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6.4 Consumer Understanding and Perceptions	Version 1.0

## Module 6 : Research

### 6.4 Consumer Understanding and Perceptions

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## 1. CONSUMER UNDERSTANDING AND PERCEPTIONS

### 1.1. Introduction

To measure the potential benefit of marketing a MRTP to the public, the FDA Modified Risk Tobacco Product Applications Guidance recommended investigating several areas, including the effect of marketing on consumer understanding and perceptions<sup>1</sup>. In this section, we provide data from both pre-market studies included in the original MRTPA<sup>2</sup>, and postmarket studies conducted both within the U.S. and internationally, on the effect of *IQOS* marketing on consumer understanding and perceptions. In addition, we cross-reference Module 7 of the original MRTPA for the Authorized *IQOS* products with related appendices and data, and with subsequent amendments, and Module 7 of the supplemental PMTA for the Authorized *IQOS* 3 System (PM0000634), as well as Module 7 of the supplemental MRPTA for *IQOS* 3 System (MR0000192).

### 1.2. U.S. Pre-market Studies

#### 1.2.1. Background

(b) (4)

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<sup>1</sup> FDA. Modified Risk Tobacco Product Applications. Guidance for Industry. Rockville, MD: U.S. Department of Health and Human Services. March 2012.  
<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf>.

<sup>2</sup> Modified Risk Granted Orders (MRGOs) – Exposure Modification issued on July 7, 2020 for the *IQOS* 2.4 System (MR0000133) with three (3) variants of *HeatStick* (MR0000059 - MR0000061)

<sup>3</sup> MO PM0000424-PM0000426, PM0000479 dated April 30, 2019 (section 6.2.2 Product Usage) and MGO MR0000059-MR000061 and MR0000133 dated July 7, 2020 (section 6.2.2 Product Usage)

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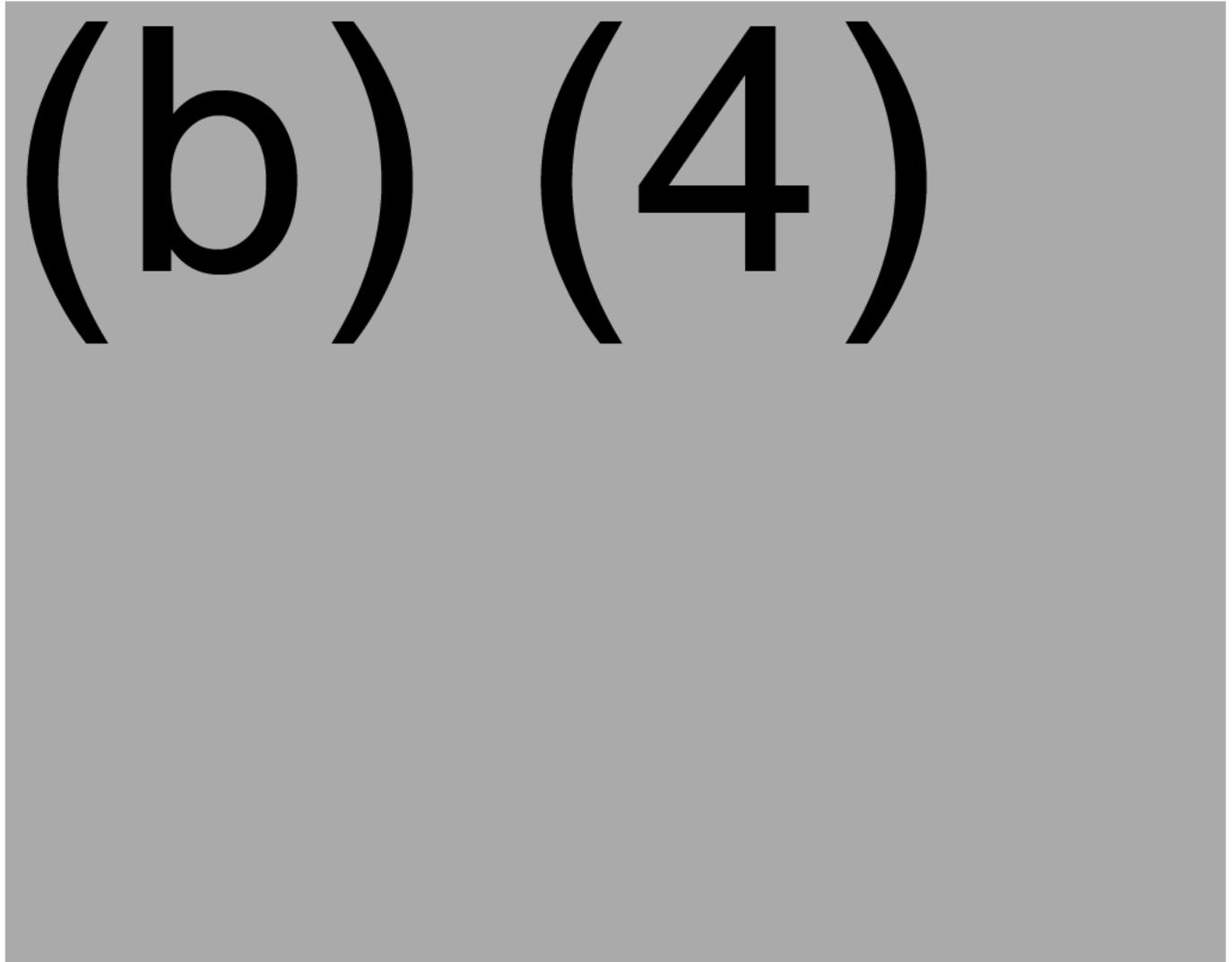
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*1.2.1. Effect of THS Label, Labeling and Marketing Material on Comprehension*



**Figure 1 Comprehension of Level of Exposure to Harmful and Potentially Harmful Chemicals Associated with the THS 2.2 Brochure and Associated with the HeatSticks Pack Within the Main Sample in THS-PBA-05-REC-US**

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*1.2.2. Effect of THS Label, Labeling and Marketing Material on Perceived Health Risk*

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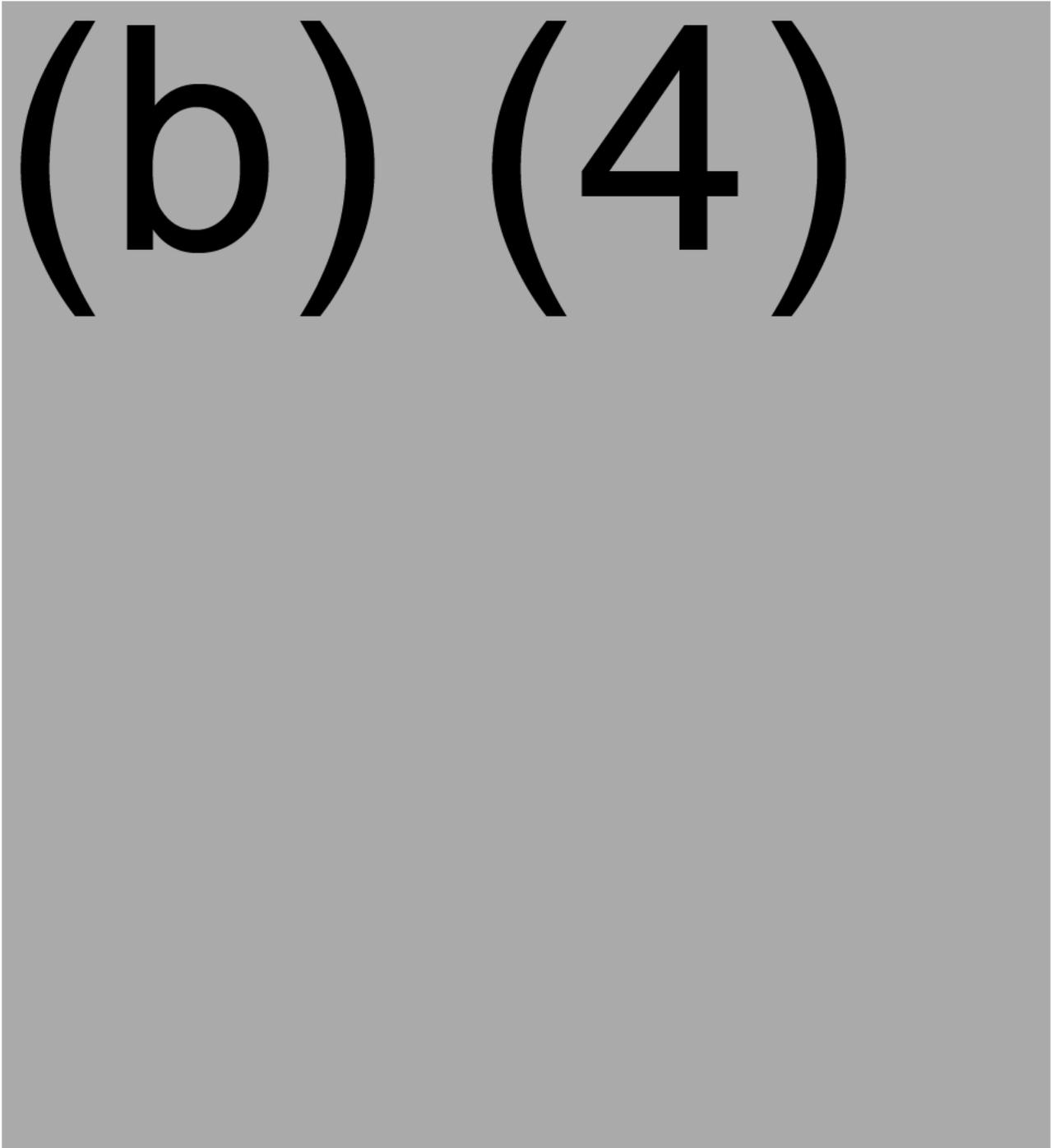
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**Figure 2 Perceived Health Risk – THS 2.2 Brochure with Surgeon General’s Warnings, Arm 1 and HeatSticks Pack with Surgeon General’s warnings, Arm 3 in THS-PBA-05-REC-US**

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### 1.2.3. Conclusion of Pre-market U.S studies

Based on TPL review of the THS-PBA-05-REC-US consumer perception study, which was part of the original MRTPA, the FDA concluded that:

*“The results of applicant’s consumer perception studies support that consumers generally comprehend the modified risk information in the context of total health. In particular, the results indicate that consumers understand that the product is not without risks and that it is more harmful than quitting smoking. Consumers also generally perceive the product as less harmful than combusted cigarettes, which is in line with the relative health risks of the product that are reasonably likely”.<sup>7</sup>*

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, as

outlined in [section 1.3](#) and in [section 1.4](#).

### 1.3. U.S. Postmarket Studies

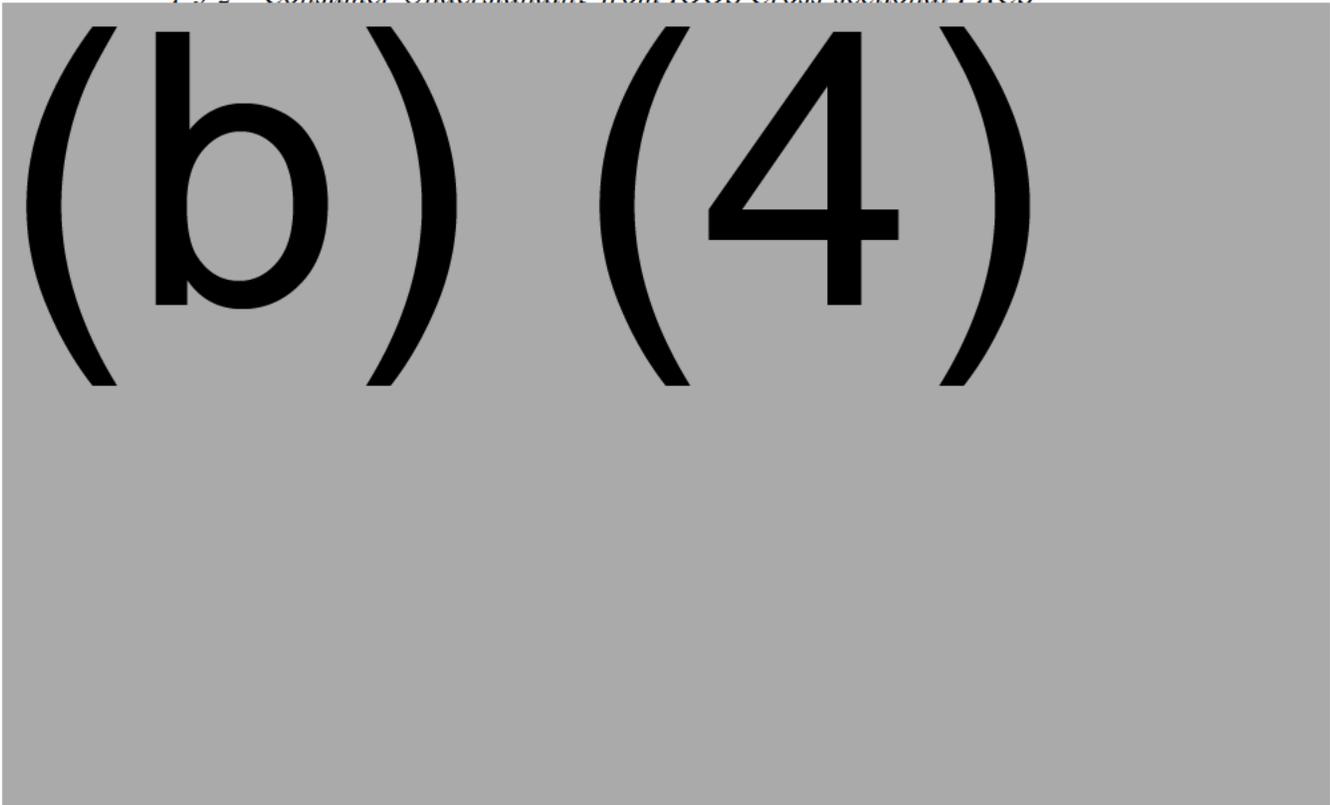
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1.3.2 Consumer Understanding from IOOS Cross-sectional PACS



**Figure 3 Perception about harmful or potentially harmful chemical exposure when switching completely from cigarettes to IQOS**



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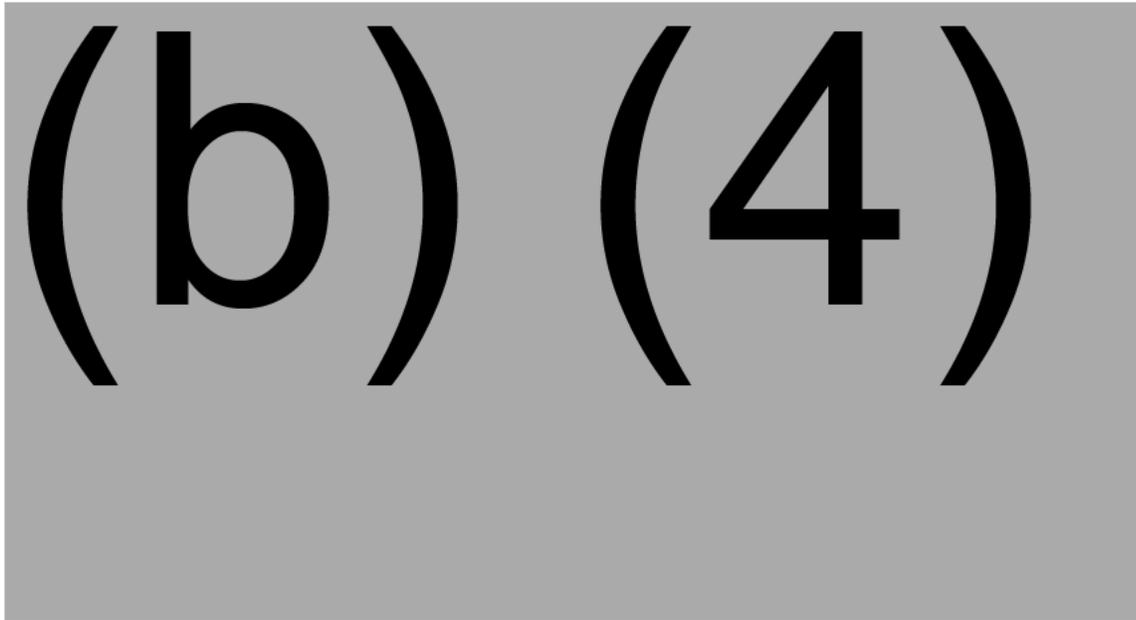
<sup>10</sup> (b) (4)

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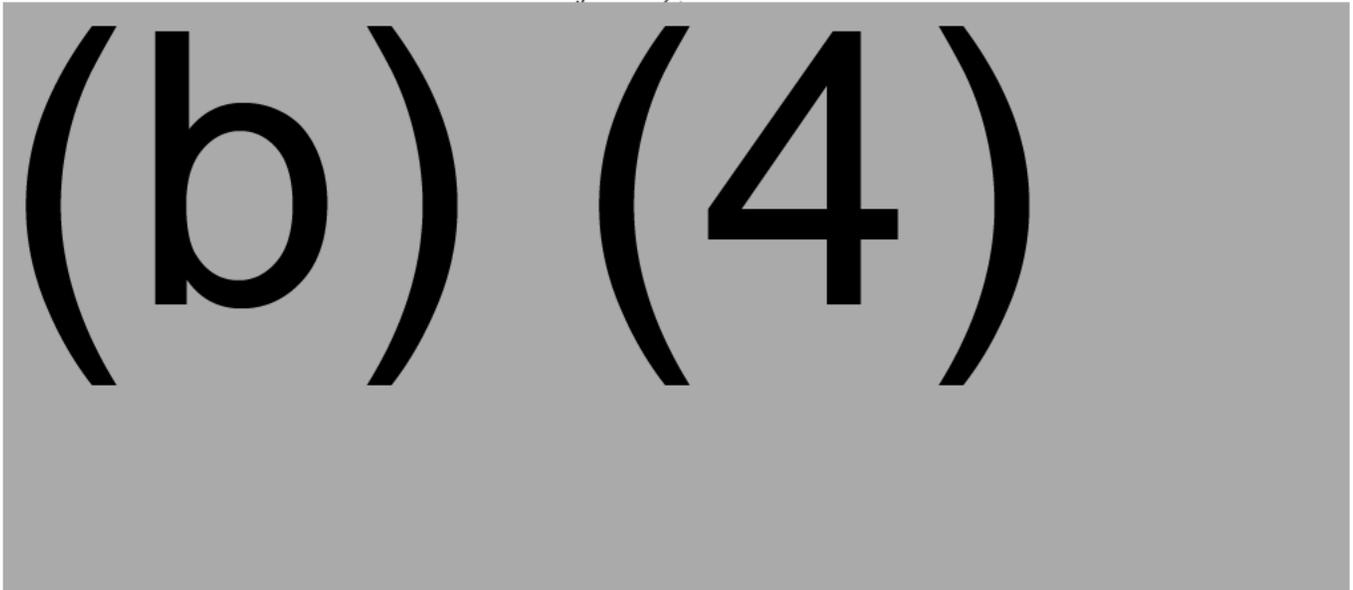
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**Figure 4 Understanding of what smokers must do to reduce their exposure to harmful or potentially harmful chemicals**

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*1.3.3. Perceived Health Risk from IQOS Cross-sectional PACS*



<sup>11</sup>(b) (4)

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**Table 1 Risk Perceptions of IQOS and Cigarette**



*1.3.4. Conclusion of U.S. Postmarket studies*



**1.4. PMP S.A. International Postmarket Data: Repeated Cross-sectional Post-Market Surveys (PMX studies)**

*1.4.1. Background*



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<sup>12</sup> (b) (4)

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**Figure 5 Perceived Health Risk Associated with Cigarettes /Using IQOS - Trend Data - IQOS Users in Japan.**

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#### 1.4.1. Conclusion of International Postmarket studies

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#### 1.5. Independent Studies

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## 2. CONCLUSION

The results of the U.S. pre-market study, submitted as part of the original MRTPA, showed that consumers were able to understand that, upon switching completely from CC to IQOS, they would benefit from a reduction of exposure to HPHCs. A high level of understanding that completely switching to IQOS would reduce exposure to HPHCs compared to smoking was also found in the U.S. postmarket study.

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<sup>14</sup> For the list of Annual Reports see [section 4.2 Marketing Plan](#)

<sup>15</sup> 2023 Annual Report and PMSS report submitted on April 28, 2023

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Thus, the combined evidence from our pre-market and post-market studies conducted in the U.S. and internationally provides evidence that *IQOS* continues to satisfy MRTP requirements in accordance with section 911(g)(2)(B) of the FD&C Act as evidence continue to show that *consumers generally comprehend the modified risk information in the context of total health, that consumers understand that the product is not without risks and that it is more harmful than quitting smoking and that consumers also generally perceive the product as less harmful than combusted cigarettes, which is in line with the relative health risks of the product that are reasonably likely.*<sup>16</sup>

### 3. REFERENCES

AlMoosawi, S., Bajec, M., Mainy, N., Kallischnigg, G., Zwisele, B., Fischer, K., Magnani, P. and Roulet, S., 2022. Risk perception of IQOS™ and cigarettes: Temporal and cross-country comparisons. *SSM-Population Health*, 18, p.101123.

Cano, S., Chrea, C., Salzberger, T., Alfieri, T., Emilien, G., Mainy, N., ... & Weitkunat, R. (2018). Development and validation of a new instrument to measure perceived risks associated with the use of tobacco and nicotine-containing products. *Health and Quality of Life Outcomes*, 16(1), 1-15.

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<sup>16</sup> Technical Project Lead (TPL) Review for the MRTP exposure modification orders granted on July 7, 2020.

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