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Can Environmental Monitoring Coupled with Finished Product Testing Validate Adequacy of Food Safety Control Programs for Continuous Low Moisture Process???

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Disclaimer

The following presentation represents my personal evaluation of the science and issues associated with this food safety question

Biases

- Microbiological testing is almost always an important component of any integrated program to assure the safety of foods
- Strong advocate for overtly describing the risk mitigation achieved by microbiological testing programs

Complex Question

- Scientific Basis
- Regulatory Basis
- Food Safety Goals and Expectations
- Food Safety Capabilities
- Intended Use of the Product
- Actual Use of the Product

Complex Question

- Dry products include a wide variety of foods and ingredients
  - Powders (flour, cake mixes, powdered infant formula, salt, spices)
  - Nuts, seeds, beans (peanuts, lentils, soybeans)
  - Pastes (peanut butter, cookie dough)
  - Candy and Jellies
  - Dry pet food
  - Dried meat, fish, and dairy products

Characteristics of Product

- Ready-to-eat vs. raw ingredient?
- Production includes an effective inactivation treatment?
- Degree of manipulation and handling after an inactivation treatment?
- Presence of other parameters (e.g., pH, fat content) that influence microbial survival?

Characteristics of Product

- Products that receive a treatment that effectively eliminate pathogens become contaminated due to reintroduction of pathogens
- This type of contamination has traditionally been considered by regulatory agencies as “preventable”

Intended Use of Products

- RTE food have traditionally been held to a higher level of control , i.e., expected to be pathogen free
- Difficult to achieve if there is no effective microbial inactivation step during manufacturing
- Non-RTE foods are increasing held to a higher level of control if hazards are reasonably preventable

Actual Use of Products

- Need to consider how dried foods and ingredients are actually being used by consumers
- Example: Flour
  - Traditional to assume that it is an ingredient that will be cooked
  - However, a substantial amount is used for dusting and other applications
- Example: Cookie dough, cake mixes

Scientific Issues

What to Test???

- Analyzing for indicators vs. pathogen
- Using an “indicator” organisms vs. an “index” organism
- Correlation between pathogen and indicator
- Source of pathogens

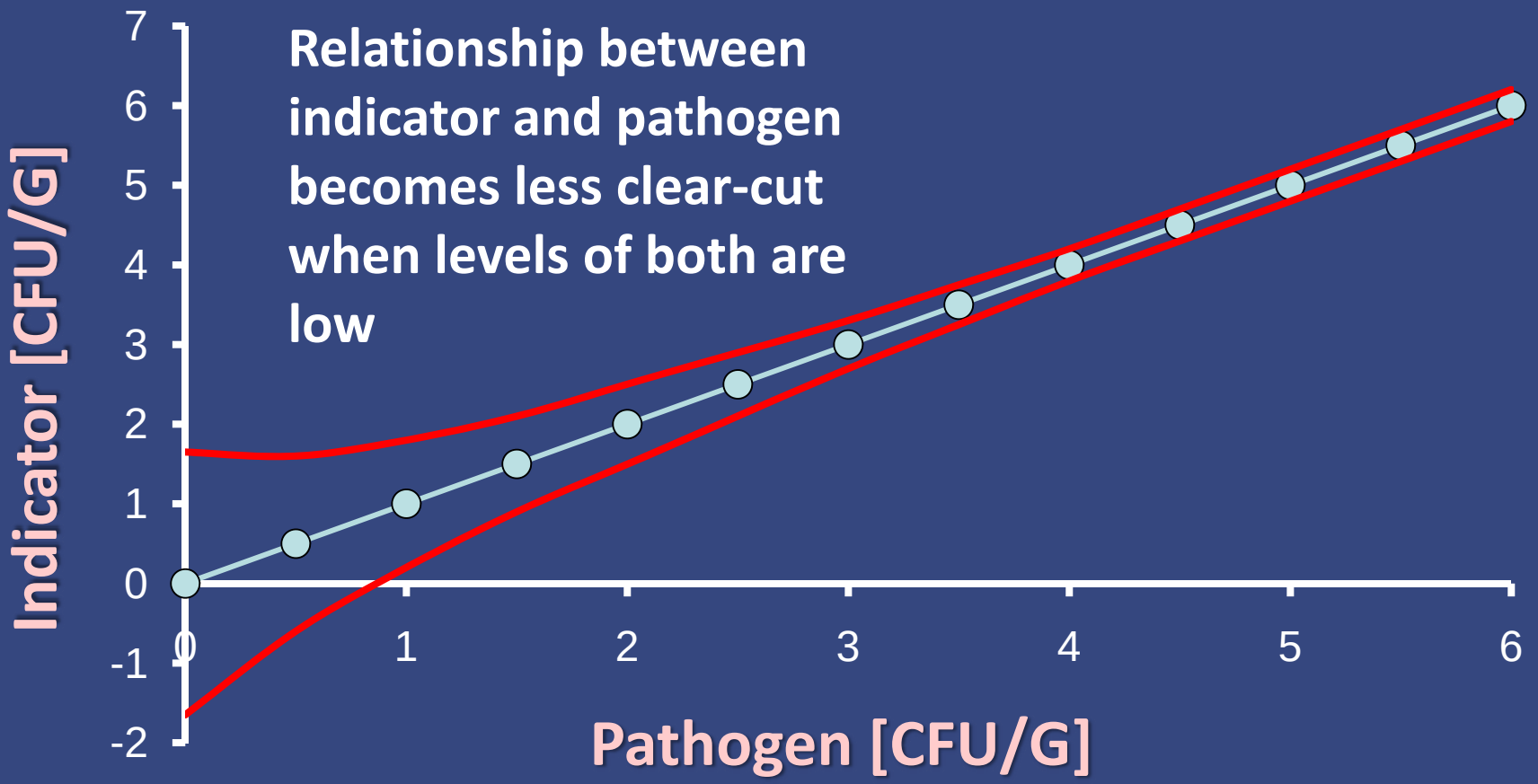
Indicators vs. Pathogen

- If pathogen in environment and food
  - Easiest to interpret
  - Adulterated if find in RTE food
- If indicator in environment and pathogen in food**
  - Need to establish relationship between the two
- Indicator in food and environment*
  - Need to demonstrated that indicator is predictor of pathogen or condition indicative of control

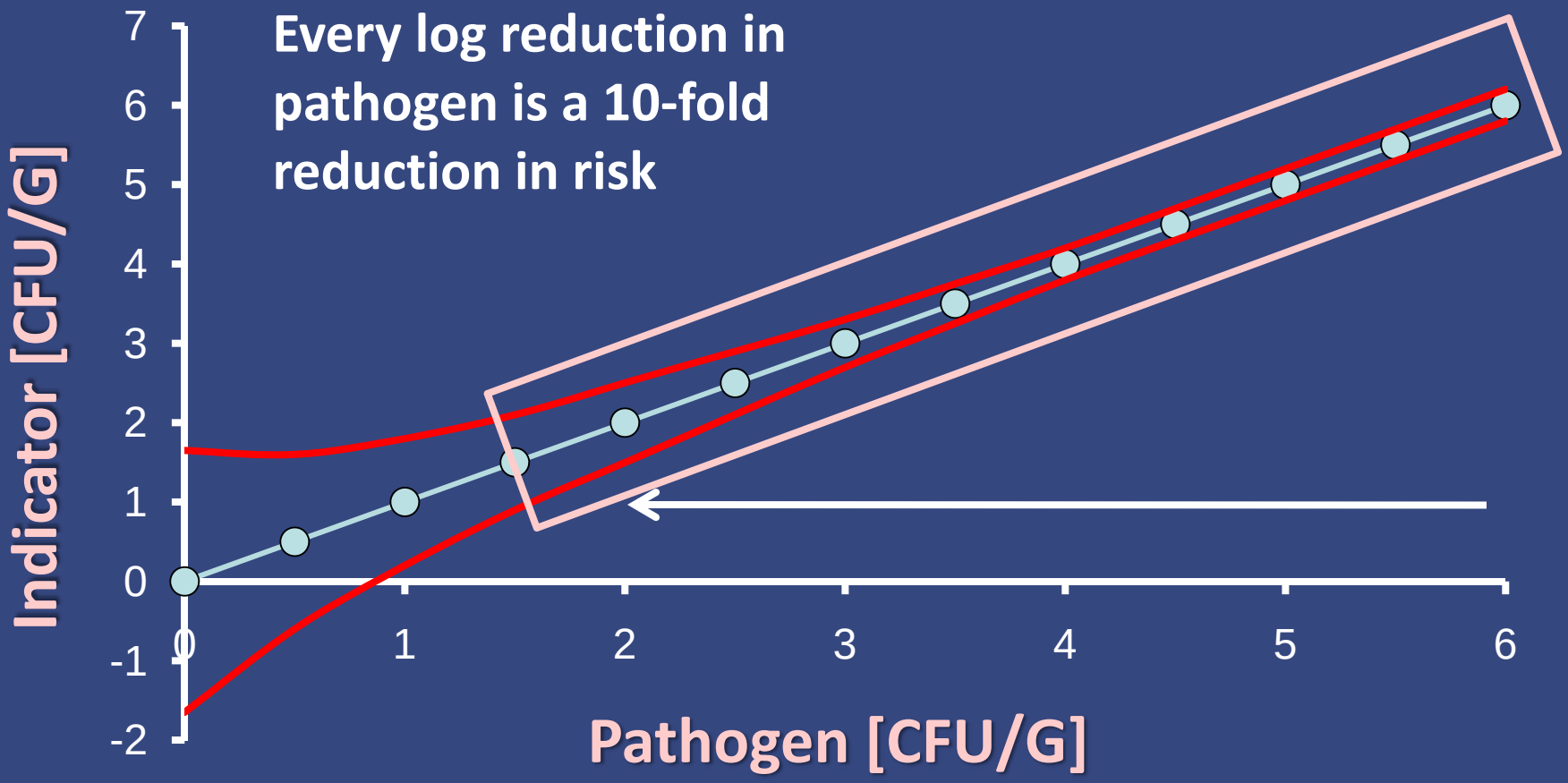
Indicators vs. Index Microorganisms

- "Index" Microorganism
  - Direct predictor of the presence of pathogen
  - Example: *Enterobacteriaceae* as predictor of *Salmonella*
  - Historically has not worked well
- "Indicator" Microorganism*
  - Indicator of a condition associated with increased risk of pathogen
  - Examples: *E. coli* as indicator of fecal contamination, *Enterobacteriaceae* as indicator of sanitation
  - History of being reasonably successful

Regression Confidence Intervals



Regression Confidence Intervals



How Much Testing

- Need to make pragmatic, informed decisions concerning on the stringency of testing
  - Number of samples
  - Size of samples
  - Frequency of testing
- Since cannot sample every serving, introduce uncertainty

How Much Testing Is Enough?

Sample Size (g)	n	c	σ	Mean Level (Log(CFU/g) for 50% acceptance	Expressed as amount of food that contains one pathogen (g)
10 g	5	0	0.5	-2.08	120
25 g	5	0	0.5	-2.48	302
100 g	5	0	0.5	-3.08	1202
500 g	5	0	0.5	-3.78	6026
1000 g	5	0	0.5	-4.08	12,023

What Kind of Testing

- Lot-by-lot (test and release) testing
  - Most rigorous but most expense
  - Most often used with pathogens
- Less than lot-by-lot testing for verification
- Process control testing
  - Assumes control measures are in place and testing is to verify and correct before limit passed
  - Used most effectively with indicators

Identification of Contaminants

- Simply isolating a microorganism may not be enough
  - Flour with occasional *Salmonella* isolates of mixed genetic fingerprints – chance contamination during cultivation and harvest
  - Flour with occasional *Salmonella* isolates predominately of a single genotype – likely harborage site or re-occurring source within facility

The Question

Can Environmental Monitoring Coupled with Finished Product Testing Validate Adequacy of Food Safety Control Programs for Continuous Low Moisture Process???

The Answer

- Yes, but it is going to require the regulatory agencies to work with industry, academia, consumers, and other interested parties to establish pragmatic expectations and performance criteria

What Would It Look Like????

What Would It Look Like?

- Need to establish a common approach for all dry products to establish a "level playing field"

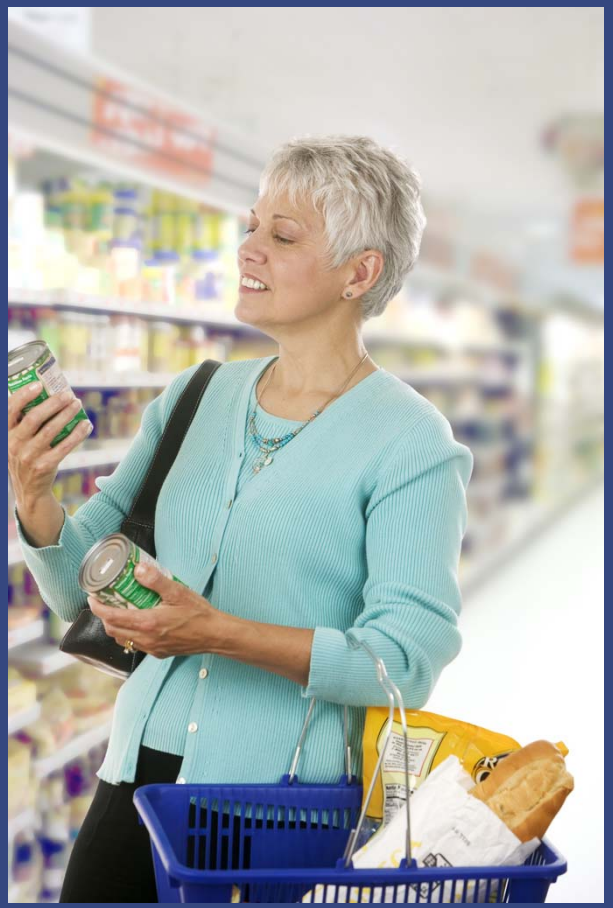
- Need to establish commodity specific standards to make it practical

What Would It Look Like?

- Stringency based on class of food?
  - RTE foods that receive a lethal treatment
  - RTE foods that do not receive a lethal treatment
  - Non-RTE foods

What Would It Look Like?

- Means for ensuring that consumers understand which type they are buying and the level of control that they can expect
- Labeling?



What Would It Look Like?

- Stringency required cannot be absolute but reflect what can be reasonably expected from well run Good Manufacturing Practices and HACCP programs

What Would It Look Like?

- Stringency needs to be clearly articulated in definitive terms so system is "predictable"
- All parties need to know and understand the required level of performance their system must deliver to establish lots sizes or durations

What Would It Look Like?

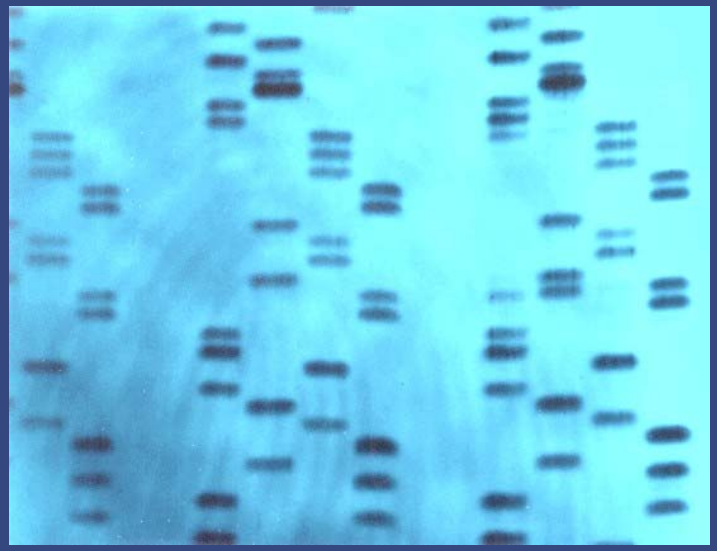
- Establish quantitative standards and standard methods that articulate overtly the degree of control achieved for acceptable level of control for both environment and finished product
  - Indicators for environments
  - Indicators and pathogens for finished product
  - Consider increased sampling if indicators exceeded
  - Consider process control testing approaches

What Would It Look Like?

- No re-work!!!!
- Good records that can be easily accessed

What Would It Look Like?

- Periodic "fingerprinting" of isolates to ensure that contamination is not due to a systemic problem within the facility



Regulatory Vehicles???

- Environmental Testing: FFDCA 401a4 [[21 USC 341]
  - Help define manufacturing conditions under which food would be considered adulterated
- Environmental and Product Testing: GMPs [21 CFR 110]
  - Help establish scientifically sound performance standards for enforcing GMPs
- Product Testing: Sec. 406. [21 USC 346] Tolerances for Poisonous Ingredients in Food
  - Help define the current level of microbiological control that current food technologies are capable of delivering

Concluding Remark

- Assuming that the Senate passes S510 and it is reconciled with HR2749, this is a great opportunity to get the science right
- Overtly deal with the basic risk-based concepts that are now covertly discussed in our current hazards-based food safety system