Module 6: Summary

6.1 Summary of the Product Formulation

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1. SUMMARY OF DESCRIPTIVE INFORMATION

1.1. Description of the Tobacco Product

The *IQOS* 3 System is an upgraded version of the Authorized *IQOS* System developed by Philip Morris Products S.A. (PMP S.A.), which is intended to be exclusively used with a specially-designed non-combustible cigarettes currently commercialized under the brand name *Marlboro HeatSticks* (also refered as *HeatSticks*). It consists of two main components:

- The *IQOS* 3 Holder
- The *IQOS* 3 Charger

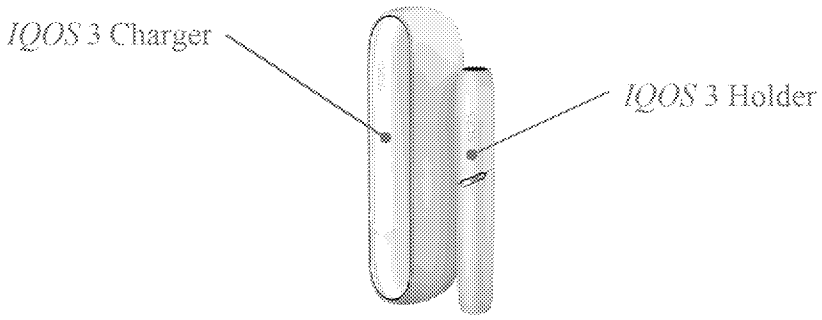


Figure 1: *IQOS* 3 System[1]

The *IQOS* 3 System retains all the functional elements of the Authorized *IQOS* System. Importantly, the principles of aerosol generation remain unchanged and this is why, as demonstrated in this sPMTA, the aerosol generated with both *IQOS* Systems is comparable.

1.2. Compliance to Tobacco Product Standards

At the moment, there are no tobacco product standards under section 907 of the Federal Food, Drug and Cosmetic Act that are applicable to the *IQOS* 3 System.

Nonetheless, the *IQOS* 3 System is designed and manufactured in accordance with various current international standards. The manufacturing sites are certified according to ISO 9001:2015 standard, while the *IQOS* 3 System complies with multiple safety standards for electronic devices (e.g. battery cell standards IEC 62133 (2nd Ed.) and UL 1642 (5th Ed.), CFR regulations for transmissions, …). For additional information on IQOS 3 System compliance with standards please refer to section 3.1.2 *Compliance to Tobacco Product Standards*.

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[1] This figure depicts the *IQOS* 3 System in white. The product will be available in multiple colors.

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1.3. Product Naming

The upgraded version of the Authorized *IQOS* System developed by Philip Morris Products S.A. (PMP S.A.) and the subject of this application will be commercialized under the brand name *IQOS* 3.

1.4. Similar Marketed Products or Prototypes

1.4.1. *Summary of the Developmental Activities for IQOS 3*

In July 2016 PMP S.A. started development activities in collaboration with (b) (4) (b) (4) on the *IQOS* 3 System, to incorporate learnings from consumer research among adult smokers and recent advances in electronic technology.

The new design of the *IQOS* 3 System was aimed to achieve the following main objectives:

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During the development all the design objectives for the *IQOS* 3 System were researched, but not all of them were successfully achieved and incorporated in the final design (b) (4) (b) (4) The selected design was verified before the launch of the product in selected markets in late 2018. Post-market development and optimization continued within 2019, when the U.S. version of the *IQOS* 3 System was finalized.

For more details on the development activities for the *IQOS* 3 System, see section 3.1.4 *Similar Marketed Products or Prototypes*, chapter 1.2. Development of IQOS 3 System.

1.4.2. *Similar Marketed Tobacco Products*

The *IQOS* 3 System is an upgraded version of the Authorized *IQOS* System (a non-combusted cigarette), which received Marketing Order (PM0000479) on April 30, 2019, and was commercialized in the following months.

The user operates the *IQOS* 3 System in the same manner as the Authorized *IQOS* System. A *HeatStick* is inserted into the *IQOS* 3 Holder. Once inserted, the electronically controlled and chemically inert heater blade will heat the *HeatStick*, reaching target temperatures between

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320-350°C, and thus generate aerosol. The duration of a single use of *HeatSticks* or the number of puffs provided by the Holder remain the same between the *IQOS* 3 System and the Authorized *IQOS* System. After use, the used *HeatStick* is to be discarded appropriately and the Holder to be recharged by the Charger for the next use.

Detailed comparison of the between *IQOS* 3 System and Authorized *IQOS* System is provided in Table 1.

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Table 1: Detailed comparison of Authorized *IQOS* System and *IQOS* 3 Systems

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Besides the Authorized *IQOS* System one other product from the same category (non-combusted cigarettes) has been have been authorized to be sold in the United States. This is *Eclipse* from R.J. Reynolds Tobacco Company, which was commercialized on the US market at various times since the 1990s.

Although that product also heats tobacco, its composition, heat source (smoldering carbon tip) and how the user uses the product is quite different from the *IQOS* 3 System.

1.5. Restrictions on Sale, Distribution, Advertising or Promotion

The *IQOS* 3 System will be marketed under the same restrictions on sale, distribution, advertising and promotion that are currently applicable to the Authorized *IQOS* 2.4 System in the U.S. by Altria affiliate, Philip Morris USA ("PM USA"), licensed to sell both the Authorized *IQOS* System and the *IQOS* 3 System in the United States.

In addition, FDA has imposed restrictions on the sale, distribution, advertising and promotion of the Authorized *IQOS* System in the Marketing Order for that product that we believe will be similarly mandated for the *IQOS* 3 System and with which PM USA will comply.

2. SUMMARY OF THE PRODUCT FORMULATION

2.1. Components or parts, materials, ingredients, additives, and constituents

2.1.1. *Components or Parts*

Analogous to the Authorized *IQOS* System, the *IQOS* 3 System consists of the heating unit called the *IQOS* 3 Holder into which a *HeatStick* is inserted, and a charging unit, which is called the *IQOS* 3 Charger, to facilitate easy recharging of the Holder.

The ***IQOS* 3 Holder** is 92 mm long and 14 mm wide electrically powered and rechargeable unit, which uses glass-coated ceramic heating blade to heat tobacco material in *HeatSticks* and generate nicotine-containing aerosol. It is comprised of a heating element, power source (battery), electronic parts, user interface and structural and housing parts. The complete composition of the Holder is provided in the table below.

Table 2: Composition of *IQOS* 3 Holder

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The ***IQOS* 3 Charger** is 115 mm long and 46 mm wide and 23 mm thick case intended for storing and recharging the Holder between individual uses. The Charger is constructed from power source (battery), electronic parts, user interface and structural and housing parts as provided in Table 3.

Table 3: Composition of *IQOS* 3 Charger

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2.1.2. *Materials*

IQOS 3 components and parts are made out different base materials, which include different plastic resins, elastomers, metal, ceramic, glass, batteries, electronics and other materials. As with the Authorized *IQOS* System, all materials (including paints) were evaluated from the various physical properties and toxicological perspective and were found to be suitable.

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2.1.3. *Ingredients other than tobacco*

Not applicable.

2.1.4. *Tobacco Ingredients*

Not applicable.

2.1.5. *Constituents*

Chemical and physical properties of the aerosol generated with U.S. version of the *IQOS* 3 System were also evaluated as part of the *IQOS* 3 System aerosol characterization in accordance with the current version of the TSH 2.2 Comparability Strategy. During the characterization 3 testing were performed and compared with the Authorized *IQOS* System (*IQOS* 2.4 System):

- Determination of the PMI's list of 58 compounds (PMI-58[2]), which contain 54 Harmful and Potentially Harmful Constituents (HPHCs) and four other aerosol constituents,
- Determination of four additional HPHCs (glycidol, furfural, 2-furanmethanol, 3-chloro-1,2-propondiol), which were identified in the non-targeted differential screening from the Authorized *IQOS* System as representative for *IQOS* system and
- Determination of the droplet size distribution (DSD).

The results of the testing confirmed that the emissions generated by both heating profiles of the *IQOS* 3 System are comparable to the emissions of the Authorized *IQOS* System.

2.1.6. *Container Closure System*

The *IQOS* 3 System is packaged in a customized paperboard box, which also contains molded fiber pulp trays to hold the Holder and Charger and accompanying accessories (e.g. AC adapter, USB charging cable, cleaning tool …) securely during transportation and storage. *IQOS* 3 System documentation (e.g. User Guide and Warranty Card) is included in the box as well. The assembled package/kit is then wrapped with plastic film.

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[2] For additional information about of how this list of constituents was selected and justification, please refer to the original submission of PMTA for *IQOS* 2.4 System with three variants of *Marlboro HeatSticks* (STNs: PM0000424-PM0000426 and PM0000479), Module 3, Appendix A3.2.1-12 and Appendix A3.3-2.

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No packaging elements are considered as a container closure system.

2.1.7. *Statement of Tobacco Blending, Reconstitution, Manipulation*

Not applicable.

2.2. Other properties

2.2.1. *Product Dimensions and Construction*

The overall dimensions of both components of *IQOS* 3 System are provided the table below.

Table 4: Dimensions of the *IQOS* 3 System

Component	Overall dimensions* (mm)	
Holder	Length	(b) (4)
	Diameter	
Charger	Length	
	Width	
	Thickness	

(b) (4)

2.2.2. *Design Parameters and Test Data*

During the development of the *IQOS* 3 System, the device was evaluated, to determine if it met all identified needs and the intended use as documented in the Design Inputs. Some of the critical design features are provided in the table below, while the complete list is provided in section 3.2.2.2 *Design Parameters and Test Data*.

Table 5: Summary of some critical design features of *IQOS* 3

Tested item	Critical design features
(b) (4)	

(table continues)

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2.2.3. *Function*

The upgraded version of the *IQOS* System – *IQOS* 3 consists of two main components, consistent with the Authorized *IQOS* System:

- *IQOS* 3 Holder (electrical heating unit) and
- *IQOS* 3 Charger (recharging case for the Holder).

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The ***IQOS* 3 Holder** is used to heat tobacco material (tobacco plug) in specially-designed non-combusted cigarettes called *HeatSticks*.

It contains the following functional parts:

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The Holder will turn off the heating process in the event that overheating is detected by the thermal monitoring system.

The Holder (shown with housing removed in figure below) is designed to hold the *HeatStick* and heat it upon user initiation in a controlled and repeatable manner. The size and weight ensure that it can be comfortably held by the user.

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The ***IQOS* 3 Charger** is used to recharge the Holder. It is also used to store the Holder when not in use and to provide a safe and secure environment for the periodic thermal cleaning process of the Holder's heating blade.

The Charger includes the following functional parts:

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The Charger (shown with housing removed in figure below) is designed to recharge the Holder and store the Holder when not in use. The size and weight ensure that it can be comfortably carried by the user in a pocket.

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Figure 5: Schematic exploded view of the *IQOS* 3 Charger

2.2.4. *pH of Product and Nicotine Formulation*

Not applicable.

2.2.5. *Fermentation Process*

Not applicable.

2.2.6. *Storage and Stability Information*

As part of design verification testing, the *IQOS* 3 System was evaluated with regards to the device robustness in terms of number of experiences and ambient conditions for operating a device.

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The design verification testing has demonstrated that the *IQOS* 3 System should be operated[4] in ambient temperature conditions[5] between 3°C and 50°C and humidity range from 5 % to 93 % RH (non-condensing).

2.2.7. *Product and Packaging Design Risks and Misuse Hazards*

As part of the development process, all the risks related to the intended use and foreseeable misuse of the product are identified and assessed in the Use-Hazard Analysis (UHA). Once the risks associated with the product use have been identified and evaluated, risk reduction measures are proposed depending on the risk criticality, which are also captured in the UHA. For additional information regarding the UHA please see section 3.2.2.7 *Product and Packaging Design Risks and Misuse Hazards*.

2.3. Principles of Operation

Before the user can use the IQOS 3 System, the user must turn on the Charger (also referred as the Pocket Charger) by pressing and holding the power button for 4 seconds. Two sets of lights (holder status and charger battery status) will flash. Afterwards the user inserts the Holder into the Charger. Once the holder battery is fully charged the holder status light is solid white.

Once the battery is fully charged, the user inserts the *HeatStick* into the Holder, tobacco-side down, and pushes until the line indicated on the filter of the *HeatStick*. The user initiates the heating of the *HeatStick* by pressing and holding the holder button until the Holder vibrates and the holder button LED starts to pulsate white. Once the Holder vibrates twice and the holder button LED turns to solid white, the initial heating process (pre-heating phase) is complete and the user can begin the inhalation experience.

The *IQOS* 3 System is used in much the same way as a conventional cigarette:

- The user draws air through the *HeatStick* (puff).
- This initiates the use heating cycle, which follows a puff-by-puff heating profile designed to provide a consistent user experience throughout use.
- The Holder and *HeatStick* can deliver aerosol for up to either approximately 6 minutes or 14 puffs.
- The user is informed that the usage is about to end when the Holder vibrates twice and the holder button LED starts to pulsate white (approximately 30 seconds or 2 puffs remaining).

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[4] For the charging of the battery in *IQOS* 3 Charger, the ambient temperature should be in range from 0°C to 40°C at a humidity range from 5 % to 93 % RH (non-condensing).

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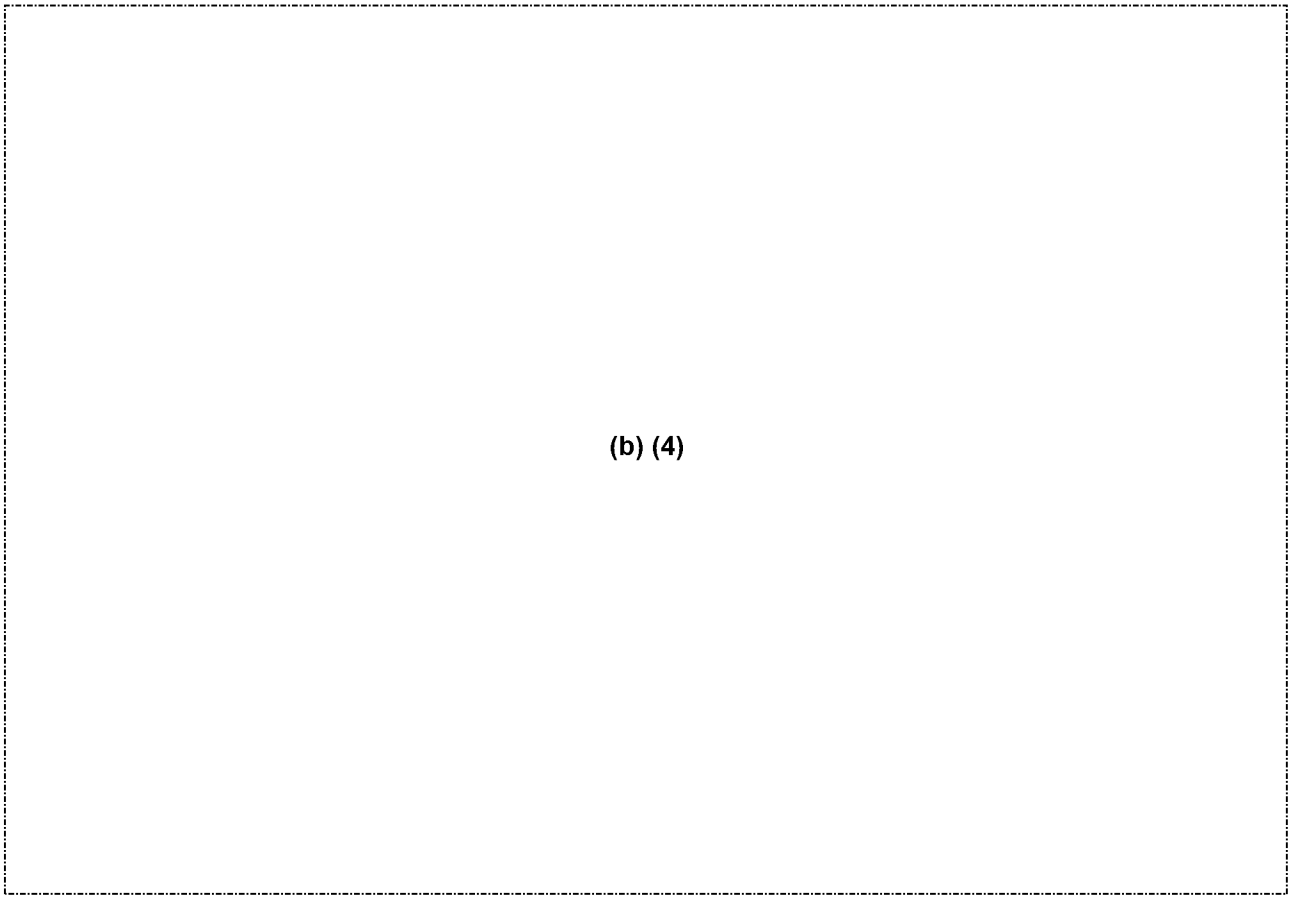
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- When the holder button LED goes off, the use is finished.

After the inhalation experience is complete, the user removes the used *HeatStick* from the Holder by sliding the front housing (cap) upward and removing it from the Holder. Once removed, the front housing is pushed down again and Holder is inserted into the Charger to be recharged before the next inhalation experience.

2.3.1. *Heating Source*

The *IQOS* 3 Holder uses a heating blade (part of the overmolded heater seal), to heat the *HeatStick*. When user inserts a *HeatStick* in the *IQOS* 3 Holder, this V-shaped blade is inserted into the tobacco plug of the *HeatStick*.



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2.4. Product Testing and Analysis Information

Once the design of the US version of *IQOS* 3 system was set, the product was tested in an independent laboratory Labstat International Inc. for FDA's abbreviated list of 18 Harmful and Potentially Harmful Constituents (HPHCs)[6], which are required under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act.

The results of testing performed on the U.S. commercial version of the IQOS 3 System, using all three currently commercialized variants of *HeatSticks* under two aerosol-generating regimes (ISO standard and Health Canada Intense) is provided in section 3.2.4 *Product Testing and Analysis Information*. In addition, results of the Kentucky reference cigarette 1R6F, which was also tested, are provided as well.

[6] FDA's Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act, March 2012

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