

A Generic HACCP Model for a Raw Intact Wild-caught Catfish Product

The United States Department of Agriculture (USDA) published the [Pathogen Reduction/Hazard Analysis Critical Control Point \(HACCP\) Systems Final Rule](#) in July 1996. The HACCP regulations ([9 CFR Part 417](#)) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model's focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics.

With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in regulation [9 CFR 417.2\(b\)\(1\)](#). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated [Guidebook for the Preparation of HACCP Plans](#) when developing an establishment-specific HACCP plan.

Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. FSIS recommends that establishments tailor the model(s) to fit the establishment's operations.

On December 2, 2015, FSIS published the final rule [Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish](#) (80 Federal Register 75590). The final rule amended the Agency's regulations to establish a mandatory inspection program for catfish and for products derived from catfish.¹ The final rule explains that, because catfish are an amenable species under the [Federal Meat Inspection Act](#) (FMIA) (21 U.S.C. 601(w)(2)), the catfish inspection program is part of the FSIS meat inspection program.²

Generally, live catfish are processed into whole fish, fillets, steaks, strips, and nuggets. These products are typically sold raw. Raw products may be marinated, vacuum-tumbled, injected, or single-ingredient.

This model illustrates the raw intact processing of wild-caught catfish into whole fish, fillets, steaks, strips, and nuggets. The model may not necessarily apply to all operations or products. Products or operations may require fewer or more Critical Control Points (CCPs) depending on the operation.

The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. For additional guidance see the [FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products](#).

The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP decisionmaking records ([9 CFR 417.5\(a\)](#)). Ensure you maintain the documents produced while developing a HACCP plan.³ For further assistance with developing HACCP plans see the [Guidebook for the Preparation of HACCP Plans](#) and the guidance materials available on the FSIS [HACCP](#) webpage.

¹ For purposes of convenience, the term "catfish" is used in this HACCP model. Other FSIS documents may use "fish of the order Siluriformes", "Siluriformes fish," or simply "fish" in addition to "catfish".

² See the Executive Summary of the final rule [Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish](#) (page 75590).

³ Prior to developing the HACCP plan, please read the [Guidebook for the Preparation of HACCP Plans](#) for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in [Title 9 Code of Federal Regulations \(9 CFR\) Part 417](#). The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.

EXAMPLE PRODUCT DESCRIPTION⁴

Raw Intact Catfish	
Process or Product name	Raw intact wild-caught fresh catfish (whole fish, fillets, steaks, strips, nuggets)
Important product characteristics (A_w, pH, Preservatives, etc.)	None
Intended use⁵	To be fully cooked prior to consumption. For further processing at this facility or another establishment or intended for cooking by end consumer
Packaging (durability and storage conditions)	Vacuum-packaged, tray packs or bulk pack boxes with liners.
Shelf life and at what temperature⁶	Refrigerated - 5 days when held at 40°F.
Where it will be sold (specify intended consumers, especially at-risk populations)⁷	Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI).
Labeling instructions and requirements	Product name, inspection legend and establishment number, handling statement, safe handling instructions, net weight statement, address line, nutrition facts panel, and ingredients list. ⁸
Special distribution control	None

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⁴ Prior to developing the HACCP plan please read the FSIS [Guidebook for the Preparation of HACCP Plans](#) for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in [Title 9 Code of Federal Regulations \(9 CFR\) Part 417](#). The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.

⁵ The intended use or consumer of the product must be identified in accordance with [9 CFR 417.2\(a\)\(2\)](#). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2).

⁶ Each establishment's products may have their own defined shelf life.

⁷ At-risk populations include young children, the elderly, and immunocompromised persons.

⁸ See the [Labeling and Label Approval](#) webpage for information on required labeling features and other labeling resources.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL⁹

Raw Intact Catfish	
Meat	Live wild-caught catfish
Non-meat food ingredients	None
Antimicrobial interventions¹⁰ and processing aids	None
Packaging material	Plastic wrap and trays, boxes and liners
Restricted ingredients or Allergens	Catfish contains allergenic proteins
Other	None

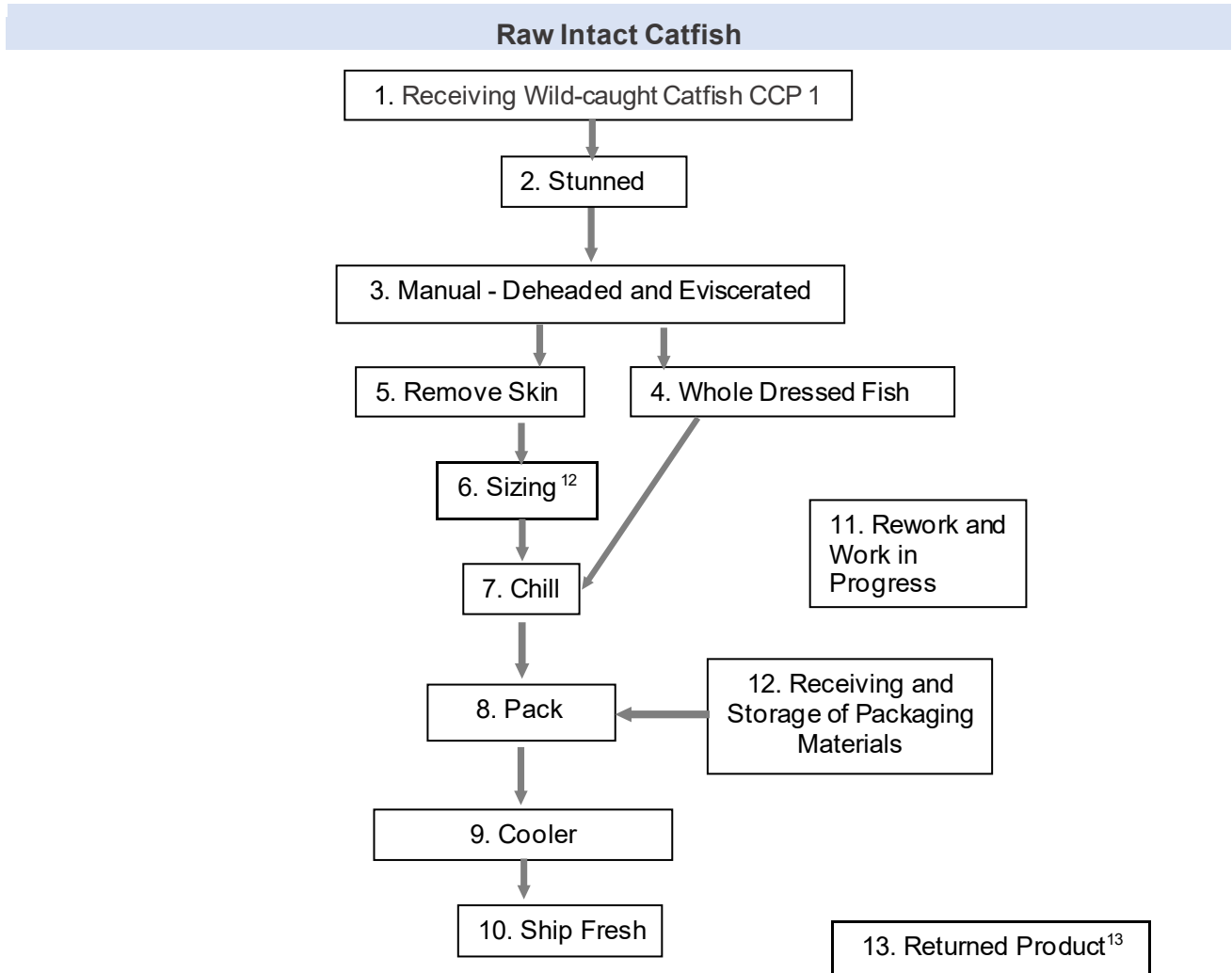
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⁹List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the [FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling](#) for detailed information on allergens.

¹⁰FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding ([MOU](#)) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the [Federal Food, Drug & Cosmetic Act \(FD&C Act\)](#) and its implementing regulations. See [FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients.](#)

EXAMPLE PROCESS FLOW DIAGRAM¹¹



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¹¹ This is an example flow diagram. Establishments' flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis.

¹² Step 7 "Sizing" represents the manual processing procedures used to produce fillets, steaks, strips, and nuggets.

¹³ The Returned Product step (18) is shown not connected to another step. Returned product may re-enter the production system at different process steps depending on condition or food safety concerns. Returned product may be relabeled, repackaged, or discarded.

EXAMPLE HAZARD ANALYSIS

Raw Intact Catfish				
Potential Hazard ¹⁴	Is the Hazard Reasonably Likely to occur (RLTO)?	Justification or Basis for Decision ¹⁵	If yes in Column 2 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels ¹⁶	Is this Step a Critical Control Point (CCP)?
1. Receiving Wild-caught Catfish CCP 1				
B: <i>Salmonella</i>	No	<p>A hazard identification study identified <i>Salmonella</i> as one of the few potential hazards.¹⁷ There is evidence that at least one outbreak of human salmonellosis may have been related to catfish consumption.</p> <p>Although <i>Salmonella</i> has been isolated from wild-caught catfish product, <i>Salmonella</i> is considered not reasonably likely to occur when processing wild-caught catfish.¹⁸</p>		

¹⁴ Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the [Guidebook for the Preparation of HACCP Plans](#) for more information about hazards identification.

¹⁵ Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced articles must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence – that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan.

¹⁶ Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis ([9 CFR 417.5\(a\)](#)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, or antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see [FSIS Compliance Guideline HACCP Systems Validation](#), page 5).

¹⁷ See the [Assessment of the Potential Change in Human Health Risk associated with Applying Inspection to Fish of the order Siluriformes](#).

¹⁸ Abstract: [Effect of Federal Inspection on Louisiana Wild-Caught Catfish Industry, Prevalence of Salmonella, and Microbial Characteristics of Raw Wild-Caught Catfish Fillets](#)

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
		Product is to be fully cooked prior to consumption.		
C: Environmental Chemicals	Yes	Wild-caught catfish can be harvested from waters that are contaminated by varying amounts of industrial chemicals, including heavy metals, herbicides and pesticides. ¹⁹ Catfish harvested from waters that are closed to commercial harvesting or under a consumption advisory may contain contaminants above the federal tolerance or action levels. Contaminants may accumulate in wild-caught catfish at levels that can cause human health problems. ²⁰ Wild-caught Catfish SOP for verification of the consumption advisory status of the harvest waters. ²¹ The establishment reviews consumption advisories and publicly available residue test results from authorities responsible for the waters where the catfish are harvested.	The catfish are harvested from the Potomac River Basin. Consumption advisories exist for Channel Catfish harvested from the Potomac River Basin. Channel Catfish ≥ 18 inches are not processed. ²³ These catfish are not processed due the harmful levels of Polychlorinated biphenyls (PCBs). ²⁴	Environmental Chemicals CCP 1
Allergens	No	Catfish is a food allergen. Products are properly labeled. ²²		

¹⁹ FSIS recommends establishments consider the guidance in FDA's [Fish and Fishery Products Hazards and Controls Guidance](#) (Chapter 9, Environmental Chemical Contaminants and Pesticides (page 158)) recommending processors consider environmental contaminants and pesticides historically found in the areas where the fish are caught. State and local health or environmental authorities generally maintain this data.

²⁰ See the U.S. Environment Protection Agency (EPA) Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories volume 2 [Risk Assessment and Fish Consumption Limits](#) for monthly consumption limit tables and the risk assessment methods used to derive the limits.

²¹ [Historical Advisories Where You Live](#) is an EPA web-based tool that provides detailed consumption advisory information. For current advisories, click on the [State, Territory and Tribe fish Advisory Contacts](#) link. Consumption advisory information can be a valuable tool for assisting establishments in avoiding illegal residues in processed fish by identifying the consumption advisory status of the source waters. Without source water information, it is not possible for an establishment to institute effective residue controls.

²² FSIS recommends establishments processing fish use prevention and control measures for undeclared allergens. For guidance, review the chapter titled Prevention and Control Measures for Undeclared Allergens in the FSIS guideline [Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling](#).

²³ The [Virginia Department of Health](#) advises that catfish harvested from the Potomac River Basin that are [18 inches or larger should not be consumed](#) (03/1/2022).

²⁴ The Federal Food and Drug Administration sets tolerance levels for PCBs ([21 CFR 109.30](#)). Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. Therefore, tolerances for residues of PCB's are established. The tolerances for residues of PCB's are 2 parts per million in fish and shellfish (edible portion).

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
P: None				
2. Stunned				
B: None				
C: None				
P: None				
3. Manual – Deheaded and Eviscerated				
B: Salmonella Outgrowth	No	Written Sanitation Standard Operating Procedures (Sanitation SOPs) to prevent or minimize cross-contamination. Temperature Control Standard Operating Procedures (SOPs) for the processing area to aid in the control of <i>Salmonella</i> outgrowth. The total time required to remove heads, eviscerate, and prepare products for packaging is short enough to preclude the outgrowth of <i>Salmonella</i> and meets the time and temperature parameters in the Federal Food and Drug Administration’s (FDA’s) guidance. ²⁵		
C: Sanitizers	No	Written Chemical Receiving, Storage, and Use SOP.		
P: None				

²⁵ [See the FDA’s Fish and Fishery Products Hazards and Controls Guidance](#) (Table A-2 page 421).

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
4. Whole Dressed Fish				
B: <i>Salmonella</i> Outgrowth	No	Written Sanitation SOPs to prevent or minimize cross-contamination. Temperature Control SOP for the processing area to aid in the control of <i>Salmonella</i> outgrowth. The total time required to remove heads, eviscerate, and prepare products for packaging is short enough to preclude the outgrowth of <i>Salmonella</i> and meets the time and temperature parameters in the FDA guidance. ²⁶		
C: Sanitizers	No	Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]). ²⁷		
P: Foreign Materials	No	Written Foreign Material SOP requires daily equipment examination and preventive maintenance to prevent foreign materials (e.g., metal, rubber, plastic) from contaminating the product. ²⁸ No historical findings of foreign material contamination. ²⁹		

²⁶ [See the Federal Food and Drug Administration's Fish and Fishery Products Hazards and Controls Guidance \(Table A-2 page 421\).](#)

²⁷ Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. [FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products](#) contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability.

²⁸ This Foreign Material SOP (prerequisite program) should have details on how this procedure (such as metal prevention controls) is preventing the hazard from occurring as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historical data.

²⁹ Note: this "historical data" must be supported with evidence from the establishment through the establishment's history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence. Such as the [Fish and Fishery Products Hazards and Controls Guidance](#) which states "preventive measures for metal inclusion can include periodically checking equipment for damaged or missing parts" (page 386).

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
5. Remove Skin				
B: None				
C: None				
P: None				

6. Sizing				
B: None				
C: None				
P: None				

7. Chill				
B: <i>Salmonella</i> Outgrowth	No	<p><i>Salmonella</i> outgrowth during catfish processing is not reasonably likely to occur. Product internal temperature is lowered to $\leq 40^{\circ}\text{F}$ during processing.³⁰</p> <p>Product temperature during processing is not to exceed the time and temperature parameters in the FDA's Fish and Fishery Products Hazards and Control Guidance (Table A-2, page 421).³¹</p> <p>Written Processing SOP for maintenance of ice and water solution</p>		

³⁰ Establishments may be able to safely process catfish without an ice and water chilling process, relying instead on the coolers and freezers to bring down product temperatures.

³¹ If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27).

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
		temperature.		
C: None				
P: None				

8. Pack

B: None				
C: Allergens		Product does not contain non-meat allergenic ingredients. Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation. Catfish contains allergenic proteins.		
P: None				

9. Cooler

B: <i>Salmonella</i> Outgrowth	No	Cooler ambient temperature is ≤ 40°F. Written Cooler Temperature Monitoring SOP.		
C: None				
P: None				

10. Ship Fresh

B: <i>Salmonella</i> Outgrowth	No	Catfish products are chilled in ice and held at ≤ 40°F. Product Transport SOP to ensure product temperatures are maintained when transported via company owned or contracted carriers.		
C: None				
P: None				

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
11. Rework and Work in Progress				
B: <i>Salmonella</i> Outgrowth	No	Catfish products are chilled in ice and held at ≤ 40°F.		
C: None				
P: None				
12. Receiving and Storage of Packaging Materials				
B: None				
C: Chemical Contamination	No	<p>Packaging materials are received, stored, and handled according to Written Receiving, Storage, and Use SOP to prevent contamination of products.</p> <p>LOG for all packaging materials describing quality controls and prevention procedures.</p> <p>Written Sanitation SOP for procedures used to protect packaging materials from environmental contamination.</p>		
P: None				
13. Returned Product				
B: Outgrowth of Pathogens	No	Returned Product Evaluation SOP implemented before accepting returned product. Person(s) or business returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted.		

Potential Hazard	RLTO	Justification or Basis	Controls	CCP
C: None				
P: None				

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Example Raw Intact Catfish HACCP Plan

Receiving Wild-caught Catfish CCP 1		
Hazard(s)	Environmental Chemicals - PCBs	
Critical Limits	Channel catfish harvested from the Potomac River Basin which are \geq 18 inches in length are not processed. ³²	
Monitoring procedures	What	Sort catfish \geq 18 inches in length
	How	Identify catfish that approach 18 inches in length and measure the sorted fish.
	Frequency	Each fish that \geq 18 inches in length.
	Who	Designated employee.
Corrective Action	<p>If a deviation from the critical limit occurs, a supervisor will:</p> <ul style="list-style-type: none"> - 1. Hold the product lot until appropriate disposition is taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence (9 CFR 417.3) 	
Verification	Randomly, once per week, the supervisor will directly observe designated employee sorting and measuring the fish. Once every three months, the supervisor will review records.	
Records	Corrective Action Log, Lab Results Form, Records Review Form, Preshipment Records	

³² This critical limit reflects the consumption advisory for catfish harvested from the Potomac River Basin (2022), it would not apply to all sources of wild-caught catfish. Different regions may include reports for different chemicals. Consumption advisories for a region may change over time.