



Swabbing Zones, Understanding Zones and Interpretation of Data

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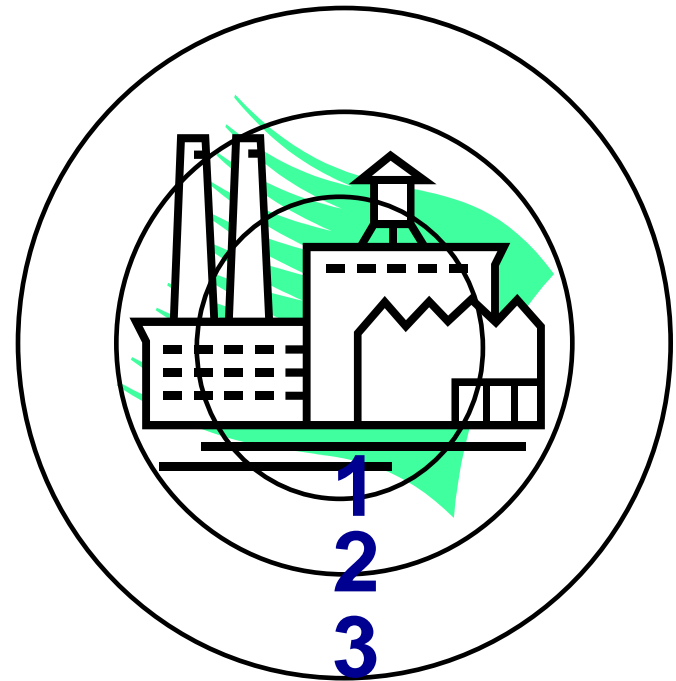
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The Zone Concept

- 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

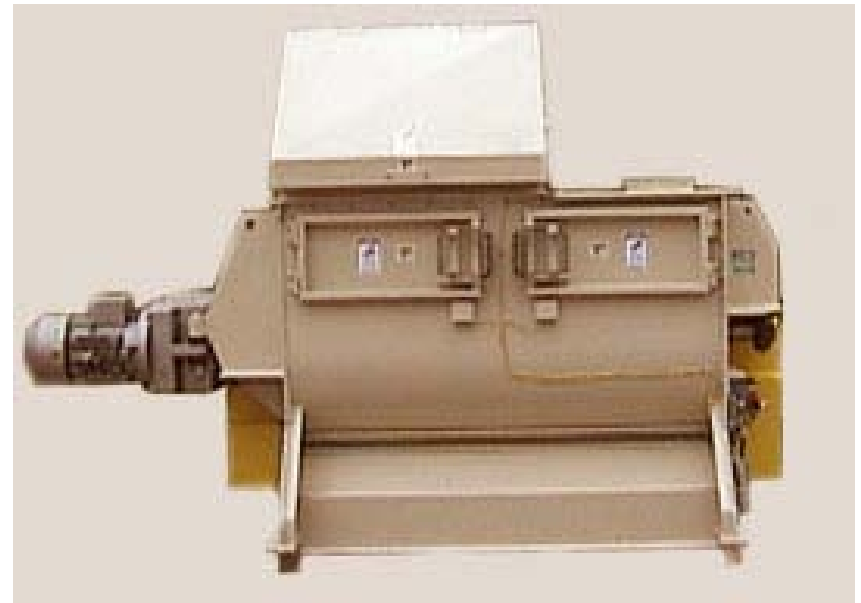
The Zone Concept

- 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 overhangs 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

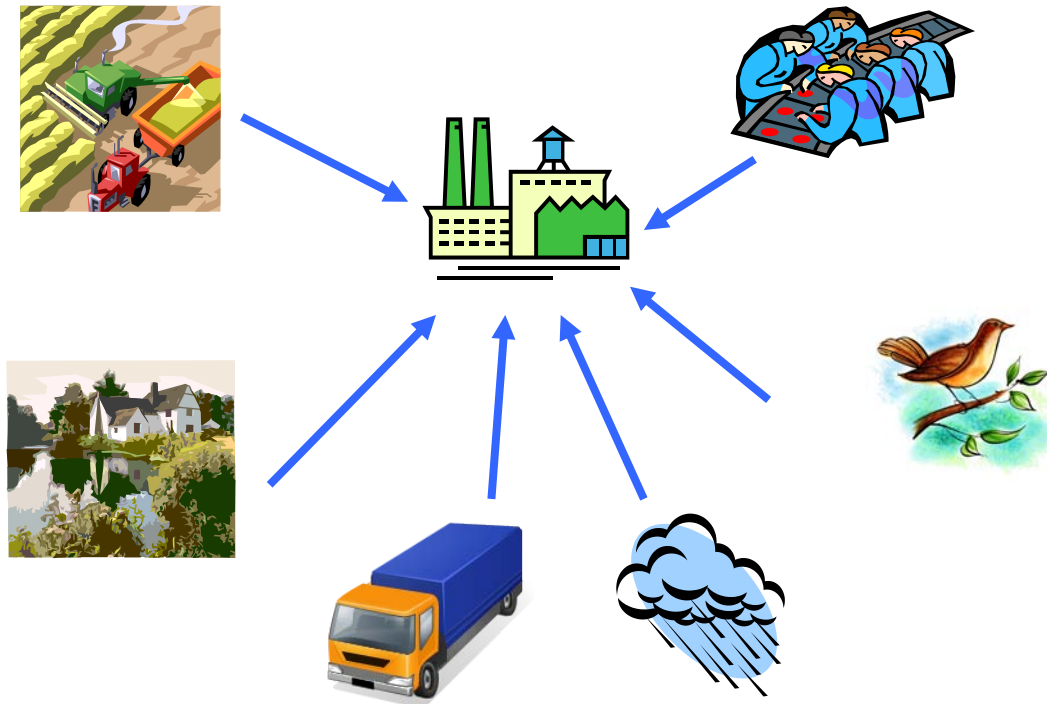
- Probability of product contamination:
 - **Zone 1** – a pathogen in this zone is certain to contaminate product
 - **Zone 2** – a pathogen in this zone will not contaminate product without some help from workers, machinery, water usage or air currents
 - **Zone 3** – a pathogen in this zone has no 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

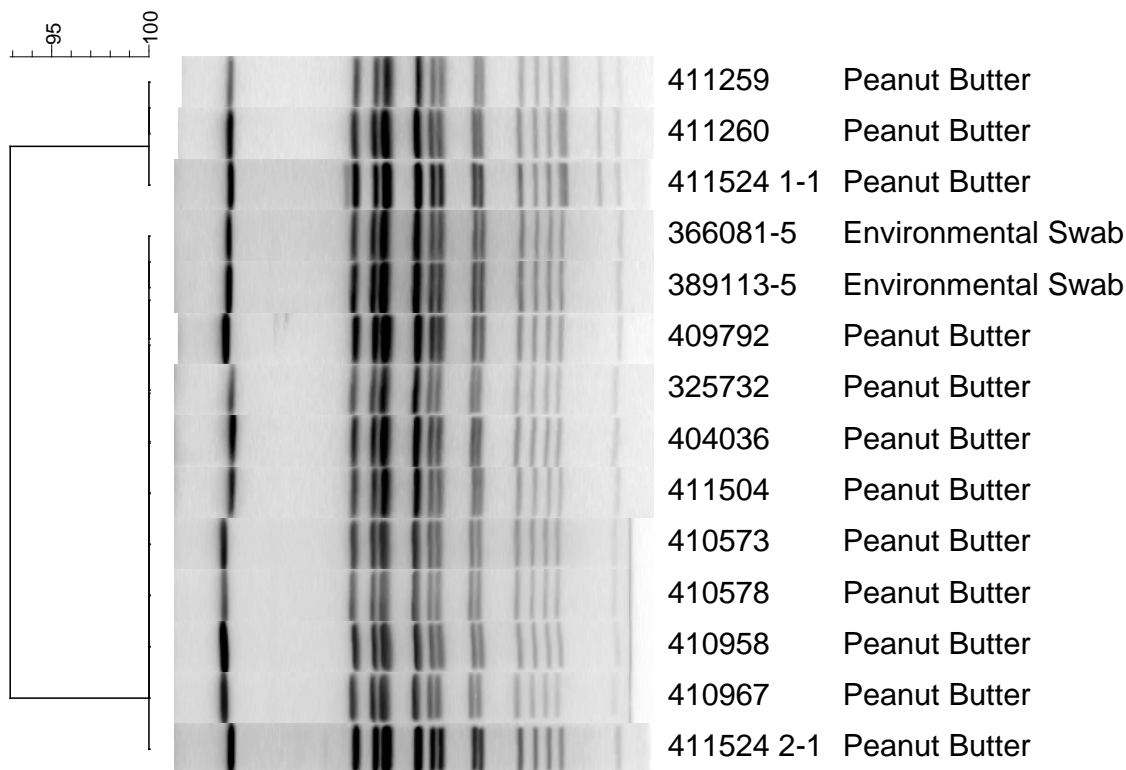
- Process all samples ASAP, ideally within 24 hours of collection
- Be aware of the possibility of atypical isolates, particularly for *Salmonella* in dairy environments
- PFGE or more sophisticated typing of isolates must be done ASAP – strain differences and similarities tell the story

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-Xbal

PFGE-Xbal

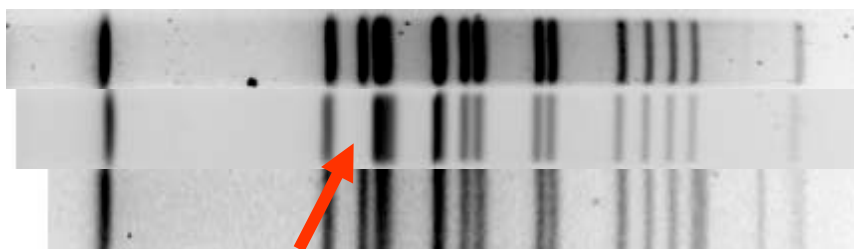


*Slide provided courtesy of Christine Keys, FDA-CFSAN

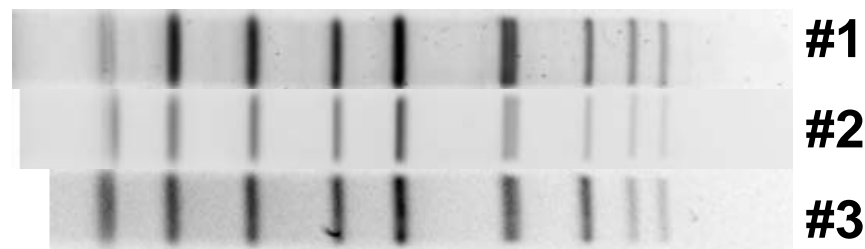
Peanut Butter *Salmonella* Isolates*

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

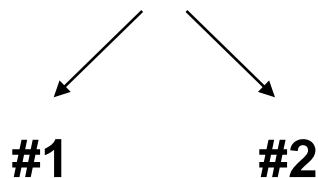
*Xba*I – Primary Enzyme



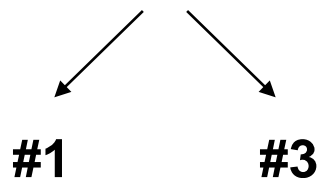
*Bln*I – Secondary Enzyme



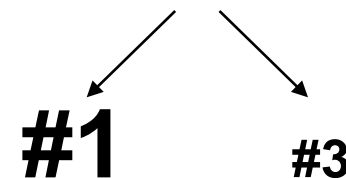
Patient A



Patient B



Peanut Butter



(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