



AOAC STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN) MEETING

**Sheraton New Orleans Hotel
New Orleans, LA**

Saturday, September 17, 2011

DRAFT PROCEEDINGS

I. WELCOME/INTRODUCTIONS

Darryl Sullivan, Chair of the Stakeholder Panel on Infant Formula and Adult Nutrition, welcomed everyone to the third stakeholder meeting for this project. There has been eight (8) working group meetings to work on nutrients and has moved eleven new Official First Action Methods. The Expert Review Panel (ERP) will also meeting during these meetings. In addition to the stakeholder panels in the US and since this is an international activity/global effort, we have interest in holding a stakeholder panel and working group meetings in India that will occur in first quarter 2012. We have also generated interests to conduct these proceedings in China and South America (Brazil). As we generate these methods, we would like to see these standards as Official Methods of Analysis (OMA) and have them gain Official Methods status in ISO/CEN, GB standards in China, and BIS standards in India and around the world. The voting members in attendance were introduced and recorded for meeting.

II. STATUS OF SECURING BASE MATERIALS FOR FUTURE VALIDATION STUDIES

Dan Schmitz gave an update on base material for validation. There are a lot of products in the market currently; we are looking at protein and fat compositions. We have 12 product types that include 1 SRM, 7 infant formulas and 4 adult nutritionals. Added were the classical powders (including partially hydrolyzed from milk proteins), milk base (including liquid and unfortified; absence of vitamins and minerals), and soy base. The Elemental formula does not have intact protein; it has amino acids. The Pediatric formula has an unfortified vegetable derived source w/D2 D3. The adult nutritional, there is a powder (unfortified), a high protein (unfortified), high & low fat (fortified). There will be twenty (20) materials that make up the SPIFAN suite of products for the validation plan. Covance laboratories will be housing the products and will work with AOAC to develop a proficiency program. The product information will include:

- Availability: the materials will be available by the end of October 2011
- Supplemental material: includes composition and certificates of analysis (manufacturers products)
- Dispensing information: will work on a plan for the distribution of products & proficiency program
- Validation guidelines: develop guidelines on approaching validation and reporting mechanism

III. PRESENTATION AND VOTE ON FINAL SMPR DOCUMENTS FOR SECOND SET OF PRIORITY NUTRIENTS INCLUDING VITAMIN E AND METHOD PRESENTATIONS

3.1 Vitamin E: Presentation given by working group chair (Jon DeVries, General Mills). The participants requested that the language be refined and rework the applicability statement. We want to agree on the principle parameters, finalize the applicability and endorse the majority of the work.

Changes to the applicability statement includes:

- Delete the 3rd sentence
- Delete “focus” from the 1st sentence
- “all racemic-alpha tocopherol”
- Replace “methods capable” with “must report”
- Limit method to separate and accurately quantify
- Change to “must” be able to report the quantity of alpha tocopherol and esters separately

Motion: Sneh Bhandari moved and John Szpylka second to accept the applicability statement at revised; pass.

Approve: 16
Reject: 3
Abstain: 0

Motion: Erik Konings moved and Matt Sliva second to accept that the equivalent must be changed in the SMPR; pass.

Approve: 15
Reject: 3
Abstain: 1

~Due to the changes made in the Vitamin E applicability statement, several methods were unable to move forward.

A. Method Author’s Report(s)

1. **Vit E-12** (Don Gilliland, Abbott Nutrition) - *Simultaneous Determination of 13-CIS and All-Trans Vitamin A Palmitate and Alpha Vitamin E Acetate by HPLC and Column Switching*

Vitamin E-12 discussion included:

- The method does not include tocopherol
- quantify fortified only
- Methylene chloride is an issue
- Universal standards; report in mg (convert)

ACTION ITEM (Vitamin E): Issue a call for methods on the revised applicability statement and SMPR.

3.2 Ultra Trace Minerals (UTM): Presentation given by working group chair (Joe Thompson, Abbott Nutrition).

UTM Discussion included:

- Total element, no speciation
- No official method for all three; chromium/selenium/molybdenum
- Contaminants are outside of the current scope

Motion: Sneh Bhandari moved and Socrates Trujillo second to accept the SMPR; pass.

Approve: 17

Reject: 0

Abstain: 1

A. Method Author's Report(s)

1. **Chrom-06** (Joe Thompson, Abbott Nutrition) - *Simultaneous Determination of Chromium, Selenium, and Molybdenum in Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: SLV*

Chrom-06 Discussion included:

- Pre-requisite of method, should have latest technology
- Everyone is diluting before measurement; standardize across all methods

2. **Chrom-07** (Eric Poitevin, Nestlé) - *Chromium, Selenium, and Molybdenum in Fortified Nutritional Products; High Pressure Ashing by Inductively Coupled Plasma-Mass Spectrometry*

Chrom-07 Discussion included:

- High Pressure Ashing (HPA)
- Isopropyl Alcohol (IPA)
- Needs flexibility in the instrumentation
- Molybdenum RSD is high
- Optimize method for infant formula and adult nutrition
- Chemical forms:
 - Common forms of these products
 - Contain all variable (no other exotic forms)

3. **Chrom-09** (Replacement for Lei Bao) – *Determination Method of Chromium, Selenium, and Molybdenum in Formulas by Inductively Coupled Plasma-Mass Spectrometry*

Chrom-09 Discussion included:

- Precision is wider than expected
- Used external calibration curve
- Isopropyl Alcohol (IPA); no organic solvents
- Nitric acid digestion system
- Need organic modifier

3.3 Nucleotides: Presentation given by working group chair (Brendon Gill, Fonterra).

Nucleotides discussion included:

- Regulations, it has to measure 5'-monophosphates. Contact regulatory agency to determine
- Can there be two (2) methods for “tides” and “sides”? There needs to be a method to capture both.
 - Intact
 - Equivalents

Motion: Matt Sliva moved and Sneha Bhandari second to accept the Nucleotides SMPR; pass.

Approve: 16

Reject: 1

Abstain: 2

A. Method Author's Report(s)

1. ***Nuc-01*** (Brendon Gill, Fonterra) - *Determination of Nucleotides and Nucleosides in Milks and Pediatric Formulas*

Nuc-01 Discussion included:

- External calibration could have been used
- SAX (clean up) 1000g
- AMP has no impact on results
- Caprinae based matrix

2. ***Nuc-02*** (Koichi Inoue, Kinjo Gakuin Univ.) – *Development and Application of an HILIC-MS/MS Method for the Quantitation of Nucleotides in Infant Formula*

Nuc-02 Discussion included:

- No discussion

ACTION ITEM (Nucleotides): Dan Schmitz to draft a letter to the regulatory agencies for the determination of measurement.

IV. THIRD SET OF PRIORITY NUTRIENTS INCL

4.1 Carnitine: Presentation given by working group co-chair (John Austad, Covance Laboratories).

Carnitine discussion included:

- Measurement of total Carnitine
- Must be naturally occurring
- Carnitine is added in two (2) forms
- The reporting convention for Carnitine
 - Carnitine
 - Carnitine HCC
- Fitness for purpose should be across all methods

- 0.9 mg as a limit of range
- Bound L-Carnitine
- 4-20 regulatory
- 0.1 mg could be extended higher/lower

Motion: John Szpylka moved and Dan Schmitz second to accept the Fitness for Purpose; pass.

Approve: 18
 Reject: 0
 Abstain: 0

4.2 Iodine: Presentation given by working group co-chair (Darryl Sullivan, Covance Laboratories).

Iodine discussion included:

- Measurement change to from " mg" to "k/cal"
- K1/1⁸
- Changed to "total" iodine
- Discussed total iodine not molecule
- Use "I" instead of the word "iodine"

Motion: Socrates Trujillo moved and John Szpylka second to accept the Fitness for Purpose; pass.

Approve: 17
 Reject: 0
 Abstain: 0

4.3 Pantothenic Acid: Presentation given by working group co-chair (Shang-Jing Pan, Abbott Nutrition).

Iodine discussion included:

- Fortified level
- "Total" is the regulation
- Working group should look for others

Motion: Erik Konings moved and Sneha Bhandari second to accept the Fitness for Purpose; pass.

Approve: 17
 Reject: 0
 Abstain: 0