AOAC INTERNATIONAL

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Food Allergen Advisory Panel

Wednesday, June 15, 2016

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AOAC INTERNATIONAL
BYLAWS

As Amended September 26, 2010

ARTICLE I
Name

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

ARTICLE II
Purpose

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

ARTICLE III
Membership

Section 1. Types of Membership

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

A. Individual Members

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

B. Sustaining Member Organizations

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

C. Organizational Affiliate

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

Section 2. Qualifications for Membership

A. Individual Members

[1] Members

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

[2] Retired Members

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

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

[3] Student Members

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

[4] Honorary Members

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

B. Sustaining Member Organizations

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

C. Organizational Affiliate

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

Section 3. Application for Membership

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

Section 4. Expulsion

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

Section 5. Dues, Membership Year, and Waivers

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

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

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

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

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

Section 6. Members in Good Standing; Rights and Privileges

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

ARTICLE IV
Officers

Section 1. Elected Officers

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

A. President

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

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

B. President-Elect

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

C. Secretary

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

D. Treasurer

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

E. Immediate Past President

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

Section 2. Appointed Officers

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

A. Executive Director

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

B. Other Appointed Officers

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

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

Section 1. Nominating Committee

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

Section 2. Elections and Terms of Office

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

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

Section 3. Appointments

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

ARTICLE VI
Board of Directors

Section 1. Composition

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

Section 2. Powers and Duties

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

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

Section 3. Meetings

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

Section 4. Quorum

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

Section 5. Absence

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

Section 6. Compensation

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

Section 7. Resignation or Removal

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

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

Section 8. Vacancies: Members of the Board

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

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

Section 9. Vacancies: President and Other Officers

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

ARTICLE VII
Committees

Section 1. Committee Formation

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

Section 2. Committee Appointments

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

ARTICLE VIII
Official Methods of Analysis

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

Section 1. Composition of the Official Methods Board

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

Section 2. Purpose of the Official Methods Board

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

Section 3. Principles of the Official Methods Program

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

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

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

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

E. The OMB shall adopt methods as Final Action.

ARTICLE IX
Meetings

Section 1. Annual Meeting

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

Section 2. Quorum

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

ARTICLE X
Voting

Section 1. Voting by Ballot

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

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

Section 2. Voting by Proxy

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

ARTICLE XI
Earnings and Assets

Section 1. Non-Profit Status

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

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

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

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

Section 2. Political Activities

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

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

ARTICLE XII
Sections

Section 1. Sections

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

Section 2. Purpose of Sections

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

Section 3. Membership in Sections

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

Section 4. Bylaws of Sections

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

Section 5. Dissolution of Sections

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

Section 6. Actions of Sections

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

ARTICLE XIII
Technical Divisions

Section 1. Purpose

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

Section 2. Creation, Combination, Discontinuance, or Change

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

ARTICLE XIV
Indemnification

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

ARTICLE XV
Parliamentary Authority

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

ARTICLE XVI
Amendments to the Bylaws

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

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

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

Introduction

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

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

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

The Scientific Association Dedicated to Analytical Excellence®

Policy

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

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

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

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

Instructions

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

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

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

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

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

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

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

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

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

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

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

Sanctions

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

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

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

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

AOAC INTERNATIONAL
ANTITRUST POLICY
STATEMENT AND GUIDELINES

Introduction

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

Responsibility for Antitrust Compliance

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

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

Antitrust Guidelines

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

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

* * * * *

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

AOAC INTERNATIONAL

POLICY AND PROCEDURES ON

VOLUNTEER CONFLICT OF INTEREST

Statement of Policy

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

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

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

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

Illustrations of Conflicts of Interest

1. A volunteer who is serving as a committee member or referee engaged in the evaluation of a method or device; who is also an employee of or receiving a fee from the firm which is manufacturing or distributing the method or device or is an employee of or receiving a fee from a competing firm.

2. A volunteer who is requested to evaluate a proposed method or a related collaborative study in which data are presented that appear detrimental (or favorable) to a product distributed or a position supported by the volunteer's employer.

3. A referee who is conducting a study and evaluating the results of an instrument, a kit, or a piece of equipment which will be provided gratis by the manufacturer or distributor to one or more of the participating laboratories, including his or her own laboratory, at the conclusion of the study.

4. Sponsorship of a collaborative study by an interest (which may include the referee) which stands to profit from the results; such sponsorship usually involving the privilege granted by the investigator to permit the sponsor to review and comment upon the results prior to AOAC evaluation.

5. A volunteer asked to review a manuscript submitted for publication when the manuscript contains information which is critical of a proprietary or other interest of the reviewer.

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

Do's and Don'ts

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

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

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

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

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

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

Procedures

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

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

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

* * * * * *

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

International Stakeholder Panel on Alternative Methods (ISPAM)
Advisory Panel on Food Allergens

Meeting held at
AOAC INTERNATIONAL
2275 Research Blvd., Suite 300, Rockville, MD 20850

Wednesday, June 15, 2016
9:00AM – 5:00PM (Eastern US)

Draft Meeting Agenda

I. WELCOME AND INTRODUCTIONS; OVERVIEW OF MEETING AGENDA AND OUTCOME *(Jim Bradford, AOAC)* – 9:00am-9:15am

Bradford will welcome attendees, lead introductions and introduce ISPAM chair, Erin Crowley (Q Laboratories). Crowley will review the meeting agenda and specify the outcomes of the meeting and how the outcomes will impact ISPAM's direction in developing standards for food allergens.

II. OVERVIEW OF AOAC ISPAM *(Erin Crowley, Q Laboratories)* – 9:15am-9:30am

Crowley will provide an overview of AOAC ISPAM including its mission and achievements.

III. AOAC STANDARD METHOD PERFORMANCE REQUIREMENTS *(Scott Coates, AOAC)* – 9:30am-9:40am

Coates will provide overview of what are AOAC Standard Method Performance Requirements (SMPRs) that the AOAC ISPAM Working Group on Food Allergens will develop.

IV. PRIORITIES AND CHALLENGES FOR FOOD ALLERGEN DETECTION: REGULATORY PERSPECTIVES – 9:40am-10:40am

a. **US Perspective** *(Gregory Noonan, FDA CFSAN)*
b. **EU and Codex Perspective** *(Samuel Godefroy, Université Laval)*

V. *PRIORITIES AND CHALLENGES FOR FOOD ALLERGEN DETECTION: F*OOD INDUSTRY PERSPECTIVES – 11:00am-12:00pm

a. **Global Perspectives on Food Allergen Priorities – Issues and Challenges** *(Jupiter Yeung, Nestlé)*
b. **Food Industry – Grocery Manufacturers Association (GMA)** *(Kristen Spotz, GMA)*

VI. PRIORITIES AND CHALLENGES FOR FOOD ALLERGEN DETECTION: TECHNOLOGY PROVIDER PERSPECTIVES – 1:00pm-2:00pm

a. **Molecular and Nucleic Technologies** *(Markus Lacorn, R-Biopharm, Inc.)*
b. **Immunoassays** *(Scott Radcliffe, Romer Labs)*
c. **Emerging Technologies** *(Brooke Schwartz, Brooke Schwartz Consulting)*

VII. PRIORITY SETTING FOR ISPAM FOOD ALLERGEN WORKING GROUP *(Samuel Godefroy, Université Laval)* – 2:00pm-4:20pm

Godefroy will moderate the discussion on identifying the top food allergens, matrices, and technologies for which standards are needed.

VIII. ENGAGEMENT *(Krystyna McIver, AOAC)* – 4:20pm-4:35pm

McIver will solicit experts in priority areas chosen, discuss potential chairs and members of working group(s)

IX. NEXT STEPS & ADJOURNMENT *(Erin Crowley, Q Laboratories)* – 4:35pm-5:00pm

Crowley will provide next steps with the ongoing efforts for the ISPAM program.

MEETING ITINERARY:

REGISTRATION (8:00AM)

MEETING START TIME (9:00AM)

MORNING BREAK (10:40AM-11:00AM)

LUNCH (12:00PM–1:00PM)

AFTERNOON BREAK (3:00PM-3:20PM)

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Erin Crowley, Ph.D.
Q Laboratories, Inc. & ISPAM Chair

Erin Crowley has been the Microbiology Research and Development Supervisor at Q Laboratories, Inc. in Cincinnati, Ohio since 2006. For the past 10 years, Erin and her R&D team have served as an independent third-party laboratory with a primary focus on providing high quality method validation for microbiological rapid detection methods. These validations include Independent laboratory evaluations for pathogen detection, qualitative methods and confirmatory biochemical assays for AOAC Official Methods of Analysis, AOAC Research Institute Performance Tested Methods Program and MicroVal Certification Program. In addition to being an active member of the International Association of Food Protection (IAFP) and AOAC, Erin currently serves as Vice-Chair of the AOAC Official Methods Board and Chair of the International Stakeholder Panel on Alternative Methods (ISPAM). Erin earned a B.S. from the University of Cincinnati in Cincinnati, Ohio and an M.A. from Tufts University in Medford, MA.

AOAC INTERNATIONAL
INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS
OVERVIEW

Erin S. Crowley

Q Laboratories, Inc.

ISPAM Chair

Agenda

International Stakeholder Panel on Alternative Methodology (ISPAM)
Advisory Panel on Food Allergens

June 15, 2016
9:00AM – 5:00 PM EDT
AOAC INTERNATIONAL
2275 Research Blvd., Suite 300, Rockville, MD 20850

1. **Welcome and Introductions; Overview of meeting agenda and outcome 9:00am-9:15am**

- *Jim Bradford (AOAC INTERNATIONAL) will welcome attendees and lead introductions and introduce ISPAM chair, Erin Crowley, Q Laboratories. Crowley will review the meeting agenda and specify the outcomes of the meeting and how the outcomes will impact ISPAM's direction in developing standards for food allergens.*

2. **Overview of AOAC ISPAM** *(Erin Crowley, Q Laboratories)* **– 9:15am-9:30am**

- *Crowley will provide an overview of AOAC ISPAM, including its mission and achievements.*

3. **AOAC Standard Method Performance Requirements** *(Scott Coates, AOAC)*-**9:30am-9:40am**

- *Coates will provide overview of what are AOAC Standard Method Performance Requirements (SMPRs) that the AOAC ISPAM Working Group on Food Allergens will develop.*

Agenda

4. **PRIORITIES AND CHALLENGES FOR FOOD ALLERGEN DETECTION: REGULATORY PERSPECTIVES – 9:40am-10:40am**
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   - Godefroy will moderate the discussion on identifying the top food allergens, matrices, and technologies for which standards are needed.

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8. **ENGAGEMENT *(Krystyna McIver, AOAC)* – 4:20pm-4:35pm**
   – McIver will solicit experts in priority areas chosen, discuss potential chairs and members of working group(s)

9. **NEXT STEPS & ADJOURNMENT *(Erin Crowley, Q Laboratories)* – 4:35pm-5:00pm**
   – Crowley will provide next steps with the ongoing efforts for the ISPAM program.

- MORNING BREAK (10:40AM-11:00AM)
- LUNCH (12:00PM–1:00PM)
- AFTERNOON BREAK (3:00PM-3:20PM)
- DINNER (TBD BY GROUP)

AOAC International

- AOAC provides standards development and conformity assessment for a broad spectrum of safety interests including
  - Food and beverages
  - Dietary supplements
  - Infant formula
  - Feeds
  - Fertilizers
  - Soil and water
  - Veterinary drugs
  - Pharmaceuticals

- Benefit to members and Organizational Affiliates
  - Standardization of the science
  - Credibility, defensibility and acceptance of standards
  - Level playing field
  - International credibility/acceptance
  - Participation of method developers, contract labs, and food companies

AOAC Stakeholder Panel Process

Key Terms	Definition
Advisory Panel	***Ad hoc* planning committee of key stakeholders – decide priorities, recommend stakeholders**
Stakeholder Panel	**Represent perspectives and interests of topic; Approves standards. Members ≥ 60 with 20-25 voting members.**
Standard Method Performance Requirements (SMPR)	**Minimum acceptable performance criteria of a method - determined by the community represented by the Stakeholder Panel.**
Expert Review Panel (ERP)	**Panel created to reviewed candidate methods and approve First Action *Official Methods of Analysis* (OMA).** **ERP members are subject matter experts on methodology or topic, and are vetted by the AOAC Official Methods Board.**

Projects using AOAC Standards Development Process

- **International Formula Council**

  Nestlé, Danone, Mead Johnson, Abbott Nutrition, PBM…

  Developed consensus standards and Official Method of Analysis for analysis of priority nutrients (e.g. Vitamins A/E, Vitamin D, Vitamin B12, Folate, Inositol, Nucleotides, Ultra trace minerals, Pantothenic acid)

- **Coca Cola and PepsiCo**

  Delivered AOAC® Official Method℠ for pesticide residues in soft drinks

  Accepted by Bureau of Indian Standards as official method

- **Elanco Animal Health, Eli Lilly and Co.**

  Developed standards for drug residues in animal feed

- **International Stakeholder Panel on Alternative Methods**

  Harmonization of Validation methods between ISO and AOAC

International Stakeholder Panel on Alternative Methods (ISPAM)

- Driven and supported by AOAC Organizational Affiliates and contributing members who participate in the AOAC Research Institute Program

- ISPAM was formed initially to develop harmonized, internationally accepted standard validation guidelines for alternative (rapid) chemical and microbiological methods by leveraging global networks of experts to reach consensus on an analytical validation protocol.
  - The goal is to achieve optimal efficiency and avoid duplication of efforts in order to meet regulatory and product safety testing requirements.

- Initially three (3) working groups:
  - Microbiology
  - Qualitative Chemistry
  - Statistics

Examples of ISPAM Registered Organizations

- 3M Food Safety
- ADRIA
- AFNOR Certification
- MicroVal*
- National Association Of Testing Authorities AsureQuality
- Bayer CropScience
- BioControl Systems
- bioMérieux
- Nexidia
- NordVal*
- NSF International
- Phenomenex
- Brodsky Consultants
- FDA - CFSAN
- FDA - CFSAN (Retired)
- Q Laboratories
- QIAGEN
- Rockline Industries
- Florida Department Of Agriculture And Consumer Services
- Health Canada
- Maxxam Analytics
- Shanghai Exit And Entry Inspection & Quarantine Bureau
- Sigma-Aldrich
- Thiex Laboratory Solutions
- Mérieux NutriSciences
- US Pharmacopeia (USP)
- Vanguard Sciences

ISPAM Accomplishments

- Approved harmonized approaches for several testing parameters
  - Number of levels/samples/fractional positives
  - Results analysis/criteria/statistical analysis
  - Number of data sets for collaborative study/sample size
  - ISPAM voted to recommend to replace “all foods” with a claim for a “broad range of foods”

ISPAM Accomplishments

- ISPAM recommended that developers of analytical methods follow ISO 16140-2 Annex A, *Guidance on food matrices and food categories for method validation,* as a guidance for choosing food categories to make a "broad range of foods" claim

- ISPAM agreed to adopt the ISO 16140-1 Part 1: "Terminology of method validation" working definitions for "validation" and "verification"

ISPAM Accomplishments

- *Appendix N: ISPAM Guidelines for Validation of Qualitative Binary Chemistry Methods*
  - Approved March 14, 2013

- ISPAM-Annual Meeting 2014-Boca Raton, FL
  - Approved WG development of Harmonization of BAM, USDA, Health Canada and ISO *Salmonella* methods

  - First Microbiology SMPR approved- 2014.017 Detection of *Salmonella* species in romaine lettuce and baby spinach as presented.
    - Unanimous approval on 9/6/14

History in the Making-
AOAC Annual Meeting 2015

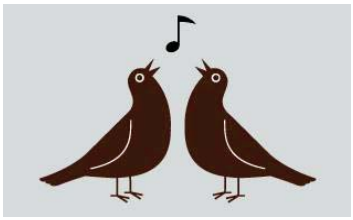
Harmonization

Program Administration of Bilateral Program Validation Studies

Organizational representatives from MicroVal, AFNOR, NordVal, and AOAC Research Institute

A. MicroVal

Imola Ferro, MicroVal



B. AFNOR

Valentine Digonnet, AFNOR Certification

C. NordVal

Hilde Skar-Norli, NMKL/NordVal International

D. AOAC Research Institute

Deborah McKenzie, AOAC INTERNATIONAL and AOAC Research Institute

Changing the Course

- How can we develop SMPRs in areas of interest to the Stakeholders?
- Consensus based priorities drive the direction of ISPAM
- SMPRs, developed and approved by Stakeholders, are used to evaluate the best candidate methods for possible adoption as First Action Official Methods℠
- Accepted worldwide, relevant and valuable to industry

ISPAM Mid-Year Meeting 2016

- Panel discussion on Global Food Safety Needs
  - Speakers
    - GMA
    - FDA-ORA
    - USDA-FSIS
    - Chinese Institute of Food Science and Technology
    - University of Buenos Aires
    - Labororatorio Technologico del Uruguay
  - Most critical needs
    - Allergen detection methods
    - Enrichment issues with Pathogen Detection
    - Environmental Sampling Plans and Testing- Data Acceptance
    - Whole Genome Sequencing- Standards

ISPAM Mid-Year Meeting 2016

- AOAC-RI Board of Directors agreed to form a working group on food allergens
  - Focus on rapid method technology
  - Molecular, Immunoassay, new and emerging technologies
  - Complement to SPSFAM current WG for select allergen detection using mass spectroscopy.

……Here we are!!

You're Invited!

Interested in becoming part of these initiatives?

Visit: http://www.aoac.org/iMIS15_Prod/AOAC/SD/ISPAM

NAME	TITLE	PHONE	EMAIL
Krystyna McIver	Executive, Scientific Business Development	(301) 924-7077 x111	kmciver@aoac.org
Scott Coates	Chief Scientific Officer	(301) 924-7077 x137	scoates@aoac.org
Deborah McKenzie	Senior Director, Approval Processes & AOAC Research Institute	(301) 927-7077 x157	dmckenzie@aoac.org

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.

Standard Methods Performance Requirements

Scott Coates, AOAC INTERNATIONAL
Chief Scientific Officer

June 15, 2016
AOAC Headquarters, Rockville, Md., USA

AOAC and the Development of Standards for Food Allergens

- Background on *Standard Methods Performance Requirements* (SMPRs).
- SMPR for food allergens using mass spec.
- SMPR for food allergen test kits.

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.

SMPR Format

- Intended use
- Applicability
- Analytical technique
- Definitions

SMPR Format

- System suitability
- Reference materials
- Validation guidance
- Maximum time-to-determination
- Method performance requirements table

SMPRs are published in the OMA.

SMPR ID numbers use the year and 3 numerals.

OMA ID numbers use the year and 2 numerals.

AOAC SMPR 2012.002

Standard Method Performance Requirements for Whey Protein:Casein Ratio in Infant Formula

Intended Use: Global dispute resolution method

1 Applicability

Determination of total whey proteins, including hydrolyzed forms, as a percent of protein content (protein content as defined by appropriate regulatory agencies). To be applicable to milk-based infant formula products (including those from bovine milk and, if possible, milk of other species and products containing hydrolyzed casein).

2 Analytical Technique

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

3 Definitions

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, whey, hydrolyzed milk protein, starch, and amino acids, with and without intact protein.

Whey protein.—For the purpose of this SMPR, whey protein is defined as the proteinaceous components obtained from milk after removal of casein components by various processing technologies.

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 ... conditions constant by using the same instru...

Table 1. Method performance requirements		
Analytical range	20–100*	
Limit of quantitation (LOQ)	≤10*	
Repeatability (RSD_r)	20–100*	≤3%
Recovery	95 to 105% of theoretical	
Reproducibility (RSD_R)	20–100*	≤6%

* g/100 g protein (unless otherwise specified in regulation).

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 deviation 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 analyte that is recovered versus a known amount in a test sample when 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 check standards at the lowest point and midrange point of the analytical range.

6 Reference Material(s)

To be determined.

7 Validation Guidance

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

8 Maximum Time-to-Re...

No maxi...

SMPR for Food Allergens using Mass Spectrometry

- Funded by SCIEX Corporation.
- Stakeholder Panel for Strategic Food Analytical Methods (SPSFAM).
- Launched working group at the AOAC Annual Meeting in September 2015.

Scope

•Mass spectrometry based method or methods able to detect and/or quantify peanut, egg, milk, and hazelnut food allergens in selected finished products and ingredients.

•Each allergen should be uniquely identified.




Method performance requirements.

Parameter	Target allergen			
	whole egg	milk	peanut	hazelnut
Analytical Range (ppm)	10-1000	10-1000	10-1000	10-1000
LOQ (ppm*)	5	10	10	10
MDL (ppm*)	1.65	3	3	3
Recovery (%)	60-120%	60-120%	60-120%	60-120%
% RSD_r	≤20 %	≤20 %	≤20 %	≤20 %
% RSD_R	≤ 30%	≤ 30%	≤ 30%	≤ 30%

MDL = method detection limit

Priority Allergen/Matrix Combinations

whole egg	cookies bread dough salad dressing wine
milk	cookies, baked goods infant formula wine dark chocolate (optional matrix for methods that claim a chocolate matrix)
peanut	cookies ice cream breakfast cereal milk chocolate (optional matrix for methods that claim a chocolate matrix)
hazelnut	cookies ice cream breakfast cereal milk chocolate (optional matrix for methods that claim a chocolate matrix)

New Project

- Develop SMPRs for food allergen (detection) test kits.
- Likely will be detection assays.
  - No problem for SMPR.
  - Use Probability of Detection (POD) criteria and selectivity panels.

Thank you for taking the time to be here today to help us prioritize standard needs for food allergens.

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Gregory Noonan, Ph.D.
US Food & Drug Administration (FDA)

Dr. Gregory Noonan joined the US Food and Drug Administration in 2002 and is currently the Director of the Division of Bioanalytical Chemistry (DBC) in the Office of Regulatory Science. The Division of Bioanalytical Chemistry contains over 35 scientists performing research and developing analytical methods in numerous subject areas, including, toxic elements analysis, immunodiagnostic and DNA-based allergen detection, radionuclides, pesticide analysis, mycotoxin analysis, dietary supplements and botanicals, nutritional ingredients and cosmetics. Prior to becoming Director, Dr. Noonan was a Research Chemist in the Method Development Branch of the Division of Analytical Chemistry. His research focused on developing methods for the determination of food additives, including indirect additives, and process induced contaminants. Dr. Noonan also serves as the US Delegate to the Codex Committee on Methods of Analysis and Sampling (CCMAS), where he chairs the Working Group on the Endorsement of Methods. Dr. Noonan received his PhD in Chemistry from Michigan State University in 1996. After graduation he worked for the Diagnostic Division of Abbott Laboratories, where he developed diagnostic immunoassays for Hepatitis A, B and C and HIV. After leaving Abbott Laboratories and prior to joining the FDA, he left was a postdoctoral fellow in the Civil and Environmental Engineering department of the Massachusetts Institute of Technology, where he studied the fate and transport of polar, water soluble environmental contaminants.

ISPAM Advisory Panel on Food Allergens

June 15, 2016

Gregory Noonan
Office of Regulatory Science
US FDA

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004

- FALCPA is an amendment to the Federal Food, Drug, and Cosmetic Act and requires food manufacturers to label food products that contain an ingredient or protein from a major food allergen (Peanut, Egg, Milk, Fish, Shellfish, Soy, Tree Nut, Wheat)
- Requires the type of tree nut (e.g., almonds, pecans, walnuts); the type of fish (e.g., bass, flounder, cod); and the type of Crustacean shellfish (e.g., crab, lobster, shrimp) to be declared.
- Ingredients must be listed by “common or usual name”.
- FALCPA does **not** require FDA to establish thresholds.

Gluten Labeling of Foods

Gluten Free Labeling, Final Rule 2013

- the final rule defines "gluten-free" as meaning that the food either is inherently gluten free; or does not contain an ingredient that is:
  - 1) a gluten-containing grain (e.g., spelt wheat);
  - 2) derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); or
  - 3) derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food. Also, any unavoidable presence of gluten in the food must be less than 20 ppm.

Gluten Free Labeling of Fermented and Hydrolyzed Foods

- Comment Period is Still Open

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Food Safety and Modernization Act (FSMA)

(b) Hazard Analysis - The owner, operator, or agent in charge of a facility shall--

> (1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including--
> biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, **allergens**, and unapproved food and color additives;

(c) Preventive Controls —The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

Office of Regulatory Science

Allergen Regulatory Testing

- Two Different Test Kits
  - Encompass antibody differences and extraction differences
- Analyze in triplicate (minimum)
- Multiple Controls
  - False Negative
  - False Positive
  - Dynamic Range
  - Determine and identify analyst error
- Additional confirmation testing may be performed
  - Multi-allergen antibody detection (profiles)
  - DNA (PCR and/or "barcoding")
  - Mass Spectrometry
  - Western blots

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Technical Challenges

- Appropriate Standards for Hydrolyzed and Fermented Foods
- Appropriate Standards for Processed Foods
- Multi-allergen antibody detection (profiles/cross reactivity)
- Measure of Cross Reactivity
- Clear protocols:
  - Fortification/Recovery
  - Cross Reactivity

Office of Regulatory Science

Validation and Verification

- Clear protocols:
  - Fortification/Recovery
  - Cross Reactivity
- AOAC General Guidance
  - Percent Recovery
  - Precision
- Reporting of Performance Data (package insert)

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Samuel Godefroy, Ph.D.
Université Laval

Samuel Godefroy is a Full Professor of Food Risk Analysis and Regulatory Systems at the Department of Food Science, Faculty of Agriculture and Food Sciences, University Laval, Québec, Canada. He is also a professor at the Global Institute for Food Security (GIFS) at Queen's University of Belfast, in the UK. Samuel is currently leading the development of a Food Risk Analysis and Regulatory Excellence Platform (FRAREP) hosted by the Institute of Nutrition and Functional Foods (INAF) of Université Laval.

Before Joining Université Laval in the fall of 2015, Dr. Godefroy completed a secondment with the World Bank's Global Food Safety Partnership where he led the Strategic Development of this initiative. Under his leadership, this public-- private partnership developed and adopted its 2015--2020 strategic framework, to guide its actions in food safety capacity building globally.

Dr. Godefroy assumed senior food regulatory positions at the executive level with Health Canada for over 10 years, including the position of Director General of Health Canada's Food Directorate, the Federal food standard setting organization in Canada from 2009 to 2015.

Samuel served as Vice Chair of the FAO/WHO Codex Alimentarius Commission (CAC), the international food standard setting body from 2011 to 2014. During his tenure, Samuel led the development and facilitated the adoption by consensus of the organization's strategic plan for 2014-19.

Dr. Godefroy currently serves as a senior food science and regulatory expert on a number of advisory bodies and committees domestically and internationally, including expert advice to food safety projects led by the United Nations Industrial Development Organization (UNIDO) and serving on the International Advisory Committee of the China Centre for Food Safety Risk Assessment (CFSA). Samuel authored over 65 scientific publications and book chapters and serves on a number of international editorial boards of scientific journals related to food safety and nutrition.

Dr. Godefroy received his Ph.D. in Analytical Chemistry from the University of Pierre et Marie Curie (Paris VI). He holds degrees in Chemistry, Biochemistry and Chemical Engineering from the same University and from the École Nationale Supérieure de Chimie de Paris, France.

Université Laval
Département Sciences des aliments
Department of Food Science

Food Allergen Management: International Regulatory Environment

AOAC International – ISPAM Advisory Panel
Food Allergens

AOAC HQ – 15 June 2016

Samuel B. Godefroy, Ph.D.
Full Professor, Food Risk Analysis and Regulatory Systems
Platform for Food Risk Analysis and Regulatory Excellence

INAF RAE
Food Risk Analysis
& Regulatory Excellence Platform

OUTLINE

- ✓ Review of International Standards
- ✓ Current trends of Food Allergen Regulatory Measures

CODEX ALIMENTARIUS 50 1963-2013

International Standards related to Food Allergens

The **presence** of priority (allergenic) foods should be always subject to **declaration in the list of ingredients** on a food label

CODEX DEVELOPED AN INITIAL LIST OF PRIORITY ALLERGENS

Codex developed a list of foods and ingredients that are known to cause hypersensitivity and should always be declared:

cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
crustacea and products of these;
egg and egg products;
fish and fish products;
peanuts, soybeans, and products of these;
milk and milk products (lactose included);
tree nuts and nut products; and
sulfites in concentrations of 10 mg/kg or more.

This list was adopted as a final text by the Codex Alimentarius Commission (CAC) in June 1999, with the understanding that future additions and/or deletions from the list will be considered by the CCFL taking into account advice received from JECFA.

http://www.fao.org/docrep/meeting/X2670e.htm

CODEX LIST IS MEANT TO BE BUILT UPON – CONSIDERATION OF REGIONAL DIFFERENCES

ADOPTION OF THESE LISTS IN DOMESTIC REGULATIONS

CONSIDERATIONS FOR PRIORITY ALLERGENS

Priority Lists of Food Allergens

- Hazard Identification: Allergens associated with inadvertent consumption: Anaphylaxis
- Hazard Characterization: Allergens known to have Low thresholds
- Prevalence: Prevalence of a particular allergy in a given population
- Level of use in Processes Foods (Pervasive use / presence in the food supply)
- Potential that the ingredient be not covered by "general" labeling provisions.
  - Example: Spice ingredients

JECFA ADVICE

Criteria for inclusion to a priority list: JECFA

Existence of cause-and-effect relashionship (food consumption/adverse reaction:

- Based on double-blind placebo-controlled food challenge
- Unequivocal reports of reactions: severe allergies and intolerance reactions

Reports of severe systemic reactions following exposure to foodstuff.

Prevalence of the food allergy in children and adults supported by clinical studies

The need to rely on expert advice upon review of the list :

- Representation of various geographical perspectives required

CANADIAN LIST : PRIORITY ALLERGENS

"Food Allergen" Defined

Any protein from any of the following foods or any modified protein, including any protein fraction, that is derived from the following foods:

Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts

Peanuts

Sesame seeds

Wheat, kamut, spelt, triticale

- ❑ Eggs
- ❑ Milk
- ❑ Soybeans
- ❑ Crustacea
- ❑ Fish
- ❑ Shellfish
- ❑ Mustard (added in 2012)

Labelling Directive 2003-89-EC

- Mandatory labelling of ingredients containing or made of allergens:

ANNEX

'ANNEX IIIa

Ingredients referred to in Article 6(3a), (10) and (11)

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof

Crustaceans and products thereof

Eggs and products thereof

Fish and products thereof

Peanuts and products thereof

Soybeans and products thereof

Milk and products thereof (including lactose)

Nuts i. e. Almond (*Amygdalus communis L.*), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoiesis (Wangenh.) K. Koch*), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof

Celery and products thereof

Mustard and products thereof

Sesame seeds and products thereof

Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO_2.'

Directive 2006/142/EC : Lupin & Molluscs

COMMISSION DIRECTIVE 2006/142/EC

of 22 December 2006

amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients which must under all circumstances appear on the labelling of foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1] and in particular Article 6(11), third paragraph, thereof,

Having regard to the opinions of the European Food Safety Authority of 6 December 2005 and 15 February 2006,

(5) In the case of molluscs (gastropods, bivalves or cephalopods), the EFSA states in its opinion of 15 February 2006 that they are most often consumed in their current state but are also used as ingredients, after any processing, in a number of preparations and in products such as surimi. Allergic reactions, which can be serious, affect up to 0,4 % of the population, i.e. 20 % of all cases of allergic reactions to seafood. The main allergenic protein in molluscs is tropomyosin, which is the same as that in crustaceans, and cases of cross-allergies between molluscs and crustaceans occur frequently.

(6) It can be concluded from these observations that lupin and molluscs should be added to the list in Annex IIIa of Directive 2000/13/EC.

EU LIST: PRIORITY ALLERGENS

European List

EU Directive 2003/89/EC (amending Directive 2000/13/EC) on the indication of ingredients in food.

The Directive entered into force in November 2004

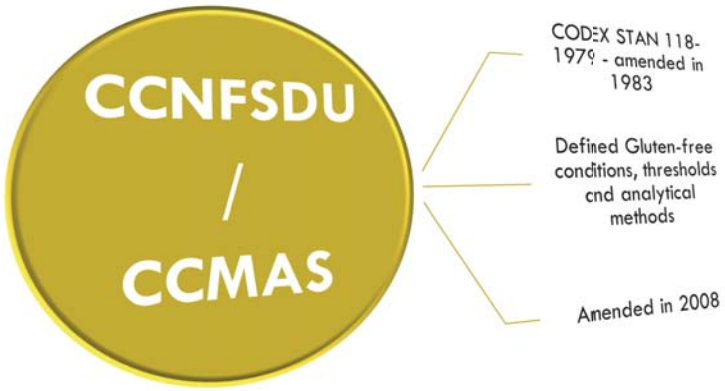
Directive amended in 2006 and requires food manufacturers to list potentially allergic ingredients

- Cereals containing gluten,
- fish,
- crustaceans,
- eggs,
- peanuts,
- soy,
- milk and dairy products,
- nuts,
- celery, mustard,
- Lupin
- sesame seed and
- sulphites.

GENERAL APPROACH OF REGULATORY REQUIREMENTS

- Declaration of Deliberately added ingredients:
  - ✓ Use **Simple, Consistent and Systematic** Language for Allergen Declaration **of Ingredients** (Milk and not Beta Lactoglobulin) – The consumer should not shop with a dictionary
  - ✓ A priority allergen can not be **"hidden"** – No exemption would hold
- No requirements for Precautionary Statements:
  - At the exception of Japan – where "may contain" is not allowed.
- Gluten Free requirements : Based on Codex standard
- Little to no requirements associated with allergen methodologies (continues to evolve)

« GLUTEN-FREE » IN CODEX STANDARDS



GLUTEN-FREE REQUIREMENTS IN CODEX

Gluten is a series of protein present in the following cereals

Wheat, spelt, kamut (triticum species), Barley, Rye

✓Food that do not contain these grains or that have been processed to eliminate these ingredients are eligible to the "Gluten-free" claim

✓Presence is determined through an analytical threshold set at 20 ppm of Gluten (as defined in the standard)

✓Reference method is an immunochemical-based method using « R5 Mendez method » - 10 ppm LOD or below.

✓Inclusion of Oats (pure oats) is left at the discretion of national jurisdictions

✓Standard also defines « Low Gluten » claims : Gluten present btw. 20 and 100 ppm).

TRENDS IN ALLERGEN REGULATIONS

- An increased interest in updating food labeling laws or regulations
  - Latin America: Argentina, Columbia, Chile
- An increasing number of ASEAN countries have considered or are undertaking updates to labelling requirements to consider Allergens as a priority
  - Issue moving from import/export concern to domestic issue
  - Increased awareness of burden of incidents on public health systems
- China considering (mandatory) food allergen regulations

Changes being contemplated

- *Consideration of exemptions from declaration in select cases*
- *Possible consideration of updates to the list of priority allergens*
- *Possible updates to the « Gluten free » rules*

- *Implications of the implementation of the Food Safety Modernization Act:*
  - *Preventive controls specific to food allergen management*

- *Updates to the « Gluten-free » rule*
- *Impacts of the Safe Food for Canadians Act and subsequent regulations :*
  - *Development of preventive control measures associated with allergen control*

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Département Sciences des aliments
Department of Food Science

INAFRAE

Food Risk Analysis
& Regulatory Excellence Platform

MERCI / THANK YOU

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Jupiter Yeung, Ph.D.
Nestlé

Jupiter is a Principal Scientist for Global Food Safety for Nestle Nutrition. He joined Nestle in 2008. Jupiter has more than 20 years of food safety experience in physical, chemical and food allergen risk analyses and management to ensure safe and nutritious food supply to all stakeholders.

Prior to joining Nestle, Jupiter worked for GMA, academia and government. He holds a BSc in Pharmacy and PhD in Chemistry. He published over 120 manuscripts and book chapters on a wide range of subjects related to food safety, and health and wellness.

Nestlé Research

Global Perspectives on Food Allergen Priorities – Issues and Challenges

Jupiter Yeung, Ph.D.
Nestlé Nutrition

AOAC TLA on Food Allergens,
June 15, 2016, Rockville, MD, USA

Topics

Game changing

- Prevalence of food allergy increasing
- Food recalls increasing
- Consumer confidence eroding

New normal

- Emerging new regulations from different countries
- Increasing use of precautionary allergen labeling (PAL)
- Growing risk-taking behavior among allergic consumers

Emerging Trends

- Increase global trade – imports and exports
- Urgent need for a generally recognized thresholds for risk assessment / management
- Increase demand for reliable detection methods

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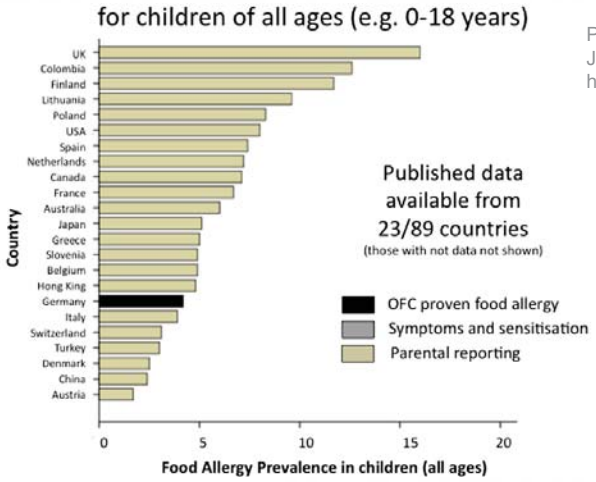
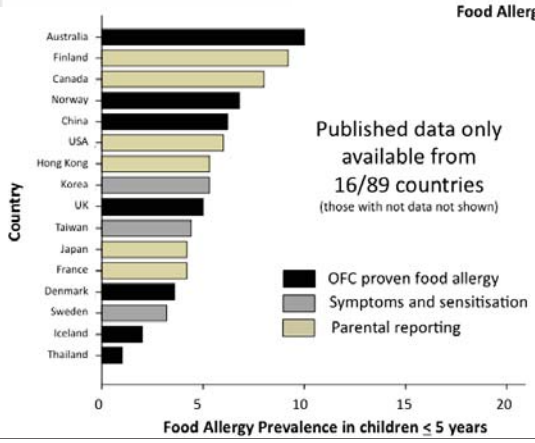
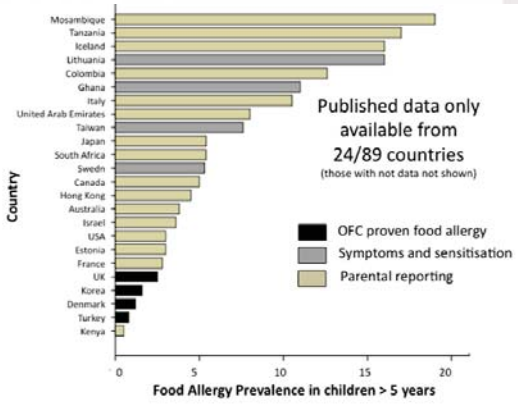
Global Food Allergy Prevalence



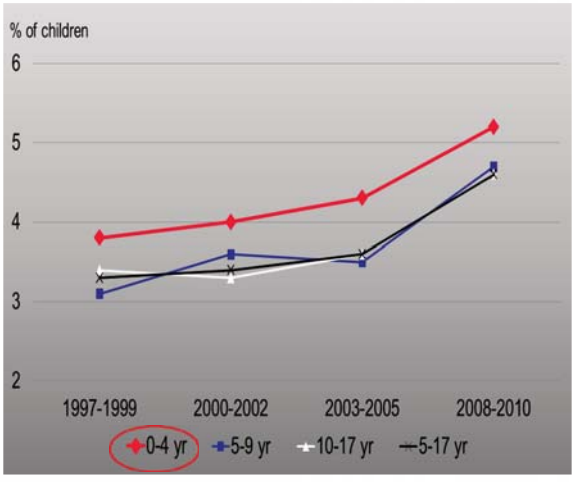
Prescott et al. World Allergy Organization Journal 2013, 6:21
http://www.waojournal.org/content/6/1/21





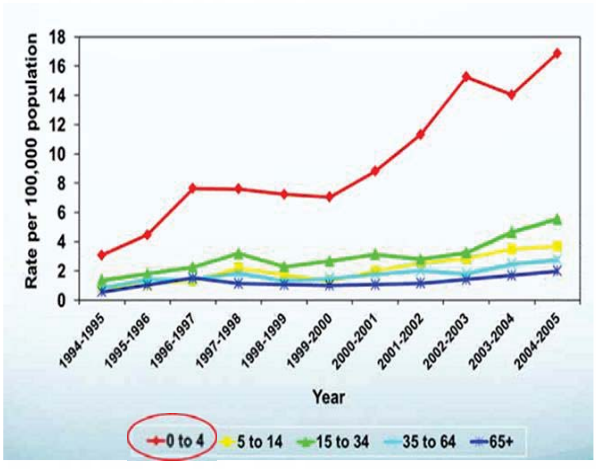
Food Allergy Prevalence and Anaphylaxis

Food allergy prevalence among children in the US



CDC National Center for Health Statistics, 2011

Sharp rise in food anaphylaxis



Liew WK, Williamson E, Tang MLK. J Allergy Clin Immunol 2009;123:434-42

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Economic Impact

Gupta RS, Holdford D, Bilaver L, Dyer A, Holl J, Meltzer D. The high economic impact of childhood food allergy in the United States. JAMA Pediatrics Sept 2013 16.

- Indirect cost
- Quality of life

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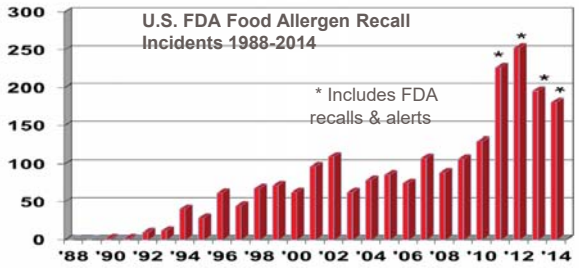
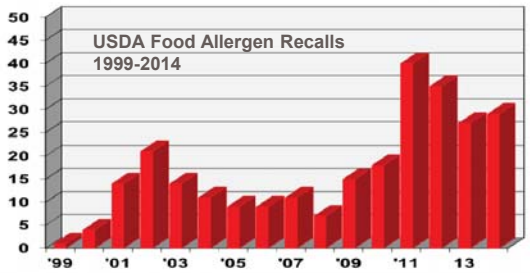
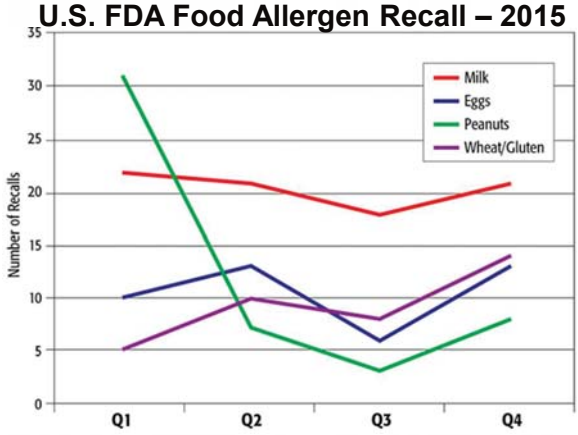
Food Allergen Recalls





U.S. FDA Food Allergen Recall – 2015



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FOOD ADDITIVES & CONTAMINANTS: PART A, 2016
VOL. 33, NO. 5, 760–771
http://dx.doi.org/10.1080/19440049.2016.1169444

Taylor & Francis
Taylor & Francis Group

Analysis and critical comparison of food allergen recalls from the European Union, USA, Canada, Hong Kong, Australia and New Zealand

Luca Bucchini[a], Antonella Guzzon[a], Roland Poms[b] and Hamide Senyuva[c]

Table 4. Alerts and recalls (with recalled product/allergen combinations in parentheses) in the dataset, by year and source.

Year	RASFF	FSA	FSAI	USFDA	USDA-FSIS	CFIA	CFS	FSANZ
2011	75 (82)	82 (103)	20 (34)	126 (563)	41 (115)	146 (456)	0 (0)	21 (80)
2012	72 (80)	71 (175)	14 (26)	107 (466)	29 (56)	159 (404)	3 (3)	13 (26)
2013	50 (54)	46 (108)	12 (45)	118 (283)	25 (60)	212 (832)	4 (7)	16 (29)
2014	69 (78)	53 (140)	24 (44)	102 (279)	33 (147)	343 (1581)	2 (2)	27 (83)
Total	266 (294)	252 (526)	70 (149)	453 (1591)	128 (378)	860 (3273)	9 (12)	77 (218)

Table 6. Products with alerts and recalls in the dataset, by cause and source.

Cause	RASFF	FSA	FSAI	USFDA	USDA	CFIA	CFS	FSANZ
Allergic reaction	–	–	2	35	7	121	–	–
False label claim	6	12	23	16	1	12	–	4
Labelling error	–	2	–	48	–	–	–	13
Not indicated on label	252	219	63	955	341	2813	12	180
Packaging error	2	46	20	53	11	3	–	7
Unauthorised or undeclared sulphites	6	106	–	40	–	318	–	–
Unintended presence	28	26	2	264	1	3	–	14
Wrong allergen advice	–	104	39	124	–	–	–	–
Wrong label	–	11	–	56	17	3	–	–
Total	294	526	149	1591	378	3273	12	218

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Recall - May Contain [Allergen]

FOOD SAFETY & DEFENSE ALERTS
25-Mar-16 [F] (Fri) 16:25

Product Recall Bulletin

Snapshot

Trader Joe's Recalls Chocolate Orange Sticks and Chocolate Raspberry Sticks (undeclared milk)

Reason: Because the products may contain more than the stated "traces of milk" on the label.
Trader Joe's initiated the voluntary removal of these products after noticing the chocolate coating appeared lighter in color than expected.

Distribution: [Nationwide U.S.]: The products were distributed to Trader Joe's stores nationwide.

Illnesses: [Reactions Reported]: Two allergic reactions have been reported to date.

FOOD SAFETY & DEFENSE ALERTS
29-Mar-16 [J] (Tue) 20:10

Product Recall Bulletin

[Trader Joe's – UD #1]

Snapshot

Transilvania Trading Recalls Trader Joe's brand Chocolate Orange Sticks and Chocolate Raspl (undeclared milk)

Reason: Allergen – Milk
This recall was triggered by a recall in another country.

Distribution: [Canada]: British Columbia; Extent of the distribution: Retail

Illnesses: There have been reported reactions associated with the consumption of these products.

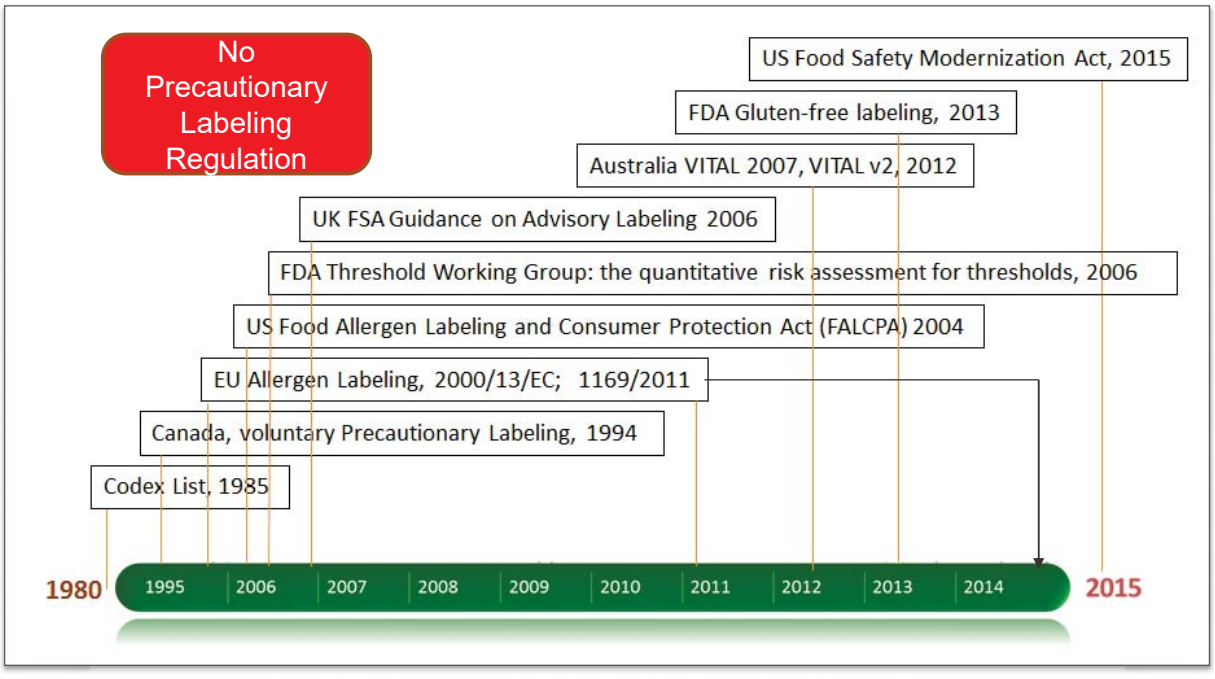
Root Causes of Food Allergen Recalls

Cause	Number of Recalls
Wrong package or label	82
Terminology	59
Failure to carry forward information from an ingredient to final label	41
Cross-contact	28
Ingredient mislabeled from supplier	21

12%

Learning from FDA Food Allergen Recalls and Reportable Foods - Food Safety Magazine, 10/9/2014

Significant Allergen Regulations, Guidance and Milestones

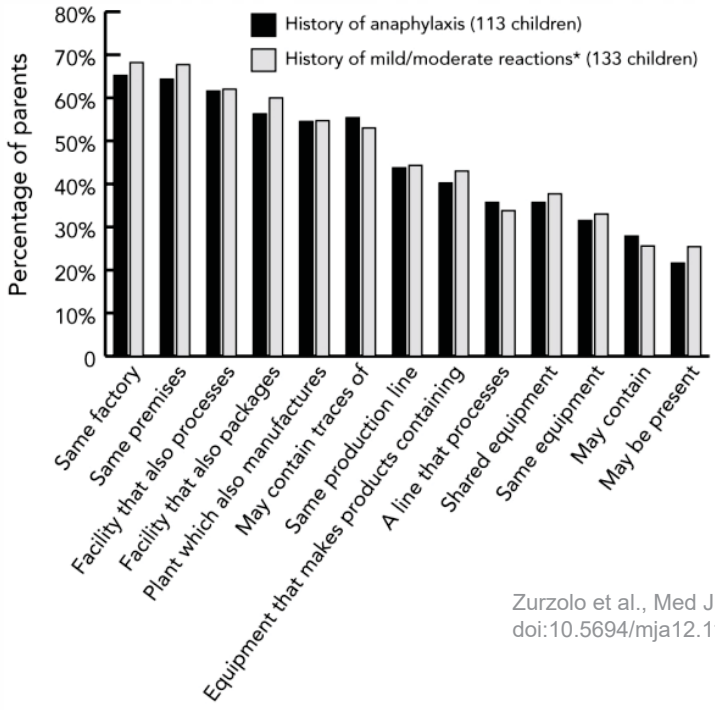


Precautionary Allergen Labeling (PAL) – Time for change

- PAL is neither mandatory nor regulated
  - Proliferation of PAL
  - Broad array of expressions
  - Consumers are confused and cynical
  - Allergic consumers group wish list:
    - Wider choices of safe products
    - Fewer products with PAL
    - Consistent standards for PAL and gluten-free labeling
  - The status quo is not working and reduces quality of life
    - Time for change
- Should be simple, clear, truthful and trusted by consumers
- Message should be harmonized
  - e.g. May contain [Allergen]
- Should indicate level of risk
  - "Safe or Not Safe"
    - if "thresholds" are recognized
  - e.g. VITAL

Research

Parent Survey (n=298) of Which Precautionary Labels They Would Ignore for Their Allergic Children

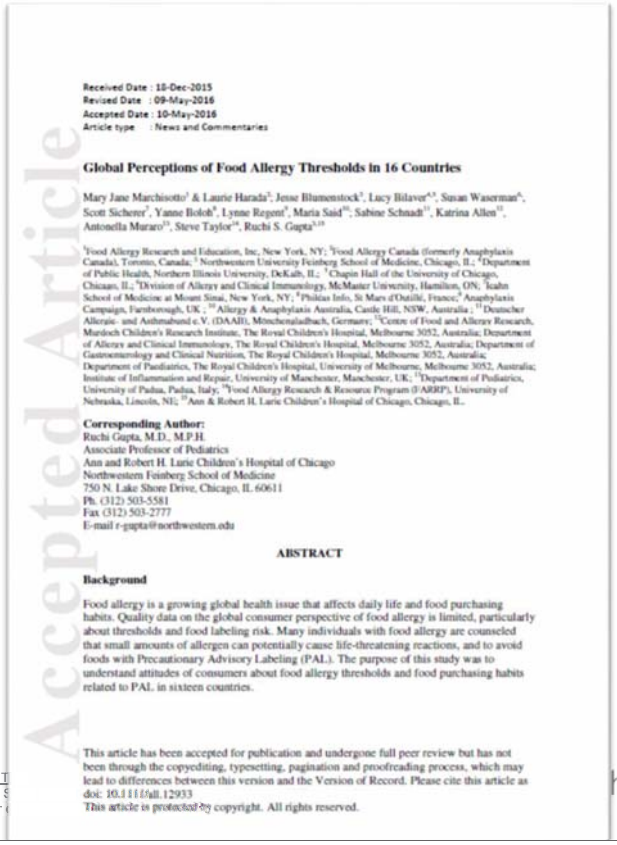


Zurzolo et al., Med J Aust 2013; 198 (11): 621-623.
doi:10.5694/mja12.11669

Nestlé Research

Global Perceptions of Food Allergy Thresholds in 16 Countries

- Marchisotto MJ at al., (2016) Allergy, (In print)
- Consumer attitudes about food allergy thresholds and food purchasing habits related to PAL.
- A questionnaire was distributed by patient support groups in 16 countries to consumers with food allergy.
- The questionnaire gathered opinions about food allergy thresholds and PAL purchasing habits.
- 9,689 respondents from 16 countries completed the survey.



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Article type : News and Commentaries

Global Perceptions of Food Allergy Thresholds in 16 Countries

Mary Jane Marchisotto[1] & Laurie Harada[2], Jesse Blumenstock[3], Lucy Bilaver[4,5], Susan Waserman[6], Scott Sicherer[7], Yanne Boloh[8], Lynne Regent[9], Maria Said[10], Sabine Schnadt[11], Katrina Allen[12], Antonella Muraro[13], Steve Taylor[14], Ruchi S. Gupta[2,15]

[1]Food Allergy Research and Education, Inc, New York, NY; [2]Food Allergy Canada (formerly Anaphylaxis Canada), Toronto, Canada; [3] Northwestern University Feinberg School of Medicine, Chicago, IL; [4]Department of Public Health, Northern Illinois University, DeKalb, IL; [5] Chapin Hall of the University of Chicago, Chicago, IL; [6]Division of Allergy and Clinical Immunology, McMaster University, Hamilton, ON; [7]Icahn School of Medicine at Mount Sinai, New York, NY; [8]Phildas Info, St Mars d'Outillé, France; [9] Anaphylaxis Campaign, Farnborough, UK ; [10] Allergy & Anaphylaxis Australia, Castle Hill, NSW , Australia ; [11] Deutscher Allergie- und Asthmabund e.V. (DAAB), Mönchenladbach, Germany; [12]Centre of Food and Allergy Research, Murdoch Children's Research Institute, The Royal Children's Hospital, Melbourne 3052, Australia; Department of Allergy and Clinical Immunology, The Royal Children's Hospital, Melbourne 3052, Australia; Department of Gastroenterology and Clinical Nutrition, The Royal Children's Hospital, Melbourne 3052, Australia; Department of Paediatrics, The Royal Children's Hospital, University of Melbourne, Melbourne 3052, Australia; Institute of Inflammation and Repair, University of Manchester, Manchester, UK; [13]Department of Pediatrics, University of Padua, Padua, Italy; [14]Food Allergy Research & Resource Program (FARRP), University of Nebraska, Lincoln, NE; [15]Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL.

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ABSTRACT

Background

Food allergy is a growing global health issue that affects daily life and food purchasing habits. Quality data on the global consumer perspective of food allergy is limited, particularly about thresholds and food labeling risk. Many individuals with food allergy are counseled that small amounts of allergen can potentially cause life-threatening reactions, and to avoid foods with Precautionary Advisory Labeling (PAL). The purpose of this study was to understand attitudes of consumers about food allergy thresholds and food purchasing habits related to PAL in sixteen countries.

Table 2. Respondent Opinions on Allergen Thresholds and Industry Labeling

	Would you purchase food that contains allergen(s) …		Would you purchase a packaged food with the label…		
	…not capable of triggering an allergic reaction?	… only capable of triggering a mild allergic reaction?	"may contain allergen"	"may contain traces of allergen"	"manufactured in a facility that also processes allergen"
Country	% Yes	% Yes	% Yes[a]	% Yes[a]	% Yes[a]
Australia	22	4	34	63	60
Canada	17	3	20	27	32
Chile	21	3	11	19	23
France	22	2	28	56	56
Germany	17	8	27	50	55
Ireland	25	2	24	34	41
Israel	39	6	28	39	63
Italy	14	2	24	39	39
Japan	44	15	35	43	72
Mexico	19	5	13	21	N/A[b]
New Zealand	31	8	44	67	76
South Africa	36	8	53	25	25
Spain	16	1	6	22	20
The Netherlands	30	10	31	53	60
UK	17	2	28	36	44
US	17	2	10	14	41
Weighted Average	19	3	16	25	41

& Pizza
- in Washington metropolitan areas

- Example of threshold application in a private fast food restaurant chain

&

MENU
LOCATIONS
CAREERS
ABOUT
CONNECT

GET OUR SWAG

NUTRITION STATEMENT

- All of our products are MSG-free.
- Our dough is organic.
- None of our products contain high fructose corn syrup.
- Fresh produce is locally-sourced when possible and adjusted for seasonality to ensure freshness and quality.
- Where we can control the source of seed in our suppliers' crops, we do not allow the use of GMO seeds. Our suppliers' dairy cattle is hormone-free.

ALLERGY WARNING:

&pizza prepares food with eggs, shellfish, tree nuts and wheat.

GLUTEN WARNING:

&pizza advises against GF dough for extreme gluten intolerances; cross contamination may occur.

15

Peanut Recall: Low Levels of Peanut Residue in Limited Flour and Flour Products

Food Track™

FOOD SAFETY & DEFENSE ALERTS
3-Jun-16 [O] (Fri) 20:51

Product Recall Bulletin

Snapshot

...lect Snack Cakes And Donuts, Possible ...Residue

...ty Advisory Regarding Grain Craft Flour

...recalling 710,000 cases of select snack cakes ...recent recall by our supplier, Grain Craft, of ...ed peanut residue.

...has received notice of two allergic reactions ...this recall.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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Food

Home > Food > Recalls, Outbreaks & Emergencies > Safety Alerts & Advisories

Safety Alerts & Advisories

FDA Investigates Low Levels of Peanut Residue Found in Limited Flour and Flour Products

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Fast Facts

- FDA advises consumers with severe peanut allergies to avoid the following products being recalled because of peanut residue in certain flour originating from Grain Craft.
- Grain Craft has recalled its affected flour. FDA is working with other companies that received the affected flour product from Grain Craft to determine if further recalls are needed.
- On June 3, 2016, Hostess recalled products containing flour it had received from Grain Craft.

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Recall 3-Jun-16 [P] (Fri) 21:16
FDA Investigates Low Levels o

Recall 3-Jun-16 [O] (Fri) 20:51
UD#8]:
Hostess Brands, LLC Recalls 71
Peanut Residue

Recall 2-May-16 [ ] (Mon) 13:4
CSM Bakery Solutions Voluntar
Decorated Chocolate Chip Cook

Recall 29-Apr-16 [T] (Fri) 17:5
#6]:
CSM Bakery Solutions' Recalls

Recall 29-Apr-16 [O] (Fri) 14:1
Bakery Express of Central FL , F

Recall 28-Apr-16 [J] (Thu) 21:
7-Eleven, Inc. Recalls Fresh Full
[produced by CSM Bakery Solut

Recall 28-Apr-16 [I] (Thu) 21:
Safeway Recalls Red Velvet Cak
](undeclared allergens)

Recall 28-Apr-16 [C] (Thu) 10:
Old Home Kitchens Recalls "O

Recall 22-Apr-16 [L] (Fri) 14:3
CSM Bakery Solutions Recalls (

Recall 22-Apr-16 [D] (Fri) 10:4
Chick-fil-A Pulls Chocolate (
(undeclared peanuts)

Recall 28-Apr-16 [B] (Thu) 10:03 [C.A.] [7-Eleven Fresh To Go Cookies – UD #2]:
Bakery Express Recalls 7-Eleven Fresh To Go Cookies (undeclared peanut)

Product Recall 27-Apr-16 [N] (Wed) 16:22 [NY] [Glenn Wayne Wholesale Bakery – UD #1]:
Updated with UPC Codes and Pictures: Glenn Wayne Wholesale Bakery Recalls Select 7-Eleven Fresh To Go Cookies (undeclared peanuts)

Recall 26-Apr-16 [J] (Tue) 16:46 [NY]:
Glenn Wayne Wholesale Bakery Recalls Some 7-Eleven Cookies (undeclared peanuts)

Food Track™

FOOD SAFETY & DEFENSE ALERTS

7-Jun-16 [G] (Tue) 10:37

Product Recall Bulletin

[Grain Craft – UD #10]

Snapshot

Frito-Lay Recalls Select Rold Gold Tiny Twists, Rold Gold Thins, Rold Gold Sticks and Rold Gold Honey Wheat Braided (undeclared peanut allergen)

Reason: This recall is the direct result of a recent recall by a Frito-Lay supplier of certain lots of flour for undeclared peanut residue. The Rold Gold products subject to the recall may have been produced using the recalled flour and, as a result, these Rold Gold products may contain low levels of undeclared peanut residue.

Illnesses: To date, Frito-Lay has received no reports of illness related to the products covered by this recall.

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Quantitative Risk Assessment

Food and Chemical Toxicology 62 (2013) 179–187

Contents lists available at ScienceDirect

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

ELSEVIER

Quantitative risk assessment of foods containing peanut advisory labeling

Benjamin C. Remington [a], Joseph L. Baumert [a], David B. Marx [b], Steve L. Taylor [a,*]

[a] Food Allergy Research & Resource Program, Department of Food Science & Technology, University of Nebraska-Lincoln, Lincoln, NE, USA
[b] Department of Statistics, University of Nebraska-Lincoln, Lincoln, NE, USA

- Among 202 peanut products bearing PAL and peanut listed as minor ingredients (last 3), 8.6% and 37.5% contained peanuts >2.5 ppm respectively.
- This 2013 results are similar to 2005 and 2009 surveys.
- Doing nothing is not working.
- A true safe threshold for any one food and person is impossible to determine. However, the aim of quantitative risk assessment is to reduce the risk of harm from cross-contact allergen to a level considered tolerable, rather than to eliminate the risk altogether.

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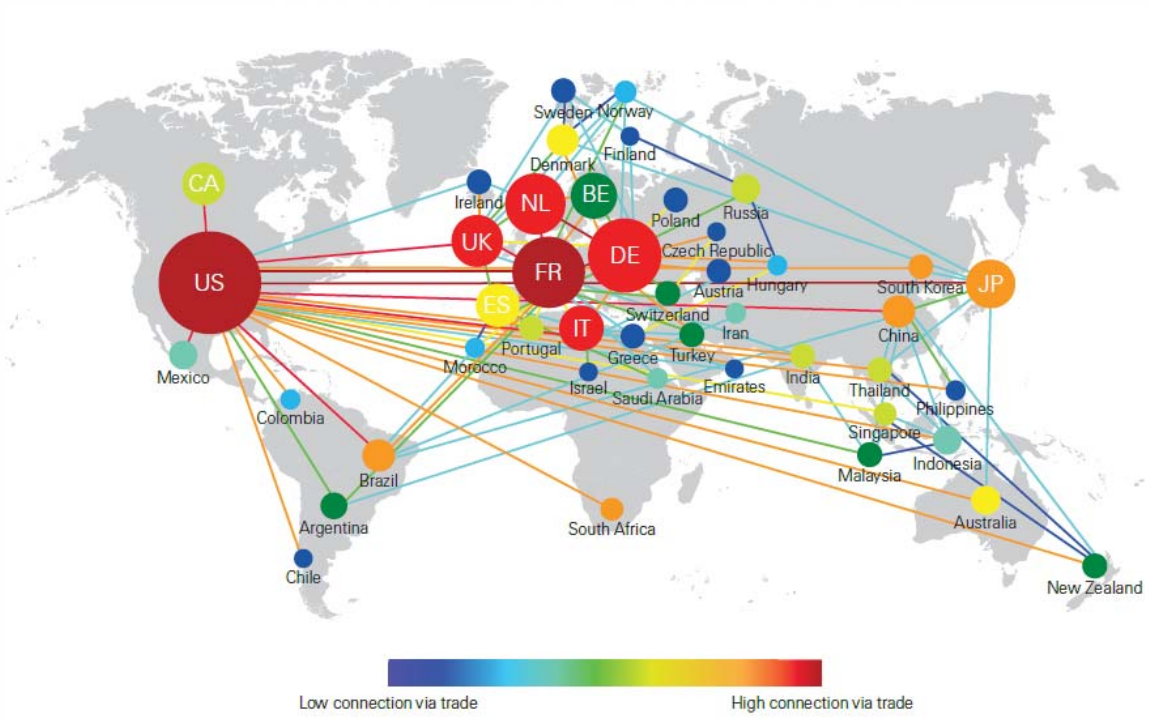
VITAL Approach (Voluntary Incidental Trace Allergen Labeling)

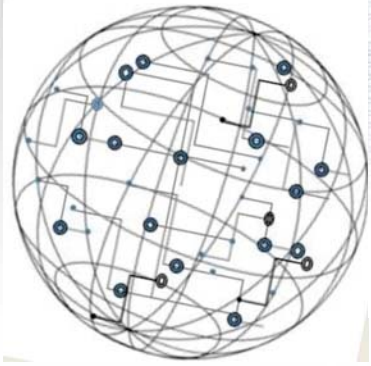
- The Allergen Bureau's VITAL Program is a standardized allergen risk assessment process for food industry.
- VITAL produces a 'labeling outcome' of cross contact allergens in PAL.
  - PAL are used only when warranted
  - PAL are standardized, so providing clear and simple information to consumers
  - Process needs to be traceable and transparent
    - Greater transparency creates more trust between manufacturers and consumers
- Reference doses are evidence-based and recognized by EAACI
- PAL needs to convey accurate information; over-stringent measures reduce food choice, increase anxiety, and affect quality of life.
- Although highly sensitive people may react to the action level, they are more likely to avoid the problematic foods.

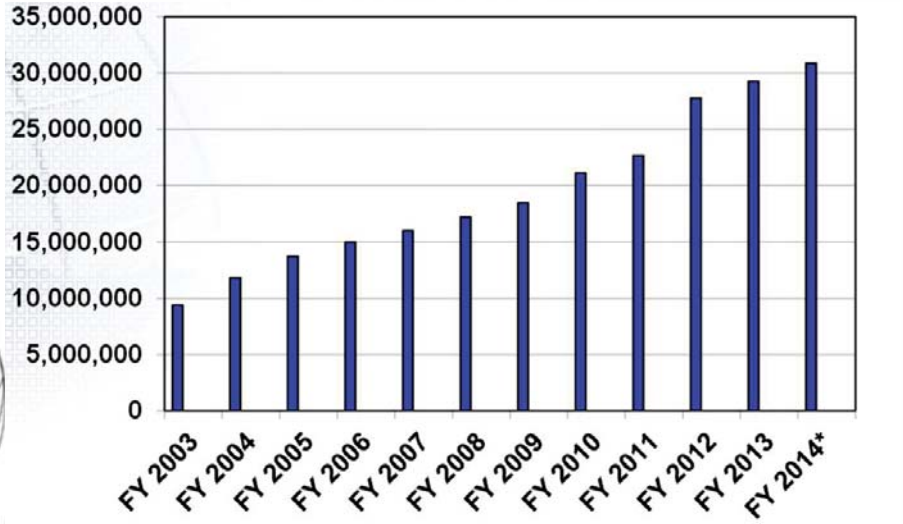
Global Food Trade Network



Source: Swiss Re Food Safety in a Globalized World

Number of Import Entry Lines Electronically Screened since 2002





http://www.fda.gov/downloads/Forindustry/ImportProgram/UCM310772.pdf

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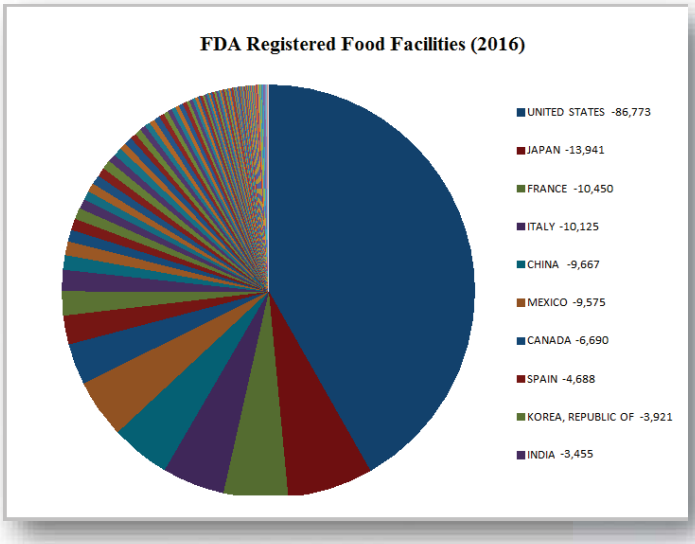
2016 U.S. FDA Food Facility Registration Data – Supply chain vulnerability



http://www.registrarcorp.com/fda-food/registration/data-2016.jsp?lang=en

- Americans each consume about 2,000 lb of food annually, according to USDA.
- About 19%, roughly 390 lb per person, comes from foreign sources.
- U.S. food imports have increased by about 300% since the North American Free Trade Agreement (NAFTA) was adopted.
- Imports:
  - 80% seafood
  - 40% fruits
  - 20% vegetables
- Economically-motivated Adulteration (EMA)
  - e.g. peanut and almond in cumin, 2014

Nestlé Research

How do we compare ?

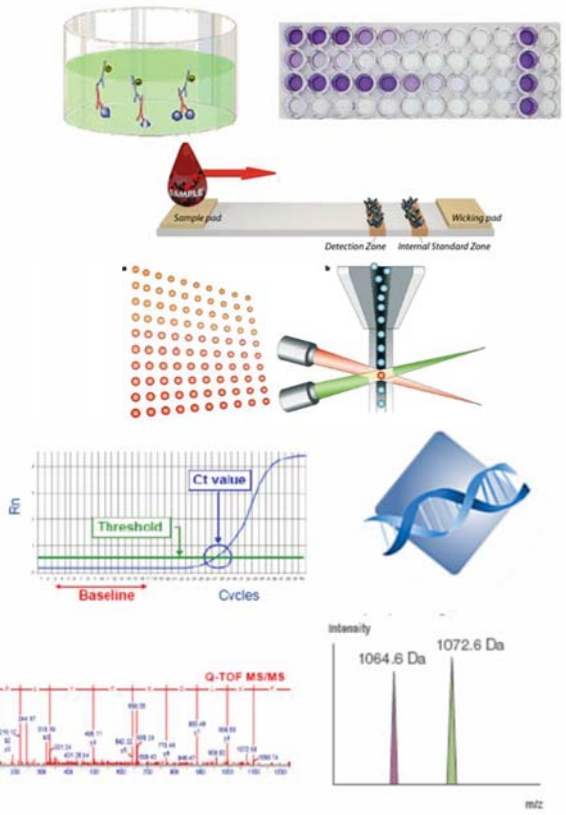
Research

We are here

- No harmonized precautionary allergen labeling (PAL)
  - Loss of consumer confidence
- No recognized thresholds
  - Zero is neither achievable nor scientifically/clinically relevant
  - Over use of PAL
  - VITAL 2.0 – Ref dose is a evidence-based quantitative risk assessment
- No harmonized analytical methods
  - Results are not comparable between different test kits and methods

Allergen Testing

- Results are not comparable between different test kits and methods
- No recognized standard reference materials
- No reference method, except for gluten
- No standardized reporting unit
- No standardized sampling plan



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Is food allergen analysis flawed?

- Key industry standards emphasize transparency, traceability and integrity in the supply chain, which in turn require testing to ensure that food is what it is claimed to be, e.g. labeling claims, gluten-free, surveillance ….
- Presence of peanut and almond (or Mahaleb) in cumin due to initially flawed analysis resulted in hundreds of recalls in 2014-2015
  - Unequivocal presence of peanut proteins
  - False positive for almond by ELISA due to cross reactivity to an unknown spice
  - LC-MS/MS confirmed absence of almond and identified presence of mahaleb
  - Multiplex methods show other possible contaminants: almond, Brazil nut, cashew, hazelnut, and pistachio

JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY
Article
pubs.acs.org/JAFC

Presence of Undeclared Food Allergens in Cumin: The Need for Multiplex Methods

Eric A. E. Garber,*,† Christine H. Parker,† Sara M. Handy,† Chung Y. Cho,† Rakhi Panda,† Mansour Samadpour,‡ Danica H. Reynaud,§ and George C. Ziobro∥

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Is food allergen analysis flawed? (Cont'd)

- Risk assessment and risk management of food allergens depend on the ability to detect and accurately quantify them reproducibly.
- All current analytical methods exhibit deficiencies that jeopardize accurate results and risk false positives and false negatives.
- ELISA is widely used for an extensive period of time, and evidence of deficiencies are published.
- PCR and LC-MS/MS are newer technologies, similar deficiencies are not studied but are expected to be similar.
  - Better proteomic and genomic databases / bioinformatics help
- Uncertainties remain:
  - ✓ Clinical vs Bioinformatics
  - ✓ Reference material vs calibrants
  - ✓ Allergen structural changes by food processing
  - ✓ Impact of food matrix
  - ✓ Extraction efficiency
  - ✓ Quantification depends on markers chosen
  - ✓ Diversity of foods and commodities in global market

Complexity of allergen sampling plan

Where to next ?

	Precautionary Labeling	Thresholds	Analytical Methods
Gaps	Precautionary statements are very confusing to consumers	No recognized thresholds by health authorities No transparent risk-based standards	No reference materials for some No reference method, except gluten No standardized reporting unit
Key tasks	Industry should use uniform precautionary allergen statement, e.g.**may contain [allergen]**	Stakeholders to define a **globally harmonised threshold** to determine the framework for precautionary allergen labeling	Develop reference materials Develop reference methods Standardize reporting unit Develop harmonized sampling plan

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Concluding remarks

- While I realize we have a lot of challenges ahead of us, I believe our opportunities far outweigh those challenges.
- Risk-based food safety and health standards drive innovations and improve quality of life.
- The processes need to be transparent. Transparency creates trust between our services and consumers.
- Only collaborative efforts and buy ins with health care professionals, consumer supporting groups, regulatory agencies and food industry can deliver safe and healthy foods for all.
- Safety is not a business advantage, but the right to all parties.
- We test the product not to check if product is safe; we do it to verify it is.

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Food For Thought

"Our heads are round so our thoughts can change direction."

Francis Picabia

Gerber®

Nestlé Research

Nestlé Research

Nestlé 150 Years of Good Food, Good Life

Nestlé Research

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Kristen Spotz
Grocery Manufacturers Association (GMA)

GMA

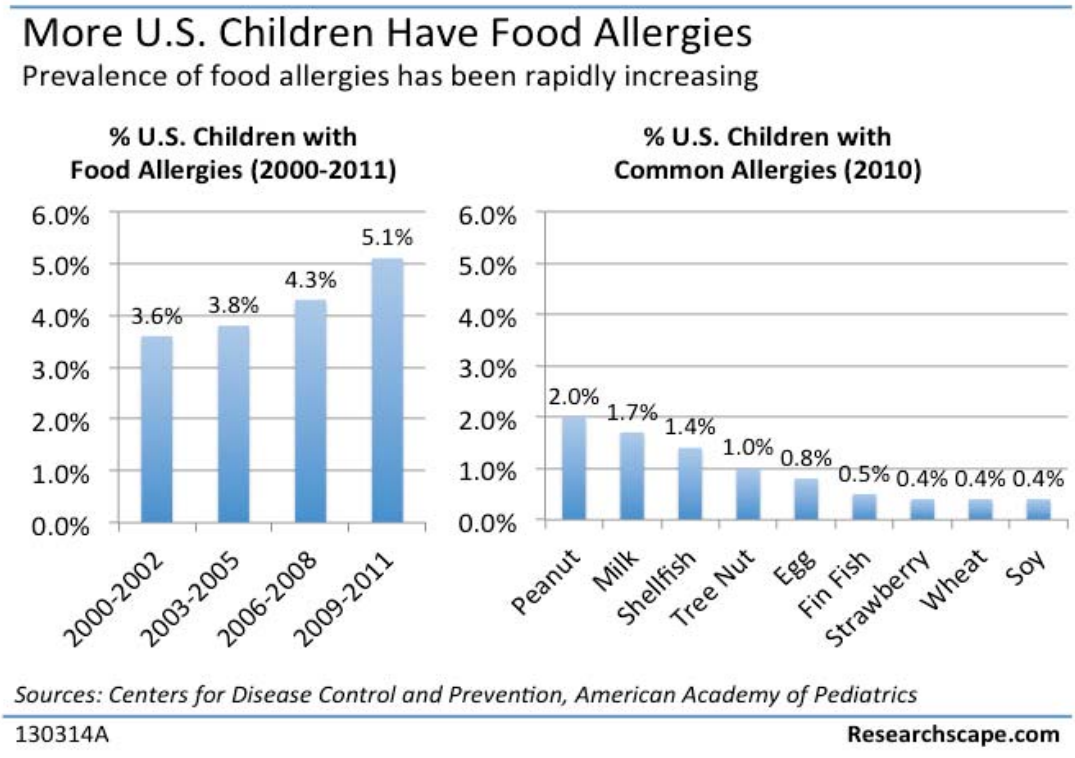
Representing the Makers of the World's Favorite Food, Beverage and Consumer Products

Priorities and Challenges for Food Allergen Detection: Food Industry Perspective

Kristen Spotz
Senior Manager, Food Safety and Quality Assurance
Grocery Manufacturers Association

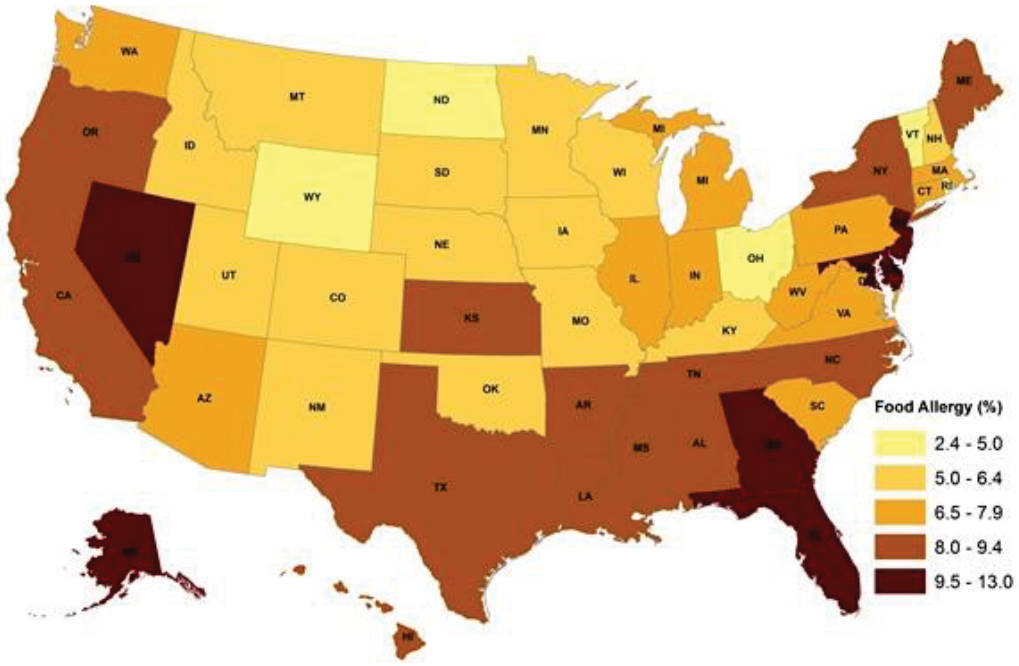
www.gmaonline.org

Clinical Incidence – A growing problem



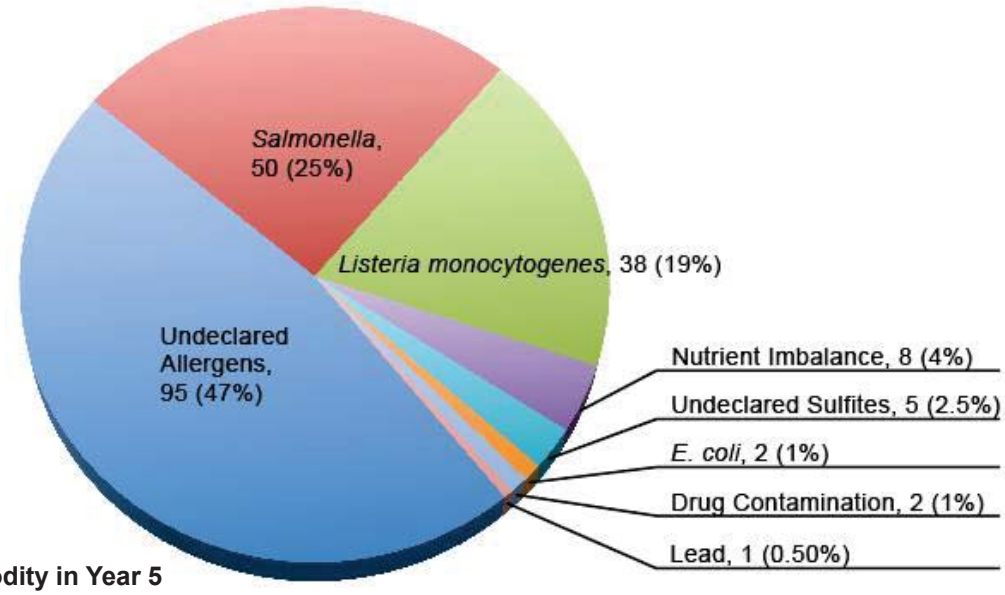
Distribution can be regional and irregular

The prevalence of childhood food allergy by state in the United States (CFAS 2009-2010)



GMA

Distribution of Primary RFR Entries by Food Safety Hazard: 9/18/13 to 9/7/13



Bakery-Top commodity in Year 5 for RFR entries with hazard of undeclared allergens

Source: http://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM502117.pdf

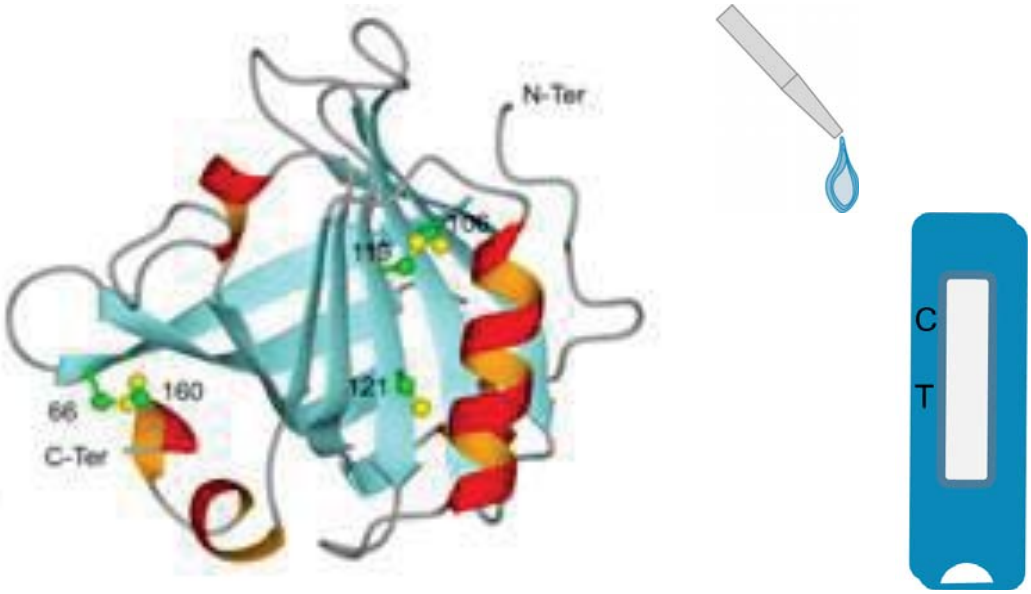
GMA

What is one outcome from the following factors:

- Increasing number of food recalls for undeclared allergens with no end in sight
- Recalls back to the agricultural level for low levels of an allergen in a raw agricultural commodity
- Increasing prevalence of food allergies with some studies showing the prevalence of food allergies has grown by at least 50% since the 1990's

(source: http://www.hopkinsmedicine.org; "Despite Recent Increases in Reported Food Allergy, Study Finds No Change in Antibody Levels Associated with Food Allergy"; Release date of April 25, 2016)

One Outcome is Need for Reliable Detection Methods....



Fundamental Concept Regarding Allergen Sampling and Testing Program

- Ultimately food manufacturers protect those food allergic consumers by a comprehensive programs to prevent allergen cross contact and to properly label products with accurate allergen declarations
- Allergen testing does *NOT* replace a comprehensive allergen management program
- Allergen Testing is *NOT* a control measure; rather, allergen testing may ***Verify*** that programs designed to prevent the unintended inclusion of an undeclared food allergen are effective.

In terms of Method Detection, what are some priority allergen targets?

- Target method detection to the largest allergic population
  - Peanut
  - Milk
  - Egg
- Shift focus to tree-nuts
- Detection of allergens in challenging matrixes (e.g. peanut allergen in peanut oil)
- Focus on allergens with no test methods
  - What priority does method development for these allergens deserve?

What are Some Specific Detection Challenges?

- Fundamental differences between assay types/companies and limit of detection
- Lack of harmonization between reporting units
  - Tendency to just compare ppm which might not be correct
    - ppm milk (powder or liquid) or ppm milk protein (total protein or soluble protein)?
- Cross reactivity with other allergens/non-allergens
  - Important that method will quantify all or most of the active allergens in a food sample
- Ability to detect allergen protein upon food processing (e.g. cooking, roasting)
  - Area requiring specific focus

GMA

Food Categories with Highest Priority

- Candy (chocolate)/Confectionary
- Baked goods (e.g. Muffins and Pastries)
- Snack Foods
- Reference the RFR Annual Report and number of recalls for undeclared allergens by commodity

GMA

Challenges for Implementation of Allergen Testing

- Resources
  - People
  - Space (sometimes no analytical lab available in plants)
  - Time (time for running assays and obtaining results)
    - Total turnaround time must be quick
  - Cost of test (kits)-cannot be cost prohibitive
- Kit availability-As allergen awareness increases, potentially demand for test kits will also increase. Kits have to be readily available with little to no lead time.
- Assays not available for every allergen

Challenges for Implementation of Allergen Testing (continued)…

- What to test and are all test methods appropriate for these applications?
  - Food contact surface swabs
  - Environmental swabs
  - CIP rinse waters
  - Finished product samples
- General knowledge gap
  - What result, after allergen swabbing, indicates that equipment is safe for use? Is it zero?
  - Does 10mg of egg allergen after swabbing 1,500 square cm of a food contact surface represent a real health risk to consumers?

Emerging Priorities and Unmet Needs

- Guidance on sampling plans and sample preparation
  - How much ingredient/finished product to test from the entire production lot
  - What is representative of the lot? (samples from beginning, middle and end of lot?)
- Regulatory Thresholds

Any Questions?

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Markus Lacorn, Ph.D.
R-Biopharm

Since April 2013

R&D Food & Feed: Study Management and Validation at R-Biopharm AG, Germany

- Initialization, planning and documentation of in-house validation projects
- Preparation of Quality Management documents for the validation of assay systems
- Management of approvals for AACC, AOAC, ASBC, ICC
- Membership in following organisations: AOAC, ASBC, OIV, Eurachem, ACS
- Working in the following international organizations as expert: AOAC, AACC, ISO, CEN, DIN, Eurachem, OIV
- Oral and Poster presentations at international congresses; preparation of manuscripts
- Product development: Enzymatic, Allergens
- Expert for: Allergens, Reference Materials, Statistics, Qualitative Methods, Enzymatic methods

April 2008 until March 2013

Group leader Research & Development Food & Feed at R-Biopharm AG, Germany

- Initialization, planning and documentation of new projects
- Reporting to the company management
- Product development and product improvement
- Head of Laboratory for Allergens, Hormones, Antibiotics, Mycotoxins, Microbiology
- Head of Application Laboratory (customers questions, validation, complaints)
- Scientific adviser for bachelor and master students
- Oral and Poster presentations at international congresses; preparation of manuscripts

October 1999 until March 2008

Scientific co-worker at the Institute for Animal Husbandry and Animal Breeding, University of Hohenheim, Stuttgart, Germany; Prof. Dr. Claus

- Head of Laboratory: Chromatography, Immunoassays, Spectrometry
- Scientific adviser for bachelor, master, and phD students
- preparation of manuscripts Oral and Poster presentations at congresses
- Oral lectures and practical laboratory exercises

June 1996 until September 1999

Scientific co-worker at the Institute for Biochemistry and Food Chemistry, University of Hamburg, Germany; Prof. Dr. Dr. Steinhart

- phD study: „Influence of natural and anthropogenic stressors on the induction of metallothionein isoforms in the dab (Limanda limanda L.)
- publications, posters, oral presentations
- own funding by third parties
- initiation of new third party fundings

THINK LEADER ADVISORY PANEL FOR FOOD ALLERGENS/GLUTEN

PRIORITIES AND CHALLENGES FOR FOOD ALLERGEN DETECTION: TECHNOLOGY PROVIDERS

Markus Lacorn (R-Biopharm)

JUNE 15, 2016

AOAC International Headquarters
2275 Research Blvd., Suite 300
Rockville, MD 20860–3250

CEN TC275 WG 12 "Food Allergens"

EN 15842:2010 Detection of food allergens - General considerations and validation of methods

EN 15633-1:2009 Detection of food allergens by **immunological methods** - Part 1: **General considerations**

EN 15634-1:2009 Detection of food allergens by **molecular biological methods** - Part 1: **General considerations**

CEN/TR 16338:2012 **Template** for supplying information about immunological methods and molecular biological methods

CEN TC275 WG 12 "Food Allergens"

CEN/TS 15634-2:2012 **Celery** in cooked sausages by **real-time PCR**

CEN/TS 15634-3:2016 **Hazelnut** in chocolate by **real-time PCR**

CEN/TS 15634-4:2016 **Peanut** in chocolate by **real-time PCR**

FprCEN/TS 15634-5:2015 **Mustard** and **soya** in sausages by **real-time PCR**

-> non-proprietary "open" methods; collaboratively studied

TLA Panel Allergens: priorities and challenges for food allergen detection
June 15, 2016

CEN TC275 WG 12 "Food Allergens" and ISO activities

CEN/TS 15633-2:2013 Quantitative determination of **hazelnut** with an enzyme **immunoassay** using monoclonal antibodies

CEN/TS 15633-3:2012 Quantitative determination of **hazelnut** with an enzyme **immunoassay** using polyclonal antibodies

-> Collaboratively studied

-> Two proprietary methods: This was an exception!

ISO 21572:2013 Molecular biomarker analysis – Protein-based methods developed by ISO TC34 SC16 "Horizontal methods for molecular biomarker analysis" normally dealing with GMO and not allergens

MPR for gluten: CEN activities (I)

- A test kit producer tried to implement a gluten method as CEN standard in 2014
- It is not the intention of CEN to implement proprietary methods as European Standards
- As a consequence, delegates from Germany and JRC introduced the AOAC SMPR approach as a possible solution in spring 2015

TLA Panel Allergens: priorities and challenges for food allergen detection
June 15, 2016

MPR for gluten: CEN activities (II)

- A first MPR version from Austria was not accepted by WG12 due to its broad scope on gluten and allergens
- Consequence: Ad hoc group on gluten was built in March 2016
- Physical meeting in Vienna in April 2016 with a first draft
- Circulation of draft in June 2016 in WG12 with ask for comments

MPR for gluten: CEN activities (III)

- Structure follows CEN requirements but also contains important AOAC SMPR elements
- **Title**: Minimum Performance Requirements for quantitative gluten measurement by ELISA
- **Scope**: …specifies minimum requirements on information and performance for immunological methods that quantify intact or fragmented gluten from wheat, rye, and barley in raw and processed foodstuffs. Information on applicability, antibody, construction of the test system, calibration material, curve fitting algorithm, and reporting of results shall be given by the method provider. Performance characteristics that shall be validated for each method are specificity, selectivity, limit of detection, limit of quantification, cross reactivity, interfering substances, recovery, precision, accuracy, trueness, and robustness.

TLA Panel Allergens: priorities and challenges for food allergen detection
June 15, 2016

MPR for gluten: CEN activities (IV)

- Normative References
- Terms and Definitions: gluten, prolamin, exception for oats
- General information on the test system
- Performance criteria (how to determine…..)
- Overview on Minimum Performance Requirements
  - Table 1: Intact gluten
  - Table 2: fragmented gluten

Parameter	Gluten
Analytical Range [mg/kg]	10 to 40
LOQ [mg/kg]	10
LOD [mg/kg]	5
Recovery [%]	70 to 130
RSD_r [%]	15
RSD_R [%]	30
Specificity	Gluten from wheat, rye, and barley

MPR for gluten: CEN activities (V)

- 5 persons in a physical meeting
- 1.5 day of work for the draft
- Quantitative gluten only
- Give guidance on how to determine “performance”
- disputed issues (e.g. LoD and LoQ) will be solved at WG12 level
- Make changes possible
- Only methods studied collaboratively will be considered
- This draft will be used as a template for allergens if WG12 could agree on it

TLA Panel Allergens: priorities and challenges for food allergen detection
June 15, 2016

RT-PCR advantages

- Very specific
- consistent/common extraction
- DNA often more stable than proteins during processing
- Multiplexing possible
- Open and standardized methods (see CEN)

RT-PCR disadvantages

- If "quantitative" - Not traceable to amount protein or commodity
- Matrix effects (inhibitors from spices or chocolate)
- Not suitable for egg and milk

TLA Panel Allergens: priorities and challenges for food allergen detection
June 15, 2016

Possible targets (PCR)	Priority targets (ELISA)
celery	gluten (wheat, rye, and barley)
fish	egg
mustard	milk (not only cow)
almond	Peanut
wheat-rye-barley	casein, soy
differentiation	

New techniques on the horizon

Iso-thermal PCR -> not for routine yet

Digital PCR -> not for routine yet

Next generation sequencing -> not for routine yet

-> no priority now but maybe in a few years

TLA Panel Allergens: priorities and challenges for food allergen detection
June 15, 2016

Food matrices: examples from categories

- We cannot cover all matrices -

Heated:	cookies or bread
Polyphenols:	chocolate or cocoa based
Acid:	juice or wine
Raw and easy:	cereals (rice flour)
Fat and protein:	sausages
Important:	Infant formulas
Gluten-free:	special needs

Proposal

Normally the choice of validated matrices is customer driven

but for comparison (->SMPR),

all test kit could be validated with cookies, chocolate, and cereals

(recipes were checked by Qlab during an PTM approval)

TLA Panel Allergens: priorities and challenges for food allergen detection
June 15, 2016

Do not forget

Sampling / homogeneity (e.g. gluten in oats)

Standardization of calibrator materials by MoniQA

Thresholds - CRMs - sensitivity

Different validation guidelines e.g. EURACHEM, CEN and AOAC

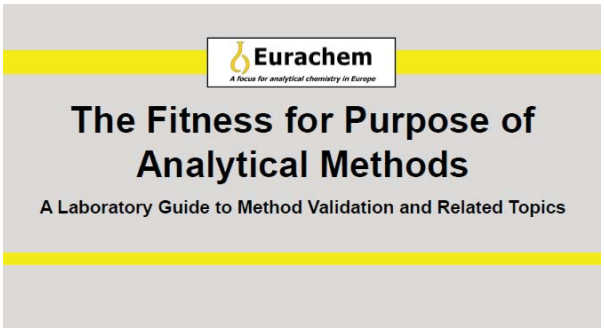
Environmental aspects: user safety and toxic waste

Common extraction for (groups of) allergens

Quantitative (multiplex) LFDs (with reader)

Collaborative tests for surface swabbing and analysis

Thank you


Eurachem
A focus for analytical chemistry in Europe
The Fitness for Purpose of Analytical Methods
A Laboratory Guide to Method Validation and Related Topics

INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Scott Radcliffe, Ph.D.
Romer Labs

Scott Radcliffe is a technical support scientist, application developer and trainer at Romer Labs, focusing on immunoassays for detection of food allergens. He has been published in the Journal of AOAC International and the International Journal of Celiac Disease, and regularly presents research posters at meetings of IAFP and AOAC International. Prior to joining Romer Labs in 2013, Scott worked to develop hepatotoxicity screening methods for Johnson & Johnson, and researched cardiomyocyte receptor signaling in response to catecholamine toxicity for Thomas Jefferson University. Scott earned a B.S. in Biology from Lebanon Valley College in 2000, and an Advanced Graduate Certificate in Cell, Molecular and Developmental Biology from Villanova University in 2013.

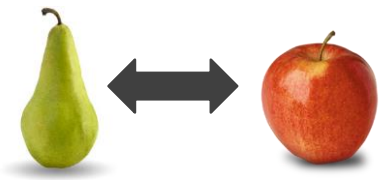
Priorities and Challenges for Food Allergen Detection: Immunoassays

Scott Radcliffe, Romer Labs

The problem with ELISA test kits…

Comparability!

A variety of factors contributes to the different performance of ELISA test kits for the same allergen.



"The result of which ELISA kit is correct?"

Making the World's Food Safer®

ROMER Romer Labs®

Contribution from I. Taverniers (ILVO) & N. Gillard (CER)

Belgian NRL-Allergens (2 labs + Federal Food Safety Agency)

Validation study: ELISA and qPCR detection of traces of peanut in rice, cookies, and cumin powder (2015) - **Setup**

- 3 matrices – 4 x 4 samples
  - Rice spiked with unroasted peanuts
  - Rice with roasted peanuts
  - Baked biscuits with unroasted peanuts;
  - Cumin powder with roasted peanut
- Spiked levels except cookies: 50-20-2-0 ppm peanut
- Spiking procedure: stock of 40.000 ppm peanuts-in-matrix first made (10 g nuts in 250 g matrix); then diluted further in matrix
- Final concentrations of peanut in cookies: 20-8-0,8-0 ppm
- Homogeneity tested at CER-Groupe
- 9 commercial ELISA kits tested in 2 labs
- 2 commercial qPCR kits tested in 2 labs

→ Are kits able to detect down to (claimed) LOD values (0,3-1 ppm total peanut)?
→ Are kits able to quantify accurately down to (claimed) LOQ values (0,8-4 ppm total peanut)?
→ Are kits' results reproducible?

Making the World's Food Safer®

ROMER Romer Labs®

Contribution from I. Taverniers (ILVO) & N. Gillard (CER)

Belgian NRL-Allergens (2 labs + Federal Food Safety Agency)

Validation study on peanut detection – **Data Summary**

matrix	ppm peanut	ELISA 1		ELISA 2		ELISA 3		ELISA 4		ELISA 5		qPCR 1		qPCR 2	
		CER	ILVO	CER	ILVO	CER	ILVO	CER	ILVO	CER	ILVO	CER	ILVO	CER	ILVO
Rice + unroasted peanut	0	< LOQ	< LOQ	1,56	< LOQ	< LOQ	5,84	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	1,48	< LOQ
		< LOQ		1,53	< LOQ	< LOQ	-1,28	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	2,06	< LOQ
	2	23,4	5,2	16,72	25,18	10,53	-5,22	< LOQ	1,5	26,62	17,20	< LOQ	2,03	8,00	9,43
		21,2		17,28	25,71	10,30	-2,13	< LOQ	< LOQ	24,87	18,22	< LOQ	1,76	8,95	9,51
	20	> 25	51,9	54,70	99,02	41,74	23,34	4,56	5,2	31,69	93,25	9,31	4,64	91,02	35,97
		> 25		53,96	97,15	41,58	25,22	4,21	4,6	28,90	91,68	9,51	3,51	101,20	37,21
	50	> 25	242,7	61,17	212,84	85,94	126,74	11,7	11,9	32,66	227,31	38,77	7,13	159,86	55,88
		> 25		60,13	221,10	83,27	25,57	10,36	12,7	25,93	241,86	36,67	6,15	169,68	56,35
Cookies + unroasted peanut	0	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	34,53	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
		< LOQ		< LOQ	< LOQ	< LOQ	44,83	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	0,8	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	23,45	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
		< LOQ		< LOQ	< LOQ	< LOQ	13,14	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	8	4,3	6,3	2,28	< LOQ	< LOQ	92,29	< LOQ	< LOQ	2,69	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
		4,3		2,41	< LOQ	< LOQ	70,56	< LOQ	< LOQ	2,63	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	20	> 25	19,9	19,53	20,14	12,06	119,25	< LOQ	< LOQ	22,78	< LOQ	5,57	7,46	2,83	< LOQ
		> 25		18,55	17,93	11,60	69,60	< LOQ	< LOQ	23,94	< LOQ	4,36	6,11	2,90	< LOQ

Lab variation

Kit variation

Method variation

Processing influence

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Contribution from I. Taverniers (ILVO) & N. Gillard (CER)

Belgian NRL-Allergens (2 labs + Federal Food Safety Agency)

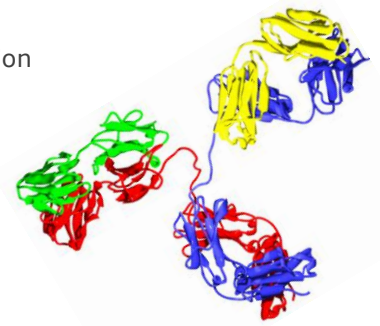
Validation study on peanut detection - **Conclusions**

- ELISA and qPCR useful for peanut detection and quantification
- Quantities obtained by qPCR in rice might be slightly more accurate (more true compared to the expected/theoretical values) than quantities obtained by ELISA
- **Kit to kit** variation
- **Matrix to matrix** variation:
  - Baked cookies, cumin powder less applicable matrices in this study (influence of **processing**)
  - Effect of mixing flour to other cookies ingredients and the effect of high-temperature baking clearly observed, in terms of less detection and quantification in both ELISA and qPCR
  - This effect was even stronger for qPCR compared to ELISA
- Variation **between the two labs** who used exactly the same test materials for exactly the same set of 11 peanut test kits

Factors influencing ELISA measurements

Antibodies

- Monoclonal or polyclonal
- Target of the antibody: single/several proteins, fractionated, modified, synthesized
- Material used for immunization



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What are we looking for?

Identify the target:

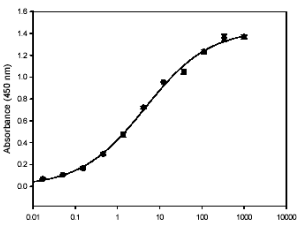
Raw protein or processed commodity?

- Choose antibodies accordingly
- Similar calibrators
- **SMPR's can harmonize allergen methods, but will be most effective if allergen reference standards identified**

Factors influencing ELISA measurements

Calibrators

- Match the antibodies of the kit
- Not the same as sample material



Extraction

- What is extracted (efficiency)?
- Antibody can only detect what has previously been detected

Factors influencing ELISA comparability

Limit of Detection (LOD)

- Lowest amount of allergen to be distinguished from a true blank
- LOD mostly determined in buffer
- May be completely different in food samples

Recovery

- Ideally 80 – 120%
- Not possible for all matrices (pH, salts, polyphenols,…)
- Spiked vs. incurred samples

Matrix Choices: Sources of Interference

- High protein concentration
- High lipid concentration
- High polysaccharide concentration
- Extremes of pH
  - May push past pH-buffering capacity of kit reagents
- Reactive biomolecules
  - Polyphenols
  - Tannins
  - Anthocyanins

Should choose matrices which test ability of the assay to buffer sources of interference

Matrix Choices: Allergen Material

- Incurred
  - Better option – allergen processed along with food matrix
  - True evaluation of extraction efficiency
  - Difficult to design/predict allergen levels precisely
  - Challenge for method developer
  - Some incurred RM available for purchase
  - No CRM
  - Reasonable goal could be one incurred RM per allergen for validation of trueness

Matrix Choices: Allergen Material

- Spike
  - Necessary when validating more than a couple matrices
  - Necessary for certain matrices which cannot be produced in lab
  - Generally recover close to 100% of spike
  - Useful for measuring precision, interference
  - Allergen extract vs whole allergen
  - Homogeneity

Factors influencing ELISA comparability

Cross reactivity

- Positive response to a sample without target allergen
- Test products genetically similar to target allergen
- Different response than in study possible:
  - raw vs. processed product
  - variations within globally used cultivars

Factors influencing ELISA comparability

Cross reactivity

- Choose appropriate cross reactivity panel based on:
  - Genetic closeness
  - Tree of life closeness
  - Search for conserved domains
- Panel should not only be exclusive, but also inclusive:
  - Bovine/sheep/goat milk reactivity
  - Gliadin/hordein/secalin reactivity
- Consider cross reactor panel choices from international perspective

Factors influencing ELISA comparability

Immunological test system

- Environmental influences
- Experimental conditions
- Stability affected by transport & storage conditions
- Robustness vs ruggedness

Summary

- Food allergens are extremely diverse
- Significant variability of results between immunoassay methods, labs, matrices
- No certified reference standard
  → no common reference point for ELISA comparison
- Many matrix factors influence accuracy – take into account when choosing matrices
- Consider both inclusivity and exclusivity when testing cross reactors
- Consider both robustness and ruggedness

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Thank you!

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INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Brooke Schwartz

Principal, Brooke Schwartz Consulting

Brooke Schwartz Consulting assists companies with the commercialization and adoption of new technologies in food safety. Applications include detection and identification of pathogens, residues, toxins, allergens and adulterants in food and environmental samples; antimicrobial interventions in food processing; and information management for food safety.

Brooke Schwartz is a business leader with over 20 years of general management, strategy and business development experience in life science, food and agriculture, and consumer markets. Ms. Schwartz currently serves as Chair of the AOAC Research Institute, an international standards organization that validates testing methods. She recently chaired the AOAC International Fresh Produce Initiative, which led stakeholders from the global produce industry, testing industry, and regulatory agencies in standards development for produce safety. Previously she served on the Corporate Leadership Council of the Association of Public Health Laboratories. She has been a featured speaker at global industry meetings including the International Conference on Fresh-cut Produce and the China Food Safety & Quality Conference.

Ms. Schwartz has held business management and corporate development roles at Applied Biosystems / Life Technologies. As Business Segment Leader for Food and Environmental Testing, she led the re-launch of the AB/Life global food testing business. Previously she led strategy and innovation engagements for Deloitte Consulting's Health Care and Life Science practice, and managed a global consumer chemicals business for Monsanto Company. She began her career as a policy analyst and trade negotiator for the U.S. Department of Agriculture.

Ms. Schwartz's public service leadership includes serving as Trustee of the National Organization of Girls Incorporated and as a board member of the Alameda County affiliate of Girls Inc. She has led pro bono consulting engagements for the California Academy of Sciences, the Bay Area Red Cross, and KQED Public Media.

Ms. Schwartz earned an M.B.A from the Harvard Business School, an M.S. in Food and Resource Economics from the University of Florida, and a B.A. in Latin American Studies from the University of California, Los Angeles. She speaks Spanish and Portuguese.

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Technology Provider Perspectives

Emerging Technologies for Allergen Detection

International Stakeholder Panel on Alternative Methods (ISPAM)
Advisory Panel on Food Allergens

Brooke Schwartz

June 15, 2016

AOAC INTERNATIONAL

Pre-commercial technologies for allergen detection

Technology developers are working to develop a range of systems to address unmet allergen detection needs. Capabilities in development include:

- Small, portable, rugged detection platform for allergen detection
  - Battery powered for use in lab, plant and field
- Ability to detect up to 20 targets in a sample
  - Single, simplified extraction method across analytes
  - 10-minute time to results
- Single system that can do quantitative, semi-quantitative or qualitative allergen testing
- Ability to detect molecular targets plus proteins in same sample
- Ability to test samples for a broad range of allergens and other contaminants using a universal DNA test.
- Ability to simultaneously test for allergens and toxins in a single sample
- Ability to simultaneously test for expected and unexpected allergens, toxigenic plants, bacteria and adulterants in a single sample

Issues and Background

- As method developers prepare to commercialize products, they are looking to industry for guidance on standards-related questions, as well as features most needed by industry.
  - Most important detection targets?
  - Should methods detect DNA vs. protein?
  - Should methods detect denatured proteins?
  - Qualitative, quantitative, or semi-quantitative tests?
  - How important is the ability to detect multiple targets?
  - Is there value to detecting unexpected targets?

To participate in the working group for “Food Allergen” Click Here

or

https://form.jotform.com/61316935887165