

Cross-Sectional Survey in Japan

Study Report

Year 5 (2021-2022)

Study Title	Repeated Cross-Sectional Survey on the Use of Tobacco and Nicotine Containing Products in the General Adult Population and among Users of <i>IQOS™</i> in Japan
Study Number	P1-PMX-01-JP (Year 5)
Product Name	<i>IQOS™</i>
Sponsor	Philip Morris Products S.A. Avenue de Rhodanie 50 1007 Lausanne Switzerland
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Study Completion (Year 5)	August 30, 2022- End of Year 5 fieldwork (waves 17-20) for <i>IQOS</i> User Sample
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2 LIST OF ABBREVIATIONS AND TERMS

Abbreviation	Definition
CI	Confidence Interval
HEETS	Tobacco sticks (disposables) to be used with the <i>IQOS™</i> device; these comprise all available <i>IQOS</i> tobacco stick brand names in Japan: <i>Marlboro HeatSticks™</i> , <i>HEETS™</i> , and <i>TEREA™</i> .
HTP	Heated Tobacco Product
MET	Metabolic Equivalent of Task
PAPI	Pen-and-Paper interview
PMI	Philip Morris International Inc. (general entity)
PMP S.A.	Philip Morris Products S.A. (part of the PMI group of companies)
RPC	Rating of Perceived Capacity
SAS	Statistical Analysis System
SD	Standard Deviation
SRCQ	Self-Reported Changes Questionnaire
TNP	Tobacco or Nicotine-Containing Product
Year 1	Reporting year 1 (2016-2017) of the study
Year 2	Reporting year 2 (2017-2018) of the study
Year 3	Reporting year 3 (2018-2019) of the study
Year 4	Reporting year 4 (2020-2021) of the study
Year 5	Reporting year 5 (2021-2022) of the study

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Term	Definition
Cigarettes	Include manufactured and roll/make-your own cigarettes
Combustible TNP	Cigarettes, cigars, cigarillos/tobacco pipes/kiseru/shisha, water pipes
Current use	Having used any TNP more than the respective lifetime criterion and currently using the TNP at the time of the survey.
Dual use	Current use of two TNPs.
Exclusive use	Current use of only one TNP.
Former use	Having used a particular TNP (or multiple TNPs) more than the respective lifetime criterion and not using the TNP (or any TNP) at the time of the survey.
Initiation of TNP use	The first time in life a TNP was used regularly (daily or occasionally) and (if applicable) to the respective lifetime criterion.
Initiation rate of TNP use	The proportion of the surveyed population that initiated the use of a particular TNP in the last 12 months.
Lifetime criterion	The threshold of lifetime use for the category cigarettes and for the heated tobacco product (HTP) <i>IQOS™</i> with <i>HEETS™</i> ¹ to qualify as a “user”. For cigarettes: smoked ≥100 cigarettes; for <i>IQOS</i> with <i>HEETS™</i> : used ≥100 <i>HEETS™</i> . For other TNPs including (a) other combustible TNPs (such as cigarillos, cigars, pipes, kiseru, water pipes), (b) e-cigarettes, (c) smokeless pipes/tobacco (such as chewing tobacco, snus, snuff, dissolvables), and (d) any Ploom and Glo TNPs, no threshold of lifetime use was defined.
Never use	No use of any TNP up to the respective lifetime criterion.
Smoke-free (non-combustible) TNP	Include <i>IQOS™</i> , Ploom TNPs, Glo TNPs, e-cigarettes, smokeless tobacco pipe, smokeless tobacco (chewing tobacco/snus/snuff)
Poly use	Current use of more than two TNPs.
Quit/Stop using attempt	Having used a particular TNP according to the lifetime criterion (e.g., ≥100 cigarettes in lifetime) and at the time of the survey having at least once tried to stop using the TNP, regardless of the consumption of other TNPs.
Quitting/Stop using a TNP	Having used a particular TNP according to the lifetime criterion (e.g., ≥100 cigarettes in lifetime) and at the time of the survey not using the TNP anymore, regardless of the consumption of other TNPs.
Reinitiation with a TNP	Using a particular TNP again after stopping/quitting the TNP for >12 months during the most recent attempt to quit TNPs.
Relapse to a TNP	Using a particular TNP again after stopping/quitting the TNP for ≤12 months during the most recent attempt to quit TNPs.

¹ Tobacco sticks (disposables) to be used with the *IQOS™* device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks™*, *HEETS™*, and *TEREA™*.

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3 EXECUTIVE SUMMARY

Study Background and Overall Objectives

This report presents data from the fifth reporting year (Year 5, 2021-2022) of repeated cross-sectional studies in Japan. The aim of these repeated cross-sectional studies is to investigate the current and past use of tobacco or nicotine-containing products (TNP) in Japan to understand and characterize how Philip Morris International (PMI)'s smoke-free product *IQOS*[™] is used by the general adult Japanese population and among adult *IQOS* users compared to other TNPs. As part of trend analysis, individual results from the present reporting Year 5 (2021-2022) are also compared with results from the previous reporting years Year 1 (2016-2017), Year 2 (2017-2018), Year 3 (2018-2019), and Year 4 (2020-2021).

Each annual study is conducted in a representative sample of the general adult Japanese population (**General Adult Population Sample**), as well as in a sample of adult current *IQOS*[™] users registered in the *IQOS* user database of PMI's affiliate in Japan (**IQOS User Sample**). In the General Adult Population Sample, the survey interviews are conducted face-to-face, whereas in the *IQOS* User Sample, the surveys are conducted online.

In the present Year 5 study (2021-2022), the General Adult Population Sample included 7,140 participants with the data being collected between September 03, 2021, and August 14, 2022, in six survey waves (waves 21 to 26). The *IQOS* User Sample comprised 1,999 participants with the data collection taking place between November 19, 2021, and August 30, 2022, in four survey waves (waves 17 to 20).

Throughout the report, if not indicated otherwise, the sample sizes are based on participants with non-missing information on the respective measure/outcome reported.

3.1 GENERAL ADULT POPULATION SAMPLE

Demographic Characteristics

Of the total General Adult Population Sample participants (N=7,140) who completed the study in Year 5 (2021-2022), 54.4% were female (n=3,883) and 45.6% (n=3,257) were male. The mean age of the participants was 56.0 (SD=18.26, range: 20-97) years. The demographic characteristics of the study participants were overall similar across study Year 1 to Year 5.

Prevalence

In Year 5, the prevalence of overall current TNP use in the General Adult Population Sample with non-missing information on current TNP use (N=7,016) was 15.6% (n=1,094), while the prevalence of former TNP use was 16.5% (n=1,159), and the prevalence of never TNP use was 67.9% (n=4,763). The prevalence of overall current TNP use was rather stable across the first three study years (Year 1: 18.5%; Year 2: 18.9%; Year 3: 18.2%), while it decreased to 16.1% in Year 4 and to 15.6% in Year 5.

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In Year 5, the prevalence of overall current combustible TNP use² was 12.4%³ and that of overall current smoke-free TNP use⁴ was 5.6%. The prevalence of current use of cigarettes (12.4%)⁵ was higher than that of overall HTPs (5.4%) - including *IQOS*TM (3.5%), Glo (1.4%), and Ploom (1.1%) - as well as higher than that of e-cigarettes⁶ (1.8%), other combustible TNPs (0.2%), smokeless TNPs (0.1%), and any other TNPs⁷ (1.0%).

Over time, the prevalence of overall current combustible TNP use decreased from 17.6% in Year 1 to 12.4% in Year 5, while the prevalence of overall current smoke-free TNP use increased from 2.5% in Year 1 to 5.6% in Year 5. At the same time, the prevalence of current cigarette smoking decreased from 17.6% in Year 1 to 12.4% in Year 5, while the prevalence of current individual smoke-free TNP use increased between Year 1 and Year 5, i.e., for *IQOS* from 1.8% to 3.5%, Glo 0.0% to 1.4%, Ploom 0.1% to 1.1%, and e-cigarettes 0.7% to 1.8%.

Frequency and Intensity

In Year 5, current cigarette smokers (N=868) smoked on average on 28.7 days of the last 30 days. On the days they smoked, they consumed on average of 14.8 cigarettes/day. The corresponding average consumption based on the last 30-day period was 14.4 cigarettes/day.⁸ Over time, the average daily last 30-day consumption of cigarettes decreased from 16.0 cigarettes/day in Year 1 to 14.4 cigarettes/day in Year 5.

Current *IQOS*TM users (N=249) used *IQOS* on average on 27.4 days of the last 30 days. On the days they used *IQOS*, they consumed on average 12.7 *HEETS*TM⁹/day. The corresponding average

² Combustible TNPs include cigarettes and other combustible TNPs (e.g., cigars, pipes, kiseru, water pipes/shisha cigarillos). TNP, tobacco or nicotine-containing product.

³ The prevalence of overall combustible TNP use comprises nearly only cigarette use, therefore the prevalence of overall combustible TNP use and the prevalence of cigarette use differ only in the second decimal place.

⁴ Smoke-free TNPs include heated tobacco products (HTPs, i.e., *IQOS*TM, any Glo TNPs, any Ploom TNPs]), e-cigarettes, and smokeless TNPs (smokeless tobacco pipes and smokeless tobacco [e.g., chewing tobacco, snus, or snuff]). TNP, tobacco or nicotine-containing product.

⁵ The prevalence of overall combustible TNP use comprises nearly only cigarette use, therefore the prevalence of overall combustible TNP use and the prevalence of cigarette use differ only in the second decimal place.

⁶ In Japan, e-cigarettes with nicotine are regulated under the pharmaceutical law and are currently not commercially available, while importation of nicotine liquid (up to 120 ml) and 1-2 devices for self-consumption is permitted. The questions on e-cigarette use did not differentiate between nicotine-containing vs. non nicotine-containing e-cigarettes.

⁷ Any other TNPs (Table 3) include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy.

⁸ Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used/smoked on these days divided by 30.

⁹ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

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consumption based on the last 30-day period was 12.0 *HEETS*[™]/day.¹⁰ Over time, the average daily last 30-day consumption of *HEETS*[™] increased from 10.5 *HEETS*[™]/day in Year 1 to 12.0 *HEETS*[™]/day in Year 5.

Current e-cigarette¹¹ users (N=123) used e-cigarettes on average on 25.8 days of the last 30 days. On the days they consumed e-cigarettes, they used them on average 12.5 times/day. The corresponding average daily consumption based on the last 30-day period was 11.5 times/day.¹² Over time, the average daily last 30-day consumption of e-cigarettes increased from 8.6 times/day in Year 1 to 11.5 times/day in Year 5.

Use Patterns

In Year 5, among all current TNP users (N=1,094), the frequency of exclusive TNP use (68.9%; use of only one TNP) was higher than that of dual use (21.2%; use of two different TNPs) or poly use (6.6%; use of more than two different TNPs).¹³ Over time, the frequency of exclusive TNP use decreased from 82.3% in Year 1 to 68.1% in Year 4 to stabilize with 68.9% in Year 5, while the frequency of dual TNP use steadily increased from 14.3% in Year 1 to 21.2% in Year 5. The prevalence of poly TNP use increased from 1.4% in Year 1 to 10.0% in Year 3, but then decreased to 7.5% in Year 4 and 6.6% in Year 5. Overall, this reflects a stabilization of exclusive use as of Year 4 together with a shift to dual TNP use rather than poly TNP use.

History of TNP use - Initiation / Relapse / Reinitiation

In Year 5, among all never TNP users in the year prior to the survey (N=4,800),¹⁴ 0.19% initiated TNP use with cigarettes and 0.08% with *IQOS*[™]. Among ever *IQOS* users (N=349), 99.7% had a previous history of cigarette smoking before starting to use *IQOS*, i.e., only 0.3% of *IQOS* users were never smokers before they started to use *IQOS*. Among current TNP users (N=1,094) who quit cigarette smoking more than 2 years ago (n=2), 0.00% (n=0) relapsed to *IQOS*[™], 0.09% (n=1) reinitiated TNP use with *IQOS* in the last 12 months, and 0.09% (n=1) provided no information. Over time, the rates of last year initiation, relapse, and reinitiation with *IQOS*[™] remained stable and low across Year 1 to Year 5.

¹⁰ Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used/smoked on these days divided by 30.

¹¹ In Japan, e-cigarettes with nicotine are regulated under the pharmaceutical law and are currently not commercially available, while importation of nicotine liquid (up to 120 ml) and 1-2 devices for self-consumption is permitted. The questions on e-cigarette use did not differentiate between nicotine-containing vs. non nicotine-containing e-cigarettes.

¹² Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used/smoked on these days divided by 30.

¹³ A total of 3.3% (n=36) current TNP users could not be classified as exclusive, dual, or poly users based on the self-reported data.

¹⁴ Never TNP users: Never smoked cigarettes/used *IQOS*[™] up to 1 year prior to the survey.

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Quitting

In Year 5, among current cigarette smokers, 55.2% (of N=860) were interested in quitting smoking and 51.0% (of N=858) had ever attempted to quit smoking cigarettes. Most of the smokers with quit attempts (62.4%) quit for less than 6 months, while 14.1% quit for 6-12 months, and 23.5% quit for more than 12 months. Over time, the percentage of cigarette smokers with interest in quitting cigarette smoking and those with cigarette quit attempts remained rather stable across Year 1 to Year 5. Regarding the quitting rate of cigarette smoking, among participants who had been cigarette smokers more than one year prior to the survey (N=899), 3.4% quit cigarette smoking in the last 12 months, with 2.4% quitting all TNPs. Across Year 3 to 5,¹⁵ both the rates for quitting cigarettes (Year 3: 3.4%; Year 4: 3.7%; Year 5: 3.4%) and quitting all TNPs (Year 3: 2.2%; Year 4: 3.2%; Year 5: 2.4%) remained stable over time.

In Year 5, among current *IQOS*TM users, 38.7% (of N=243) were interested in stopping using *IQOS* and 18.8% (of N=240) had ever attempted to stop using *IQOS*, with most (79.5%) stopping using *IQOS* for less than 6 months, 4.5% stopping for 6-12 months, and 15.9% stopping for more than 12 months. While across Year 1 to Year 5, the percentage of *IQOS* users with interest in stopping using *IQOS* remained rather stable over time, the percentage of *IQOS* users with stop attempts increased from 4.9% in Year 1 to 18.8% in Year 5. In terms of the rate of stopping using *IQOS*TM, among *IQOS* users who had used *IQOS* more than one year prior to the survey (N=258), 3.5% stopped using *IQOS* in the last 12 months, with 1.5% stopping all TNPs. Across Year 3 to Year 5,¹⁶ both the rate of stopping using *IQOS* (Year 3: 9.4%, Year 4: 6.7%, Year 5: 3.5%) and the rate of stopping all TNPs (Year 3: 2.6%, Year 4: 1.9%, Year 5: 1.5%) slightly decreased over time, likely related to an increase in exclusive *IQOS* users in the General Adult Population Sample over time.¹⁷

3.2 *IQOS* USER SAMPLE

Demographic Characteristics

Of the total participants (N=1,999) in the *IQOS* User Sample who completed the study in Year 5 (2021-2022), 19.8% were female and 80.2% were male. The mean age of the participants was 40.2 years (SD=10.37, range: 20-75 years). The gender and age demographic characteristics of the study participants were overall similar across study Year 1 to Year 5.

¹⁵ This information was assessed only from Year 3 onwards.

¹⁶ This information was assessed only from Year 3 onwards.

¹⁷ The decrease in *IQOS* or all TNP stopping rates is likely related to the fact that the percentage of exclusive *IQOS* users among all *IQOS* users in the General Adult Population Samples increased over time, with exclusive *IQOS* users being less likely to stop *IQOS* or all TNPs than *IQOS* users who use *IQOS* together with other TNPs.

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Frequency and Intensity

In Year 5, current *IQOS*TM users (N=1,999) used *IQOS* on average on 28.9 days of the last 30 days. On the days they used *IQOS*, they consumed on average 16.7 *HEETS*TM¹⁸/day. The corresponding average consumption based on the last 30-day period¹⁹ was 16.3 *HEETS*TM/day. Both the number of days on which *IQOS* was used in the last 30 days (Year 1: 29.1; Year 2: 28.9; Year 3: 28.8, Year 4: 28.7, Year 5: 28.9) and the average daily last 30-day consumption (Year 1: 15.9; Year 2: 16.1; Year 3: 15.5; Year 4: 15.9, Year 5: 16.3) remained rather stable across study Year 1 to Year 5.

IQOS Use Patterns

In Year 5, among current *IQOS*TM users with sufficient classifiable information (N=1,982), 55.5% (n=1,100) used *IQOS* exclusively, 27.2% (n=540) used *IQOS* together with other smoke-free TNPs, and 17.3% (n=342) used *IQOS* with combustible TNPs. The proportion of exclusive *IQOS* use was comparatively lower among men (54.0%) than women (61.6%), while it was similar across age groups with a slight skew towards older age groups. Over time,²⁰ the proportion of exclusive *IQOS*TM use decreased from 63.4% in Year 1 to 55.5% in Year 5, while the proportion of *IQOS* use together with smoke-free TNPs markedly increased from 7.6% in Year 1 to 27.2% in Year 5. Finally, and importantly, the proportion of *IQOS* use together with combustible TNPs markedly decreased from 28.4% in Year 1 to 17.3% in Year 5.

History of *IQOS* Use

In Year 5, among current *IQOS*TM users (N=1,999), 97.4% (n=1,948) had a previous smoking history, i.e., were current (91.2%; n=1,823;) or former (6.3%; n=125) smokers, before starting to use *IQOS*. This also means that 2.6% were never smokers who started TNP use with *IQOS*. Among all current *IQOS*TM users with a smoking history prior to starting using *IQOS* (N=1,948), 0.6% relapsed to *IQOS* and 1.5% reinitiated TNP use with *IQOS*. Across Year 3 to 5,²¹ the percentage of current *IQOS* users who did not have a previous smoking history remained low, but slightly increased from 0.7% in Year 3 to 1.9% in Year 4 to 2.6% in Year 5, while relapse to *IQOS* and reinitiation of TNP use with *IQOS* remained stable at low levels.

Quitting

In Year 5, among current *IQOS*TM users (N=1,999), 44.9% were interested in stopping using *IQOS* and 34.4% had ever attempted to stop using *IQOS*. Across Year 1 to Year 4, both the interest in stopping using *IQOS* (36.0% in Year 1 to 50.9% in Year 4) and the percentage of *IQOS* users with

¹⁸ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all in Japan available *IQOS* tobacco stick brand names *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

¹⁹ Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used/smoked on these days divided by 30.

²⁰ The presented data for Year 1 and Year 2 differ from those presented in the Year 1 and Year 2 study reports due to marginal rounding errors in Year 1 and Year 2 that were corrected as of the Year 4 report.

²¹ This information was assessed only from Year 3 onwards.

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stop attempts (17.0% in Year 1 to 34.9% in Year 4) continuously increased, but then slightly decreased in Year 5 to 44.9% (quitting interest) and 34.4% (quit attempts).

Among current *IQOS*[™] users who also smoked (N=334), 60.8% were interested in quitting smoking cigarettes and 62.6% had ever attempted to quit cigarette smoking. Across Year 1 to Year 5, both the interest in quitting cigarettes (79.2% in Year 1 to 60.8% in Year 5) and the percentage of *IQOS* users with cigarette quit attempts (71.4% in Year 1 to 62.6% in Year 5), decreased over time, but overall, still remained high. Among current *IQOS*[™] users who had been cigarette smokers more than one year prior to the survey (N=377), 11.4% successfully quit cigarette smoking in the last 12 months. Across Year 3 to Year 5,²² the rate of *IQOS* users who successfully quit cigarette smoking in the last 12 months increased from 9.8% in Year 3 to 14.0% in Year 4, but then decreased to 11.4% in Year 5.

Risk Perception

In Year 5, current *IQOS*[™] users (N=1,999) reported that they perceive the health risk [score: 0-100]²³ associated with smoking cigarettes (score: 63.0) as higher than the health risk associated with using *IQOS* (score: 49.6). While the perceived health risk score associated with smoking cigarettes remained rather stable across Year 1 to Year 5, the perceived health risk score associated with using *IQOS* increased from 44.0 in Year 1 to 49.6 in Year 5.

Respiratory Symptoms

In Year 5, among current exclusive *IQOS*[™] users (N=1,100), 9.7% reported respiratory cough and/or phlegm symptoms, while among current *IQOS* users who used *IQOS* together with combustible TNPs (N=342), 17.8% reported respiratory symptoms. Also, exclusive *IQOS* users (N=1,100) reported overall improvements in cough (10.5%) and phlegm (9.1%) symptoms in the last 12 months prior to the survey, which were similarly frequent as the improvements that *IQOS* users who used *IQOS* together with combustible TNPs (N=342) reported for cough (11.4%) and phlegm (8.5%) symptoms. Across Year 3 to Year 5,²⁴ the percentage of those who reported improvement in cough and phlegm symptoms mostly decreased among both current exclusive *IQOS*[™] users (cough: 18.5% to 10.5% and phlegm: 18.8% to 9.1%) and current *IQOS* users who used *IQOS* together with combustible TNPs (cough: 15.8% to 11.4% and phlegm: 11.6% to 8.5%). This could be because over time more and more *IQOS* users had used *IQOS* for a longer period and/or increasingly more *IQOS* users used *IQOS* exclusively or together with other smoke-free TNPs and, thus, had already reached substantial improvement in respiratory symptoms from using *IQOS*.

²² This information was assessed only from Year 3 onwards.

²³ Score ranging from 0 [no-risk] to 100 [very-high risk].

²⁴ This information was assessed only from Year 3 onwards.

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Exercise capacity

Exercise capacity measured in Metabolic Equivalent of Tasks (METs),²⁵ was slightly higher among female (8.7 MET, N=242) and male (9.6 MET, N=858) exclusive *IQOS*TM users than among female (8.0 MET, N=50) and male (9.1 MET, N=292) *IQOS* users who used *IQOS* together with combustible TNPs. Also, among exclusive *IQOS* users (N=1,100), 16.2% reported an improvement in exercise capacity in the last 12 months, whereas among *IQOS* users who used *IQOS* together with combustible TNPs (N=342), 13.2% reported an improvement in exercise capacity. Across Year 3 to Year 5,²⁶ among both exclusive *IQOS* users (Year 3: 20.0%; Year 4: 18.4%; Year 5: 16.2%) and *IQOS* users who used *IQOS* together with combustible TNPs (Year 3: 16.3%; Year 4: 14.8%; Year 5: 13.2%), the percentage who reported an improvement in exercise capacity in the last 12 months steadily decreased. This could be because over time more and more *IQOS* users had used *IQOS* for a longer period and/or increasingly more *IQOS* users used *IQOS* exclusively or together with other smoke-free TNPs and, thus, had already reached substantial improvement in exercise capacity from using *IQOS*.

Hygiene, beauty, and fitness benefits

When all *IQOS*TM users (N=1,999) confirmed their agreement regarding the perception of beneficial changes^{27, 28, 29} related to six hygiene, beauty, and fitness aspects since they had switched from cigarettes to *IQOS*, the hierarchy of beneficial changes that were perceived most often was (i) “My teeth appear less stained or yellowish” (58.8%), (ii) “My breath smells better” (47.3%), and (iii) “My sense of smell has improved” (23.0%), (iv) “My sense of taste has improved” (21.9%), (v) “I feel that it is easier to exercise” (15.1%), and (vi) “My face skin appears smoother and firmer” (7.7%).

Among exclusive *IQOS*TM users (N=1,100), the frequency of agreement with perceived beneficial changes was for all hygiene, beauty, and fitness aspects similar to those among *IQOS* users (N=540) who used *IQOS* together with smoke-free TNPs, whereas it was much higher than that among *IQOS* users (N=342) who used *IQOS* together with combustible TNPs.

Across Year 1 to Year 5, while the hierarchy of the frequency of agreement with perceived beneficial changes was similar among both exclusive *IQOS* users, *IQOS* users who used *IQOS* together with smoke-free TNPs, and *IQOS* users who used *IQOS* together with combustible TNPs,

²⁵ Single item questionnaire; MET values from 1 to 20 in men and 1 to 18 in women are listed on a progressive scale linked to specific physical activities. Participants had to indicate the most strenuous activity they could sustain for at least 30 min. 1 MET equals energy expenditure in terms of oxygen consumption per 1 kg of body mass while sitting at rest.

²⁶ This information was assessed only from Year 3 onwards.

²⁷ Seven-point rating scale ranging from “strongly disagree” to “strongly agree”.

²⁸ The Self-Reported Change Questionnaire (SRCQ) was developed by PMI and the translation into the Japanese language was linguistically validated by TransPerfect (<https://www.transperfect.com>).

²⁹ Selecting “somewhat agree”, “agree”, or “strongly agree” was considered confirming the statement.

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among all three user groups the frequency of agreement with perceived beneficial changes decreased over time. This could be because over time more and more *IQOS* users had used *IQOS* for a longer period and/or increasingly more *IQOS* users used *IQOS* exclusively or together with other smoke-free TNP and, thus, had already reached substantial improvement in the six hygiene, beauty, and fitness aspects from using *IQOS*.

3.3 CONCLUSIONS

During Year 1 to Year 5 (2016-2022) of PMI's repeated cross-sectional studies in Japan, in the General Adult Population Samples, the prevalence of overall current TNP use remained rather stable across study Year 1 to Year 3 (2016 to 2019), whereas it decreased in Year 4 and Year 5 (2020-2022). Over time, the prevalence of cigarette and other combustible TNP use markedly decreased, while the prevalence of smoke-free TNP use increased, so that for the first time more than 1 out of 3 TNP users in Japan were using smoke-free TNPs, and about 1 out of 5 Japanese TNP users were using smoke-free TNPs exclusively. The observed decline in the prevalence of overall combustible TNP use over time is in line with the data reported in the Japan National Health and Nutrition Survey³⁰ as well as in the WHO Global Report on Trends in Prevalence of Tobacco Smoking 2000-2025.³¹ Overall, this shift from combustible to smoke-free TNP use is in line with the principles of tobacco harm reduction, and, moreover, suggests that smoke-free TNPs, in particular *IQOS*, other HTPs, and e-cigarettes,³² are acceptable alternatives to cigarette smoking.

Across Year 1 to Year 5 (2016 to 2022), nearly all current *IQOS*™ users from both the General Adult Population Samples and *IQOS* User Samples were adult cigarette smokers when they started using *IQOS* and there was low initiation, reinitiation, and relapse with *IQOS*.

In the General Adult Population Samples, the frequency (average number of days out of the last 30 days) and intensity (average daily product consumption) of TNP use among cigarette smokers and *IQOS*™ users was overall similar across Year 1 to Year 5. While the cigarette consumption among cigarette smokers slightly decreased and the *HEETS*™³³ consumption among *IQOS* users slightly increased, the average daily cigarette and *HEETS* consumption steadily approached each other over time. These similarities of patterns in frequency and intensity of cigarette and *IQOS*

³⁰Japan National Health and Nutrition Survey home page: National Health and Nutrition Survey | Health Japan 21 (nibiohn.go.jp); specifically: Japan National Health and Nutrition Survey (2019). <https://www.mhlw.go.jp/content/10900000/000687163.pdf>. Published in 2020 October 27.

³¹ WHO Global Report on Trends in Prevalence of Tobacco Smoking 2000-2025 (second edition): 9789241514170-eng.pdf (who.int)

³² In Japan, e-cigarettes with nicotine are regulated under the pharmaceutical law and are currently not commercially available, while importation of nicotine liquid (up to 120 ml) and 1-2 devices for self-consumption is permitted. The questions on e-cigarette use did not differentiate between nicotine-containing vs. non nicotine-containing e-cigarettes.

³³ Tobacco sticks (disposables) to be used with the *IQOS*™ device; these comprise all in Japan available *IQOS* tobacco stick brand names *HeatSticks*™, *HEETS*™, and *TEREA*™.

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use suggest that the use behaviors of cigarette smokers and *IQOS* users were overall similar. Moreover, the decline in cigarette consumption among cigarette smokers over time is in line with tobacco harm reduction and is likely to have a positive impact on public health in Japan.

Regarding multiple TNP use across Year 1 and Year 5, in the Japanese General Adult Population Samples, there was a stabilization of exclusive TNP use³⁴ as of Year 4 together with a shift to dual TNP use³⁵ rather than poly TNP use,³⁶ suggesting that poly TNP use is not likely to become a sizable TNP use pattern in the general adult population of Japan. In the *IQOS* User Samples, the majority of *IQOS* users completely switched away from combustible TNPs to exclusive *IQOS* use or, in particular in the last three years, to *IQOS* use together with other smoke-free TNPs, resulting in an overall smoke-free TNP use proportion of over 80% in Year 5. This shift from combustible to smoke-free TNP use among *IQOS* users is contributing to tobacco harm reduction and indicates that the marketing of *IQOS* and other smoke-free TNPs is likely to have a positive impact on public health in Japan.

In the General Adult Population Samples, among cigarette smokers, the rates of quitting cigarettes and all TNPs remained stable over time indicating that *IQOS* does not seem to prevent adult smokers who want to quit cigarettes or all TNPs to do so. Among *IQOS*TM users, although the willingness of quitting remained high over time, the rates of stopping using *IQOS* and quitting all TNPs slightly decreased. This is most likely related to the increase in the percentage of exclusive *IQOS* users among all *IQOS* users over time, with exclusive *IQOS* users likely showing high product satisfaction with using *IQOS*. In the *IQOS* User Sample, among *IQOS* users who also smoked cigarettes, the willingness to quit cigarette smoking slightly declined during the last years, while the cigarette quitting rate, remained rather stable. The slight decline in the willingness to quit cigarette smoking may reflect the fact that a proportion of *IQOS* users who also smoked cigarettes did not want to stop cigarette smoking completely.

In the *IQOS* user samples, the *IQOS*TM users reported that they perceive *IQOS* as not risk-free and that they perceive the health risk of using *IQOS* as lower than the health risk of smoking cigarettes. This means that the understanding about the health risk of *IQOS* is in line with the relative risks of the product that are reasonably likely.³⁷

While the perceived health risk of cigarettes remained rather stable across Year 1 to Year 5, the perceived health risk of *IQOS*TM initially increased but then stabilized over time, probably due to miscommunication and misperception of the actual health risk of individual TNP categories that are widely prevalent.

³⁴ Use of only one tobacco or nicotine containing product.

³⁵ Use of two different tobacco or nicotine containing products.

³⁶ Use of more than two different tobacco or nicotine containing products.

³⁷ FDA TPL Review PMI's IQOS MRTPA. [Technical Project Lead \(TPL\) Review: MR0000059-MR0000061, MR0000133 \(fda.gov\)](#)

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In the *IQOS* User Samples, the improvements in perceived respiratory symptoms, exercise capacity, and hygiene, beauty, and fitness related benefits reported by the *IQOS*[™] users were overall more frequent among exclusive *IQOS* users and *IQOS* users who used *IQOS* together with smoke-free TNPs than among *IQOS* users who used *IQOS* together with combustible TNPs. However, over time, the frequency of reported perceived improvements among all three user groups decreased from Year 1 to Year 5. This could be because over time more and more *IQOS* users had used *IQOS* for a longer period and/or increasingly more *IQOS* users had used *IQOS* exclusively or together with other smoke-free TNPs and, thus, had already reached substantial improvement in respiratory symptoms, exercise capacity, and hygiene, beauty, and fitness related benefits from using *IQOS*. However, it may also be explained by the COVID pandemic during which the overall perception of health worsened over time.

Finally, PMI's repeated cross-sectional study in Japan will be continued in 2023 (Year 6).

4 OVERALL AIM AND STUDY OBJECTIVES

The overall aim of the repeated cross-sectional studies in Japan is to investigate the current and past TNP use in the general adult Japanese population and among Japanese adult *IQOS*[™] users registered in the *IQOS* user database of PMI's affiliate in Japan to understand and characterize how PMI's smoke-free product *IQOS* is used by the general adult Japanese population and among adult *IQOS* users in comparison to other TNPs.

More specifically, the study objectives in the target populations were:

1. Estimate the prevalence/frequency of TNP use broken down into (i) current, former, and never use and (ii) exclusive, dual, and poly use.
2. Describe the past TNP use status to estimate (i) TNP initiation (based on first TNP regularly used); (ii) relapse and reinitiation; and (iii) intention to quit, quit attempts, and successful quitting of TNPs in the target populations.
3. Estimate self-reported risk perceptions related to smoking cigarettes and using *IQOS*[™] among current *IQOS* users.
4. Estimate self-reported perceived changes in health outcomes as well as in hygiene, beauty, and fitness related benefits among current *IQOS*[™] users.

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5 OVERALL STUDY DESIGN AND PLAN

As in previous study years, the Year 5 observational cross-sectional study in Japan was conducted in two different samples (**Figure 1**):

- A General Adult Population Sample
- An *IQOS* User Sample

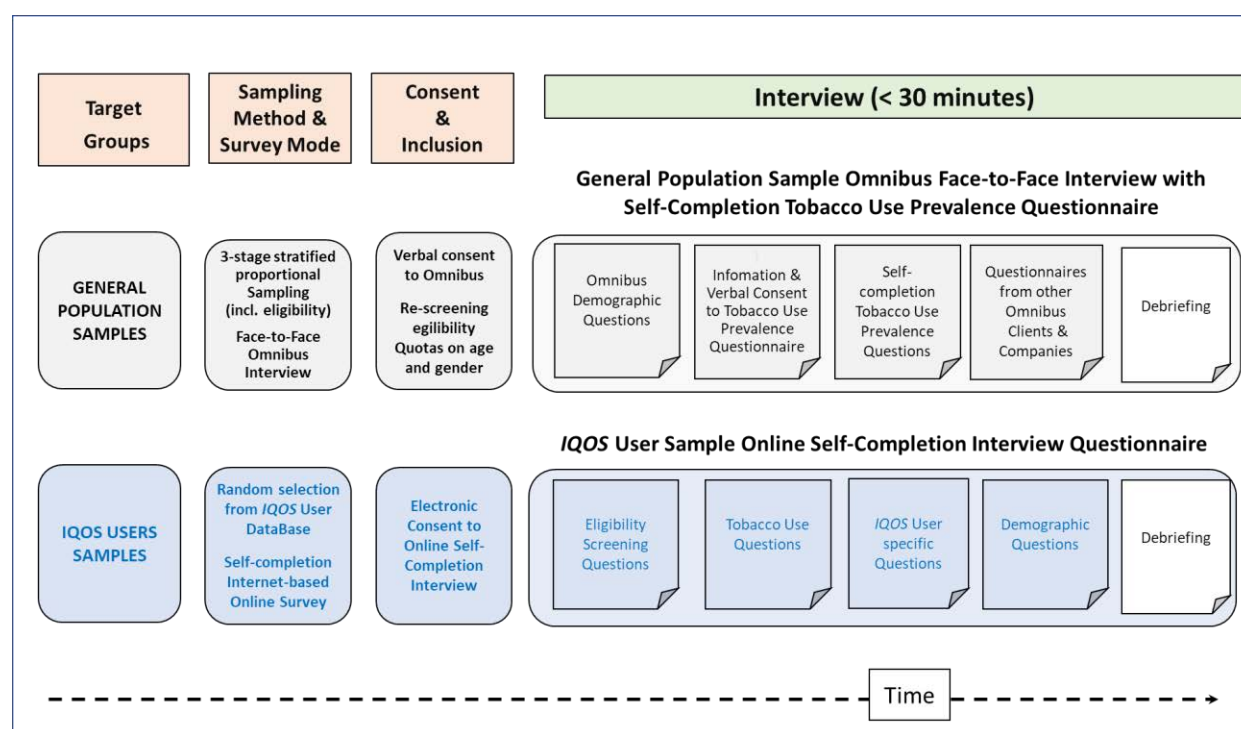


Figure 1 Study Design

General Adult Population Sample. In each survey wave, the surveys were conducted by interviewers as part of a multi-purpose survey (Omnibus). The Omnibus is a syndicated vehicle with multiple participating clients and, therefore, several topics are captured within the same interview. The face-to-face interviews of the Omnibus started with a general introduction by the interviewer about the general purpose of the Omnibus. The participants were then informed by the interviewer about the specific survey including the aim, study participation duration, the voluntary nature of participation, confidentiality, use of data, and data privacy. Also, the participants were provided an information sheet with background information on the research. After orally consenting to participate in the survey, the interviewer proceeded with the

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demographic questions. Although most of the data collected in the Omnibus including the demographic questions were collected using a face-to-face interview approach, the main study questionnaire was handed to the participants for a self-completion Pen-and-Paper interview (PAPI). This approach of collecting TNP use information is preferable to avoid bias due to social desirability because participants might feel uncomfortable to answer specific questions in the presence of an interviewer. For completing the Omnibus questionnaire, participants were given a book coupon for 500 JPY (about 4 USD), which is a standard incentive in public opinion surveys in Japan.

IQOS User Sample. In each wave, the surveys were conducted through an online survey. A randomly selected number of adult *IQOS*™ users registered in the *IQOS* user database of PMI's affiliate in Japan were invited to participate in the survey. The potential participants were presented with a consent form, which included information about the aim of the study, study participation duration, the voluntary nature of their participation, confidentiality, use of data, and data privacy. Informed consent was obtained electronically from all participants before completing the survey online, i.e., participants had to indicate that they had read and understood the information about the study and agree to participate in the survey. After consenting to participate, the participants were provided a screener questionnaire. Eligible participants proceeded to the demographic questions and then to the main study questionnaire. For completing the online survey, participants were given a gift code valued at 500 JPY (about 4 USD), which is a standard incentive in public opinion surveys in Japan.

5.1 SELECTION OF STUDY POPULATION

5.1.1 GENERAL ADULT POPULATION SAMPLE

5.1.1.1 STUDY POPULATION

The target population for the General Adult Population Sample was defined as adults (≥ 20 years of age) living in a registered household in Japan (close to 105 Mio. based on residents' registry as of January 1, 2016).³⁸

³⁸ Statistics of Japan: https://www.e-stat.go.jp/en/stat-search/files?page=1&layout=datalist&toukei=00200524&tstat=000000090001&cycle=1&tclass1=000001011678&result_page=1&tclass2val=0.

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5.1.1.2 *SAMPLING FRAME*

Sampling Method

The sampling design for the General Adult Population Sample was a nationwide three-stage stratified proportional sampling that covered the whole of Japan. The sampling was conducted in three key stages:

First stage: Census Unit

The Statistics Bureau of Japan divided the households of the nation into 940,000 census units, with each unit containing approximately 50 households.³⁹ At this stage, all household units were eligible for selection. The nation was divided into the 47 Japanese prefectures and although there was no one way to group them into specific regions, there were two main acceptable groupings of 8 or 12 regions. For the Omnibus, the 12-region grouping was used. Sampling points (from the census units) were then allocated among the 12 regions based on population share, and these were further subdivided according to major cities, other cities, and urban areas. Normally, a total of 157 sampling points was selected for an initial sample selection of about 4,000 to 6,000 addresses.

Second stage: Household selection

An electronic residential map was used to identify the households within each selected census unit. This map covered the whole country and was updated annually. Specifically, not all 940,000 units could be precisely identified because not all addresses within each unit were officially published. However, there were enough addresses published for all units and these were used along with the residential map to define the route to be taken within each unit. The addresses that qualify within each route were revisited at least three times if no contact was made with a resident on the first visit.

Third stage: Respondent within household

Respondents were selected on the basis that they were part of the household and aged 20 years or older, with controls placed on gender and age to prevent over-indexing on respondent groups with higher response rates.

Interviews took place in the presence of the interviewer who may have used showcards for some questions if this was deemed necessary.

³⁹ Statistics Bureau of Japan: <http://www.stat.go.jp/english/>.

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Sample Size

A sample size of 7,000 participants per year is sufficient to estimate with a 95% confidence interval a 5% prevalence of *IQOS*[™] use with a precision of ± 0.51 percent units. The achievable accuracy (95% Confidence Interval [CI]) is shown for an assumed prevalence in a range of 1 to 10% ([Table 1](#)).

Table 1 Achievable Accuracy (95% CI) for Assumed Prevalence - General Adult Population Sample

Level	Sample Size	95% Confidence Interval by Prevalence of <i>IQOS</i> [™] use			
	n	1.0%	3.0%	5.0%	10.0%
General Adult Population Sample	7,000	$\pm 0.23\%$	$\pm 0.40\%$	$\pm 0.51\%$	$\pm 0.70\%$

Sampling Frequency

The annual sample comprised in Year 1 and Year 2 the participants of four waves equally spaced throughout the year, whereas as of Year 3, it comprised the participants of six waves ([Figure 2](#)). The increase in waves as of Year 3 enlarged the sample size from 5,000 to 7,000 subjects per study year, which translated into an improvement of the accuracy of the estimates.

5.1.2 *IQOS* USER SAMPLE

5.1.2.1 STUDY POPULATION

The target group for the *IQOS* User Sample was defined as adults (≥ 20 years of age) registered in the *IQOS*[™] user database of PMI's affiliate in Japan and agreed to be contacted for research purposes at the time of registration. End of 2021, about 8.1 million⁴⁰ *IQOS* users were registered in the *IQOS* user database of PMI's affiliate in Japan.

5.1.2.2 SAMPLING FRAME

Sampling Method

IQOS[™] users registered in the *IQOS* user database of PMI's affiliate in Japan were randomly selected from the database and were provided a link to access the online survey.

⁴⁰ End of December 2021, 8,102,223 registered *IQOS* users (including no-device-linked and currently deactivated user). In 2021/2022, the *IQOS* user database of PMI's affiliate in Japan was cleaned up by removing suspicious and/or "dead" accounts, while keeping currently deactivated accounts.

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Sample Size

A sample size of 2,000 participants per year is sufficient to estimate with a 95% confidence interval a 50% proportion of exclusive *IQOS* use with a precision of $\pm 2.19\%$ units. The achievable accuracy (95% CI) is shown for an assumed proportion of exclusive *IQOS* use in the range of 30% to 70% (Table 2).

Table 2 Achievable Accuracy (95% CI) for Assumed Exclusive *IQOS* Use Proportion - *IQOS* User Sample

Level	Sample Size	95% Confidence Interval by Proportion of Exclusive <i>IQOS</i> ™ use				
	n	30%	40%	50%	60%	70%
<i>IQOS</i> User Sample	2,000	$\pm 2.01\%$	$\pm 2.15\%$	$\pm 2.19\%$	$\pm 2.15\%$	$\pm 2.01\%$

Sampling Frequency

The annual sample comprised of participants from four waves approximately equally spaced throughout the year (Figure 2).

5.1.3 SAMPLING PERIODS

Each annual sampling (i.e., data collected within a 12-month period; no more than one wave per month) consisted for the General Adult Population Sample of four (in Year 1 and Year 2) or six (as of Year 3 onwards) approximately equally sized survey waves that were equally spaced throughout the year, whereas for the *IQOS* User Sample, in all years, each annual sampling consisted of four approximately equally sized survey waves that were equally spaced throughout the year.

Each annual sample comprised both the participants of the General Adult Population Sample and of the *IQOS* User Sample. The study year was defined as the 12-month period from start of data collection of the first survey wave until the end of data collection of the last survey wave.

The data collection (sampling periods) of PMI's repeated cross-sectional study in Japan in Year 5 (2021-2022) took place from September 3, 2021, to August 14, 2022, in six waves (waves 21 to 26) for the General Adult Population Sample, and from November 19, 2021, to August 30, 2022, in four waves (waves 17 to 20) for the *IQOS* User Sample (Figure 2).

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Throughout the report, if not indicated otherwise, sample sizes are based on participants with non-missing information on the respective outcome reported.

As of Year 4, advanced categorization of TNPs in six common TNP categories (cigarettes, other combustible TNPs, heated tobacco products [HTP], e-cigarettes, smokeless TNPs, and any other TNPs)⁴² as well as two overarching TNP umbrella classes (overall combustible TNPs and overall smoke-free TNPs) was introduced and presented for the respective data (Table 3). The previous way of TNP presentation in Year 1-3 (based on individual brands for HTPs but on categories for most other TNPs) was still retained, particularly to allow for the presentation of trend data from the past.

Table 3 Categorization of TNPs in Three Levels of TNP Categories

Categorization I	Categorization II	Categorization III
TNPs	TNP category	TNP class
Cigarettes	Cigarettes	Overall Combustible TNPs
Cigars/pipes/ kiseru/shisha/cigarillos	Other combustible TNPs	
IQOS™	HTPs	Overall Smoke-free TNPs
Any Ploom TNPs		
Any Glo TNPs		
E-cigarettes	E-cigarettes	
Smokeless tobacco pipe	Smokeless TNPs	
Smokeless tobacco (e.g., chewing tobacco, snus, or snuff)		
Any other TNPs*	Any other TNPs	Any other TNPs

Note: Categorization I is based on the initial grouping of TNPs (Year 1 to Year 3) including individual brands for HTPs as well as certain TNP categories for other TNPs. Categorization II was introduced in Year 4 and comprises six common TNP categories (i.e., cigarettes, other combustible TNPs, HTPs, e-cigarettes, smokeless TNPs, and other TNPs). Categorization III was also introduced in Year 4 and comprises the two overarching TNP umbrella classes overall combustible TNPs and overall smoke-free TNPs. TNP, tobacco or nicotine-containing product.

*Any other TNPs include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy.

⁴² Any other TNPs include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy.

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6 RESULTS

6.1 GENERAL ADULT POPULATION SAMPLE

6.1.1 DISPOSITION GROUPS

In Year 5, the **General Adult Population Sample** included 7,140 participants with the data being collected between September 3, 2021, and August 14, 2022.

A total of 24,000 households were visited to participate in the Year 5 study. Of these, 16,784 candidates did not respond for various reasons (mainly due to refusal to participate, short-term absence, and relocation/change in address; **Figure 3**). Of the remaining 7,216 individuals who were willing to participate in the study, 76 participants did not complete the questionnaire, leading to an analytical sample size of 7,140 participants who completed the Year 5 survey (**Figure 3**).

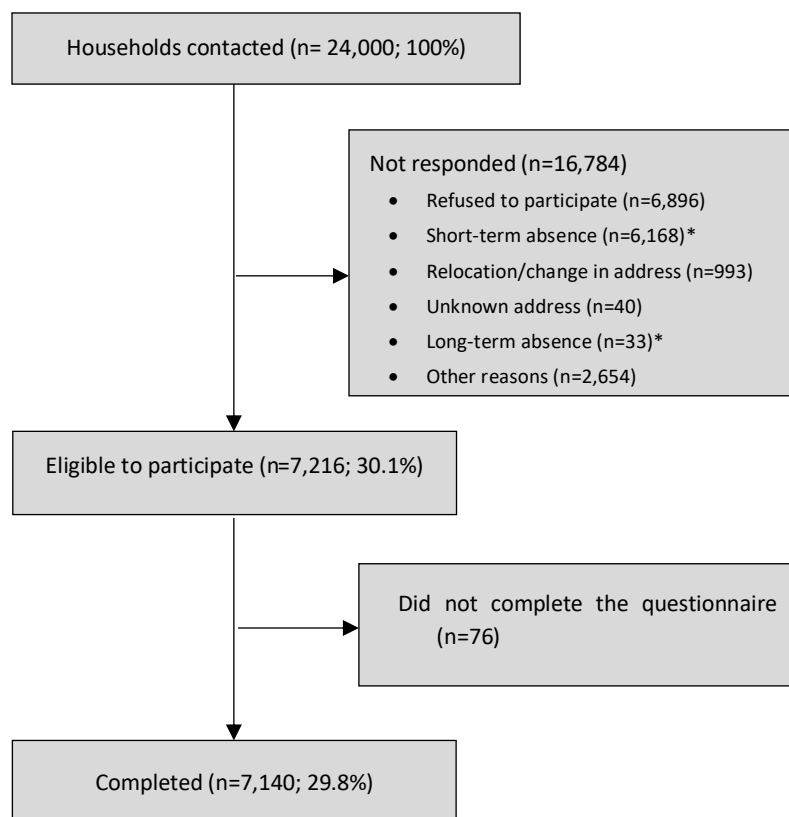


Figure 3 Disposition – General Adult Population Sample

* Long-term absence (respondents are not at home during the fieldwork period, e.g., due to hospitalization, business trip); short-term absence (respondents are not at home when the interviewer comes for the interview)

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6.1.2 DEMOGRAPHIC CHARACTERISTICS

Over the 12-month study period (2021-2022), a total of N=7,140 participants in the General Adult Population Sample completed the study (Table 4). A total of 54.4% participants (n=3,883) in the sample were female and 45.6% (n=3,257) were male. The age of the participants ranged from 20 to 97 years with a mean age of 56.0 (SD=18.26).

The demographic characteristics of the participants were overall similar across Year 1 to Year 5.

Table 4 Demographic Characteristics – General Adult Population Sample

		General Adult Population Sample (N=7,140)
		n (%)
Gender		
	Male	3,257 (45.6%)
	Female	3,883 (54.4%)
Age group		
	20 – 29	676 (9.5%)
	30 – 39	887 (12.4%)
	40 – 49	1,212 (17%)
	50+	4,365 (61.1%)
	Min	20
	Median	57
	Mean [95% CI]	56.0 [55.5; 56.4]
	SD	18.26
	Max	97
Region		
	Hokkaido	309 (4.3%)
	Tohoku	514 (7.2%)
	Kanto	2,414 (33.8%)
	Kinki	1,135 (15.9%)
	Chubu	1,258 (17.6%)
	Chugoku	454 (6.4%)
	Shikoku	233 (3.3%)
	Kyushu	823 (11.5%)

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Table 4 Demographic Characteristics – General Adult Population Sample – Continued

		General Adult Population Sample (N=7,140)
		n (%)
City Size		
	Major city	2,049 (28.7%)
	Another city	4,444 (62.2%)
	Rural	647 (9.1%)
Highest level of education		
	Junior High School	544 (7.6%)
	High School	3,460 (48.5%)
	College/University	3,102 (43.4%)
	Don't know/Not applicable	34 (0.5%)
Occupation or profession		
	Farming/Agriculture/Fishery	109 (1.5%)
	Self-employed/Small private business	861 (12.1%)
	Clerical employee	1,312 (18.4%)
	Manual employee	1,571 (22.0%)
	Managing profession	178 (2.5%)
	Housewife	1,731 (24.2%)
	Student	182 (2.5%)
	Retired/Unemployed	1,196 (16.8%)

6.1.3 PREVALENCE OF CURRENT, PAST, AND NEVER TNP USE

In Year 5, between the beginning (September 3, 2021) of the first fieldwork wave and the end (August 14, 2022) of the last fieldwork wave of the General Adult Population Sample (N=7,140), among the surveyed participants with non-missing information on current TNP use (N=7,016), 15.6% (n=1,094) were current TNP users, 16.5% (n=1,159) were former TNP users, and 67.9% (n=4,763) were never TNP users ([Table 5](#)).

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Table 5 Prevalence Current, Former, Never TNP Use by Gender/Age Group – General Adult Population

Gender	Age Group	N	Statistics	Current TNP Users	Former TNP Users	Never TNP Users
Total	20 – 29	667	n (%)	105 (15.7%)	26 (3.9%)	536 (80.4%)
			[LCL;UCL]	[13.0; 18.8]	[2.5; 5.7]	[77.1; 83.4]
	30 – 39	879	n (%)	203 (23.1%)	110 (12.5%)	566 (64.4%)
			[LCL;UCL]	[20.3; 26.1]	[10.3; 14.9]	[61.1; 67.6]
	40 – 49	1,189	n (%)	250 (21.0%)	194 (16.3%)	745 (62.7%)
			[LCL;UCL]	[18.7; 23.5]	[14.2; 18.6]	[59.8; 65.5]
	50+	4,281	n (%)	536 (12.5%)	829 (19.4%)	2,916 (68.1%)
			[LCL;UCL]	[11.5; 13.6]	[18.1; 20.6]	[66.6; 69.6]
	Total	7,016	n (%)	1,094 (15.6%)	1,159 (16.5%)	4,763 (67.9%)
			[LCL;UCL]	[14.7; 16.5]	[15.6; 17.5]	[66.7; 69]
Male	20 – 29	348	n (%)	73 (21.0%)	15 (4.3%)	260 (74.7%)
			[LCL;UCL]	[16.8; 25.7]	[2.4; 7.1]	[69.8; 79.2]
	30 – 39	489	n (%)	150 (30.7%)	74 (15.1%)	265 (54.2%)
			[LCL;UCL]	[26.6; 35]	[12.0; 18.7]	[49.6; 58.7]
	40 – 49	550	n (%)	180 (32.7%)	119 (21.6%)	251 (45.6%)
			[LCL;UCL]	[28.8; 36.9]	[18.2; 25.4]	[41.4; 50]
	50+	1,807	n (%)	412 (22.8%)	683 (37.8%)	712 (39.4%)
			[LCL;UCL]	[20.8; 24.9]	[35.5; 40.1]	[37.1; 41.7]
	Total	3,194	n (%)	815 (25.5%)	891 (27.9%)	1,488 (46.6%)
			[LCL;UCL]	[24.0; 27.1]	[26.3; 29.5]	[44.8; 48.4]
Female	20 – 29	319	n (%)	32 (10%)	11 (3.4%)	276 (86.5%)
			[LCL;UCL]	[16.8; 25.7]	[1.7; 6.1]	[82.2; 90.1]
	30 – 39	390	n (%)	53 (13.6%)	36 (9.2%)	301 (77.2%)
			[LCL;UCL]	[10.3; 17.4]	[6.5; 12.6]	[72.6; 81.3]
	40 – 49	639	n (%)	70 (11.0%)	75 (11.7%)	494 (77.3%)
			[LCL;UCL]	[8.6; 13.7]	[9.3; 14.5]	[73.8; 80.6]
	50+	2,474	n (%)	124 (5.0%)	146 (5.9%)	2,204 (89.1%)
			[LCL;UCL]	[4.1; 6.0]	[5.0; 7.0]	[87.7; 90.3]
	Total	3,822	n (%)	279 (7.3%)	268 (7.0%)	3,275 (85.7%)
			[LCL;UCL]	[6.4; 8.2]	[6.2; 7.9]	[84.5; 86.8]

Note: The sample sizes are based on participants with non-missing information on current TNP use. LCL, Lower Confidence Limit of 95% CI; TNP, tobacco or nicotine-containing product; UCL, Upper Confidence Limit of 95% CI.

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Across Year 1 to Year 3, the prevalence of overall current TNP use ([Figure 4](#)) was rather stable, i.e., 18.5% in Year 1 (December 2, 2016 to July 17, 2017), 18.9% in Year 2 (November 3, 2017 to July 16, 2018), and 18.2% in Year 3 (September 6, 2018 to October 14, 2019), while it decreased to 16.1% in Year 4 (July 3, 2020 to June 18, 2021) and further to 15.6% in Year 5 (September 3, 2021 to August 14, 2022).

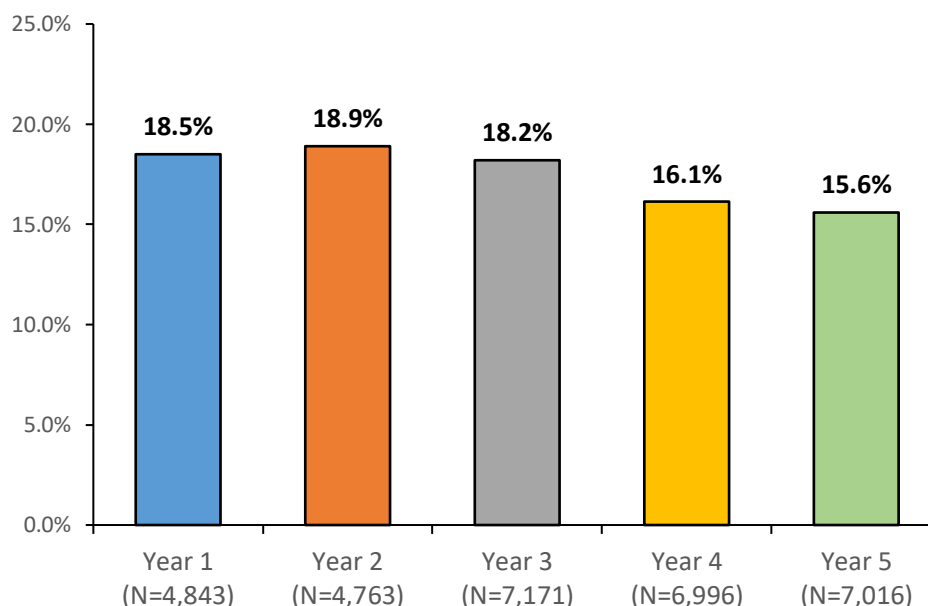


Figure 4 Prevalence of Current TNP Use – Trend Data – General Adult Population Sample
Note: Sample sizes are based on participants with non-missing information on current TNP use. TNP, tobacco or nicotine-containing product.

As of Year 4, advanced categorization of TNPs in six common TNP categories (cigarettes, other combustible TNPs, heated tobacco products [HTP], e-cigarettes, smokeless TNPs, and any other TNPs)⁴³ as well as two overarching TNP umbrella classes (overall combustible TNPs and overall smoke-free TNPs) was introduced ([Section 5.3](#)) and presented for the respective TNP prevalence data.

⁴³ Any other TNPs ([Table 3](#)) include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy.

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Over time (**Figure 5**), the prevalence of overall current combustible TNP use decreased (from 17.6% in Year 1 to 12.4%⁴⁴ in Year 5), while the prevalence of overall smoke-free TNP use increased (from 2.5% in Year 1 to 5.6% in Year 5), resulting in Year 5 among current TNP users (N=1,094) in 36% smoke-free (1 out of 3 TNP users) and 19% exclusive smoke-free (about 1 out of 5 TNP users) current TNP use. The decline in overall combustible TNP use prevalence over time is line with the data reported in the Japan National Health and Nutrition Survey⁴⁵ of the Japanese Ministry of Health, Labour and Welfare as well as in the WHO Global Report on Trends in Prevalence of Tobacco Smoking 2000-2025.⁴⁶

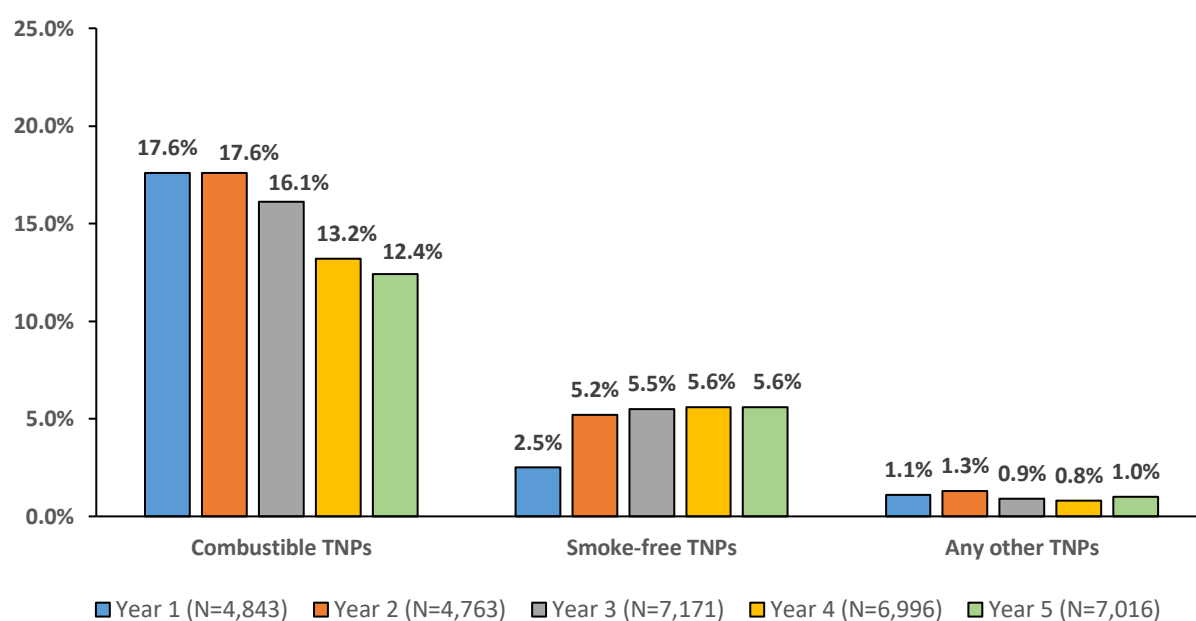


Figure 5 Prevalence Overall Combustible/Smoke-free TNP Use - Trend Data – General Adult Population

Note: Sample sizes are based on participants with non-missing information on current TNP use.

TNP, tobacco or nicotine-containing product.

⁴⁴ The prevalence of overall combustible TNP use comprises nearly only cigarette use, therefore the prevalence of overall combustible TNP use and the prevalence of cigarette use only differ in the second decimal place.

⁴⁵ Japan National Health and Nutrition Survey home page: National Health and Nutrition Survey | Health Japan 21 (nibiohn.go.jp); specifically: Japan National Health and Nutrition Survey (2019). <https://www.mhlw.go.jp/content/10900000/000687163.pdf>. Published in 2020 October 27.

⁴⁶ WHO Global Report on Trends in Prevalence of Tobacco Smoking 2000-2025 (second edition): 9789241514170-eng.pdf (who.int).

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In Year 5, the prevalence of current use of cigarettes (12.4%,⁴⁷ n=868) was higher than that of HTPs (5.4%, n=382) - including *IQOS™* (3.5%, n=249), *Glo* (1.4%, n=97), and *Ploom* (1.1%, n=80) - and that of e-cigarettes⁴⁸ (1.8%, n=123), other combustible TNPs (0.2%, n=12), smokeless TNPs (0.1%, n=6), and any other TNPs⁴⁹ (1.0%, n=67) (**Figure 6**). The prevalence of overall current combustible TNP use was 12.4%⁵⁰ (n=871) and of overall current smoke-free TNP use was 5.6% (n=395) (**Figure 6**).

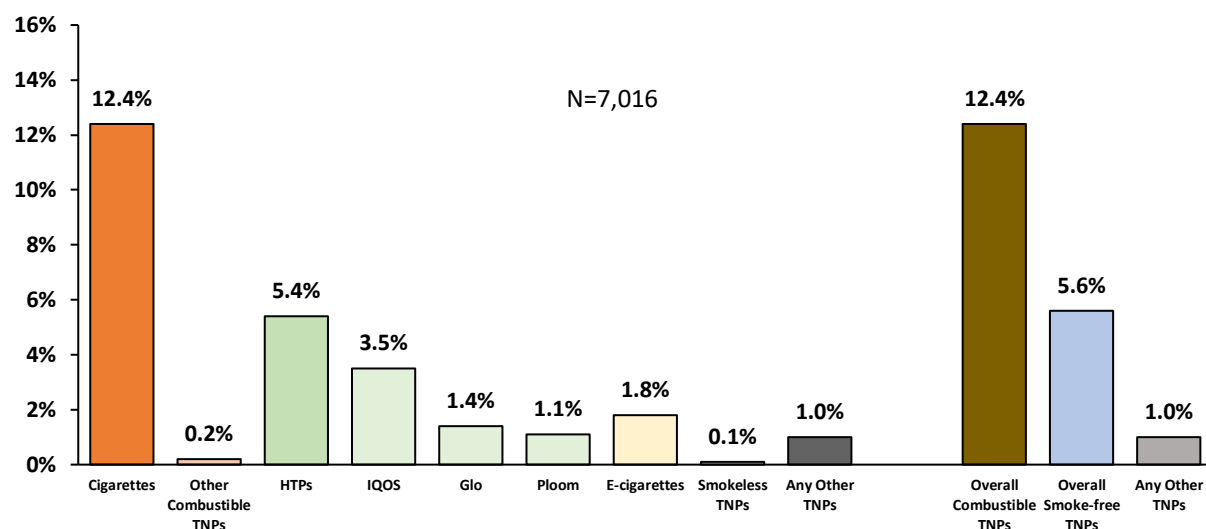


Figure 6 Prevalence of TNP categories and HTP brands - Year 5 - General Population Sample

Note: The sample size (N=7,016) is based on participants with non-missing information on current TNP use. The sum percentage of individual HTP brands is higher than the percentage for the overall HTP category due to possible multiple HTP brand use. Any other TNPs (**Table 3**) include and any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy. HTP, heated tobacco product; TNP, tobacco or nicotine containing product.

⁴⁷ The prevalence of overall combustible TNP use comprises nearly only cigarette use, therefore the prevalence of overall combustible TNP use and the prevalence of cigarette use only differ in the second decimal place.

⁴⁸ In Japan, e-cigarettes with nicotine are regulated under the pharmaceutical law and are currently not commercially available, while importation of nicotine liquid (up to 120 ml) and 1-2 devices for self-consumption is permitted. The questions on e-cigarette use did not differentiate between nicotine-containing vs. non nicotine-containing e-cigarettes.

⁴⁹ Any other TNPs (**Table 3**) include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy.

⁵⁰ The prevalence of overall combustible TNP use comprises nearly only cigarette use, therefore the prevalence of overall combustible TNP use and the prevalence of cigarette use only differ in the second decimal place.

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Across Year 1 to Year 5, regarding the current use prevalence of individual TNP categories and HTP brands, cigarette smoking decreased from 17.6% in Year 1 to 12.4%⁵¹ in Year 5. At the same time, the current use prevalence of smoke-free TNPs overall increased between Year 1 and Year 5, i.e., for overall HTPs from 1.9% to 5.4% (including *IQOS*™ from 1.8% to 3.5%, Ploom from 0.1% to 1.1%, and Glo from 0.0% to 1.4%) and for e-cigarettes from 0.7 to 1.8% (Figure 7).

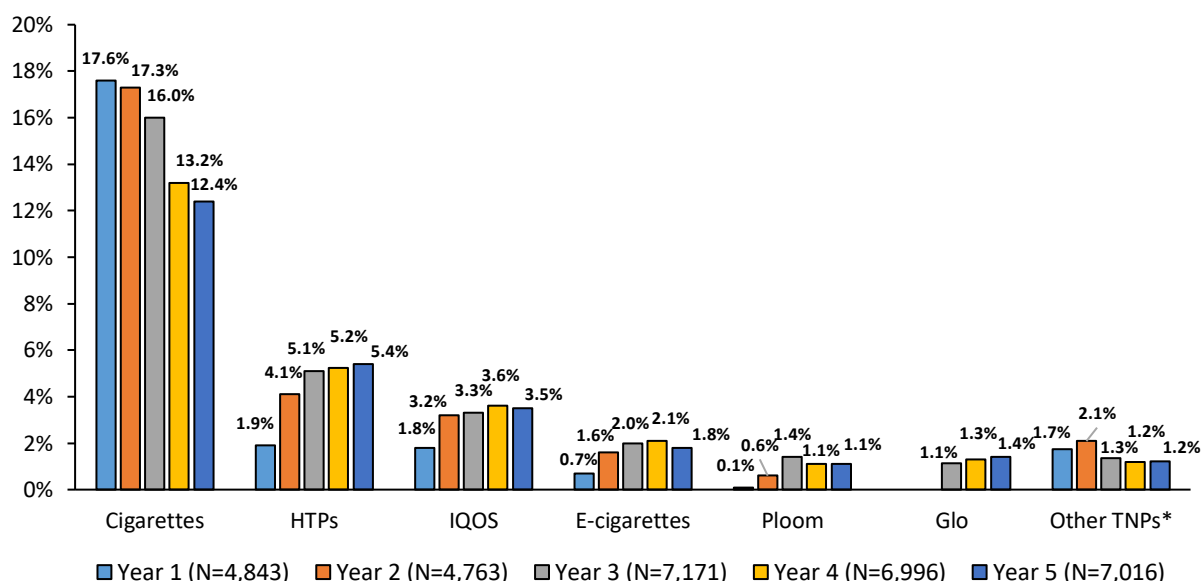


Figure 7 Prevalence of TNP Use – Trend Data – General Adult Population Sample

Note: The sample sizes are based on participants with non-missing information on current TNP use. For trend analysis only the depicted categories/HTP brands were available. HTP, heated tobacco product; TNP, tobacco or nicotine containing product.

*Other TNPs include here: smokeless tobacco pipe, smokeless tobacco (chewing tobacco, snus or snuff), cigars/pipes/kiseru /shisha, and nicotine replacement therapy.

Regarding the current prevalence of individual TNP use by gender and age groups in Year 5 (Table 6), among men (N=3,194) the prevalence of cigarette smoking (20.5%; n=654) was higher than that (5.6%; n=214) among women (N=3,822). Among men, the prevalence of cigarette smoking was highest among 30-39-year-olds (22.7%) and 40-49-year-olds (24.7%) compared to other age groups. Similarly, but on a much lower level, among women the prevalence of cigarette smoking was highest among 30-39-year-olds (9.7%) and 40-49-year-olds (8.0%) compared to other age groups.

⁵¹ The prevalence of overall combustible TNP use comprises nearly only cigarette use, therefore the prevalence of overall combustible TNP use and the prevalence of cigarette use only differ in the second decimal place.

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Regarding the current prevalence of *IQOS*[™] use in Year 5, among men (N=3,194), the prevalence of *IQOS*[™] use (5.7%; n=181) was higher than that (1.8%; n=68) among women (N=3,822). Among both men and women, the prevalence of *IQOS* use was highest among 30-39-year-olds (10.2% among men and 4.4% among women) ([Table 6](#)).

Table 6 Prevalence of Current TNP Use by Age and Gender – General Adult Population Sample

Gender	Age Group	N (%)	Statistics	Cigarettes	<i>IQOS</i> [™]	E-Cigarettes	Ploom TNPs	Glo TNPs
Total	20 – 29	667	n (%)	74 (11.1%)	39 (5.8%)	12 (1.8%)	6 (0.9%)	13 (1.9%)
			[LCL;UCL]	[8.8; 13.8]	[4.1; 8]	[0.9; 3.2]	[0.3; 2]	[1; 3.4]
	30 – 39	879	n (%)	149 (17.0%)	67 (7.6%)	27 (3.1%)	18 (2.0%)	20 (2.3%)
			[LCL;UCL]	[14.5; 19.6]	[5.9; 9.6]	[2; 4.5]	[1.2; 3.3]	[1.3; 3.5]
	40 – 49	1,189	n (%)	187 (15.7%)	63 (5.3%)	25 (2.1%)	22 (1.9%)	24 (2.0%)
			[LCL;UCL]	[13.7; 18]	[4; 6.8]	[1.3; 3.1]	[1.1; 2.8]	[1.2; 3]
	50+	4,281	n (%)	458 (10.7%)	80 (1.9%)	59 (1.4%)	34 (0.8%)	40 (0.9%)
			[LCL;UCL]	[9.7; 11.7]	[1.4; 2.4]	[1; 1.8]	[0.5; 1.2]	[0.6; 1.3]
	Total	7,016	n (%)	868 (12.4%)	249 (3.5%)	123 (1.8%)	80 (1.1%)	97 (1.4%)
			[LCL;UCL]	[11.6; 13.2]	[3.1; 4.1]	[1.4; 2.1]	[0.9; 1.5]	[1.1; 1.7]
Male	20 – 29	348	n (%)	54 (15.5%)	27 (7.8%)	8 (2.3%)	4 (1.1%)	8 (2.3%)
			[LCL;UCL]	[11.8; 19.8]	[5.1; 11.1]	[0.9; 4.5]	[0.3; 3]	[0.9; 4.5]
	30 – 39	489	n (%)	111 (22.7%)	50 (10.2%)	22 (4.5%)	11 (2.2%)	16 (3.3%)
			[LCL;UCL]	[26.6; 35]	[19; 26.7]	[2.8; 6.8]	[1.1; 4]	[1.8; 5.3]
	40 – 49	550	n (%)	136 (24.7%)	46 (8.4%)	17 (3.1%)	14 (2.5%)	15 (2.7%)
			[LCL;UCL]	[21.1; 28.6]	[6.1; 11]	[1.8; 5]	[1.3; 4.3]	[1.5; 4.5]
	50+	1,807	n (%)	353 (19.5%)	58 (3.2%)	49 (2.7%)	25 (1.4%)	32 (1.8%)
			[LCL;UCL]	[17.7; 21.5]	[2.4; 4.2]	[2; 3.6]	[0.8; 2.1]	[1.2; 2.5]
	Total	3,194	n (%)	654 (20.5%)	181 (5.7%)	96 (3.0%)	54 (1.7%)	71 (2.2%)
			[LCL;UCL]	[19; 22]	[4.8; 6.6]	[2.4; 3.7]	[1.2; 2.3]	[1.7; 2.8]
Female	20 – 29	319	n (%)	20 (6.3%)	12 (3.8%)	4 (1.3%)	2 (0.6%)	5 (1.6%)
			[LCL;UCL]	[3.8; 9.6]	[1.9; 6.5]	[0.3; 3.2]	[0; 2.3]	[0.5; 3.7]
	30 – 39	390	n (%)	38 (9.7%)	17 (4.4%)	5 (1.3%)	7 (1.8%)	4 (1.0%)
			[LCL;UCL]	[6.9; 13.2]	[2.5; 6.9]	[0.4; 3]	[0.7; 3.7]	[0.2; 2.7]
	40 – 49	639	n (%)	51 (8.0%)	17 (2.7%)	8 (1.3%)	8 (1.3%)	9 (1.4%)
			[LCL;UCL]	[6; 10.4]	[1.5; 4.3]	[0.5; 2.5]	[0.5; 2.5]	[0.6; 2.7]
	50+	2,474	n (%)	105 (4.2%)	22 (0.9%)	10 (0.4%)	9 (0.4%)	8 (0.3%)
			[LCL;UCL]	[3.4; 5.2]	[0.5; 1.4]	[0.1; 0.8]	[0.1; 0.7]	[0.1; 0.7]
	Total	3,822	n (%)	214 (5.6%)	68 (1.8%)	27 (0.7%)	26 (0.7%)	26 (0.7%)
			[LCL;UCL]	[4.8; 6.4]	[1.3; 2.3]	[0.4; 1.1]	[0.4; 1]	[0.4; 1]

Note: The sample sizes are based on participants with non-missing information on current TNP use. LCL, Lower Confidence Limit of 95% CI; TNP, tobacco or nicotine-containing product; UCL, Upper Confidence Limit of 95% CI.

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6.1.4 FREQUENCY AND INTENSITY OF TNP USE

Current cigarette smokers (N=868) smoked on average on 28.7 days of the last 30 days, and on days they smoked, they consumed on average 14.8 cigarettes/day. This resulted in an average consumption of 14.4 cigarettes/day in the last 30 days (Table 7).

Current IQOS™ users (N=249) used IQOS on average on 27.4 days of the last 30 days, and on days they used IQOS, they consumed on average 12.7 HEETS™⁵²/day. This resulted in an average consumption of 12.0 HEETS™/day⁵³ in the last 30 days (Table 7).

Current e-cigarettes users (N=123) used e-cigarettes on 25.8 days of the last 30 days, and on days they used e-cigarettes, they consumed them on average 12.5 times/day. This resulted in an average e-cigarette consumption of 11.5 times/day in the last 30 days (Table 7).

Table 7 Consumption Per Day Current Smokers/Users – General Adult Population Sample

		Year 5		
		Current Cigarette Smokers	Current IQOS™ Users	Current E-Cigarette Users
	Statistics	(N=868)	(N=249)	(N=123)
Number of days cigarettes/IQOS™/e-cigarette smoked/used in the last 30 days	n (%)	820 (94.5)	234 (94.0)	116 (94.3)
	Min	1	3	2
	Mean [95% CI]	28.7 [28.3; 29.1]	27.4 [26.5; 28.3]	25.8 [24.2; 27.3]
	SD	5.06	6.6	8.19
	Max	30	30	30
Number of cigarettes/HEETS™ ⁵⁴ /e-cigarette smoked/used per day (on smoking/usage days only)	n (%)	829 (95.5)	236 (94.8)	119 (96.7)
	Min	1	1	1
	Mean [95% CI]	14.8 [14.2; 15.3]	12.7 [11.6; 13.7]	12.5 [10.9; 14.1]
	SD	7.71	7.69	8.56
	Max	60	60	60
Number of cigarettes/HEETS™/e-cigarettes smoked/used per day on terms of the last 30-day period ⁵⁵	n (%)	814 (93.8)	230 (92.4)	115 (93.5)
	Min	0	0	0
	Mean [95% CI]	14.4 [13.8; 15.0]	12.0 [11.0; 13.1]	11.5 [9.8; 13.2]
	SD	7.92	8.05	9.06
	Max	60	60	60

Note: The sample sizes are based on participants with non-missing information on current TNP use. TNP, tobacco or nicotine containing product.

⁵² Tobacco sticks (disposables) to be used with the IQOS™ device; these comprise all available IQOS tobacco stick brand names in Japan: Marlboro HeatSticks™, HEETS™, and TERA™.

⁵³ The average daily consumption (e.g., last 30-day consumption) among IQOS users in the General Adult Population Sample is lower than that among IQOS users in the IQOS User Sample because the IQOS User Sample has a higher proportion of exclusive IQOS users and a higher proportion of males.

⁵⁴ Tobacco sticks (disposables) to be used with the IQOS™ device; these comprise all available IQOS tobacco stick brand names in Japan: Marlboro HeatSticks™, HEETS™, and TERA™.

⁵⁵ Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used/smoked on these days divided by 30.

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Across Year 1 to Year 5, the average daily last 30-day cigarette consumption decreased from 16.0 in Year 1 to 14.4 in Year 5, while the corresponding average daily last 30-day *HEETS*⁵⁶ consumption increased from 10.5 in Year 1 to 12.0 in Year 5. The average daily last 30-day e-cigarette consumption also increased from 8.6 times in Year 1 to 11.5 in Year 5 ([Table 8](#)).

Table 8 Consumption Per day Current Smokers/Users – Trend Data – General Adult Population Sample

Average daily last 30-day consumption ⁵⁷		Year 1	Year 2	Year 3	Year 4	Year 5
Current cigarette smokers Number of cigarettes smoked per day	Statistics	(N=852)	(N=825)	(N=1,150)	(N=921)	(N=868)
	n (%)	813 (95.4)	789 (95.6)	1,094 (95.1)	875 (95.0)	814 (93.8)
	Min	0	0	0	0	0
	Mean [95% CI]	16.0 [15.3; 16.6]	15.7 [15.1; 16.4]	15.5 [14.9; 16.0]	14.5 [13.9; 15.1]	14.4 [13.8; 15.0]
	SD	8.91	8.44	8.27	7.83	7.92
	Max	100	80	60	60	60
Current <i>IQOS</i> TM users Number of <i>HEETS</i> TM ⁵⁸ used per day	Statistics	(N=86)	(N=152)	(N=240)	(N=252)	(N=249)
	n (%)	81 (94.2)	143 (94.1)	233 (97.1)	235 (93.3)	230 (92.4)
	Min	0	0	0	0	0
	Mean [95% CI]	10.5 [9.0; 12.0]	12.1 [10.7; 13.6]	11.5 [10.2; 12.7]	12.0 [11.0; 13.0]	12.0 [11.0; 13.1]
	SD	6.42	8.28	9.37	7.45	8.05
	Max	25	50	100	40	60
Current e-cigarette users Number of times of e-cigarette use per day	Statistics	(N=35)	(N=76)	(N=146)	(N=144)	(N=123)
	n (%)	31 (88.6)	72 (94.7)	135 (92.5)	128 (88.9)	115 (93.5)
	Min	0	0	0	0	0
	Mean [95% CI]	8.6 [5.2; 12.0]	9.1 [7.2; 11.0]	9.5 [7.6; 11.4]	10.4 [9.0; 11.7]	11.5 [9.8; 13.2]
	SD	9.13	7.89	10.88	7.64	9.06
	Max	40	30	100	30	60

Note: The sample sizes are based on participants with non-missing information on current TNP use. TNP, tobacco or nicotine containing product.

⁵⁶ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

⁵⁷ Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used/smoked on these days divided by 30.

⁵⁸ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

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6.1.5 PATTERNS OF TNP USE

In Year 5, among current TNP users (N=1,094), 68.9% were exclusive users of only one particular TNP, 21.2% were dual users (i.e., using two different TNPs), 6.6% were poly users (i.e., using more than two different TNPs), and 3.3% were undefinable.⁵⁹ The highest proportions of TNP dual and poly use were with cigarettes (Table 9).

Table 9 TNP Use Patterns – General Adult Population Sample

	Current TNP Users (N=1,094)			
	n	%	LCL	UCL
Exclusive TNP use	754	68.9%	66	71.7
- Cigarettes	610	55.8%	52.7	58.8
- IQOS™	93	8.5%	6.9	10.4
- One other TNP*	47	4.3%	3.1	5.7
- E-cigarettes	4	0.4%	0	1
Dual TNP use	232	21.2%	18.8	23.8
- Cigarettes & Other TNP	113	10.3%	8.5	12.3
- Cigarettes & IQOS™	52	4.8%	3.5	6.2
- IQOS™ & e-cigarettes	29	2.7%	1.7	3.8
- Cigarettes & e-cigarettes	5	0.5%	0.1	1.1
- IQOS™ & Other TNP	9	0.8%	0.3	1.6
- E-cigarettes & Other TNP	24	2.2%	1.4	3.3
- Two Other TNPs	0	0.0%	0	0.4
Poly TNP use	72	6.6%	5.1	8.3
- Cigarettes & e-cigarettes & Other TNPs	17	1.6%	0.9	2.5
- Cigarettes & IQOS™ & e-cigarettes	22	2.0%	1.2	3.1
- Cigarettes & IQOS™ & Other TNPs	9	0.8%	0.3	1.6
- Cigarettes & IQOS™ & e-cigarettes & Other TNPs	14	1.3%	0.7	2.2
- Cigarettes & Other TNPs	3	0.3%	0	0.8
- IQOS™ & e-cigarettes & Other TNPs	7	0.6%	0.2	1.4
- IQOS™ & Other TNPs	0	0.0%	0	0.4
- E-cigarettes & Other TNPs	0	0.0%	0	0.4
- Three or more Other TNPs	0	0.0%	0	0.4
Undefined ⁶⁰	36	3.3%	2.3	4.6

Note: The sample sizes are based on participants with non-missing information on current TNP use. LCL, Lower Confidence Limit of 95% CI; TNP, tobacco or nicotine-containing product; UCL, Upper Confidence Limit of 95% CI.

*Other TNPs include here: smokeless tobacco pipe, smokeless tobacco (chewing tobacco, snus, or snuff) cigars/pipes/kiseru/shisha & Ploom, Glo with NeoStiks, and nicotine replacement therapy.

⁵⁹ A total of 3.3% (n=36) current users could not be classified as exclusive, dual, or poly users based on the self-reported data.

⁶⁰ A total of 3.3% (n=36) current users could not be classified as exclusive, dual, or poly users based on the self-reported data.

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Across Year 1 to Year 5, among current TNP users, the frequency of exclusive TNP use⁶¹ decreased from 82.3% in Year 1 to 68.1% in Year 4 to stabilize with 68.9% in Year 5 (**Figure 8**). At the same time, the frequency of dual TNP use⁶² increased from 14.3% in Year 1 to 21.2% in Year 5, while the frequency of poly TNP use⁶³ noticeably increased from 1.4% in Year 1 to 10.0% in Year 3, but then decreased to 7.5% in Year 4 and 6.6% in Year 5. Overall, this reflects a stabilization of exclusive use as of Year 4 together with a shift to dual TNP use rather than poly TNP use.

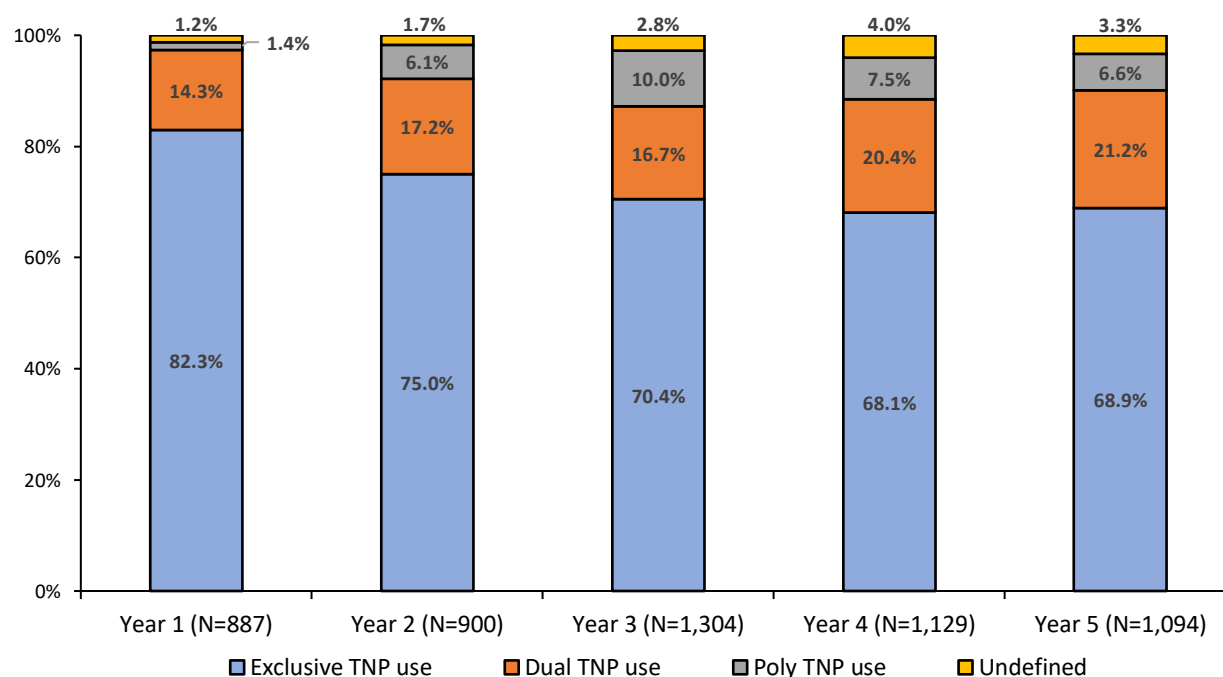


Figure 8 Patterns of TNP Use – Trend Data – General Adult Population Sample

Note: The sample sizes are based on participants with non-missing information on current TNP use. TNP, tobacco or nicotine containing product.

⁶¹ Use of only one tobacco or nicotine containing product.

⁶² Use of two different tobacco or nicotine containing products.

⁶³ Use of more than two different tobacco or nicotine containing products.

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6.1.6 HISTORY OF TNP USE

Initiation

In the last 12 months prior to the Year 5 survey, among all never TNP users (N=4,800),⁶⁴ 0.19% (n=9) initiated TNP use with cigarettes and 0.08% (n=4) with IQOS™.

Over time, the rate of last year TNP initiation with IQOS™ remained low across Year 1 to Year 5 (Table 10).

Table 10 TNP Initiation of Never TNP Users Last 12 Months - Trend Data - General Adult Population

	Year 1 Never TNP users 1 year prior to survey (N=3,066)		Year 2 Never TNP users 1 year prior to survey (N=3,109)		Year 3 Never TNP users 1 year prior to survey (N=4,685)		Year 4 Never TNP users 1 year prior to survey (N=4,705)		Year 5 Never TNP users 1 year prior to survey (N=4,800)	
	n (%)	[LCL; UCL]	n (%)	[LCL; UCL]	n (%)	[LCL; UCL]	n (%)	[LCL; UCL]	n (%)	[LCL; UCL]
Cigarettes (including hand-rolled cigarettes)	7 (0.2%)	[0.0; 0.5]	9 (0.3%)	[0.1; 0.6]	10 (0.2%)	[0.1; 0.4]	6 (0.1%)	[0.0; 0.3]	9 (0.19%)	[0; 0.4]
IQOS™ with HEETS™⁶⁵	1 (0.03%)	[0.0; 0.2]	4 (0.1%)	[0.0; 0.4]	5 (0.1%)	[0.0; 0.3]	1 (0.02%)	[0.0; 0.2]	4 (0.08%)	[0; 0.3]

Note: The sample sizes are based on participants with non-missing information on current TNP use. Initiation with e-cigarettes was not measured as part of the study. LCL, Lower Confidence Limit of 95% CI; TNP, tobacco or nicotine-containing product; UCL, Upper Confidence Limit of 95% CI.

In Year 5, among ever IQOS™ users (N=349), 99.7% (n=348) had a previous smoking history before they started to use IQOS, i.e., only 0.3% (n=1) were never smokers before they started using IQOS. A total of 99.7% of IQOS users with a smoking history is the same percentage (99.7%) as in the previous Year 4, and is also similar to the IQOS User Sample in Year 5 where 97.4% of the IQOS users had a previous smoking history before starting to use IQOS (Section 6.2.5).

Reinitiation/Relapse

In Year 5, among current TNP users (N=1,094) who quit cigarette smoking more than 2 years ago (n=2), none (0.00%, n=0) relapsed to IQOS™ and only 0.09% (n=1) reinitiated TNP use with IQOS in the year prior to the survey, while one (0.09%, n=1) provided no information. Over time, the rates of last year relapse to IQOS and reinitiation with IQOS remained low and stable across Year 1 to Year 5 (Table 11).

⁶⁴ Never TNP users: Never smoked cigarettes/used IQOS™ up to 1 year prior to survey.

⁶⁵ Tobacco sticks (disposables) to be used with the IQOS™ device; these comprise all in Japan available IQOS tobacco stick brand names Marlboro HeatSticks™, HEETS™, and TEREAT™.

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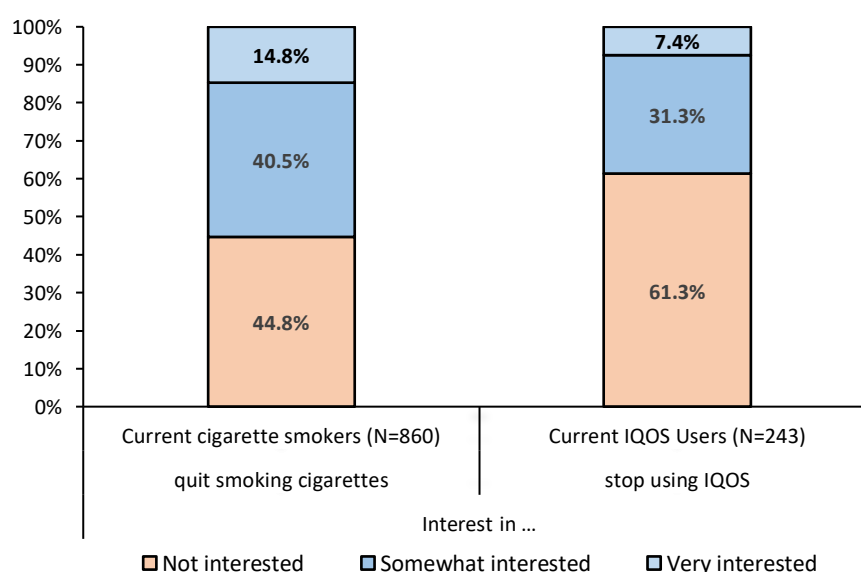
Table 11 Relapse/Relapse Last 12 Months among Current TNP Users – General Adult Population

Relapse/ reinitiation ⁶⁶	Year 1 Current TNP Users (N=894)		Year 2 Current TNP Users (N=900)		Year 3 Current TNP Users (N=1,304)		Year 4 Current TNP Users (N=1,129)		Year 5 Current TNP Users (N=1,094)	
	n (%)	[LCL, UCL]	n (%)	[LCL, UCL]	n (%)	[LCL, UCL]	n (%)	[LCL, UCL]	n (%)	[LCL, UCL]
Relapse to <i>IQOS</i> TM	0 (0.0%)	[0.0; 0.5]	0 (0.0%)	[0.0; 0.5]	0 (0.0%)	[0.0; 0.3]	0 (0.0%)	[0.0; 0.4]	0 (0.0%)	[0.0; 0.4]
Reinitiation with <i>IQOS</i> TM	1 (0.1%)	[0.0; 0.7]	1 (0.1%)	[0.0; 0.7]	1 (0.07%)	[0.0; 0.5]	1 (0.09%)	[0.0; 0.5]	1 (0.09%)	[0.0; 0.6]

Note: The sample sizes are based on participants with non-missing information on current TNP use. Relapse/reinitiation with e-cigarettes was not measured as part of the study. LCL, Lower Confidence Limit of 95% CI; TNP, tobacco or nicotine-containing product; UCL, Upper Confidence Limit of 95% CI.

6.1.7 QUITTING

In Year 5, among current cigarette smokers (N=860), 55.2% (n=475) were interested (14.8% very interested and 40.5% somewhat interested) in quitting smoking cigarettes, while among current *IQOS*TM users (N=243), 38.7% were interested (7.4% very interested and 31.3% somewhat interested) in stopping using *IQOS* (Figure 9).

**Figure 9** Interest in Quit Smoking Cigarettes/Stop Using *IQOS* (%) – General Adult Population Sample

Note: The sample sizes are based on participants with non-missing information on current TNP use. TNP, tobacco or nicotine containing product.

⁶⁶ **Relapse:** Using a particular TNP again after stopping/quitting the TNP for ≤12 months during an attempt to quit TNPs. **Reinitiation:** Using a particular TNP again after stopping/quitting the TNP for >12 months during an attempt to quit TNPs.

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In Year 5, among current cigarette smokers (N=860), 51.0% (n=438) had ever attempted to quit smoking cigarettes. Most of these quitters (62.4%) quit cigarettes for less than 6 months, while 14.1% quit for 6-12 months, and 23.5% for more than 12 months before they relapsed to or reinitiated TNP use with cigarettes. Over time, the percentage of cigarette smokers with interest in quitting cigarette smoking and those with cigarette quit attempts remained rather stable across Year 1 to Year 5.

Regarding the quitting rate for cigarette smoking in Year 5, among participants who had been cigarette smokers more than 12 months before the start of the survey (N=899), 3.4% (n=31) quit cigarette smoking in the past 12 month, with 2.4% (n=22) quitting all TNPs, 0.2% (n=2) switching to *IQOS*[™], 0.1% (n=1) switching to *IQOS* & e-cigarettes, 0.1% (n=1) switching to *IQOS* & one other TNP, 0.2% (n=2) switching to e-cigarettes and another TNP, 0.1% (n=1) switching to one other TNP (n=1), and 0.2% (n=2) providing no information. In the previous Year 4 (N=1,191), 3.7% (n=35) quit cigarettes in the last 12 months, with 3.2% (n=31) quitting all TNPs, 0.2% (n=2) switching to *IQOS*, 0.1% (n=1) switching to e-cigarettes, and 0.1% (n=1) providing no information. Across Year 3 to Year 5,⁶⁷ both the rates for quitting cigarettes (Year 3: 3.4%; Year 4: 3.7%; Year 5: 3.4%) and quitting all TNPs (Year 3: 2.2%; Year 4: 3.2%; Year 5: 2.4%) remained stable.

Among all current *IQOS*[™] users (N=240), in Year 5, 18.8% (n=45) had ever attempted to stop using *IQOS*, with most of them (79.5%) stopping for less than 6 months, 4.5% stopping for 6-12 months, and another 15.9% stopping for more than 12 months. While the percentage of *IQOS* users with interest in stopping using *IQOS* remained rather stable over time, the percentage of *IQOS* users with stop attempts increased from 4.9% in Year 1 to 18.8% in Year 5.

Regarding the stopping rate of using *IQOS*[™] in Year 5, among all participants who had been *IQOS* users more than one year prior to the survey (N=258), 3.5% (n=9) successfully stopped using *IQOS* in the last 12 months, with 1.5% (n=4) stopping all TNPs, 0.7% (n=2) switching to cigarettes, 0.4% (n=1) switching to a poly use of cigarettes with e-cigarettes and other TNPs, and 0.4% (n=1) switching to cigarettes with one other TNP, and 0.4% (n=1) providing no information. In the previous Year 4, among *IQOS*[™] users who had used *IQOS* more than 12 months prior to the survey (N=270), 6.7% (n=18) successfully stopped using *IQOS* in the last 12 months, with 3.7% (n=10) stopping all TNPs, 1.9% (n=5) switching to cigarettes, 0.7% (n=2) switching to e-cigarettes together with at least one other TNP, and 0.4% (n=1) switching to cigarettes with one other TNP. Across Year 3 to Year 5,⁶⁸ both the rate of stopping using *IQOS* (9.4% in Year 3; 6.7% in Year 4; 3.5% in Year 5) and the rate of stopping all TNPs (2.6% in Year 3; 1.9% in Year 4; 1.5% in Year 5) slightly decreased over time. This decrease in *IQOS* or all TNP stopping rates is likely related to the fact that the percentage of exclusive *IQOS* users among all *IQOS* users in the General Adult Population Samples increased over time, with exclusive *IQOS* users being less likely to quit *IQOS* or all TNPs than *IQOS* users who use *IQOS* together with other TNPs.

⁶⁷ This information was assessed only from Year 3 onwards.

⁶⁸ This information was assessed only from Year 3 onwards.

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6.2 IQOS USER SAMPLE

6.2.1 DISPOSITION GROUPS

In Year 5, the **IQOS User Sample** comprised 1,999 participants with the data collection taking place between November 19, 2021, and August 30, 2022, in survey waves 17 to 20.

A total of 75,536 candidates received an invitation to participate in the Year 5 study. Of these, 71,708 candidates did not respond (i.e., did not click on link/e-mail not opened). Of the remaining 3,828 individuals who were willing to participate in the study, 513 were not eligible to participate. From the remaining individuals who were eligible to participate, 1,011 did not complete the questionnaire, 304 could not be considered as the quota had already been reached, and 1 had inconsistent answers and hence was not be considered in the analysis, leading to an analytical sample size of 1,999 participants who successfully completed the Year 5 survey ([Figure 10](#)).

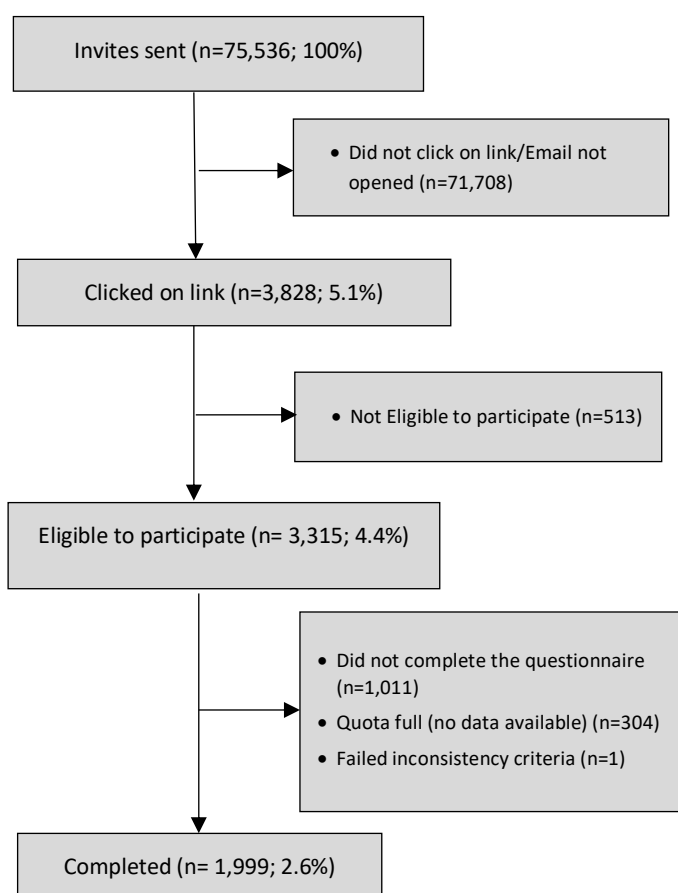


Figure 10 Disposition – IQOS User Sample

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6.2.2 DEMOGRAPHIC CHARACTERISTICS

Over the study period of Year 5, a total of N=1,999 participants of the IQOS™ user population completed the survey. Among these, 19.8% were female and 80.2% were male ([Table 12](#)).

The age of the participants in the IQOS User Sample ranged from 20 to 75 years with a mean age of 40.2 years (SD=10.37). The gender and age demographic characteristics of the participants were similar across study Year 1 to Year 5.

Table 12 Demographic Characteristics – IQOS User Sample

		IQOS User Sample (N=1,999)
		(n %)
Gender		
	Male	1,603 (80.2%)
	Female	396 (19.8%)
Age group		
	20 – 29	340 (17.0%)
	30 – 39	691 (34.6%)
	40 – 49	628 (31.4%)
	50+	340 (17.0%)
	Min	20
	Median	39
	Mean [95% CI]	40.2 [39.7; 40.7]
	SD	10.37
	Max	75
Region [inhabitants]		
	Hokkaido	88 (4.4%)
	Tohoku	134 (6.7%)
	Kanto	880 (44.0%)
	Kinki	328 (16.4%)
	Chubu	266 (13.3%)
	Chugoku	78 (3.9%)
	Shikoku	36 (1.8%)
	Kyusyu	189 (9.5%)

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Table 12 Demographic Characteristics – *IQOS* User Sample – Continued

		<i>IQOS</i> User Sample (N=1,999)
		(n %)
Highest level of education		
	Junior High School	140 (7.0%)
	High School	709 (35.5%)
	College/University	1,113 (55.7%)
	Don't know/Not applicable	37 (1.9%)
Occupation or profession		
	Farming/Agriculture/Fishery	17 (0.9%)
	Self-employed/Small private business	207 (10.4%)
	Clerical employee	1,198 (59.9%)
	Manual employee	136 (6.8%)
	Managing profession	126 (6.3%)
	Housewife	101 (5.1%)
	Student	29 (1.5%)
	Retired/Unemployed	53 (2.7%)
	Don't know/Not applicable	132 (6.6%)

6.2.3 FREQUENCY AND INTENSITY OF *IQOS* USE

In Year 5, between the beginning (November 19, 2021) of the first fieldwork wave and the end (August 30, 2022) of the last fieldwork wave of the *IQOS* User Sample, current *IQOS*™ users (N=1,999) used *IQOS* on average on 28.9 days of the last 30 days, and on the days they used *IQOS*, they consumed on average 16.7 *HEETS*™⁶⁹/day. This resulted in an average consumption of 16.3 *HEETS*™/day⁷⁰ in the last 30 days, which is slightly higher than the average last 30-day cigarette consumption among cigarette smokers (14.4 cigarettes/day) in the General Adult Population Sample (Table 13).

⁶⁹ Tobacco sticks (disposables) to be used with the *IQOS*™ device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*™, *HEETS*™, and *TEREA*™.

⁷⁰ The average daily consumption (e.g., last 30-day consumption) among *IQOS* users in the General Adult Population Sample is lower than that among *IQOS* users in the *IQOS* User Sample because the *IQOS* User Sample has a higher proportion of exclusive *IQOS* users and a higher proportion of males.

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Across Year 1 to Year 5, the average number of days when *IQOS*TM was used remained stable (Year 1: 29.1 [28.9; 29.3]; Year 2: 28.9 [28.7; 29.1]; Year 3: 28.8 [28.5; 29.0], Year 4: 28.7 [28.5, 29.0] Year 5: 28.9 [28.6; 29.1]).

The average daily last 30-day consumption of *HEETS*^{TM71} remained also stable across Year 1 to Year 5 (Year 1: 15.9 [15.5; 16.3]; Year 2: 16.1 [15.7; 16.5]; Year 3: 15.5 [15.1; 15.9], Year 4: 15.9 [15.5, 16.3], Year 5: 16.3 [15.9; 16.7]).

Table 13 Current TNP Consumption – Total – *IQOS* User Sample and General Adult Population Sample

		<i>HEETS</i> ^{TM72} consumption Current <i>IQOS</i> TM Users	Cigarette consumption Current cigarette smokers (General Adult Population Sample)
	Statistics	(N=1999)	(N=868)
Number of days <i>IQOS</i> TM used/ cigarettes smoked in the last 30 days	n (%)	1,999 (100.0)	820 (94.5)
	Min	1	1
	Mean [95% CI]	28.9 [28.6; 29.1]	28.7 [28.3; 29.1]
	SD	4.51	5.06
	Max	30	30
Number of <i>HEETS</i> TM used/cigarettes smoked per day (on use days only)	n (%)	1,999 (100.0)	829 (95.5)
	Min	1	1
	Mean [95% CI]	16.7 [16.3; 17.1]	14.8 [14.2; 15.3]
	SD	7.95	7.71
	Max	90	60
Number of <i>HEETS</i> TM used/cigarettes smoked per day in terms of the last 30-day period ⁷³	n (%)	1,999 (100.0)	814 (93.8)
	Min	0	0
	Mean [95% CI]	16.3 [15.9; 16.7]	14.4 [13.8; 15.0]
	SD	8.29	7.92
	Max	90	60

The results stratified by gender ([Table 14](#)) and age ([Table 15](#)) are presented below.

⁷¹ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

⁷² Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

⁷³ Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used/smoked on these days divided by 30.

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By gender ([Table 14](#)), while the number of days *IQOS*TM was used was nearly identical between men and women (28.8 vs. 28.9, respectively), men consumed on average 1.5 *HEETS*TM⁷⁴/day more than women.

Table 14 Current *IQOS* Consumption – By Gender – *IQOS* User Sample

	Current <i>IQOS</i> TM Users (N=1,999)		
	Statistics	Male	Female
Number of days <i>IQOS</i>TM used in the last 30 days	n (%)	1,603 (100.0)	396 (100.0)
	Min	1	2
	Mean [95% CI]	28.8 [28.6; 29.1]	28.9 [28.4; 29.4]
	SD	4.49	4.60
	Max	30	30
Number of <i>HEETS</i>TM⁷⁵ used per day (on usage days only)	n (%)	1,603 (100.0)	396 (100.0)
	Min	1	1
	Mean [95% CI]	17.0 [16.6; 17.5]	15.5 [14.8; 16.3]
	SD	8.17	6.88
	Max	90	60
Number of <i>HEETS</i>TM used per day in terms of the last 30-day period⁷⁶	n (%)	1,603 (100.0)	396 (100.0)
	Min	0	0
	Mean [95% CI]	16.6 [16.1; 17.1]	15.1 [14.4; 15.9]
	SD	8.50	7.23
	Max	90	60

⁷⁴ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

⁷⁵ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

⁷⁶ Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used on these days divided by 30.

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Across age groups ([Table 15](#)), while the number of days *IQOS*TM was used only slightly increased across age groups (from 28.6 to 29.2 days), the number of *HEETS*^{TM77}/day on the days *IQOS* was used ranged from 13.3 sticks/day (age 20-29) to 18.7 stick/day (age 50+). Similarly, the average last 30-day consumption ranged from 13.0 sticks/day (age 20-29) to 18.4 stick/day (age 50+).

Table 15 Current *IQOS* Consumption – By Age – *IQOS* User Sample

	Current <i>IQOS</i> TM Users (N=1,999)				
	Statistics	Age 20 – 29	Age 30 – 39	Age 40 – 49	Age 50+
Number of days <i>IQOS</i>TM used in the last 30 days	n (%)	340 (100.0)	691 (100.0)	628 (100.0)	340 (100.0)
	Min	2	1	1	1
	Mean [95% CI]	28.6 [28.1; 29.2]	28.8 [28.4; 29.2]	28.8 [28.4; 29.2]	29.2 [28.8; 29.6]
	SD	4.54	4.65	4.72	3.71
	Max	30	30	30	30
Number of <i>HEETS</i>^{TM78} used per day (on usage days only)	n (%)	340 (100.0)	691 (100.0)	628 (100.0)	340 (100.0)
	Min	1	2	1	1
	Mean [95% CI]	13.3 [12.5; 14.0]	16.7 [16.1; 17.4]	17.5 [16.8; 18.1]	18.7 [17.7; 19.7]
	SD	6.41	7.98	7.38	9.19
	Max	40	90	50	60
Number of <i>HEETS</i>TM used per day in terms of the last 30-day period⁷⁹	n (%)	340 (100.0)	691 (100.0)	628 (100.0)	340 (100.0)
	Min	0	0	0	0
	Mean [95% CI]	13.0 [12.2; 13.8]	16.3 [15.6; 17.0]	17.0 [16.3; 17.6]	18.4 [17.3; 19.5]
	SD	6.68	8.32	7.84	9.46
	Max	40	90	50	60

⁷⁷ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

⁷⁸ Tobacco sticks (disposables) to be used with the *IQOS*TM device; these comprise all available *IQOS* tobacco stick brand names in Japan: *Marlboro HeatSticks*TM, *HEETS*TM, and *TEREA*TM.

⁷⁹ Average last 30-day consumption was calculated from the number of days the products were used multiplied by the number of products used on these days divided by 30.

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6.2.4 PATTERNS OF IQOS USE

As of Year 4, advanced categorization of TNPs in six common TNP categories (cigarettes, other combustible TNPs, heated tobacco products [HTP], e-cigarettes, smokeless TNPs, and any other TNPs) as well as two overarching TNP umbrella classes (overall combustible TNPs and overall smoke-free TNPs) was introduced ([Section 5.3](#)) and presented for the respective TNP use data.

Regarding *IQOS*™ use together with overall other smoke-free TNPs and overall other combustible TNPs in Year 5, among current *IQOS* users with classifiable information on TNP use (N=1,982), 55.5% (N=1,100) used *IQOS* exclusively, 27.2% (N=540) used *IQOS* together with smoke-free TNPs (mainly other HTPs), and 17.3%⁸⁰ (N=342) used *IQOS* together with combustible TNPs ([Table 16](#)).

The proportion of exclusive *IQOS*™ use was comparatively lower among men (54.0%) than among women (61.6%), but rather similar across age groups ([Table 16](#)).

Table 16 *IQOS* Use Patterns – by Age and Gender – *IQOS* User Sample

	Exclusive <i>IQOS</i> ™ use (N=1100)	<i>IQOS</i> use with smoke-free TNPs (N=540)	<i>IQOS</i> use with combustible TNPs (N=342)
	n (%) [LCL; UCL]	n (%) [LCL; UCL]	n (%) [LCL; UCL]
Sample (N=1,982) ⁸¹	1100 (55.5%)	540 (27.2%)	342 (17.3%) ⁸²
	[53.2; 57.8]	[25.2; 29.3]	[15.6; 19]
Male (N=1,589)	858 (54.0%)	439 (27.6%)	292 (18.4%)
	[51.5; 56.5]	[25.4; 29.9]	[16.5; 20.4]
Female (N=393)	242 (61.6%)	101 (25.7%)	50 (12.7%)
	[56.5; 66.5]	[21.4; 30.4]	[9.5; 16.5]
Age Group – 20 – 29 (N=337)	176 (52.2%)	84 (24.9%)	77 (22.8%)
	[46.7; 57.7]	[20.3; 30]	[18.4; 27.8]
Age Group – 30 – 39 (N=686)	368 (53.6%)	189 (27.6%)	129 (18.8%)
	[49.8; 57.5]	[24.2; 31.1]	[15.9; 22]
Age Group – 40 – 49 (N=624)	368 (59.0%)	169 (27.1%)	87 (13.9%)
	[54.9; 62.9]	[23.6; 30.8]	[11.3; 17]
Age Group – 50+ (N=335)	188 (56.1%)	98 (29.3%)	49 (14.6%)
	[50.6; 61.6]	[24.4; 34.5]	[11; 18.9]

Note: The sample sizes are only based on participants with classifiable information on TNP use. TNP, tobacco or nicotine containing product. LCL, Lower Confidence Limit of 95% CI; TNP, tobacco or nicotine-containing product; UCL, Upper Confidence Limit of 95% CI.

⁸⁰ The percentage 17.3% (N=1,982) differs from the percentage 17.1% (N=1,999) in [Figure 12](#) and [Figure 13](#) due to different analytical sample sizes.

⁸¹ The sample size is lower than the full *IQOS* User Sample (n=1,999) due to non-classifiable information.

⁸² The percentage 17.3% (N=1,982) differs from the percentage 17.1% (N=1,999) in [Figure 12](#) and [Figure 13](#) due to different analytical sample sizes.

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Across Year 1 to Year 5, after an initial decrease from 63.4% in Year 1 to 49.4% in Year 3, the proportion of exclusive *IQOS*™ use increased with surpassing the 50% mark with 55.5% in Year 5. At the same time the proportion of *IQOS* use together with smoke-free TNPs increased from 7.6% in Year 1 to 27.2% in Year 5. Finally, and importantly, the proportion of *IQOS* use together with overall combustible TNPs decreased from 28.4% in Year 1 to 17.3%⁸³ in Year 5 (Figure 11).⁸⁴

This suggests that from Year 1 to Year 5, the majority of *IQOS*™ users (82.7% [55.5% + 27.2%] in Year 5) had no longer smoked combustible TNPs, but used *IQOS* exclusively, or in particular in the last three study years, used *IQOS* together with other smoke-free TNPs (Figure 11).⁸⁵

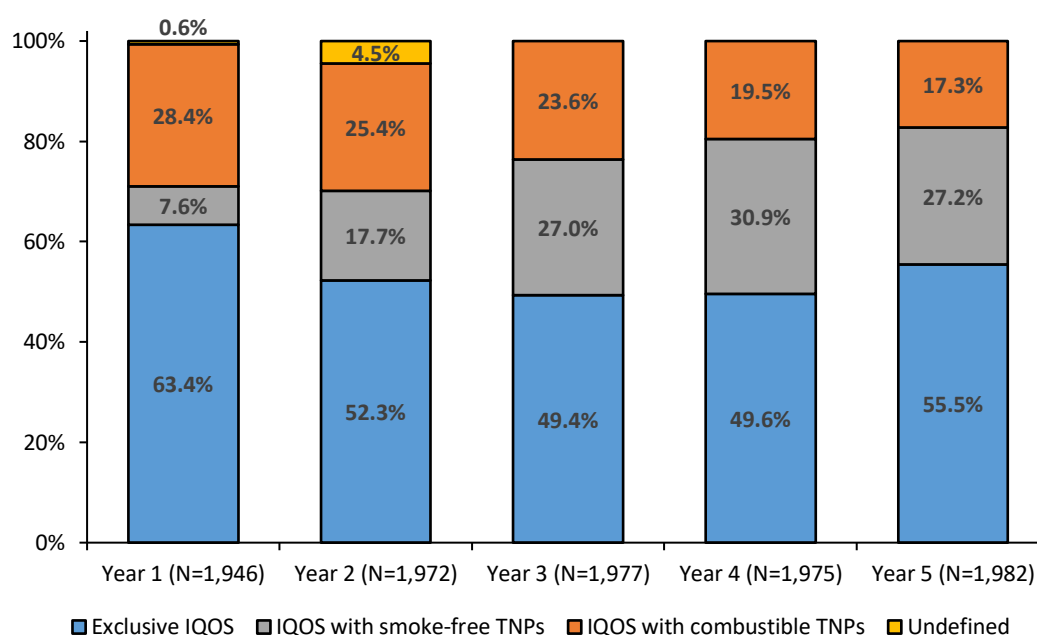


Figure 11 Patterns of TNP Use - Trend Data - *IQOS* User Sample

Note: The sample sizes are based on participants with classifiable information on TNP use. The data presented for Year 1 and Year 2 differ from those presented in the Year 1 and Year 2 study reports due to marginal rounding errors in Year 1 and Year 2 that have now in the Year 5 report been corrected. The percentage 17.3% (N=1,982) differs from the percentage 17.1% (N=1,999) in Figure 12 and Figure 13 due to different analytical sample sizes. TNP, tobacco or nicotine containing product.

⁸³ The percentage 17.3% (N=1,982) differs from the percentage 17.1% (N=1,999) in Figure 12 and Figure 13 due to different analytical sample sizes.

⁸⁴ The presented data for Year 1 and Year 2 differ from those presented in the Year 1 and Year 2 study reports due to marginal rounding errors in Year 1 and Year 2 that have now in the Year and 5 report been corrected.

⁸⁵ The presented data for Year 1 and Year 2 differ from those presented in the Year 1 and Year 2 study reports due to marginal rounding errors in Year 1 and Year 2 that have now in the Year and 5 report been corrected.

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In Year 5, among all current *IQOS* users (N=1,999), the frequency of *IQOS*TM use together with smoke-free TNPs was highest with Ploom (21.2%, n=423), followed by Glo (16.9%, n=338), e-cigarettes (12.1%, n=242), and smokeless TNPs (1.6%, n=32).

The frequency of *IQOS* use together with overall combustible TNPs (17.1%,⁸⁶ n=342) was much higher for cigarettes (16.7%, n=334) than for other combustible TNPs (1%, n=19). The frequency of *IQOS* use together other TNPs⁸⁷ was 2% (n=39) (**Figure 12**).

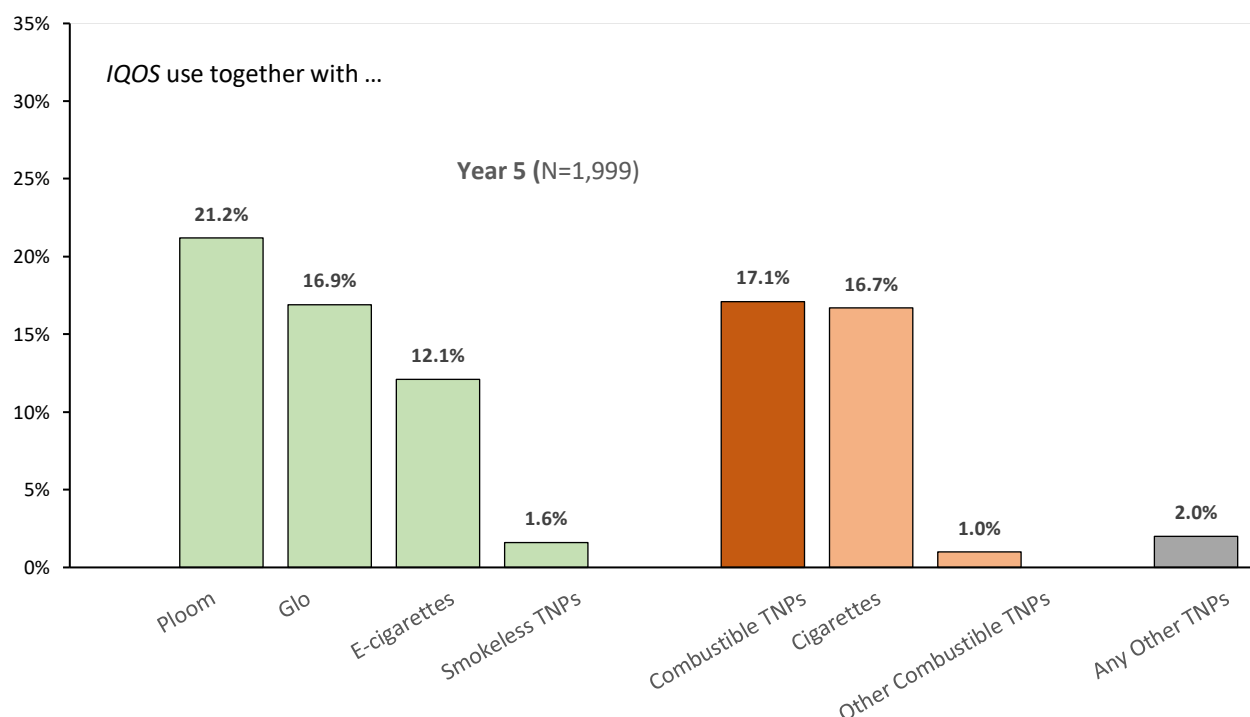


Figure 12 *IQOS* Use with other Smoke-Free and Combustible TNPs - Year 5 – *IQOS* User Sample

Note: Any other TNPs (**Table 3**) include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy. The percentage 17.1% (N=1,999) differs from the percentage 17.3% (N=1,982) in **Table 16** and **Figure 11** due to different analytical sample sizes. HTP, heated tobacco product; TNP, tobacco or nicotine containing product.

⁸⁶ The percentage 17.1% (N=1,999) differs from the percentage 17.3% (N=1,982) in **Table 16** and **Figure 11** due to different analytical sample sizes.

⁸⁷ Any other TNPs (**Table 3**) include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy.

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Compared to the previous Year 4, in Year 5, the percentage of *IQOS*™ use together with other smoke-free and combustible TNPs decreased for all other TNPs besides for e-cigarettes and smokeless TNPs. This indicating that exclusive *IQOS* use overall increased from Year 4 to Year 5 (**Figure 13**).

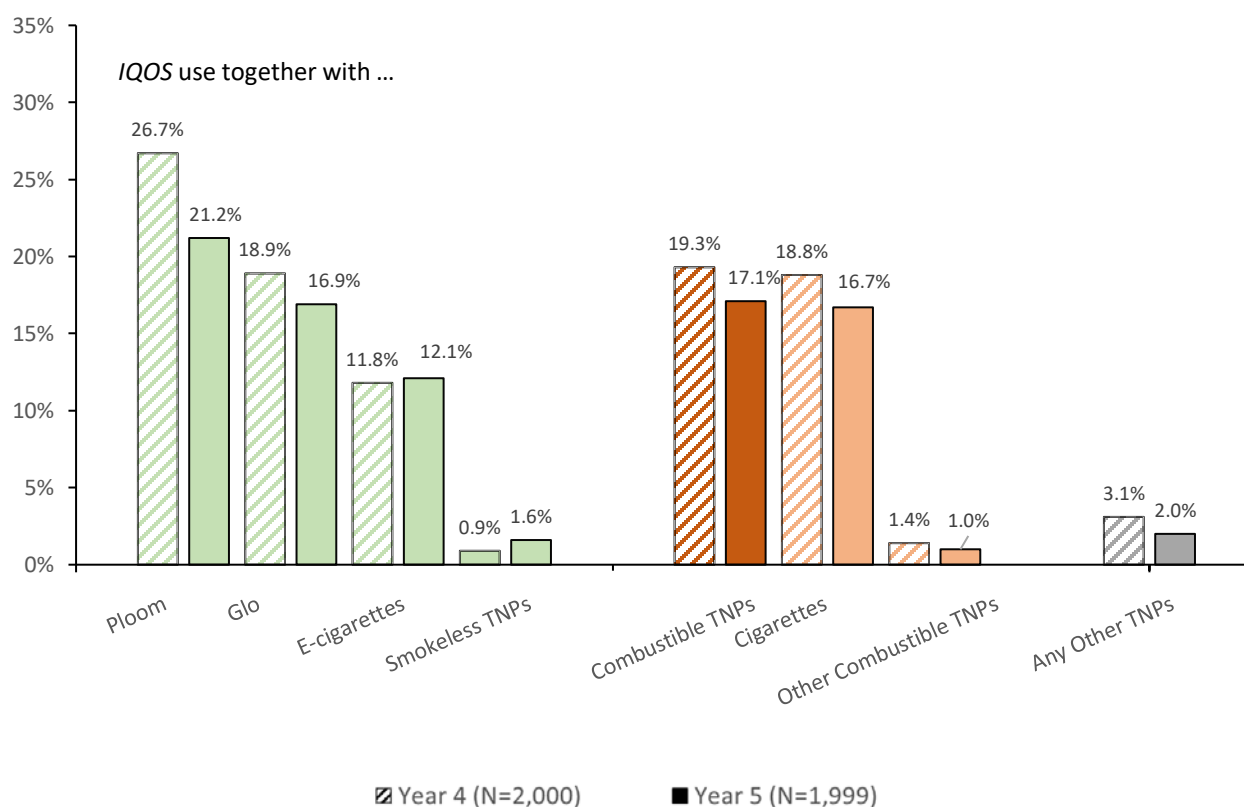


Figure 13 *IQOS* Use with other Smoke-Free and Combustible TNPs – Year 4 vs. 5 – *IQOS* User Sample

Note: Any other TNPs (**Table 3**) include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy.

HTP, heated tobacco product; TNP, tobacco or nicotine containing product. The percentage 17.1% (N=1,999) differs from the percentage 17.3% (N=1,982) in **Table 16** and **Figure 11** due to different analytical sample sizes.

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Across Year 3 to Year 5⁸⁸ (Figure 14), the frequency of *IQOS* use together with cigarettes or other combustible TNPs steadily decreased. At the same time, the frequency of *IQOS* use together with e-cigarettes slightly increased, while the frequency of *IQOS* use together with other HTPs (Glo and Ploom) only initially increased from Year 3 to Year 4, but then decreased from Year 4 to Year 5.

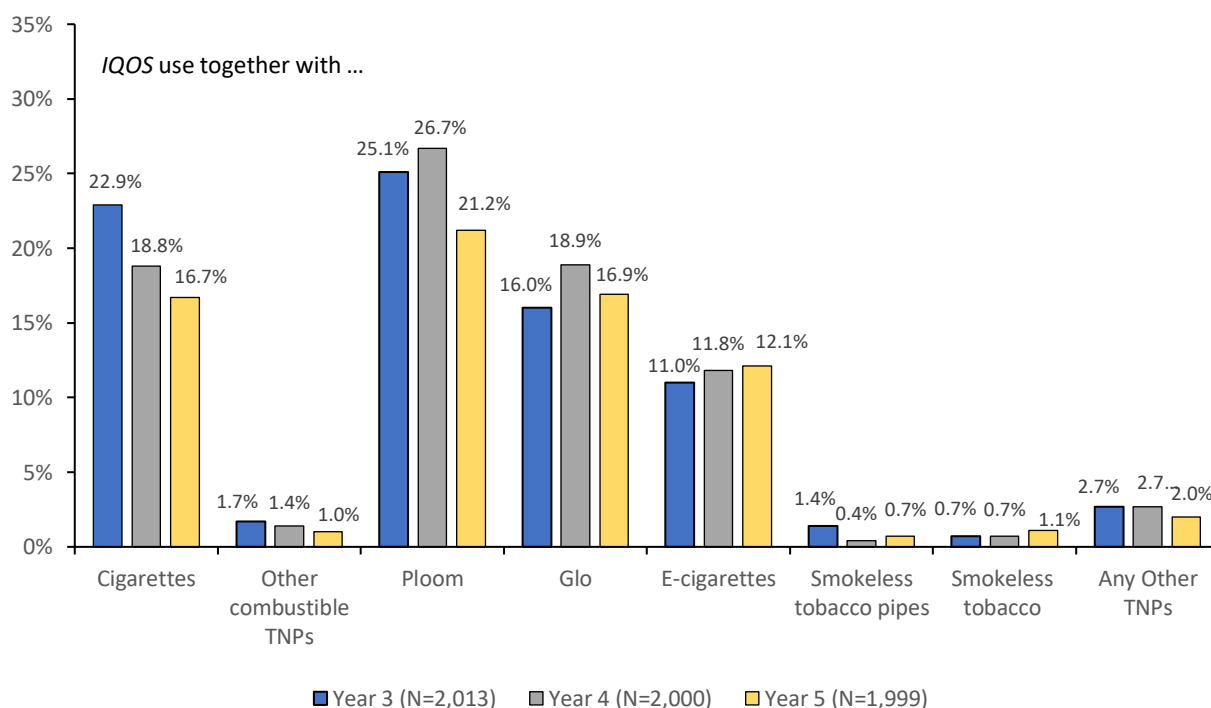


Figure 14 *IQOS* Use with other TNP categories and HTP brands – Trend Data – *IQOS* User Sample

Note: Any other TNPs (Table 3) include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy. HTP, heated tobacco product; TNP, tobacco or nicotine containing product.

⁸⁸ This information was assessed only from Year 3 onwards

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6.2.5 HISTORY OF IQOS USE

In Year 5, among current *IQOS*[™] users (N=1,999), 97.4% (n=1,948) had a previous smoking history, i.e., were current (91.2%, n=1,823) or former (6.3%, n=125) smokers before starting to use *IQOS*[™]. This also means that only 2.6% were never smokers who started TNP use with *IQOS*.

Among all current *IQOS*[™] users with a smoking history prior to starting using *IQOS* (N=1,948), 0.6% (n=11) relapsed to *IQOS* after less than 12 months of quitting cigarettes, 1.5% (n=30) reinitiated TNP use with *IQOS* after more than 12 months of quitting cigarettes, and 4.3% (n=84) did not know/could not remember.

Across Year 3 to Year 5,⁸⁹ the percentage of current *IQOS*[™] users who had a previous smoking history before they started using *IQOS* remained high, although it slightly decreased from 99.3% (n=1,958) in Year 3 to 98.1% (n=1,961) in Year 4 to 97.4% (n=1,948) in Year 5, while the corresponding percentage of current *IQOS* users with no previous smoking history slightly increased from 0.7% in Year 3 to 1.9 in Year 4 to 2.6% in Year 5.

6.2.6 QUITTING

Among all current *IQOS*[™] users (N=1,999) in Year 5, 44.9% (n=897) were interested (5.8% very interested and 39.1% somewhat interested) in stopping using *IQOS* (Figure 15).

Across Year 1 to Year 5, the interest in stopping using *IQOS* among all current *IQOS*[™] users continuously increased from 36.0% (N=2,000) in Year 1 to 42.8% (N=2,044) in Year 2 to 48.8% (N=2,013) in Year 3 to 50.9% (N=2,000) in Year 4, but then decreased to 44.9% (N=1,999) in Year 5.

Among current *IQOS*[™] users who also smoked cigarettes (N=334), 60.8% (n=203) were interested (very interested 16.5% or somewhat 44.3% interested) in quitting smoking cigarettes (Figure 15). This was higher than in the General Adult Population Sample, where 55.2% were interested in quitting smoking cigarettes.

Across Year 1 to Year 5, the interest in quitting cigarettes among current *IQOS*[™] users who also smoked remained high although it continuously decreased from 79.2% (N=552) in Year 1 to 74.6% (N=500) in Year 2 to 68.5% (N=460) in Year 3 to 67.5% (N=375) in Year 4 to 60.8% (N=334) in Year 5.

⁸⁹ This information was assessed only from Year 3 onwards.

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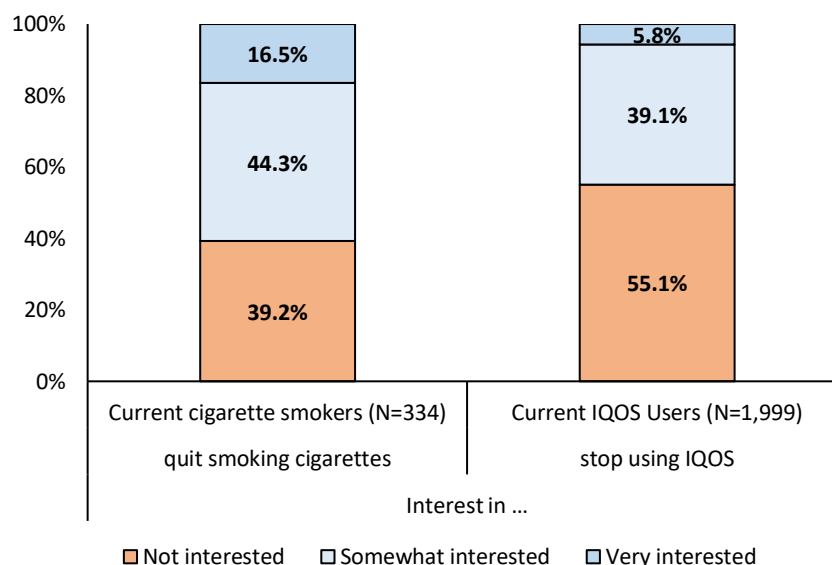


Figure 15 Level of Interest in Quit Smoking Cigarettes/Stop Using *IQOS* (%) - *IQOS* User Sample

Note: The sample size for current cigarette smokers is based on participants with non-missing information on current TNP use.

Among current *IQOS*[™] users (N=1,999), 34.4% (n=688) had ever attempted to stop using *IQOS*. Of these, among those with non-missing information on the duration of the stop attempt (99.1%, n=682), the majority (77.4%, n=528) stopped *IQOS* for less than 6 months, 10.7% (n=73) for 6-12 months, and 11.9% (n=81) for more than 12 months. Across Year 1 to Year 5, among all current *IQOS*[™] users, the percentage of *IQOS* users with stop attempts continuously increased from 17.0% (N=2,000) in Year 1 to 24.2% (N=2,044) in Year 2 to 33.3% (N=2,013) in Year 3, but then stabilized with to 34.9% (N=2,000) in Year 4 and 34.4% (N=1,999) in Year 5.

Among current *IQOS*[™] users who also smoked cigarettes (N=334), 62.6% (n=209) had ever attempted to quit smoking cigarettes. Of these, among those with non-missing information on the quit duration (99.5%, n=208), the majority (70.2%) quit cigarettes for less than 6 months, 12.0% for 6-12 months, and 17.8% for more than 12 months. Across Year 1 to Year 5, among current *IQOS*[™] users who also smoked, the percentage of *IQOS* users with quit attempts remained high although it continuously decreased from 71.4% (N=552) in Year 1 to 67.6% (n=500) in Year 2 to 69.3% (n=460) in Year 3 to 67.7% (n=375) in Year 4 to 62.6% (n=334) in Year 5. Regarding the quitting rate for cigarette smoking, among *IQOS*[™] users who had been cigarette smokers more than one year prior to the survey (N=377), 11.4% (n=43) successfully quit cigarette smoking in the last 12 months, with 8.0% (n=30) switching to exclusive *IQOS* use, 0.5% (n=2) using *IQOS* together with e-cigarettes, 1.3% (n=5) using *IQOS* with one other TNP, 0.8% (n=3) using *IQOS* with more than 1 other TNP, and 0.8% (n=3) using *IQOS* together with e-cigarettes & other

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TNP(s). Across Year 3 to 5,⁹⁰ among *IQOS*TM users who had been cigarette smokers more than one year prior to the survey, the rate of *IQOS* users who successfully quit smoking in the last 12 months increased from 9.8% (N=510) in Year 3 to 14.0% (N=436) in Year 4, but then decreased to 11.4% (N=377) in Year 5.

6.2.7 RISK PERCEPTION

In Year 5, current *IQOS*TM users (N=1,999) reported that they perceive the health risk (score from 0 [no-risk] to 100 [very-high risk])⁹¹ associated with smoking cigarettes (score: 63.0 [62.2; 63.8]) as higher than the health risk associated with using *IQOS* (score: 49.6 [48.8; 50.5]) (Figure 16). The reported health risk score of 49.6 associated with using *IQOS*TM also indicates that *IQOS* users perceived that using *IQOS*TM is associated with health risk, i.e., that *IQOS* was not perceived as risk-free.

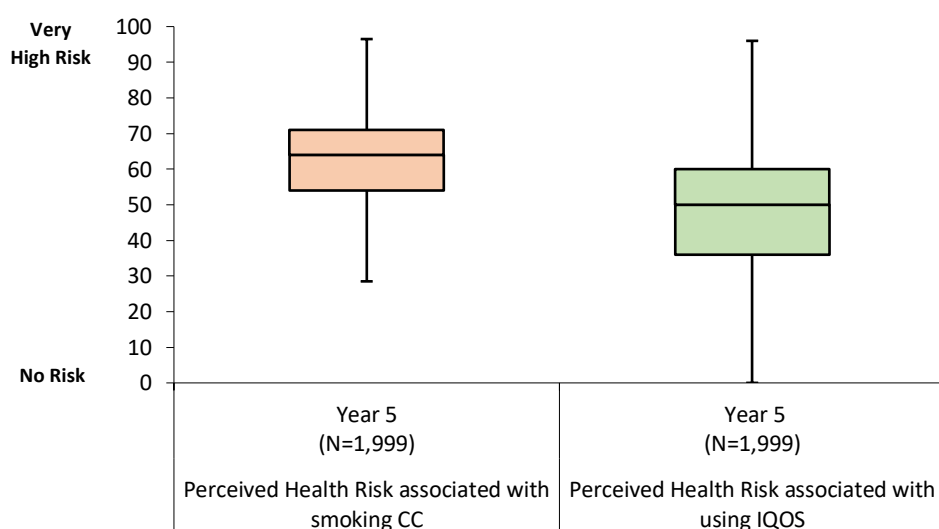


Figure 16 Perceived Health Risk Associated with Cigarettes /Using *IQOS* – Year 5 - *IQOS* Users

Note: Risk score (0 [no-risk] to 100 [very-high risk]). CC, cigarettes including manufactured and roll/make-your own cigarettes.

⁹⁰ This information was assessed only from Year 3 onwards.

⁹¹ Participants were asked to rate the general perceived risk of getting 18 different diseases or adverse health conditions separately for smoking cigarettes or for using *IQOS*TM on a 5-point Likert-like scale (ranging from 0 [no risk] to 4 [very high risk]) using PMI's psychometrically validated ABOUT-Perceived Risk, General version, Health Risk Instrument (18-item). Based on the 18 rated items, an overall score ranging from 0 [no risk] to 100 [very high risk] was derived from the total raw score by Rasch model analysis. The ABOUT-Perceived Risk Instrument General version was formerly known as Perceived Risk Instrument General (PRI-G) and is now part of PMI's ABOUT Toolbox. Cano S. et al. (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), 192-206.

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Across Year 1 to Year 5 (Figure 17), while the reported perceived health risk associated with smoking cigarettes remained stable with a score of 63.7 [62.8; 64.6] in Year 1, 62.1 [61.3; 62.9] in Year 2, 63.3 [62.6; 64.1] in Year 3, 62.2 [61.4; 63.0] in Year 4, and 63.0 [62.2; 63.8] in Year 5, the reported perceived health risk associated with using IQOS™ initially increased, from 44.0 [43.1; 44.9] in Year 1, to 45.9 [45.1; 46.8] in Year 2, to 48.6 [47.8; 49.5] in Year 3, but then stabilized with 49.4 [48.5; 50.3] in Year 4 and 49.6 [48.8; 50.5] in Year 5.

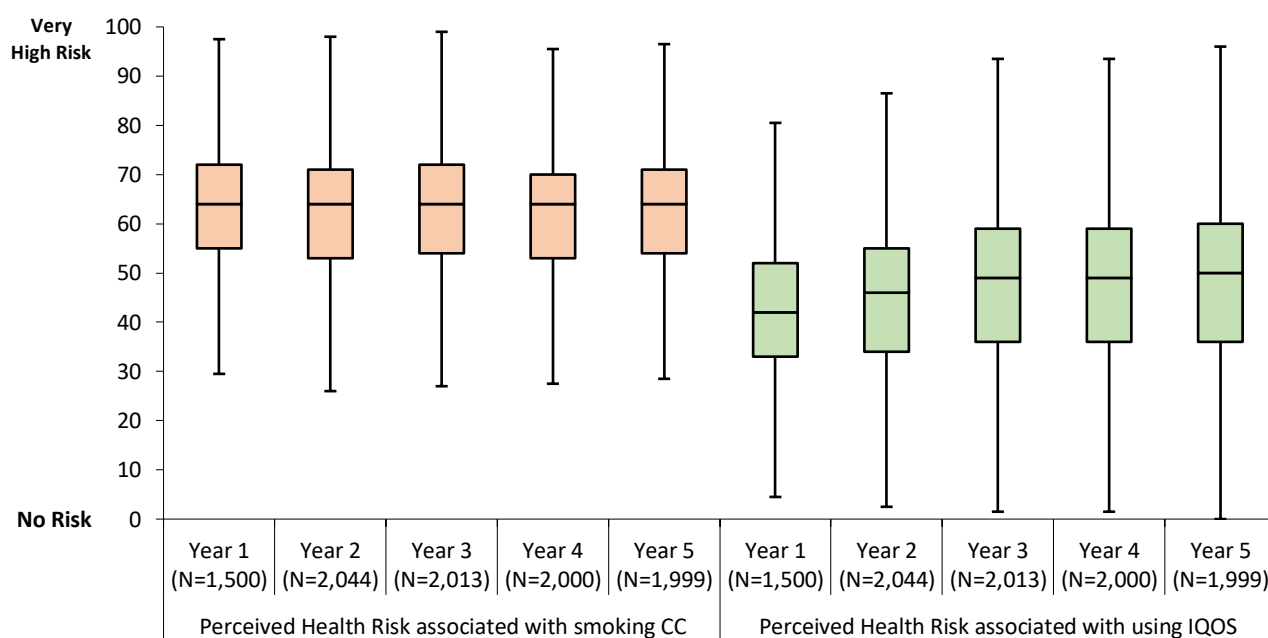


Figure 17 Perceived Health Risk Associated with Cigarettes /Using IQOS - Trend Data - IQOS Users

Note: CC, cigarettes

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6.2.8 PERCEIVED HEALTH RELATED SYMPTOMS AND ESTHETIC BENEFITS OF IQOS USE

6.2.8.1 RESPIRATORY SYMPTOMS

Among current exclusive *IQOS*TM users (N=1,100), 9.7% reported some respiratory symptoms (part day or all day),⁹² whereas among *IQOS* users who used *IQOS* together with combustible TNPs (N=342), 17.8% reported respiratory symptoms.

Moreover, among current exclusive *IQOS*TM users (N=1,100), 10.5% reported an overall improvement in cough symptoms in the last 12 months prior to the Year 5 survey, while 69.3% reported no change, and 3.4% reported a deterioration. Similar results were observed for phlegm symptoms, for which 9.1% reported an improvement, 67.9% reported no change, and 2.9% reported a deterioration ([Table 17](#)).

Current *IQOS*TM users who used *IQOS* together with combustible TNPs (N=342), also reported improvements in cough (11.4%) and phlegm (8.5%) symptoms in the last 12 months prior to the survey that were similar to those of reported by the exclusive *IQOS* users ([Table 17](#)).

Table 17 Change Cough/Phlegm Symptoms Last 12 Months by *IQOS* Use Pattern - *IQOS* User Sample

		Exclusive <i>IQOS</i> TM use (N=1,100)	<i>IQOS</i> use with combustible TNPs (N=342)
		n (%)	n (%)
Cough	Has improved	115 (10.5%)	39 (11.4%)
	No change	762 (69.3%)	233 (68.1%)
	Has worsened	37 (3.4%)	22 (6.4%)
Phlegm	Has improved	100 (9.1%)	29 (8.5%)
	No change	747 (67.9%)	241 (70.5%)
	Has worsened	32 (2.9%)	21 (6.1%)

Note: The sample sizes are based on participants with non-missing information on current TNP use. TNP, tobacco or nicotine containing product.

⁹² Two subscales of the Medical Research Council Questionnaire (MRCQ) were used to estimate selected respiratory symptoms. Participants were asked to evaluate the presence of cough (3 items) and phlegm symptoms (3 items). Additionally, participants were asked if their respiratory symptoms changed as compared to 12 months ago using a 7-point scale from “very much improved” to “very much worse”.

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Across Year 3 to Year 5,⁹³ the percentage of current exclusive *IQOS*TM users who reported an overall improvement in cough symptoms (18.5% [N=976] in Year 3, 12.8% [N=980] in Year 4, and 10.5% [N=1,100] in Year 5) and phlegm symptoms (18.8% [976] in Year 3, 12.8% [N=980] in Year 4, and 9.1% [N=1,100]) decreased over time. Similarly, the percentage of current *IQOS*TM users who used *IQOS* together with combustible TNPs and reported an overall improvement in cough symptoms (15.8% [N=467] in Year 3, 9.9% [N=385] in Year 4, and 11.4% [N=342] in Year 5) and phlegm symptoms (11.6% [467] in Year 3, and 8.6% [N=385] in Year 4, and 8.5% [N=342] in Year 5) mostly decreased across Year 3 to Year 5. This reduced frequency in reported respiratory improvement among both user groups could be because over time more and more *IQOS*TM users had used *IQOS* for a longer period and/or increasingly more *IQOS* users used *IQOS* exclusively or together with other smoke-free TNPs, and thus, had already reached substantial improvement in respiratory symptoms from using *IQOS*. However, it may also be explained by the COVID pandemic during which the overall perception of health worsened over time.

6.2.8.2 EXERCISE CAPACITY

The Rating of Perceived Capacity (RPC)⁹⁴ instrument was used to estimate maximal exercise capacity based on Metabolic Equivalent of Task (MET; a higher MET value indicates a better exercise capacity).

In Year 5, among female *IQOS* users (N=396), the rated exercise capacity was slightly higher among female exclusive *IQOS*TM users (8.7 [8.1; 9.3] MET; N=242) than female *IQOS* users who used *IQOS* together with combustible TNPs (8.0 [6.6; 9.5] MET; N=50). Similarly, among male *IQOS* users (N=1,603), the rated exercise capacity was slightly higher among male exclusive *IQOS*TM users (9.6 [9.2; 10.0] MET; N=858) than male *IQOS* users who used *IQOS* together with combustible TNPs (9.1 [8.5; 9.8] MET; N=292). Across Year 3 to Year 5,⁹⁵ these MET values among female and males *IQOS* users remained rather stable over time.⁹⁶

⁹³ This information was assessed only from Year 3 onwards.

⁹⁴ MET values from 1 to 20 in men and 1 to 18 in women are listed on a progressive scale linked to specific physical activities. Participants had to indicate the most strenuous activity they could sustain for at least 30 min. 1 MET equals energy expenditure in terms of oxygen consumption per 1 kg of body mass while sitting at rest.

Wisén, A.G., Farazdaghi, R.G. & Wohlfart, B. A novel rating scale to predict maximal exercise capacity. *Eur J Appl Physiol* 87, 350-357 (2002). <https://doi.org/10.1007/s00421-002-0636-y>.

⁹⁵ This information was assessed only from Year 3 onwards.

⁹⁶ Among female exclusive *IQOS*TM users, exercise capacity remained rather stable with 8.6 MET (Year 3), 8.7 MET (Year 4), and 8.7 MET (Year 5), while among male exclusive *IQOS* users, exercise capacity slightly increased from 9.2 MET (Year 3) to 9.7 MET (Year 4), but then slightly decreased to 9.6 MET (Year 5). Regarding *IQOS*TM users who used *IQOS* together with combustible TNPs, among women, exercise capacity increased from 7.8 MET (Year 3) to 8.6 MET (Year 4) but then decreased to 8.0 MET (Year 5). Similarly, among men, exercise capacity slightly increased from 9.1 MET (Year 3) to 9.6 MET (Year 4), but then decreased to 9.1 MET (Year 5).

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Regarding the change in exercise capacity compared to 12 months prior to the survey, among exclusive *IQOS*[™] users (N=1,100), 16.2% reported an improvement in exercise capacity,⁹⁷ while among *IQOS* users who used *IQOS* together with combustible TNPs (N=342), 13.2% reported an improvement (Table 18). At the same time, among exclusive *IQOS*[™] users (N=1,100), 15.2% reported a worsening of exercise capacity, while among those who used *IQOS* together with combustible TNPs (N=342), 17.8% reported a worsening. In comparison, only 6.3% of the current cigarette smokers (N=854) in the General Adult Population Sample reported an improvement and 20.6% reported a worsening of exercise capacity (Table 18).

Table 18 Change Exercise Capacity by *IQOS* Use Pattern - *IQOS* User/General Adult Population Sample

	Exclusive <i>IQOS</i> [™] use (N=1,100)	<i>IQOS</i> use with combustible TNPs (N=342)	General Adult Population (Current cigarette smokers (N=854)
	n (%)	n (%)	n (%)
Has improved	178 (16.2%)	45 (13.2%)	54 (6.3%)
No change	755 (68.6%)	236 (69.0%)	624 (73.1%)
Has worsened	167 (15.2%)	61 (17.8%)	176 (20.6%)

Note: The sample sizes are based on participants with non-missing information on current TNP use. TNP, tobacco or nicotine containing product.

Across Year3 to Year 5,⁹⁸ among both exclusive *IQOS* users (Year 3: 20.0%; Year 4: 18.4%; Year 5: 16.2%) and *IQOS* users who used *IQOS* together with combustible TNPs (Year 3: 16.3%; Year 4: 14.8%; Year 5: 13.2%), the percentage who reported an improvement in exercise capacity in the last 12 months steadily decreased. This could be because over time more and more *IQOS*[™] users had used *IQOS* for a longer period and/or increasingly more *IQOS* users used *IQOS* exclusively or together with other smoke-free TNPs, and thus, had already reached substantial improvement in exercise capacity from using *IQOS*. It may, however, also be explained by the COVID pandemic during which the overall perception of health worsened over time.

⁹⁷ A dichotomous variable of “improvement” is derived by combining the 3 positive categories of minimally improved”, “much improved” and “very much improved”.

⁹⁸ This information was assessed only from Year 3 onwards.

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6.2.8.3 *HYGIENE, BEAUTY, AND FITNESS PERCEIVED BENEFITS*

All IQOS™ users (N=1,999) were asked to rate their agreement with the perception of beneficial changes^{99, 100, 101} regarding six benefits related to hygiene, beauty, and fitness since they had switched from cigarettes to IQOS using the Self-Reported Change Questionnaire (SRCQ).¹⁰²

The frequency of agreement (positive items: “somewhat agree”, “agree”, or “strongly agree”)¹⁰³ regarding the perception of beneficial changes related to the individual six benefits is reported for the full IQOS User Sample (N=1,999) as well as by IQOS™ use patterns (Table 19). Among all IQOS users (N=1,999), the changes that were perceived most often, were “My teeth appear less stained or yellowish” (58.8%), “My breath smells better” (47.3%), and “My sense of smell has improved” (23.0%) (Table 19).

Comparing the patterns of the three IQOS user groups, the frequency of agreement with perceived positive changes in the perception of benefits was similar among exclusive IQOS™ users (N=1,100) and IQOS users who used IQOS together with smoke-free TNPs (N=540), whereas it was much lower among IQOS users who used IQOS together with combustible TNPs (N=342) (Table 19).

Table 19 Self-reported Change Questionnaire - Positive Agreement Items - IQOS User Sample

Self-reported Change Questionnaire (SRCQ)	Full Sample (N=1,999)	IQOS™ Use Patterns		
		Exclusive IQOS™ use (N=1,100)	IQOS use with smoke-free TNPs (N=540)	IQOS use with combustible TNPs (N=342)
Positive items (“Somewhat Agree”, “Agree” or “Strongly Agree”) ¹⁰⁴	n (%)	n (%)	n (%)	n (%)
My Teeth Appear Less Stained or Yellowish	1,176 (58.8%)	718 (65.3%)	327 (60.5%)	120 (35.1%)
My Breath Smells Better	945 (47.3%)	578 (52.5%)	264 (48.9%)	95 (27.8%)
My Sense of Smell Has Improved	459 (23.0%)	286 (26.0%)	132 (24.5%)	39 (11.4%)
My Sense of Taste Has Improved	437 (21.9%)	269 (24.4%)	124 (22.9%)	42 (12.3%)
I Feel that It is Easier to Exercise	301 (15.1%)	188 (17.1%)	90 (16.6%)	21 (6.2%)
My Face Skin Appears Smoother and Firmer	153 (7.7%)	98 (8.9%)	41 (7.6%)	12 (3.5%)

Note: The sample sizes are based on participants with non-missing information on current TNP use. TNP, tobacco or nicotine containing product.

⁹⁹ Seven-point rating scale ranging from “strongly disagree” to “strongly agree”.

¹⁰⁰ The Self-Reported Change Questionnaire (SRCQ) has been developed by PMI and translation into Japanese language has been linguistically validated by TransPerfect (<https://www.transperfect.com>).

¹⁰¹ Selecting “somewhat agree”, “agree”, or “strongly agree” was considered confirming the statement.

¹⁰² Seven-point rating scale ranging from “strongly disagree” to “strongly agree”.

¹⁰³ Selecting “somewhat agree”, “agree”, or “strongly agree” was considered confirming the statement.

¹⁰⁴ Selecting “somewhat agree”, “agree”, or “strongly agree” was considered confirming the statement.

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Across Year 1 to Year 5,¹⁰⁵ in the full *IQOS* User Samples, the hierarchy of the frequency of agreement regarding the perception of beneficial changes was similar, however, the frequency of reported perceived beneficial changes decreased from Year 1 to Year 5 (**Figure 18**). This decrease was also observed among both exclusive *IQOS* users, *IQOS* users who used *IQOS* together with smoke-free TNPs, and *IQOS* users who used *IQOS* together with combustible TNPs, and might be explained by the fact that over time more and more *IQOS*TM users had used *IQOS* already for a longer period and/or increasingly more *IQOS* users used *IQOS* exclusively or together with other smoke-free TNPs, and thus, had already reached substantial improvement in health, hygiene, beauty, and fitness benefits from using *IQOS*. The decrease in perceived beneficial changes may, however, also be related to the COVID pandemic, during which the overall perception of health and wellbeing worsened over time.

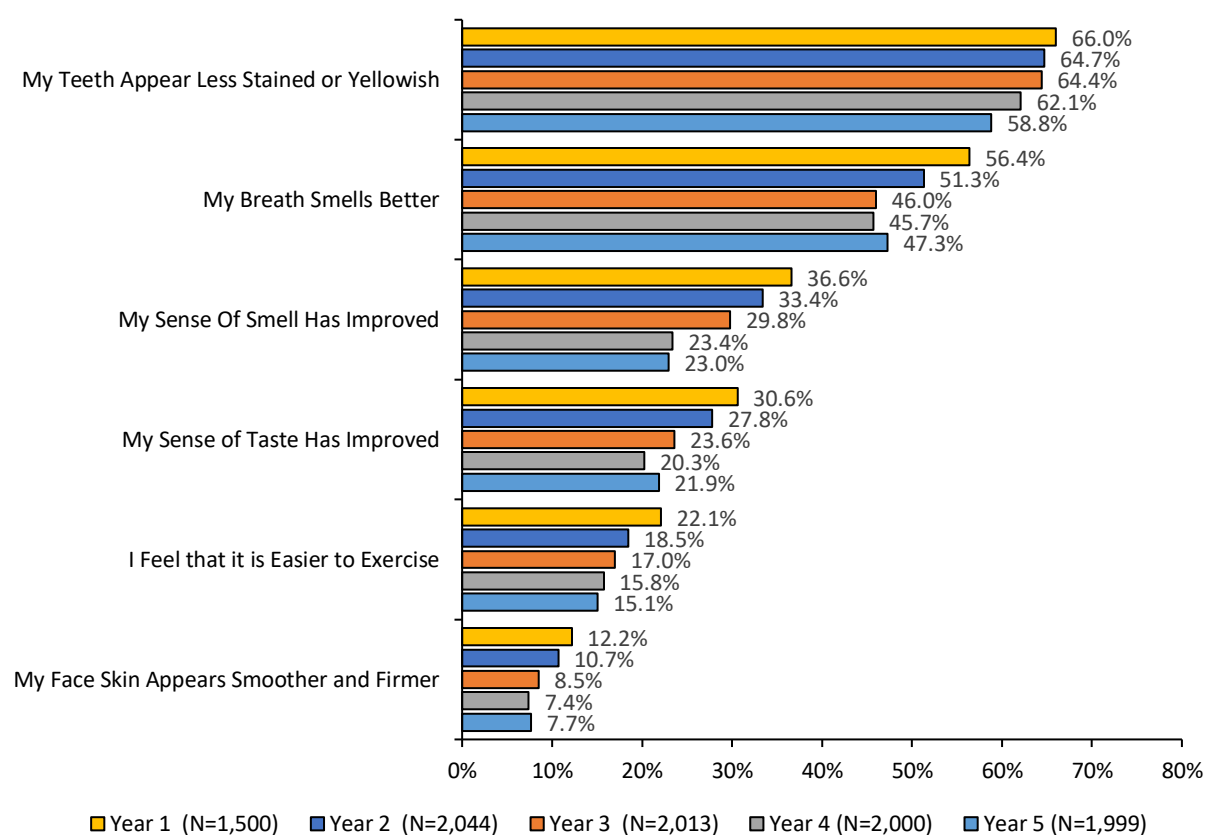


Figure 18 Self-reported Change Questionnaire – Positive Items - Trend Data (%) - *IQOS* User Sample

Note: Positive Agreement items: “Somewhat Agree” or “Strongly Agree” Items¹⁰⁶

¹⁰⁵ This information was assessed only from Year 3 onwards.

¹⁰⁶ Selecting “somewhat agree” or “strongly agree” was considered confirming the statement.

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7 CONCLUSIONS

Across the first five reporting years (2016-2022) of PMI's repeated cross-sectional studies in Japan, the prevalence of overall TNP use in the surveyed Japanese General Adult Population Samples remained rather stable across study Year 1 to Year 3 (2016 to 2019), but then decreased in Year 4 and Year 5 (2020-2022). While cigarettes remained by far the most often used TNP in Japan, during the 5-year study period, there was a shift in TNP use prevalence, i.e., a decrease in the use prevalence of cigarettes and other combustible TNPs together with an increase in the use prevalence of smoke-free TNPs, in particular of HTPs and e-cigarettes. This shift resulted in Year 5 in a total of 36% current smoke-free use and 19% current exclusive smoke-free TNP use, meaning that for the first time more than one out of three TNP users in Japan were using smoke-free TNPs and about one out of five TNP users were using smoke-free TNPs exclusively.

A decline in the prevalence of overall combustible TNP use in Japan over time has also been reported in the Japan National Health and Nutrition Survey¹⁰⁷ of the Japanese Ministry of Health, Labour and Welfare as well as in the WHO Global Report on Trends in Prevalence of Tobacco Smoking 2000-2025.¹⁰⁸ Moreover, the shift in TNP use prevalence observed across study Year 1 to Year 5 are in line with those reported by Cummings et al.¹⁰⁹ who found that *"the accelerated decline in cigarette only sales in Japan since 2016 corresponds to the introduction and growth in the sales of HTPs"*. Overall, the study data suggest that the observed shift from combustible to smoke-free TNP use over time is in line with the principles of tobacco harm reduction and suggests that the marketing of IQOS and other smoke-free TNPs is likely to have a positive impact on public health in Japan. This shift also suggests that smoke-free TNPs, in particular IQOS™, other HTPs, and e-cigarettes,¹¹⁰ are acceptable alternatives to cigarette smoking.

Across the five study years, in both the surveyed Japanese General Adult Population Samples and surveyed Japanese IQOS User Samples, nearly all current IQOS™ users were adult cigarette smokers with a smoking history when they started to use IQOS. This indicates that there was low

¹⁰⁷ Japan National Health and Nutrition Survey home page: National Health and Nutrition Survey | Health Japan 21 (nibiohn.go.jp); specifically: Japan National Health and Nutrition Survey (2019). <https://www.mhlw.go.jp/content/10900000/000687163.pdf>. Published in 2020 October 27.

¹⁰⁸ WHO Global Report on Trends in Prevalence of Tobacco Smoking 2000-2025 (second edition): 9789241514170-eng.pdf (who.int).

¹⁰⁹ Cummings KM, Nahhas GJ, Sweanor DT. What Is Accounting for the Rapid Decline in Cigarette Sales in Japan? Int J Environ Res Public Health. 2020 May 20;17(10):3570. doi: 10.3390/ijerph17103570.

¹¹⁰ In Japan, e-cigarettes with nicotine are regulated under the pharmaceutical law and are currently not commercially available, while importation of nicotine liquid (up to 120 ml) and 1-2 devices for self-consumption is permitted. The questions on e-cigarette use did not differentiate between nicotine-containing vs. non nicotine-containing e-cigarettes.

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initiation with *IQOS*. Moreover, because the majority of current TNP users with a smoking history prior to starting using *IQOS* restarted TNP use with cigarettes, also relapse to *IQOS* and reinitiation with *IQOS* were low.

In the Japanese General Adult Population Samples, the frequency of TNP use, (i.e., average number of days out of the last 30 days) and intensity of TNP use (i.e., average daily consumption) were overall similar among cigarette smokers and *IQOS*[™] users across the 5 study years. There was a trend towards slightly decreasing cigarette consumption among cigarette smokers together with a slightly increasing *HEETS*[™]¹¹¹ consumption among *IQOS* users, with both approaching each other regarding the average daily consumption. This similarity in patterns of frequency and intensity of cigarette consumption among cigarette smokers and *IQOS* use among *IQOS* users suggests that the use behaviors of cigarette smokers and *IQOS* users were overall similar. The decline in daily cigarette consumption among cigarette smokers over time is also in line with tobacco harm reduction and is likely to have a positive impact on public health in Japan.

Regarding the use of multiple TNPs over time, in the surveyed Japanese General Adult Population Samples, there was a stabilization of exclusive TNP use from Year 4 onwards¹¹² together with a shift towards dual TNP use¹¹³ rather than poly TNP use.¹¹⁴ This suggests that poly TNP use is not likely to become a sizable TNP use pattern in the adult Japanese population.

In the surveyed Japanese *IQOS* User Samples, across Year 1 and Year 5, the majority of *IQOS*[™] users had no longer smoked combustible TNPs, but used *IQOS* exclusively, or in particular in the last three years, used *IQOS* together with other smoke-free TNPs. This overall shift in *IQOS* use patterns among *IQOS* users resulted in Year 5 in an overall smoke-free TNP use proportion of over 80% and suggests that the marketing of *IQOS* and other smoke-free TNPs is in line with tobacco harm reduction and is likely to have a positive impact on public health in Japan. These study results are in line with the findings from the Japan National Health and Nutrition Survey,¹¹⁵ which reported that the majority of HTP users (74.6 % among men and 81.0% among women) were using HTPs exclusively. Moreover, the data from the National Health and Nutrition Survey also showed a growing number of *IQOS* users who were using *IQOS* together with other HTPs.

¹¹¹ Tobacco sticks (disposables) to be used with the *IQOS*[™] device; these comprise all in Japan available *IQOS* tobacco stick brand names *Marlboro HeatSticks*[™], *HEETS*[™], and *TEREA*[™].

¹¹² Use of only one tobacco or nicotine containing product.

¹¹³ Use of two different tobacco or nicotine containing products.

¹¹⁴ Use of more than two different tobacco or nicotine containing products.

¹¹⁵ Japan National Health and Nutrition Survey home page: National Health and Nutrition Survey | Health Japan 21 (nibiohn.go.jp); specifically: Japan National Health and Nutrition Survey (2019). <https://www.mhlw.go.jp/content/10900000/000687163.pdf>. Published in 2020 October 27.

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In the surveyed Japanese General Adult Population Samples, the willingness to quit, rates of quitting cigarettes, and quitting all TNPs among cigarette smokers remained stable over time indicating that *IQOS* does not seem to prevent adult smokers who want to quit from quitting cigarettes or all TNPs. Among *IQOS*TM users, although the willingness of quitting was high, both the rate of stopping using *IQOS* and the rate of quitting all TNPs slightly decreased over time. This decrease, however, is likely due to the fact that the percentage of exclusive *IQOS* users among all *IQOS* users in the General Adult Population Samples increased over time, with exclusive *IQOS* users being less likely to stop using *IQOS* or all TNPs because they are satisfied with using *IQOS*.

In the surveyed Japanese *IQOS* User Samples, among *IQOS* users who also smoked cigarettes, the willingness to quit cigarettes, although declining, remained high during the last study years, while the cigarette quitting rate, remained rather overall stable. The slight decrease in the willingness to completely quit smoking cigarettes may be explained by the fact that a proportion of *IQOS* users who also smoked cigarettes does not want to stop cigarette smoking completely.

The data from the surveyed Japanese *IQOS* User Samples also show that in Year 5, *IQOS*TM users reported that they perceive that there is a health risk associated with using *IQOS*, i.e., *IQOS* was not perceived as a risk-free TNP. Moreover, *IQOS* users also reported that they perceive the health risk associated with using *IQOS* as lower than the health risk associated with smoking cigarettes. This means that the consumer understanding about the health risk of *IQOS* is in line with the relative risks of the product that are reasonably likely.¹¹⁶ However, while the health risk perception associated with cigarettes smoking remained rather stable across the five study years, the health risk perception associated with using *IQOS* initially increased, but later stabilized over time. The increase in the perceived health risk associated with using *IQOS* may be due to the miscommunication of the health risk of individual TNP categories and/or the related misperceptions of tobacco consumers, such as that HTPs or e-cigarettes are equally or even more harmful than cigarettes.

Furthermore, the study data from the surveyed Japanese *IQOS* User Samples show that the perceived improvement in respiratory symptoms (cough and phlegm), exercise capacity, and aspects of hygiene (e.g., “My breath smells better”), beauty (e.g., “My teeth appear less stained or yellowish”), and fitness (e.g., “I feel that it is easier to exercise”) was more frequently reported among exclusive *IQOS*TM users and among *IQOS* users who used *IQOS* together with other smoke-free TNPs than among *IQOS* users who used *IQOS* together with combustible TNPs.

However, over time, the frequency of reported perceived improvements among both exclusive *IQOS* users, *IQOS* users who used *IQOS* together with smoke-free TNPs, and *IQOS* users who used

¹¹⁶ FDA TPL Review PMI’s *IQOS* MRTPA. Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov)

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IQOS together with combustible TNPs decreased over time. This development across study years could be explained by the fact that over time more and more *IQOS*[™] users had used *IQOS* for a longer period and/or more and more *IQOS* users had used *IQOS* exclusively or together with other smoke-free TNPs, and therefore, had already reached substantial improvement in hygiene, beauty, and fitness benefits from using *IQOS*. This development may, however, also be explained by the COVID pandemic during which the overall perception of health worsened over time.

Finally, Philip Morris International's repeated cross-sectional study in Japan will also be continued in 2023 (Year 6).

8 STRENGTHS AND LIMITATIONS

8.1 STRENGTHS

As with the previous repeated cross-sectional studies in Japan, the Year 5 cross-sectional study has several strengths. It is the fifth repeated annual standardized collection of data using the same sampling framework and standardized methods over time, namely face-to-face interviews of a nationally representative sample of randomly selected participants coupled with an online survey in a large *IQOS* User Sample. Moreover, the three-stage stratified proportional sampling method for the General Adult Population Sample was based on 940,000 census units created by the Statistics Bureau of Japan and covers the whole of Japan. The study applied widely accepted definitions of TNP use that are in accordance with the guidelines for controlling and monitoring the tobacco epidemic of the World Health Organization.¹¹⁷

The respective sample sizes in the General Adult Population and *IQOS* User Sample were large and provided a sufficiently high level of precision for the main outcomes (e.g., prevalence, initiation, relapse, and reinitiation). Moreover, the numerous survey waves conducted throughout the study year ensured a good representation of a full study year compared to only a single time point. Most other similar cross-sectional surveys on TNP use are currently only using one survey wave per year and, thus, are collecting data that are not representative for a whole annual year.

Furthermore, each year, the survey questionnaires are updated to reflect possible changes in the available TNP/ HTP categories on the Japanese market.

Also, as of study Year 4, advanced categorization of TNPs in six common TNP categories (cigarettes, other combustible TNPs, heated tobacco products [HTP], e-cigarettes, smokeless

¹¹⁷ World Health Organization. Measuring tobacco use behaviours. IARC Handbook of Cancer Prevention, vol 12. 2008:75-106. Available from: <http://publications.iarc.fr/Book-And-Report-Series/Iarc-Handbooks-Of-Cancer-Prevention/Methods-For-Evaluating-Tobacco-Control-Policies-2008>.

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TNPs, and any other TNPs)¹¹⁸ as well as of two overarching TNP umbrella classes (overall combustible TNPs and overall smoke-free TNPs) was introduced.

Finally, to be able to provide solid trend data over time, each year, identical or, if needed, harmonized measures were used to calculate and compare trends of TNP use over time.

8.2 LIMITATIONS

This study also has some limitations. The study may have suffered from several types of bias, including reporting bias, sampling and selection bias, as well all biases typically associated with self-reported measures and response bias. Because the study heavily relied on self-reported measures, the study may have especially suffered from different types of response bias, such as recall or social desirability¹¹⁹ bias. In particular, some survey questions were about the participant's history of TNP use (e.g., age of start using a TNP regularly), which may have been difficult to remember accurately for those with a long history of TNP use and, therefore, may have been subject to recall bias. However, previous studies examining bias in a self-reporting setting have not found meaningful evidence of bias, but have shown that the reliability of self-reported smoking data among adults has generally been high, suggesting that self-reported data provide reasonably valid estimates of cigarette smoking in the population.^{120 121 122} Nevertheless, the reliability of self-report assessments for smoke-free TNPs such as *IQOS*TM and e-cigarettes has not yet been investigated and confirmed to the same extent.

Moreover, because of the cross-sectional nature of the study design (i.e., not following up the same participants as part of a prospective design), the reported data does not allow to draw cause-effect conclusions.

Finally, the surveys in the *IQOS*TM user population were based on *IQOS* users who were registered in the *IQOS* user database of PMI's affiliate in Japan and who agreed to be contacted for research purposes. Accordingly, the study results among this particular participant group of *IQOS* users may not fully reflect the total universe of Japanese *IQOS* users.

¹¹⁸ Any other TNPs include any other TNP(s) that were not specified by the participants (i.e., participants could indicate that they use other TNP(s) than those targeted in the questionnaire, but these other TNP(s) were not further specified), and nicotine replacement therapy.

¹¹⁹ Persoskie, A. and W.L. Nelson: Just blowing smoke? Social desirability and reporting of intentions to quit smoking; *Nicotine Tob Res* 15 (2013) 2088-93. DOI: 10.1093/ntr/ntt10

¹²⁰ Rebagliato M. Validation of self-reported smoking. *Journal of epidemiology and community health*. 2002;56(3):163-164.

¹²¹ Wong SL, Shields M, Leatherdale S, Malaisson E, Hammond D. Assessment of validity of self-reported smoking status. *Health reports*. 2012;23(1):47-53.

¹²² Yeager, D.S. and J.A. Krosnick: The validity of self-reported nicotine product use in the 2001-2008 National Health and Nutrition Examination Survey; *Med Care* 48 (2010) 1128-32. DOI: 10.1097/MLR.0b013e3181ef9948

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