

ESTABLISHMENT PROFILE

Objectives

After completion of this module the participant will be able to:

1. Describe the Establishment Profile in PHIS and why it is important to maintain the accuracy of information in this section.
2. Describe when and how to perform the Update Profile task in PHIS
3. Access, enter and edit information in the Establishment Profile.
4. Describe what to discuss and do at the weekly meeting related to the profile.
5. Identify the HACCP processing category for any given product.
6. Determine the finished product group and average daily production volume.

References

1. FSIS Directive 5300.1, Rev. 1 Managing the Establishment Profile in the Public Health Information System (PHIS), Dated 10-19-16.
2. FSIS Notice 05-15 Interpreting Results of FSIS Verification Sampling of Domestic Beef Product Derived From Advanced Meat Recovery Systems (AMR01/FAMR01), Dated 1/14/15
3. 9 CFR Part 300 to End
4. PHIS Quick Reference Guide

Background

The Establishment Profile (EP) is a series of web-pages in PHIS that Inspection Program Personnel (IPP) use to enter data about official establishments and other facilities where FSIS provides inspection services. The profile includes information on the products produced, the processes performed, the equipment employed, the HACCP systems that the establishment has put in place, and other general information.

PHIS uses the establishment profile information to assign routine inspection tasks, to create tailored inspection tasks, to generate FSIS sample requests, and to manage inspection assignments. Therefore, it is critical to make sure that the profile is accurate and reflects what the establishment is actually producing and the food safety system it is using to ensure that its products are safe.

For new establishments, the district office enters information in PHIS to populate parts of the profile and IPP complete the remainder and verify the accuracy of information on an ongoing basis. For existing establishments, IPP maintain and verify accuracy of information on an ongoing basis. During the process of granting inspection, the Grant Curator (GC) is to assign an establishment number

and enter information regarding the application for grant of inspection or inspection services. A Frontline Supervisor (FLS), EIAO, or other designated personnel will visit the applicant's establishment and report the information gathered at the establishment which will be used to complete parts of the establishment profile. After the grant process is complete, the assigned inspector in charge (IIC) is responsible for keeping the information in the establishment profile up-to-date and accurate as part of their in-plant duties.

The EP information is essential to the Agency's goal of protecting public health because FSIS uses the establishment profile information for generating inspection tasks, determining eligibility for sampling programs, for automated reporting and for ad-hoc data analysis... When an establishment begins production of a new product, there is a significant change in product volume, an establishment address changes or there is a jurisdiction change, IPP are to update the establishment profile as soon as the change occurs to ensure the appropriate inspection tasks are being generated. Other changes, not directly related to task scheduling and sampling eligibility, can be completed during the next routine monthly Update Establishment Profile task.

The following profile features aid in the determination of task scheduling and sampling eligibility and are critical to keep updated and accurate:

- 1. HACCP Processing Category**
- 2. Product Volume Information**
- 3. Jurisdiction**
- 4. Sampling Supplies Address**

Other Establishment Profile information of critical importance includes:

- Grants and Approvals
- Operating Status
- Inspection Activities
- Shifts
- Slaughter
- Products produced

Grants include all information related to the Application for Federal Inspection (AFI) and Application for Voluntary Reimbursable Services (AVRS). **Operating Status** is the overall status of the establishment (not just of a particular grant) and is "active" or "inactive". When Operating Status is "inactive", no inspection tasks are allocated to the establishment so it is critical to recognize & correct an "inactive" status as soon as possible. An **Inspection Activity** is one of the following: meat slaughter, meat processing, poultry slaughter, poultry processing, egg product, or imported product. Inaccurate inspection activities indicate that EP information needs changing and as a result the proper tasks may not show up in the establishment task list. **Shift** information is critical to ensure that all shifts receive the appropriate inspection tasks and coverage. Operating Status,

Inspection Activities, Grants and Shifts cannot be modified by IPP as it is “Read Only”. However, it is very important that this information is corrected as soon as possible so IPP should examine it right away. Contact the DO through supervisory channels if it is incorrect.

Slaughter includes the slaughter system, inspection system, number of slaughter lines, number of slaughter lines operating simultaneously, maximum line speed, and staffing. **HACCP Processing Categories** are critical because the tasks for each category will only be assigned if reflected in the profile. It is important that **Inspection Tasks** assigned to the establishment’s inspection task list are applicable and no tasks are missing. The **Products** and **Production Volume Information** has an impact on sampling projects and sampling frequencies. The **Jurisdiction** information identifies the government organization that performs inspection of food products at the establishment. The **Sampling Supplies Address** is critical since lab sampling supplies cannot be delivered to the establishment if this information is missing or not accurate. This information can be entered or edited by IPP.

Performing the Update Profile Task

PHIS will display the routine update profile task on the establishment task list monthly.

- IPP are to perform the routine Update Establishment Profile inspection task monthly by updating the information in the establishment profile with any new information and reviewing the establishment task list. IPP are also to focus on verifying the accuracy of a specific area of the establishment profile each month according to the following schedule:

Table: Establishment Profile Update Schedule	
<u>Month</u>	<u>Profile Information Focus Area</u>
January	Establishment Contacts
February	HACCP Systems Information for Raw-Intact product categories
March	HACCP Systems Information for Raw-Non-Intact product categories
April	HACCP Systems Information for Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Heat Treated Shelf Stable product categories

May	HACCP Systems Information for Fully Cooked–Not Shelf Stable, Product with Secondary Inhibitors–Not Shelf Stable, and Heat Treated but Not Fully Cooked–Not Shelf Stable product categories
June	General Profile Information
July	Product Information for Raw-Intact product categories
August	Product Information for Raw-Non-Intact product categories
September	Product Information for Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Heat Treated Shelf Stable product categories
October	Product Information for Fully Cooked–Not Shelf Stable, Product with Secondary Inhibitors–Not Shelf Stable, and Heat Treated but Not Fully Cooked–Not Shelf Stable product categories
November	Slaughter Information
December	General Profile Information

- IPP are to also perform the Update Establishment Profile task if they become aware while performing other inspection tasks, or through communication with a management official, that the establishment is producing a **new product**. A directed task may be used for this purpose if the routine task has already been performed for that month. IPP perform the update profile task by reviewing and updating the information in the establishment profile. The EP link on the left navigation menu contains the sub-links needed to access the various establishment profile pages. IPP can only edit profile information for establishments in their inspection assignments.
- IPP provide a copy of the EP report to establishment management during the next weekly meeting upon entering a new assignment, or following a change to an existing assignment. Management will have an opportunity to affirm or correct any of the profile information in PHIS. When management responds with a correction, IPP are to change their response only after seeing establishment records or other data that is needed to support the basis for the correction. IPP are to resolve any issues or discrepancies regarding profile information before they document the task as completed in PHIS.

- To generate the Establishment Profile Report, IPP are to:
 - Select the establishment under the **Establishment Profile** tab on the left navigation menu;
 - Scroll down to the bottom of the page and find the **Reports** tab; and
 - Click on **Reports**, then select **Establishment Profile Report**. This will generate the report that can then be saved or printed.

Note: Refer to the PHIS user guide or the PHIS Help Button for step-by-step information.

When performing the **Update Establishment Profile** task, IPP are to gather information from a management official at the establishment or facility and complete or update information as needed. The following parts of the EP will be accessed in making updates:

- Establishment Contacts
- General
- Establishment Task List
- HACCP Systems Information (meat and poultry establishments only)
- Slaughter Information (meat and poultry establishments only)
- Product Information (meat and poultry establishments only)
- Production Volume Information (meat and poultry establishments only)
- Profile Questionnaires

Note: Information concerning Grants and Approvals (Read only), Profile Summary, Operating Schedule, Facilities, Equipment (Thermal Processing), and Training can also be accessed.

Hands-On Activities

The following hands-on section is intended to provide familiarity and experience with the EP features in PHIS. Open Beef, Inc., a beef slaughter and processing combination establishment, is the example establishment used for most of the activities. The profile has already been created in PHIS.

Follow these steps along with the instructor.

- ▶ Open the laptop
- ▶ Log-onto laptop:
 - User Name: **FSIS_user**
 - Password: **FSIS**
- ▶ Start Internet Explorer (double click icon)
- ▶ PHIS Log-in
 - Select User: **Robert Allen (your #)**

1. Click the down arrow next to **Establishment Profile** in left navigation menu to expand it.
 2. Click **Select Establishment** in left navigation menu
 3. Type “Open” in Name box
 4. Click **Search**
 - Results are presented in a grid below the search criteria
- ▶ Shortcut to access establishments to which you are assigned
5. Click **My Establishments** tab
 6. Click **House icon** associated with Open Beef
- ▶ Open Beef is selected and the **Establishment Homepage** is presented.
- ▶ The homepage is a series of collapsible/expandable panels
7. Click **Basic** to collapse
 8. Click **Basic** to expand

Establishment Homepage

All domestic and import establishments, ID warehouses or other facilities where FSIS provides inspection services will have a PHIS establishment homepage that contains relevant inspection information. The purpose of the establishment homepage is to present useful information about an establishment in a format that is more easily accessible than the profile data entry pages. The homepage contains information about the establishment from every available source within the Agency. In some cases, Agency personnel at headquarters and in field offices are the primary source of information that is available on the establishment homepage.

Please note that initially some sections of the EP, such as appeals and FSA, are not fully functional at this time. Also note that the establishment homepage doesn't always show all of the information needed to make an assessment, so if something looks wrong on the homepage, it may be necessary for IPP to access one of other profile pages to make a complete assessment. IPP are to use the information on the establishment homepage to assist them in performing verification tasks.

The **Basic** panel of the establishment homepage contains information of interest to a broad range of PHIS users such as Operating and Enforcement Status which cannot be edited by the CSI. Generally speaking, the Operating Status should be “active”. No inspection tasks are allocated to an establishment unless its Operating Status is “Active”. If any information on the Basic panel which cannot be edited by the CSI is not correct, e.g., **Operating Status and**

Inspection Activities, IPP should contact their supervisor. **Jurisdiction and HACCP Processing Categories** are critical data. If necessary, the CSI may correct this data by recording appropriate General and HACCP system information via the Establishment Profile HACCP page which will be covered later in this course.

9. Click on **Basic** to collapse
10. Click on **Products** to expand

The **Products** panel presents Finished Product categories (FPCs) under which the establishment produces product. Note that products and production volumes are critical EP data but they are better assessed via Products page which will be described later. The CSI can fix errors / gaps using EP Products page. Products and production volumes are critical EP data because they drive some of the sampling algorithms (risk-based rules).

11. Click **Products** to collapse
12. Click **Reports** to expand

The **Reports** panel provides the link to the Establishment Profile Report that should be shared with establishment management during a weekly meeting.

13. Click **Reports** to collapse
14. Click **Personnel** to expand

The **Personnel** panel provides information related to IPP assignments. In-Plant Personnel, Rotations, and Approved Hours of Operation are not maintained by the CSI. If they are incorrect, inform your supervisor.

15. Click **Personnel** to collapse
16. Click **Noncompliance Records** to expand

The **Noncompliance Records** panel presents NRs issued to the establishment.

17. Click **Noncompliance Records** to collapse
18. Click **Food Safety Assessments** to expand

Food Safety Assessments (FSA) presents information about FSAs performed at the establishment after PHIS implementation.

19. Click **Food Safety Assessments** to collapse
20. Click **Laboratory Sampling** to expand

The **Laboratory Sampling** panel presents information about FSIS sampling that has been conducted at the establishment. The CSI can view information about sampling verification programs that apply to a particular establishment. The CSI

can also access the FSIS sampling history and see pending sample requests for a particular establishment.

21. Click **Laboratory Sampling** to collapse
22. Click **Types of Inspection** to expand

The **Types of Inspection** panel presents information about mandatory and voluntary inspection carried out at the establishment.

Grants and Approvals

23. Scroll up and click **Grants & Approvals** in the left navigation menu

The **Grants & Approvals** section of the profile presents information found on the Application for Federal Inspection, FSIS Form 5200-2 (AFI) and the Application for Voluntary Reimbursable Service, FSIS Form 5200-6 (AVRS). The district office must complete the grant application and information in PHIS in order for PHIS to display the information. The status values in the grid are hyperlinked and provide access to AFI and AVRS data. Operating Status is for the establishment as a whole. An operating Status of “Inactive” will prevent any “actions” for establishment tasks. For example, all inspection tasks will be removed by the next day. If any information is incorrect, inform supervisory personnel since the CSI cannot change this information.

Note that meat and poultry grants must have a status of “Conditional” or “Granted” for inspection tasks to be allocated to the establishment task list.

Establishment Contacts

24. Click **Contacts** in left navigation menu

The **Contacts** submenu contains two tabs - **Establishment** and **Personnel**. IPP are to click on **Add New Contact** to enter establishment contacts. Contact information may be added by operating shift if necessary.

25. Click **Add new Contact**

Contact types are used in PHIS to designate a person that will receive system generated notifications or official Agency correspondence. Their contact information will be available in other parts of PHIS such as when IPP are selecting a contact to receive notification of noncompliance records.

IPP are to select one or more of the following **contact types** for each contact person:

- Select **Recall Contact** if the person serves as a contact during a recall.

- Select **Emergency Contact** if the Agency is to contact this person during an emergency such as a natural disaster or sudden closure at the establishment.
- Select **Export Coordinator** if the Agency is to contact this person regarding issues pertaining to exported products.
- Select **Lab Sample Results Contact** if the Agency is to send laboratory sample results to this person electronically.

Note: PHIS links with LIMS Direct. LIMS Direct only allows one Lab Sample Result Contact. The contact should be entered separately and the lab sample contact indicator should be checked.

- Select **Establishment Administrator** when the establishment provides the name of the individual who will serve as the first Establishment administrator. In order for an establishment to access PHIS there must be an individual designated to serve as Establishment Administrator entered into the profile. IPP only need enter the initial Establishment Administrator in PHIS for enrollment validation.

Note: Establishment Administrator is actually a selection from the dropdown for **Position**.

Other possible selections for contact types include AMS EV Program Contact and Public Outreach Contact.

26. Enter the following:
- Position: Select **President / GM**
 - Type: Check **Emergency Contact**
 - First Name: Type **Sam**
 - Last Name: Type **Hawthorne**
 - Telephone: Type **7072123651**
 - Fax: Type **7072124444**
 - Email 1: Type **Sam@openbeef.com**
 - Shifts: Select **Shift 1**
 - Comments: Type **Owner**

27. Click **Save**

The **Personnel tab** provides contact information for all IPP assigned to the establishment.

28. Click **Personnel**
- FSIS Personnel page is presented

General

The **General** submenu option contains five data entry tabs that contain establishment addresses and general information regarding the establishment. Its purpose is to provide access to information about the establishment of a generic nature.

29. Click **General** in the left navigation menu
 - Establishment tab is presented

Establishment tab purpose: Present information from the establishment section of the AFI / AVRS page.

30. Scroll to the **List of Addresses**

- **Address Information.** IPP are to maintain and update establishment addresses other than the physical address. The physical address is the address where IPP perform inspection. FSIS also considers this address the primary address. The physical address will display in PHIS to IPP users as a pre-populated address in the **List of Addresses** table.
- The district office has permissions to edit the physical address while managing the grant application process. If IPP note changes to the physical address, IPP are to inform the establishment management official to contact the district office with the address change.

IPP are to click on **Add New Address** to enter additional establishment addresses and select the following address types from a list of options for each address entered:

- Select **Company Mailing Address** if the Agency is to use the address to mail official constituent information and other general correspondence regarding FSIS inspection.
- Select **Overnight Mailing Address** if FSIS is to use the address for its contract service, FedEx, to deliver express mail or packages. FedEx will not deliver to certain addresses such as a P.O. Box.
- Select **FSIS Inspection Office Mailing Address** for the address to use for mailing information to IPP assigned at the establishment or facility.
- Select **Laboratory Sample Supplies Address** if the Agency is to use the address to deliver laboratory sample supplies to IPP via Fed Ex. In many cases, this address will be the same as the Overnight Mailing Address.

Note: FSIS Directive 5300.1, Revision 1 instructs IPP to verify that each official meat and poultry establishment in the Public Health Information System (PHIS) has a current, valid Laboratory Sample Supplies Address in the establishment profile (not a P.O. Box number) for shipment of FSIS laboratory sampling supplies via the Agency-contracted overnight carrier service. This information must be in PHIS regardless of whether FSIS has collected samples at the establishment or not.

31. Click **Add new Address**
 - **Edit Plant Address Page** is presented

32. Enter the following information

Address Type:	Select	Overnight Mailing Address
Address Line1:	Type	8305 Hawthorne Way
City:	Type	Petaluma
State:	Select	CA
Postal Code:	Type	94954

33. Click **Save**
 - The new address is presented in the grid.

Ownership tab purpose: Presents information from the applicant section of the AFI / AVRS page.

Jurisdiction tab purpose: Identify government organization which performs inspection of food products at the establishment and if the establishment produces product under the **AMS grading/National School Lunch programs or has dual jurisdiction with FDA**. IPP are to review the establishment's approved grant of inspection to verify that the establishment is an approved dual jurisdiction establishment before making changes.

34. Click on the **Jurisdiction** tab

Exemptions tab purpose: Identify exemptions from FSIS inspection that apply to the establishment.

Note: IPP are to verify that establishments are properly performing under a religious exemption for the slaughter and handling of poultry before making changes to this section (Please refer to FSIS Directive 6030.1, *Religious Exemption for the Slaughter and Processing of Poultry*, and 9 CFR 381.11).

35. Click on the **Exemptions** tab
36. Check the **Custom Slaughter** box
37. Click the **Save** button

The **Other** tab contains the following information:

- **Recall Plan information**
- **Food Defense Plan**
- **Establishment HACCP size**
- **Geographic location**
- **Names** under which the establishment is **Doing Business As (DBA)**
- **FSIS Inspector's office** telephone and fax numbers

38. Click on the **Other** tab

Many of the features in the general section are read-only for IPP. The district office has responsibility to edit this information while managing the grant application process. However, IPP can enter information concerning whether the establishment has a written **Recall Plan**, which is a regulatory requirement, a written **Food Defense Plan**, which is not a regulatory requirement, and the **HACCP Establishment Size**. Guidance in FSIS Directive 5420.1, Rev. 9, Food Defense Verification Tasks and Threat Notification Response Procedures For the Office of Field Operations, states, under "Plans" to place a check mark in the box after the question, "Does the establishment have a written Food Defense Plan?" if the establishment has a functional Food Defense Plan (FDP). If the establishment does not have a functional FDP, leave the box blank. More information will be presented in the Food Defense module.

Note: IPP are to review and verify the profile information is accurate for recall plan information, food defense plan, and establishment size. ***IPP are to enter a size for every establishment in PHIS, including egg products plants and facilities under voluntary inspection.***

Note: IPP are to update and maintain information under the **Jurisdiction**, **Exemptions**, and **Other** tabs when performing the Update Establishment Profile task.

HACCP

The 9 categories listed in 9 CFR 417.2(b)(1) are very similar to the HACCP categories in PHIS, however, there is a slight difference for raw product. In the regulations, the raw product categories are: raw product - not ground and raw product - ground. In PHIS, these categories are raw product intact and raw product non-intact. The 9 HACCP categories in PHIS are:

- Slaughter
- Raw product – intact
- Raw product – non-intact
- Thermally processed – commercially sterile

- Not heat treated – shelf stable
- Heat treated – shelf stable
- Fully cooked – not shelf stable
- Heat treated but not fully cooked – not shelf stable
- Product with secondary inhibitors – not shelf stable

When completing FSIS Form 5200-2 as part of the grant application process, the establishment will document the HACCP processing categories representing the products they will be producing. IPP verify the HACCP processing categories entered into PHIS based on the establishment's processes and finished product. Before the products page of the establishment profile can be populated, a hazard analysis must be created and the HACCP processing category must be verified.

The description for each HACCP processing category is in Attachment 1 of FSIS Directive 5300.1, Revision 1 which is included in the back of this handout. IPP are to gather information from the establishment on its HACCP system including the Hazard Analysis, HACCP plan (if applicable), and written pre-requisite programs that are referenced in the hazard analysis. IPP are to be familiar with the establishment's processing steps and corresponding hazards addressed in the establishment's food safety programs.

Establishments **ARE** required to provide access to HACCP system information. Section 417.5(f) states that "All records required by this part (Part 417) and all plans and procedures required by this part shall be available for official review."

IPP are to treat HACCP system information as proprietary and confidential in accordance with current Agency standards, thus ensuring that they safeguard establishment information from intentional or accidental exposure to non-FSIS personnel at other establishments or the public. IPP are to follow the guidelines in FSIS Directive 1300.7, *Managing Information Technology (IT) Resources*, Revision one, part three that addresses computer equipment use.

If an establishment refuses to provide access to its hazard analysis, HACCP plan or other supporting documentation for review and recording of HACCP information into PHIS, IPP are to document a noncompliance, citing 9 CFR 417.5(f). IPP are then to discuss this noncompliance with establishment management at the next weekly meeting, and document that fact and any establishment response in the memorandum of interview (MOI) that is generated from the weekly meeting. If the establishment continues in its refusal, IPP are to immediately contact their Frontline Supervisor.

39. Click the **HACCP** link in the left navigation menu
 - The **HACCP Processing page** is presented

The Summary panel, hazard analysis grid and prerequisite programs and interventions links are always displayed. The **Summary Panel** lists the HACCP processing categories that are pertinent to the establishment. FSIS defines HACCP processing categories (9 CFR 417.2) based on food science principles. Recall from previous presentations, that HACCP processing categories are critical information because they affect the allocation of inspection tasks to the establishment task list and other PHIS functionality. The summary panel is a convenient way of accessing and verifying the processing categories. Purpose of the pre-requisite program link is to present a grid of the pre-requisite programs which are applicable to the establishment.

HACCP categories are entered by the District Office from the Application for Federal Inspection, FSIS Form 5200-2 (AFI). The panel can be collapsed to allow more viewing area on the screen.

40. Click the **up arrow** in the right corner of the **summary panel** to collapse it
41. Click the **down arrow** in the right corner of the **summary panel** to expand it

Adding/Creating a Hazard Analysis

Open Beef has three existing hazard analyses that have already been entered into PHIS for training purposes. To add a new hazard analysis, IPP click “**Add Hazard Analysis.**” IPP are to complete the following information in PHIS for the establishment’s hazard analysis:

- ▶ **Name the hazard analysis.** If the establishment does not title their hazard analysis, IPP identify it using a name that other IPP can use to identify the plan easily (i.e., Raw Intact Steak Hazard Analysis). PHIS allows duplicate content for hazard analyses but the name must be unique.
- ▶ **The date.** Enter the most recent date recorded on the hazard analysis.
- ▶ **HACCP processing category.** IPP are to select one or more HACCP processing categories from the list displayed in PHIS based on the establishment’s processes and finished product shipped from the establishment.

When the slaughter HACCP processing category is selected, PHIS generates a list of Slaughter Class Group choices.

- Beef => Cattle, Calf
- Pork => Swine
- Other Meat => Goat, Sheep
- Poultry => Chicken, Turkey, Duck, Goose, Guinea, Squab, Ratite

- ▶ **Lot Definition.** Enter a brief description of the lot definition.

42. Click **Add Hazard Analysis**

- Data entry fields for basic hazard analysis information are presented

43. Enter the following information:

Document Name:	Type	Slaughter and Raw Intact/Non-intact Product
Date:	Type	Today's
HACCP Processing Category:	Check	Raw–Non Intact, Raw–Intact, and Slaughter
Class Group:	Check	Beef
Lot Definition	Type	8 hour's production

44. Click **Save**

If the slaughter HACCP processing category was selected, PHIS determines if an appropriate slaughter line is defined for the establishment after the **Save** button is clicked. If not, a warning is issued to the inspector such as “slaughter line information has not been recorded for the selection”. The warning did not appear at the top of the page because a slaughter line has been recorded in the pre-filled hazard analysis for Open Beef already entered in PHIS.

Note: IPP must create a hazard analysis before PHIS allows users to enter HACCP plans and product information.

Adding/Creating a HACCP Plan

At least one hazard analysis must exist for an establishment in order to create a HACCP Plan. Multiple HACCP plans may be associated with a given hazard analysis. HACCP plans for a hazard analysis are sorted alphabetically (A - Z) by plan name. IPP are to complete the following information in PHIS for the establishment's HACCP plan:

- ▶ **Name the HACCP plan.** If the establishment does not title their HACCP plan, IPP identify it using a name that other IPP can use to identify the plan easily (i.e., Raw Intact Steak HACCP Plan). PHIS allows duplicate content for HACCP plans but the name must be unique.
- ▶ **The date.** Enter the most recent date recorded on the HACCP plan.
- ▶ **HACCP processing category.** IPP are to select one or more HACCP processing categories from the list displayed in PHIS.

The Slaughter and Raw Intact and Raw Non-intact hazard analysis that was created above does not have any HACCP plans associated with it.

45. Click the **Arrow icon** next to the Slaughter, and Raw Intact /Raw Non-Intact Product hazard analysis to expand it
46. Click the **Add HACCP Plan**
 - The **HACCP plan page** is presented
47. Enter the following information:

Plan Name:	Type	Slaughter and Raw Intact/Non-Intact Product
Signature Date:	Type	Today's

Note: When actually entering this information in establishment, enter the most recent date of the HACCP plan or hazard analysis.

Hazard Analysis:	Already Selected	Slaughter and Raw Intact/Non-Intact Product
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HACCP Processing Category:	Check	Slaughter, Raw-Intact, and Raw Non-intact
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Note: The HACCP processing category options presented are the ones selected when the hazard analysis was created. At least one HACCP processing category must be selected.

48. Click **Save**

Products

The **Products** page is used to record the product groups that are produced by the establishment and the associated volume information. FSIS uses microbial risk assessment and risk based algorithms to allocate Agency resources including verification sampling programs. The production volume in PHIS must be accurate so that sample requests are generated at the proper frequency in an establishment subject to verification sampling, e.g., RTE product sampling, *E. coli* O157:H7 testing, etc.

The products page is also used to enter the lot definition and the product's intended use. For establishments with HACCP plans under the Slaughter, Raw-Intact, and Raw-Non-Intact processing categories, IPP are to select the intended use (e.g. for cooking only, for non-intact use) of the establishment's product after it leaves the establishment.

The page has **two tabs**:

- The **Products** tab lists product groups and corresponding volumes
- The **Volumes** tab provides volume produced on an average day for each HACCP category.

The Product groups listed in the Products tab are identified in Attachment 2 of FSIS Directive 5300.1, Rev. 1. The table in Attachment 2 has **3 columns**:

- HACCP Processing Category
- Finished Product Category
- Product Group – Production Volume Categories

When a new product group is to be added, IPP will click on the **Add New Product Group** link which will present a maximum of 4 tabs, each representing one of the **four finished product categories** listed below:

- Raw
- NRTE
- RTE
- Thermally Processed

IPP are to click on the appropriate tab and complete product information in PHIS. Table 3 given below contains the HACCP process categories associated with raw products, Not Ready to eat products (NRTE), Ready to eat products (RTE) and thermally processed products. FSIS defines RTE products in the 9 CFR 430.1 regulatory requirements.

Table 3: PHIS Product Tabs By HACCP Category				
<u>HACCP Processing Categories</u>	<u>Finished Products</u>			
	<u>Raw Product</u>	<u>NRTE Product</u>	<u>RTE Products</u>	<u>Thermally Processed Product</u>
Slaughter	•			
Raw Intact (Raw Not Ground)	•			
Raw Non-Intact (Raw Ground)	•			

Thermally Processed Commercially Sterile				•
Not Heat Treated Shelf stable		•	•	
Heat Treated Shelf Stable		•	•	
Fully Cooked -Not Shelf Stable			•	
Product with Secondary Inhibitors-Not Shelf Stable		•	•	
Heat Treated but Not Fully Cooked – Not Shelf Stable		•		

Note: All finished products produced under the Fully Cooked – Not Shelf Stable HACCP processing category are considered RTE. If the establishment does not consider the products RTE, IPP are to enter the establishment’s HACCP information under the heat treated but not fully cooked – not shelf stable HACCP processing category. Products in the Thermally Processed-Commercially Sterile HACCP Category must be RTE.

Production Volume Information

IPP will complete product volume information for each product group on the **Products** tabs. IPP enter the production volume for each product group. The system will estimate the production volume for the finished product category (FPC).

IPP are to enter average daily production volume information for the products produced during the production days from the previous month by following three steps.

First, estimate the total volume produced for all products produced in each **Product Group** entry in the previous calendar month. IPP are to review the establishment’s shipping records, receipts, production records, or any other records that are available and that bear on establishment production volume. If little or no records exist, IPP are to select the highest reasonable volume range for a particular product group based on the production capacity at the establishment.

Note: If the product is box-in box-out (i.e., just being stored at the establishment) it should not be included in the finished product category information. Next, determine the number of days the product group was produced in the previous calendar month and divide the total volume produced for each product group by that number. IPP are also to enter the number of days of production in the field at the bottom of the page when adding or editing information for each product group.

Finally, IPP are to select a volume range in Table 2 that best represents the average daily production for particular product groups. If there was no production for that product group in the previous month but the establishment plans to produce the product in the future (i.e. seasonal product) IPP can enter "0" for the production volume.

Note: After making changes concerning products and volume, IPP are to present an updated establishment profile report to establishment management officials at a weekly meeting. If the establishment does not agree with the volume range chosen, they should provide evidence to support the volume estimate.

Table 2: PHIS Volume Ranges
Average Daily Volume (lbs. per day)
0
1 – 100
101 – 1,000
1,001 – 3,000
3,001 – 6,000
6,001 – 50,000
50,001 – 250,000
250,001 – 600,000
600,001 – 1,000,000
> 1,000,000

If an establishment produces two or more types of product that are **within the same product group** and have the same intended use, IPP are to enter the total volume for all products within that product group in a single entry.

For example, if an establishment produces raw chicken patties (average daily production of 3,000 pounds) and raw chicken sausage (average daily production

of 5,000 pounds) that are not intended for a lethality treatment at another federally-inspected establishment, IPP would enter both types of poultry products as a single entry under “Other Comminuted,” with the average daily volume representative of the total volume of both products (8,000 pounds).

After entering all information for all product groups, click on the **Volumes** tab and ensure that a volume range value is selected for each HACCP Processing Category. If a volume range value is not selected for each HACCP Processing Category, appropriate tasks will not be generated by PHIS for the establishment.

Recording Product Information Hands-on Activity

49. Click **Products** in left navigation menu
50. Click **Add new Product Group**
51. Enter the following:
 - HACCP Category: Select **Raw - Intact**
 - HACCP Plan: Select **Beef Raw Intact HACCP Plan**

 - Finished Product Category: Select **Raw intact beef**
 - Product Group: Check **Beef Manufacturing Trimmings**

 - Enter: Average Daily Volume: Select **6,001 - 50,000**
 - Intended Use: check **“Other”** (leave the text box blank)

Note: IPP are to select “Other” for the intended use if product is intended for consumer cooking (the product is ready-to-cook), goes to other official establishments for further processing (but not RTE treatment), is exported, goes to hotels/restaurants/institutions, or goes to a facility other than official domestic establishment.

Note: Checking the intended use box is required for some product categories such as raw intact beef because it is very important in determining risk and sampling programs for that product. For example, an establishment will not be subject to MT65 or MT60 sampling tasks in PHIS if all of the eligible finished product groups selected in the PHIS profile are intended “For RTE Cooking Only.” IPP are to enter or update one product group entry in the profile at a time. If IPP enter or update multiple product groups at the same time, PHIS will not apply the intended use field correctly, which will affect sampling assignments. If more than one intended use is listed for a finished product group (ex. Some Beef Manufacturing Trimmings are intended for producing raw non-intact product, i.e.,

patties, and some Beef Manufacturing Trimmings are used to produce a cooked, RTE product such as summer sausage), then IPP are to enter the product group separately (one time under each intended use). Do not select both and do not leave it blank.

- No. of Days of Production: Type **23**

52. Click **Save**

53. Click **Volumes** tab

- HACCP Category Volumes are presented as specified by the CSI

54. Enter the following information:

- Raw - Intact: Select **50,001 - 250,000**
- Raw – Non Intact: Select **1,001 - 3,000**
- Slaughter: Select **6,001 - 50,000**

55. Click **Save**

Other Product Tabs

56. Other Product tabs, such as RTE and NRTE do not apply to Open Beef so we must change assignments by doing the following:

- Sign out **Robert Allen (your #)**
- Log on **Robert Barclay (your #)**
- Click **Establishment Profile**
- Click **Select Establishment**
- **Click the My Establishments tab**
- Select **Holland Point Foods**
- Go to **Products – Products Tab**

Holland Point Foods began producing two new RTE products last month, Beef Salami and Pork Cotto Salami. Shipping records indicated that it sold 35,220 lb. of Beef Salami and 21,127 lb. of Cotto Salami under Alternative 3 produced over 25 days last month.

57. Click **Add new Product Group**

- **RTE tab** is presented

58. Enter the following:

- HACCP Category: Select **Fully cooked-NSS**
- HACCP Plan: Select **Deli Meat HACCP Plan**
- Finished Product Category: Select **RTE fully-cooked meat**

- Product Group: Select **Sausage Products**
- Species: Check **Meat Only**
- Lm Alternatives: Click **Alternative 3**
- How often do you test food contact surfaces per line each month? Select **4 times**
- Average Daily Volume: Select **1,001 - 3,000**
- No. of Days of Production: Type **25**

59. Click **Save**

60. Click the **Volumes tab**

- The average daily production of the sausage products (2,254 lb.) did not change the production volume.

61. Click the **Products Tab**

- A “Stuffed” product group for the HT NFC NSS process is listed in the grid
- The establishment also produces sliced bacon (900 lbs. per day) that is also HT NFC NSS product but the product group for this product *is not* listed

62. Click **Add new Product Group**

63. Click the **Non-RTE tab**

64. Enter the following:

- HACCP Category: Select **Heat Treated-Not Fully Cooked-Not Shelf Stable**
- HACCP Plan: Select **Smoked Product**
- Finished Product Category: Select **NRTE otherwise processed meat**
- Product Group: Check **Not-stuffed**
- Average Daily Volume: Select **1 -1,000**
- Species : Check **Swine:**
- No. of Days of Production: Type **12**

65. Click **Save**

66. Click the **Volumes tab**

67. Verify that **1,001-3,000** is selected for the Heat-treated-Not Fully Cooked-Not Shelf Stable category.

68. Click **Save**

Inspection Tasks

PHIS will maintain an establishment task list in the profile for each establishment. PHIS will compare the task definitions in the task library to establishment characteristics captured in the establishment profile. Based on this comparison, PHIS will generate a list of the appropriate inspection tasks to be performed in each establishment.

Some inspection tasks that appear on the establishment task list may not apply to the establishment's operations. IPP review the establishment task list when they review the establishment profile and de-select those tasks that do not apply to the establishment's current operations. IPP are also to review the tasks, if any that have previously been de-selected to ensure that those tasks still do not apply to the establishment's current operations.

For some tasks, the information in the profile is not sufficient to determine whether the task applies. For example, the Other Consumer Protection inspection task to verify economic wholesomeness of products labeled with "X% added solutions" applies only to establishments that use such labels. Because PHIS cannot determine which establishments apply labels with an "X% added solution" claim, the IPP will have to manually de-select that task in establishments that do not produce products labeled with "X% added solution". An establishment may make a temporary or seasonal change in its operations which makes some inspection tasks not applicable for part of the year. For example, an establishment produces beef jerky as a heat treated, shelf stable product. However, during the Holidays (October through December), the establishment also produces smoked turkeys as a heat treated, not fully cooked, not shelf stable product. At the beginning of October the IPP would have manually select the HACCP verification task for the heat treated, not fully cooked, not shelf stable process. When the seasonal period of smoked turkey production is over, IPP would have to manually de-select this task.

69. Change assignments by doing the following:
 - Sign out as **Robert Barclay (#)**
 - Login as **Robert Allen (your #)**
 - Click down arrow for **Establishment Profile**
 - Click **Select Establishment**
 - Click **the My Establishments tab**
 - Click **House Icon** for Open Beef
 - Click **Inspection Tasks** on left navigation menu
 - The **Inspection Tasks** page is presented
70. Scroll down the **Establishment Task List** to become familiar with the 3 levels listed below.
 - **Inspection Activity**
 - **Inspection Type**
 - **Inspection Task**

IPP are responsible for ensuring the correct inspection tasks are on the establishment task list in the profile.

CSI may not add or delete items in the list since it is the Task Distributor that maintains the task list. The Task List is duplicated for each of the establishment's shifts and the default is for the inspection task to be performed. IPP may de-select an inspection task for a single shift, for example, if that shift does not produce a certain product on a shift. The List is hierarchical and each level in the hierarchy may be collapsed or expanded except for the lowest level. The lowest level in the hierarchy is the inspection task and it is the only level that may be selected (enabled) or de-selected (disabled).

Selected (checked) inspection tasks must be performed for the establishment. IPP use the edit icon to toggle (select/unselect) an inspection task and must provide a reason when making a change. PHIS updates the establishment task list approximately once per day, usually overnight. If IPP make changes in the establishment profile information, it will take up to 24 hours for PHIS to make any resulting changes to the establishment task list.

When IPP review the establishment profile, they also determine if any applicable inspection tasks appear to be **missing from the establishment task list**. If an applicable inspection task appears to be missing, IPP are to first review the establishment profile to make sure the other profile information regarding the establishment operations and products is accurate. If the profile is inaccurate, PHIS may not add the correct tasks to the establishment task list on the **Task Calendar** page.

If IPP believe the establishment profile accurately represents the establishment's operations and product types, and still believe that an applicable inspection task is missing from the task list, they are to contact the Policy Development Division through askFSIS for assistance.

Establishment Task List Hands-on Activity

Open Beef no longer produces X% solution labeled products.

71. Scroll to **Economic Wholesomeness** inspection activity and locate the Economic inspection type and X percent (%) solution for corned beef task.
72. Click the **Edit** icon next to X percent (%) solution inspection task
73. Enter the following information:
Reason: Select "**Establishment temporarily not producing applicable product**"
 - The justification control is then removed
74. Click **Save**

Open Beef no longer produces partially defatted beef fatty tissue (PDBFT).

75. Click the **edit icon** next to **MSS; MSP; PDBFT...** inspection task
 - Data entry controls are presented below **MSS; MSP; PDBFT...**
76. Enter the following reason: select “**Establishment temporarily not producing applicable product**”
 - The justification control is then removed
77. Click **Save**
 - Checkbox is unchecked and the inspection task will be removed the next day

Slaughter

IPP enter slaughter information for establishments in the slaughter HACCP processing category. The district office must complete voluntary slaughter information in PHIS in order for PHIS to display voluntary slaughter options. IPP are to update the voluntary slaughter classes based on the operations at the establishment. The district office is notified automatically of any changes to the voluntary slaughter classes when IPP update the information in the profile.

Slaughter Hands-on Activity

IPP are to complete the following information on the establishment's slaughter operation in PHIS for each shift:

78. Click **Slaughter** in left navigation menu
 - Slaughter page is presented.
79. Click the **down arrow** next to the number of physical slaughter lines box
80. Click the **down arrow** next to the box below the number of slaughter lines operating simultaneously
81. Click the **Save** button
82. Click the **Edit** icon to the right of Slaughter Line 1 information.
 - Slaughter line details page is presented.
83. Enter the following information:
 - Shift: Select **Shift 1**
 - Inspection Type: Select **Meat**
 - Line Name: Select **Slaughter Line 1** in drop-down list
 - Class: Select **Cattle**
 - Slaughter System: Select **Chain Driven Rail**
 - Inspection System: Select **Using Viscera Table with Tongue-In**
 - Subclass: Check **Steer**
 - Line Speed: Select **87 to 143 heads/hour**
 - Subclass: Check **Heifer**

Line Speed: Select **87 to 143 heads/hour**
84. Click the **Save** button

Profile Questionnaire

PHIS profile questionnaires are added to the establishment profile by FSIS headquarter staffs. IPP are notified of the questionnaire through the issuance of an FSIS Notice and are to review this section monthly as part of the **Update Establishment Profile** task. The **Profile Questionnaire** page contains periodic questionnaires with “begin” and “end” dates. The questions may seek information regarding the establishments’ HACCP system reassessments, pathogen control programs, chemical interventions, microbiological testing programs or other information regarding establishment practices that can be used to inform Agency activities. When a profile questionnaire appears in PHIS, IPP are to complete and submit the questionnaire during their next scheduled **Update Establishment Profile** task unless otherwise instructed. If IPP have already completed the monthly **Update Establishment Profile** task before receiving the profile questionnaire, they are to create a directed task in order to complete the profile questionnaire.

After clicking on the **Profile Questionnaire** page, IPP are to locate the applicable questionnaire in the box and click the “open” icon. IPP may view or print the questions before completing the questionnaire. To view or print the questions, IPP are to click the “open” arrow to access the questionnaire, select “reports”, then select “Full Questionnaire Report” to generate a PDF file for viewing or printing. Next, IPP are to select “Go Back to Questionnaire” and select “Save and Close.” After completing all questions in the questionnaire, IPP are to submit the profile questionnaire before marking the **Update Establishment Profile** task as completed.

IPP are not to issue noncompliance records (NRs) or take enforcement actions based on the responses to questionnaires. If IPP determine that there is noncompliance with regulatory requirements while reviewing establishment information for completing the questionnaire, they are to initiate a directed instance of the relevant verification task, record their findings, and document the noncompliance as a part of the directed task.

85. Click the **Profile Questionnaire** in the left navigation menu

Training

IPP can view the type of training required to perform inspection verification at a particular establishment.

86. Click **Training** in the left navigation menu

3. Use Attachment 3 - RTE Product Flowchart and Attachment 1 and 2 from FSIS Directive 5300.1 to answer the 3 questions for the products below.
 - a. Beef jerky, heated and dried in smokehouse
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?
 - b. Smoked pork sausage, fully cooked, refrigerated, post-lethality exposed
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?
 - c. Marinated (no vacuum), raw boneless chicken breasts
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?
 - d. Pepperoni, fermented and dried, post-lethality exposed
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?
 - e. Frozen dinner with Steak tips (fully cooked) and Portobello mushrooms (not cooked), labeled "Cook Thoroughly"
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?
 - f. Beef chili, canned, retorted
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?
 - g. Beef steaks purchased from another establishment, raw, mechanically tenderized
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?

- h. Mechanically separated turkey, raw
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?

- i. Beef, porterhouse steak, raw, not tenderized
 - i. What is the HACCP Processing Category?
 - ii. What is the Finished Product Category?
 - iii. What is the Product Group?

4. Why is the intended use critical information for some products?

5. Use the following information from Open Beef Company to update the establishment profile in PHIS. Use the general information on the next page regarding Open Beef to accomplish the following:

- a. Login as Robert Allen (your #)
- b. Review and Update the slaughter operations information in PHIS.
- c. Update the production volumes for the products and the HACCP categories in PHIS.

Open Beef - General Information

Open Beef is a one shift (8 hours) combination slaughter processing establishment in Petaluma, CA. The establishment slaughters 500 steers or heifers per day that are less than 30 months of age. It produces carcasses halves and quarters, primal and sub-primal parts, edible offal, beef trimmings, head meat, cheek meat and advanced meat recovery (AMR) product. Open Beef applies lactic acid as an antimicrobial spray to carcasses at the final wash step. The beef trimmings, head meat, cheek meat, and AMR product are intended for use in ground beef products at other establishments after being sold. The intended use of carcasses, including carcass halves or quarters, the primals and subprimals, and the edible offal produced at Open Beef is for intact products at other official establishments. Open Beef identifies controls to ensure that the products are used as intended. It has a written Sanitation SOP and one HACCP plan covering slaughter, fabrication (cut-up), boning, and AMR product. An 8-hour shift's production is considered a lot.

New Information

The establishment slaughters approximately 63 head an hour. After stunning, the carcasses are hoisted on a chain driven rail. The head and tongue are removed for head inspection. The heads go through a wash/antimicrobial rinse cabinet before boning. The viscera are removed onto a moving line for viscera inspection. The edible offal is sprayed with lactic acid before chilling.

Shipping records and receipts indicate that Open Beef has sold the following amounts of beef products for 25 production days last month.

- 4,240,600 lb. of carcasses halves and quarters
- 430,000 of beef trimmings
- 210,000 lb. of edible offal
- 5,260,420 lb. of primals and sub-primals
- 380,000 lb. of head meat
- 420,000 lb. of cheek meat
- 82,480 lb. of meat from advanced meat recovery (AMR)/bone separation machinery.

ATTACHMENT 1: HACCP PROCESSING CATEGORIES

A. **Slaughter:** This HACCP processing category applies to establishments that slaughter livestock or poultry. Slaughter establishments typically produce raw intact finished products.

Note: If the establishment produces raw intact products that could be listed under either the Slaughter or Raw Product-Intact category, IPP are to list the product under only one of the categories to prevent duplicate entries. IPP are to use the Raw Product-Intact category for these products whenever possible.

B. **Raw Product—Intact:** This HACCP processing category applies to establishments that further process directly following the slaughter processing steps or after receiving raw products. The processing steps at the establishment include the meat fabrication or poultry cut-up. If the establishment also slaughters, these steps are typically applied after the chilling requirements (9 CFR 381.66) are met for poultry carcasses, or after meat carcasses are cooled. Establishments in the Raw Product-Intact HACCP processing category may produce finished products such as raw poultry (in whole or in part) or raw meat products such as primal or subprimals. Beef manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts) is also an example of intact raw beef product. Product that has been marinated intact or non-vacuum tumbled is considered raw intact product. FSIS considers raw products to be intact unless they have undergone any of the processes associated with the non-intact HACCP processing category.

C. **Raw Product—Non-intact:** This HACCP processing category applies to establishments that further process by using processing steps such as grinding, comminuting, injecting product with solutions or other liquids, marinating non-intact, vacuum tumbling, or mechanical tenderization by needling, cubing, pounding devices or other means of creating non-intact product. Examples of finished products in this category include raw products reconstructed into formed entrees, comminuted products and advanced meat recovery product. If the establishment produces bench trim or pieces of meat produced from non-intact meat, then the bench trim or pieces are also considered non-intact.

D. **Thermally Processed-Commercially Sterile:** This HACCP processing category applies to establishments that use a thermal processing step. Thermally processed, commercially sterile finished products are products in cans or flexible containers such as pouches, or semi-rigid, as in lunch bowls. Thermally processed, commercially sterile products are addressed in Subpart G, 318.300 – 311 for meat food products, and Subpart X, 381.300 to 311, for poultry products.

E. Not Heat Treated – Shelf Stable: This HACCP processing category applies to establishments that further process by curing, drying, or fermenting processing step as the sole means by which product achieves food safety. Establishments in this HACCP processing category may apply a low-level heat treatment as long as the heat treatment is not used as means to achieve food safety. The finished products produced under this HACCP processing category are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes.

F. Heat Treated-Shelf Stable: This HACCP processing category applies to establishments that further process by using a heat treatment processing step to achieve food safety in combination with curing, drying, or fermenting processing step to achieve food safety. The finished products produced under this HACCP processing category are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes. If the establishment produces product using the processing steps applicable under this processing category and the product is not shelf stable, the establishment is producing product under the HACCP processing category, Fully Cooked – Not Shelf Stable.

G. Fully Cooked-Not Shelf Stable: This HACCP processing category applies to establishments that further process products by using primarily a full lethality heat process step (i.e. cooking) to achieve food safety. The finished products that establishments produce under this HACCP processing category are not shelf stable. FSIS requires the products to be frozen or refrigerated for food safety purposes. These products also meet the definition of Ready to Eat (RTE) as defined in 9 CFR 430.1.

H. Heat Treated but Not Fully Cooked – Not Shelf Stable: This HACCP processing category applies to an establishment that further processes products that are (1) not ready-to-eat products (NRTE) or (2) raw otherwise processed products that are refrigerated or frozen throughout the product's shelf life. Meat and poultry products are produced using a heat process that meet one of the following criteria:

- The heat-processing step is not adequate to achieve food safety. Products may be partially cooked or heated to set batter on a raw product.
- The heat processing step applied to meat or poultry component was adequate to achieve food safety, however product is further processed, assembled, or packaged so that cooked meat or poultry products contacts non-ready to-eat product ingredients. In this case, the final product is in a form that is not edible without additional preparing to achieve food safety. An example of this product is potpie product that contains cooked chicken and raw dough.

I. Product with Secondary Inhibitors-Not Shelf Stable: This HACCP processing category applies to establishments that further process by using a curing processing step or a processing step using other ingredients that inhibit bacterial growth. These products are generally refrigerated or frozen throughout the product's shelf life. This would be products that received treatment or whose formulations contain ingredients that change the product characteristics (e.g., lower water activity, change the pH, etc.) to the point that product characteristics are altered, promoting microbial inhibiting qualities associated with the treatments or additives. An example of this type of product would be dry cured ham. Depending on the process and ingredients, these products may or may not meet the definition of RTE as defined in 9 CFR 430.1.

ATTACHMENT 2: PRODUCTS

PHIS Product Category List (Meat & Poultry Establishments)		
HACCP Processing Categories	Finished Product Category	Production Volume Categories (by Product Groups)
Slaughter Raw Product - Intact	Raw intact beef	<ul style="list-style-type: none"> - Carcass (including carcass halves or quarters) - Primals and Subprimals¹ - Beef Manufacturing Trimmings - Cheek Meat - Cuts² (including Bone-in and Boneless Meats) - Head Meat - Weasand Meat - Heart Meat - Edible Offal³ - Bench Trim (trimmings from animals not slaughter at the est.) - Trim produced by sister processing establishment - Other Intact⁴
	Raw intact pork	<ul style="list-style-type: none"> - Carcass (including carcass halves or quarters) - Primals and Subprimals¹ - Cheek Meat - Cuts² (including Bone-In and Boneless Meats) - Head Meat - Edible Offal³ - Trimmings from Intact Pork - Other Intact⁴
	Raw intact meat – other (sheep, goat)	<ul style="list-style-type: none"> - Carcass (including carcass halves or quarters) - Primals and Subprimals¹ - Cuts² (including Bone-In and Boneless Meats) - Edible Offal³ - Other Intact^{4,5}
	Raw intact chicken ⁵	<ul style="list-style-type: none"> - Whole bird - Poultry Parts (legs, breasts, wings ONLY)⁶ - Other Poultry Parts (including feet, necks, and giblets) - Raw Stuffed Poultry Products - Other Intact Poultry Products
	Raw intact turkey ⁵	<ul style="list-style-type: none"> - Whole bird - Poultry Parts (legs, breasts, wings ONLY) - Other Poultry Parts (including feet, neck, and giblets) - Raw Stuffed Poultry Products - Other Intact Poultry Products
	Raw intact poultry – other (ducks, geese, squab)	<ul style="list-style-type: none"> - Whole bird - Poultry parts (including necks/feet & giblets) - Boneless and/or Skinless Parts

<p>Slaughter</p> <p>Raw Product – Non-Intact</p>	<p>Raw ground, comminuted, or otherwise non-intact beef</p>	<ul style="list-style-type: none"> - Ground Beef Product from in-house source materials - Hamburger/Beef Patty Product - Advanced Meat Recovery (AMR) - Formed Steaks - Ammoniated Beef - Beef trimming from non-intact beef - Bench Trim (derived from non-intact beef not slaughtered at the establishment) - Low Temperature Rendered Product- Finely Textured Beef (FTB) - Low Temperature Rendered Product- Partially Defatted Beef Fatty Tissue (PDBFT) - Low Temperature Rendered Product-Partially Defatted Chopped Beef (PDCB) - Non-Intact Cuts² (including Bone-In and Boneless Meats) - Other Non-Intact Product (fresh sausage, meatloaf, gyros, meatballs, etc.) - Ground Beef Product from purchased source materials - Ground Beef combined with other species from in-house source materials - Ground Beef combined with other species from purchased source materials - Fabricated Steaks and other Non-Intact Subprimals - Hamburger/Beef Patty combined with other species from in-house source materials - Hamburger/Beef Patty combined with other species from purchased source materials - Mechanically tenderized products from in- house source materials - Mechanically tenderized products from purchased source materials - Portioned raw ground beef product - Raw ground beef product produced from source materials accompanied by a COA, no bench trim - Raw ground beef product from non-intact source materials, no bench trim
	<p>Raw ground, comminuted, or otherwise non-intact pork</p>	<ul style="list-style-type: none"> - Cuts² (Tenderized, Injected, Pumped, or Vacuum-Tumbled- including Bone-In and Boneless) - Primals and Subprimals¹ (Tenderized, Injected, Pumped, or Vacuum-Tumbled) - Trimmings from non-intact pork - Ground Product - Advanced Meat Recovery (AMR) - Mechanically Separated (Species) - Sausage, Patties, or other formed products - Other Comminuted - Other Non-Intact
	<p>Raw ground, comminuted, or otherwise non-intact meat – other (sheep, goat, combination species)</p>	<ul style="list-style-type: none"> - Ground Product - Advanced Meat Recovery (AMR) - Other Non-Intact - Mechanically Separated (Species)
	<p>Raw ground, comminuted, or otherwise non-intact chicken ⁷</p>	<ul style="list-style-type: none"> - Ground Product - Mechanically Separated (Species) - Other Comminuted - Injected, Tenderized, or Vacuum Tumbled Parts (legs, breasts, wings ONLY) - Injected, Tenderized, or Vacuum tumbled Other Parts (including feet, neck, and giblets) - Injected, Tenderized, or Vacuum Tumbled Whole Bird

		<ul style="list-style-type: none"> - Raw Stuffed Poultry Products - Other Non-Intact but not Comminuted Poultry Products
	Raw ground, comminuted, or otherwise non-intact turkey 7	<ul style="list-style-type: none"> - Ground Product - Mechanically Separated (Species) 8 - Other Comminuted - Injected, Tenderized, or Vacuum Tumbled Parts (legs, breasts, wings ONLY) - Injected, Tenderized, or Vacuum Tumbled Other Parts (including feet, neck, and giblets) - Injected, Tenderized, or Vacuum Tumbled Whole Bird - Raw Stuffed Poultry Products - Other Non-Intact but not Comminuted Poultry Products
	Raw ground, comminuted, or otherwise non-intact poultry – other (ducks, geese, squab)	<ul style="list-style-type: none"> - Ground Product - Mechanically Separated (Species) - Other Non-Intact
Not Heat Treated – Shelf Stable	Raw (NRTE) otherwise processed meat	<ul style="list-style-type: none"> - Not-Stuffed - NRTE Product with RTE Component¹² - Stuffed
	Raw (NRTE) otherwise processed poultry	<ul style="list-style-type: none"> - Not-Stuffed - NRTE Product with RTE Component¹² - Stuffed
Heat Treated – Shelf Stable	RTE ⁹ acidified/fermented meat (without cooking)	<ul style="list-style-type: none"> - RTE fermented meat (sliced and not-sliced) according to Lm Alternative¹¹ – post-lethality exposed - RTE fermented meat (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ acidified/fermented poultry (without cooking)	<ul style="list-style-type: none"> - RTE fermented poultry (sliced and not-sliced) according to Lm Alternative¹¹ – post-lethality exposed - RTE fermented poultry (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ dried meat	<ul style="list-style-type: none"> - RTE dried meat (sliced and not-sliced) according to Lm Alternative¹¹ – post-lethality exposed - RTE dried meat (sliced and not-sliced) not post-lethality exposed - Lard/oils¹³
	RTE ⁹ dried poultry	<ul style="list-style-type: none"> - RTE dried poultry (sliced and not-sliced) according to Lm Alternative¹¹ – post-lethality exposed - RTE dried poultry (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ salt-cured meat	<ul style="list-style-type: none"> - RTE salt cured meat (sliced and not-sliced) according to Lm Alternative¹¹ – post-lethality exposed - RTE salt cured meat (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ salt-cured poultry	<ul style="list-style-type: none"> - RTE salt cured poultry (sliced and not-sliced) according to Lm Alternative¹¹ – post-lethality exposed - RTE salt cured poultry (sliced and not-sliced) not post-lethality exposed

Heat Treated but Not Fully Cooked – Not Shelf Stable	Raw (NRTE) otherwise processed meat	<ul style="list-style-type: none"> - Not-Stuffed - NRTE Product with RTE Component¹² - Stuffed
	Raw (NRTE) otherwise processed poultry	<ul style="list-style-type: none"> - Not-Stuffed - NRTE Product with RTE Component¹² - NRTE Stuffed Chicken Products that appear RTE¹⁰
Product with Secondary Inhibitors – Not Shelf Stable	RTE ⁹ salt-cured meat (PLE)	<ul style="list-style-type: none"> - RTE salt cured meat (sliced and not-sliced) according to Lm Alternative¹¹ – post-lethality exposed - RTE salt cured meat (sliced and not-sliced) not post-lethality exposed
	RTE ⁹ salt-cured poultry	<ul style="list-style-type: none"> - RTE salt cured poultry (sliced and not-sliced) according to Lm Alternative¹¹ –post-lethality exposed - RTE salt cured poultry (sliced and not-sliced) not post-lethality exposed
	Raw (NRTE) otherwise processed meat	<ul style="list-style-type: none"> - Not-Stuffed - NRTE Product with RTE Component¹² - Stuffed
	Raw (NRTE) otherwise processed poultry	<ul style="list-style-type: none"> - Not-Stuffed - NRTE Product with RTE Component¹² - Stuffed
Fully Cooked – Not Shelf Stable	RTE ⁹ fully-cooked meat (PLE)	<ul style="list-style-type: none"> - Hot Dog Products according to Lm Alternative⁷ - Salad/Spread/Pate according to Lm Alternative¹¹ - Meat + Nonmeat Multicomponent according to Lm Alternative¹¹ - Sausage Products - Diced/Shredded according to Lm Alternative¹¹ - Patties/Nuggets according to Lm Alternative¹¹ - Other Fully cooked sliced product according to Lm Alternative¹¹ - Other Fully cooked not sliced product according to Lm Alternative¹¹ - Poultry Parts or Meat Cuts according to Lm Alternative¹¹
	RTE ⁹ fully- cooked poultry (PLE)	<ul style="list-style-type: none"> - Hot Dog Products according to Lm Alternative⁷ - Salad/Spread/Pate according to Lm Alternative¹¹ - Poultry + Non-poultry Components according to Lm Alternative¹¹ - Sausage Products - Diced/Shredded according to Lm Alternative¹¹ - Patties/Nuggets according to Lm Alternative¹¹ - Other Fully cooked sliced product according to Lm Alternative¹¹ - Other Fully cooked not sliced product according to Lm Alternative¹¹ - Poultry Parts or Poultry Cuts according to Lm Alternative¹¹
	RTE ⁹ fully-cooked meat without subsequent exposure to the environment	<ul style="list-style-type: none"> - Hot Dog Products not post-lethality exposed - Salad/Spread/Pate not post-lethality exposed - Meat + Nonmeat Components not post-lethality exposed - Sausage Products not post-lethality exposed - Diced/Shredded not post-lethality exposed - Patties/Nuggets not post-lethality exposed - Other Fully cooked sliced product not post-lethality exposed - Other Fully cooked not sliced product not post-lethality exposed - Poultry Parts or Meat Cuts

	<p>RTE² fully-cooked poultry without subsequent exposure to the environment</p>	<ul style="list-style-type: none"> - Hot Dog Products not post-lethality exposed - Salad/Spread/Pate not post-lethality exposed - Poultry + Non-poultry Components - Poultry Parts or Poultry Cuts - Sausage Products not post-lethality exposed - Diced/Shredded not post-lethality exposed - Patties/Nuggets not post-lethality exposed - Other Fully cooked sliced product not post-lethality exposed - Other Fully cooked not sliced product not post-lethality exposed
<p>Thermally Processed - Commercially Sterile</p>	<p>Thermally processed, commercially sterile</p>	<ul style="list-style-type: none"> - Thermally Processed Products (includes products in Cans/Pails, Flexible Pouches, Trays, Jars and Bag-n-Box)

¹ 9 CFR 316.9(b) defines primal parts as wholesale cuts of carcasses customarily distributed to retailers. Primals are further cut down into subprimals.

² A “cut is a consumer size portion from primals, portion cuts, or tray ready products.

³ Edible Offal includes tails, feet, etc.

⁴Other Intact includes fat.

⁵ The product groups “Poultry Parts (including necks/feet and giblets”, “Further processed poultry parts (Boneless and/or Skinless Parts)” and “Boneless and/or Skinless Parts” are obsolete and are not to be used.

⁶ As defined in 9 CFR 381.170(b), Standards for kinds and classes and for cuts of raw poultry.

⁷ The Product Group “Other non-Intact” is obsolete and is not to be used.

⁸ As defined in 9 CFR 381.173.

⁹ RTE is defined in 9 CFR 430.

¹⁰ NRTE stuffed chicken products that appear RTE contain raw, comminuted chicken breast meat or whole chicken breast meat, but the finished product is heat-treated only to set the batter or breading and impart an RTE appearance. The product typically is stuffed with ingredients such as a raw vegetable, butter, cheese or meat such as ham.

¹¹*Listeria monocytogenes* (Lm) alternatives are Alt 1; Alt 2, Choice 1; Alt 2, Choice 2; Lm Alt 3

¹² Product that contains both a cooked meat or poultry RTE component and a Not-ready-to-eat component, such as a Pot Pie with an RTE filling and raw dough.

¹³Oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats.

Note: By definition, RTE cured, dried or fermented product meet at least Alt 2 Lm requirements.

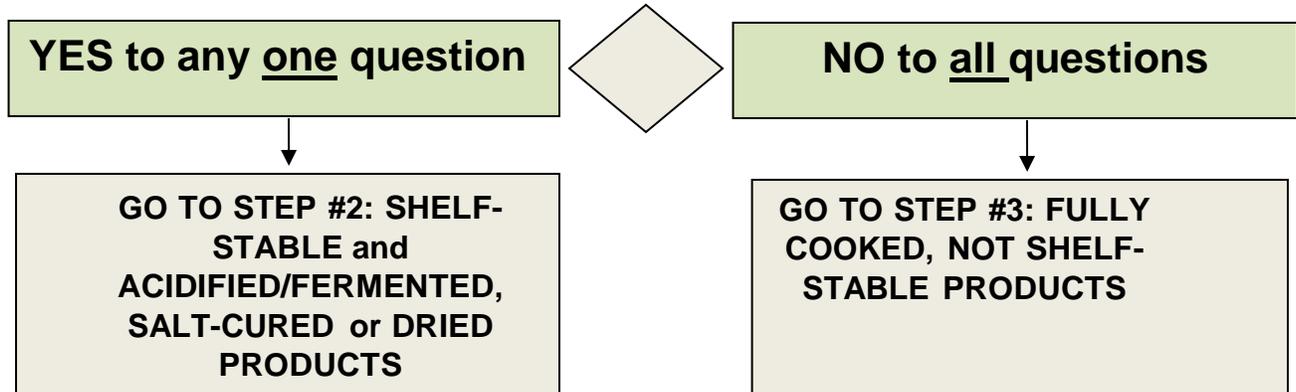
Note: Lm Alternative questions and log reductions from FSIS From 10,240-1 apply to each RTE product group

Attachment 3: RTE PRODUCT GROUP FLOWCHART

NOTE: The Flowchart has been designed to select the single best representative product category/group in which a given product might be classified, based on the overall microbial lethality, preservation and production method, while being aware that mixed, multiple production steps can occur. (For example, many fermented products may include a cooking/heating step after fermentation).

STEP 1: SHELF- STABLE vs. NOT SHELF STABLE

- 1) Is the RTE meat or poultry product produced under a HACCP plan for “Not Heat Treated—Shelf Stable” product, “Heat Treated—Shelf Stable” product, or “Thermally Processed—Commercially Sterile” product?
- 2) Does the RTE product's label exclude a handling statement, for example, the label does not state "keep refrigerated" or "keep frozen"?
- 3) Does the RTE product's label include a “Refrigerate After Opening” statement?
- 4) For non-fermented RTE products, does the product achieve a water activity of 0.85 or less and have measures (e.g., short pull dates, low pH, antimicrobials, coatings, gas packed or vacuum in an oxygen impervious package, or any combination of these measures) to prevent mold growth?
- 5) For non-fermented RTE products, does the product achieve a water activity from 0.92 to 0.85 and either gas packed or vacuum packed in an oxygen impervious package and labeled “Refrigerate After Opening”?
- 6) Does the RTE dry sausage achieve a MPR of $\leq 1.9:1$?
- 7) Does the RTE semi-dry sausage achieve a MPR of 3.1:1 or less and a pH of 5.0 or less?
- 8) Does the RTE semi-dry sausage achieve a pH of ≤ 4.5 (or 4.6 combined with an aw of < 0.91), a brine concentration of $\geq 5.0\%$ and is in an intact form (or sliced and vacuum packaged), cured with nitrite or nitrate, and smoked with wood?
- 9) For acidified RTE products (e.g., pickled pig feet) that are cold filled, does the establishment have documentation (e.g., challenge study) that validates that the product is shelf stable and prevents the growth of microorganisms (e.g., yeasts, molds, Lactobacilli, or Clostridium botulinum) at room temperature?
- 10) For acidified RTE products (e.g., pickled pig feet) that are hot filled, does the finished product achieve a pH of 4.6 or lower within 24 hours?
11. Does the RTE meat or poultry product achieve commercial sterility and fall under the canning regulations (9 CFR 318.300-311 or 9 CFR 381.300-311)?



STEP 2: SHELF- STABLE AND ACIDIFIED/FERMENTED, SALT CURED OR DRIED PRODUCTS PRODUCTS

Step #2A: 1) Does the RTE meat or poultry product achieve commercial sterility and fall under the canning regulations (9 CFR 318.300-311 or 9 CFR 381.300-311)?

NO

YES = THERMALLY PROCESSED COMMERCIALY STERILE

Step #2B: 1) Is a starter culture added to the product during formulation?
2) Is a chemical acidulant added to product during formulation in order to decrease the product pH?
3) Is the establishment following the degree hours concept (pH reaches 5.3 within a certain timeframe based on the fermentation temperature) to inhibit the growth of Staphylococcus aureus and prevent its enterotoxin production?

YES to ANY ONE or more QUESTIONS = ACIDIFIED/FERMENTED

NO TO ALL QUESTIONS

GO TO STEP #2C: CURED or DRIED

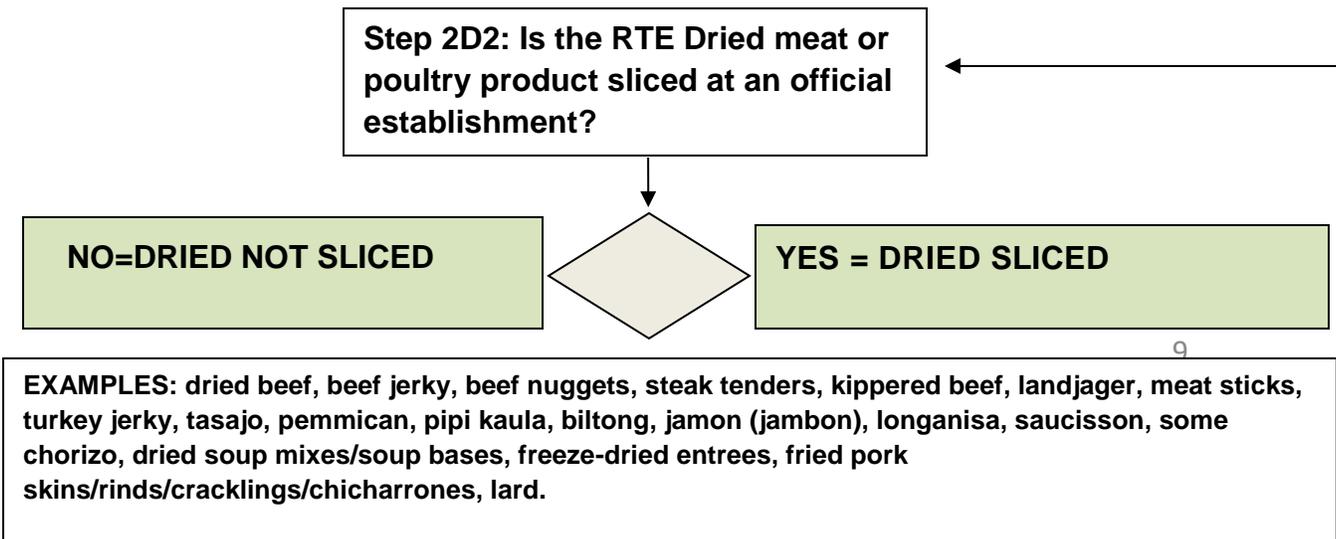
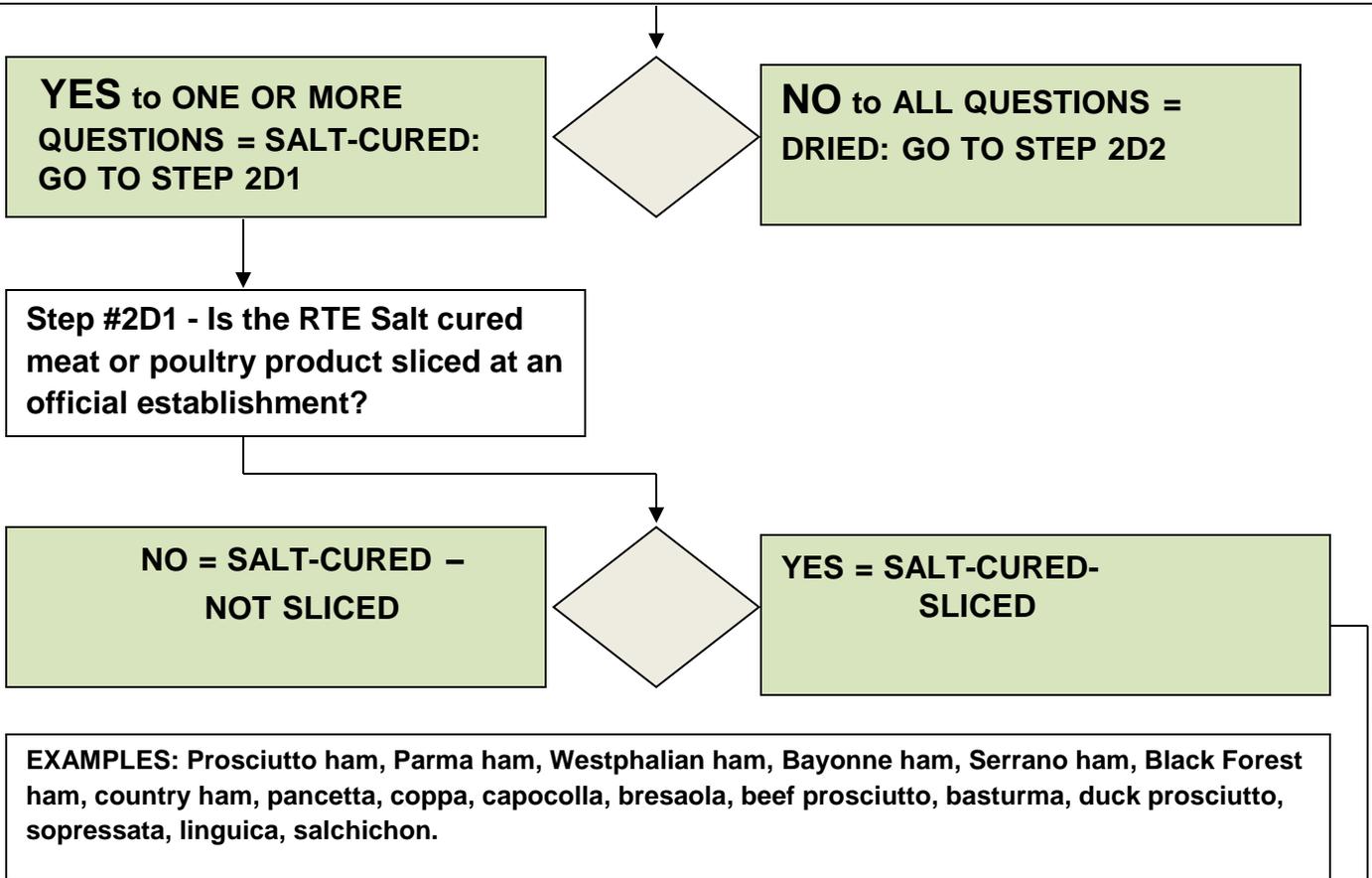
Step #2B1: Is the RTE Acidified/ Fermented meat or poultry product sliced at an official establishment?

NO = ACIDIFIED/ FERMENTED – NOT SLICED

YES = ACIDIFIED/ FERMENTED – SLICED

Examples – Genoa Salami, hard salami, pepperoni, turkey pepperoni, summer sausage, Abruzzese, Lebanon bologna, thuringer, mordatella, mettwurst, chorizo, chourico, sucuk (soujuk), pickled pigs* , feet, bologna in vinegar*. (*If yes, to step 1, question 9)

Step # 2C: 1) Is the meat or poultry product dry rubbed (dry curing) with a cure mixture (salt and nitrate and/or nitrite) and then undergoes a curing/equalization step and a drying step?
2) Is the meat or poultry product immersed in a concentrated brine solution (pickle curing) and then undergoes a curing/equalization step and a drying step?
3) Is the meat or poultry product injected with a brine solution (injection curing) and then undergoes a curing/equalization step and a drying step?
4) Does the finished meat or poultry product achieve an internal salt content of at least 4 percent when sodium or potassium nitrate and/or sodium or potassium nitrite is used with the application of salt (NaCl)?
5) Does the finished meat or poultry product achieve a brine concentration of at least 10 percent when no sodium or potassium nitrate and/or sodium or potassium nitrite is used with the application of salt (NaCl)?



STEP 3: FULLY COOKED, NOT SHELF-STABLE (NSS) PRODUCTS

Page 1 of 3

3A. Does the product consist in whole or in part of a cooked sausage (hotdog) product as defined in 9 CFR 319.180, 319.181, or 9 CFR 430.1?

Yes = FULLY COOKED HOT DOG PRODUCT

NO

EXAMPLES: Hot dogs, frankfurters/franks, cheese dogs, corn dogs, knockwurst (knackwurst), wieners.

3B. Is the product a cooked sausage or sausage-like product, or cooked linked sausage or sausage-like product, other than a 9 CFR 319.180/319.181/430.1 product (i.e., other than a hot dog)?

Yes = FULLY COOKED SAUSAGE PRODUCT

NO

EXAMPLES: Andouille, beer sausages/beerwurst, blood sausage, blood pudding, pork blood, bratwurst, bockwurst, braunschweiger, breakfast sausages (fully cooked), chicken/turkey sausage (fully cooked), German sausage, polish sausage, Krakow, kielbasa, cervelat, boudin, cha lua (gio lua), other ethnic sausages. (For sausage patties, see FC3E. For sausage products that are sliced, crumbled, chopped, etc., see FC3F).

3C. Is this a salad product with meat or poultry (e.g., a vegetable or pasta mix with dressing or a mayonnaise or oil-based mix), or a meat or poultry spread or pate-type product?

Yes = FULLY COOKED SALAD/ SPREAD/PATE

EXAMPLES: antipasto salads, Asian style salads, Caesar salads, chef salads, Cobb salads, pasta salads, salad spreads ALL with meat/poultry added; chicken salad, chopped liver, ham salad, liver, mush, mousse, pate, sandwich spreads, turkey salad.

GO TO NEXT PAGE (FC 3D: FULLY COOKED MEAT + NONMEAT MULTICOMPONENT PRODUCT)

STEP 3: FULLY COOKED NSS Page 2 of 3

3D. Is the product a meat or poultry filling enclosed in dough or pastry, or is the product any combination of meat and non-meat items other than salad/spread/pate?

YES = FULLY COOKED MEAT + NONMEAT

NO

EXAMPLES: burritos, egg rolls, empanadas, enchiladas, fajitas, meat/bean combinations, meat/egg/ cheese combinations, meat/pasta combinations (lasagna, ravioli, etc.), meat/poultry pizza products, meat/poultry-containing sauces, meat/poultry-containing soups (fully cooked, not shelf-stable), pasties, pinwheels, pot pies, pot stickers (Chinese dumplings; gyoza), piroshki, shumai, chili, quesadillas, samosas, tacos, tamales, teriyaki bowls, turnovers, gyros, wraps.

3E. Is the product a comminuted product other than sausage/sausage link (e.g., patty or meatball) or a breaded or unbreaded molded product (e.g., nugget)?

YES = FULLY COOKED PATTIES/NUGGETS

NO

EXAMPLES: Nuggets/fingers/tenders, popcorn chicken, meatballs, meat loaf, fully cooked hamburger/meat/poultry patties (including sausage patties), pork roll, and scrapple.

3F. Is the product a comminuted or whole muscle product that has been diced or shredded or cut or crumbled or chopped or shaved or sliced for non- deli purposes (i.e., not typically intended for sandwich purposes as per 9 CFR 430.1)?

YES = FULLY COOKED DICED SHREDDED

EXAMPLES: Bacon/Canadian bacon slices (if fully cooked), barbequed diced/shredded/sliced meat/ poultry products, carne asada, chopped ham, diced meat/diced ham, diced poultry, ground ham, gyro slices, jerk chicken, meat/poultry crumbles, meat/poultry strips, meat/poultry taco filling, pulled pork, kahlua shredded pork, other shredded meat/poultry products, sliced pork roll (fully cooked), fully cooked sliced meat/poultry for non-deli purposes, e.g., sliced sausage for use as pizza topping.

GO TO NEXT PAGE (ALL OTHER FULLY COOKED)

STEP 3: FULLY COOKED NSS Page 3 of 3

3G1. Is the product an RTE fully cooked meat or poultry product that is sliced in official establishment and typically is (or is intended to be) assembled in a sandwich for consumption (i.e., deli products as per 9CFR 430.1)? OR 3G2. Is the product an RTE fully cooked meat or poultry product that is sliced in official establishment and is OTHER THAN a hotdog, sausage, salad/spread/pate, nugget/patty, diced/shredded or multicomponent product?

**YES TO EITHER =
OTHER FULLY
COOKED - SLICED**

NO

3H1. Is the product an RTE fully cooked meat or poultry product that is NOT sliced in official establishment but is intended to be assembled in a sandwich for consumption by the end user (i.e., deli products as per 9CFR 430.1)? OR
3H2. Is the product an RTE fully cooked meat or poultry product that is NOT sliced in official establishment and is OTHER THAN a hotdog, sausage, salad/spread/pate, nugget/patty, diced/shredded or multicomponent product?

**YES TO EITHER = OTHER FULLY
COOKED- NOT SLICED**

EXAMPLES (3G1 [SLICED] or 3H1 [UNSLICED]): Ham (if cooked), bologna (exception is Lebanon bologna), chicken roll, turkey breast, olive loaf, corned beef, pastrami, roast beef, brisket, pickle loaf, pimento loaf (pimiento), pepper loaf, liverwurst, tongue, head cheese (AKA souse or sulze), capocola (capicola) labeled as cooked, olive loaf, luncheon loaf, jellied beef loaf, Dutch loaf.

EXAMPLES (3G2 [SLICED] or 3H2 [UNSLICED]): Baked products, barbecued intact products, battered or breaded products (if not a molded nugget-type product), broiled products, chicken or turkey breasts (for reheating as opposed to slicing for deli purposes), fried products, grilled products, tasso, meat ribs, legs, pork parts and bacon (all fully cooked), pot roasts, legs/drumsticks (fully cooked), wings, roasted products, smoked fully cooked products (high-temperature smoked products), whole chickens or turkeys (fully cooked), single-component RTE soup broths, pickled pigs feet*, bologna in vinegar*. (* = If No to Step 1, question 9 or question 10).

Note: Lard is fully cooked but shelf stable. Based on a combination of HACCP for Heat Treated Shelf Stable Products and obvious low water activity this product has been classified under "Dried".

Note: The term "deli" applies to any RTE product class/group in which the product is intended to be used in a sandwich as per 9 CFR 430.1. However, "deli" is not a formal part of the existing product classification system.