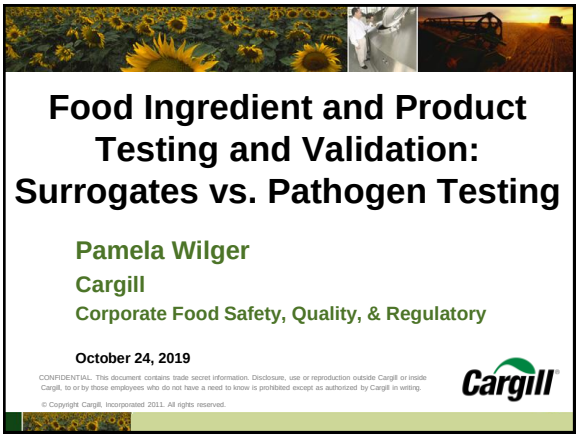
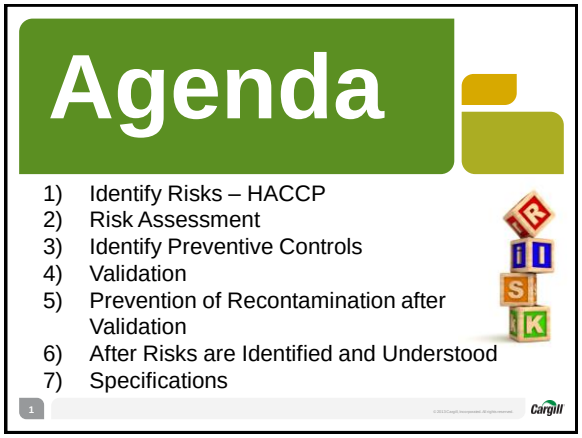
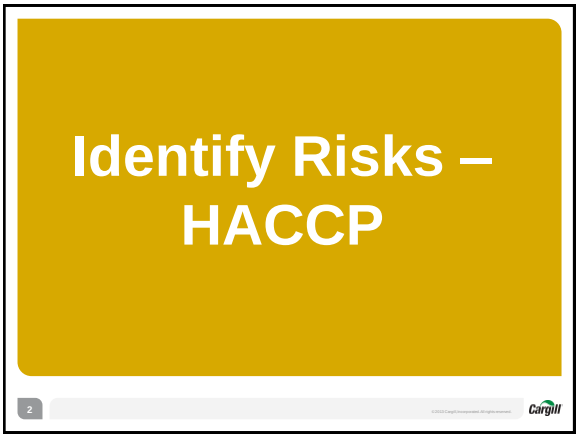
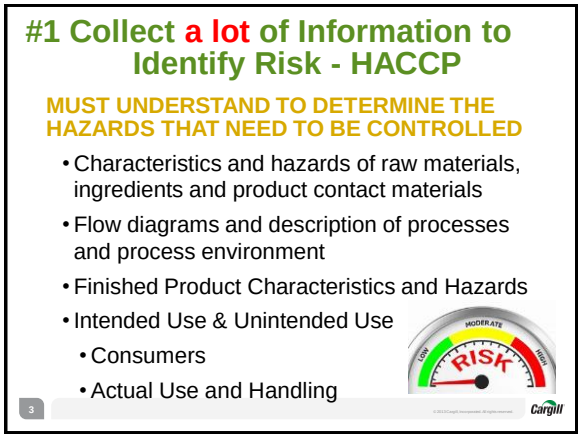

Food Ingredient and Product Testing and Validation: Surrogates vs. Pathogen Testing
Pamela Wilger
Cargill
Corporate Food Safety, Quality, & Regulatory
October 24, 2019
CONFIDENTIAL. This document contains trade secret information. Disclosure, use or reproduction outside Cargill or inside Cargill, to or by those employees who do not have a need to know is prohibited except as authorized by Cargill in writing.
© Copyright Cargill, Incorporated 2011. All rights reserved.
Cargill


Agenda
1) Identify Risks – HACCP
2) Risk Assessment
3) Identify Preventive Controls
4) Validation
5) Prevention of Recontamination after Validation
6) After Risks are Identified and Understood
7) Specifications
1


Identify Risks – HACCP
2


#1 Collect a lot of Information to Identify Risk - HACCP
MUST UNDERSTAND TO DETERMINE THE HAZARDS THAT NEED TO BE CONTROLLED
• Characteristics and hazards of raw materials, ingredients and product contact materials
• Flow diagrams and description of processes and process environment
• Finished Product Characteristics and Hazards
• Intended Use & Unintended Use
• Consumers
• Actual Use and Handling
LOW
MODERATE
HIGH
RISK
3


Identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment.
THE HAZARD IDENTIFICATION SHALL BE BASED ON:
a) the preliminary information and data collected
b) experience;
c) internal and external information including, to the extent possible, epidemiological, scientific and other historical data;
d) information from the food chain on food safety hazards related to the safety of the end products, intermediate products and the food at the time of consumption;
e) statutory, regulatory and customer requirements.
HAZARD
4


Risk Assessment
5

#2 Assess the Risk(s)

RISK = SEVERITY X LIKELIHOOD

- Severity is the Seriousness of Adverse HEALTH Effects in relation to the intended use
- Likelihood is the Probability of a Hazard to Occur in the end product prior to application of control measures
- Significant Risk
  - Is likely to happen and cause a serious health issue
  - MUST be controlled for prevention or reduction to an acceptable level

6

Risk = Severity X Likelihood			SEVERITY		
			Seriousness of Adverse HEALTH Effects		
			Low	Medium	High
		Definitions	Could Cause Limited Damage	Could Result in Serious Illness or Injury	Expected to Lead to Long Term Disability or Death
LIKELIHOOD	Remote	Can occur, has not occurred in the last 5 years	RL	RM	RH
Probability of a hazard to occur; time frame of a minimum 5 years experience from other Cargill relevant plants or industry if applicable	Low	Occurred less than 5 times in the last 5 years	LL	LM	LH
	Medium	Occurred 5-10 times in the last 5 years	ML	MM	MH
	High	Occurred more than 10 times in the last 5 years	HL	HM	HH

Risk Definitions/Keys:

Red identified risk hazards (HM, MH, HH) are considered significant and must be controlled by an OPRP or CCP (Use Cargill decision tree to determine which one, CCP or OPRP).

Red/Orange identified risk hazards (MM), the HACCP Team will justifiy if the hazard needs to be treated as a Red or Orange risk and handle accordingly.

Orange identified risk hazards (HL, LH) will be minimally controlled by generally verifiable focused measures such as good operation practices (Prerequisite Programmes or PRP).

Green identified risk hazards (RL, RM, RH, LL, LM, ML) are considered insignificant and are controlled by PRPs, if they happen.

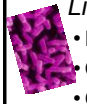
7

Identify Preventive Controls

8

#3 Identify Preventive Controls

- Based on the hazard risk assessment, appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified significant food safety hazards to defined acceptable levels will be identified.
- For Example to control Salmonella or *Listeria monocytogenes:*
  - Pasteurizer – Time or Flow and Temperature
  - Oven – Time and Temperature and Moisture
  - Chemical Wash – Concentration and Time



9

Define Preventive Controls

INCLUDE AN ASSESSMENT OF THE FEASIBILITY OF FOR EACH CONTROL MEASURE:

a) establishing measurable critical limits and/or measurable/observable action criteria;

b) monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria;

c) applying timely corrections in case of failure.

Testing can be done here:

- ➢Monitor/Measure all of these parameters
- ➢Verify control with finished product testing

10

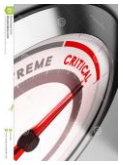
Validation

11

#4 Validation = Will it Work

VALIDATE THAT THE SELECTED CONTROL MEASURE(S) IS CAPABLE OF ACHIEVING THE INTENDED CONTROL OF THE SIGNIFICANT FOOD SAFETY HAZARD(S).

- Critical limits and action criteria shall be based on
  - scientific literature
  - government regulations
  - laboratory/pilot-plant experiments
  - or in-plant studies
- Critical limits and action criteria shall not be confused with operational limits that are established for reasons other than for food safety



12

Looking at a process…

DO YOU KNOW YOUR PROCESS??

Is it…

- **Described:** Operational Procedures & Limits
- **Controlled:** Operational Limits are met (includes reliable measurements and corrective actions)
- **Reproducible:** Trend Analysis shows no drift

Which parameters need to be considered to control a given hazard?

- Moisture (Steam, Water additions)
- Time (Speed, Type of material flow–laminar – turbulent)
- Temperature (even distribution/ cold spots)
- Pressure / Gas / Irradiation
- Weight and potential others (instrument specific)

13

Process Validation Preparation

- Ensure that critical parameters established by scientific studies are applicable for the process
- Evaluate process variability with respect to critical parameters, e.g. unevenness of roasting, cold spots in equipment
- Define allowable difference(s) in process / equipment
- In case of major differences review whole process with engineering and adapt parameters
- Ensure to run equipment under critical conditions
- Ensure that critical parameters are being monitored in the product/material being processed
- Record important material characteristics, e.g. in-going temperature, moisture before and after processing
- Consider tolerance of measuring devices used at treatment conditions
- Ensure all devices used for measuring are calibrated and work within defined tolerances

14

Looking at process and product…

Even under variable conditions the process shall control the biological hazard. Therefore, variabilities of conditions need to be taken into account such as:

PROCESS VARIABLES, E.G. :

- ✓ CONTROL OF STARTUP & END OF RUN
- ✓ TIME
- ✓ TEMPERATURES/ TEMPERATURE DISTRIBUTION
- ✓ MOISTURE
- ✓ MIXING EFFICIENCY (SURFACE EXPOSURE)
- ✓ WEIGHT
- ✓ DIVERT/SHUTDOWN FEATURES/ALARM SETTINGS

PRODUCT VARIABLES, E.G. :

- ✓ FAT / SUGAR / SALT / PROTEIN
- ✓ WATER CONTENT
- ✓ SIZES / DENSITY
- ✓ TEMPERATURE
- ✓ PRESEVATIVES
- ✓ pH
- ✓ INITIAL FORM (e.g. raw or pre-processed)
- ✓ FINAL FORM (e.g. pieces, whole, pastes)

15

Looking at process and product…

- Which biological hazards are considered significant and must be addressed / controlled in the process? (HACCP)
- Leads to the **target pathogen(s)** to be controlled by the process
- "Target pathogen" referring to the organism(s) which express the highest resistance to the treatment / process used, and thereby controlling those would enable control of others.
- Are prevalence data known for the target organism(s), i.e. levels / likelihood of occurrence?
- Is there a **surrogate** available which could be used in the industrial process?
- "Surrogate" referring to a non-pathogenic organism, which behaves equivalent/similar to the target pathogen in the matrix and process.

16

Usage of Surrogate Microorganisms

CRITERIA FOR SELECTION OF AN "IDEAL" SURROGATE:

- Stable and consistent growth characteristics
- Easy to cultivate to high populations
- High populations remain stable until utilized
- Easy and inexpensive to enumerate
- Easy to differentiate from other microbes
- Behave (minimum) like target microorganism at processing conditions, e.g. resistance to processing conditions is at least the same as for the target pathogen considered in the same matrix
- Does not introduce a risk (spoilage or safety) to facility

See also: M. Hu and J.B. Gurtler(2017) "Selection of Surrogate Bacteria for use in food safety challenge studies: A Review" JFP 80(9): 1506-1536.

17

Usage of Surrogate Microorganisms

PREWORK FOR USING THE SURROGATE FOR PROCESS VALIDATION:

- Run a study showing the surrogate is as resistant as the pathogen being studied in the matrix being studied e.g. D- and Z-values
- Ensure that product characteristics are not changed when inoculated with the surrogate, e.g. increase in moisture
- Demonstrate the stability of the process resistance of surrogate over time – needs to be repeated for each validation if in liquid form
- Write the procedure for the application techniques used to inoculate the food product
- Determine if adaptation of the surrogate prior to validation is needed
- Write procedures for culturing and harvesting techniques, as well as recovery post process
- Consider variability of method of detection, think about recovery of injured cells
- Describe the experimental controls


18

Usage of Surrogate Microorganisms

Advantages

- Direct reading of lethal step effectiveness (log-reductions achieved)
- Validation data based on inoculated material
- No quality or safety risk to the facility

Disadvantages

- Requires microbiological laboratory, external services, and experts
- Requires specific controls to be put in place
- Resistance (e.g. Heat) of the organism has to be confirmed with pathogen in question in the same matrix
- The inoculated material needs to be confined for testing

19

Validation Report

SHALL INCLUDE (OR REFERENCE):

- Hazard Analysis
- Process Description
- Product Description
- Experimental Design
- Study Results
- Conclusions (final outcome, summary, recommendations, design of future monitoring, alarms, corrective actions
- Contributors (Experts involved)

- The report shall be available at the site(s) as part of their Food Safety Management System.

20

Prevention of Recontamination after Validation

21

#5 Prevention of Recontamination after Validation

MANY ARE PREREQUISITE PROGRAMS (PRPS)

Drives the Design, Implementation, and Culture of the Workers

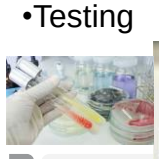
- Facility and Equipment Design
  - ➢Zoning of people and processes
- Cleaning and Sanitation
- Personal Hygiene and Behaviors
- Air, Water, & Waste
- Packaging and/or Transportation
- Rework

22

How Do We Measure These PRPs

- Audits
- Swabbing the people, equipment and environment for indicators or pathogens

- Testing



23

Environmental Monitoring Decision Tree

1) Perform Risk Assessment of Hazards see Appendix A

2)

Is there a microbiological hazard identified for the product and intended use which needs to be controlled by a CCP or OPRP in this facility?

NO → No EMP or Only Indicator EMP at select sites is needed

E.g. Salt, Oils, Some Starches, Malt, Some Sweeteners, some Lecithin, Some Corn Products, Citric Acid, Glucosamine, Some Feed Products

YES → EMP is needed - could be for pathogen(s) and/or indicators

E.g. Cocoa, Chocolate, Texturizers, Soy Flour, Extruded Soy, Some Sweeteners, Eggs, RTE Beef, RTE Poultry, Pet Food and Treats, Meal, Some Starches, Some Lecithin, Some Corn Products, Tallow/Lard, Sauces

24

Use Of Indicators or Index Organisms for EMP

- Gives more options such as testing Zone 1 (Product Contact surfaces) and not causing a situation with the products, e.g. testing for Listeria species (Index organism) instead of *Listeria monocytogenes* or Enterobacteriaceae (Indicator organism) instead of Salmonella
  - In contrast to "indicator organisms," organisms whose presence (or detection above a threshold) actually suggest an increased risk for the presence of an ecologically similar pathogen are referred to as "index organisms."
- Tells more of the bigger picture of the true microbial hygiene in the facility or equipment
- Allows us to be more proactive since the data is more than a positive or negative

25

After Risks are Identified and Understood

26

#6 After Risks are Identified and Understood…

- Microbiological Product Risk Assessments can be written and used to educate others on the microbiological risks of the product(s)
- Valuable and Proper Microbial Specifications can be determined
- Monitoring System for each control measure (who, what, when and how) can be established
- Corrective Actions can be established
- Verification Procedures can be established
- Documentation and Record Keeping can be established

27

RISK THINKING

IDENTIFY > ASSESS > MITIGATE RISKS ALL THE TIME

Microbiological Product Risk Assessments include:

- Microbiological Hazards from the Hazard Analysis performed for each product and process
- Physical and functional characteristics of the raw materials, finished products, packaging or transport, and processes
- Scientifically published studies on the microbiological ecology of our ingredients, products, and processes
- Results of microbiological and/or challenge tests performed internally or externally on the products and/or processes
- Historical test data from our production channels including environmental monitoring data, if available
- Knowledge and Approval of our suppliers and service providers.

28

Specifications

29

#7 Specifications
Ingredient and Finished Product Testing

LET ALL YOUR HARD WORK GUIDE YOU

- Based on all the information collected in the above exercises and programs the testing of what to look for, how much, and how often can be defined.
- Trend data to drive changes and improvements
- Based on the Microbiological Risk Assessments completed we no longer test every lot of ingredients nor finished products
- Testing can comfortably be rationalized to focus on the process and environmental monitoring

30 Cargill

Finished Product Testing

Does the Data Guide me in My Decisions?

Pathogens versus Indicators

PATHOGENS

- ✓ Are specific
- ✓ Another verification of the controls in place to make safe product.
- ✓ Is NOT a guarantee of safe product!!!!!
- ✓ Typically Qualitative so not able to react proactively

INDICATORS

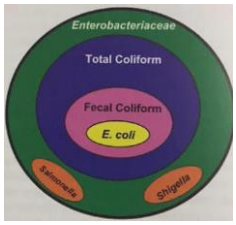
- ✓ INDICATE SOMETHING SUCH AS SANITATION WORKED OR THE ENVIRONMENT IS IN CONTROL
- ✓ IS TYPICALLY A QUANTITATIVE RESULT SO THE DATA CAN BE TRENDED AND ANALYZED MORE PROACTIVELY

31 Cargill

Gram Negative Enterics

Only Total Enterobacteriaceae (EB) Testing includes Salmonella

- **Total EB testing is typically used outside of the US – Used more today globally**
- **Total EB is more inclusive when looking at hygiene as well as focusing on Salmonella**
- **Generic *E. coli* is very targeted and does not include any pathogenic *E. coli***
- **Coliform testing as well as Fecal *E. coli* is a carry over from ground water testing**



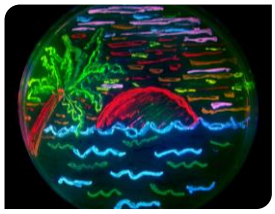
32 Cargill

In Summary

- **HACCP and all the preliminary information is needed to set valuable microbial specifications and controls**
- **Validation is more meaningful today with the use of appropriate surrogates**
- **EMP is a verification for preventing contamination after the "kill step" and cleaning & sanitation was done correctly**
- **Indicators and/or Index Organisms are very valuable when used correctly**

33 Cargill

THANK YOU!



QUESTIONS?

34 Cargill