SUPPLEMENTARY GUIDANCE ON THE USE OF ANTIMICROBIAL AGENTS TO CONTROL *LISTERIA MONOCYTOGENES* IN POST-LETHALITY EXPOSED READY-TO-EAT MEAT AND POULTRY PRODUCTS

An investigation of a 2007 recall of ready-to-eat (RTE) cooked chicken products because of the presence of *Listeria monocytogenes* (LM) showed that the establishment had failed to maintain sanitary practices and had applied antimicrobial agents that failed to suppress LM growth in challenge studies. To prevent recurrence of recalls attributable to these causes, FSIS is issuing this guidance to establishments to reiterate and emphasize: 1) Resources on the validation and application of antimicrobial agents or processes for effective control of LM; 2) Recommendations on the validation and application of antimicrobial agents or processes; and 3) Sanitation practices to control *Listeria* in RTE operations.

I. Resources on the Validation and Application of Antimicrobial Agents or Processes

The FSIS 'Compliance Guidelines To Control *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products' (LM compliance guidelines, May 2006) provide the following guidance and resource materials on conducting challenge studies. (http://www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf)

- Some published studies about challenge studies regarding the use of antimicrobial agents are available. FSIS' general observations based on these studies are found on pp. 59-67 of the LM compliance guidelines.
- Attachment 7 on pp. 93-97 of the LM compliance guidelines gives definitions and an explanation of challenge studies, validation, shelf life studies, and summaries of published challenge studies. These summaries give the critical variables used in the challenge study, such as time, temperature, pH, concentration, and others, and the results of the challenge study in terms of log reduction of LM.
- A link to the article (p. 101 of the Lm compliance guidelines): GUIDELINES FOR CONDUCTING *LISTERIA MONOCYTOGENES* CHALLENGE TESTING OF FOODS (Scott et al., 2005) is available at www.foodprotection.org/publications/TOCarchive/2005TOC/November2005.htm This article gives guidance on how to conduct a challenge study for antimicrobial agents and post-lethality treatments to determine suppression, reduction, or inactivation of LM. It addresses factors to be considered when conducting a challenge study, such as strains of *L. monocytogenes* to be used, inoculum level, inoculum preparation and method of inoculation, formulation of the product, delivery of the lethal treatment, incubation of samples, length of the study, frequency of sampling, and sample analyses.
- Another resource article for conducting challenge studies for validation of antimicrobial agents is the article on p. 101 of the compliance guidelines: CONSIDERATIONS FOR ESTABLISHING SAFETY-BASED CONSUME-BY DATE LABELS FOR REFRIGERATED READY-TO-EAT FOODS (NACMCF,

2004) www.fsis.usda.gov/ophs/nacmcf/2004/NACMCF_Safety-based_Date_Labels_082704.pdf
This article, developed by the National Advisory Committee on Microbial Criteria for Foods (NACMCF), gives guidance on how to determine the shelf-life of a RTE product containing an added antimicrobial agent that is supposed to suppress LM growth during the refrigerated shelf-life. Most studies use the temperature which the product is normally held during storage as the temperature during shelf life studies, e.g., refrigerated temperature of 38-40° F. Shelf-life studies also should use or include a temperature of 45° F which reflects consumer handling. The NACMCF document recommended to using a higher temperature for shelf-life studies because foods can encounter a range of temperatures below and above 45° F, with higher temperatures more likely in grocery store cases and during consumer handling. Therefore these temperatures more accurately reflect reality. A product with an added antimicrobial agent showing *L. monocytogenes* growth of <2 log at a storage temperature of 38-40 ° F and at 45° F or above would be viewed by FSIS as more protective of public health than another product showing the same growth only when stored at 38-40° F. Establishments planning to conduct shelf life studies can use the guidance for other factors important in designing a shelf life study provided in the full NACMCF report cited above.

- FSIS Directive 7120.1, Amendment 13 (August 16, 2007 through October 23, 2007, i.e., the date of publication of the last amendment) is an updated list of substances, including antimicrobial agents that have been accepted by FSIS for use in the production of meat and poultry products. This list is available at: http://www.fsis.usda.gov/Regulations_&_Policies/7000_Series-Processed_Products/index.asp
- The FSIS Web site contains new technologies, including studies and application of antimicrobial agents or processes and post-lethality treatments that may be used in post-lethality exposed RTE products. http://www.fsis.usda.gov/Regulations_&_Policies/New_Technologies/index.asp

II. Validation and Application of Antimicrobial Agents or Processes

An establishment can validate antimicrobial agents or processes in its RTE product or product formulation using a challenge study for the product, a published study or modeling program. In addition to the information from the resources listed in Section I, establishments should consider the following **recommendations** on the validation and application of antimicrobial agents or processes:

Conducting a Challenge Study

Conducting a challenge study is one way to validate the effectiveness of an antimicrobial agent/process or any post-lethality treatment. A challenge study can determine the ability of LM to grow in a food, show the effectiveness of an antimicrobial agent in suppressing LM growth, and the ability of a post-lethality treatment to reduce LM.

- A challenge study should be conducted by a microbiologist trained in these studies. The challenge study should be conducted in a food microbiological laboratory and not in the establishment.
- A University Extension Service may help in finding the appropriate microbiologist and laboratory for the study or provide guidance in conducting a challenge study.
- There are a variety of antimicrobial agents approved for use to suppress growth of *L. monocytogenes.* The necessary information on the use of the antimicrobial agent can be obtained from the manufacturer.
- A challenge study conducted for the specific product of the establishment provides a better means to validate compared to the use of a published study or a modeling program. In this case, the product formulation and critical variables for the specific product are used.
- When using lactate or diacetate for the study as the antimicrobial agents, check the moisture content of the finished product so that it is the same as that recommended for the level of lactate or diacetate being used.

  One of the findings in the RTE cooked chicken product recall is that the validation showed that **exceeding the product moisture content limits recommended for the use of lactates and diacetates for the particular formulation resulted in LM growth.**

  An article by Seman et al., (2002), referred to on p. 61 of the LM compliance guidelines emphasized the importance of MOISTURE CONTENT in the application of lactates and diacetates as antimicrobial agents. The article says, ***"The results show that increasing amounts of potassium lactate syrup and sodium diacetate decreased the growth rate of L. monocytogenes, while increasing finished product moisture increased the growth rate. Sodium chloride content was not significant but was found to have a negative correlation to growth rate.*** *This study provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of L. monocytogenes. The calculations would also require knowledge of the finished product sodium chloride and moisture contents."*
  Table 2 from the study shows that different finished product moisture levels, amount of sodium chloride, and lactate and diacetate result in different levels of LM growth rate. The following are excerpts from the published study.

% salt	% sodium diacetate	% potassium lactate syrup	% product moisture	LM growth rate (wk^{-1})
1.50	0.15	7.0	74.0	0.0
1.50	0.05	2.5	74.0	0.0991
2.20	0.20	4.75	64.5	0.0
2.20	0.10	0.25	64.5	0.1338

The investigators advised that this validated model is specific to the products designed for the study and the *L. monocytogenes* strains used. Testing of this model in other environments and with other *Listeria* spp., and to formulations that are outside the model's limits may result in different maximum growth rates.

- For the shelf life study, use at least two sets of temperatures: 1) The refrigerated temperature that the product is usually maintained and stored, e.g., 40 º F; and 2) A higher temperature to reflect consumer handling, e.g., 45 º F. An antimicrobial agent or process showing less than 2 $\log_{10}$ growth of LM when stored at these temperatures during the product's shelf-life is considered protective of public health.

  Note: A criterion of no more than 1 $\log_{10}$ growth of Lm during 1.3 times the expected shelf life of the product at 8º C (46º F) can put the product in the no growth category. Use of a temperature at or below 8º C was cited by the FSIS-FDA risk assessment to be protective of public health because this would achieve a predicted estimate of 50 % reduction in the number of cases of listeriosis in deli meats. FSIS compliance guidelines suggest the potential of reduced regulatory sampling for products in which growth is equal to or less than 1 $\log_{10}$ throughout the product's shelf life.
- Verify the effectiveness of the antimicrobial agent/process used by testing for LM growth during the shelf life of the product, at a certain frequency.
- Maintain and monitor records of validation, verification, and corrective actions for deviations from the effective application of antimicrobial agents/processes.

<u>Using Published Studies for Validation</u>

- Establishments can seek guidance from University Extension Service specialists or authors of the studies on how to apply the controls from a published challenge study.
- If using a published study or modeling program, use the same product or product formulation, treatment, and procedure as in the study. Applying the treatment to a different product or product formulation may result in a different rate of growth inhibition.
- Use the same critical variables of time and temperature of treatment, concentration, pH, moisture, water activity, fat, salt content, time and temperature of storage, packaging material, packaging atmosphere, and other critical variables or factors detailed in the study.
- Use the same or similar product or product formulation, procedures, and equipment as those detailed in the study.
- If using product, product formulation, treatments, or other critical variables that are different from those in the published study, conduct additional validation using the new variables and verify the effectiveness of the antimicrobial agent in the product after the treatment by testing for LM growth during shelf-life storage.
- Use only validated studies, published studies, and modeling programs that include a shelf-life study.

- When using challenge studies, use only those showing that the LM growth or growth rate is lower in the product with antimicrobial agent/process than in product without antimicrobial agent/process.
- Use only challenge studies showing that the antimicrobial agent/process used in the product suppressed growth of LM throughout the commercial shelf life of the product at < 2 $\log_{10}$ growth, or better growth suppression.
- Obtain the necessary information on the use of the antimicrobial agent from the manufacturer.
- Verify the effectiveness of the antimicrobial agent/process used by testing for LM growth during the shelf life of the product, at a certain frequency.
- Maintain and monitor records of validation, verification, and corrective actions for deviations from the effective application of antimicrobial agents/processes.

Using a Modeling Program for Validation

- Modeling programs can be obtained from published studies or from the manufacturer of an antimicrobial agent. Information and guidance on the application of the antimicrobial agent may be obtained from the manufacturer.
- Establishments can also seek guidance from University Extension Service specialists or authors of the modeling programs on how to use a modeling program.
- If using a modeling program to determine the amount of antimicrobial agent to use, follow the directions with regards to salt content, moisture level of the finished products, and other information needed. For example, a modeling program may ask to confirm that the product is a cured product because the model is only valid for cured products. It will ask for the following: Shelf life of product in days, product specification, salt content (%) and finished product moisture content (%). The program will calculate the amount of lactate/diacetate to be used and the log suppression of LM based on the information provided.
- **Growth models on the use of antimicrobial agents are available mostly for cured products. For uncured products where there are no growth models, validation studies need to be conducted per product.**
- Verify the effectiveness of the antimicrobial agent/process used by testing for LM growth during the shelf life of the product, at a certain frequency.
- Maintain and monitor records of validation, verification, and corrective actions for deviations from the effective application of antimicrobial agents/processes.

III. Sanitation Practices to Control *Listeria* in RTE Operations

The use of antimicrobial agents or processes in a product does not mean that control of the sanitation in the RTE operation can be neglected. The effectiveness of the antimicrobial activity is affected by the level of microbial contaminants on equipment surfaces and in the processing environment. The 2007 recall of RTE chicken breast products showed that sanitation plays a great role in controlling LM contamination in the product and in the processing environment. The FSIS LM compliance guidelines include

recommendations for sanitation controls in RTE processing plants; Section G, I-VI, of the compliance guidelines include guidance to establishments on sanitation control. Section G-VII gives guidance on testing frequencies for food contact surfaces and recommended validated methods for testing.

The following **recommendations** are developed as a result of findings from the 2007 LM recall. Most of these are found in the guidance contained in the FSIS LM Compliance Guidelines, Section G I-VII, but are being highlighted for establishments to take extra notice. Establishments should consider the following **recommendations** on sanitation controls**.**

A. *Listeria* sanitation program

- Maintain a record of all food contact surfaces and environmental surfaces in the processing area that are to be tested. Focus on the sites that are likely to be contaminated or that tested positive in the past. Make sure all of the identified surfaces are actively sampled and have an equal opportunity of being sampled during each sampling event.
- Include the supporting documentation of the testing frequency in your LM sanitation program.
- Include testing and monitoring of drains after an LM positive finding.
- Do not use LM testing to support that LM is a hazard not reasonably likely to occur. LM testing is a verification of the effectiveness of the establishment's food safety program to control LM.
- Include supporting documentation in the Sanitation SOP or other prerequisite program to support your claim in the HACCP plan that LM is a hazard not reasonably likely to occur in your RTE processing.
- Include supporting documentation for the alternative chosen for the product.
- When there is a repeated LM positive finding, suspend RTE operations to determine the cause or origin of the contamination and develop measures for removal of contamination and prevention of recurrence and to verify that there is no remaining contamination.
- Sample food contact surfaces and environmental surfaces at other points of the production process, in addition to sampling at pre-op and about 3 hours after production has started.

B. Sanitation Procedures

<u>Dripping, Condensation and Standing Water</u>

- IMMEDIATELY address and correct problems of dripping, condensation and standing water.
  L. monocytogenes is an environmental pathogen and may be present in dripping, standing water and condensation. The moist environment caused by condensation is conducive to the growth of the pathogen.
- Stop production of RTE products during repairs and corrective actions for these

problems.

- Clean and sanitize equipment and the processing area after all the repairs and corrective actions are finished.
- Verify effective sanitizing of equipment and of the processing area environment after the repairs or construction by tests showing that LM or *Listeria* spp. tested negative, before resuming RTE production.

Personnel Hygiene

- Train and require personnel to wash hands before putting gloves on.
- Train and require personnel to wash hands before resuming duties after breaks.
- Train personnel on hygienic practices in an RTE processing establishment once a month.
- Monitor personnel hygiene practices.

Separation of RTE and Non-RTE Areas

- If processing both RTE and raw products, completely separate the processing areas, such as by complete wall separation or by scheduling processing on different days. If separate processing areas or scheduling on different days is not possible, schedule RTE processing first, then follow with raw products processing. Always have a complete clean-up and sanitization after each processing and pre-op testing of equipment and processing area environment before starting RTE processing.
- Use separate equipment for RTE and raw processing. If separate equipment is not possible, schedule to use equipment for RTE processing first, then for raw processing.
- Assign different personnel for RTE and raw processing areas, especially if both are conducted on the same day. If not possible, have personnel clean hands very well and use unused, clean coats, new gloves and hairnets, and sanitized boots for RTE processing.
- Restrict movement of personnel from and to NRTE area during RTE processing. If necessary, use footbath, wash hands, and use new gloves and clean, unused coats and hairnets when returning to RTE area processing.
- Locate coat racks for coats used in RTE processing in an identified RTE area.
- Use color coded coats for use in RTE processing area, in raw processing area, and in other areas.
- Maintain procedures so that personnel coming from any area common to RTE and raw processing are not transferring contamination to RTE areas.
- Establish procedures for moving equipment from a non-processing area to a RTE processing area to prevent *Listeria* contamination from the equipment and during the moving operation.
- Avoid passing raw product through RTE areas and RTE product through raw production areas.
- Do not allow RTE product to come in contact with surfaces or raw products in

coolers.

Records of Sanitation Procedures

- Keep records of sanitation procedures to be used in conjunction with processing of RTE products that are covered by the *Listeria* rule.
- Maintain monitoring records of sanitation procedures.
- Maintain records of preventive measures taken after a finding of direct product contamination, including the steps taken to clean the affected equipment or environmental surface, or to modify the procedure affected; other corrective actions employed, verification that the corrective action will prevent recurrence of the deviation; dates of the deviation, corrective action, and verification; and identification of personnel involved in addressing the contamination.

Room Temperature

- Maintain temperature in processing areas and packaging rooms as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs.
- Maintain cold temperature (<50º F) in packaging room for products that are to be refrigerated or frozen, as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs, to prevent LM growth in the RTE processing environment.
- Monitor temperatures as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs.

Miscellaneous

- For establishments processing deli salads and similar products, establish procedures to ensure that other non-meat or non-poultry RTE ingredients do not cause cross-contamination with *Listeria*.
- Maintain an effective rodent and insect infestation preventive and control program. Rats, mice and insects are sources of *Listeria* and other microbial contamination.
- Develop and maintain procedures to ensure that sanitizer concentrations in footbaths are adequately maintained.
- Maintain records and verify the correct procedures for the concentrations and mixing of sanitizers.
- Maintain a rotation of sanitizers used.
- Avoid the creation of aerosols and airborne dust when cleaning equipment or surfaces during operation.
- Discard products that touch environmental surfaces, such as products falling on the floor or on the conveyor belt.
- During cleaning and sanitizing, make sure food residues are not left on the equipment.
- Maintain procedures for routine cleaning and develop procedures for intensified cleaning.

- When adding ingredients to second container, do not to bang or contact the first container against the interior of the other container.

C. Facilities and Equipment

- IMMEDIATELY FIX leaky roof, broken and cracked equipment, floors, doors, windows, etc. Suspend operations during leakage and during repairs. Test the environment for *Listeria* spp. after repairs are finished and resume operation only after tests are negative.
- DISCARD rusty, pitted, peeling tools or parts of equipment and replace with new, smooth-surfaced ones. These rusty, pitted tools and equipment parts serve as ideal places for LM to grow and multiply.
- Always dismantle equipment for cleaning and sanitizing.
- Remove equipment not in use from the RTE processing area.
- Use equipment according to the intended use, with the recommended cleaning and sanitizing procedures.
- Document equipment maintenance and monitoring to check for broken, pitted, rusty, peeling, or dirty equipment needing replacement, repair, cleaning, etc.
- Choose equipment that is designed to be easily assembled, cleaned and sanitized.

D. Dual-Jurisdiction Establishments

FDA regulated products produced in dual jurisdiction establishments are not subject to FSIS regulations. Therefore they do not have to comply with 9 CFR Parts 416, 417, or 430. FSIS and FDA entered into a Memorandum of Understanding in 1999 regarding inspection coordination in dual jurisdiction establishments. The MOU can be accessed at: http://www.fda.gov/oc/mous/domestic/225-99-2001.html

FSIS developed FSIS Directive 5730.1, "Responsibilities in Dual Jurisdiction Establishments" providing instruction to its inspection program personnel about their responsibilities in dual jurisdiction establishments. Establishments producing FDA and FSIS regulated products should consider the differences in regulatory requirements between the two agencies when designing their food safety systems.

The following list of recommendations could be used by establishments to prevent post-lethality exposed RTE meat and poultry products from becoming adulterated with LM.

- Completely separate processing areas for FSIS regulated products and FDA regulated products, such as by complete wall separation, or scheduling processing on different days. If not possible, schedule FSIS product processing first, then FDA product processing. Always have a complete clean-up and sanitization after each processing and pre-op testing of equipment and processing environment before starting FSIS product processing.
- FSIS and FDA product processing areas should each have separate equipment. If not possible, schedule to use equipment for FSIS product processing first, then for FDA processing.

- Assign different personnel to FSIS product and FDA processing areas, especially if both are conducted on the same day. If not possible, have personnel clean hands thoroughly, and use unused, clean coats, new gloves and hairnets, and sanitized boots for FSIS and FDA processing.
- Maintain a list of FSIS and FDA products processed to avoid confusion.
- Maintain the same sanitation procedures for LM in both FSIS and FDA processing to avoid LM cross-contamination or growth in the processing environment.