

**Programmatic Environmental Assessment
for Modified Risk Granted Orders for Heated Tobacco
Products
Manufactured by
Philip Morris Products S.A.**

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

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Table of Contents

1.	Introduction	1
1.1	Background	1
1.2	Purpose of and Need for Action	1
1.3	Related Actions	1
1.4	Scope of Environmental Assessment.....	2
2.	Proposed Actions and Alternative	3
2.1	The Need for the Proposed Actions.....	3
2.2	No Action	4
3.	Potential Environmental Effects	4
4.	List of Preparers	4
5.	List of Agencies and Persons Consulted	5

1. Introduction

1.1 Background

On July 5, 2023, Philip Morris Products (PMP) S.A. submitted renewal modified risk tobacco product applications (MRTPAs) for IQOS 2.4 System Holder and Charger (MR0000254.PD1), IQOS 3.0 System Holder and Charger (MR0000254.PD3), Marlboro Amber HeatSticks (MR0000254.PD5), Marlboro Green Menthol HeatSticks (MR0000254.PD6), and Marlboro Blue Menthol HeatSticks (MR0000254.PD7). In the submissions PMP is requesting renewal authorization to continue marketing the modified risk tobacco products (MRTPs) in the United States under Section 911(g)(2) of the U.S. Food, Drug, and Cosmetic Act (FD&C Act) (Public Law 111-31).

Issuing a risk 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) and FDA's NEPA implementation regulations (21 CFR 25). FDA prepared this programmatic environmental assessment (PEA) to evaluate the potential environmental effects from marketing the tobacco products with the modified risk claims in the United States under the proposed actions and from the no-action alternative of the Agency not issuing modified risk granted orders for the products.

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 whether an applicant has shown that the tobacco product, as it is actually used by consumers, would (1) significantly reduce harm and the risk of tobacco-related disease to individual users and (2) 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) 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 to issue a modified risk granted order (MRGO) for the proposed MRTPs.

1.3 Related Actions

On May 15, 2017, PMP submitted premarket tobacco product applications (PMTA) for three flavors of heatsticks and the IQOS System Holder and Charger. In the PMTAs, PMP requested the FDA to authorize marketing these new tobacco products in the United States under section 910 of the FD&C Act (Public Law 111-31). FDA prepared a programmatic environmental assessment (PEA) for the PMTAs as required by NEPA and issued marketing granted orders on April 30, 2019.

Additionally, on December 5, 2016, PMP submitted MRTPAs for the products mentioned above requesting the FDA to authorize marketing the tobacco products in the United States with modified risk claims under section 911 of the FD&C Act. FDA prepared a PEA for the MRTPAs as required by NEPA, and issued MRGOs on July 7, 2020.

Further, on March 30, 2020, PMP submitted a supplemental premarket tobacco product application for the IQOS 3 System Holder and Charger. In the supplemental PMTA, PMP requested the FDA to authorize marketing the new tobacco product in the United States under section 910 of the FD&C Act (Public Law 111-31). FDA prepared an environmental assessment (EA) for the supplemental PMTA as required by NEPA, and issued marketing granted on December 7, 2020. On March 18, 2021, PMP also submitted a supplemental MRTPA for the IQOS 3 System Holder and Charger requesting that the FDA authorize the marketing of the MRTP in the United States under section 911 of the FD&C Act (Public Law 111-31). An EA for the supplemental MRTPA was prepared as required by NEPA, and marketing orders were granted on March 11, 2022.

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-2021-N-0408-0037 (www.regulations.gov) for the MRTPAs for these MRTPs. 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. Using input from the scoping process described above, this PEA evaluates the following:

- The **actions** in this PEA are the issuing MRGOs for five MRTPs. 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 MRTPs. FDA did not identify any connected actions. FDA also did not identify any effects 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 MRTPs. The no-action alternative is FDA does not issue MRGOs for the MRTPs.
- The **impacts** evaluated in this PEA, described in Section 3, include direct and indirect impacts to environmental resources.

2. Proposed Actions and Alternative

2.1 The Need for the Proposed Actions

The proposed action, requested by the applicant, is for FDA to issue marketing granted orders under section 911(g)(2) of the FD&C Act for three flavors of Heatsticks and two IQOS Holders and Chargers (described in Table 1) with the same claims authorized in the previous MRGOs issued on July 7, 2020 and March 11, 2022. These modified claims, provided by the applicant, are:

- The IQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.

Table 1. Description of the Proposed Modified Risk Tobacco Products

STN*	Name	Description
MR0000254.PD1	IQOS 2.4 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
MR0000254.PD3	IQOS 3.0 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
MR0000254.PD5	Marlboro Amber HeatSticks	<ul style="list-style-type: none">• Pack of 20 Heatsticks• Carton of 10 packs
MR0000254.PD6	Marlboro Green Menthol HeatSticks	<ul style="list-style-type: none">• Pack of 20 Heatsticks• Carton of 10 packs
MR0000254.PD7	Marlboro Blue Menthol HeatSticks	<ul style="list-style-type: none">• Pack of 20 Heatsticks• Carton of 10 packs

*STN = submission tracking number.

The MRTPs are manufactured outside of the United States by a supplier on behalf of PMP.

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 IQOS System Holders and Chargers contains two main components; the IQOS Holder and the IQOS Charger. The IQOS 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, and it must be recharged after each use. The IQOS 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 3.0 System Holder and Charger does not differ in the aerosol generation from the IQOS 2.4 System Holder and Charger.

2.2 No Action

The no-action alternative is for FDA to deny the MRTPAs. The proposed MRTPs would not be marketed with the reduced risk claims in the United States. 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 Effects

Potential impacts of the proposed actions and no action, from product manufacturing, use, and disposal, are discussed in the agency prepared EAs for the IQOS PMTAs (STNs PM0000424, PM0000425, PM0000426, PM0000479, and PM0000634) and in the agency prepared EAs for the previous IQOS MRTPAs (STNs MR0000059, MR0000060, MR0000061, MR0000133, and MR0000192). The EAs discussed the potential direct and indirect effects 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 and the initial MRTPAs. The applicant further stated that information related to the environmental effects as submitted with the initial MRTPAs and PMTAs with related appendices and data remains valid and does not require reanalysis for this renewal. The Agency did not identify any new environmental effects from the proposed and alternative actions as compared to the previously prepared PEA and EAs.

4. List of Preparers

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

Preparer:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Twelve years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

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Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-eight years in various scientific activities including fourteen years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

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, the Agency, or publicly available information sources.