Swabbing Zones, Understanding Zones and Interpretation of Data

Don L. Zink, Ph.D.
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
College Park, MD
The Zone Concept

- Based on the vulnerability of a RTE food that is exposed to the food production environment
- Zone 1 is the most sensitive to contamination
- Zone 3 is the least sensitive to contamination
- Zone 2 is somewhere in between 1 and 2
The Zone Concept

• Zones are defined based on the probability of product contamination if a pathogen were to be present in the zone

• In order to define and identify zones, you must think in terms of pathways to product contamination

• Zone 1 is easy to define, but zones 2 and 3 are defined conceptually, not by a rigid physical description
The Zone Concept

- **Zone 1** is a food contact surface
- **Zone 2** is an area that if contaminated with a pathogen there is a likelihood that zone 1 could become contaminated by the actions of human or machine
- **Zone 3** is an area that if contaminated with a pathogen there is a likelihood that zone 2 could become contaminated by the actions of human or machine
The Zone Concept

• Zone 1 is the surface of a conveyor that transports un-packaged food, a table top where food is handled, the interior surfaces of a pipe that transports food, the interior surfaces of a mixing vessel, a filler nozzle, the interior of a storage bin, the surface of a cooling rack and utensils used to handle food
The Zone Concept

• Zone 2 can be the floor near a piece of equipment where food is exposed, it can be on a piece of equipment that over hangs exposed food, it is usually an area in the same room as zone 1 areas.
The Zone Concept

- Zone 3 is a warehouse where food is enclosed in a package, an employee locker room, a loading dock, a restroom, a hallway outside a room where food is produced. It is rarely in the same room as food production.
The Zone Concept

• Probability of product contamination:
  – **Zone 1** – a pathogen in this zone is certain to contaminate product
  – **Zone 2** – a pathogen in this zone will not contaminate product without some help from workers, machinery, water usage or air currents
  – **Zone 3** – a pathogen in this zone has no chance of contaminating product but could get into zones 1 or 2 with some help from workers, machinery, water usage or air currents
The Zone Concept

• Originally developed for *Salmonella* control but now also applied to *Listeria*

• These two pathogens differ greatly in their habitats and this causes confusion:
  
  – When swabbing for *Salmonella*, zone 1 is usually a waste of effort, focus on zones 2 and 3
  
  – When swabbing for *Listeria*, zone 1 is often productive, focus on zones 1 and 2

  – But use intuition, observation and common sense!
Salmonella Hunting

You must understand your quarry if you expect to be successful
Environmental Swabbing Strategies

• Survey the facility and plan your sampling mission – start in the cleanest area
• Document every sample by photo or diagram with notes on possible path to product contamination
• Get as much sample or sample area as possible
• Overkill is good
In the Laboratory

• Process all samples ASAP, ideally within 24 hours of collection

• Be aware of the possibility of atypical isolates, particularly for *Salmonella* in dairy environments

• PFGE or more sophisticated typing of isolates must be done ASAP – strain differences and similarities tell the story
PFGE Patterns of Peanut Butter Outbreak Isolates*

Dice (Opt:1.50%) (Tol 1.5%-1.5%) (H>0.0% S>0.0%) [0.0%-91.2%] 

PFGE-XbaI

411259  Peanut Butter
411260  Peanut Butter
411524 1-1 Peanut Butter
411524 2-1 Peanut Butter
366081-5 Environmental Swab
389113-5 Environmental Swab
409792  Peanut Butter
325732  Peanut Butter
404036  Peanut Butter
411504  Peanut Butter
410573  Peanut Butter
410578  Peanut Butter
410958  Peanut Butter
410967  Peanut Butter

*Slide provided courtesy of Christine Keys, FDA-CFSAN
Peanut Butter *Salmonella* Isolates*

3 Different, but related PFGE patterns were linked to the same product

\[ XbaI \text{ – Primary Enzyme} \quad BlnI \text{ – Secondary Enzyme} \]

Patient A  
\[ #1 \quad #2 \]

Patient B  
\[ #1 \quad #3 \]

Peanut Butter  
\[ #1 \quad #3 \]

(With confirmed history of peanut butter consumption)

*Slide provided courtesy of Christine Keys, FDA-CFSAN*
Progress Report

• Industry is doing more environmental testing because regulators are testing

• Industry leaders are getting an education about pathogen control and detecting and solving problems

• Process validation is getting some attention

• A problem plant often leads to business distress or failure

• More training and experience is needed for investigators
Progress Report

• We need a better understanding of how pathogens move in a food plant
  – Early indications are that *Salmonella* gets around better than we ever imagined!

• We need to better understand the public health risk of *Salmonella* exposure

• We need to use the authority we have now to make cases under 402(a)(4) for environmental positives in sensitive areas