VALIDATION
WHY, WHAT & HOW

Presented by: Martin Mitchell
Managing Director
Certified Food Safety Center
At: ASTA Annual Meeting
Phoenix, AZ
Date: April 4, 2011

Certified Laboratories, Inc.
Full Service Laboratory – Est. 1926

- INTRODUCTION
  - WHY WE ARE HERE
  - VALIDATION
  - SURROGATES
  - TEMPERATURE
- MICROBIAL REDUCTION PROCESS'S (MRP)
  - ETO/PPO
  - STEAM
  - IRRADIATION
- ENVIRONMENTAL MONITORING

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Red & Black Pepper Spice Recalls Linked to the *Salmonella* Montevideo Outbreak Investigation *(Updated March 30, 2010)*

The CDC reports that more than 250 people have been infected with a matching strain of *Salmonella* Montevideo in at least 44 states and the District of Columbia.


Daniele
DELI SELECTION
MADE IN USA
KEEP REFRIGERATED

Company Recalls Little Caesars Spice Paks

Blue Line Foodservice Distribution Announces Recall

POSTED: Wednesday, March 24, 2010

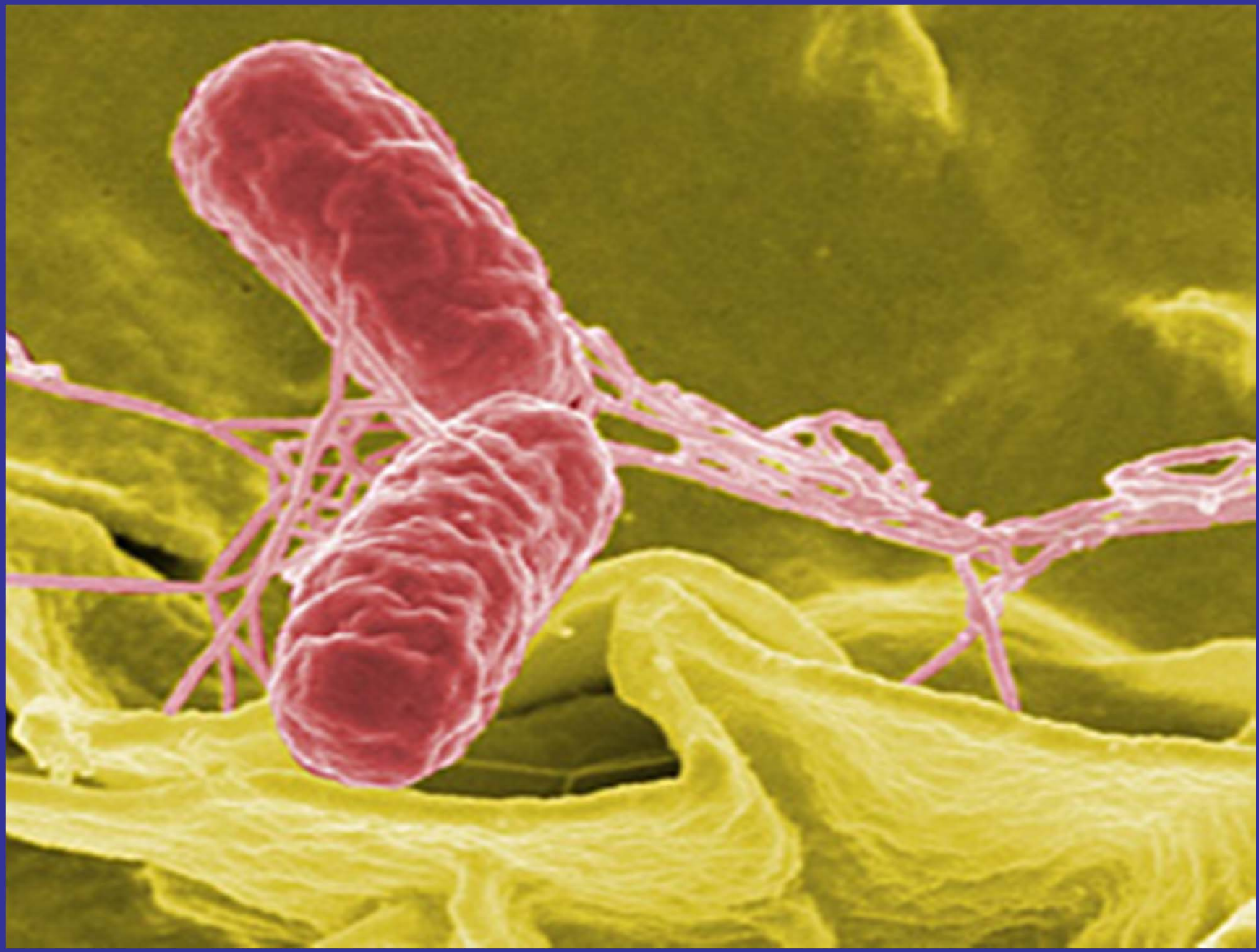
UPDATED: 3:26 pm EDT March 25, 2010

J Food Prot. 2006 Jan;69(1):233-7.

Recalls of spices due to bacterial contamination monitored by the U.S. Food and Drug Administration: the predominance of Salmonella.

Vij V, Ailes E, Wolyniak C, Angulo FJ, Klontz KC.
The George Washington University School of Public Health and Health Services, Washington, D.C. 20052, USA.

In recent years the U.S. Food and Drug Administration (FDA) has noted an increased number of recalls of dried spices due to bacterial contamination. From fiscal years 1970 to 2003. the FDA monitored 21 recalls involving 12 spice types contaminated with bacterial pathogens; in all but one instance, the recalled spices contained Salmonella. Paprika was the spice most often involved in the recalls. A wide variety of countries were the source of the recalled spices. A variety of effective methods exist to disinfect spices, procedures that have attained increased importance given the frequent use of spices in ready-to-eat foods.



CDC estimates of top five pathogens causing domestically acquired foodborne illnesses each year

Source: CDC's *Foodborne Illness Acquired in the United States--Major Pathogens*

Pathogen	Estimated annual number of illnesses	90% credible interval	Percentage of all foodborne illness
Norovirus	5,461,73	3,227,078 - 8,309,480	58%
Salmonella, nontyphoidal	1,027,561	644,786 - 1,679,667	11%
Clostridium perfringens	965,958	192,316 - 2,483,309	10%
Campylobacter spp.	845,024	337,031 - 1,611,083	9%
Staphylococcus aureus	241,148	72,341 - 529,417	3%

CDC estimates of top five pathogens causing domestically acquired foodborne illnesses resulting in hospitalization each year

Source: CDC's *Foodborne Illness Acquired in the United States--Major Pathogens*

Pathogen	Estimated annual number of hospitalizations	90% credible interval	Percentage of all food-related hospitalizations
Salmonella, nontyphoidal	19,336	8,545 - 37,490	35%
Norovirus	14,663	8,097 - 23,323	26%
Campylobacter spp.	8,463	4,300 - 15,227	15%
Toxoplasma gondii	4,428	3,060 - 7,146	8%
E. coli (STEC) O157	2,138	549 - 4,614	4%

CDC estimates of top five pathogens causing domestically acquired foodborne illnesses resulting in death each year

Source: CDC's *Foodborne Illness Acquired in the United States--Major Pathogens*

Pathogen	Estimated annual number of deaths	90% credible interval	Percentage of all deaths caused by foodborne illness
Salmonella, nontyphoidal	378	0 - 1,011	28%
Toxoplasma gondii	327	200 - 482	24%
Listeria monocytogenes	255	0 - 733	19%
Norovirus	149	84 - 237	11%
Campylobacter spp.	76	0 - 332	6%

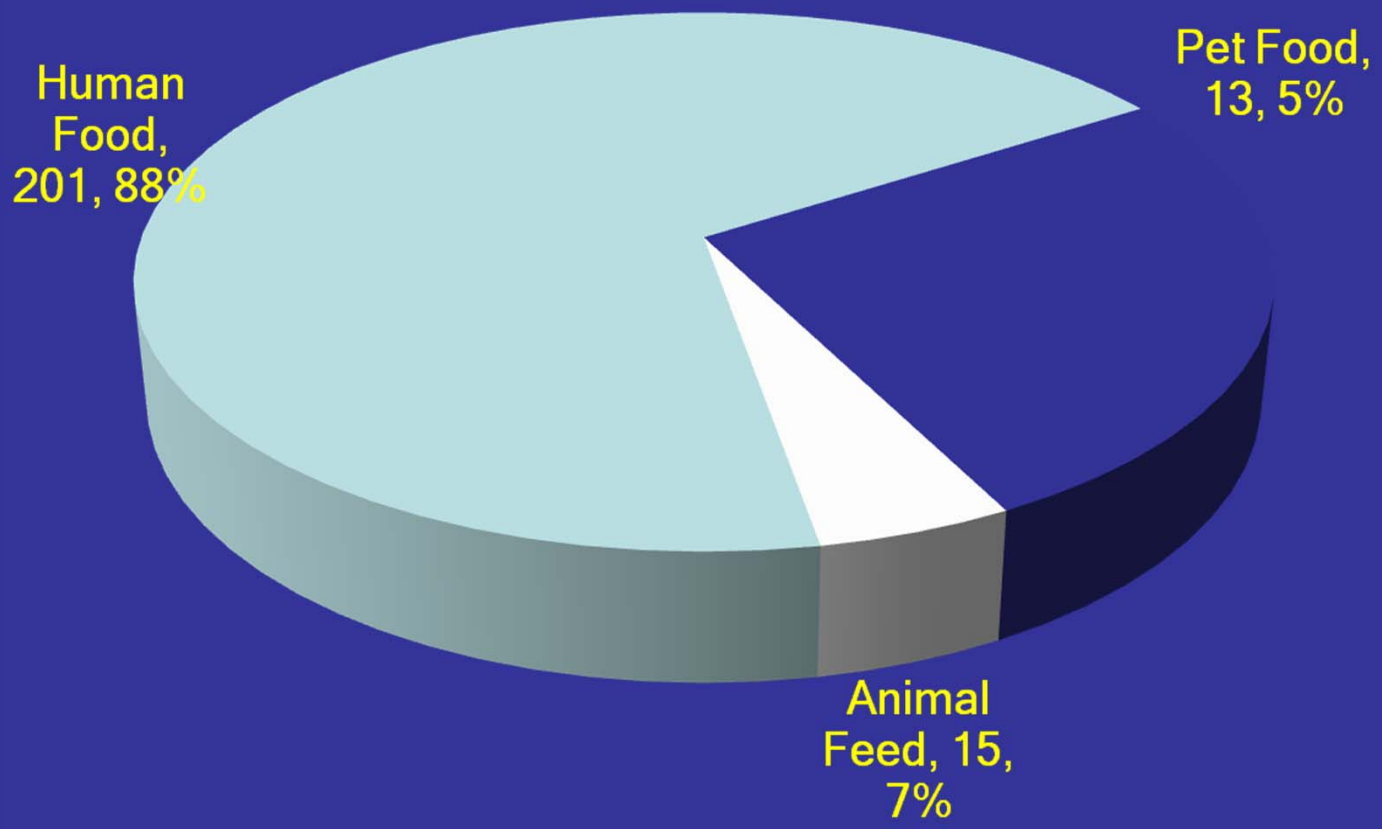
REPORTABLE FOOD REGISTRY (RFR)

The Reportable Food Registry: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration

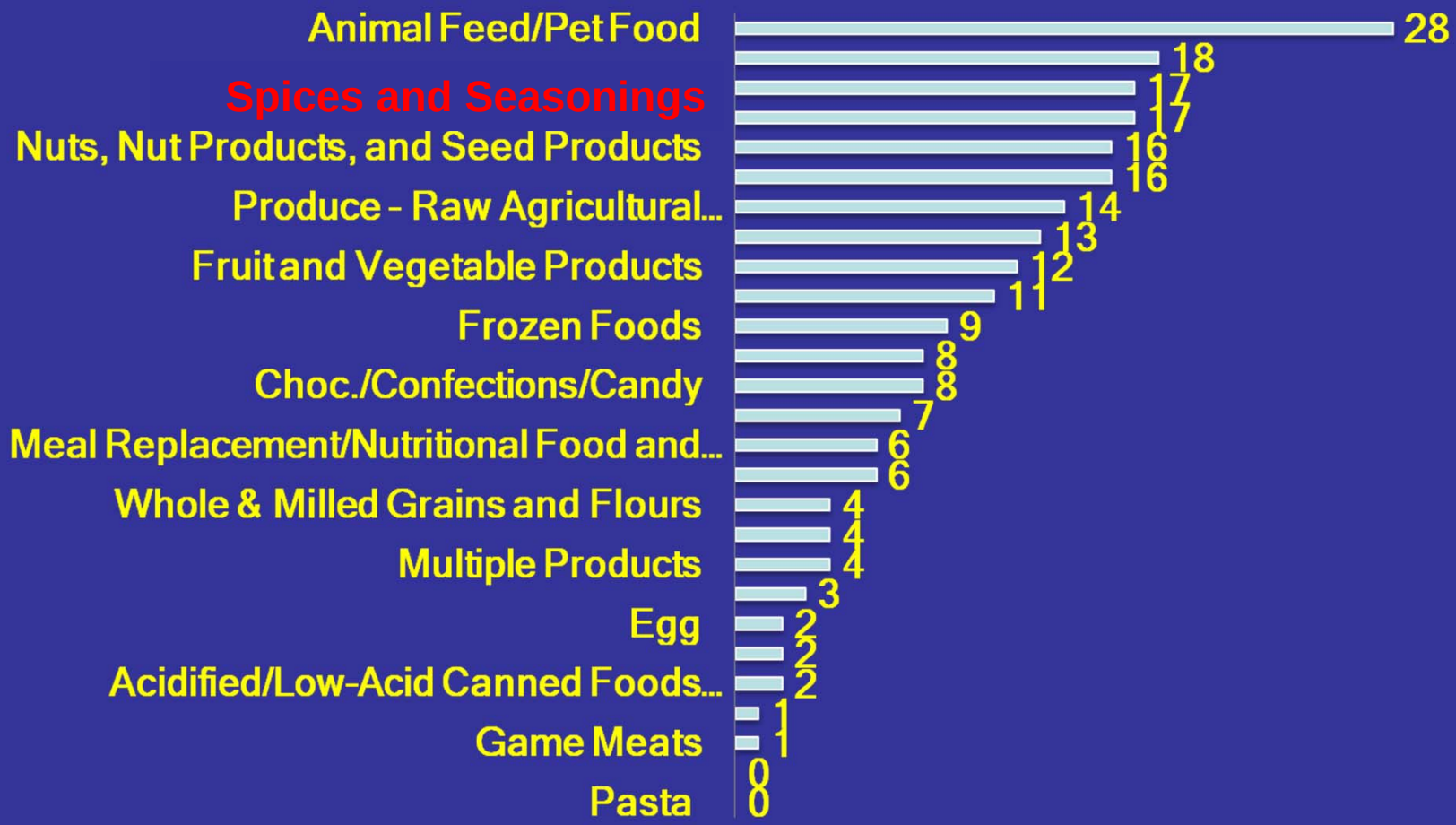
The intent of the Registry is to help FDA better protect public health by tracking patterns of food and feed adulteration and targeting inspection resources.

KEY FINDINGS

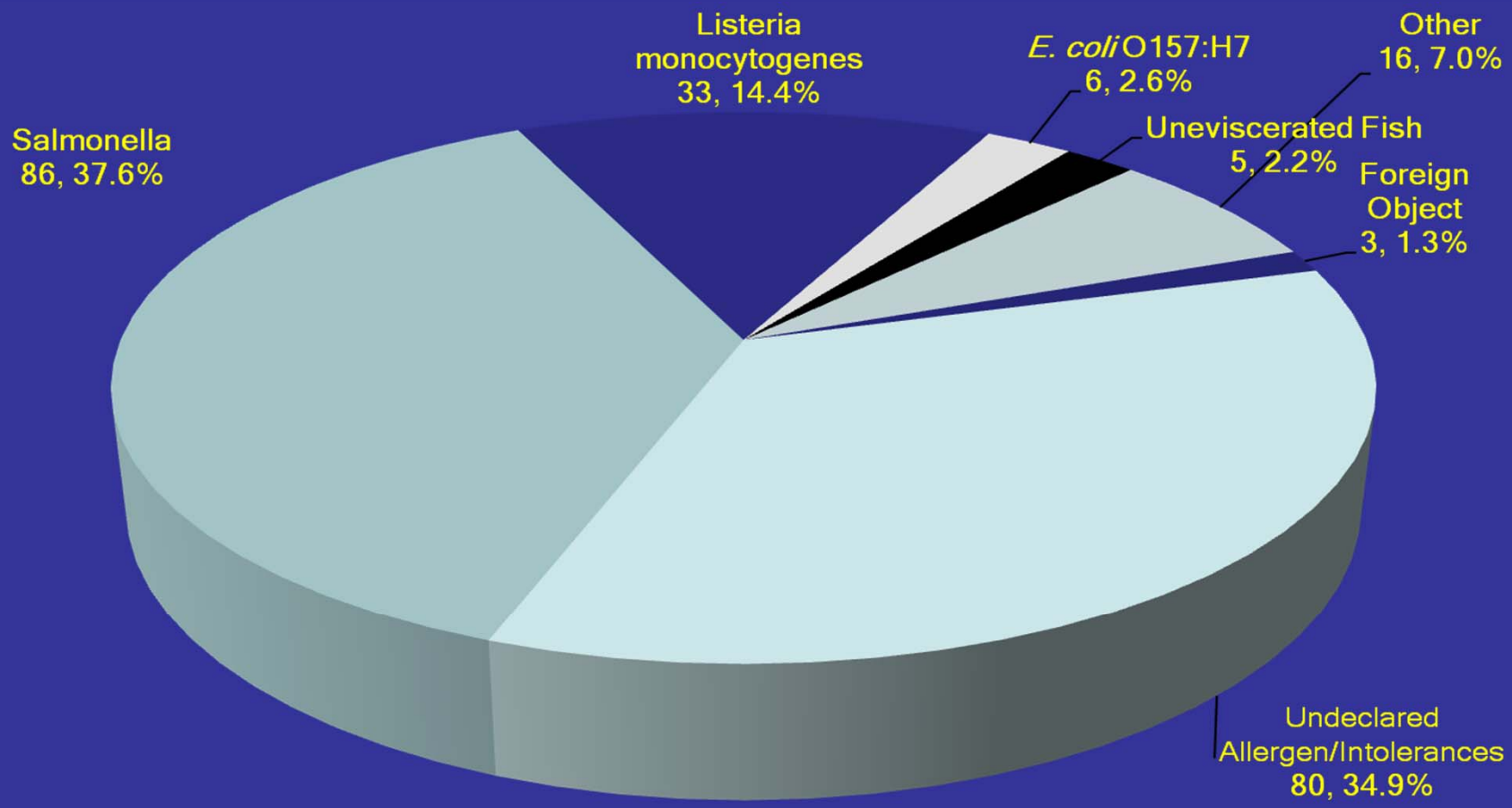
Distribution of 229 Primary Reports by Human Food, Pet Food and Animal Feed



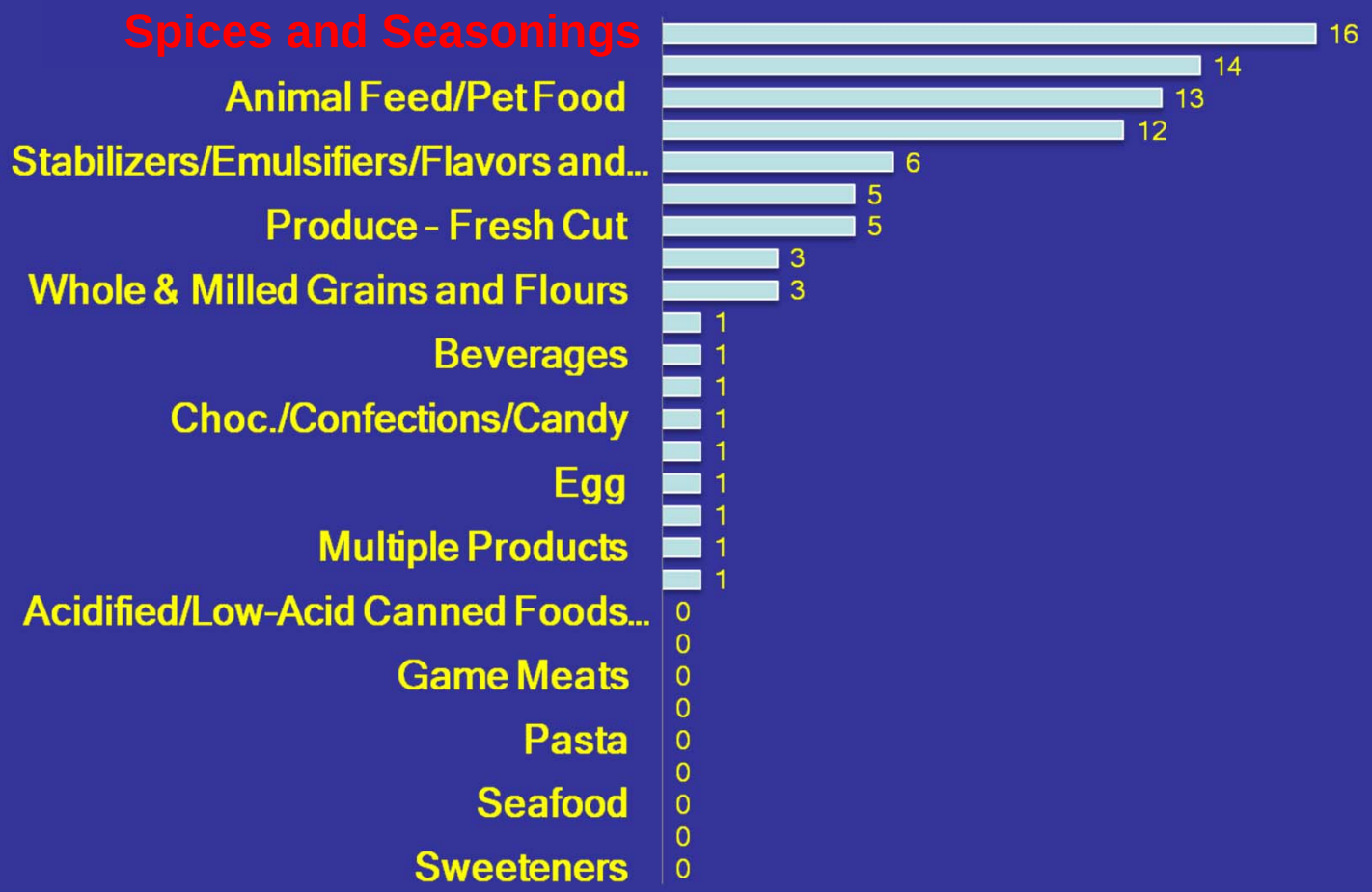
Distribution of 229 Primary RFR Entries by Commodity



Distribution of 229 Primary RFR Entries by Food Safety Hazard



Distribution of *Salmonella* Primary RFR Entries by



Distribution of Internationally - Sourced Primary RFR Entries by Country of Origin

Country	Entries	Country	Entries
China	13	Greece	1
Mexico	5	Indonesia	1
Canada	4	Italy	1
India	4	Malawi	1
Turkey	4	Nicaragua	1
Guatemala	2	Nigeria	1
Poland	2	Norway	1
Russia	2	Pakistan	1
South Africa	2	Venezuela	1
United Kingdom	2	Multiple (China, India, and Vietnam)	1
Vietnam	2		
Afghanistan	1	Total	53

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0195]

Risk Profile: Pathogens and Filth in Spices: Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration,

HHS.

ACTION: Notice; request for comments and for scientific data and information.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Draft Guidance for Industry: Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods

- Consider any confirmed positive result to be valid (even if subsequent tests on the original sample or other samples from the food are negative), absent other circumstances clearly demonstrating the inaccuracy of the first test result.

Draft Guidance for Industry: Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods

- Validate any treatment or process used to adequately reduce[5] *Salmonella* spp. in a food.

[5] In this document, we use the phrase "adequately reduce" to mean reducing the presence of *Salmonella* spp. to an extent sufficient to prevent illness. The extent of reduction sufficient to prevent illness is usually determined by the estimated extent to which *Salmonella* spp. may be present in the food combined with a safety factor to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1000(i.e., 3 logs) *Salmonella* organisms per gram of food, and a safety factor of 100 (i.e., 2 logs) is employed, a process adequate to reduce *Salmonella* spp. would be a process capable of reducing *Salmonella* spp. 5 logs per gram of food.

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Validation

As defined by the National Advisory Committee on Microbiological Criteria for Food

"Is the collection and evaluation of scientific and technical information to determine if the treatment, when properly applied, will effectively control the hazard(s)."

Guidelines for Validation
Important Considerations

- Conduct multiple trials.
- The specificity and sensitivity of the microbiological method used to recover the target pathogen.
- The use of multiple microbial strains including product isolates from the food being studied.
- Use of strains with high resistance.

Guidelines for Validation
Important Considerations (cont'd)

- Varying the critical factors to determine the margin of safety achieved by the process.
- Appropriate experimental and data analysis procedures to confirm that the least lethal treatment is included in measurements.
- The use of previously validated approaches or safe harbors.

Examples of established control measures

- Low-Acid canned food regulations / guidelines (Retort, Aseptic Processing)
- Milk Pasteurization & other Heat Treatments
- Egg Processing
- Meat Processing

What about dry/low-moisture foods

Before the 1st recognized outbreaks in the 1970's (confectionery) dry foods have been regarded as safe :

They would not allow for growth due to low water activity in the final products.

Since then numerous studies have been undertaken & revealed striking differences to high moisture foods.

What about dry/low-moisture foods

Extremely low level contamination with Salmonella can cause illness in dry & high fatty foods!

3 cfu/g in 1996 peanut butter

2 cfu/g in chocolate (1983)

1 - 20 cfu/g in almonds (2001)

Are the controls sufficient to manage the given hazards

- Lethal step adequately delivered,
- Correct critical parameters identified and controlled,
- Correct location of temperature sensors,
- Tolerance of temperature sensors included in CCP settings,
- Start up procedure adequate,
- Adequate corrective actions defined & followed,
- Incoming material temperature controlled,
- Separation between raw & processed areas adequate.

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Selection and use of test organism

- The validity of the established process is often confirmed using an inoculated test pack study.
- Surrogate organisms are often used in confirming the efficacy of processes.
- Prevents the introduction of harmful organisms into the production facility area.
- Does the surrogate actually represent the pathogen in the process

Selection and use of test organism

- The resistance and number of organisms must be selected to equal or exceed the treatment needed to destroy the target pathogenic microorganism of concern.
- The influence of the food (moisture, size: chopped, granules, etc.) to be treated needs to be considered.
- Placement: locations of the inoculated samples include the worst-cases for process conditions, including temperature, humidity.

Validation using surrogate microorganisms

Advantages

- Direct reading of lethal step effectiveness (log-reductions achieved)
- Validation data based on inoculated material

Disadvantages

- Requires microbiological laboratory/external services
- Resistance of the organism has to be confirmed
- Requires possibility to confine inoculated material

Challenges

- Validating microbiological methods
  - Inoculation methods
    - Culture conditions
      - Collecting culture from petri dishes vs. broth
    - Inoculation and drying procedure
      - Moisture in inoculated product
    - Stability of population during storage
      - Establish storage time/temperature
    - Heat resistance during storage

Challenges

- Recovery methods
  - Diluent
  - Cooling mechanism
  - Homogenization methods
  - Plating media (injury)
  - Enrichment methods
  - Incubation

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Measuring Temperature

- Surface temperature?
  - Surface contamination with *Salmonella* is assumed in whole spices
  - For validation – uniform distribution of *Salmonella* in ground spices is assumed
- Identification of process cold spot critical

Temperature/Pressure Monitoring Devices

Summary

- Thermal resistance of *Salmonella* is greatly increased in low water activity foods

- Survivor curves can be non-linear
  - "D" values do not apply
  - Significant tailing often observed
    - This can significantly impact the efficacy of some processes
  - z values may also be impacted and are often high

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Guidelines for Validation of Propylene Oxide Pasteurization

October 2008

PPO Pasteurization Operating Parameters

Parameters	Operational Level
Initial product temperature	Not less than 86° F (30° C)
Chamber temperature at start and during sterilization	117 - 125° F (47 - 51° C)
Chamber vacuum before PPO injection	At least 27"HG vacuum
PPO vaporizer temperature	140 - 160° F (60 - 71° C)
PPO concentration	Not less than 0.5oz PPO/ft^3
Chamber vacuum at completion of inert gas injection	5 - 6 Hg vacuum
Duration of pasteurization	4 hours
Aeration cycles	Not <4 and not > 14
Post ventilation	100 - 110° F (38 - 43° C) for 2 days or above 59° F (15° C) for 5 days

PPO Pasteurization Operating Parameters

This procedure is only applicable for pasteurization of bulk-packed almonds on double or single stacked pallets. The procedure is not applicable for retail packed bags.

Handlers and third parties who have PPO treatment facilities must follow the SOP in order to ensure they are achieving the 5-log pathogen reduction required by FDA. Individual treatment facilities must be validated and equipment calibrated to demonstrate they are operating within the established parameters.

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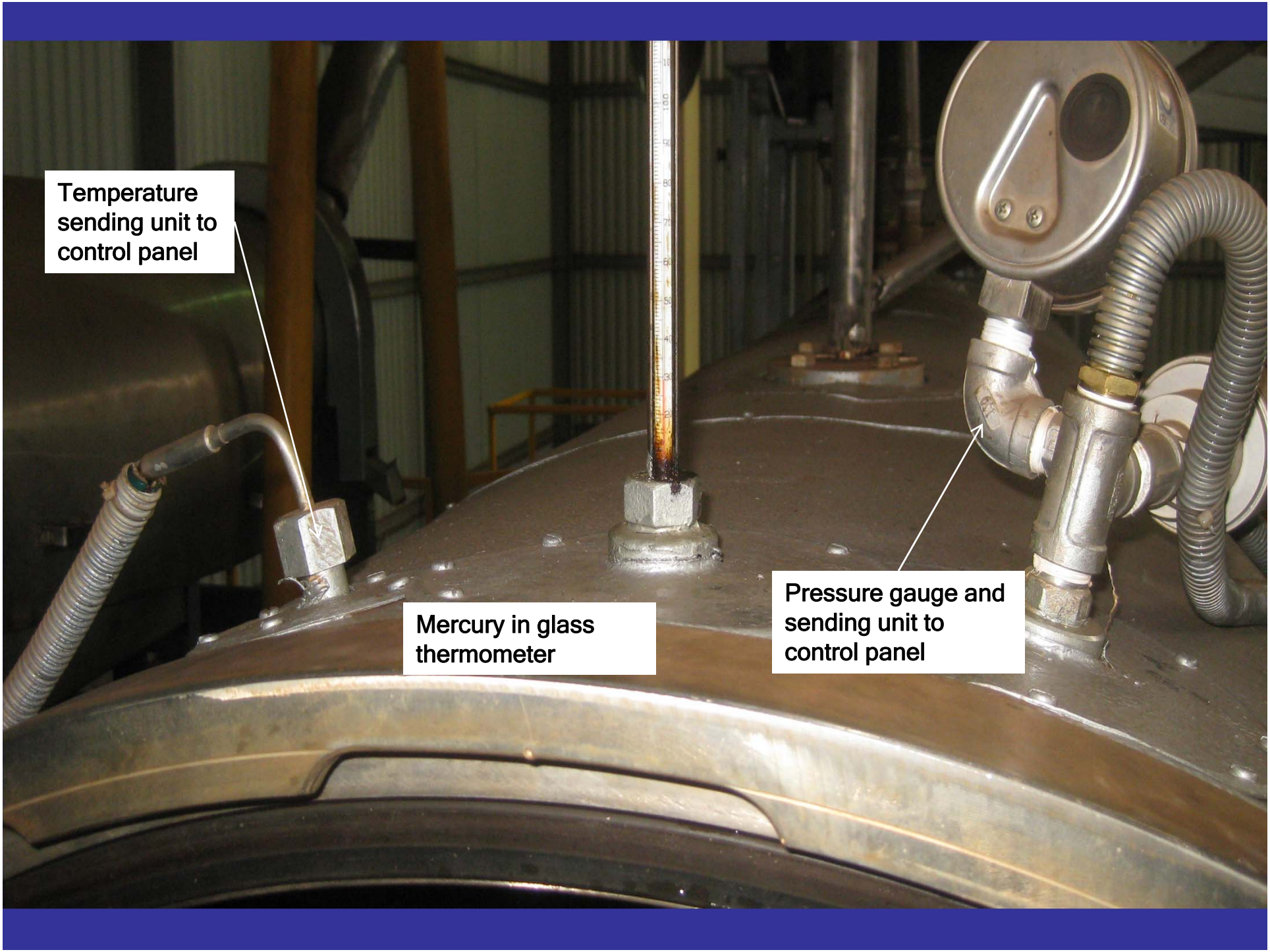
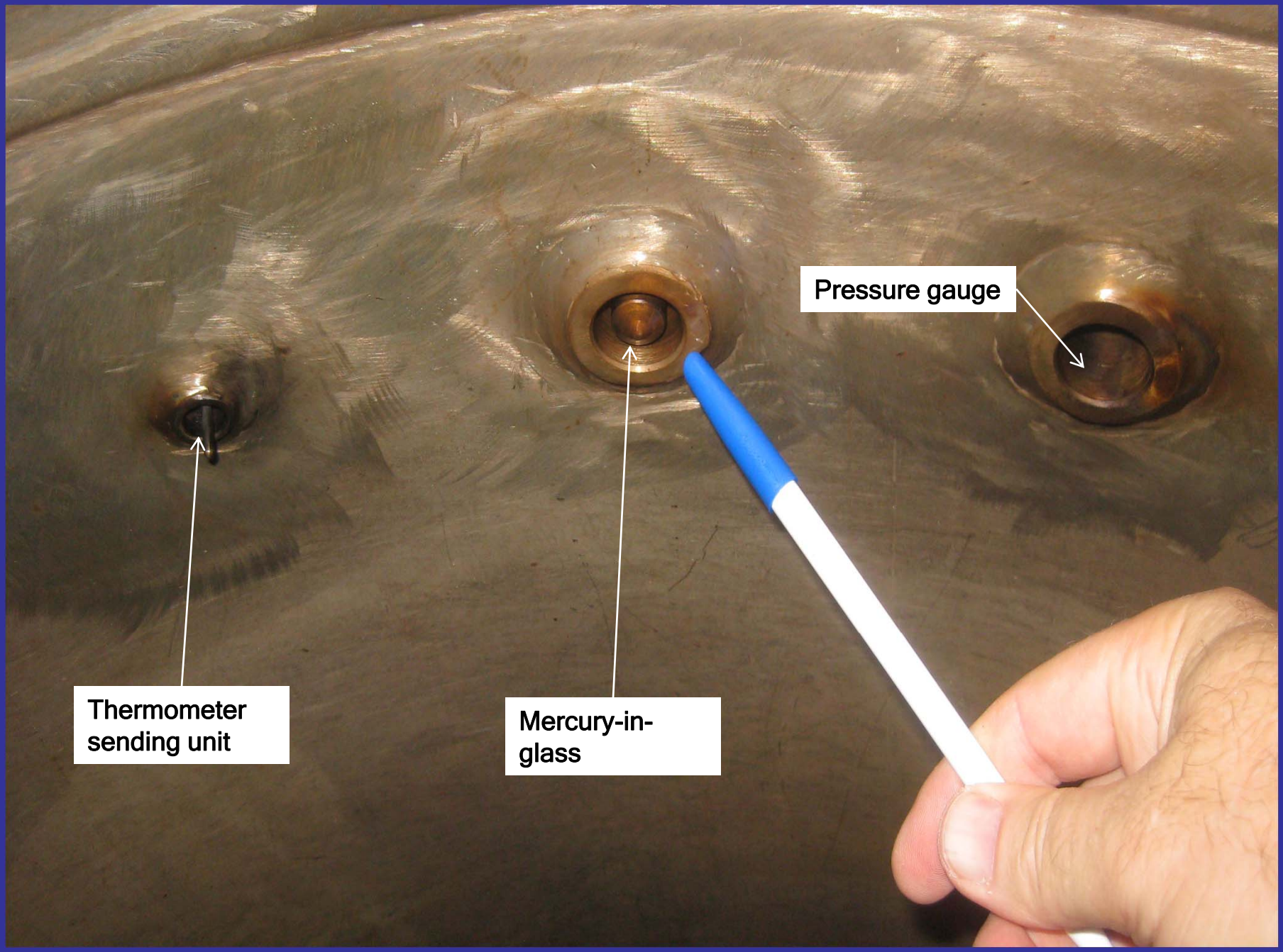
Product feed into rotary valve
Rotary valve – feeding into steamer
Steamer


Temperature sending unit to control panel
Mercury in glass thermometer
Pressure gauge and sending unit to control panel


Pressure gauge
Thermometer sending unit
Mercury-in-glass

Temperature/Pressure Monitoring Devices

Critical Process Parameters Summary

Standard Operating Parameters		
Parameter	Unit	Item
30	°C	Initial product temperature
123.6	°C	“Steamer” temperature
1.25	Bar	“Steamer” pressure
48.1	Hz	Reciprocating conveyor speed
1.5	Metric Ton/H	Product throughput

Whole Black and White Peppercorns		
Critical Parameter	Unit	Set-Point
Initial Product Temperature	°C	≥ 30
Process Temperature	°C	≥ 118
Process Pressure	Bar	≥ 0.90
Residence time	Hz	48.0
Feed Rate	Metric Tons/hr	≤ 2.8

Certified Food Safety Center, Inc.
Food Safety and Process Technology

Equipment Information				
Description	Equipment Manufacturer	Model #	Serial #	Validation #
Steam Sterilization	Ventilex	Bokfard 3T	20078	CFSC10281

Scheduled Process for Whole Black or White Peppercorns

Process	Process Lethality	Minimum Steam Temperature (°C) / Pressure (bar)	Minimum Time (Hz)
W/B Peppercorns	> 5-Log	120 / 1.10	48.0

Operating Critical Parameters
(To ensure the scheduled process is reached)

Process	Unit	Minimum Pasteurizer Operating Parameters
Initial Product Temperature	°C	30.0
Process Temperature	°C	120.0
Process Pressure	Bar	1.1
Residence Time	Hz	48.0
Feed Rate	maximum, Metric Tons/hr	2.8

Monitor Frequency	All process data is manually recorded 15 minute increments. Record at start-up and shutdown daily when changing back to alternate processes. Records are reviewed daily by the HACCP program administrator. Any process deviation must be documented and a corresponding corrective action identified and recorded.	
Comments	System has manual control to divert product flow when critical values of time, temperature, pressure, and product flow (high side) are not achieved based on set-point deviations.	System has been tested and it functions properly by diverting product.

Product Identification: Pasteurized

Product segregation: Unpasteurized

Product Packing: 22 kg Kraft Bags

Deviation Instructions: Acknowledge low temperature or low pressure observation, investigates, segregate and hold product not meeting above parameters. Inform PA for corrective action

Process Authority:
Rick Falkenberg, Ph.D.

Signature:_____ Date: 10/19/2010

¤ 200 Express Street •Plainview, NY 11803 •800.CERT.LAB •516.576.1400 •516.576.1410 Fax
¤ 6460 Dale Street •Buena Park, CA 90621 •888.FOOD.LAB •714.562.8622 •714.562.8799 Fax
¤ 240 Riggs Avenue •Merced, CA 95341 •866.915.LAB3 •209.383.9190•209.383.9194 Fax
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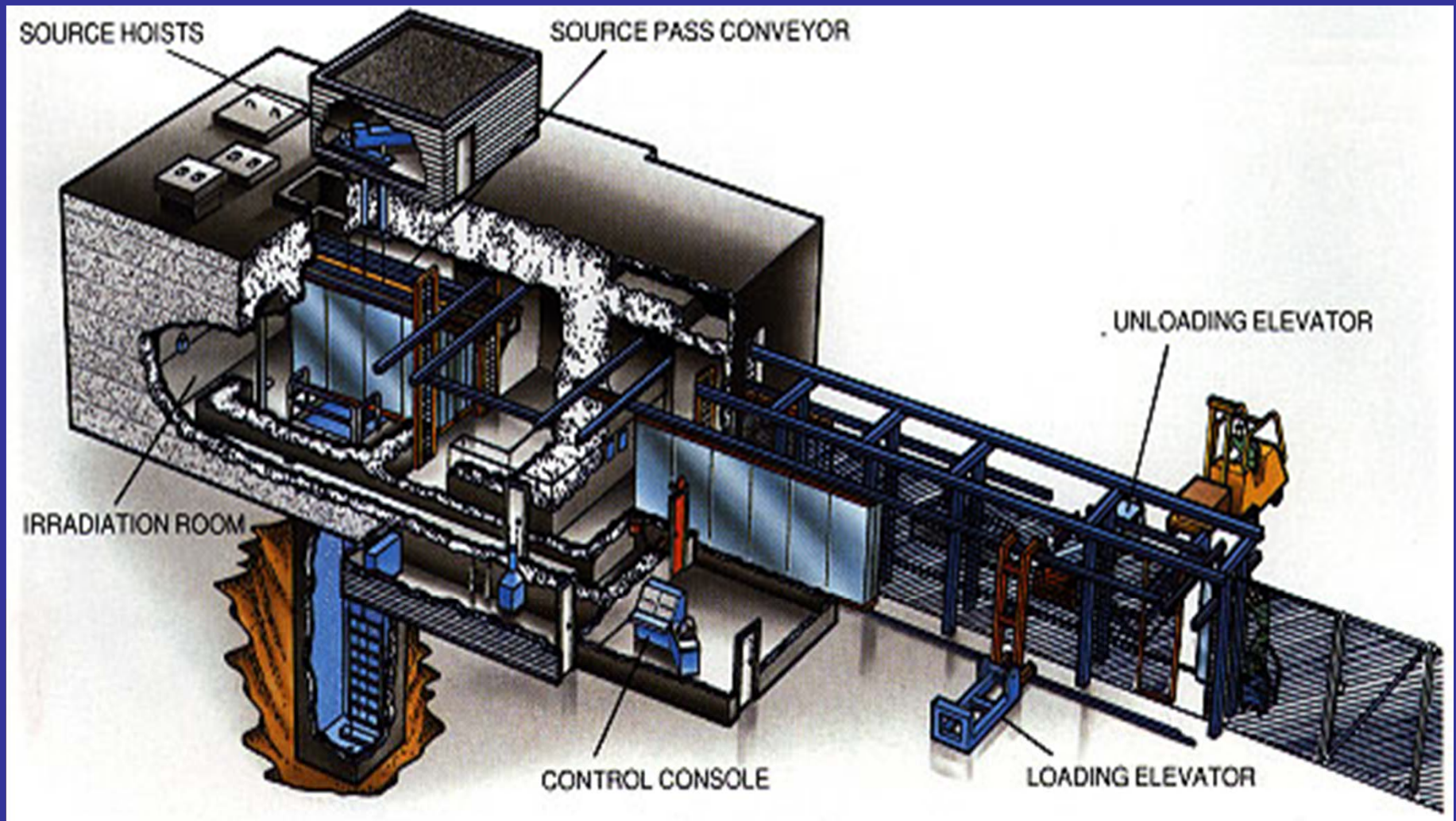
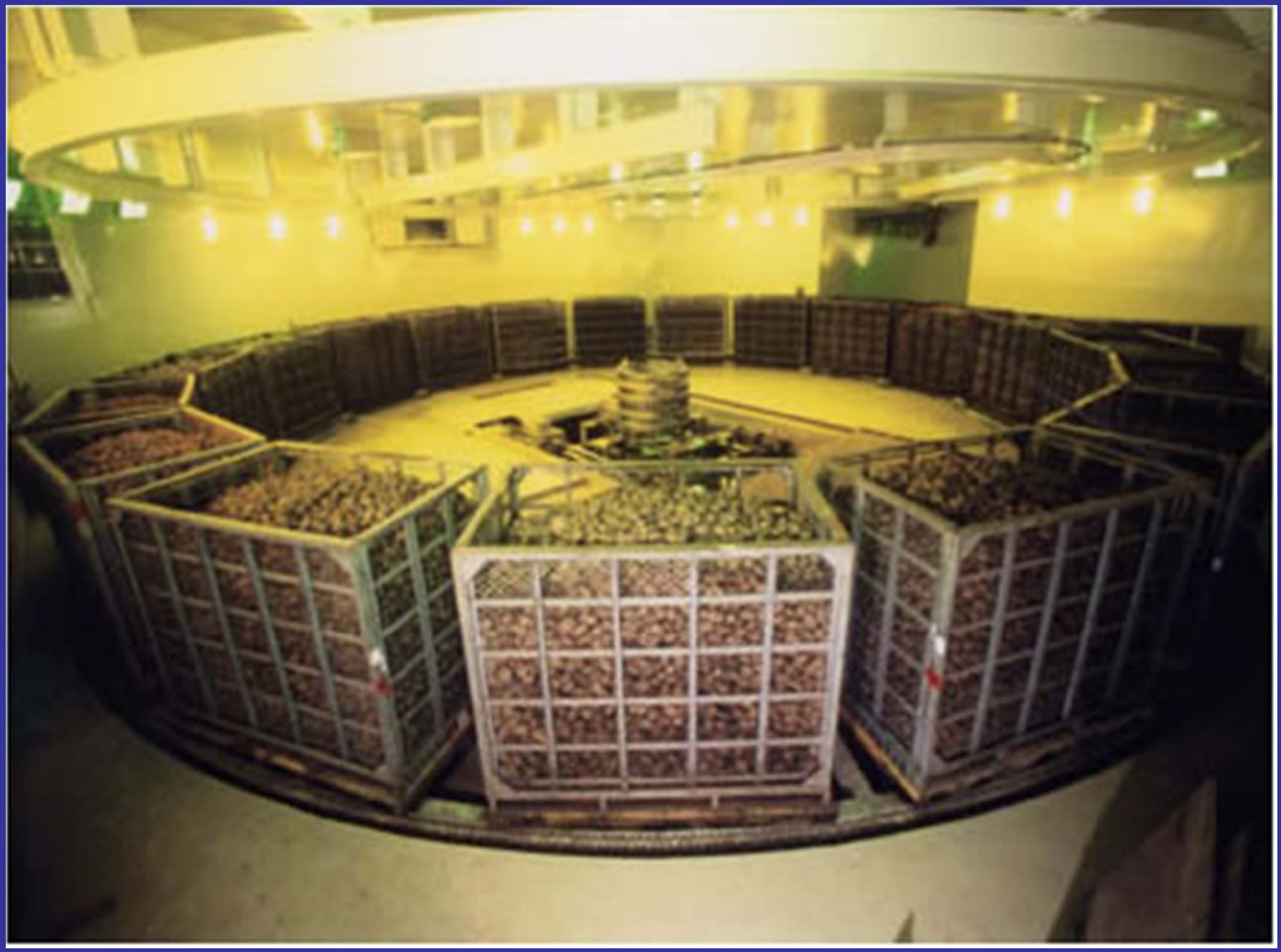


Figure 1: JS-8900 Unit Carrier Irradiator



Benefits of Food Irradiation

- Pathogens are reduced or eliminated
- The nutritional value of the food is preserved
- Decreased incidence of food-borne illness
- Reduced spoilage in global food supply
- Increased level of quality assurance in international trade of food products

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Salmonella as Wild Game?

- Bacteria may be small, but there is no bag limit!
- Look for them where they live, feed, and breed
- They are numerous where they live, but only wander about in small numbers

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

Example of an environmental monitoring program for production of low-moisture foods

Sampling Zone	Definition	Examples of sample Sites*	Test for	Frequency	Number of Samples**
Zone 1	Product contact surfaces (PCS) in the Primary *Salmonella* Control Area	Conveyors, filler hoppers, scrapers/utensils, packaging equipment, etc.	Indicator organisms (e.g. Aerobic Plate Count; Enterobacteriaccae); *Salmonella* only when special circumstances dictate	Post-Sanitation or as needed for investigational, or verification purposes	Line dependent

Example of an environmental monitoring program for production of low-moisture foods

Sampling Zone	Definition	Examples of sample Sites*	Test for	Frequency	Number of Samples**
Zone 2	Non-PCS within close proximity to PCS in Zone 1. •Areas that, if contaminated, could reasonably lead to PCS contamination (i.e. under normal operational practices)	Exterior of equipment, legs/frameworks, motor housings, catwalks, control panels, scrap carts, floor drains, HVAC vents, vacuum cleaners if used near PCSs, air filters, weight scales, floor mats at packaging, etc.	*Salmonella*	Weekly, Biweekly, or Monthly	5 - 10

Example of an environmental monitoring program for production of low-moisture foods

Sampling Zone	Definition	Examples of sample Sites*	Test for	Frequency	Number of Samples**
Zone 3	Non-PCS within process area but more removed from PCS. •Areas that, if contaminated, could not reasonably lead to PCS contamination without *mechanical* or *human intervention* (i.e. employee using compressed air to clean floors or a piece of equipment being moved)	Cleaning tools (brooms, squeegees), floor scrubbers, forklifts, floor drains, traffic pathways into process area, ceiling drain pipes, wall/floor junctures, wash stations, ingredient storage areas, etc.	*Salmonella*	Weekly or Monthly	3 - 6

Example of an environmental monitoring program for production of low-moisture foods

Sampling Zone	Definition	Examples of sample Sites*	Test for	Frequency	Number of Samples**
Zone 4	Non-PCS outside processing areas. •Areas that, if contaminated, could spread to the processing area via foot or equipment traffic (i.e. waste carts picking up contamination in compactor room)	Compactor areas, employee entrances, locker rooms, storage rooms, labs, etc.	*Salmonella*	Monthly or Quarterly	2 - 4

*It is recommended that a facility assessment be done to identify sampling sites, in order to include potentially problematic areas. Weekly monitoring may be considered as a starting point to establish a sold baseline and the frequency may be revised based on results over time.

**In general, a greater number of samples are taken in Zone 2 than Zone 3 and in Zone 3 than Zone 4 – a ratio of 5:3:2, 6:3:1, 7:2:1, 8:1:1 have been used depending on the product and process, although other approaches may be effective.

Defining Principles

- The search for *Salmonella* is driven by:
  - the need to sample in areas where the organism is likely to be present in high numbers
  - possible routes of food product contamination
  - traffic patterns for people and equipment
  - extraordinary circumstances in the facility
  - the quality of facility design and housekeeping

Examples of locations and situations in facilities that can serve as potential sources for spread of *Salmonella*

Process Area

- Aspirator line
- Dust collection system
- Filter sock
- Air conveyance system, e.g. rotary air lock, cyclone, air locks, duct work, pneumatic conveyance system
- Inside a pump that was disassembled
- Inside an air duct
- Exposed insulation
- Eroded flooring
- Space between walls
- Poorly sealed wall/floor junction
- Leaky roof
- Leaky drain pipe
- Conveyor
- Bucket elevator
- Fork lift
- Employees
- Fans
- Cat walks
- Central and/or portable vacuums
- Maintenance tools
- Floor scrubber
- Floor squeegee
- Mop head
- Drain
- Insects, rodents, and other pests

Examples of locations and situations in facilities that can serve as potential sources for spread of *Salmonella*

Outside of Process Area

- Fire exit, for example, used by construction crew to enter and exit the facility
- Entrance to employee locker room
- Pathway to trash compactor
- Receiving dock
- Insect light reaps
- Areas where employees may congregate, such as a designated smoking area

Examples of corrective action procedures following positive *Salmonella* findings in the plant environment

Response to a Single Positive

Corrective actions must be taken when a *Salmonella* positive is found in any zone. Corrective actions should be initiated based on presumptive positive test results. The actions should aim to eliminate potential sources of the contamination.

- Take immediate actions to correct any GMP deficiencies based on findings.
- Thoroughly clean/sanitize and dry the positive site and the surrounding area. Use dry, controlled wet, and/or wet cleaning as appropriate,.
- Increase sampling frequency, e.g. from weekly to once every two days in Zone 3, from weekly to daily for Zone 2. After 3 consecutive negatives, the routine sampling frequency and rotation plan for the *Salmonella* monitoring may be resumed.

If a product sample tests positive for *Salmonella*, the tested lot is considered adulterated and should not be released into commerce. As noted previously, retesting should not be conducted for the purpose of negating the initial test results (31, 48). Resampling almost always increases the chance of accepting a contaminated lot. The lower the prevalence level of *Salmonella* in the product, the more difficult it will be to confirm, and it is virtually impossible to confirm very low prevalence by resampling (31)

THE END