FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Criteria and Principles in Developing a Verification Testing Program

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MANAGING MICROBIOLOGICAL TESTING AS A PREVENTIVE CONTROL VERIFICATION
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Food Safety - Prevention vs. Testing

- Prevention of hazards is more effective in ensuring food safety than testing to determine if they are present
- Testing plays an important role in verifying control measures

2

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CGMP & PC Rule Requirement

- A facility that has identified hazards requiring a preventive control (PC) must verify that PCs are effectively and significantly minimizing or preventing a hazard.
- Verification activities for preventive controls for microbial hazards include product testing for a pathogen (or appropriate indicator organism)
  - As appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system
  - Not to establish lot/batch acceptability

3

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Testing to What Purpose?

- Verify acceptability of a batch/lot of food?
  - Finished product
  - Ingredient from a supplier
- Verify process control?
- Verify sanitation of the environment?

4

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FDA Seeking Advice from NACMCF

- Utility and necessity of industry testing ready-to-eat (RTE) foods for pathogens
- Criteria industry could apply in determining what, if any, microbiological testing is appropriate for verifying pathogen control for the RTE foods produced

5

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Principles (1)

- Microbiological testing should be risk-based.
  - Microbiological testing is appropriate for some, but not all RTE foods.
  - Use of microbiological testing as a verification of control measures should consider risk to the consumer.
- Microbiological testing for verification of process control is different from microbiological testing for lot acceptance.
- Microbiological testing is most useful
  - (1) if ingredients in a food have the potential to contain pathogens and there is no kill step (or a marginal kill step) in the manufacture of the finished product, and/or
  - (2) when finished products may be contaminated from the environment.

6

Principles (2)

- Microbiological testing should be increased when information indicates that the operation is not under control.
- A facility should consider the nature and extent of supplier control programs for ingredients and environmental monitoring programs in the facility in determining the role of finished product testing to verify control measures in a facility.
- Sampling small amounts of product more frequently provides better information about process control than taking a larger sample equivalent in weight to the sum of the smaller samples.

7

"Criteria" for Whether and How Often to Test (1)

- Have pathogens been associated with the food or its ingredients?
  - Has the food been associated with illnesses?
- Are the ingredients likely to be contaminated?
- Are there robust processing control procedures such as a kill step or other reduction methods/controls?
  - Is the reduction due to a lethal formulation or application of a process control measure?
  - What is the magnitude of the reduction?

8

"Criteria" for Whether and How Often to Test (2)

- Is there a potential for recontamination from handling or the environment?
- Does the product support survival or growth of pathogens?
- What is the shelf life of the product?
- Is this product meant specifically for a higher risk population?
- Is consumer handling and use likely to increase or decrease risk?

9

Food Categories of Interest – Dairy Products

- Butter, margarine
- Cheese, hard (e.g., Cheddars), extra hard, grating (e.g., Parmesan, Romano)
- Cheese, fresh (Queso fresco), soft, soft-ripened (Camembert), semi-soft (Edam, Gouda), veined cheeses (Roquefort, Gorgonzola)
- Cultured, pH < 4.8
- Cultured, pH > 4.8 and <5.4
- Dried products (including dairy ingredients used to make infant formula)
- Frozen desserts
- Milk and milk products (fluid)

Applying the Principles/Criteria to Soft Cheese (1)

- Are pathogens associated with the food/ingredients?
  - Yes; *L. monocytogenes* (product has caused outbreaks)
- Are ingredients likely to be contaminated?
  - Yes; raw milk, ingredients such as spices and herbs
- Robust processing procedures?
  - Milk heat treatment (thermization, pasteurization), aging
- Potential for recontamination from the environment?
  - Yes, during aging, slicing, portioning, repackaging

11

Applying the Principles/Criteria to Soft Cheese (2)

- Does the product support survival or growth?
  - Yes
- Is the product meant specifically for a higher risk population?
  - No
- Shelf life?
  - variable

12

Other Considerations for Testing Soft Cheese

- Are there added ingredients such as herbs/spices?
  - Have these received a processing control for pathogens?
  - Have these been tested prior to use?
- Is there a robust environmental monitoring program in place?
- Is there a history of product and/or environmental testing in the facility that would impact product testing and its frequency?

13

Food Categories of Interest – Grain-Based Products

- RTE baked items, refrigerated or time-temperature controlled for safety (TCS)
- RTE baked items, shelf stable or non-TCS
- RTE cereals
- RTE cold-pressed bars

14

Applying the Principles/Criteria to RTE Cold-Pressed Bars (1)

- Are pathogens associated with the food/ingredients?
  - Yes, e.g., *Salmonella*
- Are ingredients likely to be contaminated?
  - Yes
- Robust processing procedures?
  - No
- Potential for recontamination from the environment?
  - Yes

15

Applying the Principles/Criteria to RTE Cold-Pressed Bars (2)

- Does the product support survival or growth?
  - Yes (survival, not growth)
- Is the product meant specifically for higher risk population?
  - No
- Shelf life?
  - Long (e.g., >1 year)

16

Other Considerations for Testing RTE Cold-Pressed Bars

- Is there a supplier program for verification of pathogen controls?
  - Are ingredients tested for pathogens?
  - Is the testing risk-based and robust?
- Is there a robust environmental monitoring program in place?
- Is there a history of product and/or environmental testing in the facility that would impact product testing and its frequency?

17

Food Categories of Interest – Meals and Entrees

- RTE deli salads
- RTE sandwiches
- "Heat and eat" meals/entrees

18

Applying the Principles/Criteria to RTE Deli Salads (1)

- Are pathogens associated with the food/ingredients?
  - Yes; *L. monocytogenes, Salmonella,* STEC
- Are ingredients likely to be contaminated?
  - Yes; spices, fresh produce
- Robust processing procedures?
  - No (although some ingredients may be cooked)
- Potential for recontamination from the environment?
  - Yes

19

Applying the Principles/Criteria to RTE Deli Salads (2)

- Does the product support survival or growth?
  - Yes (but growth may be controlled by pH and temperature)
- Is the product meant specifically for higher risk population?
  - No
- Shelf life?
  - Short (e.g., 1-2 weeks)

20

Other Considerations for Testing RTE Deli Salads

- Is there a supplier program for verification of pathogen controls?
  - Are ingredients tested for pathogens?
  - Is the testing risk-based and robust?
- Is there a robust environmental monitoring program in place?
- Is there a history of product and/or environmental testing in the facility that would impact product testing and its frequency?

21

Food Categories of Interest – Fruits and Vegetables

- RTE fresh-cut fruits (e.g., cut melon, sectioned grapefruit, sliced pineapple)
- RTE fresh-cut vegetables (e.g., cut celery stalks, peeled baby carrots, sliced mushrooms, shredded cabbage, chopped lettuce)
- RTE dried/dehydrated fruits (e.g., dried cranberries, raisins, dried apricots)
- Packaged uncut leafy greens (e.g., spinach leaves, baby greens leaves)


22

Applying the Principles/Criteria to RTE Fresh-cut Vegetables (1)

- Are pathogens associated with the food/ingredients?
  - Yes; e.g., *Salmonella,* pathogenic *E. coli* (variability among commodities)
- Are ingredients likely to be contaminated?
  - Yes; varies by commodity
- Robust processing procedures?
  - No; washing step provide some reduction
- Potential for recontamination from the environment?
  - Yes

23

Applying the Principles/Criteria to RTE Fresh-cut Vegetables (2)

- Does the product support survival or growth?
  - Yes
- Is the product meant specifically for higher risk population?
  - No
- Shelf life?
  - Variable, but typically short

24

Other Considerations for Testing RTE Fresh-cut Vegetables

- Is there pre-harvest testing or testing at receipt?
- Is there supplier verification?
- Is there a robust environmental monitoring program in place?
- Is there a history of product and/or environmental testing in the facility that would impact product testing and its frequency?

25

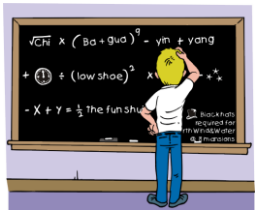
Should a Firm Test Finished Products?

- Soft cheese?
- RTE cold-pressed bars?
- RTE deli salads?

It Depends

26

The Bottom Line



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It's Complicated!

- Risk
- Existing data
- Controls measures – robustness, implementation
- Other Programs – supplier controls, EMP

27

Summary

- Many factors need to be considered in assessing whether to conduct microbiological testing and its frequency.
- Development of principles and criteria for microbiological verification testing, along with examples that apply the principles and criteria to a variety of RTE foods, will provide information much needed by manufacturers of RTE foods to develop appropriate verification testing programs.

28

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