Industry Best Practices for Control of *Listeria monocytogenes*

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Presentation Outline

- **Introduction and Regulatory Context**
  - **Best Practices : What they are, why we need them and how to implement them**
- **Good Manufacturing Practices (GMPs)**
- **Sanitation Practices**
- **Environment and Product Testing**
- **Summary**

Best Practices

- **Introduction and Regulatory Context**

- Good Manufacturing Practices (GMPs)

- Sanitation Practices

- Environment and Product Testing

Introduction & Regulatory Context

- **What are Best Practices?**

…the collective practices, processes, procedures and steps that, when implemented systematically and consistently will achieve effective control of *Listeria* in RTE meat establishments

- **Who needs to apply Best Practices?**

...every establishment producing RTE meat products

Introduction & Regulatory Context

- **Why are Best Practices needed?**

  …to strengthen protection for:

  - **Consumers and customers by preventing the occurrence of foodborne disease**
  - **Brands by reducing the likelihood of product recalls**
  - **Financial interests by reducing the likelihood of being affected by regulatory compliance and enforcement actions**

Introduction & Regulatory Context

Why are Best Practices needed?

…because listeriosis, the disease caused by *Listeria monocytogenes* has a very high mortality rate (10-44%) in susceptible populations, which include:

- **Pregnant women and the very young (fetuses, newborn)**
- **The elderly**
- **Individuals with chronic disease (e.g. cancer, diabetes, malnutrition, AIDS)**
- **Individuals being treated with immunosuppressive drugs (e.g. transplant patients)**

Introduction & Regulatory Context

Why are Best Practices needed?

…because *Listeria monocytogenes* is the most challenging foodborne pathogen to control in the RTE processing environment

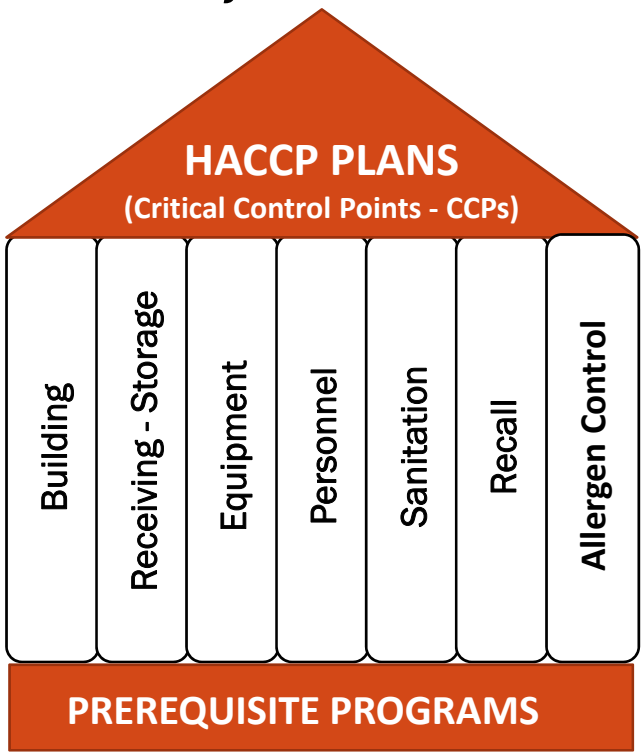
- **Widespread in the natural environment**
- **Easily transferred from place to place on people and materials**
- **Able to grow at temperatures of -0.4 to 45 °C**
- **Able to flourish in niches or harbourage sites within processing equipment and the processing environment**
- **Able to form biofilms on surfaces, which may protect the organism from the effects of cleaners and sanitizers**
- **Able to grow in RTE meat products with a pH value of 4.4 or greater and water activity (a_w)of 0.92 or higher**

Introduction & Regulatory Context

How are Best Practices implemented?

…by integrating them into the HACCP system of the establishment

- Most would be incorporated into the establishment's prerequisite programs, while interventions could be critical control points in HACCP plans



Introduction & Regulatory Context

How will Best Practices be viewed by CFIA?

…CFIA may choose to use them to assist in assessing establishments' *Listeria* control measures

Best Practices

- Introduction and Regulatory Context
- **Good Manufacturing Practices (GMPs)**
- Sanitation Practices
- Environment and Product Testing

Good Manufacturing Practices (GMPs)

- **GMPs are guidelines that outline the aspects of production that can impact the safety or quality of products**

- **The GMPs described in the Best Practices document represent the minimum sanitary and processing requirements for the control and prevention of *Listeria* contamination and the manufacture of safe products**

Good Manufacturing Practices (GMPs)

- **Effective control of *Listeria* demands diligent and consistent adherence to GMPs because of its prevalence in the environment, ease of spread, and ability to flourish in the RTE processing environment**

Good Manufacturing Practices (GMPs)

Physical Plant Design

- **When building or renovating, the design should incorporate features that will facilitate control of foodborne pathogens by:**
  - **Designing the layout with traffic control in mind**
  - **Providing sufficient space around processing equipment to help prevent cross-contamination**
  - **Compartmentalizing the RTE processing area to help prevent cross-contamination**
  - **Avoiding niches where *Listeria* could grow and persist**
  - **Providing facilities for hand washing and footwear decontamination at entrances and for clean-out-of-place (COP) tanks for removable pieces of equipment and tools**

Good Manufacturing Practices (GMPs)

Personnel Training

- Food safety knowledge and training are critical
- Everyone who will enter an RTE area should be trained or instructed on what to do and what not to do while in the RTE area - update and reinforce at appropriate intervals
- Employees especially need to understand why their actions are so important
- The curriculum and level of training should be appropriate to the reason for them being in the RTE area

Good Manufacturing Practices (GMPs)

Personnel Training

- **The training program should cover appropriate parts of the following:**
  - **The nature of *Listeria monocytogenes* and potential harbourage sites**
  - **The consequences of *Listeria* contamination for the company**
  - **Personal hygiene requirements**
  - **Basic sanitation and food handling principles and procedures**

Good Manufacturing Practices (GMPs)

Personnel Training

- The training program should cover appropriate parts of the following:
  - Control measures for *Listeria* and how to ensure they consistently operate as intended
  - Verifying the effectiveness of control through sampling and testing
  - Control of product that could be affected by positive test results
  - Planned response to positive test results and corrective actions
  - Effective coaching techniques for supervisory staff

Good Manufacturing Practices (GMPs)

Hygienic Practices

- Cleanliness
  - Hand washing and drying
  - Protective clothing
- Employee health
- Traffic control
  - Personnel
  - Product
  - Tools and equipment

Good Manufacturing Practices (GMPs)

Hygienic Practices

- Maintenance activities
  - Distinction between raw and RTE processing areas
- Equipment specifications and design
  - Emphasize ease of dismantling and cleaning
  - Apply AMI's 10 Principles of Sanitary Design for Equipment
- Sanitation activities
  - Including operational sanitation with an alcohol-based non-aqueous sanitizer – during breaks and mid-shift clean-up and between shifts
  - Complete cleaning and sanitation daily

Good Manufacturing Practices (GMPs)

Incoming Material Receiving and Storage

- **Incoming materials are potential sources of *Listeria* contamination and controls are necessary to prevent cross-contamination**

- **All materials destined for use in the RTE processing area should be protected from contamination during storage and movement**

Good Manufacturing Practices (GMPs)

Incoming Material Receiving and Storage

- Purchase of raw materials and ingredients should be limited to suppliers with the ability to deliver materials with minimal levels of *Listeria* contamination
- Potential control measures include:
  - Purchase specifications on acceptable limits on *Listeria*
  - Supplier letter of guarantee or certificate of analysis
  - Verification testing of received materials on randomly selected lots
- Establishments producing products with no lethality step (e.g. prosciutto) need to be particularly vigilant

Good Manufacturing Practices (GMPs)

- **The forgoing GMPs constitute the minimum requirements for control of *Listeria* and historically were considered adequate for that purpose but it is clear now that more control is needed in many plants**
- **Only establishments with strict adherence to the GMPs, a superior sanitation program, which includes deep cleaning of equipment, and a robust environmental testing program verifying effective control, should contemplate relying solely on those measures**
- **Other establishments should implement additional antimicrobial interventions to inhibit growth of *Listeria* in their products or to eliminate the organism altogether**

Good Manufacturing Practices (GMPs)

- **Establishments dedicated to the manufacture of products that do not support the growth of *Listeria* may have a bit more latitude**
- **Health Canada and CFIA policies now allow a tolerance of up to 100 cfu/g in such products**
- **However, these establishments should maintain the same objective for control of *Listeria* as other establishments in order to avoid regulatory compliance actions should *Listeria* numbers rise above 100 cfu/g**

Good Manufacturing Practices (GMPs)

Antimicrobial Interventions

- **Intrinsic or extrinsic factors, or a combination of factors can be used to reduce potential for contamination and subsequent growth of *Listeria***

Good Manufacturing Practices (GMPs)

Antimicrobial Interventions

- **Intrinsic factors**
  - **Moisture content – Growth can be inhibited in products that have an a_w value of 0.92 or lower**
  - **pH (acidity) – Growth can be inhibited in foods with a pH value below 4.4**
    - **Growth can also be inhibited in foods with certain combinations of a_w and pH values, such as lower than 0.94 and below 5.0, respectively**
  - **Antimicrobial agents – Growth can be inhibited in products through the use of antimicrobial additives approved by Health Canada**

Good Manufacturing Practices (GMPs)

Antimicrobial Interventions

- **Antimicrobial additives currently approved for use in Canada in RTE meat products**
  - **Sodium acetate**
  - **Sodium diacetate**
  - **Sodium lactate**
  - **Potassium lactate**
  - **Carnobacterium maltaromaticum strain CB1 (in vacuum-packed wieners, sliced roast beef, sliced cooked ham and sliced cooked turkey)**
  - **???**

Good Manufacturing Practices (GMPs)

Antimicrobial Interventions

- Natural antimicrobial agents
  - Celery seed (source of nitrite)
  - Vinegar (acetic acid)

Good Manufacturing Practices (GMPs)

Antimicrobial Interventions

- Extrinsic factors
  - Time/temperature controls
  - Lethality processes
    - Thermal (cooking)
  - Post-lethality processes
    - Thermal (steam pasteurization, hot water treatment, radiant oven heating or infrared heating of packaged products and cook-in-the-bag products)
    - Non-thermal – high pressure pasteurization (HPP)

Best Practices

- Introduction and Regulatory Context
- Good Manufacturing Practices (GMPs)
- **Sanitation Practices**
- Environment and Product Testing

Sanitation Practices

- **Sanitation is arguably the most important element for effective control of *Listeria***
  - **Any pathogens in the RTE processing area must be destroyed to avoid build-up and exposure of meat products**
- **Requires:**
  - **Structured approach**
  - **Well-trained personnel, time and patience**
  - **Meticulous attention to sequence and thoroughness of procedures**
  - **Regular tear-down and deep cleaning of equipment**

Sanitation Practices

- **General Cleaning and Sanitation Procedures**
  - **Area preparation**
  - **Scrapping**
  - **Pre-rinse**
  - **Inspection by sanitation crew**
  - **Detergent application and manual scrubbing**
  - **Final rinse**
  - **Final Inspection by supervisor or QA**
  - **Flood Sanitizing**
  - **Drying**

Sanitation Practices

- **Special Cleaning and Sanitation Procedures**
  - **Double sanitizing or shock sanitizing – e.g. during construction projects, after intensive maintenance, etc.**
    - **Higher concentration of flood sanitizer followed by a normal no-rinse sanitizer**
  - **Clean-in-place (CIP) procedures – cleaning of interior surfaces of pipes, vessels, processing equipment and fittings without disassembly**
  - **Clean-out-of-place (COP) cleaning – for small and intricate parts that can be immersed in the tank of heated chemical solution**

Sanitation Practices

- **Special Cleaning and Sanitation Procedures**
  - **Steam cleaning – use of dry steam to clean water-sensitive parts of equipment (e.g. electrical panel), remove heavy dried-on soils deep inside equipment, and to sanitize under and inside parts that do not come apart**
- **Particular attention is required to prevent development of harbourage sites and biofilm formation**

Sanitation Practices

- **Harbourage Sites**
  - **A harbourage site (aka growth niche) is a specific area where *Listeria* can survive, multiply and potentially contaminate food because the site provides conditions necessary for microbial growth (nutrients in the form of food residues, humidity, and suitable temperature).**
  - **Often located in difficult to clean areas, allowing them to develop in spite of the routine sanitation practices being carried out.**
  - **Dangerous anywhere near a food contact surface but particularly so when they develop deep within equipment**

Sanitation Practices

- **Elimination of Harbourage Sites within Equipment**
  - **Basic –daily: Removing easily-removed parts to allow proper sanitation – e.g. belts, blades, grippers, scales, some rollers, shear bars, etc.**
  - **Level 1 – Weekly to monthly (in conjunction with preventive maintenance): More extensive disassembly for deeper cleaning and sanitizing, generally done on weekends – e.g. slicing heads , check-weighers, rollers, transfer lines, vacuum packaging equipment**

Sanitation Practices

- **Elimination of Harbourage Sites within Equipment**
  - **Level 2 –Semi-annually (in conjunction with preventive maintenance): All components are removed for cleaning and sanitizing**
    - **During disassembly, sequential swabs are taken before cleaning and in the same places after cleaning**
    - **Swabs are cultured for total plate counts and *Listeria* species to determine extent and depth of contamination**
    - **Level of contamination can guide depth of disassembly required the next time**

Sanitation Practices

- **Biofilm Detection and Removal**
  - **Biofilms are communities of bacterial cells that adhere to each other and to surfaces, surrounded and protected by a polysaccharide material they produce**
  - **Can develop quickly, within a few days**
  - **Often difficult to detect on routine examination**
  - **Confirm presence by scratch-and-swab technique**
  - **Prevent formation by vigorous scrubbing of surfaces during daily cleaning and sanitation and by drying surfaces**
  - **Perform additional cleaning and sanitizing after long weekends and other significant downtime**

Best Practices

- Introduction and Regulatory Context
- Good Manufacturing Practices (GMPs)
- Sanitation Practices
- **Environment and Product Testing**

Environment and Product Testing

- **The primary purpose of environmental and product testing is to verify the effectiveness of measures in place to control *Listeria* – testing is NOT a control measure in itself**

- **The testing program must be designed to detect any *Listeria* that may be present (i.e. test-to-find) to enable appropriate corrective actions to be taken before the contamination can develop into a more serious problem**

Environment and Product Testing

- **For environmental testing, sampling both food contact surfaces (FCS) and non-food contact surfaces (NFCS) enables a more complete understanding of the effectiveness of the *Listeria* control program within the plant**

- **Testing for *Listeria* species (*L*spp) and reacting to positive results as if they reflected the presence of *Listeria monocytogenes* (*Lm*) provides a more sensitive and more cost-effective control program than would testing for *Lm* alone.**

Environment and Product Testing

- **Lot definition**

  …all RTE product produced and packaged between two complete sanitation procedures

  …may be further subdivided by production line if all equipment is dedicated to the line

  - **Relevant to both product and environmental testing**
  - **Identifies and limits the amount of product subject to detention or recall in the event of a positive test result**
  - **Products should be held pending availability of test results where a positive result could result in a recall**

Environment and Product Testing

- **Environmental Sampling Plan**
  - **Divide plant into zones based on proximity to exposed product**
  - **Zone 1 – FCS, e.g. conveyors, slicers, peelers, tables, utensils, trucks, brine chill, gloves, sleeves, aprons, etc.**
  - **Zone 2 – NFCS near FCS or exposed product, e.g. exterior of equipment, switches, refrigeration units, etc.**
  - **Zone 3 – NFCS between point of thermal processing and packaging , e.g. floors, walls, overheads, phones, forklifts, drains, etc.**
  - **Zone 4 – Surfaces remote from the production room, e.g. locker rooms, cafeteria, hallways, dry storage, drains, etc.**

Environment and Product Testing

- **Environmental Sampling Plan**
  - **Use pre-moistened sponges to sample 900 cm^2 (1 ft^2) areas with 2-3 passes, each perpendicular to the previous pass**
    - **Buffer should be specific to the test method to be used**
  - **Use pre-moistened swabs for smaller surfaces (100 cm^2) and hard to reach areas, e.g. crevices, screw and bolt heads, etc.**
  - **Sample all Zone 1 sites first, then all Zone 2 sites, followed by Zones 3 and 4 (drains last)**

Environment and Product Testing

- **Environmental Sampling Plan**
  - **Sample Zone 1 FCS sites on each line once a week at T≥3 hours**
    - **10 sponge/swab samples per line**
    - **Test individually or in composites of 5-10 samples**
  - **Sample numbers and frequencies can be proportioned across zones based on relative importance of results**
    - **Zone 1 – 40-60% of samples**
    - **Zone 2 – 20-40% of samples**
    - **Zone 3 – 10-20% of samples**
    - **Zone 4 – 0-10% of samples**
    - **For Zones 2-4, test samples in composites of up to 10 samples**
  - **Randomize sample collection days**

Environment and Product Testing

- **Environmental Sampling Plan**
  - **Biased – Select sampling sites within zones where contamination is most likely to be found, based on previous results and locations of potential transfer points and harbourage sites**
  - **Dynamic – Modify sampling sites and frequencies according to previous test results, corrective actions taken, and changes in equipment, processes and product lines**
  - **Be wary of substantially reducing the intensity of sampling solely because products do not support growth of *Listeria***

Environment and Product Testing

- **Finished Product Sampling Plan**
  - **Often driven by customer purchase specifications**
  - **In any case, finished product should be sampled at some frequency to verify that the environmental testing program is sufficiently sensitive and functioning as expected**
  - **Test product following detection of a positive FCS**
  - **n = 5 is considered satisfactory for routine testing**
  - **Test for *L*spp and follow up with confirmatory tests for *Lm***

Environment and Product Testing

- **Finished Product Sampling Plan**
  - **In choosing sample numbers, consider the circumstances (routine or investigational) and level of confidence required**

Number of Sub-Samples	Contamination Rate (95% Probability of Detecting)
n = 5	45%
n= 10	25%
n = 20	15%
n = 60	5%

Environment and Product Testing

- **Precautionary Holding of Finished Product**
  - **When testing finished product…**
  - **When testing FCS, especially if following up on a positive FCS result…**

  …hold all product that would be implicated by a positive test result, e.g. all products in the lot being tested, all products processed on the same line
    - **Ensures product will be available for follow-up testing if needed**
    - **Protects against need for a recall**

Environment and Product Testing

- **Data and Trend Analysis**
  - **Compile test results in a spreadsheet or other vehicle to facilitate review and analysis**
  - **Produce a spatial display by marking the location of positive and negative sampling sites on a floor map of the facility**
  - **All test results should be examined by an establishment team on a fixed schedule (daily, weekly)**
  - **Consider new results in the context of previous test results to identify the beginning of positive or negative trends**

Environment and Product Testing

- **Data and Trend Analysis**
  - **Look for evidence of harbourage sites (especially inside equipment), biofilms and transfer sites**
  - **Adjust the environmental sampling plan to provide further information**
  - **Respond to negative trends by reviewing, correcting and improving the execution of GMPs and sanitation procedures**

Environment and Product Testing

- **Response to Positive Test Results**
  - **React immediately and aggressively to all positives**
  - **Level of urgency dictated by location of the contamination**
  - **Have a multidisciplinary team ready to manage the response, with members drawn from management, QA, operations and maintenance**
  - **As a general rule**

…Intensify sanitation procedures in the affected area

…Retest sites that were positive and nearby or upstream areas until three consecutive tests are negative at the positive site

Summary

Essential Elements of Best Practices for *Listeria* Control

- **A strong sanitation program to control *Listeria* in the processing environment, which must include semi-annual equipment tear-down**
- **Diligent and consistent implementation of GMPs to prevent *Listeria* from entering and becoming established in the processing environment**
- **An environmental and product testing program designed and carried out to find any contamination that may be present**
- **Application of additional antimicrobial control measures to enhance consumer protection**

For Further Information

- **"Meat Industry Best Practices for Control of *Listeria monocytogenes*"**
  - **Developed by the Industry Working Group and will be published in the near future**

- **Questions or comments can be directed to the Working Group via mervbaker@sympatico.ca**