STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

DRAFT PROCEEDINGS

Meeting at the

Sheraton Denver Downtown Hotel
1550 Court Place
Denver, CO, USA

Saturday, September 7, 2019

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STAKEHOLDER PANEL MEETING PROCEEDINGS

SPIFAN CHAIR

Darryl Sullivan, Eurofins Food Integrity & Innovation

Stakeholder Attendees:

Karim Amoura, Thermo Fisher Scientific
Sean Austin, Nestle Research
Jacob Babu, MilkTestNZ
Lei Bao, Nestle
Julie Blackwell, Eurofins Food Integrity & Innovation
Joe Boison, Independent Consultant
Keren Breiterman, Eurofins Scientific
Esther Campos Gimenez, Nestlé Research
Joana Cavalheiro, Danone Nutricia Research
France Cho, Bureau Veritas Laboratories
Scott Christiansen, Perrigo nutrition
Neal Craft, Eurofins Scientific
Hans Cruijsen, Frieslandcampina
David Dain, DSM Nutritional Products
Marcel de Vreeze, NEN - ISO
Jonathan Draher, Abbott Nutrition
Aurelie Dubois, IDF
David Ellingson, Eurofins Food Integrity and Innovation
Renee Erney, Abbott Nutrition
Ping Feng, Wyeth Nutrition
Lauren Fleury, AsureQuality Ltd
Ming Gao, Mérieux NutriSciences
Geniene Stewart, Synlait Milk
Brendon Gill, Fonterra
Don Gilliland, Abbott Nutrition
Rajesh Girdhar, Abbott Nutrition
Eric Gordon, Mérieux NutriSciences
Tetsu GOTO, CDC JP
Michael Gray, RB
Philip Haselberger, Abbott Nutrition
Yoshiko Hirao, Shimadzu Corporation
Greg Jaudzems, Nestle
George Joseph, AsureQuality
Scott Kneedler, eurofins
Estela Kneeteman, INTI
Erik Konings, Nestle
Joe Konschnik, Restek Corporation
Eve Kroukamp, PerkinElmer
Eberhardt Kuhn, Shimadzu
Chang Liu, RB-Mead Johnson
Fang Liu, Alta Scientific
Kai Liu, Eurofins Nutrition Analysis Center
Alex Liu, SCIEX
Karen Mandy, Danone
Sean Mcclure, Abbott Nutrition
Mardi Mountford, INCA
Pranav Nagarnaik, CSIR-NEERI
Eystein Oveland, Institute of Marine Research
Julia, Parkot, Jennewein Biotechnologie GmbH
Melissa Meany Phillips, NIST
Jodie Preston, Synlait Milk
Robert Rankin, INCA
RJ Raterink, Triskelion
Lars Reimann, Eurofins
Joe Romano, Waters Corporation
Ben Roth, Abbott
Karen Schimpf, Abbott Nutrition
Tom Seipelt, Abbott Nutrition

Jeffrey Shippar, Eurofins
Victoria Siegel, Eurofins CAL
Dustin Starkey, Abbott Nutrition
Cheryl Stephenson, Eurofins
Hiroko Suzuki, Japan food research laboratory
John Szpylka, Mérieux NutriSciences
Jing Tan, Abbott Nutrition R&D Singapore
Yijin Tang, Applied Food Science
Joseph Thompson, Abbott Nutrition
Melissa Thompson, Eurofins Food Integrity & Innovation
Marina Torres, LATU
Larry Tucker, Metrohm
Martine Van Gool, FrieslandCampina
Jeroen VANSOEST, EUROFINS
Thomas Vennard, RB/Mead Johnson Nutrition
Yannis Vrasidas, Eurofins
David Woollard, Hill Laboratories
Kenny Xie, USP
Sudhakar Yadlapalli, FIRST SOURCE LABORATORY SOLUTIONS LLP
Jinchuan Yang, Waters Corporation
Linda Zhao, Abbott

AOAC Staff in Attendance

David Schmidt *(Executive Director)*
Palmer Orlandi *(Deputy Executive Director/CSO)*
Delia Boyd
Jonathan Goodwin *(Deputy Executive Director)*
Deborah McKenzie
Alicia Meiklejohn
Tien Milor
La'Kia Phillips

I. WELCOME/INTRODUCTIONS

Darryl Sullivan (Eurofins), chair of the AOAC SPIFAN stakeholder panel welcomed participants to the twentieth stakeholder meeting of AOAC Stakeholder Panel on Infant Formula and Adult Nutrition (SPIFAN) and led the introductions of attendees. The AOAC policy and procedures were also discussed.

II. UPDATE ON AOAC PROCESS

Deborah McKenzie (AOAC) provided an update on the new features in standards development and the OMA process. Information included products and services for a complete and harmonized quality system. AOAC has enhanced our training and educational outreach, publications and incorporated horizon-scanning as a process for future endeavors.

Additional information included the standards overview with the working group meeting to draft the standard, post the draft standard for an enhanced public comment period (minimum of 30 days), reconcile comments and recommend final draft to stakeholders. AOAC has added an online public comment web-conference session for another layer of transparency. Examples of AOAC consensus products were also provided which included:

- Performance Requirements
- Guidelines
- Sampling Standards
- Methods of Analysis
- Best Practices
- Operational Documents

Basic AOAC standards development activity framework was also discussed. New activities were presented detailing the community consensus and approval of standards with the working group chair(s) presenting final versions of the draft standard along with reconciled comments for deliberation and consensus. The launch of working group efforts is refined with a preset scope of work into a basic applicability statement from which to begin drafting the standard (SMPR) and posting the draft standard for public comments (minimum of 30 days).

McKenzie briefly discussed the Analytical Solutions Forum (ASF) program which is used to start new programs and individual working groups.

AOAC has created a new Senior Advisor volunteer position. The role was developed for the more challenging working group activities. The new position is for experienced volunteer subject matter experts to advise and assist staff and working group chairs to meet the objectives of the scope of work and serve in an advisory capacity. This position reports to the AOAC CSO.

AOAC also added a method author orientation that is open to all potential method authors and others including working group chair(s) reviewing SMPRs. AOAC will provide tutorial(s) on developing an ideal submission package. The method submission process must include methods and manuscripts in AOAC format, which can include raw data files along with paper to reduce time for publication of the method, as well as provide uniform approach for review of methods by the Expert Review Panel (ERP). The ERP will be able to easily identify changes in First Action methods for Final Action or modification reviews. Methods submitted for Final Action will need to have the manuscripts published first and ERP members will be involved in the peer review of the manuscript prior to Final Action recommendation.

III. GLOBAL ENGAGEMENT ACTIVITIES

a. AOAC CHINA SECTION

Cheng-zhu Liang (AOAC China Section) presented information on the progress of the GB evaluation program for food safety along with background information including 256 existing GB methods for 120+ participating organizations in the following sectors; governments, academics, and industries.

There is currently a proposal for new performance evaluation system to include SMPRs that will compare GB with international methods via the GB evaluation program led by CSIQ/AOAC China section which proactively facilitated the collaboration between GB Authorities and AOAC/ISO/IDF. The proposal will be to start with standards/methods for milk & dairy including Infant Formula (60 GBs), with the use the 'Comparison Template' and execute pilot to validate the template using the example of vitamin D and Aerobic Plate count.

The 2019 AOAC China Section meeting was held May 2019 in Shanghai with 500 international & China standards organizations well as government and industry. Sessions and round table discussions included GB standards follow up Evaluation Program with comparison between GB and international standards. Discussions also included high level dialogue between China and international standards community with potential cooperation on the Proficiency Testing (PT) progress of AOAC SPIFAN/SPSFAM/Food authenticity with China involvement. A workshop pilot concluded with information on Gaps in GB acknowledged and will be confirmed by data and comparative study and proposal for revision will be submitted to CFSA via CSIQ's GB evaluation program. CFSA will appoint GB drafter for revision. Proposal for next steps will continue with GB/international method comparison for methods with highest expected difference and initiate research cooperation projects based on needs GB evaluation with International Standards. The list for new GB's to compare with international methods includes phosphorus, iodine, nucleotides, fatty acids, vitamin A, vitamin E, vitamin C, and coliform count. The topics were proposed by GB evaluation working groups based on expected difference between GB and international methods.

Liang invited stakeholders to participate in the 2020 AOAC China Analytical Science & Standards Conference to be held April 14-16, 2020 in Xia Men, China.

b. AOAC INDIA SECTION

Kaushik Banerjee (Past President, AOAC India Section) updated the stakeholders on the Single Lab Validation for AOAC Official Method 2015.06 Minerals and Trace Elements in 'Indian' Infant Formula, Adult & Pediatric Nutritional.

In India, infant formula and adult nutrition falls under the mandatory product certification of Bureau of Indian Standards (BIS). India has selected the analytical method for elements AOAC 2015.06 because it is fast, robust, and has 12 elements in one test. The method has been well studied via multi-laboratory testing (MLT) and comparison to ICP-AES on large identical sample sets. It also meets Codex minimum levels, and is adaptable: e.g., at CCMAS. In May, the method was extended in scope to include Cu in edible caseins to replace current Codex method at the recommendation of ISO/IDF. Single laboratory validation (SLV) is needed for infant formula and adult nutrition products in India because it contains malt and cereals, apart from milk and soy, and were not a part of the original study. The aim is to extend the original AOAC 2015.06 method for Indian matrices and verify whether it is fit for purpose. A journey of the SLV protocol included the Indian matrices and analytical data produced.

Next steps include AOAC 2015.06 to be certified for analysis of multi-elements in infant formula and adult nutrition products which are based on indigenous ingredients, e.g. cereals and malt (September 2019). The manuscript of the SLV work will be submitted to J. AOAC Int. for consideration as well as the study presented to FSSAI Method Review Committee for adoption in November 2019.

c. ***CODEX UPDATES***

Status of SPIFAN Methods in Codex Process

Robert Rankin (INCA) provided an update on the status of methods in the SPIFAN process. The primary goal of AOAC SPIFAN is to have the most updated dispute resolution methods (Type II) in the Codex Alimentarius. The SPIFAN Codex Strategy Group develops supporting materials and conducts outreach to key delegations on joint AOAC/ISO/IDF methods submitted to Codex which included the Codex process.

Recent progress from the Codex Committee on Methods of Analysis and Sampling (CCMAS-40) in May 2019 held in Budapest includes three methods endorsed as Type II (AOAC 2015.06 / ISO 21424 | IDF 243 (Ca, Mg, P, K, Na, Cu, Fe, Mn, Zn)), Vitamin K (AOAC 2015.09/ISO 21446), and Folic Acid/Folate (AOAC 2011.06). CCMAS also endorsed an additional method for Minerals and Trace Elements as Type III, pending CCNFSDU concurrence (AOAC 2011.14 / ISO 15151 | IDF 229 (Ca, Mg, P, K, Na, Cu, Fe, Mn, Zn)).

CCMAS re-typed several Type II methods as Type III:

- ISO 8070 | IDF 119 (Ca, Mg, K)
- AOAC 986.24 (P)
- AOAC 985.35 (Cu, Mn, Zn)
- AOAC 992.05 / EN 14131 (Folic acid)

CCMAS recommended several Type III and IV methods for revocation:

- AOAC 984.27 (Ca, Mg, P, K, Na, Cu, Fe, Mn, Zn)
- J AOAC Int. 2000:83; 1141-1148 (Folic acid)
- J Chromatogr. A., 928, 77-90, 2001 (Folic acid)

Next steps for CCNFSDU-41 to be held November 24-29, 2019 in Duesseldorf, CCNFSDU will Review CCMAS' recommendation to endorse AOAC 2011.14 / ISO 15151 as Type III, consider establishing numerical method performance criteria for Ca, Mg, P, K, Na, Cu, Fe, Mn, Zn, and identify appropriate methods that meet the criteria; and consider whether AOAC 2015.09 / ISO 21446 should replace the methods for determining Vitamin K in follow up formula in CXS 234 (i.e., AOAC 999.15 / EN 14148).

The strategy group will explore possible additional methods to introduce:

- B Vitamins (B_1, B_2, B_3, B_6)
- Choline/Carnitine
- Carotenoids (Beta Carotene and Lycopene)
- Consider positions on the following:
- Supporting endorsement of AOAC 2011.14/ISO 15151 as Type III
- Discuss establishing numerical method performance criteria for Ca, Mg, P, K, Na, Cu, Fe, Mn, Zn
- Discussing whether AOAC 2015.09/ISO 21446 should replace AOAC 999.15/EN 14148 for determining Vitamin K in Follow Up Formula
- Others?

d. **AOAC/ISO/IDF Cooperative Update**

The cooperative update was presented by Marcel de Vreeze (NEN & ISO) with collaboration from Erik Konings (Nestlé/ISO) and Aurelie Dubois (IDF). The update included the current status of methods within ISO/TC 34/WG 14 (Vitamins, carotenoids, and other nutrients) and ISO/TC 34/SC 5|IDF (Milk & Milk products).

The timeline for meetings of WG 14 was July 4-5, 2019 in IMR, Bergen, Norway together with CEN/TC 275/WG 9 – Vitamins and carotenoids.

- ISO/CD 21468 (choline/carnitine):
  - Current protocol is not clear for correction for moisture content and purity standards (needs to be improved)
  - Final expression forms choline/carnitine (free or not), it needs clarification
  - Also need harmonization; powder vs. ready to feed forms. Concentrations were expressed in different types; mg/l, mg/ml, results in mg/kg or mg/100g. Will be updated in next version

- ISO/CD 21470 (vitamins B):
  - Need clarification on the description of moisture content/drying of standards, need to be harmonized. Also, there is not enough information on the stoichiometric factor, it should be clarified and given for each form.

  - ISO/CD 23443 (carotenoids) - Lutein is included in the ISO version (excluded in AOAC version) but was deleted from the body and is included in the informative annex (precision data inadequate).

- WG 14 prefers to broaden scope of current ISO 20636 (LC-MS/MS) on vitamin D rather than adopting EN 12821 (LC-UV). EU 2019/828, modifying EU regulation 2016/127 regarding lowering maximum vitamin D content in infant formula. Concerns on fitness for purpose analytical standards EN 12821 and ISO 20636 to demonstrate compliance. The CEN WG will take on the issue.

- Other methods include FOS (ISO/CD 22579 | IDF 241) the project leader will prepare the DIS before end of September (insert MLT data, align with AOAC version, Vienna Agreement (VA) between ISO and CEN). Whey protein (ISO/DIS 23293 | IDF 247) DIS is approved and the project leader answered comments; proceed to publication (skip FDIS). Amino acids include IDF and ISO WG. Method protocol available, dairy and cereals? For fluoride, GOS and lactose we are ready to start on once analytical protocol to be followed. Lactose already included in the IDF program, needs to ensure expertise in the ERP. Once there is a First Action method, ISO will include as a new work item.

- ISO/IDF standard currently developed on milk and milk products for the determination of sugar contents. An MLT has already been done and data has been analyzed and protocol included. It is currently up for draft international standard. It utilizes HPAEC-PAD technique, DIS stage quantitative LC method for galactose, glucose, fructose, sucrose, lactose, and maltose in various milk and milk products including infant formula. The collaborative study finalized and approved by IDF S01. With the Vienna Agreement it will also become a CEN standard.

The 2020 timeline for ISO/IDF WG 14 meetings will be held September 21-22, 2020 at the 6th International Vitamin Conference in Copenhagen, Denmark. The IDF/SC 5 Analytical Week will be held April 6-9, 2020 in Beijing, China.

IV. AOAC SPIFAN RELATED TOPICS CHLORATES/PERCHLORATES

a. Chlorates/Perchlorates

Dustin Starkey (Abbott) presented the challenges of chlorate/perchlorate compliance verification in infant formula, review and call to action with collaboration from Erik Konings (Nestlé) and Tom Seipelt (Abbott). Regulations specify 10 ppb limit for chlorate in infant formula and perchlorate is under discussion with a vote due in 1st quarter 2020 which may lower the limit from 20 to 10 ppb. Several analytical challenges include no standard method for foods, reference materials, lack of lab-to-lab variability, and proficiency study program. Need general feedback from SPIFAN community on how to proceed with input on the study design, from AOAC guidance on the ways of working and NIST for best practices reference materials and partners (IDF and dairy manufacturers). Background information was also presented.

Recommendations included work in 4th quarter 2019 and 1st quarter 2020 with Phase 1 to conduct collaborative proficiency study to evaluate lab-to-lab variability. IDF/dairy manufacturers to provide blinded ingredient samples and participate in testing (include enriched protein fractions). Infant formula manufacturers to provide finished product samples (SPIFAN II matrices), participate in testing and AOAC & INCA will coordinate sample distribution, data collection and third-party labs to participate in testing. Will launch ASAP to completed by the 2020 AOAC Mid-Year meeting and include in the scope of work for SPIFAN III Term 3.

Phase II will launch the working group in 2nd quarter 2020 and apply lessons learned from Phase I for consideration on standardized method for chlorate/perchlorate in infant formula. Investigate feedback from end users on performance of existing or proposed methods under the project scope. Also review if proficiency study shows agreement between labs. It may be unnecessary to pursue standard method, if results disagree, then consider end-user feedback and pursue standardization. Determine if decision is required from stakeholders at the 2020 AOAC Mid-Year meeting and include in scope of work for SPIFAN III Term 4.

A round-robin study will be conducted to learn about the current state of performance of methods, the information can be found in the back of the meeting book.

b. Update on MCPD

Erik Konings (Nestlé) provided an update on the proposal on sample composition for Multi Laboratory Testing (MLT). The presentation was given on behalf of the method authors. Two methods were given AOAC First Action *Official Methods*^{SM} status in 2018. The method authors plan to execute MLT for AOAC 2018.03 and AOAC 2018.12 in 4th quarter 2019. The study protocol is completed and submitted for review and comments by ERP, Vice-Chair OMB, and SPIFAN Chair on July 12th.

The MLT samples in the protocol consisted of SPIFAN II samples (7 powders, 1 RTF, NIST 1869). The ERP recommended including an infant formula as practice sample in addition to the oil. Study Directors recommended 3 additional Infant formula powders with higher levels of glycidol esters (GE) than current SPIFAN II and NIST samples.

Additional samples with higher GE levels are needed due to only 2 out of 8 SPIFAN II MLT materials have GE levels significantly high LOQ; which is not ideal when evaluating precision for an analytical

range of a method. AOAC MLT protocol recommends a minimum of 5 materials to cover concentration range.

Currently, it does not correspond to objective to establish AOAC Official Method for MCPD/GE in samples available on the market. The risk is that the MLT will give too high variability for low levels around/below LOQ and not meet SMPR. Potentially ERP will not designate final action for methods. AOAC 2018.03 originally validated for low levels but the ERP advised to validate for full analytical range (spiked or incurred) as indicated in SMPR. The MLT participants don't know origin of materials.

Recommendation is to include 3 blinded infant formula powders purchased by FDA on the US market in June 2019.

- Levels for GE > LOQ: factor 3-4 higher than EU reg. limit (50 μg/kg).
- Levels for 3-MCPD factor 4 higher than EU draft reg. limit (125 μg/kg).
- Levels for GE and 3-MCPD within analytical range SMPR. (1000 μg/kg for 3-MCPD, and 400 μg/kg for GE)
- Levels within range of published levels by FDA in 2017 (Leigh et al.) and reviewed in 2019 (MacMahon et al.)

Why should the FDA materials be included now?

- Difficulty finding incurred samples with a certain level of MCPD/GE.
- Further search will delay MLT, which would lead to no AOAC Final Action Official Method status to support regulatory compliance testing.
- Procuring samples from other parts of the world (e.g. Russia) will take time and potential issues with customs.

Recommendation: for SPIFAN to approve the sample set including 3 additional samples for the MLT on MCPD/GE.

c. **Vitamin D**

Don Gilliland (Abbott) presented the challenges for vitamin D compliance testing to EU regulation 2019/828 with collaboration from Brendon Gill (Fonterra).

Commission Delegated Regulation (EU) 2019/828:

(4) In its Scientific Opinion of 28 June 2018 on the update of the tolerable upper intake level for vitamin D for infants[3], the Authority concluded that the use of infant formula containing vitamin D at 3 μg/100 kcal may lead some infants aged up to 4 months to consume amounts of vitamin D above the tolerable upper intake level from the formula alone.

(5) That opinion also concluded that the use of a maximum vitamin D content of 2,5 μg/100 kcal in infant formula does not result in intakes of vitamin D above the tolerable upper intake level from the formula alone. On the basis of that opinion, the maximum vitamin D content permitted under Delegated Regulation (EU) 2016/127 for infant formula should be lowered to 2,5 μg/100 kcal, in accordance with Article 6 and paragraphs (1) to (4) of Article 9 of Regulation (EU) No 609/2013.

At the 95% Confidence Level (Standard deviation is 1/4th of regulatory range)

The performance of method precision required to meet the proposed specifications limits at the 95% confidence level is RSDR% = 5.6%.

Given the extremely tight precision required at very low concentrations, it is unlikely that any analytical method available today could reliably produce such precise results.

Response - Specialized Nutrition Europe (SNE)

- Reference to AOAC SMPR 2011.004, the Standard Method Performance Requirements for Vitamin D in Infant Formula.
- Predicted estimated non-compliance with published RSD_R.
- Probability of non-compliance will increase further when other variabilities (i.e. process variability & loss over shelf-life) are taken into consideration.
- Management of nutrient levels and of vitamin D in IF were addressed in detail during the revision of the Codex Standard for IF (CODEX STAN 72-1981). A review of actual nutrient levels was conducted by IF manufacturers✧ and resulted in the setting of a maximum for vitamin D at 3.0 μg/100 kcal.
- Vitamin D range of at least 1.0 μg/100 kcal between the minimum and maximum value rather than 0.5 μg/100kcal, will reduce the probability of non-compliance.

Responses

- CEN – Recommendation drafted for and supported by CEN TC275 to express concerns about fitness for purpose of current EN/ISO standards. In the letter to EC it can be recommended to undertake new CEN work to address the issue.
- SNE – Response issued expressing concerns about EU vitamin D range based on AOAC SMPR 2011.004 including recommendation for minimum vitamin D range
- Position Paper – in Draft – Citing SMPR and Current State of Methods (Final Action Method MLT Performance)
- Vitamin D Working Group – Take Up SMPR, Revise, Call for New Methods, etc

V. UPDATE ON THE NIST STANDARD REFERENCE MATERIALS (SRM)

Melissa Phillips (NIST) updated the stakeholder panel on the status of the NIST SRM. The current SRM (1849a) based on current sales, is projected to be out of stock by the end of 2019. The contract for the new material (SRM 1849b) has been awarded and will have the same composition of SRM 1849a but will contain additional nutrients compared to SRM 1849a (Carotenoids, Vitamin D_2 and D_3, GOS and Retinyl acetate and palmitate). The projected production in November 2019 and release date is spring 2022.

New reference materials (SPIFAN Matrices) have been produced by 2 manufacturers; hydrolyzed milk based infant formula and high protein adult nutritional powder. Certificates will be provided with each reference material will represent testing data provided by the manufacturer. The materials will be stored at NIST and distributed to Study Directors at no cost via requests through SPIFAN, to AOAC for use in SPIFAN proficiency testing and to NIST customers at reduced cost compared to SRMs (≈$400).

VI. UPDATE ON PROFICIENCY TESTING

a. Arlene Fox (AOAC) provided an update on the AOAC Proficiency Testing (PT) program. The prime objective of the AOAC Proficiency Testing program is to evaluate and improve analytical performance by providing an independent measure of the quality of the data.

Currently, the PT program consists of both water-soluble and oil-soluble vitamins programs. Other competing programs may require enrollment in one or two additional and separate programs. Participants have the ability to submit results for AOAC SPIFAN methods as well as other methods. The program meets the requirements for accreditation and supports method validation. Current challenges in the program includes participation, obtaining future supply of homogeneous stable samples, and to ensure that nutrients meet laboratory needs.

Some of the recognized problems in implementing the program included confusing instructions, units that were not consistent, need for providing corrected reports, adequate oversight and review of reports before issuance, and complaints discussed with laboratory staff. Program corrections included having the final report reviewed by a SPIFAN PT Task Force member prior to distribution, clearer instructions and consistent units.

The SPIFAN PT program cannot dictate what methods to use. Currently, participants are not using SPIFAN methods. There is a need for a mechanism to encourage/increase use of SPIFAN methods as well as participation in the PT program and encourage participants to expand scope of accreditation to include SPIFAN methods and support method validation.

b. Melissa Phillips (NIST) and Don Gilliland (Abbott) presented joint information on the SPIFAN PT Taskforce. The original directive and objective of the taskforce is to develop the proficiency testing program for infant formula and adult nutritional products while using SPIFAN product matrices. Also, to identify the proficiency test program components including frequency of testing, products type and number of analytes, general methods and also SPIFAN specific.

AOAC has successfully launched the SPIFAN PT program and updated the nutrient listing with SPIFAN Final Action methods. Method authors can submit results for two methods (SPIFAN or another method of choice).

With the on-going effort to strengthen the PT program, there was a request to reconvene the taskforce at a later date and stakeholders should contact the co-chairs for training to participate in the PT program.

VII. NEW WORKING GROUP LAUNCHES

a. **Human Milk Oligosaccharides (HMO)**

Yannis Vrasidas (Eurofins) presented background information including an historical overview, facts and health benefits and regulatory aspects of HMO. Current methods for HMO synthesis was discussed including advantages and challenges as well as analysis, techniques, and analytical tools.

The fitness-for-purpose statement:
"An analytical method to determine the level of a number of selected HMOs in infant formula and adult nutritionals, as defined by AOAC SPIFAN. The method should be applicable for dispute resolution.

Open point for discussion for Stakeholder Panel (and WG):
Do we want to have a method applicable for the determination of HMO in the raw material (ingredients)?
If yes: within the same WG & same SMPR or separate WG, separate SMPR?

b. **Lactoferrin**

Martine van Gool (FrieslandCampina) and Jeffrey Shippar (Eurofins) presented technical and regulatory information including background and history of lactoferrin. The chemical structure, biological function, application, methods overview and challenges were also discussed.

The fitness-for-purpose statement:

- An analytical method to determine the level of (total/bioactive/…) lactoferrin in infant formula (which…), in concentration ranges from … to …
- Time to signal should be …

Next steps include formation of the working groups for both HMO and lactoferrin.

VIII. AOAC SPIFAN ERP/WORKING GROUP METHODS REVIEW PROJECT

Deborah McKenzie (AOAC) provided an update on the review of First Action and updating infant formula methods currently in OMA by re-engaging the working groups and collaboration between ERP, WGs, OMB and with input from SPIFAN. The pilot program began with the first set of priority nutrients back in 2010, with the following nutrients: vitamin A, vitamin D, vitamin B_{12}, folic acid, inositol, and vitamin E.

The proposed process outline is to develop a rubric, have Official Method Board (OMB) approve the rubric, and working group complete the rubric for each method. The working group chair will share the rubric information with final input and endorsement of completed information by the SPIFAN community. The ERP uses the rubric to develop recommendation on methods and propose any policy changes to the OMB.

IX. UPDATE ON EXPERT REVIEW PANEL (ERP) STATUS

Darryl Sullivan (Eurofins) provided an update on the methods submitted for review, the status of methods in MLT, the AOAC SPIFAN methods still in First Action since the 2019 AOAC Mid-Year Meeting in Gaithersburg, MD. The ERP had a kick off meeting on July 10, 2019 reviewing the first 6 nutrients. Questions to consider for the rubric include re-opening the working and issue call for working group members. The goal is for the working groups to recommend the fate of current methods. In addition, utilize the OMB in oversight and participation in the process.

An ERP member survey was sent to inquire of their willingness to continue participation. The SPIFAN Nutrients ERP was originally formed in 2011 and has had very little volunteer turnover. The level of active participation by all members has varied slightly, but the majority was willing to continue with only on resignation.

Currently, there are 3 nutrients that have not received First Action *Official Methods*^{SM} status: alpha-carotene, GOS, and fluoride (methods submitted for review) and Final Action methods include FOS (awaiting final manuscript submission with ERP's recommendations), lutein and amino acids.

During the upcoming meeting, the ERP will review the following methods for Final Action Recommendations included candidate methods for First Action consideration:

- Amino-04 AsureQuality
- Fluor-03 Metrohm
- Fluor-04 Abbott Nutrition

- Reminder about the ERP-WG OMA Review Project
  - Review of SPIFAN First Action Methods not down selected for MLT
- Update on MLTs-no MLTs were submitted for review, but current methods awaiting MLT for SPIFAN Nutrient Methods include:
  - AOAC 2016.03 – or other method for Lutein
  - AOAC 2016.14 – FOS
  - AOAC 2018.06 – Amino Acids
- Methods awaiting MLT for SPIFAN MCPD Methods
  - AOAC 2018.03
  - AOAC 2018.12

X. UPDATE ON VITAMIN E

Hans Cruijsen (FrieslandCampina) provided an update on regulation changes for vitamin E, which are based on label legislation and changing the definition of vitamin E. Background and other information were provided with an update to Annex XIII of Reg 1169/2011 states Vitamin E (mg a-TE) for nutrition declaration on the label based on the vitamin E activity of RRR-α-tocopherol. Possible action points include:

1. Raising the issue during SPIFAN meeting(s)
2. Making position paper (need volunteers)
3. Forward position paper to SNE and other standard setting organizations?
4. Incorporation of calculation in OMA 2012.10

XI. TIMELINES/DEADLINES/WRAP-UP (Sullivan)

Darryl Sullivan (Eurofins) provided next steps including a timeline of AOAC SPIFAN activities including upcoming deadlines, review of any action items, and additional questions.

To access the stakeholder panel meeting book, click here!