



Smokeless Tobacco Sub-Group (STS) Annual Report

CORESTA Congress - Berlin Germany

October 10, 2016



STS Overview

- ❖ **Coordinator and Scientific Commission Liaison:**
 - Karl Wagner (Altria Client Services LLC, Richmond, Virginia)
- ❖ **Secretary:**
 - Johan Lindholm (Swedish Match, Stockholm, Sweden)
- ❖ **STS established in November 2008**
- ❖ **Typically two meetings per year:**
 - ~ 40 attendees
 - ~ 30 companies represented
- ❖ **STS Meetings since CORESTA 2014, Québec**
 - 2015: Hangzhou, China (April), Jeju, South Korea (October)
 - 2016: Lausanne, Switzerland (April), Berlin, Germany (October)



STS Objectives

- 1) To propose and evaluate practical and robust recommended methods for the determination of smokeless tobacco analytes**
- 2) To periodically organize collaborative and/or proficiency testing**
- 3) To organize the manufacture and maintain smokeless tobacco reference products**



2009 CORESTA Reference Products

- ❖ **The STS coordinated production of 4 CRPs in 2009**
 - **CRP1: Swedish style snus pouch**
 - **CRP2: American-style loose moist snuff**
 - **CRP3: American-style loose dry snuff powder**
 - **CRP4: American-style loose-leaf chewing tobacco**

- ❖ **CRPs are maintained by North Carolina State University**



2009 CORESTA Reference Products

- ❖ **The STS conducted annual collaborative studies to assess the stability of the CRPs (2010 – 2015)**
 - **Nicotine,**
 - **pH,**
 - **Tobacco-specific nitrosamines,**
 - **Moisture (oven volatiles)**

- ❖ **The stability results indicate that storage at -20 °C is an appropriate storage condition for the four reference products.**

- ❖ **The STS will conduct a 10-year stability study in 2019**

- ❖ **The stability reports are published at CORESTA.org**



Supply of 2009 CRPs

	Dec 2009	Dec 2010	Dec 2011	Dec 2012	Dec 2013	Dec 2014	Dec 2015	Sept 2016
CRP 1	7000	6135	5443	4895	3975	3242	1992	1399
CRP 2	7020	6363	6093	5082	4453	3680	1723	805
CRP 3	7040	6653	6207	5520	5113	4691	4191	2313
CRP 4	7000	6806	6567	6374	6236	6040	5686	2420



2016 CORESTA Reference Products

- ❖ **The STS coordinated production of new CRPs in 2016**
 - **CRP1.1: Swedish style snus pouch**
 - **CRP2.1: American-style loose moist snuff**
 - **CRP3.1: American-style loose dry snuff powder**
 - **CRP4.1: American-style chopped loose-leaf chewing tobacco**

- ❖ **CRPs are maintained by North Carolina State University**

- ❖ **Initial characterization completed in 2016**
 - **Nicotine, pH, TSNAs, Moisture, Ammonia, Benzo[a]pyrene**
 - **The report will be published by year end at CORESTA.org**



2016 CORESTA Reference Products

Parameter	2009 CRP1 Mean	2016 CRP1.1 Mean
Nicotine (%)	0.98	0.76
pH	7.85	8.30
Moisture (%)	51.06	53.95
NNN (µg/g)	0.67	0.19
NNK (µg/g)	0.21	0.052
NAT (µg/g)	0.51	0.14
NAB (µg/g)	0.035	0.009
Ammonia (µg/g)	951	1034
B[a]P (ng/g)	0.70	0.72

Parameter	2009 CRP2 Mean	2016 CRP2.1 Mean
Nicotine (%)	1.29	1.07
pH	7.65	7.74
Moisture (%)	54.34	51.41
NNN (µg/g)	1.81	3.39
NNK (µg/g)	0.44	2.06
NAT (µg/g)	1.72	4.24
NAB (µg/g)	0.152	0.265
Ammonia (µg/g)	2581	2356
B[a]P (ng/g)	56.2	143.9



CORESTA Recommended Methods

- 1) **CRM N° 36: Determination of Nitrate in Tobacco and Smokeless Tobacco products by Reduction to Nitrite and Continuous Flow Analysis (4th ed., 2015)**
- 2) **CRM N° 56: Determination of Water in Tobacco and Tobacco Products by Karl Fischer Method (2nd ed., 2011)**
- 3) **CRM N° 60: Determination of 1,2-Propylene Glycol and Glycerol in Tobacco and Tobacco Products by GC (3rd ed., 2015)**
- 4) **CRM N° 61: Determination of 1,2-Propylene Glycol, Glycerol and Sorbitol in Tobacco and Tobacco Products by HPLC (3rd ed., 2015)**
- 5) **CRM N° 69: Determination of pH in Smokeless Tobacco Products (2010)**



CORESTA Recommended Methods

- 6) CRM N° 71: Smokeless Tobacco Products – Sampling (2011)
- 7) CRM N° 72: Determination of TSNAs in Smokeless Tobacco Products by LC-MS/MS (3rd ed., 2016)
- 8) CRM N° 76: Determination of Moisture Content (Oven Volatiles) of Smokeless Tobacco Products (2014)
- 9) CRM N° 79: Determination of Ammonia in Tobacco and Tobacco Products by Ion Chromatographic Analysis (2015)
- 10) CRM N° 82: Determination of Benzo[a]pyrene in Tobacco Products by GC-MS (2016)



- ❖ **CORESTA Guide No. 11 - Technical Guideline for Sample Handling of Smokeless Tobacco and Smokeless Tobacco Products (2011)**
- ❖ **CORESTA Guide No. 15 - CORESTA Reference Products Production and Evaluation Requirements (2014)**



Technical Reports and CRMs (past 12 months)

- ❖ **2015 Collaborative Study on Benzo[a]pyrene in Tobacco Products (March 2016)**
- ❖ **CRM No. 82 - Determination of Benzo[a]pyrene in Tobacco Products by GC-MS (March 2016)**
- ❖ **CORESTA Reference Products (Smokeless Tobacco) - 2015 Analysis (December 2015)**

- 1) Characterization and maintenance of the 2016 CRPs**
 - Finalize technical report
- 2) Carbonyls – formaldehyde, acetaldehyde, crotonaldehyde**
 - Receive final data sets, draft technical report and CRM
- 3) Nicotine by GC-MS - Joint RAC / STS project**
 - Finalize study report and draft CRM
- 4) Nitrate/ nitrite**
 - Draft technical report



New Work Items

- 1) **Metals Proficiency Study – spring 2017**
 - **Arsenic, Beryllium, Cadmium, Chromium, Cobalt, Nickel, Lead, and Selenium**

- 2) **TSNAs, OV, pH collaborative study for tobacco and tobacco products**
 - **Update CRMs to include other forms of tobacco products**

- 3) **Develop CRM for expanded list of PAHs**
 - **Preliminary collaborative study**

- ❖ **ISO/CD 21045: "Tobacco and tobacco products - Determination of ammonia - Method using ion chromatographic analysis"**
 - **Approved as a Draft International Standard**

- ❖ **ISO/NP 21766: "Tobacco and tobacco products - Determination of tobacco-specific nitrosamines in tobacco products - Method using LC-MS/MS"**
 - **Approved as a Committee Draft**

- ❖ **B[a]P, Oven Volatiles, and pH have also been approved by the Scientific Commission and Board for submittal to ISO**



Progress Against Objectives

Constituents of Regulatory Concern

Constituent	Status	HPHC Abbreviated List	WHO STP Priority Toxicants	Swedish National Food Agency
Nicotine (total and free)	CRM N°62	√		
pH (calculation of nicotine)	CRM N°69	√		
NNK, NNN	CRM N°72	√	√	√
Benzo[a]pyrene	CRM N°82	√	√	√
Acetaldehyde, Croton., Form.	work item	√		
Arsenic, Cadmium	PT	√		
Lead	PT	Estab. list		√
Aflatoxin B1		Estab. list		√



Benefits to the Scientific Community

- ❖ **Production and maintenance of CRPs**
- ❖ **Development of robust methods with defined repeatability and reproducibility**
- ❖ **Collaborative and proficiency studies which:**
 - **Provide laboratory performance feedback**
 - **Support ISO 17025 accreditation**
- ❖ **Study results and methodology are a source of engagement with authorities and regulators**



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