



Scientific substantiation of the absence of combustion in the Electrically Heated Tobacco Product (EHTP) and that the aerosol emitted is not smoke

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Executive summary

This report consolidates scientific evidence substantiating that no combustion of the tobacco material occurs in Philip Morris International's (PMI) Electrically Heated Tobacco Product (EHTP) when used in the Electrically Heated Tobacco System (EHTS) (also known as the Tobacco Heating System (THS), which is marketed in various countries under the *IQOS* brand name) and that the aerosol generated is not smoke. A review was completed of the physical and chemical processes occurring in tobacco as a function of temperature, including the fundamentals behind aerosol formation in general and smoke formation in particular, as well as a consideration of the available technical and scientific definitions of smoke and combustion (see Appendix). Based on these reviews, the scientific evidence comprehensively demonstrates that no combustion of the tobacco material occurs during use of the EHTP in the EHTS Holder and that the aerosol generated from the EHTP tobacco material is not smoke.

Key takeaways of this report include the following:

- 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.
- Combustion includes both complete and incomplete (partial) combustion processes, such as smoldering (flameless) and flaming combustion.
- Combustion is initiated by ignition and is self-sustaining as long as the exothermic (heat-generating) oxidation reaction is sufficiently strong to overcome heat losses and endothermic (heat consuming) processes, such as vaporization and endothermic thermal decomposition.
- For combustion (burning) of the EHTP tobacco material to occur, the temperature of the tobacco material would need to exceed about 400°C.



- The maximum temperature measured in the tobacco material of the EHTP during use in the EHTS Holder is 320°C. This is well below the temperatures required for combustion of the tobacco material to occur.
- There are no signs of net exothermic (heat-generating) processes in the EHTP tobacco material during use in the EHTS Holder. In fact, when power to the heater is switched off, there is an immediate decrease in the temperature of the tobacco material.
- As the EHTP is heated to temperatures below the ignition temperature of the EHTP tobacco material, the tobacco material undergoes processes such as drying and vaporization, and close to the Heater also thermal decomposition (torrefaction and low-temperature pyrolysis), but no combustion (neither incomplete nor complete).
- The comparison of the chemical composition of the EHTS aerosol generated in oxidative (air) and non-oxidative (nitrogen) environments indicated that oxygen (necessary for combustion to happen) does not play a major role in the thermal decomposition of the EHTP tobacco or the aerosol formation.
- The presence of low levels of gaseous compounds in the EHTS aerosol, such as carbon monoxide, carbon dioxide, nitrogen oxides, etc. (usually associated with combustion), is not evidence that combustion has occurred, as low amounts of these compounds are generated during low-temperature thermal decomposition of tobacco components during heating, independent of the oxygen availability.
- 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.
- While smoke is an aerosol, not all aerosols are smoke. The EHTS aerosol liquid particulate matter (droplets) is not formed from condensation of byproducts of combustion or pyrolysis. The droplets are instead generated when glycerol (added to the tobacco material during processing as an aerosol former) is vaporized and reaches supersaturation and condenses on cooling, forming nuclei, onto which more glycerol, water, nicotine, and other constituents can condense to form liquid aerosol droplets.
- Aerosols formed from the condensation of water vapor, vaporized e-liquids, or vaporized glycerol from the EHTP tobacco material are not smoke and are very different in terms of origin and chemical and physical composition compared with smoke aerosols formed from the combustion and associated high-temperature pyrolysis products generated from the burning of tobacco.
- The aerosol generation process in the EHTS is equivalent to the aerosol generation process in most e-vapor products (EVP), for which aerosol formers (glycerol and propylene glycol) in the e-liquid are vaporized during heating and are subsequently cooled down to form liquid aerosol droplets.
- The EHTP, when used as intended in the EHTS Holder, does not generate solid particles, as demonstrated by detailed experiments involving scanning electron microscopy (SEM)



analysis. Thermodenuder and thermodilution techniques are not able to determine the presence of solid particles alone without being combined with microscopy analysis, such as SEM.

- As the tobacco material in the EHTP is heated and not burned when used in the EHTS Holder, the levels of the majority of the analyzed harmful and potentially harmful constituents in the EHTS aerosol were reduced by >90% compared with the levels in the mainstream smoke of a 3R4F reference cigarette.
- More than 97.8% w/w (mass fraction) of the EHTS mainstream aerosol constituents transfer via vaporization/direct transfer processes to the aerosol from the multicomponent EHTP. Less than 2.2% w/w of the EHTS mainstream aerosol constituents are likely to be formed by torrefaction and low-temperature pyrolysis processes, as suggested by the limited influence of oxygen on the aerosol composition.
- The mere presence of low amounts of pyrolysates in an aerosol does not imply that the aerosol is smoke, as the amount of the pyrolysates must be high enough to reach supersaturation to condense (nucleate) or to react with each other to form particulates. For example, the aerosols generated by EVPs contain low amounts of pyrolysates and are not considered to be smoke.
- The absence of combustion in the EHTP, when used as intended in the EHTS Holder, and that the aerosol generated is not smoke have been substantiated by scientific evidence and have been verified by third-party scientific experts in numerous countries as well as by independent research organizations.

To summarize, scientific evidence comprehensively demonstrates that there is no combustion of the EHTP tobacco material occurring during intended use of the EHTS and that the aerosol generated is not smoke.