



# AOAC INTERNATIONAL

## Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN)

### Meeting at the Gaithersburg Marriott Washingtonian Center

9751 Washingtonian Boulevard, Gaithersburg MD 20878, USA

Thursday, March 14, 2019

#### REPORT OF THE NUTRIENTS EXPERT REVIEW PANEL (ERP) PROCEEDINGS

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##### Expert Review Panel Members (in attendance):

###### **Darryl Sullivan**

Esther Campos-Giménez/Sean Austin

Scott Christiansen

Hans Cruijssen/Martin van Gool

Brendon Gill

Don Gilliland/Karen Schimpf

Estela Kneeteman

Melissa Phillips/Kate Rimmer

Shay Phillips

Jinchuan Yang

###### **Eurofins Food Integrity & Innovation (Chair)**

Nestlé

Perrigo Nutritionals

FrieslandCampina

Fonterra Cooperative

Abbott Nutrition

INTI

NIST

Reckitt Benckiser (formerly Mead Johnson)

Waters Corp.

##### Expert Review Panel Members (unable to attend):

John Austad

Sneh Bhandari

Jon DeVries

Harvey Indyk

Adrienne McMahon

Maria Ofitserova

Günther Raffler

Jie Zhang

David Woollard

Eurofins Food Integrity & Innovation

Mérieux NutriSciences

DeVries & Associates

Fonterra Cooperative

Wyeth/ Nestlé

Pickering Labs, Inc.

Eurofins/CLF

Reckitt Benckiser (formerly Mead Johnson)

Independent Consultant

##### AOAC Staff Includes:

David Schmidt (*Executive Director*)

Palmer Orlandi (*Deputy Executive Director & CSO*)

Delia Boyd

Shane Flynn

Jonathan Goodwin (*Deputy Executive Director*)

Nora Marshall

Deborah McKenzie

Alicia Meiklejohn

Tien Milor

La’Kia Phillips

Bob Rathbone

**Observers:**

Charles Barber, NIST  
Marcel de Vreeze, NEN - ISO  
Mathieu Dubois, Nestlé  
Ping Feng, Wyeth Nutrition  
Carlos Galera, Hygiene Diagnostica España  
Tetsuhisa Goto, CSC JP  
Philip Haselberger, Abbott Nutrition  
Steve Holroyd, Fonterra Cooperative  
Greg Jaudzems, Nestlé  
Joe Konschnik, Restek Corporation  
Sookwang Lee, US Food and Drug Administration  
Kai Liu, Eurofins Nutrition Analysis Center  
Sean McClure, Abbott Nutrition  
Josh Messerly, Eurofins  
Robert Rankin, INCA  
Jana Rousova, Restek  
Andre Santos, Agilent Technologies, Inc.  
Véronique Spichtig, Nestlé  
Cynthia Srigley, US Food and Drug Administration  
Dustin Starkey, Abbott Nutrition  
Joseph Thompson, Abbott Nutrition  
Marina Torres, LATU  
Jeroen van Soest, Eurofins  
Kelsey West, Abbott Nutrition  
Laura Wood, NIST  
Kenny Xie, US Pharmacopeia  
Yuichi Yotsuyanagi, Shimadzu

**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 METHOD*<sup>SM</sup> STATUS – AOAC SPIFAN II**

For each method, the ERP/Working Group Co-Chairs discussed method(s) submitted and reviewed the method(s) received First Action *Official Method*<sup>SM</sup> status.

Method	Method Title	Reviewer(s)	Recommendations
Fluoride	<i>Fluor-03 - Determination of Fluoride in Infant and Adult/Pediatric Nutritional Formula by Ion Chromatography with sequentially suppressed conductivity detection</i>	Nutrients ERP	<ul style="list-style-type: none"> <li>▪ Potential interference peak</li> <li>▪ Investigate the LOQ in infant formula matrix</li> <li>▪ Proprietary equipment (how will we get MLT data)?</li> <li>▪ Investigate an optional step to eliminate the online dialysis step</li> <li>▪ Is there a requirement for peak height vs. peak area; please investigate and explain.</li> <li>▪ The integration, how the baseline is drawn</li> <li>▪ Please consider using the SPIFAN matrices in your further development</li> </ul>

**III. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FINAL ACTION *OFFICIAL METHOD*<sup>SM</sup> STATUS – AOAC SPIFAN II**

For each method, the ERP/Working Group Chairs discussed method(s) submitted and reviewed the method(s) received Final Action *Official Method*<sup>SM</sup> status.

Method	Method Title	Reviewer(s)	Vote	Comments
<b>CAROTENOIDS</b>	<i>OMA# 2016.13 (Carot-02) - Multi-laboratory Testing Report of AOAC Method 2016.13: Determination of Lutein, β-Carotene, and Lycopene in Infant Formula and Adult Nutritionals</i>	Maria Ofitserova Jon DeVries Adrienne McMahon	<p><b>Motion:</b> To recommend method for Final Action (Beta carotene &amp; Lycopene only)</p> <p>Brendon Gill moved Karen Schimpf second</p> <p>Yes-8/ No-0/Abstain-1</p> <p>ERP recommends the method move to Final Action <i>Official Method</i><sup>SM</sup> status</p>	<ul style="list-style-type: none"> <li>▪ Lutein did not meet the SMPR</li> <li>▪ Only one sample was submitted for Lycopene</li> </ul>

<b>FOS</b>	<b>OMA# 2016.14 (FOS-03) -</b> <i>Determination of Fructans in Infant Formula and Adult Nutritionals by Anion-Exchange-Chromatography with Pulsed Amperometric Detection after Enzymatic Treatment (AOAC 2016.14): Collaborative Study</i>	Jon DeVries Karen Schimpf	<b>Motion:</b> To recommend method as Final Action with the acceptance to ISO guidelines  Karen Schimpf moved Martine van Gool second  Yes-8/ No-0/Abstain-1  ERP recommends the method move to Final Action <i>Official Method<sup>SM</sup></i> status	<ul style="list-style-type: none"> <li>▪ Method needs additional integration instruction</li> <li>▪ Emphasize the quality check</li> </ul>
<b>CARNITINE</b>	<b>2015.10 (Chol-08/Carn-07) -</b> <i>Determination of Free and Total Choline and Free and Total Carnitine in Infant Formula and Adult/Pediatric Nutritional Formula by Liquid Chromatography/Tandem Mass Spectrometry (LCMSMS)</i>	Sneh Bhandari Scott Christiansen Shay Phillips	<b>Motion: Data Review</b> To approve additional carnitine data for further evaluation  Brendon Gill moved Esther Campos-Gimenez second  Yes-10/ No-0/Abstain-0  ERP recommends the method move to Final Action <i>Official Method<sup>SM</sup></i> status	<ul style="list-style-type: none"> <li>▪ No alkaline hydrolysis step in method</li> </ul>

#### IV. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR EXTENSION – AOAC SPIFAN II

For each method, the ERP discussed method(s) submitted and reviewed for extension.

Method	Method Title	Reviewer(s)	Recommendations
<b>2015.06 Method Extension</b>	<i>AOAC Method 2015.06 “Minerals and Trace Elements in Milk, Milk Products, Infant Formula, and Adult/Pediatric Nutritional Formula”</i>	Nutrients ERP	<ul style="list-style-type: none"> <li>▪ SRM &amp; SPIFAN matrices as part of the method extension.</li> <li>▪ If any significant modification to the method occurs, it would need to be reviewed by the ERP.</li> <li>▪ See if the official method works as published on the additional matrices.</li> <li>▪ Should include a description of the matrices to be included in the study.</li> <li>▪ What is the end point to the extension? How can we help reach the endpoint?               <ul style="list-style-type: none"> <li>○ Does the India section anticipate submission of the method for review by the ERP?</li> </ul> </li> <li>▪ Define the matrices</li> <li>▪ Run an SLV</li> <li>▪ Publish the method</li> </ul>

### III. **AN OFFICIAL METHODS<sup>SM</sup> UPDATE**

Darryl Sullivan and Deborah McKenzie (AOAC) discussed with the ERP, the path forward in removing older versions of the AOAC SPIFAN methods currently in OMA. To revise the *Official Methods of Analysis<sup>SM</sup>* (OMA) Chapter 50 to replace older methods with current AOAC SPIFAN Final Action methods. Learn where and how the methods are being used with feedback to the ERP. Also, the method(s) must demonstrate value, or the ERP will recommend repealing the methods with rationale and verification on their current status to the Official Methods Board (OMB).

Recommendations included the process take several phases with phase 1 begin with the following:

- Identify and review problematic methods
- Ensure OMA contain state of the art methods
- Review QC methods that work, but were not selected

#### **PROPOSAL:**

Reengage the working group chairs to review the methods and bring information back to the ERP for final recommendation.