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Legal Considerations: Negligence for not Testing vs. Liability with False Positives

Managing Microbiological Testing as a Preventive Control Verification – Institute for Food Safety and Health & Food Research Institute Conference

October 24, 2019

Maile Gradison Hermida

Agenda

- Legal Requirements and FDA's Access to Testing Records
- Positive Results: Now What?
 - False Positives?
 - The Role of Testing Under Legal Privilege
- Impacts from Whole Genome Sequencing
- Case Studies
- Risk Mitigation Strategies



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Is this an Impossible Choice?

Option 1: Test and Get (Potentially False) Positives

Option 2: Don't Test



"C'mon, c'mon – it's either one or the other."

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If you have one takeaway

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Legal Framework – Key Points

- Federal Food Drug and Cosmetic Act (FFDCA) prohibition on adulterated food
 - Food can be adulterated several ways; two are most relevant
 - It contains a contaminant
 - It was produced under insanitary conditions
- Reportable Food Registry (RFR)
 - Report within 24 hours of when a responsible party "determines" food presents a "reasonable probability" of SAHCODHA



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Statutory and Regulatory Framework

- FFDCA § 402(a)(1) – Food is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health
- FFDCA § 402(a)(4) – Food is adulterated if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or been rendered injurious to health
- Multiple provisions in the cGMPs are designed to protect food from contamination
- 21 CFR § 117.130(c)(1)(ii) – Hazard analysis must include an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging
 - There is a presumption that you will have sanitation controls and environmental monitoring in these cases
- 21 CFR § 117.165(a) – Verification activities must include, as appropriate, product testing and written environmental monitoring, if contamination of an RTE food with an environmental pathogen is a hazard requiring a preventive control
- 21 CFR § 117.150(a)(1) – Must establish and implement corrective actions procedures to respond to testing results

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Records Access

- FSMA significantly expanded FDA's access to records during a routine facility inspection
- This expanded records access takes effect as of your compliance date for the Preventive Controls regulation

Essential Records Under the PC Rules	
Food Safety Plan	Corrective Action Procedures and Records
- Hazard Analysis (and re-analysis)	Verification Activities
- cGMPs	- Environmental and Product Testing Procedures and Results
- Sanitation Controls	Supplier Verification Plan and Implementation Activities
- Allergen Controls	Food Defense Plan and Implementation Activities
- Process Controls	Sanitary Transportation Procedures
Validation Data for Process Controls	Recall Plan and Related Records
Monitoring	

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Beware These Pitfalls

- "This is an outlier"
- "We always get a positive when we start the machine, then it goes away"
- "It must be lab error"
- "We've never had a recall in the history of our company"
- "All our ingredients have COAs"
- "Our finished product tested negative"
- "No one will get hurt"

Ignoring the problem won't make it go away

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Why Is This Important?

- Critical to catch potential contamination early and respond appropriately
- First Zone 1 or product positive shouldn't be a surprise
- Can limit potential damage
- Many foodborne illness outbreaks and recalls are exacerbated by not responding quickly to the first indication
 - A small recall is better than a big recall
 - One big recall may be better than a lot of smaller recalls
- DOJ criminal investigations often focus on ignored warning signals
- Established environmental harborages are extremely difficult to eradicate and very costly
- False positives are the exception, not the norm

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General Response Framework

- Understand the results
- Assemble your team
- Initial Decisions
- Investigation
- Final Decisions/Disposition
- Corrective Actions and Documentation



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Understand the results

- Zone 1, Product, or Ingredient
- Zone 2-4
- Pathogen?

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Assemble Your Team

- Internal QA/Micro/Food Safety
- Consultants
- Laboratory
- Legal
- Communications/PR
- Sales, Marketing, Logistics



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Initial Decisions

- Is required action obvious, or is more investigation reasonably required?
- If more investigation needed, consider:
 - Inventory/ingredient hold
 - Equipment hold
- If a recall and/or RFR report are necessary, involve key team members:
 - QA/Regulatory/Food Safety
 - Legal
 - Communications
- Are you equipped to investigate?
 - Preserve environment?

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Investigation

- Determine objective(s)
 - Root cause
 - Bookending a contamination event
 - Ingredient traceback
- Root cause investigation
 - “True” root cause
- What existing testing data can be used?



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Decide on Final Action

- Is a recall necessary?
- Notification to regulators?
- Public communications?
- Customer communications?
- Disposition of on-hand product?
- Remediation?



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Corrective Actions and Documentation

- Take steps to remediate the true source of the problem
 - Don't want to do this again in a month
 - Equipment changes?
 - Facility improvements?
 - Ingredient changes?
 - Testing protocols?
- Understand what your procedures call for, especially documentation
- Document thoughtfully
 - Procedures
 - Outside parties

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What About the Risk of False Positives?

- May 2013 report issued by the American Proficiency Institute found that during the past 14 years, participating labs had a false positive rate of 3.9% for Salmonella (and a false negative rate of 4.9% for Salmonella)
- Train your team on appropriate sampling techniques
 - E.g., Excess debris in the sample?
- Track and trend results to look for anomalies that cannot be tied to a root cause
- Use a reputable test method and lab
 - If you think there is a false positive from an inside lab, use an external lab for confirmatory testing → impact: time = \$

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What About the Risk of False Positives?

- Push the lab to investigate
 - New personnel conducting the testing? Equipment/instrument problems?
 - Cross-contamination from other products with the same findings at the same time?
- Document your conclusions and reasoning
 - Be prepared to justify your determination to FDA
- Respond as if it is a positive if you cannot definitively conclude that the result is an error

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What About Legal Privilege?



- You cannot use privilege to "hide" your testing results, though there are narrow non-routine situations where it does make sense to test under privilege
- Attorney client privilege and work product doctrines are applied narrowly
- Don't assume anything is privileged
- Just copying a lawyer is not enough to protect documents from disclosure
- Lawyers need to be involved in giving legal advice or work needs to be under the direction of counsel in anticipation of litigation
- Forwarding privileged communications can waive the privilege
- Even when documents could be privileged, there may be some situations where you ultimately choose to waive the privilege or provide an adversary with privileged documents

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Expanded Potential for Liability

- FDA and the states are routinely conducting swabathons in RTE facilities
 - FDA often swabs 200 – 300 strategically selected sites
- Technical advances
 - Whole genome sequencing allows regulators to identify precise matches between product samples and ill case patients
 - CDC and NIH are building large databases of illness strains
 - Regulatory samples are routinely tested against those strains
 - It is becoming increasingly easy to link a company's products to sporadic food illnesses or to illnesses from years ago
 - Testing can uncover outbreaks that would have never been identified in past years



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Implications of WGS Results

- WGS allows FDA to connect positive samples found in your facility to:
 - Positive samples previously found in your facility;
 - Positive samples found in finished product testing, both in your facility or in commerce; and
 - Clinical samples (i.e., foodborne illness)
- If FDA finds the repeat presence of the same strain in your facility it may conclude:
 - You have a resident strain in your facility (even if you think it was eradicated and then reintroduced), which suggests:
 - Your sanitation procedures are insufficient;
 - Any food produced between those two findings is adulterated because it was produced under insanitary conditions; and
 - You may need to recall all food produced between the two findings

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WGS and FDA Enforcement: Company 1 (2017)

- Two *Lm* strains found in facility, one of which matched finished product sample
- According to FDA:
 - Based on FDA's analytical results for the environmental samples and inspection findings documented during the inspection, we have determined that your RTE cheese products are adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. Additionally, based on FDA's analytical results for the finished product sample that yielded a strain of *L. monocytogenes*, we have determined that your RTE cheese is contaminated within the meaning of section 402(a)(1) of the Act, 21 U.S.C. § 342(a)(1), in that finished product bears or contains any poisonous or deleterious substance which may render it injurious to health.
 - The presence of *L. monocytogenes* in your facility is significant in that it demonstrates your sanitation efforts are inadequate to effectively control pathogens in your facility to prevent contamination of food. It is essential to identify the areas of the food processing plant where this organism is able to grow and survive and to take necessary corrective actions to eradicate the organism by rendering these areas unable to support the growth and survival of the organism.

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WGS and FDA Enforcement: Company 2 (2018)

- Same strain found in facility, finished product sample (collected by state regulator), and 2 clinical isolates
- According to FDA:
 - It is important to implement an effective strategy for environmental control of *L. monocytogenes* within your processing and packing environment. Although FDA recognizes that effective controls against this organism can be challenging, it is your responsibility to effectively address this challenge to ensure the safety of your products.
 - This evidence demonstrates that the same strain of *L. monocytogenes* has maintained a presence within your production facility since May 2017. The reoccurring presence of an identical strain of *L. monocytogenes* in your products and manufacturing environment indicates that a resident strain or niche harborage site is present in your facility.
 - These findings also demonstrate that your sanitation procedures are inadequate to control this pathogenic organism in your facility. Once *L. monocytogenes* is established in a production area, personnel or equipment can facilitate the pathogen's movement and contamination of food-contact surfaces and finished product.

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WGS and FDA Enforcement: Company 3 (2019)

- Same strain of *Lm* found in facility during multiple inspections, and in clinical isolate
- According to FDA:
 - [A]s evidenced by environmental findings that indicate a resident strain of *L. monocytogenes* in your facility, you did not implement sanitation controls adequate to ensure that your facility is maintained in a sanitary condition to significantly minimize or prevent the hazard of the environmental pathogen *L. monocytogenes*, as required by 21 CFR §§ 117.135(a)(1) and (c)(3).
 - The presence of the same strain of *L. monocytogenes* over multiple years indicates that there has been a resident pathogen or harborage site in your facility since 2018. Additionally, that strain of *L. monocytogenes* was genetically identical to one clinical isolate collected in 2018, which indicates this strain has the capability of causing human illness.
 - Review of your records finds that your written corrective action procedures were followed each time a positive swab was found in your facility; however, these repeated findings of *Listeria* in your environment are further evidence that additional measures may be needed in your facility to address *Listeria*.

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Risk Mitigation Strategies

- Be proactive!
- Implement strong preventive programs
 - Robust environmental and product testing programs
- Take aggressive corrective actions when pathogens are found
 - Eliminate harborage sites
 - Keep thorough records documenting corrective actions
- Build a strong food safety culture throughout the company

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Parting Thought

- The law imposes not only a positive duty to seek out and remedy violations ...
- but also ... a duty to implement measures that will assure violations will not occur



FDA FOOD SAFETY MODERNIZATION ACT



Preventive Controls

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Questions?



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Maile Hermida, Partner, Hogan Lovells

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October 24, 2019

Contact Information



Maile Hermida, Partner
(202) 637-5428
Maile.Hermida@hoganlovells.com

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