





FACILITY MAINTENANCE, HYGIENE AND PEST CONTROL A CENTROL A CENTROL

Control of People

- o Employees are a contamination risk by tracking in contaminants
- o Improper handling practices are a contributing factor

Control of Places

- o Improper traffic patterns of both personnel and equipment can contribute
- o Improper airflow and ventilation increase contamination risk

Control of Things

- o Raw materials can be a source of Salmonella
- Pests bring contaminants into the facility







- HAZARD ANALYSIS TO DETERMINE POTENTIAL SOURCES FOR SALMONELLA
- 2) REGULAR INSPECTIONS OF THE FACILITY AND TIMELY CLOSURE OR REPAIR OF ANY OPENINGS
- 3) ESTABLISH PROCEDURES TO ENSURE THAT CONTAMINATED EQUIPMENT IS NOT BROUGHT INTO THE FACILITY
- 4) **ESTABLISH CONTROLS** TO SEGREGATE INGREDIENTS KNOWN TO BE CONTAMINATED WITH *SALMONELLA*.
- ESTABLISH SUPPLIER CONTROL PREREQUISITE PROGRAM TO REVIEW AND APPROVE RAW MATERIAL SUPPLIERS
- 6) PREVENTING CROSS CONTAMINATION
- 7) ESTABLISH WATER QUALITY MAINTENANCE PROGRAM TO MINIMIZE THE RISK OF WATER AS A CONTAMINANT
- 8) CONTAINING AREAS OF CONSTRUCTION AND MAJOR EVENTS SUCH AS REMODELING
- 9) ESTABLISH TRAINING PROGRAMS TO EDUCATE EMPLOYEES ABOUT POTENTIAL SOURCES OF SALMONELLA CONTAMINATION, ADHERENCE TO TRAFFIC PATTERNS, AND PROPER HYGIENIC PRACTICES



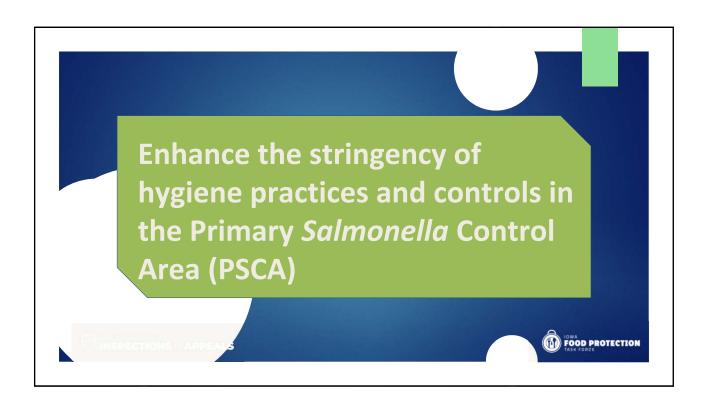


Questions For Retail Facilities

- 1. How do you manage the identified controls (employee training, traffic flow, pest control, regular in-house inspections, prevention of cross contamination, containing construction areas) in your facility?
- 1. How are you able to manage separation of ingredients or materials known to be sources of *Salmonella* in your facility, if you store them and use them in your processes?







Benefits of a designated Primary Salmonella Control Area

Control of People

- PSCA requires the highest level of hygiene control, prior to inactivation treatment, or it may encapsulate the entire processing area
- Hygiene areas other than (and including) the PSCA may need to be established as well, but the idea is to minimize Salmonella contamination to the greatest extent possible in the PSCA
- Cleanliness and good hygiene throughout the GMP is essential to maintaining the integrity of of the PSCA







Benefits of a designated Primary Solmonella Control Area • Control of Places • Barriers can restrict traffic and prevent potential Salmonella sources from passing between the GMP and PSCA. Whenever possible, there should be no direct connection between the PSCA and basic GMP area • Airborne contamination can be combated by filtering the air supply to the PSCA

Benefits of a designated Primary Salmonella Control Area



Control of Things

 Ingredients that do not go through further inactivation steps are exposed to the environment when processed through the PSCA and thus require that extra care is taken to avoid contaminating the environment







- ESTABLISH DESIGNATED AREAS IN THE FACILITY WITH DIFFERENT LEVELS OF HYGIENE CONTROLS TO MINIMIZE THE SPREAD OF SALMONELLA (24)
- ESTABLISH BARRIERS FOR THE PSCA (AROUND THE ENTRANCE AND EXIT TO THE PSCA, THE EXIT FROM THE GMP, AND TRANSITIONAL AREAS) (25)
- CONTROL ALL TRAFFIC BETWEEN THE PSCA AND THE REST OF THE FACILITY (25)
- MINIMIZE DUST ENTRY INTO THE PSCA THROUGH PHYSICAL SEPARATIONS (26)
- ESTABLISH A MASTER SANITATION SCHEDULE TO ASSURE TIMELY AND EFFECTIVE SANITATION
- ESTABLISH APPROPRIATE CLEANING AND HYGIENE
 PROCEDURES FOR THE PSCA AND THE BUFFER/VESTIBULE
 AREA TO THE PSCA
- ROUTINELY REMOVE PRODUCT BUILDUP





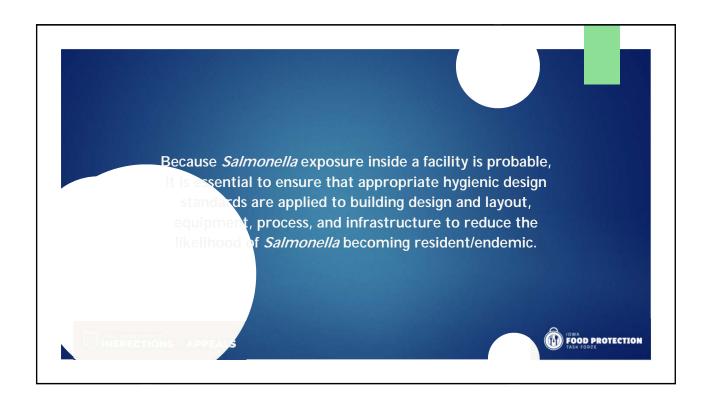
Questions for Retail Facilities

- 1. Retail facilities may not have PSCAs, but do you identify areas of concern, and if so, what interventions do you establish?
- 2. Have any of you used barriers or other methods to restrict traffic flow between areas of concern and areas where *Salmonella* control may not be a primary concern?
- 3. Do you restrict processing ingredients or material known to be sources of *Salmonella* in certain areas of or equipment in your facility?
- 4. Do you use master sanitation schedules with more frequent timelines to clean the highly susceptible areas, including the requirement to frequently remove product buildup?



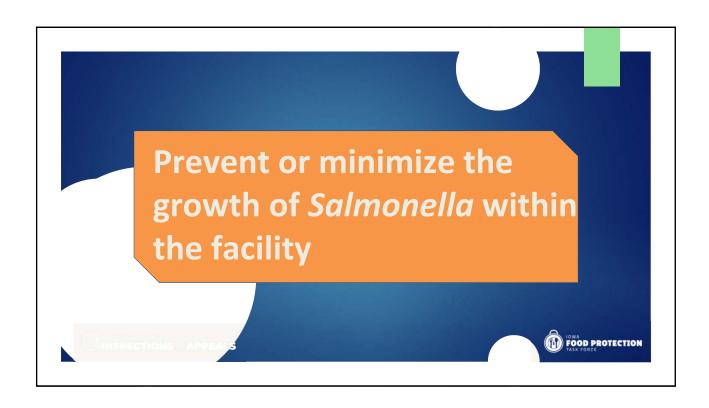








1. Do any of you use dry cleaning methods in your facilities? What are they? 1. Have you had issues with water accumulation in your facility and what improvements did you make in your designs? | Total Protection | Protectio



Moisture Control and Dry Cleaning are effective ways to reduce Salmonella growth (especially in the PSCA)

"Water in the dry processing environment is one of the most significant risk factors for *Salmonella* contamination, as water allows for pathogen growth, significantly increasing the risk for product contamination."

- ▶ Salmonella growth is only possible in water
- ▶ Humidity and condensation accumulation may cause invisible moisture niches
- ▶ Water may occur/remain due to improper use of water during cleaning
- Standing water that has dried out presents a risk of contamination, including the generation of airborne contaminated dust
- Serious Salmonella problems may develop as a consequence of wet cleaning, as it introduces moisture under equipment supports, into floor cracks, and in any other hidden/difficult-to-clean areas (harborage sites)
- Product accumulation should be removed ASAP







- MINIMIZE USE OF WATER IN THE ENTIRE PLANT ENVIRONMENT
- SPECIFY THE TYPE OF CLEANING PRACTICES TO BE USED IN DIFFERENT HYGIENE AREAS
- USE DRY CLEANING PRACTICES ROUTINELY IN THE PSCA AND CONTROLLED WET CLEANING INFREQUENTLY AND ON AN AS-NEEDED BASIS
- CONTROLLED WET CLEANING MAY BE NECESSARY. USE THE MINIMUM AMOUNT OF WATER AND TEST ENVIRONMENTS FOR SALMONELLA THAT HAVE BEEN WET CLEANED
- ELIMINATE WATER AND MINIMIZE WATER DISTRIBUTION SYSTEMS IN THE PSCA
- ESTABLISH APPROPRIATE DRY CLEANING MEASURES FOR THE PSCA
- SEPARATE CLEANING TOOLS USED IN DIFFERENT HYGIENE AREAS





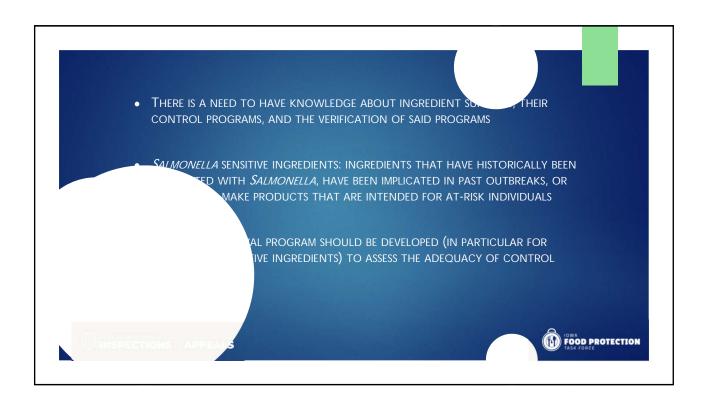
Questions for Retail Facilities

- 1. Have you considered restricting humidity or condensation accumulation in your facilities to minimize *Salmonella* growth? What interventions did you implement?
- 2. Do your cleaning procedures include proper cleaning and sanitizing of areas of standing water?
- 3. If your facility uses water for cleaning, how to you prevent or minimize aerosolization of water (for example, no high-pressure hoses to clean floors)?
- 4. Have any of you used separate cleaning tools in different hygiene areas? What method or system works best for you?

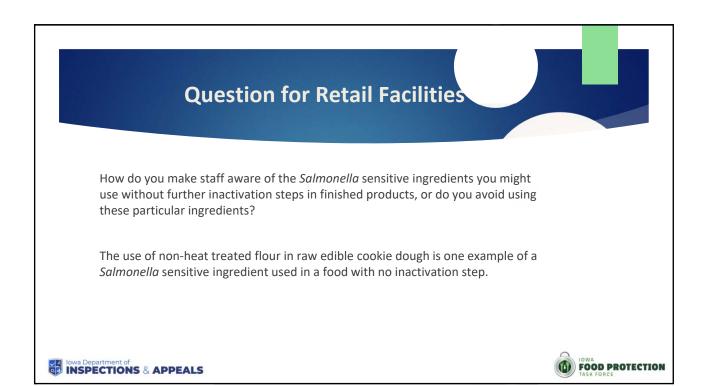
















It is important to avoid recontamination after the lethality step has been applied. The best way to avoid this is through good hygiene practices verified by environmental monitoring.

Thermal processing is the most commonly used control measure to inactivate *Salmonella*, but it is not the only control measure available. It is helpful to review available scientific data to find the processing method of interest.

Heat resistance in a product with low a_w is much greater than that in a high-moisture product.





VALIDATION

Collecting and evaluating scientific data and technical information to demonstrate that the control measures and associated critical limits, applied at a critical control point, result in safe products following the lethality step.

"Validation of lethality steps for low-moisture foods involves determining an appropriate log reduction for Salmonella, determining the critical limits in the process required to achieve the reduction, and confirming the process equipment consistently delivers the critical limit parameters in the operation."







- **DETERMINE THE TARGET LEVEL** OF *SALMONELLA* REDUCTION IN THE PRODUCT AND PROCESS UNDER CONSIDERATION. USE SUPPORT DOCUMENTS INCLUDING THE RATIONALE OUTLINES BY NACMCF (2006), HAZARD ANALYSIS, OR
- DETERMINE THE ADEQUACY OF THE SELECTED CONTROL MEASURE(S) AND
- **USE PUBLISHED DATA** TO GUIDE THE DETERMINATION OF WHETHER A CHALLENGE STUDY IS NEEDED FOR CONTROL MEASURE VALIDATION.
- CONSIDER BOTH THERMAL AND NON-THERMAL CONTROL MEASURES, WITH
- ONCE THE LETHALITY PROCESS IS VALIDATED BY SCIENTIFIC DATA, ENSURE **OPERATIONS CAN DELIVER THE CRITICAL LIMITS** AND THAT THE PARAMETERS ARE CONSISTENTLY MET THROUGH IN-PLANT VALIDATION.
- ENSURE RAW MATERIAL/INGREDIENT SUPPLIERS VALIDATE THEIR PROCESS



Question for Retail Facilities

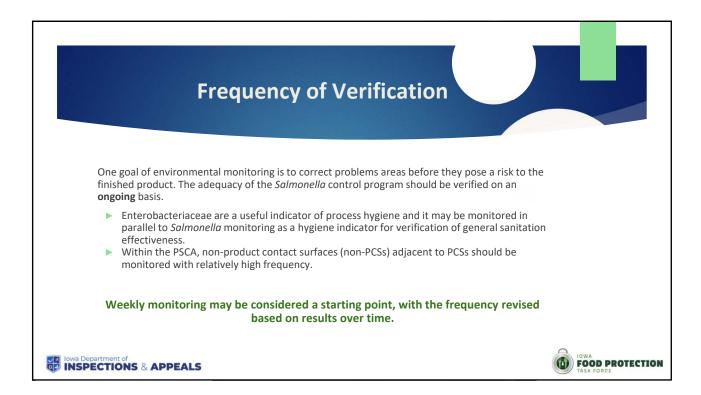
While this is not often performed in retail facilities, does your corporation or your suppliers perform validation for any products you prepare and/or sell?

Examples are challenge studies for foods, environmental monitoring in their plants or even environmental monitoring in your facilities on a routine basis











- DEVELOP A WRITTEN PROGRAM FOR ROUTINE ENVIRONMENTAL MONITORING UNDER NORMAL OPERATING CONDITIONS. ROTATE THE AREAS BEING MONITORED AND TEST DIFFERENT SURFACES AS OFTEN AS POSSIBLE.
- INCREASE ENVIRONMENTAL MONITORING AS WELL AS OTHER CONTROL
 MEASURES IN RESPONSE TO PLANT EVENTS SUCH AS DURING AND AFTER
 CONSTRUCTION, AFTER EQUIPMENT INSTALLATION, AND ONCE MAJOR
 REPAIRS ARE COMPLETED.
- DEVELOP A POLICY ON WHETHER AND WHEN TO TEST PCSAS AND/OR FINISHED PRODUCT AND A PROGRAM FOR THIS TESTING.
- USE AN OFFICIAL OR VALIDATED METHOD TO TEST SAMPLES TAKEN FROM THE ENVIRONMENT OR FINISHED PRODUCT.
- TAKE APPROPRIATE CORRECTIVE ACTIONS WHEN SALMONELLA IS
 DETECTED IN AN ENVIRONMENTAL MONITORING OR FINISHED PRODUCT
 SAMPLE, INCLUDING PRELIMINARY/PRESUMPTIVE SALMONELLA TEST
 RESULTS.





Questions for Retail Facilities

- 1. Do any of you perform environmental monitoring? Is it on a regular basis or only after an outbreak or significant event (construction, major remodeling, flood, etc.)?
- 1. If you do perform environmental monitoring, what do you do if you get positive results for *Salmonella* or other pathogens?





