

# ERP Orientation

## AOAC First Action Method Updates and Tracking

### Expert Review Panel Tracking and Recommendations of First Action Methods

Deborah McKenzie  
Sr. Dir., Standards Development  
AOAC INTERNATIONAL  
Staff Liaison - Official Methods Board



# Global confidence in consensus based analytical solutions for food safety, food integrity, and public health

AOAC

As a **leader of analytical excellence**,

**AOAC INTERNATIONAL** advances  
**food safety, food integrity, and public health,**

by **bringing together** members, organizations,  
and experts dedicated to developing and validating  
**standards, methods and technologies,**  
of **global relevance.**




The background features a collage of images related to AOAC International. At the top right is a document titled 'AOAC INTERNATIONAL' with a world map. Below it is a document titled 'AOAC INTERNATIONAL' with a world map. At the bottom left is a photograph of a meeting with people seated around a table. At the bottom center is a blue globe showing the Americas. At the bottom right is a document titled 'AOAC INTERNATIONAL' with a table of contents.

**AOAC**



## AOAC STRATEGIC PLAN



**AOAC INTERNATIONAL Strategic Plan**

**Vision**

Global confidence in consensus based analytical solutions for food safety, food integrity, and public health.


**Mission**

As a leader of analytical excellence, AOAC INTERNATIONAL advances food safety, food integrity, and public health, by bringing together members, organizations, and experts dedicated to developing and validating standards, methods and technologies, of global relevance.

**Goals**

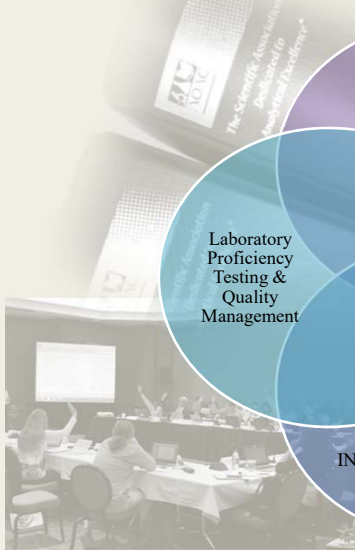
- Analytical Excellence** Address emerging issues and influence standards development as a global leader in analytical excellence.
- People** Attract and develop deeply engaged members, volunteers, staff, and customers to grow and strengthen the association and its programs.
- Relationships** Build strategic partnerships to advance food safety, food integrity, and public health.
- Core Programs** Develop and improve existing core programs, products, and services.
- Sustainability** Identify, strengthen, and grow revenue streams to ensure the association's long-term sustainability.
- Governance** Establish a highly effective governance and leadership culture providing value to all members and stakeholders.

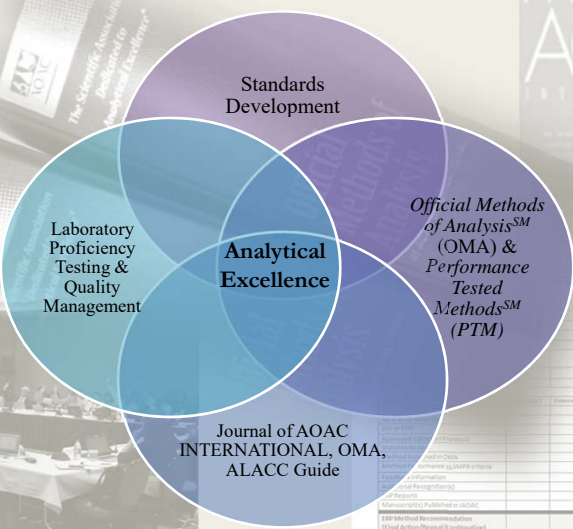
December 13, 2017  
AOAC INTERNATIONAL




Accessible at AOAC homepage  
[www.aoac.org](http://www.aoac.org)

*Analytical Excellence addresses emerging issues and influence standards development as a global leader in analytical excellence*



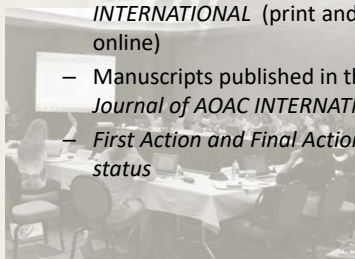




## AOAC Method Approval Programs

### ***Official Methods of Analysis<sup>SM</sup>*** **(OMA)**

- AOAC's premiere methods program
- Approved methods
  - published in the *Official Methods of Analysis of AOAC INTERNATIONAL* (print and online)
  - Manuscripts published in the *Journal of AOAC INTERNATIONAL*
  - *First Action and Final Action status*



### ***Performance Tested Methods<sup>SM</sup>*** **(PTM)**

- AOAC's method certification program
- Certified methods
  - Commercial/proprietary rapid methods (test kits)
  - Certifications published on AOAC website
  - Manuscripts published in the *Journal of AOAC INTERNATIONAL*
  - Method developers licensed to use certification mark
  - Annual review & recertification

Feedback information (Address/Phone/Email)	
ESP Report	
Manuscript Published in AOAC	
ESP Method Recommendation (Final Action/Regard/Continuation)	

## AOAC *Official Methods<sup>SM</sup>* Program

### Submit Methods Responding to issued Call for Methods

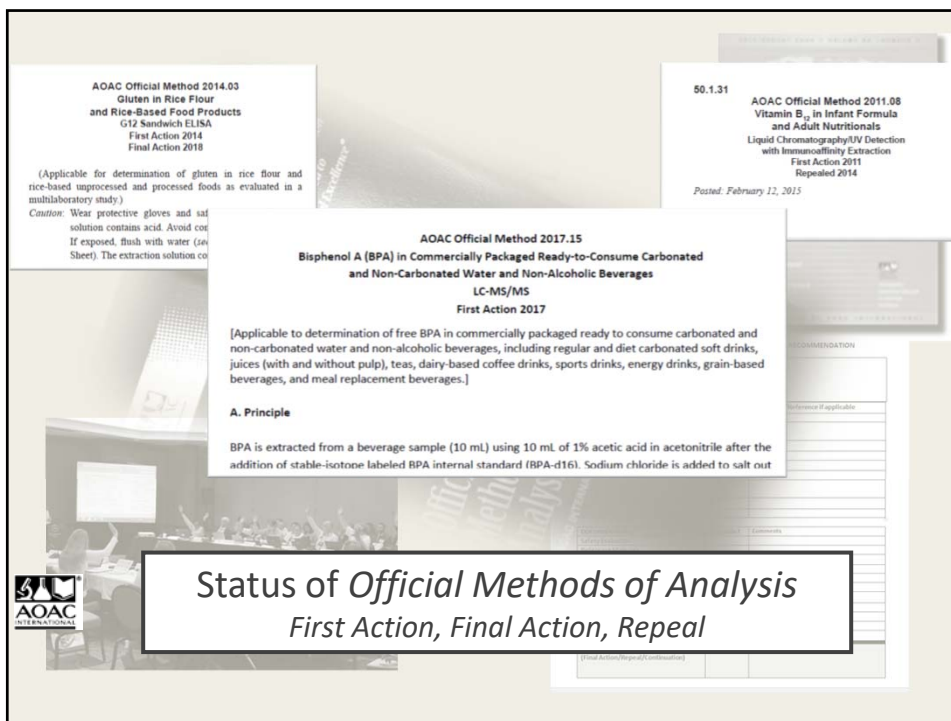
- Adoption of methods as *Official Methods* is contingent upon standards development activities
- No application fee required to submit methods in response to Call for Methods

### Submit Individual & Sole Source Methods

- Adoption of methods as *Official Methods* is contingent upon data supporting applicability and community based validation guidance information
- Including proprietary/commercial methods and harmonized PTM – OMA methods
- Application fee required



Feedback information (Address/Phone/Email)	
ESP Report	
Manuscript Published in AOAC	
ESP Method Recommendation (Final Action/Regard/Continuation)	



**AOAC Official Method 2014.03**  
Gluten in Rice Flour  
and Rice-Based Food Products  
G12 Sandwich ELISA  
First Action 2014  
Final Action 2018

(Applicable for determination of gluten in rice flour and rice-based unprocessed and processed foods as evaluated in a multilaboratory study.)  
**Caution:** Wear protective gloves and safety glasses. The extraction solution contains acid. Avoid contact with skin. If exposed, flush with water (see Safety Data Sheet). The extraction solution contains acid.

**50.1.31**  
**AOAC Official Method 2011.08**  
Vitamin B<sub>12</sub> in Infant Formula  
and Adult Nutritionals  
Liquid Chromatography/UV Detection  
with Immunoaffinity Extraction  
First Action 2011  
Repealed 2014  
Posted: February 12, 2015

**AOAC Official Method 2017.15**  
**Bisphenol A (BPA) in Commercially Packaged Ready-to-Consume Carbonated and Non-Carbonated Water and Non-Alcoholic Beverages**  
LC-MS/MS  
First Action 2017

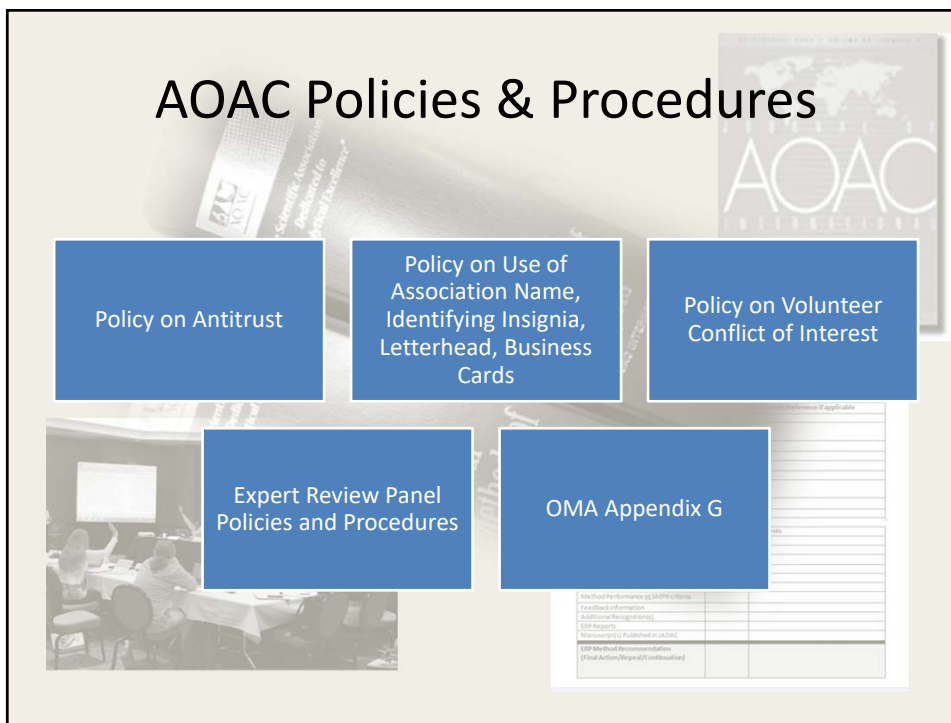
[Applicable to determination of free BPA in commercially packaged ready to consume carbonated and non-carbonated water and non-alcoholic beverages, including regular and diet carbonated soft drinks, juices (with and without pulp), teas, dairy-based coffee drinks, sports drinks, energy drinks, grain-based beverages, and meal replacement beverages.]

**A. Principle**

BPA is extracted from a beverage sample (10 mL) using 10 mL of 1% acetic acid in acetonitrile after the addition of stable-isotope labeled BPA internal standard (BPA-d16). Sodium chloride is added to salt out

**Status of Official Methods of Analysis**  
*First Action, Final Action, Repeal*

**AOAC INTERNATIONAL**



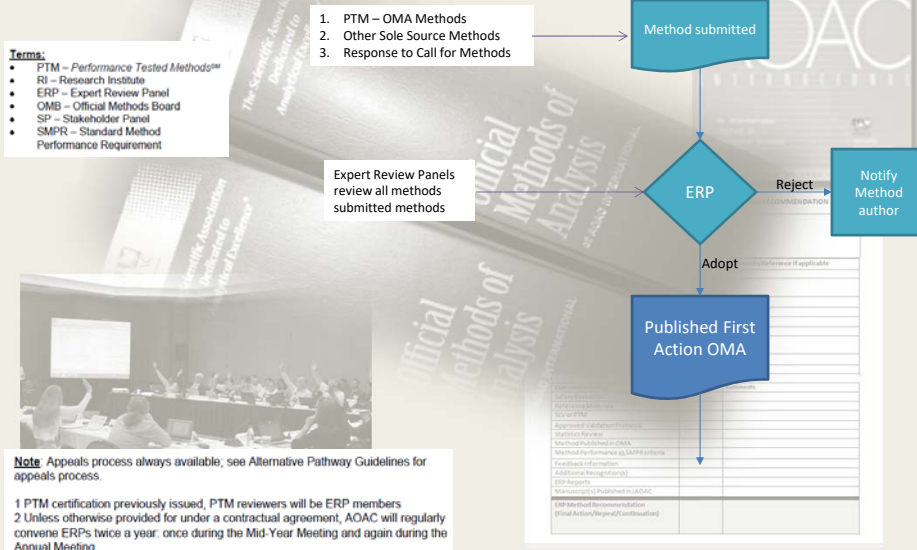
## AOAC Policies & Procedures

- 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

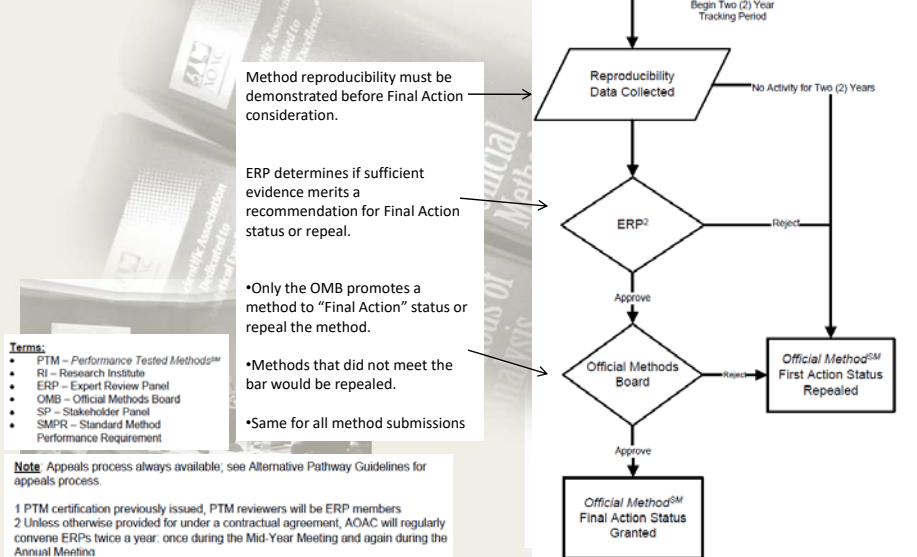
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## Road to First Action OMA Status



## Road to Final Action OMA Status



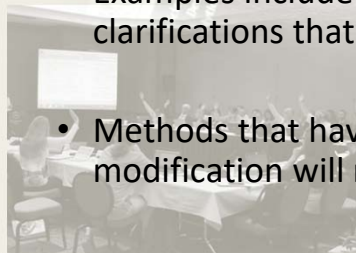
## Modifications to Official Methods

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

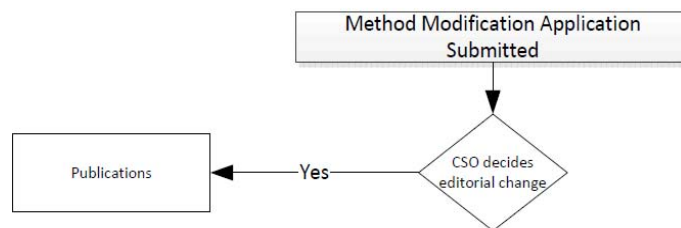


## Editorial Modifications

- 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.

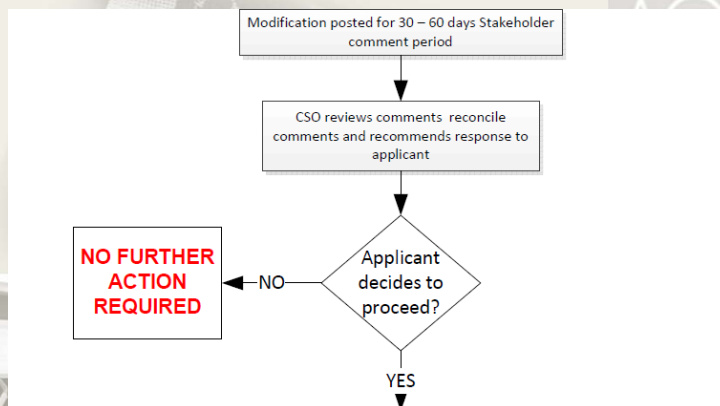
## Minor Modifications

- 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.



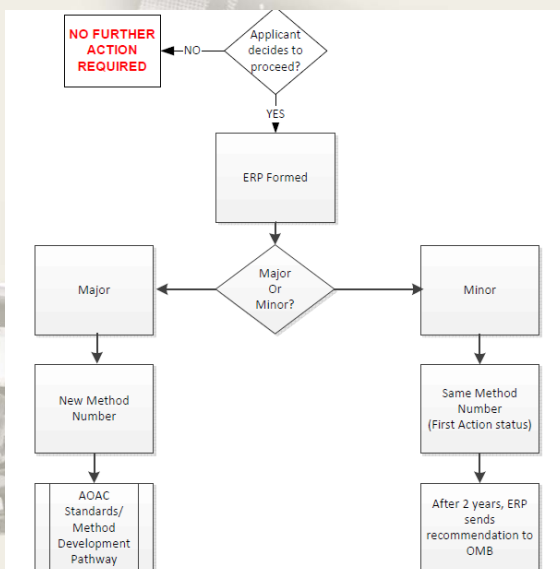


## Applicant Options



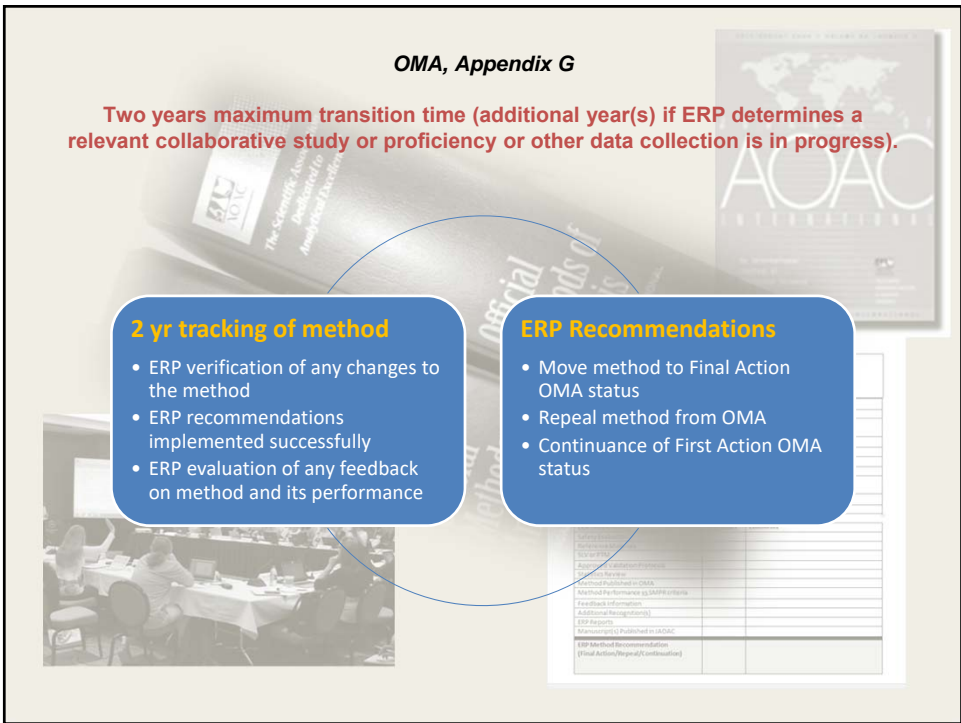
- Following the comment period, any comments are reconciled and recommends a response to the applicant.
- The applicant can decide to proceed based on the reconciled comments

## 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



**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**

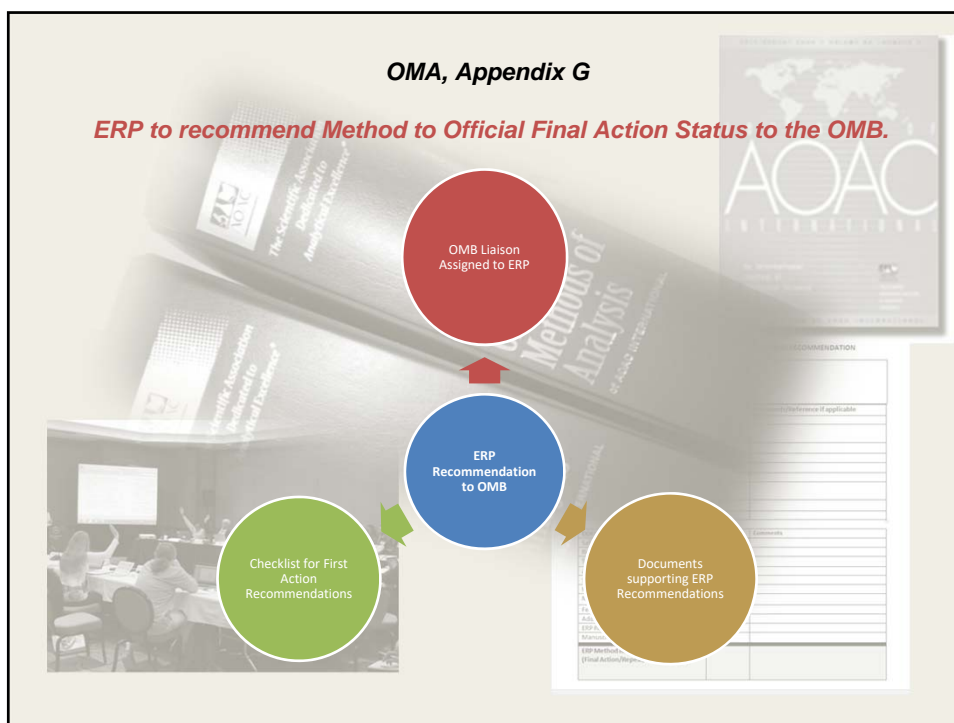
*Method removed from Official First Action and OMA if no data indicative of adequate method reproducibility is forthcoming as outlined above at the end of the transition time.*

**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.

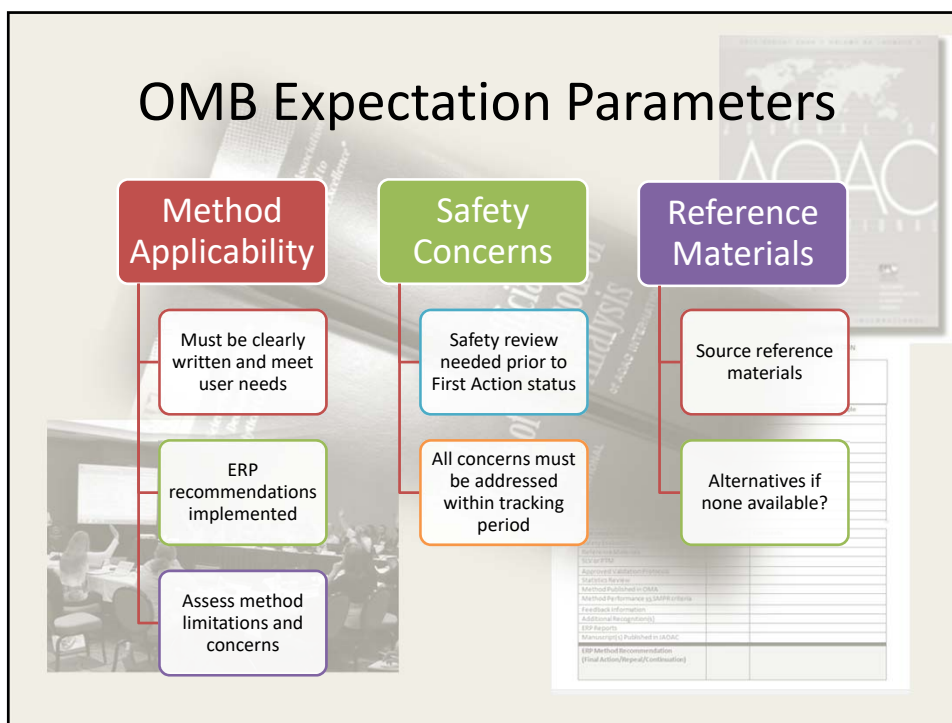
**No Demonstration of Method Reproducibility in  $\leq 2$  Years**

- Repeal from OMA

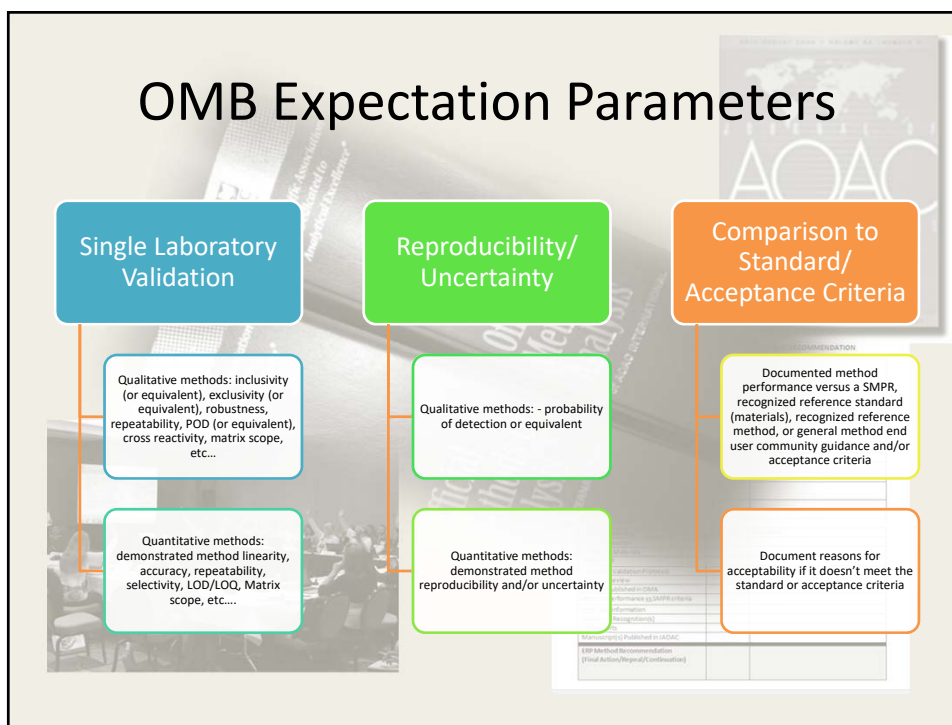




## OMB Expectation Parameters



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### 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

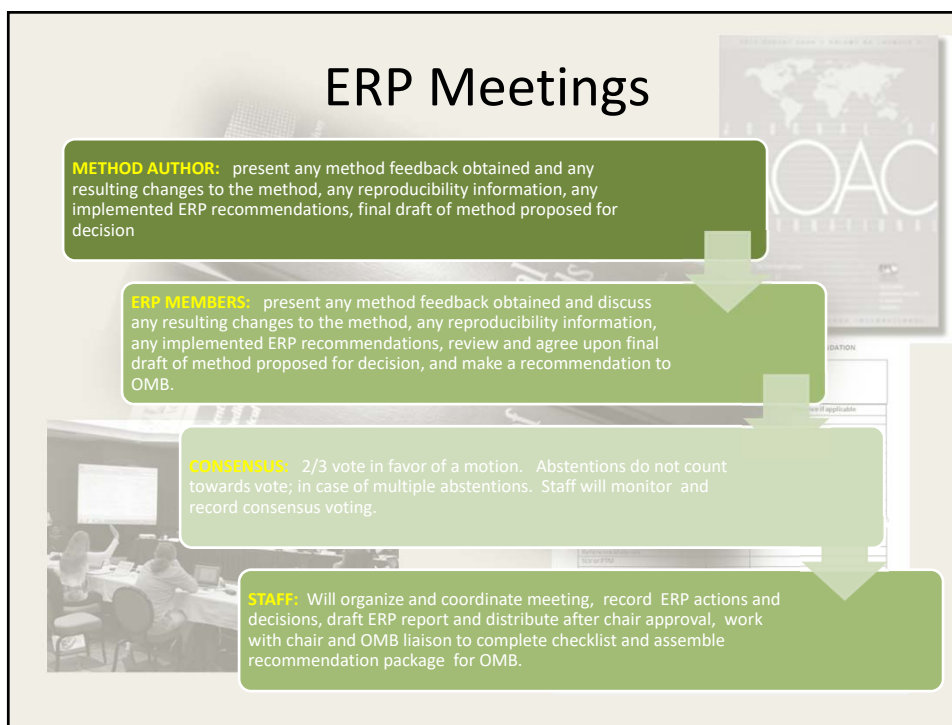
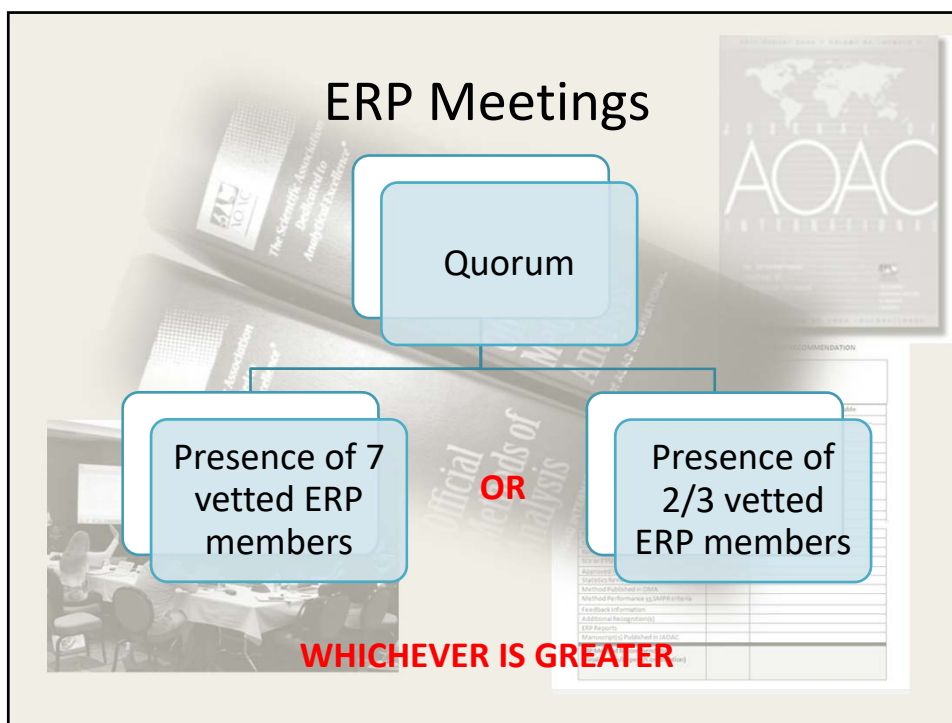
Evidence of Reproducibility Assessment

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 Recommendations/Decision

Recommend the method for Final Action OMA status

Recommend the method for continuance of First Action status

Recommend the repeal of the method from OMA

## Documentation and Communication

- AOAC carefully documents the actions of Stakeholder Panel, Working Groups, and Expert Review Panels
- 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*

## 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



## Roles and Responsibilities

### AOAC Official Methods Board

- Vet and approve stakeholder panel chair & voting members
- Vet and approve ERP membership and AOAC Experts
- Render decisions on status of First Action methods (Final Action, repeal, etc...)
- Assign a liaison to each stakeholder panel and ERP
- Coordinate OMB Awards

### AOAC Expert Review Panels

- Review methods and meet in person to render decisions on methods for First Action Official Methods<sup>SM</sup> status.
- Track First Action Official Methods<sup>SM</sup> and modify, if necessary
- Recommend First Action methods after 2 years or less to OMB for Final Action, continuance, or Repeal
- Participate in Consulting Service and PTM reviews for OMA and harmonized PTM and harmonized OMA method studies

### AOAC Experts

- Review and approve PTM validation testing protocol documentation
- Peer review of PTM validation manuscript and supporting documentation

### AOAC Research Institute - PTM Expert Reviewers

- Peer Review of PTM validation manuscripts and supporting documentation

### AOAC Research Institute Independent Laboratories

- Conduct independent evaluation of candidate method using AOAC approved testing protocols

### AOAC Stakeholder Panels

- Develop voluntary consensus standards
- Assign working groups to draft standards method performance requirements
- Voting members demonstrate consensus on behalf of stakeholders

### AOAC Staff

- Coordinate method reviews and method approval activities
- Coordinate OMB meetings
- Provide trainings and orientations
- Maintain website and communication
- Document and publish actions and decisions
- Coordinate standards development activities
- Publish standards and methods

### AOAC Research Institute Technical Consultants

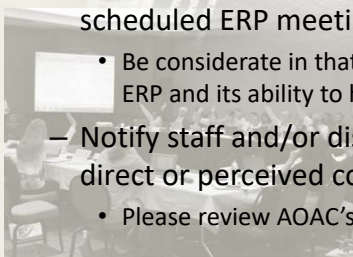
- Draft validation protocols in Consulting Service for assigned methods
- Facilitate PTM evaluation of assigned candidate methods
- Facilitate comments/responses for assigned OMA reviews

## General Expectations for ERPs

- ERP members are expected to be a proactive part of the process and sharing feedback with the ERP
- You can expect to have a minimum of three weeks to review methods prior to ERP meeting.
  - You are requested to submit written reviews by specified deadline. Please alert staff if you are not able to complete on time.
  - You may have individually assigned methods to review or all of the methods to review. Please be prepared to discuss these methods during meeting.
  - You may use the OMA appendices as guidance for types of validation work that can be expected. If additional information is needed, please ask staff.
  - ERP must review final draft of method prior to recommendation for Final Action status
- ERP Meeting Quorum
  - If there is no quorum, there is no official meeting. Please alert staff as early as possible if you are not able to attend a meeting.
- ERP Consensus
  - ERP consensus may not reflect your own personal view
  - There may be times when a method may not meet all of the criteria exactly; however, the ERP can make a recommendation on the method with justification

## Ethical Expectations of AOAC Expert Review Panel Members

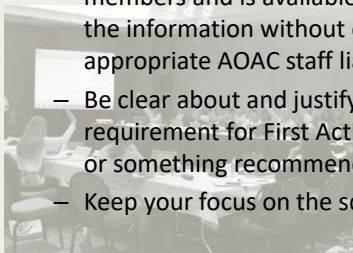
- Respect for your peer ERP members and chair
  - Each member has been vetted for expertise relevant to the review of the method(s) in the ERP
    - Be considerate of each others perspectives and points of view
    - Be considerate of the ERP's consensus even if you disagree
  - Inform staff as early as possible if you cannot attend the scheduled ERP meeting
    - Be considerate in that your absence can impact the quorum of the ERP and its ability to have an official meeting to make decisions
  - Notify staff and/or disclose in the ERP meeting if you have a direct or perceived conflict of interest for a specific method
    - Please review AOAC's policy on Volunteer Conflict of Interest



Method(s) Name(s)	Feedback Information
Method(s) Description(s)	ERP Report(s)
Method(s) Recommended in AOAC	ERP Method Recommendation
Method(s) Recommended in AOAC	Final Action/Regard/Coordination

## Ethical Expectations of Expert Review Panel Members (con't)

- Respect for Method Authors and Intellectual Property
  - Each Method Author is encouraged to attend the ERP meeting
  - Each adopted or published as *Official Methods of Analysis of AOAC INTERNATIONAL* is AOAC INTERNATIONAL; however, additional supporting information and/or data are still the intellectual property of the method author. Therefore, the information is shared only with the vetted ERP members and is available during the meetings. Please do not distribute the information without expressed written permission from an appropriate AOAC staff liaison.
  - Be clear about and justify how additional recommended work is a requirement for First Action, a requirement for Final Action consideration, or something recommended, but not necessary.
  - Keep your focus on the science



Method(s) Name(s)	Feedback Information
Method(s) Description(s)	ERP Report(s)
Method(s) Recommended in AOAC	ERP Method Recommendation
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