

Scientific substantiation of the absence of combustion and no smoke formation in the Electrically Heated Tobacco Product (EHTP) as well as the absence of Environmental Tobacco Smoke (ETS) emission during use of the Electrically Heated Tobacco System (EHTS)

Executive Summary

Philip Morris International's (PMI) Electrically Heated Tobacco Product (EHTP) is designed as a novel tobacco product that generates a nicotine-containing aerosol without involving a combustion process and formation of smoke when used in the Electrically Heated Tobacco System (EHTS) Holder. Thus, the absence of combustion and smoke during EHTS use is by design. The scientific evidence available on EHTS use comprehensively demonstrates that no combustion process occurs when the EHTP is used in the EHTS Holder and that the aerosol generated is not smoke.

Furthermore, there is no Environmental Tobacco Smoke (ETS) emitted during use of the EHTS. In addition, EHTS use has no adverse effect on air quality according to threshold limits established by existing air quality guidelines and when used in a setting where regulatory norms of adequate ventilation are respected.

The EHTS is also known as the Tobacco Heating System (THS) 2.2 and marketed in various countries under the brand name *IQOS*.

Key takeaways of the scientific reports presented here include:

Absence of combustion

- Combustion (burning) is defined as a chemical process of oxidation that occurs at a rate fast enough to produce heat and usually light in the form of either a glow or flame.
- For the tobacco in the EHTP to combust, its temperature would need to exceed about 400°C.
- The maximum temperature measured in the EHTP during use of the EHTS is 320°C and therefore is well below the temperature required for combustion. The majority of the tobacco in the EHTP remains at much lower temperatures.
- The EHTP tobacco undergoes drying and evaporation during EHTS use, and only a small portion of the tobacco close to the Heater undergoes thermochemical decomposition

(torrefaction/low-temperature pyrolysis), but no combustion (neither incomplete nor complete) occurs.

- Furthermore, there are no signs of net exothermic (heat-generating) processes in the EHTP during use of the EHTS. In fact, when the power to the Heater is switched off, there is an immediate decrease in the temperature of the tobacco.
- Oxygen is necessary for combustion. The comparison of the EHTS aerosol generated in oxidative (air) and non-oxidative (nitrogen) environments indicated that oxygen does not play a major role in the thermochemical degradation of the EHTP tobacco and further demonstrated the absence of combustion.
- Although gaseous compounds, such as carbon monoxide, carbon dioxide, and nitrogen oxides, are usually associated with combustion, low levels of these compounds in the EHTS aerosol are not evidence that combustion has occurred. These compounds are also generated at low levels during thermochemical degradation (torrefaction or mild pyrolysis) of the tobacco material, independent of the oxygen availability.

No smoke formation

- While smoke is an aerosol, not all aerosols are smoke.
- Smoke is an aerosol containing liquid and solid particles (particulate matter).
- Smoke particulate matter is formed when products of combustion and high-temperature pyrolysis (e.g., hydrocarbons) reach supersaturation and either condense to form droplets or react together to form particles, or by the nucleation and growth of positively charged hydrocarbon ions to form soot particles.
- The EHTS aerosol is not smoke, as there is no combustion or high temperature pyrolysis occurring in the EHTP during EHTS use, no solid particles are generated, and the liquid particulate matter (droplets) are not formed from condensation of byproducts of combustion or pyrolysis.
- The liquid particulate matter in the EHTS aerosol is instead generated when glycerol (added to the tobacco during processing as an aerosol former) is vaporized and reaches supersaturation and condenses on cooling, forming nuclei, onto which other constituents can condense to form droplets.
- Aerosols formed from the condensation of water vapor or vaporized aerosol formers from e-liquids or tobacco materials, such as the EHTS aerosol, are very different in terms of origin as well as chemical and physical composition compared with cigarette smoke, which is formed from the combustion and associated high-temperature pyrolysis products generated from the burning of tobacco.
- The processes that generate the aerosol during the use of EHTS and for most e-vapor products (EVP) are the same. Such products involve heating to vaporize aerosol former(s), and inhalable liquid aerosol droplets are formed as the vapor cools down.

- The absence of combustion in the EHTP and that the aerosol generated is not smoke have been substantiated by scientific evidence and verified by third-party scientific experts in numerous countries as well as by independent research organizations.

No emitted Environmental Tobacco Smoke (ETS)

- It is important to note that the purpose of PMI studies on the impact of EHTS use on air quality is to fully characterize the impact of EHTS use on the environment and on bystanders as well as to provide scientific evidence to support the creation and implementation of science-based policies for new emerging, less-harmful products, such as the EHTS. The intention is not to establish evidence in support of overcoming existing, already implemented smoking bans in any country.
- ETS is generated by the combustion of tobacco products and is composed of sidestream smoke, emitted from the smoldering tobacco, as well as exhaled mainstream smoke from the smoker.
- As there is neither sidestream nor mainstream smoke generated by the EHTP during EHTS use, there is no ETS emitted.
- The EHTS aerosol generated during use of the EHTS contains >90% lower levels of harmful and potentially harmful constituents, on average, compared with mainstream cigarette smoke.
- The environmental EHTS aerosol emitted during EHTS use (predominantly emitted from exhalation of EHTS mainstream aerosol constituents during EHTS use) is, by nature, different from the ETS emissions from cigarette smoking.
- In addition to demonstrating that the EHTS aerosol is not smoke and that no ETS is emitted during EHTS use, it is important to assess the impact of the environmental EHTS aerosol on air quality. PMI conducted scientific studies in a dedicated air quality assessment room under simulated environmental conditions.
- These studies demonstrated that only three compounds (nicotine, acetaldehyde, and glycerol) were above the background levels in air and could be attributed to EHTS use. However, glycerol is not an air pollutant and the concentrations of nicotine and acetaldehyde were much lower than the levels measured after cigarette smoking and far below the limits established by existing air quality guidelines.
- Independent studies on EHTS (as well as certain EVPs) use in indoor environments, in general, corroborated these results.
- To better understand the impact of day-to-day activities on air quality and to prepare the assessment of the impact of EHTS use in real-life settings, PMI conducted studies on the impact of activities of daily living, such as using perfume and cooking, on air quality.
 - The results of these studies showed that day-to-day activities lead to significant emissions of volatile organic compounds and particulate matter, which would need

to be considered when assessing the impact of EHTS use on bystanders in real-life settings.

- In a study conducted in Japan, in a restaurant where EHTS use was allowed but cigarette smoking was not, the results indicated that:
 - EHTS use did not negatively affect bystanders' exposure in a real-life setting when passively exposed to the environmental EHTS aerosol.
 - EHTS use had no adverse effect on air quality, considering threshold limits established by existing air quality guidelines and when used in settings where regulatory norms of adequate ventilation are respected.
- Independent scientific studies on air quality conducted in real-life settings in a nightclub and in a catering and entertainment establishment showed that:
 - The particle number concentration was found to be higher when the nightclub was in full operation with no humans present and no use of EHTS compared with what could be measured when EHTS was used and the nightclub was not in operation.
 - The levels of all compounds measured in the catering and entertainment establishment during EHTS use were far below threshold limits established by existing air quality guidelines.
- Moreover, the results from an independent study performed in Germany were in line with the results of PMI studies on air quality, with cigarette smoking leading to the greatest impact on air quality. EHTS use resulted in detectable levels of nicotine, but no other chemical markers of contamination were detected, including the absence of markers for secondhand smoke.

In summary, the scientific evidence demonstrates that there is no combustion in the EHTS, the aerosol generated is not smoke, and there is no ETS emitted during use of the EHTS. In addition, EHTS use has no adverse effect on air quality, considering threshold limits established by existing air quality guidelines and when used in a setting where regulatory norms of adequate ventilation are respected.