International Association for Food Protection®

What's Next Regarding Validation and Verification: Overview of ISO 16140 Series

Presented By: Paul in't Veld, DeAnn Benesh, Daniele Sohier

Sponsored By: Bruker Daltonics and Q Laboratories

Organized by: Methods Validation & Verification Interest Group within the Applied Laboratory Methods PDG



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Webinar Housekeeping

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- Audio is being transmitted over the computer, so please have your speakers ‘on’ and volume turned up in order to hear. A telephone connection is not available.
- Questions should be submitted to the presenters during the presentation via the **Questions section** at the right of the screen.



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Webinar Housekeeping

- It is important to note that all opinions and statements are those of the individual making the presentation and not necessarily the opinion or view of IAFP.

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

Paul in ‘t Veld

Senior Scientist – Netherlands Food and Consumer Product Safety Authority (NVWA)

- Main responsibilities involve support of inspectors on microbiological issues and standardization of methods.
- Serves as a technical assessor for laboratories having an ISO 17025 accreditation in several countries
- Convener of ISO WG3 which involves revision of ISO 16140, validation of alternative methods
- Involved in research related to bacterial toxins such as the emetic toxin for *Bacillus cereus*

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

Daniele Sohier

Bruker Daltonics, Germany

- Managed the AOAC and ISO validation studies of alternative methods at ADRIA expert laboratory (FR) for more than 10 years and over 100 studies
- Joined Bruker two years ago to design and coordinate the very first AOAC-OMA and ISO 16140-part 6 studies of a MALDI-TOF technology for rapid and reliable confirmation and identification of microbial isolates
- Member of the AFNOR Certification committee and MicroVal technical and general committees
- Current President of the European IAFP event and has organized more than 20 symposia, workshops or international conferences and has more than 100 international publications or communications

Food and Consumer Product Safety Authority
Ministry of Agriculture, Nature and Food Quality

IAFP webinar:

What's Next Regarding Validation and Verification: Overview of ISO 16140 Series:

Introduction

Paul in ‘t Veld, convenor WG3

Standards under responsibility WG 3

- WG3 belongs to ISO TC34/SC9: food microbiology.
- WG 3 started in 2006.
- Mandate:
  - Update ISO 16140 (2003): Validation of alternative (proprietary) methods
  - Develop standards on:
    - Validation of standardised methods,
    - Single lab validation,
    - Factorial design validation,
    - **Method verification** and
    - **Validation of confirmation methods**

Standards under responsibility WG 3

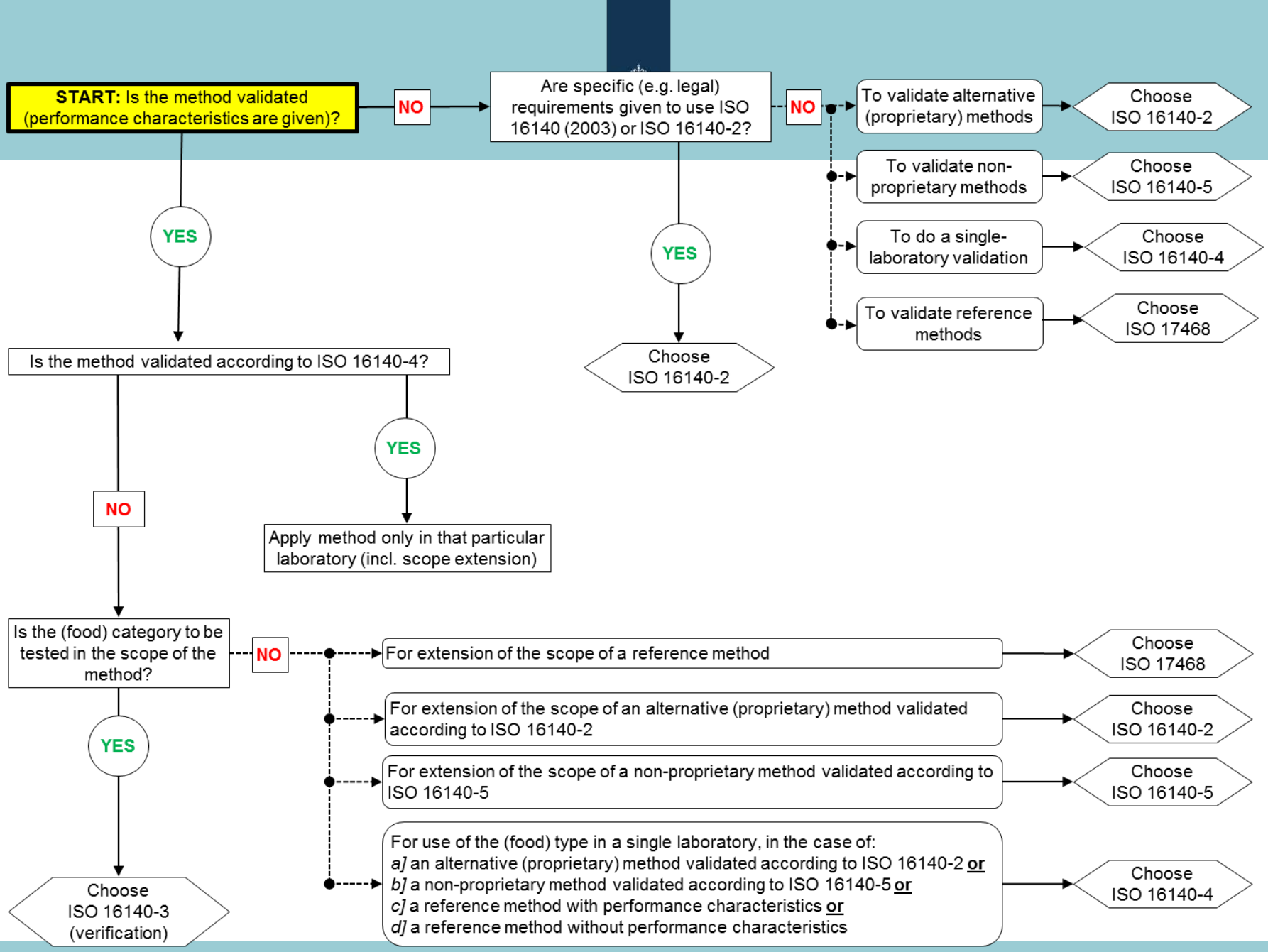
- **Validation of standardized methods** (ISO 17468) described the rules for validation or re-validation of standardized (ISO or CEN) methods. Based on principles described in ISO 16140-2.

- **Single lab validation** describes the validation against a reference method or without a reference method using a classical approach or a factorial design approach. Validation results are only valid in the lab that performed the validation.

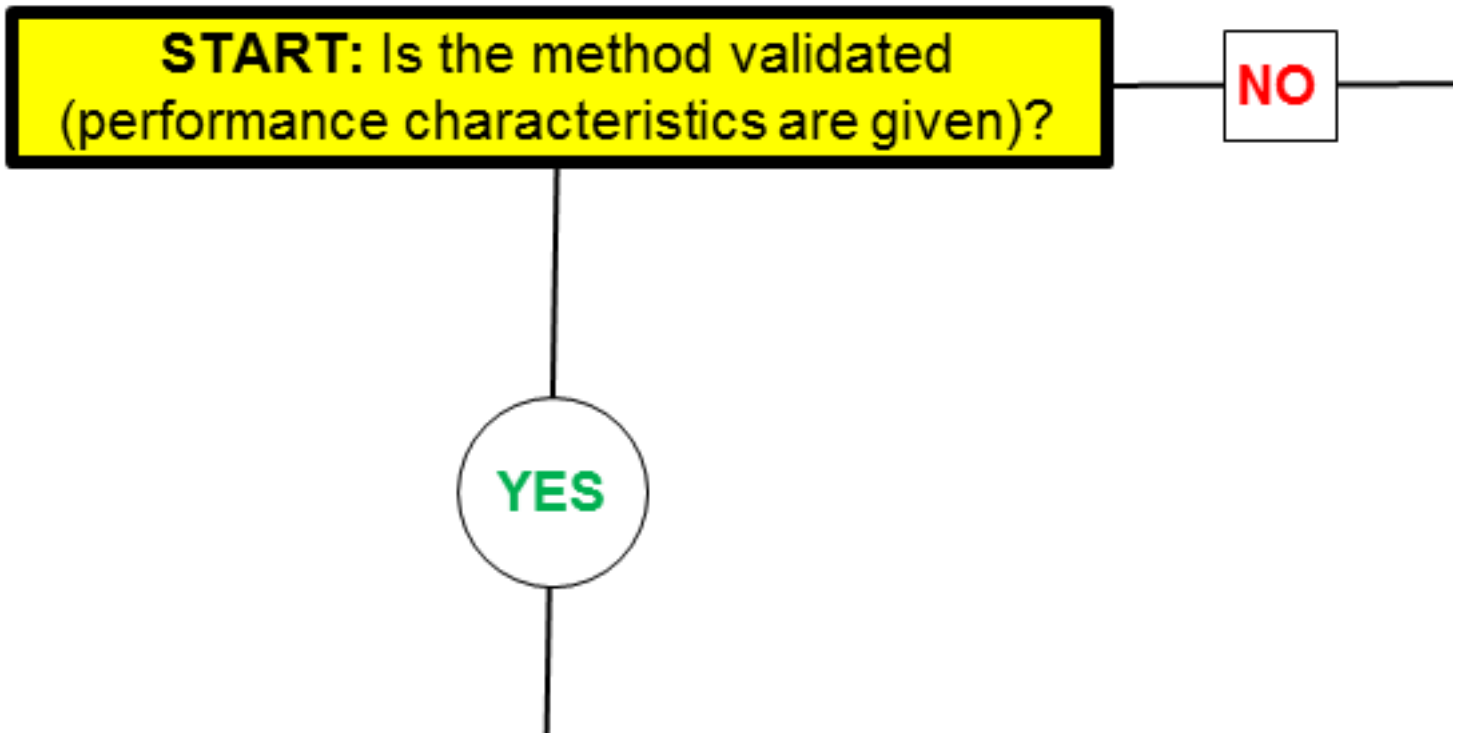
- **Factorial design validation** describes the validation using a interlaboratory study based on factorial design approach.

Current status of the standards

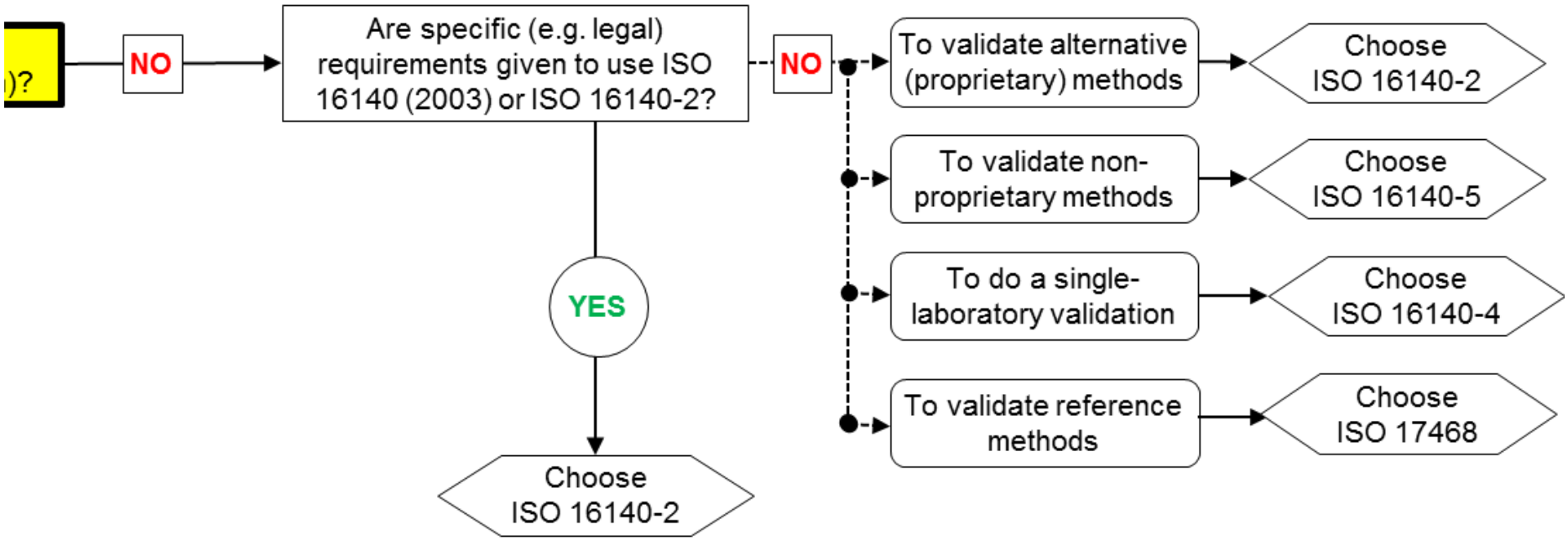
- ISO 16140-1: Vocabulary. Published in July 2016
- ISO 16140-2: Protocol for the validation of alternative (proprietary) methods. Published in July 2016.
- ISO 17468: Technical requirements and guidance on establishment or revision of a standardized reference method. Published in July 2016.
- ISO 16140-3: Protocol for the verification of reference and validated alternative methods implemented in a single laboratory. FDIS in preparation.
- ISO 16140-4: Protocol for method validation in a single laboratory. FDIS in preparation.
- ISO 16140-5: Protocol for factorial interlaboratory validation for non-proprietary methods. FDIS in preparation.
- ISO 16140-6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures. FDIS in preparation.


START: Is the method validated (performance characteristics are given)?
NO
Are specific (e.g. legal) requirements given to use ISO 16140 (2003) or ISO 16140-2?
NO
To validate alternative (proprietary) methods
Choose ISO 16140-2
To validate non-proprietary methods
Choose ISO 16140-5
To do a single-laboratory validation
Choose ISO 16140-4
To validate reference methods
Choose ISO 17468
YES
Choose ISO 16140-2
YES
Is the method validated according to ISO 16140-4?
YES
Apply method only in that particular laboratory (incl. scope extension)
NO
Is the (food) category to be tested in the scope of the method?
NO
For extension of the scope of a reference method
Choose ISO 17468
For extension of the scope of an alternative (proprietary) method validated according to ISO 16140-2
Choose ISO 16140-2
For extension of the scope of a non-proprietary method validated according to ISO 16140-5
Choose ISO 16140-5
For use of the (food) type in a single laboratory, in the case of:
a] an alternative (proprietary) method validated according to ISO 16140-2 or
b] a non-proprietary method validated according to ISO 16140-5 or
c] a reference method with performance characteristics or
d] a reference method without performance characteristics
Choose ISO 16140-4
YES
Choose ISO 16140-3 (verification)

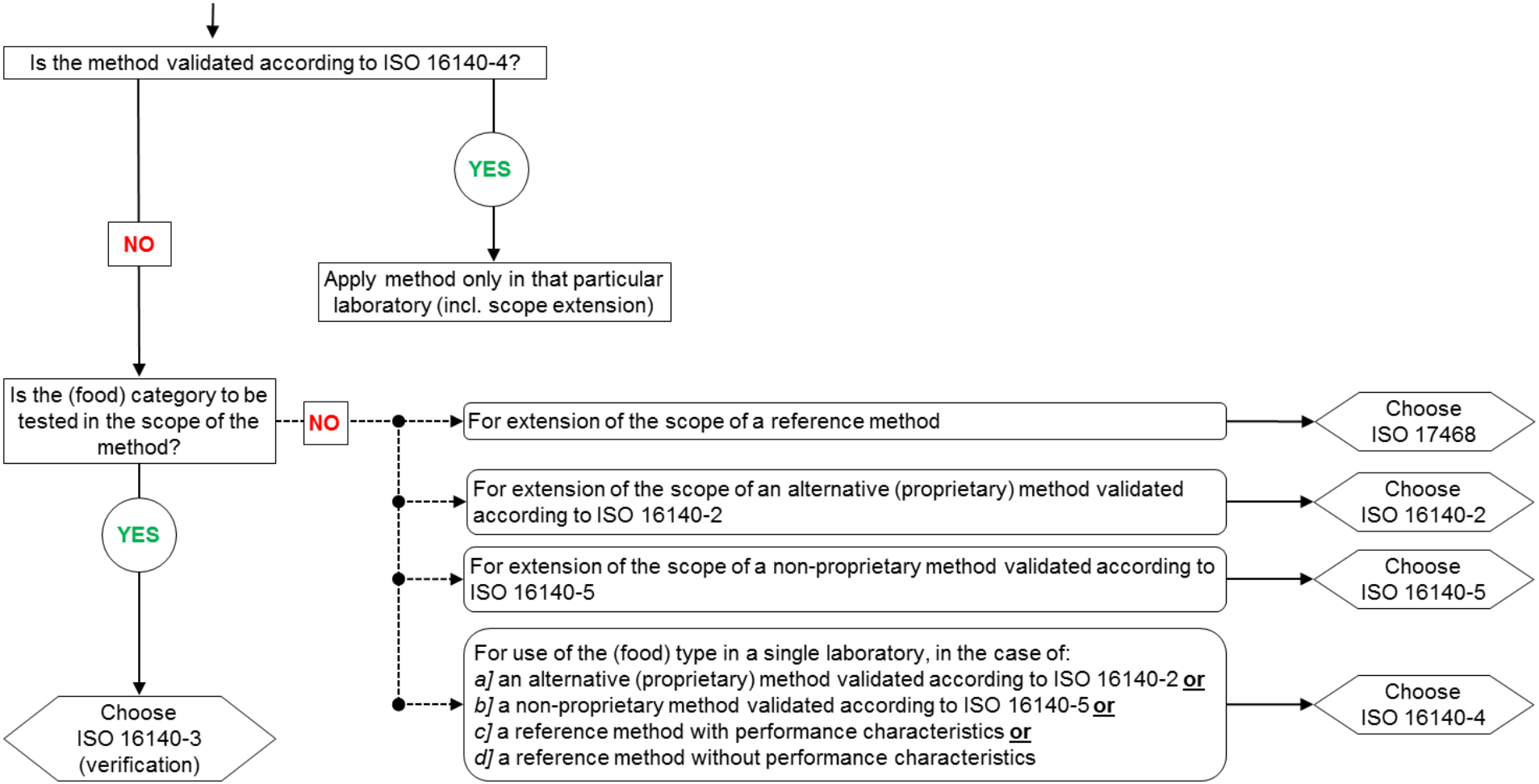
Basic question in yellow:



Method not validated



Method validated



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ISO/DIS 16140 Microbiology of the Food Chain – Method Validation – Part 3:

Protocol for the verification of reference and validated alternative methods implemented in a single laboratory

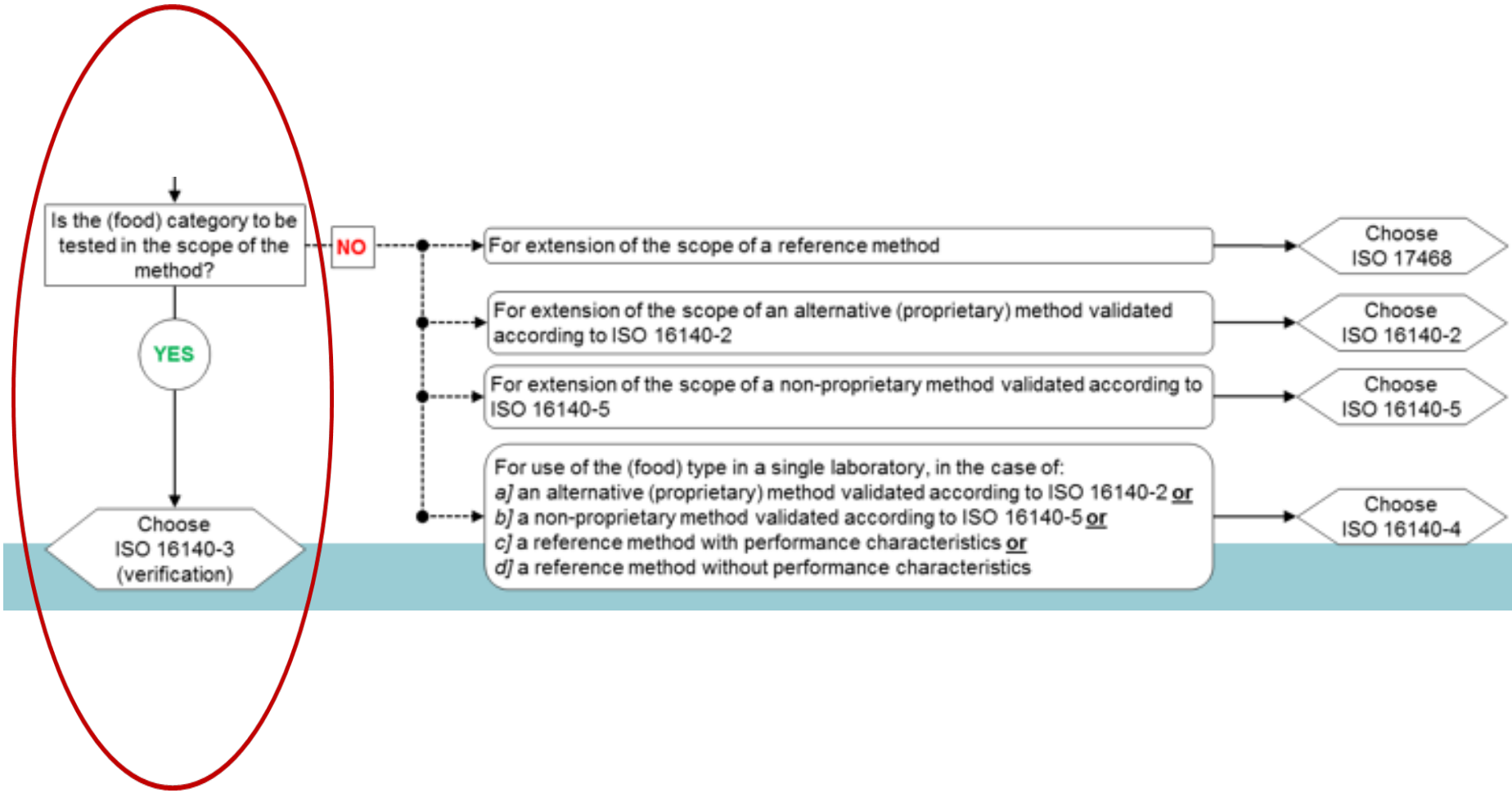
DeAnn Benesh, 3M Food Safety

- Co-Chair ISO 16140-3 (w/Benjamin Diep, Nestle)

ISO International Organization for Standardization

Method Validated?

International Organization for Standardization



Distinguishing Validation & Verification (ISO 16140-1:2016)

Validation (Clause 2.81)

- Establishment of the performance characteristics of a method and provision of objective evidence that the *performance requirements for a specified intended use are fulfilled*

Verification (Clause 2.83)

- Demonstration that a *validated method functions in the user's hands according to the method's specifications* determined in the *validation* (2.81) study and is fit for its purpose

ISO International Organization for Standardization

Published Documents on Verification

US FDA

- FDA Bacteriological Analytical Methods (BAM) Appendix 3; Section 4

Appendix 3	Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition (PDF, 1.32Mb, May 2015), FDA Foods and Veterinary Medicine Science and Research Steering Committee, US Food and Drug Administration, Office of Foods Updated 09/2015

Health Products and Food Branch (HPFB) of Health Canada

- Compendium of Methods – Volume 1, Development of Methods

Part 5: Guidelines to Verify Standard Food Microbiological Methods for Implementation in Routine Testing	April 2015

- "Click" on the link and send an email to request an emailed copy

ISO 16140-2:2016

International Organization for Standardization

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)

How many samples to test for Verification?

Number of Samples to Test? BIG Debates!

15 food categories claimed x 5 foods /category is 75 foods needed = Verification!!!

That's way too much! Only ONE Matrix is needed = Verification!!!

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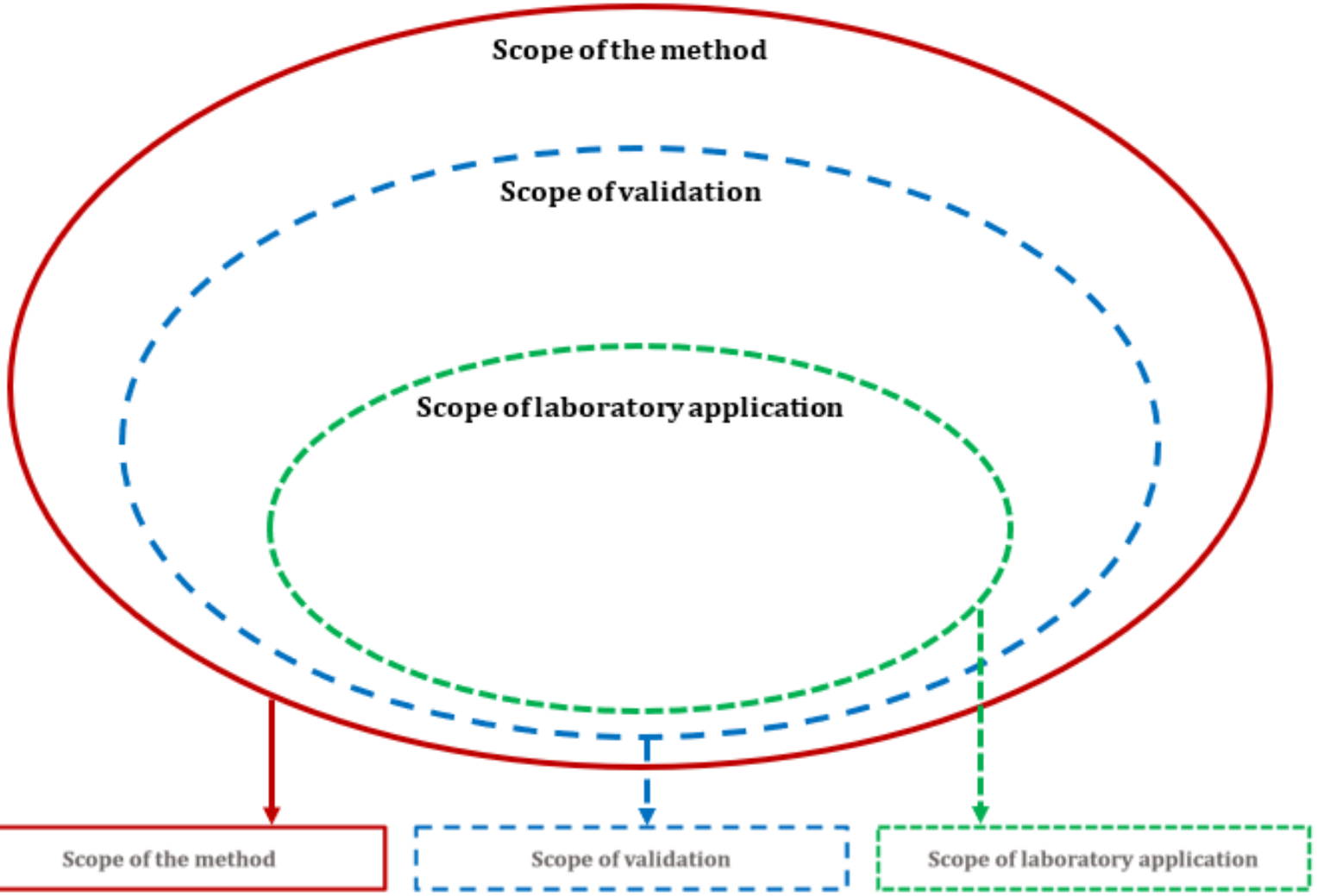
Overlap Between Scopes



"Broad Range of Foods"
Or – only specific categories?

Categories Validated

Routinely Tested in User Lab

Verification = 2 Step Procedure

1) **Implementation Verification:**

   Demonstrate the competence of the user laboratory to *perform the method*

2) (Food) item Verification :

- Demonstrate the competence of the user laboratory to *perform the method with (food) items routinely tested in the user laboratory*

Implementation

1) **Implementation Verification:**

   Demonstrate the competence of the user laboratory to *perform the method*

When published validation data are available (reference methods; validated alternative methods), the user laboratory shall

— review the published validation data for the method,

— select one (food) item tested during the validation study that belongs within the scope of laboratory application of the user laboratory, if possible, and

— use this (food) item and the sample size used in the validation study to perform implementation verification.

(Food) item

2) (Food) item Verification :

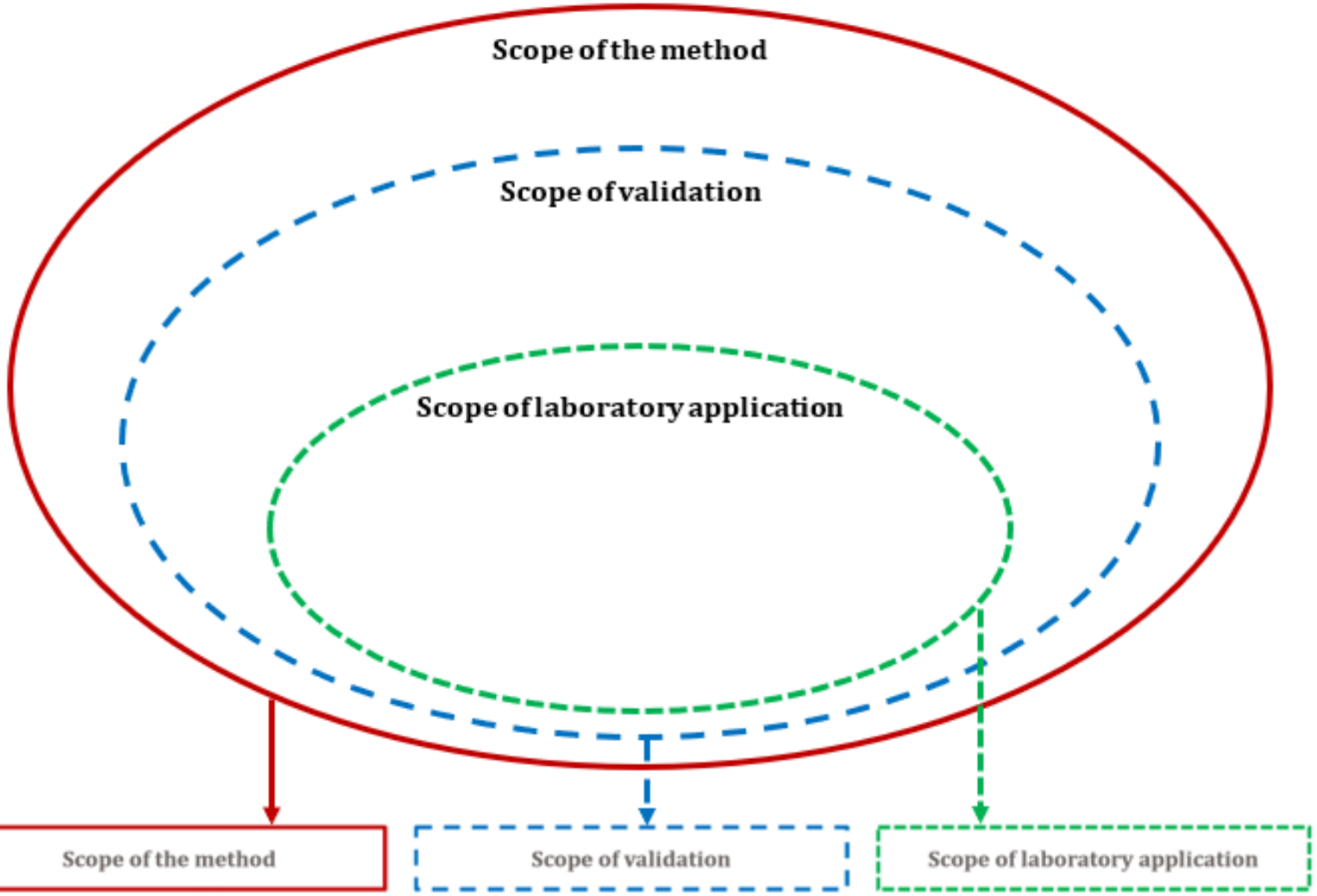
- Demonstrate the competence of the user laboratory to *perform the method with (food) items routinely tested in the user laboratory*

The user laboratory shall

— select one challenging (food) item per each (food) category listed within the scope of validation (see 4.4 for details), that is also a (food) category that is tested within the scope of laboratory application, and

— use this (food) item and the sample size used in the validation study to perform the (food) item verification.

Overlap Between Scopes

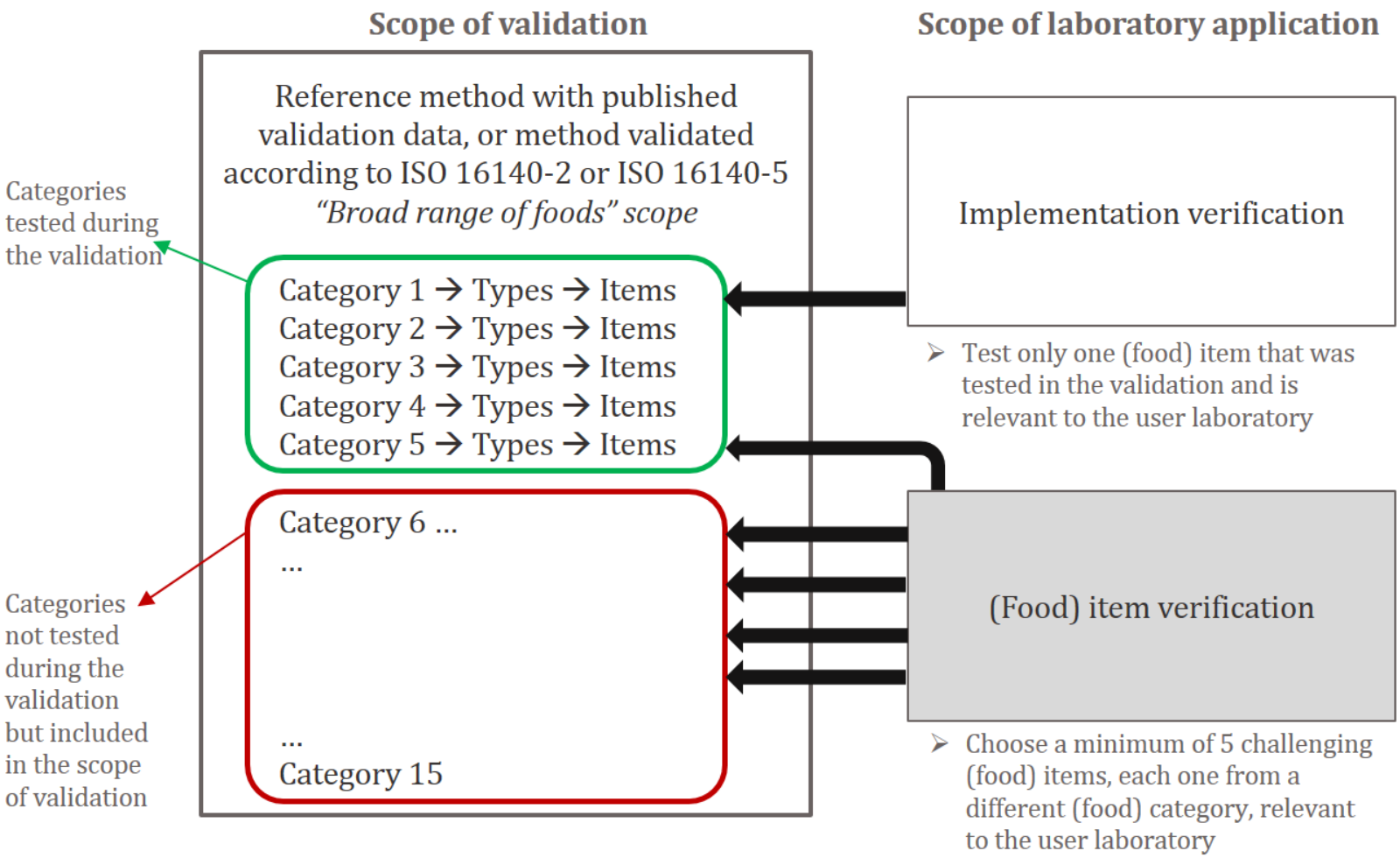


"Broad Range of Foods"
Or – only specific categories?

Categories Validated

Routinely Tested in User Lab

(Food) Item Verification – ***Broad Range of Foods***



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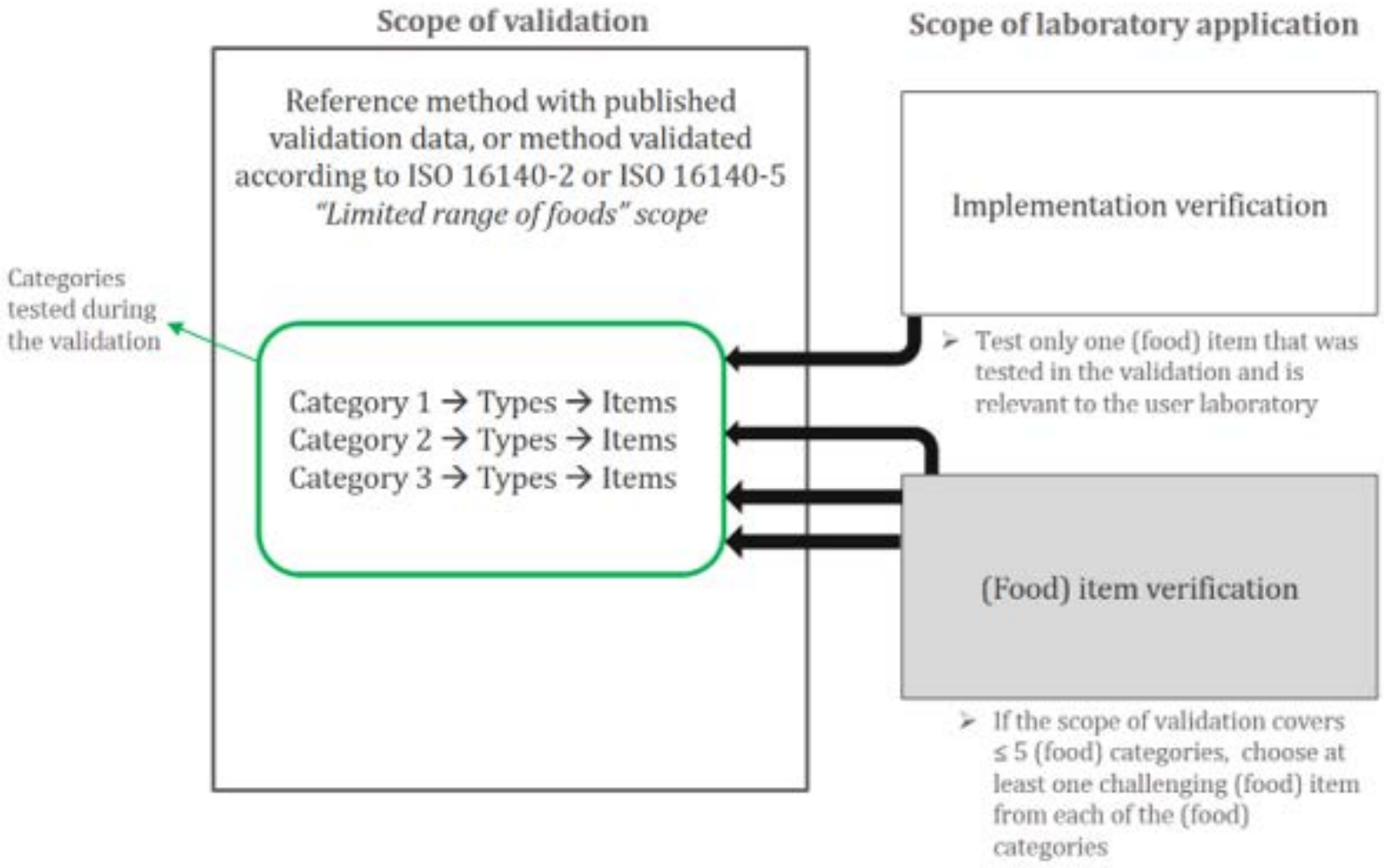
(Food) Item – ***Limited Range of Foods***



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Acceptance criteria in verification

Method	Performance characteristics	Acceptance criteria
Qualitative	$eLOD_{50}$ (when LOD_{50} available in the validation study)	$eLOD_{50} \leq 4 \times LOD_{50}$
	$eLOD_{50}$ (when no LOD_{50} available)	$eLOD_{50} \leq 4$ cfu/test portion
Quantitative	S_{IR} (for methods with validation data)	$S_{IR} \leq$ lowest S_R mean value determined in the validation study
	eBias	$\log_{10}$ cfu/g (inoculum) – mean $\log_{10}$ cfu/g (artificially contaminated [food] item) ≤ 0,5 $\log_{10}$ cfu/g for each of the inoculation levels [a]
Confirmation	Inclusivity/Exclusivity	Complete concordance between methods
[a] For readability, only cfu/g is given but the results can also be expressed in cfu/ml.		

Inter-Laboratory study required = ISO 16140-2 and AOAC OMA methods

ISO 16140 Series

ISO has recognized several ISO 16140 documents as "high profile" because they believe the global food industry has a great need for these documents:

- **ISO 16140-2** Method ***Validation*** - Published August 2016
- **ISO 16140-3** Method ***Verification*** – Expected publication 2019

Decision to gather input from USER LABORATORIES, vs just WG3 Experts

Acceptance Criteria defined BEFORE starting

- **Responses from > 30 global laboratories**
  - Various lab sizes
  - Global regions (including Africa/Middle East if possible)
  - Industry, Contract, Government
- **ALL responses to the questionnaire rated ≥ 3 on a 1-5 scale**
- **75 % of the user laboratories are able to**
  - **follow and understand ISO/CD 16140-3**
  - **for those that attempted, are able to conduct a verification**

Request to SC9 = 30 labs; Further recruiting = 60 labs

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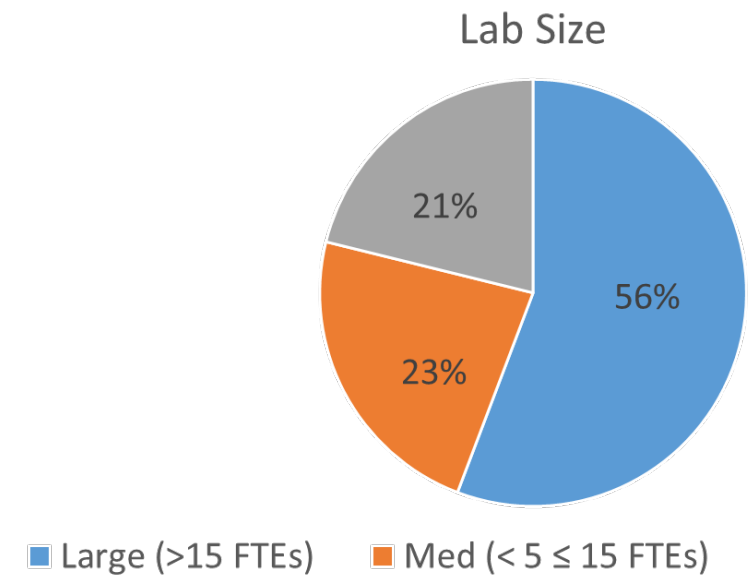
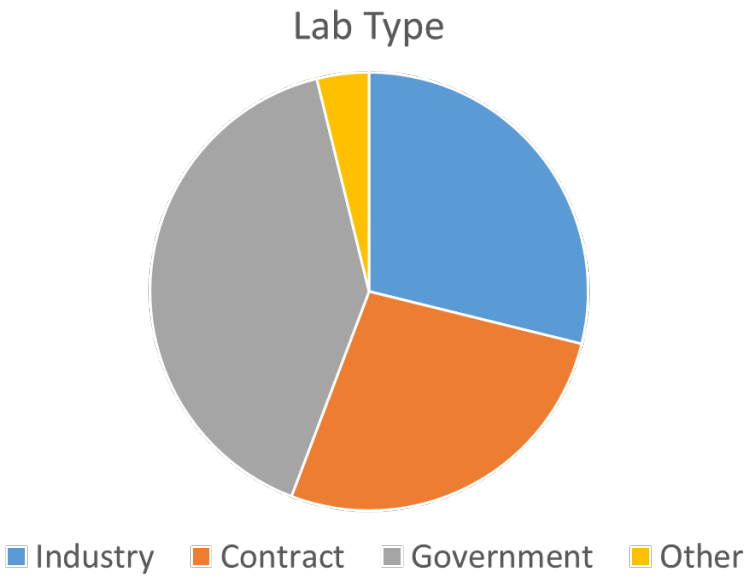
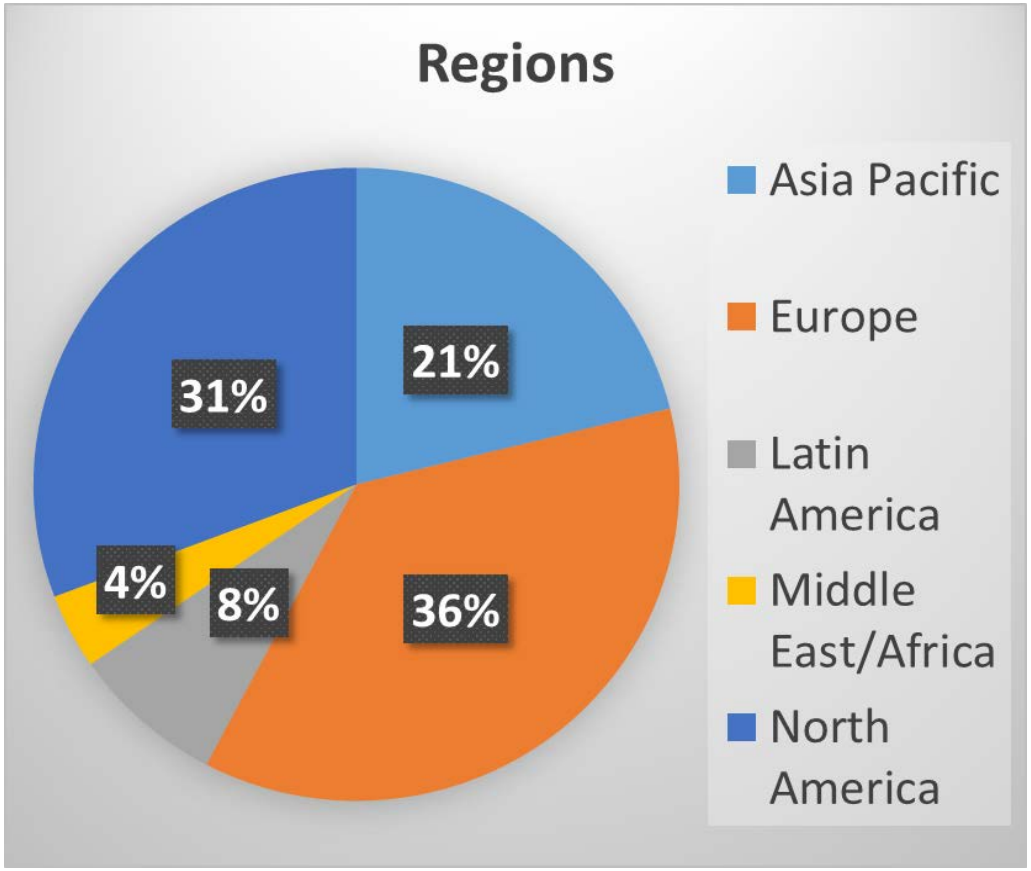
User Laboratory Response

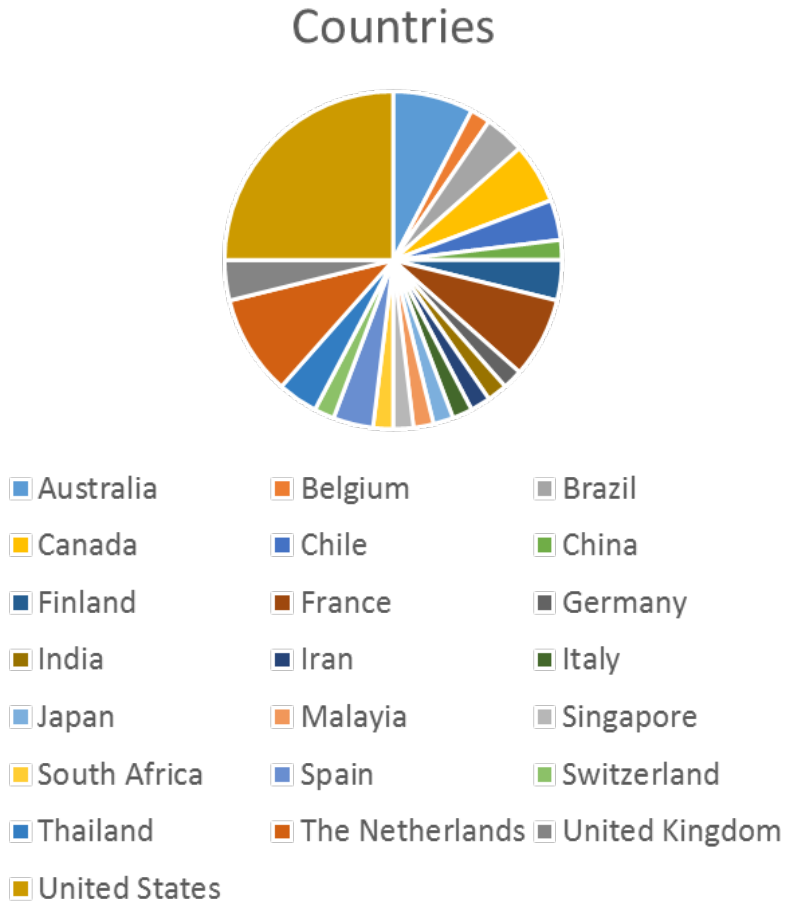
52 of 60 labs responded = 80% response rate!



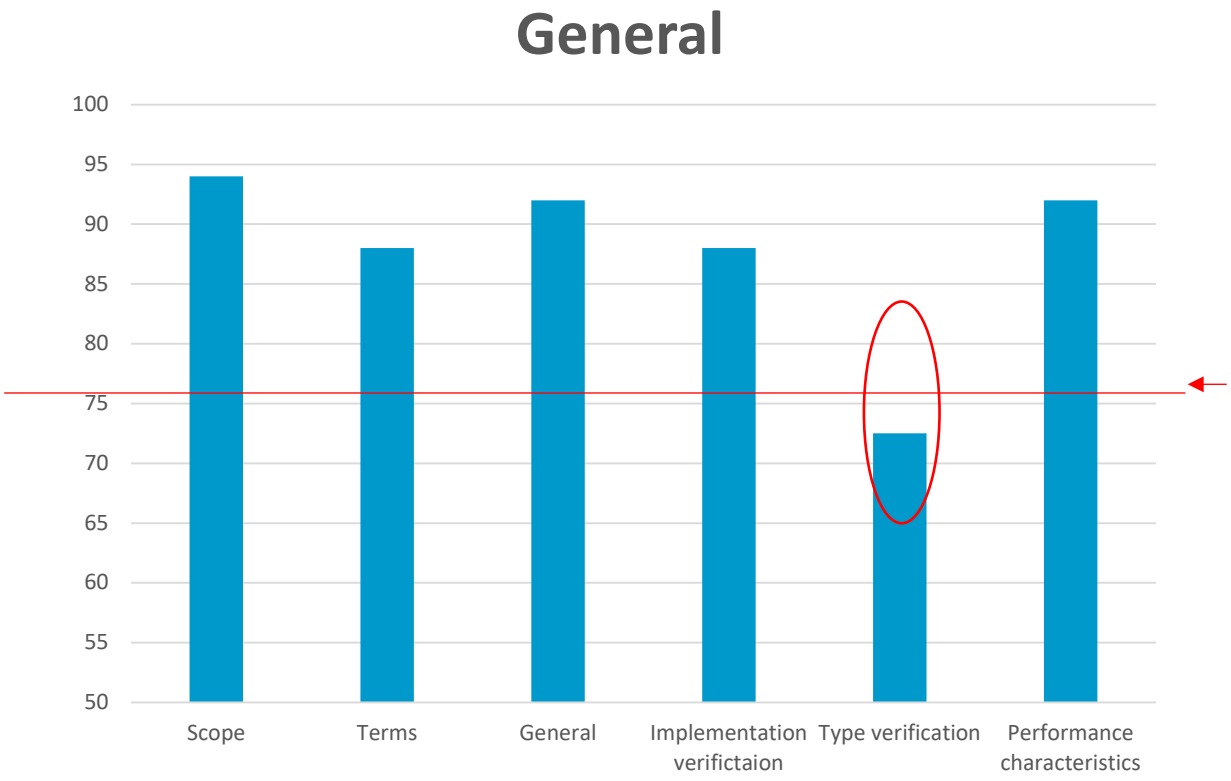


User Laboratory Participation





User Laboratory Evaluation: *Text Comprehension*



Acceptance criteria:
75% ≥ 3 (neutral)

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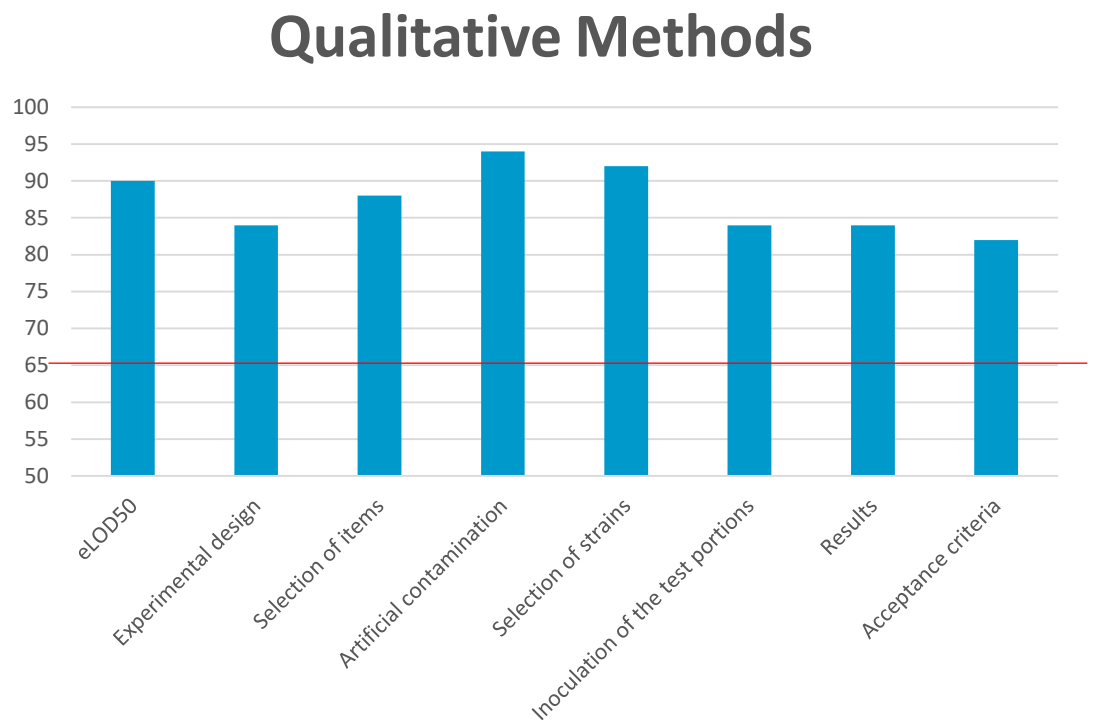
User Laboratory Evaluation: *Text Comprehension*



Acceptance criteria:
75% ≥ 3 (neutral)

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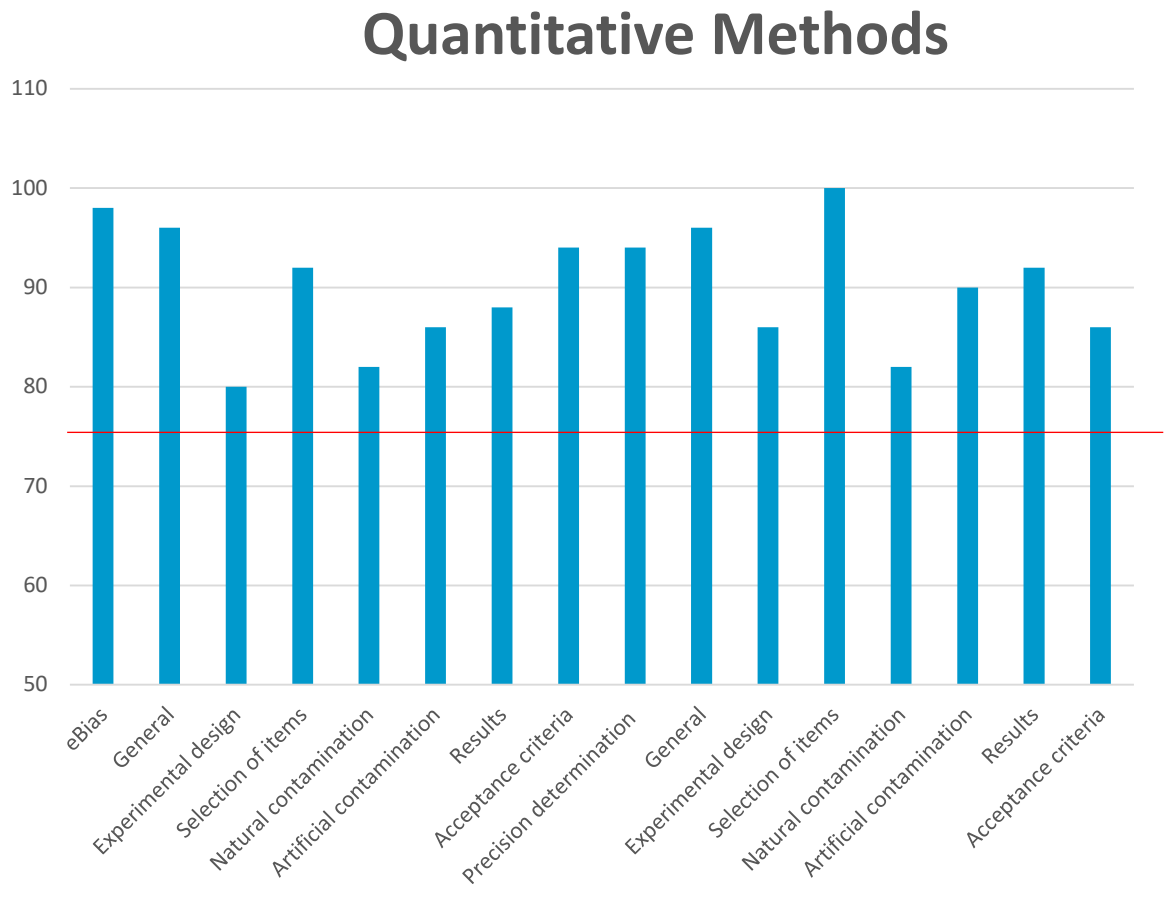
User Laboratory Evaluation: *Text Comprehension*



Acceptance criteria:
75% ≥ 3 (neutral)

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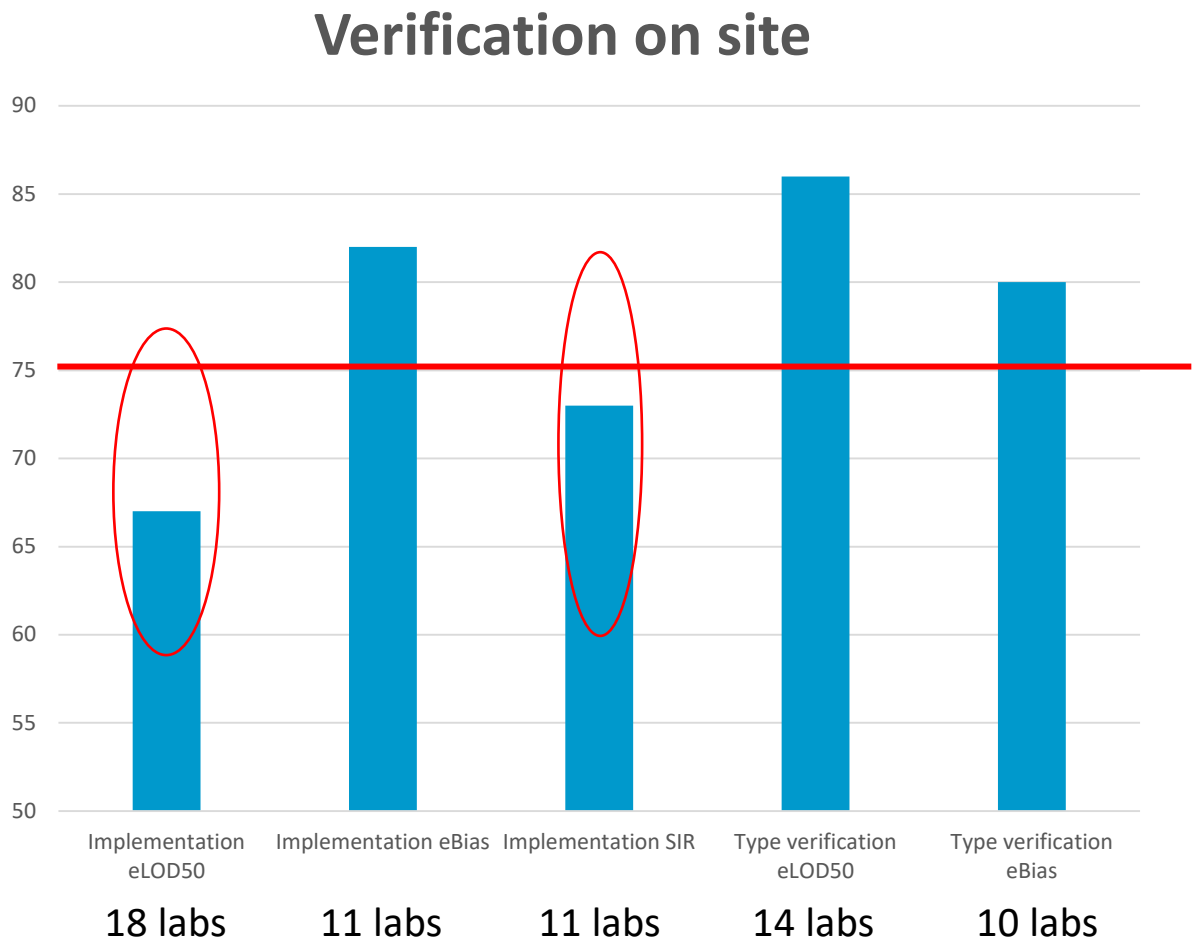
User Laboratory Evaluation: *Practice*



Acceptance criteria:
75% ≥ 3 (neutral)

Publications Expected – End of 2019

ISO 16140-3 Document

- ~ 35 pages = Protocol
- ~ 35 pages = Annexes with examples

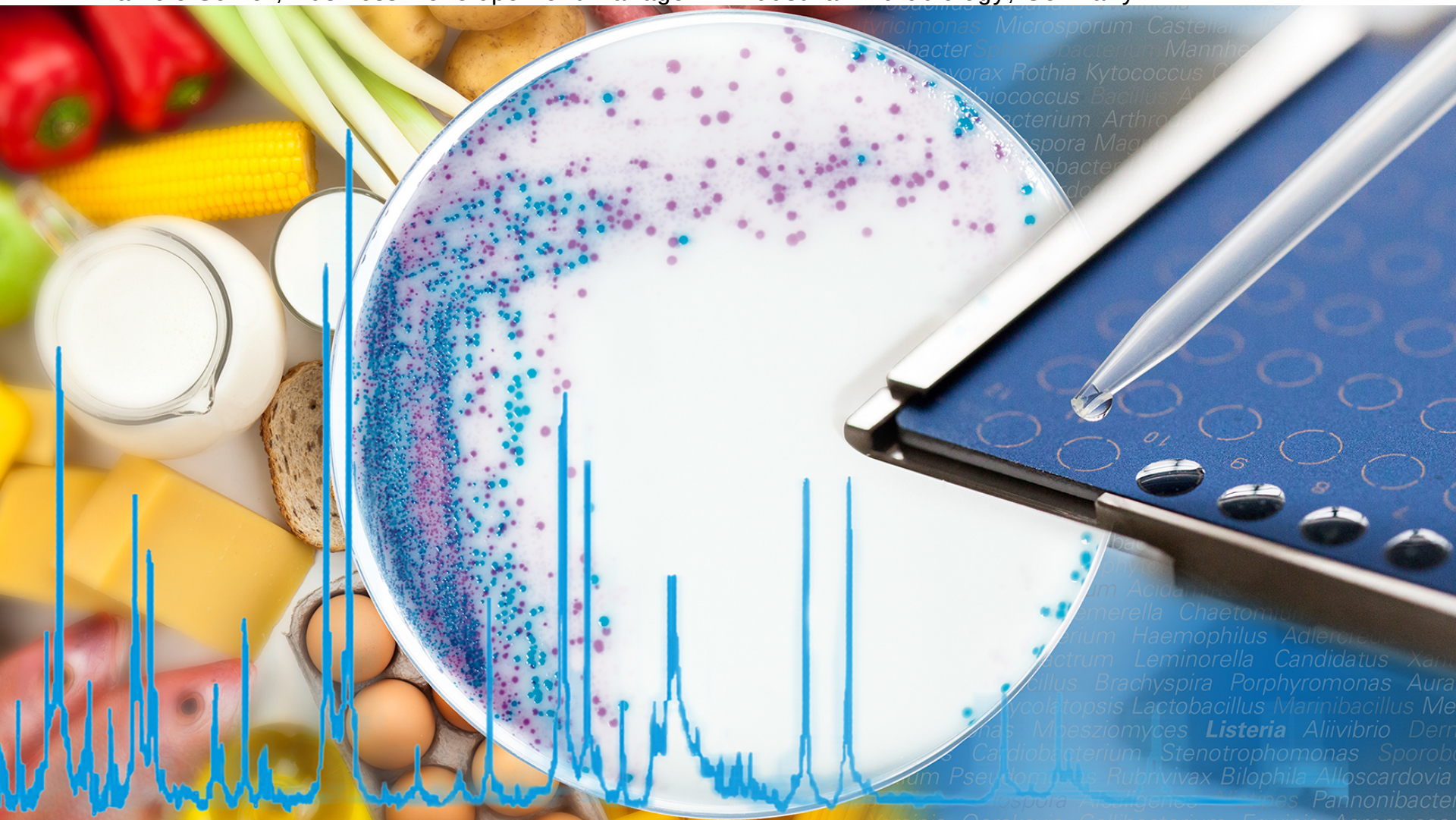
Transition Document:

- **Guidance on transition to meet ISO 17025 requirements:**
  - For Labs, Assessors (Technical), Accreditation Bodies
- **Methods currently under scope of Lab ISO 17025 accreditation:**
  - Methods under the scope of the accreditation of the laboratory for which verification has already been conducted do not need to re-verify their methods according to ISO 16140-3

ISO 16140-part 6

Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

Daniele Sohier, Business Developement Manager – Industrial Microbiology, Germany



ISO 16140 for the validation of alternative (proprietary) methods

Timeline (1/2)

- 2003 — Publication of the ISO 16140 standard - Protocol for the validation of alternative methods
- 2006 — Revision of the ISO 16140
- 2016 — Publication
  - ↪ ISO 16140–part 1: Vocabulary
  - ↪ ISO 16140–part 2: Protocol for the validation of alternative (proprietary) methods against a reference method

1. Alternative (proprietary) methods for the detection and enumeration of specific microorganisms are validated according to the ISO 16140 standard since 15 years

2. This ensures the recognition of the validated methods by regulation bodies (e.g. EU 2073/2005, FDA) and facilitate the accreditation process by the end-users

3. These alternative methods enable usually time- and cost- saving, and are easy-to-use

↪ What about the validation and recognition of confirmation and typing methods?

ISO 16140 for the validation of alternative (proprietary) methods

Timeline (2/2)

- 2003 — Publication of the ISO 16140 standard - Protocol for the validation of alternative methods
- 2006 — Revision of the ISO 16140
- 2016 — Publication
  - ↪ ISO 16140–part 1: Vocabulary
  - ↪ ISO 16140–part 2: Protocol for the validation of alternative (proprietary) methods against a reference method
- 2018 — Pre-FDIS of the ISO 16140-part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

ISO 16140-6
Final stage before publication

Date: 2018-09-28

Draft for ISO/FDIS 16140-6 *(the "pre-FDIS" as submitted to the SC 9-secretariat)*

ISO/TC 34/SC 9/WG 3/N 474

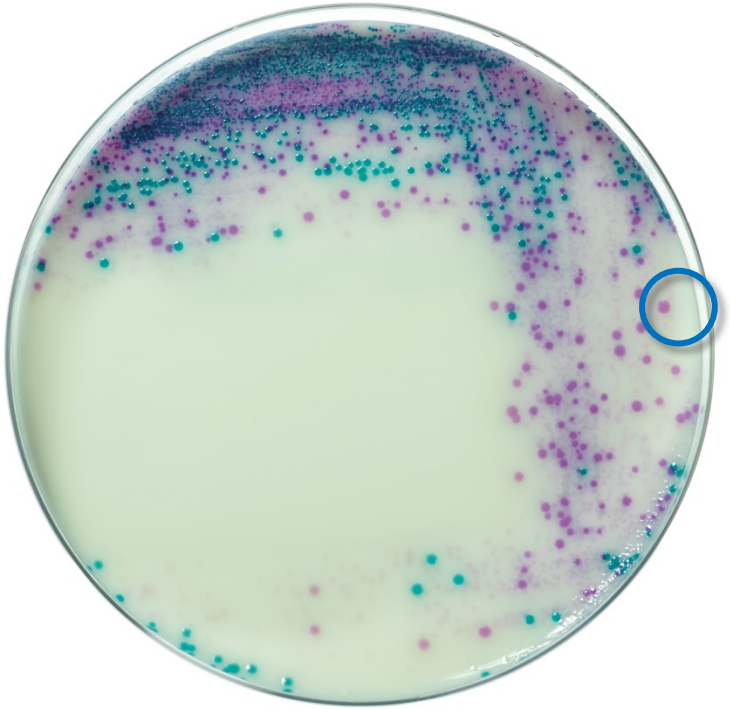
Secretariat: NEN

Project leaders: Wilma Jacobs-Reitsma and Kirsten Mooijman

Microbiology of the food chain — Method validation — Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

Publication in 2018 after translation in French and German

ISO 16140-6
General principles (1/4)
Sample

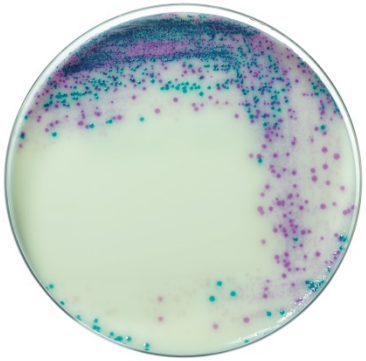


The sample is a microbial isolate on a specific culture medium

Therefore, the culture media tested during the validation shall be clearly defined

Photo kindly provided by Bio-Rad

ISO 16140-6
General principles (2/4)
Workflow

Screening step, i.e. detection or enumeration	Isolation on defined culture media	Confirmation or Typing
• Reference method, e.g. ISO or FDA method • Alternative method validated according to the ISO 16140-2 standard		• Reference method protocol, e.g. ISO or FDA method • Proprietary protocol tested during the ISO 16140-2 validation of the screening method • **Alternative method validated according to the ISO 16140-part 6 standard for defined culture media**

XLD	BGA
✓	✗

XLD	Hektoen
✓	✗

ISO 16140-6
General principles (3/4)
Study requirements

ISO 16140-6 study

- The testing and data interpretation SHALL be conducted by an **expert (independant) laboratory**
- The **data generated by the alternative method are compared to the reference method,** e.g. ISO or FDA confirmation procedure

Acceptability Limits (AL)

- **maximum positive or negative acceptable difference** between the reference value (or if not known, the accepted reference value) of a sample and an individual result obtained when applying the operating procedure of an analytical method

Interpretation

Accepted

Rejected

ISO 16140-6
General principles (4/4)
Study process

Method Comparison study on numerous
- target strains = inclusivity testing
- non-target strains = exclusivity testing

To assess the **reliability** of the method

Expert laboratory (third party)

Inter-laboratory study with a restricted number of target and non-target strains to assess the **reproducibility** of the method with different operators, instruments, materials

Minimum 10 valid data sets from different collaborators

ISO 16140-part 6
Method Comparaison Study (1/4)
Selection of test strains

1. Each strain shall be characterized biochemically and/or serologically and/or genetically in sufficient detail for **its identity to be known**.

2. Strains used should preferentially have been isolated from **foods, feeds, the food-processing environment, or primary production** taking into account the scope of the validation.

   However, clinical, environmental, and culture collection strains can be used.

3. The **original source of all isolates** should be known and **they should be held** in a local (e.g. expert laboratory), national, or international culture collection to enable them to be used in future testing, if required.

ISO 16140-part 6
Method Comparaison Study (2/4)
Inclusivity and Exclusivity Testing

The panel of strains shall be isolated on the tested culture media

Target analyte	Inclusivity panel (+)	Exclusivity panel (-)
Family level e.g. *Enterobacteriacea*	• 200 strains	• 100 strains
Genus level e.g. *Listeria* spp.	• 150 strains	• 100 strains*
Species level e.g. *L. monocytogenes*	• Usually 100 strains • 150 strains for *Salmonella* spp.	• 100 strains including 50 strains from the same genus*
Typing level e.g. *Salmonella* serotypes	• 25 strains per type	• 100 strains including 75 strains from the non-target types

*See special design for *Salmonella* spp.

e.g. Genus level with 5 selective media + 1 non-selective agar
6 media x (150 + 100) strains = 1 500 tests

ISO 16140-part 6
Method Comparaison Study (3/4)
Interpretation

Inclusivity

Root cause analysis

Reference Method	Alternative Method	Comparaison Ref / Alt	Identity of strain	Final Interpretation
+	+	PA	*Not required*	IA
+	-	ND = FN ?	+	ID
-[a]	+[a]	PD = FP?	+	IA
-[a]	-[a]	NA	*Not required*	IA

Exclusivity

Reference Method	Alternative Method	Comparaison Ref / Alt	Identity of strain	Final Interpretation
-	-	NA	*Not required*	EA
-	+	PD = FP ?	-	ED
+[a]	-[a]	ND = FN?	-	EA
+[a]	+[a]	PA	*Not required*	EA

[a]not be very likely to be found

P: Positive N: Negative D: Deviation A: Agreement F: False I: Inclusivity E: Exclusivity

ISO 16140-part 6
Method Comparaison Study (4/4)
Interpretation

Testing	Agreement	Deviation	Acceptability
Inclusivity	IA	ID	ID ≤ AL
Exclusivity	EA	ED	ED ≤ AL

Example: Genus level, Inclusivity = 150 strains , Exclusivity = 100 strains

Testing	Agreement	Deviation	AL	Acceptability	
Inclusivity	IA = 150/150	ID = 0/150	1	0 ≤ 1	✓
Exclusivity	EA = 97/100	ED = 3/100	2	3 ≰ 2	✗

D: Deviation A: Agreement F: False I: Inclusivity E: Exclusivity AL: Acceptability Limit

ISO 16140-6
General principles (4/4)
Study process

Method Comparison study on numerous
- target strains = inclusivity testing
- non-target strains = exclusivity testing

To assess the **reliability** of the method

Expert laboratory (third party)

Inter-laboratory study with a restricted number of target and non-target strains to assess the **reproducibility** of the method with different operators, instruments, materials

Minimum 10 valid data sets from different collaborators

ISO 16140-part 6
Inter-Laboratory Study (1/1)
Study Design and Interpretation

Number of blind-coded strains	Number of valid data sets	Interpretation with ID, ED and AL
• Inclusivity: 16 • Exclusivity: 8	• 10 valid data sets • minimum 5 different organizations	≤ AL Accepted Rejected

Proof of Concept
ISO 16140-6

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General Committee	Food Safety Authorities	Certification and standardization bodies	Laboratories and users	Manufacturers
	FVST **NVWA***	AOAC* NMKL Loyd's	ADRIA* Campden BRI* Nestlé*	**3M*** bioMérieux* Biotecon **Bruker*** R-Biopharm Merck

Technical Committee	Food Safety Authorities	Certification and standardization bodies	Laboratories and users	Manufacturers
	FDA* FVST **NVWA***	Loyd's	ADRIA* Campden BRI* DIL Nestlé* RIVM* **Q-Laboratories***	bioMérieux* Biotecon **Bruker*** Merck

Webinar orgnization

*Organizations involved in the ISO working group on the ISO 16140 series

A MicroVal pilot study using the MALDI Biotyper as an alternative for *Salmonella* spp. confirmation

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Proof of Concept

Bastin[1], P. Bird[1], E. Crowley[1], B. Diep[2], I. Ferro[3], T. Hammack[4], W. Jacobs[5], M. Kostrzewa[6], C. Le Doeuff[7], S. Peron[7], M. Rannou[7], D. Sohier[6], M. Timke[6], P. in 't Veld[8], J. Witsenburg[3]

[1]Q-Laboratories, [2]Nestlé Research Center, [3]MicroVal, [4]FDA, [5]RIVM & project leader of the ISO 16140-part 6, [6]BRUKER, [7]ADRIA, [8]VWA & convenor of the ISO 16140 working group

The ISO 16140 standard provides technical and interpretation rules for method validation and verification, and consists of 6 different parts. Part 6 is currently at the DIS (Draft International Standard) stage and describes the protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures. The study design was set up during the past years, and acceptability limits for the data interpretation were defined based on expert opinion, i.e. maximum number of positive or negative deviations between the reference and alternative method.

Evaluation of the ISO/DIS 16140-6:2017: Do the technical rules give sufficient detail to conduct the method comparison and inter-laboratory studies? Are the proposed acceptability limits (AL) fit for purpose or too restrictive? A pilot study was coordinated by MicroVal as a proof of concept.

The MALDI Biotyper (Bruker) was tested as an alternative to confirm *Salmonella* spp. from non-selective and selective agars. A method comparison and an inter-laboratory studies were realized. 150 *Salmonella* spp. strains and 100 non-target strains were tested by two expert laboratories in the method comparison study. The collaborative study was run by involving a minimum of 10 organizations to produce 10 valid data sets with 16 target and 8 non-target strains.

See Tables 1 and 2, with the Tested strains (N), Deviation (D) and Acceptability Limit (AL).

TABLE 1: Summary of the Method Comparison Study

Tested Media	Tested Panel of Strains	N	D	AL
Nutrient Agar	Inclusivity	150	0	Accepted
	Exclusivity	100	0	Accepted
XLD	Inclusivity	150	0	Accepted
	Exclusivity	100	0	Accepted
BGA	Inclusivity	150	0	Accepted
	Exclusivity	100	0	Accepted
RAPID' *Salmonella*	Inclusivity	150	0	Accepted
	Exclusivity	100	0	Accepted
Brilliance *Salmonella*	Inclusivity	150	0	Accepted
	Exclusivity	100	0	Accepted
ASAP	Inclusivity	150	0	Accepted
	Exclusivity	100	0	Accepted

TABLE 2: Summary of the Inter-Laboratory Study

Tested Media & Number of Labs	Tested Panel of Strains	N	D	AL
Nutrient Agar - **14 Labs**	Inclusivity	224	0	Accepted
	Exclusivity	112	0	Accepted
XLD **13 Labs**	Inclusivity	208	0	Accepted
	Exclusivity	104	0	Accepted
RAPID' *Salmonella* **12 Labs**	Inclusivity	192	0	Accepted
	Exclusivity	96	0	Accepted

The MicroVal reviewers and the expert laboratories encountered no specific difficulties in setting up the project, organizing the testing, and interpreting the generated data. The collaborating laboratories could easily understand the protocol of the ISO/DIS 16140-6:2017 and achieve the required number of tests. The defined AL were easily passed as all the *Salmonella* spp. strains were correctly confirmed with the MALDI Biotyper on all tested media in the method comparison and inter-laboratory studies.

The ISO/DIS 16140-6:2017 provides valuable technical rules and interpretation concept to validate confirmation methods. The observed results were excellent; therefore Microval issued a certificate of validation based on the ISO/DIS 16140-6:2017. The certificate is available on www.microval.org.

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The MicroVal reviewers and the expert laboratories encountered **no specific difficulties in setting up the project, organizing the testing, and interpreting the generated data**. The **collaborating laboratories could easily understand the protocol** of the ISO/DIS 16140-6:2017 and achieve the required number of tests. as all the *Salmonella* spp. strains were correctly confirmed with the MALDI Biotyper on all tested media in the method comparison and inter-laboratory studies.

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MALDI Biotyper
ISO 16140-Part 6 Certification

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ISO/DIS 16140-6: document available on the ISO website, accepted with 100% positive votes during the public enquiry
➔ No major modifications

Date: 2018-09-28

Draft for ISO/FDIS 16140-6 *(the "pre-FDIS" as submitted to the SC 9-secretariat)*

ISO/TC 34/SC 9/WG 3/N 474

Secretariat: NEN

Project leaders: Wilma Jacobs-Reitsma and Kirsten Mooijman

Microbiology of the food chain — Method validation — Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

MALDI Biotyper
ISO 16140-Part 6 Certification

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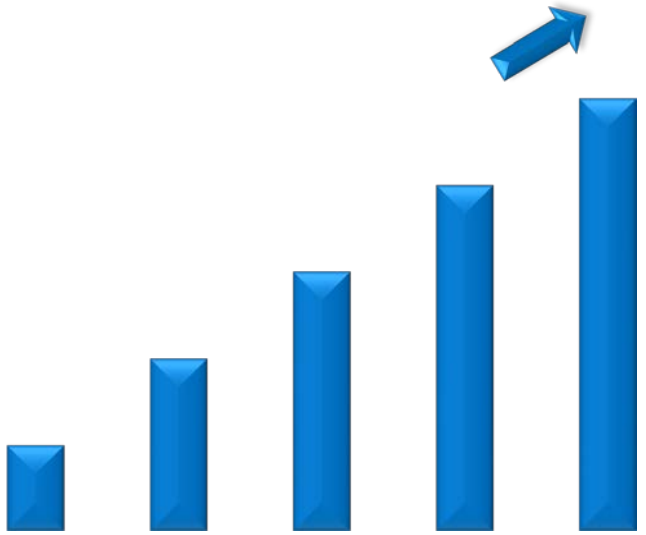
Certificate n° 2017LR72
Confirmation of *Cronobacter* spp.
by the Bruker MALDI Biotyper method

Certificate n° 2017LR73
Confirmation of *Salmonella* spp.
by the Bruker MALDI Biotyper method

Certificate n° 2017LR74
Confirmation of *Campylobacter* spp.
by the Bruker MALDI Biotyper method

Certificate n° 2017LR75
Confirmation of *Listeria* spp. and
Listeria monocytogenes
by the Bruker MALDI Biotyper method

Number of accredited laboratories



Questions?

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

International Association for Food Protection