Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs)

Ready-to-Eat (RTE) Products

In Cooperation With

North American Meat Processors; Central States Meat Association; South Eastern Meat Association; Southwest Meat Association; Food Marketing Institute; National Meat Association; and American Association of Meat Processors *(pending final approval)*

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INTRODUCTION

Ready-to-Eat (RTE) meat products are important, convenient meat food products. They are widely distributed and consumed as snack foods, sandwich fillings, picnic items, deli buffet foods, and in lots of other ways without any further food preparation. They are a truly convenient food for millions of consumers, and they are presumed to be safe to eat by consumers as purchased.

Certain strains of *Listeria* species, a microorganism that exists widely in the environment, have been found to be pathogenic to the human population as well as to the animal population. *Listeria* spp., unlike most other pathogens, continues to grow, albeit slowly, under refrigerated conditions. The heat processing of RTE products destroys these bacteria; however, extraordinary handling practices after cooking are needed to prevent recontamination. Such handling is particularly important to prevent recontamination with *Listeria* spp., because they will continue to grow even when the product is vacuum packed and held under refrigerated conditions.

Detection of pathogenic microorganisms at very low levels on product is always difficult; it's even more difficult if they occur sporadically, and the distribution is likely to be sporadic in recontamination circumstances (i.e. not uniformly distributed). Aggressive preventive strategies are the best way to assure the safety of RTE products, coupled with an environmental microbiological sampling and testing program to identify and eliminate any possible entry opportunities for this family of microorganisms when RTE products are being handled and/or packaged.

A group of organizations sponsored the development of these Guidelines for Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling and Testing Recommendations (ESTRs) for Ready-to-Eat Products. Operational personnel from firms producing RTE products met with Dr. Kerri Harris for a working group session to develop the GMPs and SOPs that are set forth herein. In addition, a group of industry microbiologists met with Dr. John Blackwell to develop the ESTRs that are set forth herein. All persons who provided their time and energy in this project are acknowledged herein.

Facilitators: Dr. Kerri Harris, Institute of Food Science & Engineering, Texas A&M University, College Station, TX and Dr. John Blackwell, Food Marketing Services International Inc., Columbia, MD

Participating Organizations: American Association of Meat Processors; North American Meat Processors; Central States Meat Association; South Eastern Meat Association; Southwest Meat Association; Food Marketing Institute; and National Meat Association

Participating Microbiologists: Dr. Steve Goodfellow, Deibel Laboratories; Mike Craig, ABC Research Corp; Ken Kenyon, Deibel Laboratories; Gina Bellinger, IDEXX Laboratories; Dr. Margaret Hardin, National Pork Producers Council

Participating Individuals: Bruce Barry, Oberto Sausage Co., Kent, WA; Chris Bodendorfer, Emmpak Foods, Inc.; Troie Burch, Quik-to-Fix, Dallas, TX; Dr. Robert Delmore, Clougherty Packing Co., Los Angeles, CA; Dr. Jill Hollingsworth, Food Marketing Institute; Jason Jennings, Jennings Premium Meats, New Franklin, PA; Teresa Frey and Rosemary Mucklow, National Meat Association; Fred Reimers, H.E.Butt Grocery, San Antonio, TX; Jonathan W. Rocke, RMH Foods, Morton, IL; Sereke-Jim Tecklu, International Trading Corp, Houston, TX; Tim Wampler, Elm Hill Meats, Lenoir City, TN.

I

Guidelines for Developing Good Manufacturing Practices (GMPs) and Standard Operating Procedures (SOPs) for Ready-to-Eat (RTE) Products

coordinated by Dr. Kerri Harris, Associate Director
The Institute of Food Science and Engineering, College Station, Texas

INTRODUCTION

Producers of ready-to-eat (RTE) products understand the importance of developing and implementing procedures to reduce the potential for contamination with microorganisms such as *Listeria monocytogenes*. Therefore, it is extremely important that manufacturers of RTE products develop and implement effective Good Manufacturing Practices (GMPs) and Standard Operating Procedures (SOPs) as the foundations of a successful HACCP program. Combining strong GMPs, SOPs, SSOPs and HACCP will increase the total process control system and help these manufacturers continue to produce the safest products possible. The development and successful implementation of these programs requires full management support and commitment.

This document provides general recommendations for developing GMPs and SOPs for RTE operations, and it can be used as a guideline for developing plant specific GMPs and SOPs. It also addresses the issues of reprocessing product and recommendations for effectively using environmental testing for *Listeria species.* These recommendations focus solely on the RTE products. It is important to note that the following items are not addressed in detail in this document, but they should be covered by existing Sanitation Standard Operating Procedures (SSOPs) or other plant-specific processing programs:

- Personnel - disease control, hygiene, clothing, training, etc.
- Plant and grounds - construction and design, product flow, drainage, etc.
- Sanitary operations - general maintenance, cleaning and sanitizing, pest control, etc.
- Sanitary facilities and controls - water supply, plumbing, sewage disposal, rubbish and offal disposal, etc.
- Freezers and coolers - monitored and maintained to ensure temperature control, recording devices, alarms, etc.
- Equipment maintenance and calibration - adequate frequency for thermometers, recording devices, compressed air equipment, etc.
- Recall program - It is recommended that all RTE facilities develop a recall program and that mock recalls should be conducted periodically to ensure that the program works as planned.

Many of the items listed above are also addressed in 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, developed by the Food and Drug Administration and can be used as a resource if more information on any of these areas is needed.

Ready-to-Eat (RTE) Products are perishable refrigerated/frozen items such as luncheon meats, frankfurters, cooked patties and other fully cooked products and meals that do not require further heating before consumption. Therefore, it is important that appropriate heat treatments are applied and that all possible steps are taken to reduce potential contamination after the heat treatment or post-processing. It should be noted that each processor must validate the cooking process for these products and meals as part of the HACCP development and implementation. Validation will ensure that the cooking process is adequate to control *Listeria.* All of these actions will help manufacturers of RTE products produce the safest products possible.

LOTTING

All RTE operations should have a lotting mechanism for coding or recording finished products to allow for tracing the product back through the system and for tracing the product forward through the chain. Some establishments may develop computerized bar codes or tracking systems that are very elaborate and detailed, and others may have simple handwritten documentation and box/package codes. Lotting is driven by some time factor (i.e., hour, shift, day, etc.) and is given a specific code. Creating smaller lots or utilizing a sub-lotting system for tracking information may help demonstrate/document process control and could possibly help to minimize the economic impact of recalls.

Regardless of the mechanism, each operation should have a record keeping system, and it is recommended that the following items be documented for each identified lot/sub-lot.

- Raw material source(s) by vendor and including vendor lot identification
- Data collected during process (temperatures, microbial data, etc.)
- Equipment evaluation records (i.e., maintenance records)
- Other items as specified by individual customer

If any abnormal indicator is found during the process then it is recommended that the product be segregated, that cleaning and sanitizing of the processing line is completed prior to reinitiating production, and that a new lot/sub-lot is started when production starts back up. Some operations are implementing a sublotting system that requires the following types of documentation:

- Batching records — These records should identify the types of raw material used by its tracking codes; the amount used in each batch of formulated product, the time it was used and the locations of equipment it was used on.
- Packaged product tracking systems — The finished products should be coded with the actual times they are packed and sealed and pallets of products should contain consecutive products off the line. Packaging systems with multiple lines should have a consistent flow of raw materials to each packaging line and the ability to code and identify products from a specific line as necessary. Downtime tracking sheets can be used to identify lines that were not packaging products at the time of suspect incidents and therefore created a break in the flow of products through the system.
- Finished Product "On-Hold" Programs — If a company is testing finished RTE products for potential microbial adulterants, then it should require appropriate product/lot(s) to be held until laboratory testing is completed and the results are available. Records for operations should include the total amount of products

produced as well as their location. However, it should be noted that end-product test and hold programs are not generally recommended.

REPROCESSING PRODUCT

As with most production systems, the issue of allowing products that do not meet the company specifications (broken, ends and pieces, leakers, etc.) to re-enter the system is an important factor that must be considered. Therefore, the following categories are recommended to help distinguish between the types of reprocessing activities that may occur during the production of RTE products.

1. Recooking — This allows products that have received the heat treatment but that do not meet the operational specifications to go through the heat treatment again. These products may be recooked as they are if the product allows it or they may be re-introduced into the system within the acceptable USDA guidelines. For example, items that:
   - Do not meet the "production specifications" (i.e., mis-sliced, broken, ends and pieces, leakers, pinholes, products that do not meet the sensory evaluation, etc.)
   - Do not meet the CCP for heat treatment
   - Do not meet the cooling requirements

2. Repackaging — This allows product that has received the heat treatment but that does not meet the operational specifications (leakers, coding, film, labels, etc.) to be repackaged without receiving an additional heat treatment. These products must still be within the post-heat treatment processing area (i.e., processing room, chiller, packaging room). After products leave the post-heat treatment production environment, the products should not be allowed to be repackaged and must re-enter via recooking as described above.

3. Returned and reinspected product — It is recommended that RTE products that are returned not be repackaged or redistributed, until the establishment can evaluate and document the safety of the product handling since it left the facility and the product integrity has been maintained. For example, if product was inadvertently loaded onto a truck and remained on the truck throughout the delivery route at an appropriate temperature and was then returned at the end of the delivery, then the establishment may allow this product to be returned to available inventory.

It should also be noted that unprotected RTE products that fall onto the floor must be discarded. They cannot be reprocessed and/or reconditioned to reenter the food supply.

The recommendations provided above should help an establishment make decisions relating to the reprocessing of products. Each establishment will need to carefully consider the options and determine which one works best within their operation based on amount of production, opportunities for further processing, etc. Each establishment is encouraged to develop specific written procedures for how it will handle these issues.

1
GOOD MANUFACTURING PRACTICES

Good Manufacturing Practices (GMPs) as defined by the Food and Drug Administration in 21 CFR part 110 are the minimum sanitary and processing requirements for food companies. GMPs are fairly broad and general and can be used to help guide the development of Standard Operating Procedures (SOPs) which are very specific.

The following guidelines for developing Good Manufacturing Practices for RTE operations are recommended for voluntary consideration and use in developing plant-specific procedures. These GMPs are not designed to control specific hazards, but are intended to provide guidelines to help processors' produce safe and wholesome products.

Receiving Meat

Incoming meat should be evaluated to ensure that it meets the plant-established purchase specifications.

Trucks, containers and carriers of raw materials should be evaluated upon receipt to ensure that the conditions meet plant requirements for transporting meat. All incoming meat should be coded/identified for plant use and for the in-plant tracking system.

Non-Meat Items

Producers of RTE products will need to make sure that all non-meat items, such as packaging materials, seasonings/spices, etc. meet the plant-established specifications. USDA currently requires companies to have a Letter of Guarantee (LOG) from suppliers of non-meat ingredients relating to the use of food grade substances, foreign materials, pest control programs, etc. After the company accepts the non-meat items, then these items should be stored, handled and used in a manner that will maintain the integrity of the items.

Storage of Raw Materials

It is recommended that raw materials be used on a First-In/First-Out (FIFO) basis or according to a plant specified product rotation/inventory control schedule, such as the oldest bone date. Raw materials should be stored at temperatures that maintain proper product condition. Frozen materials should be kept frozen, unless tempering or thawing is required prior to use. The package/pallet integrity must be maintained throughout the storage period to maintain the condition of the material. Product identity in storage should allow for the in-plant tracking system.

Tempering/Thawing of Frozen Materials

If tempering or thawing is required prior to use, then it should be done in a time/temperature controlled manner, which is adequately monitored and documented. The product package integrity is important during this process. The product's traceability should be maintained throughout the tempering/thawing process.

Processing

Processing includes the application of the heat treatment, and it may include but is not limited to — weighing, mixing, blending, grinding, forming, stuffing, or other activities conducted prior to applying the heat treatment.

An organoleptic evaluation of the raw material ingredients should be completed prior to adding the meat to the batch. If applicable, the ingredients should be evaluated for chemical composition (% fat and lean) to formulate product to desired endpoint. Procedures for ensuring proper endproduct characteristics (i.e., weights, physical characteristics, quantity, etc.) should be in place. The in-plant tracking mechanism should allow for batch identification and time of batch production, and may sublot the batch to a cooking lot if applicable.

Establishments should have validated HACCP programs that include appropriate controls for identified hazards throughout the processing system.

Post-Processing Handling

It is very important that RTE producers recognize the importance of preventing cross-contamination of post-processed (after applying the heat treatment) products with raw materials. All operations should have process control mechanisms to prevent cross-contamination. The four factors outlined below can impact the establishment's control.

1. Facility Design:
   The optimal facility design is to provide completely separate areas for raw and cooked processing. It is important that processing areas meet the "Clean Room Concept" including construction requirements provided by USDA, FDA and/or other organizations. The "Clean Room Concept" means that establishments should develop and maintain clean room standard operating procedures to eliminate cross-contamination between RTE products and raw materials. This provides a mechanism for minimizing exposure of RTE products to microbial contamination.

   Specific controls that may be addressed in the Clean Room Concept design/SOPs include:
   - Physical barrier (preferably from floor to ceiling) for separating raw and cooked processing areas

- Employee traffic flow to prevent cross-over between raw and cooked areas
- Positive air flow in exposed product packaging rooms
- Use of footbaths before entrance into a RTE area, including preparation of sanitizing agent, schedule for changing, etc.
- Separate frocks, utensils, etc.
- Proper design, use and cleaning of drains
- Designated equipment and tools for RTE when possible

Due to plant design, complete separation is not always a realistic option. If a physical barrier cannot be added, then additional steps should be taken to help minimize the risk of contaminating post-processing products. For example, if an establishment only has one packaging room that must be used for both raw and RTE products then it should designate separate "processing times." The RTE products could be packaged first while the room is clean, and then the raw products could be packaged. This allows "separation" using process schedules to prevent cross-contamination. It is important to note that all of the other facility control steps should be addressed even if scheduling processing times is used as the method for providing "physical separation." A facility that is utilizing a processing schedule to provide the separation must have a strict sanitation program and a process for evaluating equipment prior to use.

It should also be noted that if plant tours are going to be allowed, then visitors must strictly follow plant requirements related to handwashing, dress, etc., and the tour flow must ensure that contamination of cooked with raw does not occur. i.e. visit the cooked processing areas before going to the raw product areas

2. Sanitation:

All establishments must recognize the importance of the sanitation crew and the activities completed during the sanitation process. The sanitation program must be effectively implemented and appropriate results obtained. It is recommended that producers of RTE products evaluate their Sanitation Standard Operating Procedures (SSOPs) to ensure that they are adequate. Sanitation programs should include:

- Full support of management, including sufficient funding for personnel, equipment, training, and supplies
- Method to establish accountability for the sanitation programs which may include the use of:
  - Microbiological monitoring
    - Coliform plates
    - Standard plate counts
  - Environmental testing for *Listeria* species
  - Pre-operational ATP testing
  - Visual inspections (organoleptic evaluation)
  - Tracking of chemical usage, types, concentrations and rotation schedules
  - Review of sanitation crew training records

- Review of Non-compliance Records (NRs) related to sanitation with the sanitation crew and other appropriate personnel
- Third-party audits of sanitation program

- Evaluation of reporting structure for sanitation crew
- Written procedures for completing the sanitation activities including the appropriate dress/personal hygiene issues for the crews in the RTE areas
- Suggest use of separate cleaning crews and equipment as possible
- Recommend that the RTE rooms be first on the cleaning schedule to prevent contamination from previously cleaned rooms

Facilities should establish a mechanism for tracking sanitation issues to provide a systematic evaluation of the operating sanitation conditions of the RTE room. These issues may include:

- Room temperatures
- Build-up on equipment
- Debris collection
- Standing water and condensation removal
- Use of hoses (Recommend that the use of hoses be restricted during operation/processing of RTE products.)
- Cleaning/sanitation schedule for personnel contact surfaces that are not cleaned/ sanitized on a routine basis (i.e. control panels, switches, etc.)

3. Employees:
   Establishments should develop procedures for employee practices during the production of RTE products. Issues that establishments should consider include:
   - Development of a written procedure for employee hygiene and method for training. Employee training on personal hygiene is a crucial component of creating employee behavior that protects the integrity of the RTE products.
   - Developing a process for emphasizing the importance of employee handwashing and/or gloving.
   - The use of a separate color of frocks designated only for RTE product handling areas, and the use of aprons may be incorporated. Frock colors can also be used to distinguish "product handlers" from "non-product handlers" within the RTE area.
   - The use of appropriate footwear (boots) should be required, and procedures for cleaning, storing, evaluating condition, and wearing outside of the RTE area should be established.
   - Employee traffic flow must be maintained to prevent cross-contamination. Flow should not allow employees to move from raw to RTE areas without following all of the procedures outlined for RTE personnel.
   - Employee traffic flow should be maintained during operational and non-operational hours.
   - All individuals (management, maintenance, sanitation, inspectors, visitors, etc.) entering the RTE processing area must follow the established protocol.

4. Material handling:

Specific procedures for material handling should be established to help prevent cross-contamination of post-processed RTE products. Several items are provided below for the RTE establishments to consider as material handling practices are developed:

- Procedures should address the cleaning/sanitizing of combos, totes, pallets, trashcans, containers, etc. before entering the RTE processing area.
- If wooden pallets are used, controls should be established in RTE processing areas to address the condition, number, and time within the area. The minimum number needed to transfer product should be allowed and wooden pallets should not be stacked/stored within the RTE processing areas.
- Material flow must be developed to prevent raw to cook contamination.
- Procedures should be developed to prevent contamination of RTE packaging materials.
- If conveyors are used, then a process for addressing the condition and flow should be established due to the difficulty of cleaning/sanitizing the belts.
- Special attention should be given to the handling of packaging materials that remain in the room at the end of the day and is removed during cleaning of the room.
- Procedures to ensure proper labeling of ingredients/products should be developed.
- Procedures should address the process of cleaning/sanitizing the outer package surface to prevent post-processing contamination (i.e., inner cook bag, sanitizing dip of casing before removal, etc).

It should also be noted that unprotected RTE products that fall onto the floor must be discarded. They cannot be reprocessed and/or reconditioned to reenter the food supply.

Storage of Finished Product

Finished RTE products should be handled in a method that provides separation of raw and cooked products. They should be stored at plant-designated time/temperatures to maintain product shelf-life. Frozen products should be kept frozen. A FIFO or a plant specified product rotation/inventory control schedule should be maintained for finished products. The package/pallet integrity should be maintained throughout the storage period to maintain the condition of the finished product. Product identity in storage should allow for the in-plant tracking system to be used for recall and/or market withdrawal purposes.

Loading and Shipping

Finished RTE products should be handled properly on the loading docks and during transport to prevent contamination from raw products and product deterioration by temperature abuse or improper handling practices. Trucks, containers and carriers of finished products should be evaluated prior to loading and shipping to ensure that their condition meets plant requirements for transporting RTE products. It is recommended that temperature-recording devices be used when possible for monitoring the trailer temperature during transportation. All trucks and carriers should be suitable for transporting food products; therefore, it may be

important to consider what items were hauled in prior loads by the truck. All of the finished product should be coded/identified for intended use and for recall or market withdrawal purposes.

2
STANDARD OPERATING PROCEDURES

Standard Operating Procedures (SOPs) can been defined as established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations. They are very concise and specific step-by-step instructions. Establishments are encouraged to have SOPs for every task or activity in the facility. GMPs can help guide the development of SOPs. SOPs are also very useful in training employees and in establishing a consistent method for conducting daily operations. Therefore, individual establishments should develop SOPs for their operations.

The following guidelines relate to the areas identified in the GMPs listed above. However, it should be noted that these do not cover all of the areas discussed above and are only examples for which an establishment can develop plant-specific SOPs. Several of the items listed below would require more than one SOP for each specific operation. For example, it is recommended that product temperatures should be checked; therefore, a specific SOP for checking product temperatures should be developed that gives specific instructions on which combos of a load to check; the location(s) in the combo to check, how to check them, etc., and a SOP should be developed for calibrating thermometers. Both of these SOPs would be useful for checking product temperatures. Therefore, this list is basically an outline of general issues and will require additional plant-specific information to develop operational SOPs.

Receiving Meat

1. Designated employee should verify that the raw material is from a company approved supplier.
   (Each plant should set supplier requirements and maintain a list of approved suppliers. It is recommended that review of records related to the specific product and an on-site audit of the supplier be conducted to make sure they are operating as the company desires. For example, a company may require that suppliers have an intervention step or that they are operating under HACCP systems.)

2. Designated employee should evaluate and document on a product receiving log the condition of truck, container and carriers of raw material upon arrival.
   Items for evaluation may include:
   - Cleanliness of truck — no foreign materials, dirt, free of debris, free of off odors
   - Temperature of truck — Temperature of the truck must be acceptable to maintain product temperature. Plant may set specific temperature.
   - Condition of door seals
   - General truck condition — void of cracks, insulation in good condition, etc.

3. If truck condition is acceptable, then designated employee should verify that incoming material meets plant purchase specifications and/or that required documentation is provided.

The following items may be included in purchase specifications:

- Origin and manufacturer
- IMPs or product identity
- Boning date/slaughter date
- No foreign objects
- Packaging/pallet requirements — i.e. - no metal fasteners or bands, pallets in good usable condition, slip sheets, covers on combos, plastic pallets, etc.

4. If the product meets the purchase specifications, then the designated employee should evaluate the actual condition of the raw materials.

   The following items are recommended for evaluation:

   - Temperature of raw material (i.e., frozen $\leq$ 0°F; fresh $\leq$40°F). (Each operation should have a separate SOP for taking the temperature of incoming products and calibrating thermometers.)
   - Organoleptic evaluation of raw material for off odor, discoloration, improper appearance.
   - Material must have supplier code information and proper lot/load identification on materials

5. If incoming raw materials pass receiving inspection, then all raw materials should receive plant-specific tracking/coding information prior to entering the storage facility.

Storing Meat

1. Place fresh product into cold storage (recommend 35°F) and frozen product into freezers (recommend less than 10°F).
2. Complete plant specific storage records or product identification, so product will be used on a FIFO basis or according to plant product rotation/inventory control schedule.
3. Store products to maintain package/pallet integrity. It is recommended that combo bins have a protective covering (second cover) if they are being stored in racks and that the protective covering should be removed prior to entering the processing area where the primary covering is removed.
4. Procedures should be in place to maintain product integrity (i.e., prevent species contamination, drip contamination during storage, etc.)

Tempering/Thawing of Frozen Materials

1. Place frozen product in a tempering room that is $\leq$50°F and allow product to reach desired level of tempering or thawed state; actual time will vary depending on amount of product and type of packaging. (If the room temperature is higher than 50°F then one must evaluate the time/temperature relationship to reduce the risk of potential microbial growth on the surface of the product.)
2. The product should be monitored on a scheduled basis to prevent loss of package integrity and product drip, and to ensure that product drip does not contaminate other products.
3. The product temperature should be monitored and documented on a scheduled basis to ensure that the desired end temperature is not exceeded.

4. All of the products should maintain the plant-specific tracking/coding information to ensure proper traceability of product from receiving through to final end products.

Processing

1. It is recommended that the establishment utilize a validated HACCP system to control the identified hazards for RTE products.
2. Production employees should evaluate the chemical composition of the raw materials to ensure that proper formulation is obtained.
3. Production employees should evaluate the organoleptic properties for off odor, discoloration, improper appearance prior to allowing product to enter the batch.
4. Production employees should record batch identification information and times of batch production to maintain plant-specific tracking information.
5. Production employees should complete an evaluation of the equipment (grinders, defect eliminators, ovens, etc.) on a scheduled basis and the time of each evaluation should be recorded.
6. The product identification/tracking mechanism should identify specific processing lines.
7. Packaging and labeling employees are responsible for properly labeling end-products with product identity and code dates which include an expiration date, sell-by date, use-by date, production date, etc. using a dating system according to company procedures.
8. Packaging and labeling employees are responsible for including all handling and storage information according to each product's requirements.

Storing Finished Product(s)

1. Utilize products in a plant specified time-period to maintain shelf-life requirements. Shelf-life of the product is dependent upon type of product, type of package, temperature of storage, condition of incoming materials, etc. Therefore, each establishment should have specific guidelines for storing and utilizing finished products.
2. Store products to maintain package/pallet integrity.
3. Product integrity and identification should be maintained during storage.

Loading/Shipping of Finished Product(s)

1. Designated employee should evaluate and document the condition of truck, container and carriers of finished product prior to loading products.
   The following items should be evaluated:
   - Cleanliness of truck — no foreign materials, dirt, free of debris, free of off odors
     Temperature of truck — Temperature of the truck should be acceptable to maintain product temperature. Plant may set specific temperature and the use of temperature monitoring devices should be used as possible.
   - Condition of door seals
   - General truck condition — void of cracks, insulation in good condition, etc.
2. All RTE products should be handled properly to maintain the condition of the products. Therefore, it is recommended that the time the products remain on the loading and receiving docks should be controlled based on the temperature of the docks.

3. The loading/shipping employees should be aware of the products being transported and the proper handling techniques for those products.
4. Package integrity should be maintained during loading/shipping.
5. Product identification should be maintained through loading and shipping to ensure that the products can be traced if needed for recall and/or market withdrawal purpose.

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II

Guidelines for Environmental Sampling /Testing for Plants Producing Ready-to-Eat Products

coordinated by Dr. John H. Blackwell, President
Food Marketing Services International, Inc.

INTRODUCTION

Psychrotrophic pathogenic microorganisms, including *Listeria* species are a matter of public health concern. Since these microorganisms are often associated with food, especially foods of animal origin, and because of their ability to be sustained and even grow at refrigerated temperatures and to survive freezer temperatures, special efforts to prevent their entry into food production systems are highly desirable.

One strain of *Listeria* spp, *L. monocytogenes*, is considered an adulterant when found in commercial, "Ready-to-Eat" (RTE) food products that may be consumed without further cooking. Because *L. monocytogenes* is only likely to be present in very low numbers on such products in a commercial establishment, and therefore difficult to detect with the available testing capabilities, a testing plan for *Listeria* spp. is being recommended because it is easier and faster to find. Further, even false positives which are often caused because of the presence of non-pathogenic lactic acid microorganisms indicate a generally undesirable condition in an RTE area. Again, the various strains of *Listeria* spp. are sustainable and continue to grow slowly at refrigerator temperatures. Thus, there is always the possibility that an environmental or a product sample found non-detectable, if held for a protracted time under refrigeration and re-tested, could be reported positive. This poses a difficult dilemma for both food manufacturers and regulators about how best to assure the safety of the food being distributed under "keep refrigerated" requirements.

Listeria spp. are found routinely in any environment, including the home and the home refrigerator, and can have many ways of entering an establishment including on livestock, equipment, water, tools and personnel. Some of the most serious outbreaks of illness have resulted from the failure to eliminate it in the raw product through pasteurization (as in milk, ice cream and cheese products) or to prevent its transmission by humans who may track it on their clothing or skin, or by use of equipment that has been contaminated such as the wheels on rolling stock equipment moving from a raw product area into an RTE area, or in a recent case, by its re-entry through air conditioning equipment. Because it sustains itself and continues to grow slowly in cold environments, processing rooms in food production facilities and home refrigerators may provide harborage for the microorganism and are environments where it can continue its growth, albeit slowly.

These Environmental Sampling and Testing Recommendations (ESTRs) have been developed to assist meat processors to eliminate the microorganism from rooms in which RTE products are handled. Further, they are designed to assist meat processors in identifying how the micro-organism, if found, entered the room and thereby reducing the likelihood of its re-entry. Again, the intensive sampling and testing effort is directed at *Listeria* spp. because of the potentially larger population than any one particular strain, and the difficulty of finding positive results for any rarely-occurring microorganism. It needs to be noted that only some specific strains, such as *L. monocytogenes*, are pathogens capable of causing illness in people. Finally, the ESTRs are designed in a tiered system, focusing initially on the locations where this cold-loving microorganism would seek out the most ideal harborage for its survival, and moving back up the system to ever more exposed locations. Pursuit of *Listeria* spp. in this manner requires the person

charged with sampling to "think like a *Listeria* microorganism" in order to seek out its hiding places!

These Guidelines were developed by a group of food microbiologists led by Dr. John H. Blackwell, President of Food Marketing Services International Inc., and including Dr. Steve Goodfellow, Deibel Laboratories, Ken Kenyon, Deibel Laboratories, Gina Bellinger, IDEXX Laboratories, Mike Craig, ABC Research, Dr. Margaret Hardin, National Pork Producers Council, and in coordination with the industry persons working to develop GMPs and SOPs led by Dr. Kerri Harris, Institute of Food Science & Engineering, Texas A&M University, for the National Meat Association, Oakland, California

1
Recommended Approach to Environmental Microbial Sampling

The approach is simple. Look once, look twice, and keep looking for it. *Listeria's* entry vehicle may change over time, may be different at different seasons of the year, may arise because of other things happening in the larger plant facility, may be peculiar to one piece of equipment, to the footwear of one employee, and on and on. Whenever an entry point is identified, repeated treatment first by careful cleaning of the affected area and containing run-off or impact on adjacent clean areas, and then by applying USDA approved sanitizers should be performed. Further, changes in operating practices should be instituted to eliminate the entry opportunity.

Plants should make determinations as to operating modifications to be made to respond to *Listeria* spp. For example: Replacement of older drains, such as those made from concrete or cast iron with stainless steel types; thorough washing and sanitizing of wheels on rolling stock each time they enter processing rooms; or ensuring that maintenance equipment is not transferring the microorganism into the room from its prior use in a raw production area. Implicit in this approach is that each plant will make modifications based upon its individual situation. Changes should be documented for future reference in case *Listeria* spp. persists or reoccurs.

This approach initially entails the confirmation of the adequacy of pre-operative and operative tasks specified in the plant's Good Manufacturing Practices (GMPs) and Sanitation Standard Operating Procedures (SSOPs), followed by environmental sampling.

The sampling scheme is designed in tiers and begins in those locations that have the highest potential for finding *Listeria* spp. Further, if it is **not** found in each tier on repeated sampling in different locations over time, then the company should move to the next sampling tier and, once again, exhaustively sample to see if it can be found.

First Tier:
Sampling of Non-Contact locations in High Potential Areas at or during pre-op

An appropriate number of sponge samples would be collected each week at pre-operation time from cleaned and sanitized locations, such as drains, cracks in walls, cracks in floors, rollers on trucks, gondolas, drip trays under refrigeration units, electrical outlets, floors in heavily-trafficked areas, drip pans. (The number of samples will depend upon the size and the complexity of the operation, and could range from less than 10 to many times that number.) Sponge sample collection should be made in an aseptic manner from as large a target area as possible. To eliminate the potential for environmental contamination as a result of sampling activities, locations that are sampled should be sanitized immediately after sample collection. This is most easily done by use of a spray bottle to flood the area with an approved compound. Further, employees responsible for sampling should wash and sanitize their hands between taking each sample, and put on new gloves for each sample.

If samples obtained from locations being monitored in the plant are found to be negative after cleaning and sanitizing, only periodic spot checks at the same locations would subsequently be performed. when test results are negative over a reasonable period of time, the plant is ready to move to Second Tier sampling.

If samples collected from selected sites after cleaning and sanitizing are positive, the sampling sites should receive increased sampling and personnel should intensively investigate the source of

contamination at that location. Investigative efforts should focus on how the contamination reached the location.

An aggressive decontamination program must be initiated. This procedure includes initial washing and cleaning of all equipment and environmental surfaces. It may need to include ceiling to floor strip cleaning and sanitizing with the dismantling of equipment, exposing unsealed areas and the removal of insulation from pipes, or sealing of insulation whichever is most feasible, and looking behind conduits. The walls, ceilings, floors, and the product and non-product surfaces of disassembled equipment must be sanitized with an approved compound (such as hydrogen peroxide, quaternary ammonium chloride compounds, sodium hypochlorite.) Care should be taken to neutralize floors that may have been treated with an acid cleaner. The sanitizing step is followed by fogging the room with an approved compound, such as a quaternary ammonium chloride compound at a concentration of 1000 ppm. In all instances where a fogging step is applied, the proper precautions to guarantee personnel safety must be followed. Further, this treatment must be followed by a clean water rinse followed by sanitizing using recommended levels for food product contact surfaces at the desired dwell time. The target areas are then re-sampled in order to confirm that the contamination has been eliminated.

Second Tier:
Sampling of Non-Contact locations in High Potential Areas during operations

This is simply a repetition of sampling at the same locations as set forth in Tier One, but with one critical difference: Samples should be taken before the equipment is cleaned and sanitized.
It is recommended that the first round of samples be taken within the first two hours of operation, at the same locations as in Tier One, and with the same precautions, i.e. sanitizing the sampled area by flooding with an approved sanitizer after sample collection. As in Tier One, any findings of positives must be followed to the entry source, and that entry eliminated. The company may stagger the collection time once it has data showing negative results and start sampling after breaks. This will help to confirm that the sanitary practices of personnel in the area meet the stringent requirements necessary for RTE areas.

When samples collected both after cleaning (Tier One) and before cleaning (Tier Two) are reported negative, periodic spot checks should be performed to reconfirm the absence of contaminating microorganisms. The plant is ready for Third Tier.

The results of monitoring must be documented accurately. In this way, the plant can determine the location of environmental " hot spots " in the RTE areas and also indicate the type of preventive strategy to be implemented to eliminate the presence of the contaminating microorganisms.

Third Tier:
Sampling of Non-Contact locations in Moderate Potential Areas at Pre-op

The sample sites in the Third Tier focus on intensive sampling from areas such as support frames, on/off electrical switches, non-product contact side of belts, foot and wheel baths, etc. Equipment should be run for a few minutes before samples are collected by sponge.

The rules for sampling are the same as set forth in Tier One. Flood the area with approved sanitizing solution after sampling. Again, sampling should occur when the room is clean and before operations start. If samples collected from selected sites after cleaning and sanitizing are negative over time, it’s time to move to Tier Four.

If samples collected from selected sites after cleaning and sanitizing are positive, investigative efforts should focus on how the contamination reached this location. An aggressive decontamination program should be initiated, including ceiling to floor strip cleaning and sanitizing

with the dismantling of equipment, exposing unsealed areas and the removal of insulation from pipes and conduits. This procedure includes initial washing and cleaning of all equipment and environmental surfaces. The walls, ceilings, floors, and the product and non-product surfaces of disassembled equipment are sanitized with an approved compound (Such as hydrogen peroxide, quaternary ammonium chloride compounds, sodium hypochlorite). The sanitizing step is followed by fogging the room with an approved compound, such as a quaternary ammonium chloride compound at a concentration of 1000 ppm. In all instances where a fogging step is applied, the proper precautions to guarantee personnel safety must be followed. Further, this treatment must be followed by a clean water rinse followed by sanitizing using recommended levels for food product contact surfaces at the desired dwell time.

The target areas are then re-sampled in order to confirm that the contamination has been eliminated. When a pattern of negative results is developed, it's time to move to the Fourth Tier.

Fourth Tier:
Sampling of Non-Contact locations in Moderate Potential Areas during Operations

This is simply a repetition of sampling at the same locations as set forth in the Third Tier, but with one critical difference: Samples should be taken before the equipment is cleaned and sanitized.

It is recommended that the first round of samples be taken within the first two hours of operation, at the same locations as in Tier Three, and with the same precautions, i.e. sanitizing the sampled area by flooding with an approved sanitizer after sample collection. As in Tier Three, any findings of positives must be followed to the entry source, and that entry eliminated. The company may stagger the collection time once it has data showing negative results and start sampling after breaks. This will help to confirm that the sanitary practices of personnel in the area meet the stringent requirements necessary for RTE areas.

When a pattern of negative results is developed, it's time to move on the the Fifth Tier.

Fifth Tier:
Sampling of Contact Surfaces

Sampling and testing for *Listeria* spp. on contact surfaces or of debris and fines (shavings remaining on the equipment) may be interpreted by regulatory authorities as testing product itself, and a positive for *Listeria* spp. may then be interpreted by regulators as a presumptive which must be taken to confirmation. Because this is then clearly linked to the product, it is advisable that such testing be accompanied by a "Test and Hold" practice for the product lot represented by the sample. Such a decision is within the discretion of the plant at this time.

Firms can minimize product holding by taking samples and immediately shut down production, and do a full clean-up and sanitation before re-commencing. The affected lot would be from start-up to shut-down. There are disadvantages because of the elevation of room temperatures during a clean-up, the introduction of water and its consequences (the increase in room temperature from the use of hot water, inadvertent splashing, etc.) and the downtime on the work crew and loss of productivity.

Firms are advised to weigh the benefits and disincentives of contact surface and product sampling very carefully, and review their sampling plan with appropriate advisers to fully recognize the potential risks.

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DESCRIPTION OF LABORATORY PROCEDURES

It is essential to assay the samples as soon as possible after collection. The ideal situation is to process the samples in an in-house laboratory that is physically separated and secure from close contact with the plant. However, if the laboratory is located within the confines of the plant, a potential for cross-contamination of the facility exists. Therefore, a strong recommendation is made that samples should be sent out to a commercial testing laboratory.

Sending samples to outside laboratories has the advantage of reducing or eliminating the risk of contaminating the plant environment through the handling of positive samples. In addition, to the technical expertise and experience that can be provided, the outside laboratory reports non-biased, objective results, as well as being able to identify potential problems and suggest solutions.

All samples will be screened for *Listeria* spp. by an enzyme-linked immunosorbent assay (ELISA) method approved by USDA/AOAC that would allow results to be obtained within 48 hours.

1. Preparation of collection materials

Collection materials will consist of:

Sterile specimen sponges in sterile WHIRL-PAK® type bag or equivalent (DIFCO Laboratories, International BioProducts, Inc.)
25ml sterile Butterfield's phosphate diluent (BPD)or buffered peptone water
Sterile self-sealing (ziplock type) or stomacher bag
Sterile gloves
Sanitizing solution*and antibacterial soap

Clean outer lab coat or laboratory clothing
Permanent markers for labeling bags

* Recommended compounds at approved concentrations:
Quaternary ammonium chloride compounds - 200 ppm
Peroxide compounds – 25 ppm
Hypochlorite compounds- 200 ppm
Iodophor compounds – 25ppm

2. Selection of Sampling Area

Samples will be collected from cleaned locations, such as drains, cracks in walls and floors, rollers on trucks, gondolas, refrigerators, electrical outlets, floors in heavily-trafficked areas. If samples collected from selected sites after cleaning are negative; samples should be taken from these same sites before cleaning.

3. Sample Collection Procedure

Sample collection will be performed by that individual designated in the plant using a sterile moistened pre-packaged sampling sponge and:

Prior to the collection of samples, sufficient quantities of sterile Butterfield's phosphate diluent will be refrigerated for use on the day of sample collection.

Prior to entering the sampling sight, in a clean environment moisten the sponge by first opening the bag and carefully adding 10ml of chilled sterile Butterfield's phosphate diluent or buffered peptone water. Close the top of the bag to a tight seal and massage the sponge from outside of the bag until it is fully hydrated.

All necessary materials will be gathered for collection of the samples and transported to the sampling site via cart.

Sampling bags will be permanently marked with the sample number, plant location, time of sampling.

Designated personnel will put on clean laboratory outer garments just prior to entering the sampling area.

Hands and mid-arms will be washed with an antibacterial soap before sampling.

With the bag still closed, push the sponge, smallest end first, up towards the opening of the bag. Do not open the bag or touch the sponge with your fingers.

Open the bag being careful not to touch the inner surface of the bag with your fingers. The wire closure at the top of the bag will keep the bag open. Place the bag in an area away from possible contamination.

Put on sterile gloves and carefully remove the sponge from the bag with the gloved sampling hand. Avoid touching the surface of the sampling sponge.

For flat surfaces, such as walls, refrigerators, electrical outlets, and floors in heavily trafficked areas, etc., an approximate 100 cm_ sampling area should be used. If a template is used, it is retrieved by the outer edge taking care to avoid contaminating the inner edges of the sampling area of the template. Place the template over the area to be sampled, holding the template with one gloved hand and taking care not to contaminate the sampling area with your hands.

With the free hand, wipe the sponge over the 10cm X 10cm target area for 10 times in the vertical and 10 times in the horizontal direction. The swabbing pressure should not be strong enough to cause the sponge to crumble.

Repeat swabbing in an adjacent area with the same surface of the sponge

After swabbing area No. 2, transfer the template to the same hand that is holding the sponge, avoiding not contaminating the inner edges of the sampling area of the template.
Carefully, place the sponge back in the sample bag, taking care not to touch the sponge to the outside of the sample bag. While carefully holding the sample bag, add the remaining 15 ml of chilled diluent; expel excess air and fold the top of the bag containing the sponge 3 or 4 times to close. Secure the bag by folding the attached wire tie against the bag.

For non-flat surfaces and/or non-contiguous areas, such as rollers on trucks, gondolas, drains, cracks in the floor, Put on sterile gloves and carefully remove the sponge from the bag with the gloved sampling hand. Avoid touching the surface of the sampling sponge. Wipe the sponge over target area for a minimum of 20 times in a multidirectional manner. The swabbing pressure should not be strong enough to cause the sponge to crumble. While carefully holding the sample bag, add the remaining 15 ml of chilled diluent; expel excess air and fold the top of the bag containing the sponge 3 or 4 times to close. Secure the bag by folding the attached wire tie against the bag.

4. Outside Laboratory Analysis

Samples will be shipped to the designated laboratory on the same calendar day as collected. Samples will be shipped to the outside laboratory by means of a pre-chilled shipping container containing sufficient frozen gel packs to maintain refrigeration conditions. Samples must not be frozen and must be analyzed no later than the day after collection.

Pre-chill a shipping container by placing the open shipping container in the refrigerator at least one day before sampling.

Place the labeled double-bagged sample into the pre-chilled shipping container in an upright position to prevent spillage. Packing materials or newspapers can be used for cushioning the sample and holding it in the upright position, If multiple samples are collected during the day, ensure that all samples are maintained at refrigeration temperature. Refrigeration temperatures help limit multiplication of microorganisms present which ensures the most accurate results.

Place a corrugated cardboard pad on top of the samples to prevent direct contact of the frozen gel packs with the samples.

Place a sufficient number of the frozen gel packs on top of the corrugated pad in the pre-chilled shipping container to keep the sample(s) at refrigeration temperature during shipment to the designated offsite laboratory. Cover the shipping container with its lid, ensuring that there is only minimum headspace.

Ship the samples so that they are guaranteed to arrive no later than the next morning.

Record shipping label information for documentation.

Appendix

References

Deibel Laboratories of Florida
- Cleaning and Sanitizing Procedures for Ready-to-Eat Department
- Special Environmental Cleaning Procedures for Ready-to-Eat Room
- Recommended Environmental Sampling & Testing Program for RTE Areas
- Cleaning Procedures for Entering a RTE Area
- Basic Food Plant Sanitation

National Meat Association
- *Listeria monocytogenes* Prevention at the Plant and Decontamination Procedures

Food and Drug Administration
- 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

USDA Food Safety Inspection Service
- Directive 10,240.2, 8-5-98, Microbiological Sampling of Ready to Eat Products Produced by Establishments Operating Under a HACCP System
- Monitoring Policy on *Listeria monocytogenes* in Meat and Poultry

American Meat Institute Foundation
- Interim Guidelines, Microbial Control During Production of Ready-to-Eat Meat and Poultry Products, Controlling the Incidennce of Microbial Pathogens, February 1999

Guidelines for the Environmental Sampling &Testing of Facilities Producing Ready –to-Eat Products
Sampling Flow Chart