Outcomes and Future Work of the AOAC ISPAM Harmonization Project

Presented By: Erin Crowley and DeAnn Benesh
Sponsored By: AOAC INTERNATIONAL and Microbiologics
Organized by: Methods Validation & Verification Interest Group within the Applied Laboratory Methods PDG
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Webinar Housekeeping

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- This webinar is being recorded and will be available for access by IAFP members at www.foodprotection.org within one week.
DeAnn L. Benesh

Global Regulatory Affairs Manager – 3M Food Safety

• Leads regulatory activities with government and non-government entities to help drive harmonization, recognition and acceptance of microbiological methods
• Member of MicroVal General Committee
• Active member of IAFP International and Food Law PDGs
• Co-chair of WG3 drafting ISO 16140-part 3
• Fellow of AOAC INTERNATIONAL and past Chair of the Research Institute Board of Directors
• Currently serves on AOAC Board of Directors as Past-President
Erin Crowley

Chief Scientific Officer – Q Laboratories

• Leads independent third-party laboratory with a primary focus on providing high quality method validation for microbiological rapid detection methods
• Chair of the AOAC Official Methods Board
• Chair of the International Stakeholder Panel on Alternative Methods (ISPAM)
• Active member of IAFP and MicroVal Technical Committee (MVTC)
INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Outcomes and Future Work of the AOAC ISPAM Harmonization Project

Erin S. Crowley
ISPAM Chair
October 26, 2018
AOAC Roots in Food Safety

Began as Association of Official AGRICULTURAL Chemists (1884)

**USDA Bureau of Chemistry**
- Standardize methodology used for composition of fertilizers by state laboratories
- Directed by Harvey Wiley who wrote the 1906 law that began the US Food and Drug Administration (FDA)

- **1965** – Association of Official ANALYTICAL Chemists
- **1980s** - microbiologists, other food science professionals
- **1991- AOAC INTERNATIONAL** (Association of Official Analytical COMMUNITIES)
• AOAC develops and validates analytical methods for a broad spectrum of safety interests including
  – Food and beverages
  – Dietary supplements
  – Infant formula
  – Feeds
  – Fertilizers
  – Soil and water
  – Veterinary drugs
  – Pharmaceuticals
AOAC Standards Development

*Transparency, Openness, Balance, Due Process, Consensus, Appeals*

- **Advisory Panel**
- **Stakeholder Panel**
- **Established SMPRs**
- **Call for Methods Call for Experts (if needed)**
- **ERP Review of Methods and First Action status**
- **ERP Review of First Action Methods & any recommendations for Final Action Status/Repeal/etc.**
- **OMB review & rendered decisions on Final Action status/Repeal**

**PTM Certification (Optional)**
Projects using AOAC Standards Development Process

- **International Formula Council**
  Nestlé, Danone, Mead Johnson, Abbott Nutrition, PBM...
  Developed consensus standards and Official Method of Analysis for analysis of priority nutrients (e.g. Vitamins A/E, Vitamin D, Vitamin B12, Folate, Inositol, Nucleotides, Ultra trace minerals, Pantothenic acid)

- **Coca Cola and PepsiCo**
  Delivered AOAC® Official Method for pesticide residues in soft drinks
  Accepted by Bureau of Indian Standards as official method

- **Elanco Animal Health, Eli Lilly and Co.**
  Developed standards for drug residues in animal feed

- **International Stakeholder Panel on Alternative Methods**
  Harmonization of Validation methods between ISO and AOAC
International Stakeholder Panel on Alternative Methods (ISPAM)

- Driven and supported by AOAC Organizational Affiliates and contributing members who participate in the AOAC Research Institute Program

- ISPAM was formed initially to develop harmonized, internationally accepted standard validation guidelines for alternative (rapid) chemical and microbiological methods by leveraging global networks of experts to reach consensus on an analytical validation protocol.

- The goal is to achieve optimal efficiency and avoid duplication of efforts in order to meet regulatory and product safety testing requirements.

- Initially three (3) working groups:
  - Microbiology
  - Qualitative Chemistry
  - Statistics
### Participating Stakeholders

- **Government**
  - Health Canada
  - Canadian Food Inspection Agency
  - US Food & Drug Administration
  - US Dept of Agriculture
  - Meat and Livestock Australia
  - Netherlands Food & Consumer Product Safety Authority
  - ACHIPIA – Chile Ministry of Agriculture
  - ANSES – French Agency for Food, Environmental and Occupational Health & Safety
  - Maryland Department of Agriculture
  - Florida Dept of Agriculture

- **Test Kit Manufacturers**
  - 3M Food Safety
  - bioMérieux
  - BioControl
  - Bio-Rad
  - Crystal Diagnostics
  - Elution Technologies
  - Hygiena (Qualicon Diagnostics)
  - Morinaga
  - Neogen
  - QIAGEN
  - R-Biopharm
  - Romer Labs

- **Food Companies**
  - Abbott Nutrition
  - Cargill
  - Nestle
  - General Mills
  - Hershey Company
  - McCormick
  - Quaker Oats
  - Grain Millers

- **Contract Laboratories**
  - Q Laboratories
  - Adria Laboratory
  - AsureQuality
  - Mérieux NutriSciences (Silliker)
  - Eurofins
  - Microbac
  - Vanguard

- **Certification Bodies/NGOs**
  - AFNOR
  - MicroVal
  - NMKL/NordVal
  - ISO
  - GFCO-GIG
  - Allergen Control Group
Stakeholder Panel Working Groups

- Present background and history on priority analyte for stakeholder panel

- Develop draft SMPR or other assigned scope

- Will present motions to the stakeholder panel on components of the standard method performance requirements

- Can participate in ISPAM related in-person meetings
## ISPAM Working Groups

<table>
<thead>
<tr>
<th>ISPAM Working Groups</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>Working Group on Microbiology Validation Harmonization</td>
<td>Active</td>
</tr>
<tr>
<td>Working Group on Qualitative Chemistry Guidelines</td>
<td>Inactive</td>
</tr>
<tr>
<td>Working Group on Statistics</td>
<td>Inactive</td>
</tr>
<tr>
<td>Working Group on Produce Sampling Standard</td>
<td>Inactive</td>
</tr>
<tr>
<td>Working Group on Produce – Salmonella in Leafy Greens</td>
<td>Inactive</td>
</tr>
<tr>
<td>Working Group on Food Allergen Assays</td>
<td>Active</td>
</tr>
<tr>
<td>Working Group on Gluten Assays</td>
<td>Active</td>
</tr>
<tr>
<td>Working Group on Quantitative Microbiology Method</td>
<td>New 9/2017</td>
</tr>
<tr>
<td>Validation Acceptance Criteria</td>
<td></td>
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</table>
AOAC carefully documents the actions of the Stakeholder Panel and the Working groups

AOAC will prepare summaries of the meetings

Communicate summaries to the stakeholders
Publish summaries in the Referee section of AOAC’s Inside Laboratory Management

AOAC publishes its voluntary consensus standard

Official Methods of Analysis of AOAC INTERNATIONAL
Journal of AOAC INTERNATIONAL

AOAC publishes the status of standards in the Referee section of AOAC’s Inside Laboratory Management
HARMONIZATION OUTCOMES: ISPAM
“Oh, what a tangled web we weave.”
The PTM program provides the pre-collaborative study required by other validation programs. It serves as an entry to method validation.

The AOAC Consulting Service and the AOAC Performance Tested Methods℠ are flexible to develop:

- Joint validation testing protocols
- Joint data collection arrangements
- Separate or joint manuscripts reviews

Each organization maintains its program administrative and method approval procedures.

For additional information, please contact Deborah McKenzie, Sr. Director, AOAC Research Institute.
HARMONIZATION-PROGRAM TO PROGRAM

• Programs harmonized with PTM
  • *Official Methods of Analysis*<sup>SM</sup>
  • Antibiotic drug residues in milk
    • US Food & Drug Administration Center for Veterinary Medicine and the National Conference on Interstate Milk Shipments
  • Health Canada – Bureau of Chemical Safety (Food Allergens)
  • MicroVal (joint-agreement)
  • AFNOR (joint-agreement)
  • NordVal (joint-agreement)

• The goal is to achieve optimal efficiency and avoid duplication of efforts in order to meet regulatory and product safety testing requirements.
ISPAM Accomplishments: Microbiology

- Approved harmonized approaches for several testing parameters
- Number of levels/samples/fractional positives
- Results analysis/criteria/statistical analysis
- Number of data sets for collaborative study/sample size

Approved Food Classification Table- ISO 16140-2 Annex A
## Comparison of Method Validation Guidelines

<table>
<thead>
<tr>
<th>Criteria</th>
<th>ISO 16140</th>
<th>AOAC</th>
<th>Health Canada</th>
<th>NordVal</th>
<th>US FDA</th>
<th>USDA</th>
</tr>
</thead>
</table>

### Reference Method

- Defined in ISO 16140-1
  - 1st priority is ISO method, 2nd priority is CEN method if neither exists, then 3rd priority is other recognized methods
  - Note – definition still under discussion to open up for non ISO/CEN methods (PTV)
- Can use various existing recognized analytical methods (e.g., AOAC, OMA, ISO, FDA BAM, FSIS MLG, Health Canada) If no appropriate Ref can indicate “NA” in summary tables for POD
- Acceptable Ref published by EC (Part 1) May include any methods from methods organizations (i.e., AOAC, FDA, APHA, ICMSF, IDF, ISO, etc...) Where no Ref exists, MMC assess on case by case basis
- ISO, CEN, NMKL, BAM, etc... It is up to the applicant; however, as the EU regulation in EC 2073/2005 Microbiological criteria states EN ISO methods there are most frequently used.
- Most be BAM unless there is no BAM reference method. In case of no Bam, then FSIS MLG, AOAC, ISO, and Health Canada are all potential reference methods. APHA, ICMSF, and IDF methods may also be used as reference methods
- FSIS Microbiology Laboratory Guidebook (MLG) cultural methods is the is used for validating methods used by FSIS regulated establishments. FDA BAM or methods referenced by ISO or Codex. Non cultural methods applicable in some cases
ISPAM Sub-Group on Validation and Verification of “All Foods Claim”

- Based on recommendations from sub-group:
  - ISPAM voted to recommend to replace “all foods” with a claim for a “broad range of foods”
  - ISPAM recommends that method validation organizations require method developers to specify the validated food claims in the method applicability statement/product insert
  - No previously approved method with an “all foods” claim will be affected by ISPAM’s recommendation
ISPAM Sub-Group on Validation and Verification of “All Foods Claim”

- ISPAM recommended that developers of analytical methods follow ISO 16140-2 Annex A, *Guidance on food matrices and food categories for method validation*, as a guidance for choosing food categories to make a “broad range of foods” claim

- ISPAM agreed to adopt the ISO 16140-1 Part 1: “Terminology of method validation” working definitions for “validation” and “verification”
ISPAM Accomplishments cont’d

Harmonization WG in participation of the collaborative study for *Salmonella* reference method.

- Modified BPW, ISO BPW, and other BPW lactose broth
- Matrices to be determined
- Collect data to evaluate the possible differences between 35°C and 37°C selective enrichment (sensitivity study and RLOD)
- Secondary enrichment comparisons
Comparison of Select International Reference Methods for Salmonella in Food

Testing for Salmonella

- MFHPB 20
  - Pre-enrichment in BPW or nutrient broth
  - Incubation at 35 °C for 18 to 24 hours
  - Selective enrichment in RVS and TBG broth at 42.5 °C for 24 h (0.1 mL and 1 mL respectively)
  - Streak on at least 2 of the 3: Bismuth Sulfite Agar, BGS, Brilliance Salmonella agar
  - Biochemical and serology tests to confirm

- FSIS (USDA) MLG 4.04
  - Pre-enrichment in BPW
  - Incubation at 35 °C for 20 to 24 hours
  - Selective enrichment in TT and mRV broth at 42 °C for 18-24 h (0.5 mL and 0.1 mL respectively for 24 h)
  - Streak onto BGS plus one of DMLIA or XLT 4
  - Biochemical and serology tests to confirm

- FDA BAM Chapter 5
  - Pre-enrichment in Lactose Broth or TSB
  - Incubation at 35 °C for 20 to 24 hours
  - Selective enrichment in TT and RV Broth at 35 °C and 42 °C and 1 mL and 0.1 mL respectively for 24 h.
  - Note 1
  - Streak onto HE, XLD, Bismuth Sulfite agar.
  - Biochemical and serology tests to confirm

- AOAC OMA 200.06, 995.20 and 967.26
  - Pre-enrichment in Lactose or Broth TSB
  - Incubation at 35 °C for 24 hours
  - Selective enrichment in TT, RV and / or SC broth depending on method. (1 mL, 0.1 mL and 1 mL respectively) TT and SC are incubated at 35 °C and RV is incubated at 42 °C for 24 hours.
  - Streak onto XLD and one other agar (the second agar is any agar for the isolation of salmonella)
  - Bismuth Sulfite Agar, HE agar, XLD agar
  - Biochemical and serology tests to confirm

- ISO 6579
  - Pre-enrichment in BPW
  - Incubation at 37 °C for 16-20 hours.
  - Selective enrichment in RV and MKTn Broth. RVS at 37°C and 42°C and 0.1 mL and 1 mL respectively for 24 h
  - Streak onto XLD and one other agar (the second agar is any agar for the isolation of salmonella)
  - Biochemical and serology tests to confirm

Slide courtesy of I. Iugovaz Health Canada
Pre-Enrichment Media
(Salmonella)

**AOAC** – lactose broth, brilliant green water (BGW), TSB, TSB+K2SO4, Nonfat dry milk (NFDM) +BG

**BAM (FDA)** – lactose broth (some with various additives), TSB with or without ferrous sulfate, BGW, Universal enrichment broth, nutrient broth, NFDM+BG, tetrathionate broth, BPW (UPB for cantaloupes, BPW for mangoes!)

Where AOAC and BAM have the same food commodities, they are more or less in agreement (slight differences).

**MLG (FSIS-USDA)** – BPW

**HC** – usually BPW (or Nutrient Broth), plus 2 others for specific foods - skim milk medium, BGW

**ISO** – BPW (one exception when casein or sterile skim milk powder is added to BPW, plus Brilliant green for cocoa)

Slide courtesy of I. Iugovaz Health Canada
WG on Acceptance Criteria of Quantitative Microbiology Methods

– Fit-for-Purpose Statement Endorsed

To develop statistical analysis and acceptance criteria of quantitative methods that will balance the goals of:

– 1. Minimizing the chance of accepting a method that is not fit for purpose

– 2. While maximizing the chance of accepting a method that is fit for purpose

– 3. Providing guidance on relevance of deviations
- **WG on Quantitative Statistics**
  - The working group determined a priority sequence of activities based on feedback from the stakeholders.

  - **PRIORITY SEQUENCE**
    1. Difference of Means (Acceptance criteria)
      a. Indicator organism vs. pathogens
      b. Principle of the technology
    2. Number of out of range levels per assay- what is still acceptable?
      a. Recommendations for dealing with discordant results
    3. Determine acceptance criteria for low inoculation level replicates
Advisory Council determined the following priority allergens in food (food will be defined in the standard)

1. Eggs
2. Milk
3. Peanut
4. Tree nut (hazelnut, almond)
5. Celery
6. Mustard
7. Gluten

Quantitative and Qualitative methods

Next generation of harmonization.....
Benefits for Stakeholders
- Additional ISO validation initiatives from US Method Developers
- Potential increase in OMA Method due to combined study design
- Align with ISPAM Initiatives-Harmonization of Salmonella reference methods

Established Scope
- Deliverable Timeline
  - 9-12 months vs typical 12-24 months

Future Objectives
- Use as a guideline for expanding Harmonization beyond AOAC and ISO
- Pave the way for emerging technologies
  - Proteomic
  - Genomic
Next steps

• Continued activity of Harmonization, Food Allergen and Statistical WG
• Call for Methods
• Promoting new members to diversify the expertise throughout ISPAM
INTERNATIONAL STAKEHOLDER PANEL ON ALTERNATIVE METHODS (ISPAM)

Outcomes and Future Work

DeAnn Benesh
IAFP ISPAM Webinar
26 October 2018
Harmonize

Action or process of making something consistent or compatible.

"the economic group founded to harmonize national development plans"

"efforts to harmonize X country’s regulations with international standards"

Synonyms:
coordinate · systematize · correlate · match · integrate · synchronize · homogenize · bring together · make consistent · bring in line (with) · bring in tune (with)
## Certification Bodies and Validation Guidelines

<table>
<thead>
<tr>
<th><strong>AOAC Research Institute</strong></th>
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<tbody>
<tr>
<td>AOAC INTERNATIONAL Methods Committee</td>
</tr>
<tr>
<td>Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces (2012)</td>
</tr>
<tr>
<td>• Performance Tested Method℠</td>
</tr>
<tr>
<td>• Official Method of Analysis℠</td>
</tr>
<tr>
<td>• Harmonized Method</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th><strong>Certification to ISO 16140-2:2016</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol for the validation of alternative (proprietary) methods against a reference method</td>
</tr>
<tr>
<td>• NordVal Certification</td>
</tr>
<tr>
<td>• MicroVal Certification</td>
</tr>
<tr>
<td>• NF Validation via AFNOR Certification</td>
</tr>
</tbody>
</table>

[Image of certification logos]
### ISO 16140-2:2016 and AOAC TB 02MAY2016

#### Table A. 1: Classification of sample types & suggested target combinations for validation studies

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Eggs &amp; egg products (derivatives)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Raw &amp; ready-to-cook fish &amp; seafoods (unprocessed)</td>
<td>Ready-to-eat, ready-to-reheat fishery products</td>
<td>Fresh produce &amp; fruits</td>
<td>Processed fruits &amp; vegetables</td>
<td>Dried cereals, fruits, nuts, seeds and vegetables</td>
<td></td>
</tr>
<tr>
<td>Infant formula &amp; infant cereals</td>
<td>Chocolate, bakery products &amp; confectionary</td>
<td>Multi-component foods or meal components</td>
<td>Primary production samples</td>
<td>Pet food &amp; animal feed</td>
<td>Environmental samples (food or feed production)</td>
<td></td>
</tr>
</tbody>
</table>

There are 18 CATEGORIES recognized and harmonized between ISO & AOAC
Method Comparison Study

**AOAC Research Institute**

- **Method Developer Laboratory**
  - Inclusivity / Exclusivity
  - Matrix Study – *inoculated*

**ISO Certification Body**

- **Expert Laboratory**
  - Inclusivity / Exclusivity
  - Matrix study – *natural (+stressed)*

---

*Performance Tested Method*™ *(PTM)*

- **Independent Laboratory**
- 20% Foods / surfaces repeated
Inter-Laboratory Study (ILS)

**AOAC® Official Method of Analysis\textsuperscript{SM}**
- 1 + matrices (depending on claims)
- 3 levels of contamination
- Samples sent in blind duplicate

**Certification (ISO)**
- 1 Food matrix
- 3 levels of contamination
- Samples send in blind duplicate

**Repeatability**
ILS study – 10 labs QUALitative / 8 labs QUANTitative
AOAC Harmonization with Other Certification Schemes

AOAC OMA + MicroVal, or AFNOR, (or NordVal?)

- Allows performance of one large study rather than two separate
- Use common expert reviewers
- Each validating organization retains its own acceptance criteria
Certification Body Technical Review Committees

AOAC Expert Review Panel

MicroVal Technical Committee

AFNOR Technical Committee

Co-Chair

Chair*

Chair

* ISO TC34/SC9/Chair WG3: Methods
European Commission Regulation

COMMISSION REGULATION (EC) No 2073/2005
of 15 November 2005
on microbiological criteria for foodstuffs

Next Directive 2073 Update:

- validated for the food category(s) specified
- verified by the user
- certified by an independent Certification body
- subject to reassessment through renewal procedures ≤ 5 years
- summary or reference to validation results of proprietary method
- statement on the QMS of the production process of the method
Alternative Micro Method use for Official Testing
| ISO/TC 34/WG 14 | Vitamins, carotenoids and other nutrients |
| ISO/TC 34/WG 16 | Animal welfare |
| ISO/TC 34/WG 17 | Water activity |
| ISO/TC 34/WG 18 | Natural food ingredients |
| ISO/TC 34/WG 20 | Aflatoxins |
| ISO/TC 34/WG 21 | Social responsibility/sustainability |
| ISO/TC 34/WG 22 | Natural antimicrobial |
| ISO/TC 34/SC 2 | Oleaginous seeds and fruits and oilseed meals |
| ISO/TC 34/SC 3 | Fruits and vegetables and their derived products |
| ISO/TC 34/SC 4 | Cereals and pulses |
| **ISO/TC 34/SC 5** | Milk and milk products |
| ISO/TC 34/SC 6 | Meat, poultry, fish, eggs and their products |
| ISO/TC 34/SC 7 | Spices, culinary herbs and condiments |
| ISO/TC 34/SC 8 | Tea |
| ISO/TC 34/SC 9 | Microbiology |
| ISO/TC 34/SC 10 | Animal feeding stuffs |
| ISO/TC 34/SC 11 | Animal and vegetable fats and oils |
| ISO/TC 34/SC 12 | Sensory analysis |
| ISO/TC 34/SC 15 | Coffee |
| ISO/TC 34/SC 16 | Horizontal methods for molecular biomarker analysis |
| ISO/TC 34/SC 17 | Management systems for food safety |
| ISO/TC 34/SC 18 | Cocoa |
| ISO/TC 34/SC 19 | Bee products |
Each Organization keeps own standard development procedure, but aligns at critical points, to harmonize.
Importance of Codex Endorsement

In 1994, WTO Agreements on Sanitary and Phytosanitary (SPS) measures and Technical Barriers to Trade (TBT), established **CODEX Alimentarius as the relevant standard-setting organization for food safety**, and emphasized on the importance of **international** standards.
## Joint CODEX AOAC/ISO (IDF) methods as of July 2018

<table>
<thead>
<tr>
<th>Method Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AOAC 2011.10 / ISO 20634</td>
<td>Infant formula and adult nutritionals -- Determination of vitamin B12 by reversed phase high performance liquid chromatography (RP-HPLC)</td>
</tr>
<tr>
<td>AOAC 2011.18 / ISO 20637</td>
<td>Infant formula and adult nutritionals -- Determination of myo-inositol by liquid chromatography and pulsed amperometry</td>
</tr>
<tr>
<td>AOAC 2011.19 / ISO 20649</td>
<td>Infant formula and adult nutritionals -- Determination of chromium, selenium and molybdenum -- Inductively coupled plasma mass spectrometry (ICP-MS)</td>
</tr>
<tr>
<td>AOAC 2011.20 / ISO 20638</td>
<td>Infant formula -- Determination of nucleotides by liquid chromatography</td>
</tr>
<tr>
<td>AOAC 2012.10 / ISO 20633</td>
<td>Infant formula and adult nutritionals -- Determination of vitamin E and vitamin A by normal phase high performance liquid chromatography</td>
</tr>
<tr>
<td>AOAC 2012.13 / ISO 16958</td>
<td>Milk, milk products, infant formula and adult nutritionals -- Determination of fatty acids composition -- Capillary gas chromatographic method</td>
</tr>
<tr>
<td>AOAC 2012.15 / ISO 20647</td>
<td>Infant formula and adult nutritionals -- Determination of total iodine -- Inductively coupled plasma mass spectrometry (ICP-MS)</td>
</tr>
<tr>
<td>AOAC 2012.16 / ISO 20639</td>
<td>Infant formula and adult nutritionals -- Determination of pantothenic acid by ultra high performance liquid chromatography and tandem mass spectrometry method (UHPLC-MS/MS)</td>
</tr>
<tr>
<td>AOAC 2012.22 / ISO 20635</td>
<td>Infant formula and adult nutritionals -- Determination of vitamin C by (ultra) high performance liquid chromatography with ultraviolet detection ((U)HPLC-UV)</td>
</tr>
<tr>
<td>AOAC 2016.03 / ISO 21422</td>
<td>Milk, milk products, infant formula and adult nutritionals -- Determination of chloride -- Potentiometric titration method</td>
</tr>
<tr>
<td>AOAC 2016.05 / ISO 20636</td>
<td>Infant formula and adult nutritionals -- Determination of vitamin D by liquid chromatography-mass spectrometry</td>
</tr>
</tbody>
</table>
To collaborate in joint development & approval of common standards

- Harmonization increases global relevance
- Avoid duplication of work

AOAC-ISO Agreement

5-year Agreement renewed
22 October 2018
extended to include projects within the scope of ISO TC34
| ISO/TC 34/WG 14 | Vitamins, carotenoids and other nutrients |
| ISO/TC 34/WG 16 | Animal welfare |
| ISO/TC 34/WG 17 | Water activity |
| ISO/TC 34/WG 18 | Natural food ingredients |
| ISO/TC 34/WG 20 | Aflatoxins |
| ISO/TC 34/WG 21 | Social responsibility/sustainability |
| ISO/TC 34/WG 22 | Natural antimicrobial |
| ISO/TC 34/SC 2 | Oleaginous seeds and fruits and oilseed meals |
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| ISO/TC 34/SC 19 | Bee products |
Micro Methods in CODEX?

**Chemistry**

**Methods of Sampling & Analysis**

1. Serve as a CODEX coordinating body with other international groups working in methods of analysis and sampling
2. Specify Reference Methods of Analysis and Sampling appropriate to Codex Standards
3. Consider, amend, and endorse methods except:
   a) residues of pesticides or veterinary drugs
   b) micro biological quality and safety in food
   c) specifications for food additives
4. Elaborate sampling plans and procedures
5. Define procedures, protocols, guidelines for the assessment of food laboratory proficiency, and quality assurance systems for laboratories.

**Microbiology**

**Food Hygiene**

- Draft basic provisions on food hygiene
- Endorse provisions on hygiene contained in Codex commodity standards
- Draft provisions on hygiene applicable to specific food groups
- Consider specific hygiene problems assigned to it by the Commission
- Suggest and prioritize areas where there is a need for microbiological risk assessment and develop questions to be addressed by the risk assessors
- Consider microbiological risk management matters in relation to food hygiene and in relation to the risk assessment of FAO and WHO
Section Activities

- **Establish regional platform**
  - Bring together regional scientists
  - Discuss local regulatory issues

- **Participate in Standard Development**
  - Provide regional input on requirements
  - Bring regional stakeholders to Panel

- **Harmonize local with International methods**
  - Capacity building workshops
  - Local matrix validation extensions for OMAs
AOAC 2011.10
Vitamin B12 in Infant Formula
— Extension for Indian Matrices

- Infant formula and adult nutrition products in India contain:
  - *malt and cereals*, apart from milk and soy, and *were not a part of this study*

- Extend the original AOAC 2011.10 method for Indian matrices:
  - determined the method was fit for purpose
  - Required new procedure to address matrix interference
QUESTIONS?

THANK YOU

ecrowley@qlaboratories.com
dbenesh1@mmm.com

Slides and a recording of this webinar will be available for access by IAFP members at www.foodprotection.org within one week.