

# SEE THE SCIENCE FOR YOURSELF

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Delivering a smoke-free future

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### OUR PRODUCT TECHNOLOGIES

Our goal at Philip Morris International (PMI) is to offer smoke-free alternatives that have the potential to reduce the risk of developing smokingrelated diseases as compared with continued smoking. Recent advances in science and technology have made it possible to develop innovative products that current adult smokers accept and that are less harmful alternatives.

### THE TECHNOLOGIES BEHIND OUR SMOKE-FREE PRODUCTS

#### Heat-not-burn or heated tobacco products

Our heated tobacco products (HTPs), also known as heat-not-burn (HnB) products, electrically heat tobacco or a nicotine substrate, using either inductive or resistive heating, just enough to release a nicotine-containing aerosol without burning.

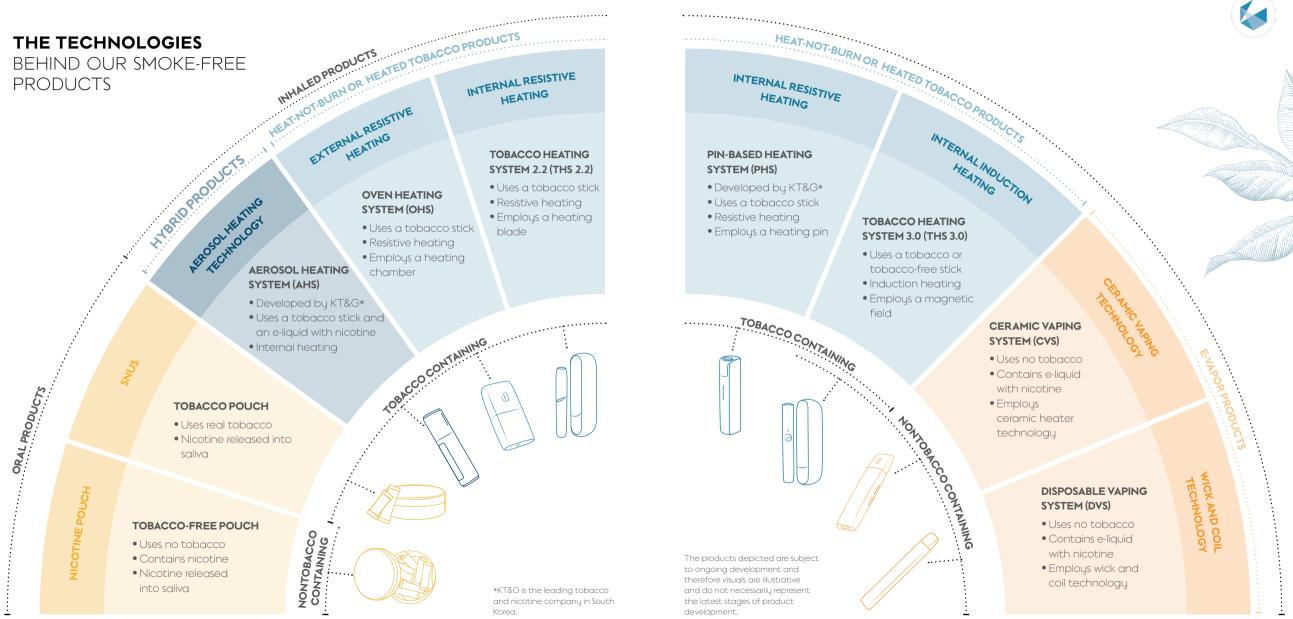
#### E-vapor products

E-vapor products are battery-powered devices, commonly known as e-cigarettes, that vaporize a liquid solution containing nicotine and flavors to create an inhalable aerosol. While traditional e-vapor products come with rechargeable batteries and replaceable or refillable cartridges, disposable e-vapor products are single-use devices that come prefilled with e-liquid.

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### Oral products

The oral smokeless category does not involve a device, heating, or the inhalation of an aerosol. Instead, oral products contain either tobacco or purified nicotine that is wrapped in a cellulose pouch and they are placed between the gum and the cheek or upper lip, with nicotine absorbed into the bloodstream mainly via the mucous membranes in the mouth.





For a deep dive into each section of our assessment program and the references supporting our statements, please consult our PMI Science Booklet, available at PMIscience.com.

Our smoke-free products are in various stages of development, scientific assessment, and commercialization; all designed to offer better alternatives for adult smokers than continuing to smoke. All newly developed products undergo rigorous testing. This leaflet summarizes the key scientific results of our leading HTP, the tobacco heating system (THS).

### THERE IS NO BURNING IN THS

Scientific data show that the primary cause of smoking-related disease is the high levels of Harmful and Potentially Harmful Constituents (HPHCs) in smoke formed during the combustion of tobacco.

We have conducted several studies to demonstrate the absence of combustion in THS, including temperature measurements, experiments demonstrating the absence of net exothermic processes, and measurements of constituents that represent typical markers of combustion.

Our studies also support that the aerosol of THS does not contain solid particles that are produced when tobacco is burned. In addition, since burning requires oxygen, we have tested THS in an oxygen-free atmosphere. The results showed that oxygen does not play a major role in the thermochemical degradation of the THS tobacco or the aerosol formation. Combustion does not occur during THS use.

### **MAJORITY OF THS USERS** NO LONGER SMOKE CIGARETTES AND USE THS EXCLUSIVELY

Our repeated post-market crosssectional surveys show that the majority of THS users no longer smoke cigarettes and use THS exclusively.

These studies also show very low to nonexisting tobacco or nicotine-containing products (TNP) initiation with THS among never TNP users (<0.1%). More than 99% of current THS users have a history of TNP use before switching to THS, and only 1% to 2% of current THS users relapsed or re-initiated tobacco use with THS.



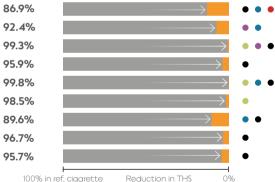
### **REDUCED EMISSIONS** OF HARMFUL CHEMICALS

By eliminating combustion, the levels of HPHCs are reduced on average by 95% in the aerosol of THS compared with those in cigarette smoke.\*

**Ref. cigarette THS** mean mean (per stick) (per stick) **HPHCs** 215 µg Acetaldehyde 1641 µg 11.8 µg Acrolein 156 µg 0.533 µg 81,1 µg Benzene Benzo[a]pyrene 0.621 ng 15 ng 1.3-butadiene 98.5 µg 0.233 µg 0.447 mg Carbon monoxide 30.2 mg Formaldehyde 85.2 µg 8.89 µg 264 ng 8.72 ng NNK\*\* 283 ng 12.3 ng **NNN**\*\*\*

This figure illustrates the reductions of HPHCs, as listed in the WHO 9 list, present in the THS aerosol compared with cigarette smoke.

### **Reduction in THS versus** ref. cigarette (per stick)



\*Based on the WHO 9 list.

Tobacco-specific nitrosamines; \*\*NNK: 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone \*\*\*NNN: N-Nitrosonornicotine

Yields are obtained under the Health Canada Intense Testing regime.

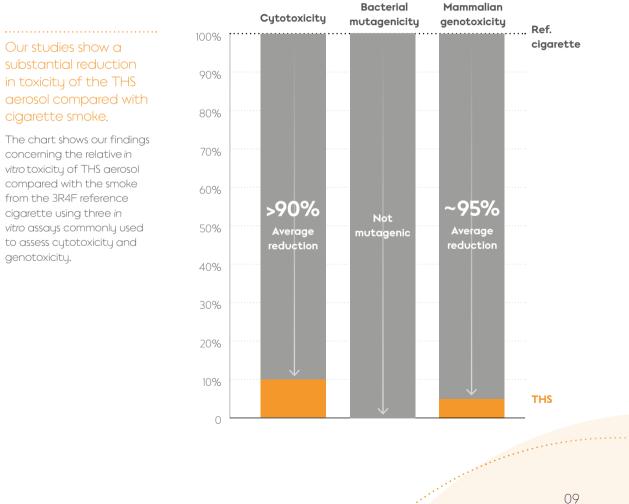
Toxicants classification based on the established U.S. Food and Drug Administration (FDA) list.



Addictive

#### **REDUCED** TOXICITY

genotoxicity.



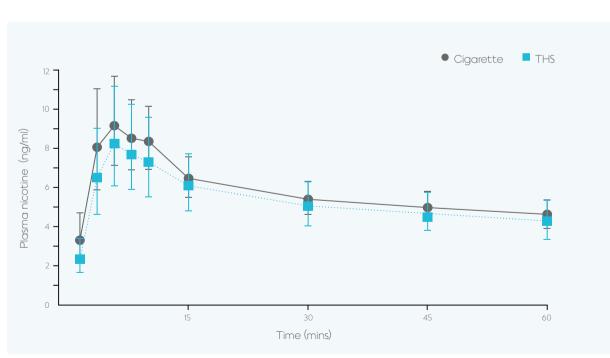
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### **KEY** FINDINGS

### NICOTINE UPTAKE

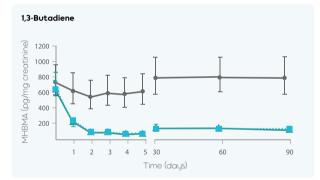
When switching to THS, the nicotine uptake and urge-to-smoke scores were comparable to those measured in subjects who continued smoking.

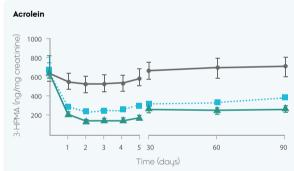
This suggests that switchers do not seek to use THS more frequently than smokers seek to use cigarettes and that switchers can find THS acceptable and satisfying.



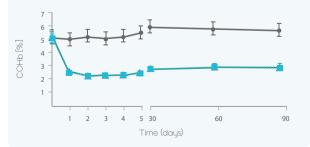
### REDUCED EXPOSURE TO HARMFUL CHEMICALS

Smokers switching completely to THS were exposed to significantly lower levels of harmful chemicals compared with those who continued smoking during the study.

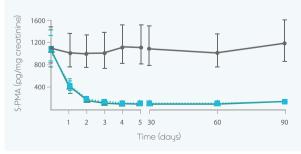




Carbon monoxide



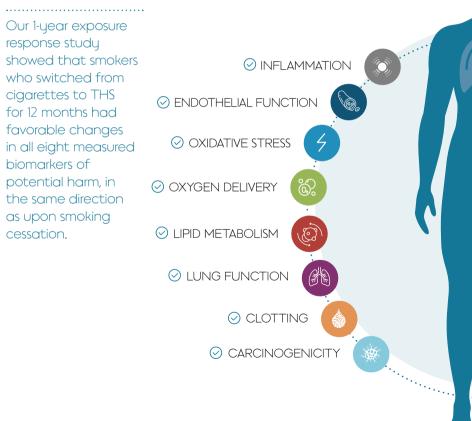












O Changes similar to the ones observed following smoking cessation

#### INTENTION TO USE AND USE BEHAVIOR

Our pre-market perception and behavior studies showed that substantial proportions of current adult smokers expressed intention to use THS and that low proportions of nonsmokers expressed intention to use THS. Furthermore, the studies showed that smokers correctly understand that switching to THS presents less risk of harm than continued cigarette smoking.

Our actual use perception and behavior studies showed that a sizeable proportion of smokers were likely to switch from cigarettes to THS exclusive or predominant use.



#### **PERCEIVED** RISK

We examined the impact of risk-related perceptions of THS on smokers' behavior and its impact on exclusive and stable use over time, highlighting the importance of factual and nonmisleading product information capable of enabling informed decision making.

The results showed that individuals who identified perceived reduced formation of harmful chemicals or perceived reduced risk of harm as reasons for using THS were more likely to switch exclusively and did so more quickly than those who did not.



### POPULATION HEALTH IMPACT MODEL

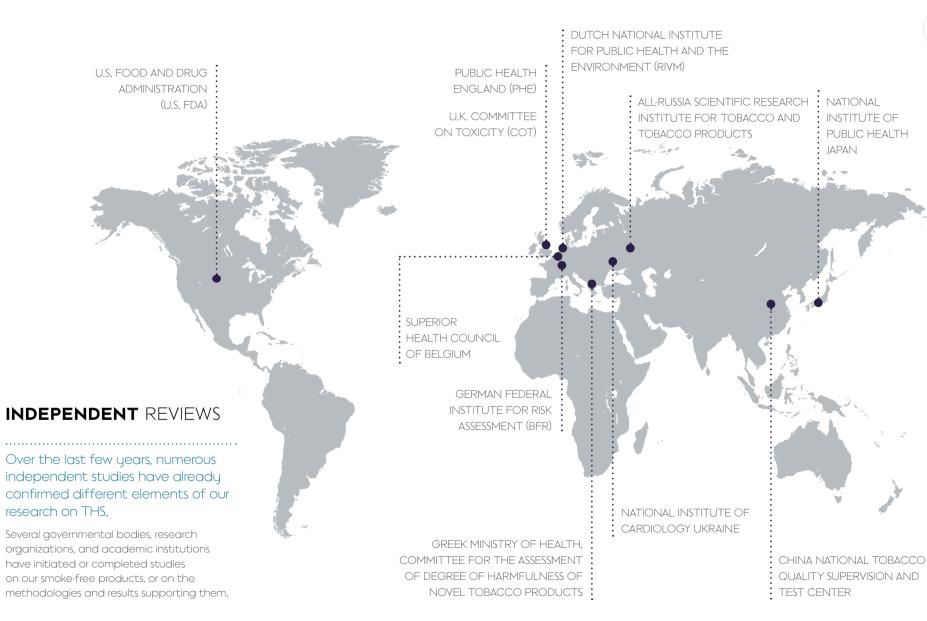
We developed an epidemiological model relying on mathematical simulations using publicly available data, the Population Health Impact Model (PHIM), with the aim to estimate, in the absence of epidemiological data, the potential effects of introducing a smokefree product on the public health of a whole population.

We have conducted several studies using our PHIM for various countries and while the PHIM has several important limitations, these simulations seem to suggest that the introduction of a smoke-free product as modeled has the possibility to substantially reduce smoking-related deaths.





research on THS.



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### FACTS AND FIGURES

The totality of evidence gathered so far demonstrates that THS is a better choice for adult smokers who would otherwise continue smoking cigarettes and that switching completely to THS presents less risk of harm than continued smoking. Smoke-free products are not risk free and contain nicotine, which is addictive. The best choice any smoker can make is to quit tobacco and nicotine altogether.

### OUR CONTRIBUTION SO FAR

Our comprehensive body of scientific evidence for our leading smoke-free product THS has been submitted to regulatory bodies in several countries.

We submitted Modified Risk Tobacco Applications (MRTPAs) in December 2016 and Premarket Tobacco Product Applications (PMTAs) in March 2017 to the U.S. FDA. We also submitted technical and scientific dossiers to regulatory authorities in several EU member states. In April 2019, following a rigorous science-based review through the PMTA pathway, the U.S. FDA determined that authorizing THS for the U.S. market is appropriate for the protection of the public health.

In July 2020, the U.S. FDA authorized the marketing of the THS as a modified risk tobacco product with reduced exposure information. The agency found that the issuance of the modified risk tobacco product orders with reduced exposure information would be "appropriate to promote the public health and is expected to benefit the health of the population as a whole."



\* Data includes employees of Swedish Match and Vectura Fertin Pharma.

\*\* Investments reflect research, product and commercial development, production capacity, scientific substantiation, and studies on adult smoker understanding. Figure does not include Swedish Match and Vectura Fertin Pharma.

\*\*\* IP5 jurisdictions are Europe (patents granted by the European Patent Office), China, South Korea, Japan, and the U.S.



#### Edition 2.0, May 2024

You can find more about our science on PMIScience.com



PMIScience.com is operated by Philip Morris International for the purpose of publishing and disseminating scientific information about Philip Morris International's efforts to develop and assess products that have the potential to reduce individual risk and population harm associated with tobacco use.

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PMI Science Neuchâtel, Switzerland

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