



Heated Tobacco Products Task Force

Technical Report

Heated Tobacco Products (HTPs): Standardized Terminology and Recommendations for the Generation and Collection of Emissions

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Table of Contents

1.	Introduction.....	3
2.	Organisations	3
	2.1 Participants	3
3.	Definitions	4
	3.1 Category Definition	5
	3.2 Sub-Category Definitions	5
	3.3 Additional Definitions	7
4.	Recommendations for the Generation and Collection of Emissions	7
	4.1 General Requirements	8
	4.2 Electrically Heated Tobacco Products (eHTPs)	9
	4.3 Aerosol Heated Tobacco Products (aHTPs)	9
	4.4 Carbon Heated Tobacco Products (cHTPs).....	10
5.	References.....	10

1. Introduction

With the emerging development and commercialization of heated tobacco products (HTPs) in the worldwide marketplace, CORESTA has recognised an urgent need for standardization of terminology, recommendations for aerosol generation and collection, identification of priority constituents, and standardization of appropriate analytical methodologies for this product category. In March of 2019, CORESTA held a Workshop in Paris, France, where CORESTA member stakeholders confirmed the need for a HTP Task Force and developed its objectives. The objectives of the Heated Tobacco Product Task Force (HTP TF) are as follows:

- 1) Establish standardized terminology and definitions that encompass all categories of Heated Tobacco Products.
- 2) Define one or more specific approaches and regimes for the generation and collection of emissions for Heated Tobacco Products.
- 3) Define and agree on priority compounds to be analysed (or not); review current CRM suitability, edit, or develop methods for Heated Tobacco Products.

This technical report provides recommended standardized terminology for the HTP category and sub-categories as well as the product attributes for each sub-category to aide with the classification of HTPs. The purpose of standardized terminology is to provide consensus on definitions that describe the HTP category and sub-categories for the purpose of consistency across the scientific community, clearly providing attributes within and differentiating between the category(s) and sub-categories, and thus ensuring that product analysis is conducted using appropriate aerosol collection and analytical methodologies. HTPs are designed to heat a specially prepared tobacco substrate by a separate heat source without combustion of the tobacco substrate, as opposed to combustible tobacco products such as cigarettes, and thus most currently available standardized methods for emission collection and analytical methodologies for constituent measurement will need to be modified or developed specifically for this tobacco product category and sub-categories. The standardized terminology will be updated as the HTP category continues to evolve.

This technical report also provides recommendations for the generation and collection of emissions from HTPs to ensure consistent analytical comparisons across the product categories within the scientific community. The recommendations included in this technical report are based upon currently available scientific literature and references are provided. These recommendations should be confirmed with future proficiency and/or collaborative studies to evaluate the repeatability and reproducibility of these generation and collection procedures.

2. Organisations

2.1 Participants

The HTP TF is comprised of a variety of stakeholders including worldwide HTP manufacturers, independent testing laboratories, manufacturing equipment providers, raw material providers, and regulatory and scientific consultant groups. Members from the following countries participated in the preparation of this technical report (Table 1).

Table 1: Participating countries

Austria	Japan
Canada	Korea
China	Spain
Cuba	Switzerland
France	United Arab Emirates
Germany	United Kingdom
India	United States

3. Definitions

To date, there are more than 100 scientific publications and numerous records (e.g. websites) discussing HTPs. Regulatory agencies, researchers, and manufacturers use a variety of terms and acronyms to describe this product category. For example, U.S. FDA uses the term “Non-Combusted Cigarettes or NCC” [FDA Website] to describe some HTPs, British American Tobacco uses the term “Tobacco Heating Products or THP” [Proctor 2018], and Philip Morris International uses the term “Tobacco Heating System or THS” [Smith 2016]. Japan Tobacco Inc. has referred to a product within this category as a “Novel Tobacco Vapor product or NTV” [Ichitsubo 2018] or “Tobacco Vapor Product or TVP.” Public Health England and the World Health Organization use the term “Heated Tobacco Product or HTP” [McNeill 2018] [WHO Website] to describe this category. These products are also often referred to as Heat-not-Burn products or HnBs by some scientific researchers [Simonavicius, 2019].

The HTP TF members have decided to use the term Heated Tobacco Product (HTP) to best describe this category of products (see section 3.1) and have adapted some additional terms to describe the heating devices and systems (when a product and a device are combined). As described in section 3.3, Additional Definitions, a device providing a source(s) of heat for HTPs is defined as the Tobacco Heating Device (THD). The specific combination of a HTP and a THD will be defined as a Tobacco Heating System (THS). See section 3.3 for complete definitions.

The HTP TF members believe that describing the product category as tobacco heating products (THPs) may lead to the erroneous assumption that tobacco is the heat source which is not the case for products in this category. Additionally, heat-not-burn excludes “tobacco” from the name.

There was also a need to provide sub-categories of HTPs as there are significant design differences among commercialized HTPs worldwide such as products that electrically heat tobacco, use an aerosol to heat tobacco, a combination of both, and products that use smouldering carbon to provide the heat. Different considerations should be made when generating and collecting the aerosols from products in the different sub-categories as described below.

These definitions are important to clearly distinguish HTPs from other tobacco products. The HTP category clearly excludes products such as conventional combustible cigarettes, cigars, roll-your own tobacco, pipe tobacco, e-vapor products (also called electronic cigarettes or e-cigarettes), moist smokeless tobacco, snus, and oral tobacco derived nicotine (OTDN) products. There are also HTPs that are currently out-of-scope for the HTP TF at this time and these are discussed below.

3.1 Category Definition

Heated Tobacco Product (HTP): A product containing a tobacco substrate that is designed to be heated and not combusted by a separate source (e.g. electrical, aerosol, carbon, etc.) to produce a nicotine-containing aerosol.

3.2 Sub-Category Definitions

Electrically Heated Tobacco Product (eHTP): A product containing a tobacco substrate that is heated with an electrical Tobacco Heating Device (THD) without combustion of the tobacco in order to produce a nicotine containing aerosol.

- eHTP category INCLUDES products that:
 - Contain a tobacco substrate
 - Are designed to be used with an electrical Tobacco Heating Device (THD) that:
 - Applies indirect resistive, inductive or other electrical method of heating of the tobacco
 - Prevents combustion of the tobacco substrate
 - Are battery powered
 - Have a puff count and/or use duration that is limited by either the fixed size of the consumable (the HTP) or device hardware/software
 - Are referred to as a Tobacco Heating System (THS) when used in conjunction with a THD
- eHTP category MAY INCLUDE products that have:
 - A consumable with tobacco wrapped in paper or other material to contain the tobacco substrate during use
- eHTP category DOES NOT INCLUDE products that have:
 - Combustion of any material including tobacco
 - Electrically heated waterpipe tobacco products (See below)
 - Electrically heated loose-leaf tobacco products that do not have a fixed size of the consumable (See below)

Aerosol Heated Tobacco Product (aHTP): A product containing a tobacco substrate that is heated by an aerosol produced from an electrical Tobacco Heating Device (THD) without combustion of the tobacco in order to produce a nicotine-containing aerosol.

- aHTP category INCLUDES products that:
 - Contain a tobacco substrate
 - Are designed to be used with an electrical Tobacco Heating Device (THD) that:
 - Produces an aerosol from an e-liquid based consumable that heats the tobacco substrate
 - Prevents combustion of the tobacco substrate
 - Are battery powered
 - Have a puff count and/or use duration that is limited by either the fixed size of the consumable (the HTP) or device hardware/software
 - Are referred to as a Tobacco Heating System (THS) when used in conjunction with a THD

- aHTP category MAY INCLUDE products that have:
 - A consumable with tobacco wrapped in paper or other material to contain the tobacco substrate during use
 - Indirect resistive, inductive or other electrical method of heating of the tobacco in addition to the e-liquid based consumable that heats the tobacco substrate
 - A tobacco consumable that is changed more frequently than the e-liquid
- aHTP category DOES NOT INCLUDE products that have:
 - Combustion of any material including tobacco

aHTPs are often referred to as “hybrids”.

Carbon Heated Tobacco Product (cHTP): A product containing a tobacco substrate that is heated by smouldering carbon in order to produce a nicotine-containing aerosol.

- cHTP category INCLUDES products that have:
 - A consumable containing a tobacco substrate
 - Indirect heating of the tobacco by smouldering carbon
 - Puff count and/or duration is limited to a single use occasion per consumable
- cHTP category MAY INCLUDE products that have:
 - A disposable tobacco heating system
 - Carbon-based heat source where smouldering is initiated by fire
 - Combustion of the heat source
- cHTP category DOES NOT INCLUDE products that are:
 - Waterpipe tobacco products where tobacco is heated by smouldering carbon (see below)

Tobacco products that heat tobacco but are currently out of scope for the CORESTA HTP TF:

- Waterpipe Tobacco Product also referred to as Shisha or Hookah. While some of these products electrically heat tobacco and some use smouldering carbon to heat tobacco, these products are currently out of scope. Unique testing considerations will need to be made to standardize emission collection and constituent measurements.
- Loose-leaf tobacco heating products that do not have a fixed size of the consumable. These products do not have fixed size tobacco consumable and thus unique testing considerations will need to be made to standardize emission collection and constituent measurements.

3.3 Additional Definitions

Aerosol – A suspension of particles in air or gas. The particles can be comprised of only liquids or a mixture of liquids and solids.

Aerosol Collected Mass (ACM) – The gravimetrically determined mass of aerosol collected.

Combustion – An exothermic chemical process of oxidation that occurs at a rate fast enough to produce heat and usually light [NFPA Glossary of Terms 2019 Edition, p354]

Consumable – A portion of the heated tobacco product consumed or depleted through single or multiple use.

E-Liquid Based Consumable – A liquid that is composed of propylene glycol and/or glycerine (also known as vegetable glycerine) similar to the liquids commonly used for e-vapor products (also called electronic cigarettes or e-cigarettes). The liquid may or may not contain some level of nicotine, flavour and water.

Emissions – Substances that are released into the aerosol when a heated tobacco product is consumed as intended.

Tobacco Heating Device (THD) – Device providing the source(s) of heat required to directly or indirectly heat a HTP without combustion of the heated tobacco substrate.

Tobacco Heating System (THS) – Specific combination of a HTP and a tobacco heating device (THD) which, based on information made available to the consumer by the provider, shall be used together.

Tobacco Substrate – A material (substrate) that contains processed tobacco and may contain aerosol generation agents and other processing aids (e.g. binders) and flavourings.

Smouldering – Sluggish burning of organic material that occurs without flame.

4. Recommendations for the Generation and Collection of Emissions

The diversity of product design across the range of HTPs in scope for the generation and collection of emissions necessitated separate approaches for each sub-category. When determining appropriate approaches, the HTP TF considered the following critical requirements:

The selected approaches must:

- A) Deliver reproducible yields of aerosols and substances of interest
- B) Be technically feasible using available technology
- C) Lie within the normal range of consumer use and/or fit within the product's intended use parameters (e.g. manufacturer design)

The purpose of the recommended approaches is to generate aerosol for analysis in order to aid product development and effective regulation. It is not intended to replicate human use behaviour. These recommendations are provided based upon the currently available published scientific literature (references provided).

4.1 General Requirements

Across all subcategories of HTP a number of considerations are universally applicable:

- A. The generated emissions are hygroscopic in nature due to the high level of propylene glycol and/or glycerol in the aerosol. As such, it is necessary to control the testing atmosphere in order to minimise the impact of environmental fluctuations on results. ISO 3402: 1999 testing atmosphere was agreed to be appropriate by HTP TF members due to its existing adoption in testing laboratories.
- B. Due to the potential for cross-contamination and the fact that HTPs typically have lower levels of harmful and potentially harmful constituents than combustible tobacco products such as cigarettes, the test environment should segregate HTPs from combusted tobacco products where practical to do so. If it is not practical to segregate HTPs from combusted tobacco products, it is imperative that the laboratory effectively monitor for contamination and carryover with puffing blanks from one or more empty ports to assess background from the environment, equipment, and supplies. Puffing blanks are collected and prepared exactly as the samples except that a HTP device is not inserted into the device holder/ aerosol trap.
- C. Sampling should reflect the known variation of consumables and devices. Test replication should be sufficient to represent the expected or known range of product variation plus any additional variation associated with the method.
- D. Sample conditioning according to ISO 3402: 1999 is required for conventional combusted cigarettes in order to normalise the temperature and moisture content of the tobacco, as this influences the burning process. It was recognised that moisture conditioning is of limited relevance to HTPs. The eHTP and aHTP consumables should be temperature equilibrated in sealed packs according to the time and environmental conditions specified in ISO 3402: 1999 and removed from the pack immediately prior to testing, in order to avoid absorption of environmental moisture by the tobacco substrate which may influence ACM yields. Samples removed from open packs may be kept in sealed containers for a maximum of 4 hours; after this time they should no longer be regarded as suitable for testing and must be discarded. The reason for this is to avoid the use of aged samples which may have slowly absorbed atmospheric moisture from the air inside the sealed container. The effect of ISO 3402: 1999 conditioning on tip ignition and yield may require evaluation for cHTP, although it was previously reported that conditioning is not applied to these products (Borgerding et al., 1990).
- E. Battery state of charge and contamination of heating surfaces may influence aerosol generation and composition. Therefore, devices should be fully charged and cleaned according to manufacturer's instructions prior to each test run.
- F. Several products with non-cylindrical mouthpieces are commercially available. If the shape of the test items is other than cylindrical, specific sealing and connection elements are required. The design of these elements shall be in a way that the test items are connected to the port of the machine in a leak free manner. They shall be impermeable to air and the generated aerosol.
- G. The neoprene washer mandated by ISO 20779:2018 must be omitted, as its purpose was specifically related to channel ventilated conventional combustible cigarettes. Furthermore, this is not a requirement of ISO 20768: 2018.
- H. If a device indicates an error or ceases to operate during the test, the results will be deemed invalid.

- I. Where glass fibre filter pads (e.g. Cambridge Filter Pads (CFPs) are used to trap generated emissions, all interior surfaces of the pad holder must be wiped with the back side of the same pad after aerosol collection to ensure condensed aerosol on these surfaces is collected.

4.2 Electrically Heated Tobacco Products (eHTPs)

Health Canada Method T-115: 2016 (HCI) (subsequently been developed into ISO 20778:2018) has been effectively used with modifications as an approach for aerosol generation in several studies on eHTP (e.g. 55 cc puff volume, 2 second puff duration, and 30 second puff interval) [Jaccard et al 2017; Forster et al 2018; Farsalinos et al 2018; Szostak et al 2019]. Due to the existing body of literature, ISO 20778:2018 (HCI T-115: 1999) it was judged appropriate for recommendation as a suitable approach for eHTP aerosol collection with the following modifications.

Preheating of commercially available eHTPs following the product's intended use parameters may be required prior to collection of the first puff. Completion of the preheating cycle is indicated on current devices by LED pattern and/or vibration. It is recommended that the start of collection is synchronized to this indication.

Currently available devices have a defined heating duration and completion of the heating cycle is indicated by LEDs and/or vibration. It is recommended that one further puff is taken after this as the endpoint. Data may be required to demonstrate that additional puffs do not give rise to increased levels of emissions.

Health Canada Method T-115:2016 and ISO 20778:2018 both require filter ventilation holes to be occluded during testing. The rationale for this is that users may block these holes with their lips or fingers during normal consumption and subsequently affect smoke yields. Vent blocking should be applied to eHTP consumables only if (a) ventilation holes in the product 'filter' section can be occluded in normal use and (b) vent blocking does not compromise the operation of the device (for example, air inlet holes in the device are not 'vents' and must not be occluded in testing) (Gee et al, 2017).

ISO 20778:2018 requires ambient air velocities surrounding cigarettes to be measured and controlled, as this will influence the combustion process. As eHTP consumables are not intended to be combusted, this requirement does not apply to eHTP aerosol generation and collection.

Care must be taken during aerosol collection to avoid overloading the collection system to prevent analyte breakthrough. For example, it has been reported that the capacity of a 44 mm Cambridge Filter Pad is up to 380 mg of smoke under the HCI regime for conventional cigarettes (Drake et al, 2012).

4.3 Aerosol Heated Tobacco Products (aHTPs)

Current products do not have a defined heating cycle but are either button- or puff-activated. Similar to e-vapour products, consistent co-ordination of device activation and puffing is required. Some devices may require positioning at angles other than horizontal for testing, and preheating of the consumable is not required.

Due to the above, an adaptation of ISO 20768:2018 was agreed to be a suitable candidate regime for the subcategory aHTP.

Termination of aerosol generation is indicated on current commercial aHTPs by manufacturer's instructions and/or LED indication. Hybrid products (aHTPs) generate large amounts of aerosol due to the vaporization and condensation of the e-liquid based consumable in addition to the tobacco aerosol; therefore, there is potential to overload the collection system. It has been reported for e-vapour aerosol that the capacity of a 44 mm Cambridge Filter Pad is up to 650 mg and this consideration should be made when collecting aerosol from aHTPs (Miller et al, 2016).

4.4 Carbon Heated Tobacco Products (cHTPs)

In contrast to the other two sub-categories, airflow must be managed around the test piece because of the combustible heat source. This necessitates machine smoking conditions corresponding to Health Canada Method T-115:2016 (e.g. 55 cm³ puff volume, 2 second puff duration, and 30 second puff interval) and ISO 20778:2018. Vent blocking should be applied to cHTP consumables only if (a) ventilation holes in the product 'filter' section can be occluded in normal use and (b) vent blocking does not compromise the operation of the product (for example, air inlet holes at the carbon heat source end of the product are not 'vents' and must not be occluded in testing).

The start of collection should be commenced once the carbon tip has been ignited, and it is recommended that an electrical lighting system is used. If electrical lighters are used they must be preheated for 30 s prior to puff initiation with the lighter within 1 mm of the carbon heat source. In order to determine the puff number to be used when testing a cHTP, a pre-test must be conducted. In that test, the number of puffs during which the heat source emits light (i.e., glows "red" during puffing) is determined for twenty (20) individual cHTP cigarettes. The puff number to be used for testing is calculated as the average result from the twenty individual cHTP, rounded to the next higher integer value, with three (3) additional "clearing" puffs added in order to ensure any aerosol yielded due to residual heat is captured.

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