



# **Smokeless Tobacco Sub-Group**

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**Secretary: Johan Lindholm (Swedish Match, Scandinavia Division)**



# STS History

- ❖ **STS established in November 2008**
- ❖ **Typical two meetings per year:**
  - **~ 40 attendees**
  - **~ 30 member companies represented**
- ❖ **STS Meetings since CORESTA SSPT 2014, Québec**
  - **Hangzhou, China (April 14)**
  - **Jeju, South Korea (October 2015)**
- ❖ **Collaboration with RAC**



# STS Objectives

- ❖ To perform collaborative studies on main chemical parameters of smokeless products.
- ❖ To develop CORESTA Recommended Methods as agreed by the Scientific Commission.
- ❖ To maintain the glossary on product definition and definitions of terms to support harmonization of nomenclature.
- ✓ To define and set standards for the manufacture of reference products and storage requirements for long term stability.



# Manufacture and Maintenance of CORESTA Reference Products (CRPs)

- ❖ **The STS established 4 smokeless tobacco reference products 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**
  
- ❖ **The STS conducts an annual collaborative study to assess the stability of the CRPs (2010 – present)**
  - **CRM N° 62: Nicotine**
  - **CRM N° 69: pH**
  - **CRM N° 72: TSNAs**
  - **CRM N° 76: Moisture (oven volatiles)**
  
- ❖ **The Annual stability reports are published at [CORESTA.org](http://CORESTA.org)**



## Current Supply of CRPs

	Dec 2009	Dec 2010	Dec 2011	Dec 2012	Dec 2013	Dec 2014	Sept 2015
CRP 1	7000	6135	5443	4895	3975	3242	2152
CRP 2	7020	6363	6093	5082	4453	3680	2623
CRP 3	7040	6653	6207	5520	5113	4691	4291
CRP 4	7000	6806	6567	6374	6236	6040	5758

➤ **The STS will remanufacture of CRP1, CRP2, and CRP3**



# Development of CRMs

## ❖ New Work Items

- Constituents of regulatory concern
- Suggestions from participating laboratories

## ❖ Joint Experiments

- Designed to investigate parameters that may contribute to within-lab and between-lab variability

## ❖ Iterative, stepwise process to develop a CRM

- identify method(s) for evaluation
  - initial small joint experiment
    - method refinements
      - large collaborative study
        - **robust CRM with defined repeatability and reproducibility**



# Progress Toward Objectives Last 6 years

- ❖ **CRM N° 69: Determination of pH in Smokeless Tobacco Products (2010)**
- ❖ **CRM N° 36: Determination of Nitrate in Tobacco and Smokeless Tobacco products by Reduction to Nitrite and Continuous Flow Analysis (updated 2011)**
- ❖ **CRM N° 56: Determination of Water in Tobacco and Tobacco Products by Karl Fischer Method (updated 2011)**
- ❖ **CORESTA Guide No. 11 - Technical Guideline for Sample Handling of Smokeless Tobacco and Smokeless Tobacco Products (2011)**
- ❖ **CRM N° 71: Smokeless Tobacco Products – Sampling (2011)**



# Progress Toward Objectives Last 6 years

- ❖ **CRM N° 72: Determination of Tobacco Specific Nitrosamines in Smokeless Tobacco Products by LC-MS/MS (2011, updated 2013)**
- ❖ **CRM N° 76: Determination of Moisture Content (Oven Volatiles) of Smokeless Tobacco Products (2014)**
- ❖ **CRM N° 79: Determination of Ammonia in Tobacco and Tobacco Products by Ion Chromatographic Analysis (2015)**
- ❖ **CRM N° 60, Third edition: Determination of 1,2-Propylene Glycol and Glycerol in Tobacco and Tobacco Products by GC (updated 2015)**
- ❖ **CRM N° 61, Third Edition: Determination of 1,2-Propylene Glycol, Glycerol and Sorbitol in Tobacco and Tobacco Products by HPLC (updated 2015)**





# Technical Reports Published in 2015

- ❖ **Determination of Nitrate in Smokeless Tobacco Products by Continuous Flow Analysis**
- ❖ **CORESTA Reference Products, 2014 Analysis**
- ❖ **Collaborative Study on Humectants**
- ❖ **Proficiency Test Report: The Determination of Arsenic, Beryllium, Cadmium, Chromium, Cobalt, Nickel, Lead, and Selenium in Reference Materials**
- ❖ ***Draft* CORESTA Reference Products, 2015 Analysis**



# Ongoing and New Work Items

- ❖ **Maintenance of the CRPs**
- ❖ **Benzo[a]pyrene by GC-MS**
  - The final collaborative study has been completed
  - A technical report and CRM will be drafted
- ❖ **Carbonyls – formaldehyde, acetaldehyde, crotonaldehyde**
  - LC-MS/MS method is being refined for a future study
- ❖ **Metals Proficiency Study**
  - Arsenic, Beryllium, Cadmium, Chromium, Cobalt, Nickel, Lead, and Selenium
- ❖ **Joint RAC/STS – CRM for nicotine by GC-MS**



# Smokeless Tobacco Constituents

Constituent	Method	HPHC Abbreviated List	WHO Priority Toxicants <sup>1</sup>
Nicotine (total and free)	CRM N°62	√	
pH (to calculate free nicotine)	CRM N°69	√	
NNK, NNN	CRM N°72	√	√
Benzo[a]pyrene	Current work item	√	√
Acetaldehyde, Crotonaldehyde, Formaldehyde	Current work item	√	
Arsenic, Cadmium	Proficiency testing	√	

1. WHO Technical Report Series 955, WHO Study Group On Tobacco Product Regulation. Report on the Scientific Basis of Tobacco Product Regulation: Third Report of a WHO Study Group, 2009.



# Benefits to the Scientific Community

- ❖ **Development and maintenance of 4 CORESTA reference smokeless tobacco products (CRPs)**
- ❖ **Collaborative and proficiency studies which:**
  - **Provide laboratory performance feedback**
  - **Support ISO accreditation**
- ❖ **The development of robust methods with defined repeatability and reproducibility**
- ❖ **Members of CORESTA are often the best qualified to develop standardized methods**
- ❖ **Study results and methodology are a source of engagement with authorities and regulators**



- ❖ **Development of CORESTA Recommended Methods**
  - A method that is reproducible in one laboratory may not be suitably robust for a CRM
  - The development of CRMs is an iterative process
  - The protocol must be strictly adhered to, otherwise data does not support study objectives (determination of r&R)
  - Full participation by the Sub-Group is needed in order to have a sufficient number of labs to calculate meaningful r&R



# Acknowledgements

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- Served as Coordinator since 2009

## ❖ Working Group 2 Coordinator

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