

RESEARCH ANALYSIS REPORT IQOS OWNERS PANEL REPORTING

Reporting of Relevant Data from the IQOS Owners Panel
(Short Title: IQOS Owners Panel Reporting)

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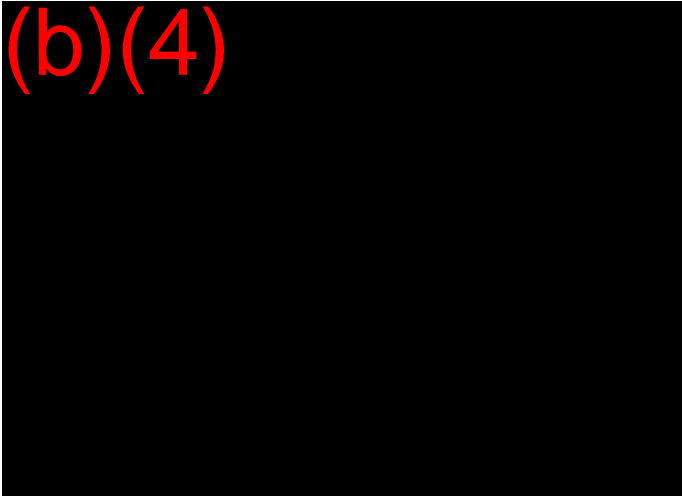
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1. INTRODUCTION

1.1. Background

Philip Morris Products S.A. (PMP S.A.) developed the IQOS Tobacco Heating System and Marlboro HeatSticks (hereinafter referred to as IQOS) as novel tobacco and nicotine-containing products with the potential to reduce harm or the risk of tobacco-related disease associated with smoking cigarettes. PMP S.A. submitted Modified Risk Tobacco Product Applications for IQOS to the U.S. Food and Drug Administration (FDA) seeking authorization to market the products as modified risk tobacco products. On July 7, 2020, FDA issued “Modified Risk Granted Orders – Exposure Modification” authorizing IQOS to be marketed with a reduced exposure claim. The Orders are conditioned upon agreement to conduct postmarket surveillance and studies (PMSS) in accordance with protocols approved by FDA. This document is prepared as part of the PMSS program for IQOS pursuant to the Orders.

1.2. Rationale

The Federal Food, Drug and Cosmetic Act (FDCA) directs the Food and Drug Administration (FDA) to condition an exposure modification order received under FDCA § 911(g)(2) on the MRTP applicants’ agreement to conduct PMSS (FDCA §§ 911(g)(2)(C)(ii)). “The outcomes evaluated in postmarket surveillance and studies should focus on the effect of the MRTP on consumer perception, behavior and health under real world conditions of use” (Food and Drug Administration, 2012). For this reason, ALCS¹ on behalf of the applicant, PMP S.A., plans to conduct certain components of PMSS to assess the effect of the MRTP among U.S. consumers. The program will consist of a collection of data over time that supports an assessment of IQOS in the postmarket setting. This IQOS Owners Panel Reporting is one component of the postmarket surveillance program. Specifically, it describes outcomes from the IQOS® Owners Panel, as commissioned in the U.S. by ALCS on behalf of Philip Morris USA (PM USA), that have been reported in support of IQOS PMTA market order and MRTPA.

2. PURPOSE AND OBJECTIVES

2.1. Purpose

The purpose of this IQOS Owners Panel Reporting is to describe outcomes of the IQOS Owners Panel that will be reported in support of the MRTP PMSS including switching and use patterns over time among adult (21 years of age or older) IQOS owners.

2.2. Objectives

The objectives of this reporting are to:

- 1) Describe adult IQOS owners’ switching behavior over time

¹ Altria Client Services (ALCS) and the parent of PMP S.A., Philip Morris International Management S.A., have entered into a distribution agreement by which ALCS and its affiliates have exclusive rights to distribute and sell IQOS in the U.S. after FDA authorization. ALCS affiliate PM USA markets IQOS in the U.S. Therefore, PMSS that involves the study of consumers and consumption in the U.S. will be conducted by ALCS to be submitted as part of PMSS reporting by PMP S.A.

- 2) Describe the usage of IQOS and other tobacco products among adult IQOS owners
- 3) Describe the demographic profile of adult IQOS owners

3. OVERVIEW OF THE IQOS OWNERS PANEL

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To enable benchmarking of study results to other countries where IQOS is available, study design and survey instruments have been adopted to resemble similar studies conducted by PMP S.A. in other countries where IQOS is available.

3.1. IQOS Owners Panel Study Duration

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3.2. IQOS Owners Panel Study Recruitment

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criteria to cap new panelists recruitment will be developed with a goal of maximizing the representativeness of the panel in relation to the composition of IQOS owners in the database.

3.3. IQOS Owners Panel Survey Instruments

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3.4. IQOS Owners Panel Inclusion and Exclusion Criteria

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3.5. Data Quality Control Process

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3.6. Weighting

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4. OUTCOME MEASURES

Outcome measures will be reported in three-month intervals to align with IQOS PMTA reporting.

Objective 1: Report the percentage of participants in the IQOS Owners Panel by usage level

Adult IQOS usage level is defined as the percentage of Marlboro HeatSticks consumption relative to the amount of Marlboro HeatSticks and cigarette consumption. Specifically, it is defined as the daily consumption in the past 7 days and is calculated by using the total daily consumption of Marlboro HeatSticks out of the total daily consumption of Marlboro HeatSticks and cigarettes:

$$IQOS \text{ usage level} = \frac{\text{HeatSticks Consumption}}{\text{TOTAL Consumption}} \times 100,$$

where TOTAL Consumption = total number of HeatSticks and cigarettes.

The following groups are defined based on the IQOS usage level as:

- Adult participants who completely switched from cigarettes to IQOS: IQOS usage level = 100%
- Adult participants who dual use with cigarettes and IQOS: IQOS usage level < 100% and IQOS usage level ≥ 5%
- Adult participants who no longer use IQOS: IQOS usage level < 5%

We will report the percentage of participants in the IQOS Owners Panel that fall into these groups.

Objective 2: Report demographic characteristics of participants in the IQOS Owners Panel

Demographic characteristics of participants in the IQOS Owners Panel including gender, age, race, ethnicity and geography, will be reported for the following groups:

- Total Adult IQOS Owners
- Adult participants who completely switched from cigarettes to IQOS
- Adult participants who dual use with cigarettes and IQOS
- Adult participants who no longer use IQOS

Objective 3: Report other tobacco products used by participants in the IQOS Owners Panel

Participants who used other tobacco products in the past 7 days will be reported for the following groups:

- Total Adult IQOS Owners

- Adult participants who completely switched from cigarettes to IQOS
- Adult participants who dual use with cigarettes and IQOS
- Adult participants who no longer use IQOS

Other tobacco products include the following:

- Fancy, hand-rolled cigars
- Less expensive, everyday cigars sold in convenience stores
- Moist smokeless tobacco or dip in loose or pouch form, sold in a round can
- Chewing tobacco in leaf or plug form, sold in a resealable bag
- Snus (a spit-less, smokeless tobacco pouch product)
- E-Cigarettes or E-Vapor
- Other tobacco-derived nicotine products, such as pouches, lozenges, etc. (e.g., Zyn, on!)
- None of the above

5. RESULTS

This section presents three quarters' of IQOS Owner Panel data as stated in the Owners Panel Analysis Plan. These data tables are the same as data tables in the IQOS Owners Panel FDA Quarter Reports ending in 05/31/2021, 08/31/2021, and 11/30/2021 that were submitted to FDA on July 30, October 30, 2021 and January 28, 2022.

5.1. IQOS Owner Panel Quarterly Report, Quarter Ending 05/31/2021

Table 5.1.1: Adoption of IQOS

Adoption Level	Number of People	% of total IQOS Owners
Adult Smokers who have completely switched to IQOS	(b)(4)	
Dual Usage		
Adult Smokers who no longer use IQOS		

Table 5.1.2: Adoption of IQOS by Gender

Gender	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %

Unweighted base	(b)(4)
Female	
Male	

Table 5.1.3: Adoption of IQOS by Age

Age	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
21-29	(b)(4)			
30-39				
40-49				
50-59				
60-69				
70+				

Table 5.1.4: Adoption of IQOS by Race

Race	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
White or Caucasian	(b)(4)			
Black or African American				
Asian or Pacific Islander				
American Indian or Alaska Native				
Mixed racial background				
Other race				

Table 5.1.5: Adoption of IQOS by Hispanic Descent

Hispanic or Latino	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Yes	(b)(4)			
No				

Table 5.1.6: Adoption of IQOS by Geography

Geography	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Northeast Region	(b)(4)			
Midwest Region				
West Region				
South Region				

Table 5.1.7: Adoption of IQOS by Other Tobacco Product Use

Other Tobacco Products used in the Past 7 days (Excludes traditional cigarettes)	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Fancy, hand-rolled cigars	(b)(4)			
Less expensive, everyday cigars sold in convenience stores				
Moist smokeless tobacco or dip in loose or pouch form, sold in a round can				

Chewing tobacco in leaf or plug form, sold in a resealable bag	(b)(4)
Snus (a spit-less, smokeless tobacco pouch product)	
E-Cigarettes or E-Vapor	
Other tobacco-derived nicotine products, such as pouches, lozenges, etc (e.g., Zyn, on!)	
None of the above	

5.2. IQOS Owner Panel Quarterly Report, Quarter Ending 08/31/2021

Table 5.2.1: Adoption of IQOS

Adoption Level	Number of People	% of total IQOS Owners
Adult Smokers who have completely switched to IQOS	(b)(4)	
Dual Usage		
Adult Smokers who no longer use IQOS		

Table 5.2.2: Adoption of IQOS by Gender

Gender	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Unweighted base	(b)(4)			
Female				
Male				

Table 5.2.3: Adoption of IQOS by Age

Age	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
21-29	(b)(4)			
30-39				
40-49				
50-59				
60-69				
70+				

Table 5.2.4: Adoption of IQOS by Race

Race	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
White or Caucasian	(b)(4)			
Black or African American				
Asian or Pacific Islander				
American Indian or Alaska Native				
Mixed racial background				
Other race				

Table 5.2.5: Adoption of IQOS by Hispanic Descent

Hispanic or Latino	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Yes	(b)(4)			
No				

Table 5.2.6: Adoption of IQOS by Geography

Geography	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Atlanta	(b)(4)			
Charlotte				
Richmond				
NOVA				
Other				
Northeast region				

Midwest region	(b)(4)
West region	
South region	

Table 5.2.7: Adoption of IQOS by Other Tobacco Product Use

Other Tobacco Products used in the Past 7 days (Excludes traditional cigarettes)	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Fancy, hand-rolled cigars	(b)(4)	(b)(4)	(b)(4)	(b)(4)
Less expensive, everyday cigars sold in convenience stores				
Moist smokeless tobacco or dip in loose or pouch form, sold in a round can				
Chewing tobacco in leaf or plug form, sold in a resealable bag				
Snus (a spit-less, smokeless tobacco pouch product)				
E-Cigarettes or E-Vapor				
Other tobacco-derived nicotine products, such as pouches,				

lozenges, etc (e.g., Zyn, on!)				
None of the above	(b)(4)			

5.3. IQOS Owner Panel Quarterly Report, Quarter Ending 11/30/2021

Table 5.3.1: Adoption of IQOS

Adoption Level	Number of People	% of total IQOS Owners
Adult Smokers who have completely switched to IQOS	(b)(4)	
Dual Usage		
Adult Smokers who no longer use IQOS		

Table 5.3.2: Adoption of IQOS by Gender

Gender	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Unweighted base	(b)(4)			
Female				
Male				

Table 5.3.3: Adoption of IQOS by Age

Age	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
21-29	(b)(4)			
30-39				
40-49				
50-59				
60-69				
70+				

Table 5.3.4: Adoption of IQOS by Race

Race	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
White or Caucasian	(b)(4)			
Black or African American				
Asian or Pacific Islander				
American Indian or Alaska Native				
Mixed racial background				
Other race				

Table 5.3.5: Adoption of IQOS by Hispanic Descent

Hispanic or Latino	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Yes	(b)(4)			
No				

Table 5.3.6: Adoption of IQOS by Geography

Geography	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Atlanta	(b)(4)			

Charlotte	(b)(4)
Richmond	
NOVA	
Other	
Northeast region	
Midwest region	
West region	
South region	

Table 5.3.7: Adoption of IQOS by Other Tobacco Product Use

Other Tobacco Products used in the Past 7 days (Excludes traditional cigarettes)	Total IQOS Owners %	Adult Smokers who have completely switched to IQOS (%)	Dual Usage %	Adult Smokers who no longer use IQOS %
Fancy, hand-rolled cigars	(b)(4)			
Less expensive, everyday cigars sold in convenience stores				
Moist smokeless tobacco or dip in loose or pouch form, sold in a round can				
Chewing tobacco in leaf or plug form, sold in a resealable bag				
Snus (a spit-less, smokeless tobacco pouch product)				
E-Cigarettes or E-Vapor				
Other tobacco-derived nicotine products, such as pouches,				

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