The Common Sense Role for Testing in FSMA

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When does testing make sense?

Preliminary to Testing

- Decide whether testing is even the right thing to do
- Understand the implications of an unexpected finding. Have a plan in place for managing affected product

Do the Right Testing

- Hazard analysis
- Risk assessment
- Test for the correct target
- Use the best method
- Use the best lab

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Finished Product Testing

- “End product testing may be used for lot acceptance when there is insufficient process or testing information available from which to evaluate product safety or utility.”

- “Similarly, for products in which no effective CCP is currently available and there is no other means of assessing product integrity, end product testing may offer the only alternative.”

ICMSF Book 8, Chapter 1, “Utility of Microbiological Testing for Safety and Quality”
Examples – Finished Product Testing - Good

- Fresh produce
  - GAP’s and GMP’s, several potential pathogen reduction steps but no definitive CCP, no consumer kill step
- Unpasteurized milk
  - Same as above
- Raw ground beef
  - Same as above, except there is an imperfectly-controlled consumer kill step
Examples – Finished Product Testing - Bad

- Raw ingredients where a validated CCP will occur later (it is important to understand intended use)
  - Wheat flour
  - Starches
  - Gums
  - Emulsifiers
  - Raw meat and poultry going to commercial establishments

- Ingredients that are antimicrobial
  - Citric acid
  - Salt
  - High fructose corn syrup
  - Mayonnaise

- RTE products that have a validated CCP with minimal exposure to the environment between the CCP and consumption
  - Pasteurized milk
  - Refined vegetable oil
The Role of Environmental Monitoring

• If there is a potential for the post-CCP environment to contaminate product before consumption, it makes sense to have an appropriate EMP in place.

• In general, *Listeria* spp. monitoring makes sense in cool, moist environments where perishable RTE products are being produced.

• In general, *Salmonella* monitoring makes sense in dry, ambient temperature environments where RTE products are being produced.
Why Don’t We Just Test More?

- False sense of security
  - Pathogens are not homogeneously distributed, especially in dry products
  - Pathogen testing is destructive, it is not possible or practical to sample 100% of the product
  - Statistical limitations of sampling

*ICMSF Book 7, Chapter 9, “Tightened, Reduce, and Investigational Sampling”*
Why Don’t We Just Test More?

• Implications of finding a positive
  – Many food manufacturing operations, especially those producing dry products, have no sanitary break point
    • A positive adulterant sample doesn’t necessarily pose a public health impact
    • HVP rolling recall scenario
  – The only practical way to sanitize a food manufacturing system to a microbiological level is through wet cleaning and sanitizing
    • Moisture is the enemy in a dry process, many plants are not designed to be wet cleaned, adding moisture can cause an explosion of Salmonella
  – Labs make mistakes – if there is no way to prove a lab error, the result stands
Summary

- Product testing and environmental monitoring must be developed on a product by product and plant by plant basis.

- A Hazard Analysis must be conducted to determine the true public health risks and the best way to mitigate those risks.

- Product testing and environmental monitoring are useful in certain situations, but one size does not fit all.

- Non science-based testing can lead to:
  - Conflicts between suppliers and customers
  - Conflicts between manufacturers and regulators
  - Destruction of wholesome product
  - Increasing the cost of food (reducing food security) with no public health benefit
  - Misdirection of resources that could be better used in other ways to reduce risks
  - Little boys crying wolf