

**International Stakeholder Panel on Alternative Methods (ISPAM) Qualitative Chemistry  
Session III Working Group**

Friday, September 16, 2011  
10:00am – 3:00 pm  
Sheraton New Orleans, New Orleans, LA

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Attendees:

Bert Pöpping – Chemistry Chair, Eurofins  
Laura Allred- ELISA Technologies  
Louis Bluhm- USDA LQAD  
Christopher Blake -Nestec Ltd  
Gregory Bone- Sensient Colors LLC  
Michael Brodsky- Brodsky Consultants  
Jo Marie Cook - Florida Dept. of Agriculture  
Hilde Skäär-Norli - NMKL  
Lars Reimann - Eurofins Scientific

Tomomichi Suzuki- Tokyo University of Science  
Brian Teeter -Silliker, Inc.  
Wayne Wolf - USDA  
Paul Wehling- General Mills  
Robert Wiebe - Maxxam  
Ren Yiping  
Carmen Diaz-Amigo- Eurofins  
Tung-Jen Fu - USFDA

Staff:

Scott Coates - CSO  
Nora Marshall  
Lakia Phillips

**A. Overview and Comparison of Current Qualitative Chemistry Method Validation Guidance**

Introductions of participants. Review of the documents to be discussed.

**B. Presentation of Draft Guidelines for Validation of Qualitative Chemistry Alternative Methods - (Coates)**

Participants were asked to review the document and recommend any revisions to each line item of the draft. Several line items were edited as follows:

a) **1 Scope**

The purpose of this document is to provide comprehensive guideline for the validation of **BINARY** qualitative methods intended to detect chemical analytes. Qualitative methods are defined as those methods of analysis whose response is either **POSITIVE OR NEGATIVE** of the analyte detected either directly or indirectly in a specified test portion.

b) **Acceptable Minimum Detection Level (AMD)** was discussed and it was entertained to replace with Lowest Level of Acceptance (LLA). This line item was suggested to be removed with agreement to return to this discussion at a later date.

- c) The inclusion of terms such as: Selectivity, cross reactivity and matrix affects were requested by the group.
- d) There was discussion on limiting the guidance to “laboratories” or proceeding with the term “collaborator”. This issue weighed heavily on the implication of the term “collaborator” versus the inclusiveness of “laboratories”. Facilities performing data studies are diverse and the term “collaborator” is more open to pertain to any entity or facility that may perform valuations.

The group concluded to rescind and return to the Guideline after reviewing the Draft AOAC SMPR example for Gluten in Foods.

**C. Development of Standard Method Performance Requirements for Gluten as an Example –(Coates)**

This discussion was a working session to revise the example SMPR into a workable guideline for Qualitative Chemistry. The following reflect the revisions agreed upon.

**Intended Use:**

**1. Applicability:**

Detection of gluten (CAS no.8002-80-0) **as defined by CODEX Standard as described by the AOAC allergen community.**

**Wheat Gluten or all gluten? Europe: Wheat, rye, barley, (and oats in CODEX)**

**Total Gluten** needs to be discussed.

**Go with the CODEX definition of Gluten, and Note Applicability “As described by the AOAC allergen community for gluten content” :**

Detection of gluten as defined by CODEX Standard gluten content as determined by AOAC food allergen working group in spiked & incurred samples (matrix)

**Incurred and spiked (formulated) samples maybe needed in guideline. Data could be different and not meet criteria.**

**Scope of method needs to define the method should be used for. material, incurred / spiked(formulated) (Bert)**

**Or add that the scope pertain to the purpose of gluten detection. (matrix specific)  
Allow the allergen WG to specify the matrix.**

**2. Analytical Technique:**

Enzyme-linked Immunoassay (ELISA) **immunological assay**

**3. Method Performance Requirements:**

	Matrix I		Matrix II	
LLA	≤ 20 ppm		≤ 20 ppm	
POD at AMDL	≥ 95%		≥ 95%	
POD (c)	0 ppm	≤ 1 %	0 ppm	≤ 1 %
	5 ppm	< 20%	5 ppm	?< 20%
	10 ppm	≈ 50%	15 ppm	?≈ 50%
	20 ppm	≥ 95%	20 ppm	?≥ 95%
Laboratory Probability of Detection @ AMDL	≥ 95%		≥ 95%	
Laboratory Probability of Detection @ 0 concentration	≤ 1%		≤ 1%	

**4. System suitability tests and/or analytical quality control:**

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the applicability range.

**9. Maximum Time-To-Result:** 2 hours.

**ACTION ITEMS:**

- 1) First Draft of Guidance to be completed by October 15<sup>th</sup>, 2011 (Coates & Working Group)
- 2) Future conference calls will be scheduled to continue discussions and revisions.
- 3) Working Group will determine the rate of {acceptable percentage of} positives at interim levels that should be considered.
- 4) Draft document to be completed by Dec./Jan. 2012