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

Cancun, Mexico

10 October 2023

TTPA Overview

- **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**
- **Typically meet twice a year**
  - **~ 50 attendees**
  - **~ 40 companies represented**
- **Last meetings:**
  - **31st meeting (19 April 2023, Antibes, France)**
  - **32nd meeting (8 October 2023, Cancun, Mexico)**

TTPA Objectives

1) To propose and maintain CORESTA Recommended Methods (CRMs) and related documents for the analysis of tobacco and unburned tobacco products

2) To organise interlaboratory testing related to Objective 1

3) To organise the manufacture of and maintain smokeless tobacco reference products

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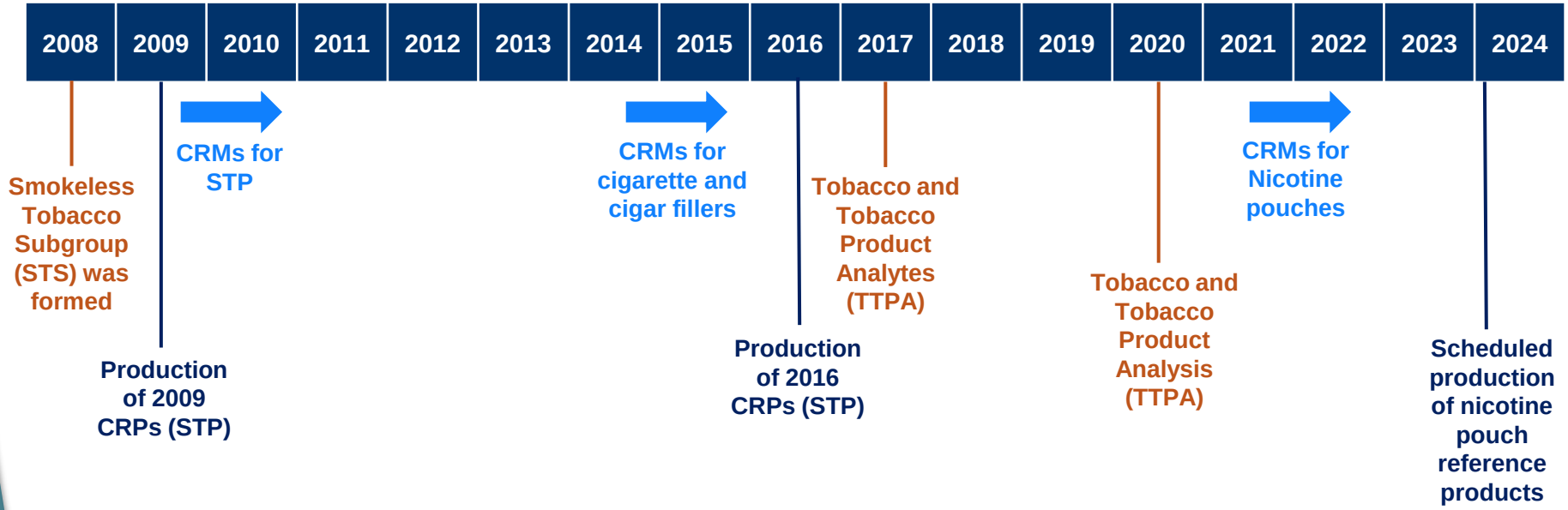
3) To organise the manufacture of traditional and modern oral nicotine reference products.

TTPA Timeline



➢ **The TTPA has published 38 collaborative studies and created and updated 19 CRMs**

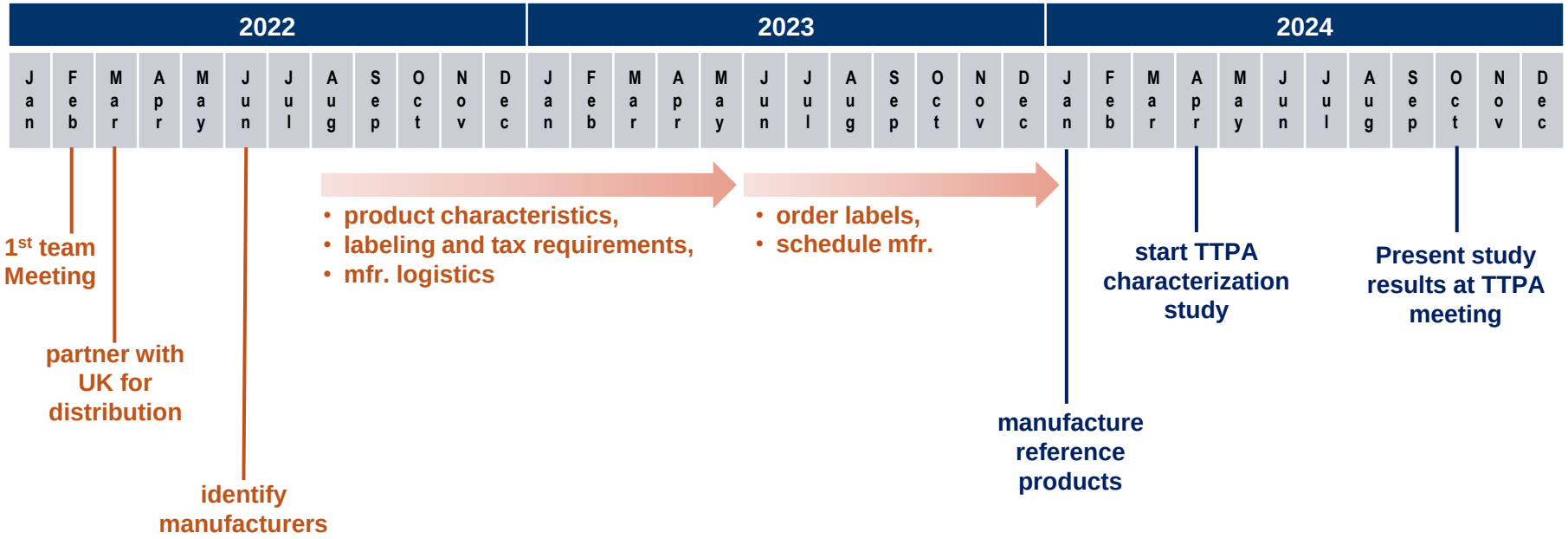
CORESTA Reference Products (CRPs)

- **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
- **Biennial collaborative studies to assess stability:**
  - Nicotine, TSNAs, pH, Moisture
- **CRPs have been shown to be stable for 10 at least years when stored at the recommended temperature of -20 °C**

2009 CRPs

2016 CRPs

CORESTA Nicotine Pouch Reference Products

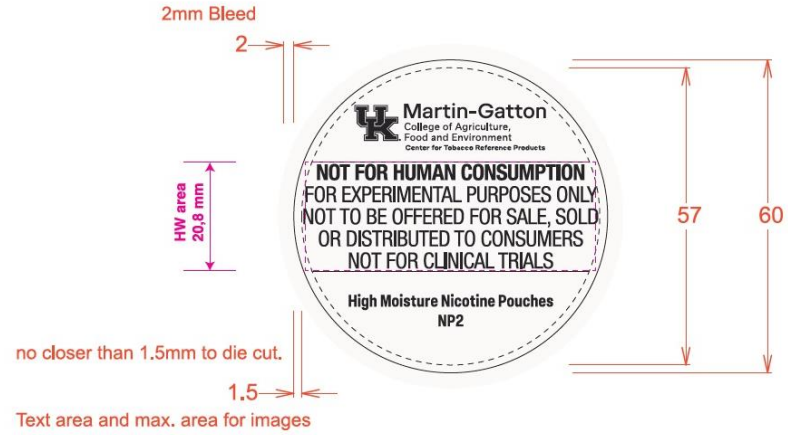


Nicotine Pouch reference Products
Proposed Product Characteristics

- **Distribution by University of Kentucky**
- **Long-term storage at -20 °C**
- **Quantities sufficient to last 3 – 5 years**
- **TTPA will conduct annual studies to monitor the product stability**

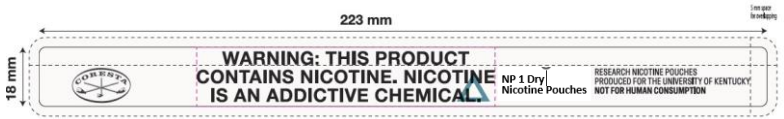
Product	Product Type	Nicotine (mg/pouch)	Moisture (%)	pH	Portion Weight (grams)
NP1	Dry granulated/powder	6	2.7	8.3	0.4
NP2	Moist fiber-based	10.9	48	8.6 – 9.0	0.7

Nicotine Pouch Reference Products – Labels



Healthwarning Calculations:
side can surface dimension
2*3,14159*35*24,93 = 5482,389 mm2,
30% = 1644,717 mm2

Height of Healthwarning = 18
Width = 1644,717 / 18 = 91,3732



NOTE: These drawings are for illustrative purposes only

Homogeneity and Characterization Studies

Homogeneity study

- **Manufacturers will conduct homogeneity testing**
- **Three cans will be pulled from each pouching head every 15 minutes**
  - Composite sample will be created from the three cans at each timepoint
  - Three sample replicates will be prepared and analyzed from each composite sample
- **Analytes and measures include:**
  - Nicotine (mg/pouch, mg/g)
  - pH
  - OV
  - portion weight
- **Results will be published in a CORESTA Technical Report**

Characterization study

- **The TTPA will conduct an initial characterization study:**
  - nicotine
  - pH
  - moisture (oven volatiles)
  - water activity
  - nicotine impurities and degradants
  - carbonyls
  - arsenic and cadmium
  - TSNAs
  - B[a]P
- **This study will serve as the basis for annual stability studies**

Completed Projects

Project No.	Type	Project name	Project Leader	Data Published
319-1	TR	2022 Collaborative study for Nitrate and Nitrite in Tobacco and Tobacco Products, (Tony Brown)	G. Prepelitskaya, T Brown	Aug 2023
319-2	CRM	CRM No. 103 - Determination of Nitrate in Tobacco and Tobacco Products by Ion Chromatography	T. Brown	Aug 2023
345	TR	Stability Study for the 2016 CORESTA Reference Products - 2023 Analysis,	R. Avagyan, M. Morton	July 2023

Ongoing Projects

Project No.	Type	Project name	Project Leader	Estimated Completion
246	CS, TR, CRM	Determination of Nicotine Degradants in Nicotine Pouches	J. Patring, F. Aldeek, M. Morton	Nov 2023
372	TR	CORESTA Nicotine Pouch Reference Products	R. Avagyan, H. Digard	Jan 2024
375	TR	Nicotine Pouch Filler Particle Size Proficiency Study	S. Platt, F. Aldeek	TBD

Benefits to the Scientific Community

- **Production and maintenance of reference products**
- **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**
  - **Yevgeniya (Genya) Prepelitskaya and Tony Brown (Altria): Nitrate and Nitrite Collaborative Study and CRM**
  - **Rozanna Avagyan (Swedish Match): 2023 CRP stability study**
  - **Fadi Aldeek (Altria): Development of a CRM for nicotine impurities and degradants in nicotine pouches**
  - **Michael Morton (Altria) co-author and statistical support**
- **Small group developing nicotine pouch reference products**
  - **Swedish Match – Johan Lindholm, Johan Redeby, Rozanna Avagyan**
  - **British American Tobacco – Helena Digard**
  - **Altria Client Services LLC – Karl Wagner**
  - **Imperial Tobacco Reemtsma – Jutta Pani**
  - **R.J. Reynolds Tobacco Company – Nolan D Spann**
  - **American Snuff Company, LLC – John Bunch**
  - **University of Kentucky – Huihua Ji, Matthew Craft, Ling Yuan**

Thank You!