



# AOAC Official Methods Board Orientation 2016-2017

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AOAC Research Institute

**September 2016**

# Outline

- AOAC Overview
- AOAC OMB Terms of Reference
- OMB Role and Responsibilities Summary
- AOAC Standards Development Overview
- AOAC Conformity Assessment Overview
- AOAC OMB Awards

# AOAC INTERNATIONAL

- Founded in 1884 in Philadelphia, Pennsylvania, USA
- Established the *Official Methods of Analysis*<sup>SM</sup> Program
- < 2700 *Official Methods of Analysis of AOAC INTERNATIONAL*
- Governed by a membership-elected volunteer Board of Directors
- 17 sections worldwide including China and India
- Analytical method based communities - chemistry and microbiology methods
- ~ 3000 members worldwide including 42 **organizational affiliate members**
  - 1/3 of members overseas
- Established a wholly owned subsidiary – AOAC Research Institute
- Standards development and conformity assessment

# About AOAC INTERNATIONAL

**AOAC is a scientific standards development association dedicated to analytical excellence.**

- ~ 3000 members worldwide including **organizational affiliate members**
  - 1/3 of members overseas
- Established a wholly owned subsidiary – AOAC Research Institute
  - administers AOAC conformity assessment programs
- Maintains 16 active international sections representing over 90 countries
- Develops voluntary consensus standard method performance requirements (SMPRs)
- Publishes the *Official Methods of Analysis of AOAC INTERNATIONAL*
- Maintains an accredited Laboratory Proficiency Testing Program
- Governed by a membership-elected volunteer Board of Directors

EST. 1884

**AOAC® INTERNATIONAL (AOAC) is an independent third-party international standards developing organization and AOAC has no vested interest in the development of standards or in the evaluation of methods of analysis.**

# About AOAC INTERNATIONAL

AOAC leverages its networks to gather stakeholders and experts to:

- Develop international voluntary consensus standards method performance requirements
- Discuss & adopt methods that are published in the *Official Methods of Analysis of AOAC INTERNATIONAL* using judgment of the world's leading experts.

**Providing fit for purpose methods through standards development**

● General Locations of AOAC stakeholder panel participants      ● General Locations of the 16 AOAC INTERNATIONAL current Sections

# About AOAC INTERNATIONAL - Resources



## Technical Division for Laboratory Management

Providing the Information You Need to Manage An Efficient, Cost-Effective Quality Laboratory



## Technical Division on Reference Materials

Improving the Quality of Laboratory Measurements through the use of Reference Materials

Analytical Communities



AOAC's Proficiency Testing Program

**SMPR<sup>SM</sup>**



**Organizational Affiliate Membership  
AOAC INTERNATIONAL**

The Highest Membership Level of Engagement and Involvement



**AOAC Mid-Year Meeting**

**AOAC**  
Annual Meeting & Exposition



**Sustaining Member Organization**

**AOAC INTERNATIONAL**

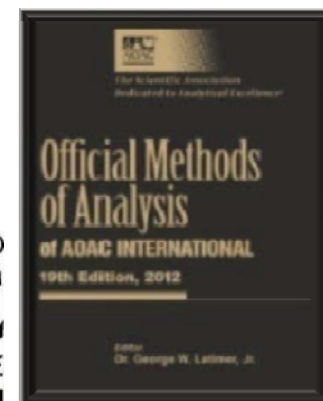
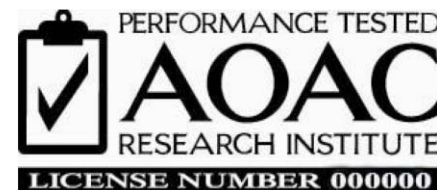
Providing Specific Benefits to Fit Your Needs



**Student Membership**

**AOAC INTERNATIONAL**

Get on Track for a Career Dedicated to Analytical Excellence



# About AOAC INTERNATIONAL

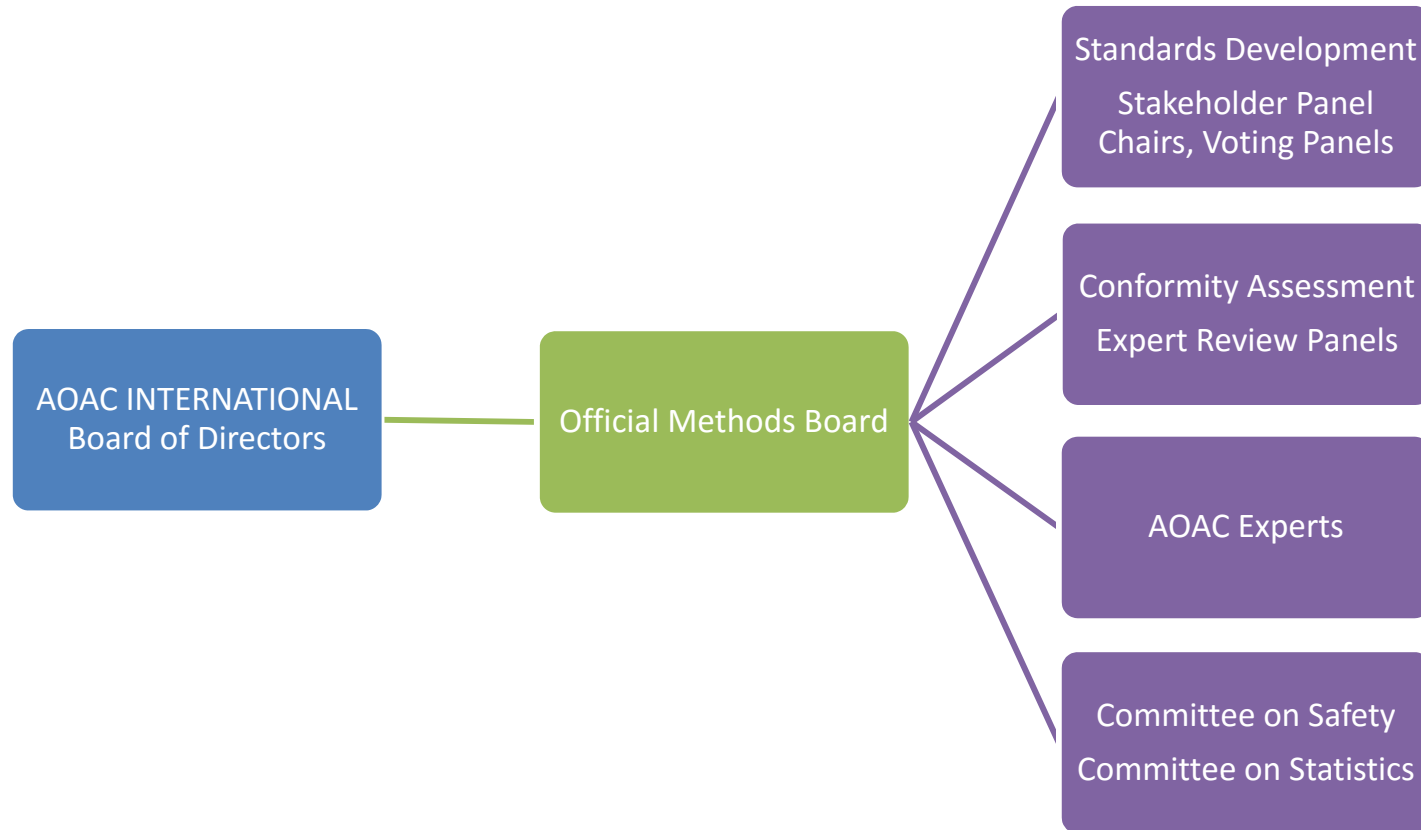
- AOAC offers a number of resources through its goods and services; however, AOAC does not:
  - Regulate products
  - Buy or sell food, beverage products, or proprietary technologies
  - Promote specific food and beverage products
  - Set tolerance levels
  - Own a laboratory or provide laboratory services

# AOAC Organizational Affiliate Members

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



# Organization

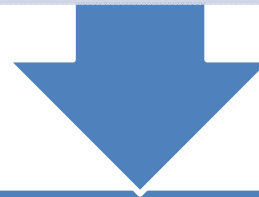


# AOAC Bylaws: Article VIII - *Official Methods of Analysis*

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.

# AOAC Bylaws: Article VIII - Official Methods of Analysis

## *Section 3. Principles of the Official Methods Program*

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.

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

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.

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.

The OMB shall adopt methods as Final Action.

# OMB Terms of Reference – II. Mission

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

# OMB Terms of Reference – III. Responsibilities

- To provide ethical, timely, open and independent scientific oversight for the policies and procedures of AOAC INTERNATIONAL;
- To approve “Final Action” status for First Action Methods (new and revised) following a proactive review;
- To repeal methods, if necessary, in accordance with established policies and procedures;
- To participate in addressing appeals and requests for action or guidance, and in resolving disputes;
- To endorse and monitor all voluntary consensus panels for appropriate representation and balance of stakeholders’ perspectives;
- To endorse and monitor all volunteer subject matter experts for volunteer conformity assessment activities;
- To adopt and monitor scientific and technical guidance and references;
- To acknowledge outstanding scientific and technical volunteer activity and achievement within AOAC;
- To actively participate in AOAC standards development activities and maintain and communicate explicit knowledge of AOAC standards development and conformity assessment;

# OMB Terms of Reference – IV. Composition & Organization

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

# OMB Terms of Reference (con't)

## IV. Composition and Organization (con't)

- The Official Methods Board represents the membership of AOAC INTERNATIONAL. It shall be composed of members representing a balance of scientific expertise, government, industry, and academia as appropriate to the scope of the Board. Every effort should be made to include international representation on the Board.
- Additional working groups, task forces, and other appropriate subgroups shall be appointed as needs arise by the Chair of the Official Methods Board.

## V. STAFF LIAISON:

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

## VI. REVIEW SCHEDULE:

- Every three years.

# Preferential Meetings of Official Methods Board

## 2015-2016

- Teleconferences – monthly on 2<sup>nd</sup> Thursday at 1:00pm-2:30pm ET
- In Person – Annual Meeting, February, Chicago/Rockville/Teleconference

## 2016-2017

- Teleconferences – to be discussed
- In Person – To be discussed



# AOAC Policies & Procedures

Policy on Antitrust

Policy on Use of  
Association Name,  
Identifying Insignia,  
Letterhead, Business  
Cards

Policy on Volunteer  
Conflict of Interest

Expert Review Panel  
Policies and Procedures

OMA Appendix G

# Meetings Involving OMB Members

- OMB Core Teleconferences
  - Planning sessions
  - Chair, Vice Chair\*, Staff
  - Optional participants: past chair of OMB, Member of Board of Directors, and other as needed.

*\* To be determined*

- AOAC Meetings
  - Serve as liaison or resource to meeting
  - AOAC Mid-Year Meeting
  - AOAC Stakeholder Panels and ERPs
  - AOAC Board of Directors

# Selection of New OMB Members

## **Composition**

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

## **Purpose**

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

## **Appointment of the Candidate**

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

# Criteria for Serving on the OMB

1. Must provide a current Curriculum Vitae
2. Must be a member of AOAC INTERNATIONAL in good standing
  - Must have a letter of support from the sponsoring organization employer
  - Must have an executed AOAC Volunteer Acceptance Form
  - Must provide two letters of recommendation from someone other than an employee, employer or supervisor.
3. Should be willing and capable of acting as a Liaison with the Communities, Technical Divisions, Research Institute, and other major Stakeholders.
4. Should possess the minimum of a Bachelor's degree in chemistry, biology, mathematics or a related scientific field
5. Should demonstrate leadership capabilities through documentation of project management, supervisory experience, or leadership positions within AOAC
6. *Should have experience in the AOAC collaborative study process (standards & conformity assessment processes)*
7. Should be familiar with the *AOAC Program Manual* and the Official Methods of Analysis appendices
8. *Should have successfully completed OMB training in the method validation process, demonstrate ability to perform adequate review of AOAC collaborative studies, and agree to appropriate retraining at least every three years.*

# Selection of OMB Vice Chair

Must have served for at least one year as a Member of the OMB

Must fulfill all the criteria for a Member of the OMB

The members of the OMB serve as the search committee for a Vice Chair.

1. They identify and recommend a slate of nominees as potential candidates for Vice Chair.
2. The nominees shall be contacted by the Chair of the OMB to confirm his/her willingness and ability to serve. Once confirmation has been received, the nominee(s) will be presented to the OMB for a vote.
3. An email ballot shall be sent out to the members of the OMB with the slate of nominees.
4. The current Vice Chair collects and tallies the ballots.

1. The selection of the Vice Chair will be decided by at least a majority vote of the OMB.
  - If there is a tie, the Chair will cast the determinative vote.
  - if no one receives a majority vote, another email ballot will be sent out with the top two nominees who received the highest number of votes.

# Vetting of AOAC Experts & Committee Members

## AOAC Chief Science Officer

- Reviews all candidates and supporting documents for expertise
- Makes a recommendation for an AOAC Expert

## AOAC Committee on Safety or Statistics

- Reviews documentation for expertise and make a recommendation for members

## AOAC Official Methods Board

- OMB Chair can review and approves AOAC Expert
- Reviews proposed recommended revised Committee slate
  - Expertise
  - Balance of panel
  - Conflicts of Interest
- Renders decision on proposed Committee members and an Committee Roster is formed.

# Vetting of Experts & Expert Review Panels

## AOAC Chief Science Officer

- Reviews all candidates and supporting documents for expertise
- Makes a recommendation for an ERP slate

## AOAC Official Methods Board

- Reviews proposed recommended ERP slate
  - Expertise
  - Balance of panel
  - Conflicts of Interest
- Renders decision on proposed ERP members and an ERP Roster is formed.

# Vetting of Stakeholder Panel Chair

- Staff presents an Executive Office recommendation for chair of a stakeholder panel
  - Chair of stakeholder panel moderates the deliberation of an AOAC advisory panel
  - Chair of stakeholder panel moderates the deliberation of an AOAC stakeholder panel
- OMB deliberates on the recommendation and renders a decision



# Proposal for Stakeholder Voting Panels



# Vetting of Stakeholder Panel Voting Members

- OMB in reviews proposal during teleconference or in person meeting
- OMB reviews and deliberates on candidates
- Can add candidates or remove candidates based on expertise or to ensure appropriate balance
- OMB approves final list of organizations as the representative stakeholder voting members for a stakeholder panel



# **AOAC Stakeholder Panels and Standards Development**

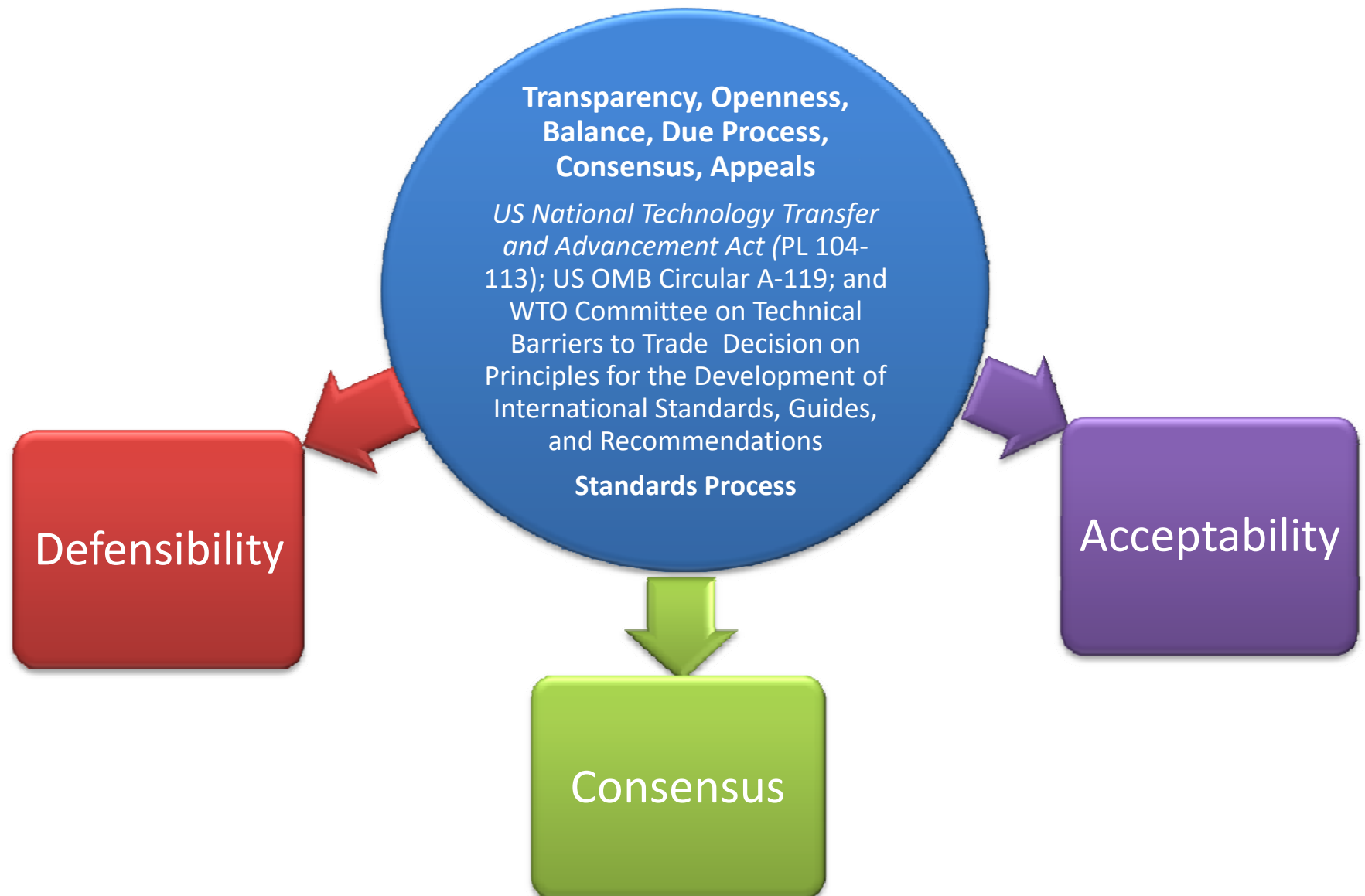
AN OVERVIEW

# About AOAC INTERNATIONAL - Power of Many

As a scientific association, *AOAC brings scientists together to do a job together that they should not do alone.*

- AOAC leverages its global networks and the value of its independent third party status to provide opportunities for scientific stakeholder groups to *talk about methods* driven by the need for reliable, scientifically valid, fit for purpose methodology.
- Reliable, scientifically valid, fit for purpose methodology are attained by beginning with the development of voluntary consensus standards.
- Methods deemed that meet the voluntary consensus standard are considered fit for purpose and are adopted and published in the *Official Methods of Analysis of AOAC INTERNATIONAL*.

# AOAC Creates International Standards



# 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.

# AOAC INTERNATIONAL

As an international standards development organization, AOAC maintains the following principles throughout all standard setting activities:

*Transparency*

*Openness*

*Balance of Interests*

*Due Process*

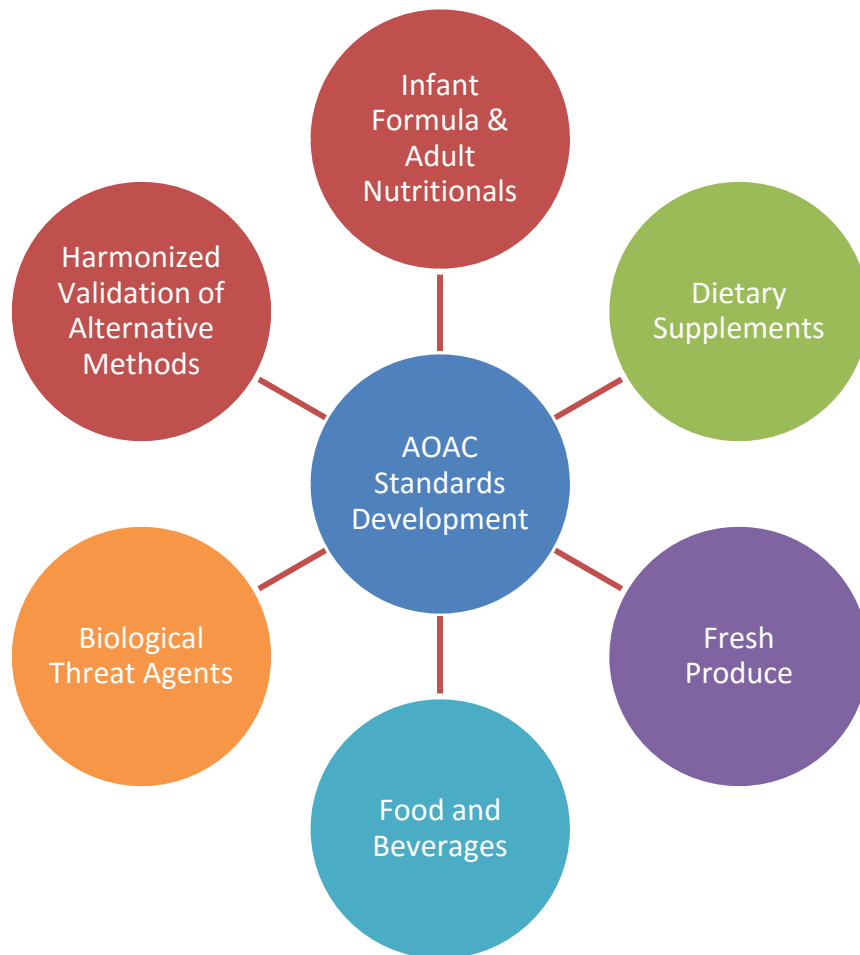
*Consensus*

*Appeals*



# How does AOAC do this?

- Active AOAC stakeholder panels cover a range of topics including



Advisory Panel\*

Stakeholder Panel\*

Working Group\*

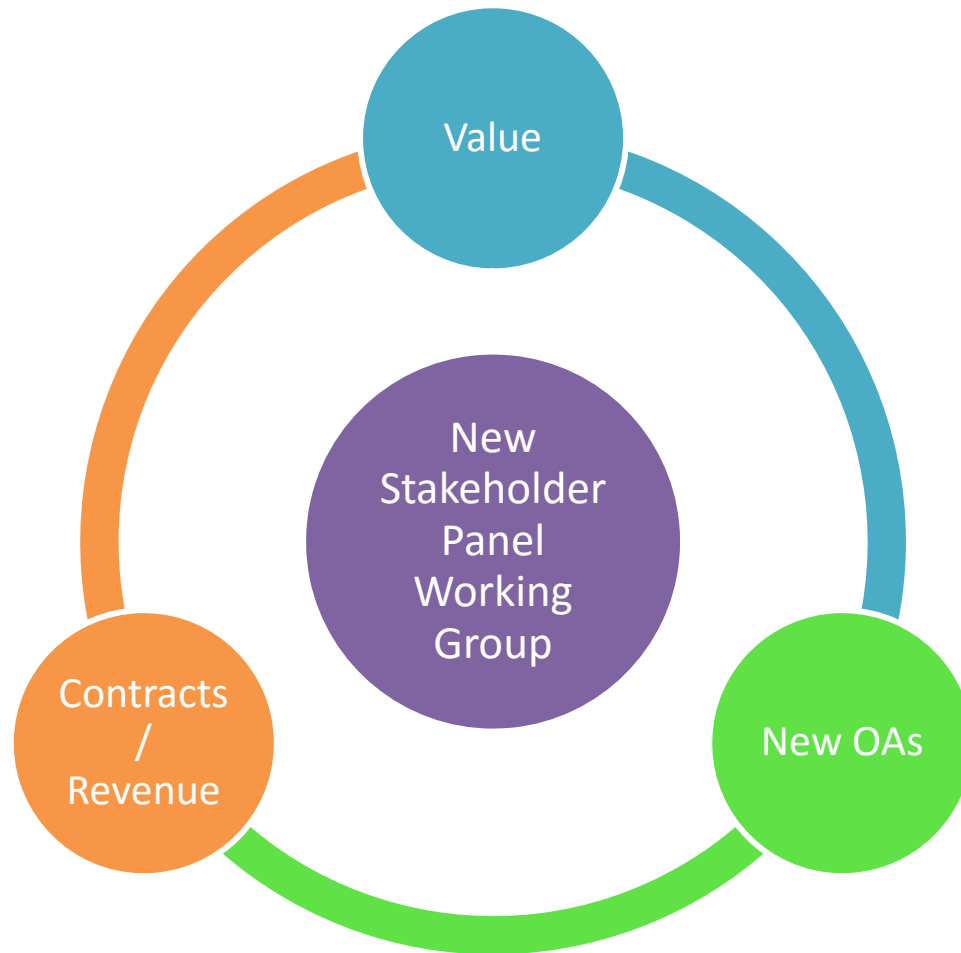
Expert Review Panel\*

*AOAC Official Methods Board*

*AOAC Board of Directors*

*\*Managed by AOAC Staff*

# New Work for Investment Stakeholder Panels



# AOAC INTERNATIONAL and Power of Many

As a scientific association, *AOAC brings scientists together to do a job together that they should not do alone.*

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- Reliable, scientifically valid, fit for purpose methodology are attained by beginning with the development of voluntary consensus standards.
- Methods deemed that meet the voluntary consensus standard are considered fit for purpose and are adopted and published in the *Official Methods of Analysis of AOAC INTERNATIONAL*.

# AOAC STAKEHOLDER COMMUNITIES

**Areas across which AOAC is currently working and contributing to the food and public safety**

Stakeholder Panel on  
Agent Detection Assays  
(US Department of Defense)  
August 30, 2016 Rockville,  
Maryland

Stakeholder Panel on  
Dietary Supplements  
(US National Institutes of  
Health)  
September 16, 2016 Dallas,  
Texas

Stakeholder Panel on  
Infant Formula & Adult  
Nutritionals  
(Infant Nutrition Council of  
America)  
September 17, 2016 Dallas,  
Texas

Stakeholder Panel on  
Strategic Food Analytical  
Methods  
(AOAC INTERNATIONAL)  
September 18, 2016 Dallas,  
Texas

International Stakeholder  
Panel on Alternative  
Methodology  
(AOAC Research Institute)  
September 18, 2016  
Dallas, Texas

# New Benefit for Organizational Affiliates

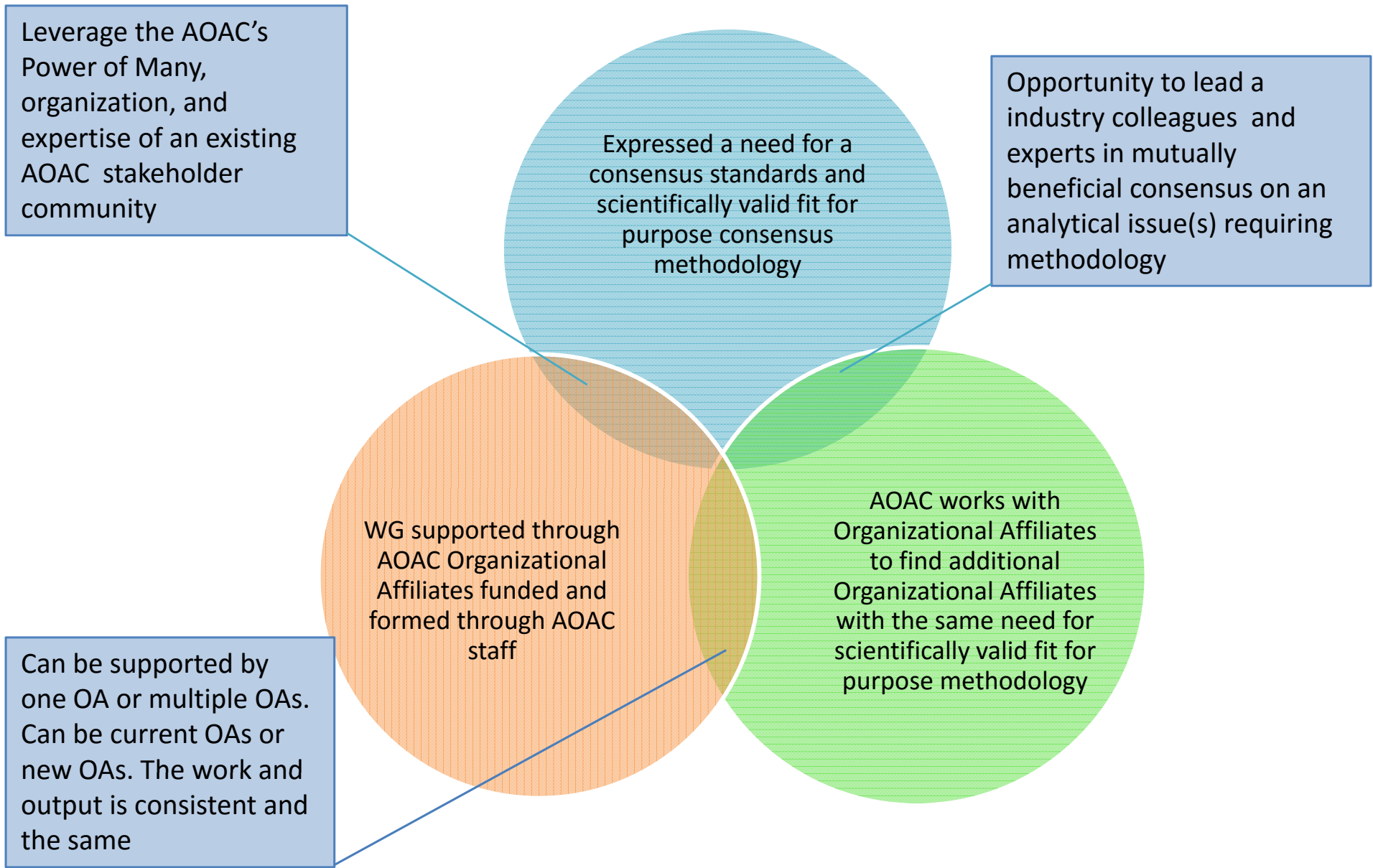
- WG Initiative is a mechanism for current and new AOAC Organizational Affiliate members to initiate relevant standard development projects using existing AOAC stakeholder panels

Brings Credibility & Defensibility through consensus

Output is Standard Method Performance Requirements

Leverage existing AOAC stakeholder panel communities

# Working Group (WG) Initiative



# Why the new WG Initiative?

- Offers companies the opportunities to solve challenges without waiting on priorities of existing stakeholder panels
  - Advisory Panel participation and discussion
- WG's funded by current OA's and new companies interested in addressing immediate needs
  - for analytical standards/standard method performance requirements; and
  - scientifically valid fit for purpose methodology.

# AOAC Forms an Advisory Panel

## Composition of:

- Bringing issue forward
- Facilitate financial support

## Works with staff to:

- Identify key stakeholders
- Identify subject matter experts
- Frame issues & set priorities for standards development
- Stakeholder Panel Chair moderates panel discussions





# Stakeholder Panel Composition

- Product Manufacturers
- Analyte/Method Subject Matter Experts
- Technology Providers
- Method Developers
- Government and Regulatory Agencies
- Contract Research Organizations
- Reference Materials Developers
- Ingredient Manufacturers
- Method End Users
- Academia
- Non-Governmental Organizations (ISO, IDF, etc...)
- Other.... as identified

**Anyone with a material interest can participate**  
**Balanced group of voting stakeholders**  
**Chair and voting members vetted**



# AOAC Stakeholder Panels

- To deliberate on priorities that result in reaching consensus on AOAC voluntary consensus standards
  - Chair of Stakeholder Panel vetted by the AOAC Official Methods Board and appointed by the President of AOAC.
  - Representative Stakeholder Voting Panel members vetted by AOAC Official Methods Board to ensure balance of perspectives represented in determining consensus.
  - Anyone with a material interest can participate in stakeholder panel deliberations.
- Stakeholder Panel form working groups and uses working groups to develop draft standards.
- Working group chair presents standard to stakeholders.

# Stakeholder Panels – Voting Panel

- To demonstrate consensus of the stakeholder panel
- Organizations do not have permanent seats or appointments on any given stakeholder panel
  - Balance of Perspectives driven
- Voting panel is determined for each meeting of a stakeholder panel using those registered for a stakeholder panel meeting
  - Vetting through AOAC Official Methods Board

# Stakeholder Panel - Working Groups

- Chair approved/appointed by Stakeholder Panel chair
- Engage in the detailed discussions and work of the stakeholders
- Develop draft fitness for purpose and standard method performance requirements (SMPRs) or other draft standard as proposed by stakeholder panel
- Recommend draft standards to the stakeholder panel
- Managed by staff



# Standard Methods Performance Requirements (SMPRs)

STANDARD METHOD PERFORMANCE REQUIREMENTS

AOAC INTERNATIONAL (2011)

## AOAC SMPR 2011.006

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

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

Final Version Date: April 5, 2011

Effective Date: April 5, 2011

#### Intended Use:

#### 1. Applicability

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

#### 2. Analytical Technique

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

#### 3. Definitions

##### Adult/Pediatric Formula

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

##### Infant Formula

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

##### Limit of Detection (LOD)

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

##### Limit of Quantitation (LOQ)

The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

##### Repeatability

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

##### Reproducibility

The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility

relative standard deviation (SD<sub>R</sub>), or % reproducibility relative standard deviation (%RSD<sub>R</sub>).

##### Recovery

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

#### 4. Method Performance Requirements

Analytical range	0.50–300*	
Limit of detection (LOD)	≤0.10*	
Limit of quantitation (LOQ)	≤0.50*	
Repeatability (RSD <sub>r</sub> )	0.50*	≤11%
	21.5*	≤7%
	43.0*	
	64.0*	
	85.0*	
Recovery	0.5	90–110%
	21.5*	
	43.0*	
	64.0*	
	85.0*	
Reproducibility (RSD <sub>R</sub> )	0.5*	≤32%
	21.5*	≤16%
	43.0*	
	64.0*	
	85.0*	

Concentrations apply to (1) "ready-to-feed" liquids "as is"; (2) reconstituted powders (25 g into 200 g water); and (3) liquid concentrates diluted 1:1 by weight.

\* µg/100 g expressed as folic acid in reconstituted final product.

#### 5. System Suitability Tests and/or Analytical Quality Control

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

#### 6. Reference Material(s)

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

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

#### 7. Validation Guidance

Recommended level of validation: *Official Methods of Analysis*<sup>2011</sup>.

#### 8. Maximum Time-to-Signal

No maximum time.

- Documents a stakeholder community analytical method needs.
- Very detailed description of the analytical requirements.
- Includes method acceptance requirements.
- Used to adopt AOAC Official Methods by AOAC Expert Review Panels.
- Published as a standard.

v6, March 13, 2011

**Standards development is complete**

# After SMPRs are Approved

- Conformity Assessment
  - AOAC *Performance Tested Methods*<sup>SM</sup>
  - AOAC *Official Methods of Analysis*<sup>SM</sup>
  - Harmonized programs
    - Commercial/Proprietary Method Developers can submit their methods to AOAC Research Institute for either or both (harmonized) AOAC programs
    - Will follow normal processes for each program.

# AOAC Expert Review Panel (ERP)

- All candidates are vetted by AOAC Official Methods Board (OMB)
- Approved members are appointed by President of AOAC
- ERP member must go through ERP Orientation
- ERP Review methods for AOAC First Action *Official Methods* status
- Adopt methods as AOAC First Action *Official Methods* status
- Tracks First Action methods for 2 years after adoption



# Final Action *Official Methods*

- During the Tracking Period:
  - ERP reviews any information on reproducibility, user feedback, etc.. using guidance by AOAC OMB (OMA, Appendix G)
- When ERP has sufficient information it can:
  - Make a recommendation for Final Action Official Method status
  - Make a recommendation to repeal the Official Method
- Official Methods Board
  - Reviews ERP recommendations and renders decisions on Final Action status or repeal





# ERP Chair Responsibilities

## Before Meeting

Work with staff on meeting coordination

Review submitted and/or assigned methods

Review method reviews if applicable

Review SMPR(s) and/or relevant guidance and criteria

## During Meeting

Moderate discussions based on agenda

Engage staff to encourage members to reach decision points

Engage staff on procedural questions

Engage discussion on feedback mechanism

# ERP Chair Responsibilities

## After Meeting

Review Meeting Report and Approve Final Version

Assist with any follow up on methods

Assist in Publication Reviews

## Other Efforts and Recognitions

Can nominate methods for OMB Award

Can nominate ERP members for OMB Award

Can assist in identifying methods for review

Can serve as a guest editor for the Journal

# AOAC Policies & Procedures

Policy on Antitrust

Policy on Use of  
Association Name,  
Identifying Insignia,  
Letterhead, Business  
Cards

Policy on Volunteer  
Conflict of Interest

Expert Review Panel  
Policies and Procedures

OMA Appendix G

# Qualifications for ERP Membership

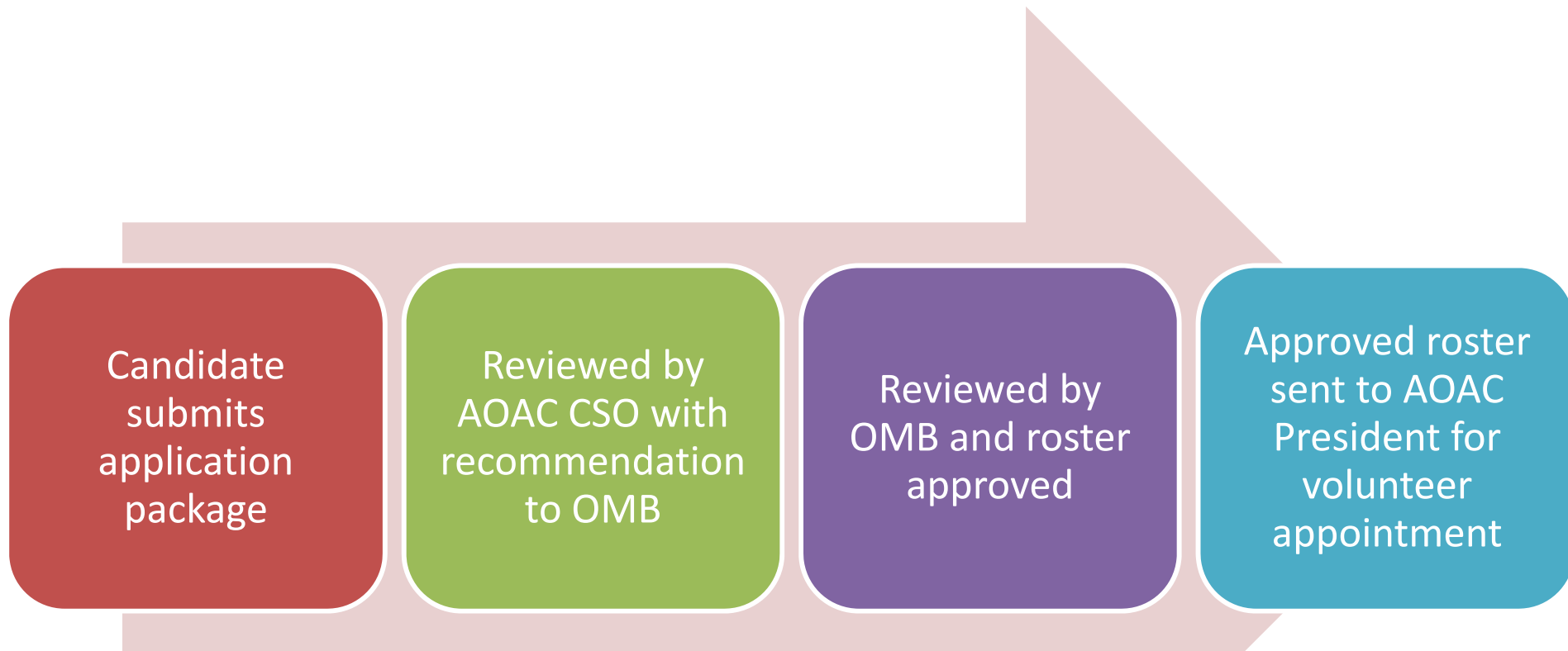
Candidate must meet one of the following:

- Demonstrated knowledge in the appropriate scientific disciplines.
- Demonstrated knowledge regarding data relevant to adequate method performance.
- Demonstrated knowledge of practical application of analytical methods to bona fide diagnostic requirements.

Candidate application package includes:

- Statement of Expertise
- Current Abridged CV or Resume

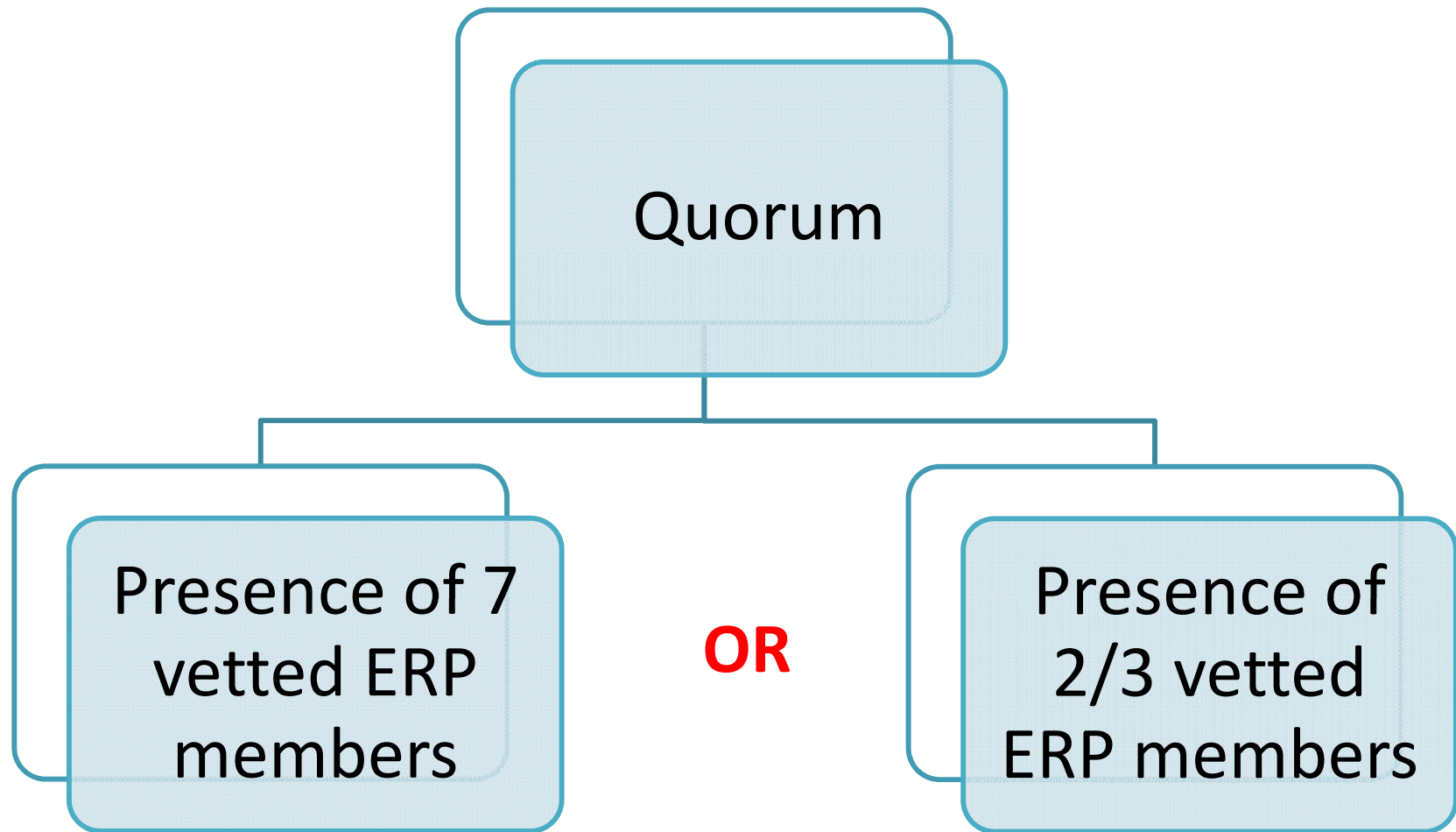
# ERP Member Vetting Process



•*All members serve at the pleasure of the AOAC President*

•*OMB assigns a representative to serve as a resource for every ERP*

# ERP Meetings



**WHICHEVER IS GREATER**  
***IF NO QUORUM, NO OFFICIAL MEETING***

# ERP Meetings – Review for First Action

**METHOD AUTHOR:** present any method and any resulting changes to the method since submission for review, summary of SLV and/or reproducibility evaluation, any recognitions (from AOAC or external) and, final draft of method proposed for decision

**ERP CHAIR & MEMBERS:** present reviews and discuss any resulting issues or questions on the method, review and agree upon final draft of method proposed for decision, and chair calls for ERP decision in accordance to procedures.

**CONSENSUS:** Method must be adopted by unanimous decision of ERP on first ballot. If not unanimous, negative votes must delineate scientific reasons. Negative voter(s) can be overridden by 2/3 of non-negative voting ERP members after due consideration.

*Abstentions do not count towards vote; in case of multiple abstentions the results will need to be evaluated. Staff will monitor and record consensus voting.*

**STAFF:** Will organize and coordinate meeting, record ERP actions and decisions, draft ERP report and distribute after chair approval, work with chair and OMB liaison to complete checklist and assemble recommendation package for OMB.

# ERP Meetings – Method Tracking

**METHOD AUTHOR:** present any method feedback obtained and any resulting changes to the method, any reproducibility information, any implemented ERP recommendations, final draft of method proposed for decision

**ERP MEMBERS:** present any method feedback obtained and discuss any resulting changes to the method, any reproducibility information, any implemented ERP recommendations, review and agree upon final draft of method proposed for decision, and make a recommendation to OMB.

**CONSENSUS:** 2/3 vote in favor of a motion. Abstentions do not count towards vote; in case of multiple abstentions. Staff will monitor and record consensus voting.

**STAFF:** Will organize and coordinate meeting, record ERP actions and decisions, draft ERP report and distribute after chair approval, work with chair and OMB liaison to complete checklist and assemble recommendation package for OMB.



# ERP Methods Review & Approval

Methods should be scientifically sound with demonstrating that it will meet the needs of those using the method (evidenced by meeting the standard, or other acceptance criteria)

ERPs have approved methods with evidence of high potential to First Action and request additional work or support be submitted for review prior to ERP convening to recommend an action to OMB

OMB requires a justification or rationale for methods that are deemed acceptable and adopted but may not fully meet the standard set or acceptance criteria.



# ***Official Methods*** **Modifications**

Terminology & Pathway for Review and  
Approval

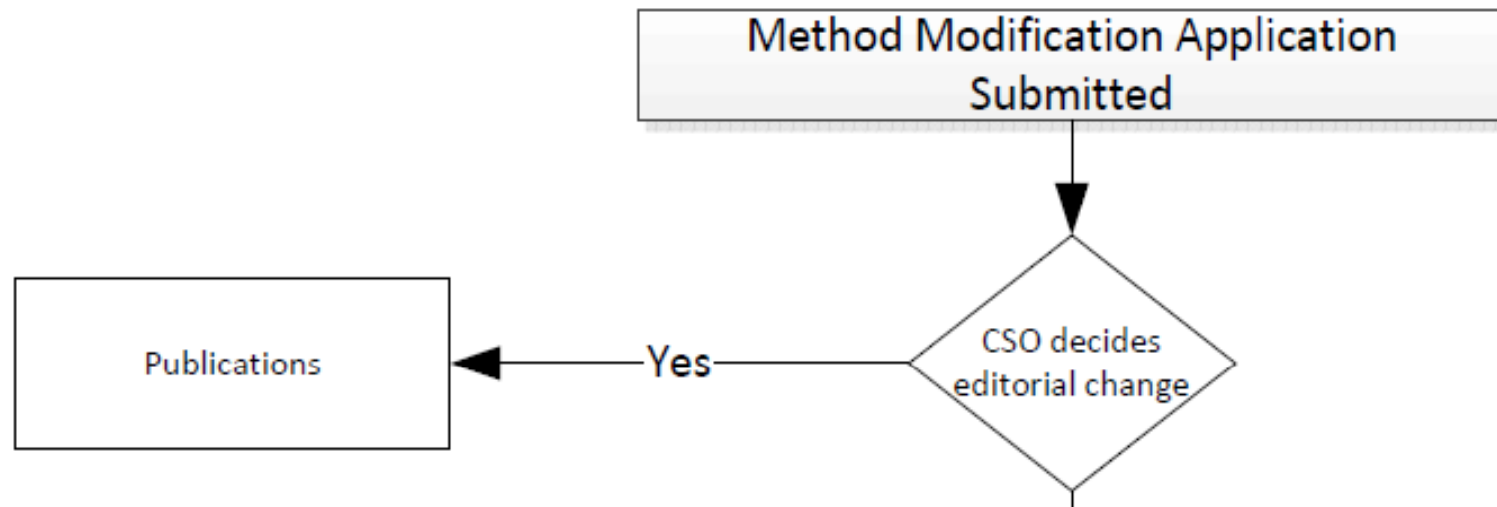
# Terms

- Types of Modifications
  - Editorial
  - Major
  - Minor
- Applicable to First Action and Final Action OMA
- Relevant to all ERPs

# Editorial Modifications

- The applicant must submit a written explanation of the change(s) including a statement that the modification does not alter the validated performance of the method.
- Examples include: Typos or editorial corrections or clarifications that strengthen instruction.
- Methods that have undergone an editorial modification will retain the same number.

# Editorial Changes



- Editorial changes to methods only require AOAC staff review and the change is made to the OMA with changes noted in next printed edition of OMA.
- A list of the methods with editorial modifications will be published in *Inside Laboratory Management* and on the Website.

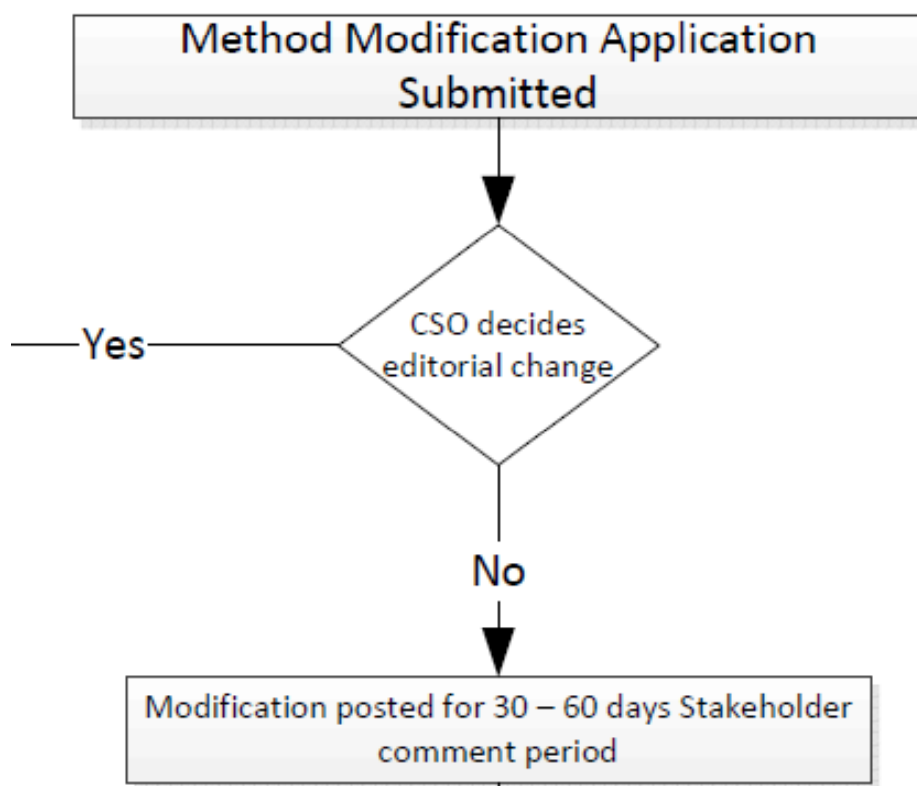
# Minor Modifications

- Results in no changes to the current validated performance. There is no significant effect to the results. The method will retain the original number.
- Supporting data to justify the proposed modification must be submitted. Equivalency data is required unless adequate Justification to exclude this data is provided.
- Examples include: Reagent change, a change in a column or consumables that do not impact the validated method performance.

# Major Modifications

- Results in a change to the current validated performance of the method.
- This level of modification will result in a new method as part of AOAC standards development and will receive a new method number.
- Examples include: significant change to the technology, sample preparation, or chemistry.

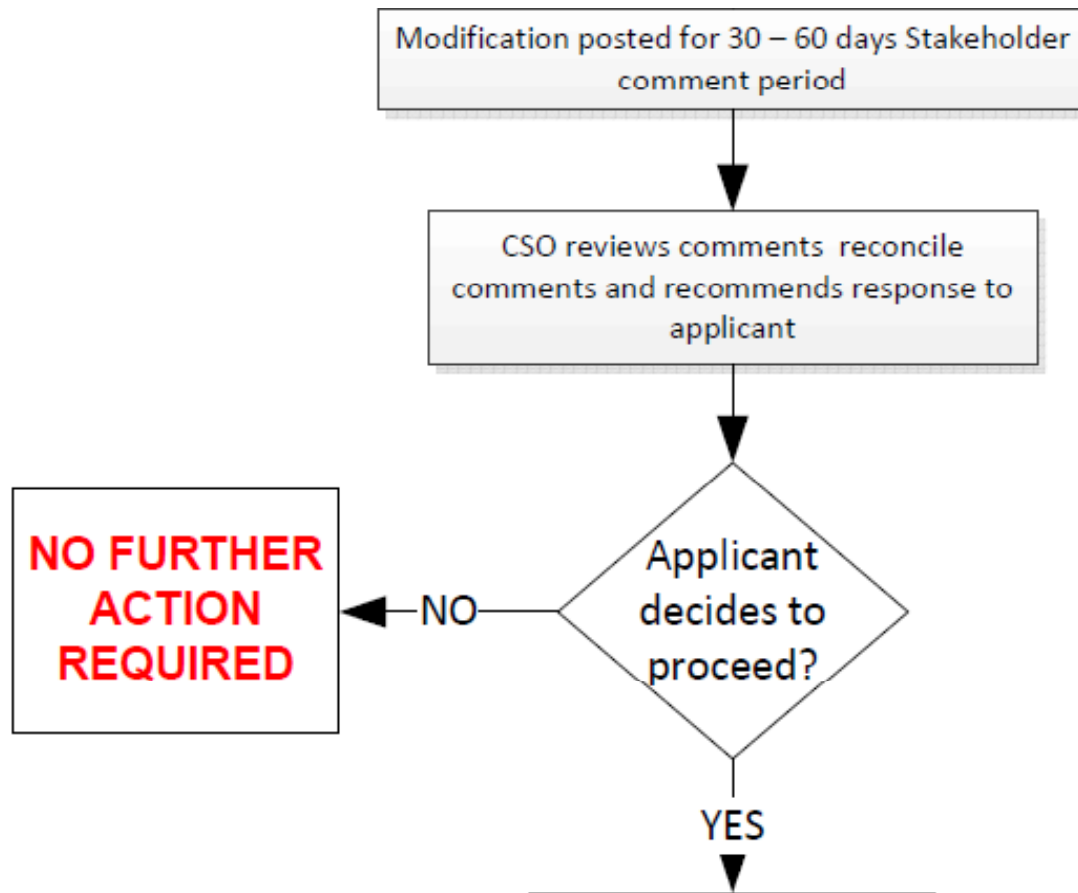
# Minor & Major Modifications



Based on AOAC staff review, a public comment period for the proposed modification is required.



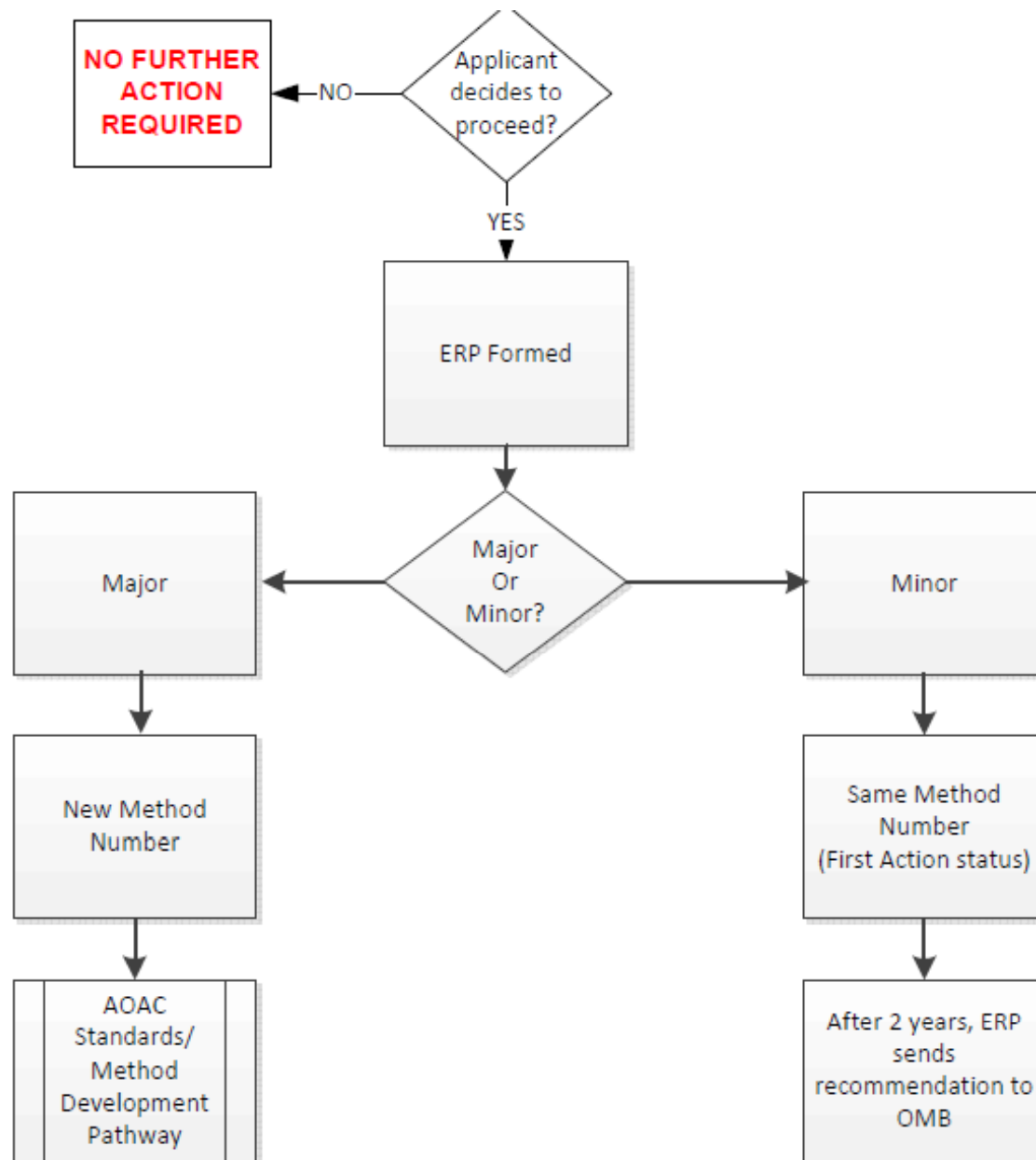
# Applicant Options



- Following the comment period, any comments are reconciled and recommends a response to the applicant.

The applicant can decide to proceed based on the reconciled comments

# Pathways for Minor & Major Modification



If applicant decides to proceed, an ERP is formed

- Level of modification determined by ERP
- Applies to modifications of First Action and Final Action methods

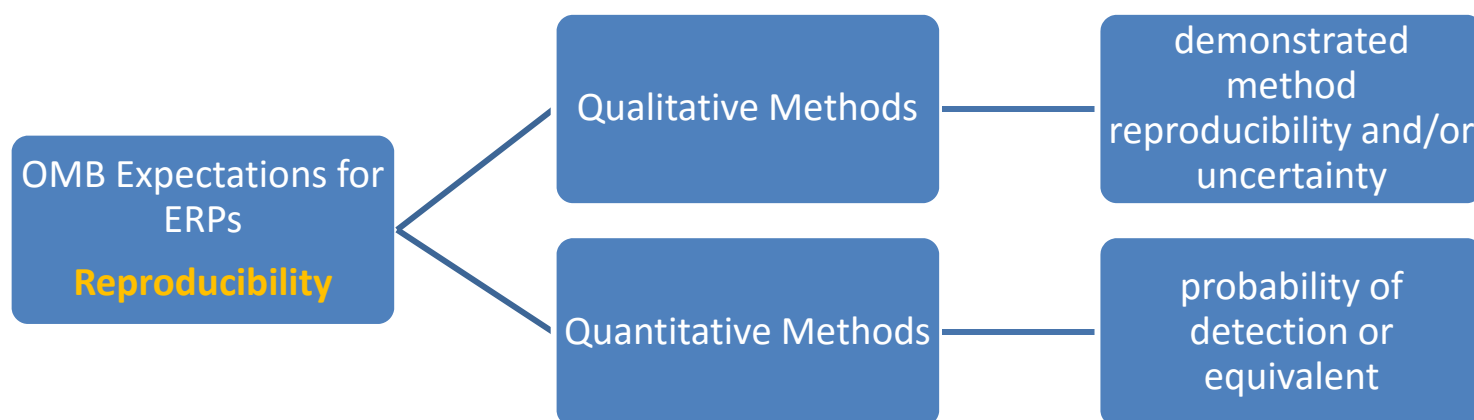


# First Action Method Updates

Expert Review Panel Tracking and Recommendations of First Action Methods

# OMA, Appendix G

*Further data indicative of adequate method reproducibility (between laboratory) performance to be collected. Data may be collected via a collaborative study or by proficiency or other testing data of similar magnitude.*



- ERP is looking to verify if method reproducibility has been appropriately assessed and satisfactorily demonstrated

# OMA, Appendix G

**Two years maximum transition time (additional year(s) if ERP determines a relevant collaborative study or proficiency or other data collection is in progress).**

## 2 yr tracking of method

- ERP verification of any changes to the method
- ERP recommendations implemented successfully
- ERP evaluation of any feedback on method and its performance

## ERP Recommendations

- Move method to Final Action OMA status
- Repeal method from OMA
- Continuance of First Action OMA status

# *OMA, Appendix G*

*Method removed from Official First Action and OMA if no evidence of method use available at the end of the transition time.*

## First Action OMA Tracking

- Tracking period is  $\leq 2$  years and begins on the date of the ERP's decision to adopt a method for OMA First Action status.

## No Use in 2 Years

- Repeal from OMA

# OMA, Appendix G

*Method removed from Official First Action and OMA if no data indicative of adequate method reproducibility is forthcoming as outlined above at the end of the transition time.*

## First Action OMA Tracking

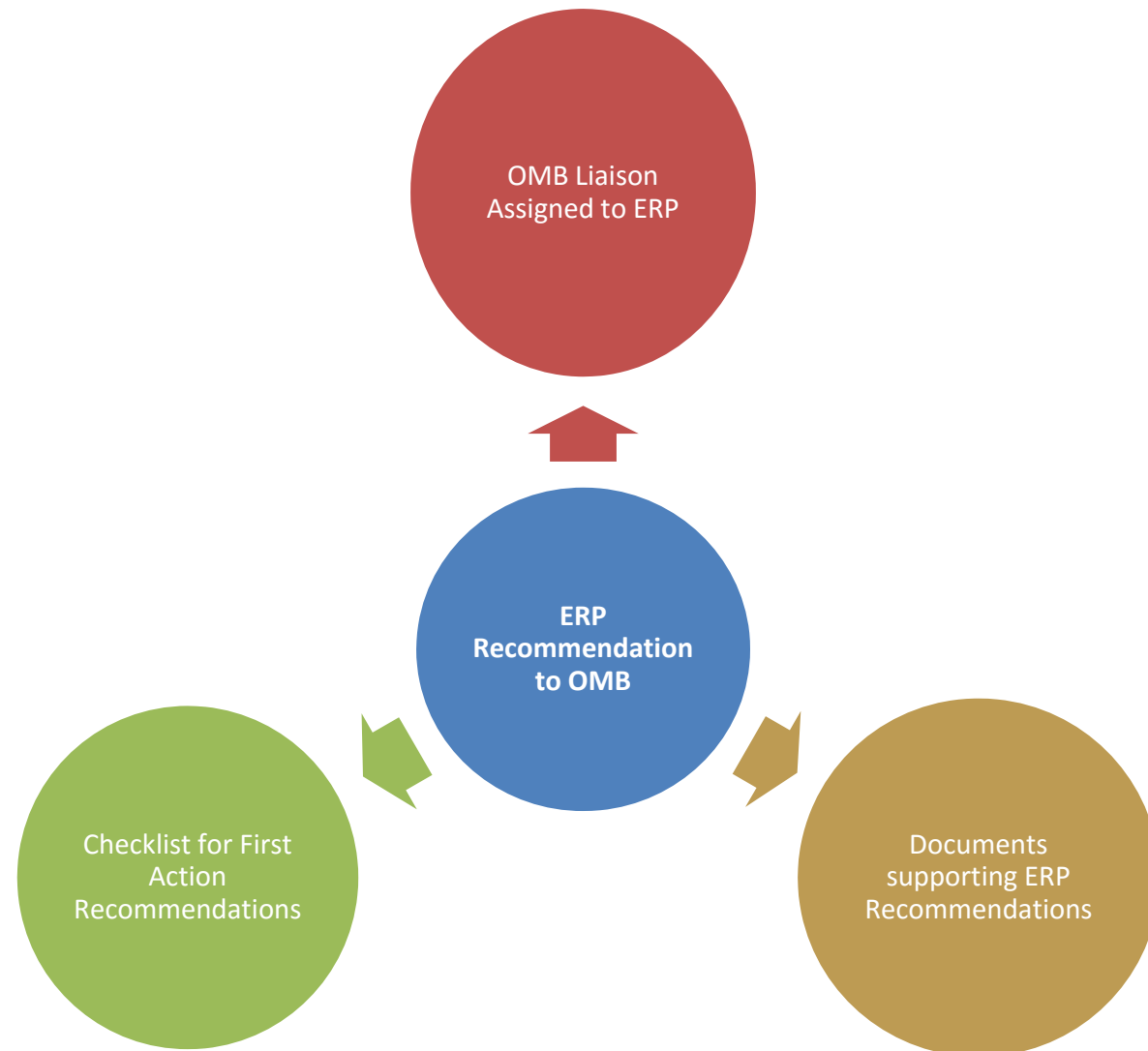
- Tracking period is  $\leq 2$  years and begins on the date of the ERP's decision to adopt a method for OMA First Action status.

## No Demonstration of Method Reproducibility in $\leq 2$ Years

- Repeal from OMA

# OMA, Appendix G

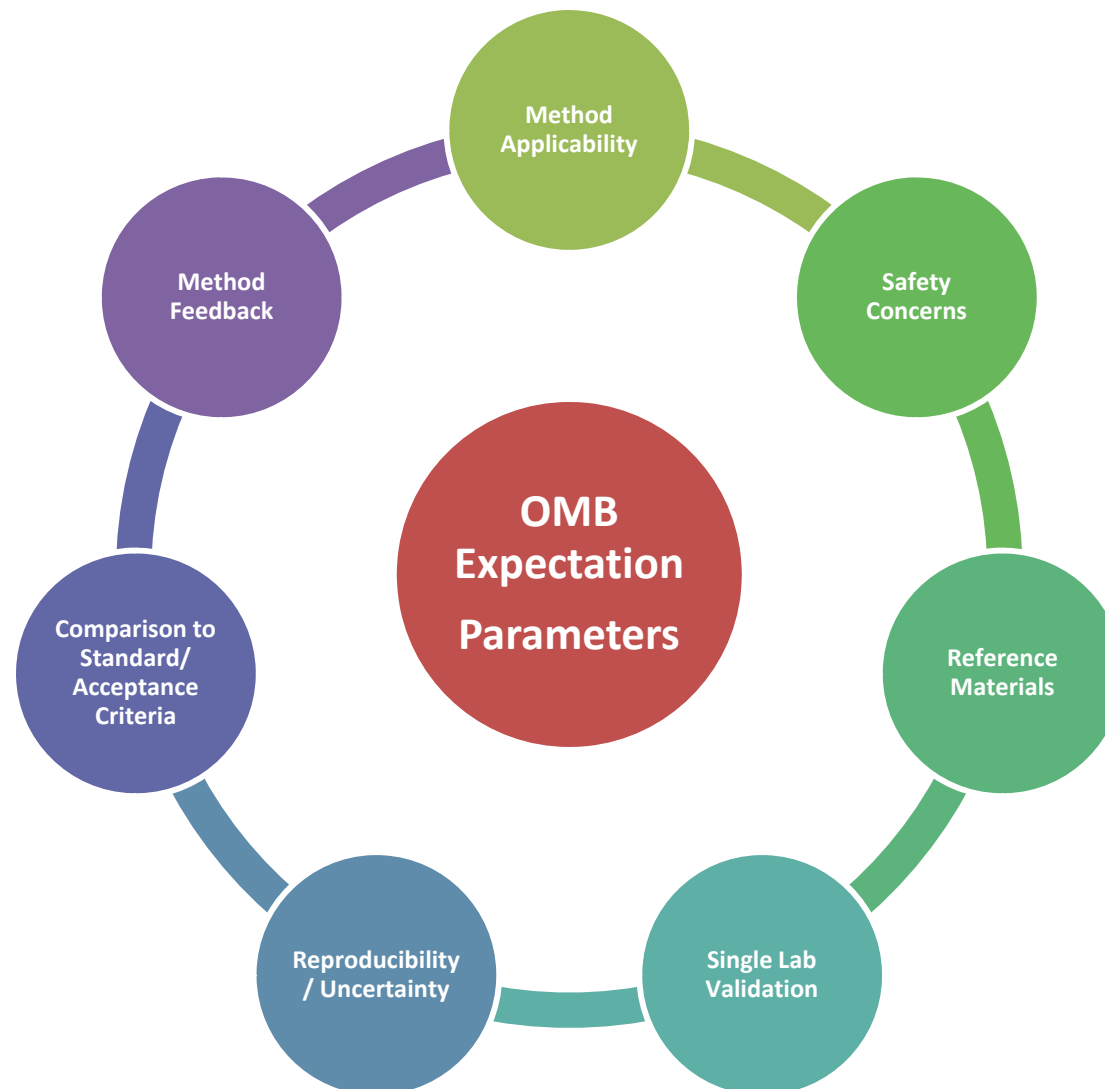
*ERP to recommend Method to Official Final Action Status to the OMB.*



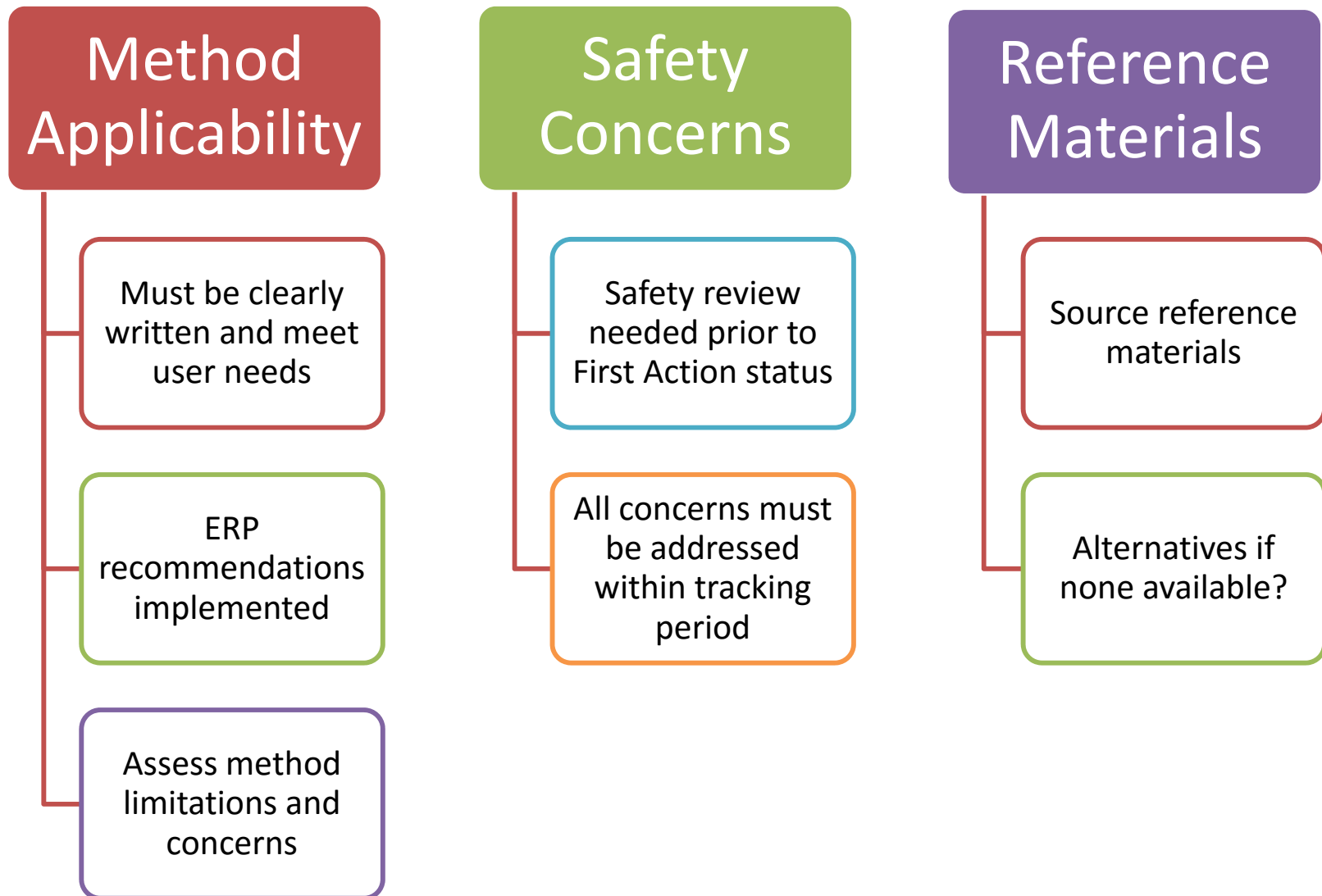


# OMA, Appendix G

## *First Action to Final Action Methods: Guidance for AOAC Expert Review Panels*



# OMB Expectation Parameters



# OMB Expectation Parameters

## Single Laboratory Validation

Qualitative methods: inclusivity (or equivalent), exclusivity (or equivalent), robustness, repeatability, POD (or equivalent), cross reactivity, matrix scope, etc...

Quantitative methods: demonstrated method linearity, accuracy, repeatability, selectivity, LOD/LOQ, Matrix scope, etc....

## Reproducibility/ Uncertainty

Qualitative methods: - probability of detection or equivalent

Quantitative methods: demonstrated method reproducibility and/or uncertainty

## Comparison to Standard/ Acceptance Criteria

Documented method performance versus a SMPR, recognized reference standard (materials), recognized reference method, or general method end user community guidance and/or acceptance criteria

Document reasons for acceptability if it doesn't meet the standard or acceptance criteria

# OMB Expectation Parameters

## Method Feedback from End Users

Consider any positive or negative feedback on overall method performance, applicability, availability of reference materials, matrix scope, method component sourcing, robustness or ruggedness parameters.

# Documentation Needed

Method Safety Evaluation

Reference Materials

Evidence of Single Laboratory Validation or equivalent

Evidence of Reproducibility Assessment

Published First Action OMA

Method Performance versus SMPR or acceptance criteria

Final draft of First Action OMA to be considered for status update

Rationale or Justification for Repeal or Continuance of First Action OMA



## ERP SUMMARY FOR FIRST TO FINAL ACTION METHOD RECOMMENDATION

AOAC No.	NAME OF METHOD
<b>GUIDANCE FOR AOAC ERPS - APPENDIX G<sup>1</sup></b>	<b>Considered?      Comments/Reference if applicable</b>
Method Applicability	
ERP First Action to Final Action recommendations & improvements	
Draft Final Action method reviewed by ERP	
Safety Concerns	
Reference Materials	
Single Laboratory Validation	
Reproducibility/Uncertainty and Probability of Detection	
Comparison to SMPR (SMPR criteria met?)	
Feedback from Users of Method	

DOCUMENTATION	Available?	Comments
Safety Evaluation		
Reference Materials		
SLV or PTM		
Approved Validation Protocols		
Statistics Review		
Method Published in OMA		
Method Performance vs SMPR criteria		
Feedback Information		
Additional Recognition(s)		
ERP Reports		
Manuscript(s) Published in JAOAC		
<b>ERP Method Recommendation (Final Action/Repeal/Continuation)</b>		

<sup>1</sup> *Official Methods of Analysis of AOAC INTERNATIONAL*, Appendix G: Procedures and Guidelines for the Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis, p.3 "First Action to Final Action Methods: Guidance for AOAC Expert Review Panels."

# ERP Meetings

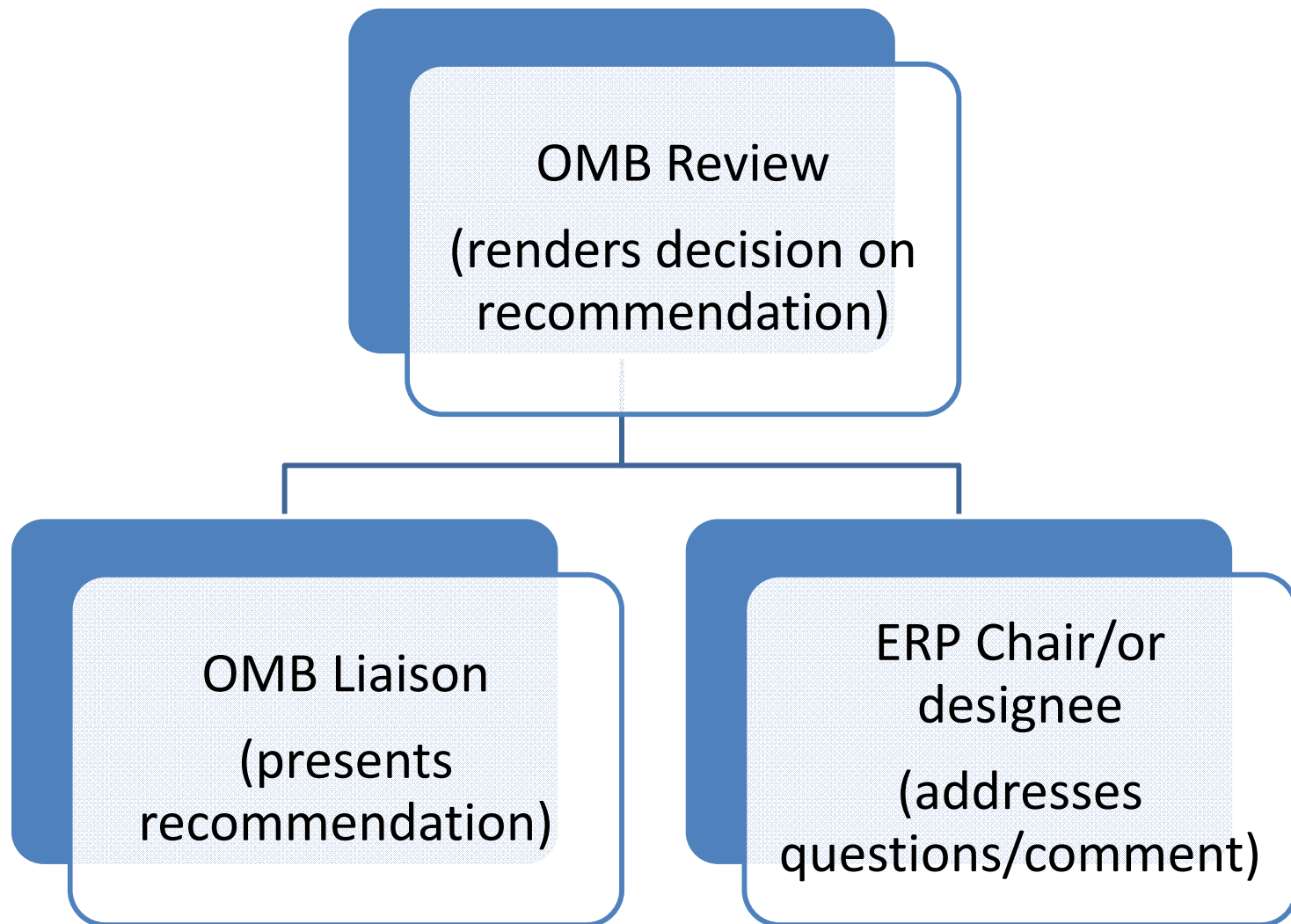
**METHOD AUTHOR:** present any method feedback obtained and any resulting changes to the method, any reproducibility information, any implemented ERP recommendations, final draft of method proposed for decision

**ERP MEMBERS:** present any method feedback obtained and discuss any resulting changes to the method, any reproducibility information, any implemented ERP recommendations, review and agree upon final draft of method proposed for decision, and make a recommendation to OMB.

**CONSENSUS:** 2/3 vote in favor of a motion. Abstentions do not count towards vote; in case of multiple abstentions. Staff will monitor and record consensus voting.

**STAFF:** Will organize and coordinate meeting, record ERP actions and decisions, draft ERP report and distribute after chair approval, work with chair and OMB liaison to complete checklist and assemble recommendation package for OMB.

# OMB Meeting for Review of ERP Recommendations







## **OFFICIAL METHODS<sup>SM</sup> PROGRAM AWARDS**

### **Contents**

#### **Team Awards:**

Award in Recognition of Technical and Scientific Excellence

Expert Review Panel of the Year

#### **Individual Achievement Awards:**

Technical Service Award

Method of the Year



## **AWARD IN RECOGNITION OF TECHNICAL AND SCIENTIFIC EXCELLENCE**

### **Selection Criteria**

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

The minimum criteria for selection are:

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

### **Selection Process:**

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

### **Award**

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



## **EXPERT REVIEW PANEL OF THE YEAR**

supporting story, will be carried in the announcement in the *ILM*.

### **Selection Criteria**

The minimum criteria for selection are:

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

### **Selection Process:**

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

### **Award**

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



### **TECHNICAL SERVICE AWARD**

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

#### **Selection Criteria includes:**

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

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

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

- f. Helps guide AOAC in the decision-making process to make the organization a leader in the field of analytical science.

#### **Selection Process**

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

#### **Award**

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



## **METHOD OF THE YEAR**

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

### **Selection Criteria**

The minimum criteria for selection are:

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

### **Selection Process:**

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

### **Award**

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

# Documentation and Communication

- AOAC carefully documents the actions of Stakeholder Panel and the Working Groups
- AOAC will prepare summaries of the meetings
  - Communicate summaries to the stakeholders
  - Publish summaries in the *Referee* section of AOAC's *Inside Laboratory Management*
- AOAC publishes its voluntary consensus standards and Official Methods
  - *Official Methods of Analysis of AOAC INTERNATIONAL*
  - *Journal of AOAC INTERNATIONAL*
- AOAC publishes the status of standards and methods in the Referee section of AOAC's *Inside Laboratory Management*

# Roles and Responsibilities

- Official Methods Board
  - Vet and approve stakeholder panel chair & voting members
  - Vet and approve ERP membership
  - Review ERP recommendations and render decisions (Final Action, repeal, etc...)
  - Assign representative to serve as a resource to ERPs
  - Coordinate OMB Awards
- AOAC Stakeholder Panels
  - Develop standards
  - Assign working groups to draft standards method performance requirements
  - Voting members demonstrate consensus on behalf of stakeholders
- AOAC Expert Review Panels
  - Review methods and meet in person to render decisions on methods for First Action Official Methods status.
  - Track First Action Official Methods and modify, if necessary
  - Recommend First Action methods after 2 years or less to OMB for Final Action, continuance, or Repeal
- AOAC Staff
  - Coordinate standards and method reviews and approval activities
  - Coordinate OMB meetings
  - Provide trainings and orientations
  - Maintain website and communication
  - Document and publish actions and decisions
  - Publish standards and methods
  - other

Questions?

Thank you.

