



AOAC INTERNATIONAL

Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN)

Meeting at the Sheraton Dallas Hotel
400 N. Olive Street
Dallas, TX 75201

Tuesday, September 20, 2016 - 8:30am (Central US)

REPORT OF THE NUTRIENTS EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Members (in attendance):

Darryl Sullivan

John Austad
Sean Austin
Sneh Bhandari
Esther Campos-Giménez/Adrienne McMahon
Scott Christiansen
Hans Cuijisen/Martine van Gool
Jon DeVries
Brendon Gill/Harvey Indyk
Don Gilliland/Karen Schimpf
Estela Kneeteman
Bill Mindak
Maria Ofitserova
Kate Rimmer
Shay Phillips
Günther Raffler
David Woollard
Jinchuan Yang

Covance Labs (Chair)

Covance Labs
Nestlé Research Centre
Mérieux NutriSciences & OMB
Wyeth/Nestlé
Perrigo Nutritionals
FrieslandCampina
Independent Consultant
Fonterra Cooperative
Abbott Nutrition
INTI
FDA CFSAN
Pickering Labs, Inc.
NIST
Mead Johnson Nutrition
Eurofins/CLF
Eurofins (formerly Hill Labs)
Waters Corp.

Expert Review Panel Members (unable to attend):

Melissa Phillips

NIST

AOAC Staff Includes:

Delia Boyd
E. James Bradford
Scott Coates
Arlene Fox
Deborah McKenzie
Tien Milor

Observers:

Brad Barrett, *GERSTEL*
Kommer Brunt, *Rotating Disc*
Carolyn Burdette, *NIST*
Hans Cruijssen, *FrieslandCampina*
Jean-Luc Deborde, *SCL-France*
George Joseph, *AsureQuality*
Sarwar Gilani, *Independent Consultant*
Don Gilliland, *Abbott Nutrition*
Greg Hostetler, *Perrigo Nutritionals*
Ruth Ivory, *Megazyme*
Greg Jaudzems, *Nestlé USA, Inc.*
Erik Konings, *Nestlé*
SooKwang Lee, *FDA*
Kai Lin, *Eurofins*
Josh Messerly, *Eurofins*
Lawrence Pacquette, *Abbott Nutrition*
Shay Phillips, *Mead Johnson Nutritionals*
Eric Poitevin, *Nestlé*
Robert Rankin, *INCA*
Lars Reimann, *Eurofins*
Aubrey Shahriari, *FDA*
Monique Steegmans, *Tienen Miher/Beneo Orafti*
Steve Tennyson, *Perrigo Nutritionals*
Joe Thompson, *Abbott Nutrition*
Linda Thompson, *Abbott Nutrition*
Wu Tong, *CNCA*
Marina Torres, *LATU*
Harrie van den Bijgaart, *IDF/ISO*
Wayne Wargo, *Abbott Nutrition*
Guy Weerasekera, *Mead Johnson Nutritionals*
Sudhakar Yadlapalli, *First Source LPN*
Shi Yiyin, *SHCIQ*
Yang Zhou, *Eurofins*
Richard Zywicki, *Covance*

I. WELCOME AND INTRODUCTIONS

Darryl Sullivan welcomed all participants to the ERP meeting and introduced the ERP members.

II. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FIRST ACTION OFFICIAL METHODSM STATUS – AOAC SPIFAN II

For each method, the ERP/Working Group Co-Chairs discussed methods submitted. Nine (9) methods were received and reviewed and one (1) method received First Action *Official MethodSM* status.

Method	Method Title	Reviewer(s)	Vote	Comments
Carotenoids	<i>Carot-02 - Determination of Lutein and β-Carotene in Infant Formula and Adult Nutritionals</i>	Maria Ofitserova Jon DeVries Adrienne McMahon	Jon DeVries (moved) Adrienne McMahon (second) Yes-15/ No-0/Abstain-1 <hr/> Method recommended for First Action <i>Official MethodSM</i> status	<ul style="list-style-type: none"> ▪ The method has no certified value for Carotenoids ▪ Method not analyzing all only lutein and beta carotene <ul style="list-style-type: none"> ○ Alpha carotene is not required ▪ No safety concerns, but add safety section ▪ Method is clear and concise ▪ LOQ is slightly above the SMPR® ▪ Method is well don including chromatograms ▪ Add sample prep for homogeneous versus non-homogeneous ▪ Must clarify if all trans and should separate the other isomers
Fructans (FOS)	<i>Fos-03 - Dual Lab Validation of a Method for the Determination of Fructans in Infant Formula & Adult Nutritionals</i>	Estela Kneeteman Sneh Bhandari Hans Crujisen	Sneh Bhandari (moved) Estela Kneeteman (second) Yes-16/ No-0/Abstain-1 <hr/> Method recommended for First Action <i>Official MethodSM</i> status	<ul style="list-style-type: none"> ▪ Questions were posed concerning the method <ol style="list-style-type: none"> 1. How was the range established? 2. Was the LOQ established after the blanks? -LOD/LOQ were determined by analyzing the blank sample 14 times (7 days in duplicates) ▪ The method is not extremely toxic
GOS	<i>GOS-01 - Determination of β-Galactooligosaccharides in Infant Formula & Adult Nutritionals</i>	Estela Kneeteman Günther Raffler Hans Crujisen	<ul style="list-style-type: none"> ▪ First Round Voting: Estela Kneeteman (moved) Günther Raffler (second) Yes-10/ No-3/Abstain-1 ▪ Second Round Voting: Don Gilliland (moved) John Austad (second) Yes-9/ No-5/Abstain-1 <hr/> Method not recommended for First Action <i>Official MethodSM</i> status	<ul style="list-style-type: none"> ▪ The method is clear and well written ▪ Method does not require any special safety precautions. ▪ The recovery data is perplexing ▪ The method is more complex than the current reference method ▪ The accuracy/recovery numbers do not meet the SMPR® requirements ▪ Fitness for purpose may be different ▪ It is necessary to know the molecular weight of each signal in the chromatogram to convert the molar quantities analyzed to mass quantities.
Vitamin B₃	<i>BVit-04 - A LC-MS/MS method of Analysis of Total Nicotinic acid and Nicotinamide in infant formula and adult nutritional samples</i>	Brendon Gill Esther Campos-Gimenez David Woollard	David Woollard (moved) Jon DeVries (second) Yes-3/ No-10/Abstain-2 <hr/> Method not recommended for First Action <i>Official MethodSM</i> status	<ul style="list-style-type: none"> ▪ Sample preparation does not require reconstitution, but validation data is provided using reconstitution ▪ Include other B vitamins in the chromatograms ▪ Should provide additional data ▪ The isotopic internal standards are added at the end of the sample preparation and therefore doesn't compensate for manipulative variations during enzyme hydrolysis. ▪ Propose two types of sample preparation: <ol style="list-style-type: none"> 1. Samples known to be homogeneous 2. samples not homogeneous

III. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR

For each method, the ERP/Working Group Co-Chairs discussed methods submitted for modification.

Method	Method Title	Reviewer(s)	Vote	Comments
Ultra Trace Minerals (UTM)	AOAC Method 2011.19/ Chrom-06 - Characterization of AOAC Final Action 2011.19 and AOAC First Action 2015.06 Performance at Analyte Levels Corresponding to CODEX STAN 72 -1981 Minimum Levels	SPIFAN Nutrients ERP (Entire)	Jon DeVries (Moved) Jinchuan Yang (Second) Yes-15/ No-0/Abstain-1 <hr/> Adopt modification based on discussions	<ul style="list-style-type: none"> Click to review submitted presentation

IV. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FINAL ACTION OFFICIAL METHODSM STATUS

The Expert Review Panel (ERP) reviewed Three (3) methods for Final Action *Official MethodsSM* status. Two (2) methods were recommended to the Official Methods Board (OMB) for Final Action *Official MethodSM* consideration.

Method	Method Title	Reviewer(s)	Vote	Comments
Choline	OMA# 2012.20 (Chol-07) - Determination of Choline in Infant Formula and Adult Nutritionals by Ion Chromatography with Suppressed Conductivity Detection	Sneh Bhandari Shay Phillips Scott Christiansen	ERP recommended no action taken at this time <hr/> Method not recommended for Final Action status	<ul style="list-style-type: none"> Method should repeat MLT with a clear study protocol Method has deficiency with the matrices (only 6 samples) Reproducibility data has trouble Need additional labs to participate in the MLT
Minerals & Trace Elements	OMA# 2015.06 (MTE-02) - Minerals and Trace Elements in Milk, Milk Products, Infant Formula and Adult/Pediatric Nutritional Formula, ICP-MS Method, First Action 2015	Jinchuan Yang Bill Mindak	Jinchuan Yang (Moved) Bill Mindak (Second) Yes-13/ No-0/Abstain-1 <hr/> Method recommended for Final Action <i>Official MethodSM</i> status	<ul style="list-style-type: none"> The method is well written and clear to follow Safety hazards in method have been addressed Method used nine (9) elements not twelve (12) Copper & iron are near low concentration limit; manganese is at low concentration Method should be combined with OMA# 2011.19
Vitamin B12	OMA# 2014.02 /Old# 2011.08 (VitB12-03) - Vitamin B ₁₂ in Infant Formula and Adult/Pediatric Formulas, AOAC Official Method 2014.02: Multi Laboratory Test (RDLS-RD160047)	Estela Kneeteman Scott Christiansen David Woollard	Jinchuan Yang (Moved) Bill Mindak (Second) Yes-15/ No-0/Abstain-1 <hr/> Method recommended for Final Action <i>Official MethodSM</i> status	<ul style="list-style-type: none"> The MLT procedure is well described, clear and easy to follow The method meets established requirements, and is fit for purpose for the analysis of vitamin B12 (cyanocobalamin) in infant formula and adult/pediatric nutritionals Safety concerns include potassium cyanide which is a safety risk but vitamin B₁₂ is required in the cyanocobalamin form for stability and for successful extraction. The method addresses the risks involved The SMPR[®] is met except the high fat sample

V. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR REPRODUCIBILITY TESTING

The ERP will collectively discuss the methods and select a single method to move forward through the AOAC SPIFAN process for reproducibility testing.

Method Evaluation Forms - Methods processed via the voting/numbering system:

Method	Method Title	Vote	Comments
Carotenoids	<i>Carot-02 - Determination of Lutein and β-Carotene in Infant Formula and Adult Nutritionals</i>	Brendon Gill (Moved) David Woollard (Second) Yes-10/No-1/Abstain-5	
Fructans (FOS)	<i>Fos-03 - Dual Lab Validation of a Method for the Determination of Fructans in Infant Formula & Adult Nutritionals</i>	Send out e-Ballot for voting to move one of the following to reproducibility testing: 1. FOS-03 2. FOS-04	

VI. NEXT STEPS/FEEDBACK FROM EXPERT REVIEW PANEL

Darryl Sullivan provided next steps including suggestions from the Expert Review Panel requesting that some of the SMPRs® be revisited by the respective working group(s).

❖ **To view the ERP Reviewer forms please [click here](#) or <https://cld.bz/emax9yu>**