AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

THE TWELFTH MEETING

of the

AOAC Stakeholder Panel on

Infant Formula and Adult Nutritionals

Meeting at:

Westin Bonaventure Hotel

404 South Figueroa Street

Los Angeles, California 90071 - USA

THE CANALS OF VENICE, CA

Saturday, September 26, 2015

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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

Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN)

Meeting at Westin Bonaventure Hotel

404 South Figueroa Street - Los Angeles, California 90071 - USA

STAKEHOLDER PANEL - DRAFT MEETING AGENDA

Saturday, September 26, 2015

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

SPIFAN Chair: Darryl Sullivan

(Covance Laboratories)

Location: Santa Anita B/C

(Registration Opens at 7:30AM)

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

Jim Bradford (AOAC)/Darryl Sullivan (Covance) will call the Stakeholder Panel meeting to order along with the introduction/welcome of participants, and review AOAC's Antitrust and Conflict of Interest Policies. Voting Members of the stakeholder panel will be introduced.

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

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

III. **WHEY PROTEIN: CASEIN RATIO UPDATE (Ziting – 9:15AM-10:00AM)**

Ziting Zhang (EUCCC) or representative will provide an update on Whey Protein: Casein Ratio.

IV. **UPDATE ON INTERNATIONAL ACTIVITIES (10:15AM-11:00AM)**

An update will be provided on current global activities.

1. **UPDATE ON AOAC SPIFAN FINAL ACTION OFFICIAL METHODS OF ANALYSIS (Sullivan)**
   Darryl Sullivan (Covance) will provide an update on the Final Action methods and their introduction to CODEX.

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

V. **UPDATE FROM PROFICIENCY TESTING (PT) PROGRAM TASKFORCE (Gilliland – 11:00AM-11:15AM)**

Don Gilliland (Abbott) will provide an update on Proficiency Testing program.

VI. AOAC ACTIVITIES: BUSINESS DEVELOPMENT REPORT (Bradford – 11:15AM-12:00PM)

Jim Bradford (AOAC) will provide details of the current development projects at AOAC INTERNATIONAL.

1. **STEPS TOWARDS CONTINUED STANDARDS DEVELOPMENT FOR INFANT FORMULA (Bradford)**
   Jim Bradford (AOAC) will provide an update on the sequence of contracted events in the progression of the AOAC SPIFAN standards development activities.

2. **UPDATE ON THE STAKEHOLDER PANEL ON STRATEGIC FOOD ANALYTICAL METHODS (SPSFAM) ACTIVITIES (Konings)**
   Erik Konings (Nestlé) will provide an update on related AOAC SPSFAM activities.

VII. PRESENTATION ON CONTAMINANTS IN MILK/MILK POWDER - *CHINA PERSPECTIVE* (Shi – 1:00PM-1:45PM)

Shi Yiyin (CIQ-Shanghai) will provide the Chinese perspective and primary concerns of contaminants in milk and milk powder in China.

VIII. PRIORITIZATION OF CONTAMINANTS IN INGREDIENTS (Sullivan – 1:45PM-3:45PM)

Sullivan will lead a guided prioritization session for contaminants in ingredients.

IX. TIMELINES/DEADLINES/WRAP-UP (Sullivan – 3:45PM-4:00PM)

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

MEETING ITINERARY:

REGISTRATION (7:30AM)

MEETING START TIME (8:30AM)

MORNING BREAK (10:00AM-10:15AM)

LUNCH ON YOUR OWN (12:00PM–1:00PM)

AFTERNOON BREAK (3:00PM-3:15PM)

AOAC INTERNATIONAL
Stakeholder Panel Voting Members

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

Due Process and Balance

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

Composition

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

Approval Process

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

Roles and Responsibilities

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

Definitions

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

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

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

Stakeholders Privileges

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

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

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

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

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

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

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

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

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Darryl Sullivan, SPIFAN Chair

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

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

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

SPIFAN Overview

Darryl Sullivan, Covance Laboratories

Los Angeles, CA

September 26, 2015

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Outline

- AOAC SPIFAN Background and Overview
- AOAC SPIFAN Accomplishments
- AOAC SPIFAN Activities
- AOAC SPIFAN Expert Review Panel and Methods
- AOAC SPIFAN Activities during AOAC Mid-Year Meeting
- AOAC SPIFAN Activities since AOAC Mid-Year Meeting

SPIFAN Overview

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

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AOAC Engages the Formula Industry

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

Completed Voluntary Consensus Standards Development

SPIFAN I (SMPRs)
2011 – 2013

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

SPIFAN II (SMPRs)
2013 – 2016

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

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SPIFAN II

- Signed June 13, 2013
- 8 stakeholder panel, WGs, and ERP meetings
  - 1/7 – AOAC Annual Meeting Chicago 2013
  - 2/7 – AOAC Mid-Year Meeting, Gaithersburg 2014
  - 3/7 – AOAC Annual Meeting, Boca Raton 2014
  - 4/7 – AOAC Mid-Year Meeting, Gaithersburg 2015
    - Approved SMPRs for Vitamins B_1, B_2, B_3, and B_6
    - ERP adopted methods for chloride, minerals and trace elements, and vitamin K as First Action OMA.
    - ERP evaluated 4 First Action methods and recommended 2 to the AOAC Official Methods Board for Final Action status.

Since the AOAC Mid-Year Meeting

- Call for Methods posted
  - Vitamins B_1, B_2, B_3, and B_6; Amino acids; and Carotenoids

- Method Submissions
  - Resulting from the posted Call for Methods
    - 2 vitamins B_1, B_2, B_3, and B_6 methods
    - 1 amino acids method
    - 1 carotenoid method
  - Additional Submissions/Resubmissions
    - 3 chloride methods
    - 1 carnitine/choline method
    - 1 fluoride method
    - 1 FOS method
    - 1 GOS method
    - 1 MTE method
    - 2 First Action methods with reproducibility information and user feedback

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Since AOAC Mid-Year Meeting (cont.)

- Investigation into new initiative of contaminants in ingredients

- AOAC OMB approved the ERP's recommendations to move the pantothenic acid and iodine methods to Final Action OMA status.

- Publication of First Action and Final Action OMAs
  - All Final Action methods have been published in the online Journal

- INCA leading effort to prepare delegations for CCNSFDU meeting in November 2015

Registered Organizations

- Abbott
- ADM
- Agilent
- AsureQuality
- Caravan Ingredients
- Covance
- Curtis S. Phinney, CNS
- Eurofins
- FDA
- Fonterra
- Friesland Campina
- Frontage Laboratories
- GERSTEL
- Independent - Consulting
- Infant Nutrition Council of America
- International Dairy Federation
- INTI
- IonSense
- ISO
- LATU
- Maxxam Analytics
- Mead Johnson Nutrition
- Mérieux NutriSciences
- Nestle
- NIST
- Perrigo/PBM Nutritionals
- Phenomenex
- R. J. Hill Laboratories
- R-Biopharm
- Independent - retired
- Rotating Disc
- SCL Laboratoire de Strasbourg
- Shanghai Exit and Entry Inspection & Quarantine
- Shimadzu Scientific Technologies
- Sunshineville Health Products
- SUPELCO/Sigma-Aldrich
- USP
- Waters

As of September 11, 2015

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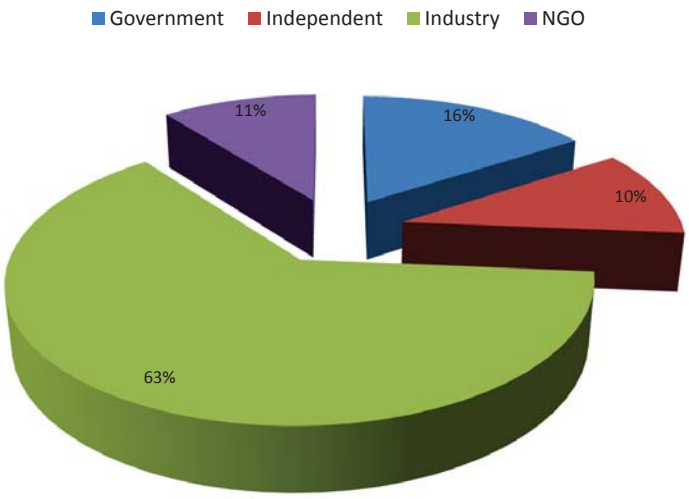
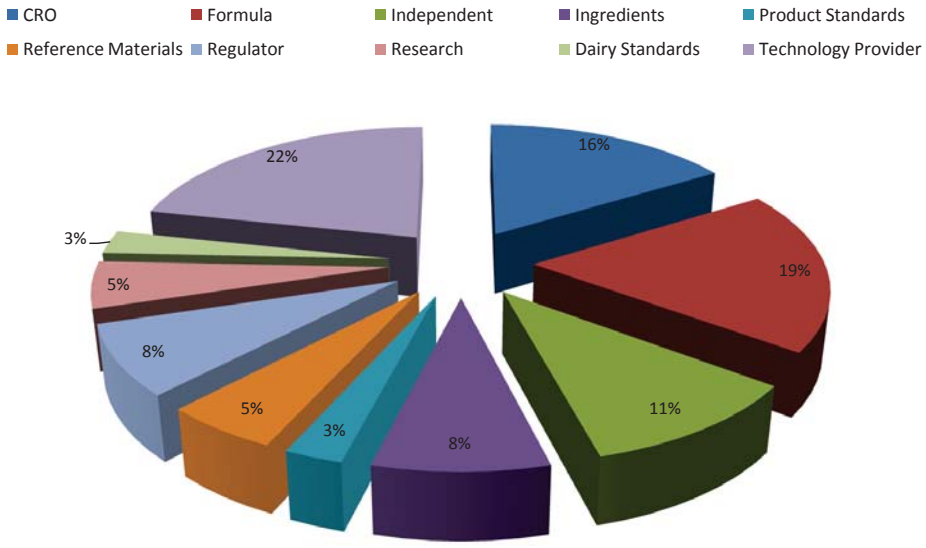
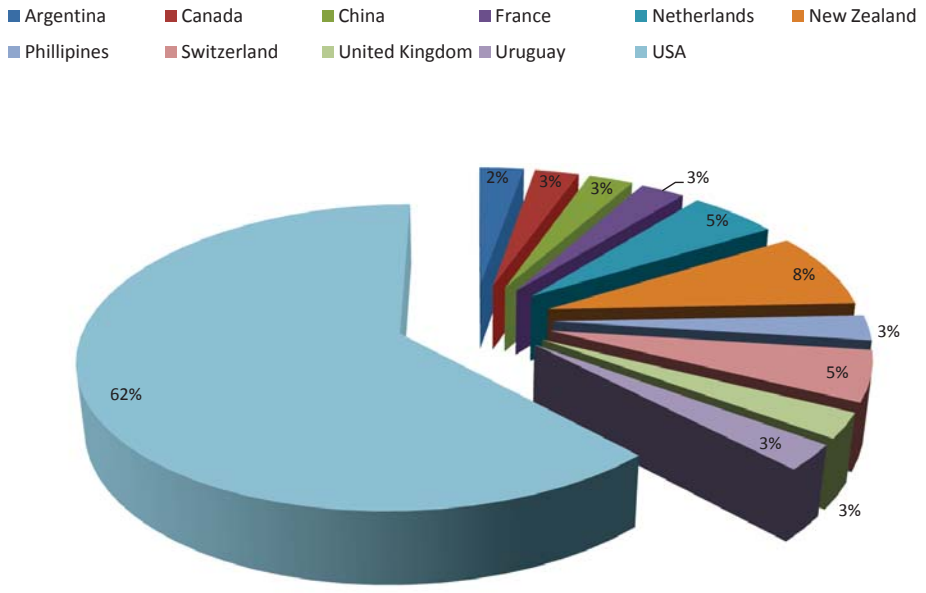
SPIFAN Registrants by Broad Perspectives



SPIFAN Registrants by Specific Perspectives



SPIFAN Registrants by Region



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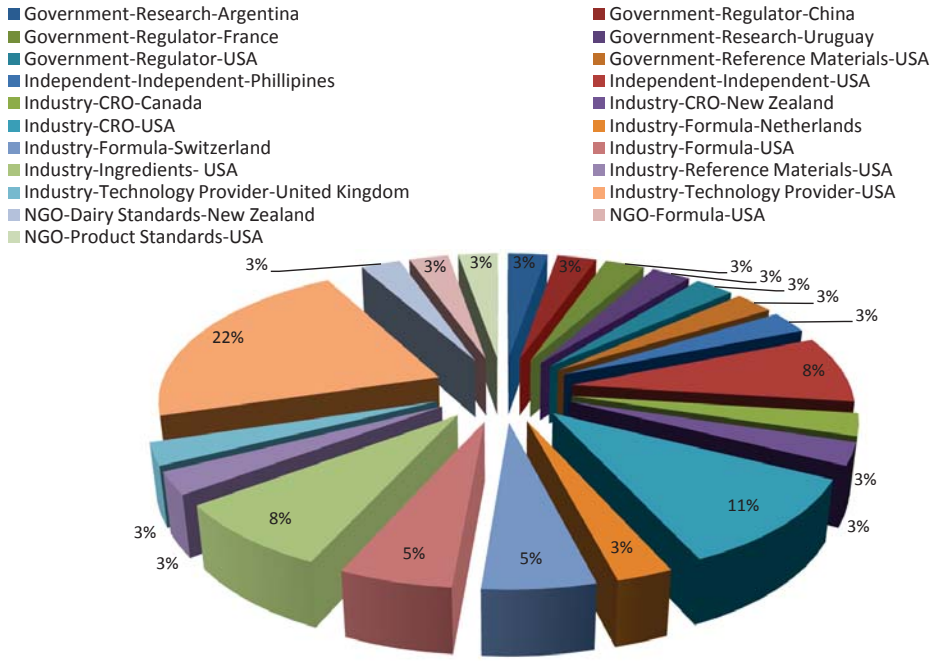
SPIFAN Registrants by Combined Perspectives



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Proposed SPIFAN Voting Members

- GOVERNMENT
  - US FDA
  - Instituto Nacional de Tecnologia
  - LATU
  - NIST
  - SCL Laboratoire de Strasbourg
  - Shanghai Exit and Entry Inspection & Quarantine

- INDUSTRY
  - Abbott
  - Fonterra Cooperative Group
  - Friesland Campina
  - Mead Johnson Nutrition
  - Nestle
  - Perrigo/PBM Nutritional
  - AsureQuality/Maxxam Analytics (alternate)
  - Eurofins
  - Covance

- INDUSTRY
  - Mérieux NutriSciences
  - Archer Daniels Midland
  - Caravan Ingredients
  - GERSTEL/Phenomenex (alternate)
  - Shimadzu Scientific Technologies
  - Agilent
  - R-Biopharm
  - Waters/IonSense (alternate)

- NGOs
  - INCA
  - USP
  - IDF

** As of September 11, 2015*

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AOAC Stakeholder Panel Role and Responsibilities

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

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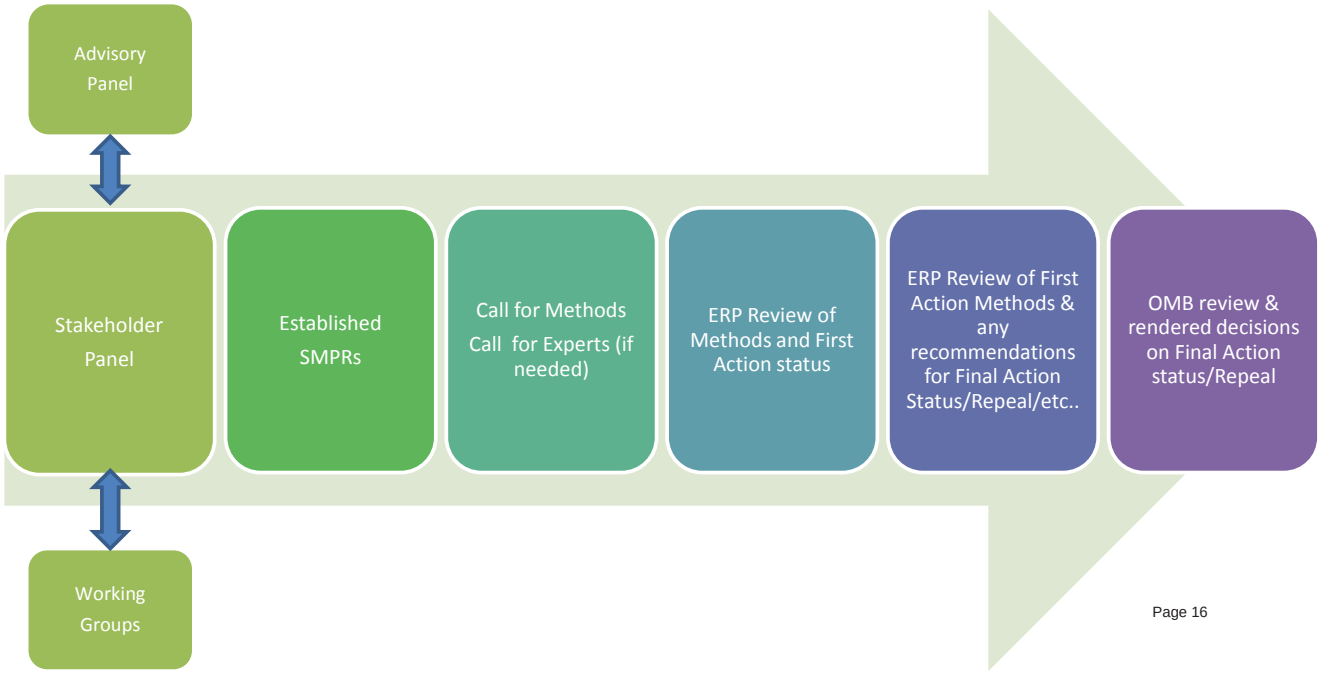
AOAC Standards Development

Initiating SMPRs to Final Action Consideration of Methods



Stakeholder Panel Working Groups

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

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SPIFAN Working Groups

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

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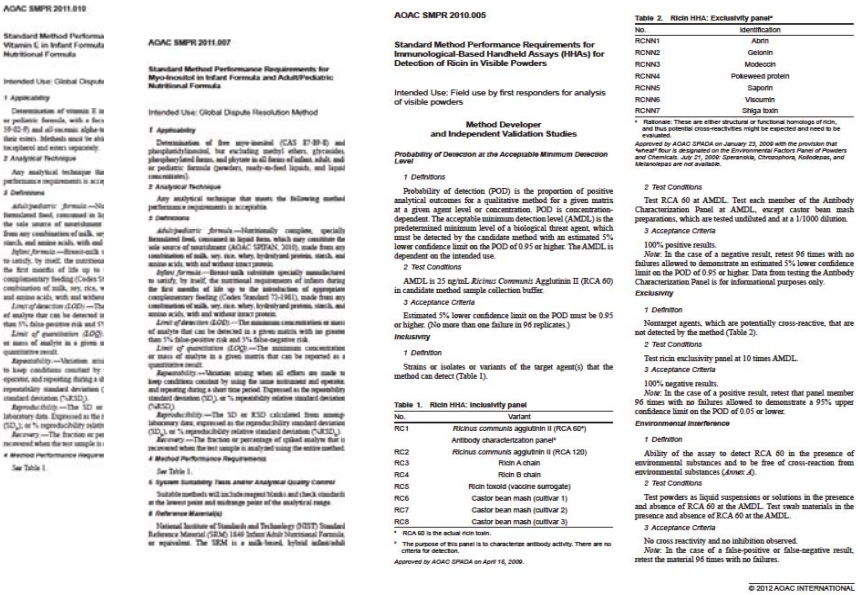
Standard Method Performance Requirements

- ***Commonly referred to as SMPR®***



AOAC SMPR 2011.010

Standard Method Performa
Vitamin E in Infant Formula
Nutritional Formula

Intended Use: Global Dispute

1 Applicability

Determination of vitamin E in
ee pediatric formula, with a flo
59-02-9) and all enantic alpha-t
their esters. Methods must be ab
tocopherol and esters separately.

2 Analytical Technique

Any analytical technique tha
performance requirements is acce

3 Definitions

Adult/pediatric formula—Nu
formulated food, consumed in liq
the sole source of nourishment
from any combination of milk, so
starch, and amino acids, with and

Infant formula—Breast-milk s
to satisfy, by itself, the nutritiona
combination of milk, soy, rice, w
and amino acids, with and without

Limit of detection (LOD)—The
of analyte that can be detected

Limit of quantitation (LOQ)—
than 5% false-positive risk and 5%

Limit of quantitation (LOQ)—
or mass of analyte in a given m
quantitative result.

Repeatability—Variation arisi
to keep conditions constant by
operator, and repeating during a sh
repeatability standard deviation (
standard deviation (%RSD$_r$).

Reproducibility—The SD or
laboratory data. Expressed as the
(SD$_R$), or % reproducibility relativ

Recovery—The fraction or pe
recovered when the test sample is

4 Method Performance Require

See Table 1.

AOAC SMPR 2011.007

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

Intended Use: Global Dispute Resolution Method

1 Applicability

Determination of free myo-inositol (CAS 87-89-8) and phosphorylated, but excluding methyl ethers, glycosides, phosphoacylated forms, and phytate in all forms of infant, adult, and/or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates).

2 Analytical Technique

Any analytical technique that meets the following method performance requirements is acceptable.

3 Definitions

Adult/pediatric formula—Nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment (AOAC SPIFAN, 2010), made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Infant formula—Breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding (Codex Standard 72-1981), made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Limit of detection (LOD)—The minimum concentration or mass of analyte that can be detected in a given matrix with no greater than 5% false-positive risk and 5% false-negative risk.

Limit of quantitation (LOQ)—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Repeatability—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator, and repeating during a short time period. Expressed as the repeatability standard deviation (SD$_r$) or % repeatability relative standard deviation (%RSD$_r$).

Reproducibility—The SD or RSD calculated from among-laboratory data, expressed as the reproducibility standard deviation (SD$_R$), or % reproducibility relative standard deviation (%RSD$_R$).

Recovery—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method.

4 Method Performance Requirements

See Table 1.

5 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include reagent blanks and check standards at the lowest point and midrange point of the analytical range.

6 Reference Material(s)

National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 1849 Infant/Adult Nutritional Formula, or equivalent. The SRM is a milk-based, hybrid infant/adult

AOAC SMPR 2010.005

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

Intended Use: Field use by first responders for analysis of visible powders

Method Developer and Independent Validation Studies

Probability of Detection at the Acceptable Minimum Detection Level

1 Definitions

Probability of detection (POD) is the proportion of positive analytical outcomes for a qualitative method for a given matrix at a given agent level or concentration. POD is concentration-dependent. The acceptable minimum detection level (AMDL) is the predetermined minimum level of a biological threat agent, which must be detected by the candidate method with an estimated 5% lower confidence limit on the POD of 0.95 or higher. The AMDL is dependent on the intended use.

2 Test Conditions

AMDL is 25 ng/mL *Ricinus Communis* Agglutinin II (RCA 60) in candidate method sample collection buffer.

3 Acceptance Criteria

Estimated 5% lower confidence limit on the POD must be 0.95 or higher. (No more than one failure in 96 replicates.)

Inclusivity

1 Definition

Strains or isolates or variants of the target agent(s) that the method can detect (Table 1).

Table 1. Ricin HHA: Inclusivity panel

No.	Variant
RC1	*Ricinus communis* agglutinin II (RCA 60*)
	Antibody characterization panel*
RC2	*Ricinus communis* agglutinin II (RCA 120)
RC3	Ricin A chain
RC4	Ricin B chain
RC5	Ricin toxoid (vaccine surrogate)
RC6	Castor bean mash (cultivar 1)
RC7	Castor bean mash (cultivar 2)
RC8	Castor bean mash (cultivar 3)

* RCA 60 is the actual ricin toxin.

* The purpose of this panel is to characterize antibody activity. There are no criteria for detection.

Approved by AOAC SPADA on April 16, 2009.

Table 2. Ricin HHA: Exclusivity panel*

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

* Rationale: These are either structural or functional homologs of ricin, and thus potential cross-reactivities might be expected and need to be evaluated.

Approved by AOAC SPADA on January 23, 2009 with the provision that "wheat" flour is designated on the Environmental Factors Panel of Powders and Chemicals. July 21, 2009: Speranskia, Chromophora, Kalladepas, and Melanolepas are not available.

2 Test Conditions

Test RCA 60 at AMDL. Test each member of the Antibody Characterization Panel at AMDL, except castor bean mash preparations, which are tested undiluted and at a 1/1000 dilution.

3 Acceptance Criteria

100% positive results.

Note: In the case of a negative result, retest 96 times with no failures allowed to demonstrate an estimated 5% lower confidence limit on the POD of 0.95 or higher. Data from testing the Antibody Characterization Panel is for informational purposes only.

Exclusivity

1 Definition

Nontarget agents, which are potentially cross-reactive, that are not detected by the method (Table 2).

2 Test Conditions

Test ricin exclusivity panel at 10 times AMDL.

3 Acceptance Criteria

100% negative results.

Note: In the case of a positive result, retest that panel member 96 times with no failures allowed to demonstrate a 95% upper confidence limit on the POD of 0.05 or lower.

Environmental Interference

1 Definition

Ability of the assay to detect RCA 60 in the presence of environmental substances and to be free of cross-reaction from environmental substances (*Annex A*).

2 Test Conditions

Test powders as liquid suspensions or solutions in the presence and absence of RCA 60 at the AMDL. Test swab materials in the presence and absence of RCA 60 at the AMDL.

3 Acceptance Criteria

No cross reactivity and no inhibition observed.

Note: In the case of a false-positive or false-negative result, retest the material 96 times with no failures.

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SMPRs

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

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Performance requirements parameters for quantitative methods

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

4. Method Performance Requirements

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

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Documentation and Communication

- AOAC will carefully document the proceedings of the stakeholder panel and the working groups
- AOAC will prepare summaries of the proceedings
  - Communicate summaries to the stakeholder panel
  - Publish summaries in the Referee section of AOAC's *Inside Laboratory Management*
- AOAC posts draft standards for comment
- AOAC issues calls for experts (for ERPs)
- AOAC issues call for methods (for candidate method authors)

ERP Overview

- ERP reviews all methods and adopts methods as First Action *Official Methods of Analysis*
- ERP tracks methods for two (2) years
  - ERP determines which method will be recommended for Final Action *Official Methods* status to the AOAC Official Methods Board
- ERP reviews any additional information on the method including user feedback

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Working Group (WG) Initiative

- AOAC Board of Directors initiates WG Initiative on December 9, 2014
- Individual or entity who expresses a need for a method
- WG may be funded and formed with assistance of AOAC
- WG will develop SMPR to present to an existing stakeholder panels for review

Why the new WG Initiative?

- Offers companies the opportunities to solve challenges without waiting on priorities of existing stakeholder panels
- WG's funded by current OA's and new companies interested in solving problems

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Compound 1080

During Mid Year Meeting

- SPIFAN launched, developed and approved one SMPR for Compound 1080
- ERP evaluated and approved 3 First Action OMAs

Since AOAC Mid-Year Meeting

- SMPRs posted for public comment
  - No comments received
- Methods published
  - Additional work on First Action methods can be submitted to the Journal of AOAC INTERNATIONAL for publication

Used AOAC's Working Group Initiative
Highly Accelerated, but Closely Monitored process
Completed within 30 days

AOAC SPIFAN Accomplishments

- Voluntary Consensus Standards
  - 29 Standard method performance requirements (SMPRs) covering more than 69 nutrient analytes and one pesticide contaminant since 2011

- Fit for Purpose Methods
  - 47 First Action methods adopted and published as in *Official Methods of Analysis of AOAC INTERNATIONAL*
  - 6 First Action methods repealed
  - 8 First Action methods promoted to Final Action status

SPIFAN Related Activities at AOAC Annual Meeting

- SPIFAN Meeting
  - Saturday, September 26, 2015 at 8:30am – 5:00pm.
    - Updates on Whey Protein-Casein Ratio; AOAC Final Action OMA and preparation for related upcoming Codex meetings, and related ISO/IDF activities
    - Discussion and prioritization on proposed contaminants in ingredients
- AOAC ERP for SPIFAN Nutrient Methods
  - Tuesday, September 29, 2015 at 8:30am – 5:00pm
    - Consideration of methods for AOAC First Action Official Methods status
    - Down selection of methods to one method per nutrient
    - Consideration of method for AOAC Final Action OMA status recommendation
- AOAC Update on Stakeholder Panel Meetings
  - Wednesday, September 30, 2015 at 3:00pm – 4:30pm
    - Annual session to provide updates on all of AOAC Stakeholder Panel related activities

Contact Information

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

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

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

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

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

Ms. Zhang will provide an update on Whey Protein: Casein Ratio

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

Whey Protein: Casein Ratio

China Update

Ziting ZHANG, European Union Chamber of Commerce in China

Los Angeles, CA

September 26, 2015

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Agenda

- Introduction the European Chamber and the Paediatric Nutrition Desk
- Update on whey protein issue in China
  - Background
  - Timeline of the whey protein testing method
  - Industry observations
  - Industry Advocacy Efforts
- Next steps

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About the European Chamber

1,800 members

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Working Group

- Aerospace
- Aviation
- Consumer Finance & NBFI
- Finance & Taxation
- ICT
- Legal & Competition
- Pharmaceuticals
- Rail
- Water
- Agriculture, Food & Beverages
- Banking & Securities
- Cosmetics
- Healthcare Equipment
- Information Security
- Logistics
- Private Equity
- Renewable Energy
- Wood
- Auto Components
- Carbon Market
- Energy
- Heating
- Insurance
- Maritime Transport
- Public Procurement
- Smart Grid
- Automotive
- Construction
- Environment
- Human Resources
- IPR
- Petrochemicals, Chemicals & Refining
- Quality & Safety Services
- Standards & Conformity Assessment

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Paediatric Nutrition Desk

7 MNC Members:

Abbott, FrieslandCampina, Mead Johnson, Nestle, Nutricia ELN, Nutricia Pharmaceutical and Wyeth Nutrition

6 Domestic Partners:

Beingmate, Biostime, Feihe, Shengyuan, Yashili, Yili

The only industry association focusing on Infant formula in China

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The Whey Protein Issue In China

I. The food safety national standard in China

Article 26 in the revised Food Safety Law:

Food safety standards shall include:

…

(III) requirements for nutrient ingredients of primary and secondary foods for infants and other specific populations;

(VII) food inspection methods and specifications relating to food safety; and …

➔ Standard of testing methods are **mandatory** in China

The Whey Protein Issue In China

II. GB10765-2010 Food Safety National Standards: Infant Formula

For milk based infant formulas, the content of whey protein should be over or equal to 60%

a) A unique requirement only in the Chinese standard
b) A new requirement in the 2010 version

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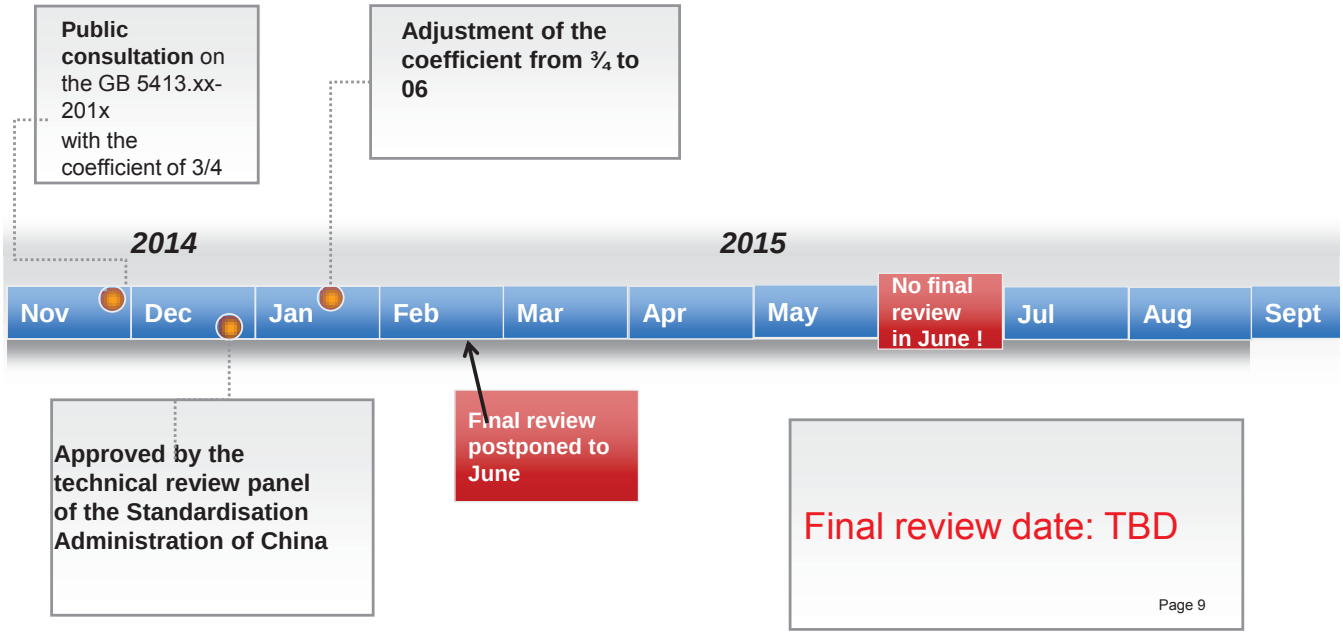
The Whey Protein Issue In China

III. The business context

a) Full GB (national standards) compliance test
b) >3000 Food analysis labs in China with uneven capacity
c) Lack of system to ensure deliver accurate analysis data

➔ *the testing methods can cause serious impacts on business.*

Timeline of the method of whey protein



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Observations from industry

- **General issues**
  - Incomparability between Method I and Method II
    - Method I: a-Lactalbumin+b-Lactoglobulin, F=0.6
    - Method II: amino acid profile

Observations from industry

- **Method I (**$\delta 0$ Lactalbumin+$\varepsilon 0$ Lactoglobulin)
- Repeatability is ok while reproduceabity is poor
- The coefficient F=0.6 is not suitable for modified whey protein (α-Lac enriched)
- Complicated process
- High requirement on capacity of laboratory personnel
- Unstandardized reagent kit(reference materials)

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Observations from industry

- **Method II (amino acid profile)**
  - Unable to identify adulteration
  - Qualitative but not quantitative method
  - Amino acid profile of α-lac enriched whey may differs from standard whey

Impact for raw materials supply

- China only rely on import WPC or demineralised whey as raw material for “whey protein” in infant formula
- The current suppliers only offer “protein data” instead of “whey protein data”
- To ensure the whey protein level with compliance, test raw material for whey protein level is logical
- Food fraud possibility is there if no such test

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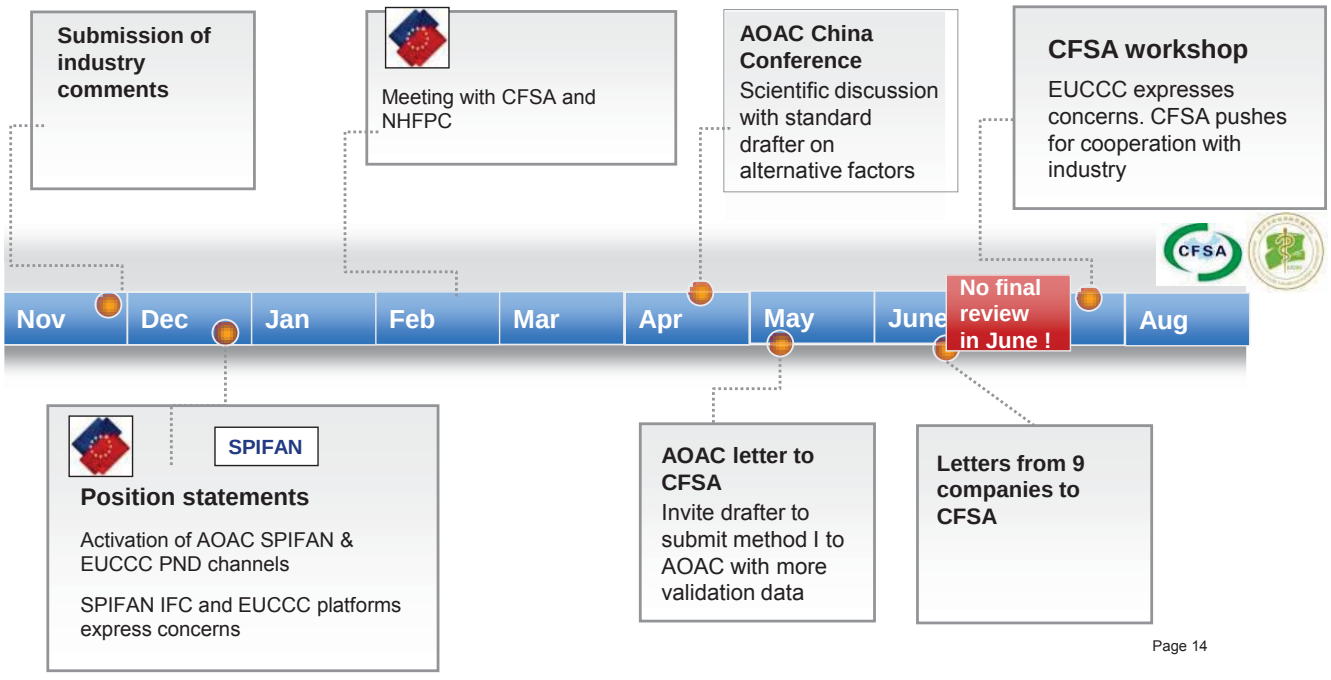
Industry Advocacy Effort



Next step

- **Validation program with China Academy of Inspection and Quarantine**
- **The Method I owner to organize further training for industry**
- **Follow up with the NHFPC regarding the final publishing date of the standard and the grace period**

Cooperation with SPIFAN/AOAC

- The progress of AOAC Testing Method of whey protein
- Validation of Method I by AOAC?
- Reference materials

Thank you

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Tel: 0086 10 64622066-33

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

(AOAC/ISO COOPERATIVE)

Erik Konings, Nestlé
SPIFAN Working Group Chair, Folic Acid
Chair, ISO/TC 34/WG 14 – Vitamins, Carotenoids and Other Nutrients

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

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

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

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

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

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Jaap Evers, International Dairy Federation (IDF)

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

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

AOAC-ISO-IDF Collaboration

Erik Konings, Nestlé Research Center, Nestec Ltd. (ISO)

Jaap Evers, Fonterra Cooperative (IDF)

Los Angeles, CA

September 26, 2015

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Submission of SPIFAN methods for endorsement by CODEX

- November 23, 2015, first opportunity to submit SPIFAN Final Action methods into the Codex system.
- Advantages of submission as AOAC/ISO/IDF
  - Globally harmonized dispute resolution methods
  - Increases global availability and accessibility

Actions/Timing for endorsement by CODEX

Action	timing
Submission recommended methods as Type II methods (Reference methods) to Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) Intended outcome: CCNFSDU agrees to request CCMAS to review and endorse the methods.	November 2015
CCMAS reviews and endorses the methods. Intended outcome: CCMAS agrees to pass the methods to the CAC for final adoption.	February 2016
Endorsement of CCMAS recommendations by the CODEX Alimentarius Commission (CAC)	July 2016
Inclusion of methods in Codex Standard 234: Recommended methods of analysis and sampling	

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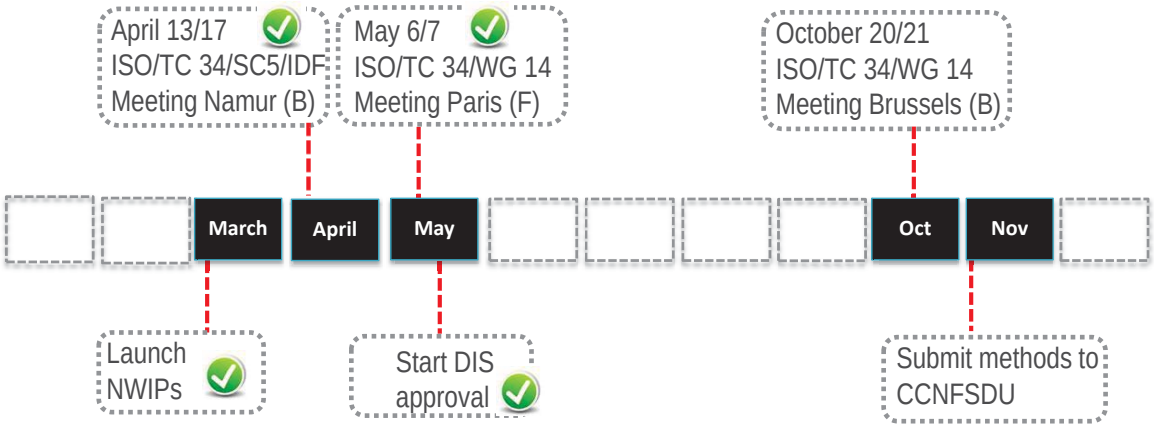
Method submission to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

Analyte	AOAC	ISO/IDF
Vitamin B_{12}	AOAC 2011.10	ISO/DIS 20634:2015
Myo-inositol	AOAC 2011.18	ISO/DIS 20637:2015
Cr, Mo, Se	AOAC 2011.19	ISO/DIS 20649 | IDF 235:2015
Nucleotides	AOAC 2011.20	ISO/DIS 20638:2015
Vitamins A and E	AOAC 2012.10	ISO/DIS 20633:2015
Fatty acid profile	AOAC 2012.13	ISO/DIS 16958 | IDF 231:2015
Iodine	AOAC 2012.15	ISO/DIS 20647 | IDF 234:2015
Pantothenic acid	AOAC 2012.16	ISO/DIS 20639:2015

2015 timeline ISO/IDF methods



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Summary

- Joint submission of 8 SPIFAN Final Action methods to CCNFSDU by AOAC/ISO/IDF on November 23 2015.
- Endorsement by CCMAS followed by the CODEX Alimentarius Commission foreseen for February and July 2016, respectively.

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Darryl Sullivan, SPIFAN Chair

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

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

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

AOAC SPIFAN Final Action Methods & Codex

Darryl Sullivan, Covance Laboratories

Los Angeles, CA

September 26, 2015

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Goal and Objectives

- Ultimate goal of industry
  - To have the AOAC Final Action OMA from SPIFAN (also adopted by ISO/IDF) recognized by the Codex Alimentarius as Type II dispute resolution methods and added to the Table of Methods of Analysis and Sampling in the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
- Objectives
  - AOAC standards development, method evaluation, achieving AOAC Final Action method status, and publication of method manuscripts
  - Engaging ISO and IDF
    - Entering into an agreement with ISO to participate in each other's work to jointly develop and approve standards

Steps and Milestones Achieved

- Developed SMPRs for nutrients
- Collected Methods for nutrients
- Evaluated methods against SMPRs & adopted First Action *Official Methods of Analysis*
- Tracked for 2 years and reproducibility determined
- Reevaluated First Action methods & recommended First Action OMA for Final Action status
- Recommended First Action OMA approved AOAC Final Action status

Nutrients for which AOAC First Action methods were recommended and approved as AOAC Final Action

1. ***Vitamins A & E***
2. ***Vitamin B12***
3. ***Inositol***
4. ***Nucleotides***
5. ***Chromium, Selenium, Molybdenum***
6. ***Fatty Acids***
7. ***Iodine***
8. ***Pantothenic Acid***

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AOAC Final Action OMA

- Expert Review Panel
  - Tracks First Action OMA for maximum of 2 years
    - Considers additional method optimization
    - Consider method end user feedback
    - Consider method reproducibility information
    - Consider AOAC OMB Guidance to ERPs on First to Final Action (OMA, Appendix G)
  - Makes recommendation to AOAC OMB for Final Action, Repeal, or Continuance of First Action method status
  - AOAC OMB reviews ERP recommendation report against the OMB Guidance (OMA Appendix G) and renders a decision on the ERP recommendation(s).

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AOAC ERP for SPIFAN Nutrient Methods Recommendations

- March 2014
  - 6 method to be repealed
- September 2014
  - 6 methods for Final Action OMA status
- March 2015
  - 2 methods for Final Action OMA status

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AOAC Official Methods Board

- November 2014
  - Approved ERP's recommendations to repeal 6 methods
  - Approved ERP's recommendation to promote 6 methods to Final Action OMA status
- July 2015
  - Approved ERP's recommendations to promote 2 method to Final Action OMA status

Prospective Introduction of Methods at Codex

- Methods to be presented to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) for agreement that the methods should move forward for technical review
  - November 23-27, 2015 in Bad Soden am Taunus, Germany
- Methods could be presented to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for technical review of the methods
  - February 22-26, 2016 in Budapest, Hungary
- Methods could be presented to Codex Alimentarius Commission for endorsement
  - June 27 – July 1, 2016 in Rome, Italy

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AOAC Preparation

- Final Action methods and manuscripts to be published
- AOAC established May 31, 2015 deadline
  - All method authors were invited to submit method manuscripts for publication in the *Journal of AOAC INTERNATIONAL*
  - Method manuscripts accepted for publication fast tracked published in the online Journal as raw data files by August 2015
    - Subsequent reformatting and publication in print Journal to follow
    - 7/8 Final Action methods manuscripts available
    - 1 Final Action method manuscript available in print and online Journal
- All “fast track articles” are available at http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac

Industry Effort Underway

- Infant Nutrition Council of America (INCA)
  - Began in May 2015
    - met with members of the US delegation to CCNFSDU
      - How methods go into Codex
      -
  - Formed a coalition to
    - Begin to leverage networks to develop contact list of various country delegations to CCNFSDU which may not be aware of the AOAC SPIFAN methods
    - Produce an outreach document
    - Conduct outreach and provide education on the methods with various country delegations prior to CCNFSDU meeting

AOAC SPIFAN Final Action Official *Methods*

2011.10	Determination of Vitamin B12 in Infant, Adult, and Pediatric Formulas by HPLC-UV and Column Switching: Collaborative Study	Schimpf, K. (Abbott)	98(6)
2011.18	Determination of Myo-Inositol in Infant, Pediatric, and Adult Formulas by IC-PAD and Column Switching: Collaborative Study	Schimpf, K. (Abbott)	98(6)
2011.19	Determination of Chromium, Selenium, and Molybdenum in Infant Formula and Adult Nutritional Products - Inductively Coupled Plasma-Mass Spectrometry: Collaborative Study	Thompson, J. (Abbott)	98(6)
2011.20	Analysis of Nucleotide 5'-Monophosphates in Infant Formulas by HPLC–UV: Collaborative Study	Gill, B & Indyk, H. (Fonterra)	98(4)
2012.10	Simultaneous Determination of 13-Cis and all-trans Vitamin A Palmitate (retinyl palmitate), Vitamin A Acetate (retinyl acetate), and Total Vitamin E (α-Tocopherol and DL-α-Tocopherol Acetate) in Infant Formula and Adult Nutritionals by Normal Phase HPLC: Collaborative Study	McMahon, A. (Nestle)	98(6)

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AOAC SPIFAN Final Action *Official Methods*

2012.13	Determination of Labeled Fatty Acids Content in Milk Products, Infant Formula and Adult/Pediatric Nutritional Formula by Capillary Gas Chromatography: AOAC Final Action 2012.13	Golay, P. (Nestle)	98(6)
2012.15	Determination of Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula by Inductively Coupled Plasma - Mass Spectrometry (ICP-MS): A Collaborative Study	Zywicki, R. (Covance)	98(5)
2012.16	Pantothenic Acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula. Ultra High Pressure Liquid Chromatography -Tandem Mass Spectrometry Method AOAC 2012.16: Collaborative study	Martin, F. (Nestle)	98(6)

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Thank you

&

Questions??

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Don Gilliland, Abbott Nutrition
SPIFAN Laboratory Proficiency Testing Advisory Taskforce &
SPIFAN Working Group Chair, Vitamin D

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

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

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

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

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

Update from Proficiency Testing (PT) Program Taskforce

Don Gilliland, Abbott Nutrition

Los Angeles, CA

September 26, 2015

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- Task Force – Membership
  - John Austad (Covance)
  - Laura Coisne (Nestle)
  - Melissa Phillips (NIST)
  - Jane Weitzel (AOAC)
  - Shane Flynn (AOAC)
  - Arlene Fox (AOAC)
  - Darryl Sullivan (Covance)

- Task Force Objectives
  - Develop Proficiency Testing Program for Infant Formula and Adult Nutritional Products
    - Utilize SPIFAN Product Matrices
  - Identify Proficiency Test Program Components
    - Frequency, Products Type and Number
    - Establishing Nutrient Reference Values and Statistics
      - Multi-Lab Data
      - SMPR-Based
  - Leverage AOAC PT Program and Expertise
  - Use Pilot Program to Evaluate PT Program

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- Utilize SPIFAN Product Matrices
  - SRM 1849a
  - Infant Formulas (1)
    - Pwd, Milk Based RTF, Milk Based
    - Pwd, Milk Based, Part Hyd Prot
    - Pwd, Soy Based Pwd, Soy Based, Part. Hydr Prot
    - Amino Acid Based Pwd
  - Pediatric Nutritional
    - Pwd
  - Adult Nutritional (1)
    - Milk Based Pwd High Protein Pwd
    - High Fat RTF High Protein RTF

- Nutrient Scope
  - Current List of Nutrients
    - Final Action
      - Inositol Iodine
      - Fatty Acids Nucleotides
      - Vitamin A, Vitamin E Vitamin B_{12}
      - Ultra-Trace Minerals (Cr, Mo, Se)
      - Pantothenic Acid
    - In Multi-Lab
      - Vitamin C Vitamin D
      - Choline

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- Next Steps - Pilot Program
  - Procedure
    - Additional Testing
      - Nutrient Listing
      - Samples
      - Reference Values
      - Number of Laboratories
    - Use of Multi-Lab Data Already In Hand
      - Evaluation of Information Needed, Forms Used and Data Evaluation
      - Potential to Completed More Quickly vs Testing
  - Complete by end-2015

- Thank You
- Questions

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

E. James Bradford, Executive Director
AOAC INTERNATIONAL

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

(AOAC/ISO COOPERATIVE)

Erik Konings, Nestlé
SPIFAN Working Group Chair, Folic Acid
Chair, ISO/TC 34/WG 14 – Vitamins, Carotenoids and Other Nutrients

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

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

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

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

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

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

Stakeholder Panel on Strategic Food Analytical Methods (SPSFAM)

Erik Konings, Nestlé Research Center, Nestec Ltd.

Los Angeles, CA

September 26, 2015

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Who participates in SPSFAM and what is the agenda?

- AOAC INTERNATIONAL Organizational Affiliates
- Multinational Food Companies
- All give direction on the analytical needs for the food industry

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AOAC SPSFAM History

- AOAC initiated this panel to address issues of Organizational Affiliate (OA) members - specifically the multi-national food and beverage companies
- SPSFAM focuses on the OA issues and builds consensus within the community related to food or strategic growth of the food industry

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SPSFAM Inaugural Meeting

- SPSFAM Inaugural Meeting held on June 30, 2011
- Initial areas decided by the Advisory Panel include antioxidants, contaminants, flavanols, and ingredients
- Working groups initiated and *Standard Method Performance Requirements® (SMPRs)* developed in each area

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AOAC Organizational Affiliate Members

- 3M Food Safety
- Abbott Nutrition
- Agilent Technologies, Inc.
- American Proficiency Institute
- Archer Daniels Midland Company
- BioControl Systems, Inc.
- BioMérieux, Inc.
- Bio-Rad Laboratories
- Canadian Food Inspection Agency
- CEM Corporation
- Coca-Cola Company
- Danone
- DuPont Nutrition & Health
- Elanco / Eli Lilly & Co.
- Fonterra Cooperative Group Ltd.
- Health Canada
- Kellogg Company
- Kraft Foods Group / Mondelez International
- Mars Botanical
- Mead Johnson Nutrition
- Medallian Labs / General Mills, Inc.
- Merck KGaA - EMD Millipore
- Mérieux NutriSciences - Silliker
- Microbac Laboratories, Inc.
- Microbiologics, Inc.
- MPI Research
- Neogen Corporation
- Nestle Research Center
- NSF International
- NSI Lab Solutions, Inc
- PepsiCo
- Promega Corporation
- Q Laboratories, Inc.
- QUIGEN Gmbh
- R-Biopharm, Inc.
- ROMER Labs Division Holding GmbH
- SCIEX
- Shimadzu Scientific Instruments, Inc.
- Starbucks Coffee Company
- Synutra International, Inc.
- The Fertilizer Institute
- The Hershey Company
- Thermo Fisher Scientific
- Waters Corporation

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SPSFAM Advisory Panel

- Chair: Erik Konings (Nestle)
- Advisory Panel Companies
  - Archer Daniels Midland
  - The Coca-Cola Company
  - General Mills, Inc.
  - Hershey Center for Health And Nutrition
  - Kellogg Company
  - Kraft Foods, Inc./Mondelez
  - Mars Chocolate
  - Nestle Research Center
  - PepsiCo
  - Starbucks Coffee Company

SPSFAM Stakeholder Panel Voting by Consensus

- SPSFAM Meeting held twice a year.
- AOAC Official Methods Board (OMB) vets the SPSFAM Voting Panel prior to meeting
  - To ensure well-balance with industry/domestic and international gov't/CROs/academia/NGO
  - EVERYONE in the room has a voice
  - Representative voting panel responsible for listening to the community and voting on recommendations
  - SMPRs from each of the working groups are discussed and a vote is requested

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Achievements to date: SMPRs

Analyte	Matrices	SMPR
Antioxidants	Foods, Beverages, Beverage Materials, Dietary Supplements	2011.11
Flavenols	Foods, Beverages and Beverage Materials, Fruit Juice, wines, Fruit & Fruit products, Cocoa Powder Chocolate, Spices and Condiments	2012.01
Heavy Metals	Foods, Beverages and Beverage Materials, Chocolate, Chocolate products, Fruit Juices, Infant formula	2012.07
St. John's Wort	Dietary Supplements	2013.01
Vitamin A	Foods	2012.03
Vitamin D	Foods	2012.04
Vitamin E	Foods	2012.05
Vitamin K	Foods	2012.06
Arsenic speciation	Selected foods and beverages	2015.006

Achievements to date: OMs First Action

AOAC Official Method First Action	Title
2012.04	Method for the Determination of Antioxidant Activity in Foods and Beverages by Reaction with 2, 2'-diphenyl-1-picrylhydrazyl (DPPH): Collaborative Study
2012.03	Analytical Parameters of the Microplate-Based ORAC-Pyrogallol Red Assay
2012.23	Development and Validation of an Improved Oxygen Radical Absorbance Capacity Assay Using Fluorescein as the Fluorescent Probe
2013.04	Method for the Determination of Catechin and Epicatechin Enantiomers in Cocoa-Based Ingredients and Products by High Performance Liquid Chromatography: Single-Laboratory Validation
2012.24	Determination of Flavanol and Procyandin (by Degree of Polymerization 1-10) Content of Chocolate, Cocoa Liquors, Powder(s), and Cocoa Flavanol Extracts by Normal Phse High-Performance Liquid Chromotography: Collaborative Study
2013.03	Analysis of Cocoa Flavanols and Procyanidins (DP 1-10) in Cocoa-Containing Ingredients and Products by Rapid Resolution Liquid Chromatography
2015.01	Heavy metals in food

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Working Group (WG) Initiative

- December 2014, AOAC Board of Directors initiates WG Initiative
  - as an a mechanism for AOAC Organizational Affiliate members to initiate relevant standard development projects using existing AOAC stakeholder panels
    - Expressed a need for a consensus standards and scientifically valid fit for purpose consensus methodology
    - WG supported through AOAC Organizational Affiliates funded and formed through AOAC staff
    - AOAC works with Organizational Affiliates to find additional Organizational Affiliates with the same need for scientifically valid fit for purpose methodology
  - WG will develop SMPR to present to an existing stakeholder panels for review

Why the new WG Initiative?

- Offers companies the opportunities to solve challenges without waiting on priorities of existing stakeholder panels

  –Advisory Panel participation and discussion

- WG's funded by current OA's and new companies interested in addressing immediate needs

  –for analytical standards/standard method performance requirements; and

  –scientifically valid fit for purpose methodology

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SPSFAM Mid-Year Meeting, March 2015

- Heavy metals
  - Arsenic speciation SMPR 2015.006 approved
  - Call for methods, 3 methods received, call extended, ERP mid-year 2016
  - Applicability: Arsenic species and/or total inorganic arsenic
  - Selected foods: Rice, Rice based products (baby food cereals, infant formula, cereal), Fruit juice (apple, grape), Fish oil based supplements, Seafood (finfish, shellfish, seaweed)

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SPSFAM Mid-Year Meeting, March 2015

- Heavy metals
  - AOAC 2015.01 First action, heavy metals (Pb, Cd, As, Hg) in foods and beverages. MLT most likely in 2016
- solid chocolate, fruit juice, fish, infant formula, and rice, using microwave digestion and inductively coupled plasma–mass spectrometry (ICP-MS)
  - Advisory Panel: no need for SMPR Cr speciation

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SPSFAM Mid-Year Meeting, March 2015

- Microbiology/rapid methods
  - Investigated potential working group for rapid testing
  - Feedback from potential working group members
- Technology providers in contact with individual industry partners to cover needs. No additional value AOAC initiative

SPSFAM Annual Meeting 2015 New Initiatives

- Launch working group Kombucha tea
  - Determination alcohol content
- Introduction potential working group allergens:
  - Volunteer consensus standard for allergens screening. The basis for a method approach would be identification and targeting of peptides associated with known allergens with LC/MS/MS
- Introduction potential working group on glyphosate in milk powder

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Getting Involved

- Individuals
  - Get involved in a working group
  - Provide feedback on SMPRs
  - Submit methods for consideration
- Companies
  - Becoming an AOAC OA and spearhead a working group
  - Provide feedback on SMPRs and submit methods
  - Indentify experts to participate in working group

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Yiyin Shi, Shanghai Inspection and Quarantine Bureau, Food Inspection, Residue analysis in food

Ms. Shi will provide the Chinese perspective and primary concerns of contaminants in milk and milk powder in China

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

Contaminants in Milk/Milk Powder
China Perspective

YIYIN SHI

China Inspection and Quarantine Bureau

Sep 26, 2015

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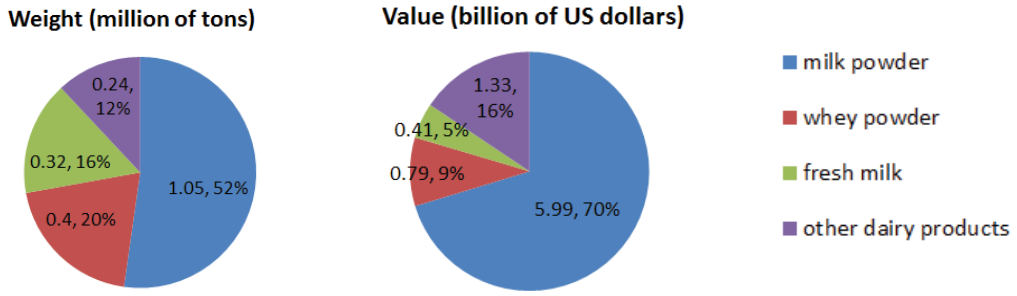
Contents

- Current status of import dairy products in China
- Legal basis of dairy products in China
- Supervision system of dairy products in China
- Standards of dairy products in China
- Monitoring program of import dairy products in China
- Further work

Current status of import dairy products in China

Since 2009, China's dairy imports continued to increase. In 2014, China imported 2.01 million tons of dairy products which valued near $ 8.52 billion with an increase of 11.9% and 18.7% respectively.

Milk powder, whey powder and fresh milk are the three dominant import dairy products in China. The imported amount of milk powder, whey powder and fresh milk were 1.05, 0.40 and 0.32 million tons respectively which valued $ 5.99, $ 0.79 and $ 0.41 billion in 2014.



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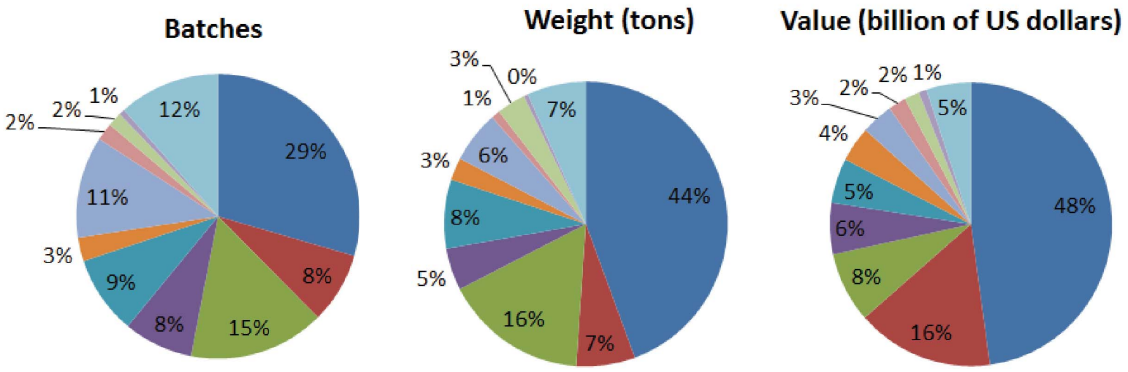
Current status of import dairy products in Shanghai port

As the biggest import port in China, Shanghai port handled 10548 batches of import dairy products, weighing 0.64 million tons, which valued $2.74 billion in 2014.

There were 116 batches of non-compliance imported dairy products discovered, which weighed 666 tons and valued $3.18 million.

Contaminants, micro-organisms, over shelf life, additives, certificate problems were the major non-compliance reasons and contaminants were on the top.

In 2014, Shanghai port imported dairy products from 29 countries, and the main countries were New Zealand, Australia, Western Europe, the United States, etc.



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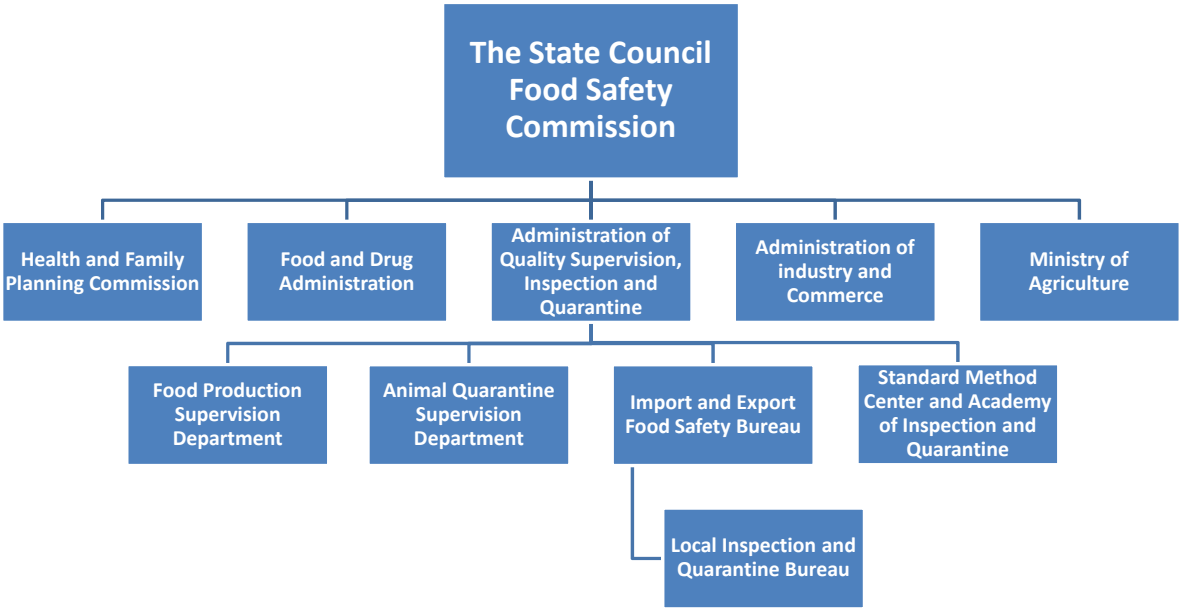
Legal basis of dairy products in China

1. **Laws**
   - Food Safety Law of the People's Republic of China
   - Inspection Law of Import and Export Commodities of the People's Republic of China

2. **Regulations**
   - Regulations of the People's Republic of China on the Implementation of the Food Safety Law
   - Regulations of the people's Republic of China on the Implementation of the Import and Export Commodity Inspection Law
   - Special Provisions of the State Council on Strengthening Safety Supervision and Administration of Food
   - Decision of the State Council on Strengthening the Work of Food Safety

Supervision system of dairy products in China



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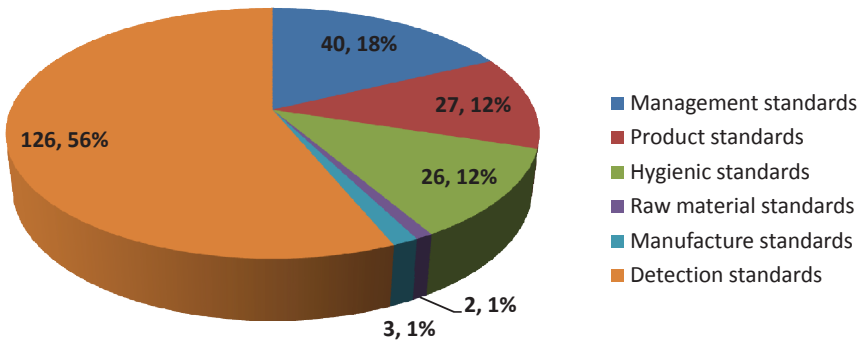
Standards of dairy products in China

At present, there are 224 standards of dairy products in China, including 113 national standards, 111 industry standards, among which 66 are compulsory standards and the other 188 are the recommended standards.



Statistical graph for classification of China's dairy products standards

Product Standards					
1	GB 19301	Raw milk	15	GB 10770	Canned complementary foods for infants and young children
2	GB 19645	Pasteurized milk	16	NY 479	Seasoning milk
3	GB 25190	Sterilized milk	17	NY 477	Calcium milk
4	GB 25191	Modulation milk	18	NY 479	Artificial cream
5	GB 19302	Fermented milk	19	NY 5045	Pollution free-Fresh milk
6	GB 13102	Condensed milk	20	NY 5140	Pollution free-Liquid milk
7	GB 19644	Milk powder	21	NY 5142	Pollution free-Yogurt
8	GB 11674	Whey powder and whey protein powder	22	NY/T 657	Organic food-Dairy products
9	GB 19646	Cream	23	NY/T 799	Fermented milk beverage
10	GB 5420	Cheese	24	NY/T 898	Organic food-Milk beverage
11	GB 25192	Processed cheese	25	QB/T 2132	Vegetable protein beverage-Soy milk
12	GB 10765	Infant formula	26	QB/T 2301	Vegetable protein beverage-Walnut milk
13	GB 10767	Older infants and young children formula	27	SB/T 10419	Vegetable cream
14	GB 10769	Cereal-based complementary foods for infants and young children			

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Standards of contaminants MRL in dairy products

GB 2760	• MRL of additives in food
GB 2761	• MRL of mycotoxins in food
GB 2762	• MRL of contaminants in food
GB 2763	• MRL of pesticide residues in food
The 235th announcement	• MRL of veterinary drugs in food of animal origin
The 176th announcement	• Banned veterinary drugs in feed and animal drinking water

According to GB 2761, the MRL of aflatoxin M1 in dairy products is 0.5 µg/kg.

According to GB 2762, the MRL of 5 contaminants in dairy products are as follows:

Contaminants	Dairy Products	MRL (mg/kg)
Lead	Raw milk, Pasteurized milk, Sterilized milk, Fermented milk, Milk modulation	0.05
	Milk powder, Non desalination whey powder	0.5
	Other dairy products	0.3
Arsenic	Raw milk, Pasteurized milk, Sterilized milk, Fermented milk, Milk modulation	0.1
	Milk powder	0.5
Mercury	Raw milk, Pasteurized milk, Sterilized milk, Fermented milk, Milk modulation	0.01
Chromium	Raw milk, Pasteurized milk, Sterilized milk, Fermented milk, Milk modulation	0.3
	Milk powder	2
Nitrite	Raw milk	0.4
	Milk powder	2

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According to GB 2763, dairy products have limitation requirements for 8 pesticides:

Pesticides	Dairy Products	MRL (mg/kg)
Endosulfan	Dairy Products	0.01
Aldrin	Dairy Products	0.006
DDT	Dairy Products	0.02
Lindane	Dairy Products	0.01
HCB	Dairy Products	0.02
Chlordane	Dairy Products	0.002
Heptane	Dairy Products	0.006
Dieldrin	Milk	0.006

According to the 235th announcement of the ministry of agriculture: acetylsalicylic acid, decoquinate, abamectin, doramectin, doxycycline, florfenicol and xylzaine are forbidden for milking cows.

Also dairy products have limitation requirements for 44 veterinary drugs :

Name	MRL (µg/kg)	Name	MRL (µg/kg)	Name	MRL (µg/kg)	Name	MRL (µg/kg)
Albendazole	10	Clopidol	20	Fenvalerate	100	Phoxim	10
Amitraz	10	Cloxacillin	30	Flugestone Acetate	1	Spectinomycin	200
Amoxicillin	10	Colistin	50	Flumequine	50	Streptomycin	200
Ampicillin	10	Danofloxacin	30	Flumethrin	30	Sulfonamides	100
Bacitracin	500	Deltamethrin	30	Gentamycin	200	Sulfadimidine	25
Benzylpenicillin	4	Dexamethasone	0.3	Isometamidium	100	Thiabendazole	100
Betamethasone	0.3	Diazinon	20	Ivermectin	10	Thiamphenicol	50
Cefalexin	100	Diminazine	150	Lincomycin	150	Tilmicosin	50
Cefquinome	20	Enrofloxacin +Ciprofloxacin	100	Neomycin	500	Trichlorfon	50
Desfuroylceftiofur	100	Erythromycin	40	Oxacillin	30	Trimethoprim	50
Clavulanic acid	200	Fenbendazole	100	Tetracyclin	100	Tylosin	50

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In addition to the MRLs from the previous slides, the 235th announcement also regulated very strict rules for animal drug using.

- **Drugs can be used for treatment but can not be detected**
  - Chlorpromazine
  - Diazepam
  - Dimetridazole
  - Estradiol Benzoate
  - Metronidazole
  - Nadrolone Phenylpropionate
  - Testosterone propinate

- **Drugs can not be used**
  - Chloramphenicol
  - Clenbuterol
  - Salbutamol
  - Cimaterol
  - Dapsone
  - Diethylstilbestrol
  - Furaltadone
  - Furazolidone
  - Nifurstyrenate sodium
  - Methaqualone
  - Ronidazole
  - Zeranol
  - Trenbolone
  - Mengestrol Acetate
  - Sodium nitrophenolate
  - Antimony potassium tartrate
  - Tryparsamile
  - Malachite green
  - Pentachlorophenol sodium
  - Calomel
  - Mercurous nitrate
  - Mercurous acetate
  - Pyridyl mercurous acetate
  - Methyltestosterone
  - Trenbolone
  - Camahechlor
  - Carbofuran
  - Chlordimeform
  - Amitraz
  - Nitrovin

According to the 176th announcement, the following veterinary drugs can not be used in feed and animal drinking water:

Receptor agonists	Sex hormones	Protein assimilation hormones	Psychotropic drugs
• Clenbuterol • Salbutamol • Ractopamine • Cimaterol • Terbutaline	• Diethylstibestrol • Estradiol • EstradiolValerate • EstradiolBenzoate • Chlorotrianisene • Ethinylestradiol • Quinestrol • Chlormadinone • Levonorgestrel • Norethisterone • Chorionic Gonadotrophin • Menotropins	• Iodinated Casein • Nandrolone phenylpropionate	• Chlorpromazine • Diazepam • Barbital • Reserpine • Estazolam • Meprobamate • Midazolam • Nitrazepam • Oxazepam • Pemoline • Triazolam • Zolpidem

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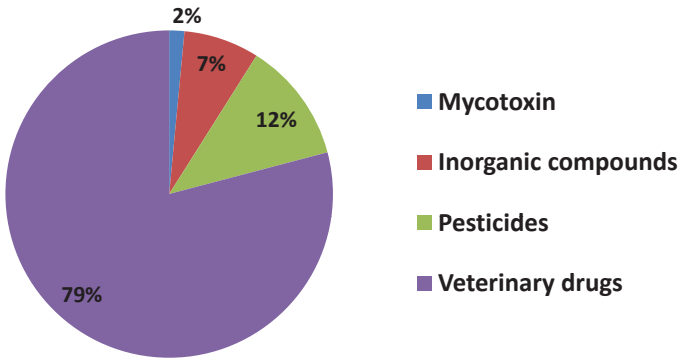
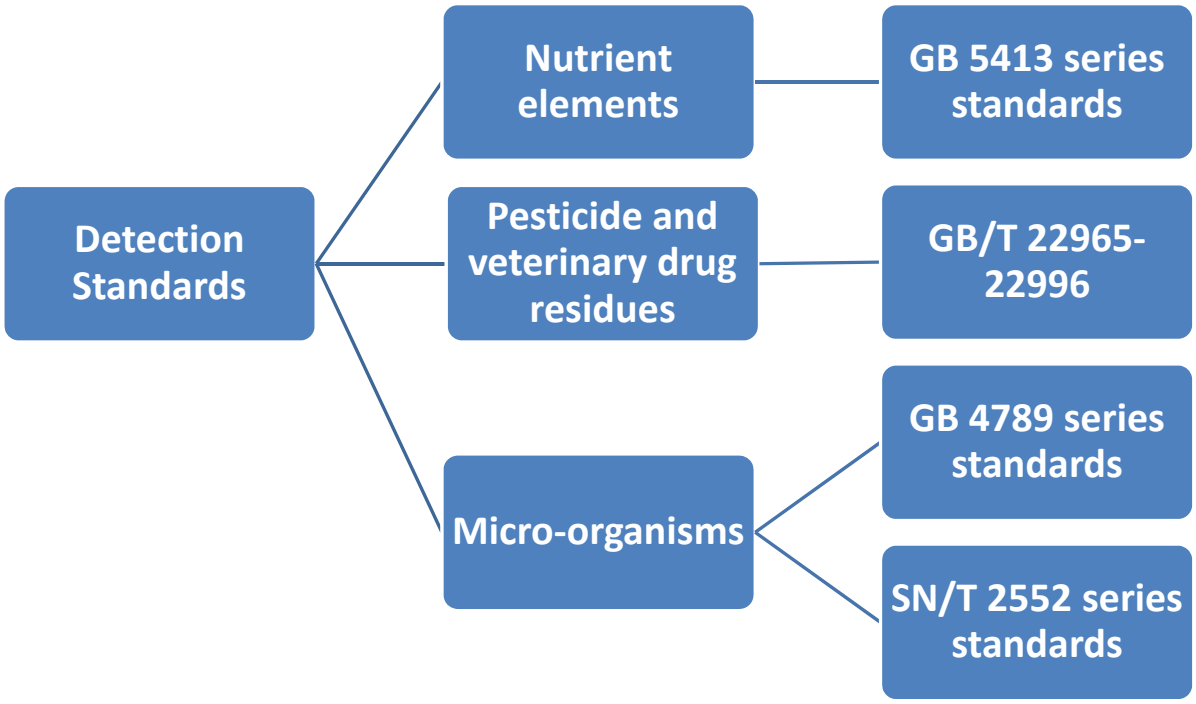
MRL distribution of contaminants in dairy products



- **4/5 of the MRLs for contaminants in dairy products are veterinary drugs, in which antibiotics accounted for the majority**
- **Pesticide residues in dairy products are focused on in organic chloride pesticides.**



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- **GB 5413 series standards of nutrient elements detection include:**
  1. **Routine inspection items (protein, fat, ash, acidity)**
  2. **Vitamins**
  3. **Metal elements**
  4. **Fatty acids**

- **GB/T 22965-22996 standards of residues detection include:**
  1. **Pesticide screening**
  2. **Antibiotics**
  3. **Hormones**

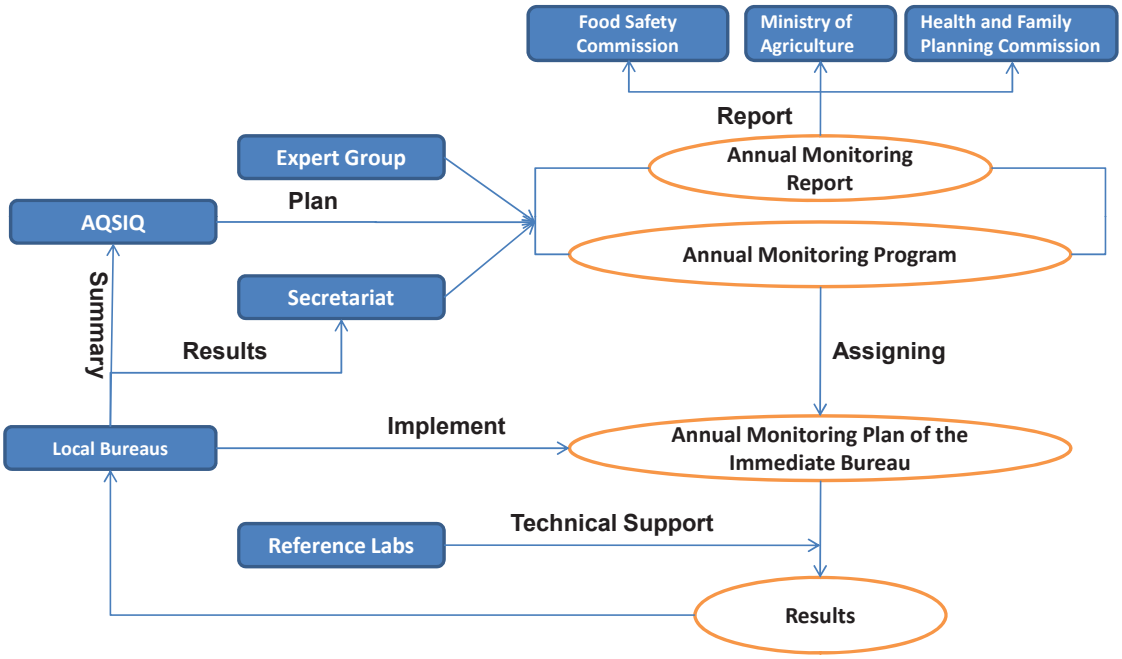
Monitoring program of import dairy products in China

In China, import dairy products supervision is based on the principles of “prevention at first; risk assessment; whole process control and national governance”.

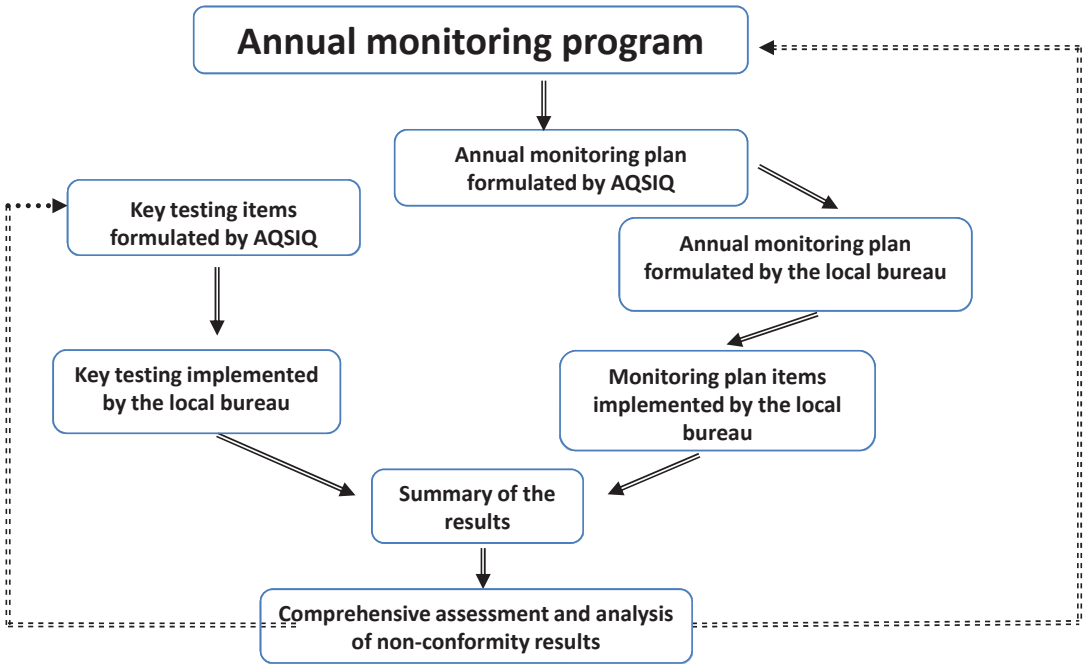
Based on the food safety market access system of dairy products, a monitoring program plays a vital role during the entire regulatory system.

Every year, AQSIQ would organize the monitoring program for import products, and usually the detection items are determined by last year's risk assessment results.

The flow chat of the monitoring program



Implementation of monitoring program



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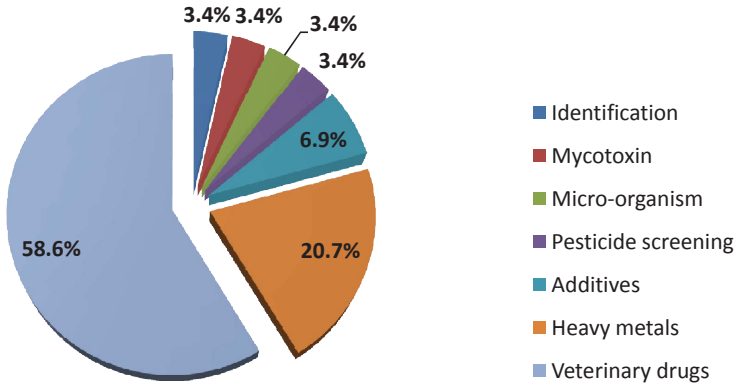
Detection items related to dairy products in the 2015 monitoring program		
1	Infant formula	Vanillin, Cadmium, Chromium, Arsenic, Mercury, Aluminum, Nickel, Diethylstilbestrol, 17-β-estradiol, Estriol, Progesterone, 17-α-hydroxyprogesterone, MCPD esters
2	Milk powder	Aluminum, Mercury, Cadmium, β-Lactamase, Chloromycetin, Streptomycin, Dihydrostreptomycin, Ampicillin, Benzyl pencillin, Pesticide screening
3	Liquid milk	Cadmium, Mercury, β-Lactamase, Chloromycetin, Danofloxacin, Difloxacin, Enrofloxacin, Ciprofloxacin, Sarafloxacin, Diethylstilbestrol, 17-β-estradiol, Estriol, Progesterone, 17-α-hydroxyprogesterone, Identification of reconstituted milk, Pesticide screening
4	Whey powder	Mercury, Aluminum, Clenbuterol HCL, Chloromycetin, Ampicillin, Benzyl pencillin
5	Cheese	Pimaricin, Nitrite, Nitrate

The 2015's monitoring program for dairy products includs: heavy metals, veterinary drugs, pesticide screening, micro-organism, mycotoxin, additives and identification.

Mornitorning program distribution



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After the melamine incident happened in 2008, the safety of dairy products got the most attention of the whole nation.

Dairy products safety events in recent years

2009	• β-Lactamase • Leather hydrolyzed protein
2010	• Perchloric acid
2011	• Formaldehyde
2012	• Radioactive contamination • Dicyandiamide
2014	• *Allantiasis bacillus*
2015	• Sodium fluoroacetate

Further work

All the food safety incidents happened in the past few years made public's focusing point on dairy products from nutrients to contaminants.

- **Processing by-products**
- **Detergent residues migration**
- **Residues from feed**
- **Environmental contaminants**

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Thank you !