



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

MEETING HELD AT

Planet Hollywood

Las Vegas, NV

Saturday, September 29, 2012

MEETING PROCEEDINGS

I. WELCOME/INTRODUCTIONS

Darryl Sullivan, Chair of the Stakeholder Panel on Infant Formula and Adult Nutrition, introduced and welcomed everyone to the sixth stakeholder meeting of the SPIFAN project. Sullivan also provided a presentation that included updates on the project since the last meeting. Since the June 18-22, 2012 meeting, there has been an additional nutrient added (Fatty Acids). The working group met to create and develop the SMPRs which were sent for public comments via the AOAC website. The Expert Review Panels (ERPs) for Whey Protein: Casein Ratio and Nutrients will also meet during the AOAC INTERNATIONAL Annual Meeting and Exposition. The voting members in attendance were introduced and recorded for meeting.

II. PRESENTATIONS AND VOTE ON FINAL SMPR DOCUMENTS AND STUDY DIRECTOR PRESENTATIONS ON PROPOSED METHODS

The Working Group Chairs presented the SMPR documents to the stakeholder panel for final approval. Study Authors provided the panel with a brief presentation on their respective methods the met the approved SMPRS. The Candidate Dispute Resolution terminology was discussed; it is an AOAC term and the hopes are that it will gain additional recognition.

- 2.1 Iodine:** Presentation given by working group chair (Darryl Sullivan, Covance Labs). It's critical to have a sample digestion in order to measure total iodine. The working group has seen some methods without the digestion.

Motion: Dan Schmitz moved and Erik Konings second to accept the SMPR as presented; Pass.

Approve: 18

Reject: 0

Abstain: 2

A. Iodine Method Author's Report(s)

- 1. Iod-01** (Pacquette/ Levenson/Thompson, Abbott Nutrition) - *Determination of Total Iodine in Infant Formula and Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single Laboratory Validation*

Iod-01 discussion(s) include:

- Ion specific method, it has not been compared to it
- No recovery studies done on all forms of iodine
- Potassium iodide would be the source in infant formula

2. **Iod-02** (Sullivan, Covance Labs) - *Determination of Total Iodine in Foods and Dietary Supplements Using Inductively Coupled Plasma–Mass Spectrometry*

Iod-02 Discussion included:

- Total iodine; method does not differentiate different forms
- Ion selective electrode only measures free iodine for total iodide; bound iodide will not be measured
- This method measures all iodide. Study Author believes the method is likely to meet the SMPR. He will serve as author if method gets approved by the ERP

2.2 **Pantothenic Acid:** Presentation given by working group chair (Shang Jing Pan, Abbott Nutrition). There's inconsistency between the analytical range and precision. The consensus of the panel was that the level of bound pantothenic acid is minimal. Currently, there are no methods available for the determination of bound form of pantothenic acid.

- ◇ Change analytical range from 52 – 2300 mcg/100 g to **50 – 2300 mcg/100 g**
- ◇ Change LOQ to **52 mcg/100 g** (tolerance level)
- ◇ For free pantothenic acid and not total; no methods were submitted for total.
- ◇ Microbiological method measures for total pantothenic acid; a deviation from other nutrients.
- ◇ No Codex method identified

Motion: Matt Sliva moved and Dan Schmitz second to accept the SMPR as presented; Pass.

Approve: 17

Reject: 1

Abstain: 2

A. Pantothenic Acid Method Author's Report(s)

1. **Panto-01** (Campos- Giménez, Nestlé) - *Pantothenic acid (Vitamin B5) in fortified foods. A comparison between a novel Ultra Performance Liquid Chromatography Tandem Mass Spectrometry method and microbiological assay (AOAC method 992.07).*

Panto-01 discussion(s) include:

- Need rationale for free pantothenic acid
- Consider how it's presented
- Currently not a total pantothenic acid method
- Provide information for reference

2.3 **Carnitine:** Presentation given by working group chair (John Austad, Covance Labs/Guenther Raffler, Danone). Version 5 of SMPR edited.

- ◇ Change to L-carnitine and its esters
- ◇ "Methods must be able to determine free and total carnitine"
- ◇ Reported as L-carnitine
- ◇ Define what are the forms

Motion: Brendon Gill moved and Sarwar Gilani second to accept the SMPR as presented; Pass.

Approve: 17

Reject: 0

Abstain: 5

A. Carnitine Method Author's Report(s)

1. **Carn-01** (Starkey, Abbott Nutrition) - *Single-Laboratory Validation of a Liquid Chromatographic/Tandem Mass Spectrometric Method for the Determination of Free and Total Carnitine in Infant Formula and Raw Ingredients*

Carn-01 discussion(s) include:

- Per NIST 1849a; measured as "total carnitine"
- Change applicability to match the changes in the SMPR version 5
- Concerns about the adulterations
- No speciation of isomers

- 2.4 **Fatty Acids:** Presentation given by working group chair (Mark Hill, Abbott Nutrition). All fatty acids including saturated, unsaturated mono, poly unsaturated. C-4 to C-24 in scope; includes everything (even if new regulations comes at a later date). Also includes trans fat.

- ◇ Reported as fatty acid methyl esters
- ◇ Change upper level to 2.7 G/ 100 grams
- ◇ Analytical range: ISO suggested to analytical range to upper limit 8 G/ 100 grams. Lower limit of analytical range .001 G/ 100 grams. Discussion on whether to include free fatty acids.
- ◇ Use tier 90-110/80-110 for accuracy.
- ◇ Grams of fatty acids per 100 grams of product

Motion: Sneha Bhandari moved and Adrienne McMahon second to accept the SMPR as presented; Pass.

Approve: 19

Reject: 0

Abstain: 1

A. Fatty Acids Method Author's Report(s)

1. **FA-01** (Golay, Nestlé) - *Milk Products and infant formulae — Determination of Labelled Fatty Acids content - Capillary gas chromatographic method*

FA-01 discussion(s) include:

- Change NIST value from 1846 to 1849a

- 2.5 **Nucleotides:** No presentation. Working group chair (Brendon Gill, Fonterra).

A. Nucleotides Method Author's Report(s)

1. **Nuc-13** (Wang, Thermo) - *Simultaneous Determination of Nutritional Nucleotides and Nucleosides by Ultrahigh Performance Liquid Chromatography with UV Detection*

Nuc-13 discussion(s) include:

- Not for total nucleotides/sides
- Method doesn't detect source

- **ACTION ITEM (Nucleotides):** Send letter to legislators to include sides.

2.6 Vitamin C: Presentation given by working group chair (Lalitha Gowda, CFTRI/Jayashree Arcot, UNSW).

Motion: Dan Schmitz moved and Erik Konings second to accept the SMPR as presented; Pass.

Approve: 18

Reject: 0

Abstain: 2

A. Vitamin C Method Author's Report(s)

1. VitC-02 (Schimpf, Abbott Nutrition) - *Determination of Vitamin C by HPLC with UV Detection*

VitC-02 discussion(s) include:

- Willing to continue work

2. VitC-03 (Campos- Giménez, Nestlé) - *Single Laboratory Validation – Vitamin C by UPLC-UV method for discussion by Working Group SPIFAN*

VitC-03 discussion(s) include:

- NIST 1849a total as Ascorbic acid.
- No problems with method concerning other SPIFAN matrices
- Will continue as study director

2.7 Choline: Presentation given by working group chair (Nick Cellar, Abbott Nutrition/Sneh Bhandari, Silliker, Inc.). The working group changed the original applicability statement from the meeting held in February 2012 (New Delhi, India); choline hydroxide was the original form to be reported, but was changed to choline ion during the comment period. It was voted upon and the applicability statement remained as presented to the stakeholder panel.

Vote/Motion: To be report as the following:

Choline hydroxide: 5

Choline ion: 9

Discussion: Input was received from the stakeholder panel because of the close vote, but remained choline ion.

Motion: Guenther Raffler moved and Kate Rimmer second to accept the SMPR as presented; Pass.

Approve: 17

Reject: 1

Abstain: 3

A. Choline Method Author's Report(s)

1. Chol-03 (Campos- Giménez, Nestlé) - *Single Laboratory Validation – Choline by UPLC-MS/MS method for discussion by Working Group SPIFAN*

Chol-03 discussion(s) include:

- Data was presented in choline hydroxide due to previous SMPR

2. Chol-06 (Jing/Thompson, Abbott Nutrition) - *Method Development for Determination of Total and Free Choline in Nutritional Products by LC-MS/MS*

Chol-06 discussion(s) include:

- Method is for total choline and meets current SMPR. Good candidate. Prove to get good recovery with SPIFAN matrices. Could do total choline and carnitine with one method.

3. Chol-07 (Mohindra, Thermo) - *Determination of Choline in Infant Formula and Adult Nutritionals by Ion Chromatography and Suppressed Conductivity*

Chol-07 discussion(s) include:

- Willing to continue work on method

2.8 Vitamin D: No presentation. Working group chair (Don Gilliland, Abbott Nutrition).

A. Vitamin D Method Author's Report(s)

1. VitD-14 (Abernethy, Fonterra – presented by Brendon Gill) - *A rapid analytical method for cholecalciferol (vitamin D3) in fortified infant formula, milk and milk powder using Diels–Alder derivatisation and liquid chromatography–tandem mass spectrometric detection*

VitD-14 discussion(s) include:

2. VitD-15 (Gössl, DSM – presented by Don Gilliland) - *Quantification of vitamin D3 in feed, food, and pharmaceuticals employing high performance liquid chromatography-tandem mass spectrometry*

VitD-15 discussion(s) include:

- Pre D₃? – Does this method measure pre D?

3. VitD-16 (Black, Abbott Nutrition) - *Simultaneous Determination of Vitamin D3 and D2 by ESI LC-MS/MS*

VitD-16 discussion(s) include:

- Utilize ESI
- VitD-13 was withdrawn and replaced with VitD-16
- Remove status of First Action for VitD-13
- No data for pre D₂

2.9 Whey Protein: Casein Ratio (WPC): No presentation. Working group co-chairs (Shane Rutherford, Massey University/Lei Bao, AQSIQ). IDF/ISO comments; the methods are included based on the existing SMPR. So they are fine and will not exclude them. With the spirit of the SMPR, no changes need to be made.

A. WPC Method Author's Report(s)

1. WPC-18 (Jacobs, Abbott Nutrition) - *Determination of Whey Protein in Milk-Based Infant Formula*

WPC-18 discussion(s) include:

- Willing to continue work on method

2. **WPC-29** (Herman, CEM) - *Analysis of Whey Proteins in Milk and Milk Products by Utilizing Automated Dye-Binding Technology for the Determination of Whey/Casein Proteins Ratio*

WPC-29 discussion(s) include:

- May underestimate
- Willing to do further experiments
- The method's reagents do not bind to free amino acids only peptides
- Use NIST 1849a reference material

3. **WPC-30** (Zhang, Thermo) - *Determination of Whey Protein Percentage by LCMS*

WPC-30 discussion(s) include:

- Look into other whey proteins

III. MOTION TO ADJOURN

Dan Schmitz moved and Joe Thompson second to adjourn; Unanimous