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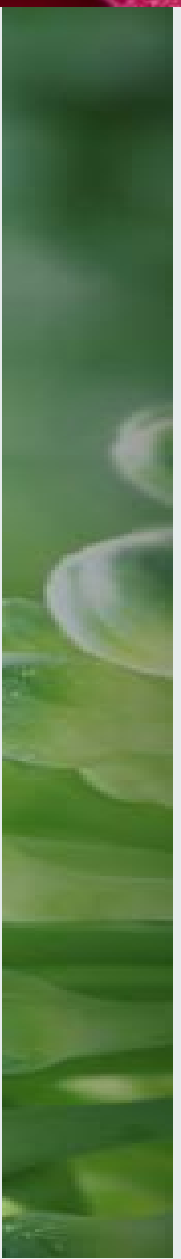

Are You Fit Enough: What Does “Fit for Purpose” Mean to Me?

Sponsored By: Eurofins Food Integrity and Innovation

Presented By: Evan Henke, Larry Cohen, David Legan, Megan Brown, and Stephanie Pollard

Organized by: The Methods Validation & Verification Interest sub-group of IAFP's Applied Laboratory Methods Professional Development Group (PDG)



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Webinar Housekeeping

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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.

WHAT IS “FIT FOR PURPOSE”?

“*degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose*”

-modified from ISO 16140

Evan Henke, PhD, MPH	3M Food Safety
Larry Cohen	Treehouse Foods
J. David Legan, PhD	Eurofins Food Integrity & Innovation

3M Science. Applied to Life.™

Fit for Purpose Validation A Test Manufacturer Perspective

September 25, 2018

Evan Henke, PhD, MPH
Pathogen Specialist
3M Food Safety

Industry Leading Solutions

Quality Indicator Testing

3M™ Petrifilm™ Plates

Pathogen Testing

3M™ Molecular Detection System

Allergen Testing

3M™ Allergen Protein ELISA & Rapid Kits

Sample Handling

3M™ Sample Handling & Media Solutions

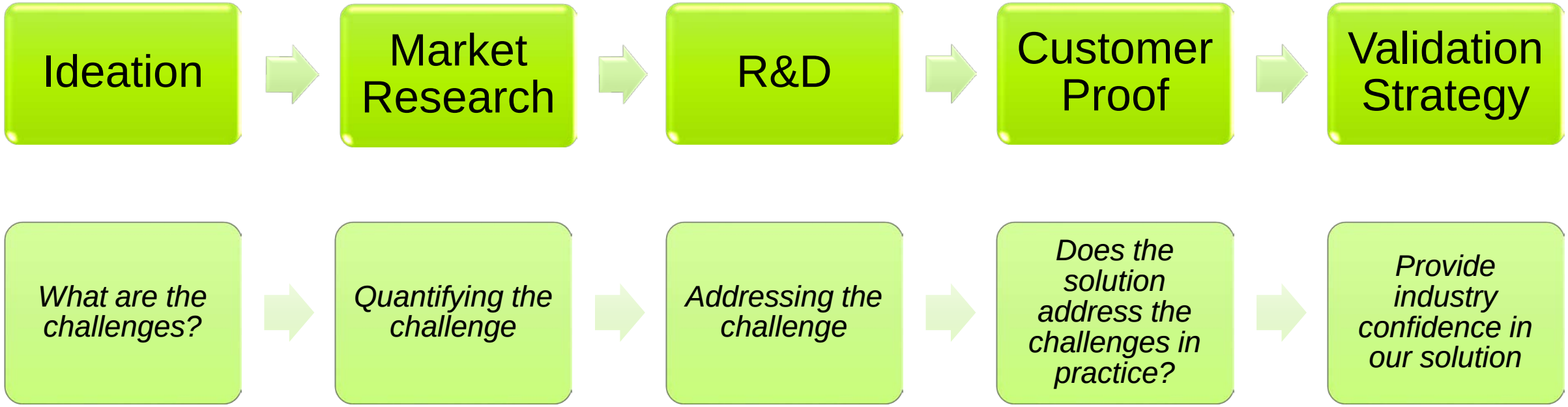
Hygiene Monitoring

3M™ Clean-Trace™
Hygiene Monitoring System

UHT Beverage Testing

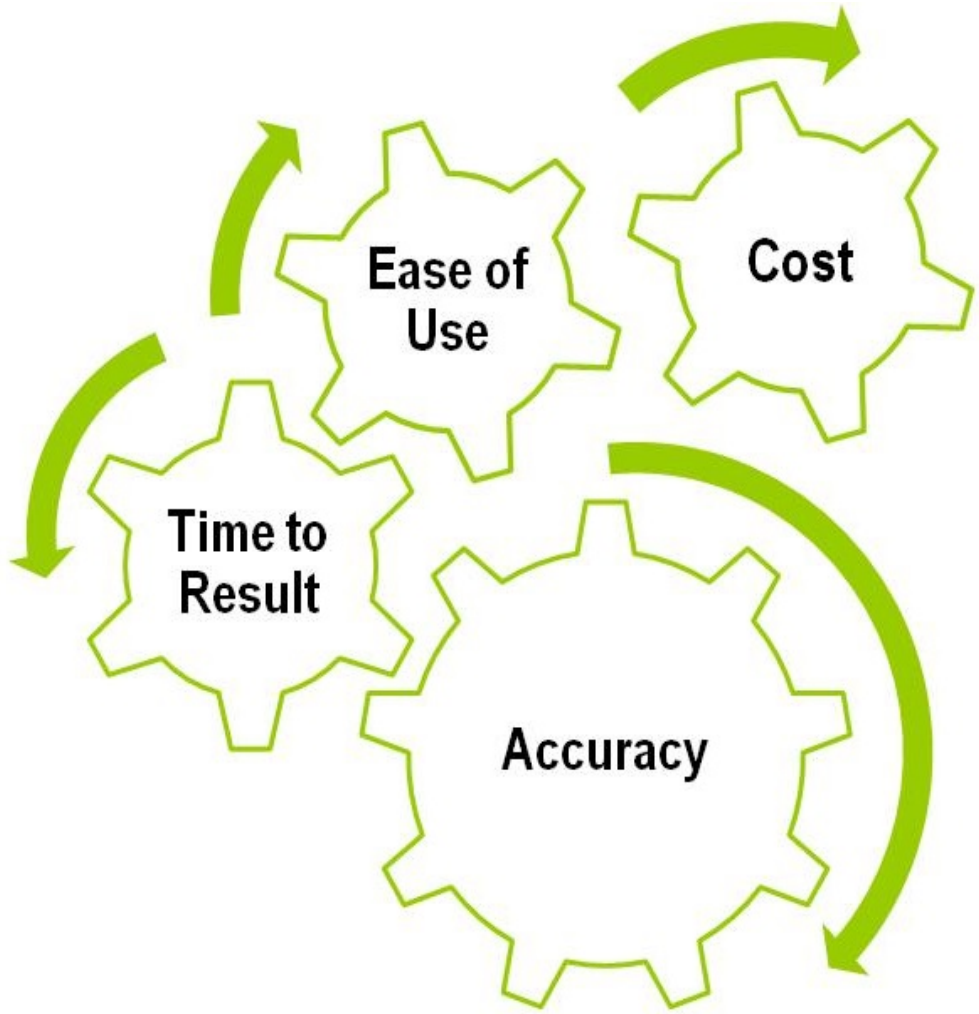
3M™ Microbial Luminescence System

3M Food Safety Innovation Philosophy: Customer



Ideation - What is the “purpose” of my method?

- Faster time to results
- Fewer false positives
- Easier to use
- Fewer transfer steps
- Industry acceptance
- Intuitive software
- Robust hardware



Market Research - Understanding the Customer & the Challenge

- Contracted market research surveys
- “Voice of Customer” exercises
- Consulting with industry experts

Which foods and matrices will I include in Validation?

- Depends on how many food industry segments can benefit from the method
- Depends on how those segments plan to apply the method

Example – Yeast & Mold

- Often used in dairy industry, environmental air sampling
- Not often assayed on environmental swabs/sponges

Example – *E. coli* O157

- Major concern for Beef, Produce, Juice, some Dairy
- Not often assayed on environmental swabs/sponges, but
- Carcass swabs

Which organizations to validate the alternative method?

- Depends on geographic distribution of customers who can benefit from method
- 3M often obtains multiple validations to serve a global food market
- 3M obtains “Inter-laboratory” studies to prove repeatability across labs

AOAC® INTERNATIONAL

- Most common in US
- US Regulators recognize
- Gaining traction globally
- Fewer matrices
- PTM and/or OMA

AFNOR/MicroVal

- Most common in EU
- EU regulators recognize
- Many more matrices
- MCS & ILS

European Union acceptance of alternative methods

EC No. 2073/2005 on microbiological criteria for foodstuff

Article 5:

- *The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.*

- *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.*

Code Federal Regulations acceptance of alternative method

USA

[**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—GENERAL

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.

Source: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=2.19

Test Manufacturer's Summary

"Fit for purpose" has a dual definition to test manufacturers

- Does the product solve a customer challenge and add value?
- Does the product work with a wide variety of foods?

The validation scheme and matrices studied are driven by customers

- "All Food" claim impossible
- Regulators place ownership of science-based decisions on the food producer

Validation/verification can be accomplished via collaboration

- Leverage your business with partners to improve product safety

Fit for Purpose Validation – A Food Manufacturer Perspective

- IAFP Applied Lab Methods PDG Webinar
- September 25, 2018

Larry Cohen
Corporate Principal Microbiologist
TreeHouse Foods, Oakbrook, IL

TreeHouse Foods, Inc.

- TreeHouse Foods is a private label food and beverage leader focused on customer brands and custom products. When customers partner with TreeHouse they can expect access to an industry-leading portfolio, strategic vision, on-trend innovation and insights, world-class supply chain, operational excellence and flexibility, collaborative approaches and dedicated customer service.

- TreeHouse Foods is best known for food and beverages produced by our two largest businesses Bay Valley Foods, LLC (including E.D. Smith and Flagstone Foods) and TreeHouse Private Brands. With more than 16,000 employees and a network of manufacturing facilities across the United States, Canada and Italy, TreeHouse Foods is based in Oak Brook, Illinois.

TreeHouse Foods portfolio includes Shelf Stable, Refrigerated &Snack Products, including:

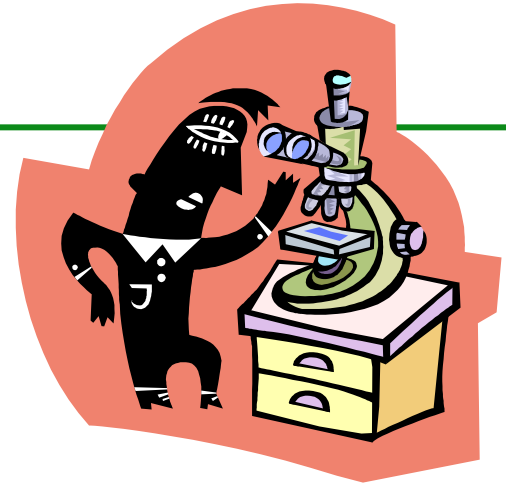
- **Baked Goods**
  Crackers, cookies, pretzels, candy, pita, refrigerated dough, griddle and in-store bakery
- **Beverages and beverage enhancers**
  Single serve beverages, coffee, tea, drink mixes, non-dairy creamers and smoothies
- **Condiments**
  Dressings, dips, gravies, jams, mayonnaise, pickles, salsa and aseptic cheese sauces
- **Healthy Snacks**
  Snack nuts, trail mixes, dried fruit and vegetables, and baking nuts
- **Meals**
  Dry dinners, macaroni and cheese, side dishes, hot and cold cereals, aseptic broths, pie filling and pudding

Microbiological Testing Applications

- Environmental pathogen testing programs
- Clean Equipment, Water, Air testing programs
- Finished product analysis (customer, product qualification, etc.)
- Incoming ingredient testing
- Pathogenic organisms – Species ID, Genetic Fingerprinting & Sequencing
- Spoilage organisms – Species ID, Genetic Fingerprinting & Sequencing
- Finished product challenge studies
- Process validation studies

Testing Locations

- In plant (limited, non-pathogens)
- Corporate Product Development (none)
- Contract Laboratories (majority)
- Non-pathogen, pathogen, analytical testing is performed for 48 THS plants across 3 contract lab service companies (20 laboratories) in 3 Countries.



Definition

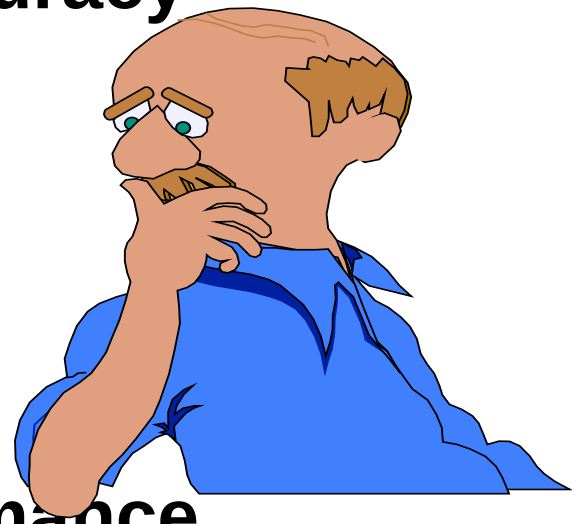
The operational techniques and activities that are used to fulfill requirements for quality. (*ISO 8402:1994*)

Procedures that ensure the quality of specific samples or batches of samples, which include:

- **Positive and negative test controls**
- **Participation in proficiency testing and ISO lab accreditation required**
- **Systematic checks on media, reagents and equipment**

Why Have a Lab QA Program

- **Ensure quality, reliability, consistency and accuracy of lab performance and data**
- **Establish lab credibility**
- **Provide defensibility and comparability of data**
- **Remove uncertainty and create defined performance standards and procedures**
- **Lab testing tools – analyses, calibration, maintenance, data management, training, monitoring**



Cont….

- **Reduce cost of poor quality performance. Increase efficiency (things are done right the first time)**
- **Ongoing Lab employee training and understanding of their job**
- **Improve protection to the business**
- **Partnership, Accountability, Empowerment and Technical Support**

Common Test Method References

- **ISO/IEC Standard 17025**
- **A2LA and FLAWG**
- **AOAC Compendium**
- **AOAC Official Methods of Analysis**
- **FDA/BAM; USDA; Health Canada; AFNOR; ISO Methods of Analysis**
- **Contract Lab Operating Methods and Internal Lab Methods. Include Trouble-shooting sections**

Lab Quality Assurance

- Corporate Food Safety & Microbiology requires testing by a specific validated method. Make science-based decisions
- Consider false positive and negative lab testing error rates
- Non-pathogen and Pathogen testing labs should participate in a proficiency testing program (AOAC, API, A2LA.)
- Ensure lab performance testing of media, reagents and equipment
- Lab environmental monitoring and traffic controls in place

Microbiological Test Methods – Fit for Use

- The different aspects of rapid pathogen test methods that are evaluated include:
- Ease of use
- Sensitivity
- Applicability – Product, Environment
- Accuracy and Reliability
- Time to detection & Time to results
- Threshold Testing / Inclusivity
- Cost per test – track annual volume
- Technical Support – Test equipment / kit provider

Testing the Rapid Tests

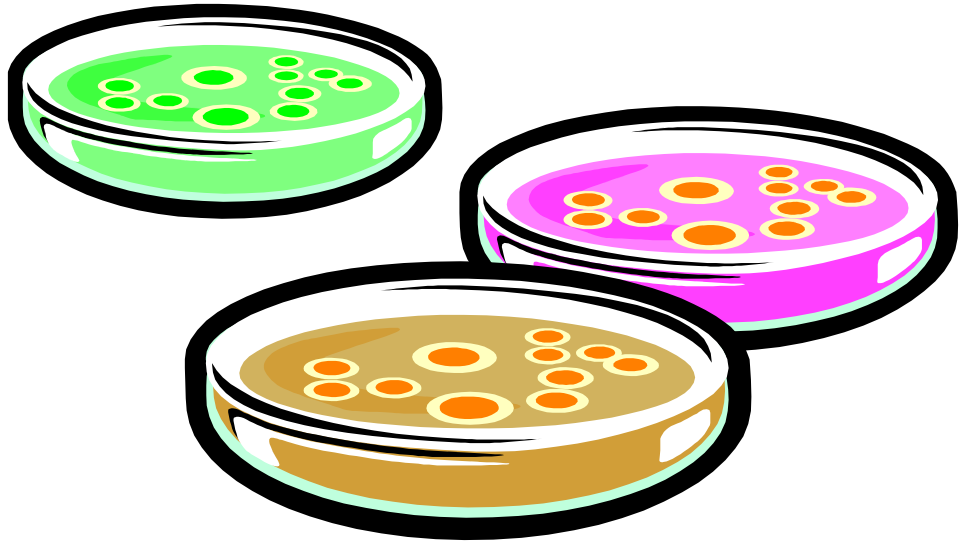
- **Why are rapid methods chosen for use in a laboratory?**
  - **Time to results**
  - **Applicability**
  - **Accuracy**
- **How is one method chosen over another?**
  - **Cost**
  - **Ease of use**
  - **Applicability**
  - **Accuracy**

Testing the Tests

- **How are applicability and accuracy assessed?**
  - **Method validation in various food matrices and environment**
  - **Method sensitivity and specificity**
    - **Rate of false positives and false negatives**

Method Error Rates

- Often used to choose one rapid method over another
- Important to consider that error rates are not only a measure of the method accuracy itself, but of the testing laboratory, sampling, and handling techniques involved in performing the method



Method Validation

- **Third party certification, i.e. AOAC, AFNOR, can be a good yardstick, but does not mean method is acceptable for your specific application**
- **Check comparison of rapid method vs. rapid method instead of only to standard cultural method**
- **Method and compositing scheme must be validated for its specific intended purpose using appropriate food matrices**

Split Sample Comparison of Qualitative Micro Tests

January, 2001 – July, 2003

	Salmonella False Positive Error Rate	Salmonella False Negative Error Rate	Listeria False Positive Error Rate	Listeria False Negative Error Rate
Participating Laboratories (Total No. Salmo = 802, ave 90 per quarter List = 549, ave. 69 per quarter)	**3.9%** (Range 0-17%)	**5.1%** (Range 0-28%)	**1.6%** (Range 0-10%)	**4.1%** (Range 0-21%)

Source: AOAC International Proficiency Sample Reports

Method Specific Error Rates

BAM Salmonella Cultural Method

AOAC Collaboratives		AOAC Proficiency	
False +	False -	False +	False –
0%	5.65%	4.3%	6.4%
	(Range 0-85%)	(Range 0-9%)	(Range 0-16%)

FDA or USDA Listeria Cultural Method

AOAC Collaboratives		AOAC Proficiency	
False +	False -	False +	False –
0%	15%	1.1%	4.5%
	(Range 0-55%)	(Range 0-5.3%)	(Range 0-21%)

What does all this mean?

- AOAC collaborative studies are an excellent tool to validate rapid methods against “gold standard” methods, but……
- They are only a starting point. Matrix effects must be taken into account, comparing to another rapid method and…
- <u>Any</u> method is only as good as the laboratory performing it!

To thine ownself…

- To get the best performance from any rapid method
  - Know your products and how well the method works with them
  - Know your laboratory, processes, and people
  - Know what's happening to your samples from beginning to end

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CHALLENGES OF PROVIDING "FIT FOR PURPOSE" METHODS IN A THIRD-PARTY LABORATORY.

J. David Legan, PhD.

September 25, 2018

DavidLegan@EurofinsUS.com

COVANCE

Covance Food Solutions is now
Eurofins Food Integrity & Innovation

CONTEXT FOR COMMENTARY

- High volume microbiology labs:
  - Madison, WI
  - Battle Creek, MI
  - Pathogen and spoilage tests on environmental and product samples
- "Projects" lab:
  - Livermore, CA (former National Food Lab)
  - Process validations and product challenge studies.
- **Opinions are mine (may not reflect Eurofins corporate view)**

“TESTING” RESPONSIBILITY UNDER FSMA

Simple, in principle:

“The owner, operator, or agent in charge of a facility must verify that their food safety preventive controls “are effectively and significantly preventing the occurrence of identified hazards”,

Boeing 747 right-seat controls by Olivier Cleynen. With permission CC-by-SA

WHAT IS “FIT FOR PURPOSE”?

- “…*degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose*” modified from ISO 16140
- Depends on **purpose**, elements of:
  - Sensitivity
  - Accuracy
  - Precision
  - Robustness
  - Reliability
  - Speed
  - Cost
  - Regulatory acceptance
  - Risk assessment: consequences arising from error
  - **Matrix**

Formal validation: AOAC, AFNOR, MicroVAL, NordVAL, etc.

Lab operations: verification,

QUESTIONS ARISING BECAUSE OF FSMA

- Customers ask about the validation status of microbiological test methods:
  - is method X validated?
  - is method X validated for matrix Y?
  - is method X validated for *my product*?
- Validations generated by diagnostics kit makers and certificated through AOAC, AFNOR, etc.
- Internal verification, matrix extension, validation.

FORMAL VALIDATIONS: AOAC

Eight food categories, plus environmental samples.

AOAC validations of commercial testing platforms for *Listeria*

Cat. #	Food type	1	2	3	4
1	Meat and Poultry	X	X	X	X
2	Fruits and Vegetables	X	X	X	X
3	Dairy Products	X	X	X	X
4	Egg Products			X	X
5	Miscellaneous Foods				
6	Seafood	X	X	X	X
7	Animal Feed				
8	Spices				
	Environmental samples	X	X	X	X

X – PTM X – OMA

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FORMAL VALIDATIONS: AOAC PRODUCT CATEGORIES

Zoom in: Meat and Poultry. 8 sub-categories.

Class (by water %)	Sub-category by protein % (P) and lipid % (L)	Examples
A < 20	None	Dehydrated beef, dehydrated broth
B 20-80	B1. P <10	Prepared foods, e.g. frozen entrees.
	B2. P 10-30, L10-30, cooked	Hot dogs, corned beef, meat patties
	B3. P 10-20, L 10-30, raw	Raw chick. beef, pork, ground beef
	B4. B3 marinated/spiced	Raw chicken, raw beef, raw pork
	B5. P10-35, L <10, cooked	Chicken drumstick, roast beef (cured, dried), beef brisket, lean.
C 80-90		Most soups, canned baby foods
D > 90		Most broth

FORMAL VALIDATIONS: AOAC PRODUCT CATEGORIES

Zoom in, Meat and Poultry: 8 sub-categories. *Listeria* spp

Class (by water %)	Sub-category	1	2	3	4
A < 20					
B 20-80	B1				
	B2.	X	X	X	
	B3.			X	X
	B4.	X			
	B5.	X		X	X
C 80-90					
D > 90					

FORMAL VALIDATIONS: AOAC PRODUCT CATEGORIES

AOAC sub-categories

Cat. #	Food type	Subcategories
1	Meat and Poultry	8
2	Fruits and Vegetables	18
3	Dairy Products	12
4	Egg Products	2
5	Miscellaneous Foods	11
6	Seafood	27
7	Animal Feed	8
8	Spices	6
	Subtotal	**92**
	Environmental samples	8
	Total	**100**

BACK TO CLIENT QUESTIONS

- Is this *Listeria* spp method validated? Yes.
- Is this *Listeria* spp method validated for meat and poultry? Yes
- Is this *Listeria* spp method validated for *my product*?

MicroSoft clip art: http://insertmedia.office.microsoft.com

HART (HEART) OF THE PROBLEM

- What do we know about the sample? Which are more similar?

HEART OF THE PROBLEM

- What do we know about the sample? Which are more similar?

Milk tablet. With permission whatmamidoing. CC-by-SA

Milk tablet = Dairy

Wheat flour. Anon. Public domain.

Flour = Miscellaneous

Milk powder. With permission projectmanhattan. CC-by-SA

Milk powder = Dairy

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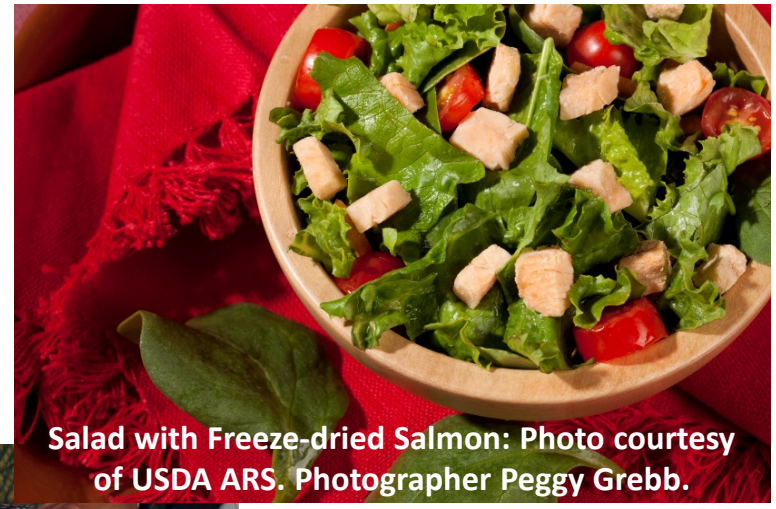
HEART OF THE PROBLEM

- What category does the product fit?


Supreme pizza. Photo courtesy of USDA-ARS. Photographer Scott Bauer.


Salad with Freeze-dried Salmon: Photo courtesy of USDA ARS. Photographer Peggy Grebb.


Fried crickets in a market in Cambodia. Photo by Thomas Schoch. With permission :CC-by-SA.

WHAT TO DO?

Basic

- Know
  - Customers and their matrices
  - Validation status of methods
    - Published
    - Diagnostic “proprietary”
    - Internal
- Be thorough when onboarding new customers
  - (customers, please don’t be irritated by questions)

Ongoing

- If unsure about an **unusual** sample, or test **purpose**, ask

WHAT TO DO?

Advanced: Verify or Validate method performance as needed / relevant

- Ideally with a risk-based approach:
  - Customer / end-user risk-assessment
    - Low-risk: Spike recovery (similar to USP Ch. 61 suitability test)
    - Medium risk: Matrix extension
    - High risk: Matrix extension or validation of LOD: AOAC “Appendix J”

- Alternatively with a cost-sensitivity approach
  - Number and likely frequency by sample type
    - Few samples, low frequency: Spike recovery (similar to USP preparatory test)
    - Moderate samples, Moderate frequency: Matrix extension
    - Many samples, high frequency: Matrix extension or validation of LOD

- If desired, customer-defined approach

CONCLUSION

- Nothing in microbiology is simple – hence assuring “fit for purpose” methods can be quite challenging:
  - Good communication is essential
  - Sometimes it takes a little while
  - We all want the same thing……

MicroSoft clip art http://insertmedia.office.microsoft.com



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Questions?

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