

Smoke Science Study Group

The CORESTA Smoke Science Study Group is one of the four Study Groups that undertake the scientific work of CORESTA. It deals with the final stage of tobacco life: where it is smoked by the consumer. This article will offer an overview of the work, both achieved and on-going.

Activities in this Study Group are currently divided into four working groups (Sub-Groups (SGs) or Task Forces (TFs)) studying smoking behaviour, biomarkers of exposure, measurement of special analytes (smoke components) and *in vitro* smoke toxicity. All topics are of great interest globally where science needs to bring facts forward for consideration by the regulators.

The work of these and previous groups has provided CORESTA Recommended Methods (CRMs) and other publications and protocols. All of the current CRMs and many SG or TF Final Reports have been made available to the general public on the CORESTA website (www.coresta.org). A number of these CRMs, which measure smoke constituents in cigarettes, roll-your-own products and environmental tobacco smoke, have been the basis of standards prepared by the International Organization for Standardization (ISO).

Tar, nicotine and carbon monoxide (TNCO) are the basis for cigarette yield regulation in many countries. Robust and standardised methods for measuring these values have been developed and published as ISO standards. Data obtained using these standards have accepted measurement tolerances, evaluated within collaborative studies and statistically validated over a series of such studies. Developing such methods requires time, and needs to involve numerous laboratories. Only then can valid comparisons be made of product yields tested after manufacture with yields obtained by regulatory verification laboratories.

Membership of CORESTA working groups and participation in their collab-

orative studies has contributed to this process internationally and supported laboratories in maintaining accreditation. Some countries (e.g. Canada, Brazil and Taiwan) now require regular testing of other smoke analytes. Unfortunately, to date, measurement tolerances have not been established which can lead to difficulties in comparing data over time within a laboratory or between laboratories. Effective regulation needs methodologies with known and accepted tolerances.

Special Analytes Sub-Group

In 1999 CORESTA established the Special Analytes SG to produce a series of CRMs for smoke components other than TNCO that would be fully validated. Initial priority compounds were benzo[a]pyrene and four tobacco specific nitrosamines (TSNAs). This produced CRMs 58 and 63 respectively. ISO took up the method for benzo[a]pyrene, producing the equivalent standard ISO 22634.

Participation has increased over the years and a current study typically involves 15–25 laboratories, depending on the particular method and the required equipment. CRM 70 for selected volatiles was published in 2010 and one for smoke carbonyls will be completed mid-2011. These “new” analytes have shown much higher inter-laboratory variability than TNCO. This is primarily because the laboratories are now dealing with component yields measured in μg or ng rather than mg . Two joint experiments by this SG, published in the scientific literature, describe smoke data variability across lab-

oratories from a wide range of smoke analytes in one study and on aromatic amines in another.

Currently, the SG is working on an LC-MS/MS method for measuring TSNAs under both ISO and the Health Canada Intense (HCI) regimes, the latter providing higher smoke yields than the former.

Smoking Behaviour Sub-Group

Since 1996 this SG has published reviews on smoker compensation, studies of ventilation hole blocking by smokers, biomarkers, as well as the uptake of nicotine and its metabolism. In 2010, the SG requested ISO/TC126 (the ISO Technical Committee in charge of Tobacco and Tobacco Products), to publish the review prepared by its Working Group 9 titled *„A review of human smoking behaviour data and recommendations for a new ISO Standard for the machine smoking of cigarettes“*. TC126 welcomed the proposal and is preparing a Technical Report which will be published on its website.

The SG has carried out joint experiments and plans to provide a draft recommended method for the estimation of smokers' mouth-level exposure based on the analysis of spent filters from human-smoked cigarettes. This methodology allows the evaluation of how different products are smoked and comparisons of human smoking with smoking machine-derived data.

Biomarkers Sub-Group

This recently formed SG monitors and evaluates the literature on devel-

opments concerning human biomarkers of exposure to smoke constituents. One of the SG's objectives is to carry out ring trials and proficiency tests on suitable biomarkers to evaluate human smoking uptake from different products. Another objective is to source and develop reference materials to support biomarker analysis.

In vitro Toxicity Testing TF

This TF has been running since 2002 to ensure that CORESTA provides leadership on developing toxicity evaluation methods, offering a forum to share accumulated experience and to produce standardised procedures. The group have used OECD guidelines to develop protocols for testing cigarette smoke using the Ames assay for mutagenicity, the micronucleus assay for genotoxicity and the Neutral Red Uptake (NRU) assay for cytotoxicity. The report is available on the website.

Proficiency tests have recently been carried out on the Ames and NRU involving 13 and 10 laboratories respectively; one using the micronucleus assay is currently in progress involving 11 laboratories. Future work is intended to study whole smoke exposure test methods. All these studies require highly skilled people in state of the art laboratories, with CORESTA as the forum to gather robust data to enable scientific debates and support regulatory decisions.

A long history of achievements

While the above SGs and TF are still active and pursuing their objectives, others, established since the early 70's, have completed their objectives, produced a Final Report and then been disbanded.

The Nicotine Uptake Task Force carried out ring trials from 2002 to 2008 on nicotine uptake in smokers by measurement of five urinary metabolites. After five successive ring trials it was acknowledged that no CRM could be produced, due to high inter-laboratory va-

riability in individual metabolites. However a technical report was written providing descriptions of the various methods studied and is available on the website.

Between 1999 and 2002 the Sidestream Smoke Task Force developed methods for collecting and measuring TNCO in sidestream smoke that are now available as CRMs 54 and 55.

Between 1990 and 1999, the Roll-Your-Own TF developed methods for measuring tar and nicotine yields from roll-your-own products. This involved a matrix approach for providing yields using two different weights of tobacco and two papers with different porosities reflecting the characteristics of such products and consumer smoking preferences. Two CRMs (42 and 43) were developed first, to deal with sampling and conditioning, as well as a 5-part report, all available on the website. Various aspects of the methodology were investigated in detail in a series of at least 16 collaborative studies. However, the TF handed over subsequent work to ISO/TC126 and several ISO standards were subsequently published.

Environmental Tobacco Smoke (ETS) became a major public health topic in the late 80's and early 90's and an ETS SG was formed by CORESTA. Three CRMs (50, 51 and 52) were developed in the early 1990s to measure various ETS components and markers. The group members also monitored ventilation standards and produced a guidance document on ETS measurement after carrying out practical studies in restaurants in a number of countries, enabled by the global reach of the CORESTA membership.

In the last decade, public health representatives challenged the ISO smoking regime, saying that it did not replicate the way real consumers smoke so that consumers were being misled about the potential harm of different cigarettes. From the outset, the industry and the regulators involved in the development of the ISO smoking regime had emphasised that its purpose is to allow the comparison between products smoked in the very same conditions, just like fuel consumption for automobiles or

energy efficiency for domestic electrical equipment.

Between 2001 and 2004, a CORESTA TF measured TNCO yields under 3 smoking regimes: the ISO, the "Health Canada" and "Massachusetts" regimes, used by regulators internationally, in Canada and in Massachusetts, USA, respectively, to develop a model for a mathematical relationship between results obtained with the three different sets of smoking parameters. An initial study was set up where all participants measured yields from 12 products. In the second stage, 90 products were studied by around 20 laboratories and correlations between them established. The TF's conclusions are described in a technical report which is available on the website, including raw data from the studies. It is interesting to note that ISO/TC126, through its Working Group 10, recently ran a similar collaborative study, with similar outputs.

Currently, some 90 scientists are involved in the work of the Smoke Science Study Group. They belong to 36 organisations, comprising consumer product manufacturers of all sizes, contract laboratories, government and independent research institutes or bodies, from America to Far East Asia.

In addition, more than 40 smoke science-related papers and posters are presented each year during the annual meetings of CORESTA and, more specifically, each working group reports on the progress of its activities. The members of the Smoke Science Study Group and the Sub-Group coordinators are committed to the success of their groups and encourage a broad participation that is vital to ensure that sound scientific principles are laid down in each study area, that relevant information is being shared and available before regulations comes into effect thus ensuring that regulatory decisions are based on appropriate science.

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Note: 1The modern Liquid chromatography separation coupled with mass spectrometry measurements (LC-MS/MS) provides a quicker and easier analysis than using gas chromatography coupled with thermal energy analysis (GC-TEA) as described in CRM 63.