



# **E-Vapour (EVAP) Sub-Group Update**

**Cancun, Mexico**

**9<sup>th</sup> October 2023**



# E-Vapour Product Sub-Group

## Scope:

- To identify areas of scientific research and conduct studies that will characterize liquids, e-vapour product emissions, and device properties and performance
- To develop and publish methods and guides
- To organize and conduct periodic proficiency/collaborative studies of identified constituents in liquids and/or e-vapour product aerosol



# E-Vapour Products SG Membership

- **SG Coordinator**
  - Gene Gillman – JUUL Labs
- **SG Secretary**
  - Colin Sinclair – Philip Morris International
- **SC Liaison**
  - Cyril Jeannet – Philip Morris International
- **SG membership**
  - ≈ 100 people US, EU, Asia (~40 attend in person meetings)
  - E-Vapour Product Companies, Suppliers, Contract Labs, Regulatory Agencies, Academia, Others, .....

- **CRM No. 102 - Determination of Tobacco-Specific Nitrosamines in E-Liquid by LC-MS/MS Published January 2023**
- **Supporting technical study report**

This Recommended Method is applicable to the determination of tobacco-specific nitrosamines (TSNAs) in electronic cigarette liquids (e-liquids). The TSNAs determined with this method are *N*-nitrosonornicotine (NNN), 4-(*N*-methylnitrosoamino)-1-(3-pyridyl)-1-butanone (NNK), *N*-nitrosoanatabine (NAT), and *N*-nitrosoanabasine (NAB). The e-liquids used may be of any flavour, including extracted tobacco-derived flavours.

- **CRM No. 98 - Determination of Select Metals in E-Liquid by ICP-MS published October 2023**
- **Supporting technical study report**

This Recommended Method is applicable to the determination of select metals in e-liquids. The metals determined with this method are: chromium, iron, nickel, copper, zinc, arsenic, cadmium, tin, silver and lead.



## Actions since last update

- **Projects launched:**
  - **2023 Collaborative Study – Reference Device for E-Cigarette Aerosol**
  - **Guidelines for Non-targeted Analysis of E-vapour and Heated Tobacco Product Substrates and Emissions (joint project with HTP)**
  - **Review of Guide No. 26 - Designing E-Vapour Product Stability Studies**
  - **Review of Guide No. 25 - Aerosol Collection and Considerations when Testing E-Vapour Product Technologies**
  - **Review of Guide No. 22 - Selection of Appropriate Intense Vaping Regimes for E-Vapour Devices**
- **Small expert group launched on glycidol in aerosol**



## October 7<sup>th</sup> SG meeting

- **38 CORESTA members jointed the Subgroup meeting on October 7<sup>th</sup>, 2023**
- **23 Organizations were represented during the meeting**
- **Updates were presented on all current work items**
- **Updates were given on the current work programs for CEN and ISO TC 126**
- **Next meeting in Spring 2024, details are to be decided in concert with the other Sub-Groups**



# **CORESTA Reference Device Collaborative Study**

**Project Lead: Randy Weidman  
R.J. Reynolds**





# New Reference Device Update

- **During our Spring 2022 Subgroup meeting the group discuss several new workstreams.**
  - **TSNAs in aerosol, aerosol pH and glycidol in aerosol**
- **Studies would have used our existing reference ENDS device, Aspire tank and Evolve power supply unit.**
  - **Devices last used to support the 2019 Collaborative Study for the Determination of Formaldehyde and Acetaldehyde in E-Vapour Product Aerosol**



# New Reference Device Update

- **Concerns about device performance and consistency were raised by Thomas Schmidt (Koerber Tech), Spring 2022**
  - Small study was initiated to determine if the issue impacted all devices.
- **During the Fall 2022 meeting, Joe Jablonski (Enthalpy) presented intra and inter day reproducibility data from the reference device**
  - Noted poor reproducibility for both intra and inter day aerosol yields. Reseating the tank and/or replacing the coil did not eliminate the issues. Device contains an internal rechargeable battery that was ~4 years old at the time of this study.
- **Device performance was not consistent with the 2019 studies. Replacement device is needed to conducted future studies**



# 2023 Aerosol Proficiency Study: New Reference Device Update

- **2023 CORESTA ENDS reference device.**
  - **Removable battery:** Simplify shipping requirements and potentially extend device service life.
  - **Devices supplied by Shenzhen Smoore Technology Limited**
    - Lithium-ion battery supplied by each laboratory
  - **Updated version of the Aspire Nautilus Tank (TPD compliant) supplied by Kober Tech.**
  - **Power supply and Tank are ready to ship.**
  - **r and R data is needed to qualify the device for use in collaborative studies.**



# 2023 Aerosol Proficiency Study: New Reference Device Update

- Repeat of 2019 Collaborative Study: Reference Device for e-Cigarette Aerosol. Approved NWIP
- Key parameters: puff count, nicotine, propylene glycol, glycerin, and ACM/Device Mass Loss
- Four e-liquid samples: Unflavored, Tobacco, Menthol and Sweet.
  - Shipped without nicotine due to shipping restrictions
- Protocol finalized and distributed to participants, Sept. 29, 2023
- Participants have begun requesting the testing materials from the product suppliers
- Study results to be presented at the Spring 2024 meeting



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# 2023 Aerosol Proficiency Study: Reference Device Update

Date	Activity
Jun-Jul, 2023	Laboratories state their intention to participate and prepare for the study
Oct, 2023	Finalize protocol and distribute to participants
Oct, 2023	Product volunteers ship samples to the laboratories
Dec, 2023	Laboratories submit results
Spring Sub-Group Meeting, 2024	Report at Task Force meeting



# **Glycidol in aerosol Small Expert Group**

**Lead: Alexandra Martin  
Enthalpy Specialty Labs**



# Glycidol in e-liquid – small group

- **Analytical method was proposed by Juul Labs Inc.**
  - **Method details presented at 2023 TSRC**
- **Propose to initiate work on just e-liquid until reference device is qualified**
- **Distributed potential method to working group.**
- **Requested each lab to perform an in-house trial.**
- **Next Steps, submit a NWIP to the Scientific Commission. If approved the SG would like to conduct a collaborative study in Q4 2023.**





# Update from SG meeting

- **Distribute potential method to working group.**
  - Draft method distributed 20-Jul-2023
  - Revised method distributed 7-Sep-2023
  - Comments received on proposed method.
- **In-house trials @ Enthalpy**
  - Preliminary trials look very promising.
  - Method has been streamlined:
  - LOQ ~ 2 ng/mL so the LOQ for e-liquid is 40 ng/mL(e-liquid)
  - GCMS ~ 15 minute run time.



# **Non-targeted analysis Joint EVAP and HTP Work Item**

**Owen Bussey – Lead (EVAP)**

**R.J. Reynolds**

**Malcolm Saxton - Lead (HTP)**

**Broughton**



# Non-targeted Analysis

- **Collaborative effort between the EVAP and HTP Sub-Groups**
- **Goal is to produce guidance documents for best practices for conducting Non-targeted studies on e-liquid, ENDS aerosol, HTP substrates and HTP aerosol**
- **NWIP approved in July 2023**
  - EVAP-HTP-376-NWIP-Guidelines for NTA of EVAP and HTP substrates and emissions\_230725\_Approved
- **22 CORESTA member scientists are working on the project**



# Project Timeline

- **July 2023 Approved NWIP**
- **August to October 2023**
  - Gather citations and potential guidelines from literature during small group meetings.
- **October 2023**
  - Submit progress report to EVAP and HTP CORESTA Subgroups
- **October to December 2023**
  - Approve final guidelines within small groups and larger NTA group
- **December 2023 to April 2024**
  - Work on draft guidelines document and send out for modifications by group
- **April 2024 to July 2024**
  - Finalize and submit to General Secretariat



## Two-year plan

1. **CORESTA reference device – NWIP approved, study underway**
2. **Glycidol in e-liquid and aerosol – e-liquid prework complete with small expert group**
3. **pH of e-liquid and aerosol – prework complete with small expert group**
4. **Water activity – Study Paused**
5. **TSNAs in aerosol – Study paused pending reference device**
6. **Organic acids (primary and degradants) – Small expert group to consider best practice guidelines**



## Five-year plan

1. **Metals in aerosol – Active workstream in ISO WG3. Guides and pre-studies in consideration**
2. **Flavours – Paused**
3. **Alternative vaping regimes – Paused**
4. **Non-targeted analysis – Underway with a joint project with HTP**



## New work proposals

- Breakout sessions during October 2023 meeting yielded 28 proposals covering literature review, best practice guidelines and new method development.
- Next steps: assess level of interest in suggested items and include relevant items in 2-year/5-year plans



# Thank you!

## Questions?