

**Chemistry Working Group Teleconference ISPAM**  
**5<sup>th</sup> floor Conference Room**  
**May 31, 2011**  
**9:30 am – 10:30am**

**Attendees:**

Russell Flowers President, Silliker  
Bert Pöpping Chair, Eurofins  
Patti Meinhardt R-Biopharm  
Max Feinberg INRA, ISO  
Lars Reimann Eurofins  
Michael McLaughlin FDA  
Stan Bacler CFIA/AOAC BoD  
Joe Boisin CFIA/AOAC RI BoD  
Mark Coleman Elanco  
Richard Cantrill AOCS ISO

Qian Graves FDA  
Harry Mark USDA/FSIS  
Ray Shillito Bayer CropScience/ISO

**AOAC Staff:**

Krystyna Mclver  
Scott Coates  
Deborah McKenzie  
Nora Marshall

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**1. Introductions:**

Chairman Pöpping provided a review from the May 27, 2011 teleconference call and the tasks that had be assigned. An overview summary will be delivered by AOAC CSO, Scott Coates, during the June 29-30<sup>th</sup> meeting in Rockville, Maryland. However, volunteers are still being recruited to review collected documents for comparison.

**2. Review of Documents:**

After review of collected documents, 7 were agreed to be the most relevant to Qualitative Chemistry.

- a) Draft Guideline MoniQA
- b) Draft Guideline ISO TC34/SC16 2011
- c) Draft Guideline AOAC SMPR
- d) Draft Guideline SLV Botanical
- e) Draft Guideline NordVal
- f) Draft Guideline AOAC BTAM
- g) AOAC POD Guidelines

**3. Comparisons**

An abstract of recommendations from these guidelines will be delivered by June 3, 2011.

- a) Paul Wehling will draft an abstract for “ A Protocol for the Validation of Qualitative Methods of Detection” (MoniQA) and “Validation Scheme for Qualitative Analytical Methods” (ISO)
- b) Scott Coates to deliver abstracts on “ Standard Format and Guidance for AOAC Standard Method Performance Requirements” (AOAC SMPR), and “Single Laboratory Validation of the Identification of [botanical or specific botanical material], AOAC Expert Review Panel for the Validation of Identity methods for Botanical Raw Materials” (AOAC SLV Botanical)
- c) Deborah McKenzie is abstract NordVal Guidance document and the “AOAC Biological Threat Agent Methods Validation Guideline” (BTAM)

See Attachment #1 for a detailed description comprising the format for abstract. What AOAC is striving to offer is equivalence of parameters between the guidelines with definitions and their recommendations for easy of comparison between all documents. Coates, with the collaboration of the group, will create a presentation/report by June 15, 2011 to be presented at the ISPAM Working Group on June 30, 2011 in Rockville, Maryland, USA.

#### 4. Define Qualitative Chemistry

Further discuss will be needed to define what “is” Qualitative Chemistry. Is it a type of method that defines it, such as PCR? What is “meant” by Qualitative Chemistry? These are types of questions that will be reviewed and presented in June for the September 2011 meeting. Presentations should be 20 minutes in length with a 10 minute question & answer period.

Volunteers to review documents:

- 4.1) **ISO:** Ray McArthur, Richard Cantrill & Paul Wehling
- 4.2) **MoniQA:** Christoph Von-Holst & Ray McArthur
- 4.3) **AOAC SMPR:** Deborah McKenzie & Scott Coates
- 4.4) **AOAC SLV Botanicals:** Recruit still needed, contact Krystyna McIver [kmciver@aoac.org](mailto:kmciver@aoac.org)
- 4.5) **NordVal:** Recruit still needed, Contact Hilde Skaar-Norli [hilde.skaar-norli@vetinst.no](mailto:hilde.skaar-norli@vetinst.no)
- 4.6) **AOAC BTAM:** Sharon Brunelle, possibly. Deborah McKenzie will confirm
- 4.7) **AOAC POD:** Robert LaBudd

Volunteer Reviewers need to answer key points regarding guidelines;

- 4.8) What is the history of the document/ Why was the document developed?
- 4.9) What is the guideline for?
- 4.10) Is it a “draft” or “approved”?
- 4.11) Regulatory Status; Who recognizes it, who is using it, does it have International status?
- 4.12) Specifics of document recommendations.

An outline will be provided by Chairman Pöpping & Michael McLaughlin.

**5. Philosophical Direction**

Discussion only. Will be visited after abstracts and reviews are completed.

**6. Next Conference Call:**

June 15<sup>th</sup>, 10:30 am Eastern Time

**7. Adjournment**

**ACTION ITEMS:**

1. Upload CODEX DNA document to the Qualitative Chemistry Website.
2. Open Recruitment Volunteer Reviewer;  
McIver – AOAC Botanicals  
McKenzie – BTAM  
Skaar-Norli - NordVal

## ATTACHMENT #1

### Chemistry Method Validation Guideline Review Plan

Coates, Wehling, McIver, and McKenzie met in May 25, to form a plan to review the various chemistry method validation guidelines.

The group decided that only 4 of the 10 documents (listed below) from the “master list” contained guidelines for specifically qualitative chemistry method validation. The other documents contained important information, but not guidance specific to qualitative chemistry. Two additional documents were identified that contain guidance specific to qualitative chemistry: NordVal guidance document; and AOAC Biological Threat Agent Methods (BTAM) validation guideline.

Coates, Wehling, and McKenzie each agreed to abstract information from two of the six documents

#### Wehling

Draft *A PROTOCOL FOR THE VALIDATION OF QUALITATIVE METHODS OF DETECTION*, Roy Macarthur (Fera) & Christoph von Holst (IRMM), (*Joint IUPAC/MoniQA protocol for validation of qualitative methods*), Monitoring and Quality Assurance (MoniQA), 2011.

Draft *Validation Scheme for Qualitative Analytical Methods*, ISO Technical Committee 34, Standing Committee 16, Horizontal methods for molecular biomarker analysis, 2011.

#### Coates

Draft *Standard Format and Guidance for AOAC Standard Method Performance Requirement (SMPR) Documents* (Version 12.1; 31-Jan-11)

Draft *Single Laboratory validation of the identification of [botanical or specific botanical material]*, AOAC Expert Review Panel for the Validation of Identity Methods for Botanical Raw Materials, AOAC INTERNATIONAL, 2011.

#### McKenzie

NordVal guidance document;

AOAC Biological Threat Agent Methods (BTAM) validation guideline.

The group agreed to:

1. Use a standard format for abstracting the information from each of the guidance documents (see attachment 1 below).
2. Report the terms used in each document (i.e. “sensitivity”, or “limit of determination”).
3. Report the recommendations for each parameter.
4. Create a table that with the document as the column, the terms and recommendations in the rows. Equivalent concepts (i.e. “sensitivity”, or “limit of determination”) will appear in the same rows.
5. Complete abstracting the documents and create table by 3 June 2011.

Coates, with help from the group, will create a presentation/report by 15 June 2011 to be presented to the working group during the ISPAM meeting on 30 June 2011.