



Tobacco and Tobacco Products Analytes Sub-Group (TTPA) Annual Report

2020 Online CORESTA Congress

October 2020



- ❖ **Coordinator and Scientific Commission Liaison**
 - Karl Wagner, Ph.D. (Altria Client Services, United States)

- ❖ **Secretary**
 - Johan Lindholm, Ph.D. (Swedish Match, Sweden)

- ❖ **Established in 2008**

- ❖ **Meet twice a year**
 - ~ 50 attendees
 - ~ 40 organisations represented

- ❖ **Meetings since 2019 SSPT Meeting, Hamburg**
 - 26th meeting – virtual (April 23, 2020)
 - 27th meeting – virtual (scheduled for October 13, 2020)



Subgroup Objectives

- ❖ **To organise the manufacture of and maintain smokeless tobacco reference products (CRPs)**
- ❖ **To propose and maintain CORESTA Recommended Methods (CRMs) and related documents for the analysis of tobacco and unburned tobacco products**
- ❖ **To organise interlaboratory testing**



Organization of RAC, SMA and TTPA SGs (COR-080/20)



- ❖ The SC conducted a review of SG workstreams to optimize the workload and the use of resources
- ❖ RAC and SMA would merge to form a new SG – Smoke Analysis (SA)
 - Co-Coordinator: Jana Jeffery and Hiromoto Yamazaki
 - Workstreams and leads:
 - Reference products – Thomas Schmidt
 - Cigar smoke HPHC methods – Anthony Brown
 - Cigarette smoke methods – Rana Tayyarah
- ❖ The scope of work would not change
- ❖ Transition projects involving smoke to the SA workstreams and the projects involving tobacco and unburned tobacco products to the TTPA



CORESTA Reference Products (CRPs)

❖ Produced in 2009 and 2016

- Swedish style snus pouch
- American-style loose moist snuff
- American-style loose dry snuff powder
- American-style loose-leaf chewing tobacco



CORESTA Reference Products (CRPs)

2009 CRP 1 – CRP 4



2016 CRP 1.1 – CRP 4.1





Maintenance of CRPs

- ❖ **Collaborative studies to assess stability:**
 - Nicotine
 - TSNAs
 - pH
 - Moisture (oven volatiles)

- ❖ **CRPs have been shown to be stable when stored at the recommended temperature of -20 °C**

- ❖ **Distributed by North Carolina State University**
 - <https://strp.wordpress.ncsu.edu/>



Ground Tobacco Reference Products

University of Kentucky, Center for Tobacco Reference Products



Dark
Fire-
Cured



Flue-Cured



Dark Air-
Cured



Oriental



Burley



Flavored
Cigar Filler



Unflavored
Cigar Filler



11 Documents Published in Last 12 Months

- ❖ **CORESTA 2016 Reference Products - 2019 Analysis (Mar 2020)**
- ❖ **CORESTA 2009 Reference Products - 2019 Analysis (July 2020)**
- ❖ **2019 Collaborative Study for the Determination of Nicotine in Tobacco and Tobacco Products (April 2020)**
 - ❑ CRM No. 62 - Determination of Nicotine in Tobacco and Tobacco Products by Gas Chromatographic Analysis (April 2020)
 - ❑ CRM No. 87 - Determination of Nicotine in Tobacco Products by GC-MS (April 2020)
- ❖ **2019 Stability Study Protocol for Sample Handling of Smokeless Tobacco and Smokeless Tobacco Products - Collaborative Study (May 2020)**
 - ❑ Guide No. 11 - Technical Guideline for Sample Handling of Smokeless Tobacco and Smokeless Tobacco Products (May 2020)
- ❖ **2018 Metals Collaborative Study (July 2020)**
 - ❑ CRM No. 93 - Determination of Selected Metals in Tobacco Products by ICP-MS (July 2020)
- ❖ **2020 Nicotine and Nicotine Degradants Proficiency Study**
- ❖ **No. 15 - CORESTA Reference Products - Production and Evaluation**



Future Work Plan

- Ongoing**
1. **Development of CRM for nicotine and nicotine degradants in nicotine pouches and e-liquids**
 - Currently in small group development
 2. **Characterization of new University of Kentucky reference products**
 - 4 certified smokeless products sponsored by FDA
 - 4 reference cigars for un-burned analytes produced by industry working group
 3. **Biennial stability study for 2016 CRP**
 4. **Evaluate CRMs for fitness of use for the analysis of tobacco free nicotine pouches**
- Not initiated**
5. **Development of CRM for nitrate and nitrite in unburned tobacco and tobacco products by IC**
 - Propose small group development
 6. **PT Study for Total Aerobic Microbial counts (TAMC), Total Yeast and Mold counts (TYMC) in unburned tobacco products**
 7. **Evaluate and update Guides No. 11 to include other products (cigars, ?)**
 - **No. 11 - Technical Guideline for Sample Handling of Smokeless Tobacco and Smokeless Tobacco Products**
 8. **Minor alkaloids proposal from RAC**



Constituents of Regulatory Concern

Unburned Tobacco Filler (cigarettes, cigars, RYO)

Constituent	CRM	ANVISA (Brazil)	Health Canada	China STMA	US FDA
Nitrate	36	✓	✓	✓	NA
Humectants	60, 61	✓	✓	✓	NA
Nicotine	62, 87	✓	✓	✓	✓
pH	69	✓	✓	✓	NA
TSNAs	72	✓	✓	✓	✓
Moisture	82	✓	✓	✓	NA
Ammonia	79	✓	✓	✓	✓
B[a]P	82	✓	✓	NA	NA
Metals	93	✓	✓	✓	✓

NA = not required



Constituents of Regulatory Concern

Smokeless Tobacco

Constituent	CRM	ANVISA (Brazil)	Health Canada	Swedish NFA	US FDA
Nitrate	36	✓	✓	NA	NA
Humectants	60, 61	✓	✓	✓	NA
Nicotine	62, 87	✓	✓	NA	✓
pH‡	69	✓	✓	NA	✓
TSNAs	72	✓	✓	✓	✓
Moisture	82	✓	✓	NA	NA
Ammonia	79	✓	✓	NA	✓
B[a]P	82	✓	✓	✓	✓
Carbonyls	86	NA	NA	NA	✓
Metals	93	✓	✓	✓	✓

The “‡” symbol indicates pH is either required or needed for the calculation of free nicotine



Benefits to the Scientific Community

- ❖ **Production and maintenance of CRPs**
- ❖ **Development of robust CRMs with defined repeatability and reproducibility values**
- ❖ **Interlaboratory studies**
 - **Provides laboratory performance feedback**
 - **Supports ISO 17025 accreditation**
- ❖ **Study results and methodology are a source of engagement with stakeholders**



Acknowledgements

- ❖ **Participating laboratories and their management's support**
- ❖ **Study Coordinators and Statistical Support**
 - **Tony Brown and Mike Morton (Altria)**
 - CORESTA 2016 Reference Products - 2019 Analysis
 - **John Bunch (American Snuff Co.) and Mike Morton (Altria)**
 - CORESTA 2009 Reference Products - 2019 Analysis
 - **Tony Brown and Mike Morton (Altria)**
 - Collaborative Study for the Determination of Nicotine in Tobacco and Tobacco Products and revision of CRM Nos. 62 and 87
 - **Johan Patring and Robert Pendrill (Swedish Match)**
 - 2019 Stability Study for Sample Handling of Smokeless Tobacco and revision of Guide No. 11
 - **Jannell Rowe (R.J. Reynolds), Chao Wei and Walter Morgan (RAI Services Company)**
 - Metals Collaborative Study and publication of CRM
 - **Fadi Aldeek and Mike Morton (Altria)**
 - 2020 Nicotine and Nicotine Degradants Proficiency Study



Thank You!