AOAC INTERNATIONAL Standards Development

- E. James Bradford, Ph.D. - Executive Director
  June 29, 2010
Standards

- Common and repeated use of rules, conditions, \textit{guidelines or characteristics for products or related processes}.

- The definition of terms; classification of components; delineation of procedures; processes, products, systems, services, or practices; \textit{test methods and sampling procedures}.
Standards

- A *Performance standard* is a standard that states requirements in terms of required results with criteria for verifying compliance but without stating the methods for achieving required results.

- *Voluntary Consensus standards* are standards developed or adopted by *voluntary consensus standards bodies*, both domestic and international.
Voluntary Consensus Standard Bodies

- Domestic or international organizations that plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures.

- Voluntary consensus standards can only be established via a participatory process involving the federal government, the state governments, academia, and especially the private sector.
OMB A-119 and NTTAA

- US OMB Circular A-119
  - Standards developed by voluntary consensus standards bodies are often appropriate for use in achieving federal policy objectives and in conducting federal activities, including procurement and regulation.
  - Encourages federal agencies to benefit from the expertise of the private sector
  - Promotes federal agency participation in such bodies to ensure creation of usable standards
  - Reduces reliance on government-unique standards
OMB A-119 and NTTAA

- **National Technology Transfer and Advancement Act of 1995**
  - Directs federal agencies with respect to their use of private sector standards and conformity assessment practices.
  - Directs federal agencies to adopt private sector standards, wherever possible, in lieu of creating proprietary non-consensus standards.
  - Codified existing policies in A-119, established reporting requirements, and authorized the National Institute of Standards and Technology (NIST) to coordinate conformity assessment activities of federal agencies.
More than 600 nongovernmental organizations comprise the U.S. standardization system. Approximately 19 of these standards developing organizations (SDOs) generate the vast majority of standards in the United States. These SDOs include:

1. ASTM International;
2. Association of American Railroads (AAR);
3. American Association of Cereal Chemists (AACC);
4. American Association of State Highway and Transportation Officials (AASHTO);
5. American Conference of Government Industrial Hygienists (ACGIH);
6. American Oil Chemists Society (AOCS);
7. American Petroleum Institute (API);
8. American Railway Engineers Association (AREA);
9. American Society of Mechanical Engineers (ASME),
10. U.S. Pharmacopia;
11. **Association of Official Analytical Chemists (AOAC);**
12. Cosmetic, Toiletry and Fragrance Association (CTFA), now known as the Personal Care Products Council;
13. Society of Automotive Engineers (SAE);
14. Aerospace Industries Association (AIA);
15. Electronic Industries Association (EIA);
16. Institute of Electrical and Electronics Engineers (IEEE);
17. Technical Association of the Pulp and Paper Industry (TAPPI),
18. Underwriters Laboratories (UL); and

These 19 leading private sector standards developers produce standards that encompass a spectrum of industry sectors, including: aerospace; electronics; automotive and mechanical engineering; petroleum products; chemicals; pulp and paper; and cosmetics. This group also includes developers of safety-related standards, such as those for fire protection, industrial hygiene, consumer product safety, and industrial product safety and protection.
As an international Standard Developing Organization, AOAC must maintain the following principles throughout all standard setting activities:

- Transparency
- Openness
- Balance of Interests
- Due Process
- Appeals
- Consensus
Transparency

- Clearly identifying the scope of work to be undertaken
- Providing information and conditions for participation
- Providing an opportunity for all interested parties to comment prior to final approval or adoption
- **Openness**
  - Process is open to participation by all materially affected interests.

- **Balance of Interests**
  - No one interest should dominate the process.

- **Due Process & Appeals**
  - Any person with a direct interest can:
    - Express a position and the basis for it;
    - Have that position considered; and
    - Appeal if adversely affected
Consensus

- The adoption of group conclusions, with fair and serious consideration given to the opinion of each group member.

- general agreement, but not necessarily unanimity.

- a process for attempting to resolve objections by interested parties.
References

- NTTAA (PL 104-113) (1996)
The Process

- AOAC establishes a stakeholder panel with the advice of an Advisory Panel
From this stakeholder panel, AOAC appoints a subset as voting members.
This enables AOAC to control the balance of the voting members from government and industry.
Thank you all for your participation!
AOAC Standards Development

DEBORAH MCKENZIE
AOAC INTERNATIONAL

DEVELOPMENT OF VOLUNTARY CONSENSUS STANDARDS
JUNE 29, 2010
Overview

1. Introduction to AOAC Products and Services
2. Standards Development Processes
3. Meeting Goals
AOAC is very old and well known

- AOAC was founded in 1884 to bring about agreement on contentious issues. AOAC standards are recognized and accepted by governments and commercial interests all over the world.

- This brings credibility to standard setting.

- AOAC brings the transparency of a third party standard developing organization to the project.
AOAC INTERNATIONAL Overview

- Founded in 1884
- ~ 3000 members worldwide
- 38 Organizational Affiliate Members
- 17 regional sections worldwide
- 8 scientific interest specific analytical communities
- Only US accredited laboratory proficiency testing program
- Publish *Official Methods*SM of Analysis
- Research Institute (RI) - 1991 as a subsidiary
Organizational Overview

- Official Methods of Analysis™
- The Journal of AOAC INTERNATIONAL
- Inside Laboratory Management Magazine
- Sections
- Technical Divisions
- Annual Meeting
- Standards Development
- Expert Review Panels
- Training Courses
- Proficiency Testing
- Laboratory Auditing
- Research Institute & Performance Tested Methods™
- Analytical Communities
- Relevant Methods Committees
- Analytical Communities
AOAC is made up of volunteers

**Board of Directors**
- Volunteers elected by the AOAC INTERNATIONAL membership
- Set policy
- Guide and provide strategic direction to the Association in support of its mission and vision
- President appoints methods volunteers
AOAC is made up of volunteers

- **Official Methods Board (OMB)**
  - Recommend and implement policy
  - Consider feedback on First Action Methods for and render a decision on Final Action status
  - Reviews and approves appointments for
    - Methods Committees
    - Methods Advisors
    - Study Directors
    - **Stakeholder Panel Chair(s) and Voting Members**
    - Expert Review Panel Chair(s) and Voting Members
AOAC is made up of volunteers

- AOAC’s volunteers will participate in stakeholder discussions, but will not vote.

- Method volunteers render decisions to approve or deny stakeholder recommendations separately from the stakeholder panel and in accord with AOAC’s policies.

- Method volunteers render decisions to approve or deny study design protocols and validation study manuscripts in accord with AOAC’s policies.

- This provides legal defensibility to standard setting (Daubert ruling).
Standards Development and Stakeholders

- AOAC conforms to NTTAA* and therefore includes all stakeholder perspectives.

  National Technology Transfer Advancement Act (Public Law 104-113) – coordination of federal standards and conformity assessment activities with private sector standards and conformity assessment activities.

- AOAC and the Steering Committee will designate a finite number of voters in the stakeholder panel representing the various perspectives.
Steering Committee (Advisory Panel)

- Formed to discuss the goals of the stakeholder panel
- Propose working objectives by which to achieve those goals.
Advisory Panel Goals

- Develop an agenda for stakeholder panel meeting
- Identify stakeholder perspectives and review and propose additional stakeholders and experts to AOAC
- Propose potential working groups and working group champions and members
Stakeholder Panel Composition

- Stakeholder Chair
- Subject Matter Experts
- Method Developers
- Government/Regulators
- Method End Users
- Academia
- Contract Research Organizations
- Other....
Stakeholder Panel Working Groups

- Can meet prior to stakeholder meeting

- Will present motions to the stakeholder panel on:
  - Analytes
  - Matrix(ces)
  - Level of Validation (i.e. single laboratory, full collaborative study, or other)
  - Type of Method(s)
  - Fitness for Purpose
  - Method Performance Criteria
    - Analytical range
    - Purpose or need for the method(s)
    - Reference and internal standard(s)
    - Matrix effects
    - Recommended Precision/Recovery
AOAC will carefully document the proceedings of the stakeholder panel and the working groups.

AOAC will prepare summaries of the proceedings:
- Communicate summaries to the stakeholders
- Publish summaries in the *Referee* section of AOAC’s *Inside Laboratory Management*
Stakeholder Panel Product

- **Voluntary Consensus Based Standard**
  - Standard method performance requirements
  - Published in *Official MethodsSM of Analysis*
  - Published in Journal of AOAC INTERNATIONAL
The published SMPR documents will contain:

- Fitness for Purpose statement
- Analytes
- Matrix(es) (i.e. surface water located near poultry, swine, and dairy animal feeding operations (AFOs))
- Level of Validation (i.e. single laboratory, full collaborative study, or other)
- Type of Method(s) (i.e. ELISA-based)
- Method Performance Criteria
  - Analytical range
  - Purpose or need for the method(s)
  - Reference and internal standard(s)
  - Matrix effects
  - Recommended Precision/Recovery
Ongoing Standards Development Efforts

- Stakeholder Panel on Agent Detection Assays
  - Department of Homeland Security
  - Threat Agent Methodology (Ba PCR technology)

- Stakeholder Panel on Endocrine Disrupters
  - EPA
  - Endocrine Disrupters in surface water and waste water runoff
After SMPR Development

- Method developers can
  - Can develop and optimize their methods based on the Standard Method Performance Requirements
  - Can submit their method(s) for validation
AOAC is an independent third party

- AOAC has no vested interest in the evaluation of methods. This provides an effective firewall between the government, the method developers, industry, and the end users.

  - Conformity Assessment Activities
  - Standards Development Activities
Conformity Assessment

- **Official Methods**$^\text{SM}$ of Analysis

- **Performance Tested Methods**$^\text{SM}$
## Basic Program Comparison

<table>
<thead>
<tr>
<th>Official Methods℠ of Analysis</th>
<th>Performance Tested Methods℠</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internationally recognized</td>
<td>Single laboratory validation</td>
</tr>
<tr>
<td>8-10 labs valid data</td>
<td>Independent laboratory verification</td>
</tr>
<tr>
<td>Assesses interlaboratory reproducibility</td>
<td>Database of 146 methods</td>
</tr>
<tr>
<td>Compendium of more than 2700 methods</td>
<td>OMA method volunteer &amp; two expert reviewers</td>
</tr>
<tr>
<td>Official Methods Board &amp; Method volunteer and consensus processes</td>
<td>Certification based on consensus of peer review</td>
</tr>
<tr>
<td>First Action approval based on consensus of peer review</td>
<td>Annual review and certification renewal</td>
</tr>
<tr>
<td>Final Action approval based on real time method performance</td>
<td>Proprietary /commercial methods</td>
</tr>
<tr>
<td>Nonproprietary and proprietary methods</td>
<td></td>
</tr>
<tr>
<td>US Code of Federal Regulations</td>
<td></td>
</tr>
</tbody>
</table>
**Official Methods℠ of Analysis**

- 18th edition, 3rd revision
- Manuscripts published in the Journal of AOAC INTERNATIONAL
- Final Action review after two years
- www.aoac.org
## Performance Tested Methods℠

### Food Allergen Test Kits

<table>
<thead>
<tr>
<th>TEST KIT NAME</th>
<th>MANUFACTURER</th>
<th>CATALOG NUMBER</th>
<th>LICENSE NUMBER</th>
<th>ORIGINAL CERTIFICATION DATE</th>
<th>ANALYTE</th>
<th>MATRICES</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioKits Peanut Assay Kit</td>
<td>Gen-Probe/Temple BioSystems, Ltd.</td>
<td>902040G</td>
<td>030402</td>
<td>May 9, 2003</td>
<td>peanuts</td>
<td>Breakfast cereal, Cookies/Biscuits, Ice Cream, Milk Chocolate, Plain Chocolate, Malted Nuts</td>
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<tr>
<td>Veritox® for Peanut Allergen</td>
<td>Neogen Corporation</td>
<td>8430</td>
<td>030403</td>
<td>May 13, 2003</td>
<td>peanuts</td>
<td>Breakfast cereal, Cookies, Ice Cream, Milk Chocolate</td>
</tr>
<tr>
<td>RIDASCREEN® FAST Peanut</td>
<td>R-Biopharm AG</td>
<td>R6202</td>
<td>030404</td>
<td>May 13, 2003</td>
<td>peanuts</td>
<td>Breakfast cereal, Cookies, Ice Cream, Milk Chocolate</td>
</tr>
<tr>
<td>RIDASCREEN® Gluten</td>
<td>R-Biopharm AG</td>
<td>R7001</td>
<td>120601</td>
<td>December 12, 2006</td>
<td>gluten, secalins, hordenins</td>
<td>wheat, buckwheat, rice, corn, oats, syrup, and sausage</td>
</tr>
</tbody>
</table>

### Microbiological Test Kits

<table>
<thead>
<tr>
<th>TEST KIT NAME</th>
<th>MANUFACTURER</th>
<th>CATALOG NUMBER</th>
<th>LICENSE NUMBER</th>
<th>ORIGINAL CERTIFICATION DATE</th>
<th>ANALYTE</th>
<th>MATRICES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxoid Listera Rapid Test</td>
<td>Oxoid Ltd.</td>
<td>none</td>
<td>960701</td>
<td>September 2, 1996</td>
<td>Listera spp.</td>
<td>food and environmental samples</td>
</tr>
<tr>
<td>Reveal Salmonella Test</td>
<td>Neogen</td>
<td>0710, 0720, 0730, 0740</td>
<td>none</td>
<td>September 4, 1996</td>
<td>Salmonella spp.</td>
<td>food</td>
</tr>
</tbody>
</table>

[www.aoac.org/testkits/testedmethods.html](http://www.aoac.org/testkits/testedmethods.html)
Thank you.

Questions?