# UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

## **FSIS NOTICE**

15-24

5/1/24

## SALMONELLA AS AN ADULTERANT IN NOT READY-TO-EAT BREADED STUFFED CHICKEN PRODUCTS

#### I. PURPOSE

- A. This notice informs inspection program personnel (IPP) that, On May 1, 2024, FSIS published the final determination, *Salmonella in Not Ready-To-Eat Breaded Stuffed Chicken Products* (89 FR 35033), which states that not ready-to-eat (NRTE) breaded stuffed chicken products that contain *Salmonella* at levels of 1 Colony Forming Unit per gram (hereinafter, "1 CFU/g") or higher are adulterated within the meaning of the Poultry Products Inspection Act (PPIA). The determination is not effective until May 1, 2025.
- B. This notice provides instructions to IPP at all establishments that produce NRTE breaded stuffed chicken products to update the Public Health Information System (PHIS) profile by May 31, 2024. This notice also instructs supervisory personnel to verify that the establishment's PHIS profile information is complete and accurate by May 31, 2024.

#### II. BACKGROUND

- A. From 1998 to 2021, public health officials investigated 14 salmonellosis outbreaks attributed to consumption of NRTE breaded stuffed chicken products that may appear ready-to-eat (RTE) to consumers. Five of the outbreaks led to a recall of FSIS-regulated products, and in some cases, a public health alert. In response to these outbreaks, manufacturers of these products took steps to improve their labeling to ensure that the consumer is aware that the product is raw, and that these products should not be microwaved because of the increased likelihood that the product will be undercooked. In 2015, in response to an additional outbreak, industry also took steps to revalidate the cooking instructions for these products.
- B. From April through August 2021, state public health officials, the Centers for Disease Control and Prevention (CDC), and FSIS investigated a multistate outbreak of *Salmonella* illnesses linked to NRTE breaded stuffed chicken products. The outbreak included 36 cases from 11 states. The establishment recalled 59,251 pounds of frozen product (RC-028-2021).
- C. Specifically, the final determination:
  - 1. Concludes that NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 CFU/g or higher are adulterated within the meaning of the PPIA;

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- 2. Defines "NRTE breaded stuffed chicken products" as those NRTE products that are both breaded and stuffed, contain raw chicken components (e.g., comminuted chicken breast meat, trim, skin, or whole chicken breast meat), and where the finished product is heat-treated only to set the batter or breading on the exterior of the product;
- 3. Notifies industry that FSIS intends to develop and implement routine sampling and verification testing for *Salmonella* on the raw chicken source materials used to produce NRTE breaded stuffed chicken and that such components and associated lots that test positive for 1 CFU/g or greater of *Salmonella* must be diverted for other uses or destroyed; and
- 4. Requires all establishments that produce NRTE breaded stuffed chicken products to reassess and, if needed, revalidate their HACCP plans by the effective date of the final determination.
- E. FSIS has added a new feature to PHIS to enable IPP to identify those establishments that produce NRTE breaded stuffed chicken products. The PHIS update also improves the specificity for IPP to select the PHIS product fields that best align with NRTE breaded stuffed chicken products and how establishments classify them in their food safety system.
- F. The PHIS update improves the accuracy of identifying establishment production and will be used for policy development, which will include FSIS verification sampling.

#### III. NRTE BREADED STUFFED CHICKEN PRODUCTS

- A. IPP are to be aware that FSIS' final determination only pertains to those products that meet the definition of NRTE breaded stuffed chicken products, i.e., NRTE products that are both breaded and stuffed, contain raw chicken components, and are heat-treated only to set the batter or breading on the exterior of the product.
- B. IPP are to be aware that there are numerous examples of NRTE breaded stuffed chicken products (such as those in Figure 1) that include—but are not limited to—breaded, pre-browned chicken cordon bleu, chicken Kiev, and chicken stuffed with broccoli and cheese.







C. IPP are to be aware that NRTE breaded stuffed chicken products **DO NOT** include stuffed products that are not breaded (e.g., turducken, whole stuffed chickens, or chicken thighs stuffed with stuffing and almonds). NRTE breaded stuffed chicken products also **DO NOT** include breaded and par-fried products that are not stuffed (e.g., chicken nuggets, chicken tenders). The product typically is stuffed with ingredients such as a raw vegetable, butter, cheese, or meat, such as ham.

D. IPP are to be aware that NRTE breaded stuffed chicken products **DO NOT** include ready-to-eat (RTE) products. IPP are to verify RTE breaded stuffed chicken products in accordance with the inspection activities applicable to the RTE Hazard Analysis Critical Control Points (HACCP) category corresponding to the operations used to make the finished product RTE. For example, a fully cooked, but not shelf stable, frozen breaded stuffed chicken product would be added to the establishment profile under the HACCP processing category and verified by IPP under the PHIS Fully-Cooked, Not-Shelf-Stable HACCP inspection verification task and the RTEPROD sampling verification task (See <u>FSIS Directive 10,240.3</u>, *FSIS Ready-to-Eat Sampling Programs*).

## IV. SAMPLING PROGRAM AND HACCP REASSESSMENT

A. IPP are to be aware that FSIS will implement its sampling and verification testing program for *Salmonella* in NRTE breaded stuffed chicken products on or after May 1, 2025. Before this date, FSIS will issue instructions and update training for IPP on how to collect samples.

B. IPP are to be aware that all establishments that produce NRTE breaded stuffed chicken products must reassess their HACCP plans before the effective date. Establishments can reassess as part of their annual reassessment if their annual reassessment occurs before the effective date. Establishments that make changes to their production process as a result of their reassessment will need to re-validate their HACCP

plans before the effective date. IPP are to verify that these establishments have adequately reassessed and completed their reassessment and revalidation before May 1, 2025.

#### V. AWARENESS MEETING WITH ESTABLISHMENT MANAGEMENT

- A. During the next weekly meeting, and prior to IPP implementing any updates to the PHIS Profile, IPP are to inform establishment management of the publication of the final determination, the issuance of this notice, and that IPP will be updating the establishment's PHIS profile.
- B. The inspector-in-charge is to make establishment management aware of this notice by providing a web link or printed copy and review the notice during the awareness meeting.
- C. IPP are to document the awareness meeting in a memorandum of interview as described in <u>FSIS</u> <u>Directive 5010.1.</u> Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management, Section IV.

#### VI. IPP RESPONSIBILITIES FOR UPDATING PRODUCTS IN THE ESTABLISHMENT PROFILE

- A. IPP at all establishments that produce NRTE breaded stuffed chicken products are to initiate a directed "Update Establishment Profile" task and schedule it on the task calendar.
- B. IPP are to follow the instructions in <u>FSIS Directive 5300.1</u>, *Managing the Establishment Profile in the Public Health Information System Revision 1*, to access the establishment's profile and add or edit products.
- C. IPP are to update all applicable products that meet the definition of NRTE breaded stuffed chicken products using the HACCP Categories in <u>Appendix 1</u>. Examples of modified establishment profiles can be found in <u>Appendix 2</u>.
- D. Per <u>FSIS Directive 5300.1</u>, 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. IPP are to make sure they do not create duplicative product groups if they choose to create a new product group instead of updating an old one. To delete a product group entry, select the trashcan icon to delete the entry.
- E. After IPP have followed the instructions in this notice to initiate and perform a directed "Update Establishment Profile" task, they are to mark the directed task as complete. IPP are to keep the information in the establishment profile up-to-date and accurate, as directed in Chapter I, Part IX of <u>FSIS Directive</u> 5300.1.

#### VII. SUPERVISOR RESPONSIBILITIES

- A. All field supervisors are to ensure IPP in all establishments producing NRTE breaded stuffed chicken products complete the task as described in <u>Section VI</u> above. Supervisory personnel refer to any Office of Field Operations (OFO) personnel who supervise IPP conducting offline verification activities.
- B. Supervisors are to ensure that IPP have accurately updated the PHIS profile in the chicken establishments listed under the HACCP Categories in <a href="Appendix 1">Appendix 1</a> and verify that the task "Update Establishment Profile" has been completed. Supervisors are to promptly follow-up with IPP for the tasks that have not been performed to ensure completion by May 31, 2024.

#### **VIII. DATA ANALYSIS**

The FSIS Office of Planning, Analysis, and Risk Management will analyze the PHIS update results. Results from the update may be used to inform future sampling programs.

## IX. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, complete the <u>web form</u> and select **Sampling** as the Inquiry Type.

**NOTE**: Refer to <u>FSIS Directive 5620.1</u>, *Using askFSIS*, for additional information on submitting questions.

**Assistant Administrator** 

Office of Policy and Program Development

<u>Appendix 1.</u> Options within PHIS to update the product groups for NRTE breaded stuffed chicken products.

HACCP Category	Finished Product	Finished Product	Product Group
	Туре	Category	
Slaughter	Raw	Raw intact chicken	Other Intact Poultry Products
Slaughter	Raw	Raw intact chicken	Other Poultry Parts
	,		(feet, necks, hearts,
			and gizzards)
Slaughter	Raw	Raw intact chicken	Other Poultry Parts
Gladgittor	T COV	raw intact chicken	(livers ONLY)
Slaughter	Raw	Raw intact chicken	Poultry Parts (legs,
Gladgillei	itaw	Naw intact chicken	breasts, wings ONLY)
Claughter	Dow	Raw intact chicken	
Slaughter	Raw	Raw intact chicken	Poultry Parts (quarters
		D : ( 1 1:1	and halves ONLY)
Slaughter	Raw	Raw intact chicken	Raw Stuffed Poultry
			Products
Raw – Intact	Raw	Raw intact chicken	Other Intact Poultry
			Products
Raw – Intact	Raw	Raw intact chicken	Other Poultry Parts
			(feet, necks, hearts,
			and gizzards)
Raw – Intact	Raw	Raw intact chicken	Other Poultry Parts
			(livers ONLY)
Raw – Intact	Raw	Raw intact chicken	Poultry Parts (legs,
	,		breasts, wings ONLY)
Raw – Intact	Raw	Raw intact chicken	Poultry Parts (quarters
			and halves ONLY)
Raw – Intact	Raw	Raw intact chicken	Raw Stuffed Poultry
raw intaot	T COV	raw intact chicken	Products
Raw – Non Intact	Raw	Raw ground,	Ground Product
raw Hon maoc	i (dv	comminuted, or	Ground i roddol
		otherwise non-intact	
		chicken	
Raw – Non Intact	Raw		Injected, Tenderized, or
Naw – Non intact	Naw	Raw ground,	-
		comminuted, or	Vacuum Tumbled Other
		otherwise non-intact	Parts (feet, necks,
		chicken	hearts, and gizzards)
Raw – Non Intact	Raw	Raw ground,	Injected, Tenderized, or
		comminuted, or	Vacuum Tumbled Other
		otherwise non-intact	Parts (livers ONLY)
		chicken	
Raw – Non Intact	Raw	Raw ground,	Injected, Tenderized, or
		comminuted, or	Vacuum Tumbled Parts
		otherwise non-intact	(legs, breasts, wings
		chicken	ONLY)
Raw – Non Intact	Raw	Raw ground,	Injected, Tenderized, or
		comminuted, or	Vacuum Tumbled Parts
		otherwise non-intact	(quarters and halves
		chicken	ONLY)
			,

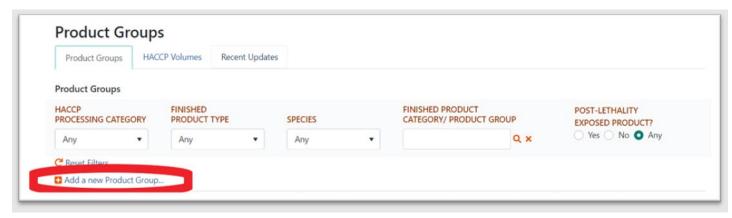
Raw – Non Intact	Raw	Raw ground, comminuted, or otherwise non-intact chicken	Injected, Tenderized, or Vacuum Tumbled Whole Bird
Raw – Non Intact	Raw	Raw ground, comminuted, or otherwise non-intact chicken	Mechanically Separated (Species)
Raw – Non Intact	Raw	Raw ground, comminuted, or otherwise non-intact chicken	Other Comminuted
Raw – Non Intact	Raw	Raw ground, comminuted, or otherwise non-intact chicken	Other Non-Intact but not Comminuted Poultry Products
Raw – Non Intact	Raw	Raw ground, comminuted, or otherwise non-intact chicken	Raw Stuffed Poultry Products
Heat Treated, Not Fully Cooked, Not Shelf Stable	NonRTE	NRTE otherwise processed poultry	NRTE stuffed chicken product that appear RTE
Heat Treated, Not Fully Cooked, Not Shelf Stable	NonRTE	NRTE otherwise processed poultry	NRTE Product with RTE Component
Heat Treated – Not Fully Cooked – Not Shelf Stable	NonRTE	NRTE otherwise processed poultry	Stuffed
Not Heat Treated – Shelf Stable	NonRTE	NRTE otherwise processed poultry	NRTE Product with RTE Component
Not Heat Treated – Shelf Stable	NonRTE	NRTE otherwise processed poultry	NRTE stuffed chicken product that appear RTE
Not Heat Treated – Shelf Stable	NonRTE	NRTE otherwise processed poultry	Stuffed
Heat Treated – Shelf Stable	NonRTE	NRTE otherwise processed poultry	NRTE Product with RTE Component
Heat Treated – Shelf Stable	NonRTE	NRTE otherwise processed poultry	NRTE stuffed chicken product that appear RTE
Heat Treated – Shelf Stable	NonRTE	NRTE otherwise processed poultry	Stuffed
Product with Secondary Inhibitors – Not Shelf Stable	NonRTE	NRTE otherwise processed poultry	NRTE Product with RTE Component
Product with Secondary Inhibitors – Not Shelf Stable	NonRTE	NRTE otherwise processed poultry	NRTE stuffed chicken product that appear RTE

Product with Secondary	NonRTE	NRTE otherwise	Stuffed
Inhibitors – Not Shelf		processed poultry	
Stable			

## **Appendix 2. Example Establishment Profile Screenshots**

## Adding a New Product Group

To get to the "Add Product Group" page within PHIS, IPP are to select the "Products" tab under the establishment name on the establishment page. IPP are to select the "Product Groups" tab and then select the "Add a new Product Group…" option as shown below. For more information, please see <u>FSIS Directive</u> 5300.1, *Managing the Establishment Profile in the Public Health Information System – Revision 1*.



#### Slaughter

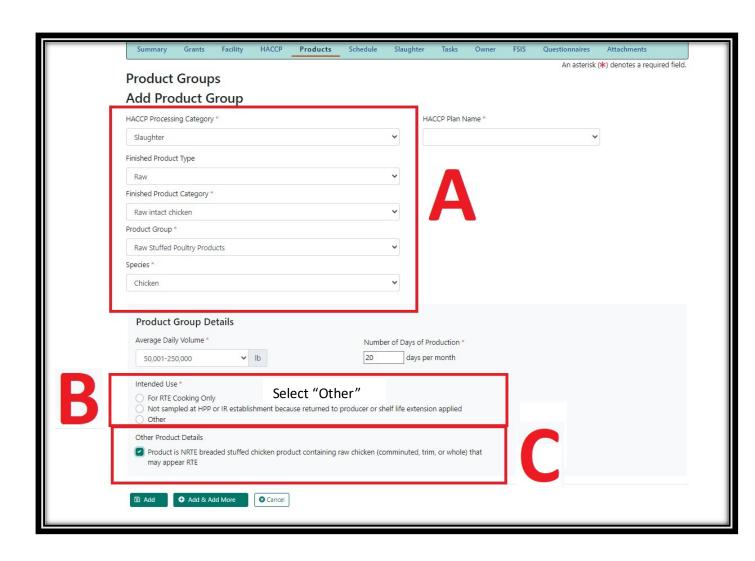
For the Slaughter HACCP Category, IPP are to select the correct options from the listed dropdowns shown in box "A" using the chart in <u>Appendix 1</u> to assist in updating the PHIS products. <u>Appendix 1</u> displays the options within PHIS to update the product groups for NRTE breaded stuffed chicken products. The options needed for selection include:

**HACCP Processing Category\*** 

- 1. Finished Product Type
- 2. Finished Product Category\*
- 3. Product Group\*; and
- 4. Species\*

#### **NOTE:** (\*) denotes a required field

At the bottom of the page within the "Product Group Details" box, IPP are to select "Other" for the intended use, within box "B", because the product is intended for consumer cooking (the product is ready-to-cook).



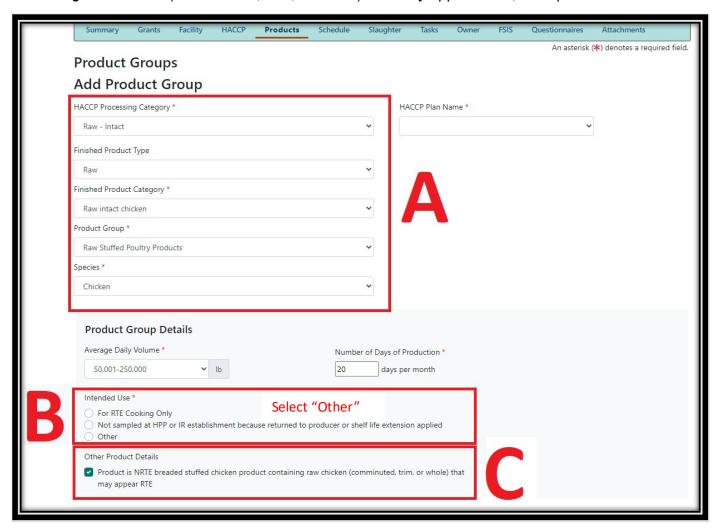
## Raw Intact

For the Raw Intact HACCP Category, IPP are to select the correct options from the listed dropdowns shown in box "A" using the chart in <u>Appendix 1</u> to assist in updating the PHIS products. <u>Appendix 1</u> displays the options within PHIS to update the product groups for NRTE breaded stuffed chicken products. The options needed for selection include:

- HACCP Processing Category\*
- 2. Finished Product Type
- 3. Finished Product Category\*
- 4. Product Group\*; and
- 5. Species\*

## **NOTE:** (\*) denotes a required field

At the bottom of the page within the "Product Group Details" box, IPP are to select "Other" for the intended use, within box "B", because the product is intended for consumer cooking (the product is ready-to-cook).



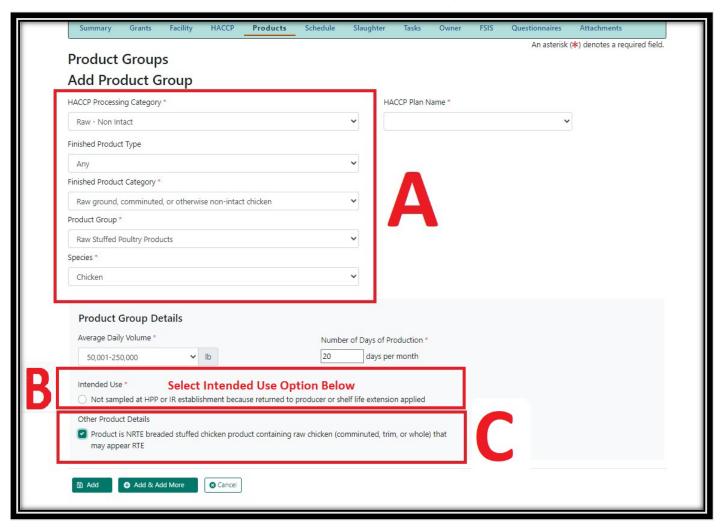
#### Raw Non-Intact

For the Raw Non-Intact HACCP Category, IPP are to select the correct options from the listed dropdowns shown in box "A" using the chart in <a href="Appendix 1">Appendix 1</a> to assist in updating the PHIS products. <a href="Appendix 1">Appendix 1</a> displays the options within PHIS to update the product groups for NRTE breaded stuffed chicken products. The options needed for selection include:

- HACCP Processing Category\*
- 2. Finished Product Type
- 3. Finished Product Category\*
- 4. Product Group\*; and
- 5. Species\*

## NOTE: (\*) denotes a required field

At the bottom of the page within the "Product Group Details" box, IPP are to select the listed intended use option, within box "B, select the radio button within box "C" for, "Product is NRTE breaded stuffed chicken product containing raw chicken (comminuted, trim, or whole) that may appear RTE," and press "Add."



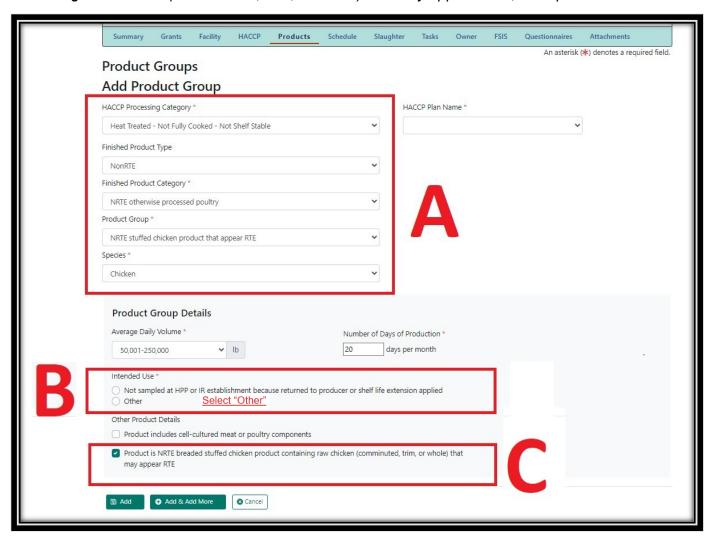
## <u>Heat Treated - Not Fully Cooked - Not Shelf Stable</u>

For the Heat Treated – Not Fully Cooked – Not Shelf Stable HACCP Category, IPP are to select the correct options from the listed dropdowns shown in box "A" using the chart in <u>Appendix 1</u> to assist in updating the PHIS products. <u>Appendix 1</u> displays the options within PHIS to update the product groups for NRTE breaded stuffed chicken products. The options needed for selection include:

- HACCP Processing Category\*
- 2. Finished Product Type
- 3. Finished Product Category\*
- 4. Product Group\*; and
- 5. Species\*

## NOTE: (\*) denotes a required field

At the bottom of the page within the "Product Group Details" box, IPP are to select "Other" for the intended use, within box "B", because the product is intended for consumer cooking (the product is ready-to-cook).



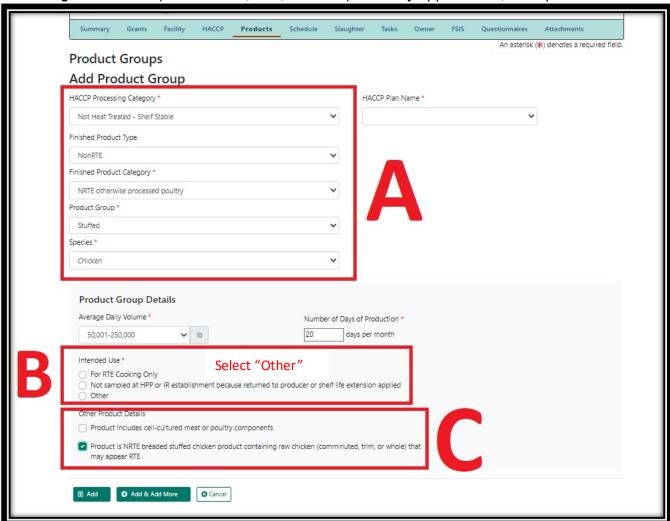
#### Not Heat Treated - Shelf Stable

For the Not Heat Treated – Shelf Stable HACCP Category, IPP are to select the correct options from the listed dropdowns shown in box "A" using the chart in <a href="Appendix 1">Appendix 1</a> to assist in updating the PHIS products. <a href="Appendix 1">Appendix 1</a> displays the options within PHIS to update the product groups for NRTE breaded stuffed chicken products. The options needed for selection include:

- HACCP Processing Category\*
- 2. Finished Product Type
- 3. Finished Product Category\*
- 4. Product Group\*; and
- 5. Species\*

## NOTE: (\*) denotes a required field

At the bottom of the page within the "Product Group Details" box, IPP are to select "Other" for the intended use, within box "B", because the product is intended for consumer cooking (the product is ready-to-cook).



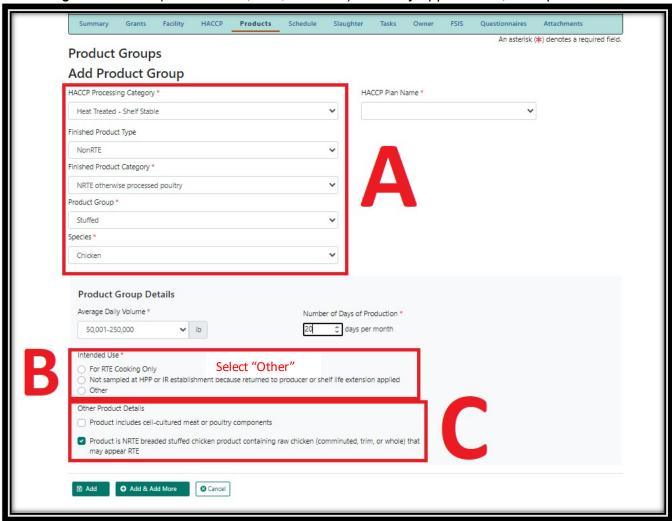
## Heat Treated - Shelf Stable

For the Heat Treated – Shelf Stable HACCP Category, IPP are to select the correct options from the listed dropdowns shown in box "A" using the chart in <u>Appendix 1</u> to assist in updating the PHIS products. <u>Appendix 1</u> displays the options within PHIS to update the product groups for NRTE breaded stuffed chicken products. The options needed for selection include:

- HACCP Processing Category\*
- 2. Finished Product Type
- 3. Finished Product Category\*
- 4. Product Group\*; and
- 5. Species\*

## NOTE: (\*) denotes a required field

At the bottom of the page within the "Product Group Details" box, IPP are to select "Other" for the intended use, within box "B", because the product is intended for consumer cooking (the product is ready-to-cook).



## <u>Product with Secondary Inhibitors – Not Shelf Stable</u>

For the Product with Secondary Inhibitors – Not Shelf Stable HACCP Category, IPP are to select the correct options from the listed dropdowns shown in box "A" using the chart in <u>Appendix 1</u> to assist in updating the PHIS products. <u>Appendix 1</u> displays the options within PHIS to update the product groups for NRTE breaded stuffed chicken products. The options needed for selection include:

- HACCP Processing Category\*
- 2. Finished Product Type
- 3. Finished Product Category\*
- 4. Product Group\*; and
- 5. Species\*

## NOTE: (\*) denotes a required field

At the bottom of the page within the "Product Group Details" box, IPP are to select "Other" for the intended use, within box "B", because the product is intended for consumer cooking (the product is ready-to-cook).

