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HACCP-3

Generic HACCP Model for Raw, Ground Meat and Poultry Products

Additional copies of the Guidebook for the Preparation of HACCP Plans and the Generic HACCP Models are available from:

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United States Department of Agriculture
Food Safety and Inspection Service
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TO THE USERS OF THESE VOLUMES

As some of you may know, the Food Safety and Inspection Service (FSIS) received a substantial package of comments on its Guidebook for Hazard Analysis and Critical Control Point (HACCP) Plan Development and the 13 Generic HACCP models, from a coalition of industry and trade associations. This package represents a large and thoughtful effort on the part of these organizations. FSIS intends to give it the careful attention and response that it deserves.

The comments included many technical suggestions for improvements in the FSIS documents. It also included reiteration of longstanding differing policy viewpoints that have been frequently discussed by the Agency and the regulated industry. For the first time, the comments revealed substantially differing expectations on the part of these organizations and FSIS with respect to the purpose of the FSIS documents and their intended use. We want to address some aspects of this latter point.

When the Pathogen Reduction/Hazard Analysis and Critical Control Point systems (PR/HACCP) final regulation was published on July 25, 1996, the DRAFT Guidebook was included as an appendix. The Generic Models, developed for FSIS under contract, were available shortly thereafter in April 1997. It was probably inevitable that there were significant differences between the final regulatory language of CFR Part 417 and the DRAFT Generic Models as they were developed independently. It would have been inappropriate for FSIS to discuss its final regulatory language with any outside group. The contractor was appropriately proceeding from what it knew best, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) documents on the subject of HACCP. Therefore, FSIS accepted that work product with full knowledge that significant revisions would be necessary.

As time passed, FSIS managers became increasingly uncomfortable with the situation in which its major technical assistance documents did not appropriately and completely inform the regulated industry of Agency expectations regarding regulatory compliance. Because the intended audience for these technical assistance materials was primarily the very small establishments, which the Agency believed to have the least HACCP-experience, the Agency began the systematic revision of the documents to overcome this problem. We targeted the summer of 1999 as the completion date for this effort.

FSIS now believes that others had very different ideas about the purpose and use of the documents than it did. As is consistently reiterated in the documents themselves, they are not designed to be used "as is." That is, they cannot be copied and used by an establishment to meet all the regulatory requirements of 9 CFR Part 417. Nor were they designed to be the ultimate teaching and training materials, as some would suggest. The development of ideal generic models is left to others who may have an interest in doing so. The generic models are not

designed to extend or further interpret existing regulations; rather, they are designed to send the user back to the regulations so he/she can become familiar with the requirements as well as the flexibility they permit. The generic models are not designed to present new or alternative methods of producing and processing meat and poultry products. That is also left to others with an interest in doing so.

FSIS envisioned that the generic models might be used in the following way: Suppose a HACCP team leader of a three-person HACCP team in a very small establishment attended a training course, but the others on his/her team were not able to do so. Suppose the HACCP training course met all the requirements of 417.7 but did not provide participants with much in the way of "take away materials" like workbooks, practical questions and answers, access to follow-up resources, etc., which the Research Triangle Institute (RTI) needs assessment indicated were so important to these establishments. The trained HACCP team leader returns to the establishment and begins the process of attempting to develop HACCP plans for the company's products and processes. He/she is quite confident that he/she has grasped the material presented in the training course and begins to work with this team immediately, while the concepts are fresh in his/her mind.

First, he/she has the rest of the team review the Canadian video and the Guidebook from FSIS so that all members of his team have a basic level of information.

The team members begin their work, and as they proceed, some questions arise as to whether what they have developed is appropriate. This is the point when FSIS expects the team to pick up the appropriate generic model and get a sense of whether they are on the right track. They should be able to determine whether the forms that they have developed, while different from the various ones in the generic models and not the same as what other companies use, are acceptable because they include the required information. They will also be able to discover what are some typical food safety hazards that are reasonably likely to occur, as explicitly defined in 417.2, and how to think through the problems that these hazards represent for their own products. They can see how critical limits might arise from existing regulatory requirements like the ones for rapid chilling of poultry products. They can also see that in the absence of settled regulatory requirements, there may be several sources of scientific expertise, and they can choose to make a conservative decision to provide a good margin of safety. They can find out the essential differences between monitoring and verification and have a basis for making their choices about verification activities and their frequencies. FSIS believes that these are useful, beneficial and worthwhile functions for which its generic models can be used.

FSIS is publishing these updated revisions of the generic models, beginning with the Guidebook and the Generic Model for Raw, Ground Product, because a large backlog of requests exists for these two documents. FSIS intends to publish revisions of all the generic models no later than September 30, 1999. Moreover, as a result of public consultation, it may publish an additional revision of some of these models, but given the backlog and the impending HACCP implementation date, we considered it important to get a version of these documents out now.

We hope that these documents are helpful.

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GENERIC HACCP MODEL

FOR

RAW, GROUND MEAT AND POULTRY PRODUCTS

Introduction

The Hazard Analysis Critical Control Point (HACCP) system is a scientific approach to process control. It is designed to prevent the occurrence of problems by assuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards include biological, chemical, or physical contamination of food products.

The Food Safety and Inspection Service (FSIS) published a final rule in July 1996 mandating that HACCP be implemented as the system of process control in all inspected meat and poultry plants. As part of its efforts to assist establishments in the preparation of plant-specific HACCP plans, FSIS determined that a generic model for each process defined in the regulation would be made available for use on a voluntary basis by inspected establishments.

The generic models have been revised since their initial publication and distribution as DRAFTS. The most important change in the revised versions is to make certain that these models are fully consistent with the features of the final regulation. Also, other technical and editorial improvements have been made.

Throughout this generic model, FSIS discusses a HACCP team, with members from different departments. In many very small establishments, there will not be separate departments with different employees. But there will be employees who perform these different functions – often several of them. For purposes of explaining concepts, it is easier to speak as if these were different people, even though in many cases, they may be the same person carrying out more than one responsibility.

Each generic model can be used as a starting point for the development of plant-specific plan(s) reflecting actual plant environments and the processes conducted. The generic model is not intended to be used "as is" for plant specific HACCP plans.

The generic models are designed for use in conjunction with the list of process categories found in the HACCP regulations in section 417.2(b)(1).

(b) The HACCP plan. (1) Every establishment shall develop and implement a written

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> *HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:*
>
> *(i) Slaughter--all species.*
>
> *(ii) Raw product--ground.*
>
> *(iii) Raw product--not ground.*
>
> *(iv) Thermally processed--commercially sterile.*
>
> *(v) Not heat treated--shelf stable.*
>
> *(vi) Heat treated--shelf stable.*
>
> *(vii) Fully cooked--not shelf stable.*
>
> *(viii) Heat treated but not fully cooked--not shelf stable.*
>
> *(ix) Product with secondary inhibitors--not shelf stable.*

This generic model is designed for use with the second process category: Raw product--ground.

The purpose of the process category listing in 417.2 is to set out the circumstances under which a HACCP team may develop a single HACCP plan for multiple products. This may be done when products are in the same process category, and food safety hazards, critical control points, and other features are essentially the same. There is a generic model for each process category, plus two for subcategories that present special issues: irradiated products and mechanically separated products.

In order to select the model or models that will be most useful for the activities performed in any specific plant, the following steps should be taken:

1) For slaughtering operations, select the model for the appropriate species.

2) For processed products, make a list of all products produced in the plant.

3) Examine the list and group like products, considering common processing steps and equipment used.

4) Compare the grouped products with the list of processes in the regulations; this step should reveal how many and which of the generic models might be useful.

Deciding on a generic model and which products can be covered by a single plan is an important achievement. If the team does it well, it can save a lot of unnecessary effort and paperwork.

Selecting an inappropriate generic model reduces its potential benefits. However, often the HACCP team will discover they have made this error when they develop their process flow diagram or during their hazard analysis. These are early stages in the process when it is relatively easy to make changes.

In any case, establishments must meet all regulatory requirements for their products.

Using This Generic Model

This generic model is designed to be used by establishments that produce raw, ground product(s), the second process category. The model can be used for all raw, ground products: either meat or poultry; with or without spices or condiments; whether fresh or frozen. The generic model is not suitable for ground products with preservatives or secondary inhibitors or for partially cooked ground products. The model can be used for those products generally referred to as comminuted. Because mechanically separated products present some unique issues, FSIS has prepared a separate generic model for these products.

The model will be most useful to a HACCP team that includes access to one trained individual, as specified in 417.7(b).

> *(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.*

It would be beneficial for other team members to have reviewed any of the various guidance materials available on how to develop a HACCP plan for your company, including several useful videos, handbooks, or computer programs. Once the HACCP team has prepared itself as thoroughly as possible in general HACCP principles and how to use them, this model should be helpful.

Note: This generic model includes a number of forms that can be used to record various types of required information. The forms themselves are samples; a company HACCP team can develop whatever forms it finds most useful. All the forms mentioned in this document are included in Appendix B; they appear in the order in which they are discussed in the text.

All FSIS generic models are designed to assist establishments in applying the seven HACCP principles to their meat and poultry processing operations **AND** to meet the regulatory requirements of Part 417. Therefore, the definitions used in this and all other FSIS generic models are those found in 417.1:

> ***§ 417.1 Definitions.***
>
> *For purposes of this part, the following definitions shall apply:*
>
> *Corrective action. Procedures to be followed when a deviation occurs.*
>
> *Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.*
>
> *Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.*
>
> *Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.*
>
> *HACCP System. The HACCP plan in operation, including the HACCP plan itself.*
>
> *Hazard. SEE Food Safety Hazard.*
>
> *Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.*
>
> *Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.*
>
> *Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.*

Process Flow Diagram and Product Description

To begin using this model, the company's HACCP team should first describe the product(s), which are part of this process category and covered by this HACCP plan. The product(s) should be described in two ways:

(1) by a simple diagram which shows the steps the company uses when it produces the product, and
(2) in a brief written description which provides key facts about the product and its use.

In this generic model, there is an example for fresh pork sausage, one of the products in this process category. FSIS has developed certain forms as part of the examples in the generic models; **company HACCP teams are not required to use these forms.**

Figure 1 is an example of a **PROCESS FLOW DIAGRAM** for the production of fresh pork sausage in generic establishment X. Figure 2 is an example of a **PRODUCT DESCRIPTION** for the fresh pork sausage produced by generic establishment X.

Once the company HACCP team in your establishment has prepared your Process Flow Diagram, they should verify it by walking through the establishment following the flow of product and making sure that all the steps of the process are included in the flow diagram. The team should also review the information provided on the Product Description to make sure all the key facts are included, such as identifying consumers, especially those with particular health problems or known to be at risk.

Note: If you are producing a raw, ground product which does not have any non-meat ingredients, such as raw, ground beef patties, you would not include the left side of the flow diagram i.e., receiving non-meat ingredients, storage of non-meat ingredients, etc. That is generally, how you use these generic model examples--just omit the features which do not apply to your operation.

By completing a Process Flow Diagram and a Product Description, you have met the requirements of 417.2(a)(2). You can use the Process Flow Diagram in particular to help you complete the rest of the hazard analysis. Use the flow diagram to systematically review each step in the process and ask the question, "Is there a food safety hazard which is reasonably likely to occur which may be introduced at this step?" In answering the question, your HACCP team needs to consider biological (including microbiological), chemical, and physical hazards.

Hazard Analysis

Once your product(s) are accurately described through the flow diagram and product description, the HACCP team should begin work on the **HAZARD ANALYSIS**. The hazard analysis is fundamental to developing a good HACCP plan and one that meets regulatory requirements. The regulatory requirements for a hazard analysis are found at 417.2(a).

§ 417.2 Hazard Analysis and HACCP Plan.

> *(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.*
>
> *(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.*

Generic establishment X, which we are using for our example, is capturing these regulatory requirements on a 6-column **Hazard Analysis Form (See Figure 3)**. A good way to use a form like this is to create the first column by using the Process Flow Diagram and the second by answering the question of whether there is a food safety hazard. Once the HACCP team has considered all the steps in the flow diagram and determined if a food safety hazard could be introduced, it needs to consider whether the hazard is "reasonably likely to occur", using the meaning of this phrase included in 417.2(a). On the 6-column form used by generic establishment X, the third and fourth columns address this issue. If the establishment's HACCP team has decided that the hazard is not reasonably likely to occur, they enter "No" in column three, explain the basis for their determination in column four, and do not need to further consider activity at this point in the process.

If, however, the team has determined there is a "food safety hazard reasonably likely to occur" introduced at a certain point in the process, column five is used to describe a measure which could be applied to "prevent, eliminate, or reduce to acceptable levels" the food safety hazard identified in column three.
Look at the entries for “Receiving-Meat” on the first page of the six column form; the HACCP team has determined that *Salmonella* may be present at high levels in incoming raw product, so it has put a “Yes” in the third column. Column four explains the basis for the team’s determination. In the fifth column, the HACCP team has described the preventive measures it will use to make sure that each hazard has been prevented, eliminated, or reduced to an acceptable level. For the *Salmonella* hazard, the HACCP team decided to tell its suppliers that product could not be accepted unless it was accompanied by certification that the supplier had not failed two consecutive *Salmonella* performance standard sets. FSIS does not consider safe handling labels alone to be an adequate CCP for any pathogenic microorganisms such as bacteria and viruses.

Note: Look at the entries for "Storage-Meat" on the second page of the six-column form: the HACCP team has determined that there is a food safety hazard reasonably likely to occur at this step in the process. Column four contains the reason for their thinking: pathogenic organisms (including *Salmonella*) can grow in this product if it is not kept sufficiently cool. Column five contains their description of a measure that will prevent the growth of pathogenic organisms: temperatures that are sufficiently low to preclude growth.

You will notice that on our generic hazard analysis for pork sausage, there are six safety hazards in which the HACCP team has identified a point in the process at which a food safety hazard is reasonably likely to occur. For each one of these they have identified a measure which can be used to control the hazard.

When your HACCP team has completed their hazard analysis (whether they use this format or not), it is a good idea to review the flow diagram, the product description and the hazard analysis itself to make sure they are complete. Part 417.2(a)(3) includes a list of sources from which food safety hazards might be expected to arise. Reviewing that list could help the HACCP team check for completeness.

Note: If you are using this generic model to produce a different raw, ground product or if you use a different process flow, you may have different hazards which are reasonably likely to occur. For these different hazards, there may be different measures that could be used for control purposes.

This, and all other FSIS generic models, contains a list of references which can help your HACCP team in making sure the hazard analysis is complete. The references for raw, ground product are found in Appendix A. A member of your HACCP team might want to review at least some of the references to make sure hazards have not been omitted from the hazard analysis.
If you are using this generic model to develop a HACCP plan for raw, ground beef, you may find the recently issued FSIS guidance material on producing this product to be useful. You may get a copy from the FSIS Docket Clerk in Room 102, Cotton Annex Building, 300 12th Street, SW, Washington, DC, 20250. An electronic version of the guidance material is available on line through the FSIS web page located **at http://www.fsis.usda.gov.**

Completing the hazard analysis is a very significant and important element in developing your HACCP system. Your HACCP team should feel a real sense of accomplishment when they get this far; this is like completing the foundation of a house.

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Developing Your HACCP Plan

The company HACCP team can now take the materials it developed while doing the hazard analysis and use them to build the **HACCP Plan**. Remember that one of the important objectives of the FSIS generic models is to provide examples that illustrate **how to meet the regulatory requirements of Part 417**, as well as to correctly apply the principles of HACCP. Part 417.2 (c) and (d) are the regulatory requirements:

> *The contents of the HACCP plan. The HACCP plan shall, at a minimum:*
>
> *(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.*
>
> *(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:*
>
> *(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and*
>
> *(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;*
>
> *(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;*
>
> *(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;*
>
> *(5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and*
>
> *(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.*
>
> *(7) List the verification procedures, and the frequency with which those procedures will*

be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

Generic establishment X has prepared its HACCP plan for pork sausage on a six column form (**See Figure 4**). You do not need to use this form, although some kind of a form is probably the easiest way to present your HACCP plan.

Identifying CCPs

The first column on this particular form is used to enter information developed and contained on the hazard analysis form. Part 417.2(c)(1) and (2) require that the food safety hazards identified in the hazard analysis be listed on the HACCP plan and that there be a CCP for each identified hazard. You will notice that there were five process steps (six food safety hazards) on the hazard analysis form where food safety hazards reasonably likely to occur were identified: presence of *Salmonella* on incoming meat products; pathogen growth at the location where meat was stored; metal shavings contamination at grinding; metal shavings contamination carried through into packaged product; presence of *trichina* in finished product being packaged and labeled; and pathogen growth in stored finished product.

The establishment HACCP team has chosen to have five CCPs to address these six hazards: supplier *Salmonella* certification review at meat receiving; temperature controls in the raw meat storage area, and temperature controls in the finished product storage area; a metal detector on the packaging line overseen by the packaging line supervisor; and clear product labeling to show the product is raw and must be fully cooked to prevent any *trichina* survival. The metal detector is the control for metal shavings contamination whether introduced through the packaging process or at some earlier point.

Determining what will be the CCPs requires knowledge of HACCP, the establishment processes, and good practical judgment. When the team gets this done, it has passed an important milestone.

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After identifying its CCPs, the HACCP team proceeded to consider critical limits, monitoring procedures and their frequencies, and verification procedures and their frequencies, and HACCP records.

In deciding what would be the critical limits, the HACCP team first considered whether there were any regulatory requirements which had to be met and would function as critical limits. They knew about the pathogen reduction performance standards for *Salmonella* on raw carcasses and raw ground products (Part 310.25) because they would be subject to one themselves. The team determined that if a supplier establishment had failed two consecutive sample sets, they would not receive that product.

They did not find any specific temperature limits which applied to red meat storage areas. The team members knew that the Food Code, which had recently been adopted in their state, recommended a transport temperature of 41° F; and they knew that the European Union required a 42° F temperature. They decided that in order to be within the recommended limits for food safety and to assure that the thermometers used which measure in 2 degree increments assured safety, the conservative 40° F critical limit was selected.

With respect to metal shavings, the team knew that their metal detector was capable of identifying metal shavings as small as 1/32 of an inch, as long as it was working well. Therefore they decided that their critical limit would be 1/32 inch.

They were aware of regulatory requirements to prevent consumer confusion about which pork products were raw. Their product did not have any ingredients that would make it appear cooked. For their critical limit, the HACCP team decided that a label that met regulatory requirements for raw pork products, with clear cooking instructions, plus the FSIS safe handling label, would be their critical limits.

Once they had decided on their critical limits, they needed to identify how the monitoring procedures would be carried out and at what frequency.

For their Receiving-Meat control on *Salmonella* prevalence on incoming products, they decided the operational personnel who normally checked arriving products would also check each shipment for the supplier certification about *Salmonella* results. The team determined that this might be an excessive frequency for suppliers with good performance, and decided that when they validated their HACCP plan (by actually trying it out and recording results), they would consider whether another frequency should be used.

For their two temperature CCPs, they decided that maintenance personnel would be in the best

position to check the temperatures in the storage areas. They decided that the temperature checks should be performed every two hours. In making this decision, the team knew that if there was a deviation from a critical limit at a CCP, they would need to perform corrective actions on the product which had potentially been affected by the deviation; they determined that two hours' worth of product was the most that they wanted to control and possibly rework at one time.

For their metal detector CCP, the HACCP team decided that the packaging line supervisor would be in the best position to assure that the metal detector was working well and that he could do so by putting a seeded sample through the detector every two hours. Company personnel have worked with this metal detector for about six months and have found that when it is properly adjusted, it works very well and meets manufacturer's specifications. However, it can get out of alignment relatively quickly, and there are no overt signs on the machine itself that it is working less than optimally. Putting a seeded sample through is a reliable way to assure its proper functioning. The team decided that putting the seeded sample through every two hours was a good frequency because they did not want to have more than two hours worth of product which they might need to rework if there were a deviation from the critical limit of 1/32 inch.

The HACCP team decided that the best way to monitor that their labeling specifications were being met was at non-meat receiving; at this location receiving personnel routinely checked all incoming non-meat materials to make sure they met specifications. Since labels were manufactured in large lots by a single company, the receiving clerks would randomly sample each arriving lot.

These decisions by the HACCP team regarding critical limits, plus monitoring procedures and their frequencies are written up in columns two and three of the HACCP Plan. By using the six-column form, the team members can see that they are making good progress on developing their plan.

The team then went on to consider appropriate verification procedures; the team knew that there were different types of verification and that Part 417.4(a)(2) included specific regulatory requirements for each. The regulatory requirements for ongoing verification are:

> *(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:*
>
> *(i) The calibration of process-monitoring instruments;*
>
> *(ii) Direct observations of monitoring activities and corrective actions; and*
>
> *(iii) The review of records generated and maintained in accordance with § 417.5(a)(3)*

of this part.

The HACCP team decided that they could verify the *Salmonella* results forwarded by suppliers by periodically seeking results directly from FSIS. Because the sample set for pork carcasses consisted of 51 samples, the team decided that seeking the information from FSIS every two months would be sufficient. QA staff would initiate these data requests.

The HACCP team determined that since maintenance personnel were performing the room temperature checks, their supervisor would be a good person to involve in verification. He will review the temperature logs, and may either observe the employee taking the temperature or take a temperature of his own, once per shift.

There is a regulatory requirement (Part 417.4(a)(2)(i)) for including as a verification, the calibration of process-monitoring instruments; the thermometers being used to take the temperature checks are obviously process monitoring instruments, so someone outside the maintenance unit, in this case the Quality Assurance unit, will check those thermometers for accuracy on a daily basis, and calibrate them to within 1 degree as necessary.

To verify the functioning of the metal detector, a QA person who is outside the packaging unit, will feed the seeded sample through the metal detector twice per shift, once in the morning and once in the afternoon.

Finally, the HACCP team decided that verification of the accuracy, clarity, and appropriateness of product labels could be handled by QA personnel, who routinely sampled packaged product to assure customer satisfaction. In this case, QA would add a verification check once a day to make sure the labeling met requirements.

The HACCP team described the verification procedures and their frequencies in the fifth column of their HACCP plan.

The HACCP team for generic establishment X knew that their HACCP Plan needed to provide for a recordkeeping system. They wanted their records to be easy to create and understand. They wanted to be sure their records met regulatory requirements, so they reviewed part 417.5(a) and (b):

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

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> *(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;*
>
> *(2) The written HACCP plan, including decision making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.*
>
> *(3) Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.*
>
> *(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*

The HACCP team decided that their records would be kept on some simple forms, some of which the team itself devised. To monitor supplier *Salmonella* data, the form now used at Receiving-Meat, had an additional box added, which would be checked. A similar simple form modification made it easy for receiving staff to check label correctness. For monitoring temperatures during storage of raw product and storage of finished products, the maintenance employees performing the checks would use a Room Temperature Log. Notice that this form can be used for both monitoring and verification temperature checks performed by maintenance personnel; the form can be used in both the raw meat storage room and in the finished products storage room.

Since the QA staff were heavily involved with verification activities, as they had been before HACCP, the HACCP team sometimes modified existing forms they used, and sometimes created simple new forms. In requesting the *Salmonella* data from FSIS, QA staff used a form letter that listed the establishment numbers of their suppliers. They retained a copy of the form letter, and when results were received, noted if the supplier had failed two consecutive sample sets. If so, they immediately notified operational staff receiving meat to refuse shipments from that supplier, and initiated contacts with the supplier.

QA staff already had a checklist which they used when they sampled packaged product, so the HACCP team just added an extra box, where the presence of complete, clear, and accurate labeling was specifically noted.

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The team created a separate form to be used by the QA personnel who were checking the thermometers and calibrating them as necessary. Each employee who was performing a temperature check had a thermometer assigned to him which was identifiable by its serial number. QA personnel picked up thermometers from employees throughout the day when employees were not using them, and checked them against a known standard; recalibration was performed immediately if it was necessary. There were only four different employees and different thermometers being used in the HACCP monitoring and verification activities, and they were to be checked once a day, so the HACCP team decided that this form could be used by QA for more than one day. QA personnel were located in a different part of the plant; employees delivered their thermometers to QA once a day immediately after they had performed a temperature check. QA checked the thermometer and returned it to the employee with a copy of the record showing results; in addition, QA e-mailed the results to the HACCP coordinator at the end of each day, and each time there was a variation of more than 2° F noted when the thermometer was checked.

The HACCP team also created a form to be used by employees with assigned tasks concerning the functioning of the metal detector. Like the Room Temperature Log, the form includes both monitoring and verification checks results; the form has entries from both the packaging supervisor and from QA personnel. The form is kept near the metal detector and is turned in to the HACCP coordinator at the end of each day.

On its HACCP Plan, generic establishment X has listed the names of the forms it will be using for monitoring and verification records.

There is one other form included in column four, where the establishment has described its recordkeeping system. That is the Corrective Actions Log; it is used to create the records of any corrective actions taken because of deviations from critical limits at CCPs. Column six references the planned corrective actions for each CCP. The HACCP team carefully reviewed the regulatory requirements for planned corrective actions, found at 417.3(a):

> ***§ 417.3 Corrective actions.***
>
> *(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:*
>
> *(1) The cause of the deviation is identified and eliminated;*
>
> *(2) The CCP will be under control after the corrective action is taken;*

> *(3) Measures to prevent recurrence are established; and*
>
> *(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*

The HACCP team has developed a specific corrective action plan which will be followed whenever there is a deviation from a critical limit at a CCP; each of the planned corrective actions meets the four regulatory requirements of 417.3(a). For example, this is the establishment's planned corrective action whenever there is a deviation from the 1/32 inch critical limit, i.e. whenever the packaging supervisor puts the seeded sample through the system and the metal detector does not respond appropriately.

Planned Corrective Actions for CCP 5P

1. Packaging Supervisor takes control of and segregates all product which may have been processed when metal detector not functioning, i.e. all product processed since the last complying monitoring check;

2. Maintenance personnel identify problem with the metal detector and repair it so that the same problem does not recur in the near future; maintenance personnel plan preventive maintenance checks;

3. QA runs a seeded sample through the repaired system and verifies that it is functioning correctly;

4. QA runs possibly adulterated product through the repaired system, and releases only that which complies; other product is returned for rework/condemnation.

The HACCP team also develops planned corrective actions for each of the other CCPs and attaches them to the HACCP plan. Whenever a deviation from a critical limit occurs, company employees follow the corrective action plan and use the Corrective Action Log to create a record of their actions. The Corrective Action Log forms are available at CCPs, so they can be used immediately when an employee performing a monitoring check discovers and records a deviation. All Corrective Action Logs, which have been used during the day, are turned in to the HACCP coordinator.

There is one final verification/recordkeeping requirement which the company must perform; it is found at 417.5(c):

> *(c) Prior to shipping product, the establishment shall review the records associated with*

> *the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.*

In generic establishment X, product is shipped out, often in small lots, throughout the day. This means that pre-shipment verification checks must be as complete as possible when finished product is in storage, so that a shipment can be made up quickly and moved into distribution channels.

The establishment uses a half day lotting system and a midshift cleanup. While the midshift cleanup is being performed, QA personnel or the HACCP coordinator review results of monitoring and verification checks applied to that lot; if there were deviations from critical limits, they review the Corrective Action Logs to make sure all appropriate planned responses were carried out. If everything is in order and there are complete records showing that the establishment has controlled production of this product through its HACCP system, the HACCP coordinator will sign the pre-shipment review form which the HACCP team devised for this purpose.

Note: It is not a regulatory requirement that a separate form be used for pre-shipment review; in addition, FSIS has indicated that it will be very flexible in accepting a variety of arrangements for accomplishing pre-shipment review to reflect the variety of commercial practices which it has encountered in the industry. It is, however, important to remember that pre-shipment review is a regulatory requirement that must be met, as it indicates that the establishment is taking full responsibility for the product having been produced under a well-functioning HACCP system.

The HACCP team believes it has now completed preparation of the documents which are necessary to meet regulatory requirements for a Hazard Analysis and a HACCP Plan for their pork sausage production process. They have secured a copy of FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to HACCP System Requirements, the HACCP Basic Compliance Checklist which will be used by inspection program personnel. The HACCP team has modified the inspection form to make the statements into positives, and now has a checklist for its own use to make sure they have not omitted anything in their plan development and preparation. When they are confident that they have done what is necessary, they will turn their Hazard Analysis and HACCP Plan over to the establishment owner for decisions about implementation.

APPENDIX A

References for HACCP Teams

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   Useful sections in particular are:
   Chapter 3 – microbiological hazards, pp. 15-26
   Chapter 4 – chemical hazards, pp. 27-32
   Chapter 5 – physical hazards, pp. 33-35
   Appendix A – NACMCF HACCP
   Appendix C – Model HACCP plans

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    Useful sections in particular are:

Chapter 10 – raw meat and poultry, pp. 176-193
Chapter 11 – roast beef, pp. 234-238
Chapter 11 – canned ham, pp. 238-242

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    Useful sections in particular are:
    Chapter 4 – microbiological hazards, pp. 72-103
    Chapter 9 – raw meat, pp. 193-199
    Chapter 9 – processed meats, pp. 199-216

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    Useful sections in particular are:
    Chapter 4 – meat and poultry slaughter, pp. 58-71
    Chapter 5 – processed meats, pp. 72-107
    Chapter 7 – risk analysis, pp. 134-154

Chapter 13 – predictive modeling, pp. 330-354

19. Pierson, M.D. and Corlett, D.A., Jr. Editors. *HACCP Principles and Applications*. Van Nostrand Reinhold, New York, 1992.

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Useful sections in particular are:
Chapter 11 – forms for hazard analysis, CCPs, critical limits, HACCP master sheet, example HACCP for breaded chicken

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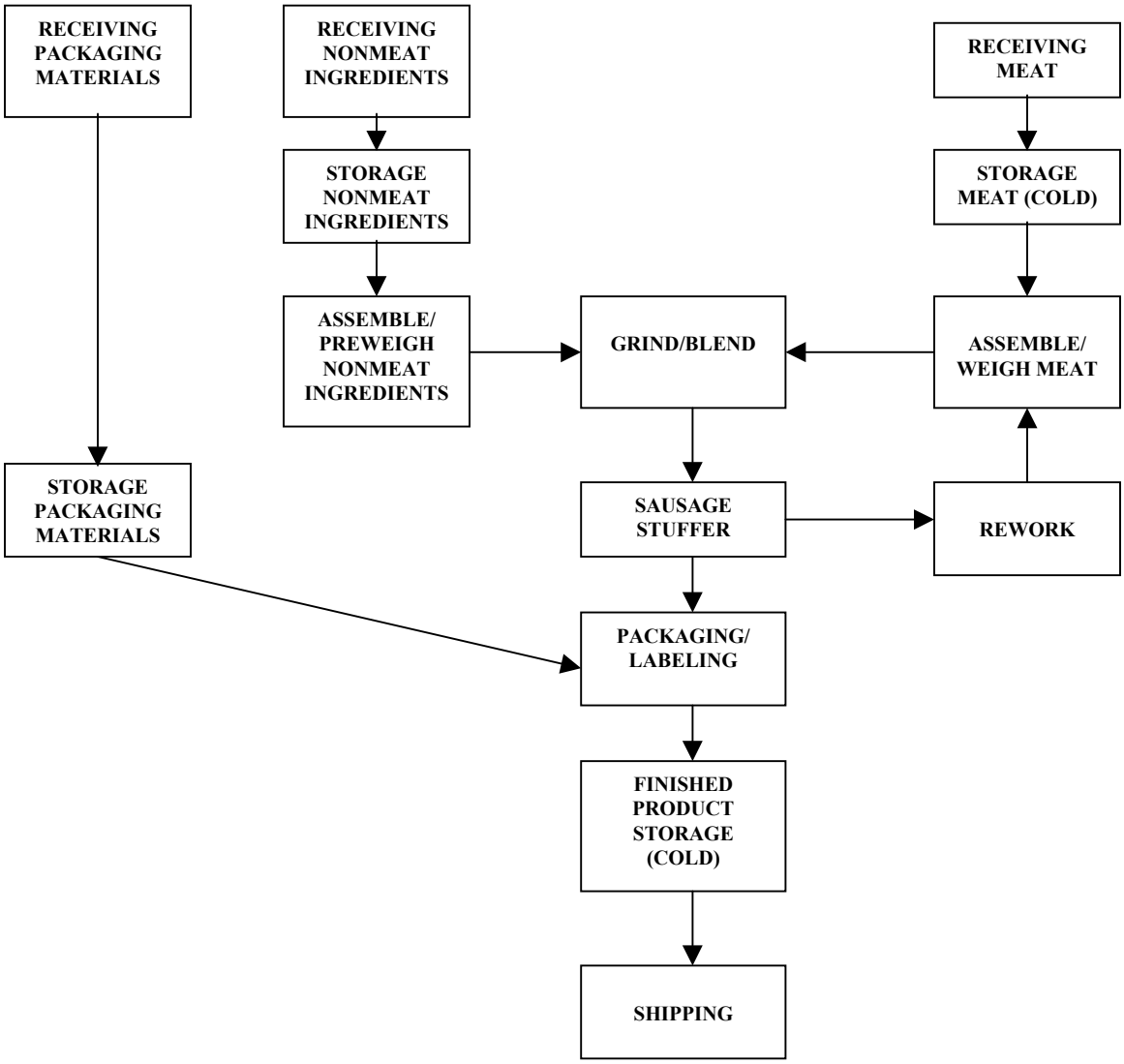
APPENDIX B

PROCESS FLOW DIAGRAM **Figure 1**

PROCESS CATEGORY: RAW PRODUCT, GROUND
PRODUCT: FRESH PORK SAUSAGE



PRODUCT DESCRIPTION **Figure 2**

PROCESS CATEGORY: RAW PRODUCT, GROUND PRODUCT: FRESH PORK SAUSAGE	
1. COMMON NAME?	FRESH PORK SAUSAGE
2. HOW IS IT TO BE USED?	COOKED AND CONSUMED
3. TYPE OF PACKAGE?	BULK-PACKED (E.G., PLASTIC BAG, VACUUM PACKED);
4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?	3-6 MONTHS AT 0° F OR BELOW; 7 DAYS AT 40° F
5. WHERE WILL IT BE SOLD? CONSUMERS? INTENDED USE?	RETAIL AND HRI, WHOLESALE GENERAL PUBLIC, NO DISTRIBUTION TO SCHOOLS OR HOSPITALS
6. LABELING INSTRUCTIONS?	KEEP REFRIGERATED; COOKING INSTRUCTIONS (MINIMUM INTERNAL TEMPERATURE FOR COOKING); SAFE FOOD HANDLING LABEL
7. IS SPECIAL DISTRIBUTION CONTROL NEEDED?	KEEP REFRIGERATED

HAZARD ANALYSIS – RAW PRODUCT, GROUND – Fresh Pork Sausage

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Receiving – Meat	**Biological: Pathogens –*Salmonella* *and* Other pathogens in pork trimmings**	**Yes**	***Salmonella* may be present on incoming raw product.**	**Certification from suppliers that product has been sampled for *Salmonella* and meets performance standards.**	**1B**
	Chemical – None				
	Physical – Foreign materials	**No**	**Plant records show that there has been no incidence of foreign materials in products received into the plant.**		
Receiving – Nonmeat Ingredients/Packaging Materials	**Biological – None**				
	Chemical – Not acceptable for intended use	**No**	**Letters of guaranty are received from all suppliers of nonmeat ingredients and packaging materials.**		
	Physical – metal, glass, wood	**No**	**Plant records demonstrate that foreign material contamination has not occurred during the past several years.**		

Figure 3

HAZARD ANALYSIS – RAW PRODUCT, GROUND

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Storage (Cold) - Meat	**Biological – Pathogens *Salmonella***	**Yes**	**Pathogens are reasonably likely to grow in this product if temperature is not maintained at or below a level sufficient to preclude the growth.**	**Maintain product temperature at or below a level sufficient to preclude pathogen growth.**	**2B**
	Chemical – None				
	Physical – None				
Storage – Nonmeat Ingredients/Packaging Materials	**Biological – None**				
	Chemical – None				
	Physical - None				
Assemble/Pre-weigh Nonmeat Ingredients	**Biological – None**				
	Chemical- None				
	Physical – None				
Assemble/ Weigh Meat	**Biological – None**				
	Chemical – None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – RAW PRODUCT, GROUND

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Grind/Blend	**Biological - None**				
	Chemical – None				
	Physical – Metal contamination	**Yes**	**Plant records show that during the grinding process metal contamination may occur.**	**Maintenance of grinder blades and plates can preclude metal contamination . Routine examination during equipment breakdown. There will be a metal detector at packaging.**	
Sausage Stuffer	**Biological – None**				
	Chemical – None				
	Physical - None				
Rework	**Biological – Pathogens** *Staphylococcus aureus*	**Yes**	**Use of rework can provide a medium for pathogen growth.**	**Rework left at the end of the day is condemned or used in a cooked product at the plant.**	
	Chemical- None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – RAW PRODUCT, GROUND

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Packaging/Labeling	**Biological: Pathogens – parasitic (*Trichina*)**	**Yes**	***Trichina* has historically occurred in raw pork products.**	**Labels that clearly indicate this is a raw product, along with cooking instructions, and the safe food handling statement.**	**3B**
	Chemical – None				
	Physical – Metal contamination	**Yes**	**Metal contamination that may have come into the establishment with raw product or occurred during the grinding and stuffing process.**	**Functional metal detector is on-line in the packaging/labeling area to remove product with metal contamination.**	**4P**
Finished Product Storage (Cold)	**Biological – Pathogens** *Salmonella* *Staphylococcus aureus*	**Yes**	**Pathogens are reasonably likely to grow in this product if temperature is not maintained at or below a level sufficient to preclude their growth.**	**Maintain product temperature at or below a level sufficient to preclude pathogen growth.**	**5B**
	Chemical – None				
	Physical - None				

Figure 3

HAZARD ANALYSIS – RAW PRODUCT, GROUND

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Shipping	**Biological – None**				
	Chemical- None				
	Physical – None				

Figure 3

HACCP PLAN

PROCESS CATEGORY: RAW PRODUCT, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
1B Receiving – Meat *Salmonella* and other pathogens in raw pork trimming.	Supplier certification that product meets FSIS performance standard for *Salmonella* must accompany shipment.	Receiving personnel will check each shipment for *Salmonella* certification.	Receiving Log	Every two months QA will request FSIS *Salmonella* data results from the company for at least 2 suppliers.	Will not receive product unaccompanied by *Salmonella* certification. If product does not have certification, it is rejected or returned. Assure that procedures for only guaranteed supplier list is kept current and guaranty on file in shipping /receiving log. If supplier does not meet FSIS performance standards product will not be purchased from them until they can maintain bacterial levels meeting performance standard.
2B Storage - (Cold) Meat	Raw product storage area shall not exceed 40° F.	Maintenance personnel will record raw product storage area temperature every 2 hours, initial / sign and date log.	Room Temperature Log Corrective Action Log Thermometer Calibration Log	Maintenance supervisor will verify accuracy of the Room Temperature Log once per shift and observe plant employee performing monitoring. QA will check all thermometers used for monitoring devices for their accuracy and verify to within 2° F on a daily basis.	QA will reject or hold meat until time/temperature deviation and its implications are reviewed. Product disposition will depend on this expert review. QA will identify the cause of the deviation and devise measures to prevent reoccurrence. Maintenance will adjust scheduled cooler upkeep & review if necessary or repair any malfunctioning equipment.

Signature : _____ **Date:**_____ **Figure 4**

HACCP PLAN

PROCESS CATEGORY: RAW PRODUCT, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
3B Packaging/ Labeling (*Trichina*)	Product must clearly be labeled as raw – Cook before eating Cooking instructions that state "cook to 145°F" must be on package. Safe food handling statement must be part of label.	Packaging line supervisor will select 2 packages of product hourly and ensure labeling requirements are met.	Corrective Action Log Labeling Log	QA will observe packaging line supervisor perform monitoring activity once per shift. QA will select 3 labels intended for use from label storage area twice weekly to ensure label accuracy. QA will check labels once a day on packaged product to ensure accurate labels are placed on packaged product.	QA will segregate and hold all affected product. QA will ensure that proper labeling is applied to all affected product prior to shipment. QA will determine cause of deviation and institute preventive action.

Signature : _____ **Date:**_____ **Figure 4**

HACCP PLAN

PROCESS CATEGORY: RAW PRODUCT, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
4P Packaging/ Labeling	No metal particles to exceed 1/32 inch. All contaminated product is removed from system by functioning kick out mechanism. All kick out product will be visually examined and any metal removed.	Packaging line supervisor will check the metal detector using a seeded sample every two hours to determine limits are not exceeded.	Metal Detection Control Log Corrective Action Log	QA, outside the packaging unit, will verify that the metal detector is functioning as intended by running the seeded sample through the metal detector twice per shift (once AM, once PM).	Packaging supervisor will control and segregate affected product. Maintenance personnel will identify and eliminate any problems with the metal detector or kick out mechanism. Preventive maintenance program will be implemented. QA will run seeded sample through detector after repair. All potentially contaminated product will be run through functional metal detector prior to shipment. All product rejected by detector will be reworked.

Signature : _____ **Date:**_____ **Figure 4**

HACCP PLAN

PROCESS CATEGORY: RAW PRODUCT, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
5B Finished Product Storage (Cold) **(Continued on next page)**	Finished product storage area shall not exceed 40° F.	Maintenance personnel will check finished product storage area temperature every two hours.	Room Temperature Log Corrective Action Log Thermometer Calibration Log	Maintenance supervisor will verify the accuracy of the room temperature log once per shift. QA will check all thermometers used for monitoring and verification activities for accuracy daily and calibrate to within 2° F accuracy as necessary. QA will observe maintenance personnel check finished product storage area once per shift.	If a deviation from a critical limit occurs, the following corrective actions will be taken: 1. Product which may not have met CL will be identified and held. 2. The cause of the temperature exceeding 40° F will be identified and eliminated. 3. The CCP will be monitored hourly after the corrective action is taken to ensure that it is under control. 4. When the cause of the deviation is identified, measures will be taken to prevent it from recurring e.g., if the cause is equipment failure, preventive maintenance program will be reviewed and revised, if necessary.

Signature : _____ **Date:** _____

Figure 4

HACCP PLAN

PROCESS CATEGORY: RAW PRODUCT, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
5B Finished Product Storage (Cold)					If a deviation from a critical limit occurs, the following corrective actions will be taken: 5. If room temperature exceeds the critical limit, the processing authority will evaluate the product temperature to ensure the temperature is sufficient to preclude pathogen growth prior to shipment. If temperature is not sufficient to preclude pathogen growth, product will be cooked in the establishment to ensure destruction of pathogens.

Signature : _____ **Date:**_____

Figure 4

FORM LETTER Confirming *Salmonella* Compliance with Performance Standards

Date

To: Plant XYZ

This is to confirm results of any *Salmonella* performance standard sample sets completed during the past six months from your establishment listed below.

Thank you.

Product	Date Results Received	Test Results	Two Consecutive Failed Tests

GENERIC ESTABLISHMENT X: ROOM TEMPERATURE LOG

ROOM:_____ DATE:_____

TIME	TEMP	Deviation from CL? (Check if yes)	If Yes, Action?	Monitored by:	Verified by:
6:36 AM	34°F			PS	
8:30 AM	33°F			PS	
10:32 AM	34°F			PS	CB
12:30 PM	49°F	✓	Notify maintenance supervisor, CB & QA	PS	

TIME/TEMPERATURE CRITICAL LIMIT --- 40°F

Raw, Ground Model

THERMOMETER CALIBRATION LOG Criteria Within ∀1 °F of Control Thermometer								
Date	Time	Department or Area	Thermometer ID#	Control Thermometer Reading	Personal Thermometer Reading	Adjustment Required (Yes or No)	Initials	Comments
6/15	1:00 PM	Chiller	2A	32°F	32°F	No	HK	

*** If a thermometer is broken or taken out of service, document this in the comment column.**

Verified by: _____

Date/Time: _____

GENERIC ESTABLISHMENT X: METAL DETECTION LOG

Date	Product	Lot #	Results	Seeded Sample	Time	Monitored By	Verified By

CORRECTIVE ACTIONS LOG

Product: _____ **Lot # _____**

CCP	Deviation/ Problem	Corrective Action Procedures/Explain	Disposition of Product	Responsible Person	Time

SIGNATURE: _____ **DATE: _____**

PRE-SHIPMENT REVIEW LOG

Date:_____

LOT ID	TIME RECORDS REVIEWED	BY WHOM	LOT RELEASED FOR SHIPMENT? SIGNATURE	COMMENTS
	11:10 a.m.			
	11:10 p.m.			

*Monitoring frequency as per plan; Critical limits met; Certification(if applicable) as per plan; Deviations if occurred were reviewed for appropriate corrective actions; Records complete and accurate