Heated Tobacco Products (HTP) Task Force: CORESTA Update

- **Task Force Coordinator: Helena Digard**
  - British American Tobacco, Southampton - UK
- **Secretary and Study Coordinator: Jason Flora**
  - Altria Client Services LLC, Richmond VA - USA

HTP – 07 October 2019, Hamburg, Germany

Potentially Reduced Risk Products (PRRP)

Tobacco based products

eHTP

Hybrids

Carbon tip

Heated Tobacco Products

Smokeless tobacco

Nicotine based products

E-Cigarettes (Vapour)

Helena Digard, Paris HTP Workshop March 26, 2019

HTP Task Force History

- October 2018 (Kunming, China) CORESTA Congress discussion and engaged interest in the potential for a HTP Task Force
- March 2019 (Paris, France): HTP Workshop confirmed the need for a HTP Task Force and developed objectives
- June 2019 (London, England): Inaugural HTP TF meeting
- October 2019 (Hamburg, Germany): 2nd HTP TF meeting

Participation in the HTP TF

There has been a continued large interest in participation in the HTP TF:

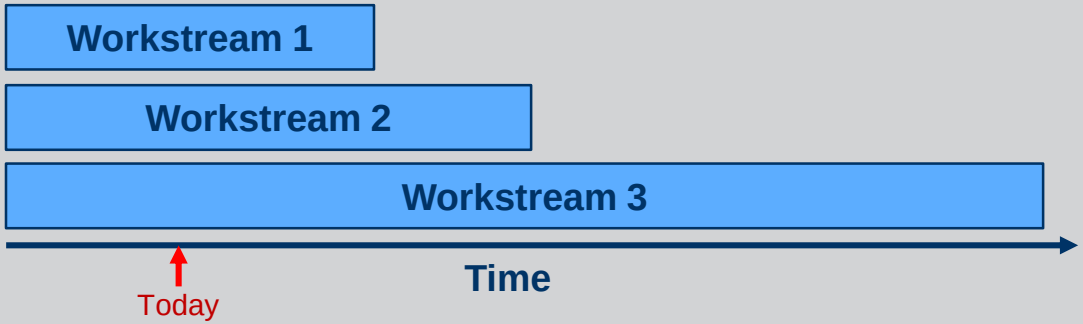
- **Attendees = 50**
- **Companies Represented = 36**
  - **Suppliers, manufacturers, laboratories etc.**
- **Countries = 13**

Objectives

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.

Workstream Approach

- In the spirit of rapid results we have taken a “divide and conquer” workstream approach to advance our objectives
- Volunteers to lead and participate in each workstream occurred in our first meeting in June 2019
- Team outputs were shared on Saturday at our Task Force Meeting and will be summarized in the following slides



June 2019 TF Meeting

❖ Created Objective Workstreams with Volunteers from Meeting Participants

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

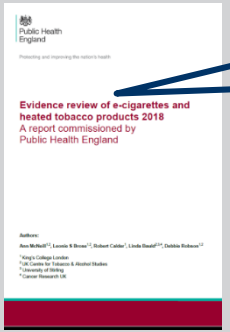
Objective 1:

Establish standardized terminology and definitions that encompass all categories of Heated Tobacco Products.

Jason Flora

What Do We Call This Category?

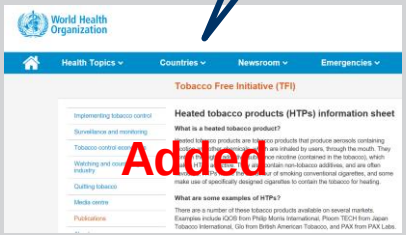
- Literature: 100s of publications on PRRPs, with approx. 100 on HTPs (as of end 2018)
- We should consider the terminology used by manufacturers and regulators



Public Health England: HTP

PMI: THS

WHO: HTP



US FDA: NCC

JTI: NTV

BAT: THP

Purpose of the Definitions

- **Providing consensus on definitions:**
  - **Heated Tobacco Product (as a category)**
  - **Sub-Categories**
  - **Terminology**
- **Creating consistency across the scientific community**
  - **Attributes within and differentiating between the category(s) and sub-categories**
- **Ensuring product analysis is conducted using appropriate aerosol collection and analytical methodologies.**

Category Definition

- The category: **Heated Tobacco Product (HTP)**
  - Tobacco Heating System or Product could suggest that the tobacco is doing the heating
  - Heat not Burn suggests a criteria that no combustion (e.g., burning) can occur

- **Definition:**

  A system containing tobacco that is heated by a separate source (e.g., electrical, aerosol, carbon) and designed to produce a nicotine containing aerosol.

Sub-Categories

- Electrically Heated Tobacco Product (eHTP)
- Aerosol Heated Tobacco Product (aHTP) – also known as a hybrid
- Carbon Heated Tobacco Product (cHTP)
- Other: Sub-categories that are currently out of scope:
  - Waterpipe Heated Tobacco Product (wpHTP)- Shisha/Hookah
  - Loose-leaf heating tobacco products (e.g. PAX)

Sub-Categories Definitions

- **eHTP** : A HTP where the tobacco is electrically heated
- **aHTP** : A HTP where the tobacco is heated by an aerosol
- **cHTP** : A HTP where the tobacco is heated by smouldering carbon

Workstream 1 - Next Steps and Actions:

- Refining the attributes for each sub-category, to include:
  - Must haves
  - May haves
  - Does not include
- Developing definitions for required “terminology”
- Begin drafting the technical report

Objective 2:

Define one or more specific approaches and regimes for the generation and collection of emissions for Heated Tobacco Products.

Colin Sinclair

Conditioning and Testing

- **The conditioning atmosphere is according to ISO 3402 (Tobacco and Tobacco Products - Atmosphere for Conditioning and Testing)**
  - **HTPs are “hydroscopic” in nature, and effects to consumables are variable within the category**
  - **The purpose of conditioning is to ensure a uniform product temperature**
  - **Samples should be tested as soon as they have been removed from their packaging**
- **The testing atmosphere is ISO 3402**
  - **Devices must be fully charged and cleaned according to manufacturer’s instructions prior to each test run.**

Proposed Aerosol Generation Regimes

- **eHTP: ISO 20778: 2018 (Cigarettes - Routine analytical cigarette smoking machine – Intense smoking regime)**
  - **55ml (puff volume); 2 second (puff duration); 30 second (puff interval)**
  - **Vent blocking only if it is possible for user to do so and device function is not compromised.**
- **aHTP - ISO 20768:2018/ CRM 81 (Vapour products – Routine analytical vaping machine)**
  - **55ml (puff volume); 3 second (puff duration); 30 second (puff interval)**
- **cHTP - ISO 20778: 2018. Vent blocking required**

Workstream 2 - Next Steps and Actions:

- **Incorporate proposed conditioning and testing regimes into Workstream 1 technical report**
  - **Will include justifications from existing scientific literature and presented data**
- **Considering collaborative study**
  - **Alignment with ISO WG 22**
  - **Identification of products for inclusion**

Objective 3:

Define and agree on priority compounds to be analysed (or not); review current CRM suitability, edit, or develop methods for Heated Tobacco Products.

Maxim Belushkin

What Analytes Do We Test (Priorities)?

- **Priority analytes identified:**

1	2	3
Basic analytes: Propylene glycol, glycerine, nicotine CO, NO, NOx	Carbonyls	TSNAs Volatiles B[a]P / PAHs

- **Review of methodologies currently used, to identify potential method development options:**
  - **What existing ISO or CRM methods can be utilized**
  - **Where no standard analytical methods are used, diversity of methods between laboratories was assessed**

Method Feedback Summary

Priority for product	Complexity	Analyte	Comments
1	1	Propylene glycol, glycerine, nicotine	Generally, CRM 84 or ISO 22253 or ISO 10315 – which are generally similar and based on GC-FID, are applied with essentially no modification, or minor adaptations (calibration range)
1	1	CO	Generally, ISO 8454 or CRM-5 or T-115 are applied with no or minor modification (calibration range, use of dual-range CO meters). Most laboratories reported methods based on ISO 8454.
1	2	NO, NOx	Despite no standardized method available at CORESTA or ISO, all laboratories reported in-house methodologies using chemiluminescence detectors (either in-house or based on T-110).

Workstream 3 - Next Steps and Actions:

- Basic Analytes: Develop a proposal for puffing regime collaborative trial
  - Alignment with ISO WG 22
- CO, NO, NOx: Develop a proposal for proficiency study
  - Calibration range considerations for sub-categories required
  - Alignment with ISO WG 22
- Evaluate appropriate justification for LOD/LOQ for “non-detectable” analytes

Key Activities

- **Draft technical report (submitted SC – Q2, 2020)**
  - **Definitions and terminology**
  - **Proposed conditioning, aerosol collection regimes and scientific justifications**
- **Participate and align with ISO technical advisory committee - ISO/TC 126/WG 22, tobacco heating systems.**
- **Develop study plans:**
  - **Collaborative trial: puffing regime with basic analytes**
  - **Proficiency study: CO, NO, NOx**

Thank You!!