

AOAC Expert Review Panels *An Orientation*




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AOAC INTERNATIONAL
Staff Liaison - Official Methods Board

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





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.

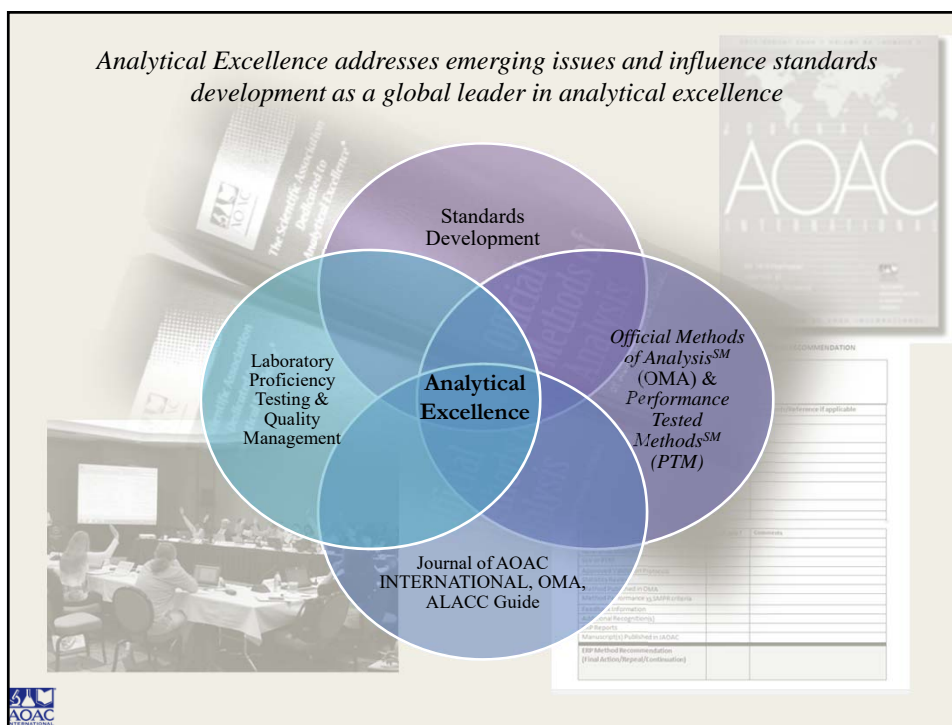
Goals

- 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



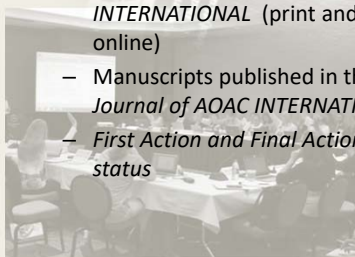
Accessible at AOAC homepage
www.aoac.org



AOAC Method Approval Programs

Official Methods of AnalysisSM **(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 MethodsSM **(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 MethodsSM* Program

Submit Methods Responding to issued Call for Methods

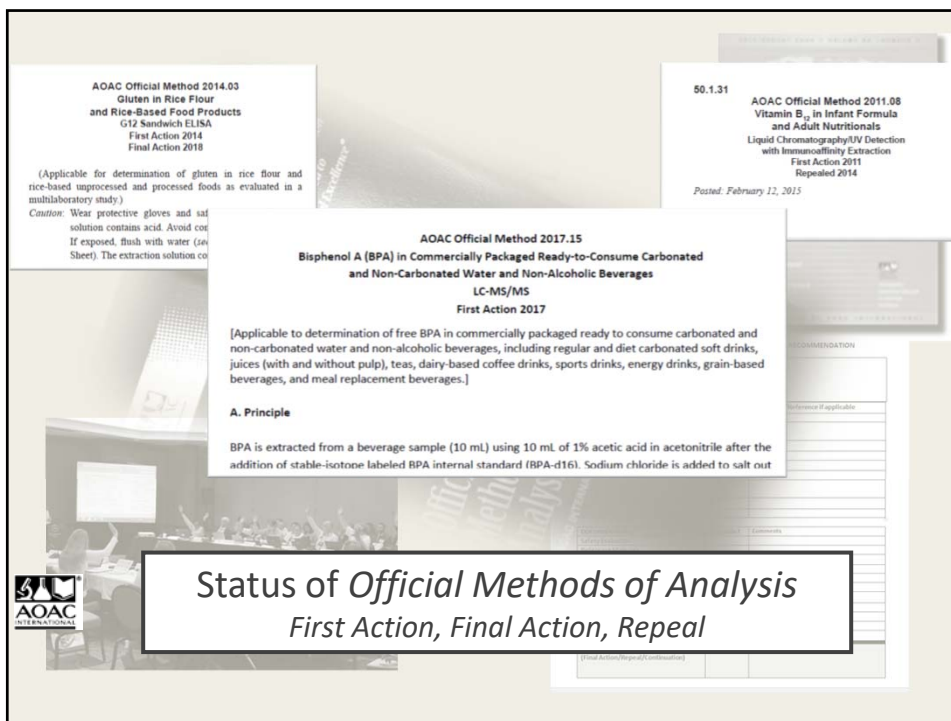
- Adoption of methods as *Official Methods* is contingent upon standards development activities
- No application fee required to submit methods in response to Call for Methods

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.

AOAC Official Method 2011.08
Vitamin B₁₂ in Infant Formula
and Adult Nutritional
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-Drink Carbonated
and Non-Carbonated Water and Non-Alcoholic Beverages
LC-MS/MS
First Action 2017

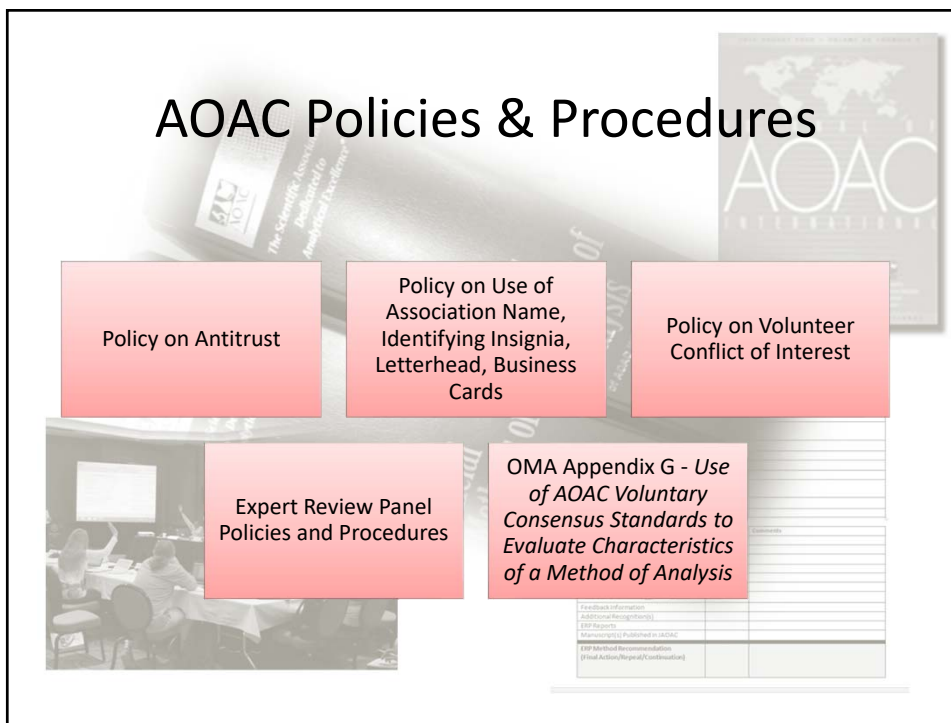
(Applicable to determination of free BPA in commercially packaged ready to consume carbonated and non-carbonated water and non-alcoholic beverages, including regular and diet carbonated soft drinks, juices (with and without pulp), teas, dairy-based coffee drinks, sports drinks, energy drinks, grain-based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

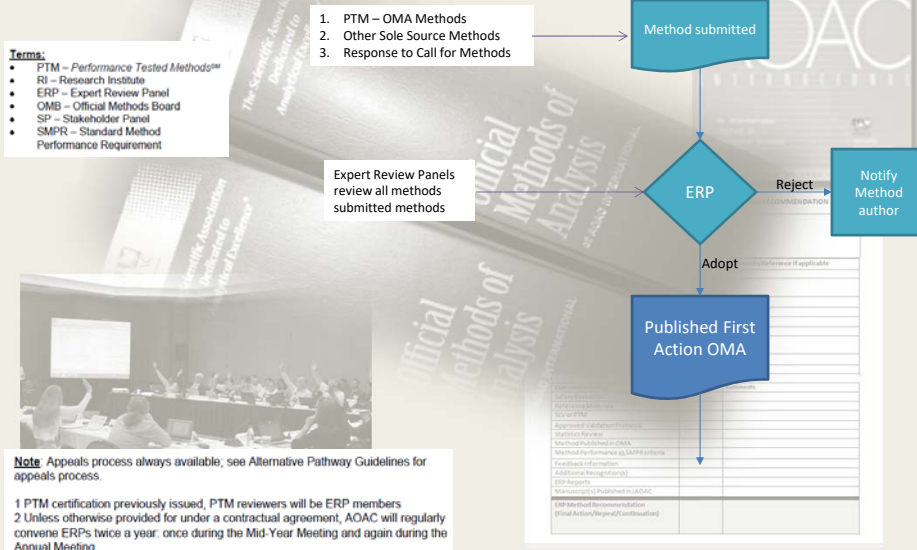


AOAC Policies & Procedures

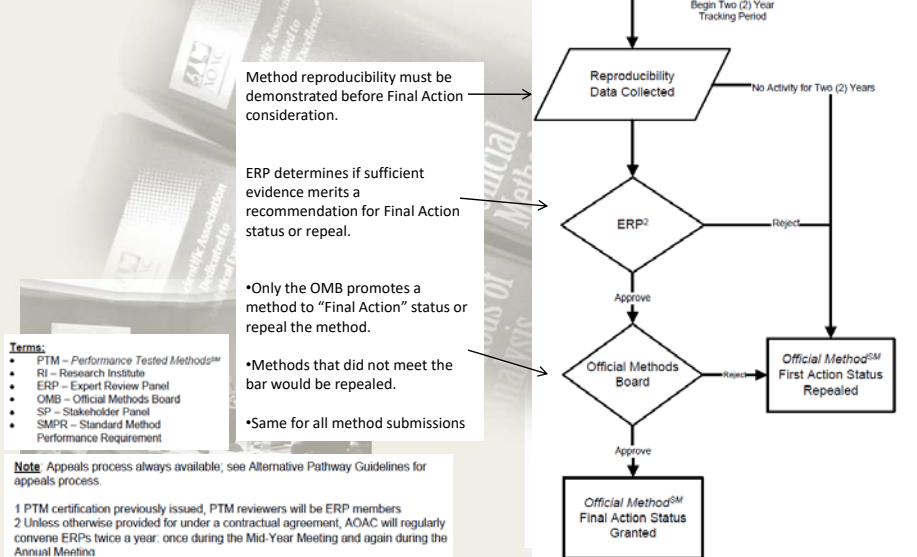
- Policy on Antitrust
- Policy on Use of Association Name, Identifying Insignia, Letterhead, Business Cards
- Policy on Volunteer Conflict of Interest
- Expert Review Panel Policies and Procedures
- OMA Appendix G - Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis

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Road to First Action OMA Status

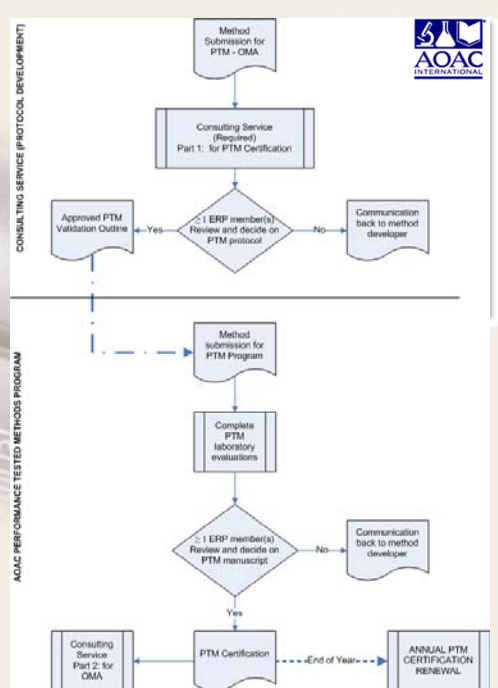


Road to Final Action OMA Status



PTM Overview for PTM-OMA Harmonized Process

- Administered by the Research Institute in 2003.
- Well established and streamlined
- Original approved by consensus with the OAs, OMB, RI Board of Directors and AOAC INTERNATIONAL Board of Directors.
- ERP may be formed during Consulting Service.
- Criterion for OMA: manufacturer's method claims.



Recruiting Experts and Methods

- AOAC issues
 - Call for Methods (*Stakeholder affiliated methods*)
 - Call for Experts
- Sole Source/Individual Method Submissions
 - Individually completed Application *not associated with an open Call for Methods*



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

Candidate submits application package

Reviewed by AOAC staff with recommendation to OMB

Reviewed by OMB and roster approved

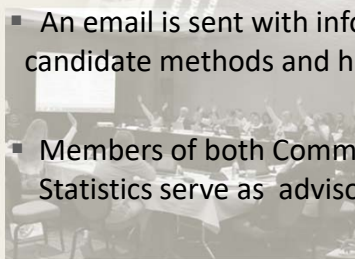
Approved roster sent to AOAC President for volunteer appointment

•All members serve at the pleasure of the AOAC President

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

Candidate Method Assignments

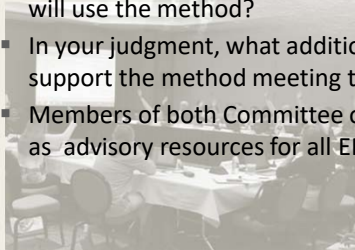
- A minimum of primary and secondary reviewers may be assigned to every method.
 - In depth review via review form
 - Prepare to attend and speak on the method and make a recommendation for ERP discussion and consideration.
 - Review forms are completed and returned to AOAC staff in advance of the meeting.
- An email is sent with information on how to access the candidate methods and how to submit reviews
- Members of both Committee on Safety and Committee on Statistics serve as advisory resources for all ERPs



Candidate Method Information	
Method Name	Method Description
ERP Report	Method Description
Method Recommendation	Method Recommendation
Final Action/Regard/Continuation	Final Action/Regard/Continuation

Candidate Method Reviews

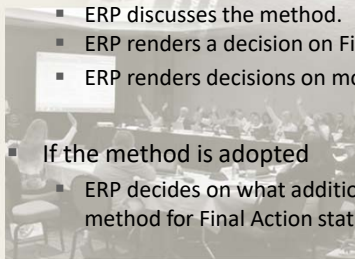
- In your judgment, does the method sufficiently meet the Standard Method Performance Requirements (SMPR) or community-based guidance?
- In your judgment, is the method scientifically sound and can be followed?
- In your judgment, what are the strengths and weaknesses of the method?
- In your judgment, how do the weaknesses weigh in your recommendation for the method?
- In your judgment, will the method serve well the stakeholder community that will use the method?
- In your judgment, what additional information may be needed to further support the method meeting the SMPR or community-based guidance?
- Members of both Committee on Safety and Committee on Statistics serve as advisory resources for all ERPs



Candidate Method Information	
Method Name	Method Description
ERP Report	Method Description
Method Recommendation	Method Recommendation
Final Action/Regard/Continuation	Final Action/Regard/Continuation

ERP Meetings

- ERPs can meet in person at a minimum of twice a year and up to four times per year*:
 - AOAC Mid-Year meeting (DC metro area)
 - AOAC Annual Meeting.
 - *2 additional designated times for proprietary method Organizational Affiliates
- At the ERP meeting:
 - Reviews will be presented and the reviewers can make a motion to the ERP whether to adopt the method as First Action OMA.
 - ERP discusses the method.
 - ERP renders a decision on First Action status.
 - ERP renders decisions on modifications to *Official Methods*.
- If the method is adopted
 - ERP decides on what additional information is needed to recommend the method for Final Action status

[illegible]

ERP Teleconferences

- Only after the initial in-person ERP meeting for First Action consideration of methods
- Possible for some method modifications
- Possible for First Action to Final Action ERP recommendations

[illegible]

ERP Meetings

Quorum

Presence of 7
vetted ERP
members

OR

Presence of
2/3 vetted
ERP members

WHICHEVER IS GREATER
IF NO QUORUM, NO OFFICIAL MEETING

Method Review Overview

- Method authors may be invited to make a presentation on their method
- REVIEWERS PRESENT THEIR REVIEWS AND MAY INITIATE A MOTION TO ADOPT THE METHOD IF THEY CHOOSE
 - Chair recognizes each reviewer
 - Reviews are presented.
 - If in favor, reviewers may make and second a motion to adopt the method
 - Chair can then entertain discussion on the method
 - Chair can call for a vote once deliberation is complete

Consensus – First Action Adoption

- First Action Official Methods status is granted:
- Method must be adopted by unanimous decision of ERP on first ballot, if not unanimous, negative votes must be based on scientific reasons.
- Negative voter(s) can be overridden by 2/3 of voting ERP members after due consideration.
- Method becomes First Action on the date when ERP decision is made.

Consensus – First Action to Final Action

- The ERP may then reach consensus on any additional information that it needs to review to be able to make a recommendation for Final Action *Official Methods* status.
- This is a separate motion.

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 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.

OMB Expectations for First Action

Safety review needed
prior to First Action
status

SLV type of supporting
information available
per the SMPR

Comparison to SMPR

- Applicability, Method Performance Requirements Table, System Suitability, Reference Materials, and Validation Guidance

- Documented method performance versus a SMPR
- Document reasons for acceptability if method does not meet the SMPR

Publication of First Action Methods

Any approved method(s) along with supporting manuscript(s) and documentation sent to AOAC Publications after the meeting.

Method incorporating ERP revisions (preferably in AOAC Format)

Method Manuscript incorporating specified ERP revisions (in AOAC Format)

Signed AOAC Copyright Authorization form

**NO OMA NUMBER ASSIGNED
UNTIL ALL DOCUMENTATION
SUBMITTED**

Method and method manuscript prepared for publication in the *Official Methods of Analysis of AOAC INTERNATIONAL* and in *Journal of AOAC INTERNATIONAL*

Updates on methods approved or status changes are published in the *Inside Laboratory Management* magazine and on the AOAC website

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.

Documentation Needed

Method Safety Evaluation

Reference Materials

Evidence of Single Laboratory Validation or equivalent

Evidence of Reproducibility Assessment

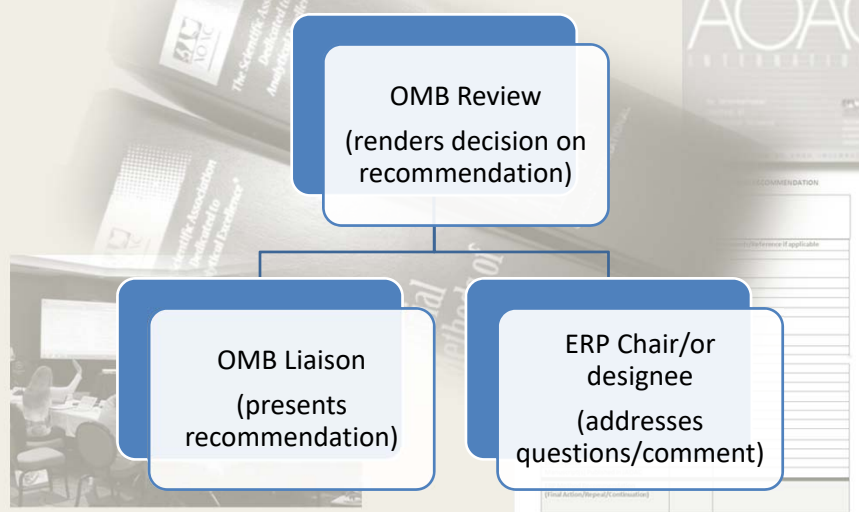
Published First Action OMA

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

OMB Meeting for Review of ERP Recommendations



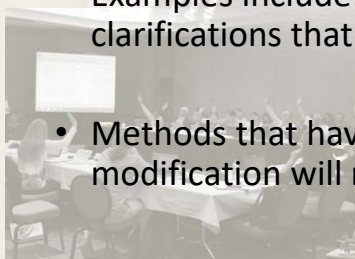
Modifications to Official Methods

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



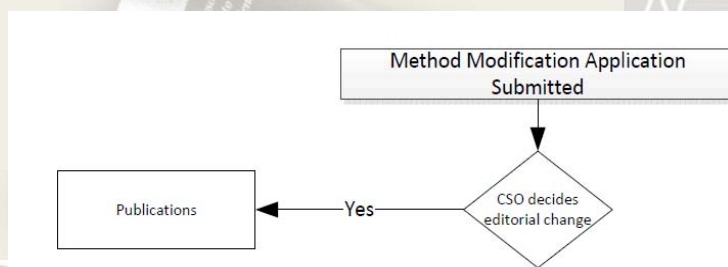
Editorial Modifications

- 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.

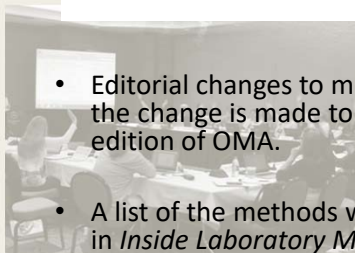


RECOMMENDATION	
Feedback Information	
Editorial/Printing/Identical	
Other Comments	
Manuscript(s) Published in OMA	
Unpublished Recommendation	
Final Action/Regrind/Continued	

Editorial Changes



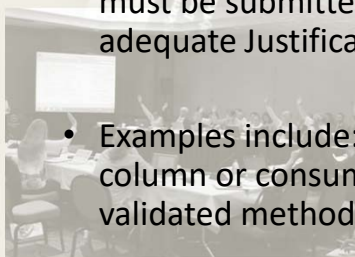
- Editorial changes to methods only require AOAC staff review and the change is made to the OMA with changes noted in next printed edition of OMA.
- A list of the methods with editorial modifications will be published in *Inside Laboratory Management* and on the Website.



Feedback Information	
Editorial/Printing/Identical	
Other Comments	
Manuscript(s) Published in OMA	
Unpublished Recommendation	
Final Action/Regrind/Continued	

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.



the proposed modification
ency data is required un
clude this data is provid
change, a change in a
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nce.

Major Modifications

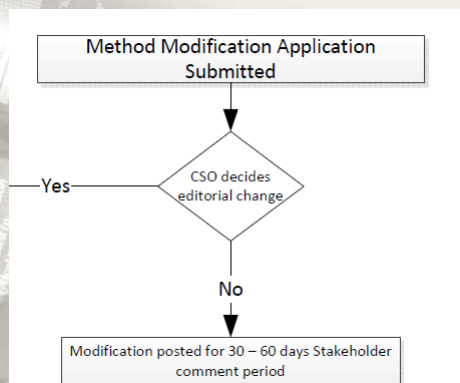
- Results in a change to the current validated performance of the method.
- This level of modification will result in a new method as part of AOAC standards development and will receive a new method number.
- Examples include: significant change to the technology, sample preparation, or chemistry.



number.

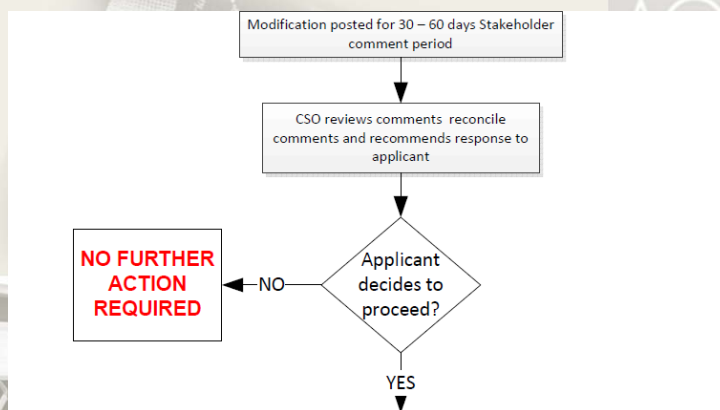
ant change to the
ration, or chemistry.

Minor & Major Modifications



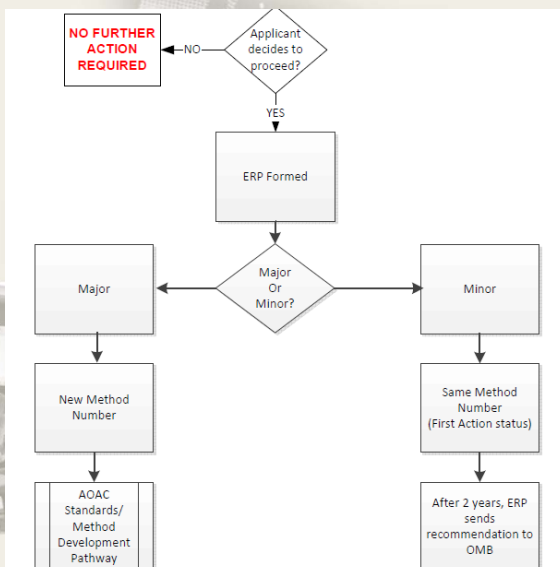
Based on AOAC staff review, a public comment period for the proposed modification is required.

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

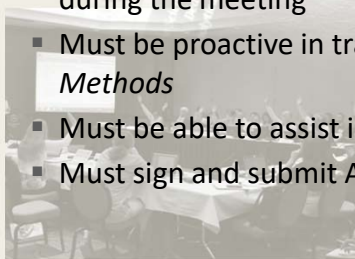
- Level of modification determined by ERP
- Applies to modifications of First Action and Final Action methods

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*

Requirements for ERP Service

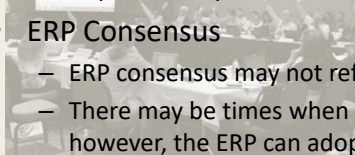
- Must have demonstrated expertise in the method, technology, analyte/matrix, etc... **Be a subject matter expert.**
- Must be able to attend ERP meetings
- Must be able to complete assigned reviews on time
- Must be prepared to speak on the method and share reviews during the meeting
- Must be proactive in tracking assigned First Action *Official Methods*
- Must be able to assist in peer reviewing paper for publication
- Must sign and submit AOAC Volunteer Acceptance Form



Feedback Information	
Method Name	
Method Number	
Method Title	
Method Description	
Method Recommendation	
Method Action/Regard/Coordination	

General Expectations for ERPs

- 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 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 adopt the method.



Feedback Information	
Method Name	
Method Number	
Method Title	
Method Description	
Method Recommendation	
Method Action/Regard/Coordination	

- 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

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 candidate methods (not yet adopted or published as *Official Methods of Analysis of AOAC INTERNATIONAL*) 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

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 MethodsSM status.
- Track First Action Official MethodsSM 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

Questions?

Thank you



RECOMMENDATION	
Method name if applicable	
Method number	
Method description	
Method type	
Method format	
Method format (e.g., SOP, etc.)	
Feedback information	
Additional Designation(s)	
ERP Report	
Comments	
ERP Method Recommendation (Final Action/Repeal/Continuation)	