



NEWSLETTER

Issue 62 – April 2022

FOREWORD

Exactly a year ago, we were hoping “for a light at the end of the Covid-19 tunnel”. The year 2022 seems to be on track for just that with countries around the world greatly easing their restrictions and life gradually returning to more normality.

CORESTA remains positive for the future and, with renewed confidence, it has begun organising in-person meetings again, albeit on a small scale to begin with. The 2022 CORESTA General Assembly will be held in June in Paris, France, in accordance with the CORESTA Statutes that require the physical attendance of the voting delegates. The Board and Scientific Commission elections will occur where organisations have the opportunity to step forward to lead the organisation. With the mandates of a number of Scientific Commission members coming to an end this year, new faces will be elected to take over the task of directing the scientific work. Taking advantage of the presence of CORESTA Member Organisation representatives at the General Assembly, a Workshop and Science Day are also planned. Brief details are included in this Newsletter.

The CORESTA Congress, originally planned in Washington D.C., USA, but cancelled due to uncertainties, will be held online for the third time, in a format similar to that of the 2021 Conferences, i.e. pre-recorded presentations followed by a live Q&A. Information is shown below and communications will be made regularly as arrangements are put in place. The Call for Papers is available and scientists are encouraged to submit abstracts before the 20 May deadline.

Working groups diligently continue their work, a number of new projects have been launched and papers have been published. Recently, three groups wrote articles in scientific journals - outlines and access details are given further on in this Newsletter. You will also find an update on the PTM Sub-Group, an interview with the CROM Sub-Group Coordinator on the online Symposium that was held late last year, and a wrap-up article on the TAG Task Force that was recently disbanded after successful completion of its objectives.

CORESTA bid farewell to François Jacob who served as CORESTA Secretary General for over 20 years from 1989 to 2010. François passed away in December and will be deeply missed by his former colleagues and tobacco industry friends.



2022 CORESTA CONGRESS ONLINE 10 – 28 October 2022

The online 2022 CORESTA Congress will be held virtually similarly to the 2020 Congress and 2021 Conferences.

Details will be published on the Congress website as and when they become available.

The Congress will be composed of daily, 2-hour sessions or workshops (1 pm to 3 pm CET) focused on a specific topic area with pre-recorded 10 to 12 minutes oral presentations followed by a live Q&A with the presenters.

The full sessions will be recorded and made available to registered participants.

The Call for Papers is published and abstracts can be submitted online at

www.coresta.org/events/coresta-congress-2022-35938.html

**Call for Papers
and Abstract
Submission:**
Now on
CORESTA
website

**Abstract
Submission
Deadline:**
Friday, 20 May

**Abstract
selection by
Reading
Committee:**
Early June

**Author
notifications:**
Mid- to late
June

**Programme
Publication:**
Available end
of June

**REGISTRATION
OPEN TO ALL
EARLY JULY
FOR A SMALL FEE**



CORESTA GENERAL ASSEMBLIES, WORKSHOP and SCIENCE DAY 8-9 June 2022 – Paris, France

The CORESTA Extraordinary and Ordinary General Assemblies will be held in Paris, France on 8 June. The main objective will be to adapt the Statutes and Rules of CORESTA to the changing environment to allow the possibility for CORESTA to hold virtual general assemblies and online consultations in the future. The Official Delegates have been invited to participate, to be represented or to give a proxy. For the General Assembly to be legally constituted, a 50 % quorum is necessary.

A Workshop and a Science Day will follow the General Assembly and elections. The objective of the Workshop will be to discuss collectively on CORESTA strategy, members' expectations and future events and strategic projects. On 9 June, keynote speakers at the Science Day will present on the themes of supply chain integrity, the role of nicotine and the challenges associated with harm reduction.

Due to limited room capacity (200 people), participation is first restricted to Voting Delegates. If you wish to participate, please contact your Official Delegate who will inform the CORESTA Secretariat, as it may be possible to extend participation.

EXTRAORDINARY GENERAL ASSEMBLY

Approval of the Revised Statutes

The documents below are being updated and amendments will be submitted for approval by the Voting Delegates of the CORESTA Member Organisations at the General Assemblies to be held on 8 June 2022.

Official Delegates will be informed in detail of the proposed changes.

CORESTA INTERNAL STRUCTURES

CORESTA is an association ruled by French law. The governing bodies and main rules are described in five documents:

A. The Statutes

This document, amended several times since the inception of CORESTA in 1956, with the last update being in October 2016, describes the general purpose of the association and the role of its governing bodies.

The governing bodies are:

- The General Assembly, which elects the Board and has many powers.
- The Board, which in practice runs the association and reports to the General Assembly.

Only fundamental elements are included in the Statutes.

B. The Internal Rules

The Internal Rules detail the procedures and dispositions needed to implement the Statutes. The latest version was also approved in 2016.

The Internal Rules give full details on the rights and duties of the Members, on the procedures to elect the Board, on the duties and empowerments of the Secretary General, and only summary indications on the existence and work of the Study Groups and Scientific Commission, which are detailed in the third essential document, as developed hereunder.

C. The Rules Governing the Functions of the Scientific Commission and Study Groups

The existence and need for this document is mentioned in the Internal Rules. This document has to be approved by the General Assembly. The latest version, also approved in 2016, describes in detail the role, composition and functioning of the Study Groups and Scientific Commission and the rules for the elections within the Study Groups.

Additional documents on the functioning of the Sub-Groups and Task Forces have been produced by the Scientific Commission, namely:

D. Guidelines for Coordinators of Task Forces and Sub-Groups

E. Participation of Non-CORESTA Members in the Activity of Working Groups

ORDINARY GENERAL ASSEMBLY

BOARD & SCIENTIFIC COMMISSION ELECTIONS

Elections are held every two years to renew the CORESTA Board and Scientific Commission. CORESTA Member Organisations have a right to vote to elect new officials for both these governing bodies. Each CORESTA Member Organisation holds a pre-defined number of votes depending on its membership category.

Due to the Covid-19 pandemic and related disruptions, the terms of office of the CORESTA Board and Scientific Commission were extended by two years during the virtual General Assembly held in 2020.

Renewal of the Board

The Board is responsible for managing CORESTA and defining CORESTA policy.

The Board consists of ten elected Member Organisations and two to four co-opted Member Organisations. The elected members hold a four-year term of office, which is renewable, and co-opted members are in office for two years. In 2022, the tenure of nine companies expires (five elected and four co-opted). The vote will seek to elect five organisations. After the election, the newly elected Board will co-opt two to four extra organisations and will elect its President and Vice-President.

The election to renew the Board will be held during the Ordinary General Assembly on the morning of Wednesday, 8 June.

| | |
|--|--|
| Members elected in 2016 whose terms were due to expire 2020 but were exceptionally extended to 2022 Alliance One International, Inc. (USA) British American Tobacco (UK) China National Tobacco Corporation (China) Imperial Tobacco (UK) Japan Tobacco Inc. (Japan) | Members elected in 2018 whose terms were due to expire 2022 but were exceptionally extended to 2024 Borgwaldt KC GmbH (Germany) delfort (Austria) Reynolds American Inc. Services Co. (USA) Swedish Match AB (Sweden) Universal Leaf Tobacco Company (USA) |
| Co-opted members whose terms were due to expire in 2020 but were exceptionally extended to 2022 Alternative Ingredients, Inc. (USA) KT&G Corporation (South Korea) SWM International, Inc. (USA) University of Kentucky (USA) | |

Renewal of the Scientific Commission

The Scientific Commission is responsible for leading and organising scientific and technical activities within CORESTA and acts as scientific counsel to the Board.

The Scientific Commission consists of a five person Executive Committee (President, Secretary and three members) for each of the four Study Groups, i.e. 20 persons. They are elected *intuitu personae* which means they cannot be replaced by another person in case of absence, resignation, etc. They can serve up to three consecutive terms of office.

The mandate of the incoming Scientific Commission will come into effect as of 1 December 2022, and the elected candidates will then meet to elect their new President and Vice-President.



CORESTA Scientific Commission and Board Meetings

The **SCIENTIFIC COMMISSION** (SC) held a series of seven virtual meetings since the beginning of 2022. Each Study Group held two breakout sessions on 18 & 19 January for AP, and on 13 & 18 January for SSPT. The objectives were to review the open actions, to present detailed SGTF reports and 2-year and 5-year plans, and to discuss potential 2022 Events. Breakout sessions were followed by three plenary meetings held on 20 & 27 January and 4 February.

The key elements reported were that:

- The TSNA SG was considering the possibility to launch a new project on the effect of KCl application.
- The BIO and BKS SGs were inviting more organisations to participate in their collaborative trials (*please contact the CORESTA Secretariat if you wish to participate*).
- Resistance to pests and diseases was dramatically impacted when nicotine levels were low in tobacco, and the SC agreed to extend the LNTP TF project to three years (maybe more) to better assess data variability.
- The GMO SG was looking for a new coordinator.
- The AA SG was considering an extension of their scope of activities to highly hazardous pesticides (HHPs).
- The work of the TAG TF was published in the *Studies in Natural Products Chemistry Journal*, under Chapter 5 - *Molecular regulation and genetic manipulation of alkaloid accumulation in tobacco plants*.
- The PUB SG project #156 on human abuse liability assessment of tobacco and nicotine products was successfully completed with the publication being selected as the *Nicotine and Tobacco Research* Editor's choice paper.
- SC members were considering setting up a new task force on green tobacco sickness. Objectives are being drafted.

The **BOARD** held two virtual meetings on 9 & 23 February 2022 with the objective to review the budget, strategy and future events.

- The FY67 budget was presented. One-off expenses will occur next financial year for i) legal advice to prepare revised Statutes and the General Assembly, ii) the migration of the CORESTA website to Drupal 9 (including website improvements suggested by CORESTA members in 2021), iii) the installation of virtual and NAS servers (a virtual server should replace the current old physical server), and iv) the implementation of a sustainable solution for the Secretariat central database. It was expected that travels would progressively resume and expenses related to the organisation of the General Assembly, a Workshop and a Science Day in June would be partly covered by registration fees.
- The description of the process of strategic subject identification, workstream scoring and project monitoring was finalised. A huge amount of work had been achieved since communication to SGTF Coordinators and Secretaries in September 2021. Most SGTFs provided their 2-year and 5-year plans with the support of the SC Liaison Members. All data were compiled into a single spreadsheet with a link to the strategic subjects and workstreams. Deliverables for the Strategy House were updated on the basis of the compilation. Information on CORESTA Strategy will be discussed during the Workshop in June, and made publicly available on the CORESTA website.

The next Board and Scientific Commission meetings are planned in June 2022, in Paris, prior to the General Assembly.

CORESTA PROJECTS

The following projects were approved by the Scientific Commission and launched:

- **Project 321: 18th FAPAS CPA Analysis Proficiency Test - 2022**
SG AA - Agrochemicals Analysis - Approved December 2021
- **Project 322: Determination of the Analysis of Selected Carbonyls in the Aerosol of HTP Products by LC-UV**
TF HTP - Heated Tobacco Products - Approved January 2022
- **Project 323: Collaborative Study for Water Activity of Heated Tobacco Product Consumables**
TF HTP - Heated Tobacco Products - Approved February 2022
- **Project 324: HTP TF Update for ISO/TC126/WG22 Meeting**
TF HTP - Heated Tobacco Products - Approved February 2022
- **Project 325: HTP TF - Generation and Collection of Aerosol from Aerosol Heated Tobacco Products (aHTPs)**
TF HTP - Heated Tobacco Products - Approved February 2022
- **Project 326: HTP TF - Generation and Collection of Aerosol from Carbon Heated Tobacco Products (cHTPs)**
TF HTP - Heated Tobacco Products - Approved February 2022
- **Project 327: HTP TF - Generation and Collection of Aerosol from Electrically Heated Tobacco Products (eHTPs)**
TF HTP - Heated Tobacco Products - Approved February 2022

CORESTA SUB-GROUPS & TASK FORCES

SMOKE SCIENCE Study Group

Revised Objectives: Sub-Group Biomarkers (BMK)

Objectives:

1. To develop a robust understanding of mechanistic pathways and clinical outcomes for smoking-related diseases to better identify fit-for-purpose biomarkers.
2. To review and summarise published literature on biomarkers that are fit-for-purpose in the assessment of potential reduced risk tobacco products (PRRPs).
3. To evaluate and recommend guidelines and best practice for utilising fit-for-purpose biomarkers in studies assessing PRRPs.

The objectives of the Sub-Group were amended to fit the revised vision of the group, which is to identify and assess fit-for-purpose biomarkers for tobacco product research.

PHYTOPATHOLOGY & GENETICS Study Group

Disbanded: Task Force Tobacco Biotechnology and Omics (TBO)

The objectives of the TBO Task Force were to describe and summarise publicly available literature regarding the biotechnology and omics techniques and nomenclature commonly used in agriculture in different countries and to prepare clear and concise definitions. Having achieved the objectives and published two reports entitled “*Literature Review on the Use of Biotechnology and Omics*” [TBO-151-1-CTR] and “*Genome Editing and Plant Breeding*” [TBO-151-2-CTR], the Task Force, formed in 2017, was formally disbanded by the Scientific Commission.

Disbanded: Task Force Tobacco Alkaloid Genetics (TAG)

The TAG Task Force, formed in 2017, was also formally disbanded by the Scientific Commission following the completion of its objectives and the publication of its report “*Molecular regulation and genetic manipulation of alkaloid accumulation in tobacco plants*” [TAG-140-CXP] published in the journal *Studies in Natural Products Chemistry - Bioactive Natural Products*. A report on the work of the Task Force is published on page 10 of this Newsletter.

Physical Test Methods (PTM) Sub-Group

In 2021 the Physical Test Methods (PTM) Sub-Group had the opportunity to hold two meetings, the 32nd meeting on 20-21 April and the 33rd meeting on 28-29 September. The meetings again had to be held in a virtual format and were each split into two two-hour meetings on consecutive days, a format which has also proved to be useful during the previous meetings. Both meetings were well attended, with more than 20 participants, thus exceeding the participation that may normally be expected for in-person meetings.

The work in the PTM Sub-Group continues as planned, only a few projects experienced delays due to the pandemic. In 2021 the PTM Sub-Group was able to complete the 14th Collaborative Study on Physical Parameters of Cigarettes and Filters, which is the main annual collaborative study in this Sub-Group. Furthermore the 2nd Collaborative Study on Air Permeability has been carried out and completed, which allowed laboratories to assess their performance when measuring the air permeability of cigarette, tipping and plug wrap papers and also to monitor repeatability and reproducibility of ISO 2965. The Technical Reports of both these projects have been published recently.

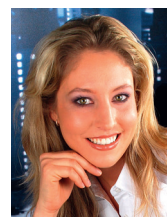
The PTM Sub-Group also carries out round robin tests of calibration standards for pressure drop, filter ventilation and air permeability. These round robin tests have been regionally extended by including a laboratory in the USA and also technically, by including a pressure drop calibration standard for low pressure drops and a slim filter ventilation calibration standard. It is expected that the measurement of low pressure drops will become important for heated tobacco products and their components. For this reason, the PTM Sub-Group wants to ensure that calibration of instruments for low pressure drops is possible and is sufficiently accurate for the intended measurements.

Also in 2022 the PTM Sub-Group will carry out its routine collaborative studies and participation in any of these studies is highly welcomed. Furthermore new topics might be discussed and projects launched, particularly in relation to the measurement of permeability of materials for oral tobacco pouches and the extension of CORESTA Recommended Methods on some physical parameters to heated tobacco products.

The 34th PTM Sub-Group Meeting is scheduled for 20-21 April 2022. It will again be held as two two-hour virtual meetings, to allow for participation from a wide range of time zones.



Bernhard EITZINGER
PTM SG Coordinator



Patricia MÜLLER
PTM SG Secretary

CORESTA REPORTS

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

- **2nd Collaborative Study on Air Permeability in Accordance with ISO 2965:2019**

Technical Report [PTM-302-CTR] – December 2021 (Sub-Group Physical Test Methods)

After a first Collaborative Study related to air permeability, which is an important parameter of wrapping papers for tobacco products, a regular Collaborative Study related to this parameter was carried out. The method for measuring air permeability is specified in ISO 2965:2019, which allows the use of the 2×15 mm² measuring head for air permeability measurement on cigarette paper. The first Collaborative Study provided the repeatability and reproducibility data for the 2×15 mm² measuring head. This second Collaborative Study serves to verify these results. In addition, this study allows the participating laboratories to monitor their performance in comparison to other laboratories, to derive actions for improvement of their internal processes and to fulfil accreditation requirements.

- **14th Collaborative Study (2021) on Physical Parameters of Cigarettes and Filter Rods**

Technical Report [PTM-303-CTR] – January 2022 (Sub-Group Physical Test Methods)

The Physical Test Methods (PTM) Sub-Group annual inter-laboratory study on physical parameters of cigarettes and filter rods monitors the repeatability and reproducibility of the test methods used and allows the participating laboratories to assess their performance when measuring certain physical parameters of cigarettes and filter rods, such as weight, diameter, pressure drop, draw resistance and ventilation. The results from this study also allow each laboratory to evaluate its proficiency in comparison to other laboratories, to derive actions for improvement and to fulfil accreditation requirements. This report covers the results of the 14th Collaborative Study on physical parameters conducted in 2021.

- **Cigar Smoke Analysis - 15th Collaborative Study**

Technical Report [CSM-293-CTR] – December 2021 (Sub-Group Cigar Smoking Methods)

Since 2006, the CORESTA Cigar Smoking Methods Sub-Group conducts periodic collaborative studies in order to improve repeatability and reproducibility measurement methods of different cigar sizes and types. The purpose of the 15th Collaborative Study was to estimate the mean values, repeatability, and reproducibility for NFDPM (tar), nicotine, carbon monoxide and other measures for different sizes and types of cigar products and test pieces and to provide a tool for participating laboratories to prove competence in cigar smoke analysis. Most of the mean values were in good agreement with the 2020 results with the possible exception of the smoke yields for one of the test items that tended to be ~20 % higher than the 2020 results. However, only the CO difference was statistically significant.

- **2021 Collaborative Study of CORESTA Ignition Propensity Monitor Test Piece CM IP 2 for the Determination of Ignition Propensity**

Technical Report [SA-305-CTR] – March 2022 (Sub-Group Smoke Analysis)

The Smoke Analysis (SA) Sub-Group has taken over the responsibility to check the stability of the monitor test piece specific for ignition propensity testing from the former Routine Analytical Chemistry (RAC) Sub-Group. The test piece manufactured in 2014 qualified as CORESTA Monitor Test Piece CM IP 2 in 2015, based on a 2014 Collaborative Study. The test piece was also tested in 2015, 2016, and as part of an alternative substrate study in 2019. This report provides the statistical assessment of the results of the most recent Collaborative Study conducted in 2021.

- **2021 Collaborative Study of CORESTA Monitor 9 (CM9) for the Determination of Test Piece Weight, TPM, Water, Nicotine, NFDPM, Carbon Monoxide and Puff Count Obtained under Mainstream ‘Non-Intense’ and ‘Intense’ Smoking Regimes**

Technical Report [SA-306-CTR] – March 2022 (Sub-Group Smoke Analysis)

The Smoke Analysis (SA) Sub-Group is now responsible for organising the annual testing of the CORESTA Monitor test piece, having taken over the task from the Routine Analytical Chemistry (RAC) Sub-Group. The 2021 study was designed to measure mainstream non-intense (ISO 3308) and intense (ISO 20778) smoke yields of nicotine-free dry particulate matter (NFDPM or tar), nicotine, and carbon monoxide; to determine intra- and inter-laboratory variability for the measured non-intense and intense smoke yields for the CM9; and to verify the conditioned weight for the CM9. The performance of the monitor was quite similar to its historical performance and continues to be a suitable smoke analysis monitor.

JOURNAL PUBLICATIONS

The Tobacco Alkaloid Genetics (TAG) Task Force published the results of its work [TAG-140-CXP].

(Also see article on next page)

Molecular regulation and genetic manipulation of alkaloid accumulation in tobacco plants

Yongfeng Guo^(a), Ernie Hiatt^(b), Christelle Bonnet^(c), Chengalrayan Kudithipudi^(d), Ramsey S. Lewis^(e), Hongzhi Shi^(f), Barunava Patra^(g), Xue Zhao^(a), François Dorlhac de Borne^(h), Tijs Gilles⁽ⁱ⁾, Shengming Yang^(g), Hongbo Zhang^(a), Mengyue Zhang^(f), Marcos Lusso^(d), Irving J. Berger⁽ⁱ⁾, Dongmei Xu^(d), Liuying Wen^(a)

(a) Tobacco Research Institute, Chinese Academy of Agricultural Sciences, Qingdao, China; (b) RJ Reynolds Tobacco Co., Winston-Salem, NC, USA; (c) Japan Tobacco International, Geneva, Switzerland; (d) Research Development & Regulatory Affairs, Altria Client Services LLC, Richmond, VA, USA; (e) Department of Crop and Soil Sciences, North Carolina State University, Raleigh, NC, USA; (f) National Tobacco Cultivation & Physiology & Biochemistry Research Center, Henan Agricultural University, Zhengzhou, China; (g) Department of Plant & Soil Sciences, University of Kentucky, Lexington, KY, USA; (h) Leaf Research, Imperial Tobacco, Bergerac, France; (i) BAT Science, British American Tobacco Research & Development, Regents Park Road, Millbrook, Southampton, SO15 8TL, UK; (j) British American Tobacco, Cachoeirinha, RS, Brazil

Studies in Natural Products Chemistry, Volume 70, July 2021, pg 119-149

<https://doi.org/10.1016/B978-0-12-819489-8.00006-5>

DOI: 10.1016/B978-0-12-819489-8.00006-5

The Biomarkers (BMK) Sub-Group published an external publication [BMK-161-2-CXP] as follows:

Review of recent lung biomarkers of potential harm/effect for tobacco research

Erin Beattie⁽¹⁾, Jeffery Edmiston⁽²⁾, Patrudu Makena⁽³⁾, Elizabeth Mason⁽⁴⁾, Mike McEwan⁽⁵⁾, Krishna Prasad⁽⁵⁾

(1) Clianza Research, 1310 Fewster Drive, Mississauga, ON L4W 1A4, Canada; (2) Altria Client Services, Richmond, Virginia, USA; (3) RAI Services Company, Winston-Salem, North Carolina, USA; (4) Imperial Brands, Bristol, UK; (5) British American Tobacco, Southampton, UK

F1000Research 2021, December 2021, 10:1293

<https://doi.org/10.12688/f1000research.55411.1>

DOI: 10.12688/f1000research.55411.1

The Product Use Behaviour (PUB) Sub-Group led the development of a publication that summarised background information and provided practical recommendations for performing human abuse liability assessments of nicotine products to meet tobacco regulatory needs [PUB-156-CXP]. As a tribute to the quality of this work, the manuscript was selected as an Editor's Choice article. (Also see article on next page)

Human Abuse Liability Assessment of Tobacco and Nicotine Products: Approaches for Meeting Current Regulatory Recommendations

Andrea Vansickel⁽¹⁾, Sarah Baxter⁽²⁾, Neil Sherwood⁽³⁾, Michael Kong⁽⁴⁾, Leanne Campbell⁽²⁾

(1) Regulatory Affairs, Altria Client Services LLC, Richmond, VA, USA; (2) Clinical Studies, RAI Services Company, Winston-Salem, NC, USA; (3) Independent Consultant, Nyon, Switzerland; (4) Altasciences Clinical Research, Montreal, Canada

Nicotine & Tobacco Research, Volume 24, Issue 3, March 2022, pg 295–305

<https://doi.org/10.1093/ntr/ntab183>

DOI: 10.1093/ntr/ntab183



TOBACCO WORKERS' CONFERENCE (TWC)

Similarly to previous years, presentations made at the Tobacco Workers' Conference held in January 2022 have been uploaded in PDF format to the CORESTA website and can be found under the "Abstracts" tab.

Virtual CROM Symposium 2021

Survey Methodology

December 9, 2021 | 4:00 to 7:15 pm CET

The Consumer Reported Outcome Measures Task Force (CROM TF) has the shared vision to collaborate on scientific shift, beyond competition for market share, to work with scientifically rigorous and well-respected partners to set up guidance to develop and validate new measures and research methods to achieve the strategic vision.

With this vision in mind, the CROM TF held a Symposium online on “Survey Methodology” on 9 December 2021. The event was organised by Dr Christelle Chrea, Manager Behavioural Sciences at Philip Morris International, Switzerland, the moderator was Dr Mohamadi Sarkar, Fellow, Scientific Strategy & Advocacy, at Altria Client Services, USA, and the panel discussion was led by Dr Mimi Kim, Senior Director, Population Effects, at RAI Services Company, USA.

Abstracts, presentations and presenter biosketches can be accessed on the CORESTA website at www.coresta.org/events/crom-virtual-2021-symposium-35553.html.

Dr Chrea was interviewed by the CORESTA Secretariat and shared her outlook on the planning and hosting of the event and its implications.

Christelle,

After a successful CROM Symposium held in 2020, you organised a second online Symposium in December 2021 on Survey Methodologies which proved to be a great success with 150 registered participants.

Why was the theme of the Symposium of importance for CROM?

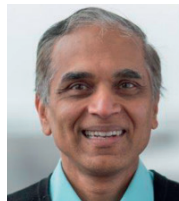
Our objective, as the CROM Task Force (TF), is to establish best practices and guidelines on how to identify, develop, and validate, and to provide access to CROM for the premarket and post market assessment of tobacco and nicotine-containing products. CROM constitute the backbone of any survey instrument and here we can differentiate between what we call psychometric CROM (i.e. CROM which are intended to measure underlying psychological attributes, such as reinforcing effects of a product) and descriptive CROM (i.e. measure behaviour directly. For example, items pertaining to tobacco product consumption, such as the average number of cigarettes smoked per day, are directly observable behaviours). We are currently developing specific guidelines for each of the two sorts of CROM and having the opportunity to exchange with renowned external experts on this topic is fundamental for us to ensure the guidelines capture the state of the science.

How did the idea of organising such an event come to your mind? What were your expectations, and why did you think that the Symposium would help to meet them?

Part of the mission of the CROM TF is to be a recognised scientific authority on CROM-related methodologies and to promote the communication



Christelle CHREA
Philip Morris International



Mohamadi SARKAR
Altria Client Services



Mimi KIM
RAI Services Company

between researchers within industry and academia. Holding a scientific symposium in the view to gather researchers from various disciplines in industry and academia is a very rich and impactful way to foster knowledge sharing and dialogue on topics relevant for tobacco regulatory science. When we organised our first Symposium in 2020, we leveraged mainly our internal expertise in the Task Force on psychometric CROM to create the agenda. Already, we were really amazed by the number of attendees and the very positive feedback we received. This year, we decided to stretch our wings and go for a broader topic, relying mainly on the contribution of external speakers. I think the Symposium has succeeded beyond our expectations, thanks to the excellent quality of the presentations and the responsiveness of the speakers to answer all questions posted on the chat. The panel discussion at the end of the symposium was a great example of how we can bring different disciplines around one central topic and create an extraordinary forum to share and discuss best practice principles that will feed the CROM TF own efforts.

The presenters were acknowledged international experts and the content of the programme was impressive. How did you contact and convince the presenters to participate? Was it difficult?

Within the CROM Working Group 01, in charge of external engagements in the CROM TF, we put a list of potential speakers based on our networks and knowledge of the main stakeholders in survey methodology. We were fortunate to get the help from Karen Gerlach and Janine Pillitteri (Womble Bond Dickinson), both regulatory

| SURVEY METHODOLOGY: THE BIG PICTURE | | |
|---|---|---|
| 4:05 p.m.- 4:55 p.m. | Adapting Web-push Survey Methods to Countries Throughout the World | Don A. Dillman, PhD Washington State University |
| 4:55 p.m.- 5:15 p.m. | Reducing Measurement Error with Qualitative Research Before and After Designing and Finalizing a Survey | David F. Harris, M.A. Insight and measurement, LLC |
| SURVEY METHODOLOGY IN THE CONTEXT OF TOBACCO REGULATORY SCIENCE | | |
| 5:15 p.m.- 5:35 p.m. | Evaluation of Tobacco Product Perception and Intention Data to Inform Tobacco Product Review | Benjamin Apelberg, PhD Center for Tobacco Products, U.S Food & Drug Administration |
| 5:35 p.m.- 5:50 p.m. | Break | |
| 5:50 p.m.- 6:10 p.m. | Longitudinal studies for modified risk tobacco products in postmarket surveillance settings | Hui Cheng, PhD and Brendan Noggle, MPH Altria Client Services |
| 6:10 p.m.- 6:30 p.m. | Design and Methods of the Adult JUUL Switching and Smoking Trajectories (ADJUST) | Nicholas I. Goldenson PhD JUUL Labs Inc. |
| 6:30 p.m.- 7:15 p.m. | Audience Q&A following panel presentations | Panel presenters |

scientists with long experience in tobacco regulatory research, to identify additional experts. We also had the support from Stéphane Colard to reach out to the external expert from FDA. After reaching out to about 20 experts, we felt very honoured for having received immediate positive responses from the three external experts who participated in the Symposium.

Overall, what were the main challenges you had to face, and how did you tackle them?

The most challenging part was probably to meet quite stringent timelines as we concretely started to work on the Symposium agenda in September only. Nonetheless, we worked in great synchrony as a team and things went very smoothly overall. Especially when it comes to the technical challenges of organising a virtual event, we were very grateful to count on the expertise and willingness to help from Stéphane Colard and Natacha de Tervarent. They researched the best option for using Microsoft Teams and managed all the logistical aspects to set up the meeting and the registration platform, while being in the control tower during the event.

What main conclusion do you draw after this Symposium?

Beside the very fruitful discussion generated in this Symposium that will allow us to further shape and refine our science in the tobacco regulatory research,

there was a fantastic energy behind the organisation of the Symposium and I truly believe that this is something that really propels our ability to connect, share, and collaborate.

Would you encourage other CORESTA members to organise similar events?

Absolutely, and I would be happy to share some of our experience in the CROM TF to ensure their event is very successful as well!

What are the next steps for you now?

We plan to have a third Symposium in December 2022 like the first two, for which we are currently discussing potential topics, so we are starting earlier this year! In addition, this year we also plan to organise smaller workshops, focusing on specific CROM topics of interest for CORESTA delegates who are involved in the design and conduct of Tobacco Product Perception and Intention Studies (TPPIS). The first one will be held on 24 May 2022, as part of the Spring CROM TF meeting, and the topic will be “*Claim Comprehension and Intention Study for JUUL E-cigarette Products: Key Findings and CROM-Related Measurement Challenges*”.

Any concluding comments? A last message to deliver to our readers?

I hope to see many of you in our upcoming events this year and do not hesitate to reach out should you have any questions on our activities or if you would like to organise a symposium and would like some tips.

CORESTA would like to thank Christelle, Mohamadi and Mimi, and all who contributed to this Symposium, for their engagement with the international scientific community, for their contribution to the dissemination of important scientific knowledge, and for the time they dedicated to CORESTA.



UPCOMING CORESTA MEETINGS (2022)

Covid-19 restrictions are gradually being lifted worldwide and in-person meetings are slowly making a comeback. Most CORESTA Sub-Group and Task Force meetings are still being held virtually, but the next Board and Scientific Commission meetings will be in-person. Below is a list of the scheduled meetings but please visit the CORESTA website for the most up-to-date information (www.coresta.org/meetings/upcoming).

| Meeting | Date | Location |
|---|---------------------------|------------------------|
| SG PTM - Physical Test Methods | 20-21 April 2022 | Online |
| SG IVT - <i>In Vitro</i> Toxicity Testing | 13 May 2022 | Online |
| TF CROM - Consumer Reported Outcome Measures Consortium | 24 May 2022 | Online |
| CROM Workshop | 24 May 2022 | Online |
| CORESTA Reading Committee | 1-6 June 2022 | Online & Paris, France |
| Scientific Commission | 6-7 June 2022 | Paris, France |
| Board | 7 June 2022 | Paris, France |
| CORESTA General Assembly & Workshop | 8 June 2022 | Paris, France |
| CORESTA Science Day | 9 June 2022 | Paris, France |
| CORESTA CONGRESS | 10-28 October 2022 | Online |

Tobacco Alkaloid Genetics (TAG) Task Force

The Tobacco Alkaloid Genetics Task Force (TAG TF) was set up in March 2017 [TAG-140] when potential regulations to dramatically reduce nicotine content in conventional cigarettes were vigorously discussed. Earlier that year, the United States Food and Drug Administration (FDA) declared “addressing the addictive levels of nicotine in combustible cigarettes must be part of the FDA’s strategy for addressing the devastating addiction crisis that is threatening American families”. In March 2018, the FDA released an advanced notice of proposed rulemaking which indicated particular interest in comments regarding the merits of nicotine levels of 0.3, 0.4, and 0.5 mg nicotine/g in tobacco cigarette filler, as well as other levels of nicotine. This is substantially lower than nicotine levels in leaves of cultivated tobacco which are typically between 18 and 36 mg/g.



Yongfeng GUO
TAG TF Coordinator

The purpose of the Task Force was to review the published scientific literature on breeding and biotechnology methods that affect alkaloid levels in tobacco and to provide an objective, non-proprietary resource to assist CORESTA members in understanding technical approaches available in lowering nicotine levels in tobacco and making proper decisions in facing this situation. The objectives of the Task Force included: 1) To understand the genetics that control alkaloid formation in tobacco plants; 2) To understand the feasibility of conventional and non-conventional breeding techniques to modify alkaloid formation in tobacco plants; 3) To understand the impact of tobacco alkaloid levels on leaf production and quality.

In early 2018, 17 participants from 10 CORESTA member companies volunteered in taking a part of writing literature reviews on nine subtitles around this topic, including the introduction, traditional breeding using low nicotine germplasm materials, alkaloids biosynthesis, transportation of alkaloids between cells and within the plant, regulatory mechanisms of biosynthesis and transportation of tobacco alkaloids, genetic engineering of alkaloid levels based on biosynthetic enzymes, genetic engineering of alkaloid levels based on transporters, genetic engineering of alkaloid levels based on regulatory genes, and impact of low alkaloid levels on tobacco leaf production and quality. The writings were collected and put together to form the first draft in early 2019. The draft was discussed and modified at every Task Force meeting since 2018 and was edited by members of the Scientific Commission and the CORESTA Board. The manuscript entitled "Molecular regulation and genetic manipulation of alkaloid accumulation in tobacco plants" was submitted to a number of peer reviewed journals before being accepted in August 2021 by the eBook *Studies in Natural Products Chemistry - Bioactive Natural Products* published by Elsevier Science Publishers – Amsterdam (Volume 70, 2021, pg 119-149, <https://doi.org/10.1016/B978-0-12-819489-8.00006-5>).

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ELSEVIER Studies in Natural Products Chemistry Volume 70, 2021, Pages 119-149

Chapter 5 - Molecular regulation and genetic manipulation of alkaloid accumulation in tobacco plants

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Abstract

Nicotine and related pyridine alkaloids of the tobacco plant are synthesized in the root and subsequently translocated via the xylem to the leaf and other aerial tissues, where they are primarily stored in the vacuole as defensive chemicals against herbivorous insects. Tobacco alkaloid accumulation depends on both biosynthesis and transport, which can be influenced by environmental conditions, phytohormones, and developmental status. Jasmonate signaling and transcription factors, including ERFs are known to play predominant regulatory roles. Genetic manipulation of alkaloid accumulation via traditional breeding, mutation breeding, and genetic engineering has been effective, but adverse effects on yields and cured leaf quality are frequently observed. Prospects for developing tobacco cultivars with ultralow alkaloid levels to meet future potential regulation of combustible cigarette nicotine content are discussed.

The content of the Task Force report can be summarised as follows: Nicotine and related pyridine alkaloids of the tobacco plant are synthesized in the root and subsequently translocated via the xylem to the leaf and other aerial tissues, where they are primarily stored in the vacuole as defensive chemicals against herbivorous insects. Tobacco alkaloid accumulation depends on both biosynthesis and transport, which can be influenced by environmental conditions, phytohormones, and developmental status. Jasmonate signaling and transcription factors, including ERFs are known to play predominant regulatory roles. Genetic manipulation of alkaloid accumulation via traditional breeding, mutation breeding, and genetic engineering has been effective, but adverse effects on yields and cured leaf quality are frequently observed. Prospects for developing tobacco cultivars with ultralow alkaloid levels to meet future potential regulation of combustible cigarette nicotine content are discussed.

The Task Force has achieved all the objectives and was disbanded by the Scientific Commission in January 2022.

Human Abuse Liability Review

Product Use (PUB) Sub-Group

The PUB Sub-Group Coordinator, Dr Krishna Prasad, is pleased to present a brief overview of the work surrounding the publication of the article “Human Abuse Liability Assessment of Tobacco and Nicotine Products: Approaches for Meeting Current Regulatory Recommendations” (<https://doi.org/10.1093/ntr/ntab183>).

Background

The CORESTA Product Use Behaviour Sub-Group proposed a project [PUB-156-CXP], to review the international regulatory recommendations for abuse liability assessment of tobacco and nicotine products. This was of increasing interest to regulatory bodies globally, especially with the emergence of novel tobacco products. The review was intended to provide background and functional recommendations for tobacco product abuse liability testing.

Approach

The writing committee led by **Michael Kong** (Altasciences Clinical Research) and the team **Andrea Vansickel** (Altria Client Services LLC), **Sarah Baxter** (RAI Services Company), **Neil Sherwood** (Independent Consultant) and **Leanne Campbell** (RAI Services Company) started by pulling together an outline of the manuscript. As the first step towards the compilation of the review the team presented at the 74th Tobacco Science Research Conference in August 2021 in Boston, Massachusetts, USA [PUB-268-CXP].

Procedure

The manuscript went through a couple of rounds of reviews within the team and the final draft was circulated among the PUB Sub-Group members for general comments. In parallel to this the contributing members pushed the document through their companies’ internal review process. All the comments were incorporated before sending to the CORESTA Scientific Commission for approval. The approved final document was submitted to *Nicotine & Tobacco Research* for publication. The reviewers’ comments were addressed by the team and the revised manuscript was submitted in June 2021. Finally, the manuscript was accepted for publication in September 2021.

Outcome

Planning, collating all the required information, drafting, editing and incorporating all the reviewers’ comments is a long process. This is particularly time consuming when the contributors have to follow various company review cycles. However, these review articles are robust scientific documents that form the basis of the CORESTA Sub-Group work in progressing and sharing knowledge across the industry. We are extremely proud of this piece of work as it was not only published in a leading journal but also selected as the “Editor’s Choice Article” for 2021.

We hope articles like this will provide inspiration and motivate and encourage others to undertake such activities to build a strong science base for CORESTA activities going forward.



CORESTA COMMUNICATION AT EXTERNAL EVENTS

International Organization for Standardization (ISO)

ISO/TC126 WG 22 Web Meeting – 16 February 2022

Presentation "Heated Tobacco Products (HTP) Task Force: Update" by Helena Digard (British American Tobacco, UK) and Jason Flora (Altria Client Services LLC, USA), Coordinator and Secretary of the CORESTA HTP Task Force.

The above presentation can be viewed in the information/CORESTA Communication section of the CORESTA website



OBITUARY – FRANÇOIS JACOB



François Jacob passed away on 14 December 2021 after an illness bravely borne.

After graduating from the French École Polytechnique with an engineering degree, François joined SEITA, the French Tobacco Monopoly, and worked at its factory in Dijon specializing in the production of cigarettes for export markets. He was then transferred to the Leaf Purchasing Department and was responsible for the sourcing of flue-cured, burley and dark fire-cured tobaccos. He was promoted to Area Manager for America Asia Pacific within SEITA's Export Department and then appointed Area Manager for Europe, a post he held until he joined CORESTA.

François was appointed Secretary General of CORESTA in 1989 and served the association until his retirement in 2010. During his tenure, he oversaw the reorganisation of the association's technological and operational structure. To ensure fairer representation of the CORESTA membership and improved efficiency, he made far reaching changes in the association's statutes and internal rules and enhanced and streamlined the cooperation between the Board, the Scientific Commission and the Secretariat. He managed the transition of the association from one beholden to SEITA into an independent entity and moved the offices from the SEITA premises to central Paris. He improved the sharing of information by consolidating the electronic database created in 1986, and the printed Bulletin, onto CD-ROMs that were distributed to the CORESTA membership. Due to a decrease in volunteer companies to organise the yearly meetings, François extended CORESTA's cooperation role to include event planning which resulted in the successful Agro-Phyto meeting in Krakow in 2007 and the Smoke-Techno meeting in Aix-en-Provence in 2009.

For his services to CORESTA, François was awarded a bronze medal in 1996, a silver medal in 1998 and a gold medal in 2010.

François always showed great adaptability, management skills, and frank contact with members and delegates from the various professional bodies that dealt with the CORESTA. His keen sense of humour and his photographic skills were much appreciated, and he built good relationships with many of his CORESTA colleagues with whom he continued to keep regular contact after his retirement.

His CORESTA colleagues and friends present their most sincere condolences to his wife, Catherine, and his three children and their families. François will be sadly missed.

