

**Environmental Assessment for
Marketing Order for a
New Heated Tobacco Product
Manufactured by
Philip Morris Products S.A.**

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

October 19, 2022

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1. Introduction

1.1 Background

On May 25, 2021, Philip Morris Products S.A. submitted a premarket tobacco product application (PMTAs) for a heated tobacco product (HTP). In the PMTA, Philip Morris Products S.A. requested the U.S. Food & Drug Administration to issue a marketing order under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Public Law 111-31).

The new IQOS HeatSticks differ from the corresponding authorized IQOS HeatSticks (PM0000424) in composition of the tipping paper, plug wrap paper, adhesives, and tipping paper ink (Confidential Appendix 1).

This document reviews the potential environmental impacts from marketing the IQOS HeatStick in the United States and from the no-action alternative of the Agency not issuing a marketing order for the new IQOS HeatSticks.

1.2 Applicant and Manufacturer Information

Applicant Name:	Philip Morris Products S.A.		
Applicant Address:	Quai Jeanrenaud Neuchatel 2000 Switzerland		
Manufacturer Information:	Manufacturer Name	Product Manufacturing Location	Products Manufactured
	Philip Morris Products S.A.	Quai Jeanrenaud Neuchatel 2000 Switzerland	Blending and grinding of tobacco leaf
	Philip Morris Manufacturing Bologna S.p.A.	Via Fratelli Rosselli 4 40069 Zola Predosa Bologna – Italy	IQOS HeatSticks manufacturing and packaging operations

1.3 Product Information

New Product Name and Submission Tracking Number (STN)

STN New Product	New Product Name	Authorized Product Name
PM0004691 – PD1	Marlboro Amber HeatSticks	Marlboro Heatsticks

Product Identification

Product Category	Heated Tobacco Product (HTP)
Product Subcategory	HTP Consumable
Product Number per Retail Unit	Twenty IQOS HeatSticks per pack with ten packs per carton and 50 cartons per shipping case
Product Package	The packaging consists of an inner frame, packing tape, and film overwrap.

2. The Need and Purpose for the Proposed Actions

Purpose: The applicant wishes to introduce the new IQOS HeatSticks in interstate commerce for commercial distribution in the United States and submitted a supplemental PMTA (sPMTA) to the Agency to obtain a marketing order. Upon receipt of an sPMTA, FDA considers the submission, using criteria detailed in section 910(b)(1) of the FD&C Act, to make a finding as to whether a marketing order for the product would be appropriate for the protection of public health.

Need: FDA's responsibility to review an sPMTA, make a finding as described in the previous paragraph, and subsequently determine whether or not to issue a marketing order for the tobacco product is a statutory requirement under section 910(b)(1) of the FD&C Act.

3. Proposed Actions and Alternatives

The proposed actions, requested by the applicant, are for FDA to issue a marketing order under the provisions of section 910 of the FD&C Act for introduction or delivery for introduction of tobacco products into interstate commerce in the United States after finding the new IQOS HeatSticks would be appropriate for the protection of public health.

The no-action alternative is FDA does not issue a marketing order for the new IQOS HeatSticks. The products would not be marketed in the United States and, for the purposes of the analysis in this environmental assessment, it is assumed that there would be no changes to the current HTP market and no changes to the current or future use of tobacco products.

4. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New IQOS HeatSticks

The applicant stated that the manufacturing facilities are in compliance with all the applicable environmental regulations. However, because the facilities are located outside the United States, the environmental impacts associated with manufacturing the new IQOS HeatSticks will not be discussed. The projected first- and fifth-year market volumes are available in Confidential Appendix 2.

5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New IQOS HeatSticks

Euromonitor reports show that in 2020, the retail value of heated tobacco products in the United States was approximately 21 million dollars accounting for a miniscule proportion of the tobacco product retail market. The retail value of HTPs is forecasted to grow to approximately 6.1 billion dollars by 2025 (Euromonitor International Ltd, 2021). HTP consumption in the United States to date has been modest compared to cigarettes, with consumption increasing from 12.3 million sticks in 2019 to 41.8 million sticks in 2020 (Euromonitor International Ltd, 2021).

The Agency considered potential impacts to resources in the environment that could be affected by use of the new IQOS HeatSticks and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes (Confidential Appendix 2) for the first- and fifth year of marketing of the new IQOS HeatSticks.

5.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new IQOS HeatSticks to be sold to consumers in the United States.

5.2. Air Quality

The Agency does not anticipate that new chemicals would be released into the environment as a result of use of the new product, relative to chemicals released into the environment due to use of other HTPs already on the market because (1) the new IQOS HeatSticks consist of minor ingredient changes in the acetate tow, plug wrap, adhesive, and tipping paper inks from the authorized IQOS HeatSticks (Confidential Appendix 1), (2) aerosol emissions to the environment from the new IQOS HeatSticks are similar to the aerosol emissions of the authorized IQOS HeatSticks because the difference of mainstream aerosols from the authorized and new IQOS HeatSticks are negligible (Confidential Appendix 3), and (3) the new IQOS HeatSticks are expected to compete with, or replace, other currently marketed HTPs.

The impacts from use of HTPs include exposure to second and thirdhand aerosols. Secondhand aerosol is created when an HTP user exhales mainstream aerosol into the environment (Hirano & Takei, 2020). Thirdhand aerosol is created when an HTP aerosol is inhaled and the chemicals in the vapor, exhaled by the user, deposit on surrounding surfaces. Available evidence indicate that HTP aerosols exposed users and bystanders to toxicants and affected indoor air quality, with potential health implications (Cancelada et al., 2019; Hirano & Takei, 2020; Ruprecht et al., 2017; Simonavicius et al., 2019). However, more research is needed to determine the health implications that secondhand and thirdhand exposure from HTP aerosol has on public and environmental health (Hirano & Takei, 2020, 2020; Ruprecht et al., 2017).

Studies on aerosols of non-mentholated Marlboro IQOS HeatSticks (product names not provided) have shown that IQOS aerosols are free from metal emissions, in contrast to combustible cigarettes (Ruprecht et al., 2017). When using the non-mentholated IQOS HeatSticks, no systematic increase in the total volatile organic compounds above background concentrations was observed. Furthermore, airborne compounds measured, other than nicotine, acetaldehyde and glycerin, remained below the reporting limits or at background levels (Mitova et al., 2016).

The applicant submitted a comparison of the user-generated aerosols in the new and authorized IQOS HeatSticks (Confidential Appendix 3). Negligible amounts of constituent change in the aerosols generated (exhaled) by the users when using the new IQOS HeatSticks compared with the authorized IQOS HeatSticks. Additionally, although there is a reduction in mainstream aerosol harmful and potentially harmful constituents (HPHCs), certain constituents, such as propylene glycol, butyrolactone, pyranone, and 2-furanmethanol, not listed on FDA's HPHC list, had higher levels in IQOS HeatSticks when compared with a reference cigarette (St. Helen et al., 2018).

5.3. Environmental Justice

There are few available studies describing HTP use related to environmental justice (EJ) populations. National Youth Tobacco Survey data for 2019 and 2020 indicate that HTP product awareness and ever use did not differ by the race, ethnicity, or both, of middle school and high school students (Dai, 2020); however, current HTP-use prevalence was higher among Hispanic school students compared to non-Hispanic Whites (Dai, 2020; Gentzke et al., 2020). Among adults, 2019 Tobacco Use Supplement to the Current Population Survey data indicates that HTP product awareness and ever use did not differ based on race, ethnicity (or both), income levels or education attainment (Azagba & Shan, 2021). Overall,

these findings do not indicate disproportionately high HTP use prevalence among minorities and low-income groups. Therefore, the Agency does not anticipate potential disproportionate environmental impacts on EJ populations from using the new IQOS HeatSticks.

5.4. Impacts from the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of HTPs because the authorized IQOS HeatSticks and many other similar HTPs would continue to be used in the United States.

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New IQOS HeatSticks

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new IQOS HeatSticks and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes (Confidential Appendix 2) for the first- and fifth year of marketing of the new IQOS HeatSticks.

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new IQOS HeatSticks to be sold to consumers nationwide who would dispose of the used product and packaging as municipal solid waste (MSW), recycled material, or litter.

6.2. Air Quality

The Agency does not anticipate disposal of the new IQOS HeatSticks or the packaging material would lead to the release of new or increased chemicals into the air.

Studies characterizing air quality impacts from disposal of used IQOS HeatSticks are currently not available. However, similar to cigarette butts, discarded IQOS HeatSticks may emit toxic chemicals such as nicotine into the air (Gong, Daniels, & Poppendieck, 2020; Gong, Khurshid, & Poppendieck, 2017). Airborne emissions from cigarette butts after disposal depend on the environmental conditions and the chemicals in the butts (Poppendieck, Gong, & Pham, 2020) as well as other factors, such as the cigarette brand, cigarette length, filter material, filler, ingredients in the cigarette, number of puffs, and the mass transfer behavior of combustion products along the cigarette (Gong et al., 2017).

The Agency does not anticipate disposal of the new IQOS HeatSticks would lead to the release of new or increased chemicals into the air because the new IQOS HeatSticks are made of minor ingredient changes from the authorized IQOS HeatSticks. The chemical constituents in the new IQOS HeatSticks are not likely to be emitted to the air in any distinguishable different amount. Additionally, no changes in air quality from disposal of the packaging materials in the new IQOS HeatSticks would be expected because (1) the paper and plastic components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, (3) the waste generated due to disposal of the packaging is a minuscule portion of the MSW based on the projected market volume of the new IQOS HeatSticks, and (4) the new IQOS HeatSticks are intended to replace the authorized IQOS HeatSticks.

6.3. Biological Resources

The proposed action is not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the Endangered Species Act. Proper disposal of the used new IQOS HeatSticks and packaging in the MSW stream would not affect biological resources. Improper disposal (littering) of the used new IQOS HeatSticks could lead to terrestrial wildlife having direct exposure to the used IQOS HeatSticks and hazardous substances leaching to aquatic environments and soils. Unlike combusted tobacco products, smoldering of used IQOS HeatSticks is not a major concern; therefore, the risk of fires from smoldering tobacco products and associated impacts to natural environments from littering are negligible.

The Agency does not anticipate new chemicals would be released into the environment as a result of disposal of the new IQOS HeatSticks because (1) the tobacco blend is unchanged compared to the authorized IQOS HeatSticks, and (2) the new IQOS HeatSticks are expected to replace the authorized IQOS HeatSticks.

6.4. Water Resources and Water Quality

Proper disposal of the used new IQOS HeatSticks and packaging in the MSW stream would not affect water resources. Improper disposal (littering) of the used, new IQOS HeatSticks could result in hazardous substances leaching into water systems. If improper disposal (littering) occurs, the leaching of metals and nicotine poses a concern for potential impacts on aquatic organisms and water resources (Baran et al., 2019; Beutel et al., 2021; Koutela et al., 2020). Toxic compounds in littered IQOS HeatSticks can leach out into water, potentially threatening human health and the environment, especially marine ecosystems. Recent literature shows a range of chemical constituents including metals such as chromium and lead leach from used IQOS HeatSticks and exhibit high toxicity to certain aquatic organisms (Baran et al., 2019; Koutela et al., 2020).

The Agency conducted a screening-level assessment of the cumulative acute toxicity risks to aquatic organisms from nicotine and heavy metals of concern in the new and authorized IQOS HeatSticks. The Agency calculated Risk Quotients (RQs) from estimated aquatic expected environmental concentrations (EEC) of the chemicals of concern and their lowest acute toxicity endpoint values (Confidential Appendix 4). The RQ values are several orders of magnitude lower than the Level of Concern for acute risks (high, restricted use or endangered species) to aquatic animals (US EPA, 2015) (Confidential Appendix 4). Based on the screening-level risk assessment, nicotine and heavy metals in the IQOS HeatSticks do not pose risks to aquatic animals. Therefore, no significant impacts on water resources and water quality from the disposal of new tobacco products are expected.

6.5. Solid Waste and Hazardous Materials

Littered IQOS HeatSticks may present environmental effects from heated or unheated tobacco, filter and other polymer components. Used IQOS HeatSticks consist of heated tobacco, polymer, paper, and filters containing low-density cellulose acetate similar to conventional cigarettes (Schaller et al., 2016; Smith et al., 2016).

Concentrations of metals leaching out of the IQOS HeatSticks are similar between unheated and heated tobacco, and less than unused cigarettes (Koutela et al., 2020). Particularly, chromium, arsenic, cadmium, mercury, selenium, and lead are listed as hazardous constituents per the Resource Conservation and Recovery Act (40 C.F.R. § 261. Identification and Listing of Hazardous Waste, 2020) are found in the IQOS HeatSticks tobacco in negligible concentrations in the leachate (Koutela et al., 2020)

from used IQOS HeatSticks. The Agency anticipates that the potential exposure of heavy metals from the new IQOS HeatSticks are comparable to the authorized IQOS HeatSticks because there is no change to the tobacco blend.

The Agency does not foresee that the introduction of the new IQOS HeatSticks into the U.S. market would notably affect the nationwide waste generated from the use of HTPs. The new IQOS HeatSticks are expected to replace the authorized IQOS HeatSticks. The distribution of waste generated due to disposal of the new IQOS HeatSticks and packaging is anticipated to correspond to the pattern of the products use in the United States.

6.6. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new IQOS HeatSticks. The waste generated due to disposal of the new IQOS HeatSticks would be handled in the same manner as the waste generated from disposal of other HTPs in the United States. No new types of emissions are expected due to disposal of the new IQOS HeatSticks; therefore, there would be no disproportionate impacts on minority or low-income populations.

6.7. Impacts from the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of HTPs and their packaging, as the authorized IQOS HeatSticks and many other similar HTPs would continue to be disposed of in the United States.

7. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

Preparer:

Bria J. Martin, B.S., Center for Tobacco Products
Education: B.S. in Biological Sciences
Experience: Five years in various scientific activities
Expertise: NEPA analysis, forestry, ecology and evolutionary studies

Reviewer:

Hoshing Chang, PhD, Center for Tobacco Products
Education: Ph.D. in Biochemistry, M.S. in Environmental Science
Experience: Thirteen years in FDA-related NEPA review
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

8. A Listing of Agencies and Persons Consulted

Not applicable.

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CONFIDENTIAL APPENDIX 1: Product Modifications

Component(s)	Change from the Authorized IQOS HeatSticks
Acetate tow	(b) (4)
Plug Wrap	
Adhesive	
Tipping Paper Inks	

CONFIDENTIAL APPENDIX 2: Market Volume Projections

Product	Unit	Market Volume Projections	
		First-Year	Fifth-Year
Marlboro Amber HeatSticks	One HeatStick	(b) (4)	

CONFIDENTIAL APPENDIX 3: Comparisons of user-generated aerosols due to use of the IQOS HeatSticks

The applicant submitted a comparison of aerosols generated by the user in the new and authorized HeatSticks. The comparison includes HPHCs, analytes and tobacco constituents. There are changes in the new and authorized IQOS HeatSticks (three batches evaluated for each); however, the differences are minor (see below). Values and percent changes are available in the table below.

Marlboro Amber HeatSticks

HPHCs/Analyte	Unit	Authorized (Average)	New (Average)	Percent Change
Ammonia	µg/cig	10.83	14.47	33.54%
Formaldehyde	µg/cig	13.47	6.82	-49.38%
Acetaldehyde	µg/cig	193.33	195.67	1.21%
Acrolein	µg/cig	9.11	9.13	0.22%
Crotonaldehyde	µg/cig	< 3.29	< 3.29	0.00%
CO	mg/cig	0.32	0.42	30.56%
Nicotine	mg/cig	1.17	1.30	10.83%
Benzo(a)pyrene	ng/cig	0.65	0.78	19.47%
1,3-butadiene	µg/cig	0.22	0.17	-23.93%
Isoprene	µg/cig	1.49	1.37	-8.04%
Acrylonitrile	µg/cig	0.12	0.14	17.86%
Benzene	µg/cig	0.45	0.56	23.53%
Toluene	µg/cig	1.38	1.99	44.10%
1-aminonaphthalene	ng/cig	0.04	0.03	-5.02%
2-aminonaphthalene	ng/cig	0.02	< 0.012	-40.59%
4-aminobiphenyl	ng/cig	0.01	0.01	1.27%
NNN	ng/cig	9.22	13.30	44.25%
NNK	ng/cig	8.21	10.50	27.89%
Tobacco Constituents				
Nicotine	µg/g	17859.33	17692.33	-0.94%
Ammonia	µg/g	428.00	440.00	2.80%
Cadmium	ng/g	653.00	602.00	-7.81%
Arsenic	ng/g	143.00	158.33	10.72%
NNN	ng/g	384.00	548.00	42.71%
NNK	ng/g	185.33	262.33	41.55%

Note 1: The measurements of crotonaldehyde were below 3.29 µg/cig; therefore, percent changes were not calculated for the new and authorized IQOS HeatSticks.

Note 2: The measurements of 2-aminonaphthalene for the new IQOS HeatSticks were below 0.012 ng/cig; therefore, 0.012 ng/cig was used to calculate the percent change. It is acknowledged that the percent change may be higher given the “less than” value.

CONFIDENTIAL APPENDIX 4: Screening-level risk assessments of nicotine and heavy metals in IQOS HeatSticks for aquatic animals

The applicant provided the aquatic environmental introduction concentrations of (b) (4) for the corresponding authorized IQOS HeatStick (PM0000424) for Marlboro Amber HeatSticks (see table below). The applicant also stated that the tobacco blend (source of heavy metals) is not changing in the new and authorized IQOS HeatSticks.

Measured [REDACTED] Levels in PM0000424 (authorized IQOS HeatStick)

Tobacco Constituent	Unit	Marlboro Amber ("Authorized HeatSticks") - Batch #1			Marlboro Amber ("Authorized HeatSticks") - Batch #2			Marlboro Amber ("Authorized HeatSticks") - Batch #3		
		Average	SD	N	Average	SD	N	Average	SD	N
(b) (4)	ng/g	(b) (4)								
	ng/g									
Tobacco Constituent	Unit	Marlboro Amber ("modified products") - Batch #1			Marlboro Amber ("modified products") - Batch #2			Marlboro Amber ("modified products") - Batch #3		
		Average	SD	N	Average	SD	N	Average	SD	N
(b) (4)	ng/g	(b) (4)								
	ng/g									
Note: SD - standard deviation; N - sample size										

The Agency estimated in the risk quotients as indicated in the table below:

Chemical	Aquatic Environmental Introduction Concentration ($\mu\text{g/L}$) ¹	Lowest Acute Toxicity Endpoint Value (EC_{50}/LC_{50}) ($\mu\text{g/L}$) ²	Species	Risk Quotient ³
(b) (4)				

¹ Expected Introduction Concentration (EIC)-aquatic (ppb or $\mu\text{g/L}$)= $A*B*C*D$; where A=kg/yr shipped quantity, B=1/1.214x10¹¹ L/day entering POTW (Source: 1996 Needs Survey, Report to Congress), C=year/365, D=10⁹ $\mu\text{g/kg}$ (Source of EIC estimation equation: Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications, 1998)

² Lowest acute toxicity endpoint value and the corresponding species for each chemical obtained from U. S. Environmental Protection Agency's ECOTOXicology Knowledgebase (ECOTOX) available at <https://cfpub.epa.gov/ecotox/search.cfm> (Retrieved December 22, 2021).

³ Risk Quotient (RQ) calculated as Environmental Exposure Concentration (EEC)/LC₅₀ or EC₅₀ per U. S. Environmental Protection Agency methodology (<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-risk>). For calculating the RQ, the Agency assumed a worse-case scenario that the EEC is the same as the Environmental Introduction concentration.