Regulatory Update

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Key Points

- FDA- zero tolerance for pathogens in ready to eat foods
  - *Salmonella* & *Listeria monocytogenes*
  - Ready to Eat = foods eaten raw
- FSMA
  - Preventive Controls: focus on env. pathogens inc *Listeria & Salmonella*
    - Preventive Controls draft guidance chapters (all foods)
    - Draft guidance on *Listeria* (all foods, not just produce)
  - PSR:
    - Sanitation requirements, but no call out for environmental pathogens
- Industry resources: United Fresh guidance, PMA resource page, GMA control of Salmonella in low moisture foods, etc.

EMP Goal:
if it's there,
find it!

But there has been a fear of finding it!

FDA History

- 2008 FDA Draft Guidance
  - If you don't speciate, assume it's mono
  - Accompanying Compliance Policy Guide
    - Recognized that RTE foods don't support growth (e.g., frozen)
- 2017 updated Draft Guidance
  - Species ≠ mono
  - Encourages/ expects testing of product contact (Zone 1) surfaces during production
  - Zero tolerance in RTE foods
- No FDA EMP guidance for *Salmonella*

FSMA – Preventive Controls

- The definition of "environmental pathogen" identifies Lm and *Salmonella* as environmental pathogens (21 CFR 117.3)

- **Hazard evaluation** required by 21 CFR 117.130 **must** include an evaluation of environmental pathogens whenever an **RTE** food is exposed to the environment …(21 CFR 117.130(c)(1)(ii)).
  - If you determine a hazard needing a preventive control, what's the control?

What about Farms/ Packinghouses?

Draft Guidance: Control of Lm in RTE Foods

- **Control of Lm in Ready-To-Eat Foods**
  - **Issued:** January 2017
  - Applies to registered facilities

- **What fresh produce items are RTE?**
- **Which are not?**

Draft Guidance: Control of Lm in RTE Foods

Ready-to-eat food (RTE food) *means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.*
(Excerpted from Preventive Controls for Human Foods Rule § 117.3 Definitions)

- Should produce RACs be treated differently?
  - Most other foods covered by this guidance have a kill step

FDA Expectations (Guidance)

- **Frequency**
  - Lowest frequency (e.g., monthly) of routine sample collection be for those RTE foods that do **not** support growth of *L. monocytogenes*. We recommend that the highest frequency (e.g., weekly) of routine sample collection be for those RTE foods that support growth of *L. monocytogenes*
- **Swabs**
  - We recommend that even the smallest processors collect samples from at least 5 sites of FCS and 5 sites of non-FCS on each production line
    - Are you comfortable testing Zone 1 FCS?
      - 3 hours into production?

Must You Hold Product?

What did you do about your positive?

I got a POSITIVE!!

- Is it *monocytogenes*?
  - In general, there is minimal value in determining whether *Listeria* spp. detected on a non-FCS is *L. monocytogenes*, because you should eliminate the *Listeria* spp. regardless of whether it is *L. monocytogenes*.

Draft Guidance: Control of Lm in RTE Foods

Table 6.--Corrective Actions when *Listeria* species is found in an environmental sample

	Non-FCS Food supports growth	Non-FCS Food does not support growth	FCS Food supports growth	FCS Food does not support growth*
Routine sampling positive #1	• Clean and sanitize area of positive • Retest during next production cycle	• Clean and sanitize area of positive • Retest during next production cycle	• Clean and sanitize area of positive • Retest during next production cycle • Conduct comprehensive investigation	• Clean and sanitize area of positive • Retest during next production cycle • Conduct comprehensive investigation
Follow up sampling positive #2	• Intensified cleaning and sanitizing (possibly including disassembly of equipment) • Intensified sampling and testing	• Intensified cleaning and sanitizing • Intensified sampling and testing Hold AFTER 2nd positive	• Intensified cleaning and sanitizing (including disassembly of equipment) • Intensified sampling and testing • Hold and test product • Reprocess, divert or destroy product on hold if there is positive product • Comprehensive investigation	• Intensified cleaning and sanitizing (including disassembly of equipment) • Intensified sampling and testing • Consider hold and test • Comprehensive investigation

Draft Guidance: Control of Lm in RTE Foods

	Non-FCS Food supports growth	Non-FCS Food does not support growth	FCS Food supports growth	FCS Food does not support growth*
Follow up sampling positive #3	Root cause analysis	Root cause analysis	• Stop production and consult experts for comprehensive investigation • Intensified cleaning and sanitizing (escalated, e.g., steam equipment) • Intensified sampling and testing • Resume production with product hold and test until 3 consecutive days of product and FCSs are negative	• Intensified cleaning and sanitizing (including disassembly of equipment) • Intensified sampling and testing • Hold and test product • Expand comprehensive investigation • Hold and test product • Reprocess, divert or destroy positive product lots
Follow up sampling positive #4				Stop production and consult experts for comprehensive investigation

Do you need to report it to FDA?

Draft Guidance: Control of Lm in RTE Foods

Product Testing

A. Periodic Sampling and Testing of RTE Foods to Verify Adequacy of Your Controls

*We recommend that you test food products for **L. monocytogenes** rather than for **Listeria spp**. because of the risk to public health from L. monocytogenes in food. If you choose to test food for Listeria spp. and find it to be positive, we recommend you determine whether the Listeria spp. is L. monocytogenes or treat the food as if it were contaminated with L. monocytogenes. We recommend that you hold all product that is represented by the food you test, e.g., food lots produced from cleanup to cleanup.*

Issues

- Difficult to test and hold fresh produce.
- Product testing seems redundant to PC verification efforts.
- Recommend coordinating: EMP & Product sampling

Do you need to report it to FDA?

Fresh Produce Has Unique Challenges

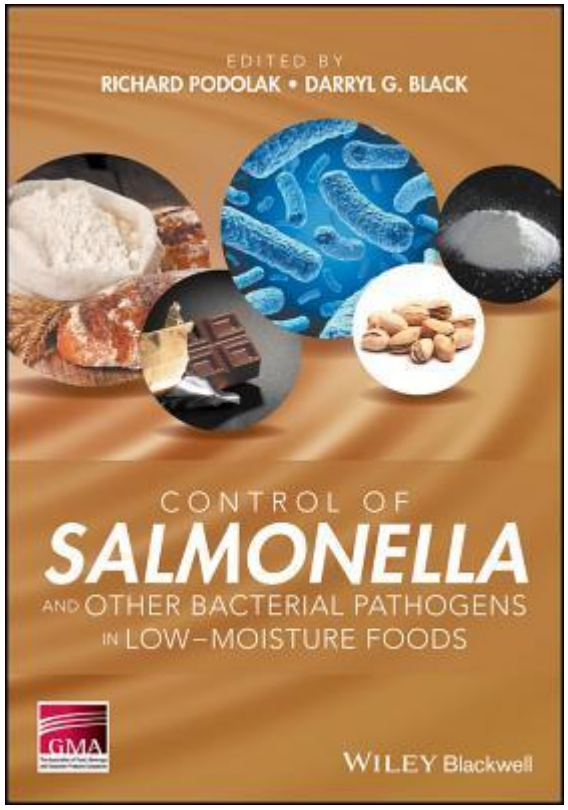
- Do not receive a listeriacidal treatment;
- May or may not support Lm growth;
- Are likely to have a low persistent prevalence of Lm as they are grown in the outdoors;
- No known preventive controls to control, reduce or eliminate the presence of Lm in fields or on fresh produce grown outdoors.

Issues

- Zero tolerance is aspirational
- Produce RAC's can't get to zero

Industry Drafted Guidance

- 2009 GMA Salmonella guidance
- 2013 first UFPA Listeria guidance
- 2018 Rev:
  - FDA Draft Listeria Guidance
  - Alignment
  - Additional Case Studies
  - “Dos and Don’ts”
- PMA resource page



Will FDA swab?

YES

(for facilities; packinghouses TBD)

For *L. monocytogenes*, NOT species *Salmonella?*

How many swabs?
What zones?
Must you hold product? (Should you)?
When will you get results?
Will positives be subjected to Whole Genome Sequencing?

Sharing your EMP results with FDA

Show that you are aggressively looking

Show that you are occasionally finding

Show that you TAKE CORRECTIVE ACTIONS

Member experiences:

- 483 for “inadequate EMP” (not testing Zone 1)
    - Inspection was “for cause” after a product positive

Summary

- Find pathogens before FDA does
- Regulatory philosophy has shifted
    - *Customer philosophy might not have*

- Questions?
- *Let's discuss Whole Genome Sequencing!*