AOAC INTERNATIONAL

OFFICIAL METHODS BOARD (OMB) MEETING BOOK

Meeting held at
AOAC INTERNATIONAL Headquarters
Rockville, MD
&
Mérieux NutriSciences/Silliker Food Science Center
Chicago, IL



Thursday, June 25, 2015
&
Friday, June 26, 2015

AOAC INTERNATIONAL
2275 Research Blvd., Ste. 300
Rockville, MD 20852
UNITED STATES
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AOAC INTERNATIONAL
OFFICIAL METHODS BOARD
2014 –2015

Chair	**Shauna Roman** Reckitt Benckiser, Inc. Shauna.Roman@reckittbenckiser.com Term: August 29, 2013 – September 21, 2016	*Member*	**Joe Boison** Canadian Food Inspection Agency Joe.Boison@inspection.gc.ca Term: August 29, 2013 – September 21, 2016
Member	**Doug Abbott** Independent Consultant dabbott2@bresnan.net Term: September 11, 2014 - September 27, 2017	*Member*	**Perry Anthony Martos** University of Guelph pmartos@uoguelph.ca Term: October 4, 2012 - September 30, 2015
Member	**Sneh Bhandari** Silliker, Inc. Sneh.Bhandari@Silliker.com Term: August 29, 2013 – September 21, 2016	*Member*	**Shang-Jing Pan** Abbott Nutrition shang-jing.pan@abbott.com Term: October 4, 2012 - September 30, 2015
Member	**Jo Marie Cook** Florida Department of Agriculture and Consumer Services JoMarie.Cook@freshfromflorida.com Term: August 29, 2013 – September 21, 2016	*Member*	**Tom Phillips** Maryland Department of Agriculture phillitd@mda.state.md.us Term: August 29, 2013 – September 21, 2016
Member	**Erin Sutphin Crowley** Q Laboratories, Inc. ecrowley@qlaboratories.com Term: October 4, 2012 - September 30, 2015	*Member*	**Victoria Siegel** Office of the Indiana State Chemist - Purdue University vsiegel@purdue.edu Term: September 11, 2014 - September 27, 2017
Member	**Qian Graves,** US FDA *AOAC Committee on Statistics, Chair* Qian.graves@fda.hhs.gov Term: August 29, 2013 – September 21, 2016	*Member*	**Bradley Stawick** Microbac Laboratories, Inc. brad.stawick@microbac.com Term: October 4, 2012 - September 30, 2015
Member	**Yvonne Salfinger,** Independent Consultant *AOAC Committee on Safety, co-Chair* Yhale@aol.com Term: August 29, 2013 – September 21, 2016	*Past Chair (Ex-officio Member)*	**John Szpylka** Silliker, Inc. John.Szpylka@Silliker.com Term: August 29, 2013 – September 21, 2016

AOAC Staff Liaisons

Deborah McKenzie Sr. Director- Standards Development Sr. Director- AOAC Research Institute dmckenzie@aoac.org	Delia Boyd Program Manager – Standards Development dboyd@aoac.org

AOAC INTENATIONAL Terms begin following the AOAC Business Meeting. Terms expire at the AOAC Business Meeting.

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.

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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

TERMS OF REFERENCE

I. NAME:

OFFICIAL METHODS BOARD (OMB)

II. MISSION:

To serve the Association in a scientific and advisory capacity on standards and methods with ethical, timely, open and independent scientific oversight for the implementation of standards development and conformity assessment policies and procedures of AOAC INTERNATIONAL.

III. RESPONSIBILITIES:

To provide ethical, timely, open and independent scientific oversight for the policies and procedures of AOAC INTERNATIONAL.

To approve "Final Action" status for First Action Methods (new and revised) following a proactive review;

To repeal methods, if necessary, in accordance with established policies and procedures;

To participate in addressing appeals and requests for action or guidance, and in resolving disputes;

To endorse and monitor all voluntary consensus panels for appropriate representation and balance of stakeholders' perspectives;

To endorse and monitor all volunteer subject matter experts for volunteer conformity assessment activities;

To adopt and monitor scientific and technical guidance and references;

To acknowledge outstanding scientific and technical volunteer activity and achievement within AOAC;

To actively participate in AOAC standards development activities and maintain and communicate explicit knowledge of AOAC standards development and conformity assessment;

IV. COMPOSITION AND ORGANIZATION:

The Official Methods Board shall consist of up to 13 voting members including a Chair, a Vice-chair, the Chair of the Committee on Safety and the Chair of the Committee on Statistics. The Committee on Safety and the Committee on Statistics may contain co-chairs. The co-chairs for these committees represent one vote on the OMB. Members of the OMB may serve in multiple volunteer roles for the benefit of the Association. The Chair of the Official Methods Board shall have previously served as a member of the Official Methods Board. The Chair, Vice-chair, and members of the Official Methods Board including the chairs of standing committees shall be appointed for a term of three years. A member of the OMB may be reappointed upon the recommendation of the Chair of the Official Methods Board with a maximum term of service of six (6) years. Exceptions may be made at the discretion of the President. The Chair of the Official Methods Board is eligible to serve an additional post chair term of up to three (3) years as an *ex-officio* member. Members of the Official Methods Board must be members of AOAC.

All members of the Official Methods Board are recommended by the Chair and appointed by the President. All Official Methods Board members serve at the pleasure of the President.

The Official Methods Board represents the membership of AOAC INTERNATIONAL. It shall be composed of members representing a balance of scientific expertise, government, industry, and academia as appropriate to the scope of the Board. Every effort should be made to include international representation on the Board.

Additional working groups, task forces, and other appropriate subgroups shall be appointed as needs arise by the Chair of the Official Methods Board.

V. STAFF LIAISON:

The Executive Director shall assign a member of the staff to serve as staff liaison.

VI. REVIEW SCHEDULE:

Every three years.

VII. DATE ESTABLISHED:

Renamed in 1981

VIII. DATES REVIEWED

01/08,

IX. DATES REVISED:

9/89; 5/90; 1/91; 8/06;
02/07; 07/07; 2/08; 4/13; 8/13

OFFICIAL METHODS BOARD MEETING

Thursday and Friday, June 25-26, 2015

9:00/10:00 AM – 5:00/6:00 PM CT/ET **(Day 1)**

8:30/9:30 AM – 4:00/5:00 PM CT/ET **(Day 2)**

DRAFT MEETING AGENDA

I. PRELIMINARY ITEMS

a. Welcome *(Bradford)*
b. Call to Order /Introductions/Announcements *(Roman)*
c. Review of Policy Documents/Terms of Reference *(Roman)*
d. Review of Draft Agenda* *(Roman)*
e. Review of May 29, 2015 OMB Teleconference Minutes* *(Roman)*
f. Review of June 11, 2015 OMB Teleconference Minutes* *(Roman)*
g. Update from OMB Report to the Board of Directors *(Roman)*
h. Update from Executive Office and Board of Directors *(Bradford)*

II. RECOMMENDATION OF 2015-2016 OMB MEMBERS

a. OMB Working Group for Selection of New OMB Members *(Roman /Szpylka)*
b. Proposal of 2015-2016 OMB* *(Roman/McKenzie)*

III. OFFICIAL METHODS OF ANALYSIS

a. Sole Source OMA Method Modifications* *(Roman/McKenzie)*
    i. AOAC 932.14 - Methods in Progress *(Roman/McKenzie)*
b. Review of OMB Guidance to ERPs on First to Final Action *(Roman)*
c. Recap of Lessons Learned in OMB's First Review of ERP Recommendation for Final Action *(Roman/McKenzie)*
d. Review of Recommendation from AOAC ERP for SPIFAN Nutrient Methods* *(Roman/Sullivan/McKenzie)*
e. Final Action for Methods Approved Without ERPs *(McKenzie)*
f. Actions for OMB Working Group *(Roman/McKenzie)*

IV. AOAC STANDARDS DEVELOPMENT & CONFORMITY ASSESSMENT

a. New Special Section of the Journal *(Rathbone)*
b. Process for OMB Vetting of Voting Panels or ERPs on Meeting Day
c. AOAC stakeholder panels *(McKenzie)*
d. AOAC ERPs *(McKenzie)*
    i. AOAC ERP for SPIFAN Nutrient Methods
e. AOAC PTM (McKenzie)
f. AOAC Annual Meeting Overview *(McKenzie)*

V. OMB RECAP ON AWARDS

a. Awards Review *(Roman/McKenzie)*

VI. ADJOURNMENT

AOAC OFFICIAL METHODS BOARD MEETING
Rockville & Chicago
June 25-26, 2015
Los Angeles, CA
Oct. 1, 2015

AOAC ERP FOR SPIFAN NUTRIENT METHODS
Teleconference
Rockville, MD - TBD

AOAC ERP FOR SPDS INGREDIENT METHODS FOR CHONDROITIN, ANTHOCYANINS, PDE5 INHIBITORS
Rockville, MD
August 3-4, 2015

AOAC SPADA MEETING
Rockville, MD
Sept 1-2, 2015

AOAC ANNUAL MEETING
Los Angeles, CA
Sept. 27 – 30, 2015

AOAC BOARD OF DIRECTORS MEETING
Los Angeles, CA
Sept. 28, 2015

AOAC MID-YEAR MEETING
Gaithersburg, MD
March 14-18, 2016

**** Items that require or may require a vote***

OFFICIAL METHODS BOARD

May 14, 2015 TELECONFERENCE

DATE: Thursday, May 14, 2015
TIME: 1:00pm – 2:30pm ET

DRAFT TELECONFERENCE MINUTES

OMB MEMBERS *(present during all or part of the meeting)*

Shauna Roman	Reckitt Benckiser	Chair
Joe Boison	CFIA	
Jo Marie Cook	Florida Department of Agriculture	Member
Erin Crowley	Q Laboratories	Member
Qian Graves	US FDA CFSAN	Member
Perry Martos	University of Guelph	Member
Shang-Jing (Jean) Pan	Abbott Nutrition	Member
Tom Phillips (proxy)	Maryland Department of Agriculture	Member
Yvonne Salfinger	Independent Consultant	Member
Victoria Siegel	Eurofins	Member
Brad Stawick (proxy)	Microbac	Member
John Szpylka	Mérieux NutriSciences	Past Chair *(ex officio member)*

OMB MEMBERS *not in attendance*

Doug Abbott	Independent Consultant	Member
Sneh Bhandari	Mérieux NutriSciences	Member

AOAC STAFF *(present during all or part of the meeting)*

Delia Boyd, Scott Coates, Deborah McKenzie

I. INTRODUCTORY ITEMS/REVIEW OF POLICY DOCUMENTS *(Roman)*

a. Call to Order/Introductions/Announcements
   i. Roman called the meeting to order at 1:08pm.

b. Roman called OMB's attention to the AOAC Policies for Antitrust, Use of Association Name, Insignia, Identifying Initials, Letterhead and Business Cards and Volunteer Conflict of Interest, as well as the current OMB Terms of Reference.

c. Approval of Draft Agenda
   MOTION: For OMB to approve the agenda as presented.
   Pan moved and Cook seconded. Consensus: passed.

d. Review of April 17, 2015 OMB Teleconference Minutes
   ACTION: Remove "(proxy)" from Salfinger's name in the OMB Member Attendee listing.
   MOTION: To approve the minutes as amended.
   Salfinger moved and Siegel seconded. Consensus: unanimous. Motion passed.

II. AOAC EXPERT REVIEW PANELS

a. AOAC ERP for SPIFAN Nutrient Methods
   ACTIONS: Staff to request statements substantiating FOS/GOS expertise from candidates and include

those ERP members to be removed on a ballot to OMB for to vote on changes to this ERP.

b. AOAC ERP for SPDS Ingredient Methods for Chondroitin, Anthocyanins, PDE5
ACTIONS: OMB to review and vote on next teleconference. Staff to provide perspectives charts on ERP for OMB during its next teleconference.

III. ASSIGNMENT OF OFFICIAL METHODS PROGRAM AWARDS NOMINATIONS

- Roman will send out the latest Excel spreadsheet to OMB members.
- OMB members to review Excel spreadsheet and inform Roman of which nominations they will review.
- OMB members to consider and forward nominations for the Award in Recognition of Technical and Scientific Excellence to Roman.
- Staff to make Awards nominations book available for OMB consideration by May 18th.
- Staff to collect and forward nominations for Technical Service Award to Roman when available.
- Staff to Survey OMB members for teleconference during which awards will be discussed.

IV. UPDATES

a. OMB Working Groups
   i. Szpylka provided an update on the Working Group for Selection of New OMB Members. Outcomes of the working group will be discussed during the June OMB meeting.
   ii. Roman provided an update on the Working Group for Sole Source Method Modification. This will also be discussed during the June OMB meeting.
   iii. McKenzie explained that this working group has not met; however, Roman recommended that the work of this working group be discussed during the June OMB meeting. McKenzie mentioned that there will be a strawman report for OMB to consider.

b. February CODEX related Meetings

Szpylka provided a brief summary on the meetings in addition to the briefing provided.

V. ADJOURNMENT

a. Crowley motioned to adjourn the meeting and Graves seconded. Consensus was unanimous. Roman adjourned the meeting.

OFFICIAL METHODS BOARD

June 11, 2015 TELECONFERENCE

DATE: Thursday, June 11, 2015
TIME: 11:00am – 12:30pm ET

DRAFT TELECONFERENCE MINUTES

OMB MEMBERS *(present during all or part of the meeting)*

Shauna Roman	Reckitt Benckiser	Chair
Doug Abbott	Independent Consultant	Member
Joe Boison	CFIA	Member
Jo Marie Cook (proxy)	Florida Department of Agriculture	Member
Erin Crowley (proxy)	Q Laboratories	Vice Chair
Qian Graves	US FDA CFSAN	Member
Perry Martos	University of Guelph	Member
Shang-Jing (Jean) Pan	Abbott Nutrition	Member
Tom Phillips	Maryland Department of Agriculture	Member
Yvonne Salfinger	Independent Consultant	Member
Brad Stawick	Microbac	Member
John Szpylka	Mérieux NutriSciences	Past Chair *(ex officio member)*

OMB MEMBERS *not in attendance*

Sneh Bhandari	Mérieux NutriSciences	Member
Victoria Siegel	Eurofins	Member

AOAC STAFF *(present during all or part of the meeting)*

Delia Boyd, Scott Coates, Deborah McKenzie

I. INTRODUCTORY ITEMS/REVIEW OF POLICY DOCUMENTS *(Roman)*

a. Call to Order/Introductions/Announcements
   i. Roman called the meeting to order at 1:05pm.

b. Roman called OMB's attention to the AOAC Policies for Antitrust, Use of Association Name, Insignia, Identifying Initials, Letterhead and Business Cards and Volunteer Conflict of Interest, as well as the current OMB Terms of Reference.

c. Approval of Draft Agenda
   MOTION: For OMB to approve the agenda as amended.
   Pan moved and Salfinger seconded. Consensus: passed.

d. Review of May 14, 2015 OMB Teleconference Minutes
   In the list of OMB Members in attendance, add "member" in Boison's row.
   MOTION: To approve the minutes as amended.
   Salfinger motioned and Boison seconded. Consensus: Passed.

e. OMB Report to the AOAC Board of Directors
   Roman reviewed the report from the OMB being presented to the Board of Directors on Friday, June 12, 2015.

II. EXPERT REVIEW PANELS

a. AOAC ERP for Dietary Supplements – Anthocyanins, Chondroitin, & PDE5 Inhibitors

MOTION: To approve all 9 candidates with designated anthocyanins expertise for SPDS Anthocyanins Methods. Darryl Sullivan was approved as an alternate for Covance.
Stawick motioned and Phillips seconded. Consensus: passed.

MOTION: To approve all 9 candidates with designated chondroitin expertise for SPDS Chondroitin Methods. Darryl Sullivan was approved as an alternate for Covance.
Abbott motioned and Graves seconded. Consensus: passed.

MOTION: To approve all 7 candidates with designated PDE5 Inhibitors expertise for SPDS PDE5 Inhibitors Methods and the addition of Tom Phillips and John Szpylka for additional technology perspectives. Darryl Sullivan was approved as an alternate for Covance.
Abbott motioned and Salfinger seconded. Consensus: passed. 1 abstention.

MOTION: To approve the addition of Tom Phillips and John Szpylka to the ERP for SPDS Anthocyanins Methods in support of additional technology perspective representation on the ERP.
Boison motioned and Pan seconded. Consensus: Passed. 1 abstention.

MOTION: To approve the addition of John Szpylka to the ERP for SPDS Chondroitin Methods in support of additional technology perspective representation on the ERP.
Pan motioned and Phillips seconded. Consensus: Passed.

MOTION: To approve Brian Schaneberg as Chair of the AOAC ERP for SPDS Methods for Anthocyanins, Chondroitin, and PDE5 Inhibitors.
Salfinger motioned and Phillips seconded. Consensus: Passed.

III. UPDATES

a. Upcoming AOAC OMB Meeting

ACTION: Boyd to send out ballot to OMB members to survey their attendance for the upcoming meeting and for going out to dinner on Thursday evening (June 25th) and send results to Shauna.

IV. ADJOURNMENT

a. Abbott motioned to adjourn the meeting. Roman adjourned the meeting.

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

DATE: **May 29, 2015**

TO: **AOAC OFFICIAL METHODS BOARD**

FROM: **DAWN FRAZIER, AOAC EXECUTIVE FOR SCIENTIFIC BUSINESS DEVELOPMENT**
CHRISTOPHER DENT, AOAC STANDARDS DEVELOPMENT COORDINATOR

SUBJECT: **AOAC Stakeholder Panel on Dietary Supplements (SPDS):**
Expert Review Panel Applications for Set 1 Ingredients

BACKGROUND:
As per AOAC's contract with the National Institutes of Health Office of Dietary Supplements (NIH-ODS Contract No. HHSN263201300015C), AOAC will convene an expert review panel to review methods submitted purporting to meet the Standard Method Performance Requirements® developed by the SPDS Working Groups and approved by the SPDS Stakeholder Panel. The contract calls for one joint ERP for each set of ingredients. Fifteen (15) applications have been submitted to review methods submitted to be weighed against the SMPRs for Set 1 ingredients, with some demonstrating expertise in multiple ingredients.

- Anthocyanins (10 experts)
- Chondroitin (10 experts)
- PDE5 Inhibitors (8 experts)

The approved ERP will consider the candidate methods for potential First Action Official Methods® Status.

RECOMMENDATION FOR ACTION BY THE AOAC OFFICIAL METHODS BOARD:

Review the attached applications and consider the appropriate membership for the SPDS Set 1 Expert Review Panel.

ATTACHMENTS:
1. Completed Set 1 ERP Applications with attached CVs

First and Last Name:	Organization:	E-mail address:	I am interested in participating on one of the following	AOAC INTERNATIONAL is seeking experts for the following Expert Review Panels. Please select the ERP of interest and submit your contact information.
Liton Roy	Sancilio and Company	lroy@sancilio.com	SPDS Expert Review Panel(s)	Anthocyanins; Chondroitin; PDE5 Inhibitors
Martha Jennens	Covance	martha.jennens@covance.com	SPDS Expert Review Panel(s)	Anthocyanins; Chondroitin
Philip Koerner	Phenomenex	PhilK@phenomenex.com	SPDS Expert Review Panel(s)	Anthocyanins; Chondroitin; PDE5 Inhibitors
Fenhong Song	FDA	Fenhong.song@fda.hhs.gov	SPDS Expert Review Panel(s)	PDE5 Inhibitors
Jana Hildreth	Synutra	Jhildreth@synutrapure.com	SPDS Expert Review Panel(s)	Chondroitin
Kelly Reins	Independent Consultant	kelly.reins@gmail.com	SPDS Expert Review Panel(s)	Chondroitin
Nour Eddine ES-SAFI	Mohammed V University, Rabat	nouressafi@yahoo.fr	SPDS Expert Review Panel(s)	Anthocyanins; Chondroitin

First and Last Name:	Organization:	E-mail address:	I am interested in participating on one of the following groups:	AOAC INTERNATIONAL is seeking experts for the following Expert Review Panels. Please select the ERP of interest and submit your contact information.
Teresa Cain	FDA	teresa.cain@fda.hhs.gov	SPDS Expert Review Panel(s)	PDE5 Inhibitors
Aniko Solyom	GAAS Analytical	asolyom@gaasanalytical.com	SPDS Expert Review Panel(s)	Anthocyanins; Chondroitin
Curtis Phinney	Curtis S.Phinney, CNS	Curtis789@comcast.net	SPDS Expert Review Panel(s)	Chondroitin
Katerina Mastovska	Covance Laboratories	katerina.mastovska@covance.com	SPDS Expert Review Panel(s)	PDE5 Inhibitors
Jerry Zweigenbaum	Agilent Technologies, Inc.	j_zweigenbaum@agilent.com	SPDS Expert Review Panel(s)	Anthocyanins; PDE5 Inhibitors
Jungmin Lee	USDA	jungmin.lee@ars.usda.gov	SPDS Expert Review Panel(s)	Anthocyanins
Melissa Phillips	NIST	melissa.phillips@nist.gov	SPDS Expert Review Panel(s)	Anthocyanins
Brian Schaneberg	Starbucks	bschaneb@starbucks.com'	SPDS Expert Review Panel(s)	Anthocyanins; Chondroitin; PDE5 Inhibitors
Darryl Sullivan	Covance	Darryl.Sullivan@covance.com	SPDS Expert Review Panel (s)	Anthocyanins, Chondroitin, PDE5 Inhibitors

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 25, 2015

To: AOAC INTERNATIONAL Official Methods Board

From: Shauna Roman, Chair – AOAC Official Methods Board

Subject: Update from OMB Report to the Board of Directors

This is a verbal report.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 25, 2015

To: AOAC INTERNATIONAL Official Methods Board

From: John Szpylka, Past Chair – AOAC Official Methods Board

Subject: OMB Working Group for Selection of New OMB Members

This is a verbal report on the working group's efforts to present candidates for new OMB members.

Spreadsheet.

Process for Selecting Members of the Official Methods Board (OMB)

The process begins with the OMB Search Committee.

Composition

The Search Committee shall consist of three (3) members: two members of the current OMB and the Immediate Past Chair of the OMB who shall serve as chair of the Search Committee.

Purpose

The objective of the Search Committee is to identify and recommend a slate of nominees as potential candidates for membership on the OMB. They shall seek candidates from such sources as the Association Membership, the Communities, and Stakeholders Groups. The OMB will select a nominee from this slate.

Process

Criteria for Member of the OMB

- Must provide a current Curriculum Vitae
- Should be a member of AOAC INTERATIONAL in good standing
  - Must have a letter of support from the sponsoring organization [employer/supervisor]
  - Must have an executed AOAC Volunteer Acceptance Form
  - Must provide two letters of recommendation from someone other than an employee, employer or supervisor.
- Should be willing and capable of acting as a Liaison with the Communities, Technical Divisions, Research Institute, and other major Stakeholders.
- Should possess the minimum of a Bachelor's degree in chemistry, biology, mathematics or a related scientific field
- Should demonstrate technically competent written and oral communication and networking skills
- Should demonstrate leadership capabilities through documentation of project management, supervisory experience, or leadership positions within AOAC
- Should have experience in the AOAC collaborative study process
- Should be familiar with the AOAC Program Manual and the Official Methods of Analysis appendices
- Should have successfully completed OMB training in the method validation process, demonstrate ability to perform adequate review of AOAC collaborative studies, and agree to appropriate retraining at least every three years.

Appointment of the Candidate

The nominee shall be contacted by the Chair of the OMB to confirm his/her willingness and ability to serve. Once confirmation has been received, the nominee shall be presented to the Board of Directors for their approval and subsequent appointment by the President of the Association.

Composition of The Official Methods Board

The OMB shall be composed of the Chair, Vice Chair, the Chair of the Safety Committee, the Chair of the Statistics Committee, and up to 9 more members not to exceed a total of 13 members at any given time. The 9 appointed members are to represent a balance of government, industry, and academia as appropriate to the needs of the Association. No more than one-half of the members of the OMB may be from a single agency and no more than one-half of the members may be from industry.

Nominee	Contact Information	Affiliation	Background	Nominator (s)	Comments
Daniel Klein	(314) 290-4777 daniel_klein@steris.com	Steris Corp.	Chair Committee M, Micro	Jim Agin (2013)	
Don Gilliliand	(614) 624-7007 don.gilliland@abbott.com mobile 614-329-6734	Abbott Laboratories	Nutrition, esp. vitamins	Lars Reimann (2013); John Szpylka (2015)	
John Austad	(608) 242-2712 x2065 John.Austad@covance.com	Covance	Lots of chem method development experience, SPs and MMC chair	Darryl Sullivan (2013)	
M. Sarita Cardozo	513-684-3401 maria.cardozo@ttb.gov	TTB	Chem, Nutrition	Norma Hill (2013)	
Wendy McMahon	No need to call	Merieux NutriSCiences / Silliker	Microbiology	John Szpylka (2013)	Member from OMB from same organization
Paul Wehling	(763) 764-4360) paul.wehling@genmills.com	General Mills	Statistics; Chemistry; Allergens	John Szpylka (2015)	Served 2 terms on OMB already.
Philip Bronstein		USDA-FSIS	Microbiology	Erin Crowley	
Dawn Mettler		Rockbridge Labs	Chemistry	Erin Crowley	
Kate Mastovska	katerina.mastovska@covance.com	Covance	Chemistry; Dietary Supplements		
Eric Verdon	Eric.VERDON@anses.fr			Jo Marie Cook	
Jon Wong	Jon.Wong@fda.hhs.gov	FDA			
Jane Weitzel			Statistics, TDLM	Deborah McKenzie	
David Tomas Fornes	David.TomasFornes@rdls.nestle.com	Nestle	Microbiology	Erik Konings (2015); Bala Jagadeesan	

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 25, 2015

To: AOAC INTERNATIONAL Official Methods Board

From: Shauna Roman, Chair – AOAC Official Methods Board

Subject: Developing a Recommended Slate for OMB 2015-2016

This is an interactive effort.

AOAC INTERNATIONAL
OFFICIAL METHODS BOARD
2014 –2015

Chair	**Shauna Roman** Reckitt Benckiser, Inc. Shauna.Roman@reckittbenckiser.com Term: August 29, 2013 – September 21, 2016	*Member*	**Joe Boison** Canadian Food Inspection Agency Joe.Boison@inspection.gc.ca Term: August 29, 2013 – September 21, 2016
Member	**Doug Abbott** Independent Consultant dabbott2@bresnan.net Term: September 11, 2014 - September 27, 2017	*Member*	**Perry Anthony Martos** University of Guelph pmartos@uoguelph.ca Term: October 4, 2012 - September 30, 2015
Member	**Sneh Bhandari** Silliker, Inc. Sneh.Bhandari@Silliker.com Term: August 29, 2013 – September 21, 2016	*Member*	**Shang-Jing Pan** Abbott Nutrition shang-jing.pan@abbott.com Term: October 4, 2012 - September 30, 2015
Member	**Jo Marie Cook** Florida Department of Agriculture and Consumer Services JoMarie.Cook@freshfromflorida.com Term: August 29, 2013 – September 21, 2016	*Member*	**Tom Phillips** Maryland Department of Agriculture phillitd@mda.state.md.us Term: August 29, 2013 – September 21, 2016
Member	**Erin Sutphin Crowley** Q Laboratories, Inc. ecrowley@qlaboratories.com Term: October 4, 2012 - September 30, 2015	*Member*	**Victoria Siegel** Office of the Indiana State Chemist - Purdue University vsiegel@purdue.edu Term: September 11, 2014 - September 27, 2017
Member	**Qian Graves,** US FDA *AOAC Committee on Statistics, Chair* Qian.graves@fda.hhs.gov Term: August 29, 2013 – September 21, 2016	*Member*	**Bradley Stawick** Microbac Laboratories, Inc. brad.stawick@microbac.com Term: October 4, 2012 - September 30, 2015
Member	**Yvonne Salfinger,** Independent Consultant *AOAC Committee on Safety, co-Chair* Yhale@aol.com Term: August 29, 2013 – September 21, 2016	*Past Chair (Ex-officio Member)*	**John Szpylka** Silliker, Inc. John.Szpylka@Silliker.com Term: August 29, 2013 – September 21, 2016

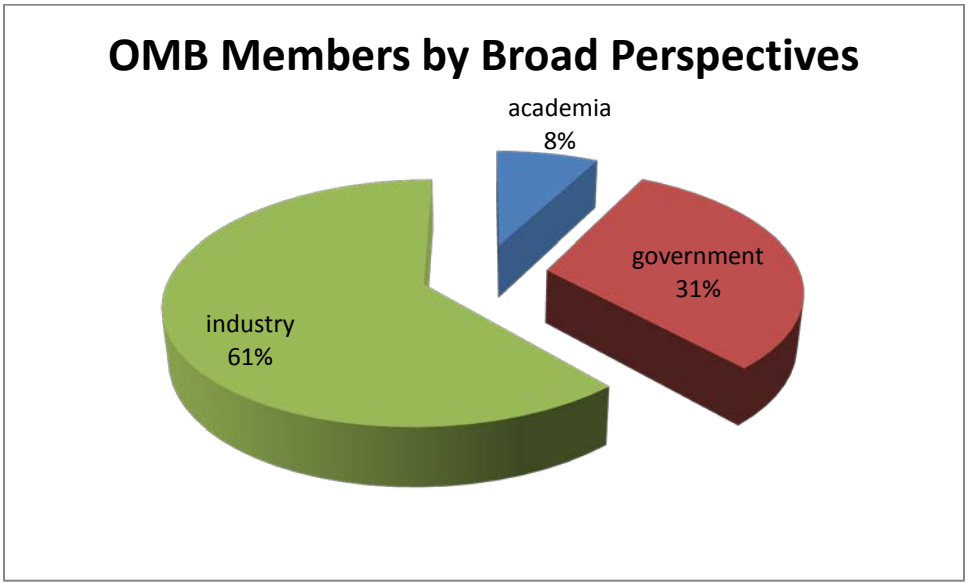
AOAC Staff Liaisons

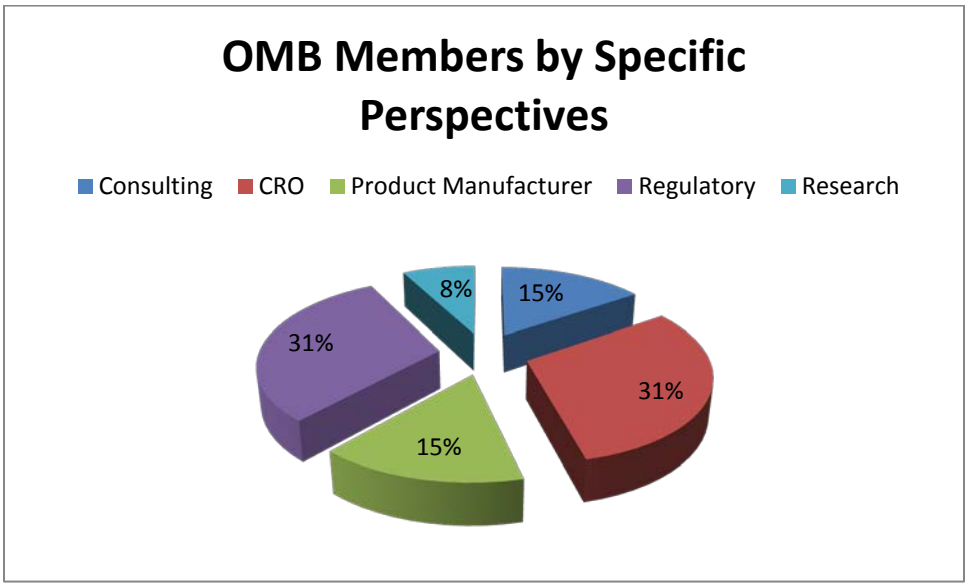
Deborah McKenzie Sr. Director- Standards Development Sr. Director- AOAC Research Institute dmckenzie@aoac.org	Delia Boyd Program Manager – Standards Development dboyd@aoac.org

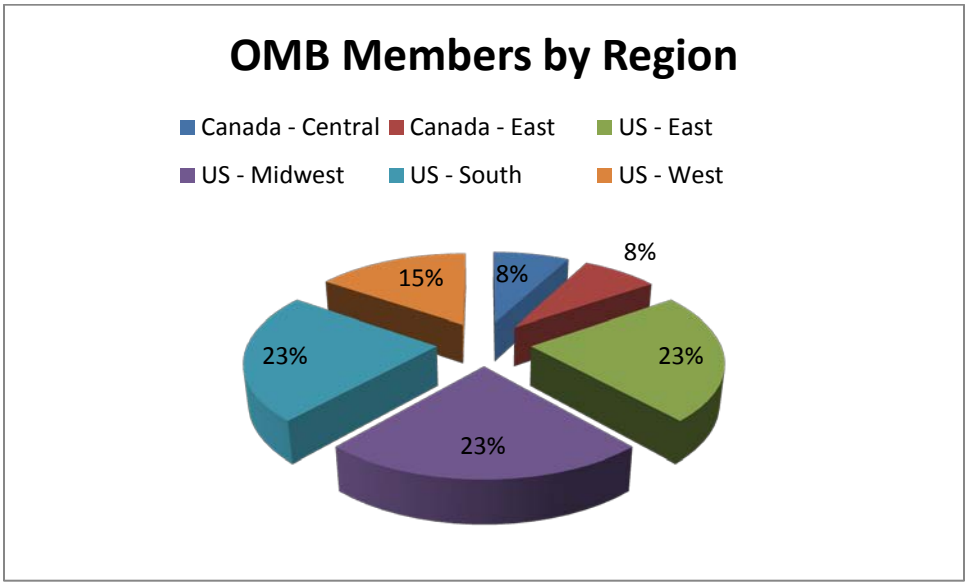
AOAC INTENATIONAL Terms begin following the AOAC Business Meeting. Terms expire at the AOAC Business Meeting.

OMB MEMBERSHIP COMPOSITION 2014-2015

5 AOAC Organizational Affiliates






OMB Members by Region
Canada - Central
Canada - East
US - East
US - Midwest
US - South
US - West
8%
8%
15%
23%
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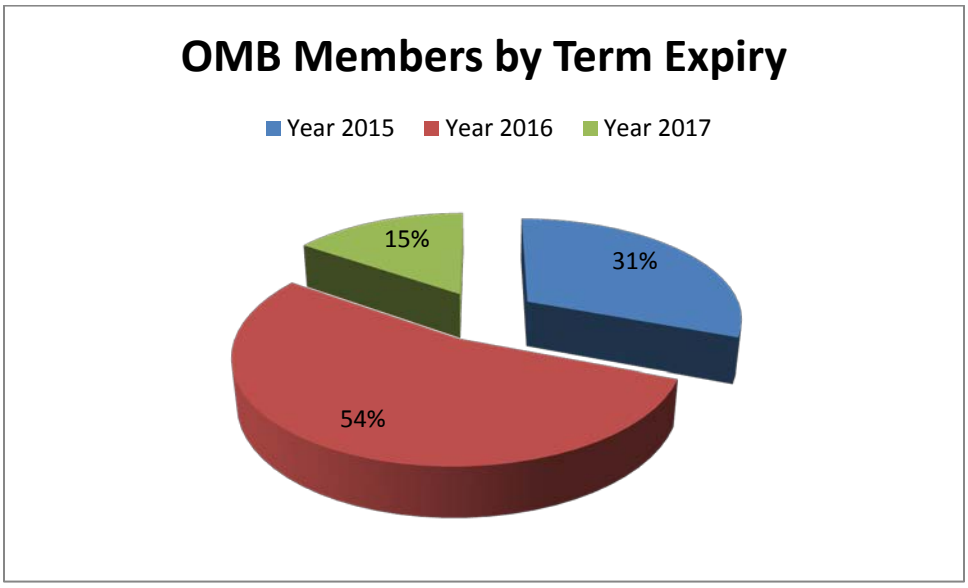
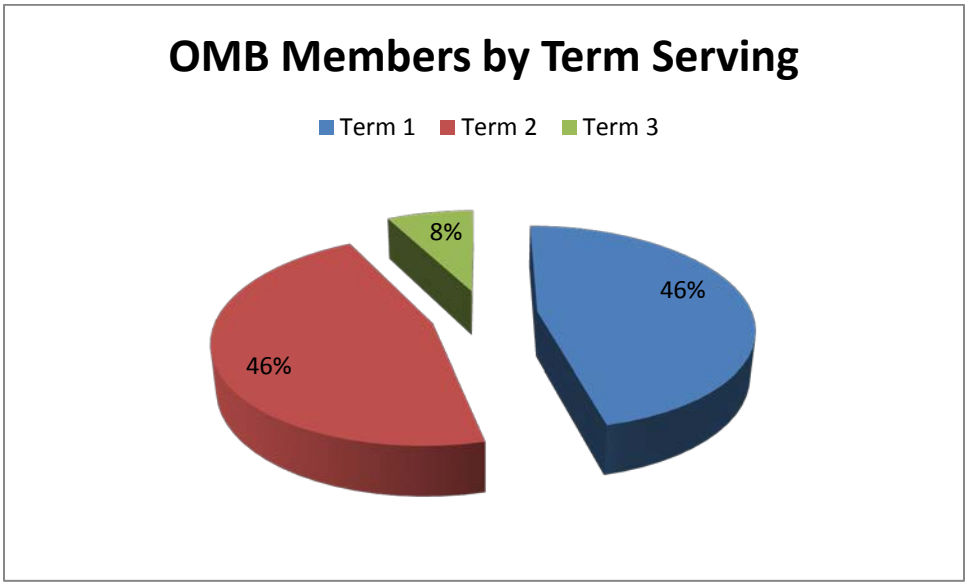
23%


OMB Members by Term Expiry
Year 2015
Year 2016
Year 2017
15%
31%
54%


OMB Members by Term Serving
Term 1
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Term 3
8%
46%
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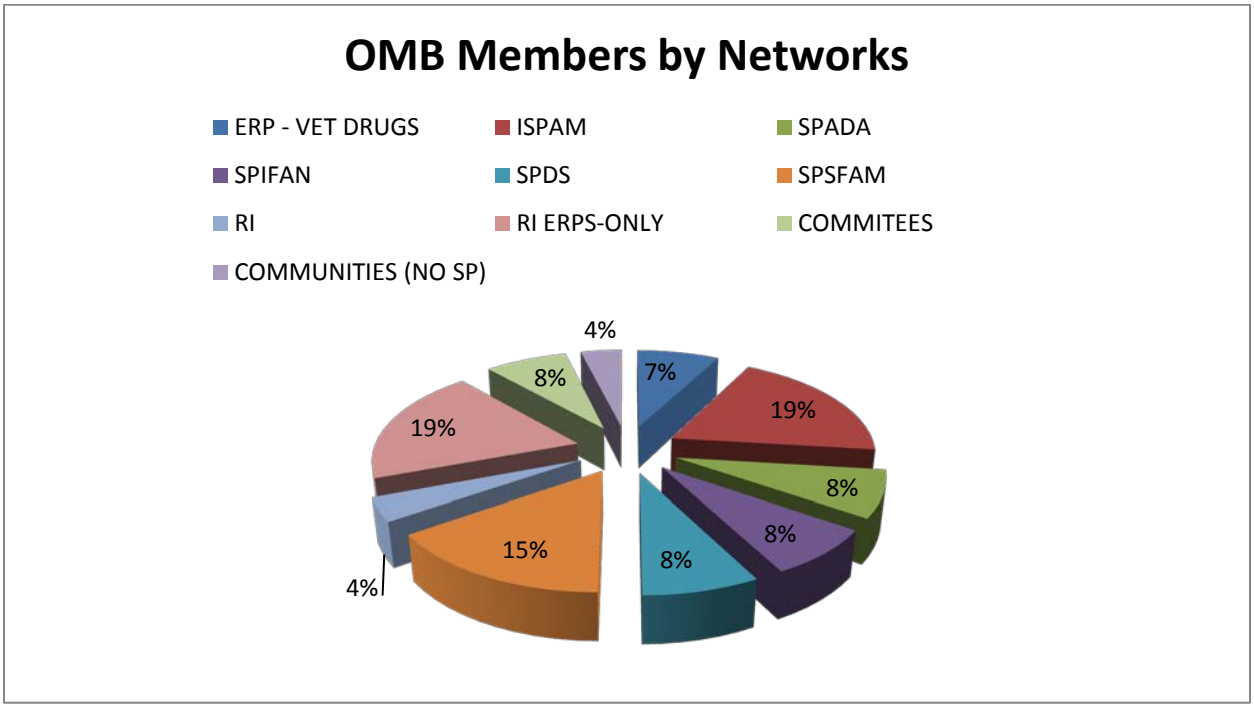
OMB Members by Networks
ERP - VET DRUGS
ISPAM
SPADA
SPIFAN
SPDS
SPSFAM
RI
RI ERPS-ONLY
COMMITEES
COMMUNITIES (NO SP)
4%
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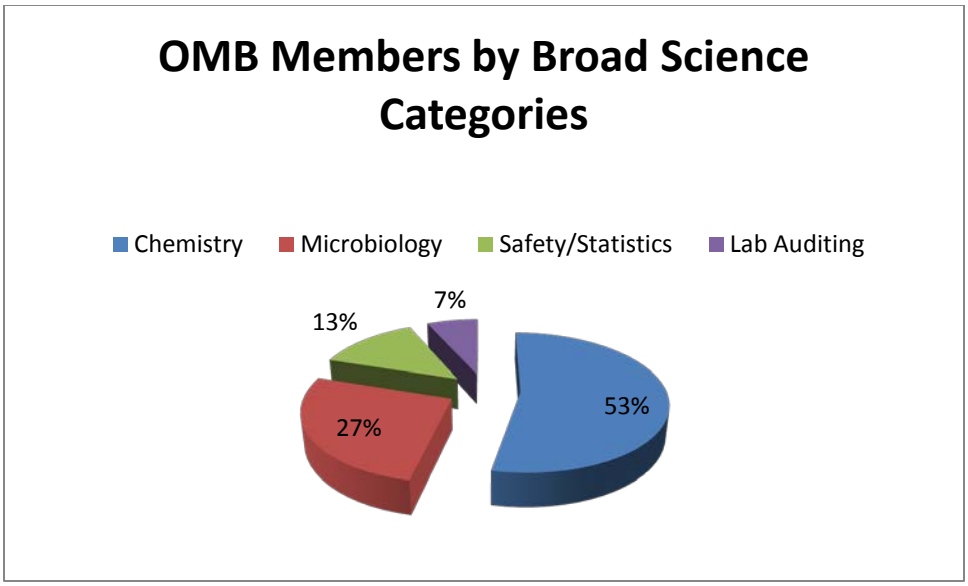
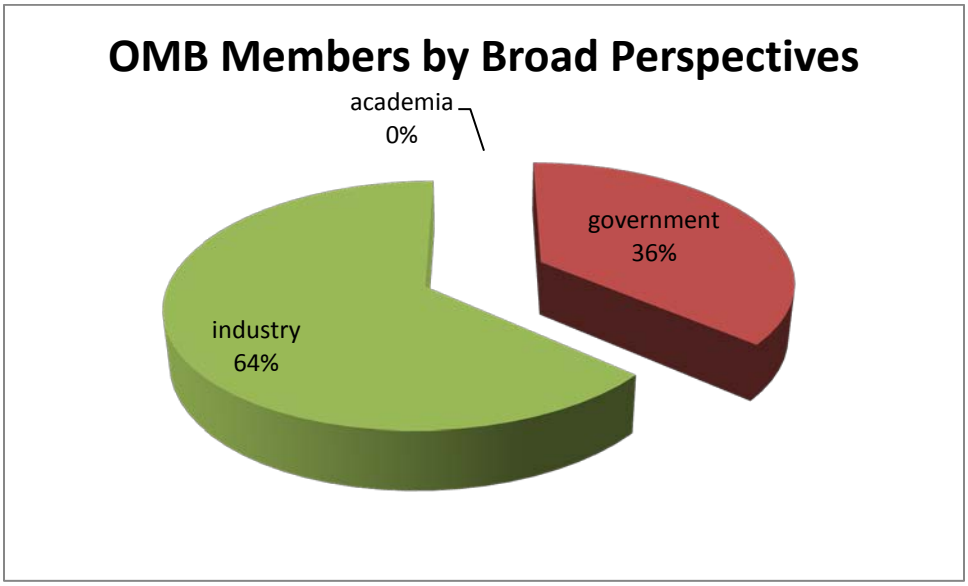
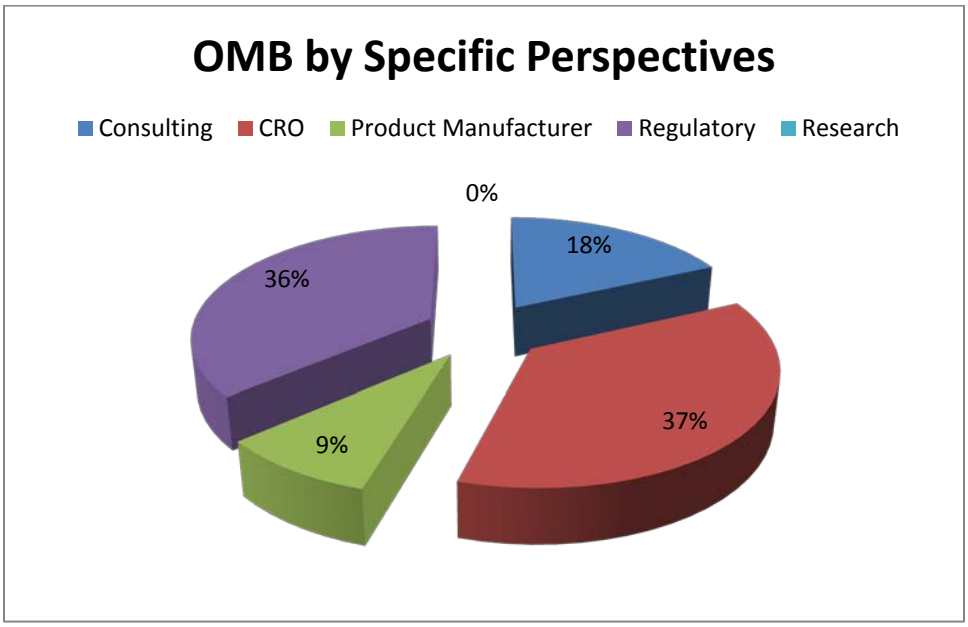
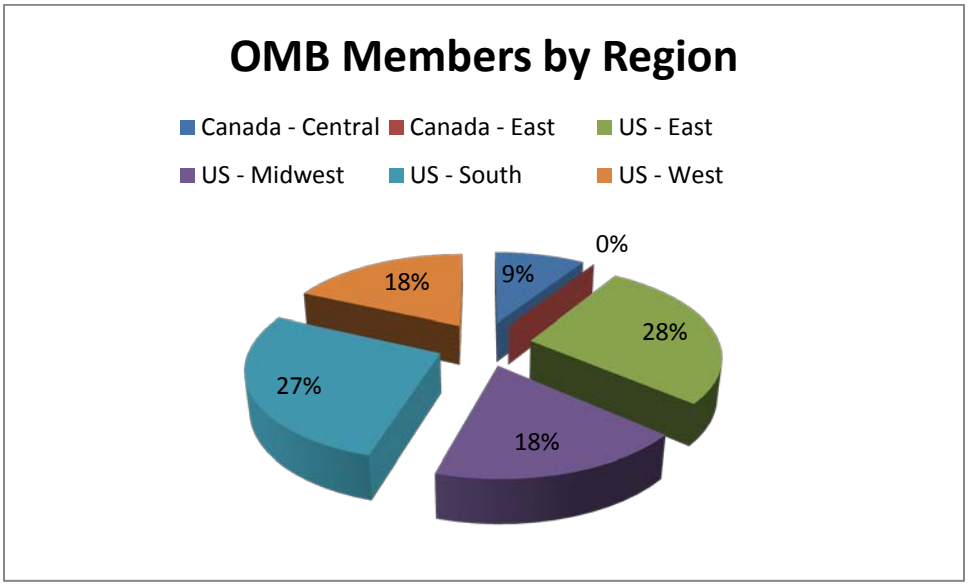

OMB Members by Broad Science Categories
Chemistry
Microbiology
Safety/Statistics
Lab Auditing
7%
13%
27%
53%

OMB COMPOSITION WITHOUT MARTOS/PAN






OMB Members by Region
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Canada - East
US - East
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US - South
US - West
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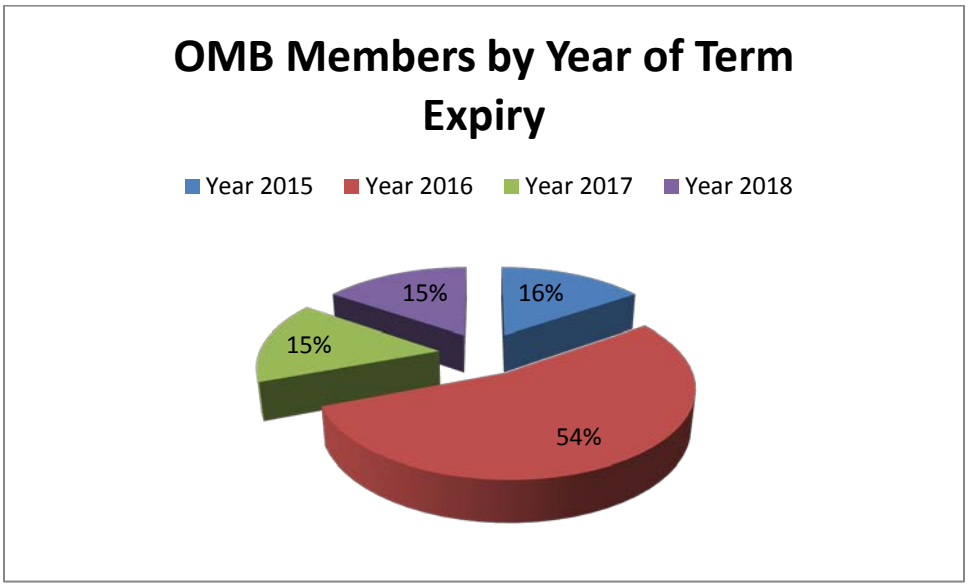
OMB Members by Year of Term Expiry
Year 2015
Year 2016
Year 2017
Year 2018
15%
16%
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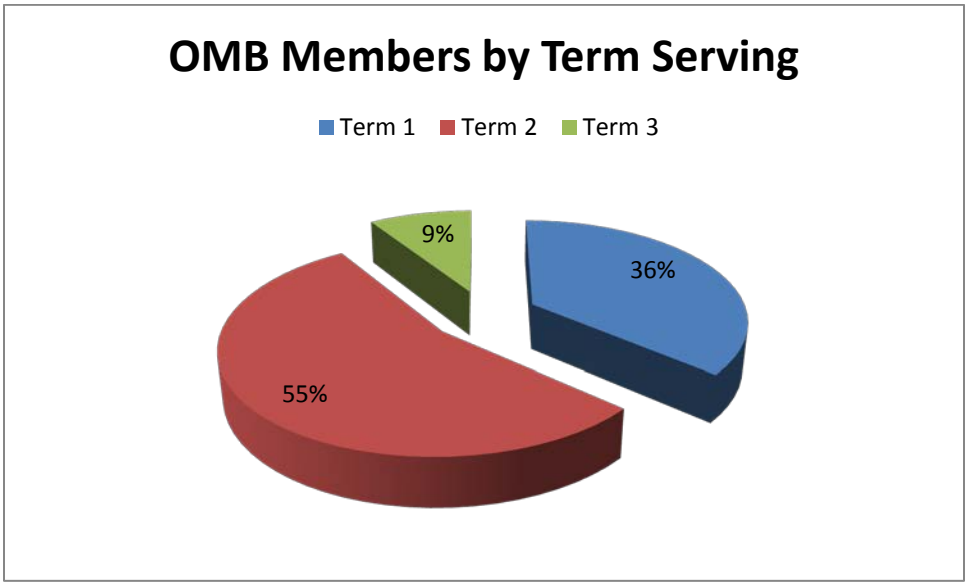
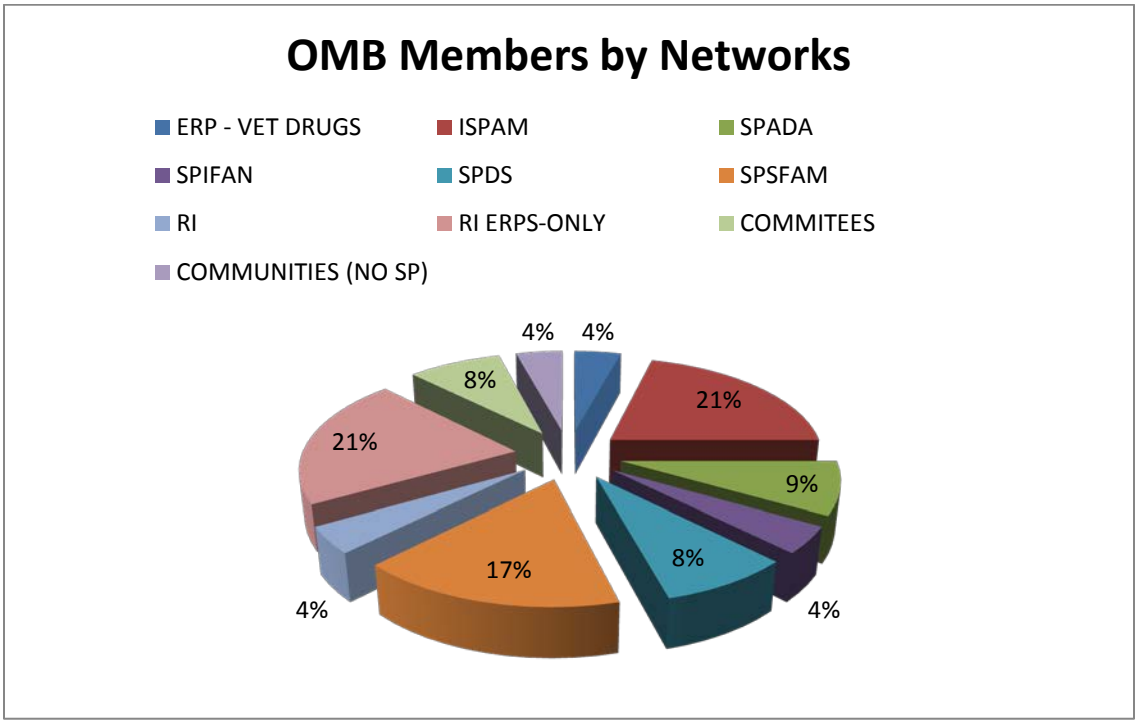

OMB Members by Term Serving
Term 1
Term 2
Term 3
9%
36%
55%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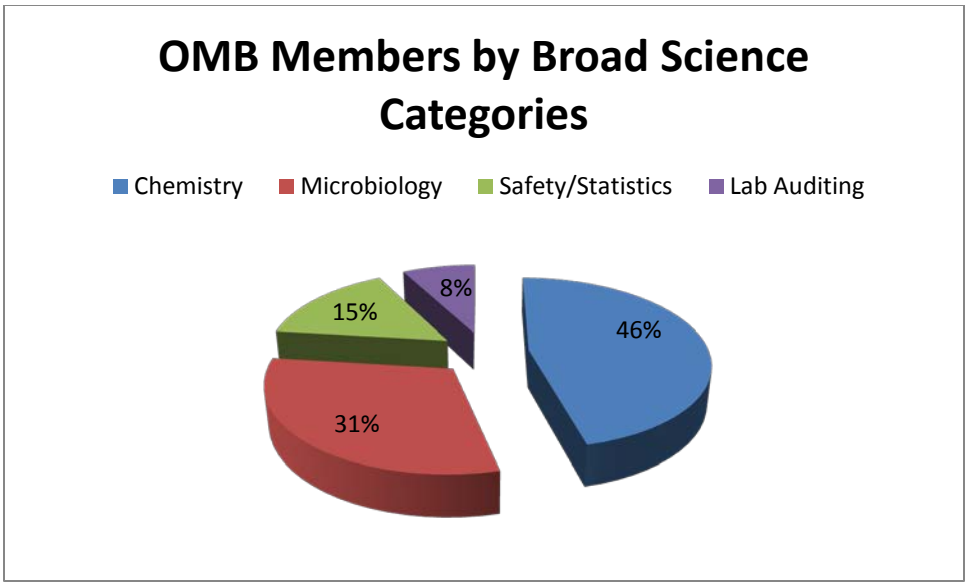
OMB Members by Broad Science Categories
Chemistry
Microbiology
Safety/Statistics
Lab Auditing
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31%

AOAC INTERNATIONAL

TERMS OF REFERENCE

I. NAME:

OFFICIAL METHODS BOARD (OMB)

II. MISSION:

To serve the Association in a scientific and advisory capacity on standards and methods with ethical, timely, open and independent scientific oversight for the implementation of standards development and conformity assessment policies and procedures of AOAC INTERNATIONAL.

III. RESPONSIBILITIES:

To provide ethical, timely, open and independent scientific oversight for the policies and procedures of AOAC INTERNATIONAL.

To approve "Final Action" status for First Action Methods (new and revised) following a proactive review;

To repeal methods, if necessary, in accordance with established policies and procedures;

To participate in addressing appeals and requests for action or guidance, and in resolving disputes;

To endorse and monitor all voluntary consensus panels for appropriate representation and balance of stakeholders' perspectives;

To endorse and monitor all volunteer subject matter experts for volunteer conformity assessment activities;

To adopt and monitor scientific and technical guidance and references;

To acknowledge outstanding scientific and technical volunteer activity and achievement within AOAC;

To actively participate in AOAC standards development activities and maintain and communicate explicit knowledge of AOAC standards development and conformity assessment;

IV. COMPOSITION AND ORGANIZATION:

The Official Methods Board shall consist of up to 13 voting members including a Chair, a Vice-chair, the Chair of the Committee on Safety and the Chair of the Committee on Statistics. The Committee on Safety and the Committee on Statistics may contain co-chairs. The co-chairs for these committees represent one vote on the OMB. Members of the OMB may serve in multiple volunteer roles for the benefit of the Association. The Chair of the Official Methods Board shall have previously served as a member of the Official Methods Board. The Chair, Vice-chair, and members of the Official Methods Board including the chairs of standing committees shall be appointed for a term of three years. A member of the OMB may be reappointed upon the recommendation of the Chair of the Official Methods Board with a maximum term of service of six (6) years. Exceptions may be made at the discretion of the President. The Chair of the Official Methods Board is eligible to serve an additional post chair term of up to three (3) years as an *ex-officio* member. Members of the Official Methods Board must be members of AOAC.

All members of the Official Methods Board are recommended by the Chair and appointed by the President. All Official Methods Board members serve at the pleasure of the President.

The Official Methods Board represents the membership of AOAC INTERNATIONAL. It shall be composed of members representing a balance of scientific expertise, government, industry, and academia as appropriate to the scope of the Board. Every effort should be made to include international representation on the Board.

Additional working groups, task forces, and other appropriate subgroups shall be appointed as needs arise by the Chair of the Official Methods Board.

V. STAFF LIAISON:

The Executive Director shall assign a member of the staff to serve as staff liaison.

VI. REVIEW SCHEDULE:

Every three years.

VII. DATE ESTABLISHED:

Renamed in 1981

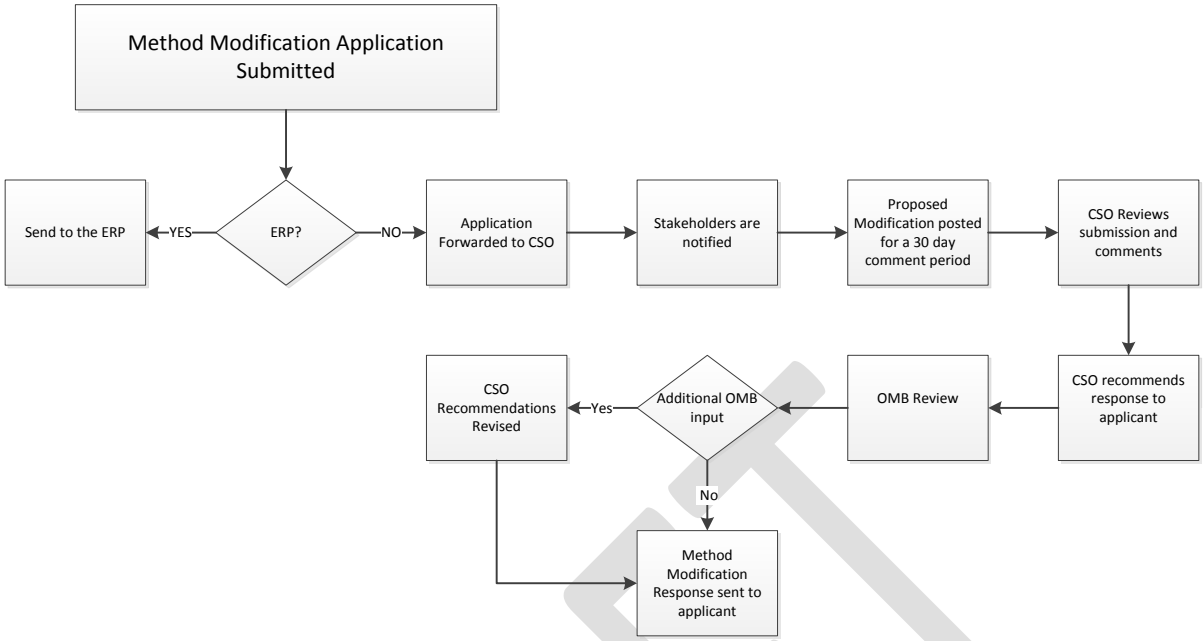
VIII. DATES REVIEWED

01/08,

IX. DATES REVISED:

9/89; 5/90; 1/91; 8/06;
02/07; 07/07; 2/08; 4/13; 8/13

Application Process



Application Process (methods without ERPs)

1. Modification Application is submitted
   a. The OMB has recommended that the application be modified to include a section that addresses potential impact on stakeholders
2. The method information and request for the proposed modification is posted for a 30 day comment period
3. To assist the OMB review, the CSO reviews the submission and any comments and recommends an appropriate response to the applicant. This includes any work that may be needed to support the modification of the method.
4. The method modification proposal, comments, and the CSO recommendations are forwarded to the OMB for review.
5. The method modification application, CSO recommendation and any supporting documentation is sent to the OMB.
   a. All OMB members will review the method modification package.
   b. The OMB chair typically appoints at least 2 OMB members to lead the discussion of the modification. These members will have experience with the method/technology and will perform an in-depth review.
   c. The OMB may also decide to consult with additional SMEs
6. Discussion of the method modification is added to the next OMB teleconference or meeting.
7. Based on the review and discussion, the OMB comes to a consensus:
   a. The OMB may accept the CSO recommendation as written.
   b. The OMB may have questions or have additional input. The CSO will revise the response to the applicant.
8. Final version of the method modification response is sent to the applicant.

*From OMB June 30-July 1 OMB meeting, Chicago, IL

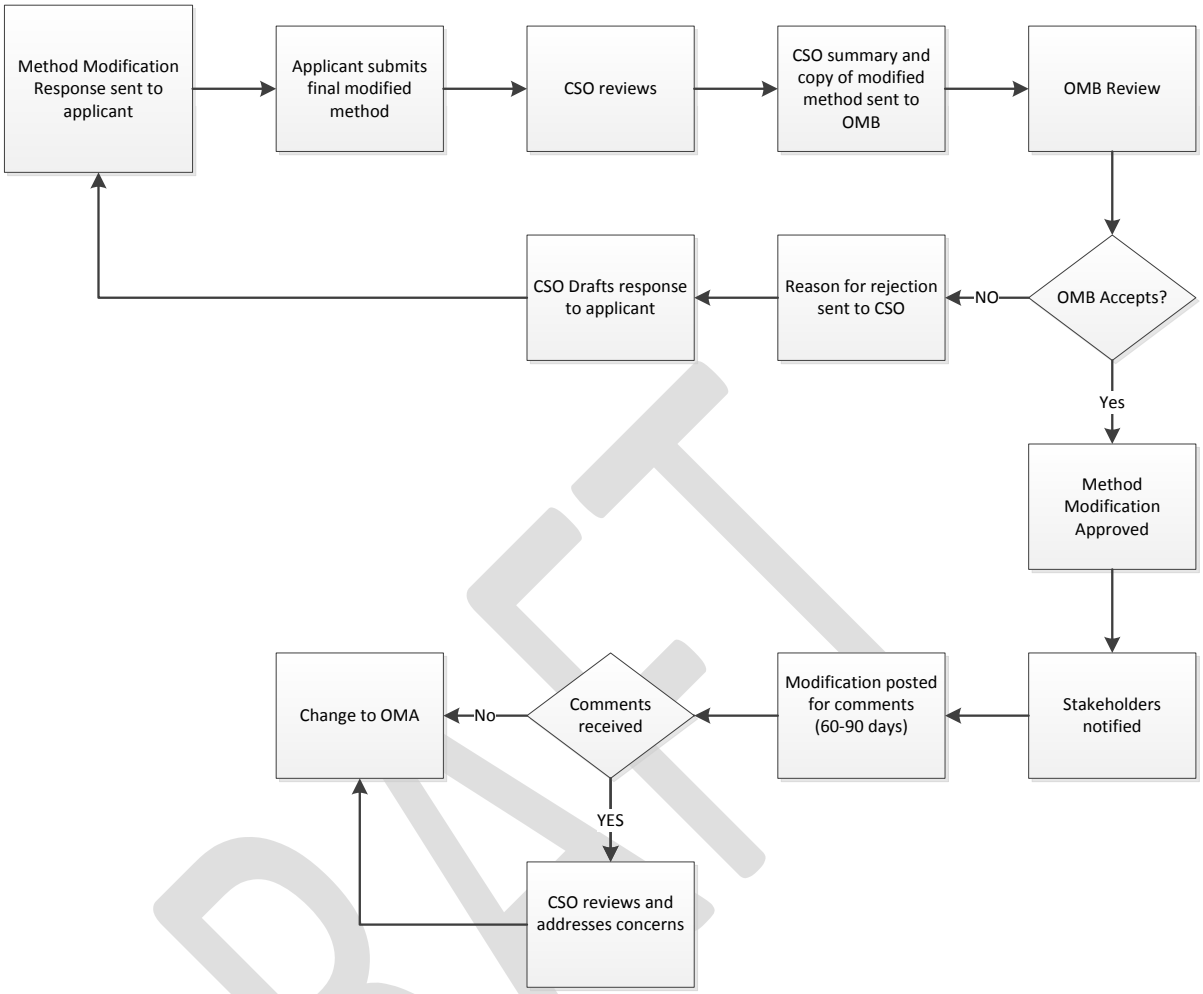
Application Process (cont.)*

Points to Consider:

- Do we have the experts (on the OMB) needed for a thorough review?
- What is the impact (of the proposed modification) on Stakeholders ?
- What is the current status of the methods (First Action, Final Action, how long?)
- Should a new method number be considered?
- What type of modification is being proposed? For example, does the modification:
    - Increase the cost of testing?
    - Require new equipment?
    - Require new chemicals?
    - Change the final result?
    - Etc.
- Is the quality of science maintained?
- Is the supporting data sufficient? Is a SLV or collaborative study needed
- Are there any First to Final Action requirements?

*From OMB June 30-July 1 OMB meeting, Chicago, IL

Modified Method Submission*



Modified Method Submission

1. Applicant submits the final modified method (with any supporting documentation)
2. To assist the OMB review , the CSO reviews the submission and prepares a packet to submit to the OMB, which may include:
   a. Summary of data
   b. Copy of the modified method (with the changes from the current method tracked)
   c. Notation of any deficiencies form the modification response
3. CSO package is sent to the OMB for review
   a. All OMB members will review the method modification package.
   b. The OMB chair will typically appoint at least 2 OMB members to lead the discussion of the modification. These members will have experience with the method/technology and will perform an in-depth review.
   c. At this point, the OMB may also decide to consult with additional SMEs.
4. Based on the review and discussion, the OMB comes to a consensus:
   a. The OMB may accept the method modification as submitted.
   b. The OMB may not accept the method modification as submitted. The reasons for not accepting must be clearly defined. The reasons and any recommendations will be forwarded to the applicant

*From OMB June 30-July 1 OMB meeting, Chicago, IL

5. If/when the method modification is approved
    a. The proposed modification will be posted for comment (60-90 days)
    b. After the comment period, OMA will be changed

*From OMB June 30-July 1 OMB meeting, Chicago, IL

AOAC OFFICIAL METHODS BOARD
Meeting at AOAC INTERNATIONAL
June 30 – July 1, 2014
10:00am – 6:00pm ET /9:00am – 5:00pm CT

DRAFT MEETING MINUTES

OMB MEMBERS *(present during all or part of the meeting)*

Shauna Roman	Reckitt Benckiser (Schiff Nutrition)	Chair
Doug Abbott	Independent Consultant	Member
Sneh Bhandari	Silliker	Member
Joe Boison	Canadian Food Inspection Agency	Member
Jo Marie Cook	Florida Dept. of Agriculture and Consumer Services	Member
Erin Crowley	Q Laboratories	Member
Qian Graves	US FDA	Member
Perry Martos	University of Guelph	Member
Shang-Jing (Jean) Pan	Abbott Nutrition	Member
Tom Phillips	Maryland State Dept. of Agriculture	Member
Yvonne Salfinger	Independent Consultant	Member
Victoria Siegel	Office of Indiana State Chemist, Purdue University	Member
Brad Stawick	Microbac	Member
John Szpylka	Silliker	Past Chair-Ex-Officio

BOARD OF DIRECTORS and INVITED GUESTS *(present during all or part of the meeting)*

Darryl Sullivan	Covance Laboratories	Board of Directors, Secretary

AOAC STAFF and CONTRACTORS PRESENT ***(present during all or part of the meeting)***

Delia Boyd	Scott Coates	Alicia Meiklejohn
Jim Bradford	Deborah McKenzie	Robert Rathbone

I. INTRODUCTORY ITEMS

a. Call to Order/Introductions/Announcements
Roman called the meeting to order.

b. Review and Approval of Draft Meeting Agenda
MOTION: For OMB to approve the agenda as proposed
Bhandari moved and Stawick seconded. Consensus: passed.

II. ORGANIZATIONAL UPDATES

a. Bradford provided a brief update pertaining to AOAC and the AOAC Board of Directors. Roman provided an update on the OMB Report to the Board of Directors
b. McKenzie provided an update on the AOAC Research Institute activities
c. McKenzie provided an update on AOAC Standards Development activities including preparation for upcoming final action consideration of SPIFAN methods.

III. OFFICIAL METHODS BOARD

a. OMB completed the OMB vice chair selection process and selected Erin Crowley to be the OMB Vice Chair
ACTIONS: Revise Roster and add Crowley to OMB Core teleconferences.

b. OMB Committees and Working Groups: McKenzie discussed with the OMB an opportunity for them to form more permanent working groups for regularly scheduled tasks as a way to provide additional leadership opportunities for members within the OMB.
ACTION: No action taken.

IV. OMA METHOD MODIFICATIONS

a. Modification of OMA methods that have no Expert Review Panels:

i. OMB considered addressing several points:Do we have the experts (on the OMB) needed for a thorough review?
ii. What is the impact (of the proposed modification) on Stakeholders?
iii. What is the current status of the methods (First Action, Final Action, how long?)
iv. Should a new method number be considered?
v. What type of modification is being proposed? For example, does the modification:
4.1..5.1 Increase the cost of testing?
4.1..5.2 Require new equipment?
4.1..5.3 Require new chemicals?
4.1..5.4 Change the final result?
4.1..5.5 Other, Etc.
vi. Is the quality of science maintained?
vii. Is the supporting data sufficient?
viii. Are there any First to Final Action requirements?

b. **<u>Proposed Modification Approval Process (for methods without ERPs)</u>**

- **Application Process**

i. Modification Application is submitted
4.2..1.1 The OMB has recommended that the application be modified to include a section that addresses potential impact on stakeholders
ii. The method information and request for the proposed modification is posted for a 30 day comment period
iii. The CSO reviews the submission and any comments and recommends an appropriate response to the applicant. This includes any work that may be needed to support the modification of the method.
iv. The method modification proposal, comments, and the CSO recommendations are forwarded to the OMB for review.
v. The method modification application, CSO recommendation and any supporting documentation is sent to the OMB.
4.2..5.1 All OMB members will review the method modification package.
4.2..5.2 The OMB chair typically appoints at least 2 OMB members to lead the discussion of the modification. These members will have experience with the method/technology and will perform an in-depth review.
4.2..5.3 The OMB may also decide to consult with additional SMEs
vi. Discussion of the method modification is added to the next OMB teleconference or meeting.
vii. Based on the review and discussion, the OMB comes to a consensus:

4.2..7.1 The OMB may accept the CSO recommendation as written.
4.2..7.2 The OMB may have questions or have additional input. The CSO will revise the response to the applicant.

viii. Final version of the method modification response is sent to the applicant.

- **Modified Method Submission**

i. Applicant submits the final modified method (with any supporting documentation)

ii. The CSO reviews the submission and prepares a packet to submit to the OMB, which may include:
4.2..2.1 Summary of data
4.2..2.2 Copy of the modified method (with the changes from the current method tracked)
4.2..2.3 Notation of any deficiencies form the modification response

iii. CSO package is sent to the OMB for review
4.2..3.1 All OMB members will review the method modification package.
4.2..3.2 The OMB chair will typically appoint at least 2 OMB members to lead the discussion of the modification. These members will have experience with the method/technology and will perform an in-depth review.
4.2..3.3 At this point, the OMB may also decide to consult with additional SMEs.

iv. Based on the review and discussion, the OMB comes to a consensus:
4.2..4.1 The OMB may accept the method modification as submitted.
4.2..4.2 The OMB may not accept the method modification as submitted. The reasons for not accepting must be clearly defined. The reasons and any recommendations will be forwarded to the applicant

v. If/when the method modification is approved
4.2..5.1 The proposed modification will be posted for comment (60-90 days)
4.2..5.2 After the comment period, OMA will be changed

ACTIONS: Share with Board of Directors; Staff to develop/revise related documentation.

c. All OMA modifications are date stamped. It was recommended to note on the method, what was corrected/revised.

d. Review of Modification of AOAC Official Methods 2009.01 and 2011.25

- Establish a review panel to discuss and recommend what additional work may be needed for Final Action consideration,
MOTION: For OMB to establish a group of experts (ERP) to review requirements for Final Action status for AOAC 2009.01 and AOAC 2011.25.
Cook moved; Bhandari seconded. Vote: Unanimous
ACTIONS: Issue a call for experts.

- Review of Modification of AOAC Official Method 932.14
Reviewed by Cook, Phillips and Bhandari

ACTIONS: Schedule a teleconference for July 15, 2014 at 11:00am ET to discuss this modification.

- Review of Modification of AOAC Official Method 998.12
  ACTIONS: item tabled until method revisions are submitted.

V. AOAC EXPERT REVIEW PANELS RECOMMENDATIONS FOR REPEAL & FINAL ACTION

a. Sullivan and McKenzie shared with OMB the review of methods for Final Action recommendation taking place during the ERP for SPIFAN Nutrient Methods. The ERP considered methods for repeal status also during their March 2014.
ACTIONS: Provide OMB with information on methods as soon in advance as possible and include the reference material documentation.

VI. ERP COMMUNICATION & BEST PRACTICES

a. McKenzie shared with the OMB the document President Harnly shared with the Board of Directors containing outcomes of recommendations for staff and best practices for ERP chairs.

VII. INCREASING EXPERTISE ENGAGEMENT

a. McKenzie discussed recruitment of new volunteers and working group chairs from among the new membership. She also discussed an improved mechanism for soliciting feedback and comments on methods; using the AOAC OMA methods from SPIFAN as an example.

VIII. AOAC ANNUAL MEETING ACTIVITIES

a. The following volunteered to be at the following meetings:
- SPDS: Roman/Phillips/Bhandari
- ISPAM: Cook/Crowley
- SPIFAN: Bhandari/Pan/Szpylka
- Board of Directors: Roman
- SPDS Working Group: Roman/Phillips
- SPSFAM: Cook/Bhandari/Phillips
- Agricultural Materials: Phillips/Siegel
- PAH ERP: Phillips
- Pesticides ERP: Boison
- Chemical Contaminants: Phillips
- SPIFAN ERP: Bhandari/Pan
- Statistics: Graves/Crowley/Pan
- Safety: Salfinger
- RI Advisory Council: Roman/Crowley
- RI Board of Directors: Roman
- Mycotoxins: Phillips/ Abbott
- Food Allergens: Salfinger
- Dietary Starch ERP: Bhandari/Phillips

IX. VETTIGN POTENTIAL AOAC EXPERT REVIEWERS

a. **ACTIONS**: Move July 10th teleconference to July 18th.

b. The following volunteered to serve as primary reviewers for the upcoming ERPs
- PAH: Phillips and Cook
- Pesticides: Boison and Cook
- Microbiology: Crowley and Abbott
- Dietary Starch: Siegel and Bhandari

X. FUTURE OMB TELECONFERENCES AND MEETINGS

a. **ACTIONS:** Move August 14th teleconference to August 21st to review Annual Meeting voting panels. Keep August 7th open as a possibility for reviewing voting panel for SPADA

XI. REVIEW OF ACTION ITEMS

a. McKenzie reviewed the revised Action Item listing with OMB

b. ACTIONS: Update the Action Items.

XII. ADJOURNMENT

a. **Motion:** To adjourn the meeting on Day 1:
Salfinger moved and Stawick seconded. Vote: Unanimous.

b. **Motion:** To adjourn the meeting on Day 2:
Bhandari moved and Stawick seconded. Vote: Unanimous.

Method Modifications Proposal

Immediately below is the process currently on the books. It relies on a single person/body to make decisions affecting the analytical communities and the Association. A change to the flowchart is proposed as shown on the next page to reflect the Board's new Working Group initiated process approved 12/9/2014. Draft major/minor modification definitions are included for clarification.

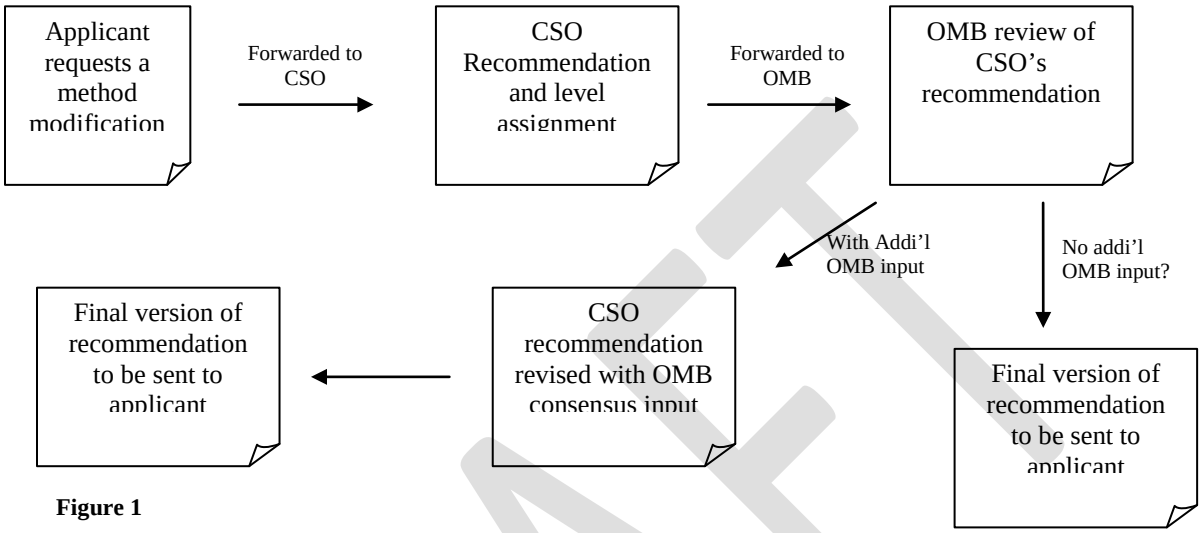


Figure 1

Modification Workflow Concepts:

Any community member may submit a request for a method modification. Modification submissions go to the Chief Scientific Officer and must include the following paperwork.

Editorial Modification:

A written explanation of the reason(s) for the modification is required.

Typos or editorial corrections or clarifications are forwarded to the OMB for approval then to the editorial board or OMA editor as appropriate. Methods that have undergone an editorial modification will retain the same number. A list of the methods with editorial modifications will be published in *Inside Laboratory Management* and on the Website.

Method Modifications:

Require the submission of data to justify the requested modification. All Method Modifications go to a Working Group. The Working Group will review the modification proposal. If the WG determines that a method modification is needed, they will draft the appropriate Standard Method Performance Requirements to reflect the needs of the community.

1.) Minor Modification, no change or a simple modification of the current SMPRs might suffice. There is no significant effect to the results; i.e. new results are within (1 or 2σ) as defined by original study and the needs of the community. Regulatory limits should inform the decision as well. For example, if the compliance limit is +/- 20% and the replicates for the new method are within about half that range (<10%), then it would probably pass regulatory approval.

2.) Major Modification will require drafting new SMPRs. There is a significant effect on the results and/or a significant change to the technology. For example, if the modification requires retraining of technical personnel; or purchase of significantly more expensive equipment; or significant change in sample prep; or changing the chemistry of any step in the process (e.g.a different catalyst, pH change, temperature change) all indicate significant changes to technology.

Method Modifications Proposal

Authorities:

Community – These are members of industry, academia and regulatory bodies that need standards or analytical methods to perform their professional duties.

WG – The WG drafts the appropriate Standard Method Performance Requirements.

SP - Final decisions on the acceptance of SMPRs remain with the appropriate Stakeholder Panel.

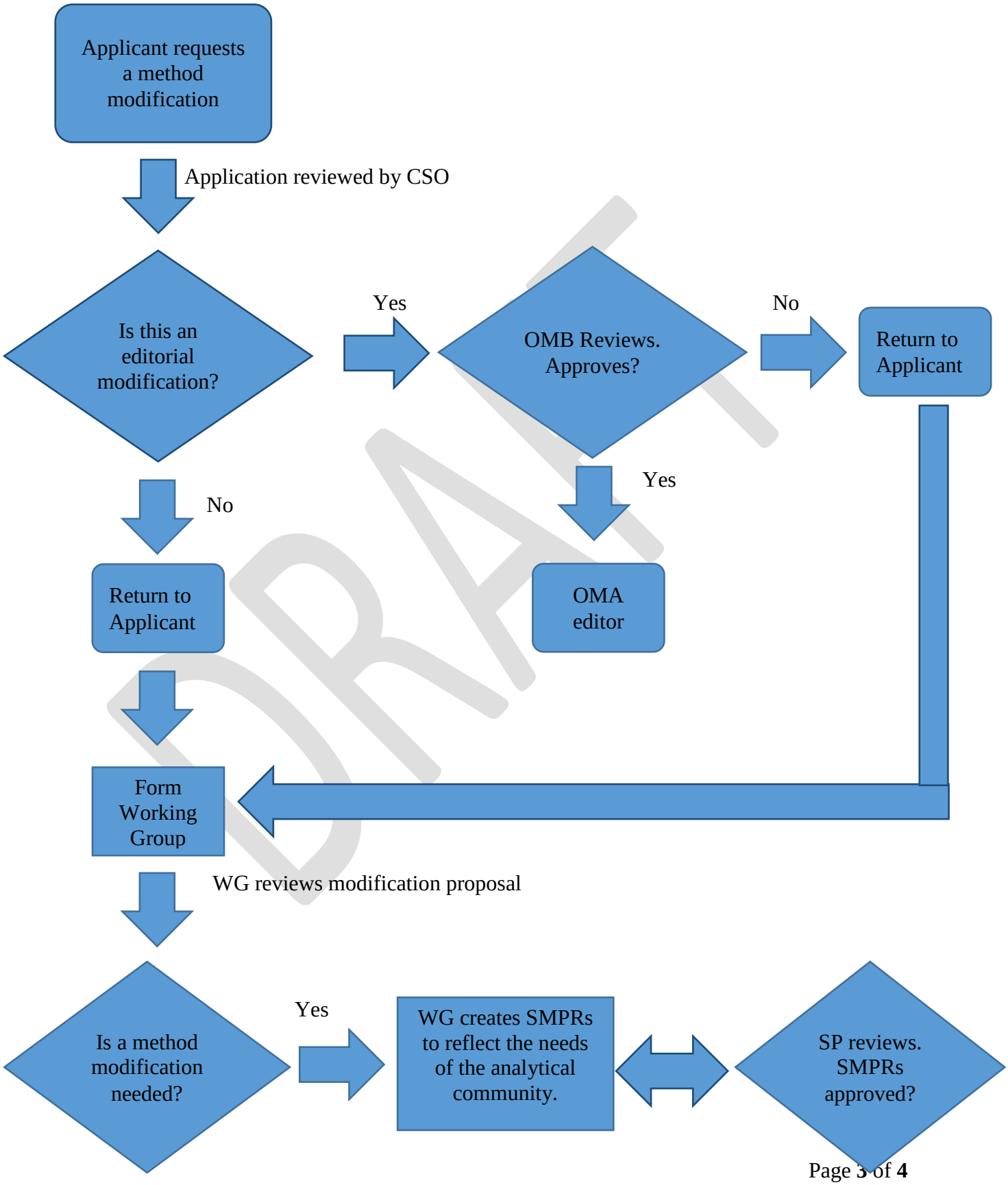
ERP - All methods are reviewed and approved for First Action and recommended for approval for Final Action or repeal by the Expert Review Panel. All methods that have undergone a method modification are defined as First Action and receive their unique OMA number.

OMB - Final decisions on acceptance of Final Action or Repeal for Official Methods of Analysis remains with the Official Methods Board. All decisions on Official Methods require a minimum 2/3 vote of the OMB members.

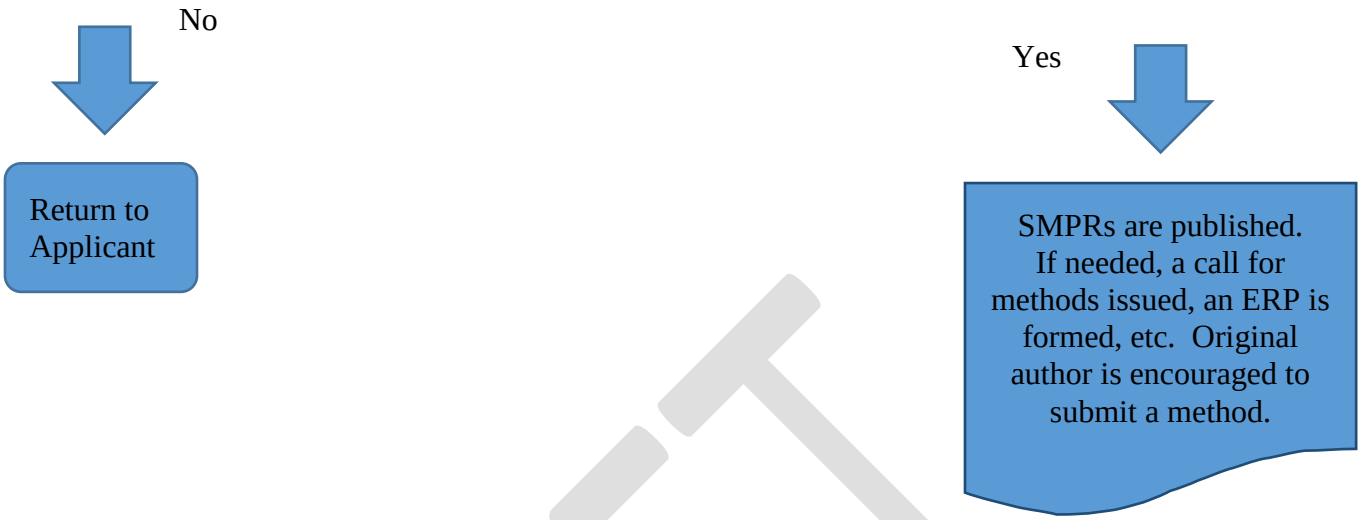
BoD - The Board of Directors reserves all decisions on Policy and Association responsibility to the Board of Directors.

Method Modifications Proposal

Recommended Flow of Work



Method Modifications Proposal



AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 25, 2015

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie – Staff Liaison, AOAC Official Methods Board

Subject: AOAC 932.14

Working group met followed by review of the method author's response. Working group members agreed that they had no further comments.

On February 2, 2015, I spoke with the method author regarding the progress of the review and explained what has happened.

RECOMMENDATION:
OMB to decide what the next steps for this method are based on the discussion regarding Sole Source OMA Method Modifications.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 25, 2015

To: AOAC INTERNATIONAL Official Methods Board

From: Shauna Roman, Chair – AOAC Official Methods Board

Subject: Review of OMB Guidance to ERPs Regarding First to Final Action

This is a verbal report.

Attachment: OMB Guidance Document and presentation.

AOAC INTERNATIONAL

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FIRST ACTION TO FINAL ACTION METHODS

GUIDANCE FOR AOAC EXPERT REVIEW PANELS

Expert Review Panels working within the AOAC alternate pathway process may recommend a First Action status method be elevated to Final Action status. Such a recommendation leverages the ERP's high level of expertise supported by data from the initial evaluation, and results from the subsequent two year method performance evaluation period.

The Official Methods Board receives the recommendation with supporting documentation, and determines if Final Action status is warranted. OMB's review verifies the method process was conducted in compliance with the guidelines and protocols of the Association.

For transparency and to expedite the review process, the main areas OMB will review when evaluating ERP recommendations to promote methods to Final Action are listed below. Documentation of the areas listed below will also increase confidence in method performance and assist users to properly and safely perform the methods at their locations.

A. Method Applicability
   a. A method's applicability to the identified Stakeholder needs is best assessed by the Stakeholder Panel and should be a part of the process from the onset. OMB liaisons will remind Stakeholder Panels to maintain this focus point.
   b. OMB may ask ERPs and Stakeholder Panels for feedback to improve the applicability of the method such as potential method scope expansions and potential points of concern.

B. Safety Concerns
   a. A safety review must be performed for a method to be recognized as First Action.
   b. All safety concerns identified during the 2 year evaluation period must be addressed.
   c. Guidance and support can be obtained from the AOAC Safety Committee.

C. Reference Materials
   a. Document efforts undertaken to locate reference materials. Methods may still progress to Final Action even if reference materials are not available.
   b. Guidance and support can be obtained from the AOAC Technical Division on Reference Materials.

D. Single Laboratory Validation
   a. Data demonstrating Response Linearity, Accuracy, Repeatability, LOD/LOQ, and Matrix Scope must be present. Experimental designs to collect this data may vary with the method protocol and the intended use of the method.

b. Resources can be identified by the AOAC Statistics Committee.

E. Reproducibility/Uncertainty and Probability of Detection
   a. For quantitative methods, data demonstrating Reproducibility & Uncertainty must be present. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method (i.e., collaborative studies, proficiency testing, etc.).
   b. For qualitative methods, data must be present demonstrating the probability of detection at specified concentration levels as defined by the SMPR. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method.
   c. Guidance and support can be obtained from the AOAC Statistics Committee.

F. Comparison to SMPR
   a. Document method performance versus SMPR criteria. Note which SMPR criteria are met. For SMPR criteria not met, the ERP documents the reasoning why the method is still acceptable.
   b. Data is present to assure the matrix and analyte scopes are covered. This is critical for methods used for dispute resolutions.

G. Feedback From Users of Method
   a. Document positive and negative feedback from users of the method during the trial period.
   b. Feedback from users demonstrating method ruggedness should be documented.
   c. Assess the future availability of vital equipment, reference materials, and supplies.

H. ERP Recommendations to Repeal First Action Methods
   a. Recommendations to repeal First Action methods shall be accompanied with detailed reasons for the decision.

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Path to Final Action

What to Expect from
Official Method Board (OMB)
Review of ERP Method
Recommendations

Standard Method Performance Pathway

- Standard Method Performance Requirements authored by Working Groups and established by Stakeholders
- Expert Review Panel (ERP) vetted by OMB
- ERP approves methods for First Action
- Method reproducibility data collected
- ERP monitors method performance
- ERP recommendations sent to OMB within 2 years
  - Final Action, continuation, or repeal

OMB Liaison

- OMB member or designee is assigned to your ERP
- Liaison monitors First Action to Final Action process
- Monitors ERP's documentation of all items in OMB Guidance document (OMA Appendix G)

Method Applicability

- Determine how method meets stakeholder's needs
  - scope, accuracy, precision, etc.
- Are ERP recommendations & improvements implemented?
- Assess method limitations & concerns

Safety Concerns

- Safety review completed for 1st Action
  - Participation by Safety Committee
- All safety issues identified during 2 year review addressed
  - Participation by Safety Committee

Reference Materials

- Identification of potential reference materials (RM)
  - If none found, define alternative options
- RM performance expectations
- Available resource is the AOAC Technical Division on Reference Materials (TDRM)

Single Laboratory Validation

Chemistry

- Linearity
- Accuracy
- Repeatability
- LOD / LOQ
- Matrix scope
- Selectivity

Microbiology

- Inclusivity/Exclusivity
- Robustness
- Repeatability
- POD or equivalent
- Matrix scope

- Statistics Committee is your resource

Quantitative Reproducibility/Uncertainty

- Experimental designs may vary
  - Collaborative study
  - PT data
  - Multi-lab study variations
- Committee on Statistics
  - is available to discuss new study design protocols
  - Formalized tools were presented at the 2013 Annual Meeting

Qualitative Reproducibility/Uncertainty

- Experimental designs may vary
- Committee on Statistics is available to discuss new study protocols designs

Compare to SMPR

- Method meets Performance Criteria
- Method does not meet Performance Criteria
  - Acceptable or not? List reasoning
- Document acceptability to Stakeholders

Feedback from Users

- Solicit and document user feedback
  - ERP Chair determines mechanism
  - May take form of
    - Proactive calls to users
    - Tally of incoming calls
    - Emails
    - Web surveys

Feedback from Users

- Method performance
- Safety Concerns
  - Warnings
  - Alternatives
- Equipment and supply availability
  - Readily available
  - Practicality
  - Suggested improvements
  - Failures
- Reference material availability

ERP Recommendations

- Supply all documentation to AOAC by established deadline
  - Documentation includes ERP review details
- Representative from ERP present at OMB review meeting
- If method to be repealed, document reasoning

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AOAC INTERNATIONAL

Assure worldwide confidence in analytical results

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 25, 2015**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Darryl Sullivan, Chair – AOAC ERP for SPIFAN Nutrient Methods**
Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: **ERP Recommendations for Final Action**

Background:
In March 2015 during the AOAC Mid Year Meeting, the AOAC ERP for SPIFAN Nutrient Methods reviewed reproducibility information and verified additional clarifications during and after the meeting for AOAC 2012.15 and AOAC 2012.16, Panthothenic acid in Infant Formula and Adult/Pediatric Nutritional Formula and Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula respectively. The ERP has reached consensus to recommend these methods to the AOAC Official Methods Board for Final Action method status consideration.

In support of these recommendations, please find attach a report for each method with attachments supporting the work done on the method and the ERP's deliberation and consensus.

Recommendations:
For the AOAC OMB to consider the ERP recommendations and promote AOAC 2012.15 and AOAC 2012.16 to AOAC Final Action *Official Methods*^{SM} status.

Attachments:
1. ERP Recommendation Report for AOAC 2012.15
2. ERP Recommendation Report for AOAC 2012.16

ERP Final Action Recommendation Report for AOAC Official Method 2012.15, *Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula – Inductively Coupled Plasma - Mass Spectrometry Method (First Action 2012)*

EXECUTIVE SUMMARY:

AOAC Official Method 2012.15, *Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula by Inductively Coupled Mass Spectrometry* (AOAC 2012.15) was originally a method submitted by Covance Laboratories in Wisconsin, USA in response to a Call for Methods that purported to meet the standard method performance requirements (SMPR) for total iodine (AOAC 2012.008) established by the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (AOAC SPIFAN) in 2012. The method was reviewed by the AOAC Expert Review Panel for SPIFAN Nutrient Methods (ERP) and was judged to have sufficiently met the AOAC 2012.008. The ERP adopted the method, making it an AOAC First Action Official Methods of Analysis.

The ERP tracked this method for two years. During this time, the method was published in the *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA) and in the *Journal of AOAC INTERNATIONAL* (Journal). Additionally, a single laboratory validation using the SPIFAN matrices was conducted and a report submitted. This report was reviewed by the ERP and they determined that any suggestions and modifications could be addressed as the method moved forward for reproducibility assessment in a multi-laboratory study.

In March 2015, the ERP reviewed the method and all data supporting the method's reproducibility. In preparation for the discussion, AOAC has listed the method in the Referee Section of the AOAC *Inside Laboratory Management* publication as the method selected for multi-laboratory testing and subsequently as the method likely to be considered for Final Action recommendation by the ERP. Additionally, AOAC sent out two email blasts to its member and network database (>5,000 contacts) to solicit feedback on the method from users of the method. No feedback was received as a result of these efforts. Additionally, ERP members were asked to review the method using a form that is based on the OMB's guidance to ERPs for First to Final Action (OMA Appendix G). The ERP did discuss some feedback from meeting attendees and concluded that there needed to be some additional clarifications to the method as it pertained to applicable samples, maintenance of the lens stack and instrument conditioning, use of second source standards, use of peristaltic pump tubing sizes and potential need for a dedicated set of cones and lenses. These clarifications have been accepted and incorporated into the

method. Also incorporated were minor modifications taken from comments provided by several collaborators as well as incorporation of components requiring clarification as suggested by the method author. It was agreed that clarifications would be provided in the method manuscript which was submitted as part of the publications review process. ERP members were asked to review the clarifications within the last 30 days. On March 18, 2015, the ERP reached consensus to recommend this method for Final Action method status. The method manuscript is now in the publication process for the Journal.

This work has been funded in part by two Documents of Understanding between AOAC INTERNATIONAL and the Infant Formula Nutrition Council of America (formerly known as International Formula Council) signed April 2010 and June 2013.

METHOD APPLICABILITY:

A. A method's applicability to the identified Stakeholder needs is best assessed by the Stakeholder Panel and should be a part of the process from the onset. OMB liaisons will remind Stakeholder Panels to maintain this focus point.

The AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) has developed AOAC Standard Method Performance Requirements (*SMPRs*) for Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula, AOAC SMPR 2012.008. The applicability of the SMPR is Determination of total iodine in all forms of infant, adult, and/or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates. A summary of the method was presented to the stakeholders following the adoption of the SMPR 2012.008 as a method that was submitted for ERP consideration. AOAC SPIFAN meeting minutes are appended to this report[1].

B. OMB may ask ERPs and Stakeholder Panels for feedback to improve the applicability of the method such as potential method scope expansions and potential points of concern.

It should be noted that the stakeholder panel does not review methods or method applicability; therefore to preserve the integrity of the roles in the standards development, the practice of presenting methods during stakeholder meetings prior to the ERP consideration has been discontinued; however, a large

[1] AOAC SPIFAN Meeting Minutes from AOAC SPIFAN meeting held on September 29, 2012

number of stakeholders were and continue to be in attendance for discussion on these methods during the ERP meetings. Please refer to ERP reports.

SAFETY CONCERNS:

A. A safety review must be performed for a method to be recognized as First Action.

ERP has addressed all safety concerns were addressed prior to and as part of the two year period. Appropriate warnings, precautionary statements, and instructions are included in the method. The method includes a number of precautions on the use of ovens and microwaves, the use caustic acids and bases, and on the need for cooling of samples that have undergone oven or microwave digestion. Method users are also instructed to consult the MSDS prior to using chemicals and to adhere to the safety precautions provided therein. In addition, method users are also instructed to where personal protective equipment when necessary.

B. All safety concerns identified during the 2 year evaluation period must be addressed.

Discussions on method safety transpired during the meeting during which the method was adopted and subsequently when the method was selected for the tract to Final Action recommendation. Please see the Method Evaluation spreadsheet[2] developed by the formula manufacturers to aid the ERP in down selecting one method per nutrient.

C. Guidance and support can be obtained from the AOAC Committee on Safety.

In addition to the expertise of ERP members' familiarity with the safety issues around chemicals used in this method, the AOAC Method Safety and Risk Assessment Guide[3] was provided and served as reference for method authors and ERP members.

REFERENCE MATERIALS:

A. Document efforts undertaken to locate reference materials. Method may still progress to Final Action even if reference materials are not available.

[2] Method Evaluation Form for AOAC 2012.15, Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula Using ICP-MS

[3] AOAC Method Safety and Risk Assessment Document

During its second meeting in April 2011, SPIFAN approved the first of the five SMPRs in which NIST Infant formula SRM 1849. This SRM is stated as the primary reference material in all SPIFAN SMPRs. The NIST SRM 1849a material was tested as part of a supplemental data set for the method and reviewed by the ERP prior to the method's adoption as AOAC 2012.15. Furthermore, during this meeting the SPIFAN Working Group on SPIFAN Matrices presented a list of testing materials that would be donated by the infant formula manufacturers, characterized, and stored[4]. See appendices – SPIFAN product matrices and SPIFAN SLV Kit[5].

B. Guidance and support can be obtained from the AOAC Technical Division on Reference Materials.

As part of the development of the SMPRs, AOAC has added a document from the AOAC Technical Division on Reference Materials (TDRM) at the request of TDRM, to the SMPR guidelines[6] (OMA Appendix F). AOAC OMB has reviewed this information prior to its publication in the OMA.

SINGLE LABORATORY VALIDATION:

A. Data demonstrating Response Linearity, Accuracy, Repeatability, LOD/LOQ, and Matrix Scope must be present. Experimental designs to collect this data may vary with the method protocol and the intended use of the method.

The ERP reviewed three papers[7,8,9] one of which included a single laboratory validation (SLV) for AOAC 2012.15. This information along with the method evaluation form was then used to confirm that this method would move forward towards Final Action recommendation with the inclusion of a reproducibility evaluation. Additionally, the SPIFAN SLV Guidelines[10] was prepared by a group chair by

[4] AOAC SPIFAN Meeting Minutes from AOAC SPIFAN meeting held on April 5, 2011 (Day 1 of AOAC SPIFAN meeting)
[5] SPIFAN Single Laboratory Validation Kit – Common infant formula reference materials.
[6] *Appendix F: Guidelines for Standard Method Performance Requirements* **Official Methods of Analysis of AOAC INTERNATIONAL** e-OMA at www.aoac.org.
[7] Sullivan, Darryl and Zywicki, Richard, *Determination of Total Iodine in Food and Dietary Supplements Using Inductively Coupled Plasma-Mass Spectrometry* **Journal of AOAC INTERNATIONAL** 2012, volume 95.
[8] Covance Laboratories Inc. Nutritional Chemistry and Food Safety, *AOAC SPIFAN Supplemental Data to IOD-2 from Iodine Analysis in Infant Formula and Adult Nutritionals Using a Covance Developed Method: "Determination of Total Iodine in Foods and Dietary Supplements using Inductively Coupled Plasma-Mass Spectrometry. Issue Date: 10 August 2012.*
[9] Covance Laboratories Inc. Nutritional Chemistry and Food Safety, *AOAC SPIFAN Single Laboratory Validation for Iodine Analysis in Infant Formula and Adult Nutritionals, First Action 2012.15, Report Issue Date: 25 July 2013.*
[10] *Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation*,

Norma Hill and discussed in a Study Directors Education Session[11] in April 2011. The final version of the guidelines was refined during September 2011 ERP meeting.

B. Resources can be identified by the AOAC Committee on Statistics.

Members of the Committee on Statistics did participate as observers during the discussions on developing general SLV protocol guidance.

REPRODUCIBILITY/UNCERTAINTY:

A. For quantitative methods, data demonstrating Reproducibility & Uncertainty must be present. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method (i.e., collaborative studies, proficiency testing, etc…)

The ERP reviewed data statistical sheets and a Final Report[12] with multi-laboratory testing data for AOAC 2012.15. The data was collected using a general multi-laboratory protocol has been established by the method authors, ERP chair and OMB liaison to SPIFAN ERP. Method authors drafted their own testing protocols and these were forwarded to the ERP chair and the OMB liaison for their input and comments. The multi-laboratory study results were submitted for the ERP's consideration during their March 2015 meeting.

B. Guidance and support can be obtained from the AOAC Committee on Statistics.

The OMB liaison served as facilitator by working with both members of the AOAC Committee on Statistics and the method author to ensure a sound study design for the multi-laboratory testing and to ensure the appropriate statistical tools were available to analyze the data. Since this method will be reviewed within ISO and IDF, members of the AOAC Committee on Statistics also reviewed the statistical tool with respect to ISO standards for methods.

COMPARISON TO SMPR:

[11] AOAC SPIFAN Study Directors Education Session Meeting Minutes held on April 4, 2011.

[12] Zywicki, Richard and Sullivan, Darryl, *Determination of Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS): A Collaborative Study*, 2015, Report submitted for review by ERP.

A. Document method performance versus SMPR criteria. Note which SMPR criteria are met. For SMPR criteria not met, the ERP documents the reasoning why the method is still acceptable.

The draft SMPR[13] was presented and approved in 2012 by AOAC SPIFAN. The ERP found that the method did meet the SMPR method performance criteria satisfactorily in their collective judgment. The ERP were satisfied that the method authors could address providing additional detail and deciding on one digestion technique in the multi-laboratory testing for AOAC 2012.15. The ERP reviewed this information during their March 18, 2015 meeting and deemed that the method sufficiently met AOAC SMPR 2012.008.

B. Data is present to assure the matrix and analyte scopes are covered. This is critical for methods used for dispute resolution.

Both the SLV information and demonstration of reproducibility were considered the ERP determined that the matrix and analyte scopes are addressed satisfactorily. The method author has developed and submitted a method manuscript clarifying additional information mentioned during the ERP meeting in March 2015. This document has been reviewed by ERP members and is in the publication process in the Journal.

FEEDBACK FROM USERS OF METHOD:

A. Document positive and negative feedback from users of the method during the trial period.
B. Feedback from users demonstrating method ruggedness should be documented.
C. Assess the future availability of vital equipment, reference materials, and supplies.

There were no comments submitted regarding this method during the two year period. However, there were some comments that came out of the ERP meetings during which the method was adopted and recommended. Additionally, there were comments from collaborators and during the March 18, 2015 ERP meeting. Comments included:

- Clarifying in the method that it is not applicable to samples containing FD&C Red Dye #3 (erythrosine).

[13] Sullivan, Darryl, *Approval of SMPR for Iodine* (2012) AOAC SPIFAN Meeting – AOAC Annual Meeting, September 29, 2012.

- Point out the possible need for increased maintenance when employing the method. Include precautions about the lens and/or lens stack possibly requiring additional maintenance and that analysis would benefit from thoroughly conditioning the instrument.
- Clarify the use and/or preparation of second source standards for continuing calibration verification standard solutions.
- If acidic sample matrices are typically analyzed on the ICP-MS instrument, perform a thorough cleaning of the entire sample introduction system and appropriate conditioning prior to analyzing basic matrices.
- Clarify the importance of adhering to the peristaltic pump tubing sizes recommended for introducing internal standard and carrier solutions.
- If possible, maintain a dedicated set of cones and/or lens.

The method author provided clarification to address the points discussed during the ERP meeting in March 2015 in a revised manuscript since the March meeting. No other concerns were raised. ERP members reviewed the manuscript in preparation for publications and the manuscript is under consideration for publication in the Journal.

ATTACHMENTS AND REFERENCES:

1. Boyd, Delia, Meeting Proceedings of the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Stakeholder Meeting, September 29, 2012. http://stakeholder.aoac.org/SPIFAN/September_29_2012_Minutes.pdf.
2. Method Evaluation Form for AOAC 2012.15, Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula Using ICP-MS.
3. AOAC Committee on Safety and McKenzie, Deborah, *AOAC Method Safety and Risk Assessment,* AOAC Official Methods Program.
4. Boyd, Delia, Meeting Proceedings of the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Meeting Minutes from AOAC SPIFAN meeting held on April 5, 2011 (Day 1 of AOAC SPIFAN meeting). http://stakeholder.aoac.org/SPIFAN/April_5_2011_Meeting_Minutes.pdf.
5. Schmitz, Dan, AOAC SPIFAN Working Group on SPIFAN Materials, *SPIFAN Single Laboratory Validation Kit* – Common infant formula reference materials, (2011).
6. *Appendix F: Guidelines for Standard Method Performance Requirements* **Official Methods of Analysis of AOAC INTERNATIONAL** e-OMA at www.aoac.org.
7. Sullivan, Darryl and Zywicki, Richard, *Determination of Total Iodine in Food and Dietary Supplements Using Inductively Coupled Plasma-Mass Spectrometry* **Journal of AOAC INTERNATIONAL** 2012, volume 95
8. Covance Laboratories Inc. Nutritional Chemistry and Food Safety, *AOAC SPIFAN Supplemental Data to IOD-2 from Iodine Analysis in Infant Formula and Adult Nutritionals Using a Covance Developed Method: "Determination of Total Iodine in Foods and Dietary Supplements using Inductively Coupled Plasma-Mass Spectrometry. Issue Date: 10 August 2012.*
9. Covance Laboratories Inc. Nutritional Chemistry and Food Safety, *AOAC SPIFAN Single Laboratory Validation for Iodine Analysis in Infant Formula and Adult Nutritionals, First Action 2012.15, Report Issue Date: 25 July 2013*
10. *Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation*, **Official Methods of Analysis of AOAC INTERNATIONAL** e-OMA at www.aoac.org or print OMA 19th edition (2012).
11. Boyd, Delia, AOAC SPIFAN Study Directors Education Session Meeting Minutes, April 4, 2011. http://stakeholder.aoac.org/SPIFAN/April_4_2011_Meeting_Minutes.pdf.

12. Zywicki, Richard and Sullivan, Darryl, *Determination of Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS): A Collaborative Study*, 2015, Report submitted for review by ERP in March 2015.
13. Sullivan, Darryl, *Approval of SMPR for Iodine* (2012) AOAC SPIFAN Meeting – AOAC Annual Meeting, September 29, 2012.

ADDITIONAL SUPPORTING INFORMATION:

14. AOAC SMPR® 2012.008 *Standard Method Performance Requirement for Total Iodine in Infant Formula and Adult Pediatric Nutritional Formula* (2012).
15. Sullivan, Darryl, *AOAC Expert Review Panel Approves Official Methods℠ for Iodine, Pantothenic Acid, Carnitine, Fatty Acids, Vitamins C and E, and Choline and Additional Methods for Vitamins A and D and Inositol* (2013) **Journal of AOAC INTERNATIONAL** , Vol. 96, No. 3.
16. AOAC Official Method 2012.15, *Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula – Inductively Coupled Plasma-Mass Spectrometry (First Action 2012)*. **Official Methods of Analysis of AOAC INTERNATIONAL** e-OMA at www.aoac.org
17. Boyd, Delia, *Expert Review Panel Report*, AOAC Expert Review Panel for SPIFAN Nutrient Methods, October 2, 2012.
18. Boyd, Delia, *Expert Review Panel Report*, AOAC Expert Review Panel for SPIFAN Nutrient Methods, August 27, 2013.
19. Boyd, Delia, *Expert Review Panel Report*, AOAC Expert Review Panel for SPIFAN Nutrient Methods, March 18, 2015.

1
2

ERP Final Action Recommendation Report for AOAC Official Method 2012.16, *Pantothenic Acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula – Ultra-Performance Liquid Chromatography – Tandem Mass Spectrometry Method (First Action 2012)*

EXECUTIVE SUMMARY:

AOAC Official Method 2012.16, *Pantothenic Acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula* (AOAC 2012.16) was originally a method submitted by Nestle Research Center in Switzerland in response to a Call for Methods that purported to meet the standard method performance requirements (SMPR) for pantothenic acid (AOAC 2012.009) established by the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (AOAC SPIFAN) in 2012. The method was reviewed by the AOAC Expert Review Panel for SPIFAN Nutrient Methods (ERP) and was judged to have sufficiently met the AOAC 2012.009. The ERP adopted the method, making it an AOAC First Action *Official Methods of Analysis*.

The ERP tracked this method for two years. During this time, the method was published in the *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA) and in the *Journal of AOAC INTERNATIONAL* (Journal). Additionally, a manuscript with a method comparison of AOAC 2012.16 to the traditional microbiological reference assay, AOAC 992.07, a microbiological assay was published in the Journal. This comparison was reviewed by the ERP and they determined that any suggestions and modifications could be addressed as the method moved forward for reproducibility assessment in a multi-laboratory study.

In March 2015, the ERP reviewed the method and all data supporting the method's reproducibility. In preparation for the discussion, AOAC has listed the method in the Referee Section of the AOAC *Inside Laboratory Management* publication as the method selected for multi-laboratory testing and subsequently as the method likely to be considered for Final Action recommendation by the ERP. Additionally, AOAC sent out two email blasts to its member and network database (>5,000 contacts) to solicit feedback on the method from users of the method. No feedback was received as a result of these efforts. Additionally, ERP members were asked to review the method using a form that is based on the OMB's guidance to ERPs for First to Final Action (OMA Appendix G). The ERP did discuss some feedback from meeting attendees. The one comment that the ERP thought should be clarified in the method is adding a comment regarding ensuring the the drying and ensuring the moisture content of the Calcium pantothenate standard before use. It was agreed that clarifications would be provided in the method

manuscript which was reviewed and approved within the last 30 days. On March 18, 2015, the ERP reached consensus to recommend this method for Final Action method status.

This work has been funded in part by two Documents of Understanding between AOAC INTERNATIONAL and the Infant Formula Nutrition Council of America (formerly known as International Formula Council) signed April 2010 and June 2013.

METHOD APPLICABILITY:

A. A method's applicability to the identified Stakeholder needs is best assessed by the Stakeholder Panel and should be a part of the process from the onset. OMB liaisons will remind Stakeholder Panels to maintain this focus point.

The AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) has developed AOAC Standard Method Performance Requirements (*SMPRs*) for Pantothenic acid in Infant Formula and Adult/Pediatric Nutritional Formula, AOAC SMPR 2012.009. The applicability of the SMPR is *Determination of d-pantothenic acid and pantothenate salts, excluding bound forms, in all forms of infant, adult, and/or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates).* A summary of the method was presented to the stakeholders following the adoption of the SMPR 2012.009 as a method that was submitted for ERP consideration. AOAC SPIFAN meeting minutes are appended to this report[1].

B. OMB may ask ERPs and Stakeholder Panels for feedback to improve the applicability of the method such as potential method scope expansions and potential points of concern.

It should be noted that the stakeholder panel does not review methods or method applicability; therefore to preserve the integrity of the roles in the standards development, the practice of presenting methods during stakeholder meetings prior to the ERP consideration has been discontinued; however, a large number of stakeholders were and continue to be in attendance for discussion on these methods during the ERP meetings. Please refer to ERP reports.

SAFETY CONCERNS:

[1] AOAC SPIFAN Meeting Minutes from AOAC SPIFAN meeting held on September 29, 2012

A. A safety review must be performed for a method to be recognized as First Action.

ERP has addressed all safety concerns were addressed as part of the two year period. Appropriate warnings, precautionary statements, and instructions are included in the method. Method users are instructed to consult the MSDS prior to using chemicals and to adhere to the safety precautions provided therein. Method users are also instructed to where personal protective equipment when necessary.

B. All safety concerns identified during the 2 year evaluation period must be addressed.

Discussions on method safety transpired during the meeting during which the method was adopted and subsequently when the method was selected for the tract to Final Action recommendation. Please see the Method Evaluation spreadsheet[2] developed by the formula manufacturers to aid the ERP in down selecting one method per nutrient.

C. Guidance and support can be obtained from the AOAC Committee on Safety.

In addition to the expertise of ERP members' familiarity with the safety issues around chemicals used in this method, the AOAC Method Safety and Risk Assessment Guide[3] was provided and served as reference for method authors and ERP members.

REFERENCE MATERIALS:

A. Document efforts undertaken to locate reference materials. Method may still progress to Final Action even if reference materials are not available.

During its second meeting in April 2011, SPIFAN approved the first of the five SMPRs in which NIST Infant formula SRM 1849 and now SRM 1849a was the stated at the primary reference material. This SRM is stated as the primary reference material in all SPIFAN SMPRs. The NIST SRM 1849a material was tested in the reproducibility assessment for AOAC 2012.16[4].

[2] Method Evaluation Form for AOAC 2012.16, Pantothenic acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula UHPLC-MS/MS

[3] AOAC Method Safety and Risk Assessment Document

[4] Data report for assessing AOAC 2012.16 with NIST SRM 1849a

Furthermore, during this meeting the SPIFAN Working Group on SPIFAN Matrices presented a list of testing materials that would be donated by the infant formula manufacturers, characterized, and stored[5]. See appendices – SPIFAN product matrices and SPIFAN SLV Kit[6].

B. Guidance and support can be obtained from the AOAC Technical Division on Reference Materials.

As part of the development of the SMPRs, AOAC has added a document from the AOAC Technical Division on Reference Materials (TDRM) at the request of TDRM, to the SMPR guidelines[7] (OMA Appendix F). AOAC OMB has reviewed this information prior to its publication in the OMA.

SINGLE LABORATORY VALIDATION:

A. Data demonstrating Response Linearity, Accuracy, Repeatability, LOD/LOQ, and Matrix Scope must be present. Experimental designs to collect this data may vary with the method protocol and the intended use of the method.

The ERP reviewed two papers[8,9] one of which included a single laboratory validation (SLV) for AOAC 2012.16. This information along with the method evaluation form was then used to confirm that this method would move forward towards Final Action recommendation with the inclusion of a reproducibility evaluation. Additionally, the SPIFAN SLV Guidelines[10] was prepared by a group chair by Norma Hill and discussed in a Study Directors Education Session[11] in April 2011. The final version of the guidelines was refined during September 2011 ERP meeting.

B. Resources can be identified by the AOAC Committee on Statistics.

[5] AOAC SPIFAN Meeting Minutes from AOAC SPIFAN meeting held on April 5, 2011 (Day 1 of AOAC SPIFAN meeting)
[6] SPIFAN Single Laboratory Validation Kit – Common infant formula reference materials.
[7] *Appendix F: Guidelines for Standard Method Performance Requirements* **Official Methods of Analysis of AOAC INTERNATIONAL** e-OMA at www.aoac.org.
[8] Andrieux et. al., *Pantothenic Acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula: First Action 2012.16*
[9] Andrieux et al., *Pantothenic Acid (Vitamin B5) in Fortified Foods: Comparison of a Novel Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry Method and a Microbiological Assay (AOAC Official Method℠ 992.07)*
[10] *Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation*,
[11] AOAC SPIFAN Study Directors Education Session Meeting Minutes held on April 4, 2011.

Members of the Committee on Statistics did participate as observers during the discussions on developing general SLV protocol guidance.

REPRODUCIBILITY/UNCERTAINTY:

A. For quantitative methods, data demonstrating Reproducibility & Uncertainty must be present. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method (i.e., collaborative studies, proficiency testing, etc…)

The ERP reviewed data statistical sheets[12] with multi-laboratory testing data for AOAC 2012.16. The data was collected using a general multi-laboratory protocol has been established by the method authors, ERP chair and OMB liaison to SPIFAN ERP. Method authors drafted their own testing protocols and these were forwarded to the ERP chair and the OMB liaison for their input and comments. The multi-laboratory study results were submitted for the ERP's consideration during their March 2015 meeting.

B. Guidance and support can be obtained from the AOAC Committee on Statistics.

The OMB liaison served as facilitator by working with both members of the AOAC Committee on Statistics and the method author to ensure a sound study design for the multi-laboratory testing and to ensure the appropriate statistical tools were available to analyze the data. Since this method will be reviewed within ISO and IDF, members of the AOAC Committee on Statistics also reviewed the statistical tool with respect to ISO standards for methods.

COMPARISON TO SMPR:

A. Document method performance versus SMPR criteria. Note which SMPR criteria are met. For SMPR criteria not met, the ERP documents the reasoning why the method is still acceptable.

The draft SMPR[13] was presented and approved in 2012 by AOAC SPIFAN. The ERP found that the method did meet the SMPR method performance criteria satisfactorily in their collective judgment. The two parameters of AOAC SMPR 2012.009 that were not met by the method at the time it was adopted for First Action OMA status included reproducibility and use of the stated reference material, NIST SRM 1849a. The ERP were satisfied that these would be addressed in the multi-laboratory testing for AOAC

[12] AOAC 2012.16 multi-laboratory testing data summary reports

[13] Pan, Shang-Jing, *Approval of SMPR for Pantothenic Acid* (2012) AOAC SPIFAN Meeting – AOAC Annual Meeting, September 29, 2012.

2012.16. The ERP reviewed this information during their March 18, 2015 meeting and deemed that the method sufficiently met AOAC SMPR 2012.009.

B. Data is present to assure the matrix and analyte scopes are covered. This is critical for methods used for dispute resolution.

Both the SLV information and demonstration of reproducibility were considered the ERP determined that the matrix and analyte scopes are addressed satisfactorily. The method author has developed and submitted a method manuscript and this document has been reviewed by ERP members and has since been accepted for publication in the Journal.

FEEDBACK FROM USERS OF METHOD:

A. Document positive and negative feedback from users of the method during the trial period.
B. Feedback from users demonstrating method ruggedness should be documented.
C. Assess the future availability of vital equipment, reference materials, and supplies.

There were no comments submitted regarding this method during the two year period. However, there were some comments that came out of the ERP meetings during which the method was adopted and recommended. The first comment was that the method originally used reference material, NIST SRM 1846. AOAC SMPR 2012.009 states NIST SRM 1849a as the reference material. During the reproducibility trials, the method was challenged with NIST SRM 1849a as stipulated by the AOAC SMPR 2012.009 and by a set of SPIFAN matrices. Additionally, there was a comment during the March 18, 2015 ERP meeting regarding drying of the calcium pantothenate standard prior to use and ensuring control of the moisture content. The method author did provide clarification to address this matter in the method manuscript since the March meeting. No other concerns were raised. ERP members reviewed the manuscript and the manuscript has since been submitted and accepted for publication in the Journal.

ATTACHMENTS AND REFERENCES:

1. Boyd, Delia, Meeting Proceedings of the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Stakeholder Meeting, September 29, 2012. http://stakeholder.aoac.org/SPIFAN/September_29_2012_Minutes.pdf.
2. Method Evaluation Form for AOAC 2012.16, Pantothenic acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula UHPLC-MS/MS.
3. AOAC Committee on Safety and McKenzie, Deborah, *AOAC Method Safety and Risk Assessment,* AOAC Official Methods

Program.
4. Campos-Gimenez, Esther, Data report for assessing AOAC 2012.16 with NIST SRM 1849a (2015) submitted for ERP review for the March 18, 2015 meeting of the AOAC ERP for SPIFAN Nutrient Methods..
5. Boyd, Delia, Meeting Proceedings of the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Meeting Minutes from AOAC SPIFAN meeting held on April 5, 2011 (Day 1 of AOAC SPIFAN meeting). http://stakeholder.aoac.org/SPIFAN/April_5_2011_Meeting_Minutes.pdf.
6. Schmitz, Dan, AOAC SPIFAN Working Group on SPIFAN Materials, *SPIFAN Single Laboratory Validation Kit* – Common infant formula reference materials, (2011).
7. *Appendix F: Guidelines for Standard Method Performance Requirements* **Official Methods of Analysis of AOAC INTERNATIONAL** e-OMA at www.aoac.org.
8. Andrieux et. al., *Pantothenic Acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula: First Action 2012.16* (2013) **Journal of AOAC INTERNATIONAL**, Vol. 96, No. 3.
9. Andrieux et al., *Pantothenic Acid (Vitamin B5) in Fortified Foods: Comparison of a Novel Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry Method and a Microbiological Assay (AOAC Official Method℠ 992.07)* (2012) **Journal of AOAC INTERNATIONAL**, Vol. 95, No. 1.
10. *Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation*, **Official Methods of Analysis of AOAC INTERNATIONAL** e-OMA at www.aoac.org or print OMA 19th edition (2012).
11. Boyd, Delia, AOAC SPIFAN Study Directors Education Session Meeting Minutes, April 4, 2011. http://stakeholder.aoac.org/SPIFAN/April_4_2011_Meeting_Minutes.pdf.
12. Campos-Gimenez, Esther, AOAC 2012.16 multi-laboratory testing data summary reports (2015) submitted for ERP review for the March 18, 2015 meeting of the AOAC ERP for SPIFAN Nutrient Methods.
13. Pan, Shang-Jing, *Approval of SMPR for Pantothenic Acid* (2012) AOAC SPIFAN Meeting – AOAC Annual Meeting.

ADDITIONAL SUPPORTING INFORMATION:

14. AOAC SMPR® 2012.009 *Standard Method Performance Requirement for Pantothenic Acid in Infant Formula and Adult Pediatric Nutritional Formula* (2012).
15. Sullivan, Darryl, *AOAC Expert Review Panel Approves Official Methods℠ for Iodine, Pantothenic Acid, Carnitine, Fatty Acids, Vitamins C and E, and Choline and Additional Methods for Vitamins A and D and Inositol* (2013) **Journal of AOAC INTERNATIONAL** , Vol. 96, No. 3.
16. AOAC Official Method 2012.16, *Pantothenic Acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula – Ultra-Performance Liquid Chromatography – Tandem Mass Spectrometry Method (First Action 2012)*. **Official Methods of Analysis of AOAC INTERNATIONAL** e-OMA at www.aoac.org
17. Boyd, Delia, *Expert Review Panel Report*, AOAC Expert Review Panel for SPIFAN Nutrient Methods, October 2, 2012.
18. Boyd, Delia, *Expert Review Panel Report*, AOAC Expert Review Panel for SPIFAN Nutrient Methods, August 27, 2013
19. Boyd, Delia, *Expert Review Panel Report*, AOAC Expert Review Panel for SPIFAN Nutrient Methods, March 18, 2015

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 25, 2015

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: Recommendations for Final Action for Methods without ERPs

This will be a verbal report.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 25, 2015

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: Actions for OMB Working Group on First to Final Action

This will be a summary via verbal report.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 25, 2015

To: AOAC INTERNATIONAL Official Methods Board

From: Robert Rathbone, Sr. Director – AOAC Publications

Subject: New Section of the Journal of AOAC INTERNATIONAL

This will be a verbal report.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 25, 2015**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Revised Voting Panel for AOAC ISPAM**

Background

On March 12, 2015 during the OMB teleconference, OMB reached consensus on the ISPAM voting panel. Following the teleconference, it was brought to my attention that an incorrect ISPAM registration listing was referenced.

Therefore, using the corrected list, please find attached another proposed set of voting members for ISPAM. In discussing this issue with OMB Chairperson, Shauna Roman she suggested that in support of the balance OMB approved for the original voting members, I should do a one to one replacement where possible and to point out specifically the changes in the registrants and the proposed voting panel as compared to the voting panel OMB reviewed and approved during the Thursday teleconference.

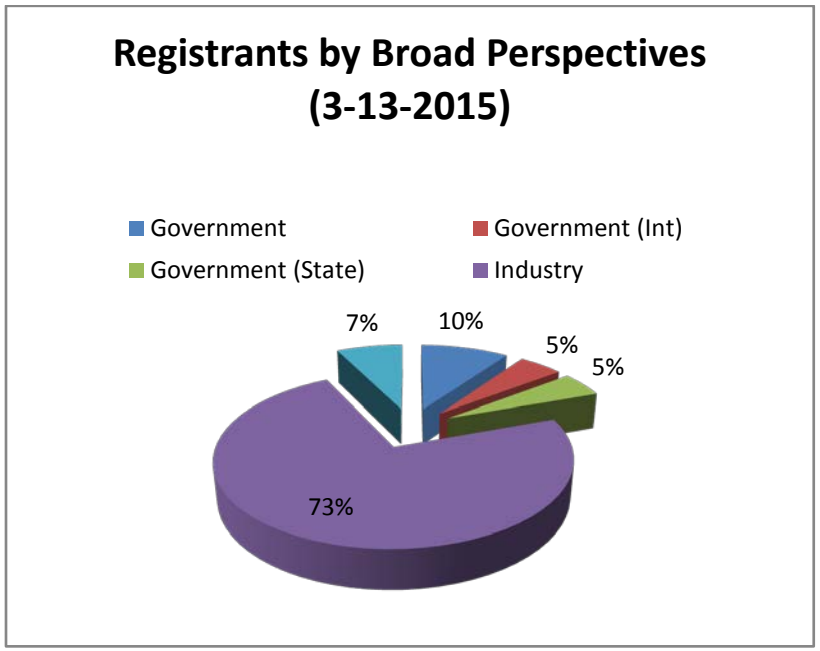
While the OMB clearly will not be able to approve this proposed list of voting members in the same manner as it did during the teleconference, with Shauna's review, please let me know if you have any questions or concerns with the proposed voting members. Otherwise, since the meeting will take place on Tuesday, I will move forward with this proposed set of voting members for ISPAM meeting on Tuesday. Currently, there are no standards on which the stakeholders will be achieving consensus.

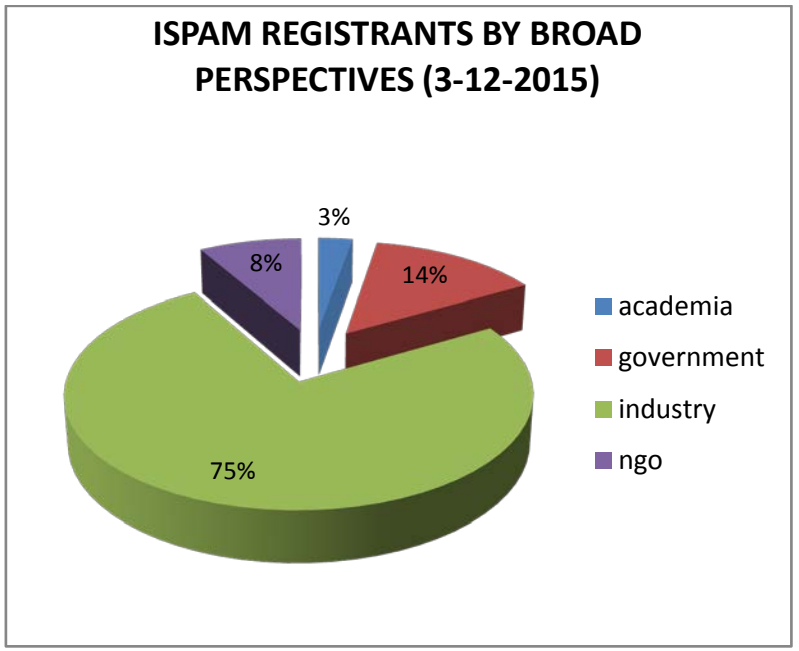
I will add discussion of this matter on the OMB April teleconference agenda. Thank you in advance for your consideration.

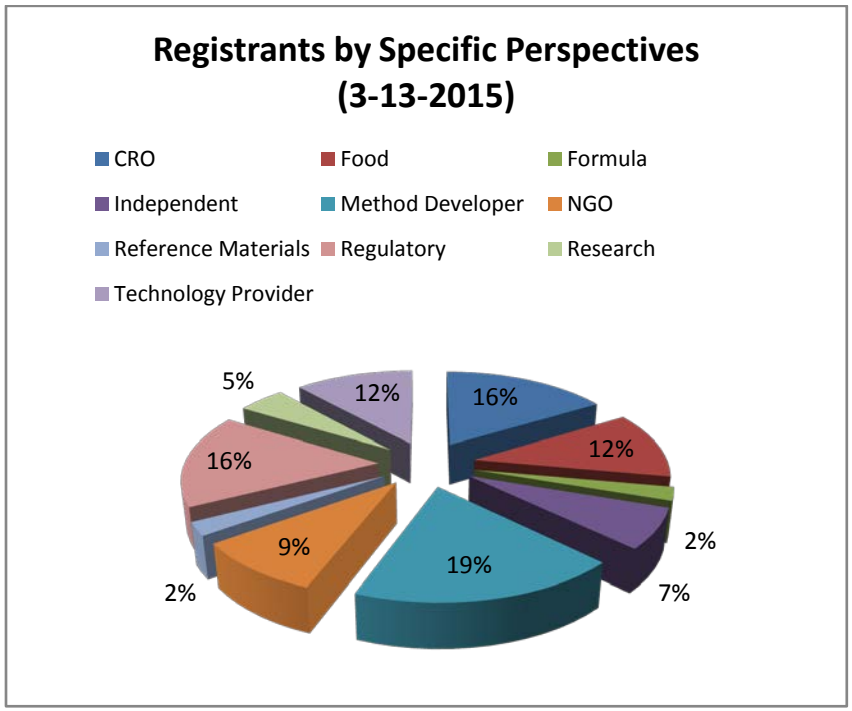
Recommendation:

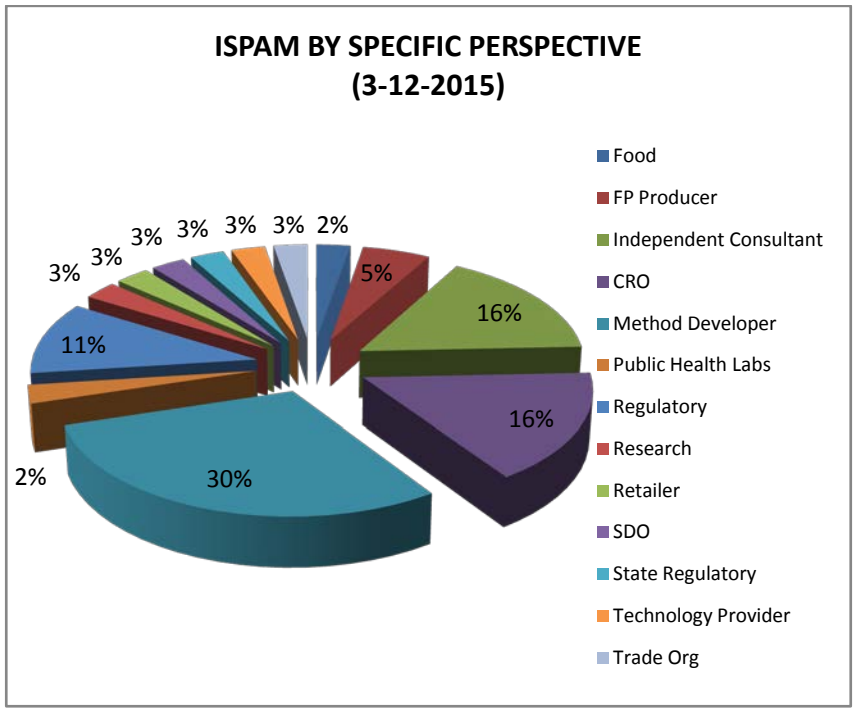
Provide any objections on this proposed set of ISPAM voting members via email.

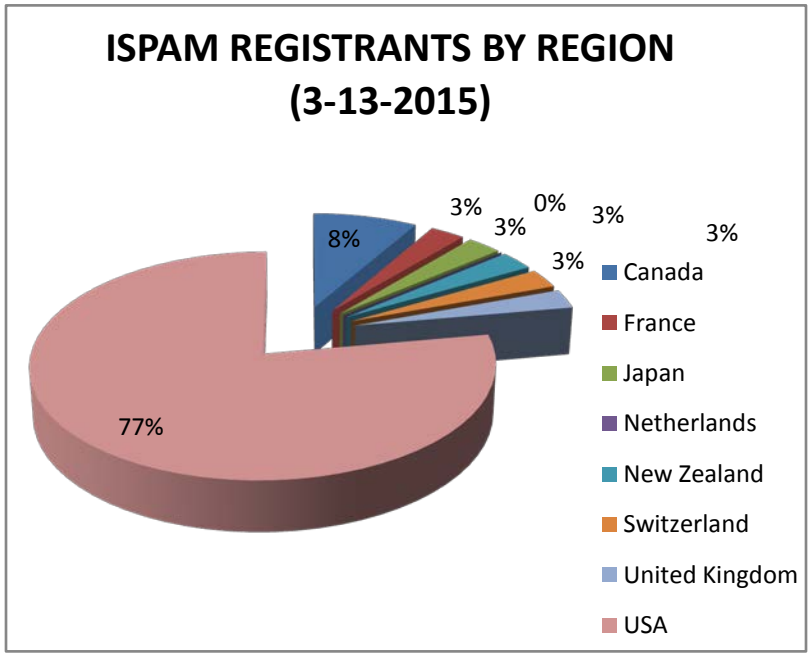
Shared with OMB on 3-12-2015		Revised for OMB on 3-13-2015	
3M Food Safety AB SCIEX Adria* AsureQuality Bayer Crop Science* BioAdvantage *(new name is Nexidia)* BioControl BioMerieux Bio-Rad Brodsky Consultants Brooke Schwartz Consulting CFIA Dole* DuPont Nutrition & Health Ecolab Research Center* FDA CFSAN FDA ORA* Frontage Laboratories* Health Canada IDEXX Laboratories Independent Consultant* Life Technologies MicroVal National Association Of Testing Authorities*	Naturipe Farms* Neogen Nestle NSF International Q Laboratories R-Biopharm* Rigaku Raman Technologies* Roka Biosciences Romer Laboratories* Sample6 Technologies* Mériuex NutriSciences (Silliker) Taylor Farms* UC Davis * United Fresh Produce Association * US Treasury (retired)* USDA (retired) ***Not Registered or Coming to the Meeting**	3M Food Safety AB SCIEX Abbott Nutrition* Association of Public Health Laboratories* AsureQuality ATCC* BioControl bioMerieux Bio-Rad Brodsky Consultants Brooke Schwartz Consulting CFIA DuPont Nutrition & Health Eurofins FDA CFSAN Florida Dept. of Agriculture Health Canada INTI* Jamieson Laboratories* Keurig Green Mountain* The Kroger Company*	Life Technologies Maryland Dept. of Agriculture Maxxam Analytics Mérieux NutriSciences MicroVal Nexidia *(new name - changed from BioAdvantage)* Nestle NSF International NIH Office of Dietary Supplements* Phenomenex* Pickering Laboratories* Q Laboratories Roka Biosciences Silliker, Meriuex NutriSciences Co. Sunshineville Health Products* Thermo Fisher Scientific Tyson Foods* US Pharmacopeia* USDA AMS* USDA (retired) Waters Corporation* *New and Registered for the meeting

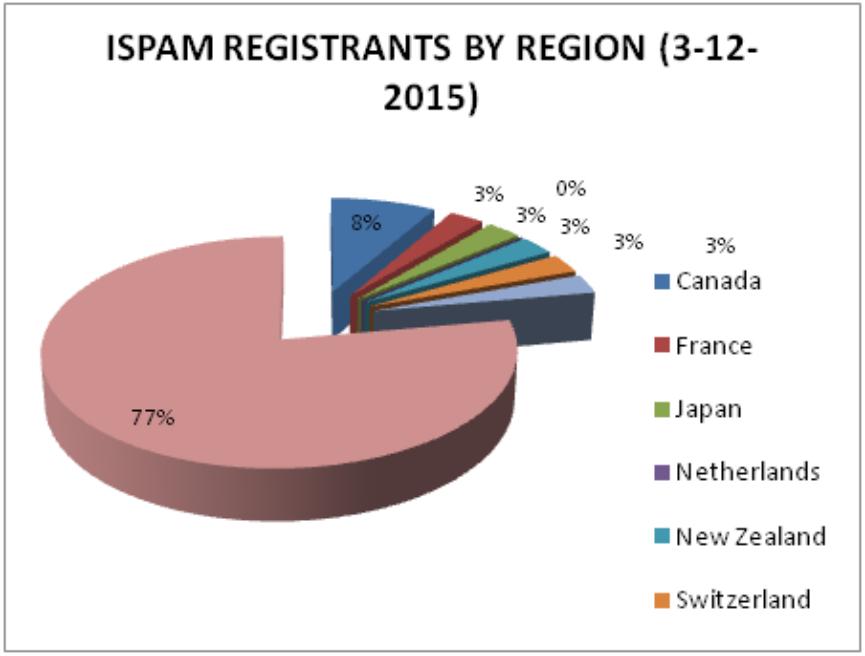

Registrants by Broad Perspectives
(3-13-2015)
Government
Government (Int)
Government (State)
Industry
7%
10%
5%
5%
73%


ISPAM REGISTRANTS BY BROAD
PERSPECTIVES (3-12-2015)
3%
14%
8%
75%
academia
government
industry
ngo


Registrants by Specific Perspectives
(3-13-2015)
CRO
Food
Formula
Independent
Method Developer
NGO
Reference Materials
Regulatory
Research
Technology Provider
16%
12%
2%
7%
19%
2%
9%
16%
5%
12%


ISPAM BY SPECIFIC PERSPECTIVE
(3-12-2015)
Food
FP Producer
Independent Consultant
CRO
Method Developer
Public Health Labs
Regulatory
Research
Retailer
SDO
State Regulatory
Technology Provider
Trade Org
5%
16%
16%
30%
2%
11%
3%
3%
3%
3%
3%
3%
2%


ISPAM REGISTRANTS BY REGION (3-13-2015)
8%
3%
3%
0%
3%
3%
3%
77%
Canada
France
Japan
Netherlands
New Zealand
Switzerland
United Kingdom
USA


ISPAM REGISTRANTS BY REGION (3-12-2015)
8%
3%
3%
0%
3%
3%
3%
77%
Canada
France
Japan
Netherlands
New Zealand
Switzerland

Approved Voting Panel		Revised Proposed Voting Panel	
Academia • University of Saskachewan **Government** • FDA CFSAN • FDA Office of Regulatory Science • Health Canada • Florida Dept of Agriculture **NGO** • MicroVal • APHL • NSF International	**Industry** • ~~UFPA~~ • 3M Food Safety • BioControl Systems • bioMerieux • Bio-Rad • Dole • DuPont Nutrition & Health • Neogen Corporation • Brodsky Consultants • Nexidia • Qiagen • ~~Q Laboratories~~ • Silliker OMB removed Not Registered	**Government** • FDA CFSAN • Health Canada • Florida Dept of Agriculture • USDA –AMS **NGO** • APHL • MicroVal • NSF International	**Industry** • 3M Food Safety • BioControl Systems • bioMerieux • Bio-Rad • DuPont Nutrition & Health • Neogen Corporation • Brooke Schwartz Consulting/Brodsky Consultants *(alternate)* • Nexidia • Merieux NutriScience (Silliker) / Eurofins *(alternate)* • Nestle/Abbott *(alternate)* • Tyson Foods / The Kroger Company *(alternate)* • Thermo Fisher Scientific / Waters Corporation *(alternate)*

Changes from 3-12-2015. Where possible, there is a one to one replacement.

1. No academic organization will be attending
2. FDA Office of Regulatory Science is now replaced with USDA AMS
3. No change to NGO or Trades perspectives
4. Qiagen is not attending
5. Brooke Schwartz Consulting has Brodsky Consulting as an alternate.
6. Dole is not attending and is replaced with Tysons with Kroger as an alternate.
7. Silliker is a voting member; however, Eurofins has been added as an alternate.
8. Both Nestle and Abbott represent formula companies and they are presented with Nestle as primary and Abbott as an alternate.
9. There are also technology providers, so Thermo is added with Waters as an alternate.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 25, 2015**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie – Staff Liaison, AOAC Official Methods Board**

Subject: **AOAC Stakeholder Panels and OMB Liaisons**

As the summer and AOAC Annual Meeting approaches, OMB liaisons need to be identified for the following meetings.

Meeting	Dates	OMB Liaison(s)
ISPAM	**Sat., Sept. 26, 2015**	
SPADA	**Tues.-Wed., Sept. 1-2, 2015**	
SPDS	**Fri., Sept. 25, 2015**	
SPDS Working Groups	**Sat., Sept. 26, 2015**	
SPIFAN	**Sat., Sept. 26, 2015**	
SPSFAM	**Sun., Sept. 27, 2015**	
ERP – Microbiology	**Sun., Sept. 27, 2015**	
ERP – Gluten	**Wed., Sept. 30, 2015**	
ERP – Feeds & Fertilizers	**Mon., Sept. 28, 2015**	
ERP – Dietary Supplements	**Mon., Sept. 28, 2015**	
ERP - Heavy Metals Speciation	**Tues., Sept. 29, 2015**	
ERP - SPIFAN Nutrients	**Tues., Sept. 29, 2015**	
ERP - SPIFAN Pesticides	**TBD**	

A SPADA meeting with working groups will be held on September 1-2, 2015. An update on the meeting activities will be provided.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 25, 2015**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Upcoming Vetting for Expert Review Panels**

In May, the OMB reviewed two candidates for the ERP for SPIFAN Nutrient Methods. Please see the attached proposal. OMB recommended that one of the candidates submit additional statement supporting his expertise for the ERP. This has not happened yet.

Attachment: Proposal submitted during the May 12, 2015 OMB teleconference.

In September, we are planning for an ERP for Feed and Fertilizer Methods to meet to review methods for First Action status. The list of candidates are being sorted; however, vetting will need to take place prior to August.

Recommendation:
For OMB to plan on having a teleconference during mid-July.

AOAC INTERNATIONAL

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EXPERT REVIEW PANEL

Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN)

DOCUMENTS REVIEW

Thursday, May 7, 2015

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

AOAC INTERNATIONAL

Expert Review Panel

Stakeholder Panel on Infant Formula & Adult Nutritionals (SPIFAN)

(May 2015)

Table of Contents

MEMORANDUM

DATE: **May 7, 2015**

TO: **AOAC Official Methods Board**

FROM: **Delia Boyd, Program Manager**

SUBJECT: **Expert Review Panel (ERP) for SPIFAN**

Background:
In accordance with the policy for Official First Action, an expert review panel is being assembled to review the methods down selected by the SPIFAN ERP for the priority nutrients.

AOAC staff has collected CVs and they are on file at AOAC in accordance with the revised ERP policies and procedures. A proposal for the SPIFAN Expert Review Panel is submitted for your consideration.

The attached package contains the following information:

- CVs for all proposed candidate(s)
- List of Expert Review Panel (ERP) members

This expert review panel operates under AOAC policies and procedures. Each expert is required to sign the AOAC Volunteer Acceptance Form which includes adherence to the AOAC policy for Volunteer Conflict of Interest, Antitrust and Use of Association Name, Letterhead and Logo.

These will be enforced by the Expert Review Panel chair and facilitated by AOAC staff. OMB is to confirm the expertise of proposed candidates and the balance of the panel and conflicts of interest of panel members.

This Expert Review Panel is scheduled to meet via a virtual meeting proposed for June 10, 2015. Your review and approval of the panel is requested. Please address questions regarding the attached package to me and thank you for your consideration.

Recommendation:

Additional Name(s) for Vetting SPIFAN Nutrients Expert Review Panel (ERP)

1.	Hans Cruijsen	FrieslandCampina	Nutrients ERP *(Fructans (FOS)/GOS only)* - Primary
2.	Wil van Loon	FrieslandCampina	Nutrients ERP *(Fructans (FOS)/GOS only)* - Secondary

Removal of Name(s) from SPIFAN Nutrients Expert Review Panel (ERP)

1.	Sarwar Gilani	Consultant	
2.	Kommer Brunt	Independent Consultant	*(Fructans (FOS)/GOS only)*

AOAC INTERNATIONAL

Stakeholder Panel on Infant Formula & Adult Nutritionals (SPIFAN)

Expert Review Panels (ERP)

(Nutrients)

May 2015

NUTRIENT PANEL

1.	***Darryl Sullivan***	***Covance Labs*** *(Chair)*
2.	John Austad	Covance Labs
3.	Sean Austin	Nestlé ***(Fos/Gos Only)***
4.	Sneh Bhandari	Silliker Labs & OMB
5.	Esther Campos-Gimenez/Adrienne McMahon	Nestlé
6.	Scott Christiansen	PBM Nutritionals
7.	Jon DeVries	General Mills/Medallion Labs
8.	Brendon Gill	Fonterra
9.	Don Gilliland/Karen Schimpf	Abbott Nutrition
10.	Min Huang	Frontage Labs
11.	Estela Kneeteman	INTI
12.	Bill Mindak	FDA ***(Minerals Only)***
13.	Maria Ofitserova	Pickering Lab
14.	Shay Phillips	Mead Johnson
15.	Guenther Raffler	CLF-Eurofins
16.	Kate Rimmer/Melissa Phillips	NIST ***(Non-Voting)***
17.	Jinchuan Yang	Waters Corp.

Proposed changes for:

Remove

1.	Sarwar Gilani	Consultant
2.	Kommer Brunt	Independent Consultant

Add for (Fructans (FOS)/GOS Only)

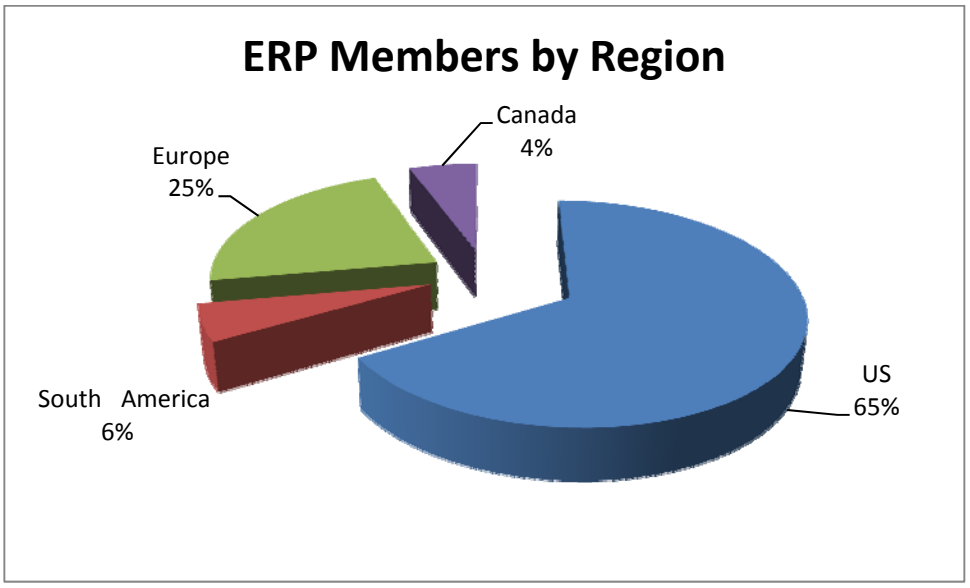
1.	Hans Cruijsen	FrieslandCampina-*Primary*
2.	Wil van Loon	FrieslandCampina-*Secondary*

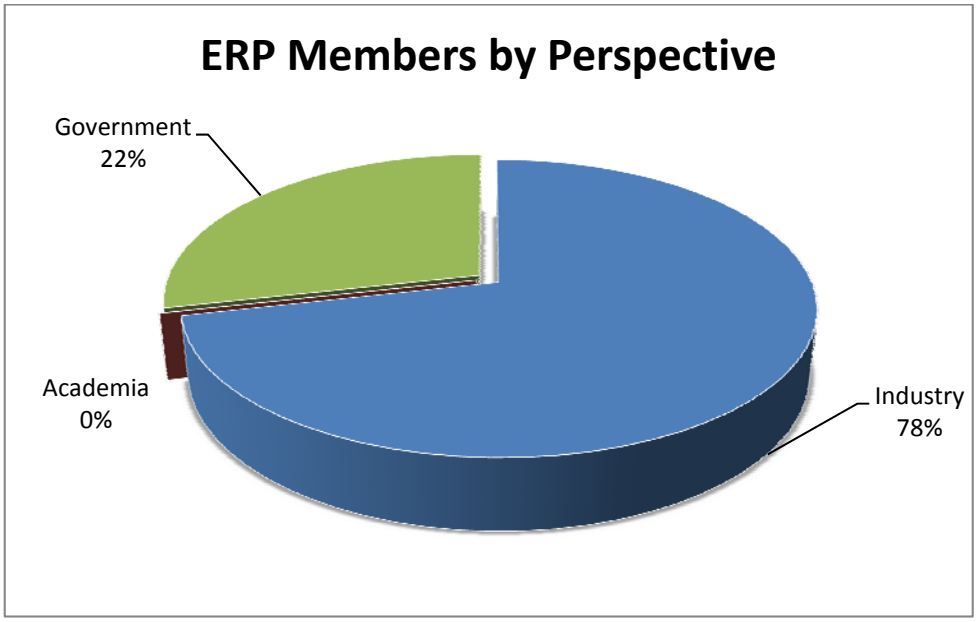
AOAC INTERNATIONAL

Expert Review Panel

STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

(BALANCE OF REGION/PERSPECTIVE)





Curriculum vitae

Family name	Cruijsen
First Names	Johannes Martinus Maria (Hans)
Date of birth	14 september 1962
Nationality	Dutch
Civil status	Married

Education

Institution	Date	Certificate
University of Wageningen The Netherlands	1996	PhD Dairy Technology
University of Wageningen The Netherlands	1987	Master Food Technology
University of Applied Sciences Venlo The Netherlands	1982	Bachelor Analytical Chemistry

Professional experience record

Date	Company-Location	Position
2001 – present	FrieslandCampina, Leeuwarden The Netherlands	Manager Analytical Chemistry
1996 – 2001	FrieslandCampina, Dronrijp The Netherlands	Senior Development manager Cheese
1987 – 1996	Danone Research, Zoetermeer The Netherlands	Researcher Infant and clinical nutrition

Participation in international method harmonization

Member of IDF Standing committee on Analytical Methods for Composition (SCAMC)
Project leader on method for minerals and trace elements.

Member of ISO TC 34 Working group 14 on vitamins and other nutrients

Member of Dutch standardization institute (NEN) on Analytical methods for Dairy products

Stakeholder of SPIFAN project

Method expertise

Development , validation and accreditation of methods on Vitamins using LC-UV, LC-FLU, LC-MS (Vitamin A, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin C, Vitamin D3, Vitamin E)

Development , validation and accreditation of methods on minerals using ICP-AES (Ca, Mg, P, Na, K, Fe, Cu, Zn, Mn)

Development , validation and accreditation of methods on trace elements using ICP-MS (Se, I)

Development , validation and accreditation of methods on carbohydrates using HPLC-PAD (GOS, Inositol, sugars)

Publications

J.M.M. Cruijsen, Development of method for quantification of sugars in food using GC-FID technique, BSc thesis (1982).
R.R. Beumer, J.M.M. Cruijsen & I. R.K. Birtantie, The occurrence of Campylobacter jejuni in raw cow's milk, *Journal of Applied Bacteriology*, 65 (1998) 93-96.
J.M.M. Cruijsen, M.A.J.S. van Boekel & P. Walstra, Effect of malto dextrins on the heat stability of casein te emulsions, Netherlands Milk & Dairy Journal 48 (1994) 237-240.
J.M.M. Cruijsen, Physical stability of caseinate –stabilized emulsions during heating, PhD thesis Agricultural University Wageningen (1996).
R. Frankhuizen, J.A.H.P. Bastiaans, E.J.F. van Arem & J.M.M. Cruijsen, Eyes on Cheese. Meetsysteem voor sturing van kaasbereiding. Voedingsmiddelentechnologie 35(23), 14-16 *(Eyes on Cheese. In-line NIRS system for cheese proces control. Food technology 35(23), 14-16)*

Curriculum vitae & Expertise

Family name	Cruijsen
First Names	Johannes Martinus Maria (Hans)
Date of birth	14 September 1962
Nationality	Dutch
Civil status	Married

Summary of Expertises

Hans Cruijsen studied higher professional laboratory education with major in analytical chemistry on gas chromatography on sugars. After graduating in 1982 he studied Food technology at University Wageningen with Minors in microbiology and Toxicology and Major in Dairy technology. After graduating in 1987 he started to work at Danone R&D in Zoetermeer (the Netherlands) and worked in the field of infant food and clinical food. In this period Hans also prepared a PhD thesis on Physical stability of caseinate – stabilized emulsions during heating. He graduated his PhD in 1996. During 1996-2001 Hans worked as development manager cheese and developed and patented in-line measuring techniques for cheese based on NIRS and in line. He also was co-developer of an optical renneting system for cheese based on diffusing wave spectrometry (DWS). After moving to the Central laboratory of FrieslandCampina in 2001 he succeeded in accreditation (ISO 17025) of the analytical chemical department in 2002. He build expertise in main components, vitamins, minerals and trace elements, NIRS (in-line technology) and allergens. Hans was member of the thesis committee of a Phd student on multi analyte screening of allergen with imaging surface plasmon resonance based biosensor . He became member of the Dutch standardization institute on analytical methods for dairy products and on IDF standing committee on analytical methods for composition. He became project leader on method for minerals and trace elements . He also became member of the Dutch standardization on analytical methods on vitamins and later on member of ISO TC 34 Working group on vitamins and other nutrients. During 2011 and 2012 worked on introducing GB methods on his laboratory in cooperation with Chinese CAIQ. As stakeholder in SPIFAN-II he participated in several multi lab studies in 2014-2015.

Curriculum vitae

Family name	Cruijsen
First Names	Johannes Martinus Maria (Hans)
Date of birth	14 September 1962
Nationality	Dutch
Civil status	Married

References in international method harmonization

Steve Holroyd, Chair of IDF Standing committee on Analytical Methods for Composition (SCAMC)

Erik Konings, Chair of ISO TC 34 Working group 14 on vitamins and other nutrients

Harrie vanden Bijaart, Chair of Dutch standardization institute (NEN) on Analytical methods for Dairy products

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

AOAC INTERNATIONAL

VOLUNTEER ACCEPTANCE FORM

1. My name, title, affiliation, address, phone and fax numbers, and e-mail address are as follows:

Name: Hans Cruijsen

Title: Dr.

Affiliation: FrieslandCampina

Address: P. Stuyvesantweg 1

Address: 8937 AC Leeuwarden, The Netherlands

Phone Number: +31 0622972198 Fax Number: _____

Email Address: hans.cruijsen@frieslandcampina.com

2. I have reviewed and understand the AOAC Policies and Procedures on Volunteer Conflict of Interest; the Antitrust Policy Statement and Guidelines; and the Policy on the Use of the Association Name, Initials, Identifying Insignia, Letterhead, and Business Cards and I agree to abide by all AOAC policies.

_____ 20 February 2015

Signature Date

J.M.M. Cruijsen

Name (Printed)

Return to AOAC INTERNATIONAL, c/o Delia Boyd at facsimile number 1.301.924.7089 or to dboyd@aoac.org at your earliest convenience. If you have questions, do not hesitate to contact your liaison.

Rev. 3/09

Curriculum Vitae

Personal details

Name	van Loon, Wilhelmus Antonius Maria (Wil)
Date of birth	May 5th, 1976
Place of birth	Veldhoven, The Netherlands
Present address	Nienke van Hichtumstraat 1, 6708 SE, Wageningen
Phone number	+31(0)651458367
E-mail	wil.vanloon@frieslandcampina.com
Nationality	Dutch
Sex	Male
Marital status:	Married, one son

Education

2001 – 2005: PhD in Food Chemistry at Wageningen University

1998 – 2000: MSc in Food Technology at Wageningen University

1994 – 1998: BSc in Food Technology at Agricultural University Den Bosch, The Netherlands

Work experience

2014 – present: Manager Business Support, FrieslandCampina R&D. Responsible for Analytical Support and Customer Support of IFT single ingredients department (Domo).

2012 – 2014: Development Manager Technology and Support, FrieslandCampina R&D. Responsible for Technology, Sensory, Pilot plant, and Specification Management & Food Law of Dairy-based Beverages and Yoghurts & Desserts department.

2010 – 2012: Innovation manager at FrieslandCampina R&D. Supporting role for Corporate R&D Director.

2005 – 2010: Senior Researcher Sensory & Consumer Science at FrieslandCampina R&D. Project leader in the field of Sensory & Consumer Science.

2001 – 2005: PhD-fellow at Wageningen University
Dissertation: "Process innovation and quality aspects of French fries".

2000 – 2001: Junior researcher at TNO Environment, Energy and Process Innovation. Development of industrial applications for novel drying techniques.

Publications

- Van Loon *et al*. (2006) Effect of pre-drying and par-frying conditions on the crispness of French fries, *Food Res Technol* 225, 929-935
- Van Loon *et al*. (2006) Antiradical power gives insight in early lipid oxidation events at frying temperature, *J Science Food Agric* 86, 1446-1451
- Van Loon *et al*. (2006) Flavor release from French fries, ACS Symposium series vol. 920, 49-60
- Knol, Van Loon *et al*. (2005) Kinetic modelling of acrylamide formation in a glucose-asparagine reaction system, *J Agric Food Chem* 53, 6133-6139
- Van Loon *et al*. (2005) Real-time flavor release from French fries using atmospheric pressure chemical ionization-mass spectrometry, *J Agric Food Chem* 53, 6438-6442
- Van Loon *et al*. (2005) Development and evaluation of a new, energy efficient process for the production of French fries, *Food Res Technol* 221, 779-786
- Van Loon *et al*. (2005) Identification and olfactometry of French fries flavour extracted at mouth conditions, *Food Chem* 90, 417-425

Summary of Expertise – Wil van Loon, FrieslandCampina

Since 2014 I have worked as Manager Business Support at FrieslandCampina Domo. In this capacity I lead the Analytical Support team within Domo R&D. We develop and execute analyses on carbohydrates (mainly oligosaccharides and sugars) and proteins (including hydrolysates) as part of R&D projects. Our focus is on GOS, as we are market leader in the world.

I have a PhD degree in Food Chemistry (Wageningen University, The Netherlands) and have experience with different analytical techniques such as HPLC, GC, and MS.

References – Wil van Loon, FrieslandCampina

- Bert Klarenbeek, Senior Research Manager, FrieslandCampina Domo (bert.klarenbeek@frieslandcampina.com, +31 317 711305)
- Hans Cruijsen, Manager Analytical Chemistry, FrieslandCampina Laboratory & Quality Services (hans.cruijsen@frieslandcampina.com, +31 58 2992352)
- Christien van Beusekom, R&D Director, FrieslandCampina Domo (christien.vanbeusekom@frieslandcampina.com, +31 317 711294)

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

AOAC INTERNATIONAL

VOLUNTEER ACCEPTANCE FORM

1. My name, title, affiliation, address, phone and fax numbers, and e-mail address are as follows:

Name: Wil van Loon

Title: PhD

Affiliation: Manager Business Support, FrieslandCampina Domo

Address: Bronland 20, 6708 WH Wageningen, The Netherlands

Address: _____

Phone Number: +31(0)651458367 Fax Number: _____

Email Address: wil.vanloon@frieslandcampina.com

2. I have reviewed and understand the AOAC Policies and Procedures on Volunteer Conflict of Interest; the Antitrust Policy Statement and Guidelines; and the Policy on the Use of the Association Name, Initials, Identifying Insignia, Letterhead, and Business Cards and I agree to abide by all AOAC policies.

Signature

02-16-2015
Date

Wil van Loon
Name (Printed)

Return to AOAC INTERNATIONAL, c/o Delia Boyd at facsimile number 1.301.924.7089 or to dboyd@aoac.org at your earliest convenience. If you have questions, do not hesitate to contact your liaison.

Rev. 3/09

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 25, 2015**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **AOAC *Performance Tested Methods*^{SM}**

This will be a verbal report.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 25, 2015**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **AOAC Annual Meeting Overview**

This will be a verbal report.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 25, 2015**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Awards Review and Advertisement for Annual Meeting**

This will be a verbal report.

Attachment:

1. OMA Program Awards Document
2. draft ILM article to be used as a promotional piece for the 2016 OMA Program Awards.

***OFFICIAL METHODS*[SM] PROGRAM AWARDS**

Contents

AWARD IN RECOGNITION OF TECHNICAL AND SCIENTIFIC EXCELLENCE

Selection Criteria

The purpose of this award is for the Official Methods Board (OMB) to recognize a team, stakeholder panel or working group that has published a major document or other body of work that demonstrates a unique or particularly noteworthy level of technical and scientific expertise.

The minimum criteria for selection are:

a. The body of work includes major initiatives or technical guidelines accepted, completed or published within the last three years.
b. The team has been instrumental in developing or modifying technical guidelines or method validation processes.
c. The team product demonstrates significant merit as to the scope of the project, the involvement of a diverse and/or international group of stakeholders or an innovative approach to difficult analytical challenges.
d. The award recognizes teamwork that enhances the reputation of the Association and fosters the mission of AOAC INTERNATIONAL.

Selection Process:

a. The chair of the OMB solicits the OMB members for nominees.
b. Written recommendations and supporting information will be submitted to the OMB chair. The information will be distributed to the members of the OMB.
c. The OMB selects the recipient of this award. The winner is selected by a 2/3 vote. If necessary, the OMB chair may cast the tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the recipient(s) of this award. The winner will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All members participating in the winning team will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winner, with supporting story, will be carried in the announcement in the *ILM*.

EXPERT REVIEW PANEL OF THE YEAR

Selection Criteria

The minimum criteria for selection are:

a. The expert review panel must have completed a significant milestone (e.g. First Action Method, Final Action Method, method modification) within the last three years.
b. Generally, some unique or particularly noteworthy aspect of the ERP's work is highlighted as making the ERP worthy of the award, such as innovative technology or application, breadth of applicability, critical need, difficult analysis, or timeliness.
c. The panel report demonstrates significant merit as to the scope of the project, the involvement of a diverse and/or international group of recognized experts or an innovative approach to difficult analytical challenge.

Selection Process:

a. AOAC staff lists all eligible panels for consideration and forwards that list along with the ERP report to the Chair of the Official Methods Board (OMB).
b. The OMB Chair forwards the list along with any supporting information to the OMB.
c. The OMB selects the Expert Review Panel of the Year. Winner is selected by a 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the members of the winning Expert Review Panel. The winning panel will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All panelists participating in the winning panel will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winning ERP, with supporting story, will be carried in the announcement in the *ILM*.

TECHNICAL SERVICE AWARD

More than one volunteer may be selected in this category each year. In each case the area of expertise should be noted at the time of presentation of the award.

Selection Criteria includes:

a. Has demonstrated timely, competent, and continuous service in an exemplary manner to a Stakeholder Panel (SP), Expert Review Panel (ERP), Working Group (WG), Section, Community, and Committee and/or to the Official Methods Board (OMB).
b. Has donated this service within the three years prior to nomination.
c. Gives outstanding expert guidance and support in all technical aspects as needed and requested.

Additional support for selection is exemplary performance in one or more of the areas below:

a. Has provided guidance on safety, statistical, technical matters, or process expertise.
b. Has been instrumental in developing, modifying or validating a high quality method for publication in the Official Methods of Analysis.
c. Communicates related activities through the appropriate channels, either through the panel/group/community chairs, the Committee on Statistics or Safety or through the Chief Scientific Officer or other staff designees.
d. Contributes significantly to AOAC INTERNATIONAL over a period of years with other accomplishments related to his/her area of expertise (e.g symposium presentations, poster presentations, publications, workshops, meetings).
e. Contributes to the development and improvement of AOAC INTERNATIONAL guidelines, OMA methods, statistics or safety programs.
f. Helps guide AOAC in the decision-making process to make the organization a leader in the field of analytical science.

Selection Process

a. The Official Method Board (OMB) will solicit the Chairs of the Stakeholder Panels, Expert Review Panels, Working Groups, Committees, Community, and the Association membership for nominees. Recommendations based on input from anyone qualified to discuss the contribution of the nominee can be submitted.
b. Written recommendations and supporting information must be submitted to the OMB Chair. The OMB chair will distribute the information to the members of the OMB.
c. The OMB selects the winner(s) of the Technical Service Award by a 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the recipient(s) of this award. The winner will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. The recipient(s) will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winner, with supporting story, will be carried in the announcement in the *ILM*.

METHOD OF THE YEAR

OMB may select more than one method in this category each year.

Selection Criteria

The minimum criteria for selection are:

a. The method must have been approved for first or final action within the last three years.
b. Generally, some unique or particularly noteworthy aspect of the method is highlighted as making it worthy of the award, such as innovative technology or application, breadth of applicability, critical need, difficult analysis, and/or range of collaborators.
c. The method demonstrates significant merit in scope or is an innovative approach to an analytical problem.

Selection Process:

a. AOAC staff lists all eligible methods for consideration and forwards that list with supporting documentation (e.g. ERP chair recommendation(s)) to the Chair of the Official Methods Board (OMB).
b. The Chair forwards the list along with any supporting information to the members of the OMB.
c. The OMB selects the Method of the Year. The winner is selected by 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the author(s) of the winning method. The corresponding author will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All authors will be acknowledged at the annual meeting, will receive an award and a letter of appreciation. The name of the winner(s), with supporting story, will be carried in the announcement in the *ILM*.

Official Methods℠ Program Awards Recognizes Volunteer Commitment and Leadership

Each year, the AOAC Official Methods Board (OMB) recognizes outstanding volunteer commitment and leadership in analytical excellence for team and individual achievement.

"Volunteers are the cornerstone of the *Official Methods*℠ process," said **Deborah McKenize,** senior director, standards development and the AOAC Research Institute. "Our dedicated volunteers spend countless hours providing guidance and technical expertise, evaluating methods, reviewing manuscripts, and much more. Their efforts are an integral part of AOAC's standards development process and are recognized."

> **"Volunteers are the cornerstone of the *Official Methods*℠ process."**
>
> **— DEBORAH MCKENIZE, STANDARDS DEVELOPMENT AND THE AOAC RESEARCH INSTITUTE**

TEAM AWARDS

Award in Recognition of Technical and Scientific Excellence

Selection Criteria

The purpose of this award is for the OMB to recognize a team, stakeholder panel, or working group that has published a major document or other body of work that demonstrates a unique or particularly noteworthy level of technical and scientific expertise.

The minimum criteria for selection are:

(1) The body of work includes major initiatives or technical guidelines accepted, completed, or published within the last 3 years.

(2) The team is instrumental in developing or modifying technical guidelines or method validation processes.

(3) The team product demonstrates significant merit as to the scope of the project, involvement of a diverse and/or international group of stakeholders, or an innovative approach to difficult analytical challenges.

(4) The award recognizes teamwork that enhances the reputation of the Association and fosters the mission of AOAC INTERNATIONAL.

Selection Process

(1) The chair of the OMB solicits OMB members for nominees.

(2) Written recommendations and supporting information are submitted to the OMB chair. The information is distributed to the members of the OMB.

(3) The OMB selects the recipient of the award. The winner is selected by a 2/3 vote. If necessary, the OMB chair may cast the tie-breaking vote.

Award

An appropriate letter of appreciation and thanks is sent to the recipients of the award. The winners are announced at the appropriate session of the AOAC INTERNATIONAL Annual Meeting, with presentation of an award. All members participating in the winning team are acknowledged at the Annual Meeting, and receive an award and a letter of appreciation. The names of the winners, with supporting story, are announced in the ILM.

Expert Review Panel (ERP) of the Year

Selection Criteria

The minimum criteria for selection are:

(1) The ERP must have completed a significant milestone (e.g., First Action Method, Final Action Method, method modification) within the last 3 years.

(2) Generally, some unique or particularly noteworthy aspect of the ERP's work is highlighted as making the ERP worthy of the award, such as innovative technology or application, breadth of applicability, critical need, difficult analysis, or timeliness.

(3) The panel report demonstrates significant merit as to the scope of the project, involvement of a diverse and/or international group of recognized experts, or an innovative approach to difficult analytical challenge.

Selection Process

(1) AOAC staff lists all eligible panels for consideration and forwards that list, along with the ERP report, to the chair of the OMB.

(2) The OMB chair forwards the list, along with any supporting information, to the OMB.

(3) The OMB selects the

(Continued on page 10)

Official Methods℠ Program Awards Recognizes Volunteer Commitment and Leadership

Continued from page 9

ERP of the Year. The winner is selected by a 2/3 vote. If necessary, the OMB chair may cast the tie-breaking vote.

Award

An appropriate letter of appreciation and thanks is sent to the members of the ERP. The panel is announced at the appropriate session of the AOAC INTERNATIONAL Annual Meeting, with presentation of an award. All panelists are acknowledged at the Annual Meeting, and receive an award and a letter of appreciation. The name of the ERP, with supporting story, is announced in ILM.

INDIVIDUAL ACHIEVEMENT AWARDS

Technical Service Award

More than one volunteer may be selected in this category each year. In each case, the area of expertise should be noted at the time of presentation of the award.

Selection Criteria

The minimum criteria for selection are:

(1) Demonstrates timely, competent, and continuous service in an exemplary manner to a stakeholder panel, ERP, working group, Section, AOAC analytical community, committee, and/or the OMB.

(2) Donates service within the 3 years prior to nomination.

(3) Provides outstanding expert guidance and support in all technical aspects as needed and requested.

Additional support for selection is exemplary performance in one or more of the following areas:

(1) Provides guidance on safety, statistical, technical matters, or process expertise.

(2) Instrumental in developing, modifying, or validating a high-quality method for publication in the *Official Methods of Analysis.*

(3) Communicates related activities through the appropriate channels, either through the panel/group/community chairs, Committee on Statistics or Safety, Chief Scientific Officer, or other staff designees.

(4) Contributes significantly to AOAC INTERNATIONAL over a period of years with other accomplishments related to his/her area of expertise (e.g., symposium presentations, poster presentations, publications, workshops, meetings).

(5) Contributes to the development and improvement of AOAC INTERNATIONAL guidelines, Official Methods, or statistics or safety programs.

(6) Helps guide AOAC in the decision-making process to ensure the organization is a leader in the field of analytical science.

Selection Process

(1) The OMB solicits the chairs of the stakeholder panels, ERPs, working groups, committees, AOAC analytical communities, and the Association membership for nominees. Recommendations based on input from anyone qualified to discuss the contribution of the nominee can be submitted.

(2) Written recommendations and supporting information must be submitted to the OMB chair. The OMB chair distributes the information to the members of the OMB.

(3) The OMB selects the winner(s) of the Technical Service Award by a 2/3 vote. If necessary, the OMB chair may cast the tie-breaking vote.

Award

An appropriate letter of appreciation and thanks is sent to the recipient(s) of the award. The winner is announced at the appropriate session of the AOAC INTERNATIONAL Annual Meeting, with presentation of an award. The recipient(s) is acknowledged at the Annual Meeting, and receive an award and a letter of appreciation. The name of the winner, with supporting story, is announced in the *ILM.*

Method of the Year

The OMB may select more than one method in this category each year.

Selection Criteria

The minimum criteria for selection are:

(1) The method must have been approved for First or Final Action within the last 3 years.

(2) Generally, some unique or particularly noteworthy aspect of the method is highlighted as making it worthy of the award, such as innovative technology or application, breadth of applicability, critical need, difficult analysis, and/or range of collaborators.

(3) The method demonstrates significant merit in scope or is an innovative approach to an analytical problem.

Selection Process

(1) AOAC staff lists all eligible methods for consideration and forwards that list with supporting documentation [e.g., ERP chair recommendation(s)] to the chair of the OMB.

(2) The OMB chair forwards the list, along with any supporting information, to the members of the OMB.

(3) The OMB selects the Method of the Year. The winner is selected by 2/3 vote. If necessary, the OMB chair may cast the tie-breaking vote.

Award

An appropriate letter of appreciation and thanks is sent to the author(s) of the winning method. The corresponding author is announced at the appropriate session of the AOAC INTERNATIONAL Annual Meeting, with presentation of an award. All authors are acknowledged at the Annual Meeting, and receive an award and a letter of appreciation. The name of the winner(s), with supporting story, is announced in the *ILM.*

Conclusion

Winners will be chosen at an upcoming OMB meeting in (DATE?), and awards will be presented at the 129th AOAC Annual Meeting in Los Angeles, California, USA.

For more information on the OMB volunteer awards, contact **Deborah McKenzie,** senior director, standards development, at dmckenzie@aoac.org. ■