MSA READY-TO-EAT SAMPLING PROGRAMS

CHAPTER I - GENERAL

I. PURPOSE

A. MSA product sampling for *Listeria monocytogenes (Lm)* and *Salmonella* are important food safety verification activities that support MSA's food safety and public health goals. This directive provides instructions to inspection program personnel (IPP) to collect and submit ready-to-eat (RTE) meat and poultry product samples to MSA laboratories and, when appropriate, to take enforcement action in response to positive test results. Instructions concerning *Lm* verification activities other than sampling and responses to positive results are contained in MSA Directive 10,240.4, *Listeria Rule Verification Activities*.

B. The directive has been revised to reflect changes to product sampling for *Lm* and updates to the sampling selection criteria to improve sampling program efficiency. The directive has been revised to clarify that both post-lethality exposed and not post-lethality exposed products are subject to sampling and that IPP are not to collect samples that are pass-through products. Pass-through products are those products that the establishment sends into commerce without further post-lethality exposure, processing, or repackaging. The directive also explains that IPP are to verify that positive product is appropriately transported to pet food manufacturers.

II. BACKGROUND

Under the Texas Meat and Poultry Inspection Act (TMPIA), MSA considers any RTE product to be adulterated if it contains a pathogen of public health concern (depending on the type and level) or its toxin that can cause illness in humans. There are some pathogens where any level would make the RTE product adulterated (such as Lm and Salmonella) because it could be injurious to health (433.004(1)). If any level of Lm or Salmonella is detected in an RTE product or on a food contact surface (FCS) that post-lethality exposed RTE product has passed over, the product is adulterated.

CHAPTER II - MSA RTE SAMPLING PROGRAMS

I. PRODUCTS SUBJECT TO SAMPLING

1. MSA considers a product to be **RTE** if it meets some or all of the following criteria:

    a. The product meets the definition of an RTE product in the *Listeria* Rule (9 CFR 430.1). The *Listeria* Rule defines an RTE product as a meat or poultry product that is in a form that is edible without additional preparation to achieve food safety.

    b. There is a standard of identity requiring that the product be fully cooked according to 9 CFR 319 (e.g., hot dogs or barbeque) or a common or usual name that consumers understand to refer to RTE product (e.g., pâtés). IIC are to be aware that not all RTE products are required to meet a standard of identity.

NOTE: The establishment may consider certain products (e.g., hams) as either RTE or not ready-to-eat (NRTE) if there is no standard of identity defining the product as RTE or common or usual name under which the product is understood to be RTE.

    c. The product <u>is not</u> labeled with safe handling instructions (SHI), as required for NRTE products by 9 CFR 317.2(l) and 381.125(b). According to 9 CFR 430.1, RTE products are not required to bear SHI or other labeling that directs that the product be cooked or otherwise treated for safety. MSA considers products labeled with SHI and cooking instructions to be NRTE.

    d. The product has been processed to meet the requirements of 9 CFR 318.17, 318.23, or 381.150 or undergone other processing to render it RTE, and it does not bear SHI or cooking instructions. IIC are to be aware that not all RTE products are required to be cooked to be considered RTE. Establishments may use other validated processes (e.g., fermenting and drying) to render the product RTE.

NOTE: A product (e.g., meat casserole) may receive a full heat treatment by the establishment and be labeled as NRTE as long as there is no standard of identity defining it as RTE or common or usual name under which the product is understood to be RTE, as described in the note above.

e. The establishment's HACCP plan, intended use statement in its hazard analysis, and flow chart are consistent with a RTE product. MSA considers products in the Fully Cooked – Not Shelf Stable HACCP category to be RTE. HACCP categories that may contain either RTE or NRTE products include Not Heat-Treated - Shelf Stable, Heat Treated – Shelf Stable, and Product with Secondary Inhibitors – Not Shelf Stable.

2. MSA considers the product to be post-lethality exposed if it is RTE, and it meets the following criteria:

   a. The product is exposed to the environment of the establishment after the lethality step.

   b. The product does not remain in a cooking bag, and it comes in contact with food contact surfaces, brine, or other environmental conditions during cooling, processing, slicing, or packaging steps.

3. MSA considers the product to be non-post-lethality exposed if it meets the following criteria**:**

   a. The product is cooked in a bag and remains in the cooking bag until it leaves the establishment.

   b. The product is treated with a process (e.g., high pressure processing (HPP) that achieves a full lethality (e.g., 5-log reduction of *Salmonella*) in the product, once it is in its final packaging.

   c. The product is hot filled (e.g., lard) at a temperature sufficient to achieve full lethality of the product (e.g., using one of the time/temperature combinations in Appendix A).

II. PRODUCTS NOT SUBJECT TO SAMPLING UNDER THE RTE SAMPLING PROGRAM

MSA does not sample NRTE products under the RTE sampling program. NRTE products are not edible without further preparation to achieve food safety and are required to bear SHI in accordance with 9 CFR 317.2(l) and 381.125(b). NRTE products may include products containing a meat or poultry component that is RTE in combination with nonmeat or poultry components that need to receive a lethality treatment by the intended user (e.g., meals containing meat and vegetables). In addition, NRTE products may include products that receive a partial or full heat treatment and do not have a standard of identity defining them

as RTE or common or usual name that consumers understand to refer to RTE products.

III. THE SAMPLED LOT

1. The sampled lot is product that is represented by the sample collected by MSA and analyzed for *Lm* and *Salmonella*. The establishment is responsible for defining the sampled lot.

2. MSA generally considers the sampled lot to be the product produced from "**clean-up to clean- up**" for RTE products, unless the establishment has a different supportable definition of the lot (e.g., products produced on different lines that are microbiologically separate from one another).

3. IIC are to be aware of the following factors or conditions that may determine a sampled lot:

    a. Frequency of cleaning and sanitizing – the establishment may perform a complete cleaning and sanitizing (following the procedures in its Sanitation SOP) to differentiate between lots.

NOTE: An official establishment may reduce its lot size on a day when MSA collects a routine RTE sample to facilitate holding the product, as long as the change does not interfere with MSA's ability to collect a representative sample.

    b. Separation between processing lines

        i. Products produced in the same room can be considered part of the same lot or different processing lots depending on how the lots are separated by time and space.

        ii. Products produced on different processing lines can be considered different lots if the lines are microbiologically and physically independent of one another (e.g., equipment, personnel, utensils, and RTE source materials are not shared among the lines).

        iii. Likewise, products produced on the same line can be considered different processing lots if they are separated by complete cleaning and sanitizing, as well as the other factors described above.

iv. Products stored in a common cooler would not necessarily be considered part of the same lot. IIC are to be aware that the establishment's Sanitation SOP should address possible cross-contamination if products from different lots are stored in the same cooler.

4. Although MSA generally considers the sampled lot to be the product produced from "clean-up to clean up" (unless the establishment has another supportable lot definition), in the event of a positive result, additional product may be implicated. The following factors may be used to determine implicated product:

a. Use of RTE source materials and brine

i. If an establishment uses RTE source materials received from another establishment, and one of the lots containing a common RTE source material tests positive by MSA, a scientific basis is necessary to justify why the other lots should not be implicated (e.g., because the source material was not the cause of the positive).

NOTE: Common raw source materials are not taken into account when determining the lot for RTE products because the products are cooked or otherwise processed to achieve food safety.

ii. The establishments' re-use of brine across lots can cross-contaminate the lots and prevent them from being microbiologically separate.

b. Processing steps employed

i. Because *Salmonella* can contaminate RTE products as a result of under-processing, if one lot of RTE product tests positive by MSA and another lot of product received the same lethality treatment, a scientific basis is necessary to justify why the later lot should not be implicated.

ii. Ingredients (e.g., pepper or other spices) added to post-lethality exposed RTE products can affect the lot definition. The establishment is required to evaluate the possible hazards from all ingredients it uses, per 9 CFR 417.2(a)(1).

CHAPTER III – COLLECTING AND SUBMITTING MSA VERIFICATION SAMPLES

I. PREPARATION FOR SAMPLE COLLECTION

1. When IIC rotate into an assignment or are newly assigned to an establishment, they are to discuss sampling with the establishment at a weekly meeting. As part of this discussion, IIC are to determine:

    a. What RTE products are produced by the establishment, and whether they are post-lethality exposed or non-post-lethality exposed; and

    b. How much notice to give the establishment when collecting a sample. IIC are to familiarize themselves with the establishment's production practices so that they are able to provide adequate time to allow the establishment to hold all product represented by the sample (i.e., the sampled lot) but not alter its production practices. IIC are to provide adequate notice to the establishment in accordance with Section I.B.4 of this chapter below.

2. To schedule the sample, IIC are to randomly select a day, shift, and time within the sample window timeframe. IIC are to schedule samples from all shifts in which the establishment produces RTE products. There should be an equal chance that sampling will occur during any shift where eligible product is produced.

3. IIC are not to wait until the end of the sampling window to schedule the sample. Scheduling the sample at the beginning of the sampling window will allow more time to ensure that the sample is available during the sampling window.

4. Before collecting a sample, IIC are to officially notify the establishment management that they will be collecting a sample and to explain the reason that they are collecting the sample). To provide establishments enough time to hold the entire sampled lot, but not enough time to alter their production practices, IIC are to:

    a. Generally, provide 1 days notice if such advance notice is sufficient for the establishment to hold the sampled lot, but not to change practices. IIC may provide 2 days' notice if necessary.

    b. Consider the establishment's request for more than 2 days' notice, in the rare case that more notice

is needed based on the establishment's product and process flow. If the establishment can support that more notice is necessary because of the innate characteristics of the process (e.g., less than daily sanitation, use of brine, or processes that span more than 2 days), IIC may provide more than 2 days' notice.

c. Inform the establishment that if it changes routine practices without a justification for doing so, MSA may provide it with less than 1 days' notice, if less time is sufficient to hold the sampled lot, but not change routine practices.

d. Inform the establishment that it is responsible for supporting its basis for defining the product represented by the sample (i.e., the sampled lot); and

5. When notifying the establishment that MSA will collect a sample, IIC are to:

a. Confirm that the establishment will be producing post-lethality exposed RTE product on the day sampling is scheduled. In addition, IIC are to confirm that the establishment is planning to implement its documented routine production, Sanitation SOP, and food-safety practices on the day the sample is scheduled.

b. Inform the establishment that, if it intends to modify its documented routine production, sanitation, or food-safety practices before the sampling, it should inform IIC as soon as possible, so that sampling can be rescheduled. If the establishment continues to change routine practices and cannot support the changes, less than 1 days' notice may be provided, or an FSA may be scheduled at the establishment.

NOTE: Justifiable reasons for changing practices may include limiting the lot size to facilitate holding the product, changes in customer orders, or documented changes to Sanitation SOPs or HACCP plans.

c. Verify that the establishment is holding or controlling the product represented by the sampled lot (the product produced from clean-up to clean-up) and record the information in PHIS as:

i. Yes, on-site;

ii. Yes, off-site under company control; or

iii. No.

6. On the day that the sample collection is scheduled, if IIC find that the establishment has altered its documented routine production, sanitation, or food-safety practices, and the establishment cannot provide a supportable rationale, then IIC are not to perform sampling and are to reschedule sampling for another day. IIC are to issue an NR under the following circumstances.

    a. If IIC find that the establishment has made changes in its food safety systems (e.g., temporarily changing its supplier of RTE product on the day the sample is collected) and does not have documents supporting the appropriateness of the change, IIC are to issue an NR. The NR would be recommended because the establishment did not consider the changes in its hazard analysis in accordance with 9 CFR 417.2(a)(1), or did not support the changes to its hazard analysis as in 9 CFR 417.5(a)(1).

    b. Likewise, if IIC find that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer only on the day the sampling is scheduled) and did not revise its Sanitation SOP to reflect these changes, IIC are to issue an NR under 9 CFR 416.14.

NOTE: If an establishment decides to limit its product lot size solely to facilitate holding the product during sampling, it would not be considered to have significantly altered its production practices, as long as IIC can collect samples that accurately represent routine production.

7. At the next weekly meeting, IIC are to discuss the altered food safety practices with the establishment. IIC are to inform the establishment that if it continues to change its practices, MSA may collect more samples and may give less than 1 days notice (if less time is enough to hold the sampled lot) or schedule a "for-cause" FSA.

II. COLLECTING THE SAMPLE

A. IIC are to collect the sample after the establishment has applied all interventions except any microbiological testing intervention. If the establishment intends to test the product for *Lm* or *Salmonella*, IIC are not to wait for the establishment to receive the test results.

B. If the establishment treats the product with an intervention (e.g., HPP), either at the establishment or at another establishment, IIC are to review the documentation that the establishment keeps as part of its HACCP program to determine the purpose of the treatment.

1. If the HPP is applied as a *Listeria* intervention, and the establishment has supporting documentation demonstrating that the treatment achieves at least a 1-log reduction of *Lm,* IIC are to collect the sample after the treatment is applied.

2. If the treatment is applied to extend the shelf life of the product, and the establishment does not have supporting documentation describing the treatment as a *Listeria* intervention, then IIC are to collect the product before the treatment. The product would not be subject to sampling at the HPP facility, as long as it has records on file supporting that the treatment was applied to extend the shelf life.

C. IIC are to collect the product at least three hours after the start of production (if possible), to allow *Lm* to work its way out of the equipment. If the establishment's production lot is typically less than three hours, IIC may collect the samples during the production shift. IIC may collect samples on the first shift or second shift (or other shifts, as applicable). IIC are to vary the shifts in which they collect samples, if possible.

D. IIC are to collect a five hundred (500) gram sample of product in an intact package. Collecting products in the final package will help ensure that the product does not become contaminated with *Lm* from the environment during the sample collection process.

E. If the establishment produces reworked product, IIC are to sample the product as part of the production lot, as long as IIC provide the establishment with adequate notice to hold the sample.

NOTE: Rework is the process of re-cooking, reprocessing, or repackaging the product. MSA considers any process that removes the product from the package and exposes it to the environment as rework.

F. If the finished product contains meat or poultry and non-meat or poultry ingredients, IIC are to follow the instructions in 1 and 2 below.

1. If the meat or poultry and non-meat or poultry ingredients are commingled (in contact) in the final package (e.g., a salad with meat or poultry mixed in), IIC are to collect a five hundred (500) gram sample of the complete product (including the meat or poultry and nonmeat or poultry component).

2. If the meat and nonmeat ingredients are <u>not</u> commingled (not in contact) in the final package (e.g., an entree with separate compartments for meat or

poultry and vegetables), then IIC are to collect a five hundred (500) gram sample of the meat or poultry component in the final package.

G. IIC are to submit the samples to the laboratory for microbiological analysis in intact packages.

H. If an intact product or product container is too large, heavy, or costly to ship to the laboratory, IIC can ask the establishment to slack-fill or short-weight a product for a five hundred (500) gram sample and send it in the usual establishment packaging such as the container liner.

1. If the slack-filled or intact package is an unsealed bag, IIC are to tie it off (e.g., twist tie or rubber band) so smaller particles (e.g., shredded meat pieces) do not spill into the shipping container. IIC are to place the slack-filled package in a secondary bag. The laboratory will discard the sample if it contains spilled or leaking products.

2. IIC are not to use any laboratory-supplied bag as the primary wrap for the sample. Laboratory supplied bags provided by the laboratory are for secondary containment only because they are not sterile. The laboratory-supplied bag protects the box in case the primary container leaks.

3. If IIC cannot collect an intact short-weighted or slack-filled sample, and the establishment is not producing any other type of RTE product that the IIC could collect, IIC are to contact their CM to discuss other options for collecting the sample.

NOTE: Examples of inappropriate samples for short-weight or slack-filled samples include a sample that would have to be cut to fit inside the shipping container, and samples that are packed in a waxed box without a liner bag that is too large to fit inside a laboratory shipping box.

III. SUBMITTING THE SAMPLE

A. IIC are to safeguard the integrity of samples during submission.

B. IIC are to ship samples overnight. IIC are to ship samples Monday through Friday so that they arrive at the laboratory overnight. IIC are not to ship samples on Saturdays or on the day before a holiday, or as directed by a user notice via e-mail.

CHAPTER IV – DOCUMENTING NONCOMPLIANCE

I. ESTABLISHMENT TEMPORARILY CHANGES PRACTICES

A. IPP are to issue an NR under the following circumstances:

1. If IPP find that the establishment has made changes in its food safety systems on the day the sample is collected (e.g., temporarily changing its supplier of RTE product or purchasing new source material for the sampled lot) and does not have documents supporting the appropriateness of the change, IPP are to issue an NR. The NR would be recommended because the establishment did not consider the changes in its hazard analysis in accordance with 9 CFR 417.2(a)(1) or did not support the changes to its hazard analysis as in 9 CFR 417.5(a)(1).

2. Likewise, if IPP find that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer only on the day the sampling is scheduled) and did not revise its Sanitation SOP to reflect these changes, IPP are to issue an NR under 9 CFR 416.14.

II. SAMPLING RESULTS FROM RTE TESTING

A. Whenever IPP are notified that a sample has been discarded and will not be analyzed by the laboratory, and product is being held on-site or controlled off-site, IPP are to notify the establishment immediately so the product can be released.

B. MSA will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all MSA test results that bear on the determination have been received.

C. If an RTE product sample collected by IPP tests positive for *Lm* or *Salmonella*, product from the sampled lot is considered adulterated. IPP are to follow the instructions in MSA Directive 5,000.1 to take regulatory action in response to positive sampling results. For information on product disposition options see Chapter V, *Verifying Product Disposition*.

D. If MSA finds the product to be positive and the establishment tested the product under its documented sampling programs, IPP are to check the establishment's *Lm* or *Salmonella* testing results to determine

whether the establishment also found the sampled product to be positive for *Lm* or *Salmonella*.

E. IPP are to determine whether the establishment held the product or otherwise maintained control of the product (e.g., the establishment moved the product off-site but did not complete pre- shipment review or transfer ownership of the product to another entity) pending MSA test results. If IPP find that the establishment did not hold or maintain control of the product, they are to issue an NR because the establishment shipped product before MSA found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in 9 CFR 417.5(c). IPP are to immediately contact the CO through the supervisory chain of command. If the results are confirmed positive for *Lm* or *Salmonella*, the CO is to take appropriate regulatory action. As appropriate, MSA will request a recall or detain the product. The CO will also consider whether additional enforcement actions are necessary.

F. Generally, if MSA finds the product positive for *Lm* or *Salmonella*, IPP are to issue an NR (cite 9 CFR 417.4(a)). However, if the establishment also found the product to be positive for *Lm* or *Salmonella* and held the product, IPP are not to issue an NR. They are to verify that the establishment performs the appropriate corrective actions, using a directed HACCP Verification Task.

III. VERIFYING CORRECTIVE ACTIONS IN RESPONSE TO AN MSA POSITIVE RESULT

A. If MSA finds a product positive for *Lm* or *Salmonella*, IPP are to verify that the establishment takes the appropriate corrective actions by performing a directed HACCP Verification Task.

B. When performing a directed HACCP Verification Task in response to a *Lm* positive result, IPP are to review the same information they review during a routine HACCP Verification Task.

1. IPP are also to verify that the establishment implemented corrective actions according to 9 CFR 417.3(a) or (b) if the measures for addressing *Lm* are included in the HACCP plan or prerequisite program, or 9 CFR 416.15 if the measures are incorporated in the Sanitation SOP.

2. If the establishment considers *Listeria* NRLTO because the establishment has a prerequisite program, IPP may also perform a

directed HAV task as described in MSA Directive 5,000.6, *Performance of the Hazard Analysis Verification (HAV) Task* to verify the establishment can continue to support its decisions in its hazard analysis.

C. When performing a directed HACCP Verification Task in response to a *Salmonella* positive result, IPP are to verify that the establishment took the appropriate corrective actions according to 9 CFR 417.3(a) or (b), or 9 CFR 416.15. As stated previously, MSA considers RTE products to be adulterated if products or FCS test positive for *Lm* and *Salmonella*. Therefore, establishments are required to take corrective actions in response to positive results and to reassess their HACCP plan if they haven't addressed these hazards. MSA will perform a PHRE in response to *Lm* or *Salmonella* positives, as described in MSA Directive 5,100.4.

NOTE: IPP are to be aware that establishments should take action in response to multiple *Listeria* positives that show relatedness through whole genome sequencing results. A trend of related positives may be an indicator of *Listeria* harborage.

D. If MSA develops a verification plan in response to an establishment's corrective actions and preventive measures, and enforcement is deferred following the issuance of a Notice of Intended Enforcement (NOIE) or a suspension is held in abeyance, IPP are to verify that the establishment implements its corrective actions, and that the corrective actions are effective.

E. IPP are to verify that the establishment took the following actions:

1. If *Lm* control is addressed as a CCP in the HACCP plan (e.g., PLT), the establishment must meet the requirements of 9 CFR 417.3(a), which requires that corrective action be taken but does not require reassessment of the HACCP plan.

2. If *Lm* is addressed in the Sanitation SOP, then the establishment must implement corrective actions in accordance with 9 CFR 417.3(b), which includes reassessment of the HACCP plan. In addition, it is to implement the corrective action requirements for the Sanitation SOP in 9 CFR 416.15, which includes appropriate reevaluation or modification of the Sanitation SOP.

3. If *Lm* is addressed in a prerequisite program (e.g., *Listeria* control program) that is used to support the decision that *Lm* is not a hazard reasonably likely to occur in the product, then the establishment

must implement the corrective actions in 9 CFR 417.3(b) and comply with 9 CFR 417.4(a)(3). As part of this, the establishment must perform a HACCP reassessment to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

4. The establishment is required under 9 CFR 417.4 (a)(3) to document the reassessment and the reasons for any changes that it made to its HACCP plan as a result of the reassessment, or, if it did not make any changes, to document the reasons why it did not.

NOTE: IPP are to refer to MSA Directive 10,240.4, *Listeria Rule Verification Activities,* for instructions to verify corrective actions in response to establishment positives.

F. If an establishment reclassifies an RTE product as a NRTE product in its HACCP plan in response to a positive result, IPP are to verify that:

1. The product is not defined by a standard of identity as fully cooked (e.g., hot dogs) or the intended use is not typically RTE (e.g., pâtés or deli meats).

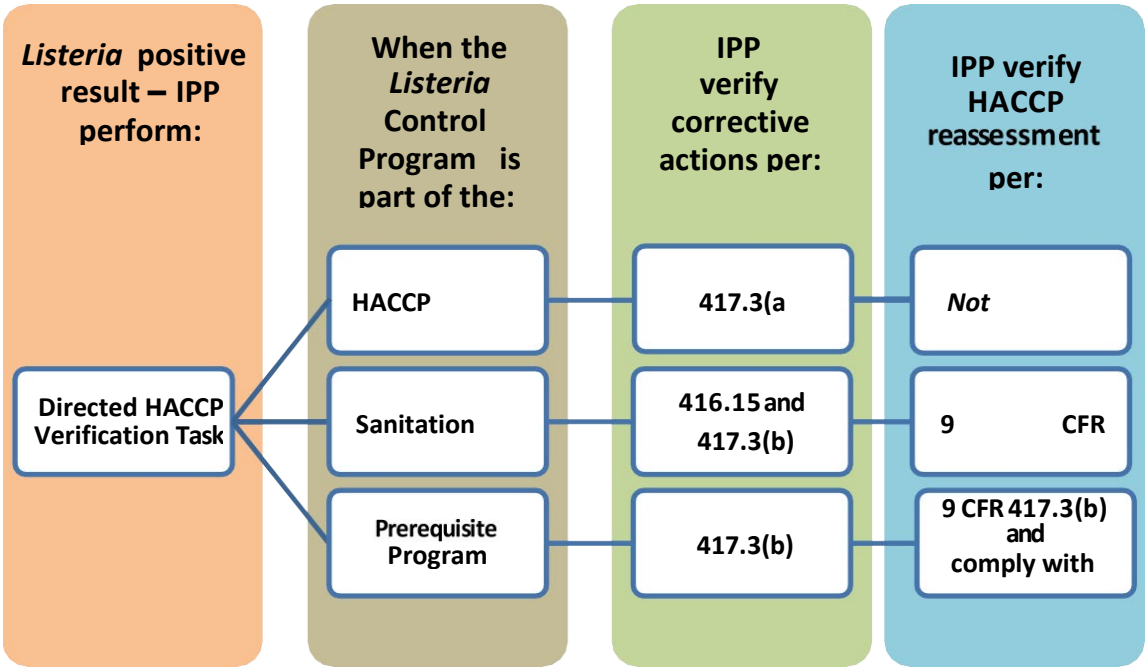
2. The establishment labels the product as one that is NRTE and requires validated cooking instructions for safety so that the product label is accurate and not misleading, in compliance with 9 CFR 317.8 or 381.129. For example, use of the terms "Baked" or "Broiled" on the label of a NRTE product (e.g., baked chicken on the label) would be false and misleading because they indicate that the product is cooked and, therefore, suggest to the consumer that the product is RTE.

3. The establishment has chosen a HACCP category consistent with that for a NRTE product. Therefore, categorizing the product in a Fully Cooked – Not Shelf Stable HACCP processing category would not make it a NRTE product.

4. The establishment clearly identifies the intended use of the product in the flow chart or hazard analysis according to 9 CFR 417.2(a)(2). For the description to be consistent with that for an NRTE product, the establishment must describe the customary preparation practices for the safe consumption of the product. The establishment should also state why these practices can be regarded as customary preparation.

5. The establishment takes corrective actions (e.g., intensified cleaning and sanitizing) and maintains sanitation in its environment according to 9 CFR 416.4(b) so that insanitary conditions, leading to product contamination, do not exist.

Figure 2. Steps for Verifying an Establishment's Corrective Actions



G. If the establishment decides to produce not post-lethality exposed (i.e., cook-in-bag product) in response to a positive result, IPP are to verify that the establishment:

1. Revises its flow chart or hazard analysis according to 9 CFR 417.2(a)(2) to include the cook-in- bag step.

2. Ensures that the cooking bag is completely sealed (impermeable), so that moisture is contained within the bag or contaminants do not enter the bag. Cooking bags may be compromised during steps such as molding or shaping. The establishment should have a process to verify the package integrity, and if leakers are observed, to reprocess or recook the product.

NOTE: If the product is dried before cooking, it would not be appropriate to recook the product multiple times using the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) as support for the process. For dried products that are cooked multiple times, the establishment would need to provide additional scientific support for the cooking process.

3. Uses a supportable process to recook the product to address potential cross-contamination
   from a thermometer stem if the establishment punctures the bag when taking the temperature of the product.

4. The establishment takes corrective actions (e.g., intensified cleaning and sanitizing) and maintains sanitation in the processing environment, according to 9 CFR 416.4 to ensure that insanitary conditions do not exist, leading to product contamination.

NOTE: It is not enough to seal and recook the product if sanitation is not maintained. The establishment, while not required to sample for *Lm* in the environment, is required to maintain sanitary conditions in the facility so that product does not become adulterated (9 CFR 416.4).

CHAPTER V – VERIFYING PRODUCT DISPOSITION

A. The establishment may reprocess or dispose of adulterated product. If the establishment reprocesses the product, IPP are to verify that it used a process that achieves adequate lethality of pathogens. MSA considers a process that has been validated to achieve a 5-log reduction of *Lm* to be sufficient for reworking contaminated product.

B. For cooked products, establishments may use the time-temperature tables in the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) to recook the product.

C. For dried products, it would not be sufficient to recook the product using the time-temperature tables in the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A), unless the establishment provides additional support for process effectiveness.

D. If the establishment chooses to dispose of the product, it may do so either on-site or off-site.

1. If the product is disposed of on-site, IPP are to verify that the establishment maintains records showing that the positive product received the proper disposition.

2. If the establishment transports positive product off-site for appropriate disposition, IPP are to verify that the establishment:

    a. Maintains records identifying the official establishment, renderer, or landfill operation that received positive product;

    b. Maintains control of product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);

    c. Maintains control of product that was destined for an official establishment while the product was in transit (e.g., through company seals) or ensured that such product moved under MSA control;

    d. Maintains records showing that positive product received the proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred;

    e. Completes pre-shipment review for the positive product only after it has received the records described above for that particular product; and

f. If an establishment ships adulterated product to a renderer or landfill operation, IPP are to verify the establishment denatures the product before it leaves the establishment (9 CFR 314).

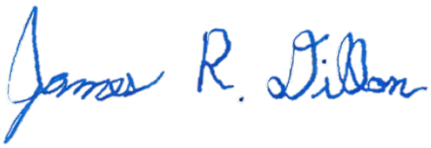
3. If the establishment transports positive product to a pet food manufacturer, IPP are to verify the product is made inedible prior to shipment. IPP are to be aware that the product does not need to be denatured first, it could be placed in an inedible container and shipped under permit from the CO (9 CFR 314). IPP are also to be aware that the establishment is not required to maintain records showing that the positive pet food product received the proper disposition.

E. If IPP find that there is noncompliance with the corrective action requirements for product disposal, they are to document the noncompliance in accordance with MSA Directive 5,000.1.

F. In situations where the establishment has not properly moved or disposed of the product, IPP are to notify the CO through supervisory channels.

CHAPTER VI – QUESTIONS

Refer questions through supervisory channels.



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