

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 1 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Annex 1:

MRTP Use Behavior and Consumer Understanding and Perception

Product	Marlboro Amber HeatSticks Marlboro Green Menthol HeatSticks Marlboro Blue Menthol HeatSticks <i>IQOS</i> System Holder and Charger
FDA STN	MR0000059, MR0000060, MR0000061, MR0000133
Reporting Period	March 1, 2021 to February 28, 2022

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 2 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

TABLE OF CONTENTS

1	SUMMARY – MRTP USE BEHAVIOR AND CONSUMER UNDERSTANDING AND PERCEPTION.....	3
2	<i>IQOS</i> MRTP POSTMARKET STUDIES AND ANALYSES UPDATE	3
3	ADULT PREVALENCE AND PRODUCT USE PATTERNS.....	7
3.1	Prevalence	7
3.2	Product Use Patterns	7
3.2.1	Product Use Patterns from <i>IQOS</i> Cross-Sectional PACS.....	7
3.2.2	Product Use Patterns from <i>IQOS</i> Owners Panel.....	12
4	ADULT CONSUMER UNDERSTANDING AND PERCEPTION.....	14
5	UNDERAGE AWARENESS, EVER USE, AND PAST 30-DAY USE	16
6	CONCLUSIONS – MRTP USE BEHAVIOR AND CONSUMER UNDERSTANDING AND PERCEPTION	18
7	ANNEXES.....	18

LIST OF TABLES

Table 1	Summary and Status of <i>IQOS</i> MRTP U.S. Postmarket Surveillance Studies	4
Table 2	Demographics and background information of current <i>IQOS</i> users.....	8
Table 3	Adult Participants in the <i>IQOS</i> Owners Panel by <i>IQOS</i> Usage Level (Total <i>IQOS</i> Owners (b)(4)).....	13
Table 4	UTUS 2021 Q2 to 2022 Q1 Estimates: Awareness, Ever Use, and Past 30-Day use of <i>IQOS</i>	17

LIST OF FIGURES

Figure 1	Current cigarette consumption compared to before trying <i>IQOS</i> , Adult smokers (b)(4)	11
Figure 2	Adult Participants in the <i>IQOS</i> Owners Panel by <i>IQOS</i> Usage Level (May 2020 to November 2021).....	14
Figure 3	a-b Adult <i>IQOS</i> Risk Perception Composite Score (a.) and Perception of exposure when switching from cigarettes to <i>IQOS</i> (b.).....	15

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 3 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

1 SUMMARY – MRTP USE BEHAVIOR AND CONSUMER UNDERSTANDING AND PERCEPTION

In this section, we provide evidence of an expansion of *IQOS* use in select markets at the beginning of the reporting period culminating in the removal of *IQOS* products from the market on November 29th, 2022.¹ Uptake of the *IQOS* system was low but growing among U.S. adult cigarette smokers (21+) in regions where the *IQOS* system was available. We observed low awareness and little uptake of *IQOS* use among underage (13-20 years old) individuals. Among adult *IQOS* users, we saw strong evidence of switching completely from cigarettes to *IQOS* and accurate risk perceptions.

2 *IQOS* MRTP POSTMARKET STUDIES AND ANALYSES UPDATE

During this reporting period, all postmarket surveillance and studies were implemented as planned. On February 24, 2021, FDA issued its letter of approval for the planned postmarket surveillance studies. Since that time, we successfully added the *IQOS* module to our ongoing Underage Tobacco Use Survey (UTUS) in the second quarter of 2021 and conducted the first wave of the *IQOS* Cross-Sectional Postmarket Adult Consumer Study (PACS; ALCS-CMI-17-36-HT) in the third and fourth quarters of 2021. This update includes the data and information gained from our ongoing market surveillance, our first wave of the *IQOS* Cross-sectional PACS, and a review of *IQOS* marketing changes that will impact planned postmarket surveillance and study (PMSS) activities.

As documented in a letter to the FDA Office of Compliance and Enforcement on November 9th, 2021,² the International Trade Commission (ITC) issued a decision that halted the importation of *IQOS* products into the United States. As of November 29, 2021, Philip Morris USA (PM USA) is no longer marketing or selling *IQOS* products in the U.S., which hinders our ability to study and surveil *IQOS* use. As such, our timing and plans for PMSS moving into 2022 have been adjusted as documented in the letter sent to FDA on January 14, 2022.³ Changes include pausing *IQOS* Cross-Sectional PACS and *IQOS* Cohort PACS (ALCS-CMI-17-37-HT) study conduct in 2022 and ending the current U.S. *IQOS* Owners Panel.

¹ In September 2021, the International Trade Commission (ITC) issued an order imposing an importation ban on the *IQOS* device and Marlboro HeatSticks into the U.S., and a cease and desist order on the marketing and sale of product already imported into the U.S.

² Letter to Ann L. Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products, on November 9th, 2021, from Altria Client Services LLC, on behalf of Philip Morris USA

³ On January 14, 2022, Philip Morris Products S.A. submitted the *Premarket Tobacco Product Application Amendment and General Correspondence Submission* to LCDR Michael Gu regarding the *Adjustment to the Postmarket Surveillance and Studies (PMSS) Plan for MR0000059 - MR0000061 and MR0000133*.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 4 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Additionally, while UTUS data collection is ongoing into 2022, we halted the oversample in Atlanta, GA, Charlotte, NC and Richmond, VA starting in the second quarter of 2022.

The current status of our postmarket studies and analyses is presented in [Table 1](#). Please note that we will notify FDA if any of our proposed study timelines need to be adjusted in 2022.

Table 1 Summary and Status of *IQOS* MRTP U.S. Postmarket Surveillance Studies

Study Name	Study Details	Status
<i>IQOS</i> With Marlboro HeatSticks Cross-Sectional Postmarket Adult Consumer Study (PACS) (b)(4)	This study is a repeated cross-sectional study of adult (21+) ever established <i>IQOS</i> users recruited from the <i>IQOS</i> consumer database. The objectives of the online survey are to 1) characterize adult ever established <i>IQOS</i> users and their tobacco use patterns; 2) characterize risk perceptions of <i>IQOS</i> ; and 3) describe initiation, complete switching from cigarette smoking to <i>IQOS</i> , transitions to/back to cigarette smoking, and quitting behaviors relevant to <i>IQOS</i> use. We plan to field the PACS annually for four years.	<p>On February 24, 2021, FDA issued its letter of approval for the planned post market surveillance studies and as directed, planned post market surveillance studies began after that approval.</p> <p>In this report we provide a summary of the first execution of the <i>IQOS</i> Cross-Sectional PACS fielded from September to November of 2021.</p> <p>We had originally planned to launch the second execution of the <i>IQOS</i> Cross-Sectional PACS in September of 2022. We do not expect a sufficient <i>IQOS</i> consumer pool to recruit from in 2022 considering the unavailability of <i>IQOS</i> and HeatSticks in the market. We currently plan to skip the <i>IQOS</i> Cross-Sectional PACS planned to be conducted in 2022, with hopes to launch the second execution of the study in 2nd or 3rd quarter of 2023 if <i>IQOS</i> has been available for a sufficient time in the U.S. market. We will communicate the detailed study timeline to FDA and provide an amended protocol when we have a firmer understanding of the return-to-market timing for <i>IQOS</i>.</p>

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 5 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Study Name	Study Details	Status
<p><i>IQOS</i> with Marlboro HeatSticks Cohort Postmarket Adult Consumer Study (PACS)</p> <p>(b)(4)</p>	<p>This study will be conducted among ~2,100 adult recent (have used <i>IQOS</i> for ≤ 6 months), current, established <i>IQOS</i> users and a reference sample of ~1,600 adult combustible cigarette smokers recruited through a mixture of sources. The objectives of this online, longitudinal cohort study are to 1) characterize tobacco product use behaviors; 2) characterize transitions (e.g., initiation, switching, transitioning to/back to cigarettes, and quitting); 3) assess self-reported health-related quality of life, signs and symptoms by product use; and 4) assess risk perceptions of <i>IQOS</i> and cigarettes among adult established <i>IQOS</i> users and cigarette smokers over time. The <i>IQOS</i> Cohort PACS involves a closed 24-month observation period, with follow-ups at 3, 6, 12, 18 and 24 months.</p>	<p>We had originally planned to launch the Cohort PACS in the 3rd quarter of 2022. We do not expect a sufficient <i>IQOS</i> consumer pool to recruit from in 2022 considering the unavailability of <i>IQOS</i> and HeatSticks in the market. We now hope to launch the Cohort PACS in the 2nd or 3rd quarter of 2023 if <i>IQOS</i> has been available for a sufficient time in the U.S. market. We will communicate the detailed study timeline to FDA and provide an amended protocol when we have a firmer understanding of the return-to-market timing for <i>IQOS</i>.</p>
<p>Secondary Analysis: Estimation of Prevalence of <i>IQOS</i> Use</p>	<p>This secondary analysis used <i>IQOS</i> relevant data drawn from ALCS' ongoing consumer research study, the Adult Tobacco Consumer Tracking Study (ATCT), among a nationally representative sample of adults in the U.S. The objectives of the secondary analyses are to estimate (1) prevalence of <i>IQOS</i> use, (2) prevalence of exclusive, dual and poly tobacco use with <i>IQOS</i>, (3) days and amount of product use among <i>IQOS</i> users and (4) initiation, quitting and complete switching behaviors relative to <i>IQOS</i> use among U.S. adults 21 years of age or older. The extent of the reported analyses depends on the number of current <i>IQOS</i> consumers identified in the ATCT dataset.</p>	<p>Data collection relevant to <i>IQOS</i> is ongoing. In this report, we provide a summary of ATCT data collected between March of 2021 and February of 2022. Because the prevalence of <i>IQOS</i> use in the adult general population is still very low, we report only frequency counts for <i>IQOS</i> use in this report.</p>

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 6 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Study Name	Study Details	Status
Reporting from the U.S. IQOS Owners Panel	We report data from ALCS' dynamic longitudinal IQOS Owners Panel. The IQOS Owners Panel tracks adult (21 years and older) tobacco consumers' use trajectories with IQOS over time. Using results from this study, we describe (1) IQOS owners' switching behavior over time, (2) the usage of IQOS and other tobacco products among adult IQOS owners, and (3) the demographic profile of adult IQOS owners. The information we report is consistent with the information reported in support of the IQOS PMTA. Outcome measures are reported in three-month intervals.	IQOS Owners Panel data collection ceased as of November 29, 2021, as a result of the ITC decision and IQOS becoming unavailable in the U.S. market. In this report, we will present IQOS Owners Panel data collected as of November 30, 2021. We will notify FDA when the IQOS Owners Panel resumes.
Secondary Analysis: Estimation of Awareness and Use of IQOS among Underage Individuals	This analysis will use IQOS relevant data drawn from ALCS' ongoing Underage Tobacco Use Survey (UTUS), a nationally representative survey of U.S. household-dwelling individuals 13-20 years of age. The objectives of the analyses are to estimate (1) awareness of IQOS and (2) ever and past 30-day IQOS use among underage individuals, as well as to estimate (3) lifetime use behavior, and (4) past 30-day use behavior among ever and past 30-day underage IQOS users, respectively. Use behaviors include exclusive, dual, and poly tobacco use with IQOS as well as frequency of use. Some requirements of postmarket reporting necessitated modifications to the UTUS survey specific to IQOS and adjustments to the sampling plan.	Data collection relevant to IQOS is ongoing. In this report we provide a summary of UTUS data collected between March 1, 2021, and February 28, 2022. We will continue IQOS relevant data collection, however, we will pause the oversample in Atlanta, GA, Charlotte, NC and Richmond, VA starting in the second quarter of 2022. We decided to pause the oversample in these regions because 1) IQOS is no longer marketed or available in those regions, 2) we do not wish to exhaust available households within those regions, and 3) we may recoup costs associated with the oversampling that may then be used for future adjustments once IQOS is back on the market. We will re-evaluate the need for an oversample and the potential regions to oversample when we have a firmer understanding of the return-to-market timing for IQOS and distribution geographies. We will communicate updated plans to FDA as we learn more.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 7 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

3 ADULT PREVALENCE AND PRODUCT USE PATTERNS

3.1 Prevalence

Prevalence of adult *IQOS* use appears to be low, which aligns with its limited time in market and limited distribution in the U.S. In fact, data from ATCT,⁴ our ongoing survey that provides a nationally representative sample of ~28,800 U.S. adults (21+) annually, revealed three reported *IQOS* past 30-day users between March 1, 2021, to February 28, 2022 (Enclosure A2). Another recent analysis of data collected from a national probability sample of 20,449 U.S. adults between November 2019 and February 2020 suggested just 8.1% of adults were aware of heated tobacco products, 0.55% had ever tried, and 0.10% were current users.⁵ Collectively, data from the ATCT and other nationally representative surveys demonstrate low prevalence of heated tobacco product use among adults in the U.S.

3.2 Product Use Patterns

For this report, we summarize data from the *IQOS* Cross-Sectional PACS ((b)(4)) and *IQOS* Owners Panel related to product use patterns. In the future, as noted in the secondary analysis plan, once a count of at least 100 current *IQOS* users are recorded in ATCT, we plan to provide information regarding dual/poly use, amount and frequency of use, initiation, complete switching, and tobacco quitting behaviors relative to *IQOS*. The *IQOS* Cohort PACS ((b)(4)) study, now planned to field in 2023, will also provide information on usage patterns for future reporting.

3.2.1 Product Use Patterns from *IQOS* Cross-Sectional PACS

We successfully conducted the first wave of *IQOS* Cross-sectional PACS from September to November of 2021 (Annex P01-1). Results from this study demonstrate that among adult current established *IQOS* users:

- almost all *IQOS* users (92%) were cigarette smokers prior to first trying *IQOS*;
- a substantial portion (31%) of current established *IQOS* users switched⁶ from cigarette smoking to *IQOS* use. Among those who were still smoking, more than 80% reported smoking fewer cigarettes compared to the amount prior to first trying *IQOS*;

⁴ PMSS: Secondary Analysis: Estimation of Prevalence of *IQOS* Use

⁵ Zhu S, Ong J, Wong S, Cole A, Zhuang Y, Shi Y (2021). Early adoption of heated tobacco products resembles that of e-cigarettes. Tobacco Control <http://dx.doi.org/10.1136/tobaccocontrol-2020-056089>

⁶ In the *IQOS* Cross-Sectional PACS, *IQOS*-relevant complete switching is defined as being a current established smoker during the 30 days prior to trying *IQOS*, now using *IQOS* and “not at all” smoking, and the last time smoked was after trying *IQOS*.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 8 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

- initiation, re-initiation, and relapse to cigarette smoking after first trying *IQOS* is extremely rare;
- the majority of current established *IQOS* users were not using smoking cessation treatment;
- about half of *IQOS* users preferred menthol HeatSticks; and
- less than 8% reported ever use of *IQOS* not as intended.⁷

Demographics and Background Information: A total of (b)(4) individuals met all inclusion criteria and completed the *IQOS* Cross-sectional PACS survey, including (b)(4) current established *IQOS* users and (b)(4) former established users. Of the (b)(4) ever established users, (b)(4) current and (b)(4) former established users completed the survey before October 13.⁸ Approximately 60% of the (b)(4) current established *IQOS* users were males; the majority were non-Hispanic white (73%), followed by non-Hispanic Asians (14%) and Hispanic and non-Hispanic black (approximately 5%). The mean age was 45 with <2% being 21-24 years of age, and almost all were from the Southern region of the United States where *IQOS* was marketed and sold. A larger proportion of *IQOS* users who preferred non-menthol HeatSticks were non-Hispanic white, whereas a larger portion of those who preferred menthol HeatSticks were non-Hispanic Asian (Table 2).

Table 2 Demographics and background information of current *IQOS* users

Measure	Current Established <i>IQOS</i> Users	Current Established <i>IQOS</i> Users Who Prefer Menthol HeatSticks	Current Established <i>IQOS</i> Users Who Prefer non-Menthol HeatSticks
Base (Total Participants)	(b)(4)	(b)(4)	(b)(4)
Gender [% (95% CI)]	(b)(4)		
Male			
Age [% (95% CI)]			
21 - 24			
25 - 34			
35 - 44			

⁷ E.g., using the *IQOS* device with a product other than a Marlboro HeatStick or using a Marlboro HeatStick without the *IQOS* device.

⁸ On October 13, 2021, *IQOS* consumers were informed that *IQOS* will not be available after November 29, 2021. Considering that the communication may alter consumer behaviors, we focus on results based on those who completed the survey by October 13 in this report. Results for those who completed the survey after October 13 are available in Appendix A1. We do not observe any substantial differences in tobacco use patterns and perceptions about *IQOS* between those who completed the survey by and after October 13.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 9 of 18
Annex 1: MRTTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Measure	Current Established <i>IQOS</i> Users	Current Established <i>IQOS</i> Users Who Prefer Menthol HeatSticks	Current Established <i>IQOS</i> Users Who Prefer non-Menthol HeatSticks
45 - 54	(b)(4)		
55 - 64			
65+			
Median Age [years (25; 75 percentile)]			
Race/Ethnicity [% (95% CI)]			
NH White/Caucasian			
NH Black/African-American			
Hispanic/Latino			
NH Asian			
Household Income [% (95% CI)]			
Under \$60,000 (Net)			
\$60,000 or More (Net)			
Education [% (95% CI)]			
High School or Less (Net)			
Some College or More (Net)			
Employment Status [% (95% CI)]			
Employed (Net)			
Not Employed (Net)			

CI: Confidence Interval, n: Number of observations; NH: non-Hispanic.

Tobacco Use History: Almost all (b)(4) current established *IQOS* users had smoked cigarettes prior to first trying *IQOS*, 95% were tobacco users during the 30 days prior to first trying *IQOS* with cigarettes being the most commonly used tobacco product (92%), followed by e-cigarettes (30%) and cigars (16%).

As *IQOS* had only been on the U.S. market since 2019, current established *IQOS* users report using *IQOS* for a mean (SD) time of 1.13 (0.81) years (median= 0.92 years). Those who were also current cigarette smokers had been smoking cigarettes for 23.22 (12.04) years (median= 22.04 years). Those who were former cigarette smokers had been smoking cigarettes for 21.35 (11.99) years (median= 20.00 years).

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 10 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Switching: Complete switching⁹ refers to the event of completely transitioning from established use of one tobacco product to now not using that product and current established use of another tobacco product. Among all (b)(4) current established *IQOS* users, 31% had switched completely from cigarettes based on the definition in the Statistical Analysis Plan (SAP). When restricting to current established *IQOS* users who were smoking during the past 30 days prior to first trying *IQOS*, 34%¹⁰ had switched completely to *IQOS*.

Among current *IQOS* users, 92% were smokers during the 30 days prior to trying *IQOS*, but only 49% were current smokers at the time of the assessment, which suggests that 43% (the difference of 92% and 49%) of *IQOS* users became non-current smokers (i.e., had not smoked a cigarette in the past 30-days) after trying *IQOS*. Among those who were still smoking, 83% reported now smoking fewer cigarettes compared to before trying *IQOS* (Figure 1).

Just 31% of current *IQOS* users met the definition of switching because of the way “complete switching” was defined in the SAP. That definition of switching required that the last time smoked be after trying *IQOS*. A larger proportion of *IQOS* users (43%) became non-current smokers after trying *IQOS* but many did not meet the SAP definition because a notable portion did not smoke cigarettes at all after trying *IQOS*. In a broader sense, these individuals can also be considered having switched, but did not meet the SAP definition.

⁹ In the *IQOS* Cross-Sectional PACS, *IQOS*-relevant complete switching is defined as being a current established smoker during the 30 days prior to trying *IQOS*, now using *IQOS* and “not at all” smoking, and the last time smoked was after trying *IQOS*.

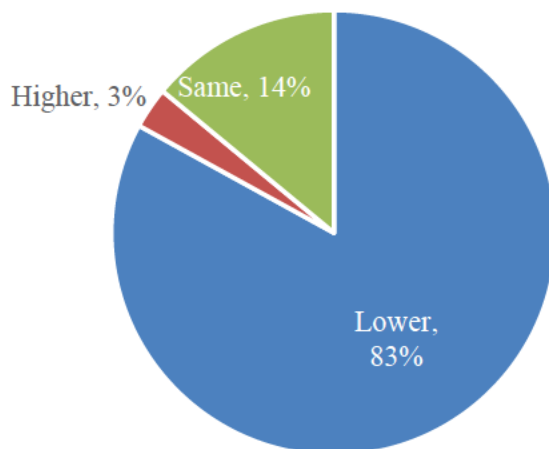
¹⁰ A total of 91.57% of current established users who were smoking cigarettes during the 30 days prior to first trying *IQOS*. Therefore, the 34% was calculated from dividing 31.21% by 91.57% (i.e., 31.21%/91.57%=34%).

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 11 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Figure 1 Current cigarette consumption compared to before trying *IQOS*, Adult smokers
(b)(4)



Exclusive/Dual/Poly Use: Among all (b)(4) current established *IQOS* users, 35% were currently using *IQOS* only, 43% were using *IQOS* and one other tobacco product, and 22% were using *IQOS* and two or more other tobacco products. The most commonly used other tobacco product was cigarette (49%), followed by e-cigarette/e-vapor (20%) and cigars (14%). Less than 5% of current established *IQOS* users used other tobacco products assessed.

Initiation/Re-initiation/Relapse: Of the (b)(4) current established *IQOS* users, only one participant (0.2%) indicated that *IQOS* was the first tobacco product ever tried. None of the never smokers initiated cigarette smoking after first trying *IQOS*, and none of the ever established¹¹ *IQOS* users relapsed to cigarette smoking. Similarly, none of the ever-established *IQOS* users reported complete switching from *IQOS* to cigarettes after initiating tobacco use with *IQOS*. Only one ever established *IQOS* user re-initiated cigarette smoking after not smoking for 12 months or longer before first trying *IQOS*.

Cessation Treatment Use: Of the (b)(4) current established *IQOS* users, less than 5% used a tobacco cessation treatment in the past 30 days. More than half (52%) never used any tobacco cessation treatment and an additional 31% did not use any tobacco cessation treatment in the past 12 months.

¹¹ Ever use refers to having used a given tobacco product in a person's lifetime and met or exceeded the lifetime established use criterion. This includes current and former established users.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 12 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

HeatStick Preference: Of the (b)(4) current established *IQOS* users, approximately half (52%) used menthol HeatSticks most often. Among users of both *IQOS* and cigarettes, 40% preferred menthol HeatSticks. While most established *IQOS* users who completely switched from cigarettes to *IQOS* preferred a HeatStick variety consistent with their cigarette preference, a larger percentage of non-menthol cigarette smokers preferred menthol HeatSticks (21%) than the proportion of menthol cigarettes smokers preferring non-menthol HeatSticks (6%).

Unintended use of *IQOS*: Among current established *IQOS* users, 7.7% reported ever using *IQOS* not as intended. The most common mode of unintended use was using the *IQOS* device with a product other than a Marlboro HeatStick (4.1%), followed by lighting the HeatStick like a cigarette (3.4%).

For the tobacco use behaviors described above, no notable differences were observed between *IQOS* users who preferred menthol and non-menthol HeatSticks.

Summary

Overall, data from the *IQOS* Cross-Sectional PACS support that *IQOS* continues to satisfy MRTP requirements for the following reasons:

1. *IQOS* consumers largely consist of existing tobacco users, especially long-term cigarette smokers.
2. During the period when *IQOS* was marketed in the U.S., a substantial portion of *IQOS* users had switched from smoking to *IQOS*. And more than 80% of *IQOS* users who were still smoking indicated that they reduced their cigarette consumption, potentially signaling a journey toward switching.
3. Initiation of *IQOS* by never users of tobacco is extremely rare. Initiation and relapse to smoking after first trying *IQOS* is extremely rare.
4. *IQOS* does not interfere with tobacco cessation treatment utilization as the majority of *IQOS* users were not using any such treatment.

3.2.2 Product Use Patterns from *IQOS* Owners Panel

As of November 30, 2021,¹² there were (b)(4) active¹³ *IQOS* Owners Panel members, approximately even (b)(4)

(b)(4)

¹² November 30, 2021, marks the closure of the panel and is the most recent data collected.

¹³ “Active” *IQOS* Owners Panel members are those who (b)(4)

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 13 of 18
Annex 1: MRTTP Use Behavior and Consumer Understanding and Perception	Version 1.0

(Table 3). The most commonly reported other tobacco product used by panel members (excluding cigarettes) was (b)(4)

Complete Switching: Among the (b)(4) adult IQOS Owners Panel members who reported switching completely to IQOS from cigarettes, the majority were (b)(4)

(b)(4)

This is not surprising given the dynamic nature of the IQOS Owners Panel sample composition, which changed constantly with new registrants opting in and other participants opting out. For example, between May of 2020 and November of 2021, the sample size changed from (b)(4), which suggests that the more recent data are among a larger portion of newer IQOS users (Figure 2).

Dual/Poly Use: Demographics were similar among the (b)(4) adult IQOS Owners Panel members who reported dual use of IQOS and cigarettes as the overall Panel. Since the last annual report, panelists engaging in dual use with cigarettes had maintained at (b)(4) of IQOS and cigarette dual users reported also using e-cigarette/e-vapor products.

Table 3 Adult Participants in the IQOS Owners Panel by IQOS Usage Level (Total IQOS Owner n=500)

<i>IQOS Usage Level</i>	Number of People	% of Total IQOS Owners
Adult participants who completely switched from cigarettes to IQOS (IQOS usage level = 100%)	(b)(4)	
Adult participants who dual use with cigarettes and IQOS (5% ≤ IQOS usage level < 100%)		
Adult participants who no longer use IQOS (IQOS usage level < 5%) *		

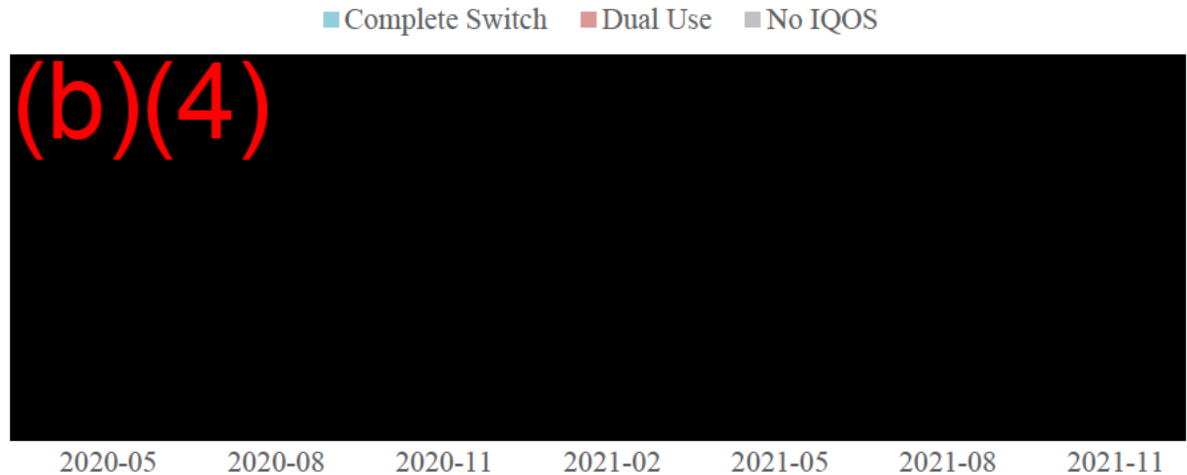
*Active panel member who no longer use IQOS continued smoking cigarettes

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 14 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Figure 2 Adult Participants in the *IQOS* Owners Panel by *IQOS* Usage Level (May 2020 to November 2021)



Sample Size:

(b)(4)

4 ADULT CONSUMER UNDERSTANDING AND PERCEPTION

For this report, we summarize data from the *IQOS* Cross-Sectional PACS related to risk perceptions and consumer understanding. In the future, the *IQOS* Cohort (b)(4) study will also provide data related to *IQOS* users' risk perceptions of *IQOS* and cigarettes.

The *IQOS* Cross-Sectional PACS study evaluated risk perceptions of *IQOS* and cigarettes using the Perceived Risk Instrument for general risk assessment (PRI-G),¹⁴ an 18-item, psychometrically valid measure of risk perceptions for various tobacco-types and levels of smoking status. The resulting PRI-G Health Risk composite score can be used to compare risk perceptions of one tobacco product to another at particular usage levels.

The *IQOS* Cross-Sectional PACS study evaluated understanding of the influence that switching completely from cigarettes to *IQOS* has on exposure to harmful or potentially harmful chemicals. Next, comprehension of switching was evaluated with the question: "Based on what you know or believe, what do smokers need to do in order to reduce their body's exposure to harmful or potentially harmful chemicals?" with the response options "stop

¹⁴ 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 Qual Life Outcomes*, 16(1), 192. doi:10.1186/s12955-018-0997-5

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 15 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

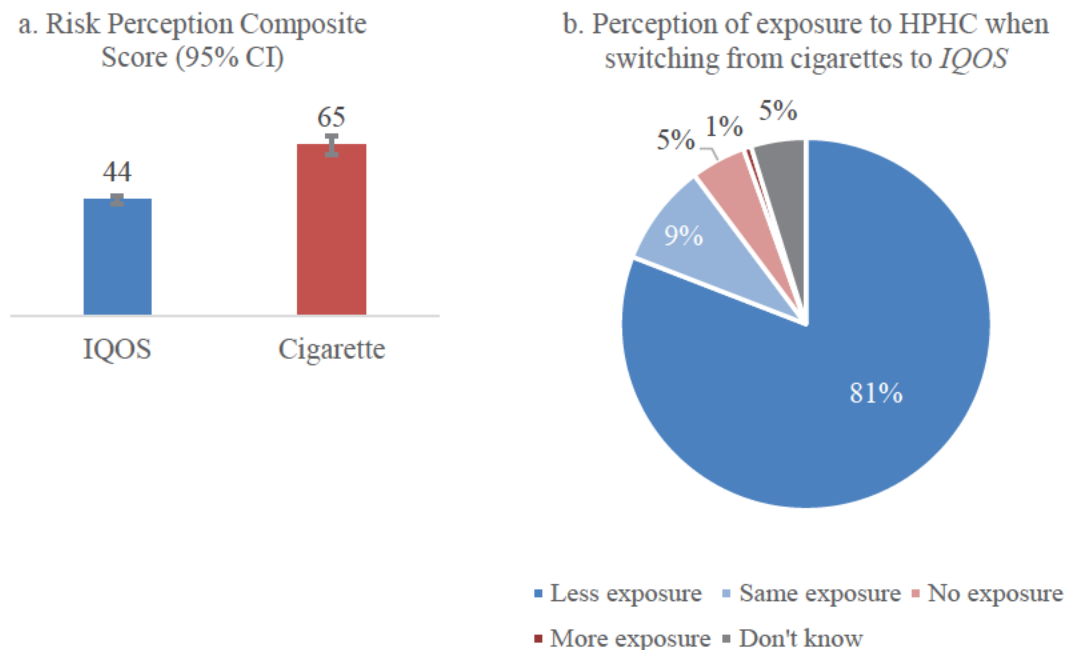
smoking cigarettes completely and only use *IQOS*,” “smoke fewer cigarettes and also use *IQOS*,” “keep smoking the same amount of cigarettes and also use *IQOS*,” and “don’t know.”

Consumer Perception: Adult established *IQOS* users perceived *IQOS* to be less harmful compared to cigarettes (PRI-G Health Risk composite score= 44.4 for *IQOS* vs. 65.4 for cigarettes).

Consumer Understanding: Among current established *IQOS* users, 81% correctly identified that completely switching from cigarettes to *IQOS* would result in less exposure to harmful or potentially harmful chemicals (HPHC); less than 5% perceived switching to *IQOS* would result in no such exposure. Similarly, 85% of those who had the correct understanding about HPHC exposure identified that to reduce one’s exposure to HPHC, the individual had to completely switch to *IQOS*, 8% reported “smoking fewer cigarettes and also use *IQOS*.”

In summary, results from the first wave of the *IQOS* Cross-sectional PACS demonstrate that adult current established *IQOS* users understood that *IQOS* was not risk free but switching to *IQOS* would reduce exposure to harmful or potentially harmful chemicals compared to smoking.

Figure 3 a-b Adult *IQOS* Risk Perception Composite Score (a.) and Perception of exposure when switching from cigarettes to *IQOS* (b.)



Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 16 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

5 UNDERAGE AWARENESS, EVER USE, AND PAST 30-DAY USE

Results of the UTUS suggest that underage awareness, ever use, and past 30-day use of *IQOS* is very low ([Annex P01-4](#)). With a sample size of 5,205, only four individuals (one 13-17 year old minor and three 18-20 year old underage young adults) reported that they used *IQOS* in the past 30 days prior to the assessment.¹⁵ Among these four individuals, one correctly identified that *IQOS* “only uses sticks containing actual tobacco,” which signals a certain level of confusion about *IQOS*, and that self-reported use may be overestimated among underage individuals.

The UTUS 2021 Q2 to 2022 Q1 results include a sample of 5,205 underage individuals; aggregated from quarters 2, 3, and 4 surveys in 2021 and quarter 1 survey in 2022, including an oversample of the three *IQOS* lead market regions (Atlanta, GA, Richmond, VA, and Charlotte, NC). In the total sample, an estimated 3.1% of youth (13-17 years) and 5.9% of young adults (18-20 years) reported having ever seen or heard of *IQOS*. An estimated 0.2% of youth and 1.0% of young adults reported ever use of *IQOS*. Less than 0.2% of youth and young adults reported past 30-day use of *IQOS* ([Table 4](#)). Estimated awareness and ever use was higher among underage young adults compared to youth and higher in the three lead market regions compared to the rest of the U.S. Among those who had seen or heard of *IQOS* (n=255), friends/peers/classmates were the most common source of information (38.8%), followed by advertisement at gas stations, convenience stores, or other retail stores (17.6%). Among those who were aware of *IQOS*, only a minority (11%) correctly identified that *IQOS* “only uses sticks containing actual tobacco;” 51% did not know.

For heated tobacco products as a whole, an estimated 0.7% of middle and high school students were current users of heated tobacco based on the National Youth Tobacco Survey (NYTS) 2020 results.¹⁶ We consider that the estimated 0.7% of current HTP use may be an overestimate for the following reasons. First, prior research indicated a proportion of participants reporting awareness and use of HTPs when these products were in very limited distribution in the U.S. For example, based on NYTS data collected during early 2019, an estimated 1.6% of middle-school and high-school students used HTPs during the 30 days prior to the assessment.¹⁷ Another study conducted in 2017 showed that an estimated 9.1% of 16-19 year olds had

¹⁵ Past 30-day *IQOS* use was assessed among individuals who were aware of heated tobacco products, had ever used a heated tobacco product, used a heated tobacco product during the past 30 days.

¹⁶ Gentzke AS, Wang TW, Cornelius M, Park-Lee E, Ren C, Sawdey MD, Cullen KA, Loretan C, Jamal A, Homa DM. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. *MMWR Morb Mortal Wkly Rep.* 2022 March 11; 71(5);1–29

¹⁷ Dai, H. Heated tobacco product use and associated factors among U.S. youth, 2019. *Drug Alcohol Depend.* 2020;214:108150.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 17 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

awareness of *IQOS*, a HTP brand.¹⁸ Both studies were conducted before *IQOS* was authorized and available for sale in the U.S. until late 2019 and when other HTPs were also in very limited distribution in the U.S. Second, based on results from UTUS, only a minority of underage individuals were able to identify *IQOS* correctly. These results suggest possible misreporting of HTP, a relatively new product category. Moreover, since NYTS began to assess HTPs in 2019, the estimated past 30-day use of HTPs was 1.6%, 1.4%, and 0.7% in 2019, 2020, and 2021, showing no increase since *IQOS* was authorized in late 2019.¹⁹ Taken together, data from the UTUS and NYTS demonstrate low usage of heated tobacco products, including *IQOS* among underage individuals in the U.S.

Table 4 UTUS 2021 Q2 to 2022 Q1 Estimates: Awareness, Ever Use, and Past 30-Day use of *IQOS*

	Awareness		Ever Use		Past 30-Day <i>IQOS</i> Use	
	Unweighted <i>n</i>	Weighted % (95% CI)	Unweighted <i>n</i>	Weighted % (95% CI)	Unweighted <i>n</i>	Weighted % (95% CI)
Total US, Youth (13-17 Years)	3054	3.1 (2.4, 3.8)	3051	0.2 (0.1, 0.4)	3052	0.1 (<0.1, 0.4)
Total US, Young Adults (18-20 Years)	2151	5.9 (4.8, 7.1)	2144	1.0 (0.6, 1.6)	2144	0.1 (<0.1, 0.5)
Lead Market Regions	(b)(4)					
Rest of US						

¹⁸ Czoli, CD; White, CM; Reid, JL, et al. Awareness and interest in *IQOS* heated tobacco products among youth in Canada, England and the USA. *Tob Control*. 2019;29(1):89-95.

¹⁹ Gentzke et al., Tobacco Product Use and Associated Factors Among Middle and High School Students - United States, 2021 *MMWR Morb Mortal Wkly Rep*.2020; 69(50): 1881-1888.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2022 PMSS Report for MR0000059-MR0000061 and MR0000133	Page 18 of 18
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

6 CONCLUSIONS – MRTP USE BEHAVIOR AND CONSUMER UNDERSTANDING AND PERCEPTION

Early evidence from the U.S. suggests limited uptake and use of the *IQOS* system among legal age adult cigarette smokers consistent with limited marketing time and distribution culminating in an end of marketing in November 2021. As the *IQOS* market reopens and adult cigarette smokers again become aware of the *IQOS* system as a reduced exposure tobacco option, we expect that adult *IQOS* uptake will increase.

Our evidence demonstrates that *IQOS* can benefit the health of the population as a whole by transitioning adult cigarette smokers away from cigarettes. Initiation of *IQOS* by never users of tobacco was rare and there was minimal initiation of, re-initiation of, and relapse to smoking among adults. In addition, there is little indication of youth and underage young adult use of *IQOS* at the time of this report. A significant proportion (almost a third in one study and over 40% in another study) of adult *IQOS* users switched from cigarette smoking to *IQOS* use. In the cross-sectional study, among those who were still smoking, more than 80% reported smoking fewer cigarettes compared to the amount prior to first trying *IQOS*.

Most adults correctly perceived *IQOS* risks and behavioral implications of *IQOS* use. Adults understood *IQOS* was not risk free and that switching to *IQOS* would reduce exposure to harmful or potentially harmful chemicals compared to smoking.

7 ANNEXES

[P01-1 - IQOS_Cross-Sectional_PACS_-_Wave_1_Final_Study_Report](#)

Including Data Tables:

[IQOS_Cross-sectional_PACS_TLF_Pre-Group_V1.0_20220110](#)

[IQOS_Cross-sectional_PACS_TLF_Post-Group_V1.0_20220110](#)

[IQOS_Cross-sectional_PACS_TLF_Full_Sample_V1.0_20220110](#)

[P01-2 - ATCT_Analysis_Report_for_IQOS_PMSS_2022_FINAL](#)

[P01-3 - IQOS_Owners_Panel_Report_for_IQOS_PMSS_2022_FINAL](#)

[P01-4 - UTUS_Analysis_Report_for_IQOS_PMSS_2022_FINAL](#)

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.
