



# **CORESTA and e-cigarettes**

**Pierre-Marie GUITTON**

**Secretary General**

**Tobacco Campus 3<sup>rd</sup> International Workshop**

**Wiesbaden, 8-9 February 2016**



# CORESTA

Centre de  
**CO**opération pour les **RE**cherches **S**cientifiques  
Relatives au **T**Abac

Cooperation Centre for Scientific Research Relative to Tobacco



**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**



## ❖ It is an Association:

- **Founded in 1956 by 24 organisations from 20 countries**
- **Headquartered in Paris and governed under French law**
- **Now 150 Member organisations in 38 countries involved in over 60 countries**

## ❖ Main bodies

- **Board (12 to 14 organisations)**
- **Scientific Commission (20 individuals)**
- **General Secretariat (3 persons)**
- **22 Sub-Groups and Task Forces within 4 Study Groups + 3 inter-group committees**

**≈ 600 persons worldwide involved in on-going work**



# The Board

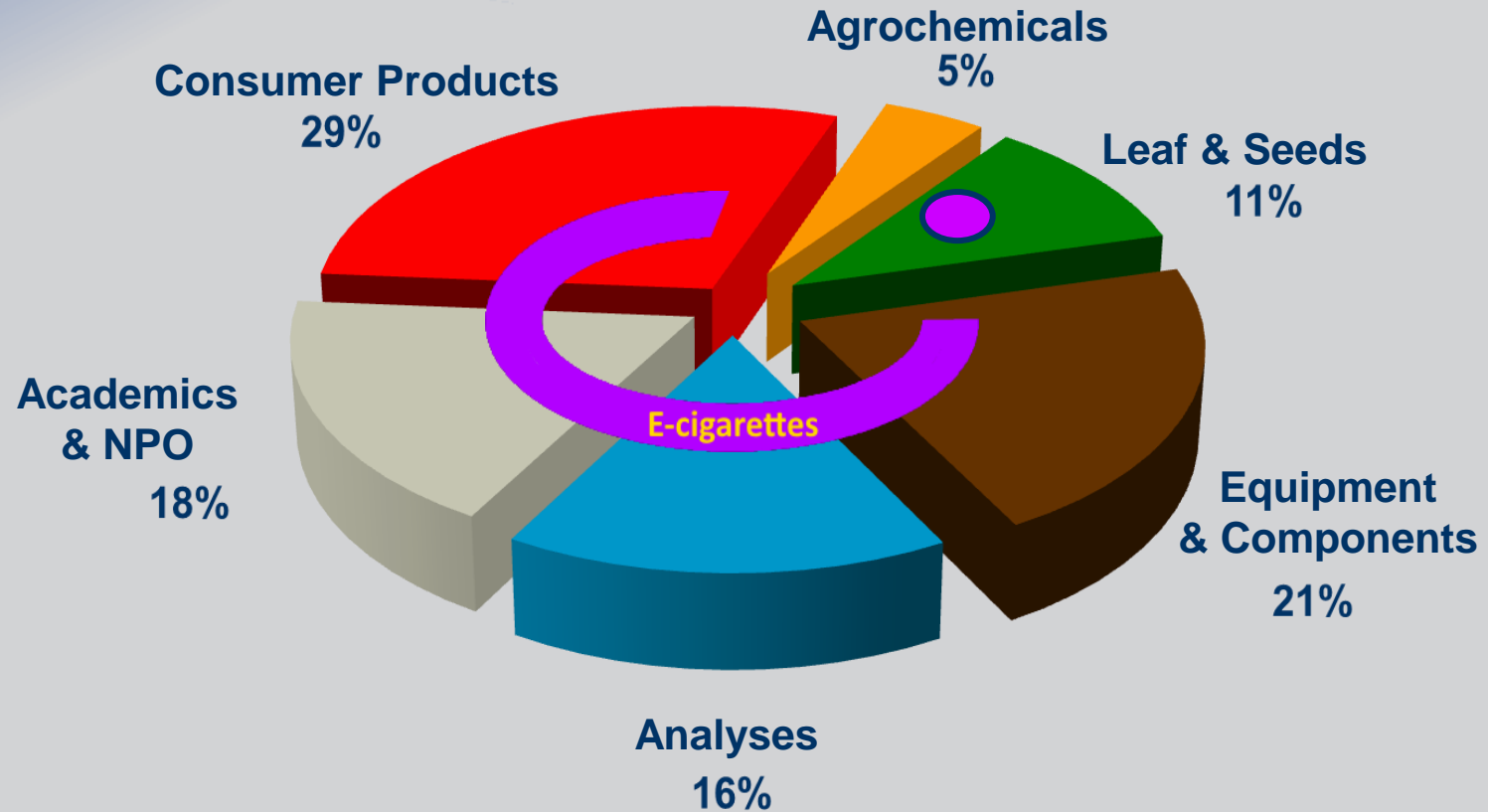
**President: Ms. Diane Raverdy-Lambert**  
**SWM International (USA)**  
**Vice-President: Mr. Huub Vizée**  
**Delfortgroup (Austria)**  
**Secretary General: Pierre-Marie Guitton**

## ❖ Member Organisations

- ✓ Alliance One International Inc. (USA)
- ✓ Borgwaldt KC (Germany)
- ✓ British American Tobacco (UK)
- ✓ China National Tobacco Corp. (China)
- ✓ Imperial Tobacco Ltd. (UK)
- ✓ Japan Tobacco Inc. (Japan)
- ✓ KT&G Corp. (South Korea)
- ✓ Delfortgroup AG (Austria)
- ✓ RAI Services Co. (USA)
- ✓ SWM International Inc. (USA)
- ✓ Swedish Match (Sweden)
- ✓ Universal Leaf Tobacco Co. (USA)
- ✓ University of Kentucky (USA)



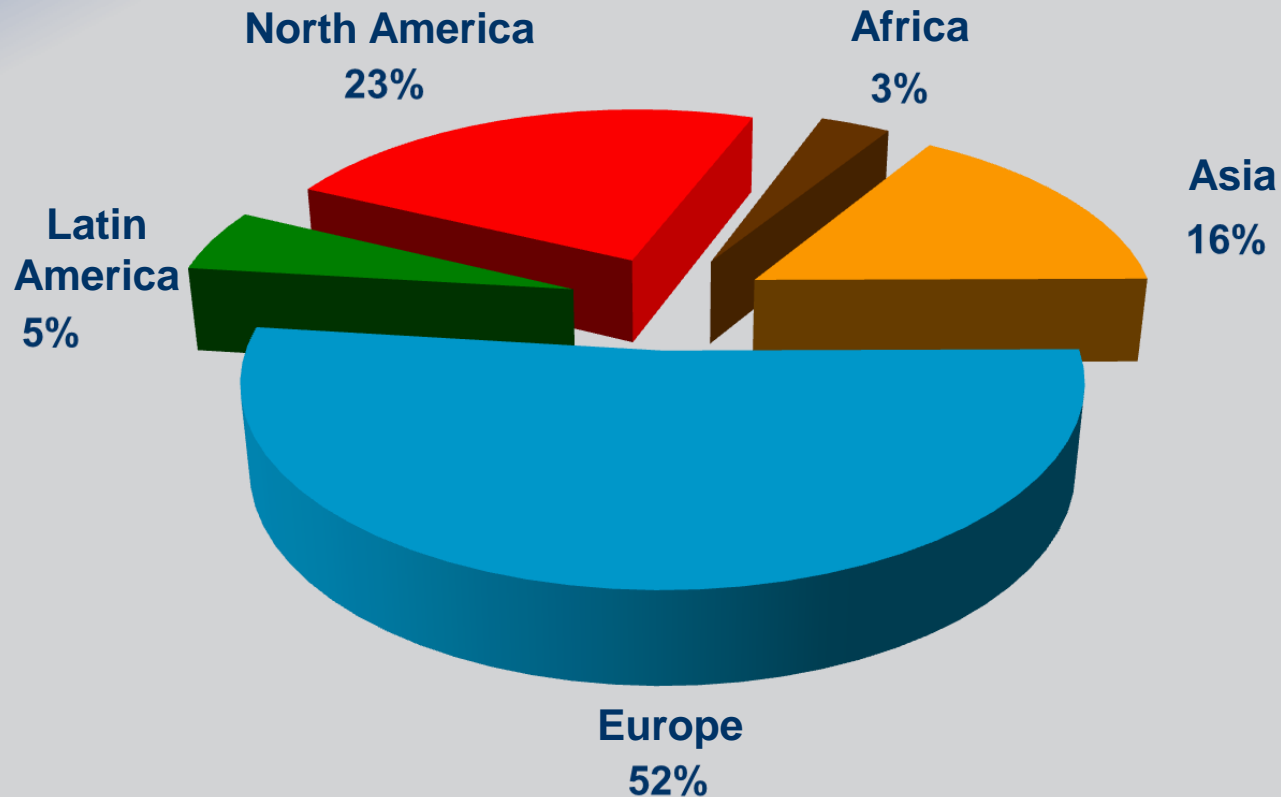
# Membership Core Activity





# Membership

## Worldwide distribution







# Involvements

## ❖ FDA Workshops

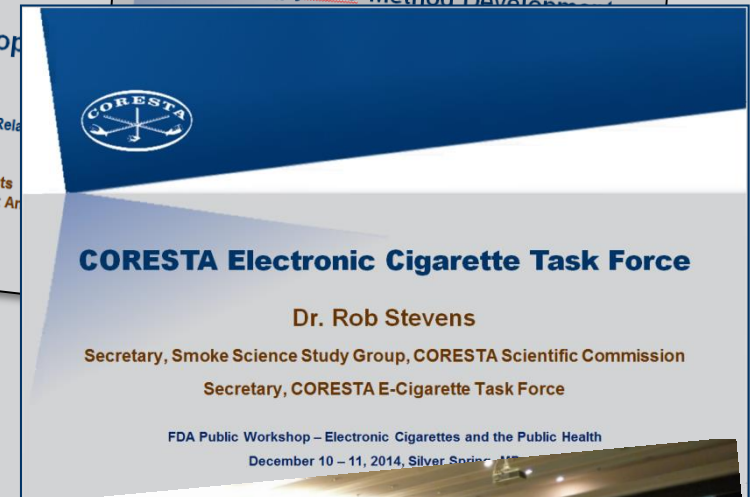
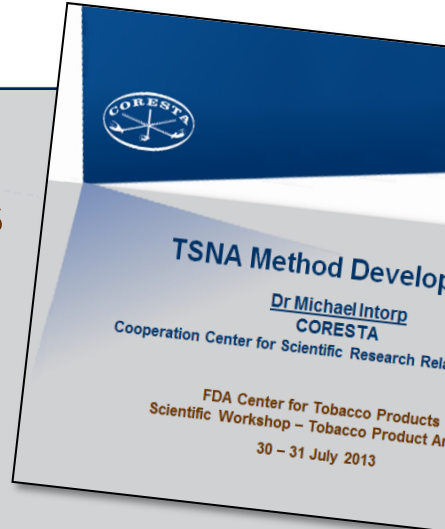
## ❖ Standards

- ISO/TC 126
- CEN/TC 437
- AFNOR

## ❖ Agrochemical Seminars

## ❖ Conferences

- Global Tobacco & Nicotine Forum
- Tobacco Campus
- E-cig Europe
- TMA
- Solvay Colloquium
- ...





## **CORESTA e-cigarette Task Force**



# CORESTA e-cigarette Task Force

## ❖ “Industry” meeting in Atlanta, November 2012

- Recommendation for CORESTA involvement
- Proposed a Task Force, with draft objectives
- Task Force confirmed by CORESTA Scientific Commission and Board

## ❖ TF Meetings

- May 2013, Geneva - Switzerland
- September 2013, Seville - Spain
- May 2014, Charlotte NC – USA
- October 2014, Québec – Canada
- June 2015, Toronto – Canada
- October 2015, Jeju Island – South Korea
- *April 2016, Lausanne - Switzerland*



# CORESTA e-cigarette Task Force

## ❖ TF Coordinator

- Dr. Charles Garner - RAI Services Company

## ❖ TF Secretary

- Dr. Rob Stevens – ITG Brands

## ❖ TF membership

- ≈ 50 participants from 40 different member organizations
- 12 countries in Asia, Europe, North America
- E-cig & Tobacco Cos, Contract Labs, Equipment Suppliers, University

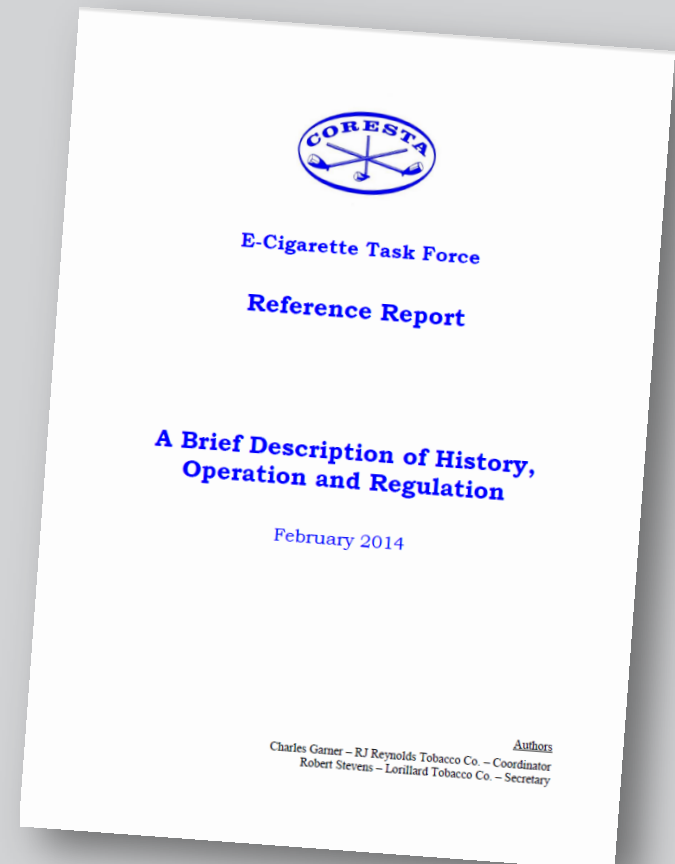


# CORESTA ECIG TF Objectives

1. To create a document on worldwide product definition and definitions of terms to support harmonization of nomenclature

## Deliverables include:

- Reference Report completed and posted on CORESTA website (March 2014)
- SC approved recommendation to no longer update regulatory status



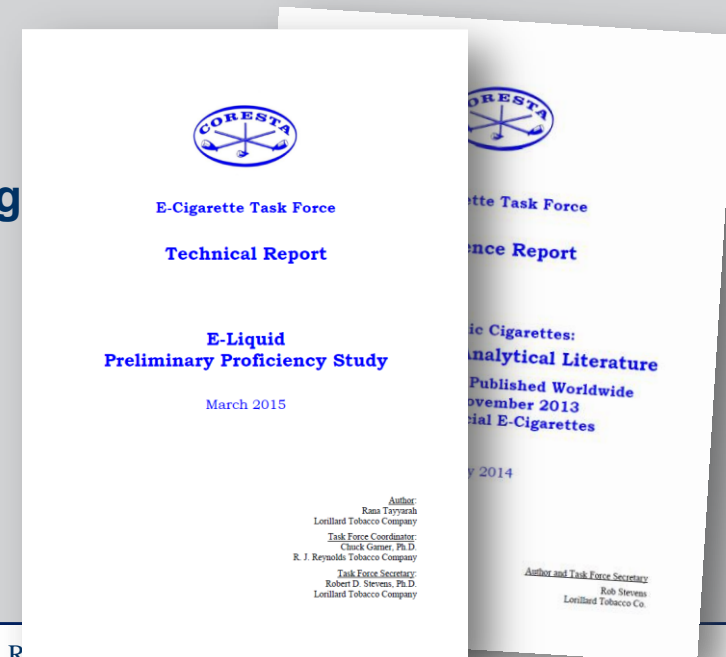


# CORESTA ECIG TF Objectives

1. To create a document on worldwide product definition and definitions of terms to support harmonization of nomenclature
2. To gather and share preliminary data on analysis relevant to e-cigarettes worldwide with a view to making recommendations for product testing

## Deliverables include:

- Reference Report on the analytical testing literature posted on CORESTA website May 2014
- Technical Report for a preliminary proficiency study for testing e-liquids posted on the CORESTA website March 2015



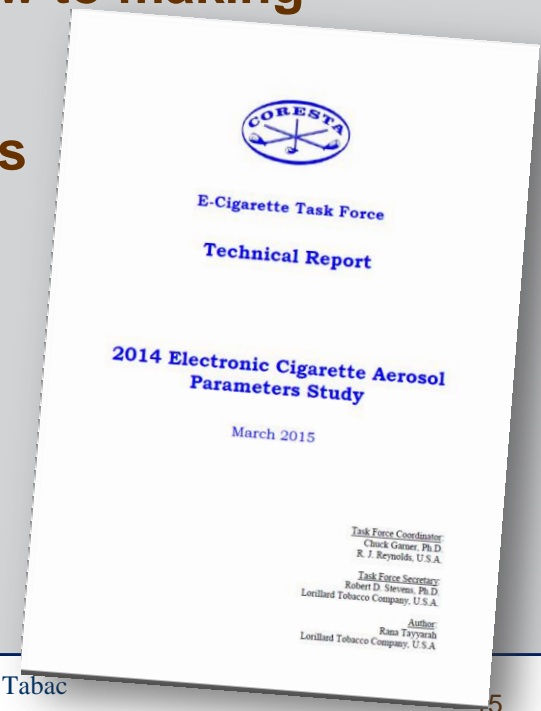


# CORESTA ECIG TF Objectives

1. To create a document on worldwide product definition and definitions of terms to support harmonization of nomenclature
2. To gather and share preliminary data on analysis relevant to e-cigarettes worldwide with a view to making recommendations for product testing
3. To define the relevant categories of products for potential further CORESTA studies

## Deliverables include:

- Technical Report for an e-cig. aerosol study posted on the CORESTA website  
March 2015
- CORESTA Recommended Method (CRM) No.81





## CORESTA RECOMMENDED METHOD N° 81

### ROUTINE ANALYTICAL MACHINE FOR E-CIGARETTE AEROSOL GENERATION AND COLLECTION – DEFINITIONS AND STANDARD CONDITIONS

*(June 2015)*

- ❖ NWIP to ISO/TC126 (April 2015)
- ❖ Accepted by ISO (June 2015)
- ❖ Creation of WG16 (Aug. 2015)
- ❖ Convener: a CORESTA Expert
- ❖ 1<sup>st</sup> meeting: 27 January 2016

RECOMMENDED METHOD N° 81

FOR E-CIGARETTE AEROSOL  
DEFINITIONS AND STANDARD  
CONDITIONS  
(June 2015)

1. INTRODUCTION

This method is necessary for the generation and collection of e-cigarette aerosol. This method is based on the findings of the CORESTA Technical Report, 2014 Electronic Cigarette Aerosol Parameters Study, March 2015 [1].

#### 1. FIELD OF APPLICATION

This Method:

- defines the parameters and specifies the standard conditions for the routine analytical generation and collection of aerosol from e-cigarettes as defined in 3.14;
- specifies technical requirements for the routine analytical machine for e-cigarette aerosol generation and collection, termed as "machine" in this document, complying with the standard conditions stated within;
- does not specify aerosol trapping nor subsequent sample preparation and analytical method analyses of components in the trapped aerosol or the gas phase;
- may also be used for products other than defined in 3.14 if a specific method references this method.

#### 2. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this method. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

*ISO 7210:2013*

Routine analytical cigarette-smoking machine – Additional test methods for machine verification

#### 3. TERMS AND DEFINITIONS

For the purposes of this recommended method the following terms and definitions apply.

##### 3.1 Test atmosphere

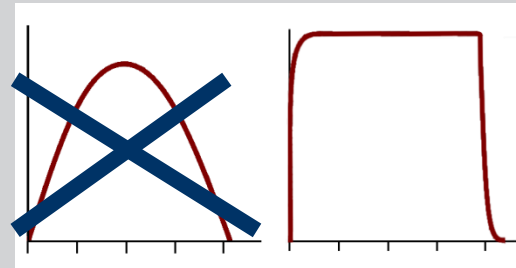
Atmosphere to which an e-cigarette sample or device is exposed throughout the test.



**CRM81 specifies technical requirements for the routine analytical machine for e-cigarette aerosol generation and collection**

❖ **Puffing parameters to collect e-cigarette aerosol based on the Technical Report**

- **Puff Volume: 55 cc**
- **Puff duration: 3 sec**
- **Puff interval : 30 sec**
- **Puff profile: square wave, to ensure system activation**



❖ **Test atmosphere variability**

- **Temperature  $\pm 2$  °C**
- **Relative Humidity  $\pm 5$  %**

**CRM81 does not specify sample preparation and analytical method analyses of components in the trapped aerosol or the gas phase.**



# Highlight on Technical Report on Puffing Parameters

	Volume (ml)	Duration (sec)	Interval (sec)	Profile
<b>Smoking regimes for combustible cigarettes</b>				
ISO 3308	35	2	60	Bell
HC-T-115	55	2	30	Bell
<b>Preliminary study for e-cigarettes</b>				
1	55	3	30	Square
2	55	4	30	Square
3	70	3	30	Square
4	70	4	30	Square

WHO Intense smoking



Limit of flow stability for machines

Limit of flow for vaporizer activation



## **Additional Work in Progress**



# Additional Work in Progress

- ❖ **Preliminary Proficiency Study for e-cigarette aerosol analysis**
  - Study on nicotine, propylene glycol , glycerin and water
  - 8 products (4 disposables and 4 rechargeables)
  - 14 labs
  - **Technical Report**
    - Aerosol methods were similar among the participating labs
    - Results across most labs were very consistent for all 4 analytes
    - E-cig mass loss to ACM ratios were good metrics to verify results



## **Additional Work in Progress**

- ❖ **Preliminary Proficiency Study for e-cigarette aerosol analysis**
  - Study on nicotine, propylene glycol , glycerin and water
  - 8 products (4 disposables and 4 rechargeables)
  - 14 labs
  - Technical Report – will be completed by April 2016
  - Publication on e-cigarette aerosol and e-liquid studies expected to be submitted mid-2016
  
- ❖ **Collaborative Study for a method to measure nicotine, propylene glycol, glycerin and water in e-cigarette aerosol**
  - Technical Report and Method to be completed in April



# Collaborative Study Design

- ❖ **≈ 20 Labs testing**
  - 4 samples (8 replicates)
  - plus a 'blank' and a 'control'
- ❖ **Aerosol Collection:**
  - 80 puffs total in three sets (10 puffs, 20 puffs, 50 puffs)
- ❖ **Analytes:**
  - Nicotine, Propylene Glycol, Glycerin, Water
- ❖ **Analytical methods:**
  - CRM 81 and a draft analytical method based in existing ones



## ❖ Samples provided by: White Cloud Electronic Cigarettes

## ❖ Testing Labs:

- ❖ Altria Client Services
- ❖ BAT Southampton
- ❖ Borgwaldt KC GmbH
- ❖ BAT Germany
- ❖ Enthalpy Analytical
- ❖ Essentra
- ❖ Global Laboratory
- ❖ Godfrey Phillips India Ltd
- ❖ ITG Brands, R&D
- ❖ Japan Tobacco Inc.
- ❖ Japan Tobacco Intl.
- ❖ Laboratoire national de métrologie et d'essais
- ❖ Labstat International ULC
- ❖ Okolab Gesellschaft (JTI)
- ❖ PMI Research & Development
- ❖ Reemtsma Cigarettenfabriken GmbH
- ❖ RJ Reynolds Tobacco Company
- ❖ SEITA Imperial Tobacco
- ❖ Shanghai Tobacco Group. CNTC
- ❖ Zhengzhou Tobacco Research Institute



# Products Tested Nominal Content Information

Sample Code	Nicotine Content	PG/VG Ratio
Sample A	0%	70:30
Sample B	2.4%	70:30
Sample C	5.4%	70:30
Sample D	2.4%	100:0

**Samples A-D = commercial cigalike rechargeable e-cigarette products**

Sample Code	Nicotine Content	Glycerin Content	PG Content	Water Content
<i>Sample E</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>
Sample F	2.0%	43%	43%	12%

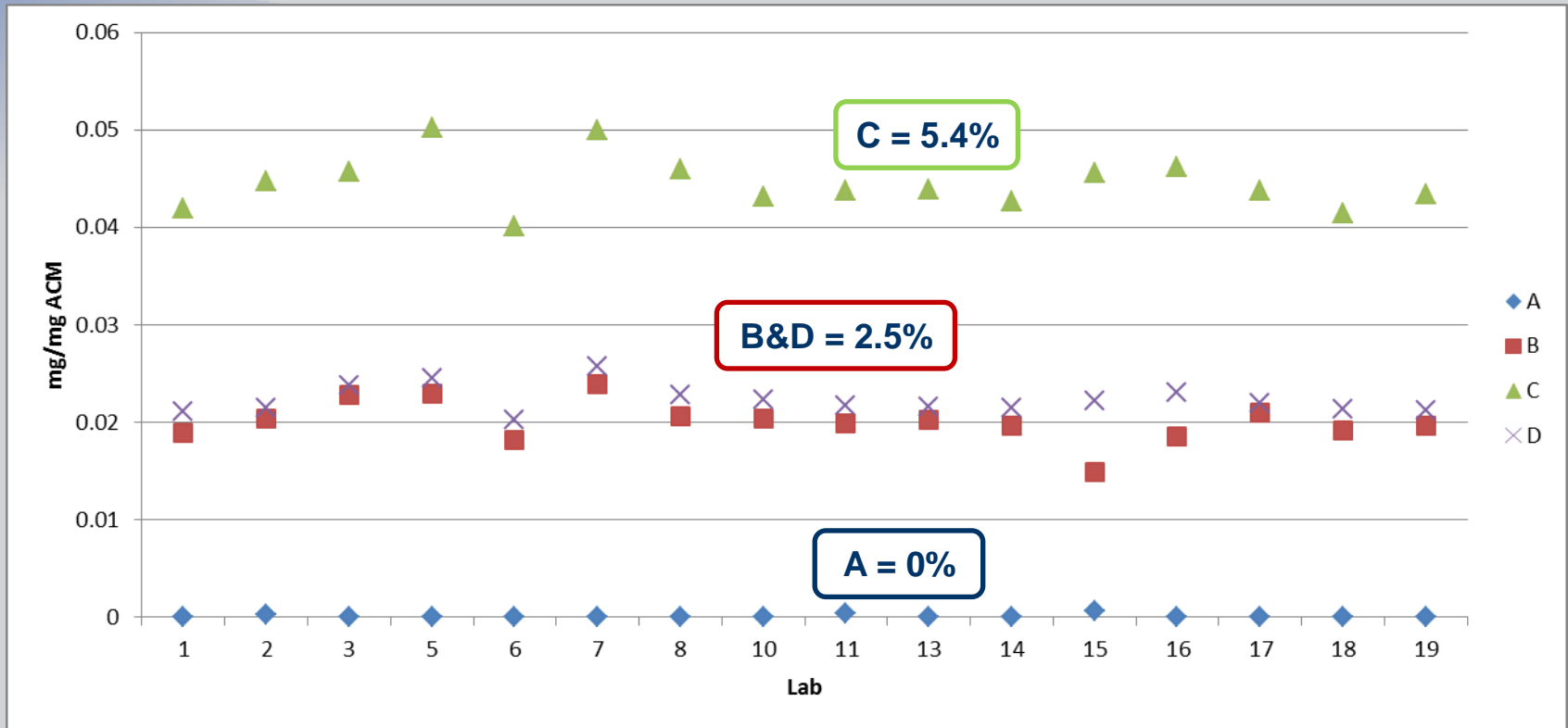
***Sample E = study blank (puffing through empty ports)***

**Sample F = lab prepared e-liquid reference**

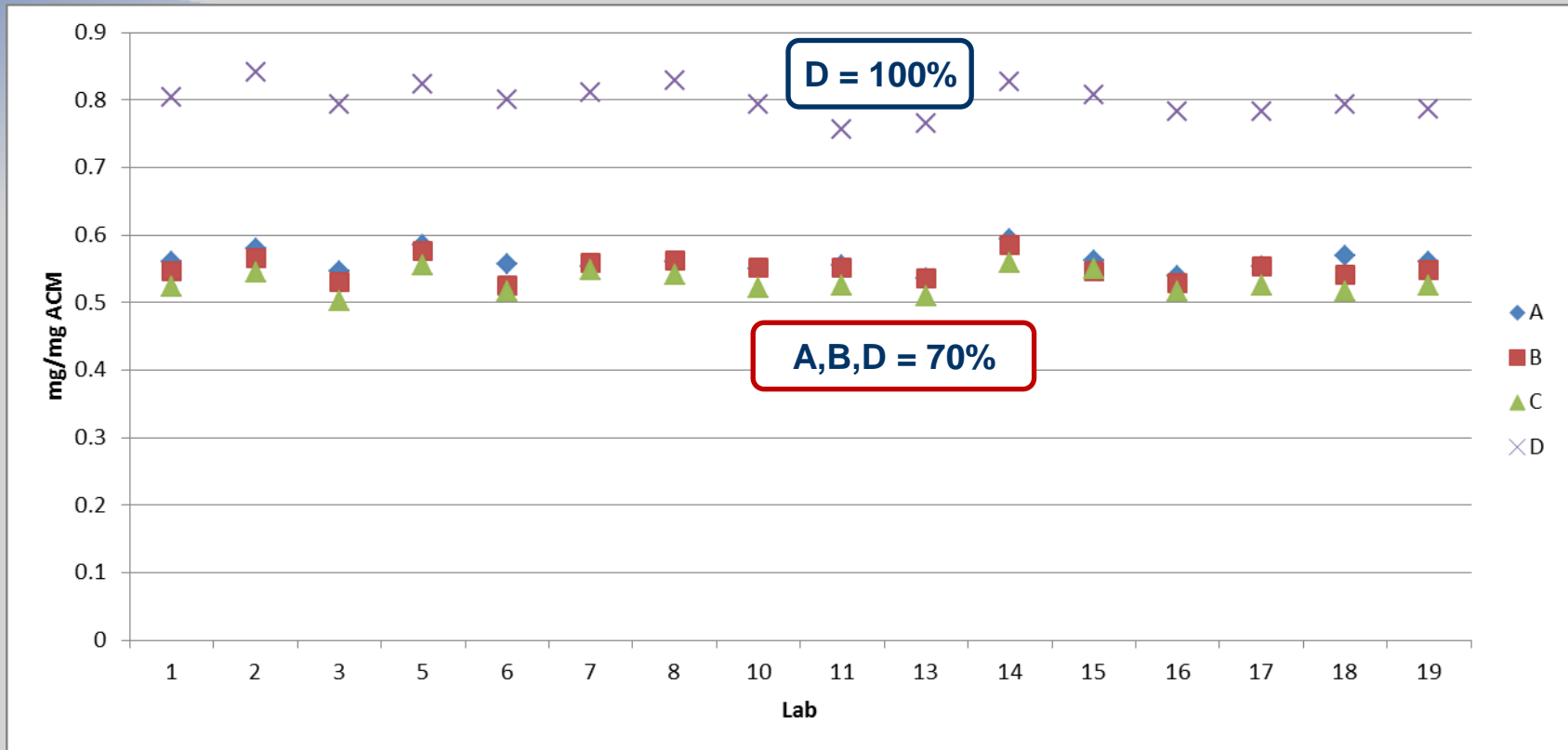




# Aerosol Nicotine



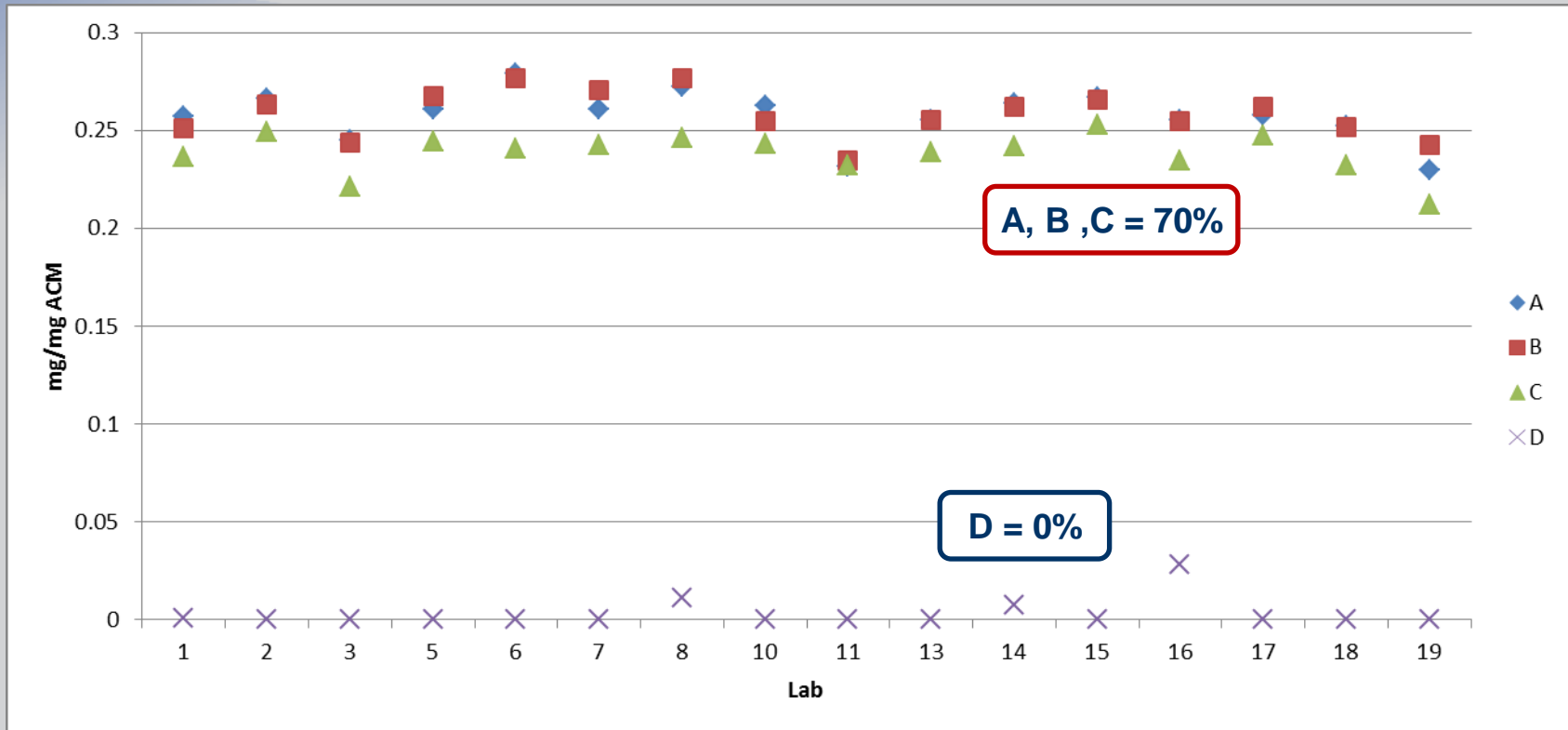
Preliminary Reporting, Information is Current as of November 2015



**Preliminary Reporting, Information is Current as of November 2015**



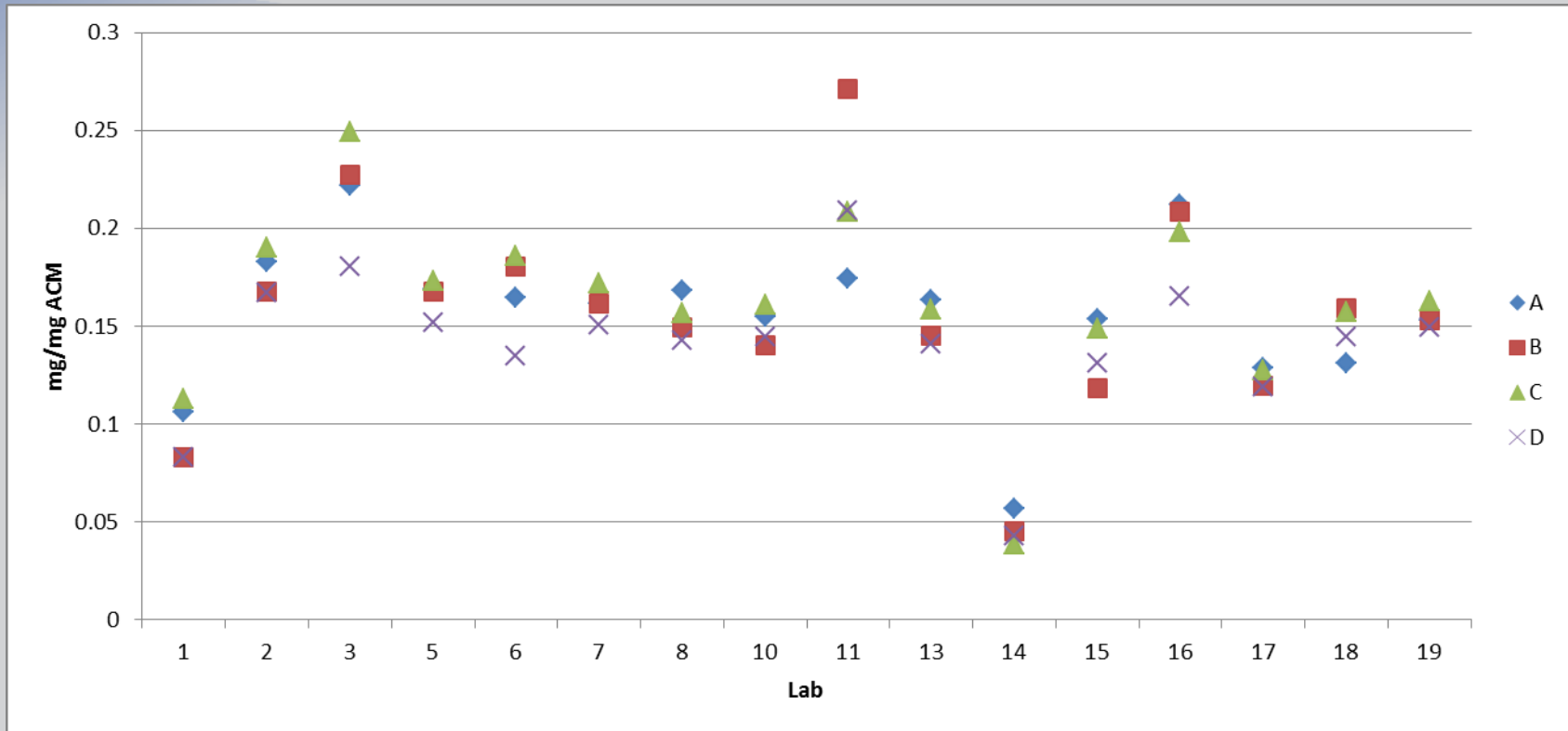
# Aerosol Glycerin



Preliminary Reporting, Information is Current as of November 2015



# Aerosol Water



**Preliminary Reporting, Information is Current as of November 2015**

## ❖ Product Handling & Sample Preparation Guidelines

- Pre-analysis considerations for e-cigarette testing
- Re-chargeable products – battery

## ❖ Aerosol Collection and Analysis Strategies for Additional Product Categories

- Gap analysis for CRM81 relative to Tanks
- Multiple Variables
- Error Handling

## ❖ Document to define the relevant categories of products and product testing recommendations for potential further CORESTA studies

**The Task Force will become a Sub-Group to focus on this important emerging science/technology area.**





# Value of CORESTA

- ❖ **Global interdisciplinary expertise from different sectors**
- ❖ **Focus on advancing scientific knowledge**
- ❖ **Leadership and coordination of inter-lab studies to recommend analytical methods**



## 2 + 2 Study Groups

### ❖ Agronomy & Leaf Integrity, Phytopathology & Genetics

- Agronomy & Breeding
- Curing
- Sustainability
- Pests & plant diseases
- Agrochemical issues

**Agro - Phyto**

**« AP »**

### ❖ Smoke Science, Product Technology

- Technical specifications
- Smoke analysis
- Analytical methods
- Consumer behaviour
- *In Vitro* Toxicology

**Smoke - Techno**

**« SSPT »**



## ❖ Agronomy & Leaf Integrity

- **SG TSNA in Air-Cured and Flue-Cured Tobacco**
- **SG Pest and Sanitation Management in Stored Tobacco**
- **SG Proficiency Testing for Detection of Transgenic Tobacco**
- **TF Agrochemical Residue Field Trials**
- **TF Sustainability in Leaf Tobacco Production**

## ❖ Phytopathology & Genetics

- **SG Virus Diseases**
- **SG Integrated Pest Management**
- **SG Collaborative Study on Black Shank**
- **SG Efficacy of Biological and Eco-Friendly CPAs**
- **TF Agro-Phyto Information Collection**
- **TF Extended Diagnostic Expert System**





# Agro-Phyto Achievements

## ❖ Agronomy & Phytopathology

- Defined and promoted industry-wide adoption of Good Agricultural Practices (GAP) for tobacco
- Defined Growth Stages for Tobacco
- Set Guidance Residue Levels (GRLs) for relevant agrochemicals
- Promoted reductions in the risk of crop loss and the use of crop protection agents (CPA)
- Organised worldwide collection of information on Blue Mould
- Organises a yearly Infestation Control Conference
- Edits Guides for the control of insects
- Translated and extends the French INRA tobacco diagnostic system to make it international





# “Smoke - Techno”

## ❖ Smoke Science

- SG Smoking Behaviour
- SG Biomarkers
- SG Special Analytes
- SG *In Vitro* Toxicity

## ❖ Product Technology

- SG Agrochemicals Analysis
- SG Routine Analytical Chemistry
- SG Physical Test Methods
- SG Cigar Smoking Methods
- SG Smokeless Tobacco
- TF E-Cigarettes
- TF Cigarette Variability



# Smoke - Techno Achievements

## ❖ Smoke Science & Product Technology

- **Developed Recommended Methods\*, Guides and Reports on tobacco, product and smoke analysis (chemical and physical)**
  - 36 ISO standards based on CORESTA Recommended Methods (CRMs)
  - + 8 CRMs currently in the process of becoming ISO standards
  - Regular collaborative studies/proficiency trials to support member labs' accreditation (agrochemicals, TNCO, physical...)
  - Protocols for *in vitro* toxicity testing of mainstream smoke
- **Developed Reference Materials**
  - CM 'CORESTA Monitor test piece' for smoking machine set-up + 1 for LIP testing
  - 4 smokeless tobacco products



**\*62 out of 81 CRMs currently active, due to obsolescence/replacement of older ones**



# Development of Recommended Methods

## ❖ Approach used for the development of robust methods

- Involvement of a relatively large number of laboratories
- Involvement of a wide range of product and design styles
- Round-table discussions during development provide valuable insight into causes and ways to reduce inter-laboratory variability
- Consensual and unanimous decisions on “standardisation”

## ❖ Conclusions & Achievements

- Methods and Reports are made available on the CORESTA website
- Experiences in method development shared within the Groups may be made publicly available in peer-review publications



# **CORESTA and the Standardisation Process for Vape and Vaping Products**



# CORESTA and e-cig standards

## ❖ AFNOR (France)

- **CORESTA participated in the ECIG Standard Commission**
- **Main achievements:**
  - adoption of the CORESTA recommended vaping regime
  - emphasis on analytical considerations for r&R of tests



# CORESTA and e-cig standards

## ❖ AFNOR (France)

## ❖ CEN (Europe)

- **CORESTA is a liaison Member of newly created TC437**
- **CORESTA Experts will contribute in:**
  - WG1: Terminology and definitions
  - WG3: Requirements in test methods for e-liquids
  - WG4: Requirements in test methods for emissions



# CORESTA and e-cig standards

## ❖ AFNOR (France)

## ❖ CEN (Europe)

## ❖ ISO (International)

- CORESTA is a liaison Member of TC126 Tobacco & Tobacco Products
- E-cig activity to be hosted by TC126 as Sub-Committee 3
- Vaping regime standard to be defined by WG16 led by CORESTA
- CRM81 to be used as a working draft (#20768)
  
- *WG15 set to work on Determination of nicotine, propylene glycol and glycerol in e-liquids” (#20714)*
- *CORESTA’s ECIG TF will not pursue work on this topic*





**Thank you – Merci - Danke**

