STAKEHOLDER PROGRAM ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

DRAFT PROCEEDINGS

Meeting at the

Gaithersburg Marriott Washingtonian Center
9751 Washingtonian Boulevard
Gaithersburg MD 20878, USA

Thursday, March 12, 2020

AOAC INTERNATIONAL
2275 Research Blvd., Suite 300
Rockville, MD, 20850
UNITED STATES
dboyd@aoac.org
301.924.7077 x126

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MEETING HELD AT

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STAKEHOLDER PROGRAM MEETING PROCEEDINGS

SPIFAN CHAIR

Darryl Sullivan, Eurofins Food Integrity & Innovation

Stakeholder Attendees:

Julie Blackwell, Eurofins
Joe Boison, EJ Consultancy
Keren Breiterman, Eurofins
David Bunk, NIST
Esther Campos Gimenez, Nestlé Research
Neal Craft, Eurofins
Hans Cruijsen, Frieslandcampina
Devin Darrell, CEM Corporation
Marcel de Vreeze, NEN-ISO
Berit Dockter, INCA
Aurelie Dubois, IDF
Ping Feng, Wyeth Nutrition
Christophe Fuerer, Société des Produits Nestlé SA
Carlos Galera, Hygiena Diagnostica España
Tetsu Goto, CSC JP
Ashley Green, NIST
Joe Hale, Agropur Inc.
Greg Jaudzems, Nestle
Chris Johnson, Hilmar Ingredients
George Joseph, AsureQuality
Estela Kneeteman, INTI
Erik Konings, Nestle
Mary Kay Krogull, Eurofins Scientific Inc.
Markus Lacorn, R-Biopharm AG
William Lipps, Shimadzu
Amanda Manolis, Thermo Fisher Scientific
Elaine Marley, R-Biopharm Rhone Ltd
John McLeod, Synlait Milk Ltd
Naren Meruva, Waters Corp
Sussman Michael, USDA, ISO
Bill Mindak, Mindak Professional Services
Maria Ofitserova, Pickering Laboratories
Shay Phillips, RB
Melissa Phillips, NIST
Cezary Poplawski, R-Biopharm Rhone
Yanqi Qu, MilliporeSigma
Brian Schuld,, Eurofins Nutritional Analysis Center
Tom Seipelt, Abbott Nutrition
Victoria Siegel, Eurofins CAL
Angela Smith Henry, Agilent Technologies Inc.
Dustin Starkey, Abbott Nutrition
Katherine Stenerson, MilliporeSigma
Geniene Stewart, Synlait
Gordon Sutton, Synlait Milk Ltd
John Szpylka, Consultant
Marina Torres, LATU
Larry Tucker, Metrohm US
Martine van Gool, FrieslandCampina
Jeroen van soest, Eurofins
Thomas Vennard, RB/MJN
Yannis Vrasidas, Eurofins
David Woollard, Hill Laboratories
Jinchuan Yang, Waters Corporation

AOAC Staff in Attendance

David Schmidt *(Executive Director)*
Palmer Orlandi *(Deputy Executive Director/CSO)*
Delia Boyd
Deborah McKenzie
Alicia Meiklejohn
Tien Milor

I. WELCOME/INTRODUCTIONS

Darryl Sullivan (Eurofins), chair of the AOAC SPIFAN stakeholder panel welcomed participants to the twenty-first stakeholder meeting of AOAC Stakeholder Program 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) presented an update on the approval process for AOAC Standards & Consensus documents for draft SMPRs including the standards development and the OMA processes. Information included products and services for a complete and harmonized quality system through analytical excellence. McKenzie briefly discussed the Analytical Solutions Forum (ASF) that met on March 10th. The ASF is used to initiate new programs and individual working groups.

AOAC makes a concerted effort to ensure we provide opportunities for participation, which includes a balance of perspectives & due process through targeted communication, invitations, email blasts & website notifications, online & written public comment formats briefings & public hearings, and various other modes of communication.

McKenzie also provided details on activities on the AOAC SPIFAN standards development activity since September 2019 through present. The information included the launch of new standards work for Human Milk Oligosaccharides (HMO) and Lactoferrin. Currently, the stakeholders will review the final versions of the documents and the working group chairs will present summaries of the working group draft standards for input and deliberation.

AOAC carefully documents the actions of AOAC SPIFAN and the working groups, prepare and communicate summaries of the meetings to the stakeholders, publish status and summaries in the "Referee" section of AOAC's Inside Laboratory Management (ILM), and publish documents in the Journal of AOAC INTERNATIONAL and *Official Methods of Analysis*℠ of AOAC INTERNATIONAL.

III. GLOBAL ENGAGEMENT ACTIVITIES

a. AOAC INDIA SECTION

Palmer Orlandi (AOAC) and Darryl Sullivan (Eurofins) updated the stakeholders on the AOAC India section meeting held February 28-29, 2020 in New Delhi, India. In India, infant formula and adult nutrition falls under the mandatory product certification of Bureau of Indian Standards (BIS).

Joe Thompson (Abbott Nutrition) provided additional information on the method extension. The goal from the 2019 AOAC annual meeting was to extend the existing AOAC 2015.06 method for Indian matrices and verify whether it is fit for purpose to test because it is fast, robust, and has twelve (12) elements using single lab validation by the AOAC India Section. The method had previously been studied via multi-laboratory testing (MLT) and the scope extended. The 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 SLV concluded that the method performed as expected using the AOAC SPIFAN materials, the SRM, and performing the typical linearity and LOQ exercises. The intermediate precision in the Indian matrices were very good and met SMPR requirements, and the accuracy (recovery) met the criteria for all of the elements in all of the products. For malt-based drinks studied, a special preparation of a direct weight of powder was needed. Method updates recommended to clarify what "high-purity"

nitric acid means and to add a new sample preparation.

The next steps included providing the study presentation to the FSSAI Methods Review Group for adoption as well as the manuscript being submitted to *J. AOAC Int.* for consideration in May 2020. In addition, to have AOAC 2015.06 be certified for analysis of multi-elements in infant formula and adult nutritional products, which is based on Indian indigenous ingredients including cereals and malt and provide information for the 2020 AOAC Annual meeting in September.

b. ***CODEX UPDATES***

Status of AOAC SPIFAN Methods in Codex Process

On behalf of Robert Rankin (INCA), Darryl Sullivan provided an update on the status of methods in the AOAC 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 includes the Codex process.

Recent progress includes the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreement to submit the following new methods to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for review, endorsement as Type II, and inclusion in CXS 234-1999:

- AOAC 2015.14 / ISO DIS 21470 (Vitamins B1, B2, B3, B6)
- AOAC 2015.10 / ISO DIS 21468 (Choline and Carnitine)
- AOAC 2016.13 / ISO DIS 23443 (Beta Carotene and Lycopene)
- AOAC 2016 17 / ISO DIS 22579 | IDF 241 (Fructans)

In addition, requested CCMAS to re-type existing Type II methods for the above nutrients and agreed to submit ISO DIS 23305 (Biotin) to CCMAS for review, endorsement as Type II, and include in CXS 234-1999. AOAC 2016.02 is currently Type II with ISO DIS 23305 would be added to the listing in CXS 234-1999.

CCNFSDU also agreed with CCMAS' recommendation to endorse AOAC 2011.14 / ISO 15151 as Type III, that AOAC 2015.09 / ISO 21446 should become the new Type II methods for determining Vitamin K in Follow-Up Formula in CXS 234-1999 (replacing AOAC 999.15 / EN 14148) and requested that CCMAS develop numerical method performance criteria for Type III methods for Ca, Mg, P, K, Na, Cu, Fe, Mn, Zn. There is currently a Type II method for Minerals Codex procedure that does not allow for a Type II method and criteria for Type III methods for the same nutrient.

The Codex strategy group coordinated activities to:

- Develop a Conference Room Document (CRD) to be submitted by AOAC/ISO/IDF that will provide rationale and technical justification to support CCMAS' endorsement of AOAC SPIFAN methods
- Engage with CCMAS experts including Greg Noonan and obtain feedback to help drive SPIFAN strategy
- Coordinate with AOAOC SPIFAN stakeholders on plans to share the CRD with CCMAS member country delegations
- AOAC/ISO/IDF CRD was submitted in early March 2020

c. ***AOAC/ISO/IDF COOPERATIVE UPDATE***

The cooperative update was presented by Marcel de Vreeze (NEN & ISO) with collaboration from Aurelie Dubois (IDF) and Erik Konings (Nestlé/ISO). 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).

Nutrient	ISO Stage	Comments	Expected pub. final version
Vitamin C	ISO 20635:2018	CEN standard?	Published
Vitamin D	ISO 20636:2018	CEN standard?	Published
Vitamin K	ISO 21446:2019		Published
Biotin	ISO/PRF 23305	Print proof checked by PL, -> **publication**	March/April 2020
Vitamins B	ISO/DIS 21470	DIS ballot ends 2020-03-18, PL answering comments, WG 14 approval, -> **publication**	June/July 2020
Choline/carnitine	ISO/DIS 21468	DIS approved, PL answered comments, Approval ISO WG 14 meeting on the 11th, -> **publication**	May 2020
Carotenoids	ISO/DIS 23443	DIS approved, PL answered comments, Approval ISO WG 14 meeting on the 11th, -> **publication**	May 2020
Folates	ISO/NP 4906	ISO NP ballot ends: 2020-04-07	24 months time frame

The working group met on March 11th in Gaithersburg, MD. The working group agenda included discussion of the following:

- ISO/DIS 21468 (choline/carnitine)
- ISO/DIS 21470 (vitamins B)
- ISO/DIS 23443 (carotenoids)

Discussions were based on the response from the European Commission (EU 2019/828) on the modification of EU regulation 2016/127 regarding lowering maximum vitamin D content in infant formula. The statements acknowledged that the maximum limit results in a narrow vitamin D range allowing for less variation in the vitamin D content that may necessitate the development of new methods of analysis to test the compliance with the requirements. Concerns on fitness for purpose on analytical standards EN 12821 and ISO 20636 to demonstrate compliance was also discussed.

Codex collaboration included:

- CCMAS review of dairy methods with
  - Submission of joint AOAC/IDF/ISO comments on dairy methods under review to the eWG
  - Submission of new methods issued from SPIFAN applicable to other dairy products (Iron, Copper, Calcium) to the eWG and to CCMAS

The 2020/2021 timeline for ISO/IDF & WG 14 meetings will include:

IDF/SC 5 Analytical Week:

- April 7-9, 2020 in Brussels, Belgium
- September 25–27, 2020 in Cape Town, South Africa
- April 2 –25, 2021, Konstanz, Germany

WG 14 meetings:

- September 21-22, 2020 in Copenhagen, Denmark (Vitamin Conference - together with CEN WG on vitamins)

d. ***REGULATORY REQUIREMENTS***

With collaboration from other stakeholders, Erik Konings (Nestlé) discussed challenges related to the regulatory requirements for infant formula nutrients and analytical method capabilities with current state-of-the-art analytical reference methods and using good manufacturing practices. Currently there are challenges with manufacturing products in multiple countries with diverging regulations along with regulatory limits.

In the overall process, the variability in finished product are comprised of three main sources; manufacturing process, materials/ingredients, and analytical method performance on the assessment of products where compliance is not often considered with new/changed regulations. We must estimate if current regulatory requirements for infant formula (min, max, tol) can be enforced with AOAC SPIFAN methods for infant formula (IF), food for special medical purpose (FSMP) and follow-up formula (FuF for 6-36 months and 1-3 years). The nutrients include vitamins A, D, E, K_1, B_1, B_2, B_6, B_{12}, C, biotin, pantothenic acid, folic acid, inositol, Fe, Cu, Zn, Se, Cr, Mo, Mn, and I. The countries are Brazil, China, Europe, India, Indonesia, Malaysia, Mexico, Pakistan, Philippines, Russia/Belarus/Kazakhstan, Singapore, South Africa, Thailand, and United States. Currently, the average for product group is not accurate for specific products.

There are four (4) steps to evaluate the method variability on assessment of product compliance:

1. Determine product specifications based on national regulations
   - Largest possible specification limits defined by using midpoint of regulatory requirements as true value in product and taking the highest possible declared value by setting USL = Max regulatory limits using $\text{Specification range } (\%) = \frac{(USL-LSL)}{(USL+LSL)}$
2. Review analytical method variability of SPIFAN methods
   - Mean RSD_R values calculated from MLT for matrices within ±25% of midpoint regulatory requirements. Degrees of freedom for each matrix taken into account to calculate SD_R.
   - All RSD_R<RSD_R(SMPR®), except for vitamin B_{12}, mean RSD_R is 15.2% whereas SMPR® value is 10%.
3. Define Method Capability (C_m)
4. Evaluation of C_m and ability of method to demonstrate compliance with regulations

The results are vitamins A, B_{12}, D, and folic acid in product categories IF, FuF older infants, FuF young children and FSMP have the highest number of country/region regulations with Cm<1.73 with several country/region regulations for these nutrients show a Cm<1, which can be considered critical, including China, some EU member states, Pakistan, Russia, Singapore, South Africa, and Thailand. Vitamins B_1 and B_6 have Cm<1 for FSMP and Russian regulation. The probability of finding a test result out of the

specification range due to analytical variability only was the highest for vitamin D and European legislation for IF is 19%.

The recommendation is some AOAC SPIFAN methods are not fit to demonstrate compliance with narrow nutritional regulatory limits of several countries (Cm<1). The probability of finding a test result outside the regulatory requirements due to analytical variability alone can be as high as 19%. The methods for vitamins A, B_{12}, D, Folic acid for country/regional regulations in China, some EU member states, Pakistan, Russia, Singapore, South Africa, and Thailand are of concern as well as with vitamins B_1 and B_6 in FSMP for Russian regulation.

IV. AOAC SPIFAN RELATED TOPICS

a. Chlorates/Perchlorates

Melissa Phillips (NIST) with collaboration from Erik Konings (Nestlé), Dustin Starkey and Tom Seipelt (Abbott) presented an update since the September 2019 meeting pertaining to the challenges of chlorate/perchlorate compliance verification in infant formula.

Measurement of chlorate and perchlorate may challenge infant formula industry within next few years with the European Commission requirements for low levels in infant formula. Analytical challenges include a lack of test methods and data. Currently there are no reference materials and no way of preparing laboratories or testing programs. AOAC SPIFAN can help industry stay ahead of the challenge by building capacity for chlorate/perchlorate determination in infant formulas in two (2) phases:

- Phase I includes a proficiency study to evaluate sample matrices and lab-to-lab variability
- Phase II is to develop an SMPR and standard method for chlorate/perchlorate in infant formula (pending Phase I outcomes)

The proposed plan was to send out samples including existing SPIFAN II materials, two (2) reference materials (available at the time) and two (2) SPIFAN III materials. The evaluation will consist of selected samples and ingredients to span the observed concentration ranges with additional samples (2) of whey protein concentrate ingredients at about 50 ppb chlorate. An interlaboratory study (ILS) is in process with sign-ups beginning December 2019, distribution of samples in February 2020, results due March 2020, and preliminary data evaluation in April 2020.

The next steps include evaluating the results from the interlaboratory study, review the overall agreement with regards to the number of methods and relative performance, and conduct a follow-up study (if necessary) with more laboratories. In addition, initiate chlorate/perchlorate working group through AOAC to identify best methods for infant formula pending outcome of ILS.

b. Vitamin D

The Vitamin D discussion was tabled.

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) is completely out of stock as of January 2020. The new material (SRM 1849b) is now being characterized 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). Laboratories interested in

characterization via interlaboratory comparison should join HAMQAP (https://qa.nist.gov/hamqap). The projected release date is spring 2022.

As previously mentioned, 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 present 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 to purchase at a reduced cost compared to SRMs (≈$400). The projected release date is Fall 2020.

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.

AOAC has added the infant formula and adult nutritionals program to the scope of accreditation with specific labs continuing to participate if included. Both water and oil soluble nutrients including Fatty Acids, Iodine, Myo-inositol, Nucleotides, and Ultra-trace Minerals are included. To overcome past issues, AOAC agrees to provide a corrective final report reviewed by an AOAC SPIFAN Task Force member prior to distribution and provide adequate oversight, and review of reports before issuance. International representation in 2019/2020 include Singapore, Kenya, New Zealand, France, Netherlands, Ireland, United Kingdom, Australia, and United States. AOAC will be working with distributors which will help broaden our distribution to these and other locations.

The AOAC SPIFAN PT program cannot dictate what methods to use. Currently, participants are not using AOAC SPIFAN methods. AOAC encourages participants to expand scope of accreditation to include AOAC SPIFAN methods and support method validation. We are also encouraging the use of AOAC SPIFAN methods by allowing accredited laboratories to submit two sets of results, a current method and AOAC SPIFAN method as well as labs being able to expand scope of accreditation.

Looking towards the future, AOAC is planning to add new members to the task force and currently working on a plan to implement training on AOAC SPIFAN methods and continued oversight of the PT program. Also looking forward to using SPIFAN III matrices and to get analysis, stability, and homogeneity data.

WORKING GROUP DISCUSSIONS:

VII. WORKING GROUP CHAIRS PRESENTATIONS AND VOTE ON FINAL SMPR DOCUMENTS

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

Working group chair, Yannis Vrasidas (Eurofins) in collaboration with the AOAC Science Advisors (Sean Austin, Nestle & Philip Haselberger, Abbott Nutrition) updated stakeholders on working group developments.

Vrasidas provided background information including the complex mixture of oligosaccharides, limited number of HMOs available in large scale, the availability of certified reference materials as well as the available methods.

The fitness-for-purpose statement was also reviewed from September 7, 2019:
"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 working group & same SMPR or separate working group and separate SMPR? In addition, decided not to include ingredients and work on finished products only.

The working group activities and SMPR development consisted of the following:

- Working group initiated on September 7, 2019
- One (1) in-person meeting with few members in Denver, CO - September 2019
- Four (4) working group teleconferences from November 2019 – January 2020
- Two (2) draft SMPRs (2'-FL, LN*n*T) completed February 2020
- Public comments period from February – March 2020
- SMPRs ready for AOAC SPIFAN review and approval

The major topic discussions during the calls included:

- Analytes? → 2'-FL, 3-FL, LN*n*T, LNT, 6'-SL, 3'-SL, DFL, (LNFP-I)
- SMPR for standards? → not in the scope of SPIFAN and current SMPRs
- Analytical range per HMO? → based on data for breast milk and IF
- Selectivity / interferences? → possible interferences discussed, incl. probiotics
- Reference materials? → not currently available

Additional information was provided for specific performance claims for 2'-FL and LN*n*T including the method performance requirements.

The draft SMPRs were posted for public comments and received two (2) comments with one (1) observation after reviewing the final draft. The first comment was related to the standards' checks, to add top range, not just low and middle. This is a general sentence found in SMPRs, however not 100% consistency has been observed on how it is expressed. A similar comment was also given in GOS SMPR. The response included 2 suggestions; to include the "high point" (as accepted for GOS) or make the phrase more general: e.g. […], and check standards at the appropriate analytical range(s).

The second comment, the numbers are expressed per 100g, but in the table it states reconstituted powder, which is confusing. The comment was discussed with the AOAC science advisors with the response being that the reconstitution is 25g powder in 200g water (so everything is given by mass). No change of the document as it is clear. The observation included that the range "5-100mg/100g" should be removed. The range is not relevant and was a typographical error that had to be removed. The response was to remove the range 5-100mg/100g.

Motion:
Move for SPIFAN to approve the SMPR for HMO (2'-FL & LN*n*T) with the following amendments:

1. Both SMPRs: in the system suitability test, add a check standard at the high point of the analytical range or rephrase the sentence as: …….
2. LN*n*T SMPR: delete the range 5-100mg/100g from Table 1, repeatability and reproducibility sections

Vote:

*Due to travel restrictions, a number of stakeholders were unable to attend the meeting. AOAC will allow voting of the HMO SMPRs via electronic balloting to determine consensus.

b. **Lactoferrin**

Working group co-chairs Martine van Gool (FrieslandCampina) and Jeffrey Shippar (Eurofins) presented information on lactoferrin. The meeting began with an update from the 14th International Lactoferrin Conference from November 4-9, 2019 held in Lima, Peru.

The co-chairs reviewed the bovine lactoferrin SMPR developed by working group including analyte definition, the rationale and implications. The draft SMPRs were posted for public comments and received two (2) comments.

Motion:

Move for SPIFAN to approve the SMPR version 3 for bovine lactoferrin with the following revisions: lines 41-43: remove the LOD definition lines

Vote:

*Due to travel restrictions, a number of stakeholders were unable to attend the meeting. AOAC will allow voting of the bovine lactoferrin SMPR via electronic balloting to determine consensus.

VIII. AOAC SPIFAN ERP/WORKING GROUP METHODS REVIEW PROJECT

Deborah McKenzie (AOAC) provided an update on the review of First Action methods and updating infant formula methods currently in OMA by re-engaging the working groups and collaboration between the ERP, WGs, and OMB along with input from AOAC SPIFAN stakeholders. The pilot program began with the first set of priority nutrients introduced in 2010, with the following nutrients: vitamin A, vitamin D, vitamin B_{12}, folic acid, inositol, and vitamin E. This collaboration between the working groups and the AOAC SPIFAN Nutrient ERP will result in a recommendation for these methods being approved with one (1) Official Method per priority nutrient that would be submitted to Codex to become the new Type II (dispute resolution) method for that nutrient listed in the CXS234.

In updating OMA, Chapter 51 for infant formula, the standard method performance requirements specifically for methods distinguished for dispute resolution status based on the change in AOAC *Official Methods*^{SM}, the ERP adopted more than one (1) method per nutrient and evolved a method to the down selection process that required MLT with involvement of ISO and IDF. If the down selected method including MLT data was approved and achieved Final Action OMA status the method was jointly (ISO, IDF) submitted into Codex for consideration for Type II status.

Update from Working Group Chairs:

The working group chairs presented an update on their respective nutrients including general nutrient introduction and background, significance or implications of nutrient in infant formula, summary of existing methods in OMA, Chapter 50 limitations with existing methods and method scope and performance vs current SMPR. Currently seventeen (17) methods have been reviewed across all methods for Folic acid, inositol, vitamins A, D, E, B_{12} in AOAC OMA Chapter 50.

PRESENTATIONS: provided to the stakeholder panel by working group chairs

- Vitamin A/E – Neal Craft (Eurofins Craft Technologies, Inc.)
- Vitamin B_{12} – Esther Campos-Giménez (Nestlé)
- Vitamin D – Don Gilliland (Abbott) – *unable to attend meeting*
- Folate (Folic Acid) – Erik Konings (Nestlé)
- Inositol (myo-Inositol) - Karen Schimpf (Abbott)/Harvey Indyk (Fonterra)

AOAC Policies:

- Methods with no evidence of use for two (2) after adoption to be repealed
- Methods with no evidence of reproducibility assessment during the 2 years after adoption to be repealed

FEEDBACK & COMMENTS:

McKenzie (AOAC) discussed comments and feedback received from ISO/IDF as US TAG to ISO TC 34 Administrator.

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, and the AOAC SPIFAN methods still in First Action since the 2019 AOAC Annual Meeting in Denver, CO. AOAC is currently awaiting methods re-submissions for alpha-carotene, fluoride and GOS. The following methods have been submitted for Final Action status, GOS, alpha-carotene, lutein, fluoride and amino acids.

During the December 4, 2020 meeting held in conjunction with the AOAC Analytical Methods Week, AOAC invited all working group chairs to discuss ideas for reviewing OMA Chapter 50 and agreed to start with first six nutrients initiating reviews for vitamins A, D, E, B_{12}, folic acid and inositol. To identify methods that have technical inconsistencies and do not work and are no longer fit for purpose. Also, request working group chairs to identify methods that are applicable, but where a more updated OMA method exists and to prepare a presentation on progress to include any changes in regulations or required analysis for the nutrient and needs for SMPRs or changes in SMPRs.

The ERP will be discussing GB methods for L-carnitine and vitamin C submitted for review along with answering questions on method AOAC 2018.06 currently in multi-laboratory testing (MLT). In addition, review comments received within ISO/TC 34 that may impact AOAC 2015.10 and comments received by US TAG to ISO/TC 34 that may impact AOAC 2016.13.

X. TIMELINES/DEADLINES/WRAP-UP

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 program meeting book, click here!