3M Science. Applied to Life.™

Microbiology Method Validation

An Overview Comparing the AOAC and ISO Processes

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Past-President, AOAC INTERNATIONAL

Laws: Regulations, Directives, Norms

Recognized Reference Methods

ISO

AOAC INTERNATIONAL

FIL IDF International Dairy Federation

cen

FDA

USDA FSIS

Recognized Method Certification Bodies

NordVal International

AOAC RESEARCH INSTITUTE

NF VALIDATION

MICROVAL

European validation and certification organisation

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Reference Methods – usually culture methods

Can vary by country

- EU – Central European Norms (+ each EU country has their own)
- SAME organism within country (based on agency: USDA vs US FDA)

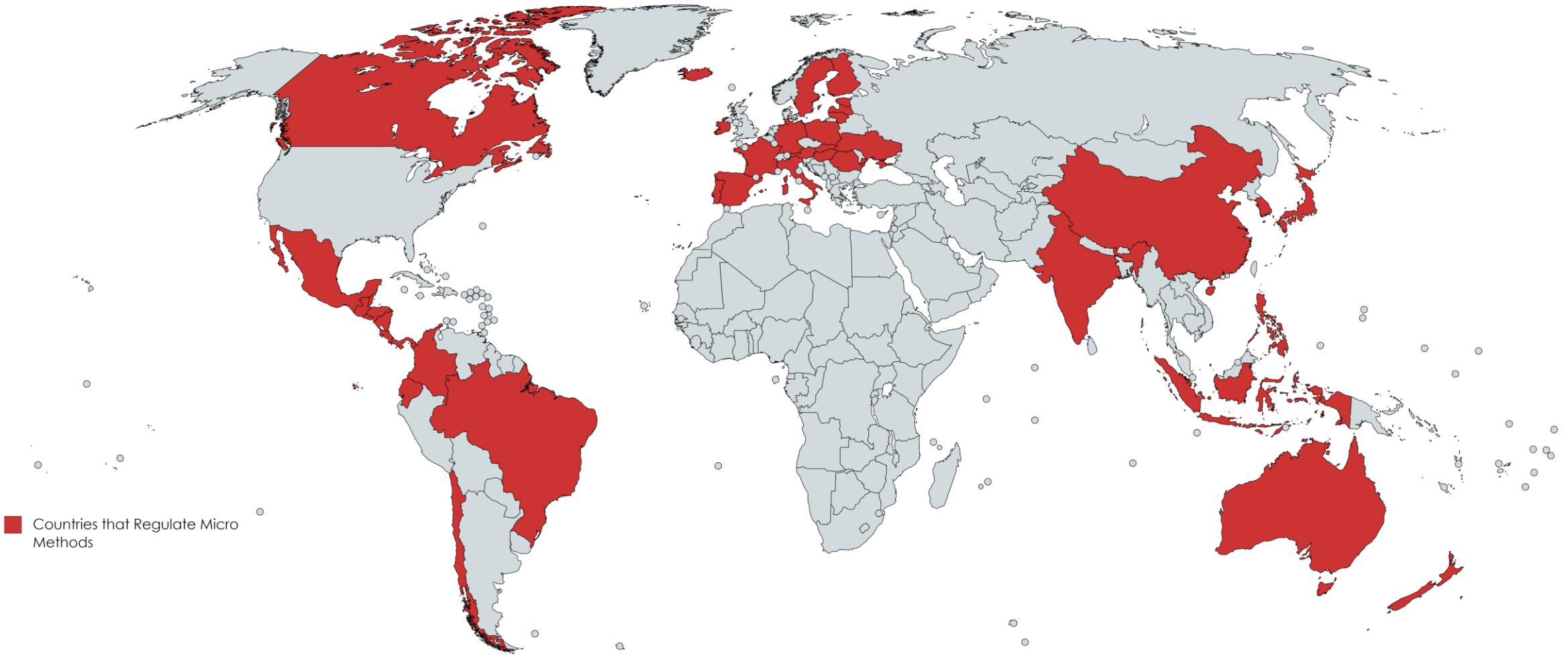
Can be ISO methods

- ISO methods ARE the reference method for many countries
- Recognized as a reference method by most
- Harmonized with some: IDF & AOAC

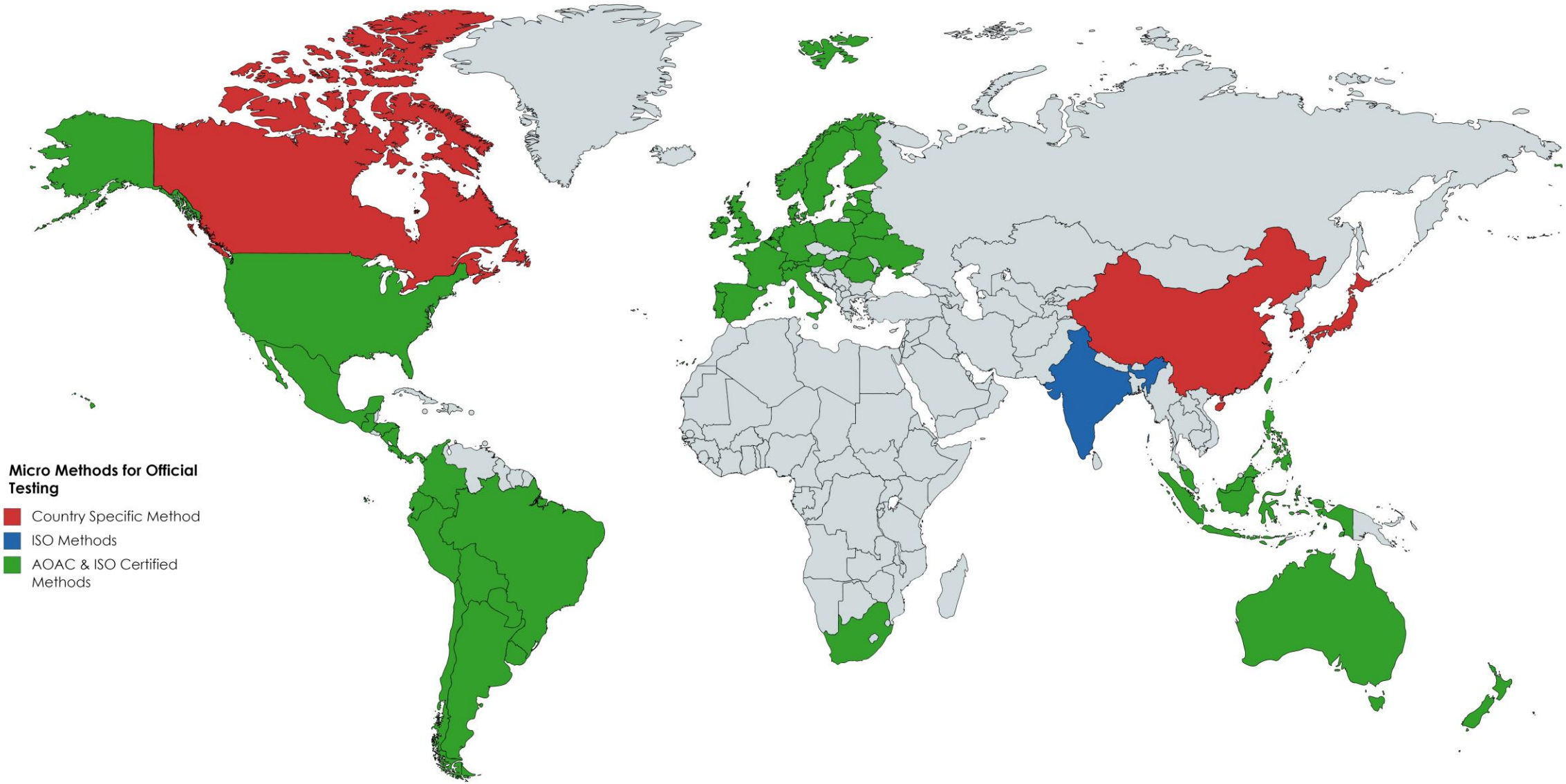
May be Legislated

- Examples…

Countries that Regulate Microbiology Methods



Microbiology Methods allowed for Official Testing



European Commission Regulation

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

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan[1]		Limits[2]		Analytical reference method[3]	Stage where the criterion applies
		n	c	m	M		
1.1. Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes[4]	Listeria monocytogenes	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2. Ready-to-eat foods able to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes	Listeria monocytogenes	5	0	100 cfu/g		EN/ISO 11290-2	Products placed on the market during their
		5	0	Absence in 25 g		EN/ISO 11190-1	Before the food has left the immediate control of the food buiness operator,who as produced it

Article 5

Specific rules for testing and sampling

The use of alternative analytical methods is acceptable when the methods are validated against the reference method in Annex I and if a proprietary method, certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, is used.

PART 2 -- GENERAL ADMINISTRATIVE RULINGS AND DECISIONS
Subpart A--General Provisions

[Code of Federal Regulations]
[Title 21, Volume 1]
[Revised as of April 1, 2017]
[CITE: 21CFR2.19]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A--GENERALPART 2 -- GENERAL ADMINISTRATIVE RULINGS AND DECISIONS Subpart A--General Provisions
Sec. 2.19 Methods of analysis.

Where the method of analysis is not prescribed in a regulation, it is the policy of the Food and Drug Administration in its enforcement programs to utilize the methods of analysis of the AOAC INTERNATIONAL (AOAC) as published in the latest edition (13th Ed., 1980) of their publication "Official Methods of Analysis of the Association of Official Analytical Chemists," and the supplements thereto ("Changes in Methods" as published in the March issues of the "Journal of the Association of Official Analytical Chemists"), which are incorporated by reference, when available and applicable. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* In the absence of an AOAC method, the Commissioner will furnish a copy of the particular method, or a reference to the published method, that the Food and Drug Administration will use in its enforcement program. Other methods may be used for quality control, specifications, contracts, surveys, and similar nonregulatory functions, but it is expected that they will be calibrated in terms of the method which the Food and Drug Administration uses in its enforcement program. Use of an AOAC method does not relieve the practioner of the responsibility to demonstrate that he can perform the method properly through the use of positive and negative controls and recovery and reproducibility studies.

[42 FR 15559, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 54 FR 9034, Mar. 3, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

Regulations allowing Choice of Methods

USDA FSIS Guidance for Evaluating Test Kit Performance

2. General Considerations

The work should be carried out in a laboratory that is independent of the manufacturer's economic interest. For example, the study may be carried out under contract to an academic laboratory, or a publicly-, or privately-owned laboratory that is not controlled by the test manufacturer. *Alternatively, the validation may be performed through an independent organization such as AOAC, AFNOR, ISO, or NordVal*. To avoid handling bias, the identity of the samples should be blinded to the analysts. The study design should be reviewed by an outside party before initiating work. FSIS can review and comment on study design6. Finally, all study reports as well as the associated raw data should be available for review by FSIS.

US FDA Bacteriological Analytical Manual (BAM)

Introduction

To test for an organism or microbial toxin not covered by the BAM, or to analyze a sample that may require special handling or processing, the user is referred to the ***Official Methods of Analysis of the AOAC International; Standard Methods for the Examination of Dairy Products, Recommended Procedures for the Examination of Seawater and Shellfish, and Compendium of Methods for the Microbiological Examination of Foods of the American Public Health Association; also, Standard Methods for Water Analysis of the Environmental Protection Agency***. FDA works closely with AOAC International, APHA, EPA, the International Dairy Federation (IDF/FIL), and, by way of participation in Codex Alimentarius, the International Organization for Standardization (ISO). However, not all methods appearing in the BAM have been collaboratively evaluated by one or more of these organizations.

Regulations allowing Choice of Methods

INDONESIA: National Agency of Drugs and Food Control (BPOM – NAFDAC) - Regulation Microbiological Criteria In Processed Food No. 16, 2016.

(3) Selain menggunakan metode analisis sebagaimana dimaksud dalam Lampiran, pengujian mikrobiologi dapat menggunakan metode analisis lain yang setara dan tervalidasi atau terverifikasi.

"In addition to using the analytical methods referred to in the Appendix, microbiological testing may use other equivalent and validated or verified analytical methods."

NEW ZEALAND: MPI Consolidated List of Tests for Animal Products: meat poultry honey, seafood, dairy, live animals and germplasm; November 2017, Version 8, pages 1-40

22.1	*Campylobacter*	Poultry (ducks, EOLs, meat chickens, turkeys)	Must follow all NMD requirements	*all*
		Turkeys	National Microbial Database	*EU*
23.1	*Escherichia coli* O157:H7	Bulk manufacturing beef and bobby veal	US OMAR	*US, China*
		Raw ground beef and raw ground beef products	Overseas Market Requirements	

Regulations Allowing Choice of Methods

PHILIPPINES: FDA Circular Number 2013-010. Revised Guidelines for Assessment of Microbiological Quality of Processed Foods

The methods used for the enumeration or detection of specified microorganisms shall be those that have been internationally established. Such methods, as well as the cited specifications were obtained from the following internationally recognized references:

1. FDA Bacteriological Analytical Manual published by the AOAC
2. Compendium of Analytical Methods of the Canadian Health Protection Branch
3. Compendium of Methods for the Microbiological Examination of Foods compiled by the American Public Health Association (APHA)
4. Specifications and Standards for Foods, Food Additives, etc., Japan External Trade Organization
5. Microorganisms in Foods by the International Commission on Microbiological Specifications for Foods (ICMSF)
6. Codex Alimentarius Commission Guidelines
7. International Standards Organization (ISO) Microbiological Methods
8. Australia New Zealand Food Authority (ANZFA)

This FDA Circular shall take effect immediately and supersede other regulations or guidelines inconsistent herewith.

CENTRAL AMERICA: Technical Rules for Microbiological Testing of Food

Determinación	Metodología
Enterobacter sakazakii	ISO/DTS 22964 IDF/RM 2102005
Coliformes Totales, coliformes fecales y *Escherichia coli*	- APHA "Compendium of methods for the microbiological examination of foods". Capítulo 8. - FDA-"Bacteriological Analytical Manual" Capítulo: 4
Escherichia coli O157H7	- APHA "Compendium of methods for the microbiological examination of foods". Capítulo 35.
Clostridium perfringens y otros anaerobios sulfito reductores	APHA "Compendium of methods for the microbiological examination of foods". Capítulo 34.
Staphylococcus aureus	- APHA-AOAC "Compendium of methods for the microbiological examination of foods". Capítulo 39. - FDA-"Bacteriological Analytical Manual" Capítulo: 12
Salmonella spp	- APHA-AOAC "Compendium of methods for the

Reference Methods - published

ISO methods – online, for a **FEE**

AOAC OMA methods – for a **FEE**

FREE:

- **US FDA Bacteriological Analytical Manual** – online
- **USDS FSIS Microbiological Laboratory Guidebook** – online
- **Health Canada** – online
- **INDIA BIS** – modify ISO, assign a BIS # and provide

HOW are Criteria for Methods currently developed?

And

HOW can they be Harmonized?

International Standards Organization (1947)

The world's largest developer of standards

International Organization for Standardization

Equal footing

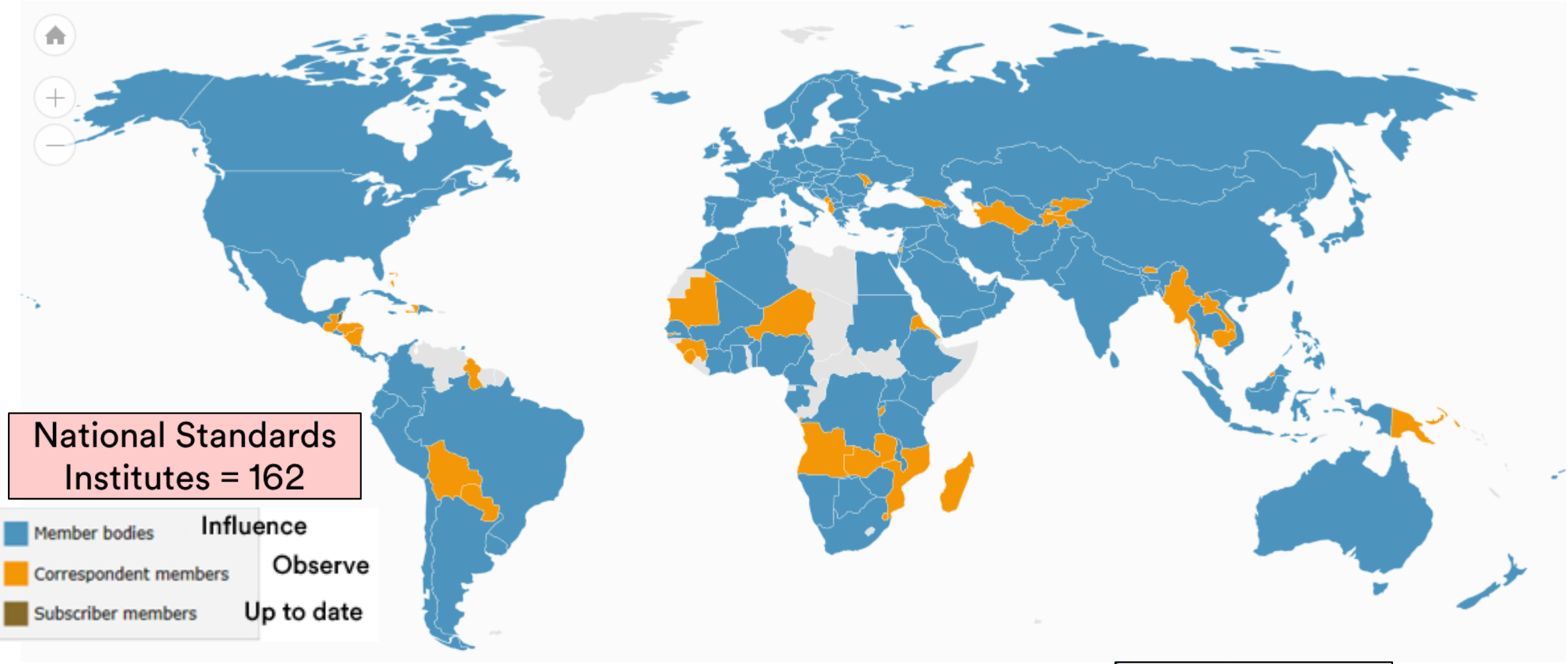
- No matter size or strength of a country economy, each ***participating*** member has **ONE** vote

Voluntary

- ISO standards are voluntary
- ISO has no legal authority to enforce their implementation
- Some ISO standards are adopted in countries as part of their regulatory framework
- Created only when a market need – 5 year review to determine: keep, toss, maintain
- Some may become market requirements, such as ISO 9000 QMS, and size of bank cards

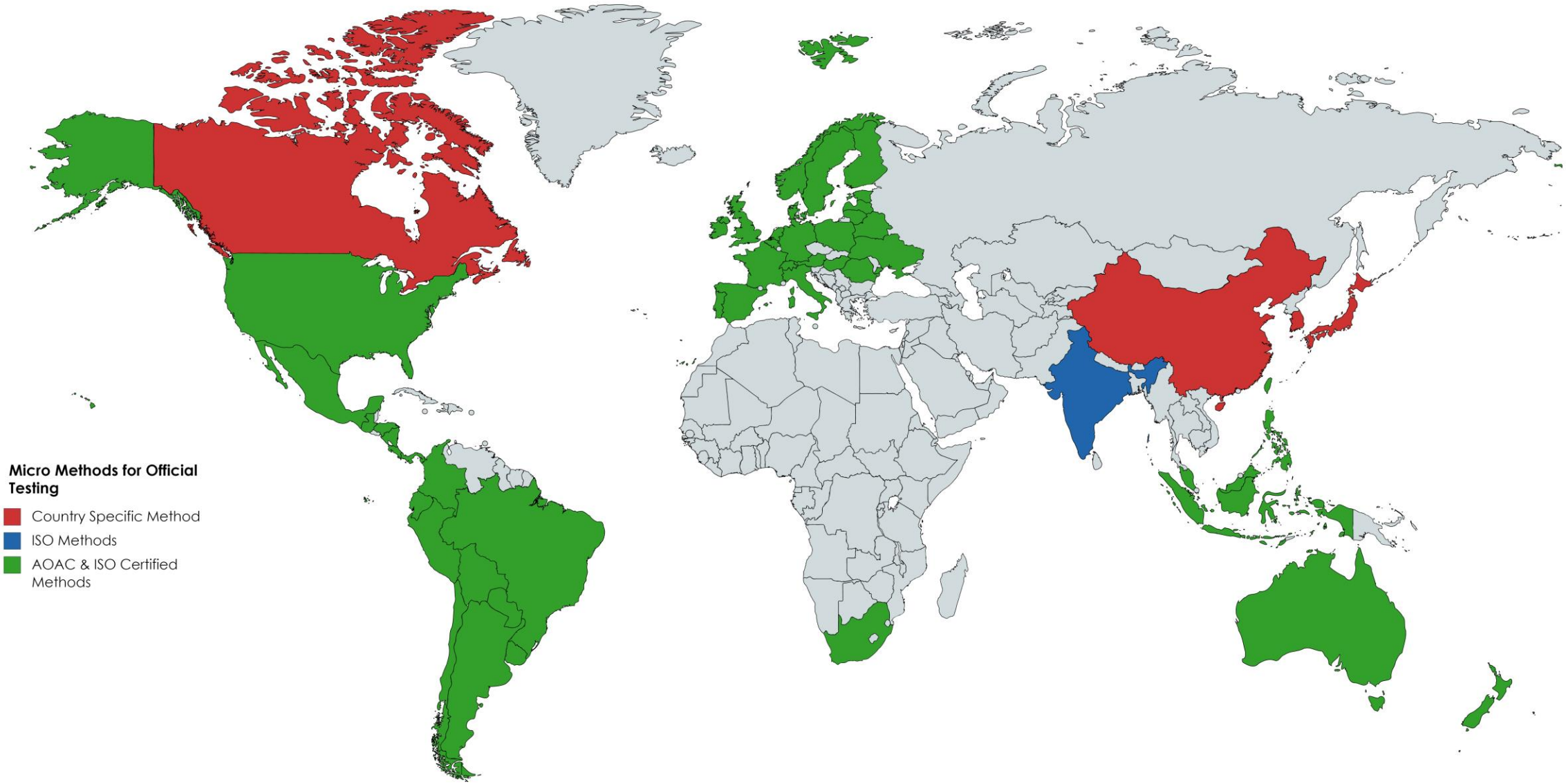
ISO Standards *impact everyone, everywhere*

ISO Members



ISO International Organization for Standardization

Microbiology Methods allowed for Official Testing



Participation in TCs

Eritrea (ESI) Correspondent Member

ISO/TC 34 - Food products (*O-Member*)

ISO/TC 34/SC 4 - Cereals and pulses (*P-Member*)

ISO/TC 120 - Leather (*O-Member*)

ISO/TC 120/SC 1 - Raw hides and skins, including pickled pelts (*P-Member*)

Countries PAY to participate in TCs, so tend to focus participation on work that applies to their larger industries or for Imports/Exports

Participation in TCs

Mexico (DGN)

ISO/REMCO - Committee on reference materials (*P-Member*)

ISO/IEC JTC 1 - Information technology (*O-Member*)

ISO/IEC JTC 1/SC 7 - Software and systems engineering (*P-Member*)

ISO/IEC JTC 1/SC 25 - Interconnection of information technology equipment (*P-Member*)

ISO/IEC JTC 1/SC 27 - IT Security techniques (*P-Member*)

ISO/IEC JTC 1/SC 34 - Document description and processing languages (*O-Member*)

ISO/IEC JTC 1/SC 40 - IT Service Management and IT Governance (*P-Member*)

ISO/IEC JPC 2 - Joint Project Committee - Energy efficiency and renewable energy sources - Commor

ISO/TC 11Stand by - Boilers and pressure vessels (*O-Member*)

ISO/TC 20 - Aircraft and space vehicles (*P-Member*)

ISO/TC 22 - Road vehicles (*P-Member*)

ISO/TC 22/SC 31 - Data communication (*O-Member*)

ISO/TC 22/SC 32 - Electrical and electronic components and general system aspects (*P-Member*)

ISO/TC 34 - Food products (*O-Member*)

ISO/TC 34/SC 3 - Fruits and vegetables and their derived products (*O-Member*)

ISO/TC 34/SC 5 - Milk and milk products (*P-Member*)

ISO/TC 34/SC 7 - Spices, culinary herbs and condiments (*O-Member*)

ISO/TC 34/SC 8 - Tea (*O-Member*)

ISO/TC 34/SC 15 - Coffee (*O-Member*)

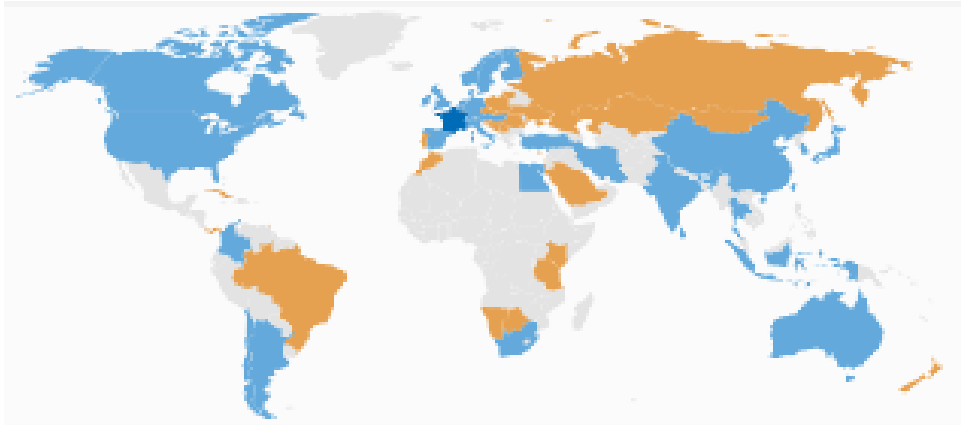
ISO/TC 34/SC 18 - Cocoa (*O-Member*)

ISO/TC 37 - Terminology and other language and content resources (*P-Member*)

Participation in SC 9 'Microbiology'

P-members (32)

- Argentina
- Australia
- Austria
- Belgium
- Canada
- Chile
- China
- Colombia
- Denmark
- Egypt
- Finland
- France
- Germany
- Hungary
- India
- Indonesia
- Iran, Islamic Republic of
- Ireland
- Italy
- Japan
- Korea, Republic of
- Netherlands
- Norway
- South Africa
- Spain
- Sri Lanka
- Sweden
- Switzerland
- Thailand
- Turkey
- United Kingdom
- United States



O-members (31)

- Bosnia and Herzegovina
- Botswana
- Brazil
- Croatia
- Cuba
- Cyprus
- Czech Republic
- Estonia
- Hong Kong
- Israel
- Kazakhstan
- Kenya
- Lithuania
- Luxembourg
- Mongolia
- Montenegro
- Morocco
- Namibia
- New Zealand
- Panama
- Poland
- Portugal
- Romania
- Russian Federation
- Saudi Arabia
- Serbia
- Slovakia
- Slovenia
- Tanzania
- Trinidad and Tobago
- Ukraine

NEN

Receive documents for review and comments

3rd draft document for ISO/WD 16140-3

ISO/TC 34/SC 9/WG 3/N 2xx

2015-10-16

Secretariat: NEN

International Organization for Standardization

EXAMPLE

Microbiology of the food chain — Method validation — Part 3: Protocol for the verification of reference and validated alternative methods implemented in a single laboratory

3rd Working Draft

Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

5.1 Preparation of the test portions (qualitative tests)

A minimum of four inoculum levels per sample type shall be used.

The 4 levels are:

Example of 1 section for review

— No inoculum: this is the blank control.

— Low inoculation level: ideally, this is the theoretical detection level determined in the validation study (e.g. 1 to 3 cfu/test portion).

— Intermediate inoculation level.

— High inoculation level: this should be at least ten times the expected theoretical detection level (e.g. 10 to 30 cfu/test portion).

Test, each level in duplicate, using the method to be verified.

The blank control level shall not produce positive results. If positive results are obtained, the experiments shall be repeated for all levels.

Template for comments and draft observations

Date: 2015-10-16	WG 3/N 289	Document: 2nd draft for ISO/WD 16140-3 *(N 270)*	Project leader:

International Organization for Standardization

Expert	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment[1]	Comments	Proposed change	DRAFT Observations of the project leader and secretariat
Leanne DeWinter (CA) **[020]**	5.1	2nd and 4th bullet points	Te	The purpose of this standard is verification. It seems onerous and unnecessary for a lab who wishes to implement a validated method to have to verify at the LOD. Testing at the LOD is more relevant and pertinent for validation as opposed to verification. This is also fairly difficult to accomplish. Verification should be a straightforward task that any lab can readily accomplish; currently I don't think that is the case.	Suggest two inoculation levels, one at 1-10X LOD, and the other at 10-30X LOD, perhaps with additional replicates in each level.	Not accepted, because the theoretical limit of detection must be assessed. More levels are needed to determine the limit of detection.
Roy Betts (UK) **[021]**	5.1		Te	4 inoculation levels are required. These are noted as 0; 1 – 3 cfu/test portion; intermediate; and 10 to 30 per test portion. Again, considering the type of laboratories involved (general testing and not Expert labs), it is not believed possible that this level of exactness is possible. The difference between the low & high levels is just 1 log. The intermediate must therefore be half a log different. It is wondered what the uncertainty of measurement values for labs undertaking this would be, but a half log uncertainty on a count would not be unexpected. The levels of inoculation required would results in great practical difficulties for laboratories.	The inoculation level requirements should be reviewed to make them practically attainable by general testing laboratories.	Noted, see comment **[020]**.
Pat Bird (US) **[022]**	5.1	3rd par	Te	For the verification of samples, it is unclear if only the presumptive result of the alternative method is required. The method should be performed through confirmation of isolates to ensure that false positive and false negative results are not obtained.	Test, each level in duplicate, using the method to be verified. Regardless of presumptive results, all samples should be evaluated by confirmation procedure, to verify the presence/absence of the analyte in the sample.	Accepted, this sentence will be added to the start of clause 5 (the verification is performed following the protocol of the laboratory).
Kirsten Mooijman / Wilma Jacobs (NL) **[023]**	5.2		Te	The RD can only be estimated if one inoculation level produces two positive results. Would this be: if at least the HL produces 2 positives?		Accepted, it will be stated that the high level must always give 2 positives.

Example of the level of detailed comments on the 1 section: entered into the specific ISO FORM required for submission

ISO Document Names & Points of Influence

Market driven

ideas

Consensus based

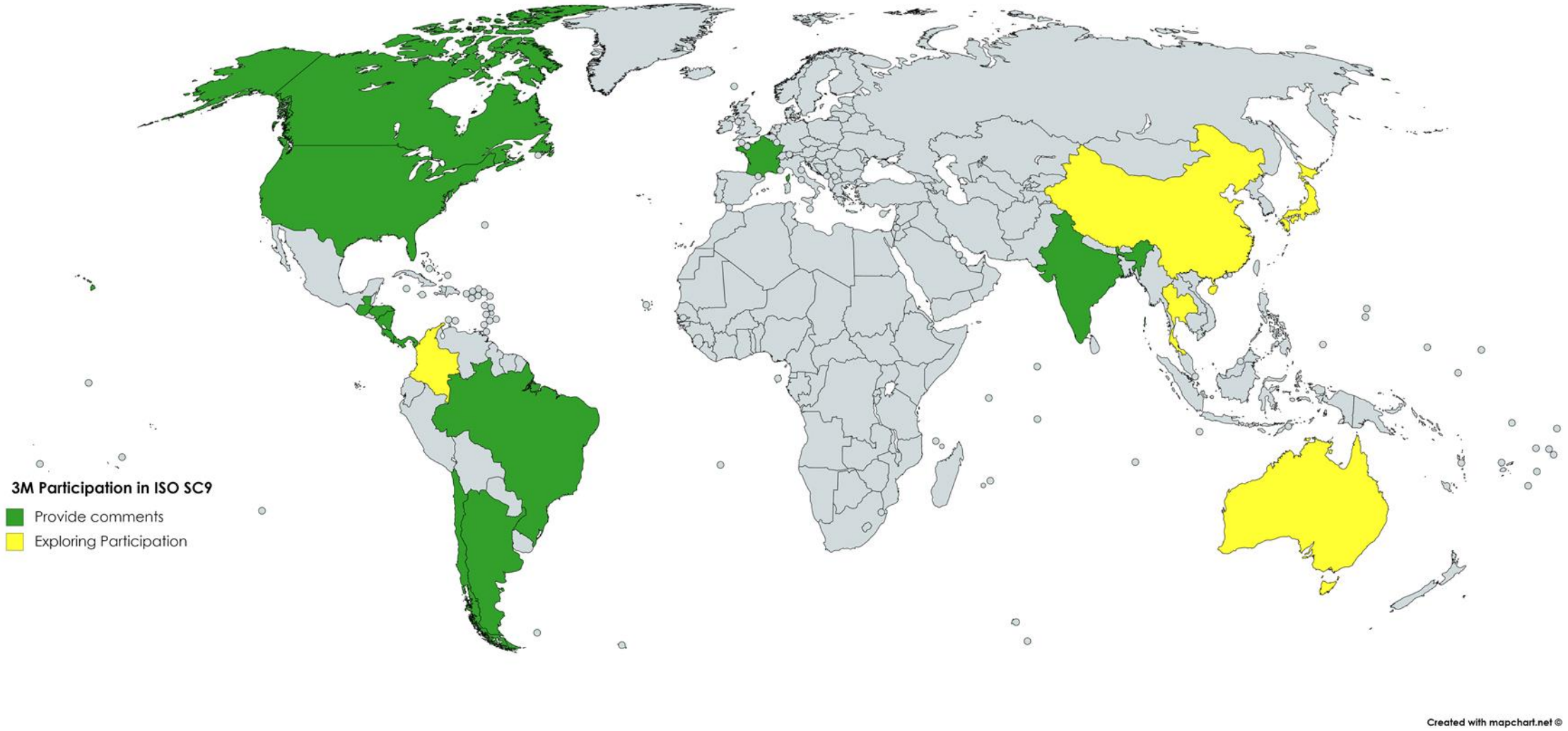
comments and/or votes

- Preliminary Work Item (**PWI**)
- New Work Item Proposal (**NWIP**)
- Working Draft (**WD**)
- Committee Draft (**CD**)
- Draft International Standard (**DIS**)
- Final Draft International Standard (**FDIS**)
- International Standard (**IS**)

Standards development time ~ 5 years?

3M Food Safety Participation in ISO TC34/SC9

International Organization for Standardization



AOAC Roots in Food Safety

AOAC 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)

AOAC - 1887 Meeting

- 1965 – Association of Official ANALYTICAL Chemists
- 1980s - microbiologists, other food science professionals
- 1991- AOAC INTERNATIONAL (Association of Official Analytical COMMUNITIES)

AOAC INTERNATIONAL
EST. 1884

ISPAM – Initial Scope of Work

International Stakeholder Panel on Alternative Methods = ISPAM

Working Group (WG) on Microbiology Guidelines

- Compare different validation guidelines
- Identified areas preventing harmonization
- Promote **harmonization** of these areas

Participating Stakeholders = >60 industry, gov, acedemia

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

Certification Bodies/NGOs

- AFNOR
- MicroVal
- NMKL/NordVal
- ISO
- GFCO-GIG
- Allergen Control Group

Contract Laboratories

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

Comparison of Method Validation Guidelines

Criteria	ISO 16140	AOAC	Health Canada	NordVal	US FDA	USDA
Qualitative Methods	ISO 16140 Doc. N 1199 (ISO CD 16140-2)PIV C2011-04-06 Pending revision of Part 2	OMA, Appendix X Draft revision document dated 3/24/2011	Health Canada Draft Part 4 dated March 2011	NordVal Protocol for the validation of alternative microbiology methods March 2009	FDA's Qualitative Microbiology Methods Validation (ORA-LAB-7 verstion 1.2), pending revision (*proposed revision marked in red*).	Draft Guidelines Disclaimer: The use of the term "validation" is not intended to have any application to the implementation of 9 CFR 417 4(a)(1) on initial validation of HACCP plans. The Draft FSIS Guidelines deals exclusively with the evaluation of pathogen test kit methods
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	Can use various existing recognized analytical methods (e.g., AOAC, OMA, ISO, FDA BAM, FSIS MLG, Health Canada) If no	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	ISO, CEN, NMKL, BAM, etc… It is up to the applicant; however, as the EU regulation in EC 2073/2005 Microbiologic al criteria	Most be BAM unless tere 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	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

Five Priority Areas Identified

1. Reference Methods
2. Number of Levels/Samples/Fractional Positives
3. Selection of Food/Category (sample matrix)
4. Results analysis & Criteria/Statistical Analysis)
5. Data Sets for Collaborative Study/Sample Size

Reference Methods

Challenges:

- Each country/region has it’s is own preferred method
- How similar are the methods?
- To what extent will each country/region/organization be willing to accept method comparison data with an external reference method?

Put aside, for now…

ISPAM Accomplishments in Method Harmonization

1. Reference method – probably won't happen!

Harmonized approaches for:

2. Number of levels/samples/fractional positives
3. Approved Food Classification Table
4. Results analysis/criteria/statistical analysis
5. Number of data sets for collaborative study/sample size

Replaced the phrase "all foods" with "broad range of foods" in ISO 16140-2 revision

WHAT are the Criteria for Validation of Methods?

Certification Bodies and Validation Guidelines

AOAC Research Institute

AOAC INTERNATIONAL *Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces* (2012)

- *Performance Tested Method℠*
- *Official Method of Analysis℠*
- *Harmonized Method*

Certification to ISO 16140-2:2016

Protocol for the validation of alternative (proprietary) methods against a reference method

- *NordVal Certification*
- *MicroVal Certification*
- *NF Validation via AFNOR Certification*

3M

MicroVal

Certification organization for validation of alternative methods for the microbiological analysis of food & beverages

- Based in the Netherlands, run by NEN [National Standards Institute]
- ISO methods preferred reference, but open to other reference methods
- Can validate methods outside the scope of ISO 16140-2:2016

>30 microbiological kits have received MicroVal Certification since 2007

MICROVAL
European validation and certification organisation

NF Validation - AFNOR Certification

Certification organization for validation of alternative methods for BOTH microbiological and chemical analysis of food and beverages

- AFNOR – French National Standards body (ISO Member)
- Certification of products, services & systems, & the NF mark
- ISO methods only, as reference; validates to ISO 16140-2:2016

>130 microbiological kits have received NF validation Mark since 1989

NordVal

Certification organization is an independent, 3rd party that evaluates the quality characteristics and applications of alternative microbiological methods in the analysis of food, water, feed and environmental samples

- Also do chemistry method validations
- Based in the Denmark- NMKL [Nordic Committee on Food Analysis]
- Mainly for “Nordic” countries: Iceland, Norway, Sweden, Denmark, Finland

>23 microbiological kits currently have NordVal Certifications since 2007

AOAC Research Institute

AOAC INTERNATIONAL Certification organization for validation of alternative methods – microbial, chemical, allergen, water, etc.

- Based in Washington DC, USA
- Can use ANY method as the reference
- AOAC PTM /OMA Harmonization
- Harmonization w/ISO Certification bodies***

>290 microbiological kits received AOAC PTM℠ Certifications since 1991

AOAC INTERNATIONAL

Requirements for Certification:

1. **Validation -** Method comparison study against the reference method

2. **Quality System** of the manufacturer must be in conformity with quality assurance requirements

3. **Renewal** of the certified methods – post certification

Method Validation per Certifying Body Criteria

Requirements	AOAC INTERNATIONAL	ISO 16140-2: 2016
1. Validation	PTM – Comparative study • Internal data • 1 Independent lab OMA - Collaborative study • 8-10 labs	Comparative study • 1 expert lab Collaborative study • 8-10 labs
2. Quality System	Review: • Paper • Data	Review : • Physical audit
3. Renewal	PTM - Annual Renewal OMA – No renewal	Method Verification - Every 4 years

As listed in ISO 16140-2:2016

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

CATEGORIES					
Raw Milk & Dairy Products	Heat Processed Milk & Dairy Products	Raw meat & Ready-to-cook meat products (except poultry)	Ready-to-eat, ready-to-reheat meat products	Raw Poultry & ready-to-cook poultry products	Ready-to-eat, ready-to-reheat meat poultry products
Eggs & egg products (derivatives)	Raw & ready-to-cook fish & seafoods (unprocessed	Ready-to-eat, ready-to-reheat fishery products	Fresh produce & fruits	Processed fruits & vegetables	Dried cereals, fruits, nuts, seeds and vegetables
Infant formula & infant cereals	Chocolate, bakery products & confectionary	Multi-component foods or meal components	Primary production samples	Pet food & animal feed	Environmental samples (food or feed production

There are 18 CATEGORIES recognized and harmonized between ISO and AOAC

Matrix Claims for AOAC Microbiology Methods

Multiple Matrix Claim	Criteria	
	Number of Matrices	Number of Catergories/Groups[1]
Broad Range of Foods	15 (3 foods/category)	5 categories
Variety of Foods	≥ 10	5 categories
Selected Foods	≥ 5	2 categories
Food Category/Group	≥ 5	1 category
Environmental Surfaces	7	Not applicable
Selected Surfaces	2-6	Not applicable

TECHNICAL BULLETIN: TB02MAY2016: Acceptable Validation Claims for Proprietary/Commercial Microbiology Methods for Foods and Environmental Surfaces

Broad Range of Foods Claim – AOAC or ISO 16140

Broad Range of Foods claim = **5 CATEGORIES** of food:

- At least 3 ***food types*** within EACH category
- Test *20 items (**samples**)* of EACH food type within the category
- = 60 results from ***different*** samples within EACH category

Example of Categories & Food types

Category	Types	Matrices (samples)
Meat products	Raw	Meat cuts, carpaccio's, minced meat… 20 items (samples)
	Heat processed	Cooked ham, cooked meat preparations…20 items
	Cured	Cured ham, bacon, etc…20 items

= 60 *different* samples tested per Meat Products Category

1. Method Comparison Study

AOAC Research Institute

Method Developer

- Inclusivity /Exclusivity
- Matrix Study – ***inoculated***

Independent Laboratory

- 20% Foods /surfaces repeated

- *Robustness*
- *Stability*
- *Lot-to-Lot Variation*
- *Instrument Variation*

ISO Certification Body

Expert Laboratory

- Inclusivity /Exclusivity
- Matrix study – ***natural contamination***

1. Method Comparison – Collaborative study

AOAC Research Institute OMA

- 1 + matrices (depending on claims)
- 3 levels of contamination
- Samples sent in blind duplicate

ISO Certification Body

- 1 Food matrix
- 3 levels of contamination
- Samples send in blind duplicate

Repeatability

Collaborative study – 10 labs QUALitative / 8 labs QUANTitative

AOAC Harmonization with Other Certification Schemes

AOAC OMA - and 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*

AOAC RESEARCH INSTITUTE

MICROVAL
European validation and certification organisation

BY AFNOR CERTIFICATION
NF VALIDATION
EN ISO 16140

Method Validation per Certifying Body Criteria

Laboratories	AOAC International	ISO 16140-2:2016
1. Validation	PTM – Comparative Study • Internal data • Independent lab **OMA:** Collaborative study: 8-10 labs	Comparative Study • 1 expert lab AND Collabortive Study: 8-10 labs
2. Quality System	**Review:** • **Paper audit**	**Review:** • **Physical audit**
3. Renewal	PTM - Annual Renewal OMA – No renewal	Method Verification - Every 4 years

2. Quality System – AOAC and NordVal

Method Developer Submits:

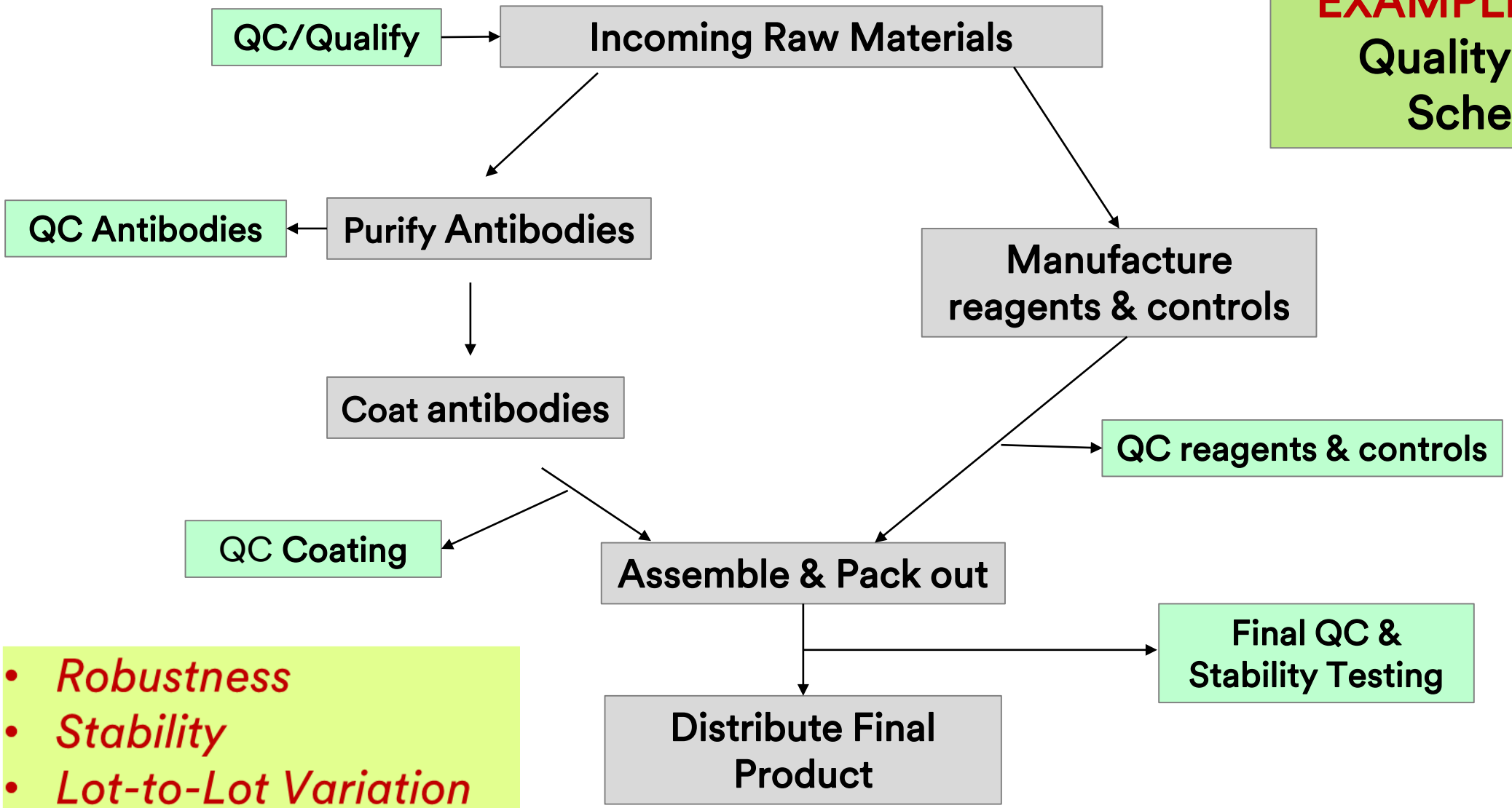
Package insert, user manual, instructions for use

Product labels

AOAC Requirement

QA/QC Schematic***

EXAMPLE: AOACI Quality System Schematic



- *Robustness*
- *Stability*
- *Lot-to-Lot Variation*
- *Instrument Variation*

2. ISO 16140: Quality System – Physical audit of production site

Cert Body	No ISO QMS	ISO 9001	ISO 13485
MicroVal	Y (full)	Y (limited)	N
AFNOR	Y	Y	Y

MicroVal – uses Certification Bodies to conduct audits

AFNOR – *is* a Certifying Body and has its own auditors

Method Validation per Certifying Body Criteria

Laboratories	AOAC International	ISO 16140-2:2016
1. Validation	PTM – Comparative Study • Internal data • Independent lab **OMA:** Collaborative study: 8-10 labs	Comparative Study • 1 expert lab AND Collabortive Study: 8-10 labs
2. Quality System	Review of Quality System • Paper	Review of Quality System • Physical audit
3. Renewal	PTM - Annual OMA – None	Method Verification - Every 2-4 years

3. ISO 16140 – Renewal (MicroVal and AFNOR)

Quality Audit:

- No ISO QMS – every 2 yrs
- ISO 9001 or 13485 – every 4 years

Renewal every 4 years: complete review of changes

- in the alternative method
- in the reference method
- in the validation [ISO 16140-2] protocol

➔**additional study** if needed

NordVal:

- renewal every 2 years
- any changes reviewed to determine extent of additional testing

3. AOAC Renewal - Yearly

PTM Certificate – granted for 1 year

- Certify no changes have been made to the test method since the original PTM approval and the method performs as originally evaluated
- Submit Method Modification Review Form if changes have been made

OMA - No renewal required

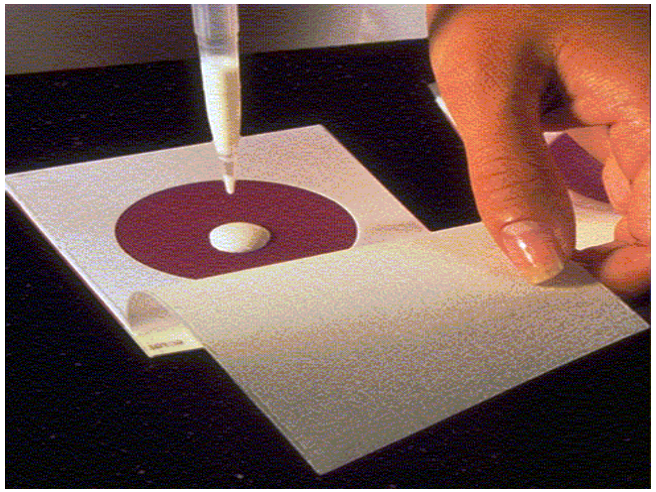
- **First Action**
- **Final Action – 2 yrs post First Action, if no concerns with method**

PTM vs OMA - WHY?

Government Agencies - require methods that have been *collaboratively* studied (Interlaboratory study = ILS)

- A “fully” validated method per ISO 16140-2:2016 = ILS
- A “fully” validated method per AOAC OMA = ILS
- EU Directive 2073:2005 = ILS
- FDA BAM and 21 CFR 2.19 = AOAC OMA (ILS)
- New Zealand, Philippines, China, Brazil, Chile, etc. = ILS

3M Food Safety 3rd Party Validations



Certification FIRSTS:

3M™ Petrifilm™ Plates:

Aerobic & Coliform Count Plates in Milk (1986)

- *AOAC INTERNATIONAL OMA*

Aerobic & Coliform Count Plates in Foods (1989)

- *AFNOR Certification*

3M™ Molecular Detection Assay 2:

Cronobactor (2018)

- *Harmonized AOAC OMA /NF Validation via AFNOR Certification*

Thank you