



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

Wednesday, March 14, 2018 - 3:00pm (Eastern US)

REPORT OF THE MCPD EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Members (in attendance):

Katerina Mastovska

Mathieu Dubois/Greg Jaudzems
Stefan Ehling
Jan Kuhlmann
Shaun MacMahon/Jessica Leigh
Joe Romano
Cheryl Stephenson
Sudhakar Yadlapalli

Covance Labs (Chair)

Nestlé
Abbott Nutrition
SGS Germany
US FDA
Waters Corp.
Eurofins
First Source Laboratory Solutions, LLP

Expert Review Panel Members (unable to attend):

Celine Lesueur
Jie Zhang

Danone
Mead Johnson

AOAC Staff Includes:

Delia Boyd
Scott Coates (*CSO*)
Chris Dent
Jennifer Diatz
Arlene Fox
Dawn Frazier
Jonathan Goodwin (*Interim Executive Director*)

Nora Marshall
Krystyna McIver
Deborah McKenzie
Alicia Meiklejohn
Tien Milor
Bob Rathbone

Observers:

Lei Bao, Nestlé
Sneh Bhandari, Silliker Laboratories
Joe Boison, Consultant
Sara Bryson, Conagra Brands
Dominik Burger, DSM Nutritional Products
Scott Christiansen, Perrigo
Hans Cruijssen, FrieslandCampina
Jean-Luc Deborde, SCL
Aurelie Dubois, IDF
Jaap Evers, IDF
Brendon Gill, Fonterra
Erik Konings, Nestlé
Mary Krogull, Eurofins Scientific, Inc.
Joanne Mayer, ADM
Sean McClure, Abbott Nutrition

Maria Ofitserova, Pickering Laboratories
Melissa Phillips, NIST
Shay Phillips, Mead Johnson
Aubrey Shahriari, FDA
David Singer, GERSTEL
Dustin Starkey, Abbott Nutrition
Darryl Sullivan, Covance
Robert Rankin, INCA
Kate Rimmer, NIST
Martine van Gool, FrieslandCampina
Lindell Ward, Lilly
Wayne Wargo, Abbott Nutrition
Jinchuan Yang, Waters Corp.
Jupiter Yeung, Nestlé

I. WELCOME AND INTRODUCTIONS

Katerina Mastovska 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*SM STATUS

For each method, the ERP discussed methods submitted. Two (2) methods were received and reviewed. Recommendations by the ERP to be completed prior to methods receiving First Action *Official Method*SM status.

Method	Method Title	Reviewer(s)	Vote	Recommendations/Comments
MCPD	<i>MCPD-01 - Single Lab Validation - Determination of 2- and 3-MCPD, 2- and 3-MCPD esters and glycidyl esters (GE) in infant and adult/pediatric nutritional formula.</i>	Stefan Ehling Shaun MacMahon	<p>Motion: to recommend for First Action <i>Official Method</i>SM status.</p> <p>Sudhakar Yadlapalli (moved) Shaun MacMahon (second)</p> <p>Yes 4/No 4/Abstain 1</p> <hr/> <p>Motion: to accept the First Action recommendations as presented.</p> <p>Stephan Ehling (moved) Sudhakar Yadlapalli (second)</p> <p>Yes 7/No 0/Abstain 1</p> <p>Motion Passed <i>(see recommendations)</i></p>	<p>RECOMMENDATIONS:</p> <ol style="list-style-type: none"> Applicable or not applicable matrices (Shaun M. will send matrices to method author) SPE confirmatory step for low level GE findings near the level of concern Additional spike levels or incurred samples at higher level Liquid concentrate to discuss applicability of the method <p>COMMENTS:</p> <ul style="list-style-type: none"> There are issues with the fat extraction Safety not defined Recommend sample size Reagent (blank) not included in the raw data There is question about the GE Issue with shelf life of samples Better define the exception(s) Include internal standard at the beginning Use of triple quadrupole GC-MS/MS with backflushing (include minimum requirements for method performance)
	<i>MCPD-02 – 2-Monochloropropanediol (2-MCPD), 3-Monochloropropanediol (3-MCPD) and Glycidol in in Infant and Adult/Pediatric Nutritional Formula Gas Chromatographic / Mass spectrometric (GC/MS) Method</i>	Jessica Leigh Cheryl Stephenson	<p>Motion: not to recommend for First Action <i>Official Method</i>SM status.</p> <p>Shaun MacMahon (moved) Cheryl Stephenson (second)</p> <p>Yes 6/No 0/Abstain 2</p> <hr/> <p>Motion: to accept the First Action recommendations as presented.</p> <p>Stephan Ehling (moved) Sudhakar Yadlapalli (second)</p> <p>Yes 6/No 0/Abstain 2</p> <p>Motion Passed <i>(see recommendations)</i></p>	<p>RECOMMENDATIONS:</p> <ol style="list-style-type: none"> Address system suitability (min. 1 control sample per batch) Verify the purity of the labelled standard with every run/batch Verify the response factors over the analytical range to demonstrate linearity on every system Written in AOAC format <ol style="list-style-type: none"> Check for missing steps and information details Add safety section <p>COMMENTS:</p> <ul style="list-style-type: none"> Requires a separate method for powder and liquid samples LOQ/accuracy meets the SMPR® Single quad GC-MS used Complete extraction procedures for liquid Include daily analysis of blank and reference samples (option) Option for a multi-point calibration

III. NEXT STEPS/FEEDBACK FROM EXPERT REVIEW PANEL

Katerina Mastovska provided next steps in the ERP process including the recommendations by the ERP.