



NEWSLETTER

Issue 44 – April 2016

CORESTA CONGRESS Berlin, Germany, 9-13 October 2016

Over the last 60 years, CORESTA has promoted collaborative research in tobacco. The Congress will be the ideal forum for scientists, regulators and other stakeholders to share and discuss their research, be informed about current challenges in the industry and plan future collaborative projects. The scope of interest in the Congress is widened by the advent of new products that have opened new avenues in scientific activity.

The 60th anniversary Congress of CORESTA will run under the theme:

"Bridging the gaps"

The focus will be on how CORESTA can provide scientific evidence, robust methods, reference products and proficiency testing as a basis for product regulation and standards development through collaboration and open exchange of knowledge. Strongly themed sessions and workshops will feature presentations that support how current research work can help "fill the gaps" in knowledge leading to better understanding for better decision making.

Berlin

Better known for its post-World War II events and its Wall, Berlin also has a fascinating past, an invigorating present, and an exciting future. The capital city of Germany since 1999, Berlin has all the attractions of a vibrant, modern, progressive metropolis tinged with reminders of its turbulent history. In addition to the many cultural, historical and architectural sights well worth seeing, visitors will appreciate Berlin's many parks and restaurants and its unique tolerant and nonchalant atmosphere.

Venue

The Congress will be held at the Berlin Hilton. This modern hotel offers comfortable and elegant fully equipped rooms and state of the art conference facilities. Exceptionally well located on the historic Gendarmenmarkt Square, the hotel is within walking distance of most major city attractions and has a metro station close by.

Timeline

Online Registration: early May until 15 September 2016
(*Earlybird registration until 18 July 2016*)

Working Programme: available end of June 2016

Further Information

Please visit the official meeting website at
www.coresta2016.org

Elections and General Assembly

Elections will be held for the renewal of the Scientific Commission and the partial renewal of the Board. Further details will be provided in the next Newsletter and through correspondence with the Official Delegates of Member Organisations.

Online Abstract Submission

Online submission is available for authors wishing to present a paper at the Congress.

The "Call for Papers" and "Abstract Guidelines and Submission" can be found under the Scientific Programme tab on the official Congress website at www.coresta2016.org.

The "Call for Papers" and online submission link is also available on the CORESTA website at www.coresta.org under the Meetings section.

Presenters are encouraged to place their work in the broad context of potential regulatory requirements affecting both conventional combustible and emerging products. Emphasis should be placed on the impact of toxicant ceilings for stakeholders, from growers to final users, in terms of sources of toxicants, opportunities for intervention and potential unintended consequences of product regulation.

Abstract submission deadline:

15 May 2016

Authors will be contacted end of June.



NEW CORESTA WEBSITE

CORESTA is pleased to announce the launch of its new website.

After trials and tribulations, hurdles and challenges, the public section of the newly developed CORESTA website is now operational and can be accessed via the address www.coresta.org.

The new website project has been divided into three development phases:

- **Phase 1:** the public section.
- **Phase 2:** the general private section.
- **Phase 3:** the Sub-Groups, Task Forces and Committees private working section.

Phase 1 is complete. The online public section contains the following information and features:

- A new graphic design.
- All the information available on the former website.
- Much of the information available on the former CORESTA CD-ROM.
- Additional information about CORESTA.
- Abstracts for which copyright has been obtained.
- CORESTA meeting presentations with author permission to publish.
- Lists of upcoming meetings.
- A full search facility for the general website and the abstracts and documents section.
- A specific search feature for the abstracts and documents section, complemented by a filter feature.

Phase 2 is under development and will include password access for CORESTA Member Organisation persons. Additional information will be made available together with extra practical features.



Phase 3 will be developed once Phase 2 is fully operational and will have a private section reserved for the work of Sub-Groups, Task Forces and Committees and accessible only by the members of these groups.

The website development is interlinked to the work of the CORESTA Standards Task Force and is evolving according to the redefined rules for data reporting, data collection, work procedures, document traceability and archiving, etc. In addition, access rights to the future private section will require strict adherence to CORESTA rules in terms of membership.

The CORESTA website is a "work in progress" and no delivery dates are scheduled yet for Phase 2 and 3 in order that an appropriate functional tool may be delivered to the CORESTA membership. The first phase of development now online has been reviewed as much as possible but will no doubt require fine tuning so all comments, suggestions and bug reports are most welcome. Please send an email to webmaster@coresta.org.

CORESTA sincerely hopes that the new website enhances users' browsing experience, enables easy accessibility to information, and supports CORESTA's mission to be an authoritative source of publically available credible science and best practices by providing a transparent sustainable cooperation process within an increasingly digitalised environment.

CORESTA Scientific Commission and Board Meetings

The **SCIENTIFIC COMMISSION** met in Nashville, USA, hosted by CORESTA. The meeting was held on 14-15 January to coincide with the 47th Tobacco Workers' Conference.

- There was discussion on updating the Purpose of CORESTA that may be amended in the Statutes at the next General Assembly. The balance between Agro-Phyto and Smoke-Techno was also debated with regards to the speakers invited by the Board at their meetings.
- **ISO/TC126 (Tobacco and Tobacco Products):** Further to CRM 75 and 81, three other CRMs (70, 74, 79) have entered the programme of TC126.
A new Sub-Committee on vapour products (SC03) has been created within TC126 after a request to launch a specific Technical Committee (TC) was not approved by ISO members. The working group based on CRM 81, led by CORESTA, will belong to SC03 as WG2.
- **ACAC:** Interest is growing on dark air-cured tobacco in view of pending regulations on cigars. Cigar producers are interested in guidance, and a GRL Guide is being considered.
- **Agronomy & Leaf Integrity:** The Agrochemical Residue Field Trials Task Force has completed their first three-year programme and will begin a second round of trials this year. Learnings have shown the necessity for the Task Force to become a Sub-Group.
- **Phytopathology & Genetics:** A number of objectives have been revised (see overleaf). The continuity of the Di@gnoplant application for tobacco raised concern since it does not belong to CORESTA.
- **Product Technology and Smoke Science:** The two Study Groups worked on how to improve efficiency and speed. An ad-hoc group was created to make recommendations.

The four CORESTA Reference Products for Smokeless Tobacco Products have been manufactured and will be used in the annual collaborative study.

- **CORESTA Standard Task Force:** The New Work Item Proposal and project procedure, explained at both AP and SSPT meetings in 2015, have been progressively implemented. All projects will now be labelled with a specific reference for traceability and archiving purposes.

* * * * *

The **BOARD** met in Greensboro, USA, on 16-17 February, hosted by RAI Services Co.

- The Science Communication Committee reported on priorities. A number of workshops were decided, which could be held during the Congress or separately or jointly with other events with a view to widening the scope of CORESTA by means of inviting and involving more people from outside the industry.
- As at the Windsor meeting in July 2015, the Board had invited top management persons from two US CORESTA Members Organisations to present their perception of what CORESTA meant for their companies. This will feed discussion on mid-term and long term CORESTA strategy. The next Board meeting will focus on Agro-Phyto topics.
- The increasing number of tasks required from the Secretariat (Congress, website, databases, visibility, involvement in standards and working groups, follow-up and review of documents, etc.) was discussed, as well as business continuity issues, with their consequences on the administration and budget of the association. A recruitment has been decided and membership fees adjusted accordingly.
- Priority was given to the new website and the 2016 Congress in October in Berlin.
- Amendments to the CORESTA Statutes and Rules were proposed, that will be formalised at the June meeting for vote at the Congress.



CORESTA NEWSLETTER

Since July 2014, the CORESTA Newsletter has been made available publicly for download in electronic format from the CORESTA website at www.coresta.org. This has enabled CORESTA information to reach a wider public audience and eased circulation within CORESTA Member Organisations.

A paper version nevertheless continued to be mailed to persons wishing to receive the Newsletter by regular post.

To cut costs, move with the times and to coincide with the launch of the new CORESTA website, it has been decided to discontinue the paper issue of the Newsletter.

Please be advised that this current issue will be the last paper version. All future Newsletters will be available in electronic format only.



CORESTA SUB-GROUPS & TASK FORCES

AGRONOMY & LEAF INTEGRITY Study Group

Amendment to Objectives: Sub-Group TSNA in Air-Cured and Fire-Cured Tobacco (TSNA)

UPDATE

Updated Objectives:

1. To determine proper placement of data loggers in curing barns to best represent the true curing conditions within the barn and produce a CORESTA Guide on data logger placement and calibration.
2. To review the issues of post-cure tobacco storage and ventilation parameters.
3. Sampling
 - (a) To define proper sampling method of post-cure tobacco for TSNA determination.
 - (b) To determine the optimal method for sample preparation for TSNA determination.
4. To collect available TSNA presentations and papers and publish them on the CORESTA website.

The first objective of the Sub-Group was amended to include the production to a CORESTA Guide.

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

UPDATE

Updated Objectives:

1. To study routine procedures used in participating laboratories.
2. To provide an independent assessment of the quality of data being produced by participating laboratories, through the Tobacco Proficiency Testing Scheme.

The objectives were streamlined to better represent the work of the Sub-Group.

Amendment to Group Type: Sub-Group Agrochemical Residue Field Trials (RFT)

The Task Force was changed to a Sub-Group as its work and activities were viewed as being long-term.

PHYTOPATHOLOGY & GENETICS Study Group

Revised Objectives: Sub-Group Viruses (VIR)

UPDATE

Updated Objectives:

1. To collate and draw conclusions from the viral data (1995-2011).
2. To publish a report in a peer-review journal.

The word "synthesise" was replaced by "collate" in the first objective. The work of the Sub-Group is nearing its end and the second objective was therefore replaced with the sole objective of publishing a report.

Objective confirmed: Sub-Group Collaborative Study Black Shank (BKS)

UPDATE

Objective:

- ◆ To test the black shank resistance of the best available varieties under different conditions.

Objective revised and confirmed: Sub-Group Efficacy of Biological and Eco-Friendly CPAs (BIO)

Objective:

- ◆ To test promising biological and eco-friendly control agents, compared with current control practices

CORESTA GUIDES

New - CORESTA Guide No. 17

Sustainability in Leaf Tobacco Production (*April 2016*)

Tobacco is grown and processed around the world, under very diverse geographic, socio-economic and cultural conditions. With this in mind, the CORESTA Sustainability in Leaf Tobacco Production Task Force has produced a Guide designed to capture the sustainable tobacco production practices implemented by its members, delivering the dimensions of environmental integrity, economic resilience, social wellbeing and governance. The guidelines focus on four key areas: governance, agronomy, curing and livelihoods. The scope of these guidelines covers sustainable tobacco production through the responsible management of tobacco growing and complements the CORESTA Guide No. 3.

CORESTA SUB-GROUPS & TASK FORCES (continued)

SMOKE SCIENCE Study Group

Revised Objectives: Sub-Group Smoking Behaviour (TSB)

UPDATE

Updated Objectives:

1. To critique and review published papers on all aspects of tobacco and related products' use behaviour, and publish the critical reviews in peer-reviewed journals.
2. To examine unpublished reports and work on the subject within member organisations, with a view to recommending publication in peer-reviewed journals.
3. To identify gaps in total information and suggest suitable work to provide the necessary information.

In the first objective, the word "smoking" was replaced by "tobacco and related products' use" in order to widen the scope of the Sub-Group's activities.

Amendment to Objectives: Sub-Group Biomarkers (BMK)

UPDATE

Updated Objectives:

1. To review present knowledge of tobacco and smoking-related biomarkers of exposure and effect.
2. To undertake ring trials / proficiency tests for selected biomarkers.
3. To source and develop reference materials to support biomarker analysis for those biomarkers selected for ring trials and proficiency tests.

The text "as agreed by the Scientific Commission" was removed from the second objective as considered part of the regular process for all groups.

Additional Objective: Sub-Group Special Analytes (SPA)

UPDATE

Updated Objectives:

1. To propose practical and robust recommended methods for smoke analytes.
2. To organise and conduct periodically proficiency testing of smoke analytes other than TNCO.

Considering the need for accredited laboratories, and the expert platform offered by CORESTA, a second objective was added to the Sub-Group's remit. In the first objective, the text "as agreed by the Scientific Commission" was removed.

CORESTA REPORTS

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

- ***In vitro* Micronucleus Assay Proficiency Study 2011**

Technical Report – March 2016 (Sub-Group *In Vitro* Toxicity Testing of Tobacco Smoke)

An *in vitro* micronucleus (MNvit) assay proficiency study was conducted to evaluate the MNvit induction of a mainstream smoke extract from three cigarettes using a common study protocol. This enabled participating laboratories to evaluate method proficiency, compare results with those of other laboratories, and obtain an external audit of documentation procedures that might identify potential areas for improvement.

- **Ames Assay Proficiency Study**

Technical Report – March 2016 (Sub-Group *In Vitro* Toxicity Testing of Tobacco Smoke)

An Ames Assay proficiency study was to evaluate the mutagenicity of a mainstream smoke extract from two cigarettes using a common study plan. Similarly to the micronucleus assay proficiency study, this enabled laboratories to evaluate method proficiency, compare results with those of other laboratories, and obtain an external audit of their documentation procedures that might identify potential areas for improvement.

- **2015 Collaborative Study on Benzo[a]pyrene in Tobacco Products**

Technical Report – March 2016 (Sub-Group Smokeless Tobacco)

From 2013 to 2015, the CORESTA Smokeless Tobacco Sub-Group (STS) conducted a series of collaborative studies for the determination of benzo[a]pyrene (B[a]P) in tobacco and smokeless tobacco products. The STS eventually settled upon a gas chromatography mass spectrometry (GC-MS) method using solid phase extraction for sample cleanup. A final collaborative study was conducted in 2015 to calculate repeatability and reproducibility (r&R). The results were suitable for inclusion into a CRM (published as CRM No. 82).

CORESTA REPORTS (continued)

- **2015 Collaborative Study of CORESTA Ignition Propensity Monitor Test Piece CM IP 2 for the Determination of Ignition Propensity**

Technical Report – April 2016 (Sub-Group Routine Analytical Chemistry)

The Sub-Group Routine Analytical Chemistry has been given the responsibility to provide a monitor test piece specific for the ignition propensity testing. A candidate CORESTA monitor test piece was manufactured in January 2014 and was qualified as CORESTA Monitor Test Piece CM IP 2 in 2015, on the basis of a 2014 collaborative test. The need to check the stability of CM IP 2 monitor test piece on the basis of a collaborative test of CM IP 2 and of NIST standard reference material 1082 for comparison purpose was agreed in April 2015 and the goal of this report is to provide the statistical assessment of the results of the 2015 collaborative test.

CORESTA RECOMMENDED METHODS

New

- **CRM No. 80** – Use of the Part-Filter Method for the Estimation of Smokers' Exposure to Nicotine and Nicotine-Free Dry Particulate Matter (*January 2016*)

This CRM, referred to as the Part-Filter Method (PFM), is applicable to the estimation of human smoke exposure to nicotine and nicotine-free dry particulate matter (NFDPM, also known as tar) using linear calibration regression equations between mainstream smoke yields and corresponding analytes from part-filter extracts. The method is based on the results of collaborative studies published in the CORESTA Smoking Behaviour Sub-Group Technical Reports *Part-Filter Method - 2012 Ring Trial*, February 2013, and *Results of the 2014 CORESTA Part-Filter Method Ring Trial and Comparison with the 2012 Ring Trial*, June 2015.

- **CRM No. 82** – Determination of Benzo[a]pyrene in Tobacco Products by GC-MS (*March 2016*)

This CRM for the determination of benzo[a]pyrene in single grades of tobacco, cigarette filler and smokeless tobacco products, including snus, moist snuff, dry snuff and chewing tobacco, is based on the outcome of the collaborative study carried out by the CORESTA Smokeless Tobacco Sub-Group and reported in the Technical Report *2015 Collaborative Study on Benzo[a]pyrene in Tobacco Products*, March 2016.

Updated

- **CRM No. 72** – Determination of Tobacco Specific Nitrosamines in Smokeless Tobacco Products by LC-MS/MS (*Third edition – February 2016*)

The CORESTA Smokeless Tobacco Sub-Group studied various widely-used procedures for the determination of tobacco-specific nitrosamines (TSNAs) in smokeless tobacco products and conducted a study in 2009 that evaluated several different methodologies (*2009 Collaborative Study Report*, July 2010 – updated January 2016). The above CRM has been updated to include repeatability and reproducibility (r&R) for the four CORESTA Reference Products.

All CORESTA Recommended Methods can be downloaded in PDF format at www.coresta.org

CORESTA IN THE PRESS

Tobacco Journal International

The *Tobacco Journal International* published an article in its February/March 2016 issue, pages 131-132, entitled "CORESTA – towards new challenges." The article is a report on the two CORESTA Joint Study Group Meetings held in South Korea and Turkey in 2015, with a focus on the Workshops on "Omics" and "E-cigarettes" and how these initiatives fit in with the CORESTA vision to be "recognised by its members and relevant external bodies as an authoritative source of publicly available, credible science and best practices related to tobacco and its derived products."



Physical Test Methods Sub-Group Meeting (UK)

The CORESTA Physical Test Methods Sub-Group (PTM) held its 22nd meeting in Milton Keynes, UK, on 7 April 2016, at the kind invitation of Cerulean. The meeting was attended by 17 participants. After the resignation of Mario Mayr as PTM Sub-Group Coordinator and earlier of Tim Mason as Secretary, Dr Bernhard Eitzinger from delfortgroup AG and Jing Yi from the China National Tobacco Quality Supervision and Test Center of the Zhengzhou Tobacco Research Institute of CNTC were appointed as the new Coordinator and Secretary, respectively, in September 2015. While both have been members of the PTM Sub-Group in the past, this was the first meeting in their new roles.

As usual, a substantial part of the meeting was dedicated to the discussion of the current status of various inter-laboratory studies such as the cross-check on calibration standards for air permeability, pressure drop and filter ventilation and the annual proficiency test on physical parameters. For these studies a number of reports are still pending and shall soon be ready for submission to the Scientific Commission and for publication.

In accordance with a request from the Scientific Commission, the objectives of the PTM Sub-Group have been revised and updated. As a result of a lively discussion at the PTM meeting the following three objectives have been agreed and will be submitted to the Scientific Commission for approval:

1. To develop and maintain CORESTA Recommended Methods (CRMs) pertinent to physical test methods related to tobacco products and their components.
2. To develop and maintain CORESTA Guides and associated Technical Reports for the application of physical test methods related to tobacco products and their components.
3. To organise, conduct and report on routine inter-laboratory studies in order to assess inter-laboratory consistency and to enable continual improvement of participating laboratories.

Furthermore, a new CORESTA Recommended Method on snus pouch sealing strength is under development in cooperation with the Smokeless Tobacco Sub-Group and is being led by Borgwaldt KC. The current status and results of the first collaborative study to determine reproducibility and repeatability, which was carried out in the past months, were presented. Further studies and further work is planned to extend the method to a measurement of the sealing strength for wet pouches.

The 23rd meeting of the PTM Sub-Group is planned for 7 October 2016 prior to the CORESTA Congress in Berlin, Germany.



Bernhard EITZINGER
PTM SG Coordinator



Jing Yi
PTM SG Secretary

US FDA CTP Public Workshop on Biomarkers of Potential Harm

On 4-5 April 2016, the US Food and Drug Administration (FDA) Center for Tobacco Products (CTP) hosted a workshop on biomarkers of potential harm (BoPH) in Silver Spring, MD, USA. The workshop began with an overview of BoPH then proceeded with presentations and panel discussions on biomarkers for cardiovascular disease (CVD), chronic obstructive pulmonary disease (COPD), cancer, and new areas of research. A diverse array of speakers from academia, industry, and the FDA participated in the workshop.

The broad range of biomarker types discussed included traditional markers, gene expression and epigenetic markers, physiological markers, and imaging. Some of the biomarkers were disease-specific while others, such as inflammatory biomarkers, were associated with multiple disease states. A challenging question posed throughout the workshop was: is there a single BoPH that addresses CVD, COPD or cancer, or is a composite of several BoPHs more appropriate?

Several speakers from the FDA Center for Drug Evaluation and Research (CDER) discussed their perspective on biomarkers. Problems encountered in the past with surrogate biomarkers have led to a conservative approach toward using biomarkers. One of the speakers from CDER discussed the CDER process for evaluation of BoPH and the steps involved in qualifying a biomarker.

During the Public Comment section at the beginning of Day Two of the workshop, Dr. Paul Nelson (member of the CORESTA Smoking Behaviour and Biomarkers Sub-Groups) made a brief presentation during which he described CORESTA and the objectives of the Biomarkers Sub-Group. He concluded by encouraging participation of all tobacco science researchers in CORESTA and the Biomarkers Sub-Group.

The workshop agenda, transcripts and archived webcasts can be found on the CTP website:
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm481513.htm>



UPCOMING CORESTA MEETINGS (2016)

Meeting	Date	Location
Sub-Group Smoking Behaviour (TSB)	11 May	Paris, France
Sub-Group Biomarkers (BMK)	11 May	Paris, France
Agrochemical Advisory Committee (ACAC)	5-6 June	Trier, Germany
Task Force Website (WS)	7 June	Trier, Germany
Reading Committee	7 June	Trier, Germany
Scientific Commission	8-9 June	Trier, Germany
Board	21-23 June	Lexington, KY, USA
Sub-Group Agrochemical Analysis (AA)	20-21 July	Chiang Mai, Thailand
Task Force CORESTA Standard (STDS)	21 July	Paris, France
Sub-Group Physical Test Methods (PTM)	7 October	Berlin, Germany
Sub-Group Routine Analytical Chemistry (RAC)	7 October	Berlin, Germany
Sub-Group Smoking Behaviour (TSB)	8 October	Berlin, Germany
Sub-Group Biomarkers (BMK)	8 October	Berlin, Germany
Sub-Group Special Analytes (SPA)	8 October	Berlin, Germany
Task Force CORESTA Standard (STDS)	8 October	Berlin, Germany
Task Force Website (WS)	8 October	Berlin, Germany
Task Force Cigarette Variability (CVAR)	8 October	Berlin, Germany
Sub-Group Agrochemical Residue Field Trials (RFT)	8 October	Berlin, Germany
Sub-Group Pest and Sanitation Management in Stored Tobacco (PSMST)	8 & 10 October	Berlin, Germany
Sub-Group In Vitro Toxicity Testing of Tobacco Smoke (IVT)	9 October	Berlin, Germany
Task Force E-Cigarettes (ECIG)	9 October	Berlin, Germany
Sub-Group Smokeless Tobacco (STS)	9 October	Berlin, Germany
Sub-Group TSNA in Air-Cured and Fire-Cured Tobacco (TSNA)	9 October	Berlin, Germany
Task Force Agro-Phyto Information Collection (APIC)	9 October	Berlin, Germany
Sub-Group Efficacy of Biological and Eco-Friendly CPAs (BIO)	9 October	Berlin, Germany
Sub-Group Collaborative Study Black Shank (BKS)	9 October	Berlin, Germany
Sub-Group Integrated Pest Management (IPM)	9 October	Berlin, Germany
Sub-Group Proficiency Testing for Detection of Transgenic Tobacco (GMO)	9 October	Berlin, Germany
Agrochemical Advisory Committee (ACAC)	9 October	Berlin, Germany
CORESTA CONGRESS	9-13 October	Berlin, Germany

ERRATUM: CORESTA Newsletter – Issue 43

CORESTA Reports: *The Sub-Group Smokeless Tobacco Technical Report on the CORESTA Reference Products 2015 Analysis should read "After the first report of the work done in 2011, **the second report on the 2012 and 2013 studies** published in July 2014, and **the third report published in January 2015**, this **fourth** report presents the results of the **fifth** collaborative study designed to assess the stability of the four smokeless CORESTA Reference Products (CRPs) and to provide an assessment of inter-laboratory variability".*

