AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

Expert Review Panel

for

Kombucha Tea

SHERATON DALLAS HOTEL
SEPTEMBER 18, 2016
1:00PM – 3:00PM
ROOM: STATE 1

contact: spsfam@aoac.org

The Scientific Association Dedicated to Analytical Excellence®

AOAC Stakeholder Panel on Strategic Food Analytical Methods

Ethanol in Kombucha Expert Review Panel

Sunday, September 18, 2016, 1 :00 p.m. – 3 :00 p.m.
Dallas Sheraton Hotel, Room State 1

A G E N D A

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1. Welcome and Introductions
   Sneh Bhandari, Mérieux NutriSciences (ERP Chair)

2. Review of AOAC Volunteer Policies & ERP Proccess Overview and Guidelines
   Deborah McKenzie, AOAC INTERNATIONAL

3. Review of Methods
   For each method, the assigned ERP members will present a review of the revised method manuscripts, after which the ERP will discuss the method and render a decision on the status for each method.

   A. KOM-01
      a. Bhandari Review
      b. Discussion and Vote

   B. KOM-02
      a. Mirzoian Review
      b. Stenerson Review
      c. Discussion and Vote

   C. KOM-03
      a. Stryffeler Review
      b. Joseph Review
      c. Discussion and Vote

   D. KOM-04
      a. Bhandari Review
      b. Discussion and Vote

   E. KOM-05
      a. Stryffeler Review
      b. Jayabalan Review
      c. Discussion and Vote

4. Final Action Requirements for Approved Method(s)

5. Adjourn

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AOAC Stakeholder Panel on Strategic Food Analytical Methods:

Expert Review Panel

AOAC Candidate Method #KOM-01

Ethanol in Kombucha – Gas Chromatographic Method

- Author(s): Blake Ebersole
- Submitted by: Blake Ebersole, NaturPro Scientific
- Enclosures: 2
- Submitter notes: None

Primary Reviewer: Bhandari

Secondary Reviewer: *Application Withdrawn*

AOAC SPSFAM ERP REVIEW: MAIN FORM

Submission Date	2016-09-12 09:20:05
Name	SNEH BHANDARI
E-mail	sneh.bhandari@mxns.com
Organization	Silliker Laboratories
Title of Method	Ethanol in Kombucha Gas Chromatographic Method
AOAC Candidate Method Number (e.g. ALN-01)	AOAC Candidate Method #KOM-01
Applicable SMPR	AOAC SMPR 2016.001

I. Summary of Method

Summary:	GC-FID method of ethanol estimation in aqueous beverages. The method employs head-space autosampler to introduce ethanol vapors into GC. The ethanol from the sample in is vaporized into head space and that's how some matrix interference are prevented. n-propanol is used as an internal std. Ethanol is estimated as ABV. Applicable for determination of 0.1 to 3.3% ABV in aqueous kombucha tea beverages.

II. Review of Method Only

1. Does the applicability of the method support the applicability of the SMPR? If not, please explain what is missing.	Yes
2. Does the analytical technique(s) used in the method meet the SMPR? If not, please specify how it differs from what is stated in the SMPR.	Yes
3. Are the definitions specified in the SMPR used and applied appropriately in the method? If no, please indicate how the terms are used.	Yes
4. Does the method, as written, contain all appropriate precautions and warnings related to the method's reagents, components, instrumentation, or method steps that may be hazardous? If no, please suggest wording or option(s).	No. The method may state precautions correctly regarding flammability of some of the solutions like ethanol and propanol used in the method. The method also state precautions in using high pressure gases used in instrumentation.

III. Review of Information in Support of the Method

1. Are the definitions specified in the SMPR used and applied appropriately in the supporting documentation (manuscripts, method studies, etc...)? If not, please explain the differences and if the method is impacted by the difference.	Yes
2. Is there information demonstrating that the method meets the SMPR Method Performance Requirements using the Reference Materials stated in the SMPR? If not, then specify what is missing and how this impacts demonstration of performance of the method.	The SLV study presented has tried evaluate the method accuracy using a variety of reference materials. Certified Reference Material (CRM) evaluation NIST-certified reference materials was initiated by the lab, and performed on Day 1 and Day 2. Percent recovery ranged from 97.1 to 99.2%. The SLV summary provides data of evaluation of (Cerilliant E-031) 0.1267% +/- 0.0011%, results obtained 0.131, 0.127, 0.129, 0.127, 0.126% ABV, mean = 0.128%; 101% of the required mean. The SLV summary also provides data of evaluation of (LGC BCR-651) 0.505% +/-0.006%; Results 0.526*, 0.455, 0.490, 0.439, 0.463% ABV, Mean = 0.475%; stated as 104%* (Beer) which may require clarification. Mean is really 94% of the specified mean and is some what lower than expected based on SMPR % recovery requirements & the BCR range. SLV also report data on evaluation of Certified Reference Material Ethanol Water (NIST 2897a) 2.53% +/- 0.057%. Results 2.59*, 2.34, 2.50, 2.29, 2.34% ABV Mean = 2.41%; less than the NIST range. Stated % of expected is 102%* which may require clarification, really its 95.3%, somewhat lower than expected.
3. Is there information demonstrating that the method performs within the SMPR Method Performance REquirements table specifications for all analytes in the SMPR applicability statement? If not, please specify what is missing and whether or not the method's applicability should be modified.	The information provided in the manuscript demonstrate that the method meets the SMPR particularly in many of its requirements. Manuscript state that the Precision was determined by analyzing six replicates of each sample of commercial Kombucha over a minimum of two days. The RSD(r) (%) the first day was satisfactory but the second day was higher than RSDr requirement of equal or less than 4%. RSD(r) (%) 5.542. The overall repeatability RSD(iR) (%) 3.888 was satisfactory. The precison evaluation of 7 different Kombucha provided satisfactory %RSD values. Accuracy was determined by testing duplicates at each of three spike levels of pure ethanol into control kombucha over three days (totaling 18 total replicates). The spike levels were 0.13, 1.3, and 3.3% ABV. Percent recovery ranged from 98.3 to 104.2%.Mean 99.6, 100.4 & 100.4. RSD(R) (%) 2.33, 1.84 & 2.03. Meets SMPR. The SLV also provided some data to recognize LOQ 0.04% ABV.Day 1 data are OK but day 2 data may need further clarification indicate lower recovery and higher variability.

IV. General Submission Package

1. Based on the supporting information, were there any additional steps in the evaluation of the method that indicated the need for any additional precautionary statements in the method?	Need of Precautionary statement regarding use of solvents and gases under high pressure already mentioned earlier.
2. Does the method contain system suitability tests or controls as specified by the SMPR? If not, please indicate if there is a need for such tests or controls and which ones.	System suitability criteria are mentioned through out manuscript but not concisely in one place and as clear specific requiremnts.

3. Is there information demonstrating that the method system suitability tests and controls as specified in the SMPR worked appropriately and as expected? If no, please specify.	yes
4. Based on the supporting information, is the method written clearly and concisely? If no, please specify the needed revisions.	The method is written in two different documents. The single final document may be required.
5. Based on the supporting information, what are the pros/strengths of the method?	Simple and straight forward method. The SLV have tried to generate sufficient information about precision and accuracy of the method.
6. Based on the supporting information, what are the cons/weaknesses of the method?	The method may not be specific enough as compared to other available methods. The variability may be on some what high side and % recovery on low side of data in support of mentioned LOQ of 0.04%.
7. Any general comments about the method?	A promising method.

Recommendation for the Method

Do you recommend this method be adopted as a First Action and published in the Official Methods of Analysis of AOAC INTERNATIONAL? Please specify rationale.	I do recommend the method for first action provided there is no other method more specific and is more precise in quantitation at lower levels.

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AOAC Stakeholder Panel on Strategic Food Analytical Methods:

Expert Review Panel

AOAC Candidate Method #KOM-02

Fluorescent Detection of Ethanol in Kombucha via Alcohol Dehydrogenase

- Author(s): Michael Valley, Jolanta Vidugiriene, and James Cali
- Submitted by: Michael Valley, Promega Corp
- Enclosures: 0
- Submitter notes: None

Primary Reviewer: Mirzoian

Secondary Reviewer: Stenerson

AOAC SPSFAM ERP REVIEW: MAIN FORM

Submission Date	2016-09-14 16:00:11
Name	Armen Mirzoian
E-mail	armen.mirzoian@ttb.gov
Organization	TTB
Title of Method	Fluorescent Detection of Ethanol in Kombucha via Alcohol Dehydrogenase
AOAC Candidate Method Number (e.g. ALN-01)	KOM-02
Applicable SMPR	Ethanol In Kombucha

I. Summary of Method

Summary:	This is an enzymatic assay for ethanol determination in Kombucha that uses alcohol dehydrogenase to oxidize alcohol and produce NADH which activates a fluorescent sensor compound. The sensor compound is detected by a fluorometer and the resulting signal is proportional to the concentration of ethanol in kombucha.

II. Review of Method Only

1. Does the applicability of the method support the applicability of the SMPR? If not, please explain what is missing.	Yes.
2. Does the analytical technique(s) used in the method meet the SMPR? If not, please specify how it differs from what is stated in the SMPR.	Not completely. 1. %wt is measured and reported instead of specified %abv 2. Method's accuracy/recovery exceeds values specified in performance requirements. 4. RSDs for repeatability were not reported(only %CV). I calculated RSDs and 3 out of 4 values exceed performance requirements. 5. Method's reproducibility was not estimated.
3. Are the definitions specified in the SMPR used and applied appropriately in the method? If no, please indicate how the terms are used.	1. Ethanol concentrations are measured and reported on %wt bases and not %abv bases and no unit conversion is performed. 2. One certified material was used as a calibration, however no accuracy/recovery studies were performed using certified reference material from a different source. 3. It is not clear how the 0.5% ethanol accuracy was measured if the only available reference material was 0.1% w/v.
4. Does the method, as written, contain all appropriate precautions and warnings related to the method's reagents, components, instrumentation, or method steps that may be hazardous? If no, please suggest wording or option(s).	No, however kombucha and ethanol are not hazardous. Also fluorometry is considered a non-hazardous technique.

III. Review of Information in Support of the Method

1. Are the definitions specified in the SMPR used and applied appropriately in the supporting documentation (manuscripts, method studies, etc...)? If not, please explain the differences and if the method is impacted by the difference.	Ethanol concentrations are measured and reported on %wt bases and not %abv bases and no unit conversion is performed. Reporting results in %wt underestimated ethanol content when it's expected to be expressed in %abv.
2. Is there information demonstrating that the method meets the SMPR Method Performance Requirements using the Reference Materials stated in the SMPR? If not, then specify what is missing and how this impacts demonstration of performance of the method.	No. One certified material was used as a calibration, however no accuracy/recovery studies were performed using listed certified reference material from a different source. Also, it is not clear how the 0.5% ethanol accuracy was measured if the only available reference material was 0.1% w/v. Please also see II.2
3. Is there information demonstrating that the method performs within the SMPR Method Performance REquirements table specifications for all analytes in the SMPR applicability statement? If not, please specify what is missing and whether or not the method's applicability should be modified.	Not applicable. Please also see II.2

IV. General Submission Package

1. Based on the supporting information, were there any additional steps in the evaluation of the method that indicated the need for any additional precautionary statements in the method?	I'm not really clear about this question. No possible interferences were indicated.
2. Does the method contain system suitability tests or controls as specified by the SMPR? If not, please indicate if there is a need for such tests or controls and which ones.	It doesn't seem so. It is not clear how test solutions that contain 0.5%, 1% and 2% ethanol were or could be prepared prepared, since only 0.1%w/v reference solution was used.
3. Is there information demonstrating that the method system suitability tests and controls as specified in the SMPR worked appropriately and as expected? If no, please specify.	It doesn't seem so. Please see above.

4. Based on the supporting information, is the method written clearly and concisely? If no, please specify the needed revisions.	Yes, generally it is clear and concise.
5. Based on the supporting information, what are the pros/strengths of the method?	High sensitivity and ease of use.
6. Based on the supporting information, what are the cons/weaknesses of the method?	Please see my comments above regarding. 1. Units 2. Accuracy and Recovery 3. Repeatability 4. Reproducibility 5. System suitability
7. Any general comments about the method?	It' may be a promising method. Particularly because a similar method used to determine alcohol in beers. However, this particular package fails to demonstrate its validity.

Recommendation for the Method

Do you recommend this method be adopted as a First Action and published in the Official Methods of Analysis of AOAC INTERNATIONAL? Please specify rationale.	No. The method doesn't meet performance requirements for accuracy and repeatability. Reproducibility was not determined. System suitability tests were not performed correctly and wrong units for alcohol concentration are measured.

AOAC SPSFAM ERP REVIEW: MAIN FORM

Submission Date	2016-09-08 09:34:57
Name	Katherine Stenerson
E-mail	katherine.stenerson@sial.com
Organization	MilliporeSigma
Title of Method	Fluorescent Detection of Ethanol in Kombucha via Alcohol Dehydrogenase
AOAC Candidate Method Number (e.g. ALN-01)	#KOM-02
Applicable SMPR	2016.001

I. Summary of Method

Summary:	Not enough data is presented to validate this method. The analytical range demonstrated does not go high enough to meet SMPR requirements. The data that is presented does not meet the SMPR requirements for accuracy and repeatibility.

II. Review of Method Only

1. Does the applicability of the method support the applicability of the SMPR? If not, please explain what is missing.	Yes, the method supports the applicability of the SMPR.
2. Does the analytical technique(s) used in the method meet the SMPR? If not, please specify how it differs from what is stated in the SMPR.	Yes, the method supports the applicability of the SMPR.
3. Are the definitions specified in the SMPR used and applied appropriately in the method? If no, please indicate how the terms are used.	-%Alcohol by volume is referred to as % ethanol -Repeatability is referred to as % CV
4. Does the method, as written, contain all appropriate precautions and warnings related to the method's reagents, components, instrumentation, or method steps that may be hazardous? If no, please suggest wording or option(s).	It does not contain this information. This information should be described for safe handling of the ethanol detection reagent (components), and stop solution.

III. Review of Information in Support of the Method

1. Are the definitions specified in the SMPR used and applied appropriately in the supporting documentation (manuscripts, method studies, etc...)? If not, please explain the differences and if the method is impacted by the difference.	% ABV is not used. This does not impact the method. Repeatability is referred to as %CV. This also does not impact the method if a simple change in verbage is made. Other definitions were used appropriately in the limited data set included to support the method.

2. Is there information demonstrating that the method meets the SMPR Method Performance Requirements using the Reference Materials stated in the SMPR? If not, then specify what is missing and how this impacts demonstration of performance of the method.	From the reagents described, it appeared that a single CRM was used to prepare the solutions for standard curves, LOQ, and spiking/ recovery studies. This really is not the intent for using a CRM. The CRM should have been used to demonstrate accuracy after determining analytical range and LOQ using 200 proof anhydrous ethanol as described in the SMPR to prepare standard solutions and spikes. Also, more CRMs at other concentrations should have been used to demonstrate accuracy of the method.
3. Is there information demonstrating that the method performs within the SMPR Method Performance REquirements table specifications for all analytes in the SMPR applicability statement? If not, please specify what is missing and whether or not the method's applicability should be modified.	-Analytical range: it is demonstrated from .01 to .04%, and not up to 2% ABV. This is too low to be applicable to all Kombucha teas. -LOQ: It is not clear how LOQ was calculated using the data provided. So, it cannot be determined if this method meets an LOQ of <0.05% -Accuracy: the spike data for ethanol in water did not meet the 97-102% range. Results were >102%. -Repeatability: Shown as % CV for spiked water and kombucha samples. It did not meet the

IV. General Submission Package

1. Based on the supporting information, were there any additional steps in the evaluation of the method that indicated the need for any additional precautionary statements in the method?	No precautionary statements were included with the submission. These could be written by the authors if this method is selected.
2. Does the method contain system suitability tests or controls as specified by the SMPR? If not, please indicate if there is a need for such tests or controls and which ones.	No true blanks were included with the data. This may be due to the nature of this type of test. Since the negative control for each sample defines "0", this would have to be considered the blank for each determination. Check standards at low, mid and high levels were conducted as part of a linearity experiment in the data submitted. Any final method protocol would have to include analysis of these as part of a batch of samples.
3. Is there information demonstrating that the method system suitability tests and controls as specified in the SMPR worked appropriately and as expected? If no, please specify.	The standards run as part of the linearity experiments can be considered the check standards, however the recovery values were outside the 97-102% range designated in the SMPR.
4. Based on the supporting information, is the method written clearly and concisely? If no, please specify the needed revisions.	The method needs the following revisions: 1. description of how to prepare the reagents 2. description of required QA/QC to be run with kombucha samples and frequency required (i.e. analysis of check standards, matrix spikes, etc.) 3. specific instructions on the maximum ethanol concentration that can accurately be determined using this method. With that, instructions on how to dilute samples within that concentration should be included.
5. Based on the supporting information, what are the pros/strengths of the	The method requires minimal hands-on steps to perform. It is also very rapid.

pros/strengths of the method?	
6. Based on the supporting information, what are the cons/weaknesses of the method?	The method accuracy, based on the recovery values presented, do not meet the SMPR. Repeatability presented as %CV, did not meet the SMPR consistently. There is a potential for interference from constituents other than ethanol in the kombucha; for example, some kombuchas will contain very small amounts of acetaldehyde.
7. Any general comments about the method?	Data showing accuracy of this method with fermented matrices of known ethanol content was not provided (i.e. CRM of beer and/or spiked kombucha samples. This would have to be provided to show the method is applicable to these types of matrices.

Recommendation for the Method

Do you recommend this method be adopted as a First Action and published in the Official Methods of Analysis of AOAC INTERNATIONAL? Please specify rationale.	Not at this time. The method lacks the following: 1. Validation from .04% ABV to 2% ABV 2. Accuracy shown in the range specified in the SMPR 3. Repeatability <4% 4. Validation of the method using matrix samples such as beer CRM and spiked kombuchas 4. Potential for interference from acetaldehyde already present in some kombuchas

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AOAC Stakeholder Panel on Strategic Food Analytical Methods:

Expert Review Panel

AOAC Candidate Method #KOM-03

Ethanol Analysis in Kombucha Drinks

- Author(s): Samuel LaBonia
- Submitted by: Samuel LaBonia, Cornerstone Laboratories, LLC
- Enclosures: 1
- Submitter notes: None

Primary Reviewer: Stryffeler

Secondary Reviewer: Joseph

AOAC SPSFAM ERP REVIEW: MAIN FORM

Submission Date	2016-09-15 11:03:13
Name	Rachel Stryffeler
E-mail	rstryffeler@coca-cola.com
Organization	The Coca-Cola Company
Title of Method	Ethanol Analysis in Kombucha Drinks
AOAC Candidate Method Number (e.g. ALN-01)	KOM-03
Applicable SMPR	Standard Method Performance Requirements (SMPRs®) for Determination of Ethanol in Kombucha

I. Summary of Method

Summary:	This method uses headspace analysis of ethanol by gas chromatography-mass spectrometry (GC-MS) for the quantitation of ethanol in kombucha. Ethanol is purged from the diluted kombucha tea and concentrated on the trap, followed by separation and detection by GC-MS. This method is highly suitable for this application, however the report lacks some method and validation details.

II. Review of Method Only

1. Does the applicability of the method support the applicability of the SMPR? If not, please explain what is missing.	GC-MS is a suitable technique for the quantitation of ethanol in liquid samples and is commonly used for the quantitation of ethanol and other volatiles in water, beverages and other liquid matrices.
2. Does the analytical technique(s) used in the method meet the SMPR? If not, please specify how it differs from what is stated in the SMPR.	Yes.
3. Are the definitions specified in the SMPR used and applied appropriately in the method? If no, please indicate how the terms are used.	In the method itself, there is mention of the “Method Detection Limit (MDL)”, yet no reference to the Limit of Quantitation (LOQ) specified by the SMPR. The “Calculation” section of the method mentions “Quantitation Limit”, but only the lowest point of the calibration curve is listed, which is not the true LOQ.
4. Does the method, as written, contain all appropriate precautions and warnings related to the method's reagents, components, instrumentation, or method steps that may be hazardous? If no, please suggest wording or option(s).	Yes.

III. Review of Information in Support of the Method

1. Are the definitions specified in the SMPR used and applied appropriately in the supporting documentation (manuscripts, method studies, etc...)? If not, please explain the differences and if the method is impacted by the difference.	(1) The Quantitation Limit is reported only as the lowest concentration in the calibration curve multiplied by the dilution factor from the sample preparation. This is not a true LOQ. (2) Instead of Repeatability and Reproducibility, Method Precision and System Precision are used. System Precision is determined from the percent relative standard deviation of the replicate analysis of standard ethanol solutions. Method Precision is defined as the percent relative deviation of the analysis of a single product analyzed in triplicate. It is unclear which of these satisfies the Repeatability requirement as one is within the SMPR requirements and the other is not. Additionally, insufficient samples were analyzed to meet either criteria defined in Appendix K: Guidelines for Dietary Supplements and Botanicals.
2. Is there information demonstrating that the method meets the SMPR Method Performance Requirements using the Reference Materials stated in the SMPR? If not, then specify what is missing and how this impacts demonstration of performance of the method.	An appropriate Reference Material is used for analysis. The concentration of ethanol used for the System Precision measurement was at 50 µg/mL, which is equivalent to 0.1 % ABV for a sample diluted 20x per the method. However, insufficient data points for Reproducibility and/or Repeatability.
3. Is there information demonstrating that the method performs within the SMPR Method Performance REquirements table specifications for all analytes in the SMPR applicability statement? If not, please specify what is missing and whether or not the method's applicability should be modified.	It is unclear how the Analytical Range of the method fits the SMPR. Samples are diluted 20x in method, yielding an Analytical Range of 0.02%-0.2%. To fit the desired upper limit of 2.0 %ABV, it is unclear if high-concentration samples are diluted further to meet necessary criteria.

IV. General Submission Package

1. Based on the supporting information, were there any additional steps in the evaluation of the method that indicated the need for any additional precautionary statements in the method?	The results for Accuracy do not fit the range of the assay. Ethanol is spiked into a placebo sample at 1.0, 2.0 and 3.0 %ABV. This does not cover the Analytical Range of the SMPR or the method itself. Even at these levels, the percent recovery ranges from 98 to 106%.
2. Does the method contain system suitability tests or controls as specified by the SMPR? If not, please indicate if there is a need for such tests or controls and which ones.	Method calls for suitability tests or controls throughout a sequence of analysis, however, the identity/concentration of these controls is not specified. These controls include a Laboratory Extraction Blank (LEB), Laboratory Control Sample (LCS, unclear), Initial Calibration Verification (ICV, unclear), and Continuing Calibration Verification (CCV, unclear). The concentrations of these check standards is not given, therefore it cannot be determined if they are at the appropriate ranges.

3. Is there information demonstrating that the method system suitability tests and controls as specified in the SMPR worked appropriately and as expected? If no, please specify.	The method lists acceptable tolerances for system check standards, but does not give examples of actual testing results. System precision was measured for an intermediate standard, however it is not clear over what period of time this data was acquired.
4. Based on the supporting information, is the method written clearly and concisely? If no, please specify the needed revisions.	The method is clearly and concisely written, but at the cost of several key details. A number of generalizations are made regarding the sample preparation and data interpretation that may have the potential to impact results.
5. Based on the supporting information, what are the pros/strengths of the method?	GC-MS is a highly selective and sensitive analytical technique. Therefore this method does not suffer from interferences the way some traditional methods for quantitation of ethanol do. The low limit of detection of this method is very suitable for the quantitation of low levels of ethanol in kombucha beverages.
6. Based on the supporting information, what are the cons/weaknesses of the method?	There is very little detail of the sample preparation for analysis, which can have a significant impact on results. Additional details would be beneficial to ensure consistent results are delivered. Second, the validation data seems to be lacking in detail and based on interpretation may not meet the SMPR requirements. This is not to say that the method is not suitable and that this testing has not been completed, rather it was not included here.
7. Any general comments about the method?	A Purge and Trap-GC-MS approach is highly suitable for the quantitation of ethanol in beverages, especially kombucha. This method has strong potential, but the details missing from the method and supporting information bring into question the level of development of the method. I would assume the author would be able to provide additional method and validation details if prompted. Purge and Trap-GC-MS is a technique commonly used in the environmental community for the quantitation of trace levels of ethanol in water samples adding credibility to the analytical approach.

Recommendation for the Method

Do you recommend this method be adopted as a First Action and published in the Official Methods of Analysis of AOAC INTERNATIONAL? Please specify rationale.	Yes, I recommend this method to be adopted as a First Action. The Purge and Trap-GC-MS technology is highly suitable for the quantitation of ethanol in kombucha, and I believe that additional inter-laboratory validation will prove its performance. Not all Method Performance Requirements were expressed in the same vocabulary as the SMPR, but the method appears to meet nearly all requirements.

AOAC SPSFAM ERP REVIEW: MAIN FORM

Submission Date	2016-09-16 01:49:23
Name	George Joseph
E-mail	george.joseph@asurequality.com
Organization	ASureQuaity
Title of Method	Ethanol Analysis in Kombucha Drinks
AOAC Candidate Method Number (e.g. ALN-01)	KOM-03
Applicable SMPR	2016.001
Summary:	A measured amount of Kombucha drink is extracted dynamically using a headspace sampler. Ethanol is concentrated on a Purge and Trap system and desorbed into a Gas Chromatograph where it is detected with a Mass Spectrometer / Total Ion Monitoring
1. Does the applicability of the method support the applicability of the SMPR? If not, please explain what is missing.	Yes
2. Does the analytical technique(s) used in the method meet the SMPR? If not, please specify how it differs from what is stated in the SMPR.	No - see attached report
3. Are the definitions specified in the SMPR used and applied appropriately in the method? If no, please indicate how the terms are used.	Yes
4. Does the method, as written, contain all appropriate precautions and warnings related to the method's reagents, components, instrumentation, or method steps that may be hazardous? If no, please suggest wording or option(s).	Yes

1. Are the definitions specified in the SMPR used and applied appropriately in the supporting documentation (manuscripts, method studies, etc...)? If not, please explain the differences and if the method is impacted by the difference.	Yes
2. Is there information demonstrating that the method meets the SMPR Method Performance Requirements using the Reference Materials stated in the SMPR? If not, then specify what is missing and how this impacts demonstration of performance of the method.	Yes
3. Is there information demonstrating that the method performs within the SMPR Method Performance REquirements table specifications for all analytes in the SMPR applicability statement? If not, please specify what is missing and whether or not the method's applicability should be modified.	No
1. Based on the supporting information, were there any additional steps in the evaluation of the method that indicated the need for any additional precautionary statements in the method?	Method need to be reviewed and re-validated
2. Does the method contain system suitability tests or controls as specified by the SMPR? If not, please indicate if there is a need for such tests or controls and which ones.	Yes, system suitability was carried out as per SMPR
3. Is there information demonstrating that the method system suitability tests and controls as specified in the SMPR worked appropriately and as expected? If no, please specify.	No, the acceptance criteria set in the method is outside the SMPR

4. Based on the supporting information, is the method written clearly and concisely? If no, please specify the needed revisions.	The method is written clearly and concisely
5. Based on the supporting information, what are the pros/strengths of the method?	The method does not meet SMPR for accuracy, acceptance criteria for system and method precision.
6. Based on the supporting information, what are the cons/weaknesses of the method?	The GCMS has the advantage of high specificity but the selection of internal standard, analytical platform for the intended is not fit for purpose. The reference were not relevant.
7. Any general comments about the method?	Attached review report
Do you recommend this method be adopted as a First Action and published in the Official Methods of Analysis of AOAC INTERNATIONAL? Please specify rationale.	No, not as it is. Selection of Analytical Technique: The instrument (GCMS with P&T) is an expensive platform compared to GC-FID and also not likely to be present in all QC labs, AOAC Official Method 986.12 use GC FID technique which is much cheaper and get same / better outcome. Purge and Trap system is good for general VOC analysis but the sensitivity requirements of SMPR 2016.001 can be achieved by much simpler Static Headspace Gas Chromatography (SHSGC). Selection of internal standard: Methanol can also be a natural product of fermentation at certain poorly crafted fermentation conditions. While ethanol fermentation mostly generates ethanol, it can also result in a smaller amount of methanol, particularly when items high in pectin are fermented. The AOAC 986.12 use tert butanol as internal standard; butanol / propanol are not natural products of fermentation and therefore better qualified as internal standard. Method References: USEPA 8260b: VOC by GC MS, whereas the IUPAC 2.301 is for the preparation of FAME and may not be relevant to the method. System Precision: The acceptance criteria (RSD 5.0%) exceed the international limit of 2%, though the value reported for the validation is 1.3%. Linearity: The acceptance criteria of correlation coefficient in the validation report (Table 1) is 0.99 which is lower than set criteria of the method which is 0.995 (Section 12.1.4). The actual value reported (0.9930) is also less than the specified method limit. Method Precision: The acceptance criteria of RSD 5% is higher than the SMR 2016.001 though results obtained was 2% within the limit. Accuracy: The acceptance criteria of the method is set as 100±10% which is greater than the SMPR 2016.001 (97 to 102%). The mean recovery at 50% and 100% of the levels are 106% outside the SMPR limits.

The Scientific Association Dedicated to Analytical Excellence®

AOAC Stakeholder Panel on Strategic Food Analytical Methods:

Expert Review Panel

AOAC Candidate Method #KOM-04

Determination of ethanol in Kombucha by Gas Chromatography-Flame Ionization Detector: Intra-Laboratory Validation

- Author(s): Xin Du and Yonglin Ren
- Submitted by: Xin Du
- Enclosures: 2
- Submitter notes:
  1. Manuscript is waiting for data to complete;
  2. Intra-lab validation experiment will finish until next Friday;
  3. Inter-lab (cross-lab) validation experiment is organizing, if timetable allows.

Primary Reviewer: Sneh Bhandari

Secondary Reviewer: *Application Withdrawn*

AOAC SPSFAM ERP REVIEW: MAIN FORM

Submission Date	2016-09-13 07:34:27
Name	SNEH BHANDARI
E-mail	sneh.bhandari@mxns.com
Organization	Silliker Laboratories
Title of Method	Determination of ethanol in Kombucha by Gas Chromatography-Flame Ionization Detector: Intra-Laboratory Validation
AOAC Candidate Method Number (e.g. ALN-01)	KOM-04
Applicable SMPR	AOAC SMPR 2016.001

I. Summary of Method

Summary:	Low level of ethanol is detected in Kombucha by gas chromatography with flame ionization detection employing 2-propanol as an internal std. Applicable for determination of 0.1-2% ABV ethanol in Kombucha tea beverage.

II. Review of Method Only

1. Does the applicability of the method support the applicability of the SMPR? If not, please explain what is missing.	yes
2. Does the analytical technique(s) used in the method meet the SMPR? If not, please specify how it differs from what is stated in the SMPR.	Yes
3. Are the definitions specified in the SMPR used and applied appropriately in the method? If no, please indicate how the terms are used.	Yes
4. Does the method, as written, contain all appropriate precautions and warnings related to the method's reagents, components, instrumentation, or method steps that may be hazardous? If no, please suggest wording or option(s).	No. The precautions in use of flammable solvents in the method may be stated. The precautions and warning in use of gases under pressure may also be mentioned.

III. Review of Information in Support of the Method

1. Are the definitions specified in the SMPR used and applied appropriately in the supporting documentation (manuscripts, method studies, etc...)? If not, please explain the differences and if the method is impacted by the difference.	Yes
2. Is there information demonstrating that the method meets the SMPR Method Performance Requirements using the Reference Materials stated in the SMPR? If not, then specify what is missing and how this impacts demonstration of performance of the method.	The SLV data to some extent may support the accuracy of the method by spike recovery evaluation. Information is not available to support the precision of the method in analysis of ethanol in Kombucha tea samples. No information available about the evaluation of the method accuracy employing the Certified reference materials, The analytical range of the method not specified.
3. Is there information demonstrating that the method performs within the SMPR Method Performance REquirements table specifications for all analytes in the SMPR applicability statement? If not, please specify what is missing and whether or not the method's applicability should be modified.	The SLV data to some extent may support the accuracy of the method by spike recovery evaluation. Information is not available to support the precision of the method in analysis of ethanol in Kombucha tea samples. No information available about the evaluation of the method accuracy employing the Certified reference materials, The analytical range of the method not specified.

IV. General Submission Package

1. Based on the supporting information, were there any additional steps in the evaluation of the method that indicated the need for any additional precautionary statements in the method?	Yes. Precaution in use of flammable solvents and gases under pressure may be mentioned.
2. Does the method contain system suitability tests or controls as specified by the SMPR? If not, please indicate if there is a need for such tests or controls and which ones.	The method does not indicate any system suitability criteria. The method may indicate resolution requirement of ethanol and internal std peak as they elute very close to each other. The method may also indicate requirement of repeat-ability of the lowest calibrant and the ruling out any interference from the method blank.
3. Is there information demonstrating that the method system suitability tests and controls as specified in the SMPR worked appropriately and as expected? If no, please specify.	The method does not indicate any system suitability criteria.

4. Based on the supporting information, is the method written clearly and concisely? If no, please specify the needed revisions.	The method as written seems not be complete. It does not provide details about how the samples are prepared for analysis. The details of the amount addition of internal std. in the sample and calibrartion std. missing. The supporting data don't provide complete details about the method, i.e., analytical range of the method, what samples were used for the spike recovery evaluation etc.
5. Based on the supporting information, what are the pros/strengths of the method?	Simple and easy method to operate. Spike recovery satisfactory (but sample details missing).
6. Based on the supporting information, what are the cons/weaknesses of the method?	1. No data available to know the method precision in analysis of ethanol in Kombucha Tea. 2. The method provide no information to rule out interference from the components of Kombucha tea in accurate and precise quantitation of ethanol in samples. 3. The method accuracy not established using Certified ref materials. 4.Information not available to rule out the possibility of carry over from injection to injection. 5.Retention time of internal std and ethanol are close. The available data on the method performance don't rule out that this does not impact the accuracy of the method particularly in ethanol estimation at the low levels. 6. Information about the Analytical Range of the method missing.
7. Any general comments about the method?	The method performance evaluation is noy yet complete. The method as written is not complete and missing many of the critical details.

Recommendation for the Method

Do you recommend this method be adopted as a First Action and published in the Official Methods of Analysis of AOAC INTERNATIONAL? Please specify rationale.	Not without getting additional details about the missing information in the method and its performance evaluation.

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AOAC Stakeholder Panel on Strategic Food Analytical Methods:

Expert Review Panel

AOAC Candidate Method #KOM-05

Determination of Alcohol Content in Kombucha Tea by Headspace Solid Phase Microextraction and Gas Chromatography-Mass Spectrometry

- Author(s): Katherine Stenerson
- Submitted by: Katherine Stenerson
- Enclosures: 0
- Submitter notes: None

Primary Reviewer: Stryffeler

Secondary Reviewer: Jayabalan

AOAC SPSFAM ERP REVIEW: MAIN FORM

Submission Date	2016-09-15 11:05:32
Name	Rachel Stryffeler
E-mail	rstryffeler@coca-cola.com
Organization	The Coca-Cola Company
Title of Method	Determination of Alcohol Content in Kombucha Tea by Headspace Solid Phase
AOAC Candidate Method Number (e.g. ALN-01)	KOM-05
Applicable SMPR	Standard Method Performance Requirements (SMPRs®) for Determination of Ethanol in Kombucha

I. Summary of Method

Summary:	This method uses the headspace analysis ethanol by gas chromatography-mass spectrometry (GC-MS) for quantitation of ethanol in kombucha. Ethanol in the headspace is extracted by solid phase micro-extraction (SPME) followed by separation and detection by GC-MS.

II. Review of Method Only

1. Does the applicability of the method support the applicability of the SMPR? If not, please explain what is missing.	GC-MS is a suitable technique for the analysis of trace volatile compounds such as ethanol. The method was applied successfully to the quantitation of ethanol in kombucha.
2. Does the analytical technique(s) used in the method meet the SMPR? If not, please specify how it differs from what is stated in the SMPR.	Yes.
3. Are the definitions specified in the SMPR used and applied appropriately in the method? If no, please indicate how the terms are used.	For a significant portion of the method validation and testing, non-kombucha teas were used for the analysis. A tea blank was prepared with tea and sugar, but it was not fermented and is assumed to be a still beverage. This may impact the results. Actual kombucha tea samples were tested in duplicate, but not used for a significant portion of the method performance testing.
4. Does the method, as written, contain all appropriate precautions and warnings related to the method's reagents, components, instrumentation, or method steps that may be hazardous? If no, please suggest wording or option(s).	There were no precautions or warnings given in the method. Safety warnings may be recommended for select reagents and solvents.

III. Review of Information in Support of the Method

1. Are the definitions specified in the SMPR used and applied appropriately in the supporting documentation (manuscripts, method studies, etc...)? If not, please explain the differences and if the method is impacted by the difference.	In the method and supporting information, intraday and interday precision are measured compared to the defined Repeatability and Reproducibility discussed in the SMPR. The intraday and interday precision generally meet the requirements for repeatability, however this testing was not performed on actual kombucha samples, but on tea blanks and certified standards in water.
2. Is there information demonstrating that the method meets the SMPR Method Performance Requirements using the Reference Materials stated in the SMPR? If not, then specify what is missing and how this impacts demonstration of performance of the method.	Approprate reference materials were used to demonstrate method performance. However, these standards were analyzed in different matrices than kombucha tea. Method accuracy measured by spike recovery was tested in tea blanks (non-fermented and still), inter- and intra-day precision was measured using tea blanks, and ethanol standards in water or certified beer standard. There is one demonstration that the ethanol standards prepared in water and the tea blank gave comparable results, however this comparison is not performed with kombucha tea. I would have expected to see data on the mean spiked recovery of ethanol over the range of the assay in the actual kombucha matrix. Two kombucha samples were spiked at a single concentration, not over the range of the assay and it is not clear how many replicates were performed.
3. Is there information demonstrating that the method performs within the SMPR Method Performance REquirements table specifications for all analytes in the SMPR applicability statement? If not, please specify what is missing and whether or not the method's applicability should be modified.	The accuracy of the spiked tea blank showed %RSD ranging from 1-5% across the analytical range. Intraday precision shows 5% RSD for 0.1 %ABV spike in the tea blank, which is greater than the 4% limit defined in the SMPR. Interday precision of a certified beer sample was 1.9%, which is within the specifications of the SMPR, but this is not the correct matrix. Therefore, depending on the concentration at which the repeatability was measured and in what matrix the method may or may not meet the criteria.

IV. General Submission Package

1. Based on the supporting information, were there any additional steps in the evaluation of the method that indicated the need for any additional precautionary statements in the method?	No.
2. Does the method contain system suitability tests or controls as specified by the SMPR? If not, please indicate if there is a need for such tests or controls and which ones.	A tea blank was analyzed at the beginning, middle and end of the sample batch to monitor for alcohol contamination and/or carryover; none was observed. However there is no mention of check standards at the lowest point and midrange point of the analytical range during routine analysis.
3. Is there information demonstrating that the method system suitability tests and controls as specified in the SMPR worked appropriately and as expected? If no, please specify.	Presumably, the spiked tea blanks would serve this purpose, but it was not clear over what period of time this data was collected. Alternatively, the certified ethanol in water would also meet this criteria, however there is no % RSD given for this data to evaluate performance.

4. Based on the supporting information, is the method written clearly and concisely? If no, please specify the needed revisions.	The method is written very clearly. Given the detail included regarding method development and validation, I would not consider the submission package concise. However, the method details could be extracted into a concise stand-alone document.
5. Based on the supporting information, what are the pros/strengths of the method?	The supporting information includes extensive method development and validation data, in some cases exceeded the expectation of the SMPR. This additional data added significant amount of credibility to the method. The method demonstrates strong performance with a number of certified standards.
6. Based on the supporting information, what are the cons/weaknesses of the method?	The majority of the method validation was performed with a tea blank that is not true kombucha. Certified standards were analyzed in water and a beer standard was also used, both of which performed well. Limited validation of the method was performed with actual kombucha. Based on the method development, one would expect the method to perform equally across the matrices, however it was not explicitly demonstrated.
7. Any general comments about the method?	A GC-MS approach is highly suitable for the quantitation of ethanol in beverages. This method demonstrates thorough development and optimization for quantitation of ethanol in liquid samples. It is weaker with regard to validation in kombucha matrix, but has potential to be highly applicable and meet all requirements.

Recommendation for the Method

Do you recommend this method be adopted as a First Action and published in the Official Methods of Analysis of AOAC INTERNATIONAL? Please specify rationale.	Yes, I recommend this method to be adopted as a First Action. The SPME-GC-MS technology is highly suitable for the analysis of ethanol in kombucha, and I believe that additional inter-laboratory validation will prove its performance. Not all Method Performance Requirements were determined in a kombucha matrix or in the same vocabulary as the SMPR, but the method appears to meet nearly all requirements.

AOAC SPSFAM ERP REVIEW: MAIN FORM

Submission Date	2016-09-09 20:56:15
Name	Rasu Jayabalan
E-mail	jayabalanr@nitrkl.ac.in
Organization	National Institute of Technology Rourkela, Odisha, India
Title of Method	Determination of alcohol content in kombucha tea by headspace solid phase microextraction and gas chromatography-mass spectrometry
AOAC Candidate Method Number (e.g. ALN-01)	KOM-05
Applicable SMPR	AOAC SMPR 2016.001

I. Summary of Method

Summary:	Proposed method of determining ethanol in kombucha tea uses the principle of headspace solid phase microextraction gas chromatography-mass spectrometry method. The optimized method has LOQ of 0.051% ABV and method accuracy ranged from 96 to 102%.

II. Review of the Method Only

1. Does the applicability of the method support the applicability of the SMPR? If not, please explain what is missing.	yes. the proposed method is able to quantitate the concentration of ethanol in samples even at 0.05% ABV. As per AOAC SMPR 2016.001 it is less than or equal to 0.05% ABV.
2. Does the analytical technique(s) used in the method meet the SMPR? If not, please specify how it differs from what is stated in the SMPR.	Yes
3. Are the definitions specified in the SMPR used and applied appropriately in the method? If no, please indicate how the terms are used.	Yes
4. Does the method, as written, contain all appropriate precautions and warnings related to the method's reagents, components, instrumentation, or method steps that may be hazardous? If no, please suggest wording or option(s).	Yes

III. Review of Information in Support of the Method

1. Are the definitions specified in the SMPR used and applied appropriately in the supporting documentation (manuscripts, method studies, etc...)? If not, please explain the differences and if the method is impacted by the difference.	Yes
2. Is there information demonstrating that the method meets the SMPR Method Performance Requirements using the Reference Materials stated in the SMPR? If not, then specify what is missing and how this impacts demonstration of performance of the method.	Yes
3. Is there information demonstrating that the method performs within the SMPR Method Performance REquirements table specifications for all analytes in the SMPR applicability statement? If not, please specify what is missing and whether or not the method's applicability should be modified.	Yes

IV. General Submission Package

1. Based on the supporting information, were there any additional steps in the evaluation of the method that indicated the need for any additional precautionary statements in the method?	Precautionary statements were not given in the method
2. Does the method contain system suitability tests or controls as specified by the SMPR? If not, please indicate if there is a need for such tests or controls and which ones.	Yes
3. Is there information demonstrating that the method system suitability tests and controls as specified in the SMPR worked appropriately and as expected? If no, please specify.	Yes. Proper standards and internal standards are used

4. Based on the supporting information, is the method written clearly and concisely? If no, please specify the needed revisions.	Yes
5. Based on the supporting information, what are the pros/strengths of the method?	1. Headspace solid phase microextraction 2. Elimination of interferences which could be introduced through a liquid injection
6. Based on the supporting information, what are the cons/weaknesses of the method?	1. Instrument cost 2. Why MS is required?
7. Any general comments about the method?	Why MS is required in the method? Only GC is not sufficient?

Recommendation for the Method

Do you recommend this method be adopted as a First Action and published in the Official Methods of Analysis of AOAC INTERNATIONAL? Please specify rationale.	Yes. This method has advantages over traditional method of injecting the sample in to GC which will be resulting in several interferences.

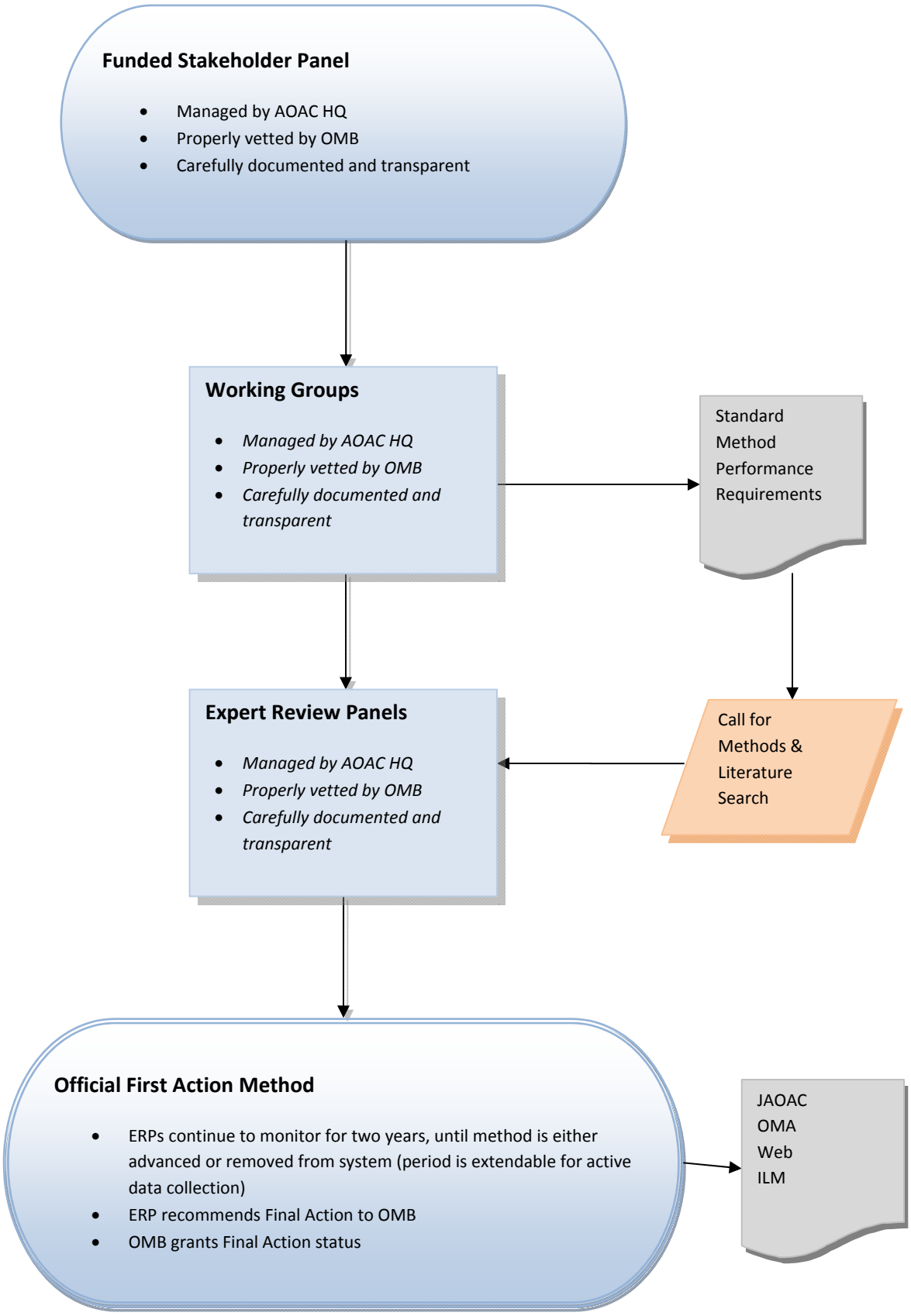
AOAC INTERNATIONAL

First Action Official Methods of Analysis[SM]

Guidance Documents

I. Process Flowchart
II. Process Guidelines
III. Expert Review Panel – Policies & Procedures

Alternate Pathway to Official First Action Method Status



Updated 2011-5-11

AOAC INTERNATIONAL (updated 2011-05-11 by APOFAMS Task Force)

ALTERNATIVE PATHWAY to OFFICIAL FIRST ACTION METHOD STATUS REQUIREMENTS

Expert Review Panels

-Must be supported by relevant stakeholders.

-Constituted solely for the ERP purpose, not for Standard Method Performance Requirements (SMPR) purposes or as an extension of an SMPR.

-Consist of a minimum of seven members representing balance of key stakeholders.

-ERP constituency must be approved by the Official Methods Board (OMB).

-Holds transparent public meetings only.

-Remains in force as long as method in First Action Status.

Official First Action Method Status decision

-Must be made by an ERP constituted or reinstated post 2011-03-28 for Official First Action Status Method Approval (OFASMA).

-Must be made by an ERP vetted for OFASMA purposes by OMB post 2011-03-28.

-Method adopted by ERP must perform adequately against the SMPR set forth by the stakeholders.

-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

-Method becomes Official First Action on date when ERP decision is made.

-Methods to be drafted into AOAC format by a knowledgeable AOAC staff member or designee in collaboration with the ERP and method author.

-Report of OFAMS decision complete with ERP report regarding decision including scientific background (references etc) to be published concurrently with method in traditional AOAC publication venues.

Method in First Action Status and Transitioning to Final Action Status

-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.

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

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

-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.

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

-OMB decision on First to Final Action Status

EXPERT REVIEW PANELS

--Policies and Procedures—

Introduction

Expert Review Panels (ERP) are created to provide stakeholders with an expert resource to evaluate analytical solutions to identified needs and concerns.

The ERP will be tasked to search for appropriate methods, issue a "Call for Methods" in the ILM and other avenues, and critically evaluate all collected methods. The ERP will then recommend appropriate methods (as submitted or modified) for adoption as Official First Action methods or for further validation. The ERP, if requested by the Committee/Topic Advisor, would be expected to assist in identifying appropriate materials to be used in the validation studies and in reviewing the protocols for such studies.

Outline of ERP establishment process

An Expert Review Panel is established as follows: A stakeholder or stakeholder body submits a request for the creation of an ERP to the AOAC staff. The request includes a description of the subject area, the desired outcome, and should include a list of recommended subject experts with supporting documentation (see "Qualifications of Expert Reviewers"). Included with this list of recommended subject experts could be a recommendation for an ERP Chair. The request is forwarded to the appropriate AOAC Chief Science Officer (CSO) who identifies potential members for the ERP from a recognized Pool of Experts, a Call for Experts on the AOAC website, and from the stakeholder recommendations. The candidate list and supporting documentation are forwarded to the Chair of the OMB who will assign the review to at least two OMB members. The OMB reviewers will review the candidates for expertise and perceived conflicts of interest and the OMB may then approve the members of the ERP. A Chair for the ERP is also selected. The Chair of the ERP will organize meetings of the ERP to discuss and make recommendations relative to method recommendations, the method(s) to be further validated, and the materials to be used in the validation studies. The conclusions and recommendations of the ERP will be transmitted by the ERP Chair to the OMB and stakeholder body. The stakeholder body will proceed with implementation of the ERP's recommendations by organizing the appropriate SLV study and other items needed for application.

Pool of Potential Expert Reviewers:

Candidates for ERPs are pulled from the following sources. Upon acceptance of the request for the formation of an ERP, a Call for Experts is posted on the AOAC website for a minimum of two weeks. Candidates can then contact AOAC with their interest and credentials. Also, AOAC maintains a Pool of Experts database containing a list of

Approved by Official Methods Board, November 13, 2008
Approved by AOAC Board of Directors, December 9, 2008
Appeals Process Appended – September 2009
Revisedby AOAC Board of Directors, May 25, 2011

AOAC members willing to serve as experts and cataloging their education, experience, and other applicable credentials. Candidates can also be recommended by the stakeholder(s). Note: Candidates (except for the chair) do not need to be members of AOAC. The appointment of experts to an ERP will be for a minimum of 3 years.

Qualification of Expert Reviewers: To qualify as an Expert Reviewer, the candidate must meet one of the following requirements: (1) Demonstrated knowledge in the appropriate scientific disciplines. (2) Demonstrated knowledge regarding data relevant to adequate method performance. (3) Demonstrated knowledge of practical application of analytical methods to bona fide diagnostic requirements. These qualifications must be clearly described in a CV submitted to the CSO and kept on file at AOAC headquarters.

Duties: Members of the Pool of Experts will be called upon to serve on ERPs as needed, and to review documents prepared in the course of the project. These documents may include: (1) procedural documents on how methods will be selected and how single laboratory validation studies will be done; (2) methods submitted for consideration as Official First Action Methods; (3) methods submitted for selection for further validation studies; (4) protocols to be used for single laboratory validation studies; (5) the selection of methods to be considered for full collaborative studies; and (6) validation study reports.

Expert Review Panel:

The CSO selects candidates for an ERP from the Pool of Experts database, the Call for Experts on the AOAC website, and from candidates recommended by the stakeholders. Selection of ERP candidates is based upon their knowledge and experience to adequately evaluate the scope of the study and the anticipated number of submitted methods. The size of the ERP will be sufficient to assure the necessary expertise is present. The CSO may recommend one of the Panel members to serve as Chair.

The CSO submits the following to the OMB Chair: The original submission package, a list of all candidates considered for inclusion on the ERP, the slate of recommended candidates, and a list of possible alternates. Explanations for the ERP choices may be included by either the CSO or a stakeholder if desired. The OMB Chair will delegate two members of the OMB to perform a review. The reviewers submit their recommendations in writing to the OMB. The OMB then votes on the reviewers' recommendations. This vote can be either by email or during an OMB meeting. The OMB may choose not to select one or more individuals on the Panel as submitted and may or may not accept the recommendation of the CSO for the panel Chair. A majority of those voting will be required for approval. The vote of the Chair will break any tie. The CSO, ERP members, and stakeholder body are notified of the vote within one week.

Conflict of Interest: It is incumbent upon each ERP member to avoid any known or potential conflicts of interest and make these known to the CSO and OMB Chair. Each pool member chosen for an ERP will be asked to agree to the AOAC Policies and Procedures on Conflicts of Interest evidenced by completing a Conflict of Interest Form.

If a Pool member being considered to serve on any particular panel is an author, or his/her laboratory is the source of a method under consideration by the Panel, they must so indicate to the CSO or OMB Chair. At the discretion of the CSO or OMB, the names of such Pool members may be removed from consideration, or they may be considered to serve on the ERP with the understanding that a deliberate effort will be required to avoid any known or potential conflicts of interest. In these latter cases, assignments of individual methods for peer review will be made in such a way by the Chair that ERP members will not review any method for which they are an author or co-author, or for which their laboratory is the source; and, most importantly, the Chair will require that they abstain from voting on such a method during the final method selection process. The CSO or OMB may also allow Pool members that qualify under the requirements of expert reviewers, but for whom there is a known or potential conflict of interest to be present as an observer on any particular Panel. In these cases, and only at the discretion of the Chair, observers may provide comments, but only if and when called upon by the Chair to do so.

Non-disclosure Statement: All members of an ERP must have signed the AOAC Volunteer Acceptance Form. For certain contracts, each Pool member or observer chosen may be asked to sign a non-disclosure statement agreeing not to discuss or disclose confidential information presented and discussed during meetings of the ERP.

Meetings of the ERP: The ERP Chair will organize meetings of the ERP, to review the methods and accompanying validation data, score them numerically, and prepare a summary report. Meetings of the ERP can include voting members of the Panel, and non-voting members (AOAC staff, stakeholder members, and observers).

The CSO may assist the Panel Chair in facilitating meetings. The members of the Panel are to review distributed documents before the meeting. To facilitate the process, the Chair may assign primary and secondary reviewers for each method. The primary and secondary reviewers prepare a short critique of the method that is distributed or presented to the ERP. If both the primary and secondary reviewers conclude that the method should not be considered further, the ERP Chair may call for a vote by the Panel; if a unanimous vote to drop a method without further discussion results, the Chair removes the method from further consideration. The Panel then discusses each of the remaining methods in turn.

Method Selection Process: The ERP will evaluate all of the methods in a scientifically unbiased manner.

Occasionally, a large number of analytical methods of variable quality are encountered. When this occurs, the following “pre-screening” procedure is suggested to eliminate methods that are not satisfactory. The Chair of the ERP with the assistance of at least one other member of the ERP may review all of the methods and remove unsatisfactory methods from consideration. The remainder of the methods would be sent to the ERP members for review.

The basic requirements for selection of methods for further validation studies will be: fitness for purpose, applicability to the scope needed, clarity of method description, satisfactory performance characteristics, and single laboratory validation data. To assist the Panel, the AOAC will provide a "Methods Selection Worksheet," which may be modified at the discretion of the ERP. ERP members will identify the best method(s) for further validation, and identify any modifications to be made to the method. An example of the Method Selection Worksheet is attached.

Samples: The ERP will be asked to recommend the specific materials (matrices) to be included in the subsequent validation studies, along with detailed justifications.

Summary Report: The Chair of the ERP prepares a Summary Report clearly enunciating the recommendations of the Panel, the manner in which these conclusions were reached, any modifications of the method(s) chosen, and the materials (matrices) to be included in the validation studies. The report is to be submitted to the ERP in a timely fashion after the concluding ERP meeting. Comments are also due back to the ERP Chair in a timely fashion. The report is then sent to the stakeholders and a copy is forwarded to the Chair of the OMB.

Post-ERP Activities: AOAC retains the right to call on the panelists, as well as members of the Industry Groups, for continued assistance in the subsequent validation studies. This may include (1) help in obtaining the required samples for use in the subsequent validation studies, as well as participating laboratories; (2) help in developing and reviewing the validation study protocols; and (3) help in reviewing the data resulting from the validation studies and reviewing the manuscript describing the results. These activities will be coordinated by the CSO.

Method Selection Worksheet

Method Title:
Method Number:

Overall evaluation score (1being lowest, 10 being highest):

Additional Factors to Consider:

Recommendation:

Signature (date):

Expert Review Panel Selection Criteria:

1. AOAC paid consultants and AOAC staff should not act as Chairs of ERPs.

2. Members of the BoD may act as voting members but it is recommended that they sit as non-voting members of the panel, unless the CSO can demonstrate that there are so few experts in the field available to the community that they are needed to move the project forward.

3. Paid consultants of AOAC and AOAC staff may not serve as voting members on ERPs.

4. If a single business location is represented by more than one person on an ERP, that location shall have only one vote.

5. The Chair of the ERP must be a member of AOAC INTERNATIONAL.

Appeals Process:

ERP - Openness of Process and Appeals:

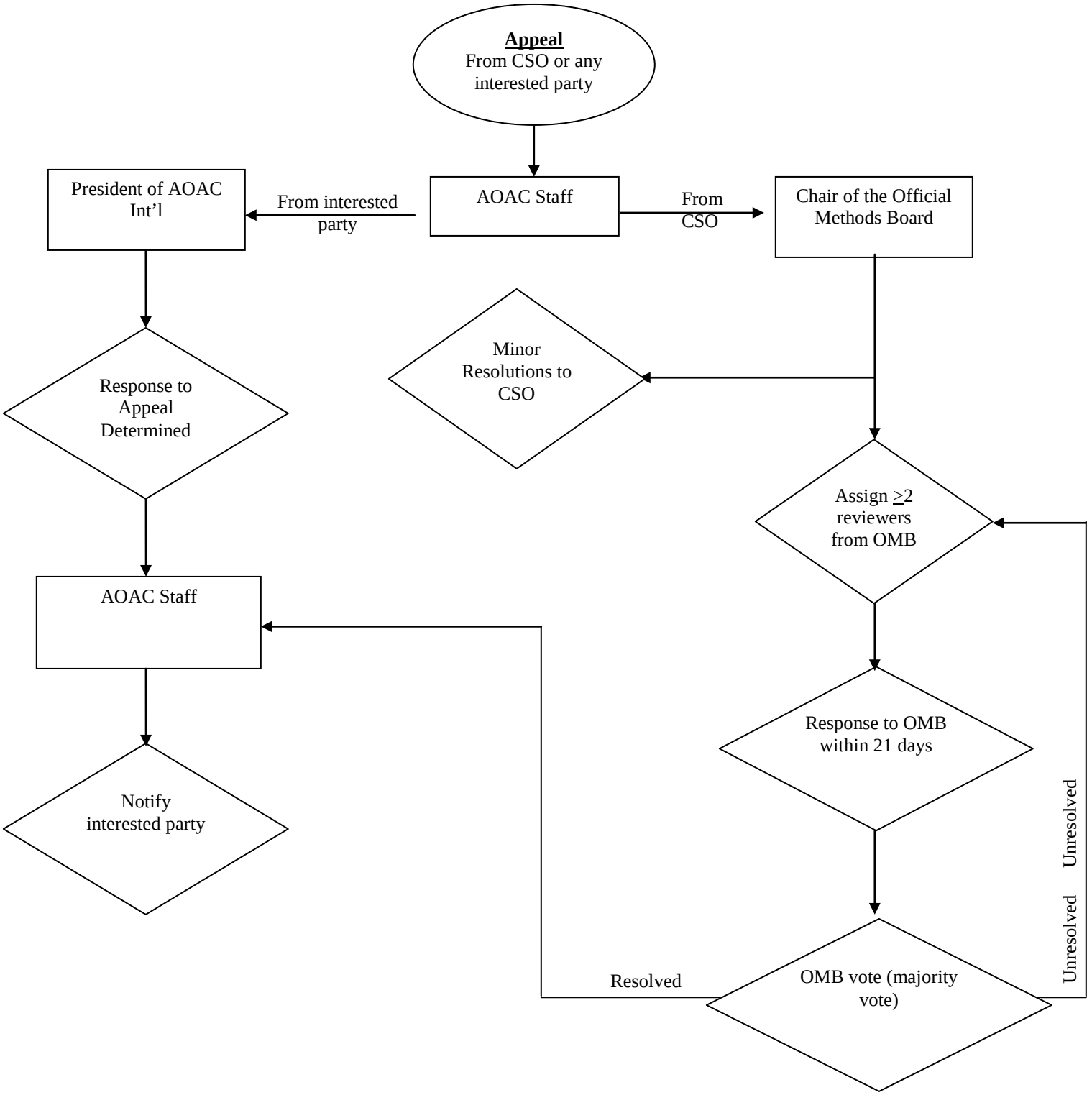
The entire ERP review process is fully open. Any interested party (person, agency, organization, association, company, Chief Scientific Officer (CSO), or group) shall have the right to comment.

Appeals or comments are sent to the AOAC Staff.

Technical decisions by the ERP are final and are not subject to review or appeal. Other questions or issues regarding procedures, conflict of interest, or impropriety may be appealed to the President of the AOAC INTERNATIONAL.

All written concerns will be considered and given a response.

If there is disagreement between the CSO and the Official Methods Board reviewers, the CSO may appeal to the Chair of the Official Methods Board for consideration. The Official Methods Board can select an impartial panel to review the issue, which must report to the Official Methods Board with a resolution within 21 days of its assignment.



Approved by Official Methods Board, November 13, 2008
Approved by AOAC Board of Directors, December 9, 2008
Appeals Process Appended – September 2009
Revisedby AOAC Board of Directors, May 25, 2011

Appendix G: Procedures and Guidelines for the Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis

Expert Review Panels, Official Methods Board, First and Final Action *Official Methods*℠

In early 2011, an AOAC Presidential Task Force recommended that AOAC use Expert review panels (ERPs) to assess candidate methods against standard method performance requirements (SMPRs) to ensure that adopted First Action Official Methods℠ are fit for purpose.

Formation of an ERP

AOAC ERPs are authorized to adopt candidate methods as First Action *Official Methods* and to recommend adoption of these methods to Final Action *Official Methods* status. Scientists are recruited to serve on ERPs by a variety of ways. Normally, a call for experts is published at the same time as a call for methods is posted. Interested scientists are invited to submit their *curriculum vitae* (CV) for consideration. Advisory panel, stakeholder panel, and working group members may make recommendations to AOAC for ERP members. All CVs are reviewed and evaluated for expertise by the AOAC Chief Scientific Officer (CSO). The CVs and CSO evaluations are forwarded to the OMB for formal review. Both the CSO and OMB strive to ensure that the composition of a proposed ERP is both qualified and represent the various stakeholder groups. The recommended ERP members are submitted to the AOAC president who then appoints the ERP members.

Review of Methods

Methods submitted to AOAC in response to a call for methods are collected and compiled by AOAC staff. The AOAC CSO and working group chair perform a preliminary review of the methods and classify them into three categories: (*1*) fully developed and written methods that appear to meet SMPRs; (*2*) fully developed and written methods that may or may not meet SMPRs; and (*3*) incomplete methods with no performance data. Method submitters are apprised of the evaluation of their methods. Method developers with submissions that are classified as Category 2 or 3 are encouraged to provide additional information if available. A list of all the submitted methods and their classifications are posted for public review.

Usually, two ERP members (sometimes more) are assigned to lead the review of each Category 1 method. An ERP meeting is convened to review the methods. ERP meetings are open to all interested parties, and are usually well-attended events with about 50–60 attendees common. Each Category 1 method is reviewed and discussed by the ERP. If stakeholders have designated the method to be a dispute resolution method (as stated in the SMPR), then the ERP is asked to identify the single best candidate method to be adopted as a First Action *Official Method*. If the SMPR does not specify the need for a dispute resolution method, then the ERP may choose to adopt all methods that meet the SMPRs, or may choose to adopt the single best method in their collective, expert opinion.

In addition, an ERP may choose to require changes to a candidate method as part of its First Action adoption and/or identify issues that are required to be resolved prior to adoption as a Final Action *Official Method.*

Methods adopted by an ERP as First Action *Official Methods* may not be in AOAC *Official Methods* format. Method developers/authors are asked to assist AOAC to rewrite the method and accompanying manuscript into an AOAC-acceptable format.

Two-Year First Action Evaluation Period

Under the new pathway, a method may be designated as a First Action *Official Method* based on the collective judgment of an ERP. *Official Methods* remain as First Action for a period of about 2 years. During the First Action period, the method will be used in laboratories, and method users will be asked to provide feedback on the performance of the method.

As previously described, two (or more) ERP members are assigned to lead the review of candidate methods for adoption as First Action *Official Methods*. After a method has been adopted as First Action, these lead reviewers are expected to keep track of the use of and experience with the First Action *Official Method*. At the conclusion of the 2-year evaluation period, one or both of the lead reviewers will report back to the ERP on the experience of the First Action *Official Method.*

The presiding ERP will monitor the performance of the method, and, at the completion of the 2-year First Action evaluation period, determine whether the method should be recommended to the OMB for adoption as an AOAC Final Action *Official Method*.

It is also possible that First Action *Official Methods* are not recommended for Final Action. There are two possibilities for an ERP to decide not to proceed with a First Action method: (*1*) feedback from method users indicates that a First Action method is not performing as well in the field as was expected; or (*2*) another method with better performance characteristics has been developed and reviewed. In either case, the ERP may choose to repeal the First Action status of a method.

OMB Review

The OMB will review all methods recommended for Final Action or repeal by the ERP, and will consider a number of factors in their decision. A guidance document for factors to consider is provided on the AOAC website at http://www.aoac.org/vmeth/OMB_ERP_Guidance.pdf. Some of the factors identified by the guidance document for OMB consideration are (*1*) feedback from method users, (*2*) comparison to the appropriate SMPR, (*3*) results from single-laboratory validation, (*4*) reproducibility/uncertainty and probability of detection, (*5*) availability of reference materials, and (*6*) safety concerns.

Conclusion

The new pathway to *Official Methods*℠ is deliberately designed to avoid creation of elaborate review systems. The intent of the model is for method experts to use their scientific knowledge, experience, and good judgment to identify and adopt the best methods possible for the analytical need.

These methods are then published as First Action *Official Methods,* and used by analysts while additional information about the method is collected.

Method reviewers may consider other forms of information in lieu of the traditional collaborative study to demonstrate method reproducibility.

Additional Information

Coates, S. (2012) "Alternative Pathway," *Inside Laboratory Management* **16**(3), pp 10–12

Expert Review Panels, Policies and Procedures, AOAC INTERNATIONAL, http://www.aoac.org/News/EXPERT%20REVIEW%20PANELS%20final%20revision.pdf

Standard Format and Guidance for AOAC Standard Method Performance Requirement (SMPR) Documents, AOAC INTERNATIONAL, http://www.aoac.org/ISPAM/pdf/3.5%20SMPR%20Guideline%20v12.1.pdf

Guidance Documents

Requirements for First Action Official Methods℠ Status

See Figure 1 for process flowchart.

Expert Review Panels

(*1*) Supported by relevant stakeholders.

(*2*) Constituted solely for the ERP purpose, not for SMPR purposes or as an extension of an SMPR.

(*3*) Consist of a minimum of seven members representing a balance of key stakeholders. A quorum is the presence of seven members or 2/3 of total vetted ERP membership, whichever is greater.

(*4*) ERP constituency must be approved by the OMB.

(*5*) Hold transparent public meetings only.

(*6*) Remain in force as long as method in First Action status.

First Action Official Method℠ Status Decision

(*1*) Must be made by an ERP constituted or reinstated post March 28, 2011 for First Action *Official Method℠* status approval.

(*2*) Must be made by an ERP vetted for First Action *Official Method℠* status purposes by OMB post March 28, 2011.

(*3*) Method adopted by ERP must perform adequately against the SMPR set forth by the stakeholders.

(*4*) Method must be adopted by unanimous decision of ERP on first ballot. If not unanimous, negative votes must delineate scientific reasons.

(*5*) Negative voter(s) can be overridden by 2/3 of voting ERP members after due consideration.

(*6*) Method becomes Official First Action on date when ERP decision is made.

(*7*) Methods to be drafted into AOAC format by a knowledgeable AOAC staff member or designee in collaboration with the ERP and method author.

(*8*) Report of First Action *Official Method℠* status decision complete with ERP report regarding decision, including scientific background (references, etc.), to be published concurrently with method in traditional AOAC publication venues.

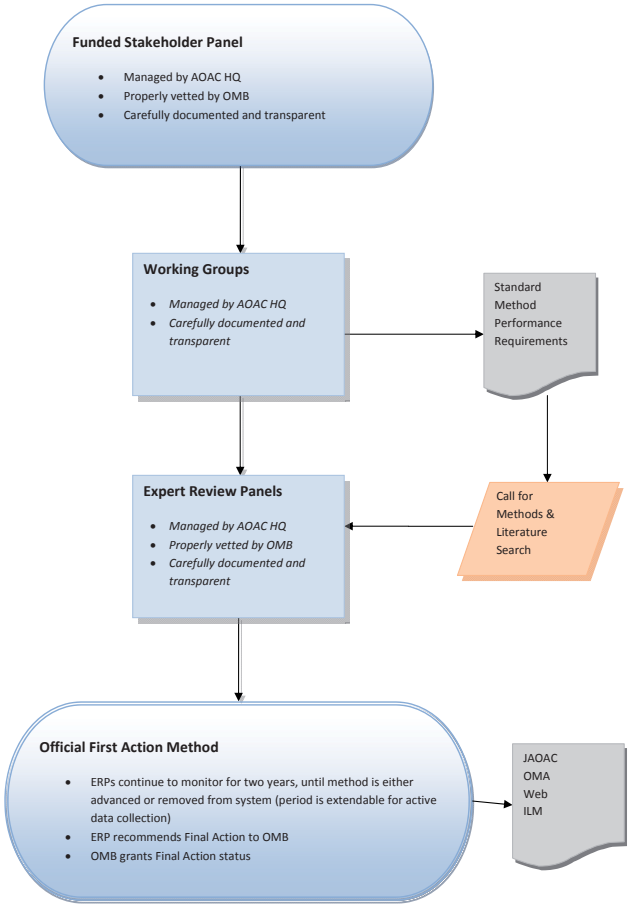


Figure 1. Summary of standards development through *Official Methods of Analysis*.

Method in First Action Status and Transitioning to Final Action Status

(*1*) 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.

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

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

(*4*) 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.

(*5*) ERP to recommend method to Final Action Official status to the OMB.

(*6*) OMB decision on First to Final Action status.

These guidance documents were approved by the AOAC Board of Directors on May 25, 2011. Revised in February 2014 to include the definition of a quorum under the section *Expert Review Panels*, item (*3*).

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

In December 2011, the Official Methods Board (OMB) approved a guidance document for ERPs to support their work as they deliberate on methods, adopt methods as Official First Action, and, subsequently, track method usage and performance between First Action status and Final Action consideration. The guideline is based on parameters of a method that the OMB will consider when deliberating on methods recommended for Final Action status. ERPs are to use this guideline in their deliberations.

ERPs working within the AOAC process may recommend a First Action status method be elevated to Final Action status. Such a recommendation leverages the ERP's high level of expertise supported by data from the initial evaluation, and results from the subsequent 2-year method performance evaluation period.

The OMB receives the recommendation with supporting documentation, and determines if Final Action status is warranted. OMB's review verifies the method process was conducted in compliance with the guidelines and protocols of the Association.

For transparency and to expedite the review process, the main areas OMB will review when evaluating ERP recommendations to promote methods to Final Action are listed below. Documentation of the areas listed below will also increase confidence in method performance and assist users to properly and safely perform the methods at their locations.

A. Method Applicability

(**a**) A method's applicability to the identified stakeholder needs is best assessed by the stakeholder panel and should be a part of the process from the onset. OMB liaisons will remind stakeholder panels to maintain this focus point.

(**b**) OMB may ask ERPs and stakeholder panels for feedback to improve the applicability of the method, such as potential method scope expansions and potential points of concern.

B. Safety Concerns

(**a**) A safety review must be performed for a method to be recognized as First Action.

(**b**) All safety concerns identified during the 2-year evaluation period must be addressed.

(**c**) Guidance and support can be obtained from the AOAC Safety Committee.

C. Reference Materials

(**a**) Document efforts undertaken to locate reference materials. Methods may still progress to Final Action even if reference materials are not available.

(**b**) Guidance and support can be obtained from the AOAC Technical Division on Reference Materials.

D. Single-Laboratory Validation

(**a**) Data demonstrating response linearity, accuracy, repeatability, LOD/LOQ, and matrix scope must be present. Experimental designs to collect this data may vary with the method protocol and the intended use of the method.

(**b**) Resources can be identified by the AOAC Statistics Committee.

E. Reproducibility/Uncertainty and Probability of Detection

(**a**) For quantitative methods, data demonstrating reproducibility and uncertainty must be present. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method (i.e., collaborative studies, proficiency testing, etc.).

(**b**) For qualitative methods, data must be present demonstrating the probability of detection at specified concentration levels as defined by the SMPR. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method.

(**c**) Guidance and support can be obtained from the AOAC Statistics Committee.

F. Comparison to SMPR

(**a**) Document method performance versus SMPR criteria. Note which SMPR criteria are met. For SMPR criteria not met, the ERP documents the reasoning why the method is still acceptable.

(**b**) Data is present to assure the matrix and analyte scopes are covered. This is critical for methods used for dispute resolutions.

G. Feedback from Users of Method

(**a**) Document positive and negative feedback from users of the method during the trial period.

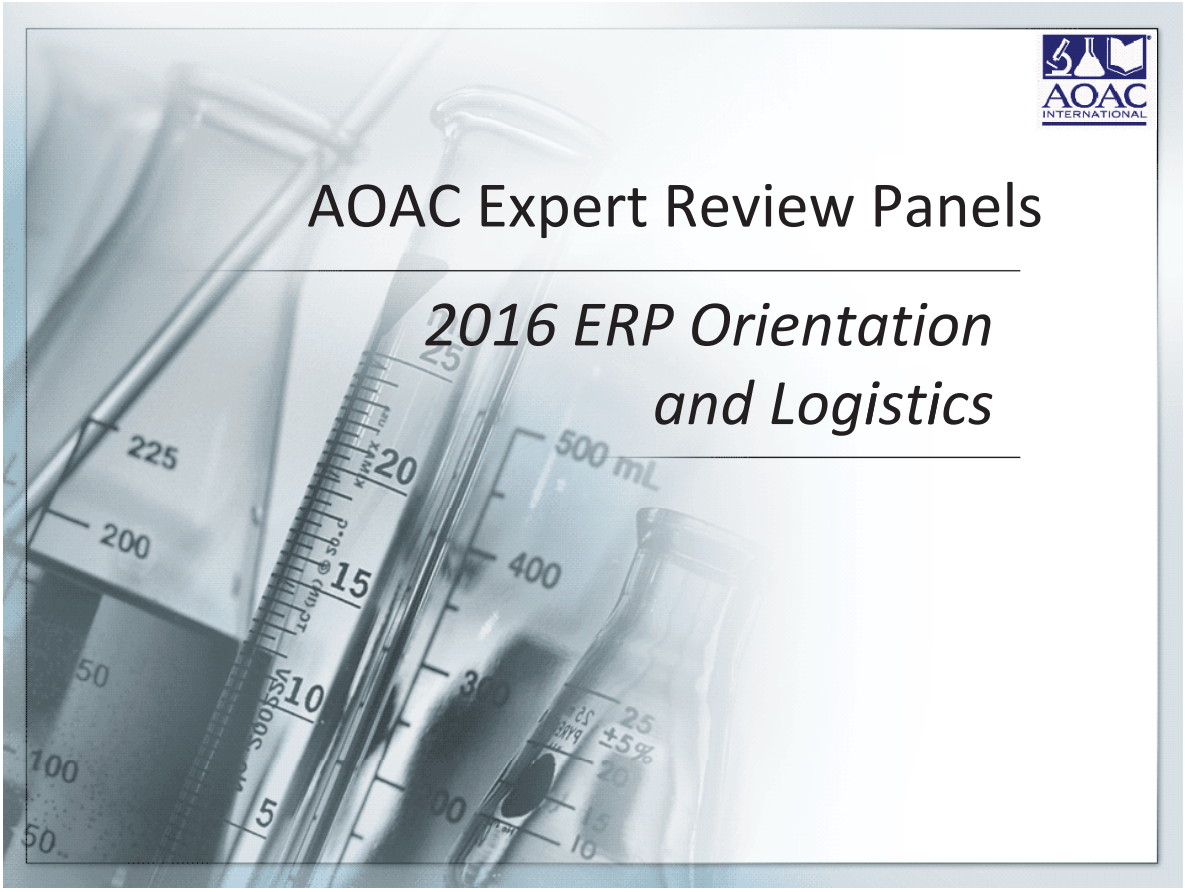
(**b**) Feedback from users demonstrating method ruggedness should be documented.

(**c**) Assess the future availability of vital equipment, reference materials, and supplies.

H. ERP Recommendations to Repeal First Action Methods

Recommendations to repeal First Action methods shall be accompanied with detailed reasons for the decision.

The First to Final Action guidance for ERPs was approved by the OMB in December 2011 and effective as of February 1, 2012.



AOAC Expert Review Panels

2016 ERP Orientation and Logistics

Session Syllabus

1. AOAC Method Submission
2. Recruitment of ERP Members
3. ERP Composition & Vetting Expertise
4. ERP Method Assignments
5. ERP Meeting
6. ERP Consensus
7. Post ERP Meeting
8. First Action to Final Action status
9. Method Modifications
10. Publications
11. Documentation
12. Summary of Responsibilities

TRACT 1

METHOD SUBMISSION

Paths to AOAC *Official Methods*

- AOAC Official Methods through AOAC Standards Development

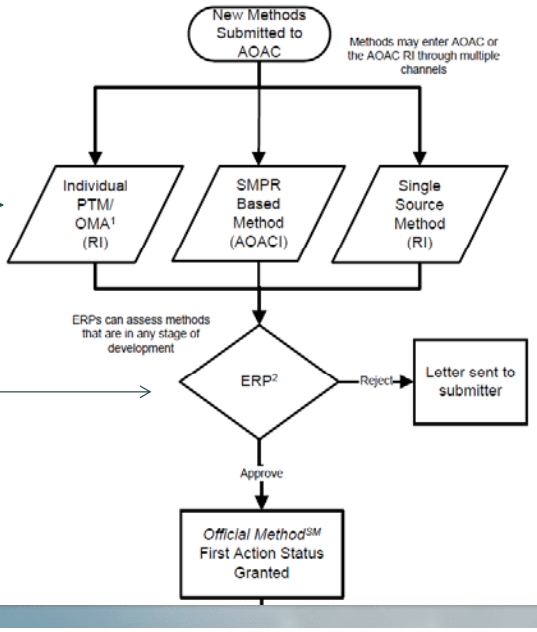
Road to First Action OMA Status

Terms:

- PTM – *Performance Tested Methods℠*
- RI – Research Institute
- ERP – Expert Review Panel
- OMB – Official Methods Board
- SP – Stakeholder Panel
- SMPR – Standard Method Performance Requirement

Three modes of entry and (program administration)

Expert Review Panels will review all methods for all three modes of entry.

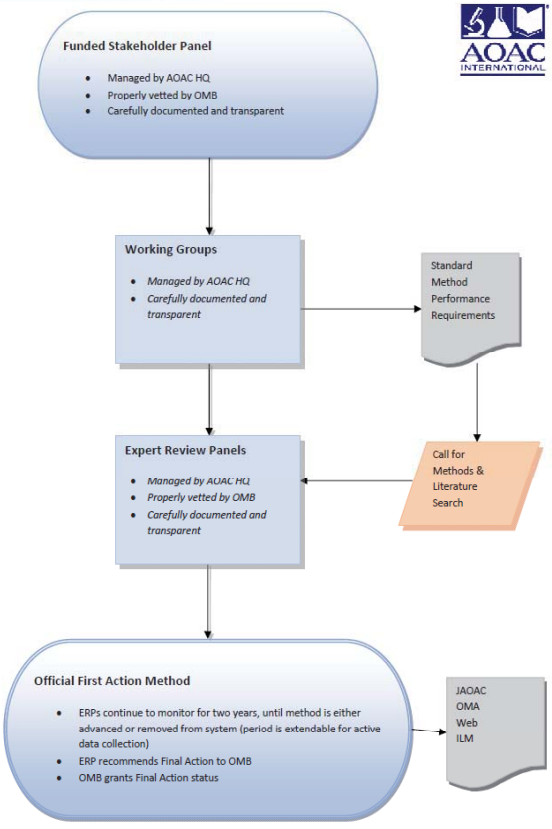


Note: Appeals process always available; see Alternative Pathway Guidelines for appeals process.

1 PTM certification previously issued, PTM reviewers will be ERP members
2 Unless otherwise provided for under a contractual agreement, AOAC will regularly convene ERPs twice a year: once during the Mid-Year Meeting and again during the Annual Meeting

Recap of the Overall Process for Methods Submitted in response to SMPRs or Call for Methods – aka "alternative pathway"

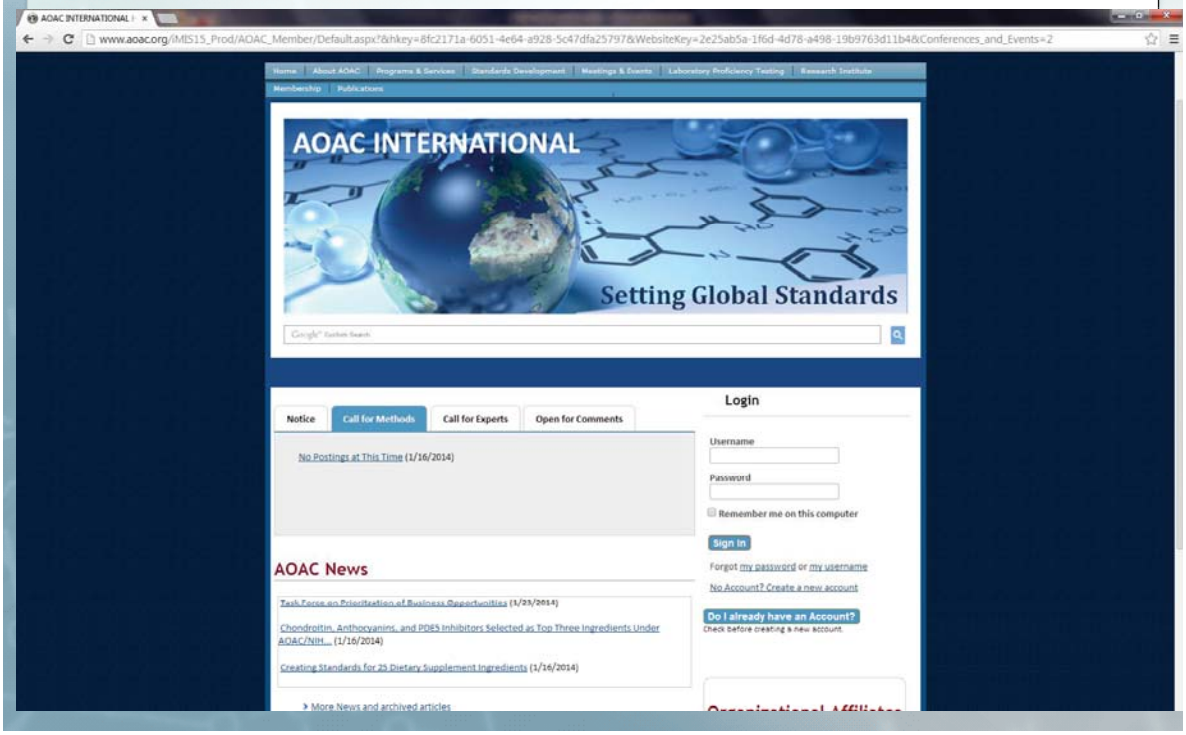
1. Allows AOAC to focus on projects addressing an urgent need of a critical mass of stakeholders.
2. Drives AOAC processes forward faster.
3. Assembles stakeholders (industry, government and academia) to neutral place to articulate and reach consensus on requirements and resolve conflicts.
4. Those requirements are codified and are published as "Standard Method Performance Requirements" (SMPRs).
5. Methods are solicited that purport to meet those requirements.
6. Expert review panels (ERPs) judge the methods against the SMPRs. Method(s) that best meet the SMPRs are adopted and designated "First Action" *Official Method of Analysis*.
7. Process for First Action status to Final Action status follows as the same process for all AOAC First Action *Official Methods*.



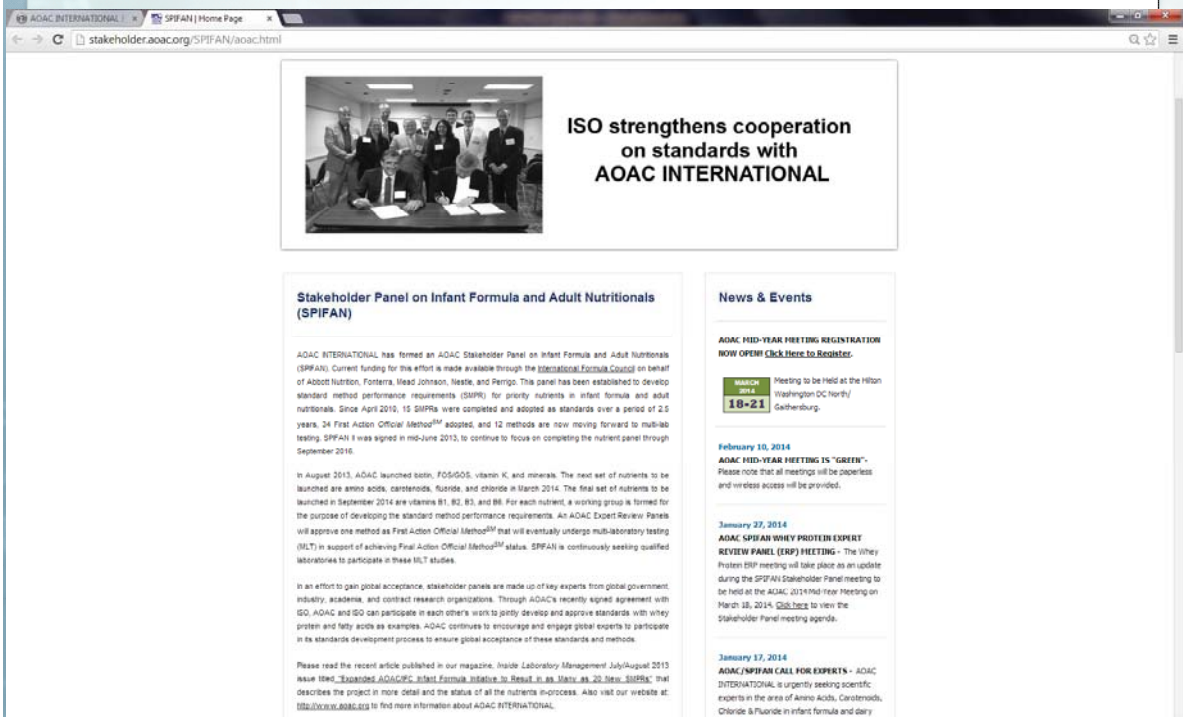
Method Submissions

- Method developers responding to an AOAC issued Call for Methods or to adopted standard method performance requirements (SMPRs) should submit their methods to AOAC INTERNATIONAL
- All other methods should be submitted to the AOAC Research Institute.
- Contact AOAC staff for details.

Calls for Methods



Call for Methods



December 19, 2013 AOAC/SPIFAN Community Update

STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN) NEWS

AOAC/SPIFAN CALL FOR CARNITINE METHODS EXTENDED

AOAC INTERNATIONAL invites method developers to submit Carnitine methods for consideration through the AOAC *Official Methods*℠ Program. Methods should meet or exceed the Standard Method Performance Requirement (SMPR). Click here to view Carnitine Call for Methods.

Interested method developers should provide a description and data demonstrating that the method will meet the SMPR. Click here to submit method(s). Deadline for submissions to be considered is **Friday, January 17, 2014**.

AOAC/SPIFAN CALL FOR EXPERTS

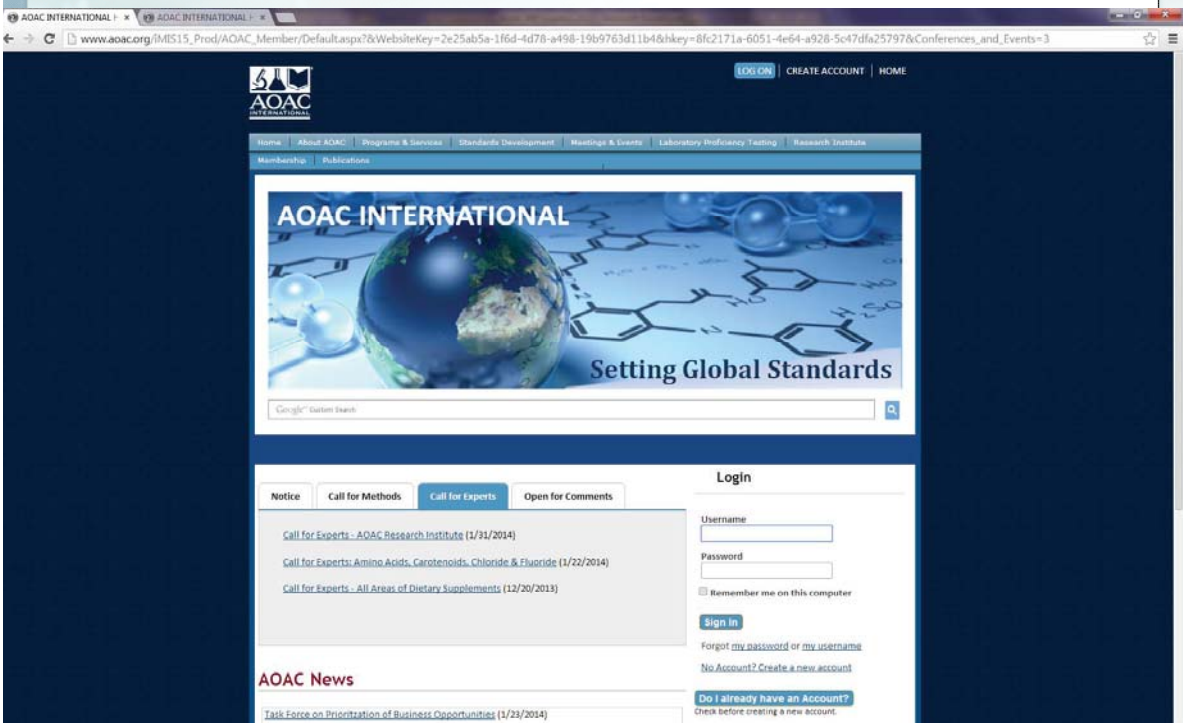
AOAC INTERNATIONAL is urgently seeking scientific experts in the area of Amino Acids, Carotenoids, Chloride & Fluoride in infant formula and dairy products to establish standard methods performance requirements (SMPRs). Click here to view Call for Experts.

SPIFAN ACTIVITIES AT AOAC INTERNATIONAL MID-YEAR MEETING (March 18-19, 2014)

TRACT 2

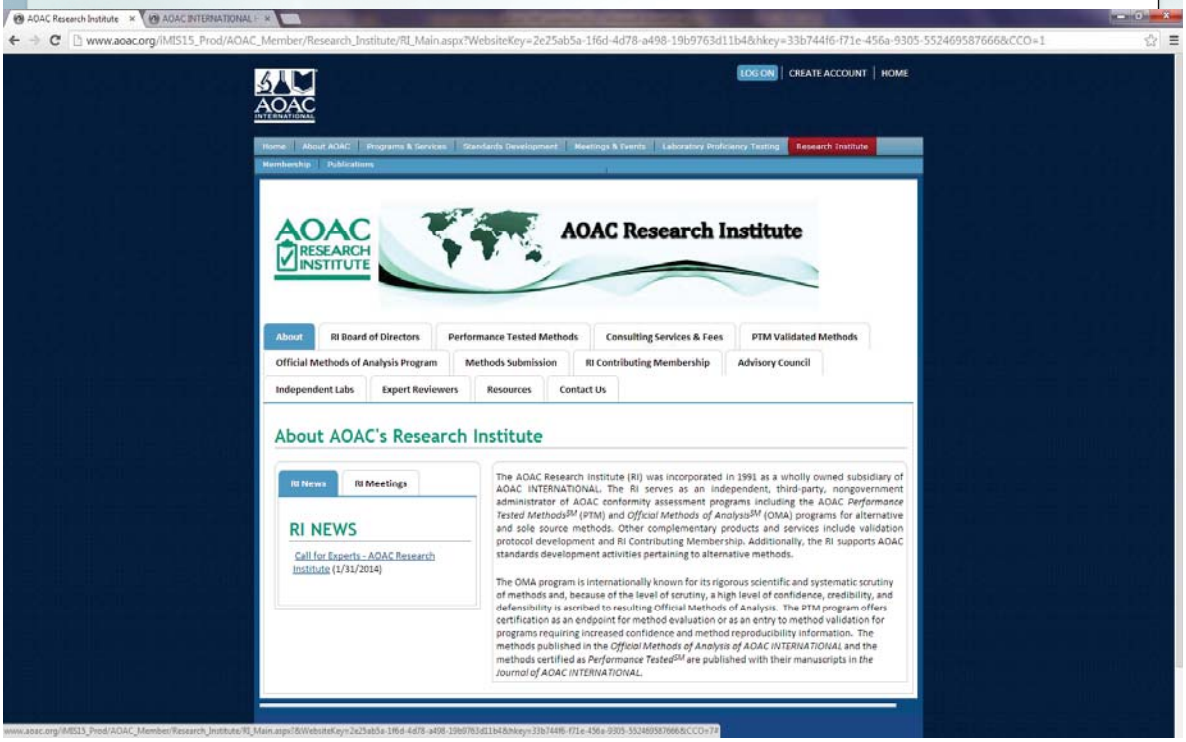
RECRUITMENT OF ERP MEMBERS

CALL FOR EXPERTS



CALL FOR EXPERTS

CALL FOR EXPERTS



Other Forms of Recruitment

- Official Methods Board
- Email Blasts to AOAC network
- Leveraging networks of Advisory Panel members, Working Group Members, AOAC Communities and Sections

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

AOAC Policies

- AOAC INTERNATIONAL Antitrust Policy
- AOAC INTERNATIONAL Policy On The Use Of The Association Name, Initials, Identifying Insignia, Letterhead, And Business Cards
- AOAC INTERNATIONAL Policy And Procedures On Volunteer Conflict Of Interest
- Volunteer Acceptance Form

Antitrust Responsibilities

- AOAC activities frequently involve cooperative undertakings and meetings where competitors may be present, it is important to emphasize the ongoing commitment of our members and the Association to full compliance with national and other antitrust laws
- Association's structure is fashioned and its programs are carried out in conformance with antitrust standards.
- An equal responsibility for antitrust compliance - which includes avoidance of even an appearance of improper activity - belongs to the individual.
  - The appearance of improper activity must be avoided because actual proof of misconduct is not required only whether misconduct can be inferred from the individual's activities.
- Compliance with AOAC policy and guidelines involves not only avoidance of antitrust violations, but avoidance of any behavior which might be perceived as such.

Antitrust Policy Document

- The document states antitrust laws in general terms, and is not a summary of applicable laws.
- It is intended only to highlight and emphasize the principal antitrust standards which are relevant to AOAC programs and activities.
- Signing the AOAC INTERNATIONAL Volunteer Acceptance Form means that the signer has read, understand and agrees to comply with the policy.

USE OF THE ASSOCIATION NAME, INITIALS, IDENTIFYING INSIGNIA, LETTERHEAD, AND BUSINESS CARDS

- to protect the reputation, image, legal integrity and property of the Association.
- "The Board approves and encourages reference to the Association by name, either as AOAC INTERNATIONAL or as AOAC; or reference to our registered trademark, AOAC®, in appropriate settings to describe our programs, products, etc., in scientific literature and other instances so long as the reference is fair, accurate, complete and truthful and **does not indicate or imply unauthorized endorsement** of any kind.
- Neither the Association's name nor its insignia nor part of its insignia may be incorporated into any personal, company, organization, or any other stationery other than that of the Association;
- Please review instructions on use and sanctions for violations.
- Signing the AOAC INTERNATIONAL Volunteer Acceptance Form means that the signer has read, understand and agrees to comply with the policy.

Volunteer Conflict Of Interest

- It is the sense of AOAC that conflicts of interest or even the appearance of conflicts of interest on the part of AOAC volunteers should be avoided
- Where this is not possible or practical under the circumstances, there shall be written disclosure by the volunteers of actual or potential conflicts of interest in order to ensure the credibility and integrity of AOAC. Such written disclosure shall be made to any individual or group within the Association which is reviewing a recommendation which the volunteer had a part in formulating and in which the volunteer has a material interest causing an actual or potential conflict of interest.
- AOAC requires disclosure of actual or potential conflicts of interest as a condition of active participation in the business of the Association. The burden of disclosure of conflicts of interest or the appearance of conflicts of interest falls upon the volunteer.

Volunteer Conflict Of Interest Policy Document

- Contains illustrations of apparent or direct conflicts of interest, but not all inclusive
- Contains guidance on Dos and Don’ts for volunteers
- Signing the AOAC INTERNATIONAL Volunteer Acceptance Form means that the signer has read, understand and agrees to comply with the policy.

TRACT 3

ERP COMPOSITION & VETTING EXPERTISE

ERP Composition

- Call for Experts or Volunteers is issued.
- Members must be vetted by AOAC Official Methods Board (OMB).
  - Demonstrated expertise
  - Diversity and balance of the overall expert review panel
- AOAC volunteer appointment
  - Serve at the pleasure of the President of AOAC INTERNATIONAL
- Additional members may be added.
- Can have non-voting members
- OMB assigns an OMB member to serve as a representative on each ERP

ERP SELECTION PROCESS

- AOAC paid consultants and AOAC staff should not act as Chairs of ERPs.
- Members of the BoD may act as voting members but it is recommended that they sit as non-voting members of the panel, unless the CSO can demonstrate that there are so few experts in the field available to the community that they are needed to move the project forward.
- Paid consultants of AOAC and AOAC staff may not serve as voting members on ERPs.
- If a single business location is represented by more than one person on an ERP, that location shall have only one vote.
- The Chair of the ERP must be a member of AOAC INTERNATIONAL.

Vetting Process

AOAC Chief Science Officer

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

Official Methods Board

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

TRACT 4

ERP METHOD ASSIGNMENTS

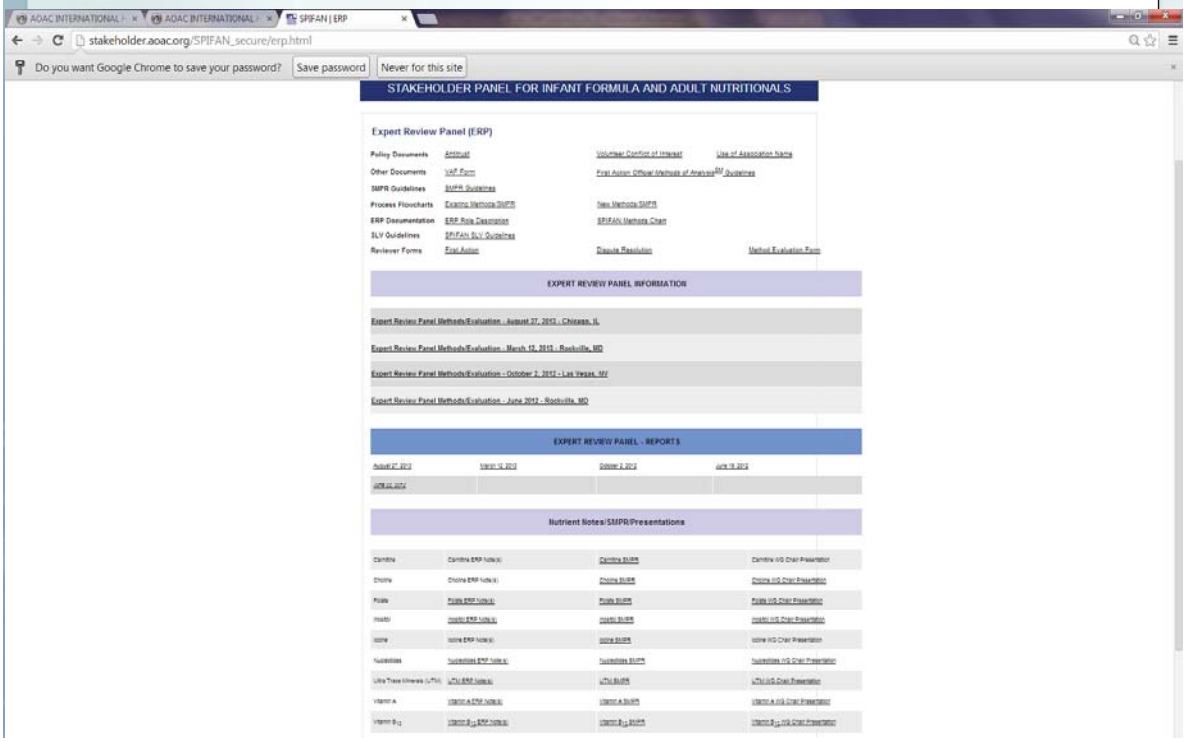
ERP Method Assignments

- A primary and secondary reviewer is 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.
- Members of both Committee on Safety and Committee on Statistics serve as advisory resources for all ERPs

ERP REVIEWS

- Primary and Secondary Reviewers and/or entire ERP conduct in-depth review of method and any supporting information.
  - In-depth review is done electronically through password protected website access and is completed prior to the in-person meeting.
  - Deadlines for submission of reviews
  - Depending on the number of methods 15 to 30 days for review
  - Track and present feedback on assigned First Action *Official Methods*.
  - Present on the method during the meeting and can make the motion to adopt the method.
  - Can recommend additional feedback or information for Final Action consideration

ERP REVIEWS



AOAC INTERNATIONAL

ERP REVIEWS

- **In your judgment, does the method sufficiently meet the Standard Method Performance Requirements (SMPR)?**

- 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?

TRACT 5

ERP MEETINGS

ERP Meetings

- ERPs will 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.
- At the ERP meeting:
  - **Primary and secondary reviewers or entire ERP** will present their reviews and makes a motion/recommendation to the ERP whether or not 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 First Action methods only.
- If the method is adopted
  - ERP decides on what additional information is needed to recommend the method for Final Action status

ERP MEETINGS

- MEETINGS ARE HELD IN-PERSON, HOSTED BY AOAC
- A QUORUM IS THE PRESENCE OF SEVEN (7) MEMBERS OR 2/3 OF THE TOTAL VETTED ERP, WHICHEVER IS GREATER.

IF NO QUORUM, THEN NO MEETING!

ERP MEETINGS

- REVIEWERS PRESENT THEIR REVIEWS AND MAY INITIATE A MOTION TO ADOPT THE METHOD IF THEY CHOOSE
  - Chair recognizes the reviewers
  - Primary and secondary / ERP reviews are presented.
    - If in favor, they may make and second a motion to adopt or not adopt the method
    - Chair can then entertain discussion on the method
    - Chair can call for a vote once deliberation is complete

ERP MEETING - Discussions

- In your collective judgment, is the method scientifically sound and can be followed as written?
- **In your collective judgment, does the method sufficiently meet the Standard Method Performance Requirements (SMPR)?**
- In your collective judgment, what are the strengths and weaknesses of the method?
- In your collective judgment, do the weaknesses outweigh the strengths in your recommendation for the method?
- In your collective judgment, is the method safe and can it serve well the stakeholder community that will use the it?
- In your collective judgment, is additional information needed to before considering this method for First Action OMA status?

TRACT 6

ERP CONSENSUS

ERP CONSENSUS

- 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 delineate 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.

ERP CONSENSUS

- 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.

TRACT 7

POST ERP MEETING

Post ERP Meeting

- An ERP report with the decisions of the ERP will be drafted
  - Review and approval by ERP chair
  - Posted on website within 15 business days after the ERP meeting
- AOAC staff will send notification to method authors/submitters regarding outcomes on specific methods

TRACT 8

FIRST ACTION TO FINAL ACTION STATUS

ERP Tracking

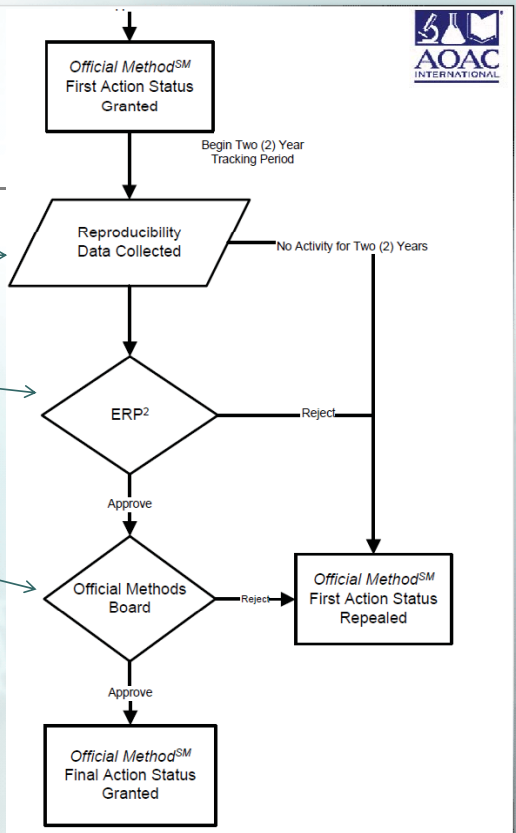
- Between First Action and Final Action:
  - The primary and secondary reviewers track the methods on behalf of the ERP over this time period.
    - Based on information from method authors, laboratories using the method, general community feedback, additional laboratory work
    - Are ERP recommendations being fulfilled?
    - Is the method meeting the standard criteria more closely?
    - How well is community guidance and OMB guidance being reflected?
  - Updates on the method are given by the primary and secondary reviewers during the ERP meetings.
  - At the end of two years, ERP makes a recommendation to OMB for Final Action status, repeal, or continuance.

Road to Final Action OMA Status

Method reproducibility must be demonstrated before Final Action consideration.

ERP determines if sufficient evidence merits a recommendation for Final Action status or repeal.

- Only the OMB promotes a method to "Final Action" status or repeal the method.
- Methods that did not meet the bar would be repealed.
- Same for all method submissions



Terms:

- PTM – *Performance Tested Methods℠*
- RI – Research Institute
- ERP – Expert Review Panel
- OMB – Official Methods Board
- SP – Stakeholder Panel
- SMPR – Standard Method Performance Requirement

Note: Appeals process always available; see Alternative Pathway Guidelines for appeals process.

1 PTM certification previously issued, PTM reviewers will be ERP members
2 Unless otherwise provided for under a contractual agreement, AOAC will regularly convene ERPs twice a year: once during the Mid-Year Meeting and again during the Annual Meeting

Path to Final Action

Review of ERP Method Recommendations

What to Expect from AOAC Official Method Board (OMB)

Standard Method Performance Pathway

1. Standard Method Performance Requirements authored by Working Groups and established by Stakeholders
2. Expert Review Panel (ERP) vetted by OMB
3. ERP approves methods for First Action
4. Method reproducibility data collected
5. ERP monitors method performance
6. ERP recommendations sent to OMB within 2 years
   - Final Action, First Action continuation, or Repeal

OMB Liaison

- OMB member or designee is assigned to your ERP
- Liaison monitors First Action to Final Action process
- Monitors ERP's documentation of all items in OMB Guidance document (OMA Appendix G)

Method Applicability

- Determine how method meets stakeholder's needs
  - scope, accuracy, precision, etc.
- Are ERP recommendations & improvements implemented?
- Assess method limitations & concerns

Safety Concerns

- Safety review completed for First Action
  - Participation by Safety Committee
- All safety issues identified during 2 year review addressed
  - Participation by Safety Committee

Reference Materials

- Identification of potential reference materials (RM)
  - If none found, define alternative options
- RM performance expectations

Available resource is the AOAC Technical Division on Reference Materials (TDRM)

Single Laboratory Validation

Chemistry

- Linearity
- Accuracy
- Repeatability
- LOD / LOQ
- Matrix scope
- Selectivity

Microbiology

- Inclusivity/Exclusivity
- Robustness
- Repeatability
- POD or equivalent
- Matrix scope

AOAC Committee on Statistics is your resource

Quantitative Reproducibility/Uncertainty

- Experimental designs may vary
  - Collaborative study
  - Proficiency Testing data
  - Multi-lab study variations
- Committee on Statistics
  - is available to discuss new study design protocols
  - Formalized tools were presented at the 2013 Annual Meeting

Qualitative Reproducibility/Uncertainty

- Experimental designs may vary
- Committee on Statistics is available to discuss new study protocols designs

Compare to SMPR

- Method meets Performance Criteria
- Method does not meet Performance Criteria
  - Acceptable or not? List reasoning
- Document acceptability to Stakeholders

Feedback from Users

- Solicit and document user feedback
  - ERP Chair determines mechanism
  - May take form of
    - Proactive calls to users
    - Tally of incoming calls
    - Emails
    - Web surveys

Feedback from Users

- Method performance
- Safety Concerns
  - Warnings
  - Alternatives
- Equipment and supply availability
  - Readily available
  - Practicality
  - Suggested improvements
  - Failures
- Reference material availability

September 20, 2004

ERP SUMMARY FOR FIRST TO FINAL ACTION METHOD RECOMMENDATION

AOAC No.	NAME OF METHOD

GUIDANCE FOR AOAC ERPS - APPENDIX G[1]	**Considered?**	**Comments/Reference if applicable**
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		
ERP Method Recommendation (Final Action/Repeal/Continuation)		

[1] *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 SUMMARY FOR FIRST TO FINAL ACTION METHOD RECOMMENDATION

AOAC 2012.25	**Residues of Three Triphenylmethane Dyes and Their Metabolites (Malachite Green, Leuco Malachite Green, Crystal Violet, and Brilliant Green) in Aquaculture Products** **Liquid Chromatography/Tandem Mass Spectrometry**

GUIDANCE FOR AOAC ERPS - APPENDIX G[1]	**Considered?**	**Comments/Reference if applicable**
Method Applicability	Yes	Triphenylmethane dyes as specified in applicability statement.
ERP First to Final Action recommendations & improvements implemented/addressed	Yes	
Draft Final Action method reviewed by ERP	Yes	
Safety Concerns	Yes	Completed and discussed during ERP meeting
Reference Materials	Yes	Currently no reference materials available for these types of drugs
Single Laboratory Validation	Yes	Hurtaud-Pessel et al., *J. AOAC Int.* **96**, 1152(2013) Andersen et al., *J. AOAC Int.* **98**, 636(2015) – modification – matrix extension
Reproducibility/Uncertainty and Probability of Detection	Yes	Schneider & Andersen *J. AOAC Int.* **98**, 658(2015)
Comparison to SMPR (SMPR criteria met?)	Yes	SMPR 2009.001 – SMPR for Quantitative Methods for Drug Residues in Shrimp, Tilapia, Catfish, and Salmon; SMPR criteria met according to ERP
Feedback from Users of Method	Yes	Discussed in ERP Meeting

DOCUMENTATION	**Available?**	**Comments**
Safety Evaluation	Yes	Completed; Discussed in ERP meeting
Reference Materials	No	None specified in SMPR; none available
SLV or PTMs	Yes	Hurtaud-Pessel et al., *J. AOAC Int.* **96**, 1152(2013) Andersen et al., *J. AOAC Int.* **98**, 636(2015)
Approved Validation Protocols	No	Used SMPR; OMA appendix D, and help from Chemical Contaminants Community subgroup
Statistics Review	Yes	Completed
Method Published in OMA	Yes	2012.25
Method Performance vs SMPR criteria	Yes	SMPR 2009.001 – SMPR for Quantitative Methods for Drug Residues in Shrimp, Tilapia, Catfish, and Salmon
Feedback Information	Yes	Discussed in ERP meeting
Additional Recognition(s)	No	
ERP Reports	Yes	10/2012; 12/2015
Manuscript(s) Published in JAOAC	Yes	Hurtaud-Pessel et al., *J. AOAC Int.* **96**, 1152(2013) Andersen et al., *J. AOAC Int.* **98**, 636(2015) Schneider & Andersen *J. AOAC Int.* **98**, 658(2015)

ERP Method Recommendation (Final Action/Repeal/Continuation)	**Final Action**	**Method scope expanded and the latest version of the method approved by ERP is in Collaborative Study Manuscript published in 2015 by Schneider and Andersen.**

ERP Recommendations

- Supply all documentation to AOAC by established deadline
  - Documentation includes ERP review details
- Representative from ERP present at OMB review meeting
- If method to be repealed, document reasoning

TRACT 9

PUBLICATIONS

Publication of First Action Methods

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

Format for AOAC *Official Methods of Analysis*

The language of the method should be concise and completely free from ambiguity. Conciseness is desirable, both to ensure clarity and to save space. Whenever there is a conflict between clarity and style, clarity is more important.

Present Tense and Imperative Mode
- Check sentences that do not begin with a verb and change them, if feasible, to the imperative mode (e.g. Pipet 10 mL..., Stir..., etc.). Exceptions are: use of adverb modifier ("Accurately weigh..."), prepositional clause ("For refined sugars, use..."), permissive statements ("Ferric hydroxide may be used..."), and statements in the "Principle" section.

Abbreviations
- Most abbreviations are the same as those used by Chemical Abstracts. Do not use abbreviations in titles and headings. See the *Definitions of Terms and Explanatory Notes*.

Repetition and Redundancy
- Eliminate repetition and redundancy as far as possible; use only for emphasis. Do not use "distilled" with water, "concentrated" with common acids, "95%" with alcohol, or "ACS" with reagents covered by ACS specifications. These are understood by definition.

Terminology, Formulae and Chemical Names
- For names of chemical compounds, use the spelling, hyphenation, and word division given in Chemical Abstracts. Use a national pharmacopeia for names for drugs. Use ISO nomenclature for pesticides and Codex nomenclature for names of food additives and color additives.

Consistency
- Watch for internal contradictions in the text: volumes that do not add up or that exceed the capacity of the container; too abrupt a transition from one operation to another (a line may be omitted); and impractical or impossible numbers (e.g., 100 g NaCl will not dissolve in 100 mL water).

Cross-references
- All new AOAC methods should be written as complete and self-contained as practical. Do not refer to other AOAC methods. If part of a procedure in an *Official Method*℠ is taken from material previously published elsewhere, incorporate those steps in the method rather than referring the analyst to another publication.

Definitions
- The section "Definition of Terms and Explanatory Notes," *Official Methods of Analysis of AOAC INTERNATIONAL*, is the basic guide to conventions and consistency.

Illustrations and Tables
- If symbols are used on the figure, include an explanation in the caption or text. Provide descriptive titles for tables. Explain any obscure headings in a footnote.

Bibliographic References
- Check all references for accuracy. Use standard Chemical Abstracts abbreviations for *Journal* titles. In general avoid references in method. Cite background references in the "Introduction" or "Discussion" section of the collaborative study manuscript -- not in the method. If part of a procedure in an *Official Method*℠ is taken from material previously published elsewhere, incorporate those steps in the method rather than referring the analyst to another publication.

Safety
- All methods must be reviewed for safety and potential hazards. Methods should automatically incorporate cross-references to the safety statement(s), or present questioned conditions to the attention of the Committee on Safety for resolution.
- Decisions regarding inclusion of safety statements should be practical, recognizing that overuse will be self-defeating.
- Methods that create toxic, obnoxious or environmentally hazardous fumes and wastes should contain practical directions for disposal.

Checking Edited Copy and Proofreading
- The author must review a copy of the original version and edited copy to ensure that there has been no change in meaning, to correct typographical errors, and to answer any questions posed by the editor. The author must review the typeset method for accuracy.

Revised October 2013

Online Technical Resources

Method Development, Optimization & Validation
- OMA - Appendix F - Guidelines for Standard Method Performance Requirements
- Homogeneity
- Guide for Writing Methods in AOAC Format
- Statistics Protocol Review Form
- OMA - Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis
- OMA - Appendix G: Procedures and Guidelines for the Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis
- OMA - Appendix I: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures
- OMA - Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces
- OMA - Appendix K: Guidelines for Dietary Supplements and Botanicals
- OMA - Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation
- OMA - Appendix M - Validation Procedures for Quantitative Food Allergen ELISA Methods: Community Guidance and Best Practices
- Safety Checklist

Method Review
- Examples of Statistical Analysis
- Statistics Manuscript Review Form
- OMA - Appendix A: Standard Solutions and Reference Materials
- OMA - Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis
- OMA - Appendix H: Probability of Detection (POD) as a Statistical Model for the Validation of Qualitative Methods

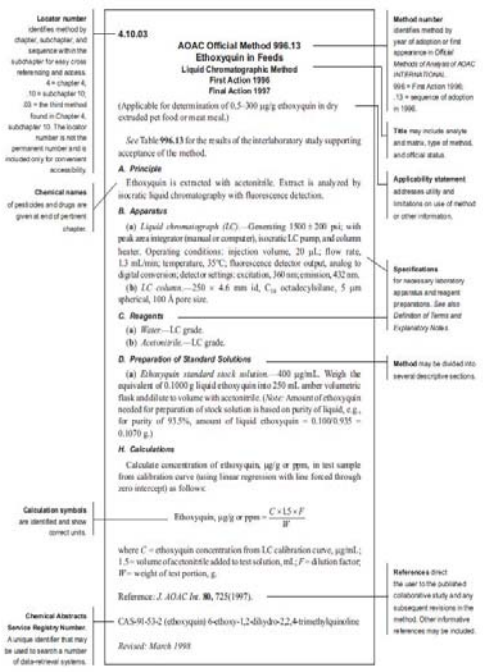
Miscellaneous
- Definition of Terms and Explanatory Notes
- OMA - Appendix B: Laboratory Safety
- OMA - Appendix E: Laboratory Quality Assurance
- OMA - Appendix C: Reference Tables

All resources are accessible at
http://www.aoac.org/imethguidelines.htm

For questions, please contact:
P 301-924-7077 x157 E dmckenzie@aoac.org

Guide to Method Format

(Method shown is incomplete to allow space for description.)



The AOAC style used for preparing methods for publication in the *Official Methods of Analysis of AOAC INTERNATIONAL* includes the following essentials:

- ✓ Standardized format that follows the order of laboratory operations.
- ✓ Use of the imperative mode.
- ✓ Cross-references to identical reagents, apparatus, and operations.
- ✓ Use of standardized definitions, terminology, and style.
- ✓ Use of accepted abbreviations and simplifications.
- ✓ Use of SI units
- ✓ Methods should be written as complete and self-contained as practical.
- ✓ Normality should be referred in terms of Molarity.
- ✓ ppm should be changed to mg/kg or mg/L
- ✓ ppb should be changed to ng/g or ng/mL
- ✓ ppt should be changed to pg/g or pg/mL

FORMAT OF AOAC® *OFFICIAL METHODS of ANALYSIS OF AOAC INTERNATIONAL*

Title:
- Includes analyte being determined, type of matrix (matrices), and analytical technique used for analysis.

Applicability:
- Includes list of matrix(es) along with specific matrix types and range or limits of determination or detection.

Precautions:
- Makes an analyst aware of hazardous materials used in analysis.

Data Collection:
- Table(s) that presents performance parameters including matrices tested in a collaborative study, levels of analyte(s), % recovery, RSD_r, RSD_R, s_r, s_R, HORRAT, number of observations, etc

Principle:
- Explains scientific premise on which the method is operates specifically the mechanism of the analysis.

Apparatus:
- Lists the equipment that requires assembly or that has specifications critical to the method performance. Describe equipment in terms of performance characteristics.

Reagents:
- List the reagents with amounts and appropriate units needed to conduct the analysis and describe the reagents in terms of performance characteristics.

Sample and Test Portion Preparation:
- Describe the preparation of samples and the test portion.

Determination:
- Describes the actual analysis.

Calculations:
- Section that explains how to calculate final results; presented in a form of equation or description.

Other sections as needed

REFERENCING *AOAC® OFFICIAL METHODS*℠

When referencing *AOAC® Official Methods*℠, only the method number should be used as seen in the following example:

(1) *Official Methods of Analysis of AOAC INTERNATIONAL* (2012) 19th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, USA, Official Method **2008.01**

Revised October 2013

Publication of First Action Methods

NO OMA NUMBER ASSIGNED

UNTIL ALL DOCUMENTATION SUBMITTED

1. Method incorporating ERP revisions (preferably in AOAC Format)
2. Method Manuscript incorporating ERP revisions (in AOAC Format)
3. Signed AOAC Copyright Authorization form

Format for AOAC First Action *Official Methods* Manuscripts and Protocols

FORMAT FOR FIRST ACTION OMA MANUSCRIPTS

TITLE: Title of manuscript includes method title which includes the analyte(s), matrix(es), and analytical technique, if applicable. It may also include a *common* method name and ends with "Collaborative Study."

AUTHOR(S): Provides authors' full (e.g. no initials) names and contact information.

ABSTRACT:
- ✓ Specific information on the method and study.

INTRODUCTION:
- ✓ Information on why collaborative study was conducted, how many collaborators participated in the study, previous work done, and information on compound or process that was studied.

COLLABORATIVE STUDY:
- ✓ Information on matrices and number of test samples tested, test sample preparations, instructions for collaborators, etc.

METHOD:
- ✓ Written in AOAC style.

COLLABORATORS' COMMENTS:
- ✓ Any comments and suggestions received from collaborators and information on how they were addressed, e.g., incorporating instructions into the method, etc.

RESULTS AND DISCUSSION:
- ✓ Information on type of statistical analyses performed on raw data, reasons for rejecting some of the data, discussion of results with references to tables and figures, discussion of the method performance, etc.

RECOMMENDATION:
- ✓ Recommendation to adopt method First Action.

ACKNOWLEDGMENTS:
- ✓ Full names and addresses of all collaborators that participated in the study.

REFERENCES:
- ✓ Included all references cited in the text.

APPENDICES or **FIGURES AND TABLES:**
- ✓ Include any figures and tables that may make the manuscript and the performance of the method easier to understand and interpret.

Revised October 2013

Online Technical Resources

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- Homogeneity
- Guide for Writing Methods in AOAC Format
- Statistics Protocol Review Form
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Miscellaneous
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- OMA - Appendix B: Laboratory Safety
- OMA - Appendix E: Laboratory Quality Assurance
- OMA - Appendix C: Reference Tables

All resources are accessible at
http://www.aoac.org/vmethodguidelines.htm

For questions, please contact:
P 301-924-7077 x157 E dmckenzie@aoac.org

TRACT 10

MODIFICATIONS

Modifications of Methods

- During First Action and Final Action, methods can be modified or extended to additional matrixes and/or analytes.

Submitting a Modification

Standards Development

- Contact staff and they will let you know the best way to submit the modification information and any additional requirements.
  - Staff will inform of the appropriate mechanism to submit a modification.
- Fully revised method manuscript and a revised version of the AOAC OMA method, both in OMA format, must be submitted.

Research Institute

- Submit request for modifying a method through the AOAC website.
  - AOAC > Research Institute > Method Submission
  - AOAC RI Application for Method Change or Modification
- Fully revised method manuscript and revised method, both in OMA format, must be submitted.

Processing Modifications

ERPs from Standard Development and Research Institute

- Review of the modification will undergo a preliminary review by at least the AOAC CSO.
  - Comments to be shared with method author.
- Original ERP reviewers will be assigned to review the method
- Method will be added to ERP agenda for their next meeting

Approval of Modifications

- If ERP approves a method modification including extensions, then the method begins a new two (2) year period.

- If the method modification is to correct an editorial error, then the method, then there is no change.

Method modifications require substantiation of the modification or extension with proof of method performance as deemed suitable by the EPR.

TRACT 11

DOCUMENTATION

Reports and Documentation

- AOAC staff or designee will capture the decisions and action items into an ERP report.
- The draft report will be sent back to the ERP Chair whose responsibility it is to sign off on the report once approved.
- The report is then distributed to the ERP.
- ERP is responsible for a drafting a written recommendation to the OMB for each method at a maximum of two years following adoption as First Action OMA
- Approved methods from the ERP meetings are published in the OMA and in the *Journal of AOAC INTERNATIONAL*.
- Meeting overviews are published in the AOAC *Inside Laboratory Management* magazine.

TRACT 12

SUMMARY OF RESPONSIBILITIES

Roles and Responsibilities

- Expert Review Panel:
  - Review methods and meet in person to discuss and render decisions on methods for First Action *Official Methods* status.
  - Track First Action *Official Methods*
  - Modify First Action methods if necessary
  - Make recommendations on First Action methods no more than 2 years after adoption to OMB.
- Official Methods Board:
  - Vet and approve ERP membership
  - Assign OMB liaison to be a resource to the ERP
  - Review ERP recommendations and render decisions (*Final Action, Repeal or remain First Action*) on First Action OMAs
- AOAC Staff
  - Coordinate the ERP and meetings, facilitate reviews, document ERP actions/decisions.
  - Issue necessary calls for experts and methods

Task Force on Communication/ ERP Best Practices

Recommendations for Staff

- Regularly debrief with ERP Chairs for input after meetings
- ERP background and training materials on website
- Offer orientation on a regular basis, to all ERP chairs and potential members, wider distribution of training materials
- Execute post training surveys
- Clearly outline expectations of reviewers prior to meeting: attendance is mandatory, cursory review of all methods to be discussed
- Encourage all method authors to attend ERP: helps process move smoothly and authors will only be privy to full discussion if they attend
- Establish a codification system in OMA for “dispute resolution methods” *
- Investigate ways to elevate the level of prestige for participation in an ERP.

** Project specific*

Task Force on Communication/ ERP Best Practices

Best Practices for ERP Chairs

1. Work closely with staff during the orientation period for ERP
2. Clearly understand consensus and quorum rules
3. Discourage abstentions unless a true conflict of interest is present; *use discretion as necessary when determining if a vote allows a method move forward.*
4. Encourage ERP reviewers to be fully prepared
5. Add brief orientation to ERP meeting agenda
6. Where in a stakeholder panel community requires only one method is desired, a 2 step process that considers multiple methods may be adopted as First Action and assessment of the best method is determined during follow up ERP meetings.
7. When considering methods for repeal, advise ERP members that repeal does not discredit method, it is simply a procedural determination that a method will not be moved forward.

Expert Review Panels

The ERPs review and approve appropriate methods (as submitted or modified) for adoption as First Action Official Methods or for further validation. ERPs also make recommendations regarding Final Action Official Methods status.

Expert Review Panels

- Must be supported by relevant stakeholders.
- Constituted for the review of methods, not for Standard Method Performance Requirements (SMPR) purposes or as an extension of a Working Group.
- Consist of a minimum of seven (7) members representing a balance of expert stakeholders. **Quorum is a minimum of 7 members present or 2/3 of the total vetted members, whichever is greater.**
- ERP constituency must be approved by the Official Methods Board (OMB).
- Holds transparent public meetings only.
- Remains in force as long as method in First Action Status.

First Action Official Method Status decision

- Must be made by an ERP constituted or reinstated post 2011-03-28 for First Action Official Method Approval (FAOMA).
- Must be made by an ERP vetted for FAOMA purposes by OMB post 2011-03-28.
- Method adopted by ERP must perform adequately against the SMPR set forth by the stakeholders. Or demonstrate performance or characteristics that meet the scope, applicability and/or claims of the method.
- 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
- Method becomes First Action Official Methods on date when ERP decision is made.
- Methods to be drafted into AOAC format by a knowledgeable AOAC staff member or designee in collaboration with the ERP and method author.
- Report of FAOMS decision complete with ERP report regarding decision including scientific background (references etc) to be published concurrently with method in traditional AOAC publication venues.

Method in First Action Status and Transitioning to Final Action Status

- 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.
- Two years maximum transition time (additional year(s) if ERP determines a relevant collaborative study or proficiency or other data collection is in progress).
- Method removed from First Action Official Methods and OMA if no evidence of method use available at the end of the transition time.
- Method removed from First Action Official Methods and OMA if no data indicative of adequate method reproducibility is forthcoming as outlined above at the end of the transition time.
- ERP to recommend Method to Official Final Action Status to the OMB.
- OMB decision on First to Final Action Status

Revised October 2013

Online Technical Resources

Method Development, Optimization & Validation

- OMA - Appendix F - Guidelines for Standard Method Performance Requirements
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- Methods and/or Procedures
- OMA - Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces
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- OMA - Appendix H: Probability of Detection (POD) as a Statistical Model for the Validation of Qualitative Methods

Miscellaneous

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- OMA - Appendix B: Laboratory Safety
- OMA - Appendix E: Laboratory Quality Assurance
- OMA - Appendix C: Reference Tables

All resources are accessible at
http://www.aoac.org/vmethguidelines.htm

For questions, please contact:
P 301-924-7077 x157 E dmckenzie@aoac.org

About Expert Review Panels (ERPs)

ERP OVERVIEW:

An Expert Review Panel (ERP) is assembled to review and adopt methods as Official First Action. ERPs will track Official Methods for two years or until such time as reproducibility has been demonstrated and cumulative feedback on method use and performance are obtained. ERPs will make a recommendation regarding Final Action method status for all OMAs to the Official Methods Board (OMB).

All ERP members are expected to serve with the highest integrity and without direct or indirect conflicts of interest. A method assignment can last two years. All members of the ERP are expected to actively participate in ERP meetings and to perform duties and reviews in timely fashion. All members should maintain strict adherence to review timelines and deadlines. AOAC staff documents ERP deliberations.

ESTABLISHING AN EXPERT REVIEW PANEL:

- AOAC staff issues a Call for Experts:
  - Based on voluntary consensus standards and methods submitted to AOAC INTERNATIONAL that may meet the standards.
  - Proprietary and sole source method developers submit individual methods to the AOAC Research Institute.
  - Candidates are asked to submit a CV or information that demonstrates expertise to AOAC staff if not already part of a recognized pool of experts.
- AOAC Chief Scientific Officer (CSO) reviews the documentation for the candidates and make recommends a slate for an expert review panel including the chair to the Official Methods Board.
- The candidate list and supporting documentation are forwarded to the Chair of the OMB who will assign the review to at least two OMB members.
- The OMB reviewers will review the candidates for expertise and perceived conflicts of interest and the OMB may then approve the members of the ERP. A Chair for the ERP is also approved.

EXPERT REVIEW PANEL (ERP):

- Review, discuss and demonstrate consensus on methods for Official First Action method status.
- Participate in the publications process of First Action methods.
- Track and discuss feedback all First Action methods for two years.
- Reach and demonstrate consensus on recommendations for Final Action method status.
- Actively participate in the broader stakeholder effort.

ERP CHAIR:

- Lead ERP discussions in the review and adoption of methods for First Action Official Methods.
- Participate in stakeholder panel activities.
- Review and approve ERP report.
- Work with AOAC staff, working groups and other stakeholder panels to ensure a thorough understanding of the standard method performance requirements and the methods to be assessed.
- Implement the OMB First Action to Final Action Guidelines with the ERP members.
- Advise and review First Action methods and post First Action publications.
- Represent the ERP in presenting the ERPs recommendation to the Official Methods Board regarding Final Action method status.

MECHANICS OF AN AOAC EXPERT REVIEW PANEL

- AOAC CSO assigns methods for review to the expert review panel members.
- For each method, 2 ERP members are assigned as primary and secondary reviewers and present at the ERP meeting.
- All members are expected to actively participate and review methods for First Action Official Method status - conducting thorough and prompt review of methods and being prepared to speak on assigned methods at ERP meetings
- The ERP chair and the 2 reviewers for each method are expected to participate in the publications peer review process for First Action methods.
- ERP reviewers track assigned methods that were adopted as First Action Official Methods and update ERP on method use during two year period between First Action and Final Action
  ERP members are expected to participant in the stakeholder panel activities and/or community at large .

- *ERPs can work with topic advisors (aka, subject matter experts)*
- *OMB can recognize a pool of experts from which ERP members can be selected*

Eligibility Criteria for Expert Reviewers

Be a key expert and/or thought leader of the method or priority under consideration.

- 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.

Be approved by the Official Methods Board

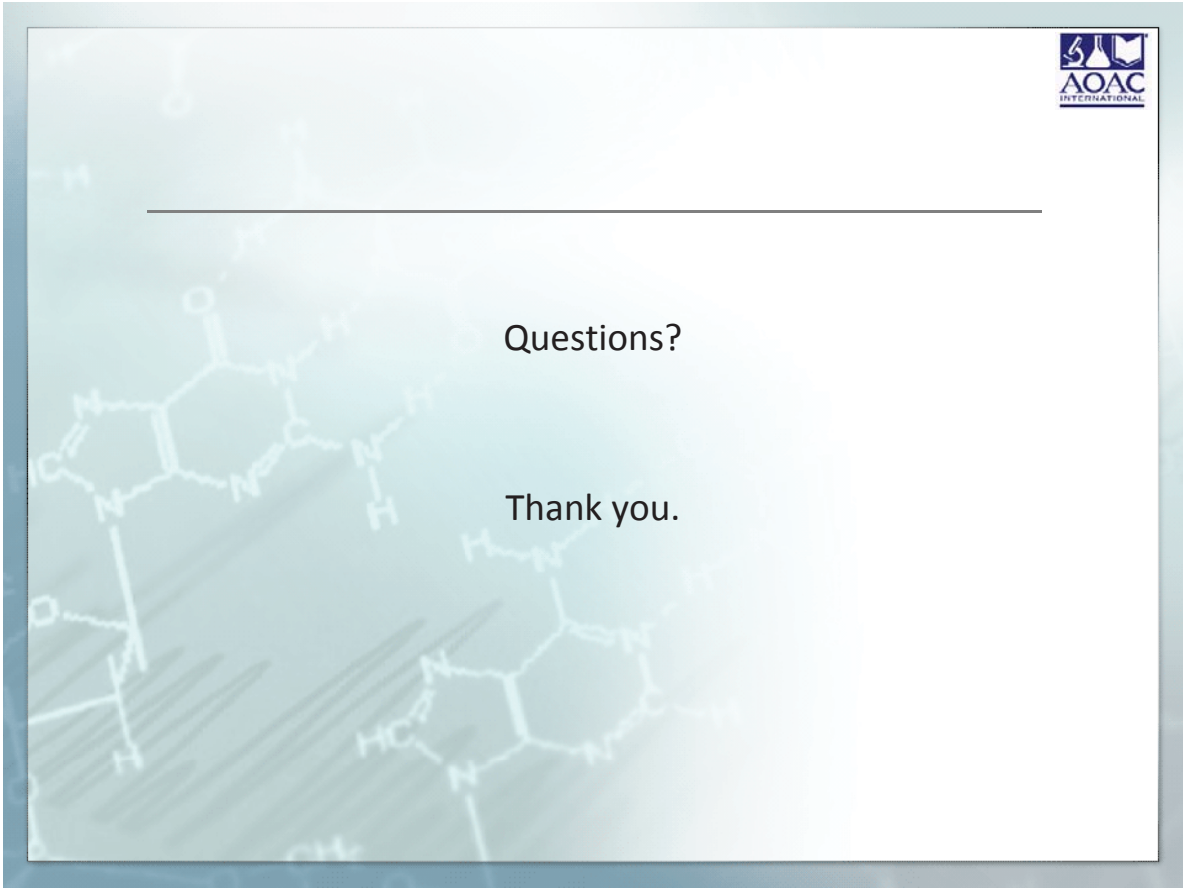
- Qualifications must be clearly described and submitted to AOAC headquarters.

Duties of Expert Reviewers

Members of the Pool of Experts will be called upon to serve on ERPs as needed and to review documents .These documents may include:

- Procedural documents on how methods will be selected and how single laboratory validation studies will be done;
- Methods submitted for consideration as First Action Official Methods;
- Methods submitted for selection for further validation studies;
- Protocols to be used for single laboratory validation studies;
- Selection of methods to be considered for full collaborative studies; and
- Validation study reports

Revised October 2013



First Action Method Updates

Expert Review Panel Tracking and Recommendations of First Action Methods

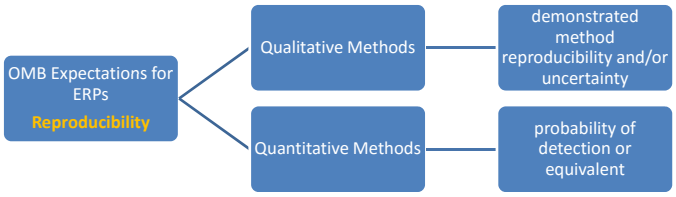
AOAC Policies & Procedures

- 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

OMA, Appendix G

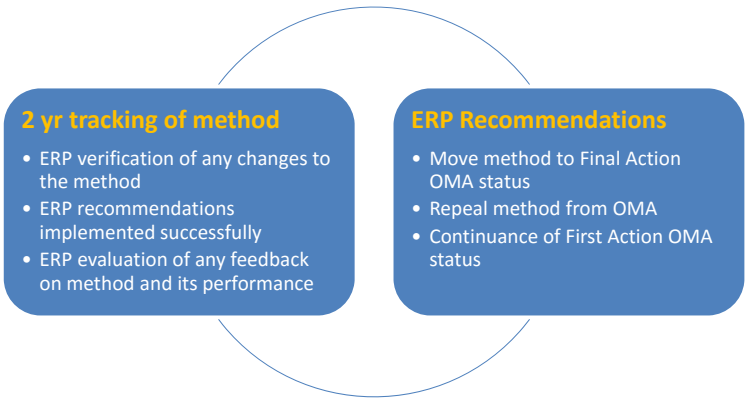
Further data indicative of adequate method reproducibility (between laboratory) performance to be collected. Data may be collected via a collaborative study or by proficiency or other testing data of similar magnitude.

- 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).



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 ≤ 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

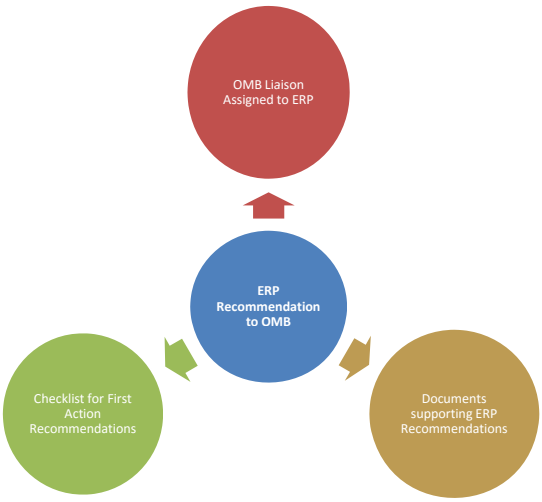
- Tracking period is ≤ 2 years and begins on the date of the ERP's decision to adopt a method for OMA First Action status.

No Demonstration of Method Reproducibility in ≤ 2 Years

- Repeal from OMA

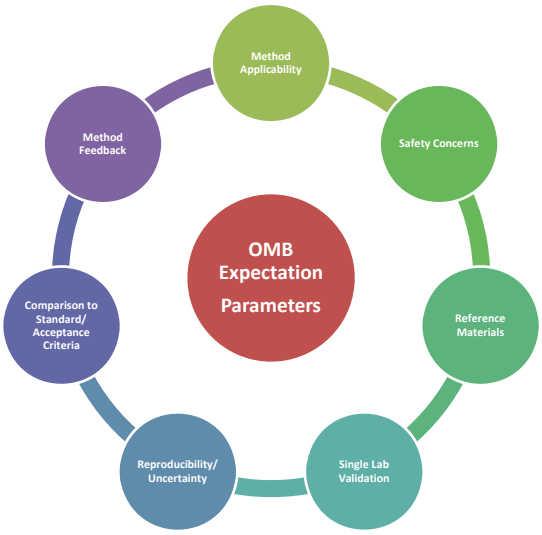
OMA, Appendix G

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

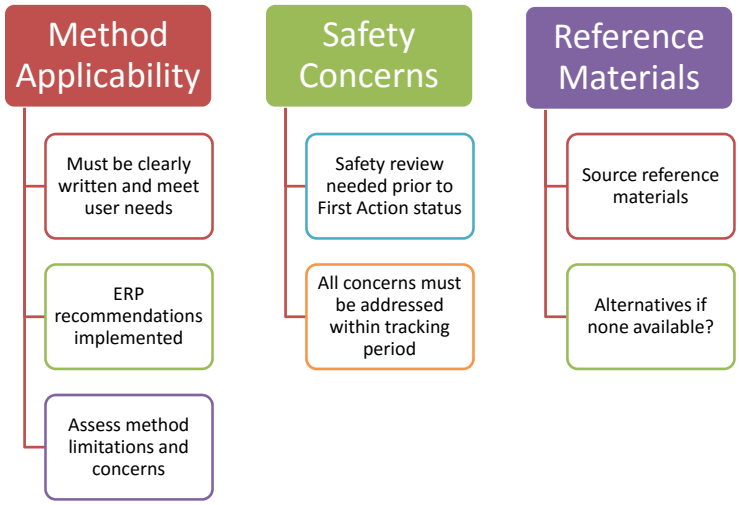


OMA, Appendix G

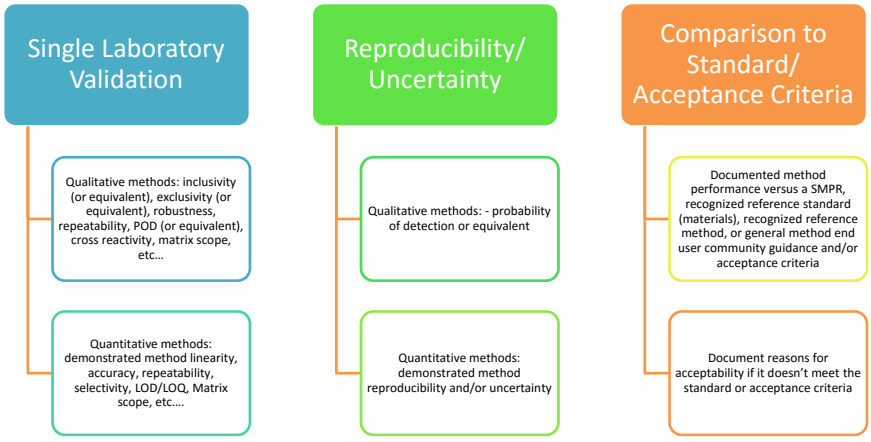
First Action to Final Action Methods: Guidance for AOAC Expert Review Panels



OMB Expectation Parameters



OMB Expectation Parameters



OMB Expectation Parameters

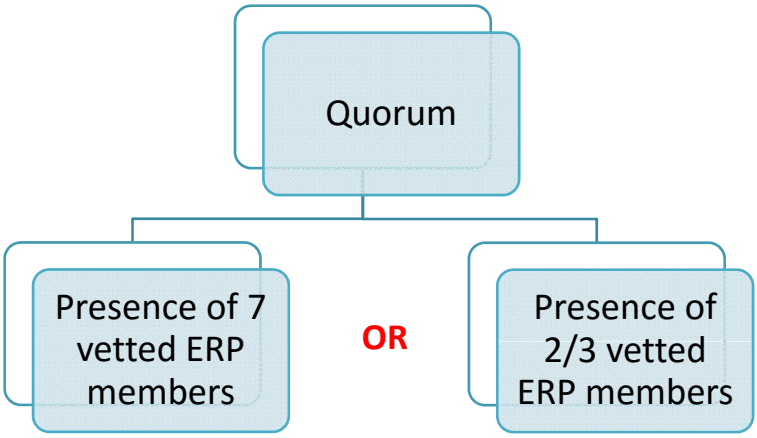
Method Feedback from End Users

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 Meetings



WHICHEVER IS GREATER

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.

Questions?

Thank you.