

NEWSLETTER

Issue 66 - August 2023

FOREWORD

The countdown to the first post-Covid in-person CORESTA Conference has started! In less than two months, we will have the great pleasure of welcoming delegates in Cancun, Mexico, for the SSPT2023 and AP2023 events, under "normal" conditions again. Arrangements are progressing smoothly, and we hope to fully benefit from the privilege of being able to interact and network face to face with nearly 250 registered participants (as of early August 2023).

The CORESTA Scientific Commission Reading Committee met in June to set the programmes, which promise to be of high scientific standard and of great interest. In addition, a set of Symposiums and Workshops are also being organised — details further in this Newsletter. The 2023 Conferences are also the opportunity for the CORESTA Sub-Groups and Task Forces to hold their meetings and present their activity reports. Following the Workshop on Tobacco Harm Reduction held in April 2023 (read about the proceedings and outcome in this Newsletter!), a presentation will be made in October on the progress made to set up a structure for the work to be done on the subject.

You will find the usual updates to working groups and lists of CORESTA documents published over the last few months. Of note is the number of new projects launched, a clear indicator that the uncertainty surrounding the Covid period has been replaced by renewed vigour and activity. Two Sub-Groups, Physical Test Methods and Smoke Analysis, have written on their recent activities, and an article on CDISC describes the role of this organisation with whom the Biomarkers Sub-Group is cooperating to develop tobacco data reporting standards.

This issue's "Insight from a Member" gives a personal view of what it means to be active in CORESTA and all the benefits that are derived, and a new scientist is highlighted under the "Researcher Spotlight" section.

Last, but not least, it is with sadness that CORESTA publishes a farewell note to a well-known agronomy colleague, Colin Archibald, who passed away recently.

Joint Study Group Conferences 2023 October 2023 – Cancun, Mexico

SSPT2023 - The Smoke Science and Product Technology Conference will be held from 8–12 October 2023. The meeting will be kindly hosted by Mother Murphy's Labs.

Registration and accommodation information is available on the official meeting website at https://sspt2023.coresta.org.

Online registration is available until 22 September.





AP2023 - The Agronomy & Leaf Integrity and Phytopathology & Genetics Conference will be held from 15–19 October 2023 and is being organised by the CORESTA Secretariat.

Registration and accommodation information can be found on the official meeting website at https://ap2023.coresta.org.

Online registration is available until 22 September.

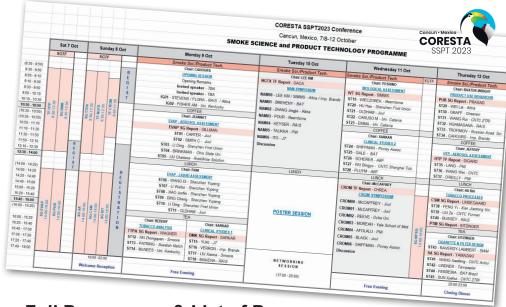
SSPT2023 Programme Sessions

128 presentations

- E-vapour Products: Aerosol Assessment and Liquid Assessment
- Tobacco Analysis
- · Clinical Studies
- · Biological Assessment
- · Product Use Behaviour
- · HTP Aerosol Assessment
- Tobacco Processes
- · Cigarette & Filter Design

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Invited Speakers, Intergroup Papers, Symposiums, Posters, Working Group Reports



Full Programme & List of Papers:

https://sspt2023.coresta.org/article/86-programmes.html

SYMPOSIUM

NAM II – Applications in Tobacco Regulatory Sciences – Tuesday, 10 October

We are excited to announce the follow-up New Approach Methods (NAMs) Symposium at the October SSPT Conference! The term NAM is no longer a new vocabulary to many CORESTA participants; in short, NAMs can be defined as in vitro and in silico or computational-based methodologies in toxicology that enable clinically relevant risk assessment, without needing new animal testing. This year's NAM Symposium is the followup from the introductory Symposium held during the virtual SSPT2021 Conference ("Advancing New Alternative Methods for Tobacco Harm Reduction"). In the two years since then, the interest and need to utilize NAMs in tobacco science has become ever more relevant, with many different categories of smoke-free alternative products being introduced worldwide. It is of concern that there is currently no consensus on how to evaluate the toxicity potential of these emerging products and we do not know the toxicological profiles of many of them. At the same time, it is simply impossible, unethical and not necessary to subject these fundamentally different products to traditional toxicity testing such as using animals. As an alternative, we explore in this symposium the applicability of cell or in vitrobased NAMs in addressing some of the immediate gaps in product assessment (NAM-TODAY; toxicity We also extend the long-term screening). application of NAMs linking in vitro outcomes to clinically relevant disease outcomes (NAM-TOMORROW; COPD progression and pathways). To cover these topics, we will have a total of six excellent talks from industry experts, while inviting attendees' active participation during the panel discussion at the end of the session.

The Symposium is endorsed by the CORESTA Scientific Commission, the 21st Century Toxicology for Next Generation Tobacco and Nicotine Products Task Force and the *In Vitro* Toxicity Testing Sub-Group and reflects the ongoing commitment to the 3Rs (reduce, replace, and refine animal testing) by CORESTA.

SYMPOSIUM

Consumer Reported Outcome Measures (CROM) – Wednesday, 11 October

Consumer reported outcome measures (CROM), such as self-report questionnaires of tobacco product dependence and risk perceptions, are a critical component of tobacco and nicotine product research, including regulatory science. Consistent with other fields of science, behavioural researchers require instruments that are reliable and valid for measuring a given construct, e.g. risk perceptions, to ensure accuracy and replicability of measurement, and to support the validity of study conclusions. CROM are typically developed and validated for one particular context of use, for example, for use with a certain population such as adult smokers, or for use with a specific product category such as e-cigarettes. When a CROM developed for one context of use is applied to a new context, this can impact the reliability and validity of those measurements, i.e. the CROM's psychometric functioning, a research question which can be evaluated empirically through the field of psychometrics.

The CORESTA CROM Task Force (TF) is charged with establishing best practices and guidelines pertaining to the use of CROM in tobacco research.

This Symposium, organized by the CROM TF, will delve into this complex psychometric topic - i.e. the application of CROM to different contexts, and quantitative approaches to evaluating the impact of such applications. Introductory presentations will review draft guidelines being developed by the CROM TF, and introduce important concepts and analyses in psychometrics.

Speakers will then discuss approaches to evaluating the psychometric functioning of a CROM when used with a different product from which it was developed, namely:

- evaluating the psychometric functioning of the mCEQ, i.e. the Modified Cigarette Evaluation Questionnaire, when used to measure the reinforcing effects of e-cigarettes rather than cigarettes
- assessing the psychometric functioning of the ABOUT-Dependence measure when applied to users of a heated tobacco product (IQOS)

Speakers will also present approaches to evaluating CROM functioning across populations, and whether CROM scores from such populations are comparable:

- examining psychometric invariance of a dependence CROM, developed for adult smokers, to determine its suitability in measuring dependence in youth
- evaluating the functioning of numerical rating risk-perception scales in individuals with limited numeracy to assess whether scores from such scales are comparable to those with limited vs. adequate numeracy.

AP2023 Programme Sessions 108 presentations

- Crop Protection Agent Management
- Sustainability: Good Agricultural Practices Training
- · Breeding & Genetics
- Biological Processes
- · Flavour & Aroma
- Tobacco-specific nitrosamines (TSNAs)
- Technology
- Pest & Disease Control
- Environmental, Social and Governance
- · Cigar Tobacco Production
- Low Nicotine

Invited Speakers, Intergroup Papers, Symposiums, Posters, Working Group Reports, CORESTA Prize presentation

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Full Programme & List of Papers:

https://ap2023.coresta.org/article/86-programmes.html

WORKSHOP

Sustainability - Monday, 16 October

Sustainability initiatives have garnered attention within the global tobacco industry. In this Workshop we will learn about some of the ways in which tobacco researchers have responded to ensure that future generations can enjoy the livelihood provided by tobacco while minimizing their impact on the environment and without depleting natural resources.

In our first presentation, David Reed (Virginia Tech) will discuss environmentally focused research that serves to provide insight about water movement, availability, and tobacco rooting depth within the soil profile. His research is novel and implements technology not presently used in tobacco production. Susan Dimbi (Tobacco Research Board - Kutsaga) will provide an informative overview of the integrated system by which Zimbabwean tobacco farmers use climate appropriate tobacco varieties and green pesticides, as well as the training mechanisms utilized by TRB for grower outreach. The TRB has been very invested in their sustainability initiatives, and Susan Dimbi's presentation will summarize currently available information. Finally, Lea Scott (Universal Leaf Tobacco) will share insight from the Agrochemical Advisory Committee and demonstrate the impact of pesticide selection and application. The goal of this Workshop is to create open dialogue among industry stakeholders that will generate new ideas for CORESTA sustainability initiatives.

WORKSHOP

Cigar Tobacco – Thursday, 19 October

Cigars can be remarkably diverse. From premium handmade to cigarillo formats, these high-value agriculture products represent one of the oldest and most interesting categories of tobacco products.

The compelling characteristics of most desirable cigar tobaccos are the result of specific crop production systems that take place in geographies where specific edaphoclimatic conditions are shaped by a prominent level of craftsmanship and enthusiasm. In order to remain competitive, however, cigar operators and stakeholders must also understand the nuances of complex, ever-changing regulatory landscapes and maintain best practice standards in operational excellence.

The CORESTA AP2023 Conference Cigar Workshop will bring together expert speakers from different areas of the cigar world to share their perspectives and insights on key aspects of leaf production, analytical testing strategies and some of the latest regulatory challenges facing the industry. The presentations will be followed by an open panel to foster exchange with presenters as well as lively discussions with questions from the floor.

You are invited to come to Cancun, meet up, learn, share your knowledge, and interact with members of the international leaf cigar community in person. We are looking forward to seeing and engaging with you!

WORKSHOP

Environmental, Social and Governance (ESG) – Wednesday, 18 October

CORESTA will hold a workshop on Environmental, Social and Governance (ESG) during the AP2023 Conference. ESG is a framework designed to assess an organization's business practices and performance on various sustainability and ethical practices and associated challenges. Dedicated ESG programmes capture both the strategy and initiatives to measure and report on sustainability results.

Against this background, Workshop presentations will provide information to participants on how companies are currently assessing sustainability in their supply chains though initiatives such the Sustainable Tobacco Programme (STP) among others.

For better understanding of industry's leadership on environmental and social protection, JTI will present a practical session exploring different ways to enhance the livelihoods of tobacco growing families and their communities.

More specifically on farming operations, the Tobacco Growers Association of North Carolina will highlight current Good Agricultural Practices and outline the collaborative way the global industry can work hand-in-hand with tobacco growers to ensure that their voices are also heard and considered in global ESG initiatives.

Please join the ESG Workshop and by interacting with presenters and participants from the industry, more insight will be gained into how ESG is contributing to the trust and reputation of a business.

TOBACCO HARM REDUCTION WORKSHOP

How can CORESTA Advance the Science Related to Tobacco Harm Reduction?

21 April 2023 – Juan-les-Pins Antibes, France

In June 2022, CORESTA held a Science Day in Paris, France. Presenters included tobacco harm reduction (THR) experts within and outside of the CORESTA membership. Topics covered included the role of nicotine in harm reduction, misperceptions on the harm of nicotine, the challenges and opportunities of harm reduction substantiation, innovation and harm reduction of alternative products, and supply chain integrity. Through guidance from the CORESTA Board and with what was learned from the Science Day, a Workshop was designed and executed in April 2023, in Juan-les-Pins Antibes, France, to develop insights into how CORESTA can advance the science related to THR. A diverse group of approximately 70 participants was selected by the CORESTA Member Organization representatives to address the following objectives:

- 1. Identify key areas where CORESTA can advance the science related to THR;
- 2. Create actionable objectives to advance the key areas of science related to THR;
- 3. Develop a recommendation for the infrastructure by which to accomplish the actionable objectives.

Rob Stevens and Jason Flora, both CORESTA Board representatives and members of the CORESTA Strategy Committee, co-chaired this all-day workshop. The agenda was designed to address each of the objectives sequentially.



After setting the stage for an interactive day and providing some background (e.g. outcomes from Science Day), they divided participants into distinct break-out groups to identify key focus areas where CORESTA can advance the science related to THR, Workshop Objective 1. These break-out groups were designed to have participants with related expertise (raw materials and supply chain, pre-clinical/product characterization, or clinical/product use) to ensure that focus areas covered the various areas of expertise represented by CORESTA's members. To ensure active discussions, break-out group leads were pre-selected based on their expertise, leadership qualities, and history of strong contributions to CORESTA (Anne Fisher, Helena Digard, Gene Gillman, Sarah Baxter-Wright, and Mohamadi Sarkar).



After lively brainstorming, reports from break-out group leads, and voting among all participants, consensus was reached on five key focus areas:

- 1. Risk reduction to harm reduction
- 2. Real world evidence in potentially reduced risk products (PRRPs) in the context of global regulations
- 3. Supply chain considerations in THR
- 4. Developing and applying new methods/techniques/models to assess PRRPs across all science areas
- 5. Nicotine science health effects and misperceptions



Once these key focus areas were determined, the next step was to create actionable objectives to advance the key areas of science related to THR, Workshop Objective 2. Participants formed new break-out groups depending on their interests and expertise.

TOBACCO HARM REDUCTION WORKSHOP (continued)

Again, after thoughtful discussions, reports from the groups, and voting among all participants, consensus on the priority actionable objectives was achieved. Fortuitously, this resulted in an actionable objective for each of the focus areas:

- 1. Define and develop a scientific framework to establish: reduced exposure to reduced individual risk to reduced population harm
- 2. Build a strategy to monitor and assess real world evidence in the context of global regulations
- 3. Create/refine guidance for agronomic management of constituents, residues, and contaminants
- 4. Develop product guidelines for each product category (e.g. performance, quality, safety)
- 5. Define known and unknown health effects of nicotine use (outside of smoking) and identify priority areas

In addition to these five priority objectives, additional objectives from the break-out groups were identified and captured by the co-coordinators for future consideration.

Now that consensus was reached on the key focus areas and actionable objectives, the final step in the Workshop was to develop a recommendation for the infrastructure by which to accomplish the actionable objectives, Workshop Objective 3. All participants reconvened for a group discussion on this topic following a review of CORESTA statutes and rules provided by the CORESTA Secretary General, Stéphane Colard. The group ultimately decided to recommend that a committee of experts (~10 to 14 members), a THR Committee, would oversee the objectives. It was recommended that work will be done within the Committee, through working groups (SGTFs), using unique workstreams, and/or partnering with external experts, as appropriate. The group also agreed that Rob Stevens and Jason Flora should co-lead the Committee initially and then the members will determine the long-term leadership.

This recommendation was presented by Rob and Jason to the CORESTA Board at the June Board meeting in Stockholm, Sweden. The Board agreed that a THR Committee should be formed once appropriate governance complying with CORESTA statutes and rules had been established. Work is underway to develop this governance and THR Committee members will be determined thereafter.

Rob and Jason plan to share the outcomes of the THR Workshop in more detail at the upcoming Tobacco Science Research Conference (TSRC), in Norfolk, VA, USA, in September, and the 2023 CORESTA SSPT and AP Conferences in Cancun, Mexico, in October.



UPCOMING CORESTA MEETINGS (2023)

Please visit the CORESTA website for the most up-to-date information (www.coresta.org/meetings/upcoming).

Meeting	Date	Location
TF NPSQ - Nicotine Pouches Safety and Quality Guidance	6 September 2023	Online
SG PTM - Physical Test Methods	19 September 2023	Milton Keynes, UK
TF HTP - Heated Tobacco Products; SG BMK - Biomarkers; SG EVAP - E-Vapour; SG PUB - Product Use Behaviour	7 October 2023	Cancun, Mexico
SG TTPA - Tobacco and Tobacco Products Analysis; TF NGTX - 21st Century Toxicology for Next Generation Tobacco and Nicotine Products; TF CROM - Consumer Reported Outcome Measures; SG SA - Smoke Analysis; SG CSM - Cigar Smoking Methods; SG IVT - In Vitro Toxicology Testing	8 October 2023	Cancun, Mexico
TF NPSQ - Nicotine Pouches Safety and Quality Guidance	11 October 2023	Cancun, Mexico
TF GTS - Green Tobacco Sickness; SG BIO - Efficacy of Biological and Eco-Friendly CPAs; SG BKS - Collaborative Study Black Shank; TF LNTP - Collaborative Study of Low Nicotine Tobacco Agronomic Production Practices;	14 October 2023	Cancun, Mexico
ACAC - Agrochemical Advisory Committee	15 October 2023	Cancun, Mexico
SG IPM - Integrated Pest Management; SG TSNA - TSNA in Air-cured and Fire-cured Tobacco; SG GMO - Proficiency Testing for Detection of Transgenic Tobacco; SG RFT - Agrochemical Residue Field Trials	15 October 2023	Cancun, Mexico
SMOKE SCIENCE and PRODUCT TECHNOLOGY (SSPT2023)	8-12 October 2023	Cancun, Mexico
AGRONOMY & LEAF INTEGRITY and PHYTOPATHOLOGY & GENETICS (AP2023)	15-19 October 2023	Cancun, Mexico
SG AA - Agrochemicals Analysis	24-26 October 2023	Charleston, SC, USA

CORESTA Scientific Commission and Board Meetings

The BOARD met in Stockholm, Sweden, on 13 and 14 June 2023. The meeting was kindly hosted by Swedish Match. The Secretary General reported on the CORESTA budget and main Secretariat projects, and the President and Vice-President of the Scientific Commission reported on the most recent SGTF achievements, the 2023 Conference programmes and the perspectives. Membership: The number of Members continues to increase reaching 168 organizations to date.

Budget: The financial audit for the last financial year was conducted on 11 July. This year, income is expected to increase due to new Members joining CORESTA. Expenses are also expected to increase due to the transfer of the costs of the Drupal 9 website migration. The financial assets remained stable over the last six months.

IT: Migration to Drupal 9 was slightly delayed with a launch date being postponed from October 2023 to January 2024. The delay has no critical impact on CORESTA and was caused by the priority use of the Secretariat resources to organize inperson meetings and a workshop in Antibes, France, in April 2023. The migration to FileMaker 19 was completed with a subscription to a perpetual licence. The development of the AP and SSPT Conference websites was completed. • Strategy: It was proposed to replace the two-year and five-year plans by a fiveyear plan and two-year deliverables. This alternative will help communicate/report more tangible short-term expectations/achievements in line with long-term plans. • Events: A survey was conducted among the participants at the 17 SGTF meetings and the workshop held in Antibes. One of the objectives was to re-engage people in face to face events after three years of virtual interactions. The number of participants reached 173 which largely exceeded the expectations. 91% of the respondents found the event excellent or very good, and were ready to repeat the experience next year. Overall, a large majority of respondents were satisfied with the organisation, the venue and the possibility to attend several meetings in one easy to reach location. Communication: Significant information on the Strategy House and additional topics was communicated to participants at the meetings held in Antibes. The next communication at SGTF meetings is planned in October.

In addition, there is a need to communicate more broadly on the benefits of being a Member Organisation of CORESTA and also to better link the Strategy House to concrete achievements. A poster will be presented at the 2023 Conferences in Cancun.

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The SCIENTIFIC COMMISSION (SC) met in Stockholm, Sweden, on 12, 13 and 14 June 2023. The meeting was kindly hosted by Swedish Match. The meeting started with the Reading Committee sessions to review the abstracts submitted for a presentation or a poster at the 2023 AP and SSPT Conferences, and to prepare the scientific programme. These sessions were followed by Study Group breakout sessions, a joint Board/SC meeting and an SC plenary meeting. Needless to say that the three days were particularly busy.

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The **BOARD** and **SCIENTIFIC COMMISSION** met together on 14 June 2023 for a half-day meeting. As far as could be remembered, this was the first time that such meeting had been arranged. The objectives were to better cooperate on strategy, communication and events, and to get mutual feedback. Breakout sessions were also organised to debate and agree on workstream assessment and priority management.



CORESTA SUB-GROUPS & TASK FORCES

AGRONOMY & LEAF INTEGRITY Study Group

Revised Objectives: Sub-Group Proficiency Testing for Detection of Transgenic Tobacco (GMO)

UPDATE

• To provide an independent assessment of the quality of data being produced by participating laboratories, through the Tobacco Proficiency Testing Scheme.

The second objective "to contribute to the update of the GMO Dossier in collaboration with ACAC" was removed as the GMO Dossier (now named "Agri-Biotech Dossier") is being fully managed by the Agrochemical Advisory Committee (ACAC).

CORESTA SUB-GROUPS & TASK FORCES (continued)

PRODUCT TECHNOLOGY Study Group

New Task Force: Nicotine Pouches Safety and Quality Guidance (NPSQ)



Objectives:

• To develop a CORESTA Technical Guideline for nicotine pouches describing safety and quality best practice.

In 2023, the CORESTA Board proposed to create the above Task Force to respond to the evolving tobacco product marketplace. Nicotine pouches are oral tobacco products that do not contain tobacco and are composed of nicotine, flavourings, sweeteners, and plant-based fibers. Considering the rapid market growth for this new product category, it is important to provide safety and quality guidelines across the product life cycle from manufacture to consumer in order for manufacturers of nicotine pouches to be able to provide quality and safety assurances to all stakeholders.

For more information please contact the group Coordinator, Karl Wagner, Altria Client Services, USA (Karl.A.Wagner@altria.com) or Secretary, Johan Lindholm, Swedish Match, Sweden (johan.lindholm@swedishmatch.com)

Amendment to Group Type & Revised Objectives: Sub-Group Heated Tobacco Products (HTP)

UPDATE

The Task Force was changed to a Sub-Group as its work and activities were viewed as being long-term. The objectives were consequently amended to fit the new long-term vision of the group.

Objectives

- 1. To identify areas of scientific research and conduct studies that will characterise HTP product emissions, device properties and performance;
- 2. To develop and publish methods and guides;
- 3. To organise and conduct periodic proficiency/collaborative studies of identified constituents in HTP product aerosol.

OTHER Groups

Disbanded: Task Force Website (WEB)



Formed in 2015 to "develop and maintain and upgrade the CORESTA website", it was considered that the WEB Task Force had completed its objectives with the launch of the new website in 2016 and the input of information to date. The management of the CORESTA website now fell fully within the scope of the CORESTA Secretariat's responsibilities.

CORESTA RECOMMENDED METHODS

Updated

• **CRM No. 47** – Cigars - Sampling (*July 2023*) [CSM-371-CRM-47]

All CORESTA Recommended Methods can be downloaded in PDF format at

www.coresta.org

This CRM specifies two methods of sampling a population of cigars manufactured for sale for the preparation of laboratory samples. Different procedures are specified according to whether sampling is undertaken at the point of sale, at the producer's premises or importer's and distributor's warehouses. In this new version, the ISO Standards have been updated under the references section.

New

• **CRM No. 103** – Determination of Nitrate in Tobacco and Tobacco Products by Ion Chromatography (August 2023) [TTPA-319-2-CRM-103]

This CRM is used to quantitatively determine the concentration of nitrate in tobacco, cigarette filler, and a variety of smokeless tobaccos using ion chromatography. Results are reported in units of $\mu g/g$ on an as-is basis. This method is applicable to samples with concentrations of nitrate in the range of 50 $\mu g/g$ - 20000 $\mu g/g$. The CRM is supported by the Technical Report 2022 Collaborative Study for the Determination of Nitrate and Nitrite in Tobacco and Tobacco Products using Ion Chromatography, published in August 2023.

CORESTA REPORTS

The following reports have been published on the CORESTA website at www.coresta.org:

• In vitro Micronucleus Assay Inter-Laboratory Proficiency Study

Technical Report [IVT-311-CTR] – April 2023 (Sub-Group *In Vitro* Toxicity Testing)

An *in vitro* micronucleus assay proficiency study was conducted with the purpose to evaluate the micronucleus induction of a mainstream smoke extract of three cigarettes using a common study protocol. Laboratories were able to evaluate method proficiency, compare results with those of other laboratories and obtain an external audit of documentation procedures. The study results showed that the sensitivity of the micronucleus assay is good enough to differentiate the test pieces.

• 2nd Collaborative Study on Crush Strength of Flavour Capsules for Filters

Technical Report [PTM-338-CTR] – June 2023 (Sub-Group Physical Test Methods)

In August 2020 the CRM No. 94 (Determination of Crush Strength of Flavour Capsules for Filters – Definitions and Measurement Principles) was published, supported by a first collaborative study [PTM-218-1-CTR]. A second collaborative study was carried out to check if during the first two years of use the laboratories are still able to maintain the r&R values determined in the first study. Results show that laboratories are in general able to reliably perform the measurement of crush strength parameters as described in the CRM No. 94.

• CORESTA Reference Products - 2023 Analysis

Technical Report [TTPA-345-CTR] – July 2023 (Sub-Group Tobacco and Tobacco Products Analysis)

In September 2022, a fourth study was carried out to assess the stability of the four CORESTA Reference Products (CRPs) manufactured in 2016, and to provide repeatability (r) and reproducibility (R) results and z-scores to support laboratory accreditation. The participating laboratories reported the levels of nicotine, pH, moisture (oven volatiles), and tobacco specific nitrosamines (TSNAs) in the CRPs using CRMs. The results from this 2023 stability analysis generally compared well to the results from the analyses done in 2016, 2019, and 2021. The only statistically significant product trends differences from the 2016 and 2019 results were slight increases in moisture for CRP3.1 and a small pH drop in CRP1.1. These results are consistent with the trends seen with the CRPs produced in 2009. The TTPA continues to recommend that the stability of the 2016 CRPs be monitored on a biennial basis.

• 2022 Collaborative Study for the Determination of Nitrate and Nitrite in Tobacco and Tobacco Products using Ion Chromatography

Technical Report [TTPA-319-1-CTR] – August 2023 (Sub-Group Tobacco and Tobacco Products Analysis)

In late 2021, an interlaboratory study was initiated for the determination of nitrate and nitrite in tobacco and tobacco products by Ion Chromatography (IC). This study included a variety of samples including ground tobacco, cigarette filler, cigar filler and four styles of smokeless tobacco. The intent of this study was to draft a technical report to include repeatability (r) and reproducibility (R) values, z-scores, and a CRM if supported by the study results. The study demonstrated that the method was suitable for the determination of nitrate in tobacco and tobacco products, resulting in the publication of the CRM No. 103. However, the results for nitrite were inconsistent and suggested either the laboratories needed further practice implementing the method or the method needed additional development for use as an international consensus standardized method.



CORESTA PROJECTS

The following projects were launched:

- Project 365: Technical Guideline Defining Quality and Safety Related Best Practices for Nicotine Pouches TF NGTX 21st Century Toxicology for Next Generation Tobacco and Nicotine Products Approved April 2023
- **Project 366: Nicotine Flux a Metric of Abuse Liability** SG PUB Product Use Behaviour Approved April 2023
- Project 367: Evaluation of ToxTracker Assay for Applicability in Tobacco Related Clinical Research SG BMK Biomarkers Approved May 2023
- Project 368: 16th Collaborative Study on Physical Parameters (2023)
 SG PTM Physical Test Methods Approved April 2023
- Project 369: 3rd Collaborative Study on Air Permeability SG PTM - Physical Test Methods - Approved April 2023
- Project 370: 17th Round Robin Test on Pressure Drop Calibration Standards
 SG PTM Physical Test Methods Approved April 2023
- Project 371: Revision of CRM No. 47 Cigars Sampling SG CSM Cigar Smoking Methods Approved April 2023
- Project 372: Nicotine Pouch Reference Products SG TTPA - Tobacco and Tobacco Products Analysis - Approved May 2023
- Project 373: Collaborative Study for the Determination of Benzo[a]pyrene in Mainstream Cigar Smoke SG SA Smoke Analysis Approved May 2023
- Project 374: Collaborative Study of Four Metals in Cigarette Mainstream Smoke with ISO Smoking Regimes SG SA Smoke Analysis Approved June 2023
- Project 375: Nicotine Pouch Filler Particle Size Proficiency Study
 SG TTPA Tobacco and Tobacco Products Analysis Approved June 2023
- Project 376: Guidelines for Non-targeted Analysis of E-vapour and Heated Tobacco Product Substrates and Emissions

SG EVAP / HTP - E-Vapour / Heated Tobacco Products - Approved July 2023

- Project 377: Review of Guide No. 22 Selection of Appropriate Intense Vaping Regimes for E-Vapour Devices SG EVAP - E-Vapour - Approved July 2023
- Project 378: Review of Guide No. 25 Aerosol Collection and Considerations when Testing E-Vapour Product Technologies

SG EVAP - E-Vapour - Approved July 2023

- Project 379: Review of Guide No. 26 Designing E-Vapour Product Stability Studies SG EVAP - E-Vapour - Approved July 2023
- Project 380: Presentation at the American Society for Cellular and Computational Toxicology (ASCCT) -October 2023

TF NGTX - 21st Century Toxicology for Next Generation Tobacco and Nicotine Products - Approved July 2023

- Project 381: 2023 Collaborative Study Reference Device for E-Cigarette Aerosol SG EVAP - E-Vapour - Approved August 2023
- Project 382: Poster Presentation on "CORESTA Strategy, Cooperation and Achievements" at TSRC and CORESTA Conferences - September / October 2023 CORESTA - Approved July 2023
- Project 383: Presentation at TSRC and CORESTA Conferences "CORESTA Tobacco Harm Reduction Workshop Overview" - September / October 2023 CORESTA - Approved July 2023

Physical Test Methods (PTM) Sub-Group

After three years of online-only meetings, the Physical Test Methods Sub-Group took the opportunity offered by CORESTA to meet for the first time again in the real world. Together with many other Sub-Groups and Task Forces the PTM Sub-Group held its 36th meeting on 19 April 2023, in Antibes, France.

As expected, attendance was lower than for online meetings, but the discussions were nevertheless fruitful. The PTM Sub-Group decided to launch several projects, including the 16th Collaborative Study on Physical Parameters of Cigarettes and Filters. This project will be carried out from May to about December 2023, as usual, and in addition to maintaining the relevant CRMs it allows participating laboratories to check their proficiency when measuring certain physical parameters. For this project already 28 laboratories have registered.

The PTM Sub-Group also decided to start the 3rd Collaborative Study on Air Permeability. Likewise, this project is expected to be completed by the end of this year and involves the measurement of air permeability on cigarette papers, plug wrap papers and tipping papers. For this study 12 laboratories have registered using about 20 instruments, which provides a solid basis for statistical evaluation.



Bernhard EITZINGER
PTM SG Coordinator



Patricia MÜLLER PTM SG Secretary

Round Robin tests on calibration standards for pressure drop, filter ventilation and air permeability also continue, with the 17th Round Robin Test on Pressure Drop Calibration Standards recently started. While the Covid-19 pandemic has caused some delays in these inter-laboratory studies, it is expected that the situation will normalize, and these tests can be completed in their usual timeframe.

The PTM Sub-Group completed the 2nd Collaborative Study on the Crush Strength of Flavour Capsules for Filters. This project was carried out to check repeatability and reproducibility data of CRM No. 94, which was published in August 2020. The Technical Report on this second collaborative study was published in June this year.

Regarding future work the PTM Sub-Group decided to start work on physical parameters related to heated tobacco products (HTPs). Based on a survey among members of the PTM Sub-Group this topic will be discussed more intensively at the next meeting with the intention to carry out an inter-laboratory study on physical parameters of HTPs within the next year.

The PTM Sub-Group is already looking forward to its second meeting this year, which will be the 37th PTM Sub-Group meeting and will take place on 19 September 2023, in Milton Keynes, UK, hosted by Cerulean. All members and all those wishing to become a member of the PTM Sub-Group are welcome to register for the meeting.

CORESTA PROJECTS (continued)

- Project 384: Update of Guide No. 19 Responsible Use of Crop Protection Agents (CPAs) in Tobacco Leaf Production
 - ACAC Agrochemical Advisory Committee Approved July 2023
- Project 385: Update of Guide No. 21 Best Practices and Crop Protection in Cigar Dark Air-Cured Tobacco ACAC Agrochemical Advisory Committee Approved July 2023
- Project 386: Update of Guide No. 27 Identification and Elimination of Highly Hazardous Pesticides (HHPs) in Leaf Tobacco Production
 - ACAC Agrochemical Advisory Committee Approved July 2023
- Project 387: Update of Guide No. 16 Molecular Markers in Tobacco Scientific Commission Approved July 2023
- Project 388: Update of Agri-Biotech Dossier
 ACAC Agrochemical Advisory Committee Approved July 2023
- Project 389: 7th Round Robin Test on Air Permeability Calibration Standards SG PTM Physical Test Methods Approved August 2023

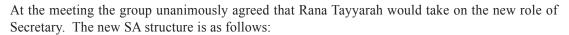
Smoke Analysis (SA) Sub-Group

The 6th meeting of the Smoke Analysis Sub-Group (SA) was held as a face-to-face meeting on 20 April 2023, in Juan-les-Pins Antibes in France after the Covid-19 pandemic. Over 50 members from tobacco product manufacturers, instrument suppliers, non-tobacco material suppliers, analytical laboratories, academia and others participated in this meeting.

This meeting was very fruitful as the participants were actively able to discuss many of the projects and topics in-person. After this meeting, the following New Work Item Proposals (NWIPs) were submitted to the CORESTA Scientific Commission and approved.

- Project No. 373 "Collaborative study for the determination of benzo[a]pyrene, B[a]P, in mainstream cigar smoke"
- Project No. 374 "Collaborative study of four metals (Pb, Cd, As and Hg) in cigarette mainstream smoke with ISO standard smoking regime and ISO intensive smoking regime"

At the end of this meeting, Jana Jeffery announced that she would step down as Co-Coordinator of the SA Sub-Group, but would remain the group's liaison on the Scientific Commission. On behalf of all members of the SA Sub-Group, she was thanked for all her contributions towards the group and the former Smoke Analytes (SMA) Sub-Group. Under her leadership, these Sub-Groups have made tremendous progress over the past several years.



SA Coordinator: Hiromoto Yamazaki (Japan Tobacco Inc.)

SA Secretary: Rana Tayyarah (Labstat)

Workstream Leads:

Reference Products: Thomas Schmidt (Koerber Technology Instruments)

Cigarette Smoke Methods: Rana Tayyarah (Labstat)

Cigar Smoke HPHC Methods: Anthony Brown (Altria Client Services)



Hiromoto YAMAZAKI SA SG Coordinator



Rana TAYYARAH SA SG Secretary



Former SA SG Coordinator

Currently, the SA Sub-Group is developing the CRMs for polycyclic aromatic hydrocarbons (PAHs), nitrogen oxides (NO/NOx) and hydrogen cyanide (HCN) in cigarette mainstream smoke within the Cigarette Smoke Methods Workstream and benzo[a]pyrene (B[a]P) within the Cigar Smoke HPHC Methods Workstream.

The SA Sub-Group is also developing CORESTA Monitor Test Pieces No. 10, CM10, for TNCO analysis and CORESTA Monitor Test Pieces Ignition Propensity No. 3, CM-IP3, in the Reference Products Workstream. After these developments, the periodic collaborative studies utilising these CORESTA Monitor Test Pieces will be carried out by the Reference Products Workstream.

Furthermore, the group has two other projects to support the ISO standard developments. One is for nicotine in smoke of very low nicotine cigarettes and the other is for four metals (Pb, Cd, As and Hg) in cigarette mainstream smoke. The collaborative studies will be conducted within the Cigarette Smoke Methods Workstream.

The SA Sub-Group is scheduled to hold its next meeting in-person in Cancun prior to the SSPT2023 Conference.

JOURNAL PUBLICATIONS

The Smoke Analysis (SA) Sub-Group published an external publication [SA-162-2-CXP] as follows:

Selected phenolic compounds in mainstream cigarette smoke, CORESTA Collaborative Study and Recommended Method

Rana Tayyarah⁽¹⁾, Douglas Knepper⁽¹⁾, and Alexander Hauleithner⁽²⁾

(1) Labstat International Inc., 262 Manitou Dr, Kitchener, Ontario, N2C 1L3, Canada; (2) ITG Brands LLC, PO BOX 21688 Greensboro, NC, USA 27420; (3) TI Ökolab, Hasnerstraße 127, 1160 Vienna, Austria

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DOI: 10.2478/cttr-2023-0003



Data Standards for FDA-CTP Submissions An Introduction to the CDISC Tobacco Implementation Guide v1.0

CORESTA members, particularly those who work on various Technical Committees, are very familiar with the concept of standardization and the collaborative process to achieve strong outcomes for standards. <u>CDISC</u>, in collaboration with the FDA's Center for Tobacco Products (CTP), is developing non-proprietary, consensus-based data standards for tobacco product submissions. The data standards, collectively referred to as the <u>CDISC Tobacco Implementation Guide (TIG) v.1.0</u>, are designed to facilitate tobacco research, scientific review, harm reduction, and information exchange.

Developed by a team of members from FDA-CTP and industry using the CDISC Standards Development Process, the TIG v1.0 reflects FDA-CTP's commitment to data standardization to expedite regulatory review and decision making as well as achieve efficiencies for all stakeholders. The TIG v1.0 will facilitate the quality and consistency of data submissions to FDA-CTP and further enable the use of tools to aid in review and policy decisions. We are excited to bring tobacco data standards forward with the support of FDA-CTP and believe the CORESTA community will benefit from a deeper understanding of this initiative as well as implementing these data standards in research, once released.

The TIG v1.0 will provide nonclinical and clinical data standards, including new dataset specifications, controlled terminology, and conformance rules, which assess adherence to standards. It will describe how to implement CDISC standards for the collection, representation, and exchange of tobacco product data with focus on implementation for common use cases in tobacco product submissions.

The use cases comprise concepts identified by CDISC TIG v1.0 team as important in the context of tobacco product studies and specifically address:

- Product Description: Concepts used to characterize tobacco products, including product specifications, HPHCs, stability and ingredient listing.
- Nonclinical: Concepts used to identify potential risks and effects on biological processes for tobacco products via in vitro and in vivo nonclinical studies.
- Product Impact on Individual Health: Concepts used to assess the impact of tobacco products on individuals.
- Product Impact on Population Health: Concepts used to assess the impact of tobacco products on populations of individuals.

Biomarkers Sub-Group (BMK SG)

In Issue 65 of the CORESTA Newsletter, the BMK Sub-Group explained how it had played an important role in supporting CDISC in developing tobacco data reporting standards.

This article presents in detail the role and work of CDISC and invites all tobacco stakeholders to participate in the Public Review process.

Development of the data standards is concluding, and the draft TIG v1.0 will undergo Public Review. If you are not already a part of the team, we invite the CORESTA membership to join the TIG team and/or participate in the Public Review process to ensure published standards are as robust and comprehensive as possible.

About CDISC

CDISC creates clarity in clinical research by convening a global community to develop and advance data standards of the highest quality. Required by the United States Food and Drug Administration (FDA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), recommended by the China National Medical Products Administration (NMPA) and adopted by the world's leading research organizations, CDISC standards enable the accessibility, interoperability, and reusability of data. With the help of CDISC standards, the entire research community can maximize the value of data for more efficient and meaningful research that has invaluable impact on global health. CDISC actively collaborates with Europe's Innovative Medicines Initiative. CDISC is also strategically positioned as a global standards governance body that supports and maintains standards not only for clinical research but also for public health. CDISC is as a global nonprofit charitable organization with entities in Austin, Texas, USA, and Brussels, Belgium, and thousands of volunteers, employees, and member organizations around the world. www.cdisc.org

RESEARCHER SPOTLIGHT

An introduction to up-and-coming graduate students and industry personnel

MAGGIE JAMES

Name:

Maggie James (formerly Short)

Current Employer and Position:

North Carolina State University
Tobacco Extension Associate & PhD Student



General Job Description:

I have research and extension responsibilities for flue-cured and cigar wrapper tobacco in North Carolina. As a student, I'm focusing on developing fertilizer rate recommendations for cigar wrapper tobacco. This includes field trials, data analysis, and turning the learned information into deliverables like presentations and ultimately, a dissertation! As an extension associate, I work with Dr Matthew Vann to support our North Carolina tobacco farmers in many different ways, from farm visits to extension publications and more.

Current Work Location:

Tobacco growing regions across North Carolina.

Place of Birth:

Greensboro, North Carolina, USA

What brought you into the tobacco industry?

I come from a long line of North Carolina tobacco farmers. However, what really sparked my interest was when my dad started doing tobacco research on our family farm for a private company. As an undergrad at NC State, I was fortunate to work as an Altria Intern with NC State's tobacco agronomy program and as an intern with RJ Reynolds the following summer. Since then, I have continued working with NC State's tobacco agronomy program while completing my Master's Degree and now pursuing my PhD.

Where do you envision the collective industry in the next decade?

In the next decade, I think the industry will continue to trend towards non-traditional, nicotine-based tobacco products. I also think there is potential for the industry to expand into more alternative uses for the tobacco plant itself, such as squalene or protein production. I believe that the industry will have the dedicated people, as it does now, to adapt to these changes.

How should we as CORESTA address the grand challenges we face?

I think we must be persistent when it comes to addressing challenges. We must appreciate and learn from our past while doing our best to anticipate the future and foster solutions for these challenges that are sustainable and that strengthen tobacco science.

INSIGHT FROM A MEMBER

IF YOU SEE SOMEONE, SAY HELLO!

Matthew Vann One of the truly amazing things about CORESTA is the way in which our organization brings together a diverse group of people from all corners of the global tobacco industry. As a kid growing up on a small farm in a very rural area, I never imagined that I would see so many of the wonderful places this world has to offer, much less get to know some of its great people. Those great people reside within CORESTA, and it goes without saying that our strength is the people that comprise our organization.

Imagine if you will a kid (me) from the very southern tip of the US flue-cured tobacco belt in North Central Florida, and the wide-eyed amazement that kid felt when he attended his first CORESTA Congress in 2010. As a fresh 24 year old – who was still wet behind the ears, as we like to say – I had no business pretending to be an authority on tobacco production (most would argue that I still don't), and yet I was welcomed with open arms into this wonderful group. Since 2010, I've had the good fortune to attend every CORESTA Congress and AP conference, except for Santiago in 2011. We'll place the blame for my absence squarely on the shoulders of my major advisor ... here's looking at you Loren Fisher (I'm kidding, of course. Loren gave me more opportunities to succeed and share information than I deserved, and I owe him more than I can ever hope to repay). Back to the topic at hand. Never, in my wildest dreams, did I think that I'd have the chance to "talk tobacco" with other researchers from places like Brazil, India, Zimbabwe, Italy, and countless other origins. What an absolute blessing it's been to learn from others for well over a decade now. I can't help but believe that being afforded the opportunity to learn from someone else's experiences and observations is one of the main purposes of CORESTA. I've yet to see that formally documented anywhere, but that doesn't take away from its validity.

Without living in the past too much, let's flash forward to 2023. I now participate in a number of CORESTA Sub-Groups and Task Forces as well as serve in a leadership role within the AP Group. It's humbling to come through the CORESTA "ranks" and to have the perspective of a graduate student, faculty member/researcher, and leader. During this time, the most important experiences I've had while active in CORESTA have been (and continue to be) the opportunities to say hello to someone new. This was particularly true in my early days, and it's why I encourage the existing CORESTA members to become acquainted with our new colleagues. As we come out of the Covid-19 lockdown and begin to meet inperson again, there will be new faces in the crowd and they need a warm, friendly hello. Likewise, for those new to CORESTA, don't be afraid to introduce yourself either! The pendulum swings both ways. From another perspective, it is equally important for us to get to know our colleagues "across the aisle". I'm ashamed to admit this, but there are some absolutely wonderful individuals in the SSPT Group that I'd not previously interacted with until my appointment to the Scientific Commission. That's time lost for me, but it doesn't have to be that way for you. So, if you see someone new at our upcoming SSPT and AP Meetings in Cancun, by all means, please say hello!

There's no final destination that stems from this conversation, and there doesn't need to be, but it's a direction in which we all must move in order to foster the collaborative spirit required to meet the grand challenges of our day and of our future. We need new members because new members bring about new ideas and new ways of thinking. They have different perspectives and different areas of expertise. They are the next generation of leaders and thinkers and doers in our industry. This is our lifeblood and they are our future. On a personal note, I can't help but think that there's also another Matthew Vann out there with a wanderlust for this world and a deep passion for tobacco science. They just need a warm hello, a friendly smile, and a word of encouragement - let's give it to them.

I'll see y'all in Cancun.

Matthew C. Vann, PhD

(Associate Professor, NCSU, and newly elected member of the CORESTA Scientific Commission)

Summer 2023

The opinions expressed in this article are not necessarily reflective of the CORESTA, the tobacco industry, or North Carolina State University.

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INSIGHT FROM A MEMBER (continued)



Author's Note:

It's hard to think back to life pre-Covid, but as I've done so my mind harkens back to the 2019 CORESTA AP meeting in Victoria Falls. Little did we know, but it would be the last time we'd convene in that manner for almost four years. It seems like an eternity ago, yet in some ways it feels just like yesterday. CORESTA meetings really are something special, and the upcoming SSPT and AP conferences in Cancun will be no exception. As the opportunity to meet in-person presents itself, I truly hope that everyone reading this newsletter will give strong consideration to attending these conferences. The AP/SSPT groups, the CORESTA Board, and the CORESTA office have worked hard to put together outstanding programs that are full of great tobacco related information. Moreover, there are so many people that we've not seen in a number of years, so there's bound to be something extra special in the comradery and fellowship. Please visit the CORESTA website for more information.

Acronyms / Abbreviations used in the Newsletter								
3Rs reduce, replace, refine AA Agrochemicals Analysis (CORESTA) ACAC CORESTA Agrochemical Advisory	GMO. Proficiency Testing for Detection of Transgenic Tobacco (CORESTA) GTS. Green Tobacco Sickness (CORESTA) HCN hydrogen cyanide Hg. mercury HPHC Harmful and Potentially Harmful Constituents (US FDA) HTP. Heated Tobacco Product IP. Ignition Propensity IPM Integrated Pest Management (CORESTA) ISO International Organization for Standardization IVT. In Vitro Toxicity Testing (CORESTA) JTI Japan Tobacco International LLC Limited Liability Company LNTP Collaborative Study of Low Nicotine Tobacco Agronomic Production Practices (CORESTA) Ltd. Limited mCEQ Modified Cigarette Evaluation Questionnaire NAM New Alternative (or Approach) Methods NC. North Carolina (USA) NCSU North Carolina State University NGTX 21st Century Toxicology for Next Generation Tobacco and Nicotine Products (CORESTA) NMPA National Medical Products Administration (China) NO nitrogen oxide NOX. oxides of nitrogen NPSQ. Nicotine Pouches Safety and Quality Guidance (CORESTA)	PaHs polycyclic aromatic hydrocarbons Pb lead PhD Doctor of Philosophy PMDA Pharmaceuticals and Medical Devices						
GAP Good Agricultural Practice	NWIP New Work Item Proposal	WEB Website (CORESTA)						





Pyxus / Alliance One International announced the peaceful passing of Colin "Archie" Archibald on 10 June 2023. For many years, Archie was the Global Agronomy Director for Alliance One International, Inc.

Commonly referred to as a "legend", Archie was an unforgettable character, not only to his current and former colleagues, but also to all those whose path he crossed in the wider tobacco agronomy world, including CORESTA. Stories of his adventures and humorous anecdotes would fill a book!

Archie was born in Johannesburg, South Africa, brought up in Malawi, and was originally a farmer, totally unrelated to the tobacco industry. He studied for a Master's degree in Agronomy at Wye College, Kent, United Kingdom.

He was employed by Standard Commercial Tobacco Services Ltd in September 1992 to work on an agronomy project for World Wide Tobacco Spain. His global role took off immediately after completion of this project. His career led him to all corners of the world until his retirement in March 2020.

Archie leaves behind his long-time partner, Sharon, as well as five children and six grandchildren. CORESTA sends them its sincere condolences.

