AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

AOAC INTERNATIONAL

International Stakeholder Panel on Alternative Methods (ISPAM)

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

Tuesday, March 15, 2016

AOAC INTERNATIONAL
2275 Research Blvd., Suite 300
Rockville, MD, 20850
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Meeting at the Gaithersburg Marriott Washingtonian Center

9751 Washingtonian Boulevard, Gaithersburg MD 20878, USA

ROUNDTABLE DRAFT MEETING AGENDA

Tuesday, March 15, 2016

Meeting Start Time: 1:00PM (Eastern US)

ISPAM Chair/Moderator: Erin Crowley

(Q Laboratories)

Location: Salon E/F

(Registration Opens at 12:00PM)

I. **INTRODUCTION & WELCOME (Bradford/Hill – 1:00PM-1:10PM)**

Jim Bradford (AOAC) will open the meeting and initiate the introduction of participants, and introduce AOAC President Norma Hill. President Hill will welcome and share brief remarks with participants.

II. **AOAC ISPAM OVERVIEW/UPDATE/GOALS (Crowley – 1:10PM-1:15PM)**

Erin Crowley (Q Labs) will call the meeting to order, acknowledge the AOAC policies for Antitrust, Volunteer Conflict of Interest, and Use of Association Name and Insignia. Crowley will summarize ISPAM's efforts to date and provide information on potential future endeavors.

III. **PERSPECTIVE ON FOOD SAFETY PRIORITY NEEDS/ROLE FOR METHODS INCLUDING RAPID ASSAYS (1:15PM-4:30PM)**

Erin Crowley (Q Labs) will lead the roundtable discussion on Food Safety Priority Needs & Alternative Methodology from various perspectives.

Brooke Schwartz (Brooke Schwartz Consulting & AOAC RI Board of Directors) will facilitate the Roundtable Q & A sessions.

A. ***FOOD INDUSTRY PERSPECTIVE: Rapid Methods: Does the Food Industry Have the Right Tools for the Job*****?** (1:15PM-1:45PM)
Melinda Hayman, Grocery Manufacturers Association (GMA)

B. ***US PERSPECTIVE:*** (1:45PM-2:45PM)

1. ***FDA*** *- Food Safety Priority Needs*
Palmer Orlandi, FDA, Office of Regulatory Affairs (ORA)

2. ***USDA*** *- Food Safety Priority Needs*
Uday Dessai, USDA, Food Safety and Inspection Service (FSIS)

C. ***CHINA PERSPECTIVE: Strategies for Adaptation of International Practice of Alternative Methodology in China*** (2:45PM-3:15PM)
Pingfan Rao, Chinese Institute of Food Science and Technology (CIFST)

~AFTERNOON BREAK - 3:15PM-3:30PM~

D. ***SOUTH AMERICAN PERSPECTIVE:*** (3:30PM-4:30PM)

1. ***Microbiology:*** *Maria Christina Fernandez, University of Buenos Aires*
2. ***Chemistry:*** *Marina Torres Rodriguez, Laboratorio Tecnológico del Uruguay (LATU)*

IV. AOAC PROFICIENCY TESTING PROGRAM (MEETING PROFICIENCY TESTING REQUIREMENTS) (4:30PM-5:00PM)
Arlene Fox, AOAC INTERNATIONAL

V. CRITERIA FOR DEVELOPING STANDARD METHOD PERFORMANCE REQUIREMENTS (SMPR®) (5:00PM-5:45PM)

VI. NEXT STEPS/WRAP-UP (Crowley – 5:45PM-6:00PM)
Erin Crowley (Q Labs) will discuss next steps for ISPAM activities, wrap up all discussions and answer any additional questions.

MEETING ITINERARY:

REGISTRATION (12:00PM)

MEETING START TIME (1:00PM)

AFTERNOON BREAK (3:15PM)

AOAC INTERNATIONAL
BYLAWS

As Amended September 26, 2010

ARTICLE I
Name

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

ARTICLE II
Purpose

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

ARTICLE III
Membership

Section 1. Types of Membership

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

A. Individual Members

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

B. Sustaining Member Organizations

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

C. Organizational Affiliate

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

Section 2. Qualifications for Membership

A. Individual Members

[1] Members

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

[2] Retired Members

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

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

[3] Student Members

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

[4] Honorary Members

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

B. Sustaining Member Organizations

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

C. Organizational Affiliate

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

Section 3. Application for Membership

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

Section 4. Expulsion

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

Section 5. Dues, Membership Year, and Waivers

A. Annual dues for membership in the Association shall be fixed by the Board of Directors, subject to approval by the majority of the Individual Members voting by ballot by any of the following means (whichever is deemed appropriate by the Board at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission.

B. Honorary Members of the Association shall be exempt from payment of dues and annual meeting registration fees.

C. The membership year and the delinquency date shall be determined by the Board of Directors.

D. The authority to grant waivers of membership dues rests with Executive Director.

E. Student Member dues shall be one-third of regular Member dues, rounded up to the nearest $5.00 increment.

Section 6. Members in Good Standing; Rights and Privileges

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

ARTICLE IV
Officers

Section 1. Elected Officers

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

A. President

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

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

B. President-Elect

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

C. Secretary

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

D. Treasurer

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

E. Immediate Past President

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

Section 2. Appointed Officers

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

A. Executive Director

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

B. Other Appointed Officers

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

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

Section 1. Nominating Committee

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

Section 2. Elections and Terms of Office

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

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

Section 3. Appointments

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

ARTICLE VI
Board of Directors

Section 1. Composition

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

Section 2. Powers and Duties

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

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

Section 3. Meetings

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

Section 4. Quorum

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

Section 5. Absence

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

Section 6. Compensation

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

Section 7. Resignation or Removal

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

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

Section 8. Vacancies: Members of the Board

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

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

Section 9. Vacancies: President and Other Officers

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

ARTICLE VII
Committees

Section 1. Committee Formation

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

Section 2. Committee Appointments

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

ARTICLE VIII
Official Methods of Analysis

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

Section 1. Composition of the Official Methods Board

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

Section 2. Purpose of the Official Methods Board

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

Section 3. Principles of the Official Methods Program

A. Adequate records of technical data, discussions, and decisions on the study, adoption, and change of status of Official Methods of Analysis shall be maintained for a reasonable time.

B. Timely notice of proposed method studies, adoption, or change in status shall be published in an Association publication that is circulated to the members.

C. Opportunity shall be provided for materially interested parties to submit input during method study and adoption procedures and to submit comments on the adoption, use of, or change in status of specific methods.

D. Methods submitted to the OMB for inclusion in the OMA shall be thoroughly studied, scientifically reviewed, and available in published form prior to adoption as Final Action by the OMB.

E. The OMB shall adopt methods as Final Action.

ARTICLE IX
Meetings

Section 1. Annual Meeting

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

Section 2. Quorum

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

ARTICLE X
Voting

Section 1. Voting by Ballot

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

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

Section 2. Voting by Proxy

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

ARTICLE XI
Earnings and Assets

Section 1. Non-Profit Status

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

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

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

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

Section 2. Political Activities

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

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

ARTICLE XII
Sections

Section 1. Sections

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

Section 2. Purpose of Sections

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

Section 3. Membership in Sections

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

Section 4. Bylaws of Sections

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

Section 5. Dissolution of Sections

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

Section 6. Actions of Sections

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

ARTICLE XIII
Technical Divisions

Section 1. Purpose

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

Section 2. Creation, Combination, Discontinuance, or Change

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

ARTICLE XIV
Indemnification

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

ARTICLE XV
Parliamentary Authority

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

ARTICLE XVI
Amendments to the Bylaws

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

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

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

Introduction

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

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

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

The Scientific Association Dedicated to Analytical Excellence®

Policy

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

> "The Board approves and encourages reference to the Association by name, either as AOAC INTERNATIONAL or as AOAC; or reference to our registered trademark, AOAC®, in appropriate settings to describe our programs, products, etc., in scientific literature and other instances so long as the reference is fair, accurate, complete and truthful and does not indicate or imply unauthorized endorsement of any kind.
>
> The insignia (logo) of AOAC INTERNATIONAL is a registered trade and service mark and shall not be reproduced or used by any person or organization other than the Association, its elected and appointed officers, sections, or committees, without the prior written permission of the Association. Those authorized to use the AOAC INTERNATIONAL insignia shall use it only for the purposes for which permission has been specifically granted.
>
> The name and insignia of the Association shall not be used by any person or organization in any way which indicates, tends to indicate, or implies AOAC official endorsement of any product, service, program, company, organization, event or person, endorsement of which, has not been authorized by the Association, or which suggests that membership in the Association is available to any organization."

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

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

Instructions

1. Reproduction or use of the Association name or insignia requires prior approval by the Executive Director or his designate.

2. Association insignia should not be altered in any manner without approval of the Executive Director or his designate, except to be enlarged or reduced in their entirety.

3. Artwork for reproducing the Association name or insignia, including those incorporating approved alterations, will be provided on request to those authorized to use them (make such requests to the AOAC Marketing Department). Examples of the types of alterations that would be approved are inclusion of a section name in or the addition of an officer's name and address to the letterhead insignia.

4. When the Association name is used without other text as a heading, it should, when possible, be set in the Largo typeface.

5. Although other colors may be used, AOAC blue, PMS 287, is the preferred color when printing the AOAC insignia, especially in formal and official documents. It is, of course, often necessary and acceptable to reproduce the insignia in black.

6. Do not print one part of the logo or insignia in one color and other parts in another color.

7. The letterhead of AOAC INTERNATIONAL shall not be used by any person or organization other than the Association, its elected and appointed officers, staff, sections, or committees; except by special permission.

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

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

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

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

Sanctions

1. Upon learning of any violation of the above policy, the Executive Director or a designate will notify the individual or organization that they are in violation of AOAC policy and will ask them to refrain from further misuse of the AOAC name or insignia.

2. If the misuse is by an Individual Member or Sustaining Member of the Association, and the misuse continues after notification, the Board of Directors will take appropriate action.

3. If continued misuse is by a nonmember of the Association or if a member continues misuse in spite of notification and Board action, ultimately, the Association will take legal action to protect its property, legal integrity, reputation, and image.

* * * * * *

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

AOAC INTERNATIONAL
ANTITRUST POLICY
STATEMENT AND GUIDELINES

Introduction

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

Responsibility for Antitrust Compliance

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

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

Antitrust Guidelines

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

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

Penalties for violating the U.S. and other antitrust laws are severe: corporations are subject to heavy fines and injunctive decrees, and may have to pay substantial damage judgments to injured competitors, suppliers, or customers. Individuals are subject to criminal prosecution, and will be punished by fines and imprisonment.
Under current U.S. federal sentencing guidelines, individuals found guilty of bid rigging, price fixing, or market allocation must be sent to jail for at least 4 to 10 months and must pay substantial minimum fines.

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

1. Don't make any effort to bring about or prevent the standardization of any method or product for the purpose or intent of preventing the manufacture or sale of any method or product not conforming to a specified standard.

2. Don't discuss with competitors your own or the competitors' prices, or anything that might affect prices such as costs, discounts, terms of sale, distribution, volume of production, profit margins, territories, or customers.

3. Don't make announcements or statements at AOAC functions, outside leased exhibit space, about your own prices or those of competitors.

4. Don't disclose to others at meetings or otherwise any competitively sensitive information.

5. Don't attempt to use the Association to restrict the economic activities of any firm or any individual.

6. Don't stay at a meeting where any such price or anti_competitive talk occurs.

7. Do conduct all AOAC business meetings in accordance with AOAC rules. These rules require that an AOAC staff member be present or available, the meeting be conducted by a knowledgeable chair, the agenda be followed, and minutes be kept.

8. Do confer with counsel before raising any topic or making any statement with competitive ramifications.

9. Do send copies of meeting minutes and all AOAC_related correspondence to the staff member involved in the activity.

10. Do alert the AOAC staff to any inaccuracies in proposed or existing methods and statements issued, or to be issued, by AOAC and to any conduct not in conformance with these guidelines.

Conclusion

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

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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.

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

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Melinda Hayman, Ph.D.
Grocery Manufacturers Association (GMA)

Melinda Hayman, Ph.D. is a food microbiologist specializing in Food Safety. Melinda received her Ph.D. in Food Science from the Pennsylvania State University and a B.S. Honors in Microbiology and Biochemistry from the University of Sydney. For both degrees her research project focus was inactivation of *Listeria monocytogenes* by high pressure processing.

Melinda joined the Grocery Manufacturers Association (GMA) in 2012 as Director of Microbiology, where she oversees GMA's food microbiology laboratory and food safety research. Furthermore, she supports GMA membership by providing guidance on food safety & microbiology technical and regulatory issues. She authors food safety publications and designs and provides food safety education. Melinda also serves a delegate to the Codex Committee on Food Hygiene and is the staff liaison for the GMA Microbiological Safety Committee.

Prior to joining GMA, Melinda was the Director of Technical Services at Food Safety Net Services, where she managed Laboratory Quality Systems, Training, Method Validation, and Special Projects. In addition, Melinda worked as a Food Microbiologist for the Commonwealth Scientific and Industrial Research Organisation (CSIRO) in Sydney Australia.

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS(ISPAM)

Rapid Methods:
Does the Food Industry Have the
Right Tools for the Job?

Melinda Hayman, Ph.D.
Gaithersburg, MD
March 15, 2016

Overview

- About GMA
- What are current industry drivers?
- What does the food industry need/want?
- Major trends
- Where to go from here?

Grocery Manufacturers Association

GMA

The Association of Food, Beverage and Consumer Products Companies

Create a regulatory and commercial environment that enables our members brands and strategies to succeed with their consumers, shoppers and retailers.

GMA Member Companies

*Represents a sample of GMA members

Science and Regulatory Affairs

- Develop science-based solutions that improve the safety and nutritional value of the world's consumer products in order to inspire confidence and trust of the world's consumers
- SRA Focus Areas:
  - Policy
  - Service
  - Education
  - Research

GMA Resources

- Guidance Documents
  - *Salmonella*
  - Laboratory Selection
  - Allergens
  - Recalls
  - Supply Chain
- Training and Education

GMA Research

Development of a Dry Inoculation Method for Thermal Challenge Studies in Low-Moisture Foods by Using Talc as a Carrier for *Salmonella* and a Surrogate (*Enterococcus faecium*)

ELENA ENACHE,* AI KATAOKA, D. GLENN BLACK, CARLA D. NAPIER, RICHARD PODOLAK, AND MELINDA M. HAYMAN

Heat Resistance of Histamine-Producing Bacteria in Irradiated Tuna Loins

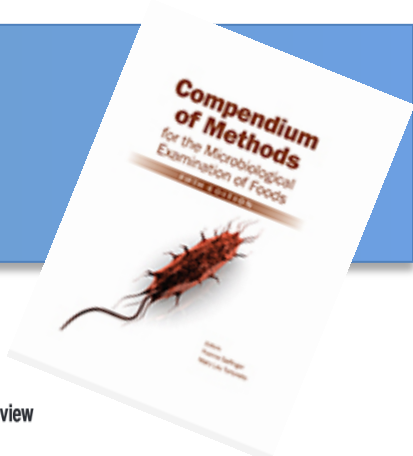
ELENA ENACHE,[1]* AI KATAOKA,[1] D. GLENN BLACK,[1] LISA WEDDIG,[2] MELINDA HAYMAN,[1] AND KRISTIN BJORNSDOTTIR-BUTLER[3]

Validation of Pepperoni Process for Control of Shiga Toxin–Producing *Escherichia coli*

KATHLEEN A. GLASS,[1]* CHARLES W. KASPAR,[1] JEFFREY J. SINDELAR,[1] ANDREW L. MILKOWSKI,[1] BRIAN M. LOTZ,[1]† JIHUN KANG,[1]‡ NANCY G. FAITH,[1] ELENA ENACHE,[2] AI KATAOKA,[2] AND CRAIG HENRY[2]§

Thermal Resistance Parameters for Shiga Toxin–Producing *Escherichia coli* in Apple Juice

ELENA ENACHE,[1]* EMILY C. MATHUSA,[1] PHILIP H. ELLIOTT,[1] D. GLENN BLACK,[1] YUHUAN CHEN,[1]† VIRGINIA N. SCOTT,[1]† AND DONALD W. SCHAFFNER[2]



Journal of Food Protection, Vol. 73, No. 9, 2010, Pages 1721–1736

Review

Non-O157 Shiga Toxin–Producing *Escherichia coli* in Foods

EMILY C. MATHUSA,* YUHUAN CHEN, ELENA ENACHE, AND LLOYD HONTZ

Grocery Manufacturers Association, 1350 I Street N.W., Suite 300, Washington, D.C. 20005, USA

MS 10-033: Received 21 January 2010/Accepted 8 May 2010

ABSTRACT

Non-O157 Shiga toxin–producing *Escherichia coli* (STEC) strains have been linked to outbreaks and sporadic cases of illness worldwide. Illnesses linked to STEC serotypes other than O157:H7 appear to be on the rise in the United States and worldwide, indicating that some of these organisms may be emerging pathogens. As more laboratories are testing for these organisms in clinical samples, more cases are uncovered. Some cases of non-O157 STEC illness appear to be as severe as cases associated with O157, although in general cases attributed to non-O157 are less severe. There is much variation in virulence potential within STEC serotypes, and many may not be pathogenic. Of more than 400 serotypes isolated, fewer than 10 serotypes cause the majority of STEC-related human illnesses. Various virulence factors are involved in non-O157 STEC pathogenicity; the combined presence of both *eae* and *stx* genes has been associated with enhanced virulence. A scientific definition of a pathogenic STEC has not yet been accepted. Several laboratories have attempted to develop detection and identification methods, and although substantial progress has been made, a practical method of STEC detection has yet to be validated. Worldwide, foods associated with non-O157 STEC illness include sausage, ice cream, milk, and lettuce, among others. Results from several studies suggest that control measures for O157 may be effective for non-O157 STEC. More research is needed to uncover unique characteristics and resistances of non-O157 STEC strains if they exist. The public health significance of non-O157 STEC and the implications for industry practices and regulatory actions are discussed.

Review

Sources and Risk Factors for Contamination, Survival, Persistence, and Heat Resistance of *Salmonella* in Low-Moisture Foods

RICHARD PODOLAK,* ELENA ENACHE, WARREN STONE, DARRYL G. BLACK, AND PHILIP H. ELLIOTT

Grocery Manufacturers Association, 1350 I Street N.W., Suite 300, Washington, D.C. 20005, USA

MS 09-513: Received 24 November 2009/Accepted 2 June 2010

ABSTRACT

Sources and risk factors for contamination, survival, persistence, and heat resistance of *Salmonella* in low-moisture foods are

GMA

www.gmaonline.org

Current Drivers for the Food Industry

- FSMA
- Continued emphasis on food safety
- Need for greater efficiency

What does industry need/want?

- Main drivers
  - Price
  - Speed
  - Accuracy/Precision
  - Limit of Detection

Are rapid Methods “Rapid”?

- Detection technologies are fast
- Enrichment is not
- Is one enrichment adequate?

Detection of *Salmonella*

- Continues to be a priority, esp low moisture foods
- Duration of enrichment
- Limit of detection
- Injured cells
- Validation of different matrices

Indicators

- Rapid tests for yeast and molds, esp in dry products
- Rapid semi-quantitative tests for non-pathogens

Environmental monitoring

- Pathogens
- Sanitation
- Allergens
  - Limit of detection

Other thoughts

- Sharing data
  - Esp validation data
- Whole Genome Sequencing
- Testing for process control

Conclusions

- Testing remains a valuable tool
- The industry continues to look for improvements in existing schemes

Thank You!

Melinda Hayman, Ph.D.

Director of Microbiology, GMA

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INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Uday Dessai, Ph.D.

Office of Public Health Science, FSIS, USDA

Dr. Uday Dessai serves as the Senior Public Health Advisor at FSIS USDA, in the Office of Public Health Science. In this position Dr. Dessai leads major interagency programs - FSIS NARMS, FSIS whole genome sequencing, role of science in policy development and scientific innovation in the Agencies strategic planning. The other leadership positions that Dr. Dessai held at FSIS include Director Science Staff, Director Microbiology Division and Branch Chief in Risk Assessment Division.

At FSIS, Dr. Dessai led significant Agency programs including the FSIS Microbiological Baseline studies, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), Microbiological and Residue issues with domestic and international implications, and Risk Assessment and Exposure Modeling - to inform science and policy considerations. More specifically, in collaboration with multidisciplinary teams of experts, Dr. Dessai has played a key role in accomplishing FSISs' food safety - public health' mission goals by providing expert guidance and advice on highly significant initiatives including Microbiological Issues (E. coli O157:H7, STECs, Salmonella, Listeria, Campylobacter and Toxoplasma), Microbiological Baselines, BSE and Harvard BSE Risk Assessment, and NACMCF (FSIS New Technology Adoption, AMS specifications, Norovirus and DOD Microbiological Criteria).

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Pingfan Rao, Ph.D.
Chinese Institute of Food Science and Technology

Pingfan Rao, Ph.D., received BEng in food technology from Fuzhou University of China in 1982, Msc in food science from Hiroshima University of Japan in 1986, and phD in biochemistry from Osaka University of Japan in 1989. He is currently Professor and founding Director of CAS.SIBS-Zhejiang Gongshang University Joint Center for Food and Nutrition Research, and a Professor of Fuzhou University in China.

He is Past President (2012-14) of the International Union of Food Science and Technology, a fellow of International Academy of Food Science and Technology, Vice President of the Chinese Institute of Food Science and Technology. His research focuses primarily on identifying and characterizing bioactive proteins and expression and scale production of recombinant enzymes, protein derivatives as the active ingredients of tradition Chinese medicine and food, new methodology for cell separation and superoxide channels.

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Strategies for Adaptation of Interational Practice of Alternative Methodology in China

Pingfan Rao, PhD
Chinese Institute of Food Science and Technology
March 15, 2016
Gaithersburg, MD

Food Safety: Overseas Perception

Ominous cloud

Food Safety: Chinese Perception

Infant formula: top on shopping list for overseas trips

Chinese navy in Australia

Food Safety: Reality and Solutions

Reality

Chemical>microbial

Adulteration >managerial, technical

Morale and Legal >Technical

Law

Infant Formula: technological approach

Killing chicken a with a cattle-slaughtering knife

2009 30 billion Yuan HPLC

2011 Consolidating: closing 80% of companies

2013 Hydration of milk powder and spray drying

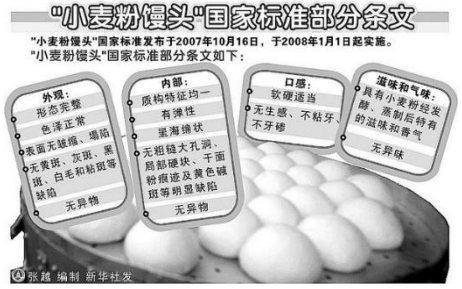
Inflated Importance of Technology

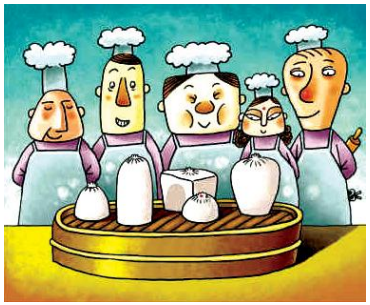
- Technological: tangible and resourceful
- Huge and repeated Investment

  CDC Vs SFDA
- Sophisticated analytical labs, unbearable frequency of testing

Sanctification of Standards, analytical methods

National Standards for Steam Buns





More than Analysis, more than methodologies

- political
- nationalism
- populism

Alternative Methodologies in China: Progress and setback

2005 Adoption of a few in GB

2009 Elimination from GB

Strategy

Education

Desensitization

Exposure

Difficult but Possible

Frozen Food Microbial Count Standards

- 80s staphylococcus aureus: negative
- 2004-2011 CIFST efforts
- 2011 GB revision 1g‹ 1000-10000

Working together

Thank You!

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Maria Cristina Fernandez, Ph.D.
University of Buenos Aires

Maria Cristina is a Biochemist and Pharmacist from the Buenos Aires University, Argentina. She has worked in Microbiology for more than 30 years.

She is a Researcher at Maimonides University, Buenos Aires, Argentina. She is a Professor of Microbiology at Pharmacy and Biochemistry, University of Buenos Aires.

She is auditor in microbiology for the Argentinean Accreditation Organism and is Coordinator of the Good Laboratory Practices group on Microbiology of the Argentine Society for Microbiology. She is member of the AOAC INTERNATIONAL Expert Review Committee for Microbiology, and a reviewer in Microbiology for the AOAC INTERNATIONAL OMA and the AOAC INTERNATIONAL Research Institute. She is member of the Executive Committee of the AOAC INTERNATIONAL Latin American and Caribbean Section. She has participated in the redaction and edition of standards, books and manuals in the field of microbiology. She is an author of 30 publications and poster presentations and she also participated in several scientific presentations.

She has been a short term expert for the Pan American Health Organization and for UE. She is the Past President of the AOAC INTERNATIONAL Latin American and Caribbean Section.

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS(ISPAM)

Food Safety: Priority Needs on microbiological alternative methods from a Latin American perspective

Maria Cristina Fernandez
Gaithersburg, MD
March 15, 2016

Priority Needs on microbiological alternative methods

- The great majority of people will experience a food or water borne disease at some point in their lives.

- This highlights the importance of making food we eat sure.

Priority Needs on microbiological alternative methods

"Food safety: from farm to plate, make food safe" was the theme of World Health Day 2015.

Priority Needs on microbiological alternative methods

- Over the past half century, the process by which food gets from the farm to the plate has changed drastically.

- Food contamination that occurs in one place may affect the health of consumers living on the other side of the planet.

Priority Needs on microbiological alternative methods

This means that everyone along the production chain, from producer to consumer, must observe safe food handling practices.

Priority Needs on microbiological alternative methods

The Latin American region is an important net exporter of food and agricultural commodities, accounting for 16% of total global food and agriculture exports.

Priority Needs on microbiological alternative methods

The region is one of the few parts of the world with significant resources of unexploited agricultural land (mainly concentrated in Brazil and Argentina), suggesting the region will continue to play a pivotal role in global food production and exports in the future

Priority Needs on microbiological alternative methods

Many of this region countries have achieved respectable rates of agricultural productivity growth in the recent past. Nevertheless, raising productivity will be essential to meet domestic food needs or to maintain or even enhance export competitiveness.

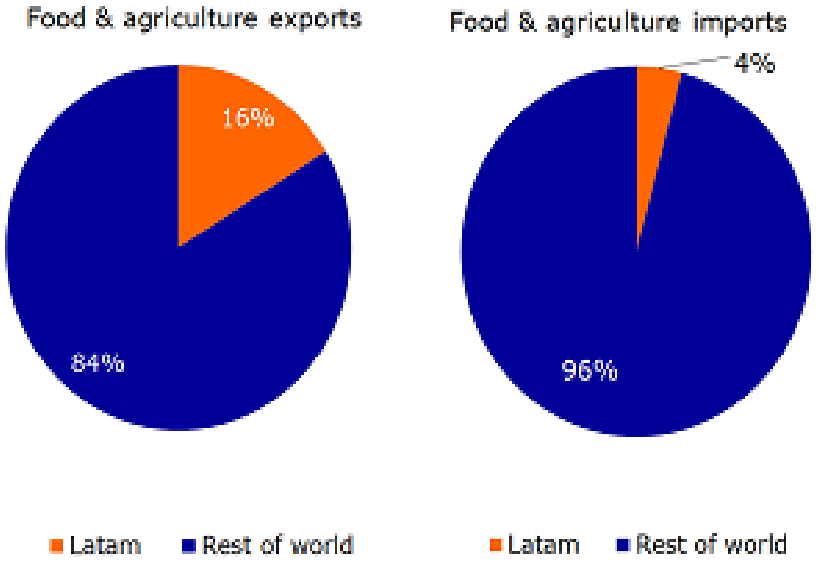
Priority Needs on microbiological alternative methods

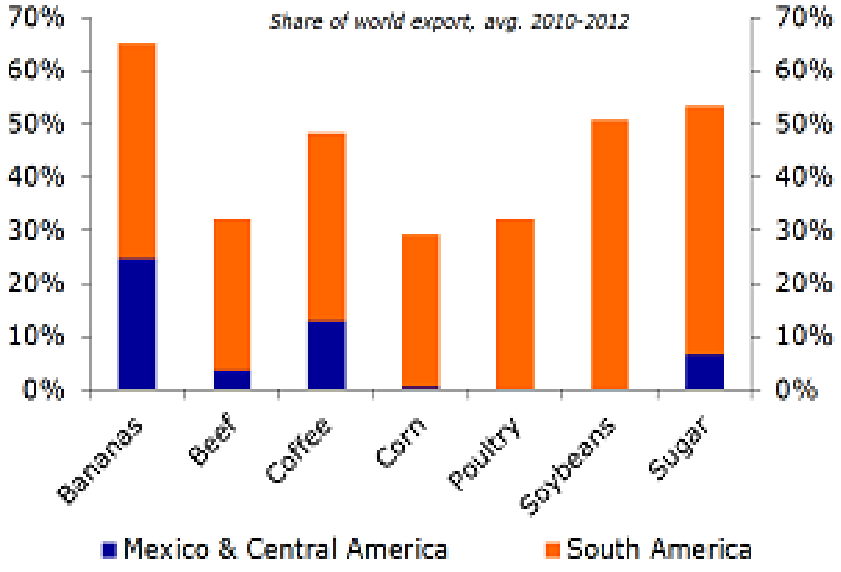
Latin America has long been associated with the production and export of a diverse range of agricultural commodities, whether it is coffee from Brazil and Colombia, beef from Argentina, or bananas from Ecuador for instance.

Priority Needs on microbiological alternative methods

Trade data show that the region is indeed an important net exporter of agricultural commodities to the world, accounting for an estimated 16% of global food and agriculture exports between 2012 and 2014, while representing just 4% of global food and agriculture imports over the same period.

Priority Needs on microbiological alternative methods



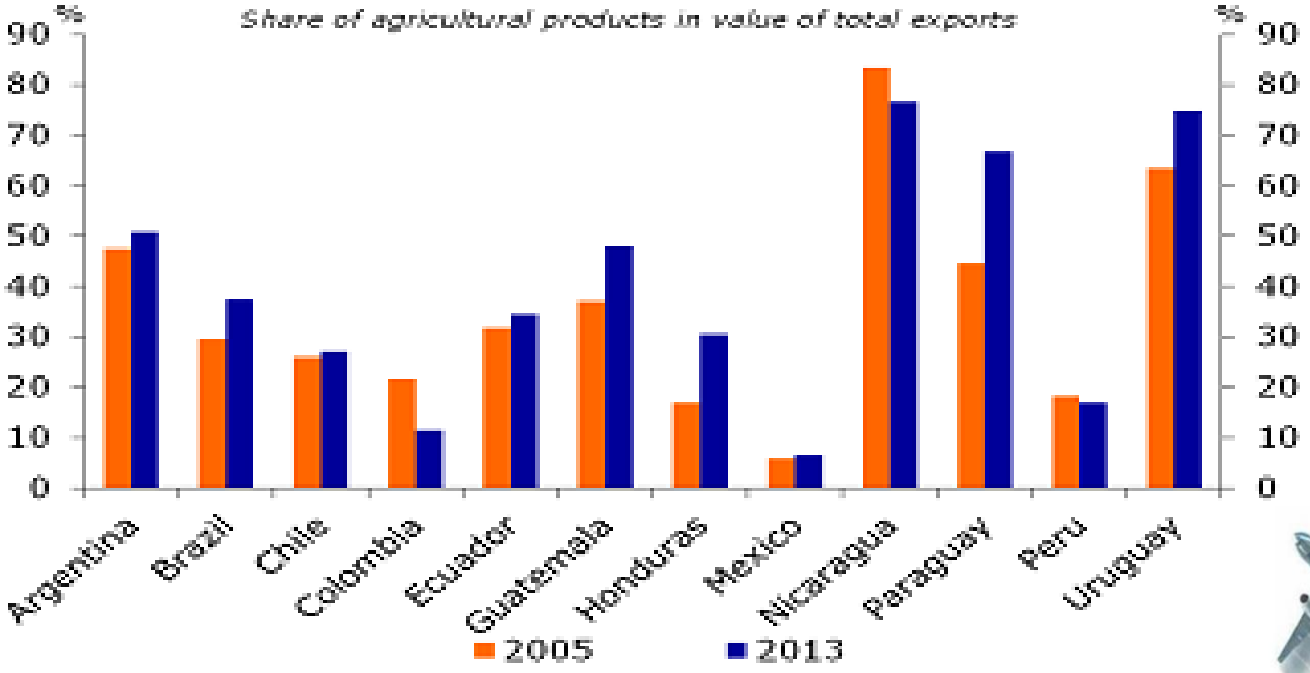


UN Comtrade database 2015

Priority Needs on microbiological alternative methods

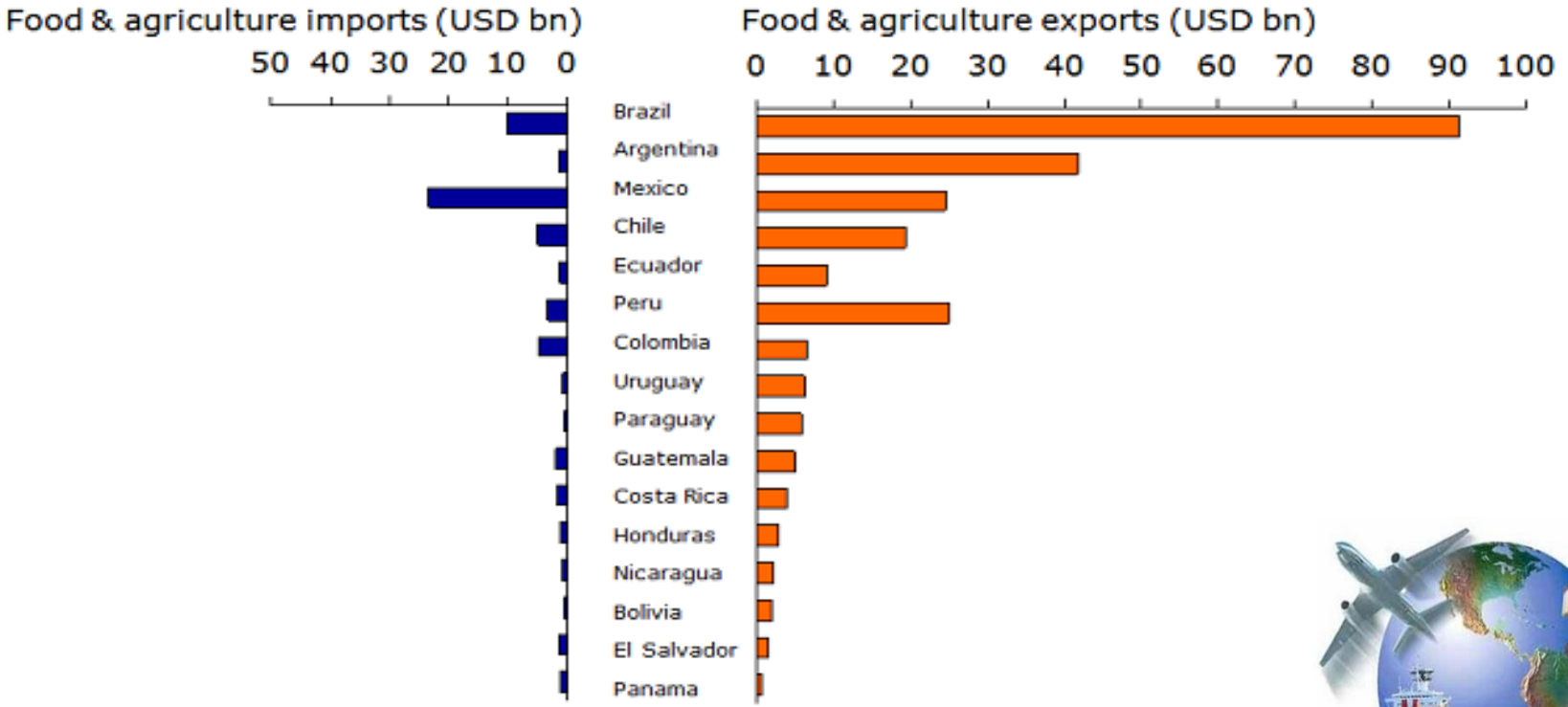
Latin America is therefore important for the global food and agriculture sector. Furthermore, it is equally true that food and agriculture is important for Latin America and the sector accounts for an important share of the total exports of the region's member states.

Priority Needs on microbiological alternative methods



UN Comtrade database 2015

Priority Needs on microbiological alternative methods



UN Comtrade database 2015

Priority Needs on microbiological alternative methods

- **Brazil** is the world's third largest agricultural exporter after the US and the EU.
- **Brazil** is the largest producer and exporter of sugar, coffee and orange juice in the world, as well as the largest exporter of beef, soybeans and poultry.

FAO (2014): *The state of food and agriculture*

Priority Needs on microbiological alternative methods

- **Chile** is the fourth-largest agricultural exporter in Latin America.
- The most important products are: nuts, almonds and hazelnuts, cherries, berries, avocado and mandarins.
- It is likely that the salmon sector will face further consolidation.

FAO (2014): *The state of food and agriculture*

Priority Needs on microbiological alternative methods

Colombia, coffee and fresh flowers account for just under two thirds of Colombia's agricultural exports, with fruits and sugar the other two relevant products sold internationally.

Colombia remains a key player in the coffee global market as the third-largest exporter overall after Brazil and Vietnam (in volume).

FAO (2014): *The state of food and agriculture*

Priority Needs on microbiological alternative methods

Ecuador's agribusiness exports are diversified into several sectors: bananas, shrimps, tuna, flowers and cocoa. Bananas continue to be the largest agribusiness export of **Ecuador**.

FAO (2014): *The state of food and agriculture*

Priority Needs on microbiological alternative methods

Mexico´s agrifood exports are mainly vegetables (23%); beverages (15%); fruits (14%); sugars and confectionery (9%); and products processed from cereals and flour (6%).

FAO (2014): *The state of food and agriculture*

Priority Needs on microbiological alternative methods

Peru is the sixth-largest exporter in Latin America specially on edible fruits and nuts, which have been growing significantly in recent years.

Avocados, asparagus, cranberry and peppers have enabled Peru to increase its presence in edible vegetables in the international market.

FAO (2014): *The state of food and agriculture*

Priority Needs on microbiological alternative methods

- **Argentina** is a major agricultural exporter, second only to Brazil among its Latin American peers.
- **Argentina** is the largest exporter of soybean meal and soybean oil in the world, and third in bean exports. Grain exports (mainly corn and wheat) are second in importance, accounting for 18% of the total.
- Meats and dairy products are secondary in importance nowadays.

FAO (2014): *The state of food and agriculture*

Analytical Needs of the Region:

- This globalized economy requires the use of rapid analytical methods to promote trade
- Screening
- confirmatory

Analytical Micro Needs for the Region:

- These assays have to be performed by microbiological laboratories accredited by ISO 17025
- Reliability of results

Analytical Micro labs Needs for the Region:

- **Methods:**

- Normed or compendial methods
- Modified normed or compendial methods
- Developed by the own laboratory methods

Validated Methods for :

- *Escherichia Coli*
- *Salmonella sp*
- *Listeria monocytogenes*
- *Escherichia Coli* O157:H7 and O157:NM
- *E.coli* no O157 (STEC serogroups O26, O45, O103, O111, O121 y O145)
- *Bacillus cereus*
- *Staphylococcus aureus*
- *Cronobacter sakazakii*
- *Pseudomonas aeruginosa*

Analytical Micro labs Needs for the Region:

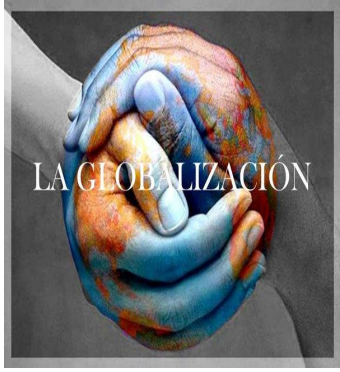
Validated Methods for:

- Coliforms
- Aerobic Count
- Molds and yeast count

Analytical Micro labs Needs for the Region:

Validated Methods to be used on:

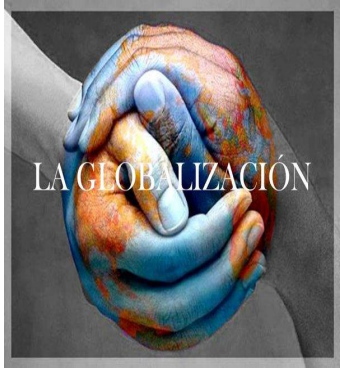
- Meat products
- Fish
- Poultry
- Vegetables and fruits
- Grains and cereals



- **Priority Needs on microbiological alternative methods from a Latin American perspective**

Validated alternative rapid methods for pathogenic and indicator microorganisms

Easy to perform on matrices related to the international trade of the region



Priority Needs on microbiological alternativemethods from a Latin American perspective

Rapid microbiological methods for the simultaneous detection of patogenic microorganisms

- Immunological methods
- Multiplex Polymerase Chain Reaction

Thank You!

In the past, distances were greater than now because space is measured by time.

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Marina Torres Rodriguez, Ph.D.
LATU

Marina was born in Montevideo Uruguay. Her Bachelor Degree is in Chemistry and her Pharmaceutical Chemist Degree were obtained from Universidad de la República Oriental del Uruguay. She has a postgraduate studies in Analytical Chemistry at Virginia Polytechnic Institute and State University, USA and postgraduate studies in Dairy Technology and Dairy Products at Universidad Católica del Uruguay.

She has been working at Technological Laboratory of Uruguay-LATU, since 1992 in Chromatography and Mass Spectrometry Department. Her primary responsibilities include method development and validation of new analytical methods in food and environmental samples. She is also responsible for the Department Quality System. She worked as an auditor at Uruguayan Accreditation Service-OUA.

Before LATU, she worked at Organic Department Faculty of Chemistry, Universidad de la República Oriental del Uruguay and at Squibb Laboratories.

She is a member of AOAC INTERNATIONAL since 2006 and a member of the Latin America and Caribbean Section since 2008. She is sub-coordinator of Uruguayan Technical Subcommittee of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS(ISPAM)

Food Safety Priority Needs/Roles for Methods including Rapid Assays (Chemistry)

The perspectives of Latin America and Caribbean Countries

Marina Torres-LATU
Gaithersburg, MD
March 15, 2016

FOOD SAFETY

21st century:

Evolution from food safety to food security

FOOD SAFETY

Consumers:

- Increased demand for nutritional information
- Consumers request good quality food
- Tendency to eat less but healthy food

FOOD SAFETY

Food safety needs:

- Modern regulatory framework in agreement with international standards (Codex Alimentarius)

FOOD SAFETY

Food safety needs:

- Design and management of a national food control system with institutions, which make operative legislation, control, inspection and information, education and communication

FOOD SAFETY

Food safety needs:

- Food safety during the entire food chain based in GMP
- Systems quality assurance based on good practices

FOOD SAFETY

Food safety needs:

- Strengthen inspections based on risk
- Collaboration between countries

LATIN AMERICA AND CARIBBEAN COUNTRIES

LATIN AMERICA AND CARIBBEAN COUNTRIES

- Differences in political, economic and cultural factors

- Food safety control systems show large differences in complexity and coverage

LATIN AMERICA AND CARIBBEAN COUNTRIES

- All countries have food regulations supported by international instruments (Codex standards) including Good Manufacturing Practices

LATIN AMERICA AND CARIBBEAN COUNTRIES

- The institutions in charge of food regulations are:
  - ✓ Ministry of Health
  - ✓ Ministry of Agriculture
  - ✓ Ministry of Industry and Trade

LATIN AMERICA AND CARIBBEAN COUNTRIES

- Some countries had created an specific agency in charge of food safety

Example: Chile

LATIN AMERICA AND CARIBBEAN COUNTRIES

In Chile, the Ministry of Health adopted the Food Health Regulations (DTO. N° 977/96 (D.OF. 13.05.97)) It contains about 500 items, harmonized to Codex Alimentarius, ensuring the safety of food consumed by the population, and regulating international trade

LATIN AMERICA AND CARIBBEAN COUNTRIES

Under the Ministry of Agriculture the Chilean Agency for Food Safety and Quality (ACHIPIA: Agencia Chilena para la Calidad e Inocuidad Alimentaria) was created. The role of the Agency is to formulate the National Policy for Food Safety and Quality and lead its implementation

LATIN AMERICA AND CARIBBEAN COUNTRIES

- Strengthening cooperation between regional blocks (MERCOSUR, CAN, SICA)
- In countries that are part of sub regional markets as in the case of the Southern Common Market (MERCOSUR), the legislation of the regional block should be included in the national regulations

EXAMPLES OF FOOD SAFETY CONTROL SYSTEMS

IN LATIN AMERICA AND CARIBBEAN COUNTRIES

Regulations by blocks and individual country regulations:

1. Central American Integration System (SICA: Sistema de Integración Centroamericana)

Members:

- Belice
- Dominican Republic
- Guatemala
- Honduras
- El Salvador
- Nicaragua
- Panamá
- Costa Rica (ex member 2015)

The technical and administrative body is the Central American Economic Integration Process (SIECA: Secretaría de Integración Económica Centroamericana)

SIECA´s technical regulations are called CENTRAL AMERICAN TECHNICAL REGULATIONS (RTCA: Reglamento Técnico Centroamericano)

RTCA: http://www.sieca.int/Documentos/DocumentoMatriz.aspx?ClasificacionId=2

2. ANDEAN COMMUNITY (CAN: Comunidad Andina de Naciones)

Members:

- Bolivia
- Colombia
- Ecuador
- Perú

Community of countries that voluntarily join together in order to achieve a more balanced and independent, comprehensive development through Andean, South American and Latin American integration.

Food Safety:

- ✓ It has been conducting the exchange of experiences on national, Andean and international regulatory framework on food security
- ✓ It is working for the establishment of an observatory of food security of the Andean Community and of each Country Member
- ✓ It is developing a strategy to ensure the health and safety of food sold in the Andean region

3. MERCOSUR: The Southern Common Market (MERCOSUR: Mercado Común del Sur)

Members:

- Argentina
- Brazil
- Paraguay
- Uruguay
- Venezuela
- Bolivia (in the accession process)

MERCOSUR

MERCOSUR is a regional integration process

- ✓ MERCOSUR regulations: http://www.mercosur.int/innovaportal/v/387/2/innova.front/busqueda-de-normativa

- ✓ There are MERCOSUR food safety regulations but at the same time each country has its own regulation

Uruguay as an example:

- ✓ Uruguay has the Bromatological National Regulation - Decree 315/94.
- ✓ MERCOSUR regulations are being included in this National Regulation
- ✓ When no regulation exists about an specific topic, Codex is used
- ✓ If Codex has no regulation, (example Maximum Residue Limit) other country regulation are used

ANALYTICAL METHODS

Analysis are required:

- ✓ to meet regulations
- ✓ to ensure authenticity
- ✓ to meet the requirements of the importing countries

Sometimes the methodologies are not available. In house methods must be used. This means a delay between the regulation arises and the laboratory has the analytical method developed and validated

Some countries requires screening official methods in order to reduce operational cost

(some technologies are still extremely expensive)

- Allergens in foods:
  - ✓ Confirmation methods required by some countries
  - ✓ Latex request by Brazil: The Law 12,849 / 2013, issued by the National Congress of Brazil, requires manufacturers and importers of products containing natural latex to present their packaging a warning about the presence of that substance in its composition

- Allergens in foods (cont)
  - ✓ Soy: There are different kits in the market but there are not official method. They have different LOD and LOQ
  - ✓ Sulfites: AOAC 990.31 and AOAC 990.28 Are they useful for labeling sulfites as allergen?

- Allergens in foods (cont):
  - ✓ Eggs and milk: Official methods are needed. There are kits in the market with different LOD and LOQ and different ways of giving final results, (some egg kits give results in egg white protein and others in whole egg powder). These differences in both the design of kits and expression of final results considerably difficult to compare the results obtained with the different kits

- Authenticity
  - ✓ In condiments and spices
  - ✓ In quince (adulterated with apple)
  - ✓ In cattle food in order to prevent bovine spongiform encephalopathy (BSE)
  - ✓ Dyes identification

Some isotopic dilution methods exist but the technology is not available in all labs

- Fiber in dairy products
- Ethyl Lauroyl Arginate (LAE) as a food additive in raw ham
- Migrations to food from containers
- Steviol glycosides in foods
- Soy protein quantification in dairy products

- Endocrine disruptors: there are screening methods (Calux) but official methods are needed

- Mycotoxins in foods:

  - ✓ official screening methods for deoxinivalenol, esterigmatocistine, citochalasine, ocratoxin A, Toxin T-2

  - ✓ saxitoxin, gonyautoxins and citochalasine E methods

  - ✓ rapid assay for simultaneous quantification of mycotoxins

- Benzoic acid and benzoyl peroxide in dairy products
- Benzoic and sorbic acid in foods (pickles included)
- Starch in meat and dairy products, tomatoes products and condiments
- Nitrates and nitrites in dairy products
- Screening methods for pesticides

Members of Latin American and Caribbean Section were asked about methods need

The list presented arises from:

Argentina

Chile

Colombia

Mexico

Uruguay

No answer from other countries

Thank You!

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Arlene Fox
AOAC INTERNATIONAL

Ms. Fox is currently employed as the Senior Director of Proficiency Testing at AOAC International where she developed, implemented and obtained accreditation for the AOAC Laboratory Proficiency Testing Program. Her responsibilities include: ensuring that the operation of the AOAC Laboratory Proficiency Testing Program remains consistent with accreditation requirements, the supervision of staff that are responsible for daily operation of the program, and coordinating activities of the department with other AOAC departments.

Ms. Fox has held a leadership role in developing tools for improving quality in both bio-threat laboratories and food laboratories. She has worked with the AOAC team and members of the bio-threat community to draft a sample collection standard and validate bio-threat test kits. She is an assessor for both bio-threat laboratories and food laboratories. She was appointed by ANSI to serve on the Expert Panel for CASCO WG28 to draft ISO 17043: 2010. Ms Fox is the AOAC staff liaison to the Technical Division for Laboratory Management and the Analytical Laboratory Accreditation Criteria Committee (ALACC). Ms Fox has coordinated the development of ALACC accreditation criteria applying ISO 17025 to a food microbiology, food chemistry, dietary supplements, and pharmaceutical laboratory.

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS(ISPAM)

Meeting Proficiency Testing Requirements

Arlene Fox
Gaithersburg, MD
March 15, 2016

Objective of Proficiency Testing:

To improve analytical performance by providing an independent measure of the quality of the data.

Proficiency Testing Requirements

- ISO 17011
- ILAC P9
- ISO 17025:2005
- ISO CD 17025 (Committee Draft)
- ALACC 2015

ISO 17011:2004

- General requirements for accreditation bodies accrediting conformity assessment bodies
- ILAC MRA
- Sec. 7.15.3 “Accreditation bodies shall ensure that its accredited laboratories participate in proficiency testing”

ILAC P9:2014

4.2 The minimum PT activity according to a laboratory's scope is:

- **Evidence of satisfactory participation prior to gaining accreditation where PT is available and appropriate;**
- **Further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan.**

ISO 17025:2005

- A laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the participation in interlaboratory comparisons or proficiency testing programmes. Other means may include the regular use of reference materials, or replicate tests using the same or different methods, retesting or recalibration of retained items, correlation of results for different characteristics of an item

ISO CD 17025

- **7.6.3 External quality assurance activities are those activities that monitor the quality of the laboratory output over a defined period.**
  - **Both external and internal quality assurance activities are required**

ISO CD 17025 continued

External activities can include, but not be limited to the following:

a) participation in proficiency tests where such activities are available and appropriate;

NOTE It is recommended to use proficiency tests that are organized by providers that meet the requirements of ISO/IEC 17043

b) participation in interlaboratory comparisons other than proficiency testing.

AOAC Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals

(ALACC) 2010

5.9 Proficiency testing covering all methods before and after accreditation

- **Frequency after accreditation not specified**

AOAC Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals

ALACC 2015

5.9.1 One PT annually for each method

ALACC Guidelines for Food Program Accreditation

- A2LA
- ANAB
- L-A-B
- PJLA

What IF No PT Is Available?

- Well organized inter-laboratory comparisons
- Internal/ external Round Robin Programs
- Internal Performance Checks
  - Regular Use of CRMs
  - Replicates
  - Retesting of Retained samples

- **Developing a New AOAC PT Program**
  - **Planning Required for Development**
  - **Assessment of Level of Interest**
  - **Funding for Implementation**
  - **Availability of Test Materials**

- **Meet Requirements of ISO/IEC 17043: 2010.**
  - **Follow plan for designing a new program**
    - **Section 4.4**
  - **Data supporting homogeneous stable samples suitable for evaluation**
- **Meet Requirements of ISO/IEC 13528**

- **Implementation of Infant Formula PT Program**
  - **Starting Point**
    - **Level of Interest**
    - **MLT SPIFAN II Test Materials**
      - **Stable and Homogeneous**

- **Feasibility Study**

  - **Goals for the Pr[illegible]am**
  - **Predicted Lev[illegible]**
  - **Cost of Implementation**

- Pilot Study to Test the Protocol:
  - **Instructions to participants**
  - **Confirm nutrients chosen and how nutrients reported**
  - **Confirm selection of matrices**
  - **Time scheduled for analysis**
  - **Data entry forms**
  - **Statistical design based on recommendations of Task Force-using SAS programming that will be used in proficiency testing program**
  - **Reports**
  - **Resolution of any problems**

- Infant Formula Proficiency Testing Pilot Study
  - Planned by Task Force
  - Six laboratories
  - March 2016
  - 30 Days for Analysis

- **Other Possible Uses of PT Data**
  - **Validation**
    - **Comparison PT Data versus Multi-lab Data**
    - **Incremental Collaborative Study**
    - **Robust reproducibility standard deviation of a PT compared to the reproducibility standard deviation of a multi-lab precision found to be similar**
      - **PAH in Sausage**

Method Performance

- Analysing historical PT data could provide helpful insight into method performance if it is possible to form groups of laboratories that apply a similar method approach.

- **Current Statistics Committee Pilot**
  - **NIH/NIST Dietary Supplement Quality Assurance Program (DSQAP) chondroitin round**

Thank You!

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Scott Coates, Ph.D.
AOAC INTERNATIONAL

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

The Scientific Association Dedicated to Analytical Excellence®

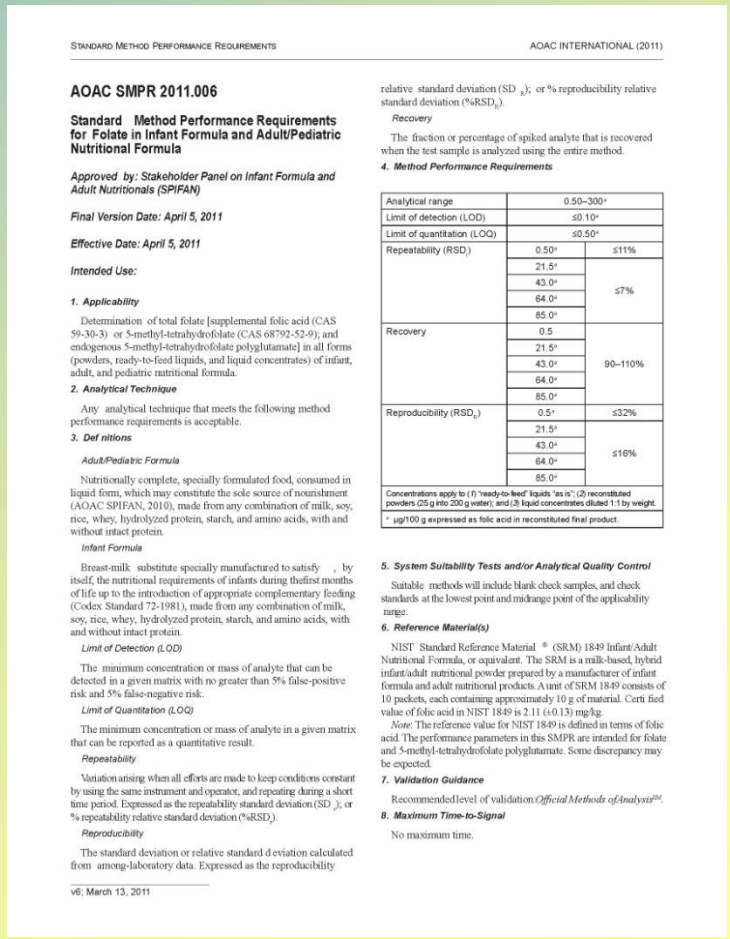
AOAC INTERNATIONAL

Standard Method Performance Requirements (SMPRs)

The Scientific Association Dedicated to Analytical Excellence®

Standard Methods Performance Requirements

- Commonly referred to as:
  - SMPRs
  - “Smipper”s



STANDARD METHOD PERFORMANCE REQUIREMENTS AOAC INTERNATIONAL (2011)

AOAC SMPR 2011.006

Standard Method Performance Requirements for Folate in Infant Formula and Adult/Pediatric Nutritional Formula

Approved by: Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN)

Final Version Date: April 5, 2011

Effective Date: April 5, 2011

Intended Use:

1. Applicability

Determination of total folate [supplemental folic acid (CAS 59-30-3) or 5-methyl-tetrahydrofolate (CAS 68792-52-9); and endogenous 5-methyl-tetrahydrofolate polyglutamate] in all forms (powders, ready-to-feed liquids, and liquid concentrates) of infant, adult, and pediatric nutritional formula.

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 thefirst 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 standard deviation or relative standard d eviation calculated from among-laboratory data. Expressed as the reproducibility relative 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

Analytical range	0.50–300[a]	
Limit of detection (LOD)	≤0.10[a]	
Limit of quantitation (LOQ)	≤0.50[a]	
Repeatability (RSD_r)	0.50[a]	≤11%
	21.5[a]	≤7%
	43.0[a]	
	64.0[a]	
	85.0[a]	
Recovery	0.5	90–110%
	21.5[a]	
	43.0[a]	
	64.0[a]	
	85.0[a]	
Reproducibility (RSD_R)	0.5[a]	≤32%
	21.5[a]	≤16%
	43.0[a]	
	64.0[a]	
	85.0[a]	

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 folic acid in reconstituted final product.

5. System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the applicability range.

6. Reference Material(s)

NIST Standard Reference Material ® (SRM) 1849 Infant/Adult Nutritional Formula, or equivalent. The SRM is a milk-based, hybrid infant/adult nutritional powder prepared by a manufacturer of infant formula and adult nutritional products. A unit of SRM 1849 consists of 10 packets, each containing approximately 10 g of material. Certi fied value of folic acid in NIST 1849 is 2.11 (±0.13) mg/kg.

Note: The reference value for NIST 1849 is defined in terms of folic acid. The performance parameters in this SMPR are intended for folate and 5-methyl-tetrahydrofolate polyglutamate. Some discrepancy may be expected.

7. Validation Guidance

Recommended level of validation: *Official Methods of Analysis*℠.

8. Maximum Time-to-Signal

No maximum time.

v6: March 13, 2011

SMPRs

- documents a community's analytical method needs.
- very detailed description of the analytical requirements.
- includes method acceptance requirements.
- published as a standard.

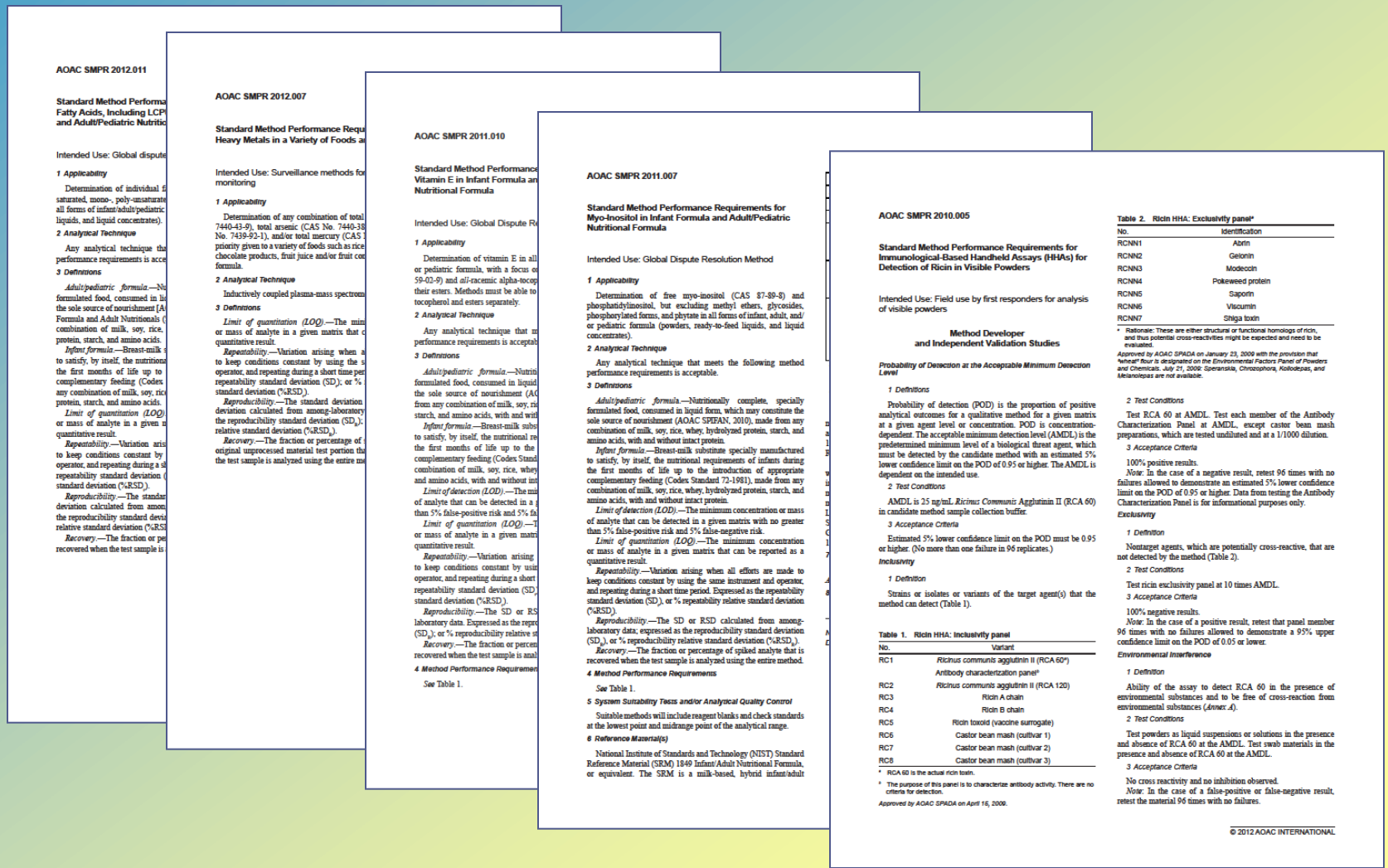
Uses of SMPRs

- Basis for method acceptance and approval.
- Guidance to method developers for the development of new methods.
- Advance the state-of-the-art in a particular direction.
- Address specific analytical needs.
- Allow AOAC to reach a broader community of method developers and users.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

AOAC has adopted 70+ SMPRs



AOAC SMPR 2012.011

Standard Method Performa
Fatty Acids, Including LCP
and Adult/Pediatric Nutritic

Intended Use: Global dispute

1 Applicability

Determination of individual f
saturated, mono-, poly-unsaturate
all forms of infant/adult/pediatric
liquids, and liquid concentrates).

2 Analytical Technique

Any analytical technique tha
performance requirements is acce

3 Definitions

Adult/pediatric formula.—Nu
formulated food, consumed in li
the sole source of nourishment [A
Formula and Adult Nutritionals (
combination of milk, soy, rice,
protein, starch, and amino acids.

Infant formula.—Breast-milk s
to satisfy, by itself, the nutritiona
the first months of life up to
complementary feeding (Codex
any combination of milk, soy, rice
protein, starch, and amino acids.

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

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

Reproducibility.—The standar
deviation calculated from amon
the reproducibility standard devia
relative standard deviation (%RSD

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

AOAC SMPR 2012.007

Standard Method Performance Requ
Heavy Metals in a Variety of Foods a

Intended Use: Surveillance methods for
monitoring

1 Applicability

Determination of any combination of total
7440-43-9), total arsenic (CAS No. 7440-38
No. 7439-92-1), and/or total mercury (CAS
priority given to a variety of foods such as rice
chocolate products, fruit juice and/or fruit con
formula.

2 Analytical Technique

Inductively coupled plasma-mass spectrom

3 Definitions

Limit of quantitation (LOQ).—The min
or mass of analyte in a given matrix that c
quantitative result.

Repeatability.—Variation arising when a
to keep conditions constant by using the s
operator, and repeating during a short time per
repeatability standard deviation (SD_r); or %
standard deviation (%RSD).

Reproducibility.—The standard deviation
deviation calculated from among-laboratory
the reproducibility standard deviation (SD_R);
relative standard deviation (%RSD_R).

Recovery.—The fraction or percentage of
original unprocessed material test portion tha
the test sample is analyzed using the entire m

AOAC SMPR 2011.010

Standard Method Performance
Vitamin E in Infant Formula an
Nutritional Formula

Intended Use: Global Dispute Re

1 Applicability

Determination of vitamin E in all
or pediatric formula, with a focus o
59-02-9) and *all*-racemic alpha-tocop
their esters. Methods must be able to
tocopherol and esters separately.

2 Analytical Technique

Any analytical technique that m
performance requirements is acceptabl

3 Definitions

Adult/pediatric formula.—Nutriti
formulated food, consumed in liquid
the sole source of nourishment (AO
from any combination of milk, soy, ri
starch, and amino acids, with and wit

Infant formula.—Breast-milk subst
to satisfy, by itself, the nutritional re
the first months of life up to the
complementary feeding (Codex Stand
combination of milk, soy, rice, whey
and amino acids, with and without int

Limit of detection (LOD).—The mi
of analyte that can be detected in a g
than 5% false-positive risk and 5% fa

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

Repeatability.—Variation arising
to keep conditions constant by usin
operator, and repeating during a short
repeatability standard deviation (SD_r)
standard deviation (%RSD).

Reproducibility.—The SD or RS
laboratory data. Expressed as the repro
(SD_R); or % reproducibility relative st

Recovery.—The fraction or percen
recovered when the test sample is anal

4 Method Performance Requiremen

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 phosphatidylinositol, but excluding methyl ethers, glycosides, phosphorylated 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).

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[a])
	Antibody characterization panel[b]
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)

[a] RCA 60 is the actual ricin toxin.

[b] 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[a]

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

[a] 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: Sperganskia, Chrozophora, Kalliodepas, 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.

When are SMPRS helpful?

- SPDS – no reference methods and very complex analytical issues.
- SPIFAN - *community* decides to modernize methods.
- SPSFAM – new analytical issues and new application.
- SPADA – new applications and guidance.

Example

- SMPR: Identification of Venezuelan Equine Encephalitis Virus (VEEV)

Identification of Venezuelan Equine Encephalitis Virus (VEEV)

- **Intended Use**: Laboratory or field use by Department of Defense trained operators.
- **Applicability**: ***Identification*** of VEEV in liquid samples from aerosol collectors. The preferential method would be a field-deployable assay.
- **Analytical Technique**: Molecular methods of detecting target-specific viral component(s).

Official Methods of Analysis of AOAC INTERNATIONAL (2012) 19th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, USA, APPENDIX I; also on-line at http://www.eoma.aoac.or

Identification of Venezuelan Equine Encephalitis Virus (VEEV)

Parameter	Minimum Performance Requirement
AMIL	5000 genome copies / mL
POI at AMIL within sample collection buffer	≥ 0.95
POI at AMIL in an aerosol environmental matrix	≥ 0.95
System False-Negative Rate using spiked aerosol environmental matrix	≤ 5%
System False-Positive Rate using aerosol environmental matrix	≤ 5%
Inclusivity panel purified DNA	All inclusivity strains (Table II) must be correctly identified at 2x the AMIL†
Exclusivity panel purified DNA	All exclusivity strains (Table III and Annex IV; part 2) must test negative at 10x the AMIL†

Identification of Venezuelan Equine Encephalitis Virus (VEEV)

Inclusivity Panel

VIRUS	Serotype / Variant	Representative Strain (s)
VEEV	VEE-IAB	Trinidad Donkey
		MF-8
	VEE-IC	ICVE93, ICVE95
	VEE-IE	IEMX63, IEPA62
	VEE-ID	1DPA61, 1DPE98, IDPE06

Identification of Venezuelan Equine Encephalitis Virus (VEEV)

Exclusivity Panel

VIRUS	Representative Strain (s)
Mosso das Pedras	78V 3531
Everglades	Fe-3-7c
Mucambo	A
	C (strain 71D-1252)
	D
Tonate	Tonate
Pixuna	Pixuna
Cabassou	Cabassou
Rio Negro	AG 80-663
EEE WEE	PE6 CBA87

Potential Interferants

Compounds		Potential Theaters of Operation
group 1: petroleum-based	JP-8	airfield
	JP-5	naval
	diesel/gasoline mixture	ground
	fog oil (standard grade fuel number 2)	naval, ground
	burning rubber	ground, airfield
group 2: exhaust	gasoline exhaust	ground
	jet exhaust	naval, airfield
	diesel exhaust	ground
group 3: obscurants	terephthalic acid	ground
	zinc chloride smoke	ground
	solvent yellow 33	ground
group 4: environmental	burning vegetation	ground, airfield
	road dust	ground
	sea water (sea spray)	naval
group 5: Chemicals	brake fluid	all

Food Microbiology

- We don’t need no stinkin’ SMPRs.
- We got:
  - reference methods.
  - international guidelines.

When are SMPRS helpful?

- No universally recognized reference methods and very complex analytical issues.
- Community decides to upgrade methods.
- New analytical issues and new application.
- New applications and guidance.

Potential Food Micro SMPR

- MALDI–TOF-MS
- Proteomics
- Application of *in silico* analysis
- New pathogens
- Viruses

Summary

- SMPR have been extremely useful to many other communities.
- AOAC is offering this process to the food microbiology community.

Discussion