



# **Product Use Behaviour (PUB) Sub-Group Annual Report**

**Coordinator: Dr Krishna Prasad (BAT)**

**Secretary/ SC Liaison: Dr Xavier Cahours (IMB)**

**Yucatan Room**

**Cancun, Mexico**

**Thursday, 12 October 2023**



# CORESTA PUB Sub-Group: Objectives

1. Critique and review published papers on all aspects of tobacco and **nicotine** products' **perception and** use behaviour, and publish in peer-reviewed journals.
2. Examine unpublished reports and work on the subject with a view to recommending publication of suitable papers in peer-reviewed journals.
3. Identify gaps in total knowledge and suggest suitable work to provide the necessary information.



# PUB Sub-Group Meetings 2023

No	Date	Meeting	Time (CET)	Chair
1	19 Apr 2023	PUB SG 2023 Spring meeting Antibes Juan Les Pins, France	14:00 – 18:00	Dr. K Prasad & Dr. X Cahours
2	07 Oct 2023	PUB SG 2023 Fall meeting Cancun, Mexico	14:00 – 18:00	Dr. K Prasad & Dr. X Cahours

The details of the topics discussed, timelines and plan of action are documented in the meeting minutes prepared by Xavier Cahours available on the CORESTA website.

Several other virtual meetings were held by the respective NWIP leaders to progress the projects in addition to CROM Task Force meetings & workshops were lead by Christelle Chrea.



# Outline: 2023 Activities

1. NWIP #169 – VLNC Watching Brief Update – Ongoing
2. NWIP #273 – Definitions of use behaviour and exposure terminology – Complete
3. NWIP #278 – Managing Data Generated by Connected Devices - Active
4. NWIP #351 – Methodological Considerations for ‘Actual Use’ Study - New
5. NWIP #366 – Examining scientific evidence on the utility of “Nicotine Flux” - New
6. Other Activities
  - Unpublished topography data collation & review
  - CROM Task Force – WG02, WG03, WG04 & WG05
7. Next Steps
  - Nicotine Pouches: Assessment of consumer exposure
  - Gap analysis from WHO Report

- **Since 2022:**

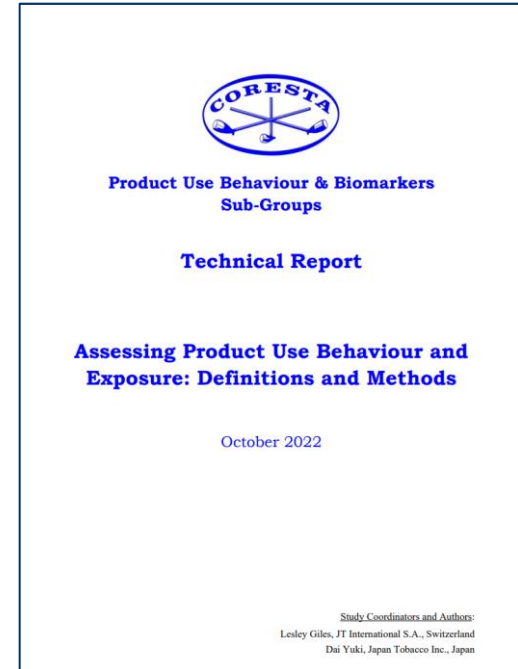
- At least, 9 peer reviewed publications have been identified and reviewed
  - Studies are not sufficiently large, representative, or of sufficient duration to be able to predict the public health impact of regulatory action, be it immediate or gradual reduction in nicotine content
  - Research and potential conclusions are impacted by participant non-compliance
  - No consensus on the level of nicotine that is non-addictive
- Seven RCTs on this topic have been registered as on-going
- Prominent researchers continue to assert that more research is needed



## 2.0 NWIP #273

Define product use behaviour terms

- To define the terms and methods used for assessing product use behaviour and tobacco exposure, with the objective of generating a uniform application of the terms used by scientists working in this field of research.
- 2013 - Use Behaviour Definitions and Methods expanded to include use behaviour of products such as e-cigarettes, HTP and oral nicotine products published on CORESTA website.
- Report is being converted to a manuscript ready for submission:
  - Prepare draft for publication scientific journal, distribute for review - Q1 2023 ✓
  - Consolidate comments and submit for publication: Contributions to Tobacco & Nicotine Research - Q1 2024





## 3.0 NWIP #278

### Recommended Methods for Managing Data Generated by Connected Devices

- Recommend best practices for the collection and management of data from connected topography devices during research and development of inhalable reduced harm products
- **Scope:**
  - Identification of data that likely provide insights into product use behaviour in actual use, real world environments
  - Framework for device data generation/collection, storage, distribution and communication
  - Considerations for data integrity (i.e., traceability), privacy, and security

## Progress to date:

- Survey puffing topography scientific literature ✓
- Summarise puffing topography parameters reported ✓
- Propose core puffing parameters ✓
- Identify data format for considerations ✓
- Draft table of contents for project report ✓

## Next Steps:

- Develop consensus on parameters and data format, and guidance on storage requirements for recommended data format
- Define connectivity requirements based on actual need of data in real life studies, including privacy and security considerations
- Perform analysis of technologies / protocols based on defined connectivity requirements





## 4.0 NWIP #351

### Methodological Considerations and Best Practices for Actual Use Study Designs

- **Background**

- Tobacco regulators such as the US FDA require information to estimate the impact of a new product on public health prior to market authorization.
  - Including use behaviors and the likelihood that the new product displace use of other, higher risk, combustible products, after introduction.
  - There are challenges in obtaining this type of information for new products that are not yet authorized for sale (investigational tobacco products).

- **Purpose**

- Provide guidance on the design or conduct of Actual Use studies shared via the FDA's 2021 PMTA final rule or the recent final guidance for conducting TPPI studies.



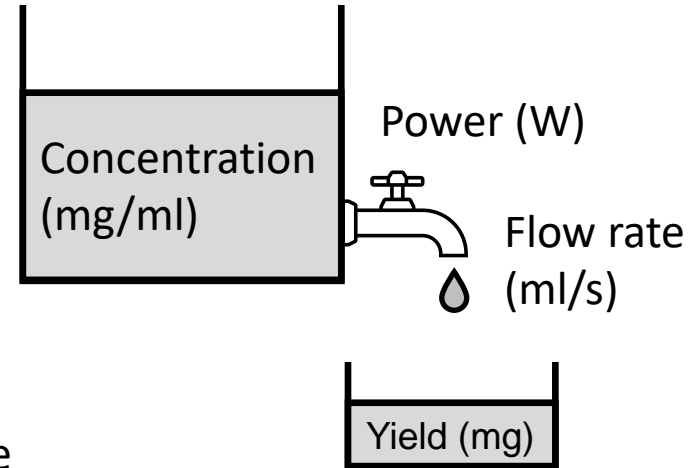
# Status Update

Deliverable/Project Stage	Expected Date
<b>Stage 1:</b> Establish core team, agree on topics and scope of work / solicit approval from CORESTA SC ( <b>Established &amp; Agreed Nov 2022</b> ) ✓	Q4 2022
<b>Stage 2:</b> Establish timeline, develop outline, assign topics among writing team ( <b>Accomplished Jun 2023</b> ) ✓	Q2 2023
<b>Stage 3:</b> Gather information, drafting, assembly into report, internal review, external review, completion of Technical Report and Submission to General Secretariat ( <b>On Track</b> ) ✓	Q1/Q2 2024
<b>Stage 4:</b> Publication of Technical Report	Q2/Q3 2024
<b>Stage 5:</b> Develop manuscript and submit for publication; disseminate results via conference engagement	Q3/Q4 2024

Examining the scientific evidence on the utility of “Nicotine Flux” as a potential screening tool to assess abuse liability across a diverse range of tobacco and nicotine products.

Nicotine flux is the rate at which nicotine is emitted or released from a product

→ the yield per unit time (mg/s or µg/s)



$$\text{Flux (mg/s)} = \text{Concentration} \times \text{Flow rate}$$

Figure adapted from El Hourani, *et al.* (2022). *Tob Control*

## Progress to date:

- **Stage 1. Scope of work – defined ✓**
  - Identify publicly available literature on nicotine flux
  - Review data and role of nicotine flux in assessing abuse liability
  - Draft report including review of methods, results and limitations to determine nicotine flux
- **Stage 2. Literature search and review – on track**
  - Data sources: Peer-reviewed literature, scientific and regulatory reports, etc.
  - Search terms: “nicotine flux”, “nicotine yield”, “nicotine emission”, to be further developed

## Next Steps:

- Complete literature and data search – Q4 2023
- Draft technical report on findings and analysis – Q2 2024
- Collate review comments from core team and scientific commission– Q4 2024
- Issue technical report – Q1 2025

### Puffing Topography Parameters of Heated Tobacco Products (HTPs)

1. Currently, very limited information is available on puffing topography of HTP and almost all research data are on eHTP.
  - Eight research studies available on topography of eHTP (Ludicke et al. 2016; Haziza et al. 2016a [REXC-03-EU]; Haziza et al. 2016b [REXC-04-JP]; Not published [REXA-07-JP]; Not published [REXA-08-US]; Gee et al. 2018; Jones et al. 2020; Prasad et al. 2022).
  - Only one study is available on topography of aHTP (Yuki et al, 2018)
  - Summarized topography data is broadly inline with HCI (55 mL puff over 2 sec every 30 sec) except for short Inter Puff Interval.
2. **CROM Task Force – WG02, WG03, WG04 & WG05**
  - Update provided by Dr Cahours yesterday (Wednesday 11 October 2023, Session 9)

#### Methodological considerations

##### Used pouches

Consumers/study participants use pouch for a defined duration

- Duration? For previous, similar research on snus, BAT used mean usage duration determined from a survey of several thousand snus users
- Number of pouches? If constituent of interest is at a very low level, several pouches may need to be collected per participant for constituent concentration to be quantifiable

##### Reference pouches

Collect reference (unused) pouch

- Suggest either one corresponding reference pouch per used pouch – taking a pouch from the same container may reduce variability

##### Containers

Consider the collection container to ensure no effect on constituent of interest (e.g. absorption)

##### Shipping

Ship samples under frozen conditions to appropriate analytical facility

# Heated tobacco products: Summary of research and evidence of health impacts



- Evidence still limited, suggests these products could contribute to the tobacco harm reduction. Long-term studies are required to substantiate similar findings.

The following research areas relating to HTP research were identified as gaps relevant to PUB SG activities:

- **Puffing topography, dual use and transitions between no use, poly- and exclusive use (and relative impact on biomarkers of exposure).**
- **Perceptions of HTPs and how they influence consumers' decisions to initiate use, poly-use, exclusive use or rejection of these products.**

<https://www.who.int/publications/i/item/9789240042490>



1. Prepare and present different options to assess consumer exposure to various ingredients from use of oral nicotine pouches for CORESTA SC's consideration
2. Prepare and discuss the NWIP for 'Human Factors' methodologies and their scope in regulatory submission 
3. Present options to progress 'Population Modelling' in a proposal document for consideration by CORESTA SC
4. Identify opportunities to fill the gaps highlighted in WHO report 1047 



*Analyses to evaluate the impact of **Human Factors** to identify risks associated with ‘real world’ use of new tobacco product and demonstrate that potential risks associated with use for both users and non-users have been mitigated.*

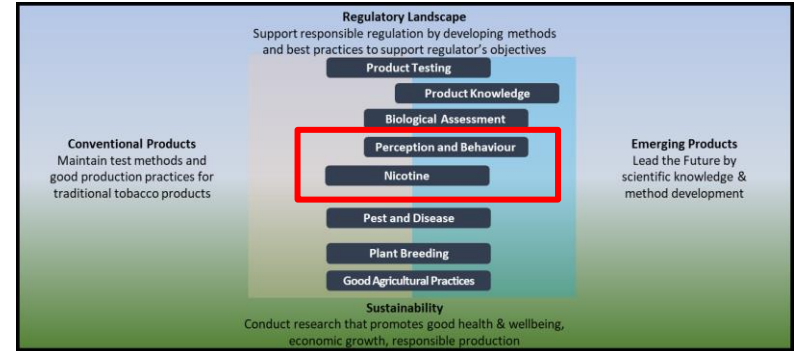


# PUB SG/TF Contributions to the Strategy House

## Strategic Areas for PUB



## Strategic Subjects for PUB



Strategic Subject	Delivered	2 year deliverables	5-year plan
<b>Consumer: Use Behaviour &amp; Exposure</b>	<ul style="list-style-type: none"> <li>3 New WIPs: Connected devices data management, AUS, Nicotine flux</li> <li>A publication on Use Behaviour and Exposure terminology</li> </ul>	<ul style="list-style-type: none"> <li>Tools for evaluation of consumer use behaviour &amp; exposure</li> <li>New TF on Population Modelling</li> </ul>	<p><b>Investigate product use behaviour for emerging products</b></p> <p><b>Provide guidance to develop fit for purpose population modeling</b></p>
<b>Comprehension and Perception</b>	CROM TF	<ul style="list-style-type: none"> <li>Tools for evaluation of consumer exposure, perception and behaviour</li> </ul>	<b>Investigate Consumer Reported Outcome Measures for emerging products</b>



# Thank You

## Any Questions?