



Emergency Use of Microbial Methods of Detection by Industry - Alternative Routes Proving Fit for Purpose

VERIFICATION GUIDANCE DOCUMENTS

US FDA Regulatory Science Steering Committee

- Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds (3rd Edition October 2019)

International Organization of Standards

- 16140-3: Microbiology of the food chain — Method validation — Part 3: Protocol for the verification of validated reference and validated alternative methods in a single laboratory

Health Canada Compendium of Methods

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



GENERAL VERIFICATION STUDY RECOMMENDATIONS

1. A method can't be verified if it has not been validated.
2. Verification is applicable to matrices from categories previously validated.
3. Inoculum concentration: LOD to <math><30\text{ cfu/test portion}</math>.
4. Samples can be individually inoculated.
5. Grow the strain under optimal conditions
6. No culture stressing or equilibration period is required.
7. Determine the inoculum level
8. Preferably use strains from the matrix of concern or similar type matrices

CATEGORIZATION OR GROUPING OF FOOD TYPES

If New Matrix is:	Then data required are:		
	For Single Lab Validation Method	For Multi-Lab Validation Method	For Harmonized Collaborative Validated Method
Situation 1: within the same sub-category/group as a validated matrix	None	None	None
Situation 2: in a new sub-category/group but within the same class as a validated matrix	Verification	Verification	Single Lab Validation
Situation 3: in a new class not previously validated	Single Lab Validation	Multiple Lab Validation	Harmonized Collaborative Validation

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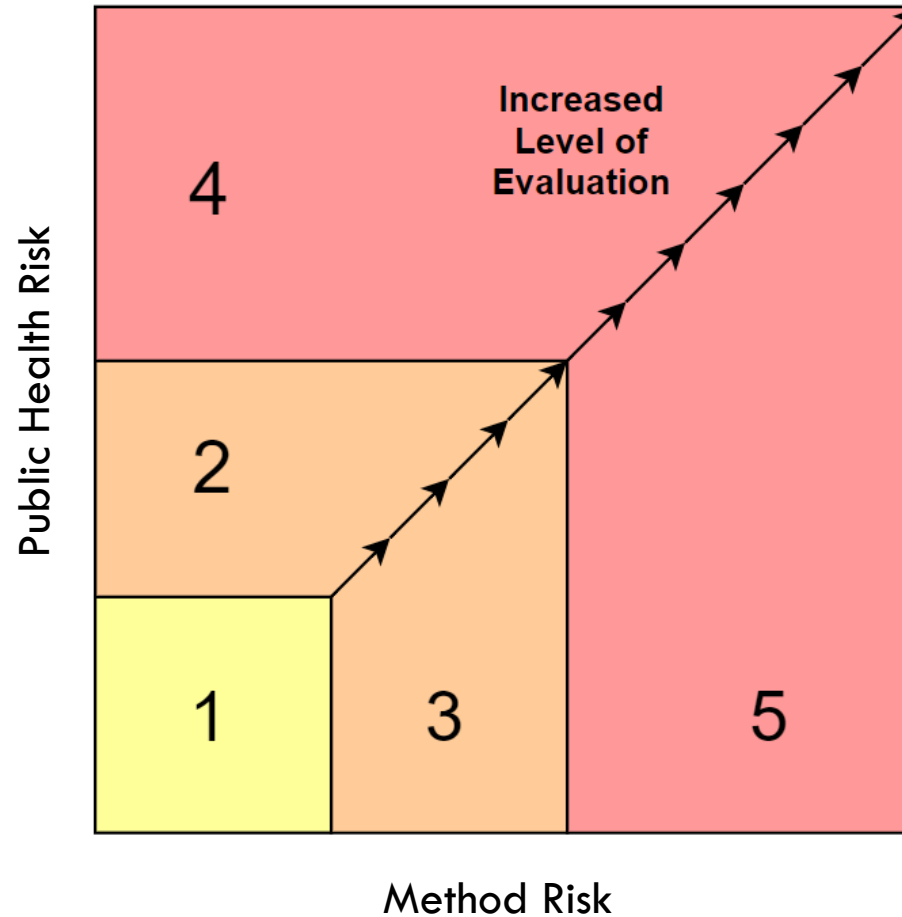
CATEGORIZATION OR GROUPING OF FOOD TYPES

Intrinsic Factors	
pH	Surface structure
Water activity	Salt
Natural occurring inhibitors – cocoa polyphenols, enzymes	Sugar
% Fat	Added humectants – Polysaccharides, Dietary Fiber, Hydrocolloid, Pectin
% Protein	Emulsifiers
% Fiber, % Carbohydrate	Fermentation products and byproducts
Added organic acids	Microbial inhibitors and preservatives used in formulation
Microbial load – active cultures, raw agricultural product, meat	Type of processing – roasted, HPP, irradiated
Physical form – dried, intermediate moisture food, high moisture	

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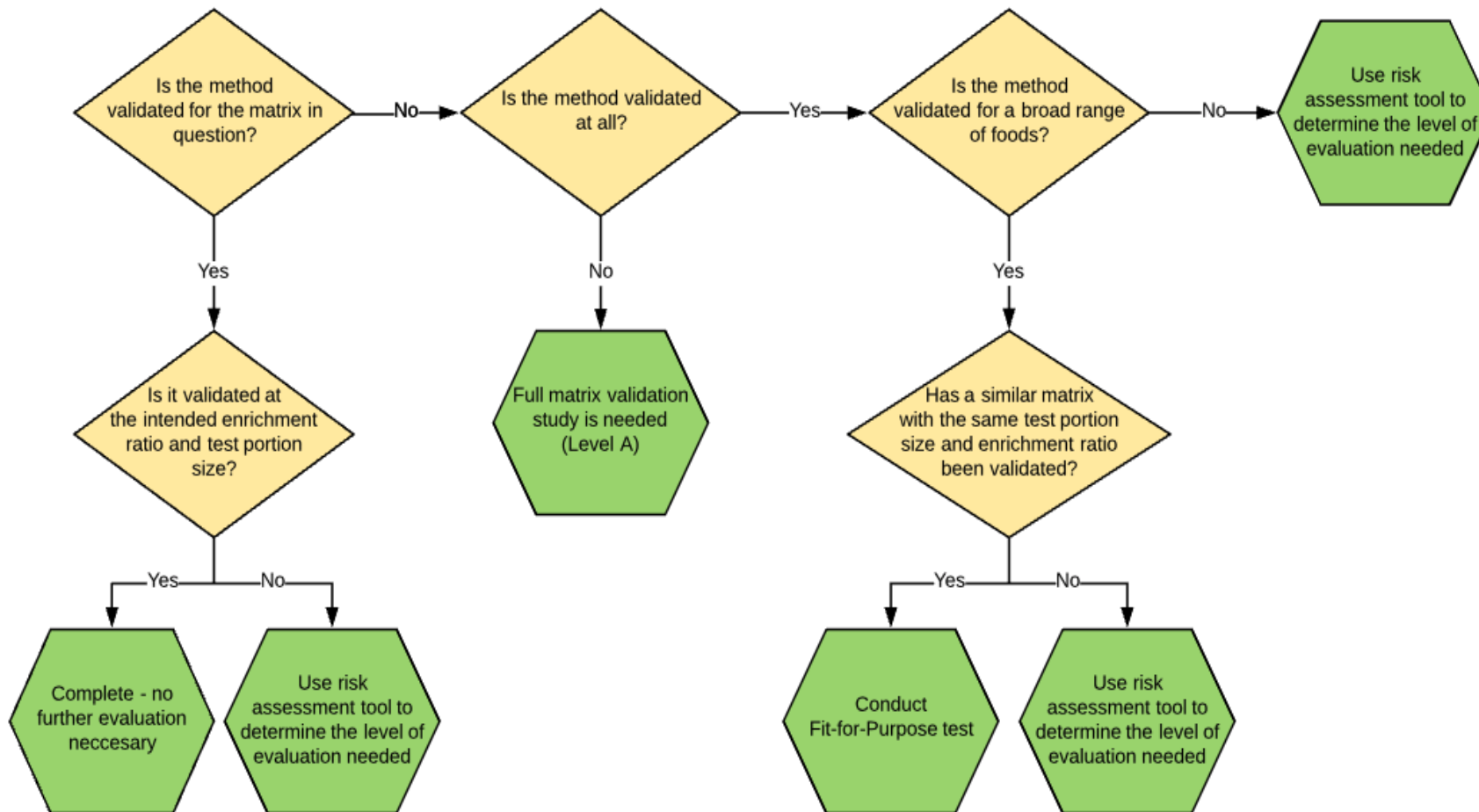
PUBLIC HEALTH RISK VS. METHOD RISK

1. Risk Low
 - a) No outbreaks or recalls associated with matrix
 - b) No pathogen risk reported
 - c) Matrix validated for method
2. Public Risk Moderate
 - a) No outbreaks and recalls associated with matrix
 - b) Pathogen Risk Reported
3. Method Risk Moderate
 - a) Matrix validation data for similar products
4. Public Risk High
 - a) Outbreaks and recalls associated with matrix
 - b) Inherent pathogen risk with product
5. Method Risk High
 - a) No matrix validation data



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VERIFICATION DECISION TREE



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<https://www.foodprotection.org/upl/downloads/library/matrix-evaluation-level-assessment-tool.xlsx>.

INDUSTRY WORK GROUPS & ORGANIZATIONS

- IAFP –Applied Laboratory Methods PDG – Sub WG on Method Validation and Verification <https://www.foodprotection.org/get-involved/professional-development-groups/applied-laboratory-methods-professional-development-group/>
Contact Megan Brown, Principal Scientist, Eurofins meganbrown@eurofinsUS.com
- IAFNS – Institute for the Advancement of Food and Nutrition Sciences <https://iafns.org/>
- IFSH – Institute for Food Safety and Health <https://www.ifsh.iit.edu/>
- APHL – Association of Public Health Laboratories <https://www.aphl.org/Pages/default.aspx>
- ISO TC34/SC9/WG3 – Method Validation for Food Microbiology <https://www.iso.org/committee/47920.html>
- AOAC – Analytical International Methods & Standard Program <https://www.aoac.org/wp-content/uploads/2020/10/AIMS-Program-Proposal-vFinal.pdf>