Need: FDA is responsible for reviewing a PMTA, making a finding as described in the previous paragraph, and subsequently determining whether or not to issue a marketing order for the proposed new 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. Additionally, a PEA for the Modified Risk Tobacco Product Applications (MRTPAs) was prepared as required by NEPA and modified risk orders were granted on July 7, 2020.

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 EA, scoping methods consisted of

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 EA.

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 EA evaluates the following:

- The **action** in this EA is issuing a marketing order for a proposed new tobacco product. The decision on whether to take this action and issue the marketing order is a result of FDA's reviews of the PMTA for the proposed new tobacco product and the PMTA and MRTPA for the original IQOS submission. FDA did not identify any other connected actions.¹ Related future actions include marketing orders for PMTAs from this or other applicants for products that are similar or have similar environmental impacts, however, such actions are purely speculative.
- The **alternatives** in this EA 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 a marketing order for the proposed new tobacco product. The no-action alternative is FDA does not issue a marketing order for the proposed new tobacco product.
- The **impacts** evaluated in this EA, described in Section 3, changes to the human environment from the proposed action or alternatives that are reasonably foreseeable and have a reasonably close causal relationship to the proposed action or alternatives, including those effects that occur at the same time and place as the proposed action or alternatives and may include effects that are later in time or farther removed in distance from the proposed action or alternatives..

2. Proposed Actions and Alternative

2.1 The Need for the Proposed Actions

Philip Morris Products S.A. submitted a supplemental PMTA for a heated tobacco product (described in Table 1) on March 30, 2020 to FDA seeking a marketing order under section 910(b)(1) of the FD&C Act.

Table 1. Description of the New Tobacco Product

STN*	Name	Description
PM0000634	IQOS 3 System Holder and Charger	<ul style="list-style-type: none"> • Electronic heating unit meant to be used with IQOS heatsticks and charger to recharge the heating unit after each use

*STN = submission tracking number.

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).

The new tobacco product would be manufactured outside of the United States. The IQOS system and accessories are manufactured by a supplier on behalf of PMP.

The IQOS 3 System is an upgraded version of the IQOS System, which is intended to be used with non-combustible heatsticks. The IQOS 3 System, similar to the IQOS System, contains two main components; the IQOS 3 Holder and the IQOS 3 Charger. The IQOS 3 Holder is an electrical heating unit in which the user inserts a heatstick. It is used to heat the tobacco in the heat stick via a heating blade. The holder is activated by the user pressing a button for a set period until the holder light blinks. The holder functions for approximately six minutes or a maximum of 14 puffs. The holder must be recharged after each use. The IQOS 3 Charger is a recharging case for the holder. The charger can recharge the holder 20 times before it needs to be recharged. The charger also holds the holder when not in use. The IQOS 3 System does not differ in the aerosol generation from the IQOS System.

The differences between the IQOS System and the IQOS 3 System include ergonomic changes, a side opening door in the charger for the holder, orientation-free insertion of the holder into the charger, a magnetic connector between the holder and charger, improved charging time of the holder via an

(b) (4)

2.2 No Action

The no-action alternative is FDA does not issue a marketing order for the proposed new tobacco product. The proposed new tobacco product would not be marketed in the United States.

3. Potential Environmental Impacts

Potential impacts of the proposed action and no action, from product manufacturing, use, and disposal, are discussed in the PEA for the original IQOS System PMTA (STNs PM0000424, PM0000425, PM0000426 and PM0000479). The PEA discussed the potential impacts on environmental resources from product use and disposal under the proposed action and no action alternative. The tobacco product in this EA is slightly modified as compared to the tobacco product in the original PMTA with the above-mentioned differences. The Agency determined that, given the modifications are mainly aesthetic, the projected market volume (Confidential Appendix 1) is similar to that of the original IQOS System, (b) (4)

the environmental impacts of the new tobacco product are considered in the original 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:

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:

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.

CONFIDENTIAL APPENDIX 1

Current and Projected First-, and Fifth-Year Market Volumes for the New and Original Products

STN	Market Volume (# of units)		
	Current	Projected First-Year	Projected Fifth-Year
PM0000634	(b)	(4)	
Original IQOS			
Total			