The History and Challenges Faced by the CORESTA EVAP Sub-Group in Developing Testing Standards for E-liquids and E-aerosols

CORESTA E-Vapour Sub-Group

Dr Derek Mariner

ENDS 2019 - London

Dr Gene Gillman

GFN2019 – Warsaw

Outline

- Introduction to CORESTA
- CORESTA E-Vapour Sub-Group
- Process for Development of Recommended Methods
- Proficiency study for metals in e-liquids
- Challenges and Opportunities

CORESTA

Centre de
COopération pour les RECherches Scientifiques
Relatives au TAbac

Cooperation Centre for Scientific Research Relative to Tobacco

www.coresta.org

The Vision

To be recognised by our members and relevant external bodies as an authoritative source of publically available credible science and best practices related to tobacco and its derived products.

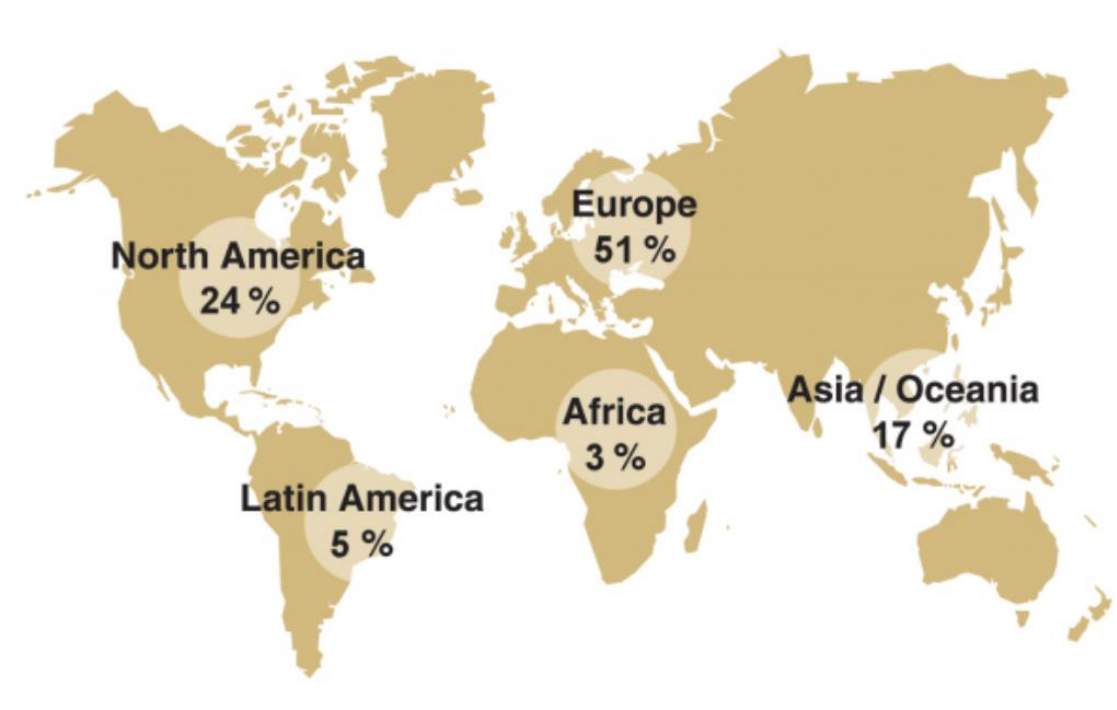
The Purpose of CORESTA

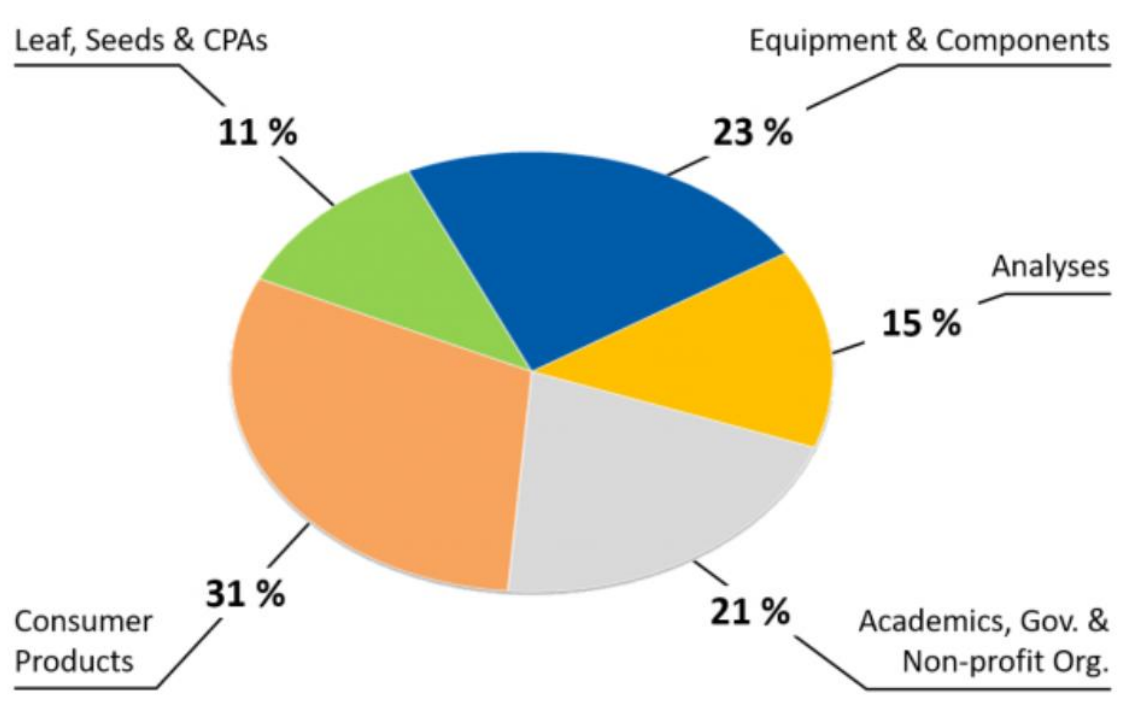
Encourage international cooperation

to actively work

on tobacco-related areas of research

156 members (May 2019)





>600 participants across 27 Sub-Groups and Task Forces

E-Vapour Sub-Group

- **Currently 35 member organisations: e-cig and e-liquid manufacturers, academia, regulators, equipment suppliers, and testing laboratories**
- **Information documents available on CORESTA website:**
  - **E-Cigarettes: A Brief Description of History, Operation and Regulation. Reference Report - February 2014**
  - **E-Cigarettes: Assessment of Analytical Literature from 55 Studies Published Worldwide prior to November 2013 on Commercial E-Cigarettes. Reference Report - May 2014**
  - **Guide No. 18: Sample Handling and Sample Collection of E-Cigarettes and E-Vapour Generating Products – November 2016**
  - **Guide No. 22: Technical Guide for the Selection of Appropriate Intense Vaping Regimes for E-Vapour Devices**
- **In development:**
  - **Guide for Designing E-Vapor Product Stability Studies**
  - **Collection Strategies and Considerations When Testing E-Vapour Product Technologies**
  - **LOD/LOQ values for the determination of metals in aerosol**

❖ Analytical Methods and Technical Reports

- E-Liquid Preliminary Proficiency Study. Technical Report - March 2015
- Electronic Cigarette Aerosol Parameters Study. Technical Report - March 2015
- CRM 81: Routine analytical machine for e-cigarette aerosol generation and collection - definitions and standard conditions – June 2015
- Collaborative Study for Determination of Glycerin, Propylene Glycol, Water and Nicotine in Collected Aerosol of E-Cigarettes. Technical Report - March 2017
- CRM 84: Determination of Glycerin, propylene glycol, water, and nicotine in the aerosol of e-cigarettes by gas chromatographic analysis – March 2017
- 2017 Collaborative Study on Carbonyl Containing Compounds in Electronic Cigarette Liquids – May 2018

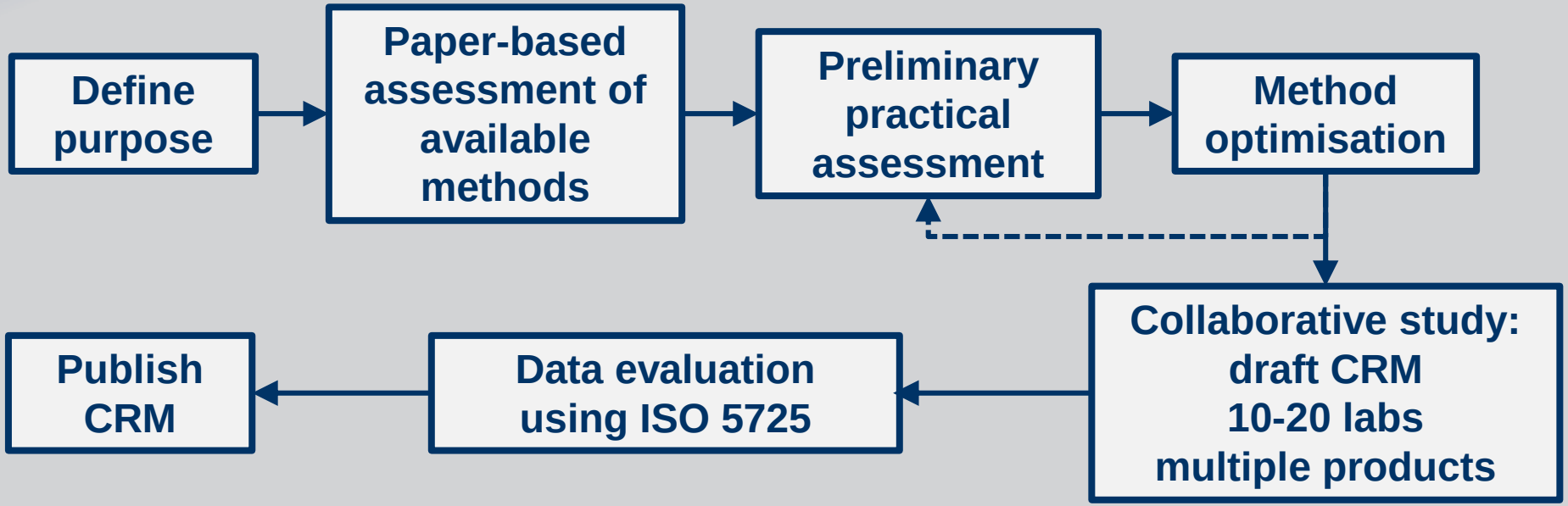
❖ In progress:

- Proficiency Study: Determination of Metals in e-liquids (reporting stage)
- Collaborative Study: Determination of Carbonyls in Aerosol
- Collaborative Study: Aerosol delivery of Nicotine, PG and Glycerin from a reference e-cigarette

Development of Recommended Methods

Approach used for the development of robust methods

- Consensus-based process



- Discussions during process provide insight into causes/reduction of intra- and inter-laboratory variability
- Methods and Reports are made available on the CORESTA website

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- CRM [illegible]ene glycol, water, and nicotine in the aerosol of e-cigarettes by gas [illegible]17
- 2017 [illegible]taining Compounds in Electronic Cigarette Liquids – May 2017

Basis for ISO 20768: "Vapour products - Routine analytical vaping machine – Definitions and standard conditions"

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Development has informed ISO 20714/FDIS: "E-liquid — Determination of nicotine, propylene glycol and glycerol in liquids used in electronic nicotine delivery devices — Gas chromatographic method"

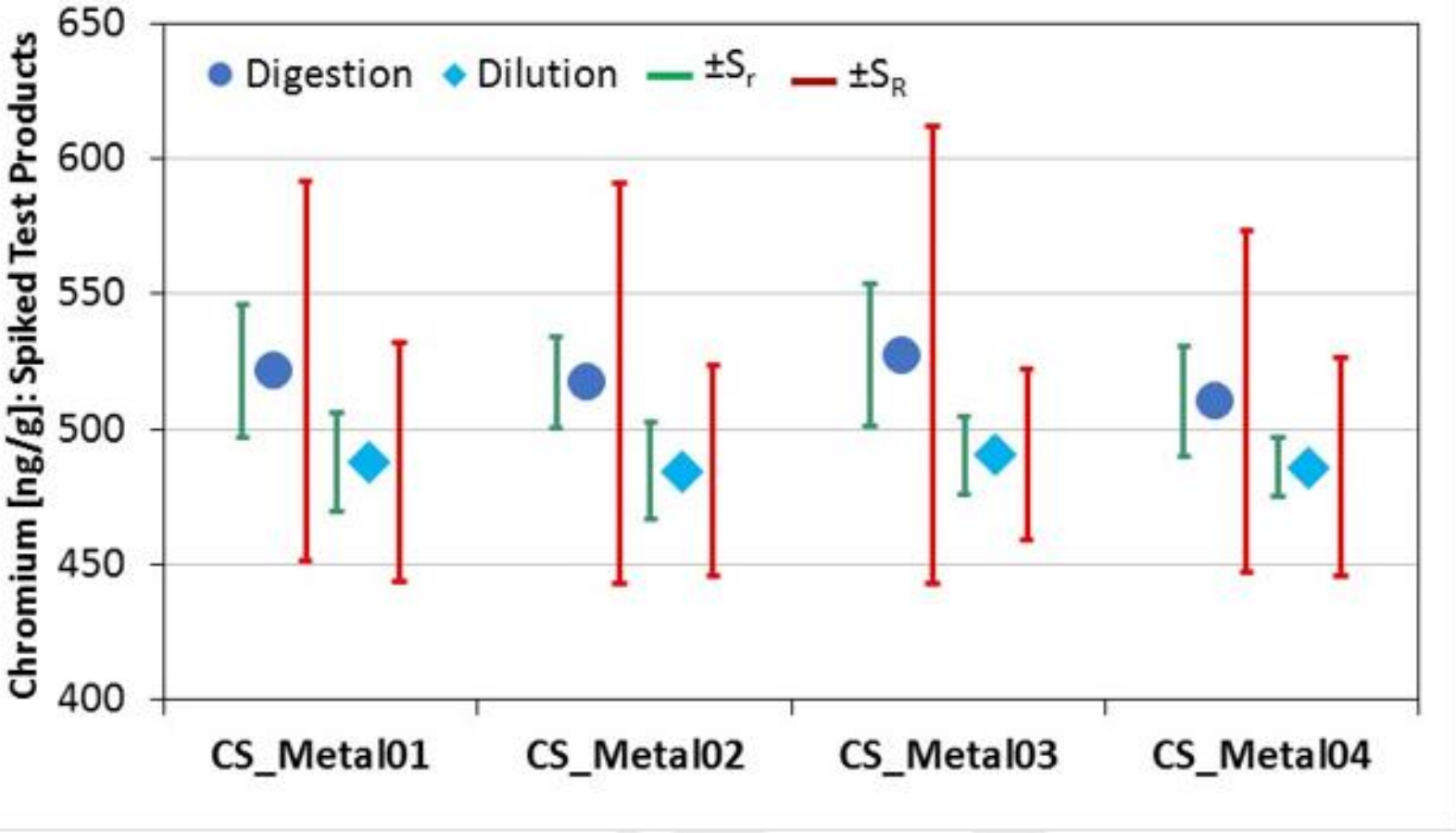
❖ In prog

- Profi
- Colla
- Colla n from a reference e-cigarette

Metals in e-liquid proficiency study

Objective: To assess whether harmonisation necessary

- 4 blank/fortified e-liq
- 8 labs using µwave digestion, 6 using dilution only
- ICP-MS analysis
- As, Cd, Cr, Cu, Fe, Pb, Ni, Ag, Sn, Zn



Challenges

- **Range of member needs**
  - Testing requirements vary according to local regulations
  - Scope of testing and target analytes are not harmonized eg EU vs US
- **Range of ENDS products**
  - Rapid advances in ENDS technology
  - Members do not have experience with all types
  - Studies cannot cover all products on the worldwide market
- **Collaborative studies**
  - Device availability for collaborative studies, members cite liability and logistics
  - Shipping of study samples worldwide complicated by varied local customs requirements, eg nicotine content and tank capacity

Opportunities

- Global interdisciplinary expertise from different sectors – non-members can get involved
- Focus on sharing and advancing scientific knowledge
- Conduct of inter-laboratory studies during development of analytical methods
- Track record supporting development of International Standards
- Emphasis on collaboration

- Thank you for your attention
- Questions?
- More information available at www.coresta.org