AOAC INTERNATIONAL

*The Scientific Association Dedicated to Analytical Excellence®*

# THE FOURTEENTH MEETING

## of the

## AOAC Stakeholder Panel on

## Infant Formula and Adult Nutritionals

Meeting at:
**Sheraton Dallas Hotel**
400 N. Olive Street
Dallas, TX, USA

## Saturday, September 17, 2016

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

# AOAC INTERNATIONAL

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

## Meeting at the Sheraton Dallas Hotel

400 N. Olive Street, Dallas, TX 75201, USA

# STAKEHOLDER PANEL - DRAFT MEETING AGENDA

***Saturday, September 17, 2016***

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

**SPIFAN Chair: Darryl Sullivan**

*(Covance Laboratories)*

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***Location: San Antonio B***

(Registration Opens at 7:30AM)

**I. INTRODUCTION (Bradford/Sullivan/Hill)**

Jim Bradford (AOAC)/Darryl Sullivan (Covance) will call the Stakeholder Panel meeting to order and introduce/welcome all participants. In addition, the AOAC policies for Antitrust, Volunteer Conflict of Interest, and Use of Association Name and Insignia will be reviewed.

**II. AOAC SPIFAN OVERVIEW (Sullivan)**

Darryl Sullivan (Covance) will provide an overview of the activities, accomplishments and achievements of SPIFAN I & II including methods adopted First/Final Action *Official Methods*$^{SM}$ since the last stakeholder meeting.

**III. UPDATE ON INTERNATIONAL ACTIVITIES**

*a.* **Codex Review and Adoption of AOAC SPIFAN Methods (Rankin/Sullivan)**
Robert Rankin (INCA) and Darryl Sullivan (Covance) will provide updates and lead discussions on the progress of AOAC SPIFAN methods through the Codex system.

*b.* **Upcoming Codex Meetings (Rankin)**
Robert Rankin (INCA) will highlight efforts in preparation for the upcoming Codex committee meetings for which AOAC SPIFAN methods may be under consideration including anticipated deadlines.

*c.* **Review of AOAC SMPRs and Codex Stan 72 (Coates)**
Scott Coates (AOAC Chief Scientific Officer) will report on a comparison study of AOAC SPIFAN SMPRs and the Codex Standard 72 for infant formula.

*d.* **AOAC/ISO/IDF Cooperative Update (Konings/van den Bijgaart)**
Erik Konings (Nestlé) and Harrie van den Bijgaart (Qlip Laboratories) will provide a report on ISO/IDF activities.

*e.* **Update on Global Outreach (Sullivan)**
Darryl Sullivan (Covance) will provide an update on AOAC's global outreach efforts.

## IV. UPDATE ON INFANT FORMULA PROFICIENCY TESTING (PT) PROGRAM TASKFORCE (Sullivan)

Darryl Sullivan (Covance) will provide an update on the Proficiency Testing pilot program.

## V. DISCUSSION ON AOAC PROCESSES & PRIORITY NUTRIENTS (McKenzie/Working Group Chairs)

Deborah McKenzie (AOAC) will provide information on AOAC processes in relation to the development of standards and will also review AOAC policies and procedures.

The Working Group Chairs will lead discussions relating to analytical challenges with Carotenoids, Fluoride, and Folic Acid (folate).

## VI. AOAC SPIFAN FUTURE ENDEAVORS (Meiklejohn/Rankin)

Alicia Meiklejohn (AOAC) and Robert Rankin (INCA) will update the stakeholder community on the potential future activities for AOAC SPIFAN.

## VII. TIMELINES/DEADLINES/WRAP-UP

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)**

**LUNCH ON YOUR OWN (12:00PM–1:00PM)**

**AFTERNOON BREAK (3:15PM)**

# 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.

* * * * * *

Adopted by the AOAC Board of Directors: September 24, 1989
Revised: June 13, 1991; February 26, 1992; March 21, 1995; October 1996

# 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

# 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

# AOAC INTERNATIONAL
# Stakeholder Panel Voting Members

AOAC INTERNATIONAL (AOAC) assembles stakeholder panels to develop voluntary consensus standards. While AOAC maintains transparency and openness in accordance with national and international guidance and regulations for standards development and its policies and procedures for assembling stakeholder panels, its policies and procedures also ensures that there is a balance of interests and perspectives in achieving consensus of the stakeholder panel.

**Due Process and Balance**

All AOAC stakeholder panels are diverse and can vary in size. Where a stakeholder panel is not balanced or if it is significantly large whereby consensus of the general assembly may be impractical, a balanced representative voting panel will be used to demonstrate consensus. AOAC encourages ALL stakeholders to participate in deliberations during stakeholder panel meetings and working group meetings, in addition to participating during any posted comment periods. To ensure that there is a balance of interests and perspectives, a ***representative subset*** of the stakeholder panel, the voting members, is selected to reach consensus for the development of AOAC voluntary consensus standards.

**Composition**

Voting members represent the perspectives of the larger stakeholder panel. The voting members consist of no more than ¼ to 1/3 of the total number of stakeholders in registered. Primary and secondary representative voting members are approved. Every attempt is made to approve a panel of voting members that represents all perspectives of the stakeholder panel. In the event of a primary voting member is not able to attend, and no alternate has been approved, the stakeholder panel chair, working with AOAC can provisionally approve an alternate from those in attendance to assure balance and lack of dominance. For stakeholder panels with scopes including diverse topics, the voting member representatives may be rotated to include other stakeholders for successive meetings to ensure a lack of dominance by any particular stakeholder.

**Approval Process**

AOAC works with the chair of the stakeholder panel and potentially other key stakeholders to develop a proposed representative voting member panel. Following AOAC policies and procedures, the proposed voting members and documentation are submitted to the AOAC Official Methods Board (OMB) for review and approval. The OMB's review ensures that the proposed panel is balanced in interests and perspectives representing the stakeholder panel and a lack of dominance.

**Roles and Responsibilities**

Every stakeholder has a voice and every stakeholder is entitled to state his/her or organizational perspective(s). This is due process. In developing AOAC standards, stakeholder consensus is demonstrated by 2/3 vote (67%) in favor of a motion to adopt a standard. It is important to note: Individual voting members do not have any additional weight, voice or status in stakeholder deliberations than other stakeholders. The role of the voting members is to demonstrate the consensus of the stakeholder panel. Voting members may vote in favor or against any motion and/or they may abstain. Stakeholder panel chair will moderate voting process. AOAC carefully documents the vote. It is important for voting members to be in the room during the time for voting. It is also important for voting members to inform the chair of his/her inability to serve as a voting member.

## Definitions

***Quorum*** — The number of members who must be present in order to validly transact business. It is determined by the number of members present, not the number present and voting. (Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 151).

***Representative Voting Panel Members*** — Every member has an obligation to vote and the right to abstain.

***Abstentions*** — Abstentions reduce the number required to obtain a majority of those present and voting. They are only counted to confirm the presence of a quorum. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 237).*

## Stakeholders Privileges

***Order*** — Meetings should address only one item of business at one time (only one pending motion at a time). Chairs should not permit digression or introduction of different topics until the business at hand is resolved. No pending motions while changing topics. (*Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 1)*.

All business must be conducted with order and should be done fairly and impartially. The presiding officer should impartially ensure that each member has an opportunity to speak. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. pp. 1-2).*

***Equality*** — All members have equal opportunity to propose motions, to participate in debate, to vote, to serve on committees or as an officer, to share in activities according to the member's abilities. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 2).*

***Justice*** — All members have the right to ask questions, to be informed, to have complex motions explained by the chair. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 2).*

***Minority Rights*** — Dissenting members have equal rights to voice opposing or minority opinions and strive to become the majority. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 2).*

***Majority Rights*** — No members, board, or officers have the right to dictate or control decisions unless the member grant such rights

Members may not take any action in conflict with federal, regional or organizational laws or policies.

Decisions are based on the will of the majority.
*(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 2).*

# 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.

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# STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

## SPIFAN OVERVIEW

**Darryl Sullivan**

**Covance Laboratories**

**Dallas, TX**

**September 17, 2016**

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# 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 Mid-Year Meeting
- AOAC SPIFAN Activities at AOAC Annual Meeting

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# 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

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# 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, Illinois - 2013
  - 2/7 – AOAC Mid-Year Meeting, Gaithersburg , Maryland- 2014
  - 3/7 – AOAC Annual Meeting, Boca Raton, Florida – 2014
  - 4/7 – AOAC Mid-Year Meeting, Gaithersburg , Maryland– 2015
  - 5/7 – AOAC Annual Meeting, Los Angeles, California – 2015
  - 6/7 – AOAC Mid-Year Meeting, Gaithersburg, Maryland - 2016
  - 7/7 – AOAC Annual Meeting, Dallas, Texas - 2016

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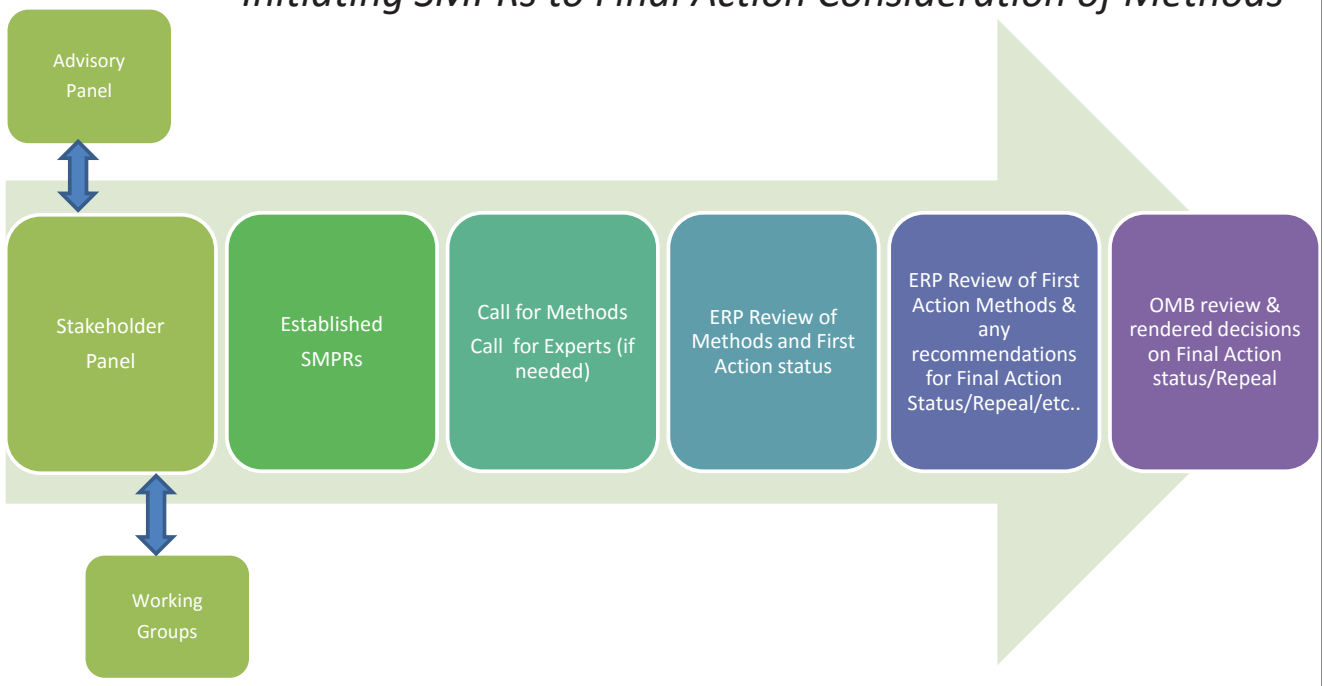
# AOAC Standards Development

*Initiating SMPRs to Final Action Consideration of Methods*

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# Stakeholder Panel Working Groups

- Present background and history on nutrient methods for stakeholder panel
- Develop draft SMPR
- Will present motions to the stakeholder panel on components of the standard method performance requirements
- Can participate in SPIFAN related in-person meetings

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# SPIFAN Working Groups

| | | | |
|---|---|---|---|
| **WG on Vitamin A** | Jon DeVries | **WG on Whey protein: Casein** | Lei Bao & Shane Rutherfurd |
| **WG on Vitamin D** | Don Gilliland | **WG on Fatty acids** | Mark Hill |
| **WG on Vitamin B12** | Esther Campos-Gimenez | **WG on Minerals & Trace Elements** | Eric Poitevin |
| **WG on Folic acid** | Erik Konings | **WG on Biotin** | George Joseph/Jean-Luc Deborde |
| **WG on Inositol** | Karen Schimpf & Harvey Indyk | **WG on Vitamin K** | Sneh Bhandari |
| **WG on Vitamin E** | Jon DeVries | **WG on FOS/GOS** | Sean Austin |
| **WG on Nucleotides** | Brendon Gill | **WG on Amino acids** | Wesley Jacobs & Ping Feng |
| **WG on Ultra Trace Minerals** | Joe Thompson | **WG on Carotenoids** | Greg Hostestler |
| **WG on Vitamin C** | Jayasharee Arcot & Lalitha Gowda | **WG on Fluoride and Chloride** | Christopher Blake |
| **WG on Choline** | Sneh Bhandari & Rajesh Girdhar/ Nick Cellars | **WG on Vitamins $B_1$, $B_2$, $B_3$, and $B_6$** | Louis Salvati |
| **WG on Pantothenic acid** | Shang-Jing Pan | **WG on SPIFAN Reference Materials** | Dan Schmitz/Wayne Wargo |
| **WG on Iodine** | Darryl Sullivan | **WG on SPIFAN Pesticide Contaminants** | Joe Boison |
| **WG on Carnitine** | John Austad & Guenther Raffler | | |

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# 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

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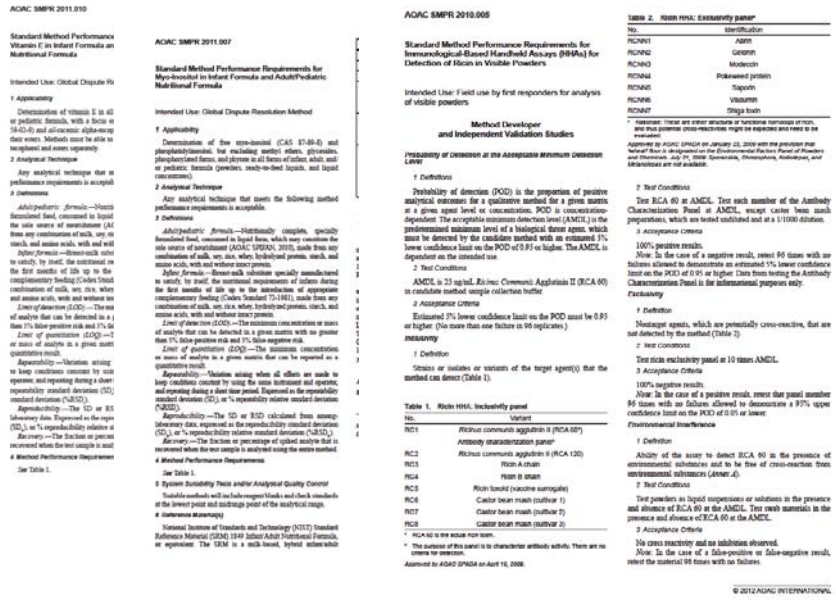
# Standard Method Performance Requirements

- ***Commonly referred to as - SMPRs***



AOAC SMPR 2011.010

Standard Method Performance Vitamin E in Infant Formula an Nutritional Formula

AOAC SMPR 2011.007

Standard Method Performance Requirements for Myo-Inositol in Infant Formula and Adult/Pediatric Nutritional Formula

AOAC SMPR 2010.005

Standard Method Performance Requirements for Immunological-Based Handheld Assays (HHAs) for Detection of Ricin in Visible Powders

Table 1. Ricin HHA: Inclusivity panel

| No. | Variant |
|---|---|
| RD1 | *Ricinus communis* agglutinin II (RCA 60*) |
| | Antibody characterization panel* |
| RC2 | *Ricinus communis* agglutinin II (RCA 120) |
| RC3 | Ricin A chain |
| RC4 | Ricin B chain |
| RC5 | Ricin toxoid (vaccine surrogate) |
| RC6 | Castor bean mash (cultivar 1) |
| RC7 | Castor bean mash (cultivar 2) |
| RC8 | Castor bean mash (cultivar 3) |

Table 2. Ricin HHA: Exclusivity panel*

| No. | Identification |
|---|---|
| RCNN1 | Abrin |
| RCNN2 | Cerotin |
| RCNN3 | Modeccin |
| RCNN4 | Pokeweed protein |
| RCNN5 | Saporin |
| RCNN6 | Viscumin |
| RCNN7 | Shiga toxin |

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# SMPRs

- Documents a community's analytical method needs
- Very detailed description of the analytical requirements
- Includes method acceptance requirements
- Used to qualify methods for AOAC approval in the *Official Methods*$^{SM}$ program
- Published as a standard

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# Performance requirements parameters for quantitative methods

- Analytical range
- Limit of detection
- Limit of Quantitation
- Repeatability
- Recovery
- Reproducibility

***4. Method Performance Requirements***

| | | |
|---|---|---|
| Analytical range | 0.01–5.0[a] | |
| Limit of detection (LOD) | ≤0.004[a] | |
| Limit of quantitation (LOQ) | ≤0.01[a] | |
| Repeatability ($RSD_r$) | 0.01[a] | ≤15% |
| | 0.2[a] | ≤7% |
| | 0.5[a] | |
| | 5.0[a] | |
| Recovery | 0.01[a] | 90–110% |
| | 0.2[a] | |
| | 0.5[a] | |
| | 5.0[a] | |
| Reproducibility ($RSD_R$) | 0.3 | ≤11% |
| | 0.6 | |
| | 1.0 | |
| | 2.5 | |
| | 5.0 | |
| Concentrations apply to (*1*) "ready-to-feed" liquids "as is"; (*2*) reconstituted powders (25 g into 200 g water); and (*3*) liquid concentrates diluted 1:1 by weight. | | |
| [a] µg/100 g expressed as cyanocobalamin in reconstituted final product. | | |

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# AOAC Mid-Year Meeting

- SPIFAN Meeting and ERP for SPIFAN Nutrient Methods Meeting

- SPIFAN Meeting
  - Updates on Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and Codex Committee on Methods of Analysis and Sampling (CCMAS) review of the submitted methods
  - Updates from working group chairs for nutrients with no First Action methods
  - Updates on ISO and IDF related activities
  - Updates on preparation for the AOAC Proficiency Testing Pilot
  - Updates on review of Whey Protein Casein Ration methods in China
  - Ideas for future SPIFAN activities

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# AOAC Mid-Year: ERP for SPIFAN Nutrient Methods

- Methods reviewed for
  - choline
  - amino acids
  - biotin
  - B vitamins
  - carotenoids
  - chloride
  - fluoride
  - folate
  - fructans
  - vitamin D

**First Action Methods**
- 2 biotin
- 1 chloride
- 1 choline
- 1 FOS
- 1 vitamin D

**Methods Selected for Final Action Consideration**
- biotin
- chloride
- Choline/Carnitine
- folate
- FOS
- Vitamin D

**Methods Recommended for Final Action**
- Vitamin C

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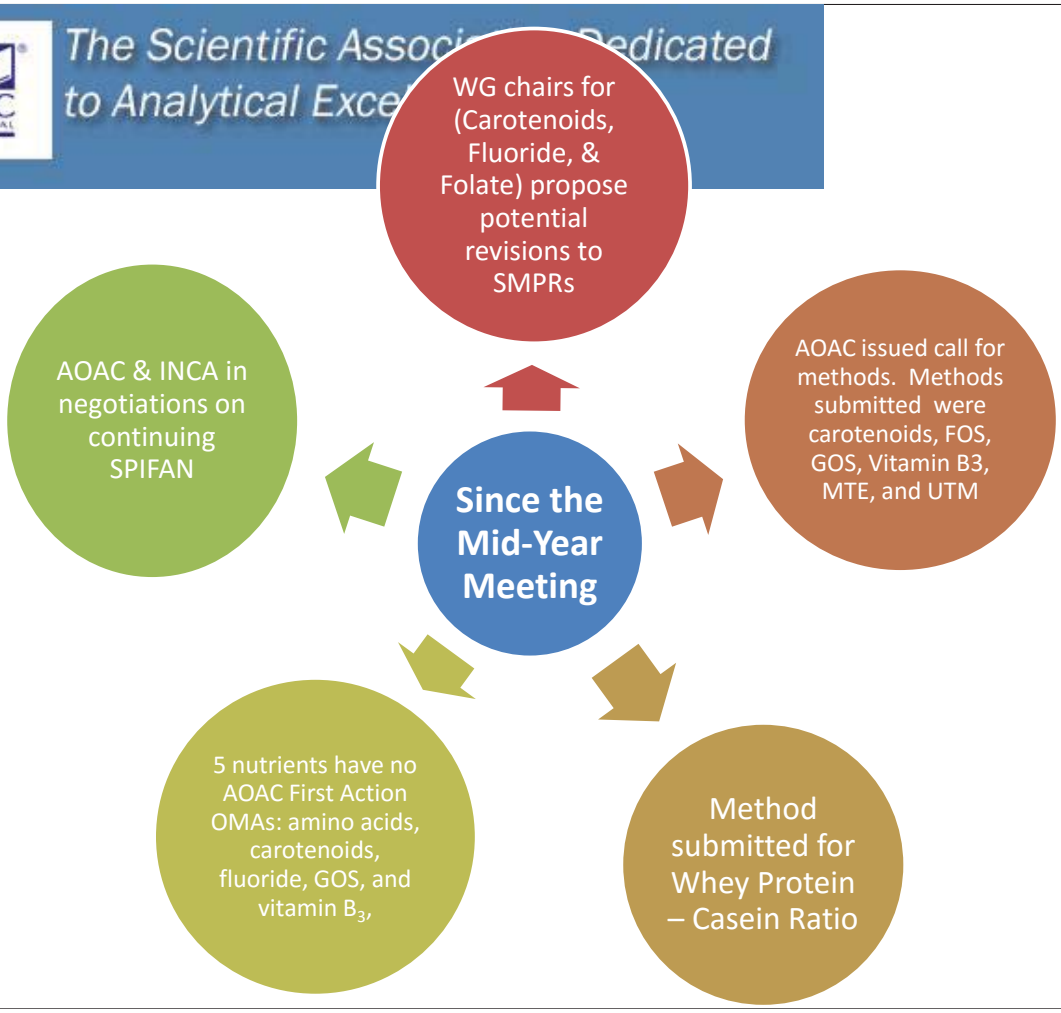


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# AOAC SPIFAN Whey Protein Casein Ratio

- Chinese regulations was to be modified impacting Whey Protein Casein Ratio determination
- Chinese government officials participated in process

- Timeline
  - 5/2012 – Working group formed to initiate developing SMPR for Whey Protein Casein Ratio methods
  - 6/2012 – SMPR approved
  - 9/2012 – ERP for SPIFAN Whey Protein Casein Ratio Methods adopted two methods as First Action OMA
    - ERP requested the methods be combined
  - 9/2013 – ERP met to review progress, but no further work was undertaken at the time
  - 9/2013 and ongoing – SPIFAN has been receiving updates on the Chinese government development & review of potential GB method
  - 9/2016 – New method submitted and ERP will be meeting to review method for First Action consideration and consider any progress to current First Action methods.

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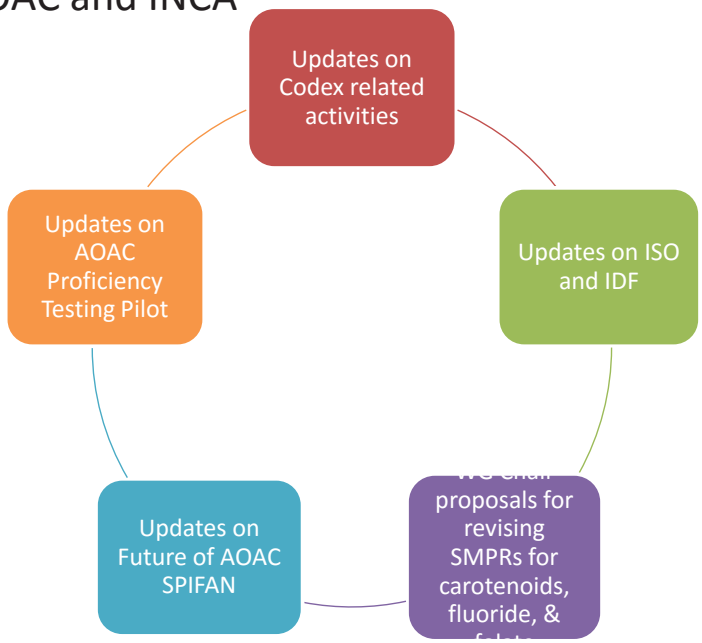
# September 2016 – SPIFAN Meeting & Activities

- Last stakeholder panel meeting under current agreement between AOAC and INCA

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# SPIFAN Organizational Registrants as of 9-2-2016

- Abbott Nutrition
- Agilent Technologies
- Archer Daniels Midland
- Arla Foods
- AsureQuality
- Ausnutria Hyproca
- Certified Laboratories
- Covance Laboratories
- Davisco Foods
- DSM Nutritional Products
- Eurofins
- First Source Laboratory Solutions
- Florida Dept. of Agriculture
- Fonterra Cooperative Group
- FrieslandCampina
- International Dairy Federation
- ISO
- INTI
- LATU
- Mead Johnson Nutrition
- Mérieux NutriSciences
- MilliporeSigma
- Nestlé
- Perrigo/PBM Nutritionals
- PhytoLab GmbH & Co.
- Pickering Laboratories
- R-Biopharm Rhone
- SCIEX
- Shimadzu Scientific Instruments
- Sigma Aldrich
- Sunshineville Health Products
- Thermo Fisher Scientific
- Tiense Suikerraffnaderji Analytical Services
- Unaffiliated
- USDA
- US FDA
- US NIST
- Waters Corporation

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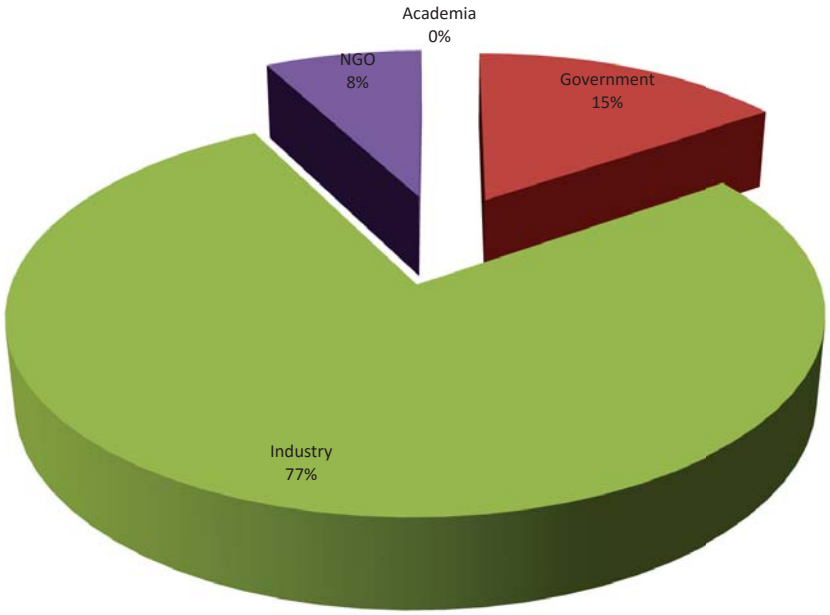
# SPIFAN Registrants by Broad Perspectives

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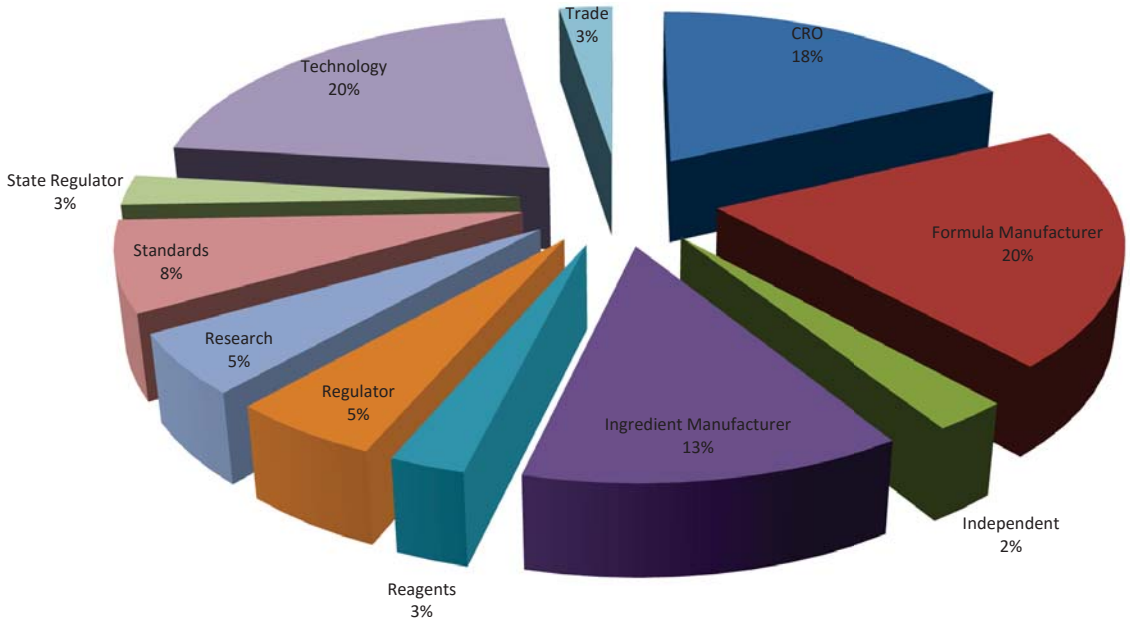
# SPIFAN Registrants by Specific Perspectives



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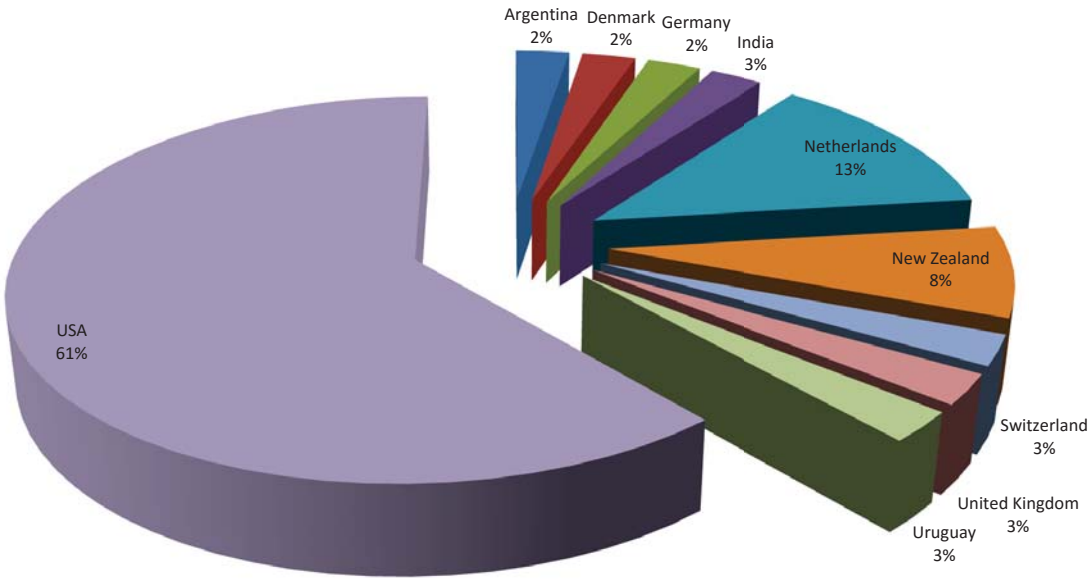
# SPIFAN Registrants by Regions

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# Proposed SPIFAN Representative Voting Members

| | |
|---|---|
| US Food and Drug Administration | Ausnutria Hyproca |
| LATU | Archer Daniels Midland / Arla Foods Ingredients |
| INTI | Davisco Foods / Tiense Suikerraffnaderji Analytical Services |
| NIST | DSM Nutritional Products / Sunshineville Health Products |
| Florida Department of Agriculture | Agilent Technologies |
| | Pickering Laboratories |
| AsureQuality, New Zealand | SCIEX / Shimadzu Scientific |
| Mérieux NutriSciences | R-Biopharm Rhone / MilliporeSigma |
| Eurofins | Thermo Fisher Scientific |
| First Source Laboratory Solutions | Waters Corporation |
| Nestle Research Center | Sigma Aldrich |
| Mead Johnson Nutrition | |
| Fonterra Cooperative | IDF |
| FrieslandCampina | ISO |
| Perrigo/PBM Nutritionals | |

alternates

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# 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

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# Related Roles and Responsibilities

- Official Methods Board
  - Vet and approve stakeholder panel chair & representative voting members for each meeting
  - Vet and approve ERP membership
  - Review ERP recommendations and render decisions regarding Final Action, Repeal or continuance
  - Assign OMB representative to serve as a resource to stakeholder panels and ERPs
- AOAC Stakeholder Panels
  - Meet in person to develop standards
  - Assign working groups to draft standards method performance requirements
  - Vetted representative voting members demonstrate consensus on behalf of stakeholders
- AOAC Working Groups
  - Draft standards, reconcile comments, present draft standards to stakeholder panel for approval
- AOAC Expert Review Panels
  - Review methods and meet in person to render decisions on methods for First Action Official Methods status.
  - Track First Action Official Methods and modify, if necessary
  - Recommend First Action methods ≤ 2 years to OMB for Final Action, continuance, or Repeal
- AOAC Staff
  - Business direction
  - Coordinate stakeholder panel, working group and expert review panel activities and meetings
  - Issue any calls for experts and methods
  - Provide trainings and orientations
  - Maintain website and communication
  - Document and publish actions and decisions
  - Publish approved standards and methods
  - Coordinate comments on standards and methods

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# AOAC Annual Meeting Activities

- Working Group Chair proposals for additional working group re-engagement on SMPRs for carotenoids, fluoride, and folate
- Updates on international activities
  - Experience of methods going through Codex process
  - ISO and IDF Activities Update
- Proficiency Testing Taskforce and Program pilot
- Ideas for SPIFAN future endeavors
- ERPs meet on Tuesday, September 20, 2016 to review methods for First Action, tracking of First Action OMAs, and/or review of OMA for Final Action recommendation
  - AOAC ERP for SPIFAN Nutrient Methods
  - AOAC ERP for SPIFAN Whey Protein – Casein Ratio Methods

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# Contact Information

SPIFAN Chair:
Darryl Sullivan
Covance Laboratory
Email: darryl.sullivan@covance.com
Telephone: (608) 232-2711

Jim Bradford – CEO and Executive Director, jbradford@aoac.org, (301) 924-7077 x102

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

# Questions?

# STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

**Robert Rankin,** INCA

Robert Rankin is a Senior Account Executive at Kellen, a global professional services firm specializing in trade associations, professional societies and communications.

Robert currently serves as Executive Director for the Infant Nutrition Council of America (INCA), an association representing manufacturers of formulated nutrition products, including infant formulas and adult nutritionals. Since 2005, Robert has worked closely with officials at key US Government agencies including the US Food and Drug Administration and US Department of Agriculture. He has also worked with the Centers for Disease Control and Prevention and other US/international government agencies. He has extensive experience in the development and communication of industry positions and has testified before U.S. state legislatures, the World Health Organization and local authorities on industry issues.

Since 2010, Robert has managed Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Project on behalf of the infant formula industry. Through SPIFAN, voluntary consensus standards and internationally recognized methods of analysis for over 40 nutrients in infant formula have been developed with the ultimate goal of having the methods adopted by Codex Alimentarius as Type II dispute resolution methods.

Robert also serves as President of the Calorie Control Council and Executive Director of the International Food Additives Council. Prior to Kellen, Robert spent two years at the Grocery Manufacturers Association where he worked in the Federal Affairs and Scientific & Regulatory Departments. Robert has a BA in Public Policy Studies from Duke University and lives in Maryland with his wife and two children.

# Codex Review and Adoption of AOAC SPIFAN Methods

Robert Rankin
Executive Director
Infant Nutrition Council of America

## Background

- SPIFAN created in part because CODEX infant formula methods were outdated and/or not validated for infant formula
- Original SPIFAN goal was/is to develop methods to replace current CODEX Type II methods
- Manufacturers produced product matrices that represent infant formulas on the market
- Stakeholders agreed Multi-Laboratory Testing studies were needed to support AOAC Final Action status
- Stakeholders also supported joint endorsement of SPIFAN methods by AOAC, ISO and IDF before submitting to CODEX

# CODEX Progress to Date

- INCA formed small group of SPIFAN stakeholders to work electronically and via phone to develop CODEX strategy
- INCA met with US Delegation to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in May 2015 to explore introduction of first SPIFAN methods into CODEX process.
- SPIFAN Codex Stakeholders developed background/rationale and considered key CCNFSDU Member Country delegations to educate on SPIFAN process and proposed methods

# CODEX Progress to Date

- Eight methods introduced/considered by CCNFSDU in November 2015
  - Vitamin A/E, Vitamin B12, Pantothenic Acid, Myo-inositol, Fatty Acids, Nucleotides, Iodine and Chromium/Molybdenum/Selenium
- All eight methods were referred to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for technical review and typing in February 2016
- CCMAS provided recommendations/feedback on all methods

# CODEX Progress to Date

- Endorsed methods for Vitamin A, Pantothenic Acid, Nucleotides and Iodine as Type II
- Endorsed method for Cr/Mo/Se as Type III
  - Also noted no methods for CODEX minimum level criteria
- Endorsed methods for Vitamin B12 and Fatty Acids as Type II but requested CCNFSDU clarification regarding existing methods
- Endorsed methods for Vitamin E and Myo-inositol provided CCNFSDU confirms forms are in accordance with CODEX Infant Formula Standard

# CODEX Progress to Date

- Codex Alimentarius Commission (CAC) adopted methods for Vitamin A, Pantothenic Acid, Nucleotides and Iodine as Type II in July
- CAC adopted method for Cr/Mo/Se as Type III
- SPIFAN Stakeholders developing responses to CCMAS questions on Vitamin E and Myo-inositol
- Company conducted additional testing to demonstrate Cr/Mo/Se meets CODEX minimum

## Next Steps

- Provide input to CCNFSDU for existing CODEX methods for Vitamin B12 and Fatty Acids
  - If CCNFSDU agrees, methods go to CAC for adoption as Type II in July 2017
- Submit responses to CCNFSDU for Vitamin E and Myo-inositol
  - If CCNFSDU agrees, methods go to CAC for adoption as Type II in July 2017
- SPIFAN ERP review new Cr/Mo/Se data and consider next steps

## Additional Next Steps

- SPIFAN method for Vitamin C to be introduced at CCNFSDU in December 2016
  - Expect referral to CCMAS for consideration and possible endorsement in May 2017, and possible adoption by CAC in July 2017
- SPIFAN methods continue to be submitted to CODEX
  - MTE, Chloride, B Vitamins, Vitamin K, Choline, Carnitine, Folate, Vitamin D, Biotin to CCNFSDU in December 2017

## Upcoming CODEX Meetings

- CCNFSDU 38 – December 5-9, 2016 (Hamburg)
  - Possible physical Working Group meeting to review SPIFAN methods
- CCMAS 38 – May 8-12, 2017 (TBD)
- CAC 40 – July 3-8, 2017 (Geneva)
- CCNFDSU 39 – December 4-8, 2017 (TBD)

## Questions?

## Thank you!

Robert Rankin
Executive Director
Infant Nutrition Council of America
rrankin@kellencompany.com

# 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 AND ADULT NUTRITIONALS (SPIFAN)

**Scott Coates,** AOAC INTERNATIONAL
*Chief Scientific Officer (CSO)*

Scott Coates is a 21-year AOAC veteran now serving as the AOAC Chief Scientific Officer. Dr. Coates joined AOAC in 1992 as a manager for the AOAC Research Institute, and ran the *Performance Method Tested* program until 2009 when he was promoted to become AOAC's Chief Scientific Officer (CSO). As CSO, Coates is involved in every major AOAC project, ranging from biological threat agent detection, food/environmental microbiology, and nutritional chemistry of infant formula. Coates was the lead author of the *Guideline for Standard Methods Performance Requirements* in the 19th edition of the *Official Methods of Analysis.* Coates is a University of Maryland alumni has a B.S. in microbiology and a M.S. in Biotechnology Management.

# Comparison of Codex Stand 72 Minimum Product Specifictions to AOAC Standard Method Performance Requirements

Assumption: 60 Kcal / 100 ml (g)
0.6 Kcal / g

| | **STAN 72** product specification minimum | | | | **AOAC LOQ** | |
|---|---|---|---|---|---|---|
| | As stated in STAND 72 | | Converted SMPR units | | | |
| biotin | 1.5 | ug/100 Kcal | 0.9 | ug/100g | 0.1 | ug/100g |
| folic | 10 | ug/100 Kcal | 6 | ug/100g | 0.5 | ug/ 100g |
| niacin | 300 | ug/100 Kcal | 180 | ug/100g | 200 | ug/ 100g |
| riboflavin | 80 | ug/100 Kcal | 48 | ug/100g | 30 | ug/ 100g |
| thiamin | 60 | ug/100 Kcal | 36 | ug/100g | 20 | ug/ 100g |
| vit A (RE) | 60 | ug/100 Kcal | 36 | ug/100g | 7 | ug/ 100g |
| vit B12 | 0.1 | ug/100 Kcal | 0.06 | ug/100g | 0.01 | ug/ 100g |
| vit B6 | 35 | ug/100 Kcal | 21 | ug/100g | 10 | ug/ 100g |
| vit D2 | 1 | ug/100 Kcal | 0.6 | ug/100g | 0.12 | ug/ 100g |
| calcium | 50 | mg/100 Kcal | 3000 | mcg/100g | 20 | mcg/100g |
| copper | 35 | ug/100 Kcal | 21 | mcg/100g | 0.001 | mcg/100g |
| iron | 0.45 | mg/100 Kcal | 270 | mcg/100g | 0.01 | mcg/100g |
| magnesium | 5 | mg/100 Kcal | 3000 | mcg/100g | 3 | mcg/100g |
| manganese | 1 | ug/100 Kcal | 0.6 | mcg/100g | 0.0010 | mcg/100g |
| pantothenic | 400 | ug/100 Kcal | 240 | mcg/100g | 50 | mcg/100g |
| phosphorus | 25 | mg/100 Kcal | 15000 | mcg/100g | 15 | mcg/100g |
| potassium | 60 | mg/100 Kcal | 36000 | mcg/100g | 10 | mcg/100g |
| sodium | 20 | mg/100 Kcal | 12 | mg/100g | 10 | mcg/100g |
| vit K | 4 | ug/100 Kcal | 2.4 | mcg/100g | 1 | mcg/100g |
| zinc | 0.5 | mg/100 Kcal | 300 | mcg/100g | 0.1 | mcg/100g |
| carnitine | 1.2 | mg/100 Kcal | 0.72 | mg/100g | 0.16 | mg/100g |
| chloride | 50 | mg/100 Kcal | 30 | mg/100g | 5 | mg/100g |
| choline | 7 | mg/100 Kcal | 4.2 | mg/100g | 2 | mg/100g |
| inositol | 4 | mg/100 Kcal | 2.4 | mg/100g | 0.5 | mg/100g |
| iodine | 10 | ug/100 Kcal | 6 | ug/100g | 5 | mg/100g |
| vit C | 10 | mg/100 Kcal | 6 | mg/100g | 1 | mg/ 100g |
| vit E | 0.5 | mg/100 Kcal | 0.3 | mg/100g | 0.2 | mg/ 100g |
| chromium | 1.5 | ug/100 Kcal | 9 | ug/kg | 20 | ug/kg |
| molybdenum | 1.5 | ug/100 Kcal | 9 | ug/kg | 20 | ug/kg |
| selenium | 1 | ug/100 Kcal | 6 | ug/kg | 10 | ug/kg |

# 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)

**Harrie van den Bijgaart,** ISO/IDF

Harrie van den Bijgaart (1958) studied Food Science and Technology at Wageningen Agricultural University. In 1988, he obtained his PhD degree from the same university for a thesis on the syneresis of rennet-induced milk gels. Since 1987 he has held positions in Dutch dairy quality assurance. At present he is working as Operations Manager at the Qlip laboratory in Zutphen.

During the years he has been active in the national and international harmonization of methods of analysis and sampling for milk and milk products. He has acted as a project leader in the development of several ISO/IDF standards. He presently chairs the Dutch NEN Committee, CEN TC/302, ISO/TC 34/SC 5 and the IDF Methods Standards Steering Group on methods of analysis and sampling of milk and milk products.

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# STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

## AOAC-ISO-IDF Collaboration

**Erik Konings, Marcel de Vreeze, Harrie van den Bijgaart**

**Dallas, TX**

**September 17, 2016**

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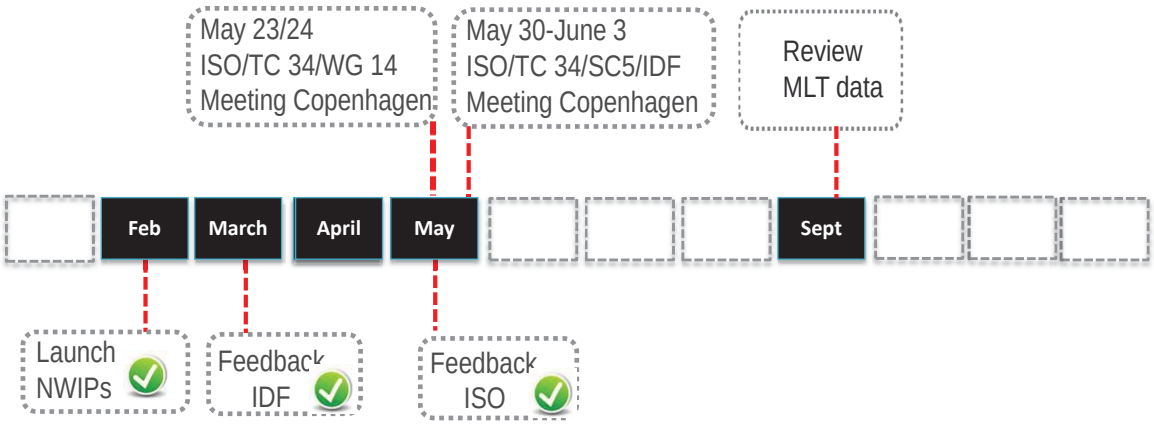
# 2016 timeline ISO/IDF methods



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# Current AOAC SPIFAN related Work Items at ISO/IDF

ISO: (ISO/TC34/WG 14)

- Vitamin K
- Carnitine/Choline
- Vitamin $B_1$, $B_2$, $B_3$, $B_6$
- Vitamin D
- Folate (in preparation)
- Biotin (in preparation)

ISO/IDF: (ISO/TC 34/SC5)

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

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# Input ISO/IDF experts improve method and description

| MB/ NC[1] | Line number | Clause/ Subclause | Paragraph | Type of comment[2] | Comments | Proposed change | Observations of the secretariat |
|---|---|---|---|---|---|---|---|
| ISO IDF | | | | | (high mass).<br>Other suitable internal standards are Sc, Rh and Ir.<br>Individual internal standard stock solutions are also suitable. | | standards will probably work just as well (we validated also with Ni, which was equivalent to Ge). However, there are no guarantees and the method must be run with the same internal standards as in the previous SLV/MLT.<br><br>One can add the IS separately – it's just more cumbersome because it's added manually to the MW vessel. |
| NL/ ISO IDF | | 3.4 | | Te | QCS - standard reference material 1849a or comparable | | The method already states that a comparable SRM may be used |
| FR/ ISO IDF | | 3.10 | | Te | In relation to the comment above, precise the specifications of Tergitol® when mentioned of equivalent to find an equivalent reagent …<br>A footnote shall be added :<br>"Tergitol ® is an example of a suitable product available commercially. This information is given for the convenience of users and does not constitute an endorsement by either ISO or IDF of this product. | | Tergitol is now to be listed as optional per NL comment. We suspect any surfactant would do as good a job to keep the spray chamber clean (we previously used Triton-X 100 before it was banned in the EU), so we will instead say "or similar surfactant". We will add the footnote. |
| NL/ ISO IDF | | 4.1 and 4.2 | | Te | Use of Tergitol solution to be listed as optional.<br>Diluted nitric acid rinse solution can serve as alternative. | | We will change to indicate it is optional |
| NZ/ IDF | | 4.5 | | Te | The calibration standards are only given a two day shelf life. This substantially increases the | | We suspect the 2-day may be extended but have |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** ge = general te = technical ed = editorial

# Examples ISO/IDF input

- "MLT protocol will be modified to take into account the possibility of using non USP standard with purity verified by UV"
- "There is no regulation for the cis and trans forms and results created by this method would not be comparable with results from the existing CEN standard"
- "Tergitol is now to be listed as optional per NL comment. We suspect any surfactant would do as good a job to keep the spray chamber clean"

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# Other examples ISO/IDF input

- Use criteria for description of equipment and chemicals (e.g. purity grade, tolerance levels), rather than specifying supplier/manufacturer.
- Explicitly describe use of broader range equipment if possible.
- Include storage temperature and shelf life of chemicals.
- Align equipment need with description in method: e.g. avoid unnecessary precision balances.

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# Other value from the cooperation

- Equivalent AOAC and ISO/IDF methods creates better positioning for their adoption (stakeholders, Codex)
- Promotes interaction and expert exchange between networks

CODEX ALIMENTARIUS
International Food Standards
World Health Organization
Food and Agriculture Organization of the United Nations

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# In process to be finalized

- ISO/DIS 20635: Infant formula and adult nutritionals — Determination of vitamin C by (ultra) high performance liquid chromatography with ultraviolet detection ((U)HPLC-UV)
- Anticipated publication date: Spring-Summer 2017

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# Work item at IDF/ISO of interest to SPIFAN?

- Determination of total sugars in dairy products
- Maltose, sucrose, lactose, galactose, glucose, fructose. Optional: trealose, palatinose, melibiose
- Matrices: milk, milk powder, sweetened condensed milk, cheese, infant formula, whey, desserts, and yoghurt.

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# Summary Status

- Coming publication of ISO 20635 vitamin C
- Finalization MLT's, drafting ISO DIS for minerals (ICP-MS, ICP-AES), chloride, and ISO CD for vitamin D, K, B, and Chol/Carn
- Launch New Work Item proposals for Folate and Biotin (MLT protocols discussed in May)
- ISO/TC34/WG14 members interested to participate in comparative measurements on SPIFAN kit for vitamins D, B, K, and biotin by CEN methods

# Next meetings

- ISO/TC34/WG14: January 2017 (provisional, depending DIS completion)
- IDF & ISO/TC 34/SC 5: May 8-12, 2017 Madison (WI)

# 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).

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**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 liquidchromatography 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 infood-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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# STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

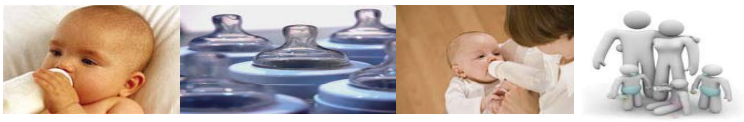
## Update from Proficiency Testing (PT) Program Taskforce

**Don Gilliland**

**Melissa Phillips**

**Dallas, TX**

**September 17, 2016**





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- Presentation Outline
  - AOAC SPIFAN Proficiency Testing Task Force
    - Definition and Objectives
  - AOAC SPIFAN Proficiency Testing – Pilot Program
    - Summary
    - Outcomes and Summary
  - Next Steps
  - Questions

- Infant Formula Proficiency Test Task Force
  - SPIFAN Resource to AOAC
    - Develop Proficiency Testing Program for Infant Formula and Adult Nutritional Products
  - Identify Proficiency Test Program Components
    - Nutrient Definition per SMPR
    - Identify SPIFAN Product Matrices
    - Testing Frequency, Products Type and Number
    - Establish Statistical Design
  - Help Design PT Pilot for Infant Formula/Adult Nutritional PT Program



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- SPIFAN Proficiency Testing – Primary Components
  - Nutrient Definition and Units of Measure per SMPRs
  - Multiple Products Included
    - Non-SRM, SPIFAN Matrices
  - Replication per Product Matrix Included
  - Method Summary Captured
    - Include Instrument Detail (SPIFAN)
  - Timing; Quarterly (Flexible)
    - Analysis - 30 day from material receipt
  - Participation using Multiple Methods
  - Data Evaluation Flexibility
    - Consensus Approach
    - SPIFAN vs. non-SPIFAN

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- SPIFAN PT Pilot Study - Objectives
  - Solicit Participant Feedback
    - Instructions to Participants
  - Evaluate Timing for Analysis (30 day from material receipt)
  - AOAC Data Evaluation
    - Data Entry Forms
    - Reports Structure, Format
    - Statistical Programming
    - Resolution of Problems/Issues
  - Feedback from Stakeholders



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- AOAC SPIFAN Proficiency Testing – Pilot Study
  - 6 Laboratories
    - 2 US SPIFAN Laboratories
    - 2 non-SPIFAN Laboratories (1 US + 1 European)
    - 2 European Laboratories
  - Participating Laboratories
    - Covance Laboratories (US)
    - Eurofins US Food Division/Nutrition Analysis Center (US)
    - Nestle NQAC (US)
    - Covance Laboratories Limited (UK)
    - Eurofins Steins Laboratorium A/S (Denmark)
    - Wyeth Nutrition Ireland (Ireland)

- AOAC SPIFAN Proficiency Testing – Pilot Study
  - SPIFAN Product Matrices Used
    - One Infant Formula, One Adult Nutritional
  - Results Tabulated
  - Laboratories only analyzed nutrients for analytes that they routinely test
  - Laboratories could submit results for one method or two methods
    - SPIFAN, AOAC, Internal



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## Results Received

| Nutrient | SPIFAN | Other | NT | SPIFAN+ Other |
|---|---|---|---|---|
| Fatty Acids | 3 | 2 | 1 | |
| Iodine | 2 | 2 | 2 | |
| Nucleotides | 1 | 3 | 2 | |
| Ultra-Trace Minerals | 2 | 1 | 3 | |
| Vitamin A (Retinol, Total) | 3 | 2 | 0 | 1 |
| Vitamin E<br>Total, as α-tocopherol<br>as α-tocopherol<br>as α-tocopherol acetate | <br>2<br>3<br>3 | <br>3<br>1<br>1 | <br>0<br>2<br>2 | 1 |
| Vitamin $B_{12}$ | 2 | 3 | 1 | |
| Pantothenic Acid | 2 | 1 | 2 | 1 |
| myo-Inositol | 1 | 4 | 1 | |

**Appendix C**
**Infant Formula Nutrients**
**06/26/2016**
**Display of All Reported Results and z-Scores (When Applicable)**
**Nutrient=Vitamin A Test=Retinol (Total) Sample=6**

| Method | Method Type | Participating Laboratory Reported Result | Participating Laboratory z-Score | Standard Uncertainty of the Assigned Value |
|---|---|---|---|---|
| AOAC OMA 2012.10 | AOAC | | | |
| AOAC OMA 2012.10 | AOAC | | | |
| AOAC OMA 2012.10 | AOAC | | | |
| AOAC OMA 2012.10 | AOAC | | | |
| EN 12823-1:2014 | OTHER | | | |
| Official Methods of Analysis, Methods 992.06, AOAC | OTHER | | | |
| AOAC 2011.07 | OTHER | | | |

- User Information can include instrument detail in “Comments” Section



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- SPIFAN PT Pilot Study – Feedback/Observations
  - Instructions to Participants: No Concerns
  - Timing for Testing: 30 days sufficient
  - Data Entry Forms
    - Participants found the data entry forms easy to navigate.
    - Online data entry submission is modeled after EXCEL forms that were used in the Pilot.
  - Reports Structure, Format
    - Follow the same format as other AOAC PT Programs.
    - Result data sheets, tables, and plots will be attachments to the technical report.

- SPIFAN PT Pilot Study – Feedback/Observations *(continued)*
  - Statistical Programming
    - Worked with SAS statistical provider to create and produce Result data sheets.
    - Result data entry sheets include z-scores, assigned values, standard deviations, measurement uncertainty, and other statistics.
    - Aside from the traditional result data sheets, the data can be mined for additional information by creating algorithms.



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- Next Steps
  - Feedback from Stakeholders
  - SPIFAN Meeting
  - SPIFAN PT Task Force Meeting
    - Tuesday, Sept. 20 @ 7:00 AM
    - Location: Dallas Ballroom A1
  - Survey of Stakeholders

→ Target Program Launch: March 2017

- Thank You
- Task Force – Membership
  - Don Gilliland, Co-Chair (Abbott)
  - Melissa Phillips, Co-Chair (NIST)
  - John Austad (Covance)
  - Laura Coisne (Nestle)
  - Jane Weitzel (consultant)
  - Darryl Sullivan (Covance)
- Questions

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# STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

## AOAC Standards Development Process

**Deborah McKenzie, AOAC INTERNATIONAL**

**Dallas, TX**

**September 17, 2016**

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# Re-engaging Stakeholder Panel Working Groups and Revising AOAC Standard Method Performance Requirements

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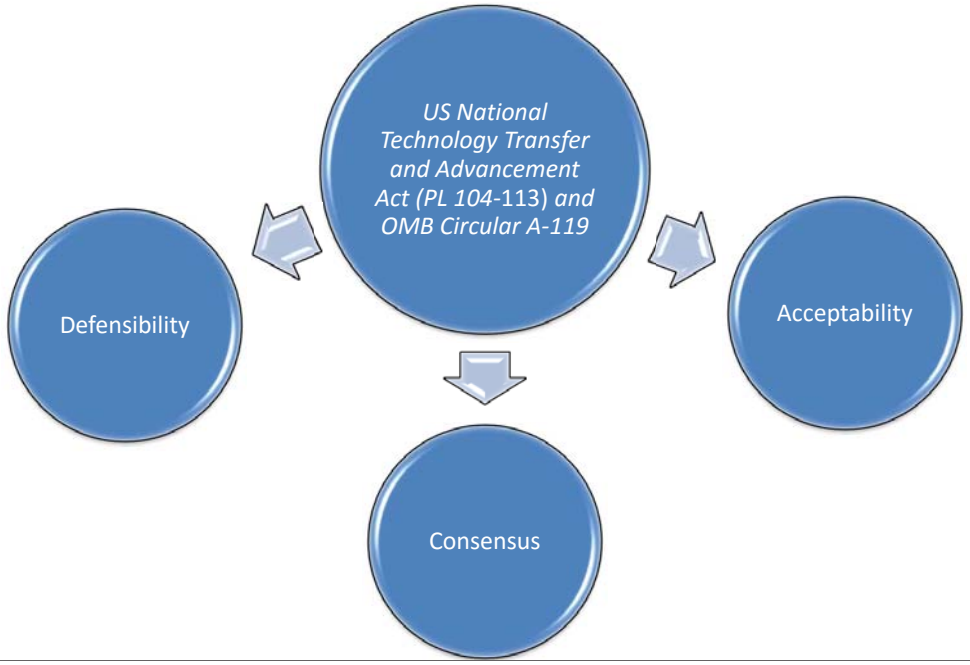
# AOAC Standard Development Process

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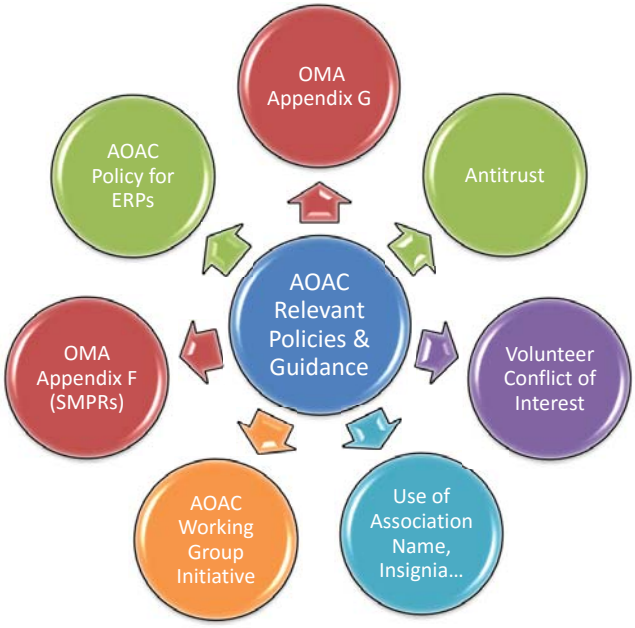
# AOAC Standards Development



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# AOAC Standards Development

- AOAC develops voluntary consensus standards using the following principles:

Transparency

Openness

Balance

Due Process

Consensus

Appeals

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# Stakeholder Panel Composition

- Product Manufacturers
- Analyte/Method Subject Matter Experts
- Technology Providers
- Method Developers
- Government and Regulators
- Contract Research Organizations
- Reference Materials Developers
- Ingredient Manufacturers
- Method End Users
- Academia & Research
- Non Governmental Organizations
- Other as identified

Anyone with a material interest can participate
Balanced group of representative voting stakeholders Chair and voting stakeholders vetted by AOAC Official Methods Board

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# Revising AOAC SMPRs – Re-engage Working Group

- Working Group Chair or designee will present on new information learned relevant to regulations, analytical challenges of the priority, etc... The WG chair will also propose a revised draft fitness for purpose statement or recommendations to support revising the current AOAC SMPR that will serve as the basis for the working group's SMPR revising activity.
- Stakeholder Panel chair will entertain deliberation on the draft statement/recommendation
- After due deliberation by ALL of the assembly, and potential tweaking, Stakeholder Panel chair will call for an endorsement of the statement / recommendation
- Upon endorsement of the statement/recommendation, the working group will work to revise the SMPR.
  - Information will be available for attendees to sign up to participate on the working group
- A revised draft SMPR will be posted for stakeholder comment followed by reconciliation of comments
- Working Group Chair or designee will present the revised draft SMRP to the stakeholder panel for deliberation and vote

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# Roles and Responsibilities

- Stakeholder Panel
  - Establish working groups to develop standards
  - Comment, deliberate, and establish voluntary consensus standards
- Stakeholder Panel Working Groups
  - Develop draft standard method performance requirements
  - Reconcile comments
  - Present draft standard to stakeholders
- Official Method Board
  - Vet and approve stakeholder panel chair and representative voting stakeholders
  - Assign representative to serve as a resource to stakeholder panel
- AOAC Staff
  - Coordinate stakeholder panel, working groups, and facilitate their meetings
  - Document actions/decisions of working groups and stakeholder panel
  - Post SMPRs and collect comments for draft SMPRs

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# Documentation and Communication

- AOAC carefully documents the actions of the Stakeholder Panel and the Working groups
- AOAC will prepare summaries of the meetings
  - Communicate summaries to the stakeholders
  - Publish summaries in the *Referee* section of AOAC's *Inside Laboratory Management*
- AOAC publishes its voluntary consensus standard
  - *Official Methods of Analysis of AOAC INTERNATIONAL*
  - *Journal of AOAC INTERNATIONAL*
- AOAC publishes the status of standards in the *Referee* section of AOAC's *Inside Laboratory Management*

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# QUESTIONS?

# THANK YOU

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- **Infant Formula Proficiency Test Task Force**
  - SPIFAN Resource to AOAC
    - Develop Proficiency Testing Program for Infant Formula and Adult Nutritional Products
  - Identify Proficiency Test Program Components
    - Nutrient Definition per SMPR
    - Identify SPIFAN Product Matrices
    - Testing Frequency, Products Type and Number
    - Establish Statistical Design
  - Help Design PT Pilot for Infant Formula/Adult Nutritional PT Program

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- **SPIFAN Proficiency Testing – Primary Components**
  - Nutrient Definition and Units of Measure per SMPRs
  - Multiple Products Included
    - Non-SRM, SPIFAN Matrices
  - Replication per Product Matrix Included
  - Method Summary Captured
    - Include Instrument Detail (SPIFAN)
  - Timing; Quarterly (Flexible)
    - Analysis - 30 day from material receipt
  - Participation using Multiple Methods
  - Data Evaluation Flexibility
    - Consensus Approach
    - SPIFAN vs. non-SPIFAN

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- **SPIFAN PT Pilot Study - Objectives**
  - Solicit Participant Feedback
    - Instructions to Participants
  - Evaluate Timing for Analysis (30 day from material receipt)
  - AOAC Data Evaluation
    - Data Entry Forms
    - Reports Structure, Format
    - Statistical Programming
    - Resolution of Problems/Issues
  - Feedback from Stakeholders

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- **AOAC SPIFAN Proficiency Testing – Pilot Study**
  - 6 Laboratories
    - 2 US SPIFAN Laboratories
    - 2 non-SPIFAN Laboratories (1 US + 1 European)
    - 2 European Laboratories
  - Participating Laboratories
    - Covance Laboratories (US)
    - Eurofins US Food Division/Nutrition Analysis Center (US)
    - Nestle NQAC (US)
    - Covance Laboratories Limited (UK)
    - Eurofins Steins Laboratorium A/S (Denmark)
    - Wyeth Nutrition Ireland (Ireland)

- **AOAC SPIFAN Proficiency Testing – Pilot Study**
  - SPIFAN Product Matrices Used
    - One Infant Formula, One Adult Nutritional
  - Results Tabulated
  - Laboratories only analyzed nutrients for analytes that they routinely test
  - Laboratories could submit results for one method or two methods
    - SPIFAN, AOAC, Internal

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## Results Received

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  - John Austad (Covance)
  - Laura Coisne (Nestle)
  - Jane Weitzel (consultant)
  - Darryl Sullivan (Covance)
- **Questions**

# STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

**Gregory Hostetler,** Perrigo Nutrition
*SPIFAN Working Group Chair, Carotenoids*

Dr. Greg Hostetler earned his B.S. in Horticulture from the University of Washington, M.S. in Pomology from Cornell University, and his Ph.D. in Food Science from the Ohio State University. His research has included the effects of food processing on the absorption of phytochemicals and the role of phytochemicals in attenuating chronic inflammation. Since graduating in 2011, he has worked in Analytical Research and Development at Perrigo Nutritionals. His work there has included analysis and method development for vitamins, carotenoids, and lipids. Greg has been active in AOAC since 2011 and also serves on the Matrices Working Group. He has authored several publications in horticulture and food chemistry.

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# STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

# CAROTENOIDS UPDATE

Greg Hostetler, Perrigo Nutritionals (Vermont, USA)

September, 2016

Texas, USA

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## Agenda

- Update on regulations since first SMPR presentation
- Update on methods
- Update on July working group conference call
- Discussion

# New US Nutrition Facts Label

- 12 µg β-Carotene = 1 µg Retinol (RAE)
- 24 µg α-Carotene = 1 µg Retinol
- 24 µg β-Cryptoxanthin = 1 µg Retinol

Codex guidelines remain 6 µg β-Carotene = 1 µg Retinol



# Method Update

- One method submitted for ERP review – for lutein and β-carotene
- No methods include α-carotene or lycopene

# July Conference Call

- α-Carotene not typically used as a vitamin A source – only found in one SPIFAN matrix
- Revise current SMPR to allow multiple methods?
- Split current SMPR into multiple SMPRs?



# Discussion

- Do we still need methods for α-carotene?
- Revise current SMPR to allow multiple methods?
- Split current SMPR into multiple SMPRs?
- Other suggestions?

# STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

**Eric Poitevin,** Nestlé
*Minerals Working Group Chair*

Dr. Eric Poitevin is a Lead Scientist in Nestlé Research Center in Switzerland. His main responsibilities are currently in the Mineral Laboratory of Analytical Sciences Department where he leverages his expertise in food mineral analysis and methods development. His experience with Nestlé has afforded Dr. Poitevin for more than 20 years significant knowledge of technology including ICP-OES, ICP-MS, LC (GC)-MS-MS in water and food sectors. He is engaged in the National Swiss accreditation organization and in European CEN Working Group of Elements and their chemical species.

He has been an AOAC member since 2008 and has been assigned since 2010 as Study Director for AOAC Official Method 2011.14 Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorus, Sodium, and Zinc in Fortified Food Products Microwave Digestion and Inductively Coupled Plasma-Optical Emission Spectrometry First Action 2011.

Besides activities in Working Groups of Iodine and Ultra Trace Elements of SPIFAN, he is also involved in Heavy Metals Working Group of SPSFAM.

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# STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN).

## CURRENT STATUS
## FLUORIDE

Eric Poitevin,
Dallas, USA
17th September, 2016






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## STANDARD METHOD PERFORMANCE REQUIREMENT AOAC SMPR 2014-016

| Element | CAS Number | Atomic Mass (Number) | Classification group | Stable isotope | Ist IP (EV) |
|---|---|---|---|---|---|
| Fluoride (F) | 16984-48-8 | 18.9984 (9) | Halogen | $^{19}F$ | 17.4 EV |

**Table 1. Method performance requirements[a]**

| Parameter | Minimum acceptable criteria | |
|---|---|---|
| Analytical range | 5–200[b] | |
| Limit of quantitation (LOQ) | ≤5[b] | |
| Recovery | 5–25 | 80–120% |
| | 26–200 | 90–110% |
| Repeatability ($RSD_r$) | 5–25 | ≤8% |
| | 26–200 | ≤5% |
| Reproducibility ($RSD_R$) | 5–25 | ≤15% |
| | 26–200 | ≤10% |

[a] Concentrations apply to: (a) 'ready-to-feed' liquids 'as is'; (b) reconstituted powders (25 g into 200 g deionized water); and (c) liquid concentrates diluted 1:1 by weight with deionized water.

[b] µg/100 g reconstituted final product.

# Regulations for Fluoride

| Regulating body | Units | Minimum | Maximum |
|---|---|---|---|
| Australia/New Zealand | - F content > 17 µg/100 kJ (≈ 50 µg/100g) "powdered/concentrated infant formula OR - F content > 0.15 mg per 100 mL, 'ready to drink' formula | | |
| China | - | - | - |
| Codex Standard 72- 1981 | µg/100 kcal (RTF ) | - | 100* (≈ 65 µg/100g) |
| EU: 2006/141/EC (infant formula) | µg/100 kcal (RTF) | - | 100 (≈ 65 µg/100g) |
| EU: 609/2013/EC (medical foods) | - | - | -** |
| USA, FDA CFR 21 Part 107 | | - | - |

* Codex states that fluoride must not be added to infant formula

** 609/2013/EU permits NaF and KF to be added to medical foods



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References 1-7 are listed in slide 16

## Examples of Fluoride content of infant formula powders. Higher concentrations have been found in soya-based products Fluoridated water: main contribution to F final content after IF reconstitution

| Country | Infant formula, Avg (mg/kg) | Infant formula, Avg RTF (µg/100g) | Soya products Range (mg/kg) | Soya products Range RTF (µg/100g) |
|---|---|---|---|---|
| Australia [1] | 0.49 | 6.1 | 1.08 - 2.80 | 13.5 – 35.0 |
| Canada [2] | 0.23 | 2.9 | | |
| Iran [3] | 1.73 | 21.6 | | |
| Poland [4] | 0.29 | 3.6 | | |
| Japan [5] | 0.41 | 5.1 | | 15 - 104 |
| USA [6] | 0.45 | 5.5 | 0.9 – 2.5 | 11.2 – 30 |
| U.K [7] | 0.25 | 3 | 0.02 - 0.28 | 2.4 – 3.4 |

Cows milk: 0.7- 35 µg/100mL of F / Breast milk: 0.4 – 2 µg/100mL of F (various studies)

References 8-9 are listed in slide 16

## Current methodology - Sample preparation [8,9]

- Open ashing
- (Alkali) Fusion
- Microdiffusion separation
- Oxygen combustion
- High pressure acid digestion
- (Ultrasonic) Extraction/Protein precipitation/Ultracentrigugation
- Distillation
- Headspace (single-drop micro-extraction)
- Derivatization

Some procedures are available for measuring total and/or free forms of fluoride in milk products.



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References 8-9 are listed in slide 16

## Current methodology – Detection [8,9]

- Electrochemistry:
  - Potentiometry (Fluoride Ion Selective Electrode : current method)
  - Voltametry (Polarographic methods)
- Chromatography:
  - Ion Chromatography - Conductivity detection / Post- column reaction with UV/VIS detector (anion current method)
  - Headspace Gas Chromatography - FID / MS after derivatization
- Spectroscopy:
  - Spectrophotometry (for waters)
  - Graphite furnace - MAS (most sensitive technique for fluoride)
  - MIP-AES / ICP-MSMS
- Titrimetry (Titration against thorium nitrate) column reaction
- Sensors

# Call for methods status - 1

## AOAC Official methods

- AOAC 961.16 (Titrimetry)
- AOAC 944.08 (Ash-Distillation-Titration)

These 2 methods are not suitable for determining low levels of fluoride in infant formula and adult nutritional products.

- Microdiffusion and F-ISE (Microdiffusion and fluoride-specific electrode determination of fluoride in infant foods: collaborative study - Dabeka, R. W., McKenzie, A. D. J. AOAC., 64, (4): 1021-1026,1981)

Results from collaborative study were not accepted by AOAC. Method not published.



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# Call for Methods status -2

## German Official Method (Fluo-01)

Amtliche Sammlung von Untersuchungsverfahren, nach Paragraph 35 LMBG.(L 49.00-7): 2pp., 2000 - Analysis of foods. Determination of fluoride in dietetic foods with an ion-sensitive electrode.

- Only validated on 2 dietetic products
- Modified and validated with 30 Healthcare products (Nestlé method):
  - PLOQ RTF: ≈50 µg/100g (Dilution factor 2 with TISAB)
  - Good RSDr (< 5%) / RSDiR (< 8%) / Recovery (83%-109%)*

  *Bad Recovery for products with high protein/thickeners/caseinates due to non specific binding of measured free fluorides

Conclusion: method not sensitive & not applicable to products with high protein / thickener/caseinates content + SLV (SPIFAN kit)

# Call for Methods status -3

## Ion Chromatography Method (Fluo-02)

ThermoFisher Scientific. Analysis of fluoride in Infant Formula and Adult Nutritionals by ion chromatography after ultracentrifugation

- Good linearity (> 0.995) and estimated LOQ (≈ 5µg/100g)
- Good RSDr (< 5%) , RSDR (<10%) and recovery (81%-105%) for 12 SPIFAN products
- Specific equipment and IC consumables (column, cartridges, buffer) needed / Chloride analysed simultaneously

Conclusion: equipment dependent / method to be improved for low F level (e.g. removal of organic acids, column and buffer used, sample volume injected) for a better chromatogram interpretation / Complete SLV & additional SLV chloride could be a plus using improved method



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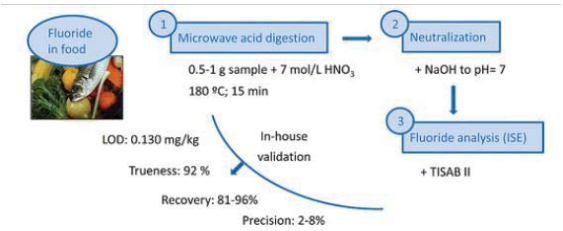
Reference 10 is listed in slide 16

# New methods -1

## Microwave acid digestion and F-ISE [10]



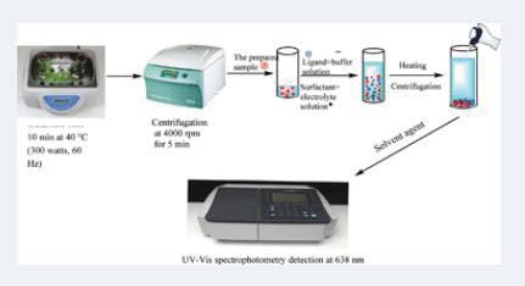

- Alternative to tedious & time consuming alkali fusion or microdiffusion
- LOQ blank: 5 µg/L / LOQsample ≈ 20 µg/100g dry matter (1g with DF=2 TISAB 20%) / 20 food samples (seafood, vegetables, fruits: 0.08 – 1.8 mg/100g dry matter)
- Not validated for infant formula: (estimated LOQ :< 20 µg/100g RTF)

Conclusion: feasibility to test for Infant Formula with some modifications (e.g. diluted $HNO_3$ / 2g IF reconstituted / F-ISE calibration type)

Reference 11 is listed in slide 16

# New methods -2

## Microwave digestion/Cloud Point Extraction/ Spectrophotometry[11]




- Alternative to F-ISE or IC detection
- LOQ blank: 5 µg/L / LOQsample: 25 µg/100g dry matter (1g with DF=50) / 20 food samples (fruit juices, soups, babyfoods: 0.01 – 28 mg/100g) /RSDr < 5% / Recovery : 97% -103%
- Not validated for infant formula: (estimated LOQ : < 20 µg/100g RTF)

Conclusion: feasibility to test for Infant Formula





# New methods -3

## TMFS derivatization / GC-FID (Poster AOAC meeting 2015)

**Analysis of Fluoride Content in Infant Formula by GC-FID**

Ryan P. Connelly, Jeremy J. Eckes, Marisa J. Feller, Vanessa A. Spencer and Darryl M. Sullivan
Covance Laboratories Inc., Madison, Wisconsin

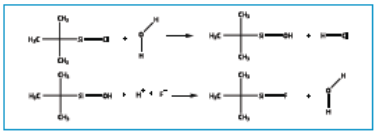


Figure 1. TMFS derivatization reaction under acidic conditions.

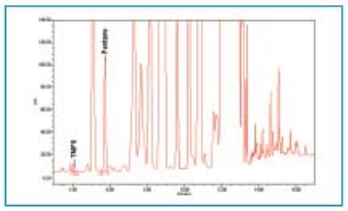



Figure 2. Fluoride chromatogram of powdered infant formula. Approximate concentration of 0.3 µg/g. TMFS and pentane are volatile enough to overcome the solvent focusing effect. This allows for the removal of nearly all matrix interference.

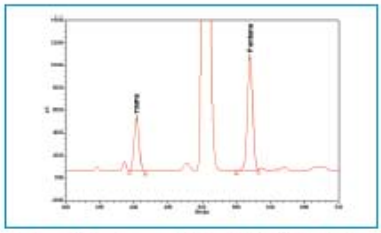



Figure 3. Chromatogram of 1.00 µg/g derivatized fluoride standard and 25 µg/g pentane internal standard. This region of the chromatogram contains only the analytes volatile enough to desolvate from the solvent front.

- Alternative to F-ISE, IC detection and spectrophotometry
- LOQ sample: 30 µg/100g dry matter (3 µg/100g RTF) / 2 samples (powdered and liquid IF) / RSD = 6% / Recovery : 87% -101%

Conclusion: SLV to perform with SPIFAN kit

References 12-16 iare listed in slide 16

# New methods -4

## Other alternative methods [12,13,14,15,16]

- Microwave Induced Combustion (MIC) followed by F-ISE or IC
  - Applied for halogens in infant formula (mainly Br and I)
  - Methods for fluoride in other food matrices (spices, plants)
- Automatic standard addition/F-ISE
- Specific extraction/Dialysis/Microwave digestion and IC
  - Specific supplier IC equipment (e.g. in line dialysis, in line SPE)
- GF-MAS
  - Specific supplier equipment (Babyfood)



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# Conclusion

- New promising methods (but not yet applied for IF) that potentially could meet current SMPR are mainly based on:
  - Microwave digestion and F-ISE or spectrophotometry detection
  - Derivatization and GC-FID/MS
- Codex requirement : F content < 100µg/100 kcal **(< 65µg/100g* reconstituted IF**) **BUT** AUS-NZ has one specific requirement: claims needed for **50 µg/100 g** in powder (corresponding to current LOQ=5 µg/100 g in SMPR)
- **Proposal for next step**:

1. If only Codex standard maximum limit* is followed: revise SMPR with higher LOQ (e.g. 50-65 µg/100g)
2. If SMPR is maintained: reopen call for methods to evaluate new methods using ISE, IC or GC with specific sample preparation (Microwave digestion, specific buffer extraction

# QUESTIONS??



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## References


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# 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.

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# STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

## Folate

**Erik Konings**

**Dallas, TX**

**September 17, 2016**

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# Status

ERP moved OMA# 2011.06 (FOL-22) – Validation of a LC-MS/MS method for Folate analysis in Infant Formula and Adult Nutritionals – to reproducibity testing

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# Folate SMPR 2011.006 (approved April 5, 2011)

Applicability:

Determination of total folate [supplemental folic acid or 5-methyl-tetrahydrofolate, and endogenous 5-methyl-tetrahydrofolate polyglutamate] in all forms (powders, ready-to-feed liquids, and liquid concnetrates) of infant, adult, and pediatric nutritional formula.

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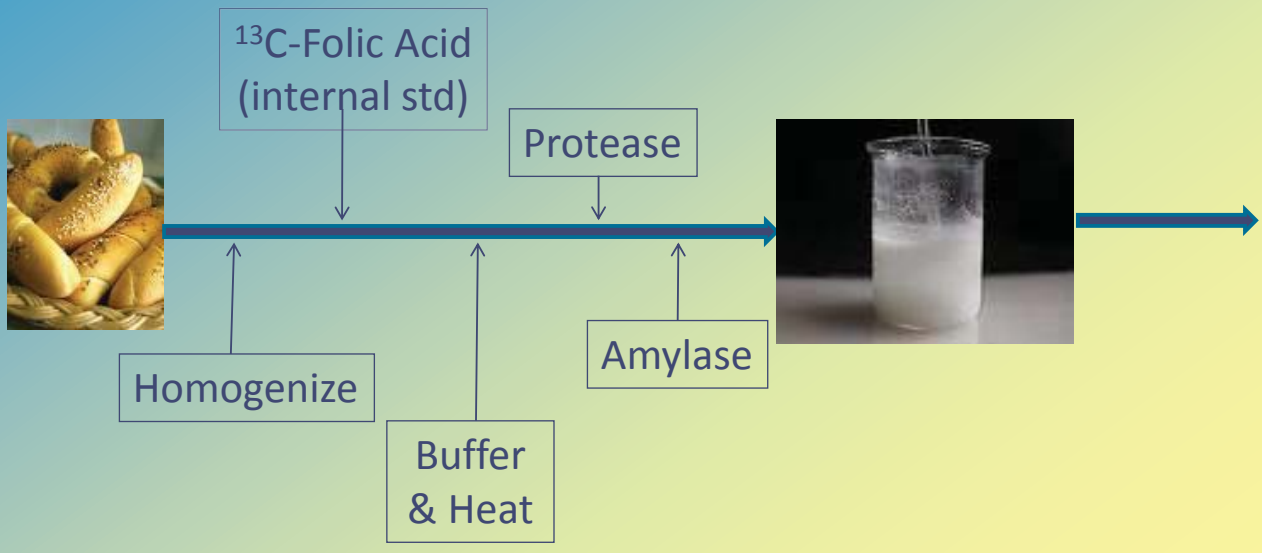
SPIFAN Stakeholder Panel September 2010

## UPLC/MS/MS procedure




T. Gbatu, J. Szpylka, A. Gheney, AOAC Annual meeting 2008.

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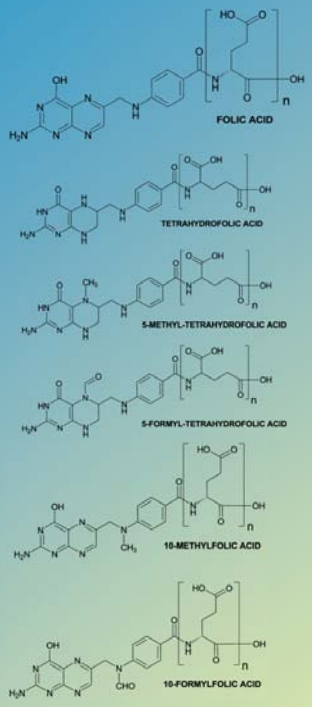
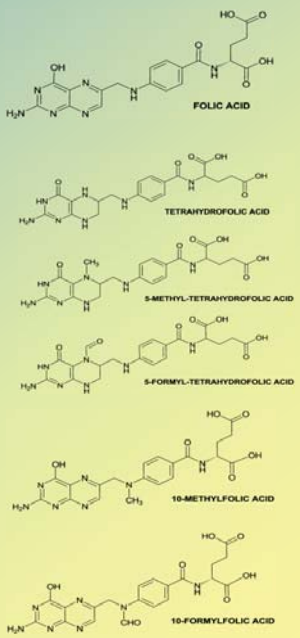



**Polyglutamates (n = 1-8)**

Deconjugation with Rat Plasma Conjugase

37 deg C for 22 hr
100 deg C for 5 min




**Monoglutamates**

T. Gbatu, J. Szpylka, A. Gheney, AOAC Annual meeting 2008.

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| | Average µg/100g | SD µg/100g | RSD % | Value µg/100g |
|---|---|---|---|---|
| Infant formula | 128 | 8 | 6.3 | 129 |
| Baby food | 15 | 1 | 8.6 | 15 |
| Protein powder | 545 | 56 | 10.2 | 540 |
| RTE cereal | 1264 | 71 | 5.6 | 1245 |
| Yogurt drin | 36 | 4 | 10.0 | |
| Soymilk | 14 | 2 | 12.2 | |
| Onion Powder | 66 | 5 | 8.3 | |
| Blackeye peas | 252 | 28 | 11.1 | |
| Eggs | 88 | 10 | 11.1 | |
| Banana | 46 | 4 | 8.3 | |
| Spinach | 257 | 12 | 4.7 | |
| Chicken liver | 1756 | 243 | 13.9 | |

T. Gbatu, J. Szpylka, A. Gheney, AOAC Annual meeting 2008.

# Decisions in 2010/2011

- 5-MTHF 2-9% of total folates (NIST 1849)
- No information on polyglutamate amount
- For Infant Formula both folic acid and 5-MTHF (polyglutamate) would result in total folate amounts

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# SLV reports 2016

1. S. D. Bhandari, J. Szpylka: Validation of an LC-MS/MS method for Folate analysis in Infant Formula and Adult nutritionals samples (Folate-22, OMA 2011.06) using SPIFAN II sample kit
2. F. Martin, Y. Oguey, K. Meisser, E. Campos Giménez: Contribution of minor folates to the total folate content of infant formula and adult/pediatric nutritionals.

# Forms included for SLV

- Folic Acid
- 5-CH3-THF
- 5-CHO-THF
- THF
- 5,10-CH=CH-THF
- 10-CH3-FA
- 10-CHO-FA

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| | | µg/100g RTF | Conjugase/no conjugase % | % of total FA |
|---|---|---|---|---|
| | CODEX STAN 72 requirement Folic acid (Min-GUL) | 6.5 - 32 | - | - |
| SLV 1 (n=9) | total folate 10 SPIFAN samples | 29.5 (RSD 3.4%) | 114 | - |
| | 5-MTHF 3* SPIFAN samples | 3.3 (RSD 8.3%) | 194 | 13.9 |
| | 5-FTHF 2 SPIFAN soy samples | 1.9 (RSD 18.3%) | 0 | 9.8 |
| SLV 2 (n=2) | total folate 10 SPIFAN samples | 33.8 (RSD 1.1%) | 101 | - |
| | 5-MTHF 3* SPIFAN samples | 2.0 (RSD 1.6%) | 133 | 8.0 |
| | 5-FTHF 2 SPIFAN soy samples | 1.7 (RSD 0.3%) | 0 | 7.5 |

* One sample was different, but all milk-based

# Conclusions of SLV

- 5-CHO-THF quantified in soy-based formulas, after conjugase treatment up to ≈ 10% of total folates
- 5-MTHF quantified in milk-based formulas, after conjugase treatment up to ≈ 14% of total folates
- THF, 10-CHO-FA, 10-CH3-FA < LOQ
- 5,10-CH=CH-THF in one milk-based sample < 6.5% total folates, not confirmed in SLV 2

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# Motion

Adapt SMPR Applicabilty Statement in:

Determination of total folate [supplemental folic acid or 5-methyl-tetrahydrofolate, 5- formyl-tetrahydrofolate and endogenous 5-methyl-tetrahydrofolate polyglutamate, and 5-formyl tetrahaydrofolate polyglutamate] in all forms (powders, ready-to-feed liquids, and liquid concnetrates) of infant, adult, and pediatric nutritional formula.

# STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

**Robert Rankin,** INCA

Robert Rankin is a Senior Account Executive at Kellen, a global professional services firm specializing in trade associations, professional societies and communications.

Robert currently serves as Executive Director for the Infant Nutrition Council of America (INCA), an association representing manufacturers of formulated nutrition products, including infant formulas and adult nutritionals. Since 2005, Robert has worked closely with officials at key US Government agencies including the US Food and Drug Administration and US Department of Agriculture. He has also worked with the Centers for Disease Control and Prevention and other US/international government agencies. He has extensive experience in the development and communication of industry positions and has testified before U.S. state legislatures, the World Health Organization and local authorities on industry issues.

Since 2010, Robert has managed Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Project on behalf of the infant formula industry. Through SPIFAN, voluntary consensus standards and internationally recognized methods of analysis for over 40 nutrients in infant formula have been developed with the ultimate goal of having the methods adopted by Codex Alimentarius as Type II dispute resolution methods.

Robert also serves as President of the Calorie Control Council and Executive Director of the International Food Additives Council. Prior to Kellen, Robert spent two years at the Grocery Manufacturers Association where he worked in the Federal Affairs and Scientific & Regulatory Departments. Robert has a BA in Public Policy Studies from Duke University and lives in Maryland with his wife and two children.

# AOAC SPIFAN Future Endeavors

Robert Rankin
Executive Director
Infant Nutrition Council of America

## SPIFAN Progress to Date

- 27 SMPRs for infant formula nutrients/groups of nutrients
- First Action Methods for 22 nutrients/groups of nutrients (5 to go!)
- AOAC Final Action Methods and ISO/IDF Standards for 8 nutrients/groups of nutrients
- 5 methods adopted by CODEX, possibly 4 more in July 2017

# SPIFAN Progress (as of 9/16/16)

| | SMPR Approved | Oficial First Action | Official Final Action | ISO/IDF Standard | Codex Adoption |
|---|---|---|---|---|---|
| Vitamin A | | | | | |
| Vitamin E | | | | | |
| Vitamin D | | | | | |
| Vitamin B12 | | | | | |
| Folate | | | | | |
| Inositol | | | | | |
| Nucleotides | | | | | |
| Cr/Mo/Se | | | | | |
| Vitamin C | | | | | |
| Choline | | | | | |
| Pantothenic Acid | | | | | |
| Carnitine | | | | | |
| Iodine | | | | | |
| Fatty Acids | | | | | |
| Biotin | | | | | |
| Vitamin K | | | | | |
| FOS | | | | | |
| GOS | | | | | |
| Minerals | | | | | |
| Amino Acids | | | | | |
| Carotenoids | | | | | |
| Chloride | | | | | |
| Fluoride | | | | | |
| Vitamin B1 | | | | | |
| Vitamin B2 | | | | | |
| Vitamin B3 | | | | | |
| Vitamin B6 | | | | | |
| | | | | | |
| | Work that has been completed | | | | |
| | Work expected to be completed by March 2017 | | | | |
| | Work still to be completed after March 2017 | | | | |

# Still to Come

- AOAC First Action Methods for remaining 5 nutrients/groups of nutrients
  - Fluor, FOS, GOS, Carots, AA
- AOAC Final Action Methods and ISO/IDF Standards for remaining 14 nutrients/groups of nutrients
  - Chol, Carn, K, Biotin, B Vits, Fol, D, MTE, Chlor, Fluor, FOS, GOS, Carots, AA
- CODEX adoption of AOAC/ISO/IDF methods for all remaining nutrients/groups of nutrients
- SPIFAN II extension to May 2017

# SPIFAN III

- Complete original SPIFAN goals (First Action Methods, Final Action Methods, ISO/IDF Standards, CODEX adoption)
  - Document policies/best practices to ensure consistency
  - Forum to consider new methods and consider repealing inferior methods
- Facilitate international awareness, acceptance and support of SPIFAN process
  - Enhanced CODEX Outreach
  - Outreach to Key Regions (China, India, Latin America)
- Facilitate international use of SPIFAN methods
- Expand vested stakeholders supporting SPIFAN

# Questions?

## Thank you!

Robert Rankin

Executive Director

Infant Nutrition Council of America

rrankin@kellencompany.com