



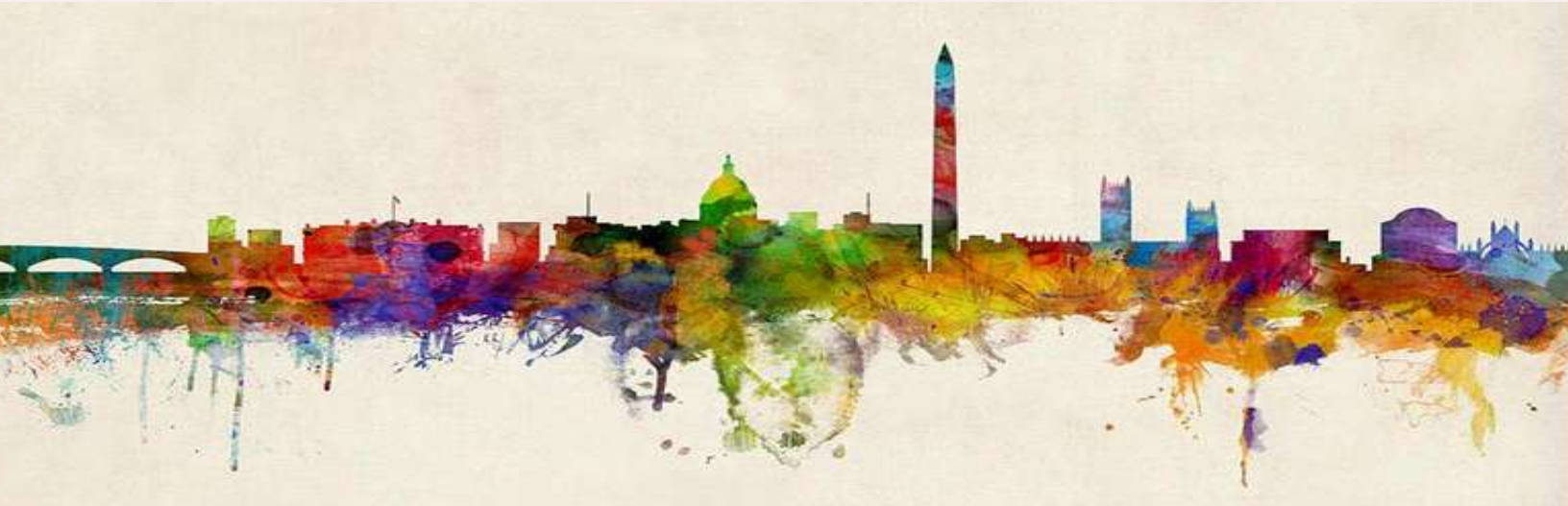
The Scientific Association Dedicated to Analytical Excellence®

THE THIRTEENTH MEETING

of the

AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals

Meeting at:
Gaithersburg Marriott Washingtonian Center
9751 Washingtonian Boulevard
Gaithersburg MD 20878, USA



Tuesday, March 15, 2016

AOAC INTERNATIONAL
2275 Research Blvd., Suite 300
Rockville, MD, 20850
UNITED STATES
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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

STAKEHOLDER PANEL - DRAFT MEETING AGENDA

Tuesday, March 15, 2016

Meeting Start Time: 8:30AM (Eastern US)

SPIFAN Chair: Darryl Sullivan

(Covance Laboratories)

Location: Salon C/D

(Registration Opens at 7:30AM)

I. INTRODUCTION (Bradford/Sullivan/Hill – 8:30AM-8:45AM)

Jim Bradford (AOAC)/Darryl Sullivan (Covance) will call the Stakeholder Panel meeting to order along with the introduction/welcome of participants by AOAC President, Norma Hill (Retired) and review of the AOAC policies for Antitrust, Volunteer Conflict of Interest, and Use of Association Name and Insignia.

II. AOAC SPIFAN OVERVIEW (Sullivan – 8:45AM-9:15AM)

Darryl Sullivan (Covance) will provide an overview of the accomplishments and achievements in SPIFAN I & II.

III. UPDATE ON INTERNATIONAL ACTIVITIES (Sullivan – 9:15AM-10:15AM)

1. UPDATE ON AOAC SPIFAN FINAL ACTION OFFICIAL METHODS OF ANALYSIS (Sullivan)

Darryl Sullivan (Covance) will provide an update on the activities related to the submission of the AOAC SPIFAN Final Action methods to the FAO/WHO Codex Alimentarius Commission.

2. AOAC/ISO/IDF ACTIVITIES (Konings/Evers)

Erik Konings (Nestlé/ISO) and Jaap Evers (IDF) will provide an update on the AOAC/ISO/IDF cooperative.

3. WHEY PROTEIN UPDATE (Zhang (presented by Angela Song (Abbott)))

Angela Song (Abbott) will present updated information on Whey Protein: Casein Ratio provide by Ziting Zhang (EUCCC).

~MORNING BREAK - 10:15AM-10:30AM~

IV. PROFICIENCY TESTING (PT) TASKFORCE - PILOT PROGRAM (Gilliland/Phillips – 10:30AM-11:00AM)

Don Gilliland (Abbott)/Melissa Phillips (NIST) will provide an update on the Proficiency Testing pilot program.

V. WORKING GROUP DISCUSSION (Working Group Chairs – 11:00AM-12:30PM)

Darryl Sullivan (Covance) will moderate discussions with the Working Group Chairs to provide updates on nutrients for which no AOAC First Action *Official Methods*SM status has been recommended.

WORKING GROUPS/CHAIRS:

1. **Amino Acids** *Ping Feng(Wyeth)/Wes Jacobs (Abbott)*
2. **Biotin** *George Joseph (AsureQuality)/Jean-Luc Deborde (SCL)*
3. **B Vitamins (B₃)** *Louis Salvati (Abbott)*
4. **Carotenoids** *Greg Hostetler (Perrigo)*
5. **Fluoride** *Chris Blake (Nestlé)*
6. **Fructans (FOS)** *Sean Austin (Nestlé)*
7. **GOS** *Sean Austin (Nestlé)*

~LUNCH ON YOUR OWN - 12:30PM-2:00PM~

VI. INCA IDEAS FOR FUTURE WORKPLAN (Rankin – 2:00PM-3:00PM)

Robert Rankin (INCA) will provide information to the AOAC SPIFAN stakeholder community on future endeavors.

VII. TIMELINES/DEADLINES/WRAP-UP (Sullivan – 3:00PM-3:30PM)

Darryl Sullivan (Covance) will provide a timeline of SPIFAN activities including upcoming deadlines, wrap up all discussions and answer any additional questions.

MEETING ITINERARY:

REGISTRATION (7:30AM)

MEETING START TIME (8:30AM)

MORNING BREAK (10:15AM-10:30AM)

LUNCH ON YOUR OWN (12:30PM–2:00PM)

AOAC INTERNATIONAL BYLAWS

As Amended September 26, 2010

ARTICLE I Name

The name by which this Association shall be known is "AOAC INTERNATIONAL" (hereinafter referred to as the "Association").¹

ARTICLE II Purpose

The primary purpose of the Association is to promote methods validation and quality measurements in the analytical sciences.

ARTICLE III Membership

Section 1. Types of Membership

There shall be three (3) types of membership in the Association: Individual Members, Sustaining Member Organizations, and Organizational Affiliates.

A. Individual Members

There shall be four (4) categories of Individual Members in the Association: Members, Retired Members, Student Members, and Honorary Members.

B. Sustaining Member Organizations

There shall be one (1) category of Sustaining Member Organizations.

C. Organizational Affiliate

There shall be one (1) category of Organizational Affiliate.

Section 2. Qualifications for Membership

A. Individual Members

[1] Members

Qualifications for Members shall be a degree in science, or equivalent as approved by the Board of Directors, and interest in supporting and furthering the purpose and goals of the Association. Such scientists shall be eligible for membership provided they are engaged, or have been engaged, directly or indirectly, in a field relevant to the purpose of the Association.

[2] Retired Members

¹ AOAC INTERNATIONAL was incorporated in the District of Columbia on January 20, 1932, as the Association of Official Agricultural Chemists. On November 10, 1965, the name of the corporation was changed to the Association of Official Analytical Chemists, and on September 12, 1991, the current name was adopted.

A current Member who is no longer actively engaged, directly or indirectly, in a field relevant to the purpose of the Association but who has served the Association as a Member for at least ten (10) years shall be eligible for Retired Member status upon written request and payment of the annual Retired Member dues. Any special benefits accorded Retired Members shall be determined by the Executive Director.

[3] Student Members

Any full-time student working toward an undergraduate or graduate degree in the areas of chemistry, microbiology, food science or other related science shall be eligible for Student Membership in AOAC INTERNATIONAL.

[4] Honorary Members

Honorary Members shall be persons recognized for their substantial contribution toward the achievement of the objectives of the Association. They shall be nominated by the Board of Directors and may be elected by a two-thirds vote of the Individual Members voting.

B. Sustaining Member Organizations

A Sustaining Member Organization shall be any agency of a local, state, provincial, national, or international government; a university, college, or academic department; or any firm, business, or organization with an interest in supporting and furthering the purpose of the Association. Every Sustaining Member Organization must have a designated representative(s). All such Sustaining Member Organization representatives must meet the qualifications for Members and become Individual Members with all the rights and privileges thereof.

C. Organizational Affiliate

An Organizational Affiliate Organization shall be any agency of a local, state, provincial, national, or international government; a university, college, or academic department; or any firm, business, or organization with an interest in supporting and furthering the purpose of the Association. Every Organizational Affiliate must have a designated representative(s). All such Organizational Affiliate representatives must meet the qualifications for Members and become Individual Members with all the rights and privileges thereof.

Section 3. Application for Membership

Applications or requests for membership shall be submitted to the Association's headquarters office. Membership shall become effective upon approval of the application or request, payment of any required membership dues, entry on the membership rolls, and assignment of a member number.

Section 4. Expulsion

The Board of Directors, at any duly called meeting of the Board, by a two-thirds vote of those holding office, may terminate the membership of any member who in its judgment has violated the Bylaws or has been guilty of conduct detrimental to the best interests of the Association. Any member convicted of a felony is subject to immediate expulsion from the Association. Expulsion of a member by the Board of Directors shall be final and shall cancel all rights, interest, or privileges of such member in the services or resources of the Association. Any member, for whom expulsion is proposed, for reasons other than conviction of a felony, shall be entitled to not less than 60 days advance notice of the charges, the date upon which a hearing will be scheduled, and the right to present evidence in defense. The date and place of any such hearing, if held other than at the headquarters or annual meeting site of the Association, must be reasonable with respect to the location of any individual so charged.

Section 5. Dues, Membership Year, and Waivers

- A. Annual dues for membership in the Association shall be fixed by the Board of Directors, subject to approval by the majority of the Individual Members voting by ballot by any of the following means (whichever is deemed appropriate by the Board at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission.
- B. Honorary Members of the Association shall be exempt from payment of dues and annual meeting registration fees.
- C. The membership year and the delinquency date shall be determined by the Board of Directors.
- D. The authority to grant waivers of membership dues rests with Executive Director.
- E. Student Member dues shall be one-third of regular Member dues, rounded up to the nearest \$5.00 increment.

Section 6. Members in Good Standing; Rights and Privileges

All Individual Members who maintain their membership by payment of dues as required under these Bylaws and who otherwise qualify shall be considered in good standing and entitled to full privileges of membership.

ARTICLE IV Officers

Section 1. Elected Officers

The elected officers of the Association shall be Individual Members and shall consist of a President, President-Elect, Secretary, Treasurer, and Immediate Past President.

A. President

The President shall be the principal elected officer of the Association, shall preside at meetings of the Association and of the Board of Directors and of the Executive Committee, and shall be a member ex-officio, with right to vote, of all committees except the Nominating Committee. He or she shall also, at the annual meeting of the Association and at such other times as he or she shall deem proper, communicate to the Association or the Board of Directors such matters and make such suggestions as may in his or her opinion tend to promote the welfare and further the purpose of the Association and shall perform such other

duties as are necessarily incident to the office of President or as may be prescribed by the Board of Directors.

B. President-Elect

In the absence of the President, or in the event of the President's inability or refusal to act, the President-Elect shall perform the duties of the President, and, when so acting, shall have all the powers of and be subject to all the restrictions upon the President. The President-Elect shall perform such other duties as from time to time may be assigned to him or her by the President or by the Board of Directors.

C. Secretary

The Secretary shall give notice of all meetings of the Association, keep a record of all proceedings, attest documents, and, in general, perform such other duties as are usual of the office of Secretary and such other duties as may be assigned by the President or by the Board of Directors.

D. Treasurer

The Treasurer shall be responsible for the funds and securities of the Association; serve as financial officer of the organization and as Chairperson of the Finance Committee; manage the Board of Director's review of and action related to the Board of Director's financial responsibilities; serve as the chief Board liaison in overseeing and reviewing the annual audit, and in general, perform such other duties as are usual of the office of Treasurer and such other duties as may be assigned by the President or by the Board of Directors.

E. Immediate Past President

The Immediate Past President shall serve as advisor to the President and Directors and perform such other duties as may be assigned from time to time by the President or by the Board of Directors.

Section 2. Appointed Officers

The appointed officers shall include the Executive Director and such other appointed officers as may be designated by the Board of Directors from time to time.

A. Executive Director

The day-to-day administration and management of the Association's offices shall be vested in a salaried manager employed or appointed by, and directly responsible to, the Board of Directors. This manager shall have the title of Executive Director with responsibility for the management and direction of all operations, programs, activities, and affairs of the Association, as approved or delegated by the Board of Directors. The Executive Director shall have direct responsibility for employment and termination of employment and the determination of compensation for staff members within the budgetary framework determined by the Board of Directors. The Executive Director functions as the chief operating officer of the Association within the guidelines established by the policies and procedures of the Board of Directors and, as necessary, with the concurrence of the President. The Executive Director shall have such other duties as may be prescribed by the Board.

B. Other Appointed Officers

Other appointed officers shall have such duties as may be prescribed by the Board.

ARTICLE V
Nominations, Elections, Terms, and Appointments to the Board of Directors

Section 1. Nominating Committee

The Nominating Committee shall annually recommend to the Board of Directors a slate of Individual Members as potential nominees for the elected positions where vacancies will occur. The Nominating Committee shall consist of five (5) members who shall be three (3) immediate Past Presidents, as available, and two (2) Individual Members-at-Large of the Association. If three Past Presidents are not available to serve, other Individual Members-at-Large shall be appointed by the President to the extent necessary to form the five (5)-member committee.

Section 2. Elections and Terms of Office

The President-Elect, the Secretary, Treasurer, and the Directors of the Board of Directors shall be elected by a majority of Individual Members voting, from a slate of nominees recommended annually by the Board of Directors.

Terms of office for all Officers and Directors shall begin with the adjournment of the annual meeting following their election and shall end with the adjournment of the annual meeting occurring nearest the expiration of their term. The six (6) Directors shall be elected to staggered three-year terms with two Directors elected to full three-year terms each year, but not to more than two (2), consecutive, three-year terms. Appointment or election to fill an unexpired term shall not affect the eligibility of a person to subsequently be elected to two (2) full terms. The Secretary shall be elected to a one-year term and may be re-elected to successive one-year terms. The Treasurer shall be elected for a one-year term and may be re-elected to successive one-year terms. The President-Elect shall be elected to a one-year term; whereupon the current President-Elect shall become President and the current President shall become the Immediate Past President, each serving a one-year term.

Section 3. Appointments

Directors-at-Large are appointed by the Board in accordance with Article VI, Section 2. Directors-at-Large are appointed for one (1) year terms, renewable at the discretion of the elected Board.

ARTICLE VI
Board of Directors

Section 1. Composition

The Board of Directors shall consist of eleven (11) elected members to include the President, President-Elect, Secretary, Treasurer, Immediate Past President, six (6) Directors, and up to three (3) appointed Directors-at-Large, all of whom shall be Individual Members of the Association. The elected Board shall reflect the makeup of the Association membership and shall not be dominated by any single interest.

Section 2. Powers and Duties

The Board of Directors shall provide supervision, control, and direction of the affairs of the Association, shall determine the Association's policies or changes therein within the limits of the Bylaws, shall actively prosecute

its purpose, and shall have discretion in the disbursement of its funds. It may adopt such rules and procedures for the conduct of its business as shall be deemed advisable, and may, in the execution of the powers granted, appoint such agents as it may consider necessary. The Board of Directors may appoint up to three (3) Directors-at-Large, if, in their opinion, such appointments advance the purpose of the Association. Directors-at-Large shall be accorded the same voting privileges as elected Directors.

Section 3. Meetings

Except that the Board shall have a regular meeting at the time and place of the annual meeting, the Board shall meet, in person or via telephone conference call, upon call of the President at such times and places as he or she may designate within the policies adopted by the Board, and shall be called to meet upon demand of a majority of its members. Notice of all meetings of the Board of Directors shall be sent by any of the following means (whichever is deemed appropriate by the President at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission to each member of the Board at his or her last recorded address or number at least fourteen (14) days in advance of in-person meetings or forty-eight (48) hours in advance of conference call meetings.

Section 4. Quorum

A quorum for any meeting of the Board is six (6) Board members elected in accordance with Article V (1). Any less number may: (1) set a time to adjourn, (2) adjourn, (3) recess, or (4) take measures to obtain a quorum.

Section 5. Absence

Any member of the Board of Directors unable to attend a meeting of the Board shall notify the President and state the reason for his or her absence. If a member of the Board is absent from two (2) consecutive meetings, he or she may be removed by a two-thirds vote of the Board Members then in office.

Section 6. Compensation

Members of the Board of Directors, as such, shall not receive any compensation for their services as Board members, but the Board may, by resolution under policies it may adopt, authorize reimbursement of expenses incurred in the performance of members' duties. Such authorization may prescribe conditions and procedures for approval and payment of such expenses. Nothing herein shall preclude a Board member from serving the Association in any other capacity and receiving compensation for such services, if compensation is customarily paid for such services.

Section 7. Resignation or Removal

Any member of the Board may resign at any time by giving written notice to the President, Secretary, Treasurer, or to the Board of Directors. Such resignation shall take effect at the time specified therein, or, if no time is specified, at the time of acceptance thereof as determined by the President or the Board.

Any member of the Board may be removed by a three-fourths vote of the Board members then in office and present at any regular or special meeting of the Board.

Section 8. Vacancies: Members of the Board

If a vacancy should occur in the membership of the elected Board of Directors, any Past President may be appointed by action of the remaining members of the Board to temporarily fill such vacancy until the next

regularly scheduled election. At the next regularly scheduled election nominations will be presented to fill the vacancy for the unexpired portion of the term remaining.

Section 9. Vacancies: President and Other Officers

If the office of the President shall become vacant, the President-Elect shall thereupon become President of the Association for the unexpired term, followed by his or her duly elected term. In the event the office of President becomes vacant at a time when the office of President-Elect is also vacant, the Presidency shall be filled for the remainder of the term by the action of the Board of Directors. If any other officer position shall become vacant, the office may be filled for the remainder of the term by action of the Board.

**ARTICLE VII
Committees**

Section 1. Committee Formation

The Board of Directors shall form and adopt terms of reference for such standing or special boards, committees, subcommittees, task forces, or task groups as may be required by these Bylaws or as the Board may determine necessary to carry out the affairs of the Association.

Section 2. Committee Appointments

Subject to the requirements of these Bylaws and the specific terms of reference adopted by the Board, the President shall make the appointments to fill the vacancies occurring in the Association's standing or special boards, committees, subcommittees, task forces, or task groups.

**ARTICLE VIII
Official Methods of Analysis**

The Board of Directors (BoD) is empowered to develop written policies and procedures for the study, adoption, and change in status of the Official Methods of Analysis of AOAC INTERNATIONAL. Implementation of the policies and procedures shall be delegated to an Official Methods Board (OMB).

Section 1. Composition of the Official Methods Board

The Official Methods Board shall consist of a chair and a vice chair, and members who are recommended by the chair. The chair, vice chair and members are appointed by the President of AOAC INTERNATIONAL. The OMB shall be composed of members representing a balance of government, industry, and academia as appropriate to the scope of the group and shall not be dominated by any single interest.

Section 2. Purpose of the Official Methods Board

The OMB shall serve the Association in a scientific and advisory capacity on methods and the process of their adoption. The OMB shall be responsible for implementation of procedures adopted by the BoD, according to the principles in section 3 below.

Section 3. Principles of the Official Methods Program

- A. Adequate records of technical data, discussions, and decisions on the study, adoption, and change of status of Official Methods of Analysis shall be maintained for a reasonable time.
- B. Timely notice of proposed method studies, adoption, or change in status shall be published in an Association publication that is circulated to the members.
- C. Opportunity shall be provided for materially interested parties to submit input during method study and adoption procedures and to submit comments on the adoption, use of, or change in status of specific methods.
- D. Methods submitted to the OMB for inclusion in the OMA shall be thoroughly studied, scientifically reviewed, and available in published form prior to adoption as Final Action by the OMB.
- E. The OMB shall adopt methods as Final Action.

**ARTICLE IX
Meetings**

Section 1. Annual Meeting

The annual business meeting of the Association shall be held at the time and place decided by the Board of Directors. A special meeting of the entire Association may be called by the Board of Directors; announcement thereof shall be made at least thirty (30) days prior to the time of said meeting.

Section 2. Quorum

One hundred Individual Members who are present in person or by proxy and entitled to vote shall constitute a quorum at any meeting of the Association which is duly called pursuant to the provisions of these Bylaws.

**ARTICLE X
Voting**

Section 1. Voting by Ballot

By direction of the Board of Directors, unless otherwise required by these Bylaws or conducted under alternative procedures established under these Bylaws, voting on any matter, including the election of officers and directors, the election of Honorary Members, amendment of the Bylaws, and the approval of dues, may be conducted by ballot of the voting membership by any of the following means (whichever is deemed appropriate at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission, and the question(s) thus presented shall be determined according to the votes received, provided in each case votes of at least five (5) percent of the voting membership shall be received. Any and all action taken in pursuance of a vote by any of the means indicated above (whichever the Board deemed appropriate at the time)

in each case shall be binding upon the Association in the same manner as would be action taken at a duly called meeting and shall become effective, unless otherwise provided for in these Bylaws or otherwise stated in the ballot, on the day following certification of the vote.

Section 2. Voting by Proxy

At any duly called meeting of Individual Members, a member-of-record, as determined thirty (30) days prior to any meeting and who is entitled to vote, may vote by proxy executed in writing by the Individual Member or his or her duly authorized attorney-in-fact. No proxy shall be valid for more than eleven (11) months after the date of its execution unless otherwise provided in the proxy.

**ARTICLE XI
Earnings and Assets**

Section 1. Non-Profit Status

A. Regardless of any provision of the Bylaws which may be construed otherwise:

[1] No part of the net earnings of the Association shall under any circumstances inure to the benefit of any member or individual.

[2] The Association shall not be operated for a private profit.

B. On lawful dissolution of the Association and after settlement of all just obligations of the Association, the Board of Directors shall distribute all remaining assets of the Association to one (1) or more organizations selected by the Board of Directors which have been held exempt from Federal Income Tax as organizations described in section 501(c)(3) of the Internal Revenue Code of 1954.

Section 2. Political Activities

A. No substantial part of the Association's activities shall consist of carrying on propaganda or otherwise attempting to influence local, state, or national legislation. All activities of the Association shall be determined by the Board of Directors.

B. The Association shall not participate or intervene in any manner in any campaign on behalf of any candidate for a political office.

**ARTICLE XII
Sections**

Section 1. Sections

The Board of Directors shall set geographic limits and grant authority to groups of Individual Members of the Association residing or working in the same geographical areas for the establishment of Sections.

Section 2. Purpose of Sections

The purpose of Sections shall be to promote and further the purpose of the Association.

Section 3. Membership in Sections

Individuals interested in the purpose of the Section shall be eligible for Section membership. Only Individual Members of the Association shall be eligible for election to the Executive Committee of the Section.

Section 4. Bylaws of Sections

Subject to approval of the Board of Directors, each Section shall adopt, for its own governance, bylaws not inconsistent with these Bylaws.

Section 5. Dissolution of Sections

When any Section shall cease to function as a Section for a period of more than one year, or if its membership shall be less than ten (10) Individual Members of the Association for a period of one (1) year, the Board of Directors may terminate the existence of such Section.

Section 6. Actions of Sections

No act of a Section or its members shall be considered an act of the Association unless expressly authorized, ratified, or affirmed by the Board of Directors.

**ARTICLE XIII
Technical Divisions**

Section 1. Purpose

Technical Divisions shall represent communities of interest within the Association which have the purpose of furthering the purpose of the Association through the development of the analytical sciences either in a commodity-based or scientific discipline-based field. Their activities shall not duplicate the organizational structure nor conflict with the policies or procedures for the adoption of official methods of analysis by the Association.

Section 2. Creation, Combination, Discontinuance, or Change

Technical Divisions may be created, existing Technical Divisions may be combined or discontinued, or the name of a Technical Division may be changed under policies and procedures adopted by the Board of Directors. Each Technical Division shall adopt bylaws not inconsistent with these Bylaws. The jurisdiction of each Technical Division shall be described in its bylaws. No act of any Technical Division or its members shall be considered an act of the Association unless expressly authorized, ratified, or affirmed by the Board of Directors.

**ARTICLE XIV
Indemnification**

The Association shall have the power to pay, by indemnity, reimbursement, or otherwise, to or for the use of any person designated by resolution of the Board of Directors who was or is a party or is threatened to be made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative (other than an action by or on behalf of the Association), by reason of the fact he or she is or was a director, officer, committee member, employee or agent of the Association, or was serving as such for another at the request of the Association, against expenses (including legal, accounting, witness and other), judgments, fines, and amounts paid in settlement so long as such person was not found by a court of competent jurisdiction to have been willfully negligent of the interests of the Association or such person had reasonable cause to believe that his or her conduct was lawful.

ARTICLE XV
Parliamentary Authority

The rules contained in the current edition of *Robert's Rules of Order Newly Revised* shall govern the Association in all cases in which they are applicable and in which they are not inconsistent with these Bylaws or any special rules of order the Association may adopt.

ARTICLE XVI
Amendments to the Bylaws

These Bylaws may be amended, repealed, or altered, in whole or in part, by a three-fourths vote: (a) of the Individual Members at any annual business or duly called special meeting of the Association, provided notice of any amendment proposed for consideration shall be sent by any of the following means (whichever may be deemed appropriate at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission to the last recorded address or number of each Individual Member at least thirty (30) days prior to the date of the meeting; or (b) by approval of the Individual Members through ballot sent by any means indicated above in accordance with the provisions of Article X, Voting.

All proposed amendments of these Bylaws shall be presented in writing to the Board of Directors. The Board shall present the proposals to the Association membership, with recommendations. All amendments to the Bylaws, unless otherwise stated, will become effective at the adjournment of the meeting where action is taken or on the day following the certification of a vote by mail ballot.

AOAC INTERNATIONAL
POLICY ON THE USE OF THE
ASSOCIATION NAME, INITIALS,
IDENTIFYING INSIGNIA, LETTERHEAD, AND BUSINESS CARDS

Introduction

The following policy and guidelines for the use of the name, initials, and other identifying insignia of AOAC INTERNATIONAL have been developed in order to protect the reputation, image, legal integrity and property of the Association.

The name of the Association, as stated in its bylaws, is "AOAC INTERNATIONAL". The Association is also known by its initials, AOAC, and by its logo, illustrated below, which incorporates the Association name and a representation of a microscope, book, and flask. The AOAC logo is owned by the Association and is registered with the U.S. Patent and Trademark Office.



The full Association insignia, illustrated below, is comprised of the logo and the tagline, "The Scientific Association Dedicated to Analytical Excellence," shown below. The typeface used is Largo. The AOAC tagline is owned by the Association and is registered with the U.S. Patent and Trademark office.



The Scientific Association Dedicated to Analytical Excellence®

Policy

Policy on the use of the Association's name and logo is established by the AOAC Board of Directors as follows:

“The Board approves and encourages reference to the Association by name, either as AOAC INTERNATIONAL or as AOAC; or reference to our registered trademark, AOAC®, in appropriate settings to describe our programs, products, etc., in scientific literature and other instances so long as the reference is fair, accurate, complete and truthful and does not indicate or imply unauthorized endorsement of any kind.

The insignia (logo) of AOAC INTERNATIONAL is a registered trade and service mark and shall not be reproduced or used by any person or organization other than the Association, its elected and appointed officers, sections, or committees, without the prior written permission of the Association. Those authorized to use the AOAC INTERNATIONAL insignia shall use it only for the purposes for which permission has been specifically granted.

The name and insignia of the Association shall not be used by any person or organization in any way which indicates, tends to indicate, or implies AOAC official endorsement of any product, service, program, company, organization, event or person, endorsement of which, has not been authorized by the Association, or which suggests that membership in the Association is available to any organization.”

The Executive Director, in accordance with the above stated policy, is authorized to process, approve, fix rules, and make available materials containing the Association name and insignia.

It should be noted that neither the Association's name nor its insignia nor part of its insignia may be incorporated into any personal, company, organization, or any other stationery other than that of the Association; nor may any statement be included in the printed portion of such stationery which states or implies that an individual, company, or other organization is a Member of the Association.

Instructions

1. Reproduction or use of the Association name or insignia requires prior approval by the Executive Director or his designate.
2. Association insignia should not be altered in any manner without approval of the Executive Director or his designate, except to be enlarged or reduced in their entirety.
3. Artwork for reproducing the Association name or insignia, including those incorporating approved alterations, will be provided on request to those authorized to use them (make such requests to the AOAC Marketing Department). Examples of the types of alterations that would be approved are inclusion of a section name in or the addition of an officer's name and address to the letterhead insignia.

4. When the Association name is used without other text as a heading, it should, when possible, be set in the Largo typeface.
5. Although other colors may be used, AOAC blue, PMS 287, is the preferred color when printing the AOAC insignia, especially in formal and official documents. It is, of course, often necessary and acceptable to reproduce the insignia in black.
6. Do not print one part of the logo or insignia in one color and other parts in another color.
7. The letterhead of AOAC INTERNATIONAL shall not be used by any person or organization other than the Association, its elected and appointed officers, staff, sections, or committees; except by special permission.

Correspondence of AOAC official business should be conducted using AOAC letterhead. However, those authorized to use AOAC letterhead shall use it for official AOAC business only.

Copies of all correspondence using AOAC letterhead or conducting AOAC official business, whether on AOAC letterhead or not, must be sent to the appropriate office at AOAC headquarters.

8. AOAC INTERNATIONAL business cards shall not be used by any person or organization other than the Association, its staff, and elected officials, except by special permission.

Those authorized to use AOAC business cards shall use them for official AOAC business only and shall not represent themselves as having authority to bind the Association beyond that authorized.

Sanctions

1. Upon learning of any violation of the above policy, the Executive Director or a designate will notify the individual or organization that they are in violation of AOAC policy and will ask them to refrain from further misuse of the AOAC name or insignia.
2. If the misuse is by an Individual Member or Sustaining Member of the Association, and the misuse continues after notification, the Board of Directors will take appropriate action.
3. If continued misuse is by a nonmember of the Association or if a member continues misuse in spite of notification and Board action, ultimately, the Association will take legal action to protect its property, legal integrity, reputation, and image.

* * * * *

AOAC INTERNATIONAL
ANTITRUST POLICY
STATEMENT AND GUIDELINES

Introduction

It is the policy of AOAC INTERNATIONAL (AOAC) and its members to comply strictly with all laws applicable to AOAC activities. Because AOAC activities frequently involve cooperative undertakings and meetings where competitors may be present, it is important to emphasize the on-going commitment of our members and the Association to full compliance with national and other antitrust laws. This statement is a reminder of that commitment and should be used as a general guide for AOAC and related individual activities and meetings.

Responsibility for Antitrust Compliance

The Association's structure is fashioned and its programs are carried out in conformance with antitrust standards. However, an equal responsibility for antitrust compliance __ which includes avoidance of even an appearance of improper activity __ belongs to the individual. Even the appearance of improper activity must be avoided because the courts have taken the position that actual proof of misconduct is not required under the law. All that is required is whether misconduct can be inferred from the individual's activities.

Employers and AOAC depend on individual good judgment to avoid all discussions and activities which may involve improper subject matter and improper procedures. AOAC staff members work conscientiously to avoid subject matter or discussion which may have unintended implications, and counsel for the Association can provide guidance with regard to these matters. It is important for the individual to realize, however, that the competitive significance of a particular conduct or communication probably is evident only to the individual who is directly involved in such matters.

Antitrust Guidelines

In general, the U.S. antitrust laws seek to preserve a free, competitive economy and trade in the United States and in commerce with foreign countries. Laws in other countries have similar objectives. Competitors (including individuals) may not restrain competition among themselves with reference to the price, quality, or distribution of their products, and they may not act in concert to restrict the competitive capabilities or opportunities of competitors, suppliers, or customers.

Although the Justice Department and Federal Trade Commission generally enforce the U.S. antitrust laws, private parties can bring their own lawsuits.

Penalties for violating the U.S. and other antitrust laws are severe: corporations are subject to heavy fines and injunctive decrees, and may have to pay substantial damage judgments to injured competitors, suppliers, or customers. Individuals are subject to criminal prosecution, and will be punished by fines and imprisonment.

Under current U.S. federal sentencing guidelines, individuals found guilty of bid rigging, price fixing, or market allocation must be sent to jail for at least 4 to 10 months and must pay substantial minimum fines.

Since the individual has an important responsibility in ensuring antitrust compliance in AOAC activities, everyone should read and heed the following guidelines.

1. Don't make any effort to bring about or prevent the standardization of any method or product for the purpose or intent of preventing the manufacture or sale of any method or product not conforming to a specified standard.
2. Don't discuss with competitors your own or the competitors' prices, or anything that might affect prices such as costs, discounts, terms of sale, distribution, volume of production, profit margins, territories, or customers.
3. Don't make announcements or statements at AOAC functions, outside leased exhibit space, about your own prices or those of competitors.
4. Don't disclose to others at meetings or otherwise any competitively sensitive information.
5. Don't attempt to use the Association to restrict the economic activities of any firm or any individual.
6. Don't stay at a meeting where any such price or anti_competitive talk occurs.
7. Do conduct all AOAC business meetings in accordance with AOAC rules. These rules require that an AOAC staff member be present or available, the meeting be conducted by a knowledgeable chair, the agenda be followed, and minutes be kept.
8. Do confer with counsel before raising any topic or making any statement with competitive ramifications.
9. Do send copies of meeting minutes and all AOAC_related correspondence to the staff member involved in the activity.
10. Do alert the AOAC staff to any inaccuracies in proposed or existing methods and statements issued, or to be issued, by AOAC and to any conduct not in conformance with these guidelines.

Conclusion

Compliance with these guidelines involves not only avoidance of antitrust violations, but avoidance of any behavior which might be so construed. Bear in mind, however, that the above antitrust laws are stated in general terms, and that this statement is not a summary of applicable laws. It is intended only to highlight and emphasize the principal antitrust standards which are relevant to AOAC programs. You must, therefore, seek the guidance of either AOAC counsel or your own counsel if antitrust questions arise.

* * * * *

Adopted by the AOAC Board of Directors: September 24, 1989
Revised: March 11, 1991
Revised October 1996



The Scientific Association Dedicated to Analytical Excellence®

AOAC INTERNATIONAL
POLICY AND PROCEDURES ON
VOLUNTEER CONFLICT OF INTEREST

Statement of Policy

While it is not the intention of AOAC INTERNATIONAL (AOAC) to restrict the personal, professional, or proprietary activities of AOAC members nor to preclude or restrict participation in Association affairs solely by reason of such activities, it is the sense of AOAC that conflicts of interest or even the appearance of conflicts of interest on the part of AOAC volunteers should be avoided. Where this is not possible or practical under the circumstances, there shall be written disclosure by the volunteers of actual or potential conflicts of interest in order to ensure the credibility and integrity of AOAC. Such written disclosure shall be made to any individual or group within the Association which is reviewing a recommendation which the volunteer had a part in formulating and in which the volunteer has a material interest causing an actual or potential conflict of interest.

AOAC requires disclosure of actual or potential conflicts of interest as a condition of active participation in the business of the Association. The burden of disclosure of conflicts of interest or the appearance of conflicts of interest falls upon the volunteer.

A disclosed conflict of interest will not in itself bar an AOAC member from participation in Association activities, but a three-fourths majority of the AOAC group reviewing the issue presenting the conflict must concur by secret ballot that the volunteer's continued participation is necessary and will not unreasonably jeopardize the integrity of the decision-making process.

Employees of AOAC are governed by the provision of the AOAC policy on conflict of interest by staff. If that policy is in disagreement with or mute on matters covered by this policy, the provisions of this policy shall prevail and apply to staff as well.

Illustrations of Conflicts of Interest

1. A volunteer who is serving as a committee member or referee engaged in the evaluation of a method or device; who is also an employee of or receiving a fee from the firm which is manufacturing or distributing the method or device or is an employee of or receiving a fee from a competing firm.
2. A volunteer who is requested to evaluate a proposed method or a related collaborative study in which data are presented that appear detrimental (or favorable) to a product distributed or a position supported by the volunteer's employer.
3. A referee who is conducting a study and evaluating the results of an instrument, a kit, or a piece of equipment which will be provided gratis by the manufacturer or distributor to one or more of the participating laboratories, including his or her own laboratory, at the conclusion of the study.

4. Sponsorship of a collaborative study by an interest (which may include the referee) which stands to profit from the results; such sponsorship usually involving the privilege granted by the investigator to permit the sponsor to review and comment upon the results prior to AOAC evaluation.
5. A volunteer asked to review a manuscript submitted for publication when the manuscript contains information which is critical of a proprietary or other interest of the reviewer.

The foregoing are intended as illustrative and should not be interpreted to be all-inclusive examples of conflicts of interest AOAC volunteers may find themselves involved in.

Do's and Don'ts

Do avoid the appearance as well as the fact of a conflict of interest.

Do make written disclosure of any material interest which may constitute a conflict of interest or the appearance of a conflict of interest.

Do not accept payment or gifts for services rendered as a volunteer of the Association without disclosing such payment or gifts.

Do not vote on any issue before an AOAC decision-making body where you have the appearance of or an actual conflict of interest regarding the recommendation or decision before that body.

Do not participate in an AOAC decision-making body without written disclosure of actual or potential conflicts of interest in the issues before that body.

Do not accept a position of responsibility as an AOAC volunteer, without disclosure, where the discharge of the accepted responsibility will be or may appear to be influenced by proprietary or other conflicting interests.

Procedures

Each volunteer elected or appointed to an AOAC position of responsibility shall be sent, at the time of election or appointment, a copy of this policy and shall be advised of the requirement to adhere to the provisions herein as a condition for active participation in the business of the Association. Each volunteer, at the time of his or her election or appointment, shall indicate, in writing, on a form provided for this purpose by AOAC, that he or she has read and accepts this policy.

Each year, at the spring meeting of the AOAC Board of Directors, the Executive Director shall submit a report certifying the requirements of this policy have been met; including the names and positions of any elected or appointed volunteers who have not at that time indicated in writing that they have accepted the policy.

Anyone with knowledge of specific instances in which the provisions of this policy have not been complied with shall report these instances to the Board of Directors, via the Office of the Executive Director, as soon as discovered.

* * * * *

Adopted: March 2, 1989
Revised: March 28, 1990
Revised: October 1996



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)



Darryl Sullivan, SPIFAN Chair

Darryl Sullivan of Covance Laboratories is the Chairperson for the Stakeholder Panel on Infant Formula and Adult Nutritionals.

Appointed by President Gayle Lancette in July 2010, Darryl Sullivan has been a champion in previous AOAC stakeholder efforts on nutrients in infant formula and adult nutritionals. He is a Fellow of AOAC and has been an active member since 1980. He has served terms as secretary, president-elect, president, past president, and director of the Board of Directors, and previously served a three-year term as Chair of the Official Methods Board. Sullivan also served a three-year term as a director on the AOAC Research Institute Board of Directors. He was a founding member of the Presidential Task Force on Dietary Supplements and a member of the Task Force on *Bacillus anthracis*, as well as the AOAC Task Force on Nutrition Labeling and the AOAC Task Force on Sulfites. Prior to becoming Chair of the OMB, he served as a member and then Chair of the Methods Committee on Commodity Foods and Commodity Products. Darryl Sullivan has been involved with methods validation for over 25 years. In addition to being involved as a Study Director for several AOAC *Official Methods*SM. Sullivan's expertise in methods validation is frequently called upon by AOAC and a number of other scientific associations. Sullivan was a founding member of the AOAC Technical Division on Reference Materials and served three terms on the Division's Executive Board. A staunch supporter of the Association, Sullivan was quite active in the e-CAM and Scholar I projects at AOAC, has exhibited at the annual meetings for many years, has presented hundreds of papers and posters at AOAC meetings, and regularly publishes his research in the journal of the AOAC. He has also presented a significant number of papers on behalf of AOAC at other scientific meetings.

STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

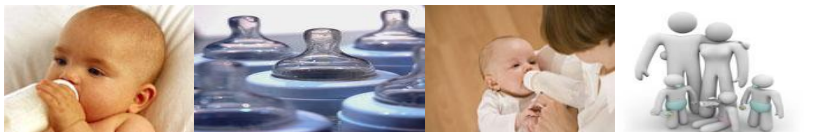
AOAC SPIFAN OVERVIEW

Darryl Sullivan , Covance

Gaithersburg, Maryland

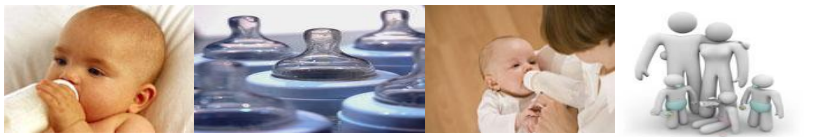
March 15, 2016





Outline

- AOAC SPIFAN Background and Overview
- AOAC SPIFAN Accomplishments
- AOAC SPIFAN Activities
- AOAC Expert Review Panel for SPIFAN Nutrient Methods
- AOAC SPIFAN Activities since AOAC Annual Meeting
- AOAC SPIFAN Activities at AOAC Mid-Year Meeting



SPIFAN Overview

- Historical Perspective
 - AOAC infant formula methods were validated in 1980s
 - New formulas exposed some gaps in validated methods
 - Infant formula is highly regulated around the world
 - Regulatory agencies use AOAC methods



AOAC Engages the Formula Industry

- Agreement with IFC signed in 2010
 - Identify gaps in methods used to analyze label nutrients in infant formula
 - Create AOAC voluntary consensus standards for methodology for 15 sets of nutrients
 - Evaluate and recommend “best” methods
 - AOAC established the Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) to develop the voluntary consensus standards
- Second agreement with IFC signed in June 2013
 - Create standards for methodology for 9 sets of nutrients
- 7 stakeholder panel, WGs, and ERP meetings
 - 1/7 – AOAC Annual Meeting, Chicago - 2013
 - 2/7 – AOAC Mid-Year Meeting, Gaithersburg - 2014
 - 3/7 – AOAC Annual Meeting, Boca Raton – 2014
 - 4/7 – AOAC Mid-Year Meeting, Gaithersburg – 2015
 - 5/7 – AOAC Annual Meeting, Los Angeles – 2015
 - 6/7 – AOAC Mid-Year Meeting, Gaithersburg, - 2016



Completed Voluntary Consensus Standards Development

SPIFAN I (SMPRs) 2011 – 2013

1. Vitamin A
2. Vitamin B12
3. Vitamin D
4. Folate
5. Inositol
6. Vitamin E
7. Whey Protein : Casein
8. Fatty Acids (ISO)
9. Carnitine
10. Vitamin C (India 2012)
11. Choline (India 2012)
12. Pantothenate
13. Iodine
14. Ultra Trace Minerals (Mo, Se, Cr)
15. Nucleotides

SPIFAN II (SMPRs) 2013 – 2016

16. Vitamin K
17. FOS
18. GOS
19. Biotin
20. Minerals
21. Amino Acids
22. Carotenoids
23. Fluoride
24. Chloride
25. Vitamin B1 (thiamine)
26. Vitamin B2 (riboflavin)
27. Vitamin B3 (niacin)
28. Vitamin B6 (pyridoxine)

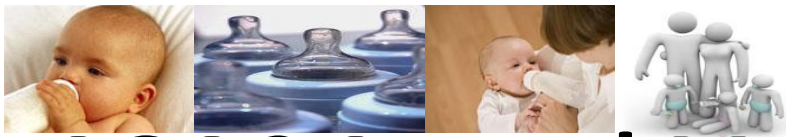
AOAC Working Group Initiative (SMPRs) 2015

29. Compound 1080



AOAC SPIFAN Accomplishments

- 29 AOAC Standard Method Performance Requirements (SMPRs®)
- 33 First Action *Official Methods*SM for nutrients in infant formula
- 8 Final Action *Official Methods*SM for nutrients in infant formula
- 3 First Action methods for Compound 1080
- Joint submission of 8 methods to Codex with ISO and IDF.



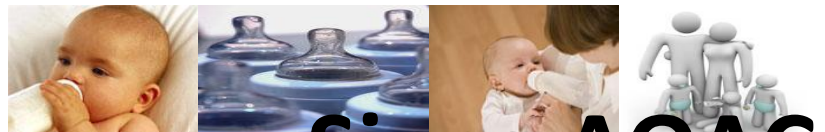
AOAC Annual Meeting SPIFAN Activities

- Ziting Zhang (EUCCC) provided an update on whey protein-casein ratio methods in China
- Update on preparation for the joint submission of the 8 Final Action methods/ISO standards to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)
- Update on the activities of the AOAC Proficiency Testing Taskforce
- Update on opportunities for continued standards development in infant formula and on the AOAC SPSFAM
- Yiyin Shi (CIQ-Shanghai) provided China's perspective on current status of imports, supervision, standards and monitoring of dairy products in China
- Stakeholders engaged in prioritizing ingredients
- ERP met to deliberate on methods for First Action OMA status and to track methods for Final Action consideration



AOAC ERP for SPIFAN Nutrient Methods

- ERP reviewed methods for carnitine/choline, amino acids, carotenoids, chloride, fluoride, fructans, GOS, minerals, B vitamins for First Action OMA status
 - Method for Vitamins B₁, B₂, and B₆ Moved to First Action OMA status
- ERP evaluated the following methods for Final Action Recommendation:
 - AOAC 2011.14 – Ca, Cu, Fe, Mn, K, P, Na, and Zn in Fortified Food Products
 - AOAC 2011.11 – Vitamin D2 and D3 in Infant Formula and Adult Nutritionals
- ERP down selected the following methods for Final Action consideration
 - AOAC 2015.10 (Carnitine/Choline), AOAC 2015.08 (Chloride), AOAC 2011.14 & AOAC 2015.06 (Minerals), AOAC 2015.09 (Vitamin K), AOAC 2015.14 (Vitamins B₁, B₂, and B₆)
- Seven nutrients with no First Action OMAs



Since AOAC Annual Meeting

- Seven (7) nutrients for which there are no AOAC First Action OMAs
 - Amino acids, biotin, carotenoids, fluoride, FOS, GOS, and vitamin B₃,
- AOAC issued a Call for Methods for amino acids, biotin, carotenoids, fluoride, folate, FOS, GOS, vitamin B₃, and vitamin D
- AOAC received methods for the following nutrients for First Action OMA consideration
 - Amino acids, biotin, B vitamins, carotenoids, chloride, chloride/fluoride, folate, FOS, vitamin D
- AOAC received AOAC 2012.22 - Vitamin C for Final Action recommendation consideration
- AOAC SPIFAN Review Team met in December 2015 and in February 2016 to review submitted methods and to assess if there is an immediate need for further standards development
- Preparations for and meetings of both the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and the Codex Committee on Methods of Analysis and Sampling (CCMAS) considered methods for the following nutrients:
 - fatty acids, inositol, iodine, nucleotides, pantothenic acid, ultra trace minerals (Cr, Mo, Se), vitamin A, vitamin B₁₂, and vitamin E.



Introduction of Methods at Codex

- ✓ Methods to be presented to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) for agreement that the methods should move forward for technical review
 - November 23-27, 2015 in Bad Soden am Taunus, Germany

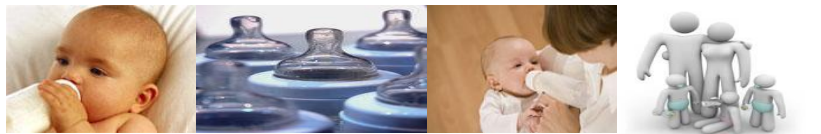
- ✓ Methods could be presented to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for technical review of the methods
 - February 22-26, 2016 in Budapest, Hungary

- Methods could be presented to Codex Alimentarius Commission for endorsement
 - June 27 – July 1, 2016 in Rome, Italy

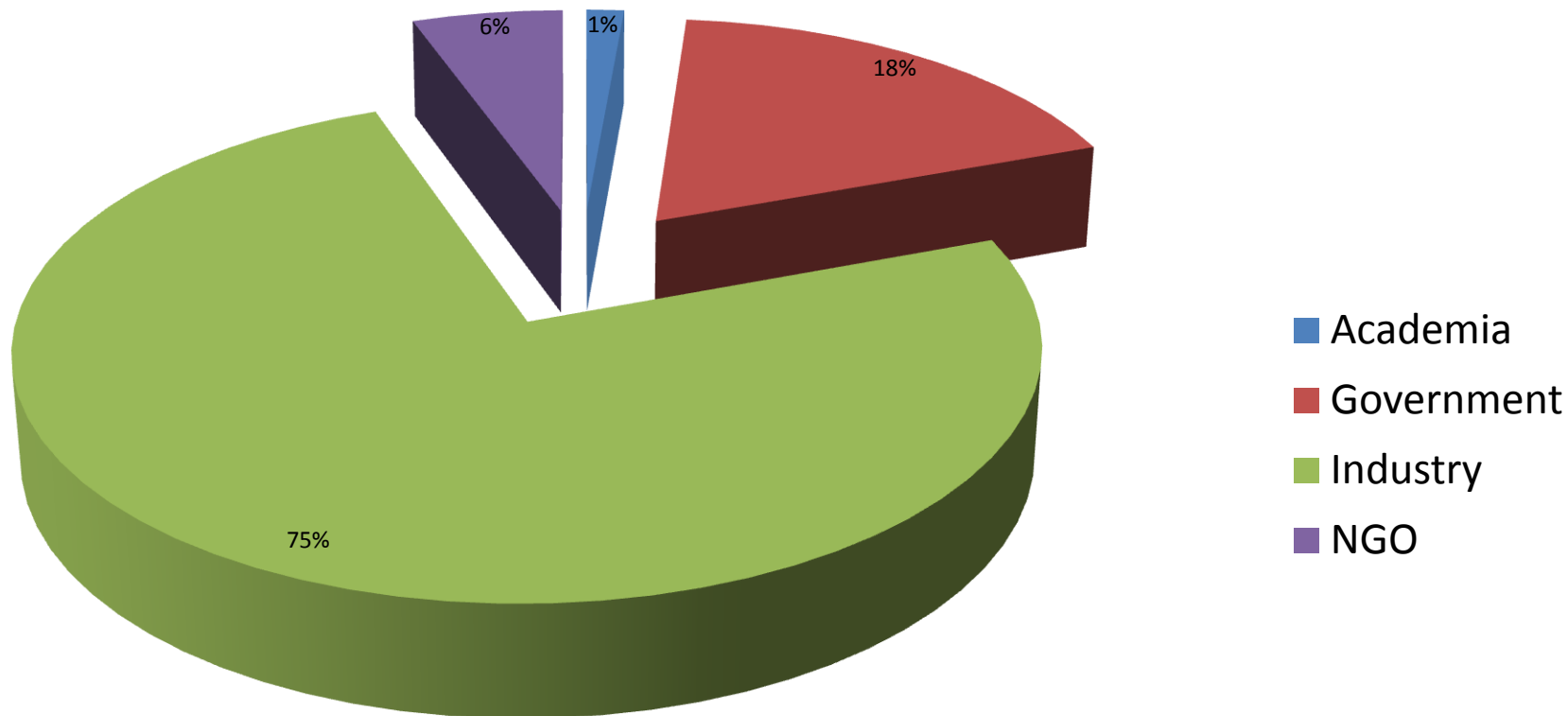


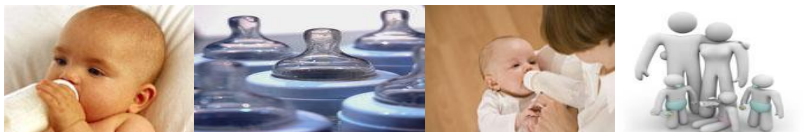
Registered Organizations

- Abbott Nutrition
- Agilent Technologies
- Archer Daniels Midland Company
- AsureQuality
- Ausnutria Hyproca
- Brooke Schwartz Consulting
- Canadian Food Inspection Agency
- Covance Laboratories
- Danone Nutricia
- Fonterra Cooperative Group
- FrieslandCampina
- GERSTEL
- Independent Consutancy
- Keurig Green Mountain
- LATU
- Mead Johnson Nutrition
- Mérieux NutriSciences
- National Institute of Industrial Technology
- Nestlé Research Center
- PANalytical
- Perrigo/PBM Nutritionals
- Curtis S. Phinney (Consulting)
- Q Laboroatories
- R-Biopharm Rhone
- Reckitt Benckiser
- Shanghai Entry Exit Inspection and Quarantine Bureau
- Shimadzu Scientific Instruments
- The Coca-Cola Company
- ThermoFisher Scientific
- Tiense Sulkerraffnaderji Analytical Services
- USDA
- US FDA CFSAN
- US Pharmacopeia
- US Treasury (Retired)
- US NIST
- Waters Corporation

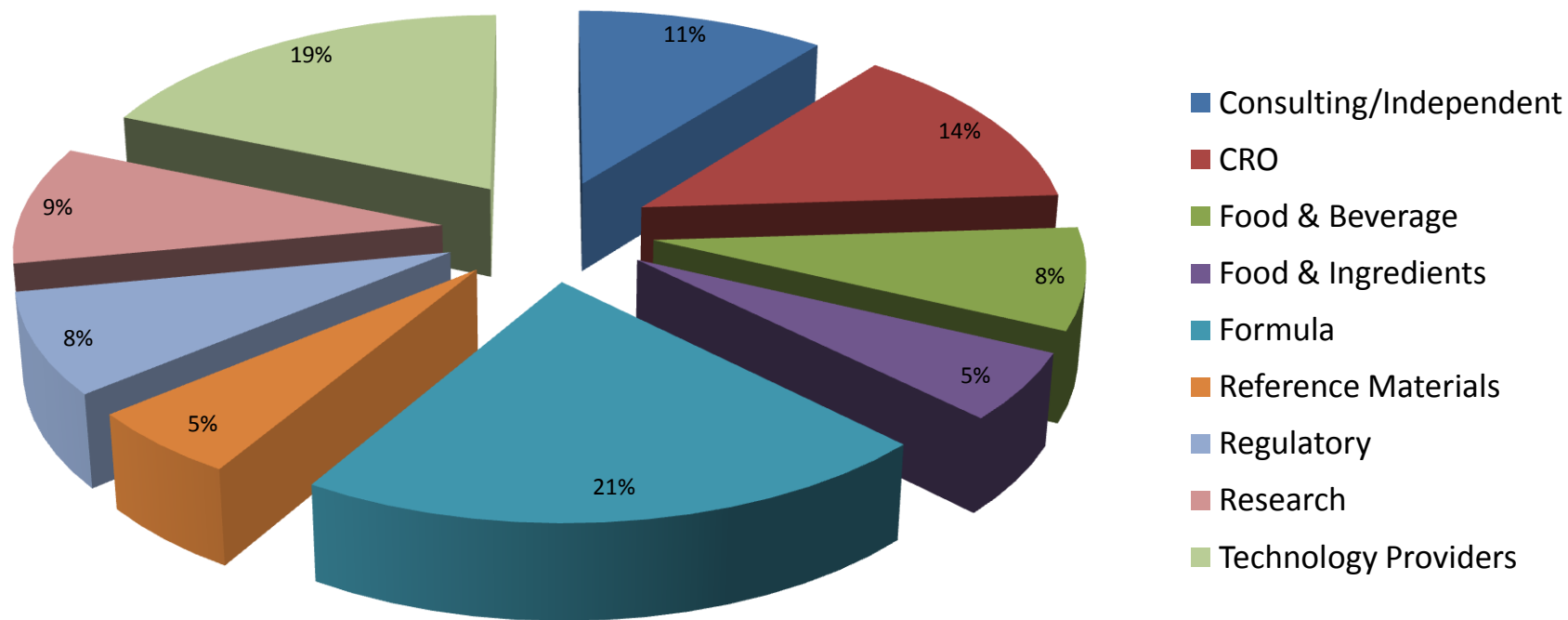


AOAC SPIFAN Registrants by Broad Perspectives





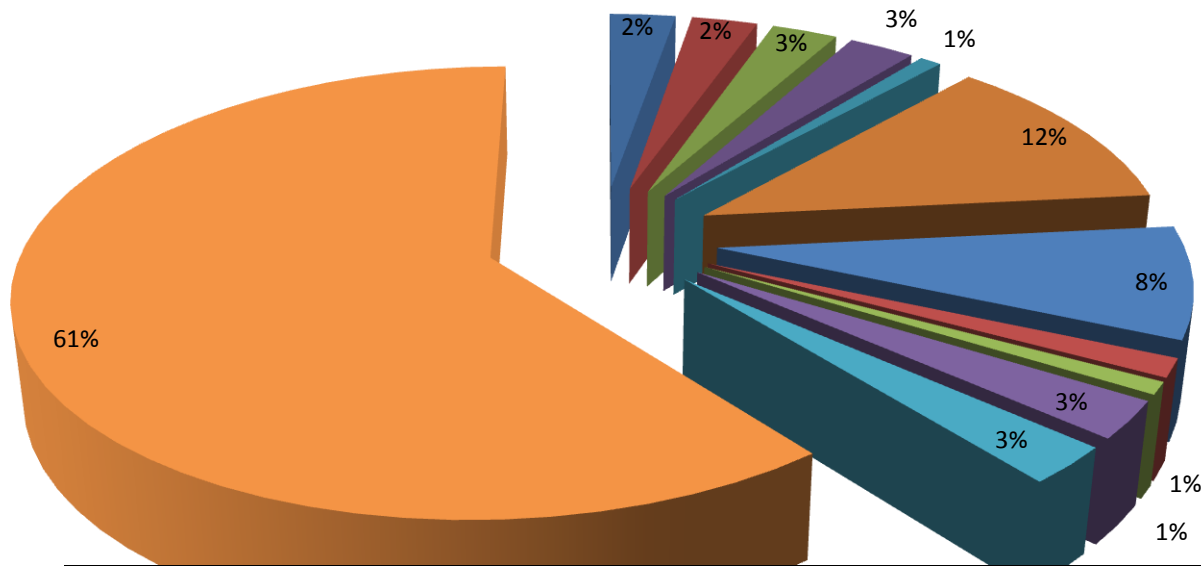
AOAC SPIFAN Registrants by Specific Perspectives





AOAC SPIFAN Registrants by Region

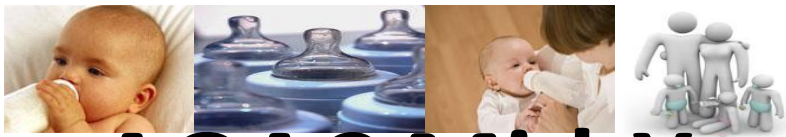
- Argentina
- Belgium
- Canada
- China
- Ireland
- Netherlands
- New Zealand
- Singapore
- Switzerland
- United Kingdom
- Uruguay
- USA





AOAC Stakeholder Panel Role and Responsibilities

- To form working groups to draft SMPR(s) based on specific priorities as specified by the Advisory Panel
- To provide comments on draft standard method performance requirements
- To respond to calls for methods and calls for experts as applicable or appropriate
- Most importantly, share your perspective.
 - To attend stakeholder panel meetings and deliberate on and adopt voluntary consensus standards



AOAC Mid-Year Meeting Activities

- No standards developed or launching
 - no representative voting panel vetted for this meeting
- Updates on international activities
 - Experience of methods going through Codex process
 - Proficiency Testing Taskforce and Program pilot
 - Updates from Working Group chairs regarding their nutrients for which there are no First Action methods
 - INCA ideas for future endeavors
- ERP meets on Wednesday, March 16, 2016 to review methods for First Action, tracking of First Action OMAs, review of OMA for Final Action recommendation



Questions?



Contact Information

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Darryl Sullivan

Covance Laboratory

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Alicia Meiklejohn – Director, Scientific Business Development, ameiklejohn@aoac.org,
(301) 924-7077 x101

Scott Coates – Chief Science Officer, scoates@aoac.org, (301) 924-7077 x137

Deborah McKenzie – Sr. Director, Standards Development & Research Institute,
dmckenzie@aoac.org, (301) 924-7077 x157

Delia Boyd – Program Manager, Standards Development, dboyd@aoac.org,
(301) 924-7077 x126

STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

CCMAS 37th session, February 22-26, 2016

**D. Sullivan (AOAC), E. Konings (AOAC), W. Wargo (AOAC),
M-N Bourquin (ISO), M. de Vreeze (ISO), S. Espeillac (ISO),
J. Evers (IDF), H. van den Bijgaart (IDF), A. Dubois (IDF)**





Meetings

- Inter Agency Meeting
- Permanent Working Group on Endorsement of Methods of Analysis and Sampling
- Codex Committee on Methods of Analysis and Sampling (47 member countries, observers from 17 international organizations)



Recomendations CCMAS to CAC (1)

Adopt as Type II (dispute resolution) methods:
vitamin B12, pantothenic acid, total nucleotides,
iodine, fatty acids including trans fatty acids,
vitamin A (Retinyl palmiate, Retinyl acetate).



Recomendations CCMAS to CAC (2)

Adopt methods for vitamin E and myo-inositol as Type II, provided that CCNFSDU 2016 confirms that the forms to be analyzed according to CODEX *STAN 72* match those analyzed by the respective methods.



Recomendations CCMAS to CAC (3)

- Adopt the analytical method for Chromium, Molybdenum, and Selenium as Type III (alternative method). CCMAS developed criteria allowing multiple methods to be used
- None of current methods meet criteria (CODEX provision), but new proposed method is best available



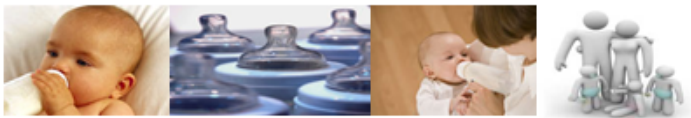
SPIFAN to consider (1)

- Ensure *CODEX STAN 72* provisions are included in SMPRs (levels, expression, nutrient compounds (*CAC/GL 10*))
- Importance and priority of Criteria Approach, and impact to AOAC/ISO/IDF methods.
Does SPIFAN support Criteria Approach for minerals/trace elements?
- Consider including current Type II methods in SLV to gather comparison data



SPIFAN to consider (2)

- CODEX considers CODEX provisions, and no (more strict) national regulations, which will affect its view re required method performances
- Need for ongoing coordination between AOAC/ISO/IDF delegations attending CCNFSDU/CCMAS/CAC
- Inclusion of CCMAS country delegates in SPIFAN stakeholder process



SPIFAN to consider (3)

- Gap between industry control methods and authority methods re 'expensive equipment'. Consider advice for developing countries
- No awareness of actual disputes in area of nutrients. No priority for some delegations
- Collaborative approach with CCMAS to review/assist with updating methods and removal of outdated methods



Preparations for CCNFSDU 2016

- Update SMPR for Cr/Mo/Se to include CODEX provision. Demonstrate that method is able to meet LOQ. Apply for method modification.
- Demonstrate that vitamin E succinate (*CAC/GL 10*) is included or not necessary to be included
- Collect information to demonstrate that applicability of myo-inositol in SMPR covers *STAN 72, GL 10* provisions



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN) (AOAC/ISO COOPERATIVE)



Erik Konings, Nestlé

SPIFAN Working Group Chair, Folic Acid

Chair, ISO/TC 34/WG 14 – Vitamins, Carotenoids and Other Nutrients

Erik Konings was born in the Netherlands. After completing Secondary school in 1977, he studied higher professional laboratory education with majors in analytical and clinical chemistry. After graduating in 1984, he started his professional career at the then called Food Inspection Service in Maastricht, the Netherlands. During 1989 to 1996 he was involved with the development of analytical methods for the analysis of vitamins in food and food products.

In 1996 he started his PhD study “Dietary folates in human nutrition” in collaboration with the departments of Human Biology and Epidemiology of Maastricht University.

During this study, which he completed in 2001, he obtained a MSc-degree in epidemiology. Since 1998 he was appointed as Senior Scientific Staff Officer at the department Research & Development of the Food and Consumer Product Safety Authority (VWA) in the Netherlands. He was (co)author of more than 30 scientific publications.

In 1997 he became a member of the Methods Committee on Food Nutrition of AOAC International and since 2001 he is convenor of a working group on vitamins & carotenoids of the European Committee for Standardization (CEN). In September 2008 he started at the European Food Safety Authority (EFSA) in Parma, Italy, for a secondment as Scientific Officer at the Data Collection and Exposure Unit and from there accepted, in June 2009, a position as Project Manager at the Quality and Safety Department of Nestlé Research Centre in Lausanne, Switzerland. Per September 2010 he was appointed as Group Manager of the Method Management Group at the Quality and Safety Department of Nestlé Research Centre in Lausanne, Switzerland.

Since 2009 he is member of the International Dairy Federation (IDF), Standing Committee Analytical Methods for Additives and Contaminants, and participates in Codex Committee for Methods of Analysis and Sampling (CCMAS) since 2010.



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)



Jaap Evers, International Dairy Federation (IDF)

Dr. Jaap Evers has 30 years of combined experience in analytical R&D and methodology development, quality assurance, global harmonisation of analytical standards and regulatory advocacy. He started his career in 1984 as a research chemist in an industrial laboratory in the Netherlands and joined the New Zealand dairy sector in 1988 where he had several senior technical, R&D and managerial roles. As from 1 March 2015, he holds two 0.5 FTE roles, i.e. Senior Regulatory Manager – Global Standards in Fonterra’s corporate regulatory team, and Global Dairy Sector Leader – Standards for the International Dairy Federation. Both roles focus strongly on international harmonization of standards affecting the global dairy sector.

STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

AOAC-ISO-IDF Collaboration

Erik Konings, Nestlé/Jaap Evers, IDF

Gaithersburg, MD

March 15 , 2016





New Work Item Proposals launched by ISO/IDF

ISO: (ISO TC34/WG 14)

- Vitamin K
- Carnitine/Choline
- Vitamin B₁, B₂, B₃, B₆

ISO/IDF: (ISO TC 34/SC5)

- Chloride
- Minerals and trace elements by ICP-AES
- Minerals and trace elements by ICP-MS



Collaborations

Chloride

Study Directors: G. Jaudzems, Nestle Quality Assurance Center (Dublin OH), Ms. Tian Yan, and Ms. Wan Xin, Chinese Academy of Inspection and Quarantine Comprehensive Test Center (Beijing)

- Merge AOAC 2015.07 and AOAC 2015.08, scope extended to milk products and dairy

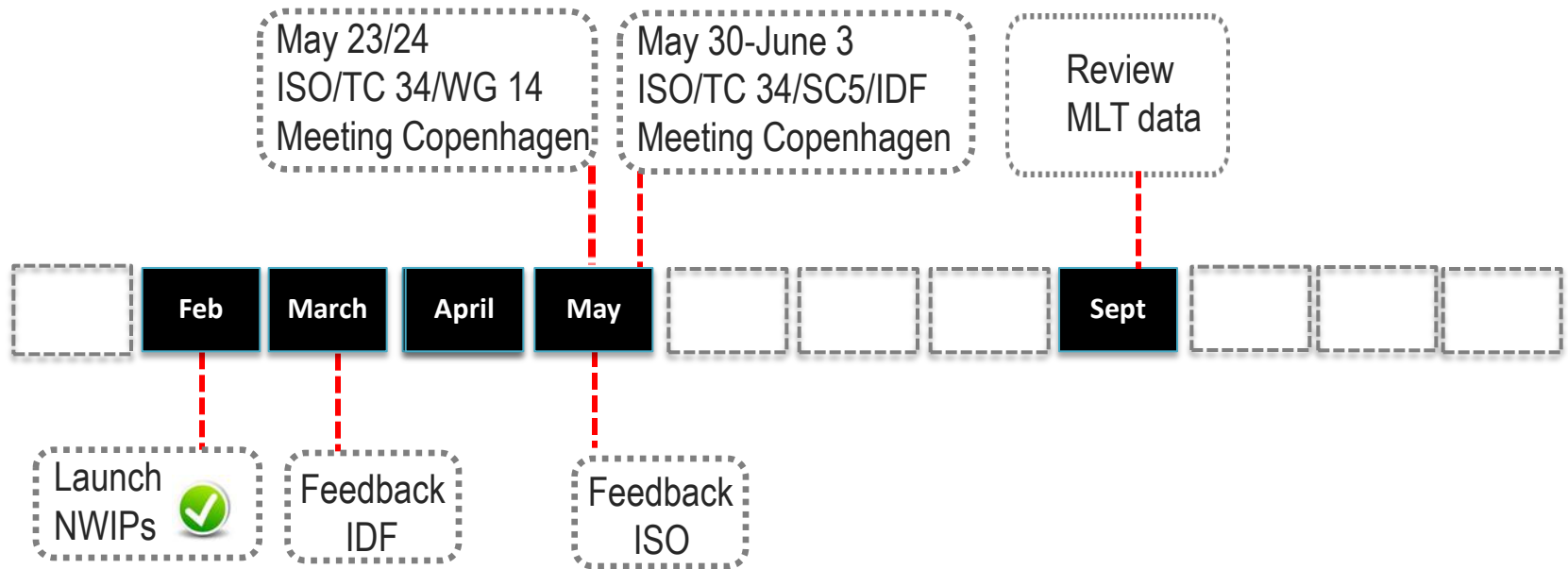
Minerals and trace elements

Study Directors: J. Thompson (Abbott), E. Poitevin (Nestlé), H. Cruijssen (FrieslandCampina)

- Merge MTE-1 and MTE3, scope extended to milk products & dairy



2016 timeline ISO/IDF methods





Status

- Finalization/review MLT protocols
- Identification and invitation of MLT labs
- Alignment on samples and shipment
 - All SPIFAN II samples will be included
- Include IDF feedback (Mid March) in MLT protocols minerals/trace elements/chloride
- ISO TC34/WG14 discussed other methods at its October 2015 meeting



Summary

Efforts are ongoing to prepare for a next set of jointly developed and harmonized analytical methods



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Ziting Zhang, EUCCC

Senior Government Affairs Desk Manager, Paediatric Nutrition Desk, European Union Chamber of Commerce in China

Ziting joined the European Union Chamber of Commerce in China in 2009, and is based in Beijing. She has been responsible for running the Paediatric Nutrition (PN) Desk since 2012. In this role, she is in charge of managing the daily operations of the industry association and working closely with member companies on the design and implementation of strategies and plans for the PN Desk. The core of her work focuses on advocacy on behalf of the paediatric nutrition industry, including the monitoring of related policies and regulations, coordinating action among international and domestic stakeholders and maintaining external relationships with relevant industry players, organisations and institutions, and government authorities.

Prior to joining European Chamber, Ziting worked for Deutsche Welle, the German international broadcaster in Berlin, where she was involved in coordinating and conducting interviews, and other journalistic activities.

Ziting Zhang holds a M.A. in Media Science and North American Studies from Freie University in Berlin, Germany.

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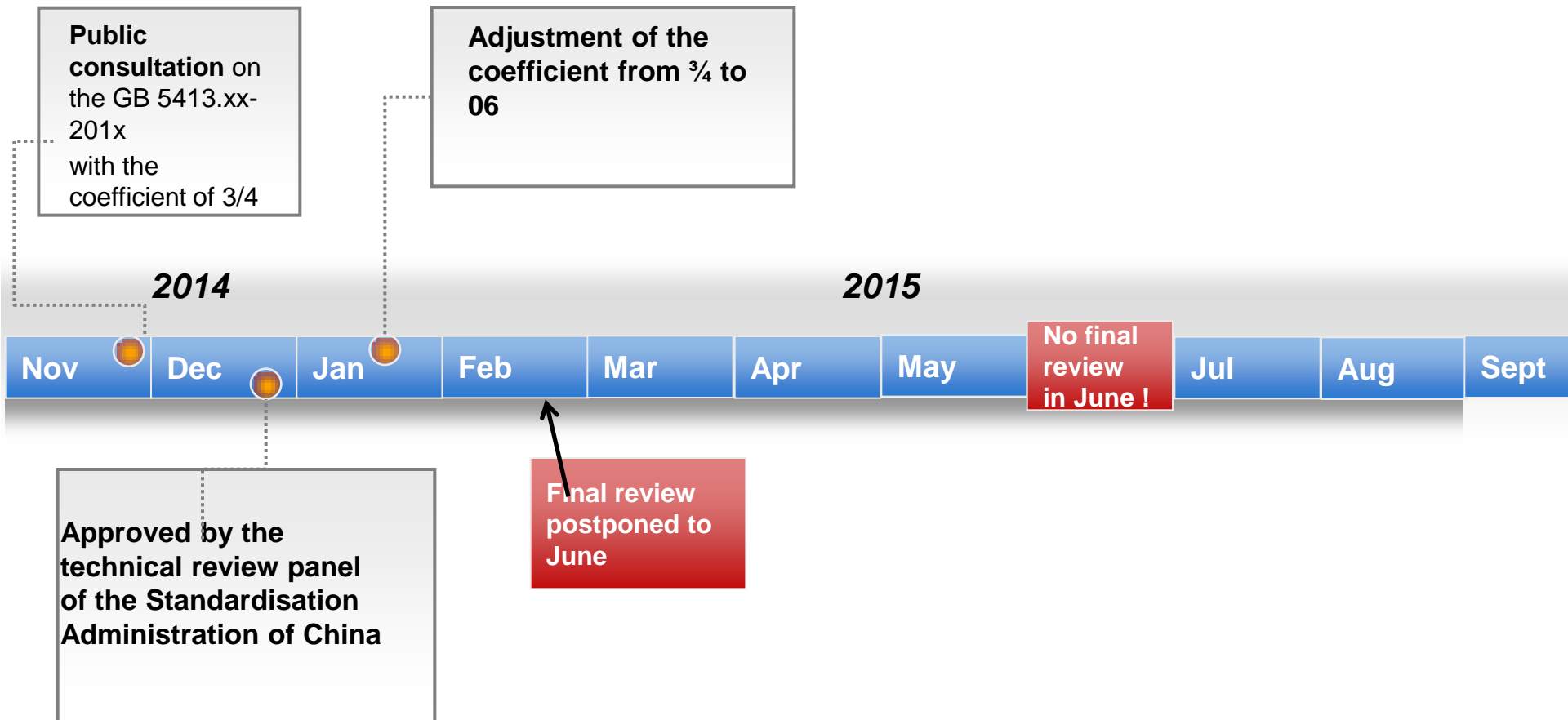
Whey Protein: Casein Ratio China Update

Ziting ZHANG
March 15th 2016



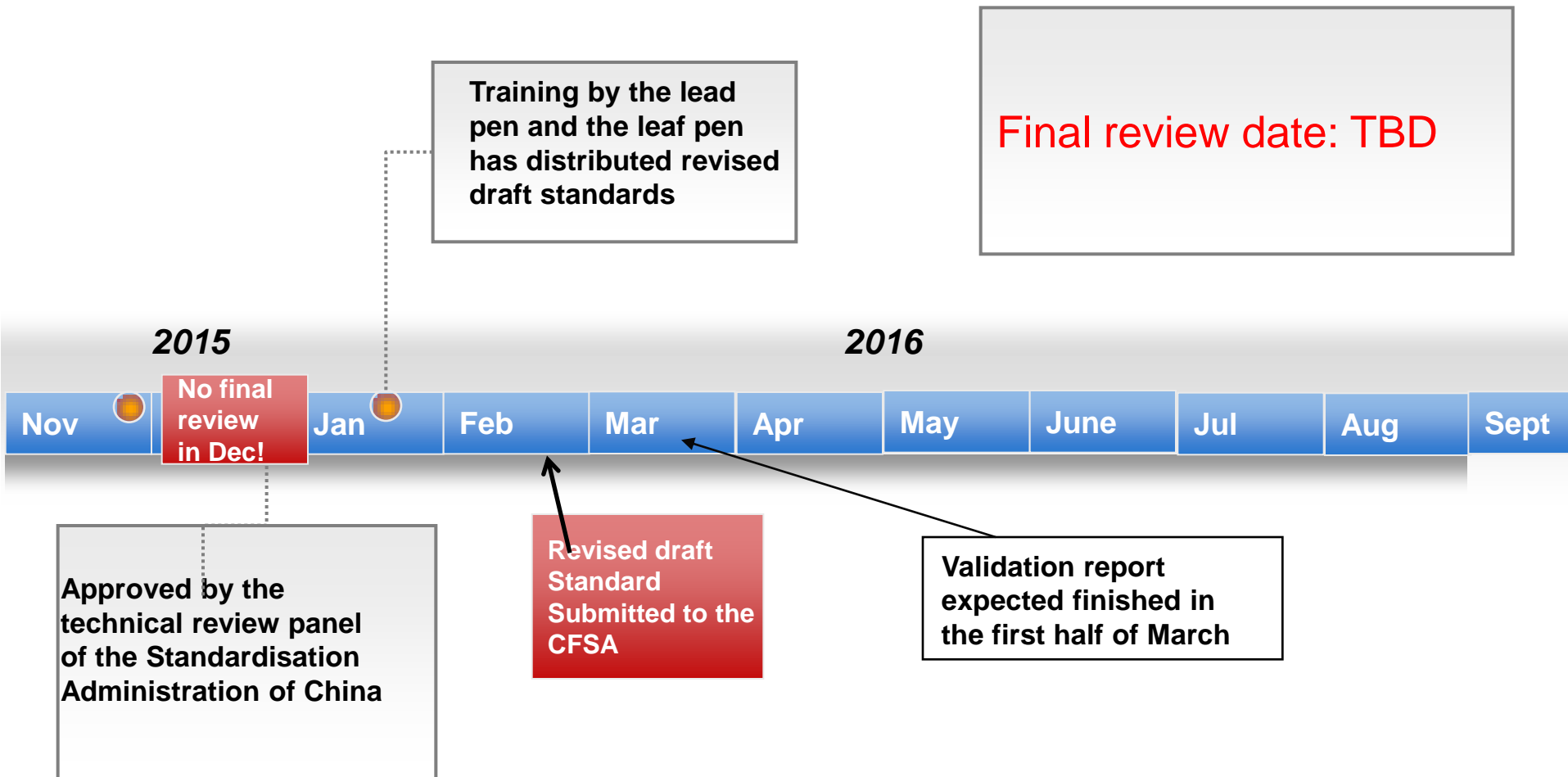


Timeline of the method of whey protein





Timeline of the method of whey protein





Changes in the revised standard

- **change from using peptide as standard to using protein as standard**



Next step

- Plan to meet with the CFSA and the NHFPC in March to understand their positions
- The final report of the validation shall be ready in the first half of March
- Key messages from companies:
 - Due to the revision, the standard shall be considered as new standard;
 - The change of the standard materials cannot help improve the accuracy of the testing method

Thank you

Ziting Zhang

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STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)



Don Gilliland, Ph.D., Abbott Nutrition
Co-Chair - Laboratory Proficiency Testing Advisory Taskforce

Donald (Don) L. Gilliland is a Senior Research Scientist in the Analytical Research and Services, External Engagement department at Abbott Nutrition. In this capacity, Don is a technical lead in the identification, assessment, development, validation, training and implementation of reference nutrient methods within Abbott Nutrition and external testing agencies.

Don has been with Abbott Nutrition for nearly 25 years. During his tenure he has been a lead scientist in the development and implementation of Liquid Chromatographic (LC) and LC-tandem mass spectrometric (MS/MS) based methods for determination of water-soluble and oil-soluble vitamins in Infant Formula and Adult Nutritional products as well as vitamin commodities and premixes.

Don is an active participant in AOAC SPIFAN and SPSFAM initiatives to identify reference methods suitable for testing Infant Formula and Adult Nutrition products and Vitamin Ingredients, respectively.

Don holds a B.S. degree in Chemistry from Muskingum College (New Concord, OH USA) and a Ph.D. in Chemistry from Purdue University (West Lafayette, IN USA).

Melissa Phillips, Ph.D., NIST
Co-Chair - Laboratory Proficiency Testing Advisory Taskforce

Melissa Phillips currently works for the Organic Chemical Metrology Group, Chemical Sciences Division (formerly Analytical Chemistry Division) of the National Institute of Standards and Technology, Gaithersburg, MD where is evaluated various approaches for integration of data from two-dimensional liquid chromatography (LCxLC) for purposes of comparing quantitative data.

She also works with certified concentrations for water-soluble vitamins in food and dietary supplement standard reference materials (SRMs) (e.g. infant formula, baby food, whole milk powder, whole egg powder, soy flour, and fortified breakfast cereal) using various extraction techniques and analytical methods such as liquid chromatography with isotope-dilution mass spectrometric detection (LC-ID-MS and LC-ID-MS/MS). She developed several methods including the following:



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

- Developed a method for high-precision determination and certified concentrations of choline and carnitine in food-matrix SRMs using microwave digestion and LC-ID-MS. Developed methods for high accuracy and high precision determination of ammonium and phosphate in a fertilizer SRM by ion chromatography with conductivity detection (IC-CD)
- Developed methods and certified concentrations of relevant active and marker compounds in botanical dietary supplement and natural product SRMs (e.g. Vaccinium berries, soy, kudzu, red clover) using various extraction techniques and analytical methods such as liquid chromatography with absorbance (LC-Abs), gas chromatography with ID-MS, IC-CD, and LC-ID-MS.
- Developed methods for separation of biomarker isomers by LC-Abs.
- Administered a quality assurance program for dietary supplement laboratories, including selection and shipment of samples, communication with participants, collection and analysis of data, and formulation and distribution of final reports.

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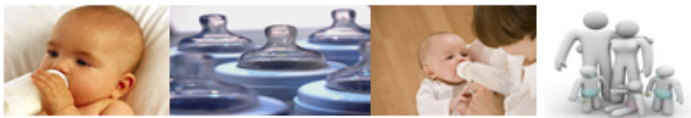
AOAC Proficiency Testing – Pilot Program

Don Gilliland; Abbott Nutrition
and

Melissa Phillips; NIST
Gaithersburg, MD USA

March 15, 2016





Proficiency Testing Task Force – Timeline

- Sep 2015:
 - Task Force met with SPIFAN Stakeholders in Los Angeles
- Oct 2015-Feb 2016:
 - Task Force Regular Teleconference Meeting - Pilot Structure
- Feb 2016
 - Documentation for pilot were distributed to SPIFAN Stakeholders for comment
 - Documentation for pilot finalized
- Mar 2016: Matrices selected for pilot
 - Samples to be shipped to participating labs
- Apr-May 2016: Results expected from participants
- June 2016: Report on pilot expected to be available



Proficiency Testing Task Force – Pilot Study

- Nutrients, Reported Forms and Units
 - Based on SMPRs
 - OMA 2011.007 (myo-Inositol) OMA 2012.008 (Iodine)
 - OMA 2011.008 (Nucleotides) OMA 2012.009 (Pantothenic Acid)
 - OMA 2011.005 (Vitamin B₁₂) OMA 2011.003 (vitamin A)
 - OMA 2011.010 (vitamin E) OMA 2011.009 (ultra-trace minerals)
 - OMA 2012.011 (fatty acids)
- Samples
 - SPIFAN II Materials - Two milk-based infant formulas (Nucleotides)



Proficiency Testing Task Force – Pilot Study

- Laboratories
 - Six Total
 - Representation from US and Europe
 - With and Without SPIFAN Experience
- Methods
 - AOAC OMA (SPIFAN) and/or Other method
- Timeline
 - Samples will be distributed in late March 2016, with results due 30 days after receipt.
 - Final report from the pilot is expected to be available in June 2016.



Proficiency Testing Task Force – Post Pilot Study

- Feedback From Labs
 - Instructions
 - Data Reporting Format
- On Line Data Reporting Form Programming
- Final SPIFAN PT Program Format
 - Address Needs of Accredited Proficiency Program – Traditional PT
 - Additional Use of Data (QC, Method Reproducibility, Capacity Building)
 - Sample Composition, Testing Frequency, Cost
- Interest in SPIFAN PT



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

WORKING GROUPS/CHAIRS DISCUSSIONS

1. **Amino Acids** *Ping Feng(Wyeth)/Wes Jacobs (Abbott)*
2. **Biotin** *George Joseph (AsureQuality)/Jean-Luc Deborde (SCL)*
3. **B Vitamins (B₃)** *Louis Salvati (Abbott)*
4. **Carotenoids** *Greg Hostetler (Perrigo)*
5. **Fluoride** *Chris Blake (Nestlé)*
6. **Fructans (FOS)** *Sean Austin (Nestlé)*
7. **GOS** *Sean Austin (Nestlé)*



STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)



Robert Rankin

International Formula Council (IFC)

Robert Rankin is the Associate Director for the International Formula Council (IFC), an association of manufacturers and marketers for formulated nutrition products, e.g., infant formulas and adult nutritionals.

Robert has worked with IFC since 2005, and is fully engaged in a number of regulatory, legislative, administrative management and other areas that utilize his expertise. Robert works with officials from the U.S. Food and Drug Administration and other governmental agencies regarding industry issues, and has extensive experience in the development and communication of industry positions. Additionally, he has worked with the World Health Organization and has testified before U.S. state legislatures and local authorities on industry issues. Robert also manages IFC staff on numerous activities, including document development, member correspondence, third party communications, and website updates.

Prior to working with IFC, Robert spent two years at the Grocery Manufacturers Association. He is a graduate of Duke University, where he earned a BA in Public Policy Studies, with a minor in History. Robert resides in Easton, Maryland, with his wife and two children.

**Participants Interested in the Proficiency Program (PT)
Program, please sign up at the following location:**

<https://form.jotform.com/60736266233152>

or

The sign-up sheet at the resource table

Delia Boyd – Program Manager, Standards Development, dboyd@aoac.org,
(301) 924-7077 x126