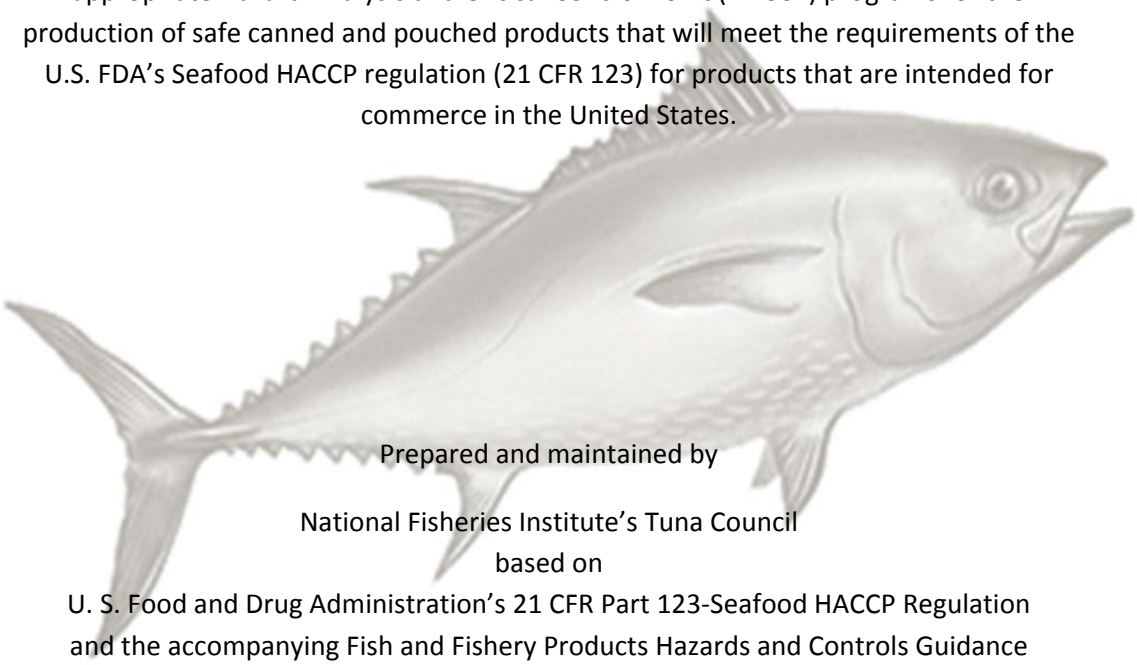
TUNA COUNCIL

HACCP Guidance

for Canned Tuna

This handbook, known as the Tuna HACCP Guide, has been prepared to assist the tuna processing industry in the development, implementation, and maintenance of appropriate Hazard Analysis and Critical Control Point (HACCP) programs for the production of safe canned and pouched products that will meet the requirements of the U.S. FDA's Seafood HACCP regulation (21 CFR 123) for products that are intended for commerce in the United States.



Prepared and maintained by

National Fisheries Institute's Tuna Council
based on
U. S. Food and Drug Administration's 21 CFR Part 123-Seafood HACCP Regulation
and the accompanying Fish and Fishery Products Hazards and Controls Guidance

First Edition

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NATIONAL FISHERIES INSTITUTE ®

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Credits

National Fisheries Institute The National Fisheries Institute (NFI) is a non-profit organization representing the fish and seafood industry. NFI member companies are engaged in the commercial fish and seafood business, spanning from "water to table" – whether they catch or cultivate, process or distribute, import or export seafood. NFI members work together on issues that affect the seafood industry, including legislative and regulatory policies, technical and scientific issues, seafood promotion, and consumer marketing opportunities.

Tuna Council The U.S. Tuna Foundation (USTF) was established in 1976 to be the representative voice on legislative and regulatory issues for the U.S. tuna fleet and the U.S. canned tuna processors. In 2007, the U. S. Tuna Foundation was dissolved, and a new council was created within the National Fisheries Institute called the Tuna Council. Today, the National Fisheries Institute's Tuna Council represents the largest processors and household names for canned and pouch tuna in the U.S. including Bumble Bee®, Chicken of the Sea® and StarKist®. The Tuna Council speaks for the tuna industry on numerous issues from fishing access arrangements and federal and state regulations, to sustainability and education and marketing.

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U.S. FDA Contributions

Although FDA cannot specifically endorse individual training programs and materials outside of their direct responsibility, the content and recommendations in this Tuna HACCP Guide have been influenced through discussions with FDA authorities either during deliberations with individual processing operations or with representatives for NFI and the Tuna Council.

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Contents

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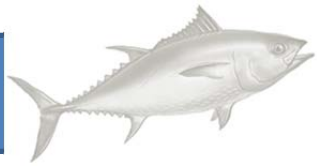
Change Log

Edition/Version	Date	Changes
Draft, Version 1	01-31-2013	First release for January 2013 Train the Trainer Workshop
First Edition Pre-Release	12-10-2013	Released for Review. Modifications based on comments from January 2013 Train the Trainer workshop and outside expert review
First Edition Pre-Release	4-13-2014	Updated references in Appendix 9
First Edition Pre-Release	4-15-2014	Chapter 7, page 7-7. Updated point 10

CHAPTER 1



INTRODUCTION

This handbook has been prepared and maintained by the National Fisheries Institute's Tuna Council and selected experts. The content is prepared with reference to the U.S. Food and Drug Administration (FDA) mandated rule, *Seafood HACCP Regulation* (Title 21 *Code of Federal Regulations*, Part 123, often referred to as '21 CFR 123') and the accompanying FDA's *Fish and Fishery Products Hazards and Controls Guidance*, 4th edition which contains the FDA's most current recommendations for commercial practices by processors intending to sell their products in the United States.

Pertinent Regulations and FDA's Guidance to Industry:

- FDA Seafood HACCP Regulation, Title 21 *Code of Federal Regulations* Part 123 (Effective Date, December 18, 1997)
- FDA *Fish and Fishery Products Hazards and Controls Guidance*, 4th Edition (April, 2011) (often referred to as 'FDA Hazards Guide')

Source: http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006764.htm

This handbook is intended for training purposes following the recognized format of the Seafood HACCP Alliance (SHA). The 'Alliance' is a collaborative training program involving the FDA, National Marine Fisheries Service, seafood industry trade organizations, and numerous academic experts across the nation and about the world. Their instructive format is recognized by the Association of Food and Drug Officials (AFDO) involving food regulatory authorities in the United States and many neighboring nations. The SHA training program details and materials can be viewed at the AFDO website (http://www.afdo.org/seafoodhaccp).

This handbook is also based on commercial experience available through the Tuna Council and its continuing efforts to maintain appropriate HACCP controls. The Tuna Council's commitment to producing safe thermally processed tuna products has been evident with prior versions of HACCP guidance documents. Following the implementation of the FDA's Seafood HACCP Regulation in 1997, the U.S. Tuna Foundation developed the *Canned/Pouched Tuna HACCP Manual* to assist in the development of HACCP plans for U.S. Tuna Foundation members. The last version of the Canned/Pouched Tuna HACCP Manual was amended in 2004. This new

handbook – *Tuna Council HACCP Guidance for Canned Tuna* – replaces all previous versions of HACCP models developed by the U.S. Tuna Foundation and is an updated edition designed to assist firms in complying with the FDA's interpretation of U.S. regulations and the FDA Hazards Guide.

SPECIAL NOTE
Updated versions of the *Tuna Council HACCP Guidance for Canned Tuna* will be maintained on the website www.CannedTunaHACCP.com

PURPOSE & SCOPE

The *Tuna Council HACCP Guidance for Canned Tuna* (referred to from now on as the 'Tuna HACCP Guide') is prepared as a reference and training handbook. This handbook can assist with the development and implementation of a HACCP plan for the commercial production of canned and pouched tuna products that will comply with U.S. FDA's Seafood HACCP regulation. It is applicable for canned and pouched tuna products that are thermally processed by any operation located anywhere in the world and intended for sale in the United States.

Products covered by this handbook include:

- Canned and pouched tuna products (including metalized or plastic pouches and plastic cups), and
- Frozen pre-cooked tuna loins destined for cans or pouches

LIMITATIONS

Although consistent with the FDA Hazards Guide, the Tuna HACCP Guide:

- Is not a substitute for the performance of a hazard analysis by individual processing facilities. Each processor must develop and maintain a HACCP program to suit their particular operation and products.
- Does not emphasize all hazards that might be introduced by non-tuna ingredients, except for general references in the example HACCP plans for any potential allergens that could be associated with certain added ingredients. FDA and the Tuna Council recognize that hazards associated with non-tuna ingredients must be considered during the hazard analysis and

specific safety controls must be included in a HACCP plan for all significant hazards associated with non-tuna ingredients.

- Does not cover the specific controls that are necessary to prevent the formation of *Clostridium botulinum* toxin in shelf-stable low-acid canned foods (LACF) or acidified low-acid foods. Mandatory controls for this specific hazard are contained in the FDA regulations, *Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers* (21 CFR 113), *Acidified Foods* (21 CFR 114), and *Emergency Permit Control* (21 CFR 108). FDA does not require that these controls be included in HACCP plans for these products.

Simply Stated:

The Tuna HACCP Guide is provided as a reference to help individual processors to develop and maintain the required HACCP program to suit each particular operation.

JUSTIFICATION (WHY NOW?)

Maintaining a HACCP program for food safety requires constant awareness and understanding of changes and additions in the processing methods, initial product sources and types, and different finished products and certain market conditions. Likewise, processors must anticipate changes in the science-based knowledge for hazards and controls and the corresponding adjustments in regulatory requirements. HACCP guidelines developed by Codex Alimentarius Commission and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommend annual reassessments of HACCP plans. FDA has maintained similar recommendations in the Seafood HACCP regulation in order to ensure that HACCP plans continue to adequately control food safety hazards. As an example, HACCP plans must be reviewed and adjusted if necessary if the method of receiving raw tuna changes from fresh to frozen, from vessel to truck, or from whole fish to frozen loins.

WHY NOW?

1. Seafood HACCP Regulation updates, additions and increasing emphasis on compliance
2. Recent FDA enforcement actions calling for adjustments in existing HACCP plans
3. New science to support existing commercial practices

1. Seafood HACCP Regulation updates, additions and increasing emphasis for compliance

In April, 2011, FDA issued an updated version of its *Fish and Fishery Products Hazards and Controls Guidance*. This fourth edition of the FDA Hazards Guide outlines new issues and practices for commercial consideration. Additionally, it reorganized the format of the prior FDA Hazards Guide to re-emphasize some previous, existing recommendations that were either not being properly followed or enforced. Previous commercial and regulatory practice must now be in compliance with the new and re-emphasized recommendations in this 4th edition of the FDA Hazards Guide.

FDA does not pre-approve HACCP plans for individual companies. It is the obligation of each processor and/or importer to ensure that its HACCP plans will meet the regulatory requirements of FDA's Seafood HACCP Regulation. One way to ensure compliance is to follow the recommendations in the most current version of FDA's *Fish and Fishery Products Hazards and Controls Guidance*.

> Henceforth, all new revisions and additions to the FDA Hazards Guide will be posted and maintained on the FDA Seafood HACCP website:
>
> http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm

Although FDA does not pre-approve HACCP plans, the HACCP plans for each company are subject to review during regulatory inspections. FDA reviews of HACCP plans for canned tuna processors during 2010-2012 have documented concerns that company HACCP plans were not in full compliance with the FDA Seafood HACCP Regulations.

2. Recent FDA inspection reports calling for adjustments in existing HACCP plans

FDA inspections and HACCP plan reviews from 2010 through 2012 for various tuna processing operations resulted in cautions, warning letters, and numerous industry meetings calling for revisions of the traditional HACCP plans.

3. New science to support existing commercial practices

Some traditional commercial practices as well as the increasing production of frozen loins have attracted regulatory concerns for proper food safety controls. In response, some recent scientific studies by commercial members of the Tuna Council have demonstrated that pre-cooking to a fish core temperature of 60°C (140°F) effectively halts further histamine formation for more than enough time required to convert pre-cooked fish to frozen tuna loins or canned tuna.

INDUSTRY RESPONSE

History of Food Safety and HACCP Responses from Industry

The major U.S. tuna companies and their suppliers have been working together to maintain food safety in their products long before the mandates for HACCP. Their positive product safety record is a testimony to their efforts and concerns. Following the FDA mandates for HACCP in 1997, the leading companies collaborated through the U.S. Tuna Foundation (the precursor organization to the NFI Tuna Council) and began working with FDA to ensure that proper food safety programs were put in place. The U.S. Tuna Foundation developed several versions of model HACCP plans for its members with the latest modification in 2004. Companies used this information in outreach programs to work with the tuna vessels and tuna processors to maintain and improve the tuna quality and safety. Since FDA's release of the *Fish and Fishery Products Hazards and Controls Guidance*, 4thedition, the NFI Tuna Council is assisting in developing appropriate commercial responses to account for some of the following changes in the FDA Hazards Guide:

- Sub-dividing ('sub-lotting') and retesting for histamine is no longer recommended after an initial failed histamine test.
- Changing the location and weight of sample for histamine testing.
- Accounting for cumulative exposure time through various processing steps.
- Recognizing pre-cook as a potential critical control point (CCP) in many operations particularly for large fish requiring longer time for processing. Emphasis on scientific validation studies, in addition to historical data, to support HACCP plans and various processing steps, e.g., pre-cooking and monitoring necessary for cumulative exposures.
- Including the labeling step as a CCP to avoid potential hazards due to undeclared allergens.
- Verifying thermometer and other monitoring instruments for accuracy and calibration.
- Changing and clarifying the guidance for metal control to include limits for special risk groups, additional information on calibration/validation, recommended critical limits and corrective actions.

Most of the new changes required further studies that were financed and conducted by the leading tuna companies. Some of the cumulative time controls emphasized in the 4thedition of the FDA Hazards Guide called for a 12-hour limit for exposure of thawed tuna at temperatures in excess of 70°F (21.1°C). This limitation was not practical for traditional thawing and processing procedures for larger tuna. This process required scientific validation of safe

historical practices. Likewise, validation data or change was also needed for managing potential *Staphylococcus aureus* risk after the pre-cooked tuna was handled for further processing.

The NFI Tuna Council recognized that modifications to the HACCP models from 2004 would greatly benefit the industry in complying with FDA Seafood HACCP regulation. The Tuna Council efforts have contributed to the science and practice for canning tuna through:

- More robust data sets on the thermal inactivation parameters for the most important histamine forming bacteria.
- *Staphylococcus aureus* challenge studies to determine any risks or potential growth and toxin production.
- Pre-cook process validations to confirm the long held belief that the partial cook from pre-cooking halted histamine formation for sufficient time to safely convert raw tuna into canned product or into frozen loins which will be subsequently converted to canned products.

This was no small effort. The Tuna Council has accumulated significant information including:

- Numerous test trials for processing whole and portions of albacore and skipjack. These tests required thousands of fish analyses across three companies working in four different geographic locations under a variety of test conditions with regular and intentionally abused fish.
- These validation studies have been repeated under different conditions and with different levels of deliberately time/temperature-abused fish to simulate potential harvest vessel abuse. Recent studies have focused on stressing the combination of worst case conditions throughout the process and on determining high levels of statistical confidence in setting the critical limits for effective control.
- The studies have shown that the certain partial cook processes (pre-cooking) can effectively halt histamine formation in tuna for up to 18 hours.
- Thermal Death Time studies were conducted during 2011 and 2012 at the Grocery Manufacturers Association laboratory in Washington, DC, to determine lethality characteristics of relevant histamine forming bacteria in tuna.
- Evaluations to confirm use of End-Point Internal Product Temperature (EPIPT) as a suitable means of monitoring the pre-cook CCP based on an end of cook fish center temperature of 60°C (140°F) that will provide a wide safety margin.

A Summary of Industry Responses

1985	Tuna Handling and Refrigeration on Purse Seiners – Frank D. Burns (Living Marine Resources, USTF-funded project)
1995	Albacore Quality Handbook (Van Camp Seafood Company)
1995	Recommendations for On-Board Handling of Purse Seine Fish (USTF)
1990's	Extensive Work with the Starkist fleet on methods to maintain quality of purse seine caught fish – Dr. John Kaneko and Dr. John Bell, (Starkist-funded project)
1990's	Workshops in Western Samoa run jointly by Chicken of the Sea and Starkist
2002	Bumble Bee Fish Quality Workshops in Fiji and Trinidad
2009	Bumble Bee Food Safety and Quality Workshops in Fiji
2011	Tuna Council HACCP Team convened to develop commercial guidelines and training materials
2011-2012	Science-based assessments to support the HACCP plans
2012	NFI Tuna Council presentation on the 4th edition of the FDA Hazards Guide to a large group of tuna processors in Thailand
2011-2012	Series of meetings with FDA to address its prevailing concerns for appropriate HACCP plans as noted in various inspections and warning letters
2013+	International training program launched with certified trainers along with process to continually review and update the Tuna HACCP Guide and website

APPLICATIONS

The instructions in this handbook apply to the processing of certain species of tuna for production of thermally canned or pouched products that **do not require refrigeration (shelf-stable).** These products are considered **ready-to-eat items (do not require cooking)** or they can be used in a variety of recipes including items that will be further cooked.

TUNA SPECIES allowed by FDA's canned tuna standard of identity (21 CFR 161.190) include:

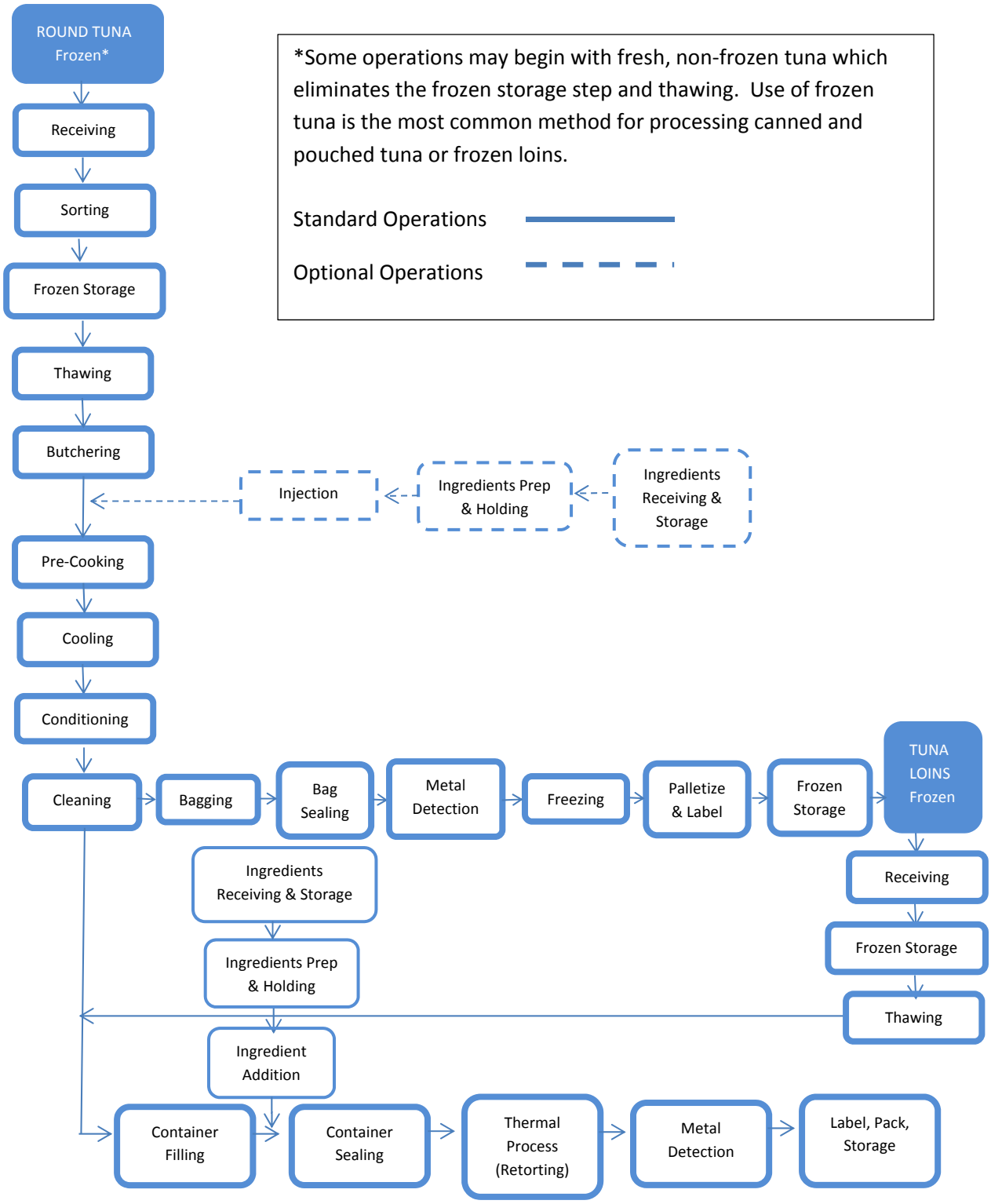
Albacore (*Thunnus alalunga*)*
Bigeye tuna (*Thunnus obesus*)*
Blackfin tuna (*Thunnus atlanticus*)
Black Skipjack tuna (*Euthynnus lineatus*)
Bluefin tuna, Northern (*Thunnus thynnus*)
Bluefin tuna, Southern (*Thunnus maccoyii*)
Bullet tuna (*Auxis rochei*)
Frigate tuna (*Auxis thazard*)
Kawakawa (*Euthynnus affinis*)
Longtail tuna (*Thunnus tonggol*)
Skipjack tuna (*Katsuwonus pelamis*)*
Slender tuna (*Allothunnus fallai*)
Spotted tunny (*Euthynnus alletteratus*)
Yellowfin (*Thunnus albacares*)*

*Primary species typically involved in production of canned tuna

PROCESSING OPERATIONS include a variety of operations that differ by condition of the tuna (whole fish, eviscerated fish, or frozen pre-cooked loins) that are received frozen or fresh directly from the harvest vessel or from transport by trucks and other shipments. The combined flow diagram illustrates the variety of processing methods and possible combinations with recognition that the following list represents the three most prevalent operations:

- Boat to Thermally Processed Cans or Pouches;
- Boat to Frozen Loins;
- Frozen Loins to Thermally Processed Cans or Pouches.

Combined Flow Diagram depicting the most common process flow from receiving fish to finished can or pouch



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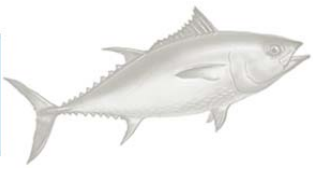
CHAPTER 2



REGULATORY REQUIREMENTS

This Tuna HACCP Guide is based upon the principles and guidelines initially outlined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 'Hazard Analysis Critical Control Point System' adopted by the NACMCF in 1992 (available at http://bit.ly/NACMCF). Likewise, the Tuna HACCP Guide is intended to comply with the requirements of the FDA's Seafood HACCP Regulation (21 CFR 123) and the accompanying recommendations provided in the 4th edition of the FDA's *Fish and Fishery Products Hazards and Controls Guidance* (April 2011).

All of these documents indicate that an effective HACCP program must be built on a solid foundation of basic or initial requirements.

FOUNDATION REQUIREMENTS

Foundation Requirements

- Compliance with all pertinent **local or regional regulations**
- Current Good Manufacturing Practices (**cGMPs**)
- Sanitation Standard Operating Procedures (**SSOPs**)
- Low-Acid Canned Food Regulations (**LACFs**)

Local and Regional Regulations

In the development of its own HACCP program, each processor must also reference any existing food safety regulations from the state, tribal, territorial, local, or foreign health or environmental authorities in the area where the processing facility is located.

Current Good Manufacturing Practice

The Current Good Manufacturing Practice (cGMP) is the U.S. FDA's regulation (Title 21 of the *Code of Federal Regulations* (CFR), Part 110 – see Appendix 12) that apply to all food manufacturers and are the basis for determining whether the process facility, methods,

practices, and controls used to process food products are safe, and whether the products have been processed under sanitary conditions. The cGMPs outline the minimum standards that a food processing facility needs to meet including (but not limited to): personnel, buildings and facilities, equipment, production and process controls, raw materials, and manufacturing operations.

Sanitation Standard Operating Procedures (SSOPs)

An important section of FDA's Seafood HACCP Regulation is section 123.11 – Sanitation Control Procedures. This section addresses specific environmental and operational conditions which provide an important foundation for the HACCP System. The Tuna HACCP Guide provides greater detail in developing the necessary and required SSOPs in Chapters 4 and 7.

Low Acid Canned Foods (LACF) Regulations

For fish and fishery products that are subject to the requirements of Title 21 CFR Part 113 regarding *Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers*, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished hermetically sealed container. However, the processor shall have this food safety hazard controlled and monitored in compliance with the requirements of 21 CFR 113.

FDA's SEAFOOD HACCP REGULATION

Requirements for Seafood HACCP programs began in 1997 when the U.S. Food and Drug Administration's regulation, formally titled the *Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products*, went into effect. This regulation, simply known as the Seafood HACCP Regulation, is found in Title 21 of the *Code of Federal Regulations* (CFR), Part 123 (often written as 21 CFR 123). The regulation applies only to the processing of seafood products intended for sale in the United States, regardless of where they are processed.

Seafood HACCP Regulation (21 CFR 123):

Applies to processing of seafood for sale in the United States regardless of where it is processed.

Tuna HACCP

The following points are condensed and reworded excerpts from the FDA Seafood HACCP Regulation that apply to processing of tuna products. The actual wording in the sections in the regulation should be referenced for a more accurate interpretation (see Appendix 11).

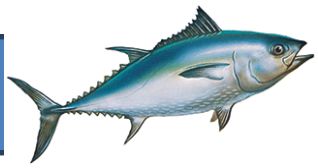
Regulatory Definitions (Section 123.3)

- Tuna is a **fish,** and all canned and pouched tuna are **fishery products** subject to the HACCP regulation because tuna is the characterizing ingredient in these products.
- **All processors**, both in domestic and foreign locations, **and importers** are subject to the HACCP regulation if they intend to conduct commerce in the United States and its related territories.
- **Processing** means handling, storing, preparing, heading, eviscerating, shucking, freezing, thawing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding fish or fishery products.
- **Processing is not defined by ownership of the product**. A cold storage or dry storage warehouse that stores raw materials or finished products as raw material for different owners is responsible for complying with the regulation as they are "storing" fish and/or fishery products.
- Certain processing practices/operations are exempt from the regulation including –
    - Fishing vessels;
    - Transporters (Refrigerated ships as bulk carriers or refrigerated containers);
    - Retail Establishments.

  SPECIAL NOTE: Although there are some exemptions, the primary processors may have to assess controls for tuna at receiving in order to account for handling during harvest and transport, and primary and secondary processors may have to include controls (e.g., label declarations of allergens) to address food safety issues in retail and other commerce.
- **SHALL** is used to state mandatory requirements (**Must** is similar to **Shall**)

Section	Key Requirement
123.6(a)	Every processor **shall** conduct a hazard analysis to determine the food safety hazards that are 'reasonably likely to occur'
123.6(b)	Every processor **shall** have and implement a ***written*** HACCP plan
123.6(c)	Written HACCP Plans **shall** include: 1. Hazards involved 2. Critical Control Points 3. Critical Limits 4. Monitoring procedures 5. Corrective Actions 6. Records 7. Verifications
123.6(d)	HACCP Plans **shall** be signed annually and when modified
123.8	Every processor **shall** ***verify*** that the HACCP plan will be and is effective in controlling the identified hazards
General	**Shall** maintain records for: • HACCP Plan • Monitoring • Corrective Actions • Verifications • Sanitation Controls • Importer Verifications
123.9(a)	All records **shall** contain: • Name and location of processor • Date and time of activity recorded • Signature or initials of the person making the record • Identity of the involved product
123.8(a)(3)	**Shall** review all HACCP records: • Within one week for CCP monitoring and corrective actions records • Within reasonable time for records of verification activities such as calibration and end product testing *NOTE: The Tuna Council recommends reviewing HACCP records more frequently than within one week and* ***ALWAYS*** *prior to product shipment*
123.9(b)	**Shall** retain HACCP records: • One year for refrigerated products • Two years for frozen or preserved (canned) products
123.10	HACCP-trained individual **shall**: • Develop the HACCP Plan • Reassess and modify the HACCP Plan and Hazard Analysis • Review HACCP records
123.11	**Shall** monitor and record sanitation control procedures *NOTE: The Tuna Council recommends the Sanitation Control Procedures be written*
123.11	**Shall** correct sanitation deficiencies in a timely manner

CHAPTER 3



POTENTIAL FOOD SAFETY HAZARDS and CONTROLS

A processor must first identify any possible seafood safety hazard and the respective controls that should occur during processing of the tuna. The processor's responsibility for the safety of the tuna begins at the moment of receiving fish, but this responsibility can extend to the vessel operations depending on the specified control procedures. The processor's responsibility can also continue through commerce of the finished products. This responsibility includes packaging and labeling that can help prevent potential hazards during the handling of the packaged product at points of purchase and by consumers.

The FDA Hazards Guide has considered seafood safety hazards that could be 'reasonably likely to occur' and require controls along with recommended HACCP controls, for certain tuna species and tuna processing methods. These specified recommendations must be considered in a hazard analysis for any tuna processing operation. Some of the FDA's recommended hazards for consideration may not apply to certain processing operations, but each individual processor is obligated to determine which hazards do apply. Likewise, the FDA Hazards Guide list of hazards that could be 'reasonably likely to occur' is not necessarily a complete or final listing. Additional hazards may come into play with certain fish produced in certain areas by particular harvesting methods or with the particular processing operations using procedures or technology that was not apparent when the FDA prepared their guidance.

Keep in mind that the FDA Hazards Guide identifies hazards for which controls are to be included in a company's HACCP program, not its sanitation programs. Sanitation procedures are equally important and are described in Chapter 7.

FDA LISTED HAZARDS THAT MAY APPLY TO CANNED/POUCHED TUNA

Based on the Product and Process Description, individual processors should **ALWAYS** refer to or consult the tables listing probable hazards in Chapter 3 of the FDA Hazards Guide. The FDA Hazards Guide has listed hazards that are considered reasonably likely to occur for certain seafood species (Table 3-2, page 34) and for various processing methods (Table 3-3, page 71). The listed hazards for each species or processing method should not be ignored. Decisions to exclude a listed hazard should be accompanied with an explanation for this decision in the

HACCP program. Likewise, additional hazards may be involved with a particular product or processing operation that have not been considered by FDA.

FDA List of Probable Seafood Related Hazards and Recommended Controls:

- Chapter 3, Table 3-2 for Potential Species Related-Hazards (Vertebrates and Fish)
- Chapter 3, Table 3-4 for Potential Process Related-Hazards (all seafood types)

Potential Species-Related Hazards

The FDA Hazards Guide Table 3-2 includes the potential species-related hazards associated with the various tuna species. This table lists the hazards that the FDA considers 'reasonably likely to occur' for all tuna species used in canned and pouched products. Each hazard refers to a chapter in the FDA Hazards Guide to provide more details for consideration and possible controls. A careful review for all tuna species listed in most processor's Product Descriptions will indicate there are two primary species-related hazards of concern: parasites and scombrotoxin (elevated histamine levels). An accompanying footnote at the end of Table 3-2 indicates that the parasite hazard should be considered if the tuna is to be consumed raw. Thus for pre-cooked tuna loins or retorted tuna there is only one primary species-related hazard of concern:

- Scombrotoxin (elevated histamine levels)

Potential Process-Related Hazards

The FDA Hazards Guide Table 3-4 includes the potential hazards associated with various processing methods and product forms. To use this table, processors need to identify the finished product food category and the package type. For the products covered in the Tuna HACCP Guide, this includes:

Tuna Product	FDA Hazards Guide Table 3-4	
	Finished Product Food	Package Type
Frozen Bagged Loins (pre-cooked)	Partially cooked or uncooked prepared foods	Reduced oxygen packaged (ROP) Or Other than ROP
Finished Can or Pouch (retorted)	Fermented, acidified, pickled, salted, and LACFs*	All

*LACF – low-acid foods packaged in hermetically sealed containers

A careful review with reference to the processing methods listed in most Process Descriptions for canned tuna indicates that there are five additional hazards of concern: Pathogenic bacteria growth, *C. botulinum* toxin, allergens and additives, metal inclusion, and glass inclusion.

Glass inclusion does not apply to tuna processed in metal or plastic cans and pouches.

C. botulinum toxin associated with possible bagging of pre-cooked tuna loins in ROP conditions would only apply to processing operations producing frozen loins as the finished product form. Frozen loins could potentially be subjected to time-temperature abuse after thawing and before the bags are opened. In accordance with the FDA Hazards Guide, concerns for *C. botulinum* toxin associated with thermal processing for canned and pouched products would be addressed with procedures performed in compliance with existing regulations for LACF foods (21 CFR 113).

> Based on the FDA Seafood HACCP regulations, the HACCP plan for fish and fishery products that are subject to the requirements of the Low-Acid Canned Food regulations, 21 CFR 113, does not need to list the food-safety hazards associated with the formation of *C. botulinum* toxin in the finished, hermetically sealed containers nor list the controls to prevent that hazard [*at the thermal processing step*]. 21 CFR Part 123.6(e)

Thus, the processing methods include three additional hazards that must be addressed in the hazard analysis:

- Pathogenic Bacteria Growth
  - *Clostridium botulinum* (for pre-cooked, reduced oxygen packaged loins)
  - *Staphylococcus aureus* (*S. aureus*)
- Allergens and Food Additives (undeclared)
- Metal Inclusion

FDA Listed Hazards That May Apply to Canned or Pouched Tuna

Combining the species and process-related hazards recommended by the FDA, the hazard analysis must consider a total of four (4) potential hazards listed below:

1. Scombrotoxin (elevated histamine levels)
2. Pathogen Bacteria Growth (and potential toxin formation)
   a. *Clostridium botulinum* (for pre-cooked, reduced oxygen packaged loins)
   b. *Staphylococcus aureus* (*S. aureus*)
3. Allergens and Food Additives (undeclared)
4. Metal Inclusion

ADDITIONAL HAZARDS

Additional hazards could be involved with certain species and processing operations that have not been addressed by the FDA Hazards Guide. Individual processors will have to decide which additional hazards to include in the hazard analysis. This approach can also be used to document that these additional hazards do not apply to a specific processing operation or they are included for some particular reason that is explained in the hazard analysis. Some additional hazards may involve:

- **Presence of foreign materials** in the tuna because of prior handling on vessels or trucks could be important for certain operations, but these issues are usually best controlled with prerequisite Standard Operating Procedures (SOPs) that can be extended to include the vessel and trucking operations. The identification and removal of fish bones is typically handled in a similar manner by SOPs.
- **Chemical residues** from exposure on the vessel during fish transport or in the processing plant are usually best controlled with the Sanitation Standard Operating Procedures (SSOPs) that can be extended to include the vessel and trucking operations.

Additional Safety Hazards that could be associated with tuna products:

- Presence of foreign materials
- Chemical residues

CONTROLS

After the species- and process-related hazards are identified, the FDA Hazards Guide directs users to individual chapters for each hazard category. These chapters propose control strategies that may be appropriate depending on the specific products produced and the processing procedures followed. Examples of HACCP critical control points (CCPs) are provided for most control strategies in the FDA Hazards Guide.

A summary of FDA guidance for the identified hazards in retorted tuna products is provided in the following pages. The identified controls provide useful information for designing effective HACCP plans which prevent or eliminate significant hazards or reduce them to acceptable levels. The FDA Hazards Guide should be consulted for additional background information and greater detail into HACCP control procedures. Keep in mind that FDA provides generic information and examples that may not be appropriate for individual operations. The Tuna HACCP Guide draws from FDA recommendations, industry-sponsored studies and experience, and Seafood HACCP Alliance training programs to provide HACCP recommendations specific to the canned tuna industry. HACCP examples specific for canned tuna production are described in Chapter 6 of this handbook.

Summary of Relevant Hazard Control Strategies Provided in FDA Hazards Guide

<table>
<tr><td>Significant Hazard</td><td>Scombrotoxin (histamine) Formation</td></tr>
<tr><td>Reference, FDA Hazard Guide, 4th ed.</td><td>Chapter 7 (pages 113-152)</td></tr>
<tr><td>Description of the Hazard</td><td>“Certain bacteria produce the enzyme histidine decarboxylase during growth. This enzyme reacts with histidine, a naturally occurring amino acid that is present in larger quantities in some fish (e.g. tuna) than in others. The result is the formation of scombrotoxin (histamine). Histamine-forming bacteria are capable of growing and producing histamine over a wide temperature range. Growth of histamine is more rapid, however, at high-abuse temperatures (e.g., 70°F (21.1°C) or higher) than at moderate-abuse temperatures (e.g., 45°F (7.2°C)). Growth is particularly rapid at temperatures near 90°F (32.2°C)….Nonetheless, there are a number of opportunities for histamine to form under more moderate-abuse temperature conditions.” [source FDA Hazards Guide, p. 113]</td></tr>
<tr><td>Control Conditions</td><td>
Table 7-2 [p. 119 of FDA Hazards Guide]
Recommended maximum hours of exposure of scombrotoxin-forming fish to ambient temperatures greater than 40°F to prevent scombrotoxin formation after proper onboard harvest vessel chilling, for differing temperature exposure and previous processing conditions[1]
<table>
<tr><td rowspan="2">When the ambient temperature (°F) of exposure is...</td><td colspan="2">Then, the maximum hours of exposure time for...</td></tr>
<tr><td>Fresh fish (not heat processed or previously frozen) is...</td><td>Previously frozen fish, or heat processed fish (that has been exposed to possible recontamination), is...</td></tr>
<tr><td>> 70°F/21.1°C at any time</td><td>≤ 4</td><td>≤ 12</td></tr>
<tr><td>≤ 70°F/21.1°C during entire exposure</td><td>≤ 8</td><td>≤ 24</td></tr>
</table>
1. This table is a summary of the preceding recommendations [p. 117-118 in FDA Hazards Guide]. For complete understanding of the recommendations refer to the text in the FDA Hazards Guide.
</td></tr>
</table>

<table>
<tr><td>Significant Hazard</td><td>Pathogenic Bacterial Growth and Toxin Formation</td></tr>
<tr><td>Reference, FDA Hazard Guide, 4th ed.</td><td>Chapter 12 (pages 209-244)</td></tr>
<tr><td>Description of the Hazard</td><td>“It is reasonable to assume that pathogenic bacteria of various types...will be present on raw fish and fishery products and non-fishery ingredients…. Pathogenic bacteria can also be introduced during processing, even after cooking. Well-designed sanitation programs will minimize their introduction. However, in most cases, it is not reasonable to assume that sanitation programs will fully prevent the introduction of pathogenic bacteria. For this reason, controls should be in place to minimize the risk of pathogenic bacteria growth….S. aureus and B. cereus do not normally produce sufficient toxin to cause illness until numbers of the pathogen reach 100,000 to 1,000,000/gram. ... Limited growth of these pathogens might not compromise the safety of the product. However, time and temperature controls must be adequate to prevent growth before the infectious or toxic dose is reached” [source, FDA Hazards Guide, p. 209-211]

The FDA Hazards Guide states that firms should identify the most relevant pathogen(s) and target controls accordingly. In other communications they have identified Staphylococcus aureus as the pathogen of greatest concern in canned tuna processing because, if allowed to grow to significant numbers, toxin could be produced which would not be eliminated by subsequent thermal processing. Staphylococcus aureus is most likely to contaminate and grow on cooked tuna during cleaning and packing steps.</td></tr>
<tr><td>Control Conditions</td><td>In addition to recognizing the importance of an effective sanitation program, FDA provides the following minimum times to toxin production for various product temperatures, Appendix 4, Table A-2, p. 421 of FDA Hazards Guide.

<table>
<tr><th>Potential Hazardous Condition</th><th>Product Temperature</th><th>Maximum Cumulative Exposure Time</th></tr>
<tr><td>Growth and toxin formation by Staphylococcus aureus</td><td>50°F (7-10°C) [or below]
51-70°F (11-21°C)
Above 70°F (21°C)</td><td>14 days
12 hours
3 hours</td></tr>
</table>
</td></tr>
</table>

Significant Hazard	**Allergens and Food Additives**
Reference, FDA Hazard Guide, 4th ed.	Chapter 19 (pages 355-384)
Description of the Hazard	"A number of foods contain allergenic proteins, which are natural constituents of the food that can pose a health risk to certain sensitive individuals. … The [Food Allergen Labeling and Consumer Protection] Act defines the following eight foods and any ingredients that contain protein derived from these eight foods…as major food allergens: • Milk; • Eggs; • Fish (e.g., bass, cod, or flounder); • Crustacean shellfish (e.g., crab, lobster, or shrimp); • Tree nuts (e.g., almonds, pecans, or walnuts); • Peanuts; • Wheat; and • Soybeans. .." [Source FDA Hazards Guide, p. 355]
Control Conditions	"Labeling controls that are designed to ensure that any major food allergen that is present in a food is declared on the label are the most effective means of controlling this hazard. However, such controls are not suitable to prevent the unintentional introduction of allergenic proteins from foods that contain these allergens into foods that are not intended to contain them, through cross-contact….Unintentional introduction of allergenic proteins should be controlled through rigorous process controls, either as part of a prerequisite program or as part of the … (HACCP) program itself." [Source FDA Hazards Guide, p. 356] Tuna processors should carefully identify and source ingredients added to canned tuna products since they may contain non-fish allergens which would also require labeling.

Significant Hazard	**Metal Inclusion**
Reference, FDA Hazard Guide, 4th ed.	Chapter 20 (pages 385-394)
Description of the Hazard	"Ingesting metal fragments can cause injury to the consumer. .. FDA's Health Hazard Evaluation Board has supported regulatory action against products with metal fragments 0.3 inch (7 mm) to 1 inch (25 mm) in length…In addition, foreign objects that are less than 0.3 inch (7 mm) may cause trauma or serious injury to persons in special risk groups, such as infants, surgery patients, and the elderly…Metal-to-metal contact (e.g., mechanical cutting or blending operations and can openers) and equipment with metal parts that can break loose (e.g., moving wire mesh belts, injection needles, screens and portion control equipment, and metal ties) are likely sources of metal that may enter food during processing." [Source FDA Hazards Guide, p. 385]
Control Conditions	"…metal fragments may be detected in the finished food by an electronic metal detector. The use of electronic metal detectors is complex, especially with regard to stainless steel, which is difficult to detect. The orientation of the metal object in the food affects the ability of the equipment to detect it. For example, if a detector is not properly calibrated and is set to detect a sphere 0.08 inch (2 mm) in diameter, it may fail to detect a stainless steel wire that is smaller in diameter but up to 0.9 inch (24 mm) long, depending on the orientation of the wire as it travels through the detector. Processing factors, such as ambient humidity or product acidity, may affect the conductivity of the product and create an interference signal that may mask metal inclusion unless the detector is properly calibrated. You should consider these factors when calibrating and using this equipment. Finally, the hazard of metal inclusion may also be controlled by periodically examining the processing equipment for damage that can contribute metal fragments to the product. This measure will not necessarily prevent metal fragments from being incorporated into the product, but it will enable you to separate products that may have been exposed to metal fragments. Visually inspecting equipment for damaged or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire mesh belts. More complex equipment that contains many parts, some of which may not be readily visible, may not be suitable for visual inspection and may require controls such as metal detection or separation." [Source FDA Hazards Guide, p.385] X-ray equipment is commonly used by tuna canneries because metal cans and foil pouches prevent the use of conventional metal detection equipment. X-ray equipment also requires proper periodic calibration and sensitivity adjustment performed by trained technicians. Some companies visually check equipment for evidence of no breakage while others (notably processors that produce precooked loins for canning at another plant) are likely to use conventional metal detection equipment. Controls must be appropriate and effective.

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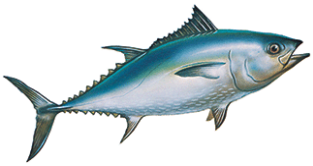
CHAPTER 4



PREREQUISITE PROGRAMS

Traditional and proven HACCP programs are built from three basic steps or parts which are described in Chapter 5. However, HACCP is not a stand-alone program and MUST be built on a foundation of proper sanitation, cGMPs and other prerequisite programs. Prerequisite programs (PRPs) contain the control procedures and practices that provide the basic proper operating conditions and environment necessary for the production of safe and wholesome quality food. Unlike critical control points (CCPs), which are meant to directly control or eliminate a food safety hazard, PRPs control the conditions of the food manufacturing plant environment that contribute to the overall safety of the product, thereby reducing the likelihood of a hazard occurring.

For example, in a tuna processing plant environment, employees who work on the butchering line represent a histamine contamination threat to the finished product. A program should be in place to control the movement of employees to prevent cross contamination between raw and pre-cooked materials in a tuna plant. The program for the control of employee movement and personnel hygiene would not directly control the hazard, i.e., the formation of histamine in precooked tuna before freezing or retorting, but it would reduce the risk of cross-contamination with histamine-forming bacteria and thus minimize the hazard.

By reducing risk, PRPs serve to sustain the justification for not adding a particular potential hazard to the HACCP plan. If any portion of the PRPs is lacking, then additional CCPs may be required until adequate PRPs are implemented. For example, a facility might have a piece of equipment or food-contact surface which is not feasible to rinse and sanitize during processing. The processor might have to implement additional CCPs or strengthen hazard control measures, e.g. reduce time of exposure for materials processed on that equipment.

The PRPs which support the HACCP plan can be grouped into general categories, for example:

- **Control of Incoming Materials, Ingredients, Packaging, and Non-Food Compounds,**
- **Control of Environmental Conditions and Physical Factors,**
- **Control of Manufacturing Operations, In-Process Food Material, and Rework**
- **Training, Supervision & Control of Employees, Contractors, and Visitors,**
- **Traceability, Recalls and Control of Finished Product & Non-Conforming Product.**
- **General Maintenance, Pest Control, and Sanitation**

Another related category would be **Site Security & Food Defense** which can impact food safety as well as food security.

Examples of some Common Prerequisite Programs used by the Canned Tuna Industry

- Supplier approval & monitoring (vendor certification)
- Incoming raw material quality evaluation
- Primary packaging material incoming evaluation
- Receiving, storage and handling of chemicals, allergen ingredients, lubricants, etc.
- General food hygiene training for tuna handlers
- Technical training for employees monitoring CCPs and their supervisors
- Employee health, cleanliness & conduct
- Equipment design, construction & installation
- Cleaning & sanitation of food-contact surfaces, equipment and implements

A list of PRPs can be found at the end of this chapter; however, the exact set of PRPs will vary since their application is facility specific.

REQUIRED PREREQUISITE PROGRAMS

Many of the conditions and practices of prerequisite programs are specified in federal, state and local regulations and guidelines, e.g., 21 CFR 7, Recalls; 21 CFR 110, Current Good Manufacturing Practice (cGMP); 21 CFR 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF); 21 CFR 123, Seafood HACCP; and the current edition of FDA's Fish and Fishery Products Hazards and Controls Guide.

Furthermore, section 123.11 of FDA's Seafood HACCP Regulation requires implementation of minimum sanitation control measures that relate to eight specific cGMP items:

1. Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
2. Condition and cleanliness of food contact surfaces, utensils, gloves, and outer garments;
3. Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
5. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces;
8. Exclusion of pests from the food plant.

Compliance for these **eight key sanitation conditions** must be in conformance with the cGMP Regulation (21 CFR 110), and the processor must be able to demonstrate conformance through written monitoring records. Some specific sanitary practices and controls designed to help the tuna industry to comply with this section of FDA's Seafood HACCP Regulation are discussed in more detail in Chapter 7 of this handbook.

Pre-requisite programs for control of food safety hazards relevant to seafood products, at a minimum, must address all eight (8) key sanitation conditions contained in 21 CFR 123.11.

1. Safety of water
2. Condition and cleanliness of food contact surfaces
3. Prevention of cross-contamination
4. Maintenance of hand-washing, hand-sanitizing and toilet facilities
5. Protection from adulterants
6. Labeling, storage and use of toxic compounds
7. Employee health conditions
8. Exclusion of pests

Although they involve more than just plant sanitation, these control measures are typically called **Sanitation Control Procedures** (**SCP**s), and the documents where they are contained are called Sanitation Standard Operating Procedures (SSOPs).

Although they involve more than just plant sanitation, FDA uses the term 'Sanitation Standard Operating Procedures' or **SSOPs** to refer to the written procedures for compliance with the sanitation control requirements of section 123.11 of the Seafood HACCP Regulation, and to differentiate these documents from the Standard Operating Procedures (SOPs) documents that are typically associated with hazard control procedures and HACCP plans.

Although the regulations do not require written PRPs or SSOPs, significant sanitary control measures should be detailed in written procedures to ensure they are performed properly, and processors should recognize and take credit for their written SSOPs and PRP procedures which substantiate their commitment to ensuring the safety and quality of their product. Guidance for writing SSOPs is provided in Appendix 2.

MANAGING PREREQUISITE PROGRAMS

PRP Monitoring and Corrections

Similar to the monitoring requirements for CCPs, FDA regulations require that PRP elements and control practices, activities and conditions be regularly monitored. At a minimum, monitoring must be sufficient to demonstrate conformance with regulations, i.e. Current Good Manufacturing Practices, Seafood HACCP, LACF, etc., as applicable. For PRPs, the frequency of monitoring should be sufficient to ensure the requirements of the PRP are consistently met.

Departures from the established practices, non-conforming results, or conditions that do not meet the specific PRP standards must be corrected and verified to ensure compliance. This must be adequately documented also, i.e., records must be available showing that the noncompliance was adequately corrected.

Verification and Reassessment

Unlike CCP monitoring records and corrective action records which must be reviewed by regulation, review of PRP records is not required by the regulations. However, it is advisable that processors review PRP and sanitation records regularly, and record review, as well as other verification activities, should be an integral part of PRP programs.

Verification actions are 'spot checks', document reviews, and other auditing activities that are additional to routine monitoring procedures and are carried out by someone other than the individuals performing the task being verified (i.e. monitors cannot verify their own work).

The frequency of reviews and verification should be sufficient to confirm that the program remains in control of any threats to the safety of the product, and should be set according to risk level and relative impact on food safety of the prerequisite element being assessed. For example, whereas monthly luminometry testing to verify the effectiveness of food-contact equipment cleaning procedures might suffice for a non-allergen production line, more frequent verification might be required on a line used to process products containing different allergens because of the significance of the potential allergen hazard. Food-contact equipment used for packing non-allergen products in a facility that also packs products containing allergenic ingredients probably should be verified after each occurrence that allergen containing products are processed, i.e., before packing non-allergen product.

Once PRPs are in place, they will need to be assessed, updated or enhanced as needed, e.g., when changes are made to buildings, facilities, equipment, environmental conditions, etc., to ensure the programs remain relevant and effective, and the required controls and conditions are maintained over time.

RELATIONSHIP TO HACCP

Certain procedures and aspects of a prerequisite program are regularly included in HACCP plans as verification procedures. For example, set-up and preventive maintenance procedures of certain processing equipment, or the calibration of measuring instruments, are typical verification activities for CCPs in HACCP plans. Sanitation/cGMP controls may even be included in the HACCP plan itself, e.g., environmental monitoring for pathogens, or control of ambient temperature in processing areas for histamine or *Staphylococcus aureus* enterotoxin control can be written and managed as part of a facility's HACCP plan.

Another example would be a processor of frozen precooked tuna loin material who receives the loins from processing facilities that process the raw tuna under U.S. FDA compliant cGMP and HACCP programs. Their supplier control and incoming material evaluation PRP program could include testing incoming material for histamine and *Staphylococcus aureus* which are hazards that would typically be managed as part of a HACCP plan. Their suppliers already control these hazards, but as part of their supplier qualification programs and Certificate of Analysis verification programs, the facility receiving the pre-processed tuna loins choose to have additional control measures which may or may not be part of their own HACCP program.

Regardless of whether cGMP and sanitation controls are incorporated into the HACCP plan or not, these controls are essential to the effectiveness of the HACCP plan. In fact, both types of controls, the cGMP or sanitary controls that support the HACCP plan and the HACCP plan itself, are so interrelated that in many cases the written programs will contain both sanitary control measures and HACCP procedures in the same documents.

For example, a processor that handles allergenic ingredients could choose to develop a written allergen control program incorporating cGMP and non-HACCP preventive controls like employee training, segregation during storage, validation of cleaning procedures, prevention of cross-contact during processing, product label supplier control, and incoming label inspection, together with the actual HACCP preventive control of product labeling all included in the same comprehensive 'SOP' document.

DIFFERENTIATING HACCP AND SANITATION CONTROLS

Food safety hazards associated with preserving and processing tuna, or any product, must be controlled if there is a significant and reasonably likely chance of the hazard to occur in the absence of controls. The selection of appropriate controls is determined by the nature of the hazard and which strategies are known to be most effective. In most cases the two control

systems available to processors, PRPs and HACCP, must both be in place to be effective, and neither system takes priority over the other.

HACCP controls address hazards specific to the products produced and to processing steps, while PRP or sanitation-type controls typically address the overall processing environment, facilities and employee practices. For example, hand washing is a general employee practice not specifically related to the product or to a processing step. Likewise, routine cleaning of food contact surfaces is not specifically related to a single product or a particular processing step. Histamine, however, is a hazard specific to processing and preserving certain species of fish, e.g., tuna. *Staphylococcus aureus* is not specific to certain species but is a hazard caused by transferring bacteria from humans or, less commonly, from processing equipment to the product and which is then allowed to grow over time.

Examples of hazards that are controlled by a HACCP plan or by a **Sanitation Control Procedure** (**SCP**) are shown in Table 1 below.

Table 1. Examples of hazards and method of control

Hazard	Control Measure	Location of Control	Type of Control	Control Program
Histamine	Control of Exposure Time to Temperatures Favorable for Histamine Formation	Time-Intensive Processing Steps where Tuna is Exposed	Product Specific & Process Step Specific	HACCP
Histamine	Thermal Inactivation of the Responsible Bacteria & Enzyme	Pre-cooker	Product Specific & Process Step Specific	HACCP
Histamine	Limit employee movement between raw and cooked areas	Entrance to Post-Pre-cooker & Fish Cooling Areas and to Cleaning & Packing Rooms	Employee	PRPs/SCP
Staph. aureus	Time & Temperature Control	Pre-cooked Fish Handling to Steam-on in Retort	Processing Step	HACCP
Staph. aureus	Employee Health	Cleaning & Packing Rooms	Employee	PRPs/SCP
Staph. aureus	Clean and sanitize food contact surfaces	Cleaning & Packing Rooms	Plant Environment	PRPs/SCP
Contamination with Pathogens	Wash Hands before Touching In-Process Unfinished Product	From Pre-cooked Fish Handling to Packaging Step	Employee	PRPs/SCP
Chemical Contamination	Use only food-grade lubrication grease	Plant Areas where Tuna is Exposed	Plant Environment	PRPs/SCP

EXAMPLES OF PREREQUISITE PROGRAMS

The following is a non-exhaustive list of programs that will most likely need to be considered and implemented as prerequisites by tuna processing facilities wishing to produce for the US market.

Premises, Buildings & Facilities

- Exterior Areas
- Building Design, Construction and Maintenance
- Lighting, Ventilation and Ambient Temperature Control
- Waste and Inedible Food Disposal
- Employee Facilities and Hand Washing Stations
- Implement and Utensil Cleaning and Sanitizing Facilities

Utilities

- Water, Steam and Ice
- Air and Gases

Site Security and Food Defense

Material Specifications

- Raw Materials
- Ingredients
- Packaging
- Non-Food Compounds

Purchasing, Receiving, Storage and Transportation

- Supplier and Service Provider Approval and Verification
- Purchasing, Receiving and Shipping
- Transportation, Storage and Handling
    - Raw Material
    - Ingredients
    - Packaging Material
    - Non-Food Compounds
    - Finished Products

Equipment

- Implements
- Production Equipment
  - Equipment Design, Construction & Installation
  - Commissioning
  - Set-up and Preventive Maintenance
- Measuring and Monitoring Devices
  - Maintenance and Calibration

Personnel

- Training and Supervision
  - General Food Hygiene Training
  - Technical Training
- Hygiene and Health Requirements
  - Cleanliness and Conduct
  - Communicable Diseases and Injuries

Sanitation

- Cleaning and Sanitation
- Pest Management

Contamination Control

- Biological, Physical and Chemical Contamination Control
- Cross-contamination Control

Production Specifications

- Preparation, Holding and Handling
  - Raw Materials
  - Ingredients
  - Direct-Contact Packaging
- In-Process Product Specifications and Control
- Container Fill Control
- Refrigeration and Freezing
- Rework and Remanufacture

Allergen Control and Management

Traceability, Recalls and Control of non-Conforming Product

- Product Coding and Labeling
- Non-conforming Product Storage, Handling and Control
- Recall Plan

Product Specifications

- Product Development & Modifications
- Product Formulations and Recipes
- Finished Product Specifications

Complaint Handling

Managing a comprehensive food safety system that combines PRPs and HACCP plans can be challenging. Some companies may find it helpful to develop a matrix which identifies programs and documentation that comprise the food safety system. An example of such a matrix is in Appendix 8.

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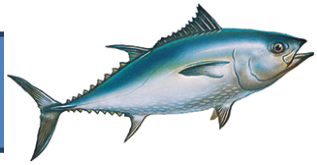
CHAPTER 5



BUILDING A HACCP PROGRAM

There are three basic parts to developing an effective HACCP program. Use of this approach ensures compliance with the FDA mandates, and it provides an easy format to explain the program and communicate with inspectors and other companies.

Three Basic Parts for HACCP Program development:

Part 1. Product and Process Descriptions
Part 2. Hazard Analysis (required by FDA regulations)
Part 3. HACCP Plan (written plan required by FDA regulations)

Part 1. Product and Process Descriptions

PRODUCT DESCRIPTIONS should include:

- Particular tuna species (market name) and source
- Initial product form and size as received
- Final product form, type of packaging, and method of distribution
- Intended use and/or consumers

Details in the product descriptions will help determine possible seafood safety hazards that are reasonably likely to be associated with the final product forms and intended uses. The final product form should represent what is produced at the specific facility. For example the final product form for a facility producing frozen loins is not canned tuna for the consumer but rather frozen loins intended for further processing.

PROCESS DESCRIPTIONS (including a flow diagram of the processing steps)

The process description will help define the specific processes or steps involved to produce a certain tuna product. All of these initial considerations can influence decisions for certain HACCP controls and monitoring procedures for a specific or particular operation. Although most canned tuna is processed in a similar manner, each processor must develop a HACCP plan specific for its individual processing operations. If a factory produces both canned tuna and

frozen loins, it would need to develop two separate HACCP plans, one for canned tuna and one for frozen loins.

Part 2. Hazard Analysis

An initial hazard analysis is required to ensure all potential seafood safety hazards that 'are reasonably likely to occur' are identified and can be controlled. The hazard analysis will identify certain critical control points (CCPs) that must be monitored in the final HACCP Plan. Although a written hazard analysis is not required, the NFI Tuna Council strongly recommends that a written hazard analysis be maintained for future reference and for use in justifying the HACCP plan or requirements for changes and additions.

> Each processing operation must conduct, or have conducted for it, a hazard analysis [21 CFR 123.6(a)]
>
> **The Tuna Council strongly recommends maintaining the hazard analysis in written and documented format**

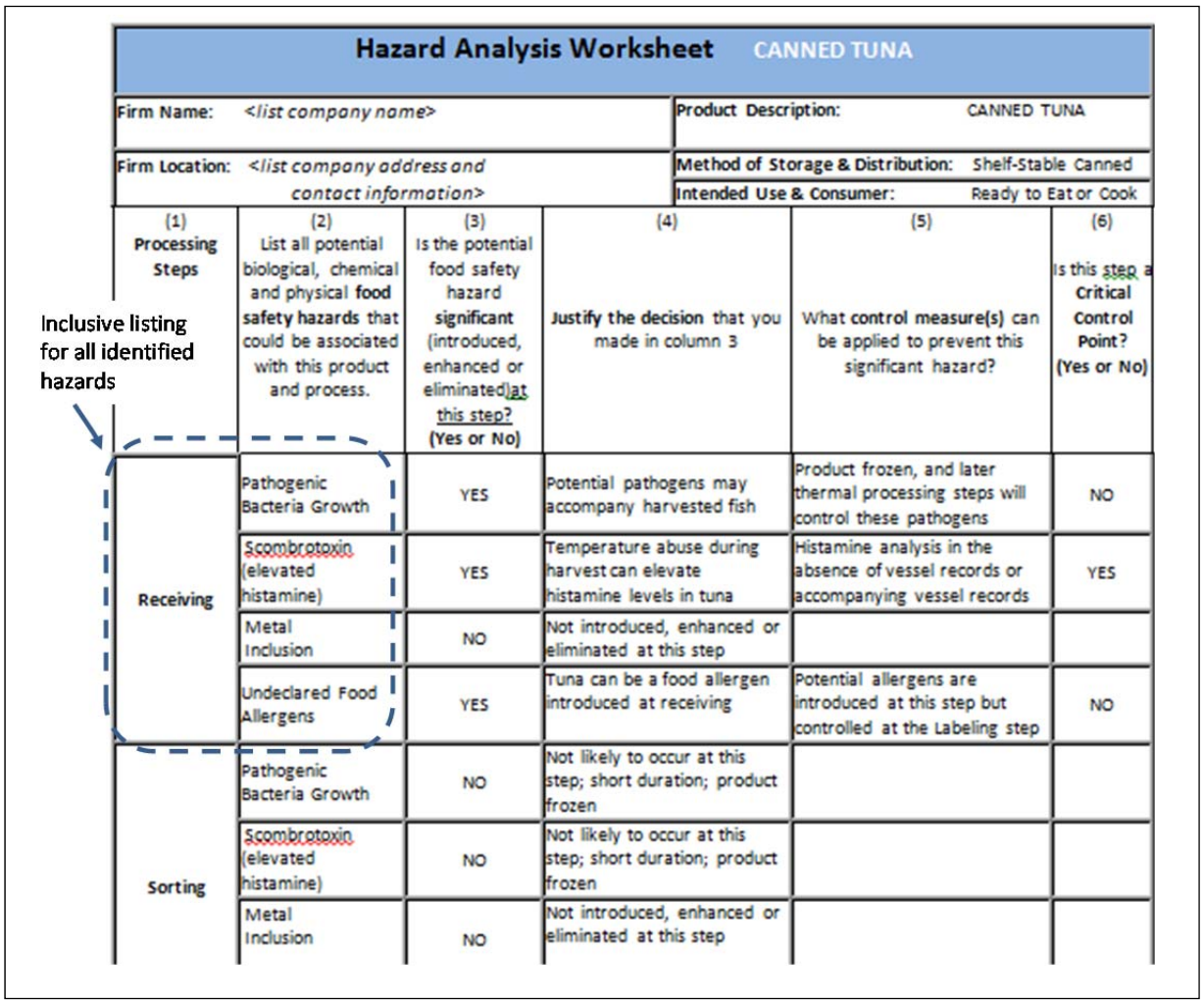
A basic hazard analysis form can be used to help identify the best location for controls for all of the potential identified hazards (Appendix 10 - HACCP Forms). The Tuna Council recommends use of the so-called 'Inclusive Approach' to account for potential controls for all hazards across all processing steps. The Inclusive Approach was introduced through the training programs developed by the Seafood HACCP Alliance to provide a more convenient and more obvious approach to assure appropriate controls for all potential hazards.

The Inclusive Approach simply lists all identified potential hazards (see Chapter 3 for how to identify the potential hazards) at each processing step to determine the necessary controls for all hazards through the entire process (Figure 1). This approach replaces the traditional method that initially attempted to put the identified hazards in various categories (biological, chemical or physical) and assume processing steps where the hazards may be introduced. The inclusive approach still assures considerations for proper controls but avoids initial categories and assumptions that complicate the development of the HACCP plan.

Inclusive Approach for Hazard Analysis

- Replaces the traditional method that initially attempted to put the identified hazards in various categories (biological, chemical or physical).
- Simply list all identified potential hazards at each processing step to determine the necessary controls for all hazards through the entire process.

Figure 1. Illustration for the initial use of the 'Inclusive' listing for all identified hazards and the questions to direct completion of the Hazard Analysis form (Appendix 10)



Hazard Analysis Worksheet CANNED TUNA

Firm Name: *<list company name>*	Product Description: CANNED TUNA
Firm Location: *<list company address and contact information>*	Method of Storage & Distribution: Shelf-Stable Canned
	Intended Use & Consumer: Ready to Eat or Cook

Inclusive listing for all identified hazards

(1) Processing Steps	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receiving	Pathogenic Bacteria Growth	YES	Potential pathogens may accompany harvested fish	Product frozen, and later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	YES	Temperature abuse during harvest can elevate histamine levels in tuna	Histamine analysis in the absence of vessel records or accompanying vessel records	YES
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Tuna can be a food allergen introduced at receiving	Potential allergens are introduced at this step but controlled at the Labeling step	NO
Sorting	Pathogenic Bacteria Growth	NO	Not likely to occur at this step; short duration; product frozen		
	Scombrotoxin (elevated histamine)	NO	Not likely to occur at this step; short duration; product frozen		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		

The Hazard Analysis form leads to decisions for appropriate location and type of controls based on a series of questions about each identified hazard at each processing step (Figure 1).

- The first question to answer is in Column 3 – "*Is the potential food safety hazard significant (introduced, enhanced or eliminated) at this step?*"

- The second question to answer is in Column 4 – "*Justify the decision that you made in column 3*". For example, at the 'Receiving' step, the answer for the significance of metal inclusion is 'NO' because metal fragments are not introduced, enhanced or eliminated at the receiving step, but the answer is 'YES' for undeclared allergens because tuna is a potential allergen introduced at the receiving step.

- If an identified hazard is considered significant ('YES' answer in column 3), then the question in Column 5 – "*What control measures can be applied to prevent this significant hazard"* **must** be answered. The control can be at the current step or a later step in the process. If a control step is not identified, then the process is considered out of control and the HACCP program is not in compliance for food safety.

  In the example at the receiving step, the significant hazard for tuna allergens introduced at Receiving will be eliminated by a later processing step involving final product labeling to identify the potential hazard. Although the hazard for potential exposure to the tuna allergens persists through all processing steps, the hazard analysis has properly identified where the hazard was introduced and where it will be eliminated or controlled. The allergen hazard was not further enhanced during any intermediate processing steps. In contrast, metal inclusion that was considered not significant at the Receiving step, can be introduced at other processing steps and would require identification of a control at a metal detection step to eliminate the potential hazard.

Part 3. HACCP PLAN

The HACCP plan is an actual written document that describes the controls and monitoring procedures to prevent potential seafood safety hazards based on the seven (7) basic principles of HACCP.

> Every seafood processing operation or processor must have and implement a written HACCP Plan whenever a hazard analysis indicates one or more food safety hazards that are 'reasonably likely to occur' [21 CFR 123.6(b)]

The HACCP Plan must indicate:

1. All potential hazards based on Product and Process descriptions
2. The required **Critical Controls Points** (CCPs) as determined by the **Hazard Analysis**
3. The **Critical Limits** (CL) set for each CCP
4. The **Monitoring** procedures for each CCP and CL
5. **Corrective Actions** (CA)
6. **Verification** procedures to assure the HACCP Plan will work and is working
7. **Records** from all monitoring and related HACCP procedures

LISTING THE CRITICAL CONTROL POINTS (CCPS)

For each significant hazard that is identified during the hazard analysis, there are one or more points or steps in the process where the hazard can be controlled. These points or steps are called Critical Control Points (CCPs). A CCP should be a specific point in the process flow where application of a control measure effectively prevents, eliminates or reduces the hazard to an acceptable level. All CCPs must be listed in the HACCP plan.

> **A Critical Control Point (CCP**) is a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

CRITICAL LIMITS

A critical limit represents the boundaries that are used to ensure that a hazard has been controlled (prevented, eliminated, or reduced to an acceptable level) at each CCP. Critical limits must be based on what research or industry experience has scientifically demonstrated or proven as necessary to control the hazard. In some cases more than one critical limit will exist at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, a_w, available chlorine, and/or sensory parameters such as odor. Critical limits must also meet applicable government standards.

> **A Critical Limit** is the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Processors may find it advantageous to establish more stringent operating limits which could be used to allow better process control and to minimize deviations from critical limits.

MONITORING

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carryout corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to ensure that the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to in-line and on-going processes, with no time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often correctly indicate microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

Four required parts of **Monitoring** in HACCP

- What will be monitored?
- How will monitoring be performed?
- What is the frequency of monitoring?
- Who will conduct the monitoring?

CORRECTIVE ACTIONS

Corrective actions shall be taken when a critical limit is violated. While FDA's regulation does not require that corrective actions be predetermined by the processor, the Tuna Council strongly recommends that appropriate correction actions be listed in the HACCP plan. This will eliminate the need to reassess the HACCP plan each time a deviation from a critical limits occurs.

A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and the cause of the deviation is corrected.

Corrective Action components:

1. Identify the product that was produced during the process deviation, evaluate its safety and determine its disposition
2. Correct and eliminate the cause of the deviation and restore process control.

Corrective actions must assure proper deposition of the suspect products.

Steps to determine the correct disposition of suspect product:

Step 1: Determine if the product presents a safety hazard.
Step 2: If no hazard exists, the product may be released.
Step 3: If a potential hazard exists, determine if the product can be:
a) Reworked/reprocessed, or
b) Diverted for a safe use.
Step 4: If a food safety hazard does exist, the product must be rejected or destroyed.

VERIFICATIONS

Verifications include the procedures that are needed to ensure that the HACCP plan is designed properly and has been implemented correctly. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. The review of CCP monitoring, corrective action and verification records within one week of processing is a component of verification. *NOTE: The Tuna Council recommends reviewing HACCP records prior to product shipment.*

Types of Verification Procedures:

- Validation before the HACCP plan is implemented; e.g. Cooker Validations
- CCP verifications (regularly scheduled activities):
  - Calibration and accuracy checks for process-monitoring devices
  - Review of monitoring records
- HACCP system verifications (periodic activity)
  - Targeted sampling and testing
  - End-product testing for histamine levels
  - Third party HACCP audits
  - Periodic Regulatory Inspections and reports
- HACCP plan reassessment (annually)

RECORDS

Written records provide documentation of the HACCP plan and demonstrate that critical limits have been met and that appropriate corrective actions and verification procedures have been taken. Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

Types of records needed in a Tuna HACCP program:

1. The HACCP plan and supporting documentation
2. CCP monitoring records
3. Corrective action records
4. Verification records
5. Sanitation (SSOP) monitoring and control records

Information **required** on HACCP monitoring records and should be included on other records:

- Title of record (e.g. Tuna Receiving Log)
- Firm name and location
- Product identification (if applicable)
- Date and time of monitoring observation
- Actual measurement or observation taken
- Signature or initials of the person performing the monitoring activity
- Signature of the trained person reviewing the monitoring record and the date of review

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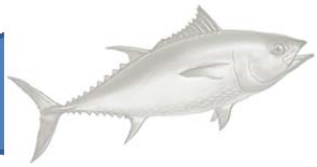
CHAPTER 6



EXAMPLES OF HACCP PROGRAMS

Three HACCP programs are provided in the Tuna HACCP Guide as examples for general guidance in preparing HACCP plans based on the FDA Seafood HACCP Regulation 21 CFR Part 123 and recommendations from the Tuna Council. The examples are not intended to apply to all processing facilities, but they do offer approaches that will be suitable for most canned tuna operations. Each tuna processing facility **must** develop a HACCP plan that specifically represents its particular products and processing methods. The discussion that accompanies each example provides some special thoughts to consider for approaches that may differ from the examples. The three selected examples include some of the most common processing operations for canning tuna, and they are also applicable to pouched tuna. The examples are strictly intended for training purposes only.

The three example HACCP Programs are distinguished by different colors:

Example 1. **CANNED TUNA from Frozen Round Tuna**

Example 2. **FROZEN PRECOOKED LOINS from Frozen Round Tuna**

Example 3. **CANNED TUNA from Frozen Pre-Cooked Loins**

Each example HACCP program is built with the three basic parts as explained in Chapter 5:

1. **Product and Process Descriptions** (including Flow Diagrams)
2. **Hazard Analysis** to determine the Critical Controls Points (CCPs) for all identified hazards through all processing steps (Inclusive Approach)
3. **HACCP Plans** to determine the controls for each CCP

Discussion sections accompany each part to provide explanations for the examples and additional information that should be considered in different operations. There is no one model that fits all tuna processing operations, and the FDA Seafood HACCP regulation requires that each different processing operation and location develop HACCP plans specific to the operation and product.

A Note About Traceability

Throughout the following HACCP examples, the ability to identify lots or batches of raw material, intermediate and finished products is essential for accurate monitoring, recording and verification activities, and, if implemented correctly, could significantly limit the scale of a corrective action.

Methods for initial lot identification and tracking of batches through subsequent handling and processing steps require a systems approach to trace planning, communication, training, reliable data collection and testing. Suggested forms provided in Appendix 13 include spaces for recording traceable lot and batch numbers but each company is responsible for linking codes and relevant records to an effective tracing system. Some plants use scanning technology to assist in this process. The subject of food traceability is discussed in detail in several review articles, including;

- National Fisheries Institute. 2011. Traceability for Seafood, U.S. Implementation Guide, version 1.1. (Available at http://www.aboutseafood.com/about/us-seafood-traceability-implementation-guide).
- McEntire, J.C. et al. 2010. Traceability (Product Tracing) in Food Systems: An IFT Report Submitted to the FDA, Volume 1: Technical Aspects and Recommendations, *Comprehensive Reviews in Food Science and Food Safety*, Vol. 9. (Available at http://bit.ly/IFTTraceReport).
- Regattieri, A., M. Gamberi, and R. Manzini. 2007. Traceability of food products: General framework and experimental evidence, *J. Food Engineering*, 81(2): 347-356. (Available at http://bit.ly/TraceabilityFramework).

Example 1. **CANNED TUNA from Frozen Round Tuna**

Part 1. Product and Process Description (Example for training only)

Product Description:

Canned tuna species can include:
- Albacore (*Thunnus alalunga*)
- Bigeye tuna (*Thunnus obesus*)
- Skipjack tuna (*Katsuwonus pelamis*)
- Yellowfin (*Thunnus albacares*)

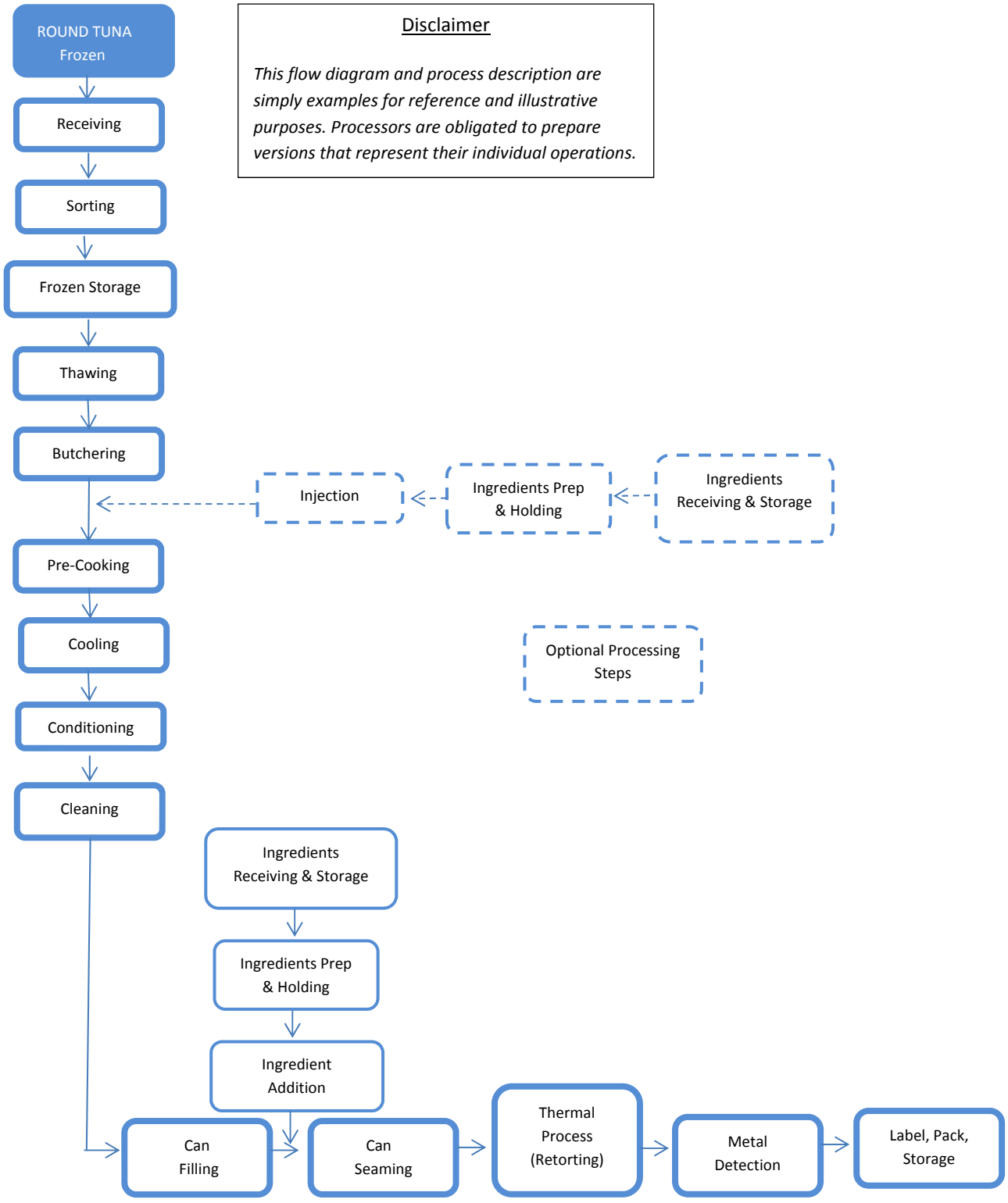
The tuna are harvested from wild sources, frozen on board vessel, and delivered frozen to the processing facilities directly from harvest vessels, refrigerated carrier vessels, and/or with intermediate trucking. Individual whole fish size can range from 1 to 100+ pounds.

The tuna is thawed and further processed for packaging as a low-acid food in hermetically sealed, rigid metal cans (e.g., 2-piece five ounce or seven ounce containers) that are thermally treated to prevent spoilage in non-refrigerated storage. The finished, canned products contain solid tuna pieces, chucks and/or flakes packed in water, olive oil or vegetable oil that may be seasoned with salt and/or vegetable broth and may include other approved ingredients.

Canned tuna is processed as a ready-to-eat product to be consumed by the general public.

Process Flow Diagram

Example 1. CANNED TUNA from Frozen Round Tuna



Disclaimer

This flow diagram and process description are simply examples for reference and illustrative purposes. Processors are obligated to prepare versions that represent their individual operations.

Process Description

For training purposes, the process description is outlined in the following table with three columns. The first two columns describe the processing procedures for each step used for Example 1. The third column discusses possible variations or considerations for each processing step. This accompanying column provides some guidance for operations that may different from Example 1.

Example 1. CANNED TUNA from Frozen Round Tuna

Processing Steps	Example 1 Procedures	Possible Variations and Considerations
Receiving	Whole frozen tuna are delivered directly from the harvest vessels with or without intermediate trucking. The tuna are unloaded into large steel boxes (scows) or bins that are identified for fish source and lots. The tuna arrive as frozen whole fish 'in the round' (non-eviscerated). There may be no vessel records that support time and temperature handling conditions immediately upon harvest, but the catch can be identified by 'lots' per vessel and single species. All incoming tuna is subject to sensory and analytical measures for product quality and safety (e.g., sensory and histamine analysis). Portions of each lot are placed in separate bins as 'test samples or test packs' for histamine and sensory analysis. For direct deliveries, all lots are distinguished by single species per harvest vessel and some lots can be distinguished by the well or hatches on a harvest vessel. Lot sizes can range from 20-100 metric tons. For container deliveries, a lot can be a container load of a single species from	*Tuna can arrive as round (non-eviscerated) or eviscerated fish. The initial form and size of fish will eventually affect sorting for uniformity for thawing and further processing steps. The fish should be sorted by size during unloading to assist planning for proper thawing times and pre-cooking.* *Tuna can be previously frozen with blast or brining systems depending on fish type or vessel. For example, blast freezing is commonly used for albacore and brine freezing for smaller skipjack.* *Some operations may receive fresh tuna. Control measures for receiving fresh tuna should be adapted from recommendations in Chapter 7 of FDA's Hazards Guide.* *Be careful how a lot is defined. The initial distinction for a 'lot' or portion of the harvest is very important in HACCP controls that no longer allow later separation into 'sub-lots' as a method to direct acceptance of a questionable harvest. A defined 'lot' is usually linked to one vessel or the vessel collecting from other boats. A clear distinction by harvest vessel, vessel hatch, day of catch or some other measure must be able to define or specify a certain 'lot'. Individual lots will be analyzed with histamine and sensory tests for acceptance. If samples from the original identified 'lot' fail the required sensory and histamine analyses, then the entire lot could fail and cannot be re-sorted by sub-lotting for further*

Processing Steps	Example 1 Procedures	Possible Variations and Considerations
Receiving cont'd	a single harvest vessel.	*analysis for acceptance.* TIP: *The test pack should be thawed with proper controls to prevent any additional increase in histamine content before analysis. The analysis must be completed before the identified lot can be accepted for further processing. (See Appendix 3 – Histamine Testing and Sensory Test Packs)*
Sorting	During unloading, the tuna are sorted by size and species to assure uniform product for proper thawing and precooking.	*Identification of the original lots must be continued through any sorting for product size or species. The fish should be sorted by size during unloading to be prepared for proper thawing time and more uniform pre-cooking.*
Frozen Storage	Frozen storage is necessary for holding the whole frozen tuna. Storage temperatures should be lower than -18°C/0°F and the duration of frozen storage can be days, weeks, or a few months depending on supply and processing schedules. Operations should follow a FIFO schedule (first in, first out).	*Identification of the original lots must be continued in frozen storage*
Thawing	Frozen tuna must be thawed prior to butchering for pre-cooking. The fish will not be removed from frozen storage until the results from the analytical test packs confirm acceptance of the identified lot. At the thawing step, lots become process batches for proper thawing and pre-cooking. A thaw batch is composed of fish that are thawed together at the same time at the same thaw station and no more than the available pre-cooker capacity. Start of thawing is the time the first frozen tuna from a thaw batch is removed from the freezer or temperature-controlled ante-room.	*Lots of tuna should be sorted into smaller groups or 'batches' based on similar sizes that would thaw at a similar rate. Each thaw batch must remain linked with the original lot and identified through further processing steps. Thaw batch size depends on the thaw system and pre-cooker capacity.* TIP: *A 'lot & batch diagram' can be useful to help follow identity of the tuna through processing steps to final product forms and storage.* TIP: *Maintaining similar sized tuna (thickness) is necessary to control thawing rates and the required pre-cooking time.* *Recommendations in the FDA Hazards Guide (Chapter 7; page 119) indicate that the thawing methods should not expose the first thawed portions (external surface of the tuna) for more than 12 hours above*

Processing Steps	Example 1 Procedures	Possible Variations and Considerations
Thawing cont'd	The ante-room is maintained below 4.4°C/40°F. The thawing procedure involves submersion of similar batches of round tuna into clean, flowing water to achieve a targeted internal or backbone temperature approaching 0°C/32°F. The water temperature can be maintained by steam injection. During the thawing process tuna is exposed to external temperatures (thaw water or ambient conditions) above 21.1°C/70°F, so the total cumulative time from start of thawing until pre-cooking is less than 12 hours.	*4.4 ℃/40 ℉, if the exposure temperatures (tuna surface during thawing) are greater than 21.1 ℃/70 ℉.* *For batches of larger tuna that may require longer than12 hours thawing time, validation trials should be conducted to support that thawing procedures do not result in a histamine risk. This would involve targeted studies which profile time, temperature and histamine levels in fish representative of the worst case scenario.* *Additional thawing procedures may be required for larger frozen tuna that cannot be thawed within 12 to 24 hours without some exposure to temperatures above 21.1 ℃/70 ℉. Optional thawing procedures should be validated with considerations for proper sanitation and heat exchange consistent with FDA recommendations as noted in Guide pages 117-118. Prior commercial thawing practices with larger tuna suggest options are available without compromising product safety due to elevated histamine.* *NOTE: If the ambient conditions for thawing are less than 21.1 ℃/70 ℉, the total accumulative time for product exposure above 4.4 ℃/40 ℉ must be less than 24 hours. This approach may require refrigerated or air conditioned thawing areas.* *Tuna can be thawed by water or air exposure. Water should be potable quality (e.g., municipal sources). Clean sea water can be used if taken from approved areas and subject to bacterial controls.* TIP: *Additional sensory evaluations can be conducted on the thawed tuna to complement, but not replace the monitoring results from the test packs.*
Butchering	The thawed tuna can be hand eviscerated and split (if necessary) to prepare similar sizes (thickness) for more uniform thawing and pre-	*Metal inclusion due to breakage of knives or saw blades can be visually monitored at this step, and/or, with calibrated metal detectors (X-ray unit for cans and pouches) used to monitor for any possible metal fragments in*

Processing Steps	Example 1 Procedures	Possible Variations and Considerations
Butchering con't	cooking. This step uses hand labor with special knifes and saw blades that are monitored for obvious breakage. Detection of possible breakage or metal fragments is monitored with X-ray units at a later step. Similar sized tuna is placed on racks or trolleys for pre-cooking.	*the final products. The preferred method for monitoring should include metal detectors.*
Ingredients Receiving & Storage	Non-tuna ingredients (e.g., salt, oil, dried vegetable broth) are received from approved suppliers, purchased based on ingredient specifications. Ingredients are either tested and/or inspected or Certificates of Analysis (COA) verified at receipt. Ingredients are stored according to particular storage temperature requirements. Ingredients containing food allergens are stored in a separate, designated storage area. Records of ingredient lot codes are maintained for traceability.	*All ingredients should be food grade and monitored for safety through specifications and temperature controls at receiving. All ingredients will be subject to labeling for declared allergens and other regulations for finished product contents.* *Warehousing SSOPs with associated records are necessary to prevent adulteration of ingredients.*
Ingredients Prep & Holding	Ingredients are removed from storage and assembled for preparation based on product formula being produced.	*Continuous SSOPs are necessary to prevent potential allergen cross-contact and bacterial contamination.* *Identity of lot control of added ingredients must be maintained.*
Injection	Thawed or partially thawed tuna can be injected with ingredients to maintain product quality and cook yields during processing. All ingredients are food grade and subject to SSOP controls during preparation and handling. Depending on formulation, some injection ingredients may be potential food	*The injection step can involve needles to penetrate the tuna muscle. Metal inclusion due to breakage of needles can be visually monitored at this step and/or with calibrated metal detectors (X-ray unit for cans and pouches) used to monitor for any possible metal fragments in the final products. The preferred method for monitoring should include metal detectors.* *Continuous SSOPs are necessary to prevent*

Processing Steps	Example 1 Procedures	Possible Variations and Considerations
Injection cont'd	allergens that require label declarations.	*potential bacterial contamination.*
Pre-Cooking	Thawed and butchered tuna are pre-cooked in large steam cookers designed and controlled to assure a partial cook to coagulate the muscle protein and connective tissues so the edible portions can be removed from the tuna skeleton and skin. The heating schedule will vary by size of the tuna and cooking load. Proper pre-cooking time is based on continuous monitoring of the internal tuna temperature with probes in the thickest portion of tuna on designated locations on the cooking racks/trolleys. The targeted internal tuna temperature is 60°C/140°F as determined by a series of thermometer measurements when racks/trolleys exit the pre-cookers.	*In consultation with FDA, the Tuna Council has conducted validation trials to determine at least 60°C/140°F is necessary as the internal pre-cook temperature to prevent elevated histamine levels above regulatory limits during further processing steps after pre-cooking. The required internal cook temperature is known as the End-Point Internal Product Temperature (EPIPT) as allowed by FDA in controlling processes for cooking seafood.* *All pre-cookers must be validated and adjusted for uniform delivery of heat and determination of any designated positions for fish in the pre-cooker and locations for probing fish. (see Appendices 5 and 6 - Cooker Validation and EPIPT Monitoring Procedures).* *In some operations, the tuna remains in the cooker after pre-cooking such that the EPIPT would be based on probe measurements in the pre-cooker. This approach may require further validations for appropriate EPIPTs.* *Identity for the tuna lots and batches must be maintained at all times through all processing steps.*
Cooling	The pre-cooked tuna must be cooled prior to handling to remove the edible portions. The duration of cooling can involve an actual application of cool sprays/rinses and general holding or staging to allow product temperature equilibration. The pre-cooked tuna remains on the original cooking racks/trolleys during this period. The tuna is not handled or exposed to any contact with materials. Pre-cooked tuna temperature will exceed 21.1°C/70°F after pre-cooking	***Histamine Controls:*** *In consultation with FDA, the Tuna Council has completed validations to determine that exposure of pre-cooked tuna for less than 12 hours to ambient temperatures that may be greater than 21.1°C/70°F will not result in elevated histamine levels when the tuna has been pre-cooked to an EPIPT greater than or equal to 60°C/140°F.* *If the pre-cooked tuna is cooled, conditioned and handled (cleaning) in ambient temperatures less than 21.1°C/70°F (i.e., a refrigerated or air conditioned room), the duration for exposure could be extended beyond 12 hours based on further validations taking into consideration that tuna will exit*

Processing Steps	Example 1 Procedures	Possible Variations and Considerations
Cooling cont'd	and through cooling and may be exposed to ambient temperatures greater the 21.1°C/70°F throughout process prior to retorting. The total time from exiting the pre-cooker until the tuna is sealed in a can and the retort process starts is less than 12 hours.	*the pre-cooker at 60 ℃/140 ℉.*
Conditioning	Cooled tuna is allowed to 'rest' or condition for a more effective removal of the edible portions. The pre-cooked tuna remains on the original cooking racks during this period. The tuna is not handled or exposed to any contact with materials.	*Conditioning is best conducted in a separate or isolated area with specific routine SSOPs to protect the warm product. The duration for conditioning can be from 2 to 8 hours depending on product size and ambient temperature, but the total conditioning time is part of the cumulative exposure time (less than 12 hours) after pre-cooking until retorting the cans.*
Cleaning	When the partially cooked tuna has cooled enough to handle, the edible portion is cleaned from the tuna skeleton and skin. This process involves hand labor and use of knife blades that are monitored for obvious breakage. The total cumulative exposure time during cleaning until retorting the canned tuna is less than 3 hours.	***Controls for S. aureus toxins:*** *The Tuna Council is recommending a target for cumulative exposure time of less than 3 hours between initial product handling (cleaning and filling) and retorting the cans. This recommendation is based on responses to FDA's expressed concerns for potential toxin development due to potential, excessive growth of S. aureus that could be introduced during hand cleaning when the pre-cooked tuna is handled at temperatures above 10 ℃/50 ℉ that may also exceed 21.1 ℃/70 ℉.* *Likewise, the Tuna Council recommends a specific SSOP program to prevent S. aureus contamination of the pre-cooked tuna during cleaning through can retorting (see Chapter 7).* *NOTE: An alternative control for potential S. aureus growth is processing product at temperatures less than 21.1 ℃/70 ℉ which can allow up to 12 hours cumulative exposure time above 10 ℃/50 ℉ for cleaning through retorting the canned tuna (FDA Hazards Guide Chapter 12, pages 234-236 and table 12-5).* *The duration for cleaning is also part of the*

Processing Steps	Example 1 Procedures	Possible Variations and Considerations
Cleaning cont'd		*cumulative time for exposure (less than 12 hours) after pre-cooking until the canned product is retorted.* *Metal inclusion due to breakage of knife blades during cleaning can be visually monitored at this step and/or with calibrated metal detectors (X-ray unit for cans and pouches) used to monitor for any possible metal fragments in the final products. The preferred method for monitoring should include metal detectors.*
Can Filling	The edible, partially cooked tuna (loins and chunks) is loaded into cans using automated fillers.	*The duration for filling, ingredient additions and can seaming is also part of the cumulative time for exposure (less than 12 hours) after pre-cooking until tuna is retorted in cans **AND** the less than 3 hour limit from initial product handling (cleaning) until retorting the canned tuna.* *The Tuna Council recommends a specific SSOP program to prevent S. aureus contamination of the pre-cooked tuna during cleaning through retorting.* *Depending on formulation, some added ingredients may be potential food allergens that require label declarations.* *In some operations the can filling and/or ingredient addition steps could introduce metal fragments that would require monitoring with x-ray or other means to eliminate the fragments.* *NOTE: Coding and the control of proper can seaming must comply with FDA's 21 CFR Part 113 - Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation.*
Ingredient Addition	Addition of ingredients in the pre-filled cans will vary per product form, flavor and pack. This procedure includes steps to prepare and hold the ingredients prior to filling.	
Can Seaming	The filled cans are mechanically sealed or seamed and individually coded prior to loading the cans into the retort for thermal processing.	
Thermal Process (Retorting)	An established thermal process schedule is used to assure the proper level of bacterial lethality to produce a shelf-stable product.	*The proper retort process schedule must comply with FDA's 21 CFR Part 113 - Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation.*
Metal Detection	All canned product is subject to metal detection with an X-ray unit preset to monitor for potential fragments.	*Accuracy checks for x-ray units and/or metal detectors must be conducted and recorded daily and calibration checks annually or as needed.*

Processing Steps	Example 1 Procedures	Possible Variations and Considerations
Label, Pack, Storage	The individual retorted cans and final packaged units are labeled to declare product type and contents relative to net weight and possible food allergens of concern. The master case packed product is held in storage ready for distribution.	*The firm should assess the best location and periods for a food allergen CCP. For example for lithographed cans and pre-printed pouches the best location may be the filling station. In most cases this may involve more than one location and one time per batch.* TIP: *Like pre-printed lithographed cans, the packaging materials for pouched tuna or tuna in plastic cups are often pre-printed with the label information.*

PART 2. HAZARD ANALYSIS

Example 1. **CANNED TUNA from Frozen Round Tuna**

Identify Hazards

A previous hazard analysis, as illustrated in Chapter 3 using the FDA Hazard Guide, concluded that four potential hazards are 'reasonably likely to occur' in the production of canned tuna from whole frozen round tuna. The FDA Guide includes:

- Pathogenic Bacteria Growth
  - *Staphylococcus aureus* (*S. aureus*) growth and enterotoxin production
  - *Clostridium botulinum* (*C. botulinum*) growth and toxin production in reduced oxygen packaging (ROP); sealed cans
- Scombrotoxin (elevated histamine levels)
- Allergens and Food Additives
- Metal Inclusion

SPECIAL NOTE: Based on concerns expressed by FDA relative to potential exposure temperatures, the Tuna Council recommends specific limitations for the cumulative duration of exposure for the raw tuna during thawing until pre-cooking and for the partially cooked tuna after pre-cooking until can retorting to prevent potential elevated histamine levels. Likewise, the Tuna Council recommends similar limitations for duration of cumulative exposure of the pre-cooked tuna during cleaning until can retorting to prevent possible production of heat-stable enterotoxins that could result from excessive growth of any *Staphylococcus aureus* that could potentially be introduced during product handling. Concerns for potential *S. aureus* that could be introduced during the cleaning step after pre-cooking, cooling and conditioning should be specifically addressed with strict Sanitation Standard Operating Procedures (SSOPs) and the accompanying monitoring procedures and records (see Chapter 7 - SSOPs).

Identify Best Locations to Control Potential Hazards (CCPs)

As explained in Chapter 5 - Building a HACCP Program - the hazard analysis is used to identify the necessary CCPs. A basic hazard analysis form was used to help identify the best location for controls for all of the potential identified hazards (Appendix 10 - HACCP Forms). The 'Inclusive Approach' was used to account for potential controls for all hazards across all processing steps.

Hazard Analysis Worksheet	**Example 1. CANNED TUNA from Frozen Round Tuna**				
Firm Name: Canned Tuna Company 1			**Product Description:** CANNED TUNA from Frozen Round Tuna		
Firm Location: 1 Main Street, Anywhere			**Method of Storage & Distribution:** Shelf-Stable Canned		
			Intended Use & Consumer: Ready-to-Eat		
(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Receiving	Pathogenic Bacteria Growth	YES	Potential pathogens may accompany harvested fish Certain *C. botulinum* may accompany raw fish	Product frozen. Later thermal processing steps will eliminate these pathogens. LACF regulations and controls during thermal retorting.	NO
	Scombrotoxin (elevated histamine)	YES	Temperature abuse during harvest can elevate histamine levels in tuna	Histamine and sensory analysis in the absence of vessel records or accompanying vessel records	YES
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Tuna is a food allergen introduced at receiving	Potential allergens are introduced at this step but controlled at the Labeling step	NO
Sorting	Pathogenic Bacteria Growth	NO	Not likely to occur at this step; short duration; product frozen		
	Scombrotoxin (elevated histamine)	NO	Not likely to occur at this step; short duration; product frozen		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Frozen Storage	Pathogenic Bacteria Growth	NO	Not likely to occur at this step; product frozen		
	Scombrotoxin (elevated histamine)	NO	Not likely to occur at this step; product frozen		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet — Example 1. CANNED TUNA from Frozen Round Tuna

Firm Name: Canned Tuna Company 1	**Product Description:** CANNED TUNA from Frozen Round Tuna
Firm Location: 1 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready-to-Eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Thawing	Pathogenic Bacteria Growth	YES	Pathogen growth could occur at this step	Later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until pre-cooking	YES*
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Butchering	Pathogenic Bacteria Growth	YES	Pathogen growth could occur at this step	Later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until pre-cooking	YES*
	Metal Inclusion	YES	Potentially introduced at this step; use of cutting blades	X-ray (metal detection) at later step	NO
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Ingredient Receiving and Storage	Pathogenic Bacteria Growth	NO	While potential pathogens may accompany ingredients, dry ingredients and oil do not support their growth		
	Scombrotoxin (elevated histamine)	NO	Step does not involve tuna		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Some food allergen ingredients may be introduced at receiving	Potential allergens may be introduced at this step but controlled at the Labeling step	NO

Hazard Analysis Worksheet — Example 1. CANNED TUNA from Frozen Round Tuna

Firm Name: Canned Tuna Company 1	**Product Description:** CANNED TUNA from Frozen Round Tuna
Firm Location: 1 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready-to-Eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Ingredient Preparation & Holding	Pathogenic Bacteria Growth	YES	Pathogens could accompany preparation of ingredients	Procedures subject to SSOP and later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	NO	Step does not involve tuna		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Some food allergen ingredients may be introduced during preparation.	Potential allergens may be introduced at this step but controlled at the Labeling step	NO
Ingredient Injection	Pathogenic Bacteria Growth	YES	Pathogens could accompany injections	Procedures subject to SSOPs and later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until pre-cooking	YES*
	Metal Inclusion	YES	Potentially introduced at this step if metal injection needles used	X-ray (metal detection) at later step	NO
	Undeclared Food Allergens	YES	Injected ingredients could introduce potential food allergens	Potential allergens can be introduced at this step but controlled at the Labeling step	NO
Pre-Cooking	Pathogenic Bacteria Growth	YES	Previously introduced pathogens could survive pre-cooking	Later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	YES	Histamine production could persist without proper pre-cooking	Proper pre-cooking procedures will help prevent further histamine development	YES
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet — Example 1. CANNED TUNA from Frozen Round Tuna

Firm Name: Canned Tuna Company 1	**Product Description:** CANNED TUNA from Frozen Round Tuna
Firm Location: 1 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready-to-Eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Cooling	Pathogenic Bacteria Growth	YES	No direct contact with the pre-cooked tuna, but pathogens could be introduced during cooling	No product contact. Cooling subject to SSOP. Later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until retorting	YES**
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Conditioning	Pathogenic Bacteria Growth	YES	No direct contact with the pre-cooked tuna, but pathogens could be introduced during conditioning	No product contact. Conditioning subject to SSOP. Later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until retorting	YES**
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Cleaning	Pathogenic Bacteria Growth	YES	Pathogens could be introduced during cleaning Product handling could potentially introduce *S. aureus* that could grow to produce heat stable toxins if exposed to temperatures above 10°C/50°F	Cleaning subject to SSOP. Later thermal processing steps will control pathogens Specific SSOPs for *S. aureus* and control exposure time*** above 10°C/50°F from start of cleaning until retorting	YES*** (*S.aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until retorting	YES**
	Metal Inclusion	YES	Potentially introduced at this step; use of cutting blades	X-ray (metal detection) at later step	NO
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet	**Example 1. CANNED TUNA from Frozen Round Tuna**				
Firm Name: Canned Tuna Company 1			**Product Description:** CANNED TUNA from Frozen Round Tuna		
Firm Location: 1 Main Street, Anywhere			**Method of Storage & Distribution:** Shelf-Stable Canned		
			Intended Use & Consumer: Ready-to-Eat		
(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Can Filling	Pathogenic Bacteria Growth	YES	Pathogens could be introduced during can filling Potential presence of *S. aureus* could grow to produce heat-stable toxins	Can filling subject to SSOP. Later thermal processing steps will control pathogens. Specific SSOPs for *S. aureus* and control exposure time*** above 10°C/50°F from start of cleaning until retorting	YES*** (*S.aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until retorting	YES**
	Metal Inclusion	YES	Potentially introduced at this step during can filling	X-ray (metal detection) at later step	NO
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Ingredient Preparation & Holding	Pathogenic Bacteria Growth	YES	Pathogens could accompany preparation of ingredients	Procedures subject to SSOP and later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	NO	Step does not involve tuna		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Some food allergen ingredients may be introduced during preparation	Potential allergens may be introduced at this step but controlled at the Labeling step	NO

Hazard Analysis Worksheet — Example 1. CANNED TUNA from Frozen Round Tuna

Firm Name: Canned Tuna Company 1	**Product Description:** CANNED TUNA from Frozen Round Tuna
Firm Location: 1 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready-to-Eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Ingredient Addition	Pathogenic Bacteria Growth	YES	Pathogen growth could occur if delays in ingredient addition Potential presence of *S. aureus* could grow to produce heat-stable toxins if exposed to temperatures above 10°C/50°F	Procedures subject to SSOP and later thermal processing steps will control pathogens. Specific SSOPs for *S. aureus* and control exposure time*** above 10°C/50°F from start of cleaning until retorting	YES*** (*S.aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until retorting	YES**
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Added ingredients could introduce potential food allergens	Potential allergens can be introduced at this step but controlled at the Labeling step	NO
Can Seaming	Pathogenic Bacteria Growth	YES (*C. bot*) YES (*S. aureus*)	Pathogens could be introduced during can seaming Pathogens could be re-introduced after thermal process due to improperly formed seams Potential presence of *S. aureus* could grow to produce heat-stable toxins if exposed to temperatures above 10°C/50°F	Later thermal processing steps will control pathogens Proper seam formation is controlled through compliance with 21 CFR Part 113 for LACF Specific SSOPs for *S. aureus* and control exposure time*** above 10°C/50°F from start of cleaning until retorting	NO (*C. bot*) (controlled by 21 CFR 113) YES*** (*S. aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until retorting	YES**
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet — Example 1. CANNED TUNA from Frozen Round Tuna

Firm Name: Canned Tuna Company 1	**Product Description:** CANNED TUNA from Frozen Round Tuna
Firm Location: 1 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready-to-Eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Thermal Process (Retorting)	Pathogenic Bacteria Growth	YES	Pathogens survival through thermal process	Proper retort processing and post-process handling in accordance with 21 CFR Part 113 for LACF that includes controls for pathogens including any potential *C. botulinum*	NO (controlled by 21 CFR 113)
	Scombrotoxin (elevated histamine)	NO	Not likely to occur at this step; application of extensive heat		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Metal Detection	Pathogenic Bacteria Growth	NO	Not introduced, enhanced or eliminated at this step		
	Scombrotoxin (elevated histamine)	NO	Not introduced, enhanced or eliminated at this step		
	Metal Inclusion	YES	Some prior processing steps may have introduced metal fragments which will be eliminated at this step	Metal Detector (X-ray unit)	YES
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Label, Pack, Storage	Pathogenic Bacteria Growth	NO	Not introduced, enhanced or eliminated at this step		
	Scombrotoxin (elevated histamine)	NO	Not introduced, enhanced or eliminated at this step		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Tuna and injected or added ingredients could include potential food allergens	Monitor labeling designating tuna and other allergenic ingredients	YES

*Cumulative time of exposure of raw tuna from start of thawing to pre-cooking to prevent elevated histamine levels.
**Cumulative time of exposure of pre-cooked tuna from start of cooling until retorting cans to prevent elevated histamine levels.
***Cumulative time of exposure of pre-cooked tuna from start of cleaning until retorting cans to prevent potential *Staphylococcus aureus* growth and enterotoxin production.

PART 3. HACCP PLAN

Example 1. **CANNED TUNA from Frozen Round Tuna**

The hazard analysis identified 7 Critical Control Points:

1. **Receiving** to control incoming Scombrotoxins (elevated histamine levels)
2. **Cumulative time*** from beginning of Thaw through start of Pre-Cooking to control potential elevated histamine levels
3. **Pre-Cooking** to prevent subsequent histamine production
4. **Cumulative time**** from end of Pre-Cooking through start of Thermal Processing (can retorting) to prevent subsequent histamine production
5. **Cumulative time***** from start of Cleaning through start of Thermal Processing (can retorting) to control potential *S. aureus* growth and potential formation of heat-stable enterotoxin
6. **Metal Detection** to eliminate metal fragments or inclusions
7. **Labeling** to declare potential food allergens

HACCP Plan Form

The written HACCP plan provides a brief description of routine activities that will occur at all CCPs to prevent the identified potential hazards. The HACCP Plan form can be completed in either a portrait or landscape format (see Appendix 10 - HACCP Forms), but either form must include descriptions for:

- **CCP** or processing step
- **Significant hazards** involved
- **Critical Limits** specify the measure for control
- **Monitoring procedures**
  - What will be done
  - How will it be done
  - When will it be done (frequency)
  - Who will do it
- **Corrective Actions** to assure:
  - That no product under deviation enters commerce and
  - The root cause of the deviation is addressed
- **Records** taken as evidence for controls and reference
- **Verifications** to assure the HACCP plan and procedures will work and are working

HACCP Plan Cover Sheet

CANNED TUNA from Frozen Round Tuna HACCP Plan

Canned Tuna Company 1

1 Main Street, Anywhere

Date Issued:

Supersedes Version Dated:

Approved by:

Name/Title:	Signature:	Date:
_____	_____	_____
_____	_____	_____
_____	_____	_____

NOTE: Remember that the HACCP plan needs to be reviewed at least annually and approved (and signed) by the most responsible individual on site or higher in the corporation.

		CCP 1 CANNED TUNA from Frozen Round Tuna	
Critical Control Point (CCP)		Receiving	
Significant Hazard		Elevated Histamine Levels	
Critical Limits		Less than 30 ppm **histamine level** in individual tuna	No more than 2 tuna in a sample of 118 tuna/lot with notable sensory decomposition, or less than 2.5% if more than 118 tuna
Monitoring	What	Histamine level in lower, anterior portion of the tuna (near visceral cavity)	Sensory measures for whole tuna, same species in identified 'lot' for noticeable and persistent odors of decomposition
	How	Collect a minimum of 18 representative fish per lot (or the entire lot for lots with fewer than 18 fish) Perform analysis on composite of 3 samples using validated test method 10 ppm screening level. The validated test method is customized to monitor lower levels of histamine corresponding to the 10 ppm screening level. If test result for the composite is greater than or equal to 10 ppm and less than 30 ppm, then analyze individual fish samples using a validated method to monitor histamine corresponding to the less than 30 ppm Critical Limit.	Examine minimum of 118 tuna per identified lot or every fish if less than 118 in the lot for persistent and readily perceptible decomposition odors
	When	Every incoming lot	Every incoming lot
	Who	Assigned trained analytical specialist	Assigned trained sensory specialist
Corrective Action		If the histamine critical limit (30 ppm) on any individual fish is exceeded then reject the entire lot.	If only the sensory critical limit is exceeded, then tag and segregate the tuna from the lot; test 60 individual tuna for histamine including all tuna suspect for decomposition. • If any sample has histamine levels greater than or equal to 30 ppm, then reject entire lot. • If no sample has histamine greater than or equal to 30 ppm, then accept the lot for processing **AND** evaluate 100% of the tuna for decomposition **AND** discard any decomposed tuna, and pack and process acceptable fish without delay. Complete an investigation of cause and necessary corrections before continuing with supplier. Only continue use of supplier with extra monitoring until receive evidence of improved performance.
Records		• Sensory Assessment and Histamine Test records with controls and periodic verifications • Corrective Action records; including disposition of any rejections • Laboratory Audit reports and associated corrections • Training Records for sensory specialist and analytical specialist	
Verifications		• Monitoring record reviewed before accepting incoming lots for processing. • Weekly review (or prior to shipping products) of monitoring, verification, and corrective action records. • Routinely test control samples to accompany daily histamine analysis (internal lab QA) • Do quarterly comparison of histamine test results with AOAC method • Training program for sensory specialists (initial and annual refresher) • Periodic internal audits and annual formal audits by third party; include annual proficiency testing for each analyst	

DISCUSSION - CCP 1 Receiving

Critical Limit

This example of a CCP at receiving for controlling for elevated histamine levels has two control measures – histamine analysis and sensory examination for decomposition. Each control measure has associated critical limits, monitoring, corrective actions, records and verification procedures. Both critical limits must be met at this CCP.

Although the FDA Hazards Guide (Chapter 7) recommends a histamine limit of 50 ppm, the Tuna Council recommends a stricter limit of 30 ppm^ **at receiving** to prevent the introduction of higher risk raw materials into the process (FDA Hazards Guide, Table 7-4 page 136). FDA Hazards Guide suggests that greater than 30 ppm is an indicator of higher variability between individual fish and there was a limit of 30 ppm set to avoid accepting lots with high fish to fish variability.

^(10 ppm if composites for 3 tuna are tested)

Monitoring

In the absence of vessel records, the FDA Hazards Guide (Chapter 7, page 132) recommends use of histamine testing with three components; 1) histamine analysis, 2) sensory exams, and 3) internal temperature checks of fresh fish. (If fish is received frozen, internal temperature checks are not necessary).

Lot Identity

Lot size and identity must be described in a manner that accounts for similar fish in terms of species and a particular harvest vessel. Lots can be from single vessels per harvest trip or from a portion from a single vessel if the portions can be clearly distinguished within the individual vessel. Carrier vessels collecting from other harvest vessels should maintain harvest vessel identity and segregation.

Monitoring Histamine Levels

If histamine tests are based on composite samples, then adjust the acceptance level from 30 ppm per tuna to 10 ppm for a composite comprised from 3 tuna. The targeted sample size per tuna is 250 grams. If the tuna are small, the sampling location should still target the lower anterior portion and collect at least 50 grams per tuna.

Collect samples that represent fish from throughout the lot, for example, bins representing the start, middle and end of the lot as it is unloaded from the harvest vessel or containers (see Appendix 3 – Histamine Testing and Sensory Test Packs).

Damaged fish are culled out during unloading. These are fish that have been damaged as a result of mechanical or physical impact.

Analytical methods to measure histamine should be based on AOAC approved procedures or methods that have been validated against AOAC approved procedures. These methods can be qualitative or quantitative. Qualitative methods provide a 'pass' or 'fail' result, for example a color change. Quantitative methods provide discrete values of histamine readings, for example readings from a fluorometer.

Qualifying Suppliers

Fish from a new supplier or a supplier without an established history of problem-free deliveries may require a larger sample size. A qualified supplier is one that has an established history with the firm and has had four consecutive problem-free deliveries.

If one lot from a harvest vessel fails then treat all lots from the same harvest vessel delivery as if the supplier is a new suppler. If more than one lot fails, then reject all fish from the harvest vessel. More than one lot with high histamine from the same fishing vessel delivery can be indicative of poor harvest vessel practices.

Sensory Monitoring

Sensory examinations should be conducted by trained person(s). Training should include initial instruction with actual tuna samples and periodic and annual refresher courses to maintain ability and check analytical proficiency. Training should be similar to hands-on and nose-on courses offered by U.S. FDA staff and the National Marine Fisheries Service (NMFS/NOAA).

Corrective Actions

If histamine level is greater than or equal to 30 ppm in any individual fish, then reject the entire lot. If the qualitative or quantitative composite analysis is greater than or equal to 10 ppm, the Tuna Council recommends that a portion of the original retained samples be tested. If the quantitative composite analysis is greater than or equal to 30 ppm, then reject the entire lot with no further testing.

If no samples exceed the 30 ppm, accept the lot and proceed with processing and 100% sensory evaluation. When further sensory evaluation is necessary, industry practice is to establish a maximum tolerance for rejected decomposed tuna per lot. Once this tolerance is exceeded the entire lot is rejected. For example when 10% by weight is considered decomposed then reject the entire lot.

		CCP 2 CANNED TUNA from Frozen Round Tuna
Critical Control Point (CCP)		Thawing → Pre-Cooking *Cumulative Time
Significant Hazard		Elevated Histamine Levels
Critical Limits		Less than or equal to 12 hours from start of thawing until the start of pre-cooking
Monitoring	What	Cumulative exposure time
	How	Visual monitoring for time from when the first fish from the thaw batch starts thawing to when pre-cooking starts (pre-cooker steam on) for the last fish from thaw batch
	When	Every thaw batch; thaw batch is defined as a number of tuna that can be distinguished as one group from thaw through pre-cooking
	Who	Production and QA inspectors collecting progressive time monitoring across all processing steps
Corrective Action		If cumulative exposure time for a group of tuna exceeds 12 hours, then specifically identify the involved bins of tuna, segregate and immediately expedite processing through the pre-cooker. Conduct histamine analysis at end of cleaning for 60 tuna randomly selected from the identified racks. Testing can be done using composites of 3 tuna (20 composites). • If any composite is greater than 50 ppm, then reject the identified pre-cooker batch. • If any of the 20 composites exceeds 17 ppm but is less than 50 ppm histamine, then individually test each fish used in that composite. • If any individual fish sample is greater than 50 ppm, then reject the identified pre-cooker batch. Determine root cause and correct the cause for the excessive exposure time.
Records		• Total time exposure records for thawing to pre-cooking • Corrective Action records • Verification records • Training Records for CCP monitoring personnel
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records. • Weekly accuracy check for proper clock performance • Appropriate training program for new employees and annual refresher training for employees responsible for time monitoring.

*Cumulative time of exposure for raw tuna from start of thawing to pre-cooking to prevent elevated histamine levels

DISCUSSION - CCP 2 Cumulative Exposure Time for 'Thawing Until Pre-Cooking'

Critical Limit

The critical limit of less than 12 hours exposure to temperatures above 4.4°C/40°F is based on controls to prevent elevated histamine levels as recommended in the FDA Hazards Guide Chapter 7, page 119, table 7-2 when the tuna may be exposed to temperatures higher than 21.1°C/70°F. If the exposure temperatures are lower than 21.1°C/70°F, the exposure time limit above 4.4°C/40°F can be extended to no more than 24 hours.

The definition for when thawing starts may be different for some firms. If there is a lengthy staging time at temperatures above 4.4°C/40°F that impacts the product temperature, this will need to be accounted for in the overall 12 hour critical limit.

> As an example: Fish lots of a single species are brought from the freezer to be thawed and are transferred to the thaw tank bins and stacked in one of the thaw zones. When the required number of thaw bins are loaded into the zone the thaw water spray system is turned on and thaw cycle started.
>
> Fish backbone temperatures will be taken per Standard Operating Procedures. Once the specified backbone temperature of the thawing fish lot is reached, the thaw cycle is complete. The time the water is turned off shall be recorded.

The critical limit of time should be controlled to the start of pre-cooking – when the fish racks are placed inside the pre-cooker, doors are closed and steam is turned on

A more stringent operating limit can be used to allow better process controls and to minimize critical limit deviations.

Monitoring

Use of monitoring methods for cumulative time of exposure are recommended and recognized as an appropriate approach as illustrated for unrefrigerated processing of blue crabs in Chapter 12, page 240, Table 12-6 of the FDA Hazards Guide. A key function will be maintaining the identity of the identified group of tuna from time of thawing through all steps until racking and loading the pre-cooker for steam-on for pre-cooking. Likewise, the Production and QA inspectors must collect all involved exposure time across all processing steps. This information helps monitor for compliance with the critical limit as well as providing information necessary to support corrective actions to prevent future occurrences.

Chapter 7, page 145, Table 7-6 of the FDA Hazards Guide also illustrates the use of monitoring cumulative exposure time to control potential scombrotoxin formation during processing.

Corrective Actions

If there is a critical limit deviation, then the fish should be expedited through the pre-cook process to avoid any further time-temperature abuse. Samples should be collected at the end of the process.

The samples should be collected at the last possible step in the process in order to represent the worst case exposure time for fish impacted by the deviation. The minimum of 60 samples are taken at the end of cleaning stage. Samples are collected from loins and the flakes, proportional to production volumes of loins and flakes generated during cleaning. Samples from loins should be taken from the anterior end of the ventral loins. (The anterior end of the ventral loins will still be evident based on the shape of the four loin quadrants.) Similar to previous CCPs, the 60 samples can be analyzed as 20 composites of 3 samples each.

It is important that histamine results and lab procedures are precise and accurate. See histamine testing procedures in CCP 1 for guidance.

The FDA has set a guidance level of 50 ppm histamine in the edible portion of fish which is a very conservative measure to ensure safe product, mindful that illnesses have been associated with levels in excess of 500 ppm. FDA's guidance provides a ten-fold safety factor. (FDA Hazards Guide page 120.)

Verification

The accuracy of the digital or analogue clocks used for time tracking needs to be verified on a weekly basis against a known standard time keeping device such as found on a centralized computer or phone system. During the weekly accuracy check, synchronize all clocks that are used in plant for monitoring time across multiple processing areas.

		CCP 3 CANNED TUNA from Frozen Round Tuna
Critical Control Point (CCP)		Pre-Cooking
Significant Hazard		Histamine
Critical Limits		Minimum pre-cooker exit core temperature of 60°C/140°F
Monitoring	What	Core temperatures of 60°C/140°F for largest whole tuna or largest portions from the slowest heating location(s) in pre-cooker at pre-cooker exit
	How	Using a calibrated thermometer(s), conduct 24 internal temperature probes to measure fish core temperature at the geometric center of largest whole tuna or largest portions at exit from the pre-cooker (End-Product Internal Point Temperatures (EPIPT)).
	When	Every pre-cooker batch. Batch defined as one pre-cooker load.
	Who	Pre-Cooker Operator
Corrective Action		Immediately return racks of tuna to the pre-cooker or alternate pre-cooker, and continue heating to achieve proper core temperatures based on additional measures of 24 probe temperatures at exit from the pre-cooker. If not able to return racks of tuna to the pre-cooker, segregate, process rapidly and hold effected product. Evaluate with a process authority to assess safety and take appropriate actions. Or destroy product. Determine cause for the deviation and necessary corrections to regain proper pre-cooking controls.
Records		• Pre-Cooker Temperature logs • Corrective Action records • Verification records for pre-cooker operation and thermometers • Training Records for pre-cook operators
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Validations for uniform pre-cooker operation • Daily thermometer accuracy checks before use • Annual calibration of the thermometer against an NIST traceable reference thermometer

DISCUSSION - CCP 3 Pre-Cooking

Critical Limit

The recommended End-Point Internal Product Temperature (EPIPT) is based on studies conducted by companies within the Tuna Council. These studies validate that when the cold spot of the tuna reaches a minimum temperature of 60°C/140°F at the end of pre-cooking, histamine production is halted for sufficient time to allow pre-cooked fish to be converted to canned tuna (see Appendix 9 - References). Biological validation studies have confirmed that a minimum 60°C/140° F pre-cooker exit fish core temperature will provide at least 12 hours from the end of pre-cooking to the start of retorting without histamine formation. If firms choose different critical limits, then additional validation studies may be required.

In certain pre-cookers, the spray cooling phase starts inside the pre-cooker, so it may not be possible to conduct EPIPT monitoring. Firms using these types of pre-cookers would need to conduct validation studies to demonstrate that adequate cook has being delivered at the end of the cooking phase to assure that the cold spot of the fish has achieved a minimum core temperature of 60°C/140°F.

Monitoring

Pre-cookers should have appropriate temperature distribution studies to confirm that the pre-cookers are delivering even heat through-out the cookers. If there is a cold spot or multiple cold spots or slower heating locations in the pre-cooker, then temperature probes or temperature measurements must be taken from these cold spots or slower heating locations inside the pre-cooker. Largest fish should be targeted for EPIPT monitoring to ensure that the worst case scenario is being recorded.

More information on EPIPT monitoring procedures is provided in Appendix 6.

Generally a pre-cooker load of fish is considered to be one pre-cooker batch. If there are different size fish in a pre-cooker where the smaller fish are pulled out earlier and the larger fish continue to cook, the firm should ensure that the batch definition accurately represents that a pre-cooker batch would be split by size.

The sample size for the number of fish to be monitored for EPIPT compliance may need to be statistically validated based upon the size of the pre-cooker and the number of fish contained in a pre-cooker.

Corrective Actions

The identified group of tuna in the suspect pre-cook must be fully pre-cooked by the appropriate procedures to meet the critical limit. If there is a deviation from the critical limit during pre-cooking, the tuna cannot be refrigerated as this presents an unacceptable risk due to the extended time needed to cool down fish that has already been exposed to steam. If these fish are processed and the finished product held until the deviation is reviewed by a process authority, thoroughly document the extent of the deviation and time-temperature conditions (fish and ambient air) to assist with the review.

Verifications

Pre-cookers should have appropriate temperature distribution studies to confirm that the pre-cookers are delivering even heat through-out the cookers. (see Appendix 5 – Cooker Validation)

Personnel conducting EPIPT monitoring must be trained in how to position the thermometer in the fish to ensure that the measurement is being taken from the cold spot in the fish and that the largest portions are being targeted for measurement. The EPIPT monitoring procedures provided in Appendix 6 can be used for training purposes.

Thermometers must be calibrated at least annually and checked for accuracy daily before use. More details on calibration and accuracy checks are provided in Appendix 6 – EPIPT Monitoring Procedure.

		CCP 4 CANNED TUNA from Frozen Round Tuna
Critical Control Point (CCP)		Pre-Cooking → Retort **Cumulative Time
Significant Hazard		Histamine
Critical Limits		Cumulative time from pre-cooker exit to the last fish of the batch to start retorting (retort steam-on) not to exceed 12 hours
Monitoring	What	Cumulative exposure time from exit from pre-cooker to start of retorting (retort steam-on)
	How	Record time from pre-cook exit (when pre-cooker doors are opened) to the last fish of the batch starts retorting (retort steam-on)
	When	Every pre-cooker batch
	Who	Production inspectors
Corrective Action		If cumulative exposure time for the pre-cooker batch exceeds 12 hours then: • clearly identify and segregate the affected product from the pre-cooker batch, • if possible, immediately expedite processing of the affected product, • maintain on HOLD after retorting until the product is evaluated for histamine levels, and Sample and perform histamine analysis on a minimum of 60 representative samples^^, randomly selected from the affected product. Testing can be done using composites of 3 samples (20 composites). • If any composite is greater than 50 ppm, then reject the affected product. • If any of the 20 composites exceeds 17 ppm but is less than 50 ppm histamine, then individually test each sample used in that composite. • If any individual sample is greater than 50 ppm, then reject the affected product . Determine root cause and correct the cause for the excessive exposure time.
Records		• Total time exposure records for end of pre-cooking to start of retorting (retort steam on) • Corrective Action records • Verification records • Training Records for CCP monitoring personnel
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Weekly accuracy check for proper clock performance • Appropriate training program for new employees and annual refresher-training for employees responsible for time monitoring.

**Cumulative time of exposure of pre-cooked tuna from start of cooling until retorting cans to prevent elevated histamine levels
^^ See discussion on page 6-34

DISCUSSION - CCP 4 Cumulative Exposure Time for 'Pre-Cooking Until Retorting'

Critical Limit

In this example, it is not necessary to have a temperature critical limit because the pre-cooked tuna will exceed 21.1°C/70°F at some point following pre-cooking.

Recommended exposure time limit after pre-cooking is based on studies conducted by Tuna Council company members to control potential production of elevated histamine levels that have been shown to occur in tuna during product handling after pre-cooking and prior to retorting cans (see Appendix 9 – References).

These studies provide evidence that 18 hours and longer may be necessary before presenting a significant risk of increased histamine levels. At this time, the Tuna Council recommends a 12 hour critical limit consistent with the FDA Hazards Guide for cumulative time between pre-cooking and start of retorting (steam on), which conservatively accommodates any lag times that occur in can cold-point temperatures after steam is first introduced to the retort and before complete histamine inhibition is known to occur (60°C/140°F).

A more stringent operating limit can be used to allow better process controls and to minimize critical limit deviations.

Monitoring

Use of monitoring methods for cumulative time of exposure is recommended and recognized as an appropriate approach as illustrated for unrefrigerated processing of blue crabs in Chapter 12, page 240, Table 12-6 of the FDA Hazards Guide. A key function will be maintaining the identity of the identified group of tuna from time of the end of pre-cooking through all steps until cans are in the retort and the retort process is started. Likewise, the Production and QA inspectors must collect all involved exposure time across all processing steps. This information helps monitor for compliance with the critical limit as well as providing information necessary to support corrective actions to prevent future occurrences. Each pre-cooker batch must be tracked to the corresponding retort baskets. Every retort basket will be identified with a lot of fish and the lots will not be mixed.

Chapter 7, page 145, Table 7-6 of the FDA Hazards Guide also illustrates the use of monitoring cumulative exposure time to control potential scombrotoxin formation during processing.

See Appendix 4 for detailed guidelines on how time can be monitored cumulatively through multiple steps of the process.

Corrective Action

Ideally a critical limit deviation will be identified during processing so the fish can be expedited through the process to minimize further delays.

^^Sampling of retorted product represents the worst case of cumulative exposure through the entire cumulative critical control point. Likewise it accounts for the fact that the CL can be exceeded while the product is in the can. A firm must have a system in place to track each pre-cooker batch to the corresponding retort basket(s).

A minimum of 60 cans must be collected after retorting from throughout the retort baskets which contain the affected product from the pre-cooker batch. Keep in mind the baskets may be in different retorts. If the batch has been separated into different retorts, then only the retort baskets that are over the time limit need to be sampled.

It is important that histamine results and lab procedures are precise and accurate. See histamine testing procedures in CCP 1 for guidance.

Verification

The accuracy of the digital or analogue clocks used for time tracking needs to be verified on a weekly basis against a known standard time keeping device such as found on a centralized computer or phone system. During the weekly accuracy check, synchronize all clocks that are used in plant for monitoring time across multiple processing areas.

		CCP 5 CANNED TUNA from Frozen Round Tuna
Critical Control Point (CCP)		Cleaning → Retort ***Cumulative Time
Significant Hazard		*Staphylococcus aureus* enterotoxin formation
Critical Limits		No more than 3 hours cumulative time beginning from when tuna are first handled after pre-cooking until seamed product is subjected to retort steam on.
Monitoring	What	Cumulative exposure time
	How	Record time when the first fish from the pre-cooker batch enters the skinning process to when the last fish product from the pre-cooker batch enters the retort and steam on
	When	Every pre-cooker batch (entire pre-cooker load or rack)
	Who	Production operator
Corrective Action		If the critical limit is not met, then either: 1) destroy the entire pre-cooker batch or 2) isolate pre-cooker batch, process separately and consult qualified process authority^ to determine product disposition. Perform root cause analysis to determine correction to bring process into compliance to avoid recurrence.
Records		• Total time exposure records for start of cleaning to retort steam on • Corrective Action records • Verification records • Training Records for monitoring personnel
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records. • Weekly check for proper clock performance • Appropriate training program for new employees and annual refresher training for employees responsible for time monitoring.

***Cumulative time of exposure of pre-cooked tuna from start of cleaning until retorting cans to prevent potential *Staphylococcus aureus* growth and enterotoxin formation.
^ see Appendix 1 - Glossary

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DISCUSSION - CCP 5 Cumulative Exposure Time for 'Initial Handling Until Retorting'

NOTE: *Staphylococcus aureus* can potentially be introduced by handling during the cleaning step. A well-designed sanitation program will minimize the introduction (see Chapter 7 - Sanitation Considerations for Canned Tuna Processing).

Critical Limit

The recommended critical limit of less than 3 hours cumulative exposure time above 10°C/50°F, if the pre-cooked product is handled in ambient temperatures above 21.1°C/ 70°F is based on FDA considerations to control potential growth of *Staphylococcus aureus* that could be introduced as a contaminant during handling and allowed to grow to in excess of 100,000 or 1,000,000 cells/gram on the pre-cooked tuna prior to retorting (FDA Hazards Guide Chapter 12 and Table 12-5).

Unpublished studies currently underway by the Tuna Council do indicate that the 3 hour critical limit is conservative. Toxin production on pre-cooked albacore and skipjack samples has only occurred at *S. aureus* levels exceeding 10,000,000 cells/gram, which requires time for growth. The FDA Hazards Guide (pp. 309-310) recognizes that formation of *S. aureus* toxin is the identified hazard rather than the microorganisms themselves.

At this time, the Tuna Council recommends a 3 hour critical limit consistent with the FDA Hazards Guide for cumulative time beginning with first human contact after pre-cooking and ending at the start of retorting (steam on). This critical limit conservatively accommodates any lag times that occur in can cold-point temperatures after steam is first introduced to the retort and before complete inhibition of growth is known to occur (50°C/122°F, FDA Hazards Guide table A-1).

A more stringent operating limit can be used to allow better process controls and to minimize critical limit deviations.

Monitoring

Use of monitoring methods for cumulative time of exposure is recommended and recognized as an appropriate approach as illustrated for unrefrigerated processing of blue crabs in Chapter 12, page 240, Table 12-6 of the FDA Hazards Guide. The monitoring method selected must ensure that batches can be time-tracked for compliance with the 3 hour critical limit. Batch size and the ability to clearly differentiate batches have implications for corrective actions.

Corrective Action

Any product disposition other than destruction requires careful science-based analysis as determined by the qualified process authority. Keeping extensive, detailed records such as room air temperatures, product temperatures, and precise extent of the time deviation will assist with this expert review. It may be possible to clear the first part of a pre-cooker load if retorted within the 3 hour critical limit, but only if distinguishable from the balance of the load and all procedures are well documented.

For example if there is a clear distinction between pre-cooker trolleys within a pre-cooker batch that may have been subjected to different exposure times (for example, some trolleys from the pre-cooker batch were kept in the conditioning room and not brought out onto the skinning and cleaning table), whereby the product from different trolleys with different exposure times can be clearly identified and isolated within a batch, then conduct the corrective actions on the trolleys from the pre-cooker batch that exceeded the critical limit.

Verification

The accuracy of the digital or analogue clocks used for time tracking needs to be verified on a weekly basis against a known standard time keeping device such as found on a centralized computer or phone system. During the weekly accuracy check, synchronize all clocks that are used in plant for monitoring time across multiple processing areas.

The monitoring and corrective action records must be reviewed prior to shipping any product, and there should be a system to retain the product identity traceable to the original retort baskets until the records have been reviewed.

		CCP 6 CANNED TUNA from Frozen Round Tuna	
Critical Control Point (CCP)		Metal Detection	
Significant Hazard		Metal Inclusion	
Critical Limits		All cans of the finished product pass through an operating x-ray unit.	No detectable metal fragments are in the product passing through the x-ray.
Monitoring	What	X-ray unit present and operating	The product for the presence of metal fragments
	How	Visual examination for presence of an operating x-ray unit	Monitoring performed by the x-ray unit
	When	Check that x-ray unit is in place and operating at the start of each production day	Continuous by x-ray unit
	Who	Packaging employee	Equipment itself
Corrective Action		If the product is processed without operating x-ray, hold all cans produced since last point x-ray was operational until they can be run through operational x-ray. Open rejected cans to determine cause of rejection, remove metal fragments from product, identify source of metal to fix the damaged equipment OR destroy rejected product. Correct operating procedures to ensure that the product is not processed without being x-rayed.	
Records		• X-ray operation monitoring log • X-ray verification log • Corrective Action records • Validation records for metal detector operation set-up • Training Records for CCP inspectors	
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Develop x-ray sensitivity standard • Conduct a validation study to determine appropriate setting for the x-ray • Challenge the x-ray unit with validated sensitivity standard daily, before start-up, every 4 hours during production, whenever processing factors change, and at the end of processing • Training program for monitoring personnel • Annual calibration of x-ray	

DISCUSSION - CCP 6 Metal Detection

Critical Limit

Ensuring that x-ray will detect a certain size and type of metal is a verification activity not the critical limit. The critical limit is that all cans will be run through the operational x-ray unit.

Monitoring

While the properly operating x-ray will continuously monitor each can for the presence of metal, a person will need to ensure that the x-ray unit is operational.

Corrective Actions

Cans that are rejected by the metal detector should be opened and the product inspected to find the metal. Identify the source of the metal to correct any damaged equipment.

Verification

It is important to work with the x-ray unit manufacturer when developing the x-ray sensitivity standard. Some variables that may impact the standard include the size of the can and formulation of the packing medium or additional ingredients such as jalapeno peppers.

		CCP 7 CANNED TUNA from Frozen Round Tuna
Critical Control Point (CCP)		Label, Pack, Storage
Significant Hazard		Undeclared food allergens
Critical Limits		The label of packages of finished product designate tuna product content and all other allergenic ingredients
Monitoring	What	The labels being applied to the packages to ensure they correspond to the formula of the product being labeled, and to ensure the labels have the required allergen declaration(s)
	How	Visual checks
	When	At start up of labeling, at each lot code change over and every 2 hours maximum intervals
	Who	Labeler Operator
Corrective Action		Segregate, place on hold, and re-label any improperly labeled product.
		Investigate cause of mislabeling and implement necessary corrections to prevent reoccurrence.
Records		• Record of labeling checks • Corrective action records • Verification records • Training records
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Training program for monitoring personnel

DISCUSSION - CCP 7 Label, Pack, Storage

Critical Limit

Each can or pouch of finished product must declare the presence of all allergens on the product label.

Monitoring

Monitoring must account for all product lot codes packed by the facility, i.e., monitoring records must be available for each production batch or lot of finished product packed and shipped from the facility.

In addition to checking to ensure that the correct labels are being applied, the labels themselves must be verified when received or applied to ensure there are no printing errors or omissions, and that all allergen declarations are present.

FDA has stated that label checks for allergens are normally best conducted at the labeling step but for companies producing a single item, the checks could be performed when the labels are received from the printer. In most cases, tuna canning operations will need to reconcile the labeled ingredients with the production run necessitating label accuracy checks at the labeling step.

FDA regulations are very specific on how allergens must be declared on labels, and there are several different ways permitted by the regulation, so each processor must decide how to best declare allergens in their labels. For the purpose of this example, the labels are expected to have the word “TUNA” on the main panel and the statement “CONTAINS: TUNA, SOY” immediately after the list of ingredients; if either is missing or incorrect, corrective action must be taken.

Corrective Actions

Segregate and destroy or re-label any improperly labeled product. Perform root-cause investigation to determine what caused the product to be mislabeled and make adjustments or changes to prevent reoccurrence. The changes implemented should be documented as part of the investigation on a case by case basis.

Verification

Monitoring records and records of re-labeling must be reviewed by a HACCP trained individual prior to shipping product. Audits and spot checks on outgoing merchandise performed regularly can provide additional verification for this CCP.

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Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna

Part 1. Product and Process Description(Example for training only)

Product Description:

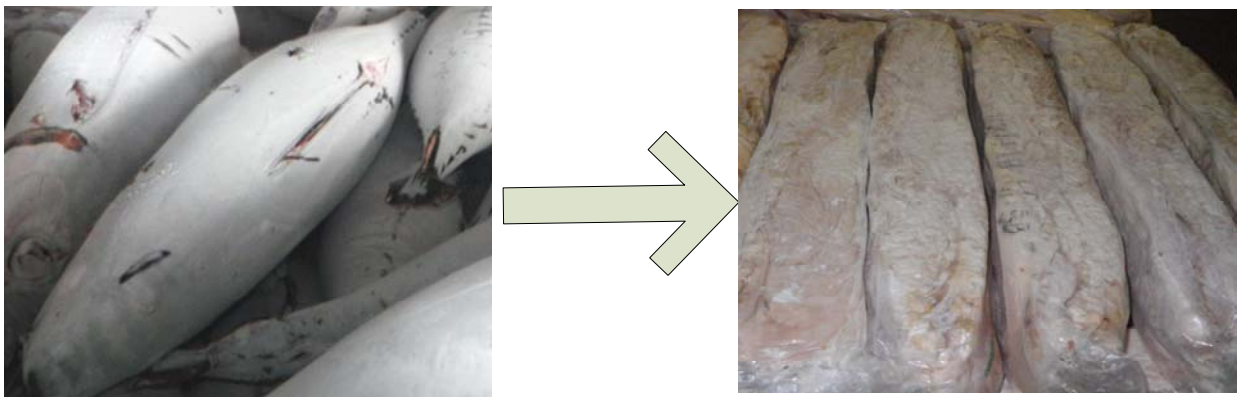
Primary processed tuna loins that has been pre-cooked and frozen in bags for secondary processing as a canned tuna. The tuna loins can be from four primary species:

Albacore (*Thunnus alalunga*)
Bigeye tuna (*Thunnus obesus*)
Skipjack tuna (*Katsuwonus pelamis*)
Yellowfin (*Thunnus albacares*)

The tuna are harvested from wild resources, frozen on board vessel, and delivered frozen to the processing operation directly from harvest vessels, refrigerated carrier vessels, and/or with intermediate trucking. Individual whole fish size can range from 1 to 100+ pounds.

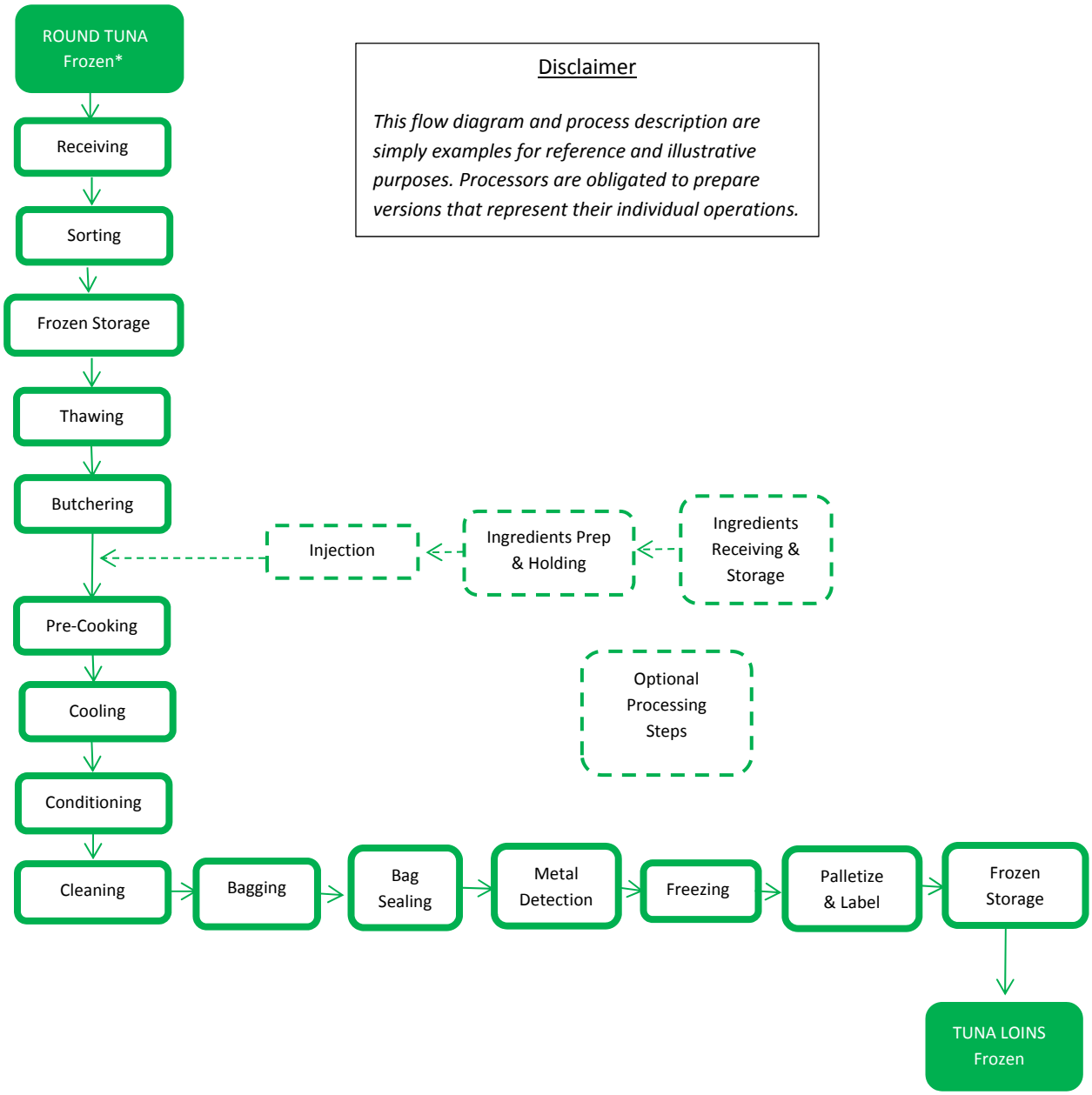
The pre-cooked loins are frozen in plastic bags and shipped to various secondary tuna processing operations for further processing for canned and pouched products. IMPORTANT to note that the frozen loins are NOT INTENDED for distribution or sale to any retail, food service or related operations other than for further secondary processing with thermal processing steps conducted in accordance with established LACF controls for thermal processes for canned or pouched products.

The frozen loins are not intended for direct consumption and are not intended for retail or restaurant commerce.



Process Flow Diagram

Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna



Disclaimer

This flow diagram and process description are simply examples for reference and illustrative purposes. Processors are obligated to prepare versions that represent their individual operations.

Process Description

For training purposes, the process description is outlined in the following table with three columns. The first two columns describe the processing procedures for each step used for Example 2. The third column discusses possible variations or considerations for each processing step. This accompanying column provides some guidance for operations that may different from Example 2.

Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna

Processing Steps	Example 2 Procedures	Possible Variations and Considerations
Receiving	Whole frozen tuna are delivered directly from the harvest vessels with or without intermediate trucking. The tuna are unloaded into large steel boxes (scows) or bins that are identified for fish source and lots. The tuna arrive as frozen whole fish 'in the round' (non-eviscerated). There may be no vessel records that support time and temperature handling conditions immediately upon harvest, but the catch can be identified by 'lots' per vessel and single species. All incoming tuna is subject to sensory and analytical measures for product quality and safety (e.g., sensory and histamine analysis). Portions of each lot are placed in separate bins as 'test samples or test packs' for histamine and sensory analysis. For direct deliveries, all lots are distinguished by single species per harvest vessel and some lots can be distinguished by the well or hatches on a harvest vessel. Lot sizes can range from 20-100 metric tons. For container deliveries, a lot can be a container load of a single species from	*Tuna can arrive as round (non-eviscerated) or eviscerated fish. The initial form and size of fish will eventually affect sorting for uniformity for thawing and further processing steps. The fish should be sorted by size during unloading to assist planning for proper thawing times and pre-cooking.* *Tuna can be previously frozen with blast or brining systems depending on fish type or vessel. For example, blast freezing is commonly used for albacore and brine freezing for smaller skipjack.* *Some operations may receive fresh tuna. Control measures for receiving fresh tuna should be adapted from recommendations in Chapter 7 of FDA's Hazards Guide.* *Be careful how a lot is defined. The initial distinction for a 'lot' or portion of the harvest is very important in HACCP controls that no longer allow later separation into 'sub-lots' as a method to direct acceptance of a questionable harvest. A defined 'lot' is usually linked to one vessel or the vessel collecting from other boats. A clear distinction by harvest vessel, vessel hatch, day of catch or some other measure must be able to define or specify a certain 'lot'. Individual lots will be analyzed with histamine and sensory tests for acceptance. If samples from the original identified 'lot' fail the required sensory and histamine analyses, then the entire lot could fail and cannot be re-sorted by sub-lotting for further*

Processing Steps	Example 2 Procedures	Possible Variations and Considerations
Receiving cont'd	a single harvest vessel.	*analysis for acceptance.* *TIP: The test pack should be thawed with proper controls to prevent any additional increase in histamine content before analysis. The analysis must be completed before the identified lot can be accepted for further processing. (See Appendix 3 – Histamine Testing and Sensory Test Packs)*
Sorting	During unloading, the tuna are sorted by size and species to assure uniform product for proper thawing and precooking.	*Identification of the original lots must be continued through any sorting for product size or species. The fish should be sorted by size during unloading to be prepared for proper thawing time and more uniform pre-cooking.*
Frozen Storage	Frozen storage is necessary for holding the whole frozen tuna. Storage temperatures should be lower than -18°C/0°F and the duration of frozen storage can be days, weeks, or a few months depending on supply and processing schedules. Operations should follow a FIFO schedule (first in, first out).	*Identification of the original lots must be continued in frozen storage*
Thawing	Frozen tuna must be thawed prior to butchering for pre-cooking. The fish will not be removed from frozen storage until the results from the analytical test packs confirm acceptance of the identified lot. At the thawing step, lots become process batches for proper thawing and pre-cooking. A thaw batch is composed of fish that are thawed together at the same time at the same thaw station and no more than the available pre-cooker capacity. Start of thawing is the time the first frozen tuna from a thaw batch is removed from the freezer or	*Lots of tuna should be sorted into smaller groups or 'batches' based on similar sizes that would thaw at a similar rate. Each thaw batch must remain linked with the original lot and identified through further processing steps. Thaw batch size depends on the thaw system and pre-cooker capacity.* *TIP: A 'lot & batch diagram' can be useful to help follow identity of the tuna through processing steps to final product forms and storage.* *TIP: Maintaining similar sized tuna (thickness) is necessary to control thawing rates and the required pre-cooking time.* *Recommendations in FDA's Hazards Guide (Chapter 7; page 119) indicate that the thawing methods should not expose the first thawed portions (external surface of the tuna) for more than12 hours above*

Processing Steps	Example 2 Procedures	Possible Variations and Considerations
Thawing cont'd	temperature-controlled ante-room. The ante-room is maintained below 4.4°C/40°F. The thawing procedure involves submersion of similar batches of round tuna into clean, flowing water to achieve a targeted internal or backbone temperature approaching 0°C/32°F. The water temperature can be maintained by steam injection. During the thawing process tuna is exposed to external temperatures (thaw water or ambient conditions) above 21.1°C/70°F, so the total cumulative time from start of thawing until pre-cooking is less than 12 hours.	*4.4℃/40℉, if the exposure temperatures (tuna surface during thawing) are greater than 21.1℃/70℉.* *For batches of larger tuna that may require longer than12 hours thawing time, validation trials should be conducted to support that thawing procedures do not result in a histamine risk. This would involve targeted studies which profile time, temperature and histamine levels in fish representative of the worst case scenario.* *Additional thawing procedures may be required for larger frozen tuna that cannot be thawed within 12 to 24 hours without some exposure to temperatures above 21.1℃/70℉. Optional thawing procedures should be validated with considerations for proper sanitation and heat exchange consistent with FDA recommendations as noted in Guide pages 117-118. Prior commercial thawing practices with larger tuna suggest options are available without compromising product safety due to elevated histamine.* *NOTE: If the ambient conditions for thawing are less than 21.1℃/70℉, the total accumulative time for product exposure above 4.4℃/40℉ must be less than 24 hours. This approach may require refrigerated or air conditioned thawing areas.* *Tuna can be thawed by water or air exposure. Water should be potable quality (e.g., municipal sources). Clean sea water can be used if taken from approved areas and subject to bacterial controls.* *TIP: Additional sensory evaluations can be conducted on the thawed tuna to complement, but not replace the monitoring results from the test packs.*
Butchering	The thawed tuna can be hand eviscerated and split (if necessary) to prepare similar sizes (thickness) for more uniform thawing and pre-	*Metal inclusion due to breakage of knives or saw blades can be visually monitored at this step and/or, with calibrated metal detectors used to monitor for any possible metal fragments in the final products. The*

Processing Steps	Example 2 Procedures	Possible Variations and Considerations
Butchering cont'd	cooking. This step uses hand labor with special knives and saw blades that are monitored for obvious breakage. Detection of possible breakage or metal fragments is monitored with metal detectors at a later step. Similar sized tuna are placed on racks or trolleys for pre-cooking.	*preferred method for monitoring should include metal detectors for the bagged loins.*
Ingredients Receiving & Storage	Non-tuna ingredients (e.g., dried vegetable broth) are received from approved suppliers, purchased based on ingredient specifications. Ingredients are either tested and/or inspected or Certificates of Analysis (COA) verified at receipt. Ingredients are stored according to particular storage temperature requirements. Ingredients containing food allergens are stored in a separate, designated storage area. Records of ingredient lot codes are maintained for traceability.	*All ingredients should be food grade and monitored for safety through specifications and temperature controls at receiving. All ingredients will be subject to labeling for declared allergens and other regulations for finished product contents.* *Warehousing SSOPs with associated records are necessary to prevent adulteration of ingredients.*
Ingredients Prep & Holding	Ingredients are removed from storage and assembled for preparation based on product formula being produced.	*Continuous SSOPs are necessary to prevent potential allergen cross-contact and bacterial contamination.* *Identity of lot control of added ingredients must be maintained.*
Injection	Thawed or partially thawed tuna can be injected with ingredients to maintain product quality and cook yields during processing. All ingredients are food grade and subject to SSOP controls during preparation and handling. Depending on formulation, some injection ingredients may be	*The injection step can involve needles to penetrate the tuna muscle. Metal inclusion due to breakage of needles can be visually monitored at this step and/or with calibrated metal detectors used to monitor for any possible metal fragments in the final products. The preferred method for monitoring should include metal detectors for the bagged loins.*

Processing Steps	Example 2 Procedures	Possible Variations and Considerations
Injection cont'd	potential food allergens that require label declarations.	*Continuous SSOPs are necessary to prevent potential bacterial contamination.*
Pre-Cooking	Thawed and butchered tuna are pre-cooked in large steam cookers designed and controlled to assure a partial cook to coagulate the muscle protein and connective tissues so the edible portions can be removed from the tuna skeleton and skin. The heating schedule will vary by size of the tuna and cooking load. Proper pre-cooking time is based on continuous monitoring of the internal tuna temperature with probes in the thickest portion of tuna on designated locations on the cooking racks/trolleys. The targeted internal tuna temperature is 60°C/140°F as determined by a series of thermometer measurements when racks/trolleys exit the pre-cookers.	*In consultation with FDA, the Tuna Council has conducted validation trials to determine at least 60 ℃/140 ℉ is necessary as the internal pre-cook temperature to prevent elevated histamine levels above regulatory limits during further processing steps after pre-cooking. The required internal cook temperature is known as the End-Point Internal Product Temperature (EPIPT) as allowed by FDA in controlling processes for cooking seafood.* *All pre-cookers must be validated and adjusted for uniform delivery of heat and determination of any designated positions for fish in the pre-cooker and locations for probing fish (see Appendices 5 and 6 - Cooker Validation and EPIPT Monitoring Procedures).* *In some operations, the tuna remains in the cooker after pre-cooking such that the EPIPT would be based on probe measurements in the pre-cooker. This approach may require further validations for appropriate EPIPTs.* *Identity for the tuna lots and batches must be maintained at all times through all processing steps.*
Cooling	The pre-cooked tuna must be cooled prior to handling to remove the edible portions. The duration of cooling can involve an actual application of cool sprays/rinses and general holding or staging to allow product temperature equilibration. The pre-cooked tuna remains on the original cooking racks/trolleys during this period. The tuna is not handled or exposed to any contact with materials. Pre-cooked tuna temperature will	***Histamine Controls**: In consultation with FDA, the Tuna Council has completed validations to determine that exposure of pre-cooked tuna for less than 12 hours to ambient temperatures that may be greater than 21.1 ℃/70 ℉ will not result in elevated histamine levels when the tuna has been pre-cooked to an EPIPT greater than or equal to 60 ℃/140 ℉.* *If the pre-cooked tuna is cooled, conditioned and handled (cleaning) in ambient temperatures less than 21.1 ℃/70 ℉ (i.e., a refrigerated or air conditioned room), the duration for exposure could be extended*

Processing Steps	Example 2 Procedures	Possible Variations and Considerations
Cooling cont'd	exceed 21.1°C/70°F after pre-cooking and through cooling and may be exposed to ambient temperature greater the 21.1°C/70°F throughout process prior to freezing. The total time from exiting the pre-cooker until the tuna enters the freezer as bagged loins is less than 12 hours.	*beyond 12 hours based on further validations taking into consideration that tuna will exit the pre-cooker at 60℃/140℉.*
Conditioning	Cooled tuna is allowed to 'rest' or condition for a more effective removal of the edible portions. The pre-cooked tuna remains on the original cooking racks during this period. The tuna is not handled or exposed to any contact with materials.	*Conditioning is best conducted in a separate or isolated area with specific routine SSOPs to protect the warm product. The duration for conditioning can be from 2 to 8 hours depending on product size and ambient temperature, but the total conditioning time is part of the cumulative exposure time (less than 12 hours) after pre-cooking until freezing the bagged loins.*
Cleaning	When the partially cooked tuna has cooled enough to handle, the edible portion is cleaned from the tuna skeleton and skin. This process involves hand labor and use of knife blades that are monitored for obvious breakage. The total cumulative exposure time during cleaning until freezing the pre-cooked loins is less than 3 hours.	***Controls for S. aureus toxins**: The Tuna Council is recommending a target for cumulative exposure time less than 3 hours between initial product handling (cleaning and bagging) and freezing the loins. This recommendation is based on responses to FDA's expressed concerns for potential toxin development due to potential, excessive growth of S. aureus that could be introduced during hand cleaning when the pre-cooked tuna is handled at temperatures above 10℃/50℉ that may also exceed 21.1℃/70℉.* *Likewise, the Tuna Council recommends a specific SSOP program to prevent S. aureus contamination of the pre-cooked tuna during cleaning through freezing (see Chapter 7).* *NOTE: An alternative control for potential S. aureus growth is processing product at temperatures less than 21.1℃/70℉ which can allow up to 12 hours cumulative exposure time above 10℃/50℉ for cleaning through freezing the bagged loins (FDA Hazards Guide Chapter 12, pages 234-236 and table 12-5).* *The duration for cleaning is also part of the cumulative time for exposure (less than 12*

Processing Steps	Example 2 Procedures	Possible Variations and Considerations
Cleaning cont'd		*hours) after pre-cooking until freezing the bagged loins.* *Metal inclusion due to breakage of knife blades can be visually monitored at this step and/or with calibrated metal detectors used to monitor for any possible metal fragments in the final products. The preferred method for monitoring should include metal detectors for the bagged loins.*
Bagging	The edible, partially cooked tuna loins and chunks are loaded into elongated plastic bags. For loins that are injected, the bags are labeled with allergen declarations.	*The duration for bagging, sealing and metal detection is also part of the cumulative time for exposure (less than 12 hours) after pre-cooking until freezing the loins **AND** the less than 3 hour limit from initial product handling (cleaning) until freezing the loins*
Bag Sealing	Bags of pre-cooked tuna are sealed prior to placement in frozen storage. Bags are printed with production code information.	*The Tuna Council recommends a specific SSOP program to prevent S. aureus contamination of the pre-cooked tuna during cleaning through bagging.*
Metal Detection	Bagged tuna can be examined by metal detectors to prevent inclusion of any metal fragments.	*All products sealed in plastic bags that may result in a reduced oxygen package (ROP) could allow germination and growth of any potential C. botulinum. Products are strictly intended for secondary processors subject to FDA's 21 CFR Part 113 - Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation.* *Accuracy checks for metal detectors must be conducted and recorded daily and calibration checks annually or as needed.*
Freezing	Bagged loins are placed in the freezer.	
Palletize & Label	All bagged tuna is palletized and the pallet is labeled for product identity and declarations of added allergens.	*It is important to note that pre-cooked bagged frozen loins are not to be sold in retail or restaurant commerce.*
Frozen Storage	Palletized bagged tuna is stored in the freezer (-18°C/0°F or colder) prior to shipments.	

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PART 2. HAZARD ANALYSIS

Example 2. **FROZEN PRE-COOKED LOINS from Frozen Round Tuna**

Identify Hazards

A previous hazard analysis, as illustrated in Chapter 3 using the FDA Hazard Guide, concluded that four potential hazards are 'reasonably likely to occur' in the production of pre-cooked frozen loins from whole frozen round tuna. The FDA Guide includes:

- Pathogenic Bacteria Growth
  - *Staphylococcus aureus* (*S. aureus*) growth and enterotoxin production
  - *Clostridium botulinum* (*C. botulinum*) growth and toxin production in reduced oxygen packaging (ROP); ROP bagged loins
- Scombrotoxin (elevated histamine levels)
- Allergens and Food Additives
- Metal Inclusion

SPECIAL NOTE: Based on concerns expressed by FDA relative to potential exposure temperatures, the Tuna Council recommends specific limitations for the cumulative duration of exposure for the raw tuna during thawing until pre-cooking and for the partially cooked tuna after pre-cooking until freezing to prevent potential elevated histamine levels. Likewise, the Tuna Council recommends similar limitations for duration of cumulative exposure of the pre-cooked tuna during cleaning until freezing to prevent possible production of heat-stable enterotoxins that could result from excessive growth of any *Staphylococcus aureus* that could potentially be introduced during product handling. Concerns for potential *S. aureus* that could be introduced during the cleaning step after pre-cooking, cooling and conditioning should be specifically addressed with strict Standard Sanitation Operating Procedures (SSOPs) and the accompanying monitoring procedures and records (See Chapter 7 - SSOPs).

Identify Best Locations to Control Potential Hazards (CCPs)

As explained in Chapter 5 - Building a HACCP Program - the hazard analysis is used to identify the necessary CCPs. A basic hazard analysis form was used to help identify the best location for controls for all of the potential identified hazards (Appendix 10 - HACCP Forms). The 'Inclusive Approach' was used to account for potential controls for all hazards across all processing steps.

Hazard Analysis Worksheet Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna

Firm Name: Canned Tuna Company 2	**Product Description:** Frozen Pre-Cooked Loins from Frozen Round Tuna
Firm Location: 2 Main Street, Anywhere	**Method of Storage & Distribution:** Frozen
	Intended Use & Consumer: Only for further processing

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Receiving	Pathogenic Bacteria Growth	YES	Potential pathogens may accompany harvested fish Certain *C. botulinum* may accompany raw fish	Product frozen. Final product form will be thoroughly heat treated during secondary processing as a canned product subject to LACF regulations and controls.	NO
	Scombrotoxin (elevated histamine)	YES	Temperature abuse during harvest can elevate histamine levels in tuna	Histamine and sensory analysis in the absence of vessel records or accompanying vessel records	YES
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Tuna is a food allergen introduced at receiving	Potential allergens are introduced at this step but controlled at the Labeling step	NO
Sorting	Pathogenic Bacteria Growth	NO	Not likely to occur at this step; short duration; product frozen		
	Scombrotoxin (elevated histamine)	NO	Not likely to occur at this step; short duration; product frozen		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Frozen Storage	Pathogenic Bacteria Growth	NO	Not likely to occur at this step; product frozen		
	Scombrotoxin (elevated histamine)	NO	Not likely to occur at this step; product frozen		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna

Firm Name: Canned Tuna Company 2	**Product Description:** Frozen Pre-Cooked Loins from Frozen Round Tuna
Firm Location: 2 Main Street, Anywhere	**Method of Storage & Distribution:** Frozen
	Intended Use & Consumer: Only for further processing

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Thawing	Pathogenic Bacteria Growth	YES	Pathogen growth could occur at this step	Final product form will be thoroughly heat treated as a canned product at secondary processor	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until pre-cooking	YES*
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Butchering	Pathogenic Bacteria Growth	YES	Pathogen growth could occur at this step	Final product form will be thoroughly heat treated as a canned product at secondary processor	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until pre-cooking	YES*
	Metal Inclusion	YES	Potentially introduced at this step; use of cutting blades	Metal detection at later step	NO
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Ingredient Receiving and Storage	Pathogenic Bacteria Growth	NO	While potential pathogens may accompany ingredients, dry ingredients and oil do not support their growth		
	Scombrotoxin (elevated histamine)	NO	Step does not involve tuna		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Some food allergen ingredients may be introduced at receiving	Potential allergens may be introduced at this step but controlled at the Labeling step	NO

Hazard Analysis Worksheet Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna

Firm Name: Canned Tuna Company 2	**Product Description:** Frozen Pre-Cooked Loins from Frozen Round Tuna
Firm Location: 2 Main Street, Anywhere	**Method of Storage & Distribution:** Frozen
	Intended Use & Consumer: Only for further processing

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Ingredient Preparation & Holding	Pathogenic Bacteria Growth	YES	Pathogens could accompany preparation of ingredients	Procedures subject to SSOP and the final product form will be thoroughly heat treated as a canned product at secondary processor	NO
	Scombrotoxin (elevated histamine)	NO	Step does not involve tuna		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Some food allergen ingredients may be introduced during preparation	Potential allergens may be introduced at this step but controlled at the Labeling step	NO
Ingredient Injection	Pathogenic Bacteria Growth	YES	Pathogens could accompany injections	Procedures subject to SSOPs. Later thermal processing steps at secondary processor will control these pathogens	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until pre-cooking	YES*
	Metal Inclusion	YES	Potentially introduced at this step if metal injection needles used	Metal detection at later step	NO
	Undeclared Food Allergens	YES	Injected ingredients could introduce potential food allergens	Potential allergens can be introduced at this step but controlled at the Labeling step	NO
Pre-Cooking	Pathogenic Bacteria Growth	YES	Previously introduced pathogens could survive pre-cooking	Final product form will be thoroughly heat treated as a canned product at secondary processor	NO
	Scombrotoxin (elevated histamine)	YES	Histamine production could persist without proper pre-cooking	Proper pre-cooking procedures will help prevent further histamine development	YES
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet **Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna**					
Firm Name: Canned Tuna Company 2			**Product Description:** Frozen Pre-Cooked Loins from Frozen Round Tuna		
Firm Location: 2 Main Street, Anywhere			**Method of Storage & Distribution:** Frozen		
			Intended Use & Consumer: Only for further processing		
(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Cooling	Pathogenic Bacteria Growth	YES	No direct contact with the pre-cooked tuna, but pathogens could be introduced during cooling	No product contact. Cooling subject to SSOP and final product form will be thoroughly heat treated as a canned product at secondary processor	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until freezing pre-cooked and bagged loins	YES**
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Conditioning	Pathogenic Bacteria Growth	YES	No direct contact with the pre-cooked tuna, but pathogens could be introduced during conditioning	No product contact. Conditioning subject to SSOP. Final product form will be thoroughly heat treated as a canned product at secondary processor	NO
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until freezing pre-cooked and bagged loins	YES**
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna

Firm Name: Canned Tuna Company 2	**Product Description:** Frozen Pre-Cooked Loins from Frozen Round Tuna
Firm Location: 2 Main Street, Anywhere	**Method of Storage & Distribution:** Frozen
	Intended Use & Consumer: Only for further processing

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Cleaning	Pathogenic Bacteria Growth	YES	Pathogens could be introduced during cleaning Product handling could potentially introduce *S. aureus* that could grow to produce heat stable toxins if exposed to temperatures above 10°C/50°F	Cleaning subject to SSOP. Final product form will be thoroughly heat treated as a canned product at secondary processor. Specific SSOPs for *S. aureus* and control exposure time*** above 10°C/50°F from start of cleaning until freezing pre-cooked and bagged loins	YES*** (*S. aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until freezing pre-cooked and bagged loins	YES**
	Metal Inclusion	YES	Potentially introduced at this step; use of cutting blades	Metal detection at later step	NO
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Bagging	Pathogenic Bacteria Growth	YES	Pathogens could be introduced during bagging Potential presence of *S. aureus* could grow to produce heat-stable toxins	Bagging subject to SSOP. Final product form will be thoroughly heat treated as a canned product at secondary processor Specific SSOPs for *S. aureus* and control exposure time*** above 50°F/10°C from start of cleaning until freezing	YES*** (*S. aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until freezing pre-cooked and bagged loins	YES**
	Metal Inclusion	NO	Not likely to occur at this step; no use of cutting blades		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet **Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna**					
Firm Name: Canned Tuna Company 2			**Product Description:** Frozen Pre-Cooked Loins from Frozen Round Tuna		
Firm Location: 2 Main Street, Anywhere			**Method of Storage & Distribution:** Frozen		
			Intended Use & Consumer: Only for further processing		
(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)<u>at this step?</u> **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Bag Sealing	Pathogenic Bacteria Growth	YES	Pathogens could be introduced during bagging, including certain *C. botulinum* spores that may not have been destroyed during pre-cooking. Potential presence of *S. aureus* could grow to produce heat-stable toxins	Short duration of step and bagging subject to SSOP. Final product form will be thoroughly heat treated as a canned product during secondary processing. Specific SSOPs for *S. aureus* and control exposure time*** above10°C/50°F from start of cleaning until freezing	NO (*C. bot* toxin) YES*** (*S. aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until freezing pre-cooked and bagged loins	YES**
	Metal Inclusion	NO	Not likely to occur at this step; no use of cutting blades		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna					
Firm Name: Canned Tuna Company 2			**Product Description:** Frozen Pre-Cooked Loins from Frozen Round Tuna		
Firm Location: 2 Main Street, Anywhere			**Method of Storage & Distribution:** Frozen		
			Intended Use & Consumer: Only for further processing		
(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Metal Detection	Pathogenic Bacteria Growth	YES	Pathogens could be introduced during bagging, including certain *C. botulinum* spores that may not have been destroyed during pre-cooking Potential presence of *S. aureus* could grow to produce heat stable toxins	Short duration of step and bagging subject to SSOP. Final product form will be thoroughly heat treated as a canned product during secondary processing. Specific SSOPs for *S. aureus* and control exposure time*** above 10°C/50°F from start of cleaning until freezing	NO (*C. bot* toxin) YES*** (*S. aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time** from start of cooling until freezing pre-cooked, bagged loins	YES**
	Metal Inclusion	YES	Certain, prior processing steps may have introduced metal fragments which will be eliminated at this step	Metal Detector	YES
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Freezing	Pathogenic Bacteria Growth	NO	Not introduced, enhanced or eliminated at this step		
	Scombrotoxin (elevated histamine)	NO	Not introduced, enhanced or eliminated at this step		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet Example 2. FROZEN PRE-COOKED LOINS from Frozen Round Tuna

Firm Name: Canned Tuna Company 2	**Product Description:** Frozen Pre-Cooked Loins from Frozen Round Tuna
Firm Location: 2 Main Street, Anywhere	**Method of Storage & Distribution:** Frozen
	Intended Use & Consumer: Only for further processing

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated)at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Palletize & Label	Pathogenic Bacteria Growth	NO	Not introduced, enhanced or eliminated at this step		
	Scombrotoxin (elevated histamine)	NO	Not introduced, enhanced or eliminated at this step		
	Metal Inclusion	NO	Not likely to occur at this step; no use of cutting blades		
	Undeclared Food Allergens	YES	Tuna and added ingredients could include potential food allergens	Monitor labeling designating tuna and other potential allergenic ingredients	YES
Frozen Storage	Pathogenic Bacteria Growth	NO	Not introduced, enhanced or eliminated at this step		
	Scombrotoxin (elevated histamine)	NO	Not introduced, enhanced or eliminated at this step		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

*Cumulative time of exposure of raw tuna from start of thawing to pre-cooking to prevent elevated histamine levels

**Cumulative time of exposure of pre-cooked tuna from start of cooling until freezing pre-cooked and bagged loins to prevent elevated histamine levels

***Cumulative time for exposure of pre-cooked and cleaned tuna from start of cleaning until freezing pre-cooked and bagged loins to prevent potential *Staphylococcus aureus* growth and enterotoxin formation.

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PART 3. HACCP PLAN

Example 2. **FROZEN PRECOOKED LOINS from Frozen Round Tuna**

The hazard analysis identified 7 Critical Control Points:

1. **Receiving** to control incoming Scombrotoxins (elevated histamine levels)
2. **Cumulative time*** from beginning of Thaw through start of Pre-Cooking to control potential elevated histamine levels
3. **Pre-Cooking** to prevent subsequent histamine production
4. **Cumulative time**** from end of Pre-Cooking to start of Freezing to prevent subsequent histamine production
5. **Cumulative time***** from start of Cleaning to start of Freezing to control potential *S. aureus* growth and potential production of heat-stable enterotoxin
6. **Metal Detection** to eliminate metal fragments or inclusions
7. **Labeling** to declare potential food allergens

HACCP Plan Form

The written HACCP Plan provides a brief description of routine activities that will occur at all CCP's to prevent the identified potential hazards. The HACCP Plan form can be completed in either a portrait or landscape format (see Appendix 10 – HACCP Forms), but either form must include descriptions for:

- **CCP** or processing step
- **Significant hazards** involved
- **Critical Limits** specify the measure for control
- **Monitoring procedures**
  - What will be done
  - How will it be done
  - When will it be done (frequency)
  - Who will do it
- **Corrective Actions** to assure:
  - That no product under deviation enters commerce and
  - The root cause of the deviation is addressed
- **Records** taken as evidence for controls and reference
- **Verifications** to assure the HACCP plan and procedures will work and are working

HACCP Plan Cover Sheet

FROZEN PRE-COOKED LOINS from Frozen Round Tuna HACCP Plan

Canned Tuna Company 2

2 Main Street, Anywhere

Date Issued:

Supersedes Version Dated:

Approved by:

Name/Title:	Signature:	Date:
_____	_____	_____
_____	_____	_____
_____	_____	_____

NOTE: Remember that the HACCP plan needs to be reviewed at least annually and approved (and signed) by the most responsible individual on site or higher in the corporation.

<table>
<tr><td></td><td colspan="3">CCP 1 FROZEN PRECOOKED LOINS from Frozen Round Tuna</td></tr>
<tr><td>Critical Control Point (CCP)</td><td colspan="3">Receiving</td></tr>
<tr><td>Significant Hazard</td><td colspan="3">Elevated Histamine Levels</td></tr>
<tr><td colspan="2">Critical Limits</td><td>Less than 30 ppm histamine level in individual tuna</td><td>No more than 2 tuna in a sample of 118 tuna/lot with notable sensory decomposition, or less than 2.5% if more than 118 tuna</td></tr>
<tr><td rowspan="4">Monitoring</td><td>What</td><td>Histamine level in lower, anterior portion of the tuna (near visceral cavity)</td><td>Sensory measures for whole tuna, same species in identified ‘lot’ for noticeable and persistent odors of decomposition</td></tr>
<tr><td>How</td><td>Collect a minimum of 18 representative fish per lot (or the entire lot for lots with fewer than 18 fish)

Perform analysis on composite of 3 samples using validated test method 10 ppm screening level. The validated test method is customized to monitor lower levels of histamine corresponding to the 10 ppm screening level.

If test result for the composite is <u>greater than or equal to</u> 10 ppm and less than 30 ppm, then analyze individual fish samples using a validated method to monitor histamine corresponding to the less than 30 ppm Critical Limit.</td><td>Examine minimum of 118 tuna per identified lot or every fish if less than 118 in the lot for persistent and readily perceptible decomposition odors</td></tr>
<tr><td>When</td><td>Every incoming lot</td><td>Every incoming lot</td></tr>
<tr><td>Who</td><td>Assigned trained analytical specialist</td><td>Assigned trained sensory specialist</td></tr>
<tr><td colspan="2">Corrective Action</td><td>If the <u>histamine critical limit</u> (30 ppm) on any individual fish is exceeded then reject the entire lot.</td><td>If <u>only</u> the <u>sensory critical limit</u> is exceeded, then tag and segregate the tuna from the lot; test 60 individual tuna for histamine including all tuna suspect for decomposition.
If any sample has histamine levels greater than or equal to 30 ppm, then reject entire lot.
If no sample has histamine greater than or equal to 30 ppm, then accept the lot for processing AND evaluate 100% of the tuna for decomposition AND discard any decomposed tuna, and pack and process acceptable fish without delay.
Complete an investigation of cause and necessary corrections before continuing with supplier. Only continue use of supplier with extra monitoring until evidence for improved performance.</td></tr>
<tr><td colspan="2">Records</td><td colspan="2">Sensory Assessment and Histamine Test records with controls and periodic verifications
Corrective Action records; including disposition of any rejections
Laboratory Audit reports and associated corrections
Training Records for sensory specialist and analytical specialist</td></tr>
<tr><td colspan="2">Verifications</td><td colspan="2">Monitoring record reviewed before accepting incoming lots for processing
Weekly review (or prior to shipping products) of monitoring, verification, and corrective action records.
Routinely test control samples to accompany daily histamine analysis (internal lab QA)
Do quarterly comparison of histamine test results with AOAC method
Training program for sensory specialists (initial and annual refresher)
Periodic internal audits and annual formal audits by third party; to include annual proficiency testing for each analyst</td></tr>
</table>

DISCUSSION - CCP 1 Receiving

Critical Limit

This example of a CCP at receiving for controlling for elevated histamine levels has two control measures – histamine analysis and sensory examination for decomposition. Each control measure has associated critical limits, monitoring, corrective actions, records and verification procedures. Both critical limits must be met at this CCP.

Although the FDA Hazards Guide (Chapter 7) recommends a histamine limit of 50 ppm, the Tuna Council recommends a stricter limit of 30 ppm^ **at receiving** to prevent the introduction of higher risk raw materials into the process (FDA Hazards Guide, Table 7-4 page 136). FDA Hazards Guide suggests that greater than 30 ppm is an indicator of higher variability between individual fish and there was a limit of 30 ppm set to avoid accepting lots with high fish to fish variability.

^(10 ppm if composites for 3 tuna are tested)

Monitoring

In the absence of vessel records, the FDA Hazards Guide (Chapter 7, page 132) recommends use of histamine testing with three components; 1) histamine analysis, 2) sensory exams, and 3) internal temperature checks of fresh fish. (If fish is received frozen, internal temperature checks are not necessary).

Lot Identity

Lot size and identity must be described in a manner that accounts for similar fish in terms of species and a particular harvest vessel. Lots can be from single vessels per harvest trip or from a portion from a single vessel if the portions can be clearly distinguished within the individual vessel. Carrier vessels collecting from other harvest vessels should maintain harvest vessel identity and segregation.

Monitoring Histamine Levels

If histamine tests are based on composite samples, then adjust the acceptance level from 30 ppm per tuna to 10 ppm for a composite comprised from 3 tuna. The targeted sample size per tuna is 250 grams. If the tuna are small, the sampling location should still target the lower anterior portion and collect at least 50 grams per tuna.

Collect samples that represent fish from throughout the lot, for example, bins representing the start, middle and end of the lot as it is unloaded from the harvest vessel or containers (see Appendix 3 – Histamine Testing and Sensory Test Packs).

Damaged fish are culled out during unloading. These are fish that have been damaged as a result of mechanical or physical impact.

Analytical methods to measure histamine should be based on AOAC approved procedures or methods that have been validated against AOAC approved procedures. These methods can be qualitative or quantitative. Qualitative methods provide a 'pass' or 'fail' result, for example a color change. Quantitative methods provide discrete values of histamine readings, for example readings from a fluorometer.

Qualifying Suppliers

Fish from a new supplier or a supplier without an established history of problem-free deliveries may require a larger sample size. A qualified supplier is one that has an established history with the firm and has had four consecutive problem-free deliveries.

If one lot from a harvest vessel fails then treat all lots from the same harvest vessel delivery as if the supplier is a new suppler. If more than one lot fails, then reject all fish from the harvest vessel. More than one lot with high histamine from the same fishing vessel delivery can be indicative of poor harvest vessel practices.

Sensory Monitoring

Sensory examinations should be conducted by trained person(s). Training should include initial instruction with actual tuna samples and periodic and annual refresher courses to maintain ability and check analytical proficiency. Training should be similar to hands-on and nose-on courses offered by U.S. FDA staff and the National Marine Fisheries Service (NMFS/NOAA).

Corrective Actions

If histamine level is greater than or equal to 30 ppm in any individual fish, then reject the entire lot. If the qualitative or quantitative composite analysis is greater than or equal to 10 ppm, the Tuna Council recommends that a portion of the original retained samples be tested. If the quantitative composite analysis is greater than or equal to 30ppm, then reject the entire lot with no further testing.

If no samples exceed the 30 ppm, accept the lot and proceed with processing and 100% sensory evaluation. When further sensory evaluation is necessary, industry practice is to establish a maximum tolerance for rejected decomposed tuna per lot. Once this tolerance is exceeded the entire lot is rejected. For example when 10% by weight is considered decomposed then reject the entire lot.

		CCP 2 FROZEN PRECOOKED LOINS from Frozen Round Tuna
Critical Control Point (CCP)		Thawing → Pre-Cooking *Cumulative Time
Significant Hazard		Elevated Histamine Levels
Critical Limits		Less than or equal to 12 hours from start of thawing until the start of pre-cooking
Monitoring	What	Cumulative exposure time
	How	Visual monitoring for time from when the first fish from the thaw batch starts thawing to when pre-cooking starts (pre-cooker steam on) for the last fish from thaw batch
	When	Every thaw batch; thaw batch is defined as a number of tuna that can be distinguished as one group from thaw through pre-cooking
	Who	Production and QA inspectors collecting progressive time monitoring across all processing steps
Corrective Action		If cumulative exposure time for a group of tuna exceeds 12 hours, then specifically identify the involved bins of tuna, segregate and immediately expedite processing through the pre-cooker. Conduct histamine analysis at end of cleaning for 60 tuna randomly selected from the identified racks. Testing can be done using composites of 3 tuna (20 composites). • If any composite is greater than 30 ppm, then reject the identified pre-cooker batch. • If any of the 20 composites exceeds 10 ppm but is less than 30 ppm histamine, then individually test each fish used in that composite. • If any individual fish sample is greater than 30 ppm, then reject the identified pre-cooker batch. Determine root cause and correct the cause for the excessive exposure time.
Records		• Total time exposure records for thawing to pre-cooking • Corrective Action records • Verification records • Training Records for CCP monitoring personnel
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records. • Weekly accuracy check for proper clock performance • Appropriate training program for new employees and annual refresher training for employees responsible for time monitoring.

*Cumulative time of exposure for raw tuna from start of thawing to pre-cooking to prevent elevated histamine levels

DISCUSSION - CCP 2 Cumulative Exposure Time for 'Thawing Until Pre-Cooking'

Critical Limit

The critical limit of less than 12 hours exposure to temperatures above 4.4°C/40°F is based on controls to prevent elevated histamine levels as recommended in the FDA Hazards Guide Chapter 7, page 119, table 7-2 when the tuna may be expose to temperatures higher than 21.1°C/70°F. If the exposure temperatures are lower than 21.1°C/70°F, the exposure time limit above 4.4°C/40°F can be extended to no more than 24 hours.

The definition for when thawing starts may be different for some firms. If there is a lengthy staging time at temperatures above 4.4°C/40°F that impact the product temperature, this will need to be accounted for in the overall 12 hour critical limit. .

> As an example: Fish lots of a single species are brought from the freezer to be thawed and are transferred to the thaw tank bins and stacked in one of the thaw zones. When the required number of thaw bins are loaded into the zone the thaw water spray system is turned on and thaw cycle started.
>
> Fish backbone temperatures will be taken per Standard Operating Procedures. Once the specified backbone temperature of the thawing fish lot is reached, the thaw cycle is complete. The time the water is turned off shall be recorded.

The critical limit should be controlled to the start of pre-cooking – when the fish racks are placed inside the pre-cooker, doors are closed and steam is turned on.

A more stringent operating limit can be used to allow better process controls and to minimize critical limit deviations.

Monitoring

Use of monitoring methods for cumulative time of exposure are recommended and recognized as an appropriate approach as illustrated for unrefrigerated processing of blue crabs in Chapter 12, page 240, Table 12-6 of the FDA Hazards Guide. A key function will be maintaining the identity of the identified group of tuna from time of thawing through all steps until racking and loading the pre-cooker for steam-on for pre-cooking. Likewise, the Production and QA inspectors must collect all involved exposure time across all processing steps. This information helps monitor for compliance with the critical limit as well as providing information necessary to support corrective actions to prevent future occurrences.

Chapter 7, page 145, Table 7-6 of the FDA Hazards Guide also illustrates the use of monitoring cumulative exposure time to control potential scombrotoxin formation during processing.

Corrective Actions

If there is a critical limit deviation, then the fish should be expedited through the pre-cook process to avoid any further time-temperature abuse. Samples should be collected at the end of the process.

The samples should be collected at the last possible step in the process in order to represent the worst case exposure time for fish impacted by the deviation. The minimum of 60 samples are taken at the end of cleaning stage. Samples are collected from loins and the flakes, proportional to production volumes of loins and flakes generated during cleaning. Samples from loins should be taken from the anterior end of the ventral loins. (The anterior end of the ventral loins will still be evident based on the shape of the four loin quadrants.) Similar to previous CCPs, the 60 samples can be analyzed as 20 composites of 3 samples each.

It is important that histamine results and lab procedures are precise and accurate. See histamine testing verification procedures in CCP 1 for guidance.

Verification

The accuracy of the digital or analogue clocks used for time tracking needs to be verified on a weekly basis against a known standard time keeping device such as found on a centralized computer or phone system. During the weekly accuracy check, synchronize all clocks that are used in plant for monitoring time across multiple processing areas.

		CCP 3 FROZEN PRECOOKED LOINS from Frozen Round Tuna
Critical Control Point (CCP)		Pre-Cooking
Significant Hazard		Histamine
Critical Limits		Minimum pre-cooker exit core temperature of 60°C/140°F
Monitoring	What	Core temperatures of 60°C/140°F for largest whole tuna or largest portions from the slowest heating location(s) in pre-cooker at pre-cooker exit
	How	Using a calibrated thermometer(s), conduct 24 internal temperature probes to measure fish core temperature at the geometric center of largest whole tuna or largest portions at exit from the pre-cooker (End-Product Internal Point Temperatures (EPIPT)).
	When	Every pre-cooker batch. Batch defined as one pre-cooker load.
	Who	Pre-Cooker Operator
Corrective Action		Immediately return racks of tuna to the pre-cooker or alternate pre-cooker, and continue heating to achieve proper core temperatures based on additional measures of 24 probe temperatures at exit from the pre-cooker. If not able to return racks of tuna to the pre-cooker, segregate, process rapidly and hold affected product. Evaluate with a process authority to assess safety and take appropriate actions. Or destroy product. Determine cause for the deviation and necessary corrections to regain proper pre-cooking controls.
Records		• Pre-Cooker Temperature logs • Corrective Action records • Verification records for pre-cooker operation and thermometers • Training Records for pre-cook operators
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Validations for uniform pre-cooker operation • Daily thermometer accuracy checks before use • Annual calibration of the thermometer against an NIST traceable reference thermometer

DISCUSSION - CCP 3 Pre-Cooking

Critical Limit

The recommended End-Point Internal Product Temperature (EPIPT) is based on studies conducted by companies within the Tuna Council. These studies validate that when the cold spot of the tuna reaches a minimum temperature of 60°C/140°F at the end of pre-cooking, histamine production is halted for sufficient time to allow pre-cooked fish to be converted to canned tuna (see Appendix 9 - References). Biological validation studies have confirmed that a minimum 60°C/140°F pre-cooker exit fish core temperature will provide at least 12 hours from the end of pre-cooking to the start of retorting without histamine formation. If firms choose different critical limits, then additional validation studies may be required.

In certain pre-cookers, the spray cooling phase starts inside the pre-cooker, so it may not be possible to conduct EPIPT monitoring. Firms using these types of pre-cookers would need to conduct validation studies to demonstrate that adequate cook has being delivered at the end of the cooking phase to assure that the cold spot of the fish has achieved a minimum core temperature of 60°C/140°F.

Monitoring

Pre-cookers should have appropriate temperature distribution studies to confirm that the pre-cookers are delivering even heat through-out the cookers. If there is a cold spot or multiple cold spots or slower heating locations in the pre-cooker, then temperature probes or temperature measurements must be taken from these cold spots or slower heating locations inside the pre-cooker. Largest fish should be targeted for EPIPT monitoring to ensure that the worst case scenario is being recorded.

More information on EPIPT monitoring procedures is provided in Appendix 6.

Generally a pre-cooker load of fish is considered to be one pre-cooker batch. If there are different size fish in a pre-cooker where the smaller fish are pulled out earlier and the larger fish continue to cook, the firm should ensure that the batch definition accurately represents that a pre-cooker batch would be split by size.

The sample size for the number of fish to be monitored for EPIPT compliance may need to be statistically validated based upon the size of the pre-cooker and the number of fish contained in a pre-cooker.

Corrective Actions

The identified group of tuna in the suspect pre-cook must be fully pre-cooked by the appropriate procedures to meet the critical limit. If there is a deviation from the critical limit during pre-cooking, the tuna cannot be refrigerated as this presents an unacceptable risk due to the extended time needed to cool down fish that has already been exposed to steam. If these fish are processed and the finished product held until the deviation is reviewed by a process authority, thoroughly document the extent of the deviation and time-temperature conditions (fish and ambient air) to assist with the review.

Verifications

Pre-cookers should have appropriate temperature distribution studies to confirm that the pre-cookers are delivering even heat through-out the cookers. (see Appendix 5 – Cooker Validation)

Personnel conducting EPIPT monitoring must be trained in how to position the thermometer in the fish to ensure that the measurement is being taken from the cold spot in the fish and that the largest portions are being targeted for measurement. The EPIPT monitoring procedures provided in Appendix 6 can be used for training purposes.

Thermometers must be calibrated at least annually and checked for accuracy daily before use. More details on calibration and accuracy checks are provided in Appendix 6 - EPIPT Monitoring Procedure.

		CCP 4 FROZEN PRECOOKED LOINS from Frozen Round Tuna
Critical Control Point (CCP)		Pre-Cooking → Freezing **Cumulative Time
Significant Hazard		Histamine
Critical Limits		Cumulative time from pre-cooker exit until last fish of the pre-cooker batch enters the freezer as a bagged loin not to exceed 12 hours
Monitoring	What	Cumulative exposure time from exit from pre-cooker to start of freezing
	How	Record time from pre-cook exit (when pre-cooker doors are opened) to start of freezing
	When	Every pre-cooker batch
	Who	Production inspectors
Corrective Action		If cumulative exposure time for the pre-cooker batch exceeds 12 hours then: • clearly identify and segregate the affected product from the pre-cooker batch, • if possible, immediately expedite processing of the affected product, • maintain on HOLD until the product is evaluated for histamine levels, and Sample and perform histamine analysis on a minimum of 60 representative samples^^, randomly selected from the affected product. Testing can be done using composites of 3 samples (20 composites). • If any composite is greater than 30 ppm, then reject the affected product. • If any of the 20 composites exceeds 10 ppm but is less than 30 ppm histamine, then individually test each fish used in that composite. • If any individual sample sample is greater than 30 ppm, then reject the affected product. Determine root cause and correct the cause for the excessive exposure time.
Records		• Total time exposure records for end of pre-cooking to start of freezing • Corrective Action records • Verification records • Training Records for CCP monitoring personnel
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Weekly accuracy check for proper clock performance • Appropriate training program for new employees and annual refresher-training for employees responsible for time monitoring.

**Cumulative time of exposure of pre-cooked tuna from start of cooling until freezing bagged loins to prevent elevated histamine levels
^^ see discussion on page 6-76

DISCUSSION - CCP 4 Cumulative Exposure Time for 'Pre-Cooking Until Freezing'

Critical Limit

In this example, it is not necessary to have a temperature critical limit because the pre-cooked tuna will exceed 21.1°C/70°F at some point following pre-cooking.

Recommended exposure time limit after pre-cooking is based on studies conducted by Tuna Council company members to control potential production of elevated histamine levels that have been shown to occur in tuna during product handling after pre-cooking (see Appendix 9 – References).

These studies provide evidence that 18 hours and longer may be necessary before presenting a significant risk of increased histamine levels. At this time, the Tuna Council recommends a 12 hour critical limit consistent with the FDA Hazards Guide for cumulative time between the end of pre-cooking and start of freezing, which conservatively accommodates any lag times that occur in loin warm spot temperatures after the loins are first placed into the freezer environment and before complete histamine inhibition is known to occur (4.4°C/40°F).

A more stringent operating limit can be used to allow better process controls and to minimize critical limit deviations.

Monitoring

Use of monitoring methods for cumulative time of exposure is recommended and recognized as an appropriate approach as illustrated for unrefrigerated processing of blue crabs in Chapter 12, page 240, Table 12-6 of the FDA Hazards Guide. Chapter 7, page 145, Table 7-6 of the FDA Hazards Guide also illustrates the use of monitoring cumulative exposure time to control potential scombrotoxin formation during processing.

A key function will be maintaining the identity of the identified group of tuna from time of the end of pre-cooking through all steps until bagging and loading the freezer. Likewise, the Production and QA inspectors must collect all involved exposure time across all processing steps. This information helps monitor for compliance with the critical limit as well as providing information necessary to support corrective actions to prevent future occurrences.

See Appendix 4 for detailed guidelines on how time can be monitored cumulatively through multiple steps of the process.

Corrective Action

If there is a critical limit deviation, then the fish should be expedited through the process to avoid any further time-temperature abuse and samples should be collected at the end of the process.

^^The samples should be collected at the last possible step in the process in order to represent the worst case exposure time for fish impacted by the deviation. The minimum of 60 samples are taken at the end of cleaning stage. Samples are collected from loins and the flakes, proportional to production volumes of loins and flakes generated during cleaning. Samples from loins should be taken from the anterior end of the ventral loins. (The anterior end of the ventral loins will still be evident based on the shape of the four loin quadrants.) Similar to previous CCPs, the 60 samples can be analyzed as 20 composites of 3 samples each.

It is important that histamine results and lab procedures are precise and accurate. See histamine testing verification procedures in CCP 1 for guidance.

Verification

The accuracy of the digital or analogue clocks used for time tracking needs to be verified on a weekly basis against a known standard time keeping device such as found on a centralized computer or phone system. During the weekly accuracy check, synchronize all clocks that are used in plant for monitoring time across multiple processing areas.

		CCP 5 FROZEN PRECOOKED LOINS from Frozen Round Tuna
Critical Control Point (CCP)		Cleaning → Freezing ***Cumulative Time
Significant Hazard		*Staphylococcus aureus* enterotoxin formation
Critical Limits		No more than 3 hours cumulative time beginning from when tuna are first handled after pre-cooking until freezing bagged loins
Monitoring	What	Cumulative exposure time
	How	Record time when the first fish from the pre-cooker batch enters the skinning process to when the last fish product from the pre-cooker batch enters the freezer.
	When	Every pre-cooker batch (entire pre-cooker load or rack)
	Who	Production operator
Corrective Action		If the critical limit is not met, then either: 1) destroy the entire pre-cooker batch or 2) isolate pre-cooker batch, process separately and consult qualified process authority^ to determine product disposition. Perform root cause analysis to determine correction to bring process into compliance to avoid recurrence.
Records		• Total time exposure records for start of cleaning to retort steam on • Corrective Action records • Verification records • Training Records for monitoring personnel
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records. • Weekly check for proper clock performance • Appropriate training program for new employees and annual refresher training for employees responsible for time monitoring.

***Cumulative time of exposure of pre-cooked tuna from start of cleaning until start of freezing to prevent potential *Staphylococcus aureus* growth and enterotoxin production.
^ see Appendix 1 - Glossary

DISCUSSION - CCP 5 Cumulative Exposure Time for 'Initial Handling Until Freezing'

NOTE: *Staphylococcus aureus* can potentially be introduced by handling during the cleaning step. A well-designed sanitation program will minimize the introduction (see Chapter 7 - Sanitation Considerations for Canned Tuna Processing).

Critical Limit

The recommended critical limit of less than 3 hours cumulative exposure time above 10°C/50°F, if the pre-cooked product is handled in ambient temperatures above 21.1°C/70°F is based on FDA considerations to control potential growth of *Staphylococcus aureus* that could be introduced as a contaminant during handling and allowed to grow to in excess of 100,000 or 1,000,000 cells/gram on the pre-cooked tuna prior to freezing (FDA Hazards Guide Chapter 12 and Table 12-5).

Unpublished studies currently underway by the Tuna Council do indicate that the 3 hour critical limit is conservative. Toxin production on pre-cooked albacore and skipjack samples has only occurred at *S. aureus* levels exceeding 10,000,000 cells/gram, which requires time for growth. The FDA Hazards Guide (pp. 309-310) recognizes that formation of *S. aureus* toxin is the identified hazard rather than the microorganisms themselves.

At this time, the Tuna Council recommends a 3 hour critical limit consistent with the FDA Hazards Guide for cumulative time beginning with first human contact after pre-cooking and ending at the start of freezing (placement into the freezer) This critical limit conservatively accommodates any lag times that occur in loin warm spot temperatures after the loins are first placed into the freezer environment and before inhibition of growth is known to occur (10°C/50°F, FDA Hazards Guide table A-1).

A more stringent operating limit can be used to allow better process controls and to minimize critical limit deviations.

Monitoring

Use of monitoring methods for cumulative time of exposure is recommended and recognized as an appropriate approach as illustrated for unrefrigerated processing of blue crabs in Chapter 12, page 240, Table 12-6 of the FDA Hazards Guide. The monitoring method selected must ensure that batches can be time-tracked for compliance with the 3 hour critical limit. Batch size and the ability to clearly differentiate batches have implications for corrective actions.

Corrective Action

Any product disposition other than destruction requires careful science-based analysis as determined by the qualified process authority. Keeping extensive, detailed records such as room air temperatures, product temperatures, and precise extent of the time deviation will assist with this expert review. It may be possible to clear the first part of a pre-cooker load if bagged loins are placed in freezer within the 3 hour critical limit, but only if distinguishable from the balance of the load and all procedures are well documented.

For example if there is a clear distinction between pre-cooker trolleys within a pre-cooker batch that may have been subjected to different exposure times (for example, some trolleys from the pre-cooker batch were kept in the conditioning room and not brought out onto the skinning and cleaning table), whereby the product from different trolleys with different exposure times can be clearly identified and isolated within a batch, then conduct the corrective actions on the trolleys from the pre-cooker batch that exceeded the critical limit.

Verification

The accuracy of the digital or analogue clocks used for time tracking needs to be verified on a weekly basis against a known standard time keeping device such as found on a centralized computer or phone system. During the weekly accuracy check, synchronize all clocks that are used in plant for monitoring time across multiple processing areas.

		CCP 6 FROZEN PRECOOKED LOINS from Frozen Round Tuna	
Critical Control Point (CCP)		Metal Detection	
Significant Hazard		Metal Inclusion	
Critical Limits		All packaged loins pass through an operating metal detector.	No detectable metal fragments are in the bagged loins passing through the metal detector
Monitoring	What	Metal detection unit present and operating	The product for the presence of metal fragments
	How	Visual examination for presence of an operating metal detection unit	Monitoring performed by the metal detector
	When	Check that metal detection unit is in place and operating at the start of each production day	Continuous by the metal detector
	Who	Packaging employee	Equipment itself
Corrective Action		If the product is processed without operating metal detection unit, hold all packaged loins produced since last point metal detection unit was operational until they can be run through operational metal detector. Open rejected bags to determine cause of rejection, remove metal fragments from product, identify source of metal to fix the damaged equipment, re-bag loins and re-run through operating metal detector OR destroy rejected product. Correct operating procedures to ensure that the product is not processed without being passed through the metal detector.	
Records		• Metal detector operation monitoring log • Metal detector verification log • Corrective Action records • Validation records for metal detector operation set-up • Training Records for CCP inspectors	
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Develop metal detector sensitivity standard • Conduct a validation study to determine appropriate setting for detector • Challenge the detector unit with validated sensitivity standard daily, before start-up, every 4 hours during production, whenever processing factors change, and at the end of processing • Training program for monitoring personnel • Annual calibration of metal detector	

DISCUSSION - CCP 6 Metal Detection

Critical Limit

Ensuring that metal detector will detect a certain size and type of metal is a verification activity not the critical limit. The critical limit is that all bags will be run through the operational detection unit.

Monitoring

While the properly operating metal detector will continuously monitor each bag for the presence of metal, a person will need to ensure that the detection unit is operational.

Corrective Actions

Bagged loins that are rejected by the metal detector should be opened and the product inspected to find the metal. Identify the source of the metal to correct any damaged equipment.

The affected loins should be re-bagged after metal is removed and run again through the metal detector before accepting.

Verification

It is important to work with the detection unit manufacturer when developing the metal detector sensitivity standard.

		CCP 7 FROZEN PRECOOKED LOINS from Frozen Round Tuna
Critical Control Point (CCP)		Label, Pack, Storage
Significant Hazard		Undeclared food allergens
Critical Limits		The label of pallets of finished product designate tuna product content and all other allergenic ingredients
Monitoring	What	The labels being applied to the pallets to ensure they correspond to the formula of the product being palletized, and to ensure the labels have the required allergen declaration(s)
	How	Visual checks
	When	At startup of palletizing, at each pallet and lot code change over
	Who	Palletizing Supervisor
Corrective Action		Segregate, place on hold, and re-label any improperly labeled pallets. Investigate cause of mislabeling and implement necessary corrections to prevent reoccurrence.
Records		• Record of labeling checks • Corrective action records • Verification records • Training records
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Training program for monitoring personnel

DISCUSSION - CCP 7 Label, Pack. Storage

Critical Limit

Each pallet of finished product must declare the presence of all allergens on the pallet label.

Monitoring

Monitoring must account for all product lot codes packed by the facility, i.e., monitoring records must be available for each production batch, lot and pallet of finished product packed and shipped from the facility.

Operating procedures should include a check to ensure that there are no printing errors or omissions on any pre-printed loin bags.

FDA has stated that label checks for allergens are normally best conducted at the labeling step but for companies producing a single item, the checks could be performed when the labels are received from the printer. In most cases, tuna loin operations will need to reconcile the labeled ingredients with the production run necessitating label accuracy checks at the labeling step.

Corrective Actions

Segregate and destroy or re-label any improperly labeled product. Perform root-cause investigation to determine what caused the product to be mislabeled and make adjustments or changes to prevent reoccurrence. The changes implemented should be documented as part of the investigation on a case by case basis.

Verification

Monitoring records and records of re-labeling must be reviewed by a HACCP trained individual prior to shipping product. Audits and spot checks on outgoing merchandise performed regularly can provide additional verification for this CCP.

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Example 3. **CANNED TUNA from Frozen Pre-Cooked Loins**

Part 1. Product and Process Description (Example for training only)

Product Description:

Canned tuna species can include:

Albacore (*Thunnus alalunga*)
Bigeye tuna (*Thunnus obesus*)
Skipjack tuna (*Katsuwonus pelamis*)
Yellowfin (*Thunnus albacares*)

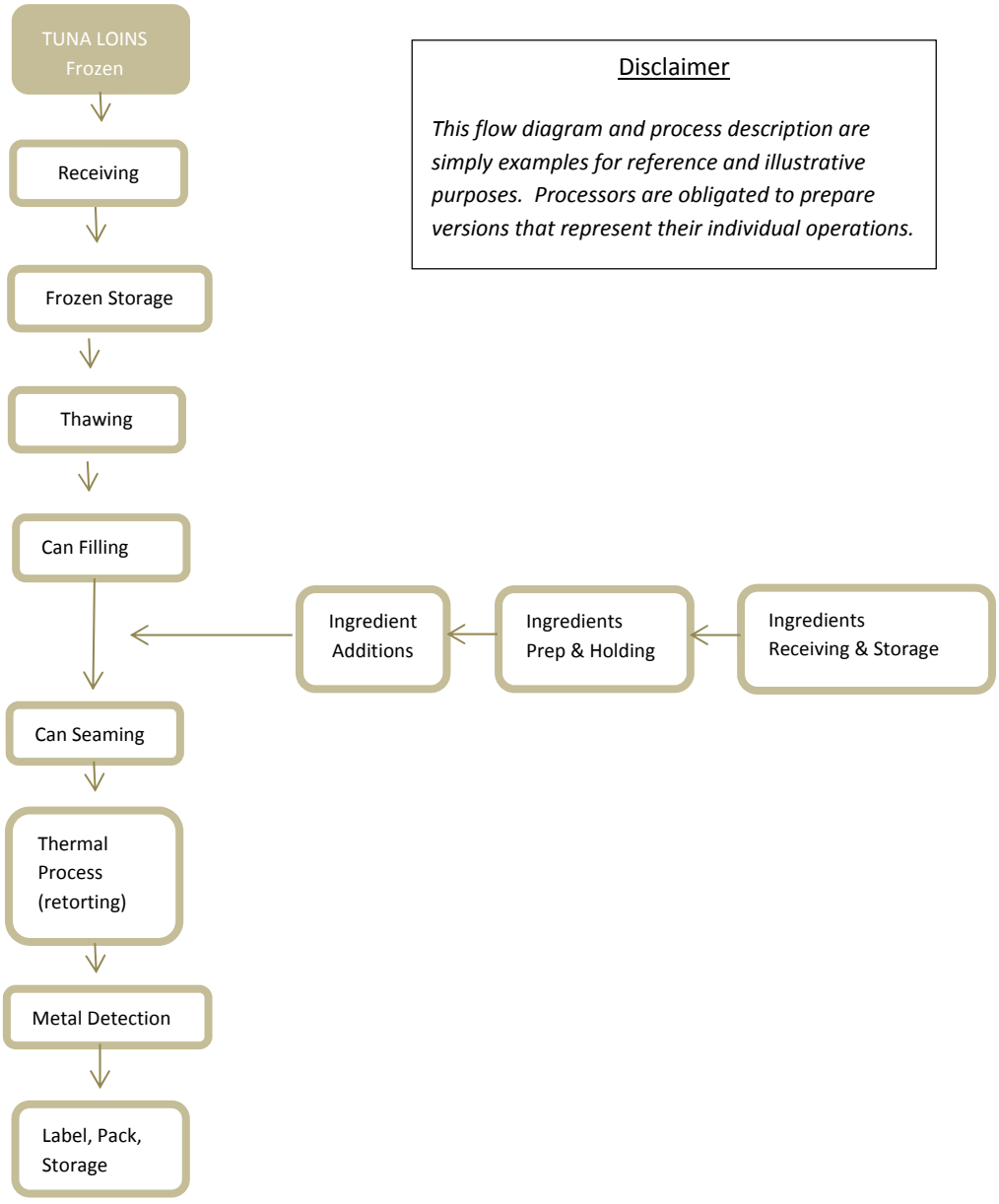
Pre-cooked, cleaned and frozen tuna meat packed in sealed plastic loin bags are shipped from primary processing facilities operating in different locations about the world to a secondary processing facility for canning. The primary processing operations obtain tuna harvested from wild resources.

At the canning facility the frozen loins are thawed and further processed for packaging as a low-acid food in hermetically sealed, rigid metal cans (e.g., 2-piece five ounce or seven ounce containers) that are thermally treated to prevent spoilage in non-refrigerated storage. The finished, canned products contain solid tuna pieces, chunks and/or flakes packed in water, olive oil or vegetable oil that may be seasoned with salt and/or vegetable broth and may include other approved ingredients.

Canned tuna is processed as a ready-to-eat product to be consumed by the general public.

Process Flow Diagram

Example 3. CANNED TUNA from Frozen Pre-Cooked Loins



Disclaimer

This flow diagram and process description are simply examples for reference and illustrative purposes. Processors are obligated to prepare versions that represent their individual operations.

Process Description

For training purposes, the process description is outlined in the following table with three columns. The first two columns describe the processing procedures for each step used for Example 3. The third column discusses possible variations or considerations for each processing step. This accompanying column provides some guidance for operations that may different from Example 3.

Example 3. CANNED TUNA from Frozen Pre-Cooked Loins

Processing Steps	Example 3 Procedures	Possible Variations and Considerations
Receiving	Frozen loins are delivered via sea freight and/or trucking from a primary processing operation. The loins have been pre-sorted for species and size by the primary processor. All deliveries are linked with HACCP records available from the primary processing operations.	*The primary processing facilities must produce all frozen loins under HACCP programs compliant with FDA's Seafood HACCP regulation to assure acceptable levels for histamine and related seafood safety concerns associated with harvest and primary processing.* *Processors who are also the importers of the frozen loins will need to follow the requirements for importing fish and fishery products outlined in 21 CFR 123.12. (See Appendix 11 – 21 CFR Part 123). This section of FDA's Seafood HACCP regulation requires importers to have and implement written verification procedures which are to include product specifications and affirmative steps necessary to ensure the primary processor is in compliance with FDA's Seafood HACCP regulation. The written product specifications must relate the acceptance criteria for product safety attributes which ensure the tuna loins received from the primary processors are not adulterated as defined in section 402 of the U.S. Federal Food, Drug and Cosmetic Act.*
Frozen Storage	Frozen storage is necessary for temporary holding and product inventory.	*Delivery information and lot identifications must be maintained to provide reference to the initial sources and associated processing records.*
Thawing	Frozen loins must be thawed prior to filling the cans. The thawing procedure involves spraying with clean	*The Tuna Council recommends a specific routine SSOP program to protect the pre-cooked tuna loins from potential contamination and pathogen growth during*

Processing Steps	Example 3 Procedures	Possible Variations and Considerations
Thawing cont'd	water to achieve a targeted internal loin temperature approaching 0°C/32°F. Thaw temperature and time is controlled to prevent potential growth of any pathogenic bacteria including *C. botulinum* and *S. aureus*, and to prevent potential elevation of histamine levels due to possible bacterial growth.	*thawing through sealing into cans and subsequent start of the retorting process.* *Recommendations for histamine control in the FDA Hazards Guide (Chapter 7; page 119) indicate that the thawing methods should not expose the first thawed portions (external surface of the tuna) for more than12 hours above 4.4°C/40°F, if the exposure temperatures (tuna surface during thawing) are greater than 21.1°C/70°F.* *NOTE: If the ambient conditions for thawing are less than 21.1°C/70°F, the total accumulative time for product exposure above 4.4°C/40°F must be less than 24 hours. This approach may require refrigerated or air conditioned thawing areas.* *Additional time and temperature controls are under investigation relative to thawing methods and times for S. aureus control.*
Ingredients Receiving & Storage	Non-tuna ingredients (e.g., salt, oil, dried vegetable broth) are received from approved suppliers, purchased based on ingredient specifications. Ingredients are either tested and/or inspected or Certificates of Analysis (COA) verified at receipt. Ingredients are stored according to particular storage temperature requirements. Records of ingredient lot codes are maintained for traceability. Ingredients containing food allergens are stored in a separate, designated storage area.	*All ingredients should be food grade and monitored for safety through specifications and temperature controls at receiving. All ingredients will be subject to labeling for declared allergens and other regulations for finished product contents.* *Warehousing SSOPs with associated records are necessary to prevent adulteration of ingredients and allergen cross-contact.*
Ingredients Prep & Holding	Ingredients are removed from storage and assembled for preparation based on product formula being produced.	*Continuous SSOPs with associated records are necessary to prevent potential allergen cross-contact and bacterial contamination.* *Identity of lot control of added ingredients must be maintained.*

Processing Steps	Example 3 Procedures	Possible Variations and Considerations
Can Filling	Thawed tuna (loins and chunks) is loaded into cans using automated fillers.	*The duration for filling, ingredient additions and can seaming is also part of the cumulative time for exposure (less than 12 hours) from thawing frozen loins until retorting the canned tuna.* *The Tuna Council recommends a specific routine SSOP program to protect the pre-cooked loins during all processing steps until the thawed loins are sealed into the cans and the retort process started.* *In some operations the can filling and/or ingredient addition steps could introduce metal fragments that would require monitoring with x-ray or other means such as equipment inspection to control potentially affected product.* *Depending on formulation, some added ingredients may be potential food allergens that require label declarations.* *NOTE: Coding and the control of proper can seaming must comply with FDA's 21 CFR Part 113 - Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation.*
Ingredient Additions	Addition of ingredients in the pre-filled cans will vary per product type, flavor and pack. This procedure includes steps to prepare and hold the ingredients prior to filling.	
Can Seaming	The filled cans are mechanically sealed or seamed and individually coded prior to loading the cans into the retort for thermal processing.	
Thermal Process (Retorting)	An established thermal process schedule is used to assure the proper level of bacterial lethality to produce a shelf-stable product.	*The proper retort process schedule must comply with FDA's 21 CFR Part 113-Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation.*
Metal Detection	All canned product is subject to metal detection with an X-ray unit preset to monitor for potential fragments.	*Accuracy checks for x-ray units must be conducted and recorded daily and calibration checks annually or as needed.*
Label, Pack, Storage	The individual retorted cans and final packaged units are labeled to declare product type and contents relative to net weight and possible food allergens of concern. The master case packed product is held in storage ready for distribution.	*The firm should assess the best location and periods for a food allergen CCP. For example for lithographed cans and pre-printed pouches the best location may be the filling station. In most cases this may involve more than one location and one time per batch.* TIP: *Like pre-printed lithographed cans, the packaging materials for pouched tuna or tuna in plastic cups are often pre-printed with the label information.*

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PART 2. HAZARD ANALYSIS

Example 3. **CANNED TUNA from Frozen Pre-Cooked Loins**

Identify Hazards

A previous hazard analysis, as illustrated in Chapter 3 using the FDA Hazard Guide, concluded that four potential hazards are 'reasonably likely to occur' in the production of canned tuna from frozen pre-cooked tuna loins. The FDA Guide includes:

- Pathogenic Bacteria Growth
  - *Staphylococcus aureus* (*S. aureus*) growth and enterotoxin production
  - *Clostridium botulinum* (*C. botulinum*) growth and toxin production in reduced oxygen packaging (ROP); ROP bagged loins and sealed cans
- Scombrotoxin (elevated histamine levels)
- Allergens and Food Additives
- Metal Inclusion

SPECIAL NOTE: Based on concerns expressed by FDA relative to exposure temperatures, the Tuna Council recommends limiting the cumulative duration of exposure for the previously pre-cooked, frozen loins during all processing steps from thawing until can retorting to prevent potential elevated histamine levels. The Tuna Council is actively researching the limits of cumulative duration of exposure necessary to prevent the production of heat-stable enterotoxins that could result from excessive growth of any *Staphylococcus aureus* that could potentially be introduced during prior handling. Concerns for potential *S. aureus* contamination should be specifically addressed with strict Sanitation Standard Operating Procedures (SSOPs) and the accompanying monitoring procedures and records (See Chapter 7 - SSOPs).

Identify Best Locations to Control Potential Hazards (CCPs)

As explained in Chapter 5 - Building a HACCP Program -the hazard analysis is used to identify the necessary CCPs. A basic hazard analysis form was used to help identify the best location for controls for all of the potential identified hazards (Appendix 10 - HACCP Forms). The 'Inclusive Approach' was used to account for potential controls for all hazards across all processing steps.

Hazard Analysis Worksheet — Example 3. CANNED TUNA from Frozen Pre-Cooked Loins

Firm Name: Canned Tuna Company 3	**Product Description:** CANNED TUNA from Frozen Pre-Cooked Tuna Loins
Firm Location: 3 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready to eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Receiving	Pathogenic Bacteria Growth	NO	Loins previously cooked and frozen by primary processor	Primary processor HACCP plan	
	Scombrotoxin (elevated histamine)	NO	Loins previously cooked and frozen by primary processor; received frozen FDA Hazards Guide (page 121) does not consider histamine formation to be a reasonably likely hazard for fish received frozen by a secondary processor		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Tuna is a food allergen introduced at receiving	Potential allergens are introduced at this step but controlled at the Labeling step	NO
Frozen Storage	Pathogenic Bacteria Growth	NO	Not likely to occur at this step; product frozen		
	Scombrotoxin (elevated histamine)	NO	Not likely to occur at this step; product frozen		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet — Example 3. CANNED TUNA from Frozen Pre-Cooked Loins

Firm Name: Canned Tuna Company 3	**Product Description:** CANNED TUNA from Frozen Pre-Cooked Tuna Loins
Firm Location: 3 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready to eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Thawing	Pathogenic Bacteria Growth	YES (*S. aureus*) YES (*C. bot*)	Potential presence of *S. aureus* could grow to produce heat-stable toxins if exposed to temperatures above 10°C/50°F *C. botulinum* could be present in ROP bagged tuna loins	Step subject to SSOP. Later thermal processing step will control pathogens. Specific SSOPs for *S. aureus* and control exposure time** above 10°C/50°F from start of thawing until retorting Proper retort processing in accordance with 21 CFR Part 113 for LACF to destroy *C. botulinum* and any heat liable toxin.	YES** (*S. aureus*) NO (*C. bot*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until retorting	YES*
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Can Filling	Pathogenic Bacteria Growth	YES (*S. aureus*)	Potential presence of *S. aureus* could grow to produce heat-stable toxins if exposed to temperatures above 10°C/50°F	Can filling subject to SSOP. Later thermal processing steps will control pathogens. Specific SSOPs for *S. aureus* and control exposure time** above 10°C/50°F from start of thawing until retorting	YES** (*S. aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until retorting	YES*
	Metal Inclusion	YES	Potentially introduced at this step during can filling	X-ray (metal detection) at later step	NO
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet — Example 3. CANNED TUNA from Frozen Pre-Cooked Loins

Firm Name: Canned Tuna Company 3	**Product Description:** CANNED TUNA from Frozen Pre-Cooked Tuna Loins
Firm Location: 3 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready to eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Ingredients Receiving & Storage	Pathogenic Bacteria Growth	NO	While potential pathogens may accompany ingredients, dry ingredients and oil do not support their growth		
	Scombrotoxin (elevated histamine)	NO	Step does not involve tuna		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Some food allergen ingredients may be introduced at receiving	Undeclared allergens controlled at the Labeling step	NO
Ingredient Prep & Holding	Pathogenic Bacteria Growth	YES	Pathogens could accompany preparation of ingredients	Procedures subject to SSOP and later thermal processing steps will control these pathogens	NO
	Scombrotoxin (elevated histamine)	NO	Step does not involve tuna		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Some food allergen ingredients may be introduced during preparation.	Undeclared allergens controlled at the Labeling step	NO

Hazard Analysis Worksheet — Example 3. CANNED TUNA from Frozen Pre-Cooked Loins

Firm Name: Canned Tuna Company 3	**Product Description:** CANNED TUNA from Frozen Pre-Cooked Tuna Loins
Firm Location: 3 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready to eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Ingredient Addition	Pathogenic Bacteria Growth	YES (*S. aureus*)	Pathogens could be introduced during ingredient addition Potential presence of *S. aureus* could grow to produce heat-stable toxins if exposed to temperatures above 10°C/50°F	Step subject to SSOP. Later thermal processing steps will control pathogens. Specific SSOPs for *S. aureus* and control exposure time** above 10°C/50°F from start of thaw until retorting	YES** (*S. aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until retorting	YES*
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Added ingredients could introduce potential food allergens	Undeclared allergens controlled at the Labeling step	NO
Can Seaming	Pathogenic Bacteria Growth	YES (*C. bot*) YES (*S. aureus*)	Pathogens could be introduced during prior steps Pathogens could be re-introduced after thermal process due to improperly formed seams Potential presence of *S. aureus* could grow to produce heat-stable toxins if exposed to temperatures above 10°C/50°F	Later thermal processing steps will control pathogens Proper seam formation is controlled through compliance with 21 CFR Part 113 for LACF Specific SSOPs for *S. aureus* and control exposure time** above 10°C/50°F from start of thaw until retorting	NO (*C. bot*) (controlled by 21 CFR 113) YES** (*S. aureus*)
	Scombrotoxin (elevated histamine)	YES	Histamine levels could be elevated at temperatures above 4.4°C/40°F	Control exposure time* from start of thaw until retorting	YES*
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		

Hazard Analysis Worksheet — Example 3. CANNED TUNA from Frozen Pre-Cooked Loins

Firm Name: Canned Tuna Company 3	**Product Description:** CANNED TUNA from Frozen Pre-Cooked Tuna Loins
Firm Location: 3 Main Street, Anywhere	**Method of Storage & Distribution:** Shelf-Stable Canned
	Intended Use & Consumer: Ready to eat

(1) **Processing Steps**	(2) List all potential biological, chemical and physical **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Thermal Process (Retorting)	Pathogenic Bacteria Growth	YES	Pathogens survival through thermal process	Proper retort processing and post-process handling in accordance with 21 CFR Part 113 for LACF that includes controls for pathogens including any potential *C. botulinum*	NO (controlled by 21 CFR 113)
	Scombrotoxin (elevated histamine)	NO	Not likely to occur at this step; application of extensive heat		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Metal Detection	Pathogenic Bacteria Growth	NO	Not introduced, enhanced or eliminated at this step		
	Scombrotoxin (elevated histamine)	NO	Not introduced, enhanced or eliminated at this step		
	Metal Inclusion	YES	Some prior processing steps may have introduced metal fragments which will be eliminated at this step	Metal Detector (X-ray unit)	YES
	Undeclared Food Allergens	NO	Not introduced, enhanced or eliminated at this step		
Label, Pack, Storage	Pathogenic Bacteria Growth	NO	Not introduced, enhanced or eliminated at this step		
	Scombrotoxin (elevated histamine)	NO	Not introduced, enhanced or eliminated at this step		
	Metal Inclusion	NO	Not introduced, enhanced or eliminated at this step		
	Undeclared Food Allergens	YES	Tuna and injected or added ingredients could include potential food allergens	Monitor labeling designating tuna and other allergenic ingredients	YES

*Cumulative time of exposure of frozen, pre-cooked loins from start of thawing until retorting cans to prevent elevated histamine levels.
**Cumulative time of exposure of frozen, pre-cooked loins from start of thawing until retorting cans to prevent potential *Staphylococcus aureus* growth and enterotoxin production.

PART 3. HACCP PLAN

Example 3. **CANNED TUNA from Frozen Pre-Cooked Loins**

The hazard analysis identified 4 Critical Control Points:

1. **Cumulative time*** from beginning of Thaw through start of Thermal Processing (can retorting) to prevent subsequent histamine production.
2. **Cumulative time**** from beginning of Thaw through start of Thermal Processing (can retorting) to control potential *S. aureus* growth and potential production of heat-stable enterotoxin
3. **Metal Detection** to eliminate metal fragments or inclusions
4. **Labeling** to declare potential food allergens

Pending Critical Limits: Active research is being conducted to establish time and temperature controls specifically designed to control growth of *Staphylococcus aureus* and potential enterotoxin formation.

HACCP Plan Form

The written HACCP Plan provides a brief description of routine activities that will occur at all CCPs to prevent the identified potential hazards. The HACCP Plan form can be completed in either a portrait or landscape format (see Appendix 10 – HACCP Forms), but either form must include descriptions for:

- **CCP** or processing step
- **Significant hazards** involved
- **Critical Limits** specify the measure for control
- **Monitoring** procedures
    - What will be done
    - How will it be done
    - When will it be done (frequency)
    - Who will do it
- **Corrective Actions** to assure:
    - That no product under deviation enters commerce and
    - The root cause of the deviation is addressed
- **Records** taken as evidence for controls and reference
- **Verifications** to assure the HACCP plan and procedures will work and are working

HACCP Plan Cover Sheet

CANNED TUNA from Frozen Pre-Cooked Loins HACCP Plan

Canned Tuna Company 3

3 Main Street, Anywhere

Date Issued:

Supersedes Version Dated:

Approved by:

Name/Title:	Signature:	Date:
_____	_____	_____
_____	_____	_____
_____	_____	_____

NOTE: Remember that the HACCP plan needs to be reviewed at least annually and approved (and signed) by the most responsible individual on site or higher in the corporation.

		CCP 1 CANNED TUNA from Frozen Pre-Cooked Tuna Loins
Critical Control Point (CCP)		Thawing → Retort *Cumulative Time
Significant Hazard		Elevated histamine levels
Critical Limits		12 hours maximum cumulative time from start of thawing until retort steam on.
Monitoring	What	Cumulative exposure time
	How	Uniquely identify each thaw rack and each retort basket; visually track time from start of thaw to when steam is turned on.
	When	Every thaw rack / each retort basket
	Who	Production inspectors
Corrective Action		If cumulative exposure time exceeds 12 hours: • clearly identify and segregate affected loin material from the thaw rack and associated retort basket, • if possible, immediately expedite processing of the affected loin material, • maintain on HOLD after retorting until the finished product is evaluated for histamine levels, • Sample and perform histamine analysis on a minimum of 60 representative samples^^, randomly selected from the affected product. Testing can be done using composites of 3 samples (20 composites). o If any composite is greater than 50 ppm, then reject the affected product. o If any of the 20 composites exceeds 17 ppm but is less than 50 ppm histamine, then individually test each sample used in that composite. o If any individual sample is greater than 50 ppm, then reject all product packed from the affected product. • Determine root cause and correct the cause for the excessive exposure time.
Records		• Total time exposure records • Corrective Action records • Verification records • Training Records for CCP monitoring personnel
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Weekly accuracy check for proper clock performance • Appropriate training program for new employees and annual refresher-training for employees responsible for time monitoring.

*Cumulative time of exposure of frozen, pre-cooked loins from start of thawing until start of retorting to prevent elevated histamine levels.

^^ See discussion on page 6-101

DISCUSSION - CCP 1 Cumulative Exposure Time for 'Thawing Until Retorting'

Critical Limit

The critical limit exposure time is based on recommendations from page 118 of the FDA Hazards Guide which states: "Scombrotoxin-forming fish that have been previously frozen, or heat processed sufficiently to destroy scombrotoxin-forming bacteria and are subsequently handled in a manner in which there is an opportunity for recontamination with scombrotoxin-forming bacteria (e.g., contact with fresh fish, employees, or introduction of raw ingredients), should not be exposed to temperatures above 40°F (4.4°C) for:

- More than 12 hours, cumulatively, if any portion of that time is at temperatures above 70°F (21.1°C); or
- More than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C)"

A more stringent operating limit can be used to allow better process controls and to minimize critical limit deviations.

Recent scientific studies by members of the Tuna Council (see Appendix 9 – References) provide evidence that it takes 18 hours or longer before presenting a significant risk of increased histamine levels. At this time, the Tuna Council recommends a conservative 12 hour critical limit consistent with the FDA Hazards Guide for cumulative time between pre-cooking and start of retorting (steam on). This conservatively accommodates any lag times that occur between the time steam is first introduced into the retort and histamine inhibition temperatures (60°C/140°F) are reached in the cans.

Monitoring

Use of monitoring methods for cumulative time of exposure is recommended and recognized as an appropriate approach as illustrated for unrefrigerated processing of blue crabs in Chapter 12, page 240, Table 12-6 of the FDA Hazards Guide. A key function will be maintaining the identity of the thaw batch from when it enters the thawing tunnel through all steps until cans are in the retort and the retort process is started. Likewise, record of cumulative exposure time across all processing steps must be maintained. This information is required to demonstrate compliance with the critical limit as well as providing, information if necessary, to determine proper corrective actions.

Chapter 7, page 145, Table 7-6 of the FDA Hazards Guide also illustrates the use of monitoring cumulative exposure time to control potential scombrotoxin formation during processing.

The facility needs to have a pre-established system for clearly identifying the thaw batch, including methods for identifying the racks and retort baskets involved with each thaw batch.

See Appendix 4 for detailed guidelines on how time can be monitored cumulatively through multiple steps of the process.

When packing rework there must be a system in place to track the cumulative time of exposure for the rework material.

Corrective Action

Ideally a critical limit deviation will be identified during processing so the loins can be expedited through the process to minimize further delays. Any products that exceed the established critical limit must be evaluated for safety after retorting or destroyed.

The facility needs to have a pre-established system for clearly identifying the thaw batch. Examples are racks, container, pallets, time frames to process.

^^A minimum of 60 cans must be collected after retorting from throughout the retort baskets which contain product from the affected thaw batch. Keep in mind the baskets may be in different retorts. If the batch has been separated into different retorts, then only the retort baskets that are over the time limit need to be sampled.

It is important that histamine results and lab procedures are precise and accurate. Analytical methods to measure histamine should be based on AOAC approved procedures or methods that have been validated against AOAC approved procedures. These methods can be qualitative or quantitative. Qualitative methods provide a 'pass' or 'fail' result, for example a color change. Quantitative methods provide discrete values of histamine readings, for example readings from a fluorometer.

Verification

The accuracy of the digital or analogue clocks used for time tracking needs to be verified on a weekly basis against a known standard time keeping device such as found on a centralized computer or phone system. During the weekly accuracy check, synchronize all clocks that are used in plant for monitoring time across multiple processing areas.

The monitoring and corrective action records must be reviewed prior to shipping any product, and there should be a system to retain the product identity traceable to the original retort baskets until the records have been reviewed.

		CCP 2 CANNED TUNA from Frozen Pre-Cooked Tuna Loins
Critical Control Point (CCP)		Thawing → Retort **Cumulative Time
Significant Hazard		*Staphylococcus aureus* enterotoxin formation
Critical Limits		10 hours maximum cumulative time from start of thawing until retort steam on
Monitoring	What	Cumulative exposure time
	How	Uniquely identify each thaw rack and each retort basket; visually track time from start of thaw to when steam is turned on
	When	Every thaw batch
	Who	Production inspectors
Corrective Action		If cumulative exposure time exceeds 10 hours: • Clearly identify and segregate the affected material (i.e., the part of the batch exceeding the exposure limit) until the full exposure time is determined, • If possible, immediately expedite processing of the affected loin material, If the critical limit is not met, then either: o destroy the affected product or o isolate and HOLD affected product; consult qualified process authority^ to determine product disposition. • Perform root cause analysis to determine correction to bring process into compliance to avoid recurrence
Records		• Total time exposure records for start of thaw to retort steam on • Corrective Action records • Verification records • Training Records for CCP monitoring personnel
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records. • Review of corrective action records prior to approving the labeling of any potentially affected product. • Weekly accuracy check for proper clock performance. • Appropriate training program for new employees and annual refresher-training for employees responsible for time monitoring.

**Cumulative time of exposure of frozen, pre-cooked loins from start of thawing until retorting cans to prevent potential *Staphylococcus aureus* growth and enterotoxin production.
^ see Appendix 1 - Glossary

DISCUSSION - CCP 2 Cumulative Exposure Time for 'Thawing Until Retorting'

NOTE: *Staphylococcus aureus* can potentially be introduced by handling during the cleaning step. A well-designed sanitation program will minimize the introduction (see Chapter 7 - Sanitation Considerations for Canned Tuna Processing).

Critical Limit

For control of *Staphylococcus aureus* FDA recommends that exposure be limited to less than 3 hours cumulative when handling seafood products at temperatures above 21.1°C/70°F.

Unpublished studies currently underway by the Tuna Council do indicate that the 3 hour critical limit is very conservative. The challenge studies, conducted at worst case temperature conditions showed that no toxin was produced in pre-cooked albacore and skipjack samples at 10 hours at 37°C/98°F.

At this time, the Tuna Council recommends a 10 hour maximum cumulative exposure critical limit consistent with findings of the inoculation studies, beginning with start of thaw and ending at the start of retorting (steam-on time).

A more stringent operating limit should be used to allow better process controls and to minimize critical limit deviations.

Monitoring

Use of monitoring methods for cumulative time of exposure is recommended and recognized as an appropriate approach as illustrated for unrefrigerated processing of blue crabs in Chapter 12, page 240, Table 12-6 of the FDA Hazards Guide. The monitoring method selected must ensure that batches can be time-tracked for compliance with the 10 hour critical limit. Batch size and the ability to clearly differentiate batches have implications for corrective actions.

Corrective Action

Any product disposition other than destruction requires careful science-based analysis as determined by the qualified process authority. Keeping extensive, detailed records such as room air temperatures, product temperatures, and precise extent of the time deviation will assist with this expert review.

Verification

The accuracy of the digital or analogue clocks used for time tracking needs to be verified on a weekly basis against a known standard time keeping device such as found on a centralized computer or phone system. During the weekly accuracy check, synchronize all clocks that are used in plant for monitoring time across multiple processing areas.

		CCP 3 CANNED TUNA from Frozen Pre-Cooked Tuna Loins	
Critical Control Point (CCP)		Metal Detection	
Significant Hazard		Metal Inclusion	
Critical Limits		All cans of the finished product passes through an operating x-ray unit.	No detectable metal fragments are in the product passing through the x-ray.
Monitoring	What	X-ray unit present and operating	The product for the presence of metal fragments
	How	Visual examination for presence of an operating x-ray unit	Monitoring performed by the x-ray unit
	When	Check that x-ray unit is in place and operating at the start of each production day	Continuous by x-ray unit
	Who	Packaging employee	Equipment itself
Corrective Action		If the product is processed without operating x-ray, hold all cans produced since last point x-ray was operational until they can be run through operational x-ray. Open rejected cans to determine cause of rejection, remove metal fragments from product, identify source metal to fix the damaged equipment OR destroy rejected product. Correct operating procedures to ensure that the product is not processed without being x-rayed.	
Records		• X-ray operation monitoring log • X-ray verification log • Corrective Action records • Validation records for x-ray operation set-up. Training Records for CCP inspectors	
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Develop x-ray sensitivity standard • Conduct a validation study to determine appropriate setting for the x-ray • Challenge the x-ray unit with validated sensitivity standard daily, before start-up, every 4 hours during production, whenever processing factors change, and at the end of processing • Training program for monitoring personnel • Annual calibration of x-ray	

DISCUSSION - CCP 3 Metal Detection

Critical Limit

Ensuring that x-ray will detect a certain size and type of metal is a verification activity not the critical limit. The critical limit is that all cans will be run through the operational x-ray unit.

Monitoring

While the properly operating x-ray will continuously monitor each can for the presence of metal, a person will need to ensure that the x-ray unit is operational.

Corrective Actions

Cans that are rejected by the metal detector should be opened and the product inspected to find the metal. Identify the source of the metal to correct any damaged equipment.

Verification

It is important to work with the x-ray unit manufacturer when developing the x-ray sensitivity standard. Some variables that may impact the standard include the size of the can and formulation of the packing medium or additional ingredients such as jalapeno peppers.

		CCP 4 CANNED TUNA from Frozen Pre-Cooked Tuna Loins
Critical Control Point (CCP)		Label, Pack, Storage
Significant Hazard		Undeclared food allergens
Critical Limits		The label of packages of finished product designate tuna product content and all other allergenic ingredients
Monitoring	What	The labels being applied to the packages to ensure they correspond to the formula of the product being labeled, and to ensure the labels have the required allergen declaration(s)
	How	Visual checks
	When	At startup of labeling, at each lot code change over and every 2 hours maximum intervals
	Who	Labeler Operator
Corrective Action		Segregate, place on hold, and re-label any improperly labeled product. Investigate cause of mislabeling and implement necessary corrections to prevent reoccurrence.
Records		• Record of labeling checks • Corrective action records • Verification records • Training records
Verifications		• Weekly review (or prior to shipping products) of monitoring, verification and corrective action records • Training program for monitoring personnel

DISCUSSION - CCP 4 Label, Pack, Storage

Critical Limit

Each can or pouch of finished product must declare the presence of all allergens on the product label.

Monitoring

Monitoring must account for all product lot codes packed by the facility, i.e., monitoring records must be available for each production batch or lot of finished product packed and shipped from the facility.

In addition to checking to ensure that the correct labels are being applied, the labels themselves must be verified when received or applied to ensure there are no printing errors or omissions, and that all allergen declarations are present.

FDA has stated that label checks for allergens are normally best conducted at the labeling step but for companies producing a single item, the checks could be performed when the labels are received from the printer. In most cases, tuna canning operations will need to reconcile the labeled ingredients with the production run necessitating label accuracy checks at the labeling step.

FDA regulations are very specific on how allergens must be declared on labels, and there are several different ways permitted by the regulation, so each processor must decide how to best declare allergens in their labels. For the purpose of this example, the labels are expected to have the word “TUNA” on the main panel and the statement “CONTAINS: TUNA, SOY” immediately after the list of ingredients; if either is missing or incorrect, corrective action must be taken.

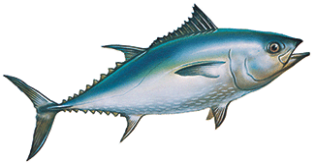
Corrective Actions

Segregate and destroy or re-label any improperly labeled product. Perform root-cause investigation to determine what caused the product to be mislabeled and make adjustments or changes to prevent reoccurrence. The changes implemented should be documented as part of the investigation on a case by case basis.

Verification

Monitoring records and records of re-labeling must be reviewed by a HACCP trained individual prior to shipping product. Audits and spot checks on outgoing merchandise performed regularly can provide additional verification for this CCP.

CHAPTER 7



SANITATION CONSIDERATIONS FOR CANNED TUNA PROCESSING

Prerequisite programs are overviewed in Chapter 4 which emphasizes implementing SSOPs that comply with the U.S. Good Manufacturing Practices and the eight (8) key sanitation conditions identified in the FDA HACCP regulation. Suggested elements of written SSOPs are provided in Appendix 2. This chapter focuses on strategies for controlling the introduction and growth of relevant bacteria, and other sanitation practices having the greatest effect on the safety of canned tuna products. As stated in Chapter 4, both sanitation and HACCP control programs are often necessary to fully manage certain hazards. Control of the pathogen *Staphylococcus aureus* provides a good example of using both control programs for one hazard.

U.S. Tuna Industry Recommended Practices for Control of Human Vegetative Pathogens, Including *Staphylococcus aureus*

Staphylococcus aureus (abbreviated as *Staph aureus* in this chapter) is a common bacteria on human skin, and approximately 50 percent of human beings are carriers. *Staph aureus* primarily occurs in the nose and on the face, but can also occur on other parts of the body, and can be easily transmitted from the face to the hands. Normal human bacterial defense mechanisms protect against illness, but if there is a cut or opening in the body the *Staph aureus* bacteria can invade and cause an infection. *Staph aureus* infections are contagious and can be transmitted from person to person, and person to product.

If allowed to grow to sufficient numbers on food, *Staph aureus* produces heat-stable (not destroyed by retorting) enterotoxins which cause illness when ingested. Although tuna cannot be processed in a sterile environment, the potential for contamination can be significantly reduced by processing in a clean environment:

1. Reduce the amount of *Staph aureus* on people's skin or possible transfer to tuna by:
    a. Hand washing
    b. Hand sanitizing
    c. Clean outer wear
    d. Face masks, hair covering, and gloves
2. Keep the equipment clean by periodic cleaning and sanitizing.

Sanitation and proper employee hygiene and health are important components of an effective control strategy for ensuring that pre-cooked tuna destined for canning does not become contaminated with *Staph aureus*. It is recognized that most processing plants perform the fish cleaning steps of removing skin and bones and separating light from dark meat using warm tuna and warm room temperatures. Warm temperatures promote faster growth of *Staph aureus*, thus the enterotoxin can form faster. *Staph aureus* is most often associated with humans but has also been known to colonize processing equipment that is inadequately cleaned. An effective sanitation program will reduce the presence of other pathogens and the overall microbial load of tuna prior to retorting, as required by U.S. cGMPs. Proper equipment design, construction and installation are also necessary to permit access for cleaning and sanitizing.

The following sections describe Sanitation Standard Operating Procedures (SSOPs) which are standard in the tuna loin and tuna canning industry and part of the Prerequisite Programs that support the HACCP Plan. They are example control strategies for meeting U.S. cGMPs and specifically, the most relevant of the eight (8) key sanitation conditions identified in the U.S. FDA Seafood HACCP regulation (21 CFR 123) for control of *Staph aureus*. These standards must be maintained and monitored as indicated. For minimizing contamination by *Staph aureus*, emphasis should be placed on the following key sanitation conditions:

#2 -- Condition and Cleanliness of Food Contact Surfaces,
#3 -- Prevention of Cross-contamination, and
#7 -- Control of Employee Health.

A successful sanitary control program intended to target the sources of *Staph aureus* most likely to contaminate tuna will contain five components:

1) cleaning and sanitizing,
2) employee hygiene,
3) employee health,
4) time-temperature conditions, and
5) monitoring / verification for compliance.

This guideline focuses on cleaning and sanitizing programs and provides basic recommendations for adoption of 'clean room' procedures in areas where pre-cooked tuna are manually handled (see final section of this chapter). Time-temperature targets for component #4 should be set based on known growth rates for *Staph aureus* as effected by starting tuna temperature, room air temperature, time for processing, and level of sanitation employed in the tuna cleaning and can filling areas of the plant, all which determines potential initial load. As such, no one maximum allowable processing time is suitable for all facilities.

It is well recognized that growth lag times for *Staph aureus*, like most bacteria, are much longer when temperature conditions change dramatically or the shifts are outside the favorable temperature range for the organism. It is also established that *Staph aureus* enterotoxin production only becomes a potential concern above 10°C (50°F) with temperatures below 37°C (98.6°F) being suboptimal. Contamination of the tuna after pre-cooking, while they are warm, i.e., above 10°C (50°F), will permit the greatest opportunity for *Staph aureus* growth. Therefore, operations using frozen, pre-cooked loins present a lower risk for *Staph aureus* contamination and growth than at the plant where the tuna are pre-cooked and cleaned while still warm. Factories that pre-cook and clean the tuna should receive the highest level of sanitation control for this microorganism.

CLEANING AND SANITATION PROGRAMS

Sanitation Standard Operating Procedures (SSOPs) should be established to provide effective and consistent results. Effective sanitation can be a complex process. The managers of a successful program must understand and apply the cleaning and sanitizing process and select the appropriate methods and chemical agents for the particular environment and equipment being cleaned. The proper selection of detergents and sanitizers, their concentrations and method of application will depend on several factors including;

1) Nature of the soil (soil is defined as matter out of place and includes meat, waste, grease, biofilms, etc.)
2) Degree of cleaning and sanitation required
3) Type of equipment used to clean and sanitize
4) Whether or not the surface being cleaned is a food contact surface.

Sanitizer alone cannot be depended upon to remove microorganisms. A cleaning system contains five parts:

1) dry clean,
2) pre-rinse,
3) detergent application,
4) post-rinse and
5) sanitizer application.

Sanitizers may or may not be rinsed off before the start of processing, depending upon the sanitizer being used, its concentration and local regulations. **Dry cleaning** is simply using a

broom, brushes or squeegee to sweep up fish waste and soil from the surfaces. Brooms and brushes should only be used in specified areas. At no time should brushes or brooms used in raw areas be used in post-cook processing areas.

Pre-rinsing uses water to remove small particles missed in the dry cleaning step and prepares surfaces for detergent application. However, scrupulous removal of particles is not necessary prior to **application of detergent**. Each detergent is different and it is important to follow directions. Alkaline or chlorinated alkaline detergents are recommended. Chlorinated alkaline products are very caustic and should not be used on corrodible surfaces. They are especially effective for heavily soiled surfaces, such as waste totes and waste handling equipment. Application of detergents in a foam cleaning system is recommended for tables, walls, floors, and large equipment. A brush or a green pad (e.g. 3-M Scotch-Brite) should be used at least periodically to facilitate removal of adhering soil. Where used, brushes, pads, floor brooms and squeegees should be designated to specific tasks in designated areas only, so as not to serve as instruments of cross-contamination.

Foam detergent should be allowed to stand 10-20 minutes before **rinsing**. Work in sections to avoid longer foam contact times, or the foam may dry which will require re-cleaning. The foam should be rinsed off with low pressure spray in most areas of a processing plant. High pressure spray can be effective when used to rinse detergents from difficult to reach surfaces, but their use in pre-cooked tuna areas is discouraged due to problems with splash and the formation of aerosols that can contaminate previously cleaned surfaces.

The **sanitizing step** involves the application of approved sanitizers. Methods for applying sanitizer may include the use of a low pressure tank sprayer or hose-mounted applicator (spray or foam). Inexpensive foamers are effective means for applying quaternary ammonium compound sanitizers (‘quats’). Use separate foamers for detergent and quats. Chlorine or quats are effective for footbaths, floors, and coolers (Note: chlorine is more effective at low temperatures than are quats.) For table tops (cleaning tables, weighing/packing tables, etc.) and other surfaces that come into direct contact with the product, 100-200ppm chlorine, 12-25 ppm iodine, or 200-400 ppm quat sanitizer is used. At these levels, U.S. regulations do not require that surfaces be rinsed but the sanitizer must drain freely.

Acidified sodium chlorite (stabilized chlorine dioxide) and peroxyacetic acid (peracetic acid) are other highly effective broad spectrum sanitizers worthy of consideration. They may also more readily meet the environmental discharge requirements of sustainability programs or regulatory agencies in some countries.

For non-food contact surfaces, such as floors and walls, the sanitizer concentration is doubled. (Note: some sanitizers have detergent-like properties and may be slick when floors are wet.)

When sanitizers are used in footbaths or dips or as an applied sanitizing solution the concentration must be confirmed using test strips or colorimetric kits.

The five-step cleaning process performed at the end of the day should be followed in the morning by a light application of sanitizer to table tops and other food contact surfaces, just prior to the start of operations. Re-dip clean knives, trays, and other small equipment in sanitizer just before use.

Verification of Sanitation

Periodically (e.g., weekly) the processing surfaces in the factory should be evaluated for cleanliness with either contact plates containing bacterial growth media or luminometry (using a luminometer) to confirm that the plant is adequately cleaned and sanitized. These test procedures are very simple and require little special equipment. After the contact plates are stored for 2-4 days (depending on temperature), very few colonies will appear from properly cleaned surfaces (e.g., table tops and door push plates). Unsanitary surfaces will give rise to many colonies. Luminometry (for example, Neogen's AccuPoint Sanitation Monitoring System, http://www.neogen.com/FoodSafety/AP_Index.html) is a rapid method for assessing overall cleanliness. Either method is an excellent way to train employees and provides positive reinforcement for a job well done. Alternatively, surfaces can be aseptically swabbed and plated from serial dilutions.

A detailed SSOP is recommended for consistent application of cleaning and sanitizing practices. An example of an SSOP is provided in a following section.

TUNA 'CLEAN ROOM'

Special Considerations for Handling Pre-Cooked Tuna

Since tuna cleaning (separation of light from dark meat and removal of skin and bone) is performed by hand, the risk of contamination with *Staph aureus* is greatest at this step. Most competitive microflora are eliminated in pre-cooking, and the tuna may be at or above room temperature during this stage of processing. These conditions favor *Staph aureus* growth if the tuna is contaminated. The following strategies may be used to control bacteria under conditions that allow for adequate processing time:

1) Lower the cleaning/filling room temperature to below 20°C (68°F), and/or
2) Process tuna in manageable batches to minimize time at room temperature, and always
3) Follow strict sanitation practices (outlined below).

<u>Clean room standard operating procedures</u>

Pre-cooked tuna must be processed under strict sanitary controls. In addition to items 1 and/or 2 described above, follow the procedures below.

1) Specify microbiological standards for pre-cooked, cleaned, and packed tuna loins. Tuna processors should establish standards for *Staph aureus* and organisms indicative of improper sanitation and handling practices, such as aerobic plate counts, total coliforms, *Staph aureus*, *Escherichia coli* (or fecal coliforms), and *Salmonella.* The Tuna Council recommends periodic sampling and testing for relevant microorganisms to assist in the evaluation of SSOP program effectiveness.

2) Designate a 'clean room' or 'clean area' especially for the purpose of processing pre-cooked tuna. The clean area must be strictly isolated from raw fish and other unsanitary or warm areas of the plant.

3) Workers must be dedicated to this clean area during production hours, barring employee access and traffic from adjacent areas. Exceptions are only made under the supervision of the Quality Assurance Manager following the procedures described below.

4) Entrances to the clean area must be supplied with a footbath containing sanitizer (see previous SSOP section), and garment changing and hand washing stations. These facilities must be used by all individuals, the activities monitored for compliance with

the SSOP, and the results of monitoring recorded on the daily sanitation monitoring form.

5) Employee hygienic practices (e.g., no hand-to-face contact without rewashing and sanitizing hands), and proper glove and garment usage must be supervised. The inspection results must be recorded on the company's daily sanitation monitoring form along with other sanitation conditions described in this guideline.

6) Employees with skin infections, especially when on hands, fingers and wrists, will be temporarily reassigned to a low-risk activity or sent home. Minor cuts can be bandaged and covered but such covers must be impervious and fully sealed by covering designed for this purpose. Employee health and hygiene procedures must be detailed in relevant sections of each company's SSOPs.

7) All equipment, utensils, tables and other food contact surfaces must be properly constructed to be readily cleanable and in nearly new condition.

8) Employees will clean and sanitize hands and sanitize or replace gloves at least every two (2) hours.

9) Waste handling containers (offal totes) must be detergent cleaned and sanitized before being returned to the clean room.

10) At regularly scheduled breaks, all food contact surfaces must be swept free of tuna debris and moistened with sanitizer, e.g., 100-200ppm chlorine. This procedure should be performed as necessary to align with HACCP cumulative time critical limits, for example every 3 hours. When water is used, care must be taken to avoid splash that could contaminate surrounding equipment or packaging. This practice assures that no tuna pieces remain on processing surfaces for extended periods and also temporarily slows bacterial growth (bacteriostatic effect). It is not intended to significantly reduce bacterial numbers.

11) Floors, splash zones of walls, processing tables, and all equipment are subject to the complete five-part cleaning/sanitizing sequence daily, as described in the SSOP.

EXAMPLE SSOP FOR CLEANING AND SANITIZING

The following program is implemented for each operation.

A. Tuna post pre-cook cooling area:

1. Once the tuna has been pre-cooked it must be protected from contamination with *Staph aureus* and histamine forming bacteria which could be introduced during the cooling and conditioning steps. Employees and implements do not contact the pre-cooked tuna directly until necessary for skinning and cleaning. See Appendix 6 – EPIPT Monitoring Procedure for guidance during temperature monitoring for pre-cooked fish. Workers who handle racks of pre-cooked tuna or work in the fish cooling or cleaning areas are prevented from entering raw fish areas of the plant or handling any equipment used in raw areas. Any exceptions require re-cleaning and sanitizing hands, smocks and gloves, and re-entering through a footbath containing double strength sanitizer (e.g., a 400-800ppm quaternary ammonium sanitizer).

2. The floor of the pre-cooked fish and air cooling areas are sanitized every four hours using a low pressure spray of 200-400ppm chlorine or other sanitizer at double strength (for example, 400ppm quat or 50ppm iodine).

3. Any hooks or tools used to position or move racks of pre-cooked tuna are cleaned and sanitized with alkaline detergent and sanitizer (food contact concentration) daily. They are misted or stored in sanitizer between uses and kept off the floor in a clean designated location.

4. Fish cooking baskets and racks are cleaned using high pressure hose and moistened with sanitizer daily and cleaned weekly with alkaline or chlorinated alkaline detergent.

5. Accessible surfaces of cooling fans or misters used to cool tuna are rinsed daily and moistened with sanitizer. Weekly, they are partially disassembled to expose fan blades and other parts for thorough cleaning and sanitizing.

6. The entire area is cleaned and sanitized following the five-step method on a rotation basis as these areas are cleared of fish (every 24-48 hours). The room and equipment, including floors and splash zone of walls, are foamed up and rinsed down in sections. Alkaline foam is allowed to stand on surfaces for at least 10 minutes and no longer than 20 minutes before rinsing. Green pads or brushes are used at least weekly.

B. Pre-cooked tuna coolers:

Daily:

1. Dry clean
2. Spray walls and floors with 400ppm chlorine

Weekly:

1. Clean and sanitize using the five-part system.
2. Sanitize the evaporator drip pan by pouring quat (400ppm) into the pan.

Twice Monthly:

1. Clean and sanitize using the five-part system including the ceiling.
2. Clean refrigeration condensers following manufacturer's recommendations.

C. Fish Cleaning and Can Filling Room (Daily):

1. Place knives and other fish-cleaning implements in alkaline detergent soak tank. At end of clean-up, rinse and dip in sanitizer.

2. Dry clean tables, floors, scales, conveyors, etc., and remove fish meat bins and scrap totes (waste containers).

3. At the end of the day thoroughly clean and sanitize tables, conveyors, hand wash sinks, and fixed equipment using the five-part system. Since these are food contact surfaces, normal strength sanitizer is used (100-200ppm chlorine, 25ppm iodine or 200-400ppm quat). Also during production, sanitize with chlorine or quat during breaks or every four hours. Excess sanitizer applied during breaks should be removed with a sanitized squeegee.

4. Floors, splash zones of walls (from four feet high to floor), and sinks are cleaned daily using the five-part system and sanitized with double strength sanitizer.

5. Fish meat, scrap and waste totes must be cleaned and sanitized after each use, before they are returned to the cleaning area. The five-part system is followed: dry cleaning, pre-rinse, detergent application, post rinse, and sanitizer application. A detergent soak tank (alkaline or chlorinated detergent) and sanitizer dip tank minimizes hand detailing and improves contact coverage. Waste totes are cleaned in a dedicated area separate from other washing areas and away from raw product.

6. Footbaths are located at the entrances to the cleaning and filling rooms. The baths contain 800ppm quat or 400ppm chlorine. The concentration of sanitizer in the bath

must be checked at the start of the work day before the workers arrive and every two hours during times of use.

7. Trays or pans used for handling tuna are sanitized before each use with 100-200ppm chlorine or 25ppm iodine.

8. Empty weigh scales as often as possible and sanitize. Wipe off excess sanitizer with a sanitized squeegee or single-use paper towel.

D. Cleaning stations for pre-cooked tuna racks and trays:

1. Clean fish racks and trays after each use following the five-part process using alkaline or chlorinated alkaline detergent and regular strength sanitizer, e.g., 100-200ppm chlorine (after each use).

2. The cleaning station area is cleaned and sanitized following the five-part system using alkaline or chlorinated alkaline detergent and regular strength sanitizer, e.g., 100-200ppm chlorine (daily).

E. Carts and Dollies:

Daily:

1. Sanitize whenever they enter a pre-cooked tuna or processing area from a raw tuna area or an unsanitary area.

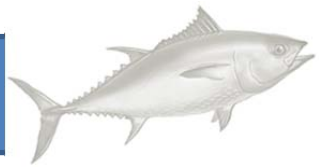
2. Color code this equipment, e.g., green for raw and white for pre-cooked.

F. Miscellaneous:

1. Thoroughly clean door handles/push plates, sinks, and faucets daily with Scotch-Brite pads, detergent and sanitizer following the five-part method.

2. Doors and walls should be cleaned and sanitized daily in splash zone (four feet to floor) and weekly in higher areas.

APPENDICES



Appendix List

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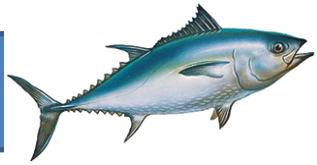
APPENDIX 1

GLOSSARY OF TERMS

Batch	A group of fish that is similarly treated in process; thawing, precooking, cooling, cleaning or retorting. If the fish from the same lot are precooked in different pre-cookers, then they are put in different batches.
CCP	Critical Control Point – A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
COA	Certificate of Analysis (COA) – A document sent to the processor from the supplier for shipments of raw material or ingredients, and which contains all the information pertinent to the safety and quality of the material being shipped. COA documents typically contain microbiological and/or laboratory analyses, and results of evaluation of the quality and physical properties of the material in each shipment which enable the processor to determine conformance with established material specification parameters.
cGMP	cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA). The "c" in cGMP stands for "current," requiring companies to use technologies and systems that are up-to-date in order to comply with the regulations.
GMPs	GMPs (Good Manufacturing Practice) is a production and testing practice that helps to ensure a quality product. GMP guidelines are not prescriptive instructions on how to manufacture products but are a series of general principles that must be observed during manufacturing.
G&G	Gilled and Gutted Tuna (G&G) - Tuna that had the gills and viscera removed before freezing or delivering to the processor.
H&G	Headless and Gutted Tuna (H&G) - Tuna that had the head and viscera removed before freezing or delivering to the processor.
HACCP	Hazard Analysis and Critical Control Points - A System that identifies, evaluates and controls hazards which are significant for food safety.
HACCP Plan	A written plan for controlling food safety hazards, required by FDA regulation to be developed by seafood processors. HACCP plans are product specific and facility specific, i.e., processors must develop a HACCP plan document (in English) for each different kind of product produced and for each manufacturing facility.
Hazard	A biological, chemical, physical or allergenic agent in food, or a condition of food, that has the potential to cause an adverse health effect.

Loins (Tuna Loins)	Tuna Loins (Frozen); Frozen tuna loins are the cleaned edible portions of the various species of tuna that have been cleaned, packed in "Cryovac" plastic bags, vacuum sealed to remove the air, and frozen in either a plate freezer or a blast freezer. These loin bags weight from 7 to 14 kg depending on the configuration.
Lot	A group of similarly treated fish of the same species from the same vessel, hatch or well. Maximum lot size should be less than or equal to 25 metric tons.
Prerequisite	The basic environmental and operational conditions in a food business that are necessary for the production of safe food. These control generic hazards covering *good manufacturing practice* and good hygienic practice and shall be considered within the HACCP study.
Process Authority	Process Authority is an individual or organization possessing the necessary expertise to assess and recommend science-based controls for potential food safety hazards. The process authority may also serve the role of reviewing and determining the acceptability of affected products involved with critical limit deviations
Round Tuna	Sea water fish from the family *Scombridae*, mostly in the genus *Thunnus*, commercialized whole, frozen, either with or without viscera.
SSOPs	Written programs which contain the step-by-step procedures and practices for maintaining a sanitary environment and for ensuring the necessary conditions for production of safe wholesome food. The term SSOPs or **Sanitation Standard Operating Procedures** has been traditionally used in food industry to differentiate between SOPs (**Standard Operating Procedures**) that deal directly with food manufacturing process control, from procedures that deal with control of the manufacturing environment, and which have been formalized and defined in written documents, i.e., to an extent comparable with process control SOPs.
Test Pack	A sample of a lot of fish that is evaluated to determine if the complete lot of fish can be processed without special handling. It is thawed, butchered and organoleptically evaluated in a special and organized fashion using trained evaluators. Product in the test pack is processed into finish goods and may also be organoleptically evaluated.

APPENDIX 2



WRITING STANDARD OPERATING PROCEDURES

The Tuna Council recommends the use of a consistent format for written SSOPs. It should be sufficiently detailed for reference, auditing and use in training but brief and itemized in construct.

ELEMENTS OF AN SOP

When developing written standard operating procedures (SOPs), keep in mind that they are your company's specific procedures for meeting food safety and sanitation requirements. These requirements might be driven by your own internal auditors, your customers or third party certifiers, not just by regulators. As such, content will often vary by company and facility. Written SOPs must be auditable, relate directly to records which document compliance with the plan, and be clear and appropriate for training purposes. At a minimum, they should include descriptions of:

- procedures;
- frequency of conducting the procedure;
- frequency of monitoring for compliance;
- responsibility for performing the procedures(s);
- responsibility for monitoring for compliance;
- applicable records;
- corrective measures; and
- means for verifying the effectiveness of the SOP.

The following simple example for key sanitation condition #7 is from the Seafood HACCP Alliance's Sanitation Control Procedures course (manual is available online at http://bit.ly/SCPManual).

7. Employee Health (FDA Key Sanitation Condition No. 7)

Controls and Monitoring:

a. Workers report to their immediate supervisor any health condition that might result in food contamination. Supervisors report suspected health problems to the plant manager. The plant manager decides if a potential food contamination situation exists. **Monitoring Frequency: Daily before operations.**

b. Supervisors check for infected lesions that might contaminate food. **Monitoring Frequency: Daily before operations.**

Corrections:

a. Workers who represent a potential risk are sent home or reassigned to non-food-contact jobs.

b. Cover lesion with impermeable bandage, reassign, or send worker home.

Records:

a-b. Daily Sanitation Control Record

Inspection results for this SSOP would be entered on the second page of the following example daily record form as identified in the SSOP:

DAILY SANITATION CONTROL RECORD

Report Date:_____ Firm Name:_____

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Firm Address:_____

Sanitation Area and Goal	Pre-Op Time:	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hose (S/U)						
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U) Line 2: (S/U) ◆ Sanitizer Strength Sanitizer Type:_____ Strength:_____ ppm Line 1: (ppm) Line 2: (ppm) ◆ Gloves and aprons clean and in good repair Line 1: (S/U) Line 2: (S/U)						
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U) ◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U) ◆ Unpackaged cooked products separated from raw products (S/U)						

S = Satisfactory / U = Unsatisfactory

Daily Sanitation Control Record (page 2)

Sanitation Area and Goal	Pre-Op Time:	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments and Corrections
4) Maintenance of Hand-washing, Hand-sanitizing, and Toilet Facilities ◆ Hand-washing and hand-sanitizing stations adequate • Hand-washing station Line 1: (S/U)	☐					
Line 2: (S/U)	☐					
• Hand-sanitizing station Sanitizer Type_____ Strength:_____ ppm						
Line 2: (ppm)	☐		☐	☐		
◆ Toilets clean, properly functioning, and adequately supplied (S/U)	☐					
5) Protection from Adulterants and 6) Labeling, Storage, and Use of Toxic Compounds ◆ Product protected from contamination (S/U)		☐	☐	☐		
◆ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)	☐					
7) Employee Health Conditions ◆ Employees do not show signs of medical problems (S/U)	☐					
8) Exclusion of Pests ◆ Pests excluded from processing area (S/U)	☐					

S = Satisfactory / U = Unsatisfactory

Signature or initials _____ Date_____

COMPONENTS OF A COMPREHENSIVE SSOP

Some common elements or components of written SSOPs are illustrated below.

FACILITY SANITATION

1. Master Sanitation Schedule

- Each food processing or handling and storage operation shall have in place a documented cleaning/sanitation schedule for all areas covered within the scope of this Quality Policy.
- Records shall be kept to demonstrate completion of the tasks as scheduled.

2. Standard Sanitation Operating Procedures

- Each site shall have documented, step-by-step Standard Sanitation Operating Procedures (SSOPs) for all areas, structures and equipment associated with the plant, including, as applicable:
    - Description of what is to be cleaned and sanitized (structures, equipment, pipes/ductwork/hoses, tools/utensil, gloves, garments, etc.).
    - Level of dismantling required and instructions for dismantling and reassembly, as required.
    - Cleaning frequencies.
    - Specific chemicals to be used, chemical strengths/concentrations, application methods, residence times and rinse procedures (see next list below and page A2-17).
    - Water temperature requirements (e.g. great than 60°C (140°F) for cleaning, or as specified by the sanitation chemical supplier).
- All sanitation chemicals and sanitizers must be strictly controlled to avoid product contamination:
    - All sanitation chemicals and sanitizers shall be prepared and handled according to specific written instructions. A log should be maintained as a record the preparation of all chemicals and verification of their strengths/concentration.
    - All containers for cleaning chemicals and sanitizers must be properly labeled.
    - All such containers must be designated for the specific chemical/sanitizer.
    - All cleaning and sanitizing chemicals must be securely stored when not in use.
    - Written procedures and associated record keeping must be in place to ensure that unused sanitation chemicals and chemical preparations are

disposed of in a manner that supports food, employee and environmental safety.

- Written procedures must be implemented for the cleaning and sanitizing of equipment, facilities and structures following maintenance procedures, prior to being put back into service.

3. Zone Approach

To help focus attention on the most significant potential sources of contamination, surfaces or areas of the plant can be categorized in the following way:

Zone Category 1	Direct product contact surfaces and surrounding structures with the potential to drip, drain or be drawn into the product stream. This includes table tops, conveyors, mixing vessels and blades, hoppers, tubs/totes/trays/racks, tools and utensils, knives/scissors/shredders/slicers, etc. as well as horizontal or vertical structures mounted above the flow of open product (especially utility conveyances – ductwork, piping, conduit, bus bars, etc.) or having an impact (e.g., fans; HVAC air flow, etc.). Zone 1 also includes employee gloves and apparel and the surfaces of labeling and packaging equipment.
Zone Category 2	Non-product contact surfaces within the immediate area where exposed product is being handled, including support framework, footings and undersides, switches, control panels, catch pans or condensate lines within refrigeration or freezer units. Includes thermal processing carts and the framework on labeling & packaging equipment.
Zone Category 3	Non-product contact surfaces in the processing area remote from the process stream, including walls, floors, drains, hoses, fork trucks and utility conveyances not mounted over product flow. Includes the inner surfaces of thermal processing vessels.
Zone Category 4	Areas remote from the handling and storage of open product, including hallways, lunchrooms, employee facilities, warehouses, etc.

4. Monitoring Cleaning Effectiveness

- Written visual pre-operational inspection procedures shall be implemented to verify that all facilities, equipment, utensils, fixtures and structures are clean and sanitary.
- Written visual inspection procedures shall be implemented at a scheduled frequency to assess the physical condition of the facilities, equipment, structures, etc. in terms of site's ability to adequately clean and sanitize.
- The use of checklists is recommended as guides for these inspections and for recording the results.
- Deficiencies noted during these inspections shall be recorded along with the corresponding corrective procedures.
- Based on the outcomes of these inspections, existing sanitation procedures may need to be revised to better capture these physical conditions.

5. Verification of Cleaning Effectiveness

- Visual inspection procedures for assessing site-level physical conditions and cleaning effectiveness may be supplemented at scheduled frequencies using objective measures such as ATP bioluminescence and/or microbiological testing.
- A written environmental monitoring program must be in place within the facility to monitor the general level of sanitation. All results must be recorded as well as any corrections taken.
- Recommended testing frequencies, adjust based on history:
    - ATP – minimum weekly, maximum after every sanitation cycle (pre-op); and/or
    - Micro – minimum monthly although weekly is recommended in most cases.
- All results must be recorded as well as any corrective measures (e.g. rewashed before production was allowed to start).
- The standard acceptance criteria for fish and seafood canning facilities shall be:
    - Total Viable Count, max. 1,000 per square inch.
- Based on the outcomes of these verification procedures, existing sanitation procedures might need to be revised to better capture these physical conditions.

6. Training Requirements

- All employees responsible for implementing the sanitation program must be appropriately trained in both the applicable cleaning procedures and the safe storage, preparation and handling of associated chemicals.
- Training must be properly recorded. Note that cleaning chemical suppliers may have such training available as part of the services they provide.

REPAIR OF FACILITY

To prevent the colonization of processing equipment with *Staphylococcus aureus*, they must be properly designed, fabricated, installed and maintained in ways that facilitate cleaning, sanitation and inspection.

DEFINITIONS

1. **Facility:**

- Structures – walls, ceiling, floors, posts/beams, lighting fixtures, pipes, doors, chill rooms/freezers.
- Equipment – conveyors, bins, tubs, totes, tanks, butcher and cleaning tables, seamers/fillers, can tracks, pre-cookers, thawing equipment, baskets, racks, scales, retorts and any other equipment used in processing or storage of the product.
- Utensils – thermometers, knives, shovels, spoons, scoops and any other utensils used in processing the product.

2. **Repair:**

- Conditions which may potentially cause a contamination hazard such as but not restricted to: flaking or peeling paint, metal fragments, rust, fraying conveyor belts, loose nuts/bolts, loose solder, ammonia leaks, leaking lubricant or grease, exposed insulation, rough welds, damaged wood.
- Conditions which may potentially cause a food safety hazard such as but not restricted to: improper seams or seals, damage to cans/pouches, inadequate maintenance that may affect the thermal process.

THE FOLLOWING MEASURES SHALL BE MAINTAINED:

1. **Preventative Maintenance Program**

A program which describes how all structures, equipment and utensils are maintained in good repair and encompasses the following:

- A description of the routine maintenance of all items, by area in the facility, described under “Definitions” above.
- A schedule for the routine maintenance of all items; ie daily, weekly, monthly, shut downs, etc.
- A description of the mechanism used to ensure that the routine maintenance activities have taken place as per the schedule.

2. Training Requirements

- All employees responsible for the routine maintenance of the facility must be appropriately trained to perform their job function properly. Training records must be kept.
- All employees responsible for inspecting the facility for repair must be properly trained. Training records must be kept.

3. Corrective Measures

- Appropriate corrective measures must be identified and verified. The positive results of such actions must be documented.

4. Verifications

- All monitoring and corrective measure records must be reviewed weekly.
- The plant QA Manager is responsible for verifying (at least annually) that the above program is being implemented as required. This is part of the annual HACCP verification and must be documented.

THE FOLLOWING MONITORING SHALL BE MAINTAINED:

ITEM	WHAT	TOLERANCE	HOW OFTEN	HOW	REQUIREMENTS / COMMENTS
Inspection of facility for state of repair	All items in the facility that could potentially contaminate the product or damage the packaging	No potential contamination hazards or potential for damage of product or packaging material.	Daily	Complete a daily checklist by visual inspection of all applicable structures, equipment or utensils.	The checklist must contain all items which are above or near product or used in the processing or transportation of product within the facility. It may be convenient to use the "Daily Sanitation Checklist" or equivalent for this purpose with an additional column for repair. Items out of compliance must be identified for corrective measures. The positive results of such measures must be verified and documented on the report.

PREVENTION OF CROSS CONTAMINATION

THE FOLLOWING MEASURES SHALL BE MAINTAINED:

1. A Written Program must be developed describing the movement of employees and equipment from raw areas into sensitive or post process areas which encompasses the following:

- Hygiene requirements for personnel entering sensitive areas from raw areas or a policy stating they may not enter sensitive areas.
- Cleaning and sanitizing requirements for any equipment from raw areas required in sensitive areas.
- Hygiene requirements for personnel working in sensitive areas and the post process area.
- A list of personnel working in RESTRICTED areas (by job function, not name).

2. Employee Practices

- Employees responsible for handling product or food contact surfaces must rewash and sanitize hands after touching face or other parts of body.
- Employees responsible for handling trash or other unsanitary materials/equipment must not touch products or food contact surfaces (direct or indirect).
- Supervisors must closely monitor employee movement, hand to body contact, contact with unsanitary surfaces and other actions that might potentially contaminate tuna products.

3. Training Requirements

- All employees working in raw product areas must be trained in hygiene requirements when entering sensitive areas OR not permitted in these areas.
- All employees must be trained to recognize and respect RESTRICTED or AUTHORIZED ONLY areas.
- All employees working in sensitive or post process areas must be trained on special hygiene requirements.
- All employees responsible for inspecting the facility for potential microbial cross contamination must be properly trained to perform their job function.
- Training records must be kept.

4. Corrections

- Appropriate corrections must be identified and verified. These actions must be documented.

5. Verifications

- All monitoring and corrections records must be reviewed weekly.
- The plant QA Manager is responsible for verifying (at least annually) that the above program is being implemented as required. This is part of the annual HACCP verification and must be documented.

THE FOLLOWING MONITORING SHALL BE MAINTAINED:

ITEM	WHAT	TOLERANCE	HOW OFTEN	HOW	REQUIREMENTS / COMMENT
Sensitive or sanitary areas	Potential microbial contamin-ation	All employees working in these areas must pass through a foot dip on entry, wash and sanitize hands/gloves on entry and every hour during processing. Employees from raw areas may only enter if authorized and then must remove outer garments and follow above hygiene requirements.	Throughout the day	Visual observation.	Documentation of monitoring may be made on a daily "GMP Checklist" which may also contain other GMP items. Hygiene requirements for sensitive areas; see "Employee Health and Hygiene".

D. TOILETS AND HANDWASHING

DEFINITIONS

- **Hand wash and sanitizing dip facilities**: Those stations in the processing area provided for the use of employees to wash their hands and sanitize their hands, gloves or boots as required.
- **Toilet facilities and employee changing/locker rooms**: Sanitary facilities provided with toilets, hand washing sinks, showers, changing facilities and locker rooms where employees may store personal belongings, street clothes and food/drink.

THE FOLLOWING MEASURES SHALL BE MAINTAINED:

- Signs must be posted instructing employees to wash and sanitize their hands before starting work, after any absence from the processing area and after using the toilet. Signs must also instruct employees to remove aprons or other outer wear before entering the toilet area.
- Hand washing stations must be available at the entrance to all processing areas and in the toilets. They must be present in enough numbers so that all employees are able to wash their hands at the start of each shift and after any absence. If any processing area has a separate entrance from the main processing entrance – it must also be equipped with a hand wash station.
- All hand wash stations in the processing area or in toilet areas should be equipped with non-hand operated taps.
- Toilet facilities must not open directly onto the processing area.
- Hand/glove dips must be available at the entrance to all processing areas and in sensitive/sanitary areas and in the post process area. Foot dips must be available in sensitive/sanitary areas and the post process area.
- All employees responsible for monitoring must be properly trained to perform their job function and this must be documented.
- Documentation must include corrections and verification.

THE FOLLOWING MONITORING SHALL BE CARRIED OUT:

ITEM	WHAT	TOLERANCE	HOW OFTEN	HOW	REQUIREMENTS / COMMENTS
Hand wash stations and toilets	Supplies and garbage	Equipped with water, soap, toilet paper and towels (or working air dryers). Garbage containers available and kept emptied.	Daily, prior to processing and during processing	Visual observation and documentation.	Hand wash stations and toilet areas must be kept in good repair and sanitary at all times to prevent the growth of microorganisms and the potential contamination of product. Documentation of monitoring may be made on a daily "GMP Checklist" which may also contain other GMP items. Note that chlorine loses its antimicrobial activity as organic material increases.
	Cleanliness and repair	Must be kept in a sanitary manner and in good repair.	Daily, prior to processing and during processing	Visual observation and documentation.	
Sanitizing dips for hands/gloves or boots.	Sanitizer concentra-tion	Iodophor – 25 ppm Free chlorine – 50 ppm	Daily during processing	Test strips. Medium tea color for iodophor.	

E. CONTROL OF EMPLOYEE HEALTH CONDITIONS

Certain employee health conditions could result in the microbiological contamination of food, food-packaging materials, and food-contact surfaces.

1. Control Measures

Workers are instructed to report to their immediate supervisor any health condition that might result in food contamination.

2. Monitoring Procedures

Supervisors report suspected health problems to the Q.A. manager, including evidence of infected hands/fingers. The Q.A. manager determines if a potential food contamination situation exists.

3. Corrective Measures

Workers who represent a potential risk are sent home or reassigned to non-food-contact jobs.

4. Record Keeping

Worker health and corrective measures are noted on the Daily Sanitation Report.

EXAMPLES OF SSOP FORMS

Example of Basic SSOP Monitoring Form

Note: modify for each facility to indicate actual monitoring points.

Daily Sanitation Report ABC Tuna, Inc.			Date:
Condition	**Initials (Passes Inspection)**		
	Before processing	**Midday Cleanup**	**End of Shift Cleanup**
Plant grounds do not cause food contamination.			
Waste is properly stored.			
Equipment and utensils are adequately cleanable.			
Food contact surfaces and utensils are clean and sanitized.			
Food, food-contact surfaces, and packaging materials protected from adulteration/contaminants.			
Non-food-contact surfaces are clean.			
Hoses have anti-siphoning devices. Floors have adequate drainage.			
Coolers and evaporators are clean.			
Cooked and raw products physically separated in coolers			
Toilets / facilities are clean, sanitary and in good repair			
Toxic compounds are identified and stored properly.			

Employee health conditions are acceptable.			
Gloves/garments contacting food are clean and sanitary.			
Employee practices do not result in food contamination (hair restraints, glove use, hand washing/sanitizing, hand to body contact, personal belonging storage, eating and drinking, boot sanitizing).			
Proper color-coded sanitation equipment is used.			
Hand and boot sanitizer strength is adequate.			
No pests are in the plant.			
Deviations from SSOP and corrections:			
Reviewed by (Plant Manager):	Date:		

Example Master Documentation of Chemicals

Chemicals Approved for Use in ABC Tuna, Inc.
Revised 1/20/2012

Chemical	Strength	Dilution
Chlorinated Alkaline Cleaner **Brand:** Ecolab Solid Kleen-Up™ **Usage:** Equipment, food-contact surfaces, utensils, toilet facilities		1 ounce of concentrate to 3 gallons of water
Liquid Sanitizing Hand Soap **Brand:** Ecolab Insurance™ (E-2) **Usage:** Hand washing facilities		Undiluted
Sodium Hypochlorite Sanitizer **Brand:** Ecolab XY-12® **Usage:** Food-contact surfaces, utensils	100 ppm	1 ounce of concentrate to 6.5 gallons of water
Quaternary Ammonium Sanitizer **Brand:** Ecolab Ster-Bac® **Usage:** Floors **Usage:** Boot sanitizing baths	400 ppm 800 ppm	1 ounce of concentrate to 2 gallons of water 1 ounce of concentrate to 1 gallon of water
Iodine Sanitizer **Brand:** Ecolab Bac-Flush™ **Usage:** Hand sanitizing solutions	25 ppm	1 ounce of concentrate to 13 gallons of water
Lubricants **Brand:** Bettcher Industries Special Whizard Grease (H-1) **Usage:** Food processing equipment **Brand:** Terand Industries White Grease Lithium Base (H-2) **Usage:** Non-food processing areas		

Reviewed by (Plant Manager):_____

Date:_____

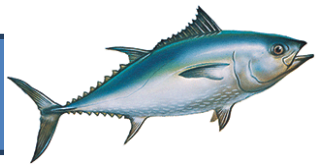
Example SSOP Records Policy

SSOP Records Policy

1. Municipal water quality reports and corrections are reviewed and kept on file for two years.
2. In-plant water quality testing and corrections are reviewed and kept on file for two years.
3. Daily Sanitation Reports are reviewed and kept on file for two years.
4. Invoices for food-grade chemicals and lubricants are reviewed and kept on file for two years.
5. Records of pest treatment are reviewed and kept on file for two years.

Revised: [date]_____
Reviewed by (Plant Manager):_____
Date: _____

APPENDIX 3



HISTAMINE TESTING AND SENSORY TEST PACKS

A combination of histamine analysis and sensory test packs can be used to monitor the quality and safety for each lot of tuna prior to processing. The following diagram provides a simplified outline of the procedures that can be used for frozen whole tuna as compiled by the Tuna Council for monitoring tuna product safety in accordance with HACCP recommendations specified in the 4th edition of the FDA Hazards Guide (2011).

NOTE*: "It is important to recognize that the Federal Food, Drug, and Cosmetic Act (the FFD&C Act) prohibits interstate commerce of adulterated foods (21 U.S.C. 331). Under the FFD&C Act, a food that is decomposed is considered adulterated (21 U.S.C 342). Accordingly, a fish or fishery product that is decomposed in whole or in part is prohibited from entering interstate commerce even if the type of decomposition may not lead to scombrotoxin (histamine) formation. You should distinguish between recommendations in this chapter for sensory screening, as a component of a HACCP control strategy for scombrotoxin formation, and your obligation to avoid otherwise violating the FFD&C Act with regard to the distribution of decomposed food." (FDA Hazards Guide, Chapter 7, page 120).*

Tuna Lot

Single tuna species from a single boat harvest with similar harvest history

(Lot size can range from 20 -100 metric tons)

Histamine Testing

Sample size = minimum 18 whole tuna per lot or all tuna in a lot with less than 18 tuna. Larger sample size recommended for new suppliers or if any issues with previous delivery.

Histamine testing with verified official methods for all individual whole tuna or composites from 3 separate tuna. For example, 6 composites from the 18 individual whole tuna sample.

Ideally Initial histamine results should precede sensory evaluations

Sensory Test Pack Evaluations

Test pack size = minimum 118 whole tuna per lot or all tuna in one lot with less than 118 tuna

Sensory ratings for each tuna based on standard procedures conducted by trained staff

Individual Tuna

ACCEPTABLE LOT if no more than 2.5% of the tuna in the test pack fish show persistent and readily perceptible sensory decomposition. For example; no more than 2 fish per 118 tuna

If ONLY the 2.5% sensory level is exceeded, test 60 individual tuna for histamine (30 ppm limit), including the samples rated for sensory decomposition, AND evaluate every tuna in the lot for decomposition

Option

Individual Tuna

ACCEPTABLE LOT if no individual tuna in the sample exceeds 30 ppm histamine

Composite Samples

ACCEPTABLE LOT if no composites from the sample exceed 10 ppm histamine

If any composite histamine level exceeds 10 ppm but is less than 30 ppm, then test all of the 18 individual tuna for histamine

- REJECT the entire lot if any individual tuna in the Histamine Testing or Sensory Test Pack exceeds 30 ppm.
- REJECT the entire lot if sensory decomposition is perceptible in more than 2.5% of the Sensory Test Pack, unless further monitoring indicates histamine levels are less than 30 ppm.
- REJECT all tuna with sensory decomposition.

RECOMMENDATIONS

Defining a 'Lot' of Tuna

- An individual harvest 'lot' includes a single tuna species caught by a single vessel that can be distinguished by period of harvest, harvest bin or other methods for common product handling prior to receiving at a processing facility (FDA Hazards Guide Chapter 7, page 128).
- Lot size can range from 20 to 100 metric tons, and the Tuna Council recognizes a common maximum size linked with a sensory test pack is 25 metric tons.

HISTAMINE ANALYSIS

- Temperature control is very important when collecting, handling, and storing the whole tuna and the samples of the raw, edible tuna. Ample ice, insulated containers and frozen storage should be available to prevent exposure to warm temperatures that could increase the histamine level in the tuna. Samples should be collected while the tuna remain frozen.
    - The histamine lab samples should remain frozen until scheduling for immediate lab analysis.
    - All samples of raw, edible tuna should be refrigerated or held with ice, avoiding direct contact with the ice, before immediate analysis.
    - All samples of raw, edible tuna that cannot be immediately analyzed should be stored frozen with proper identification per lot and sample history until the lab is able to thaw the samples under refrigeration prior to testing.

- Simple qualitative tests for the initial histamine levels in a lot of tuna should precede the sensory test pack evaluations to prevent unnecessary work in the event that a particular lot of tuna is not acceptable due to elevated histamine levels. More involved or quantitative tests can be used to determine actual histamine concentrations in the lot. The qualitative and quantitative tests should be official procedures recognized for histamine analysis.
    - **Qualitative tests** are used to determine if the histamine level is above a particular threshold, e.g., 30 ppm for individual whole tuna or 10 ppm for a composite sample from three individual tuna.
    - **Quantitative tests** are used to measure the actual concentration of histamine that can range from 0 to over 50 ppm.

- Officially recognized analytical procedures can be referenced in the Journal of the AOAC International (Association of Official Analytical Chemists; http://www.aoac.org). The Tuna Council recommends AOAC approved methods for histamine analysis.
    - For analytical control and confidence in analysis, periodic verifications of the analytical procedures and performance of the lab staff should be conducted with samples previously selected or prepared with a known concentration of histamine. These verification procedures are recommended by the FDA Hazards Guide (2011 edition, Chapter 7, page 135) and should be recorded as part of the HACCP Program.
        - The reference samples should be arranged to have histamine concentrations ranging from 0 to greater than 30 ppm.

- The FDA HACCP Guide recommends a sample size of 18 individual fish for initial monitoring of a harvest lot (2011 FDA Hazards Guide, Chapter 7, page 133). This sample should represent one single lot. The individual fish should be selected from throughout the entire lot with attention for possible mishandled fish.

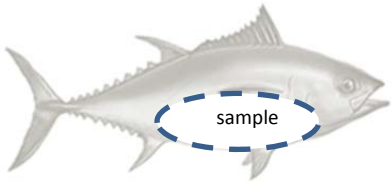
- The acceptable limits for individual fish (30 ppm) and composite samples from three tuna (10 ppm) are conservative recommendations from the Tuna Council based on recent studies and discussions with FDA through 2013. The 18 fish sample can be composited into 6 units of 3 different individual tuna in each composited unit. The acceptable limit for the composite is reduced (30 ppm/3 fish samples = 10 ppm composited sample) because the histamine concentrations will be blended amongst the three fish.

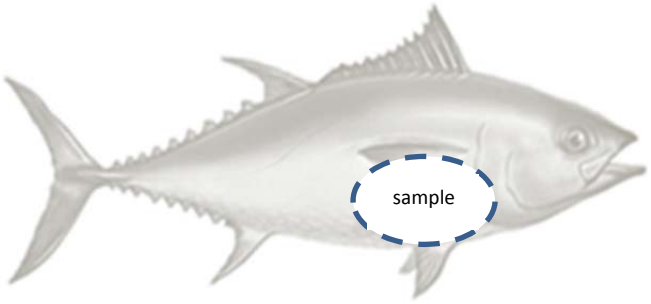
- The total amount of fish sample or tuna flesh for analysis should be 250 grams for an individual tuna. The edible raw flesh should be taken from the lower anterior part of the tuna above the visceral cavity. For smaller fish, the sample area should expand from this location until enough flesh is available. In some cases the sample may include most of the edible flesh from a smaller tuna. The composite samples (250 grams) should be mixed thoroughly before taking the smaller portion required for the official analytical procedure. In situations where the facility is receiving using small fish FDA has advised:

    "As a point of reference, on very small fish, e.g., sardines and anchovies, FDA recommends collecting 250 grams of edible portion even if that entails collecting the entirety of the fish or even multiple fish. Therefore, as the fish size moves smaller and smaller it may be justifiable to extend the sample from the lower anterior portion into the upper anterior loin if needed to obtain a 250 gram sample. Alternatively, the processor could stay focused on the lower anterior loin by reducing the size of the sample proportionately as necessary …

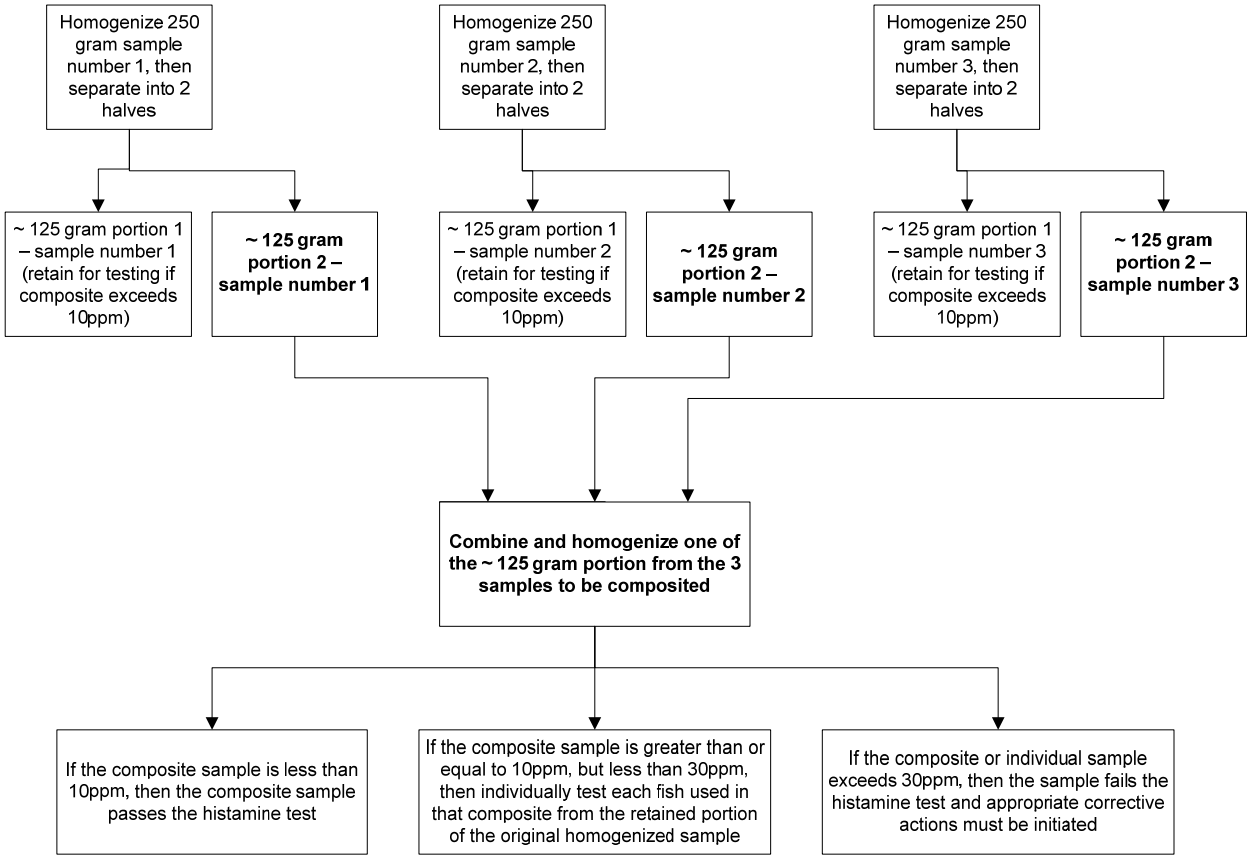
but should not collect less than 50 grams from the lower anterior loin. The processor may want to conduct studies to determine which portions give the more reliable results in its own situation. In any case, the processor's interest should be to get the most reliable indicator of elevated histamine possible in a representative portion and by no means should other portions be collected in lieu of the lower anterior loin, e.g., the nape, without studies to demonstrate the reliability of doing so."

Recommended sample site expands for smaller fish to assure enough sample for analysis





- Below are procedures to be followed for preparing homogenous composite samples from individual fish samples. The original individual sample must be retained for testing if the composite sample tests high.



- SUB-LOTTING IS NOT ALLOWED. If the analysis indicates the histamine level in the initial sample of whole tuna or composite samples exceeds the critical limit of 30 ppm, the FDA Hazards Guide no longer allows re-sampling from a smaller portion of the lot or another portion of the lot for further analysis for acceptance. If the critical limit for histamine analysis is exceeded, the lot must be rejected. The identified lot can be returned to the supplier, diverted to non-US market as long as it is within the non-US regulatory limits for histamine, or destroyed.

SENSORY TEST PACKS

- Temperature control is very important when collecting, handling, and storing the whole tuna. Adequate frozen storage should be available to prevent exposure to warm

temperatures that could increase product odors or other indication for product decomposition or spoilage.

- Tuna collected for analysis should be of a uniform size to narrow the required time for thawing for all samples.
- The samples should remain frozen until scheduling for immediate sensory analysis following the uniform thawing procedures.

Sensory evaluations should be conducted by person(s) qualified by experience or training with actual tuna products (FDA Hazards Guide Chapter 7, page 128). The Tuna Council recommends similar training to the hands-on and nose-on courses offered by U.S. FDA staff and the National Marine Fisheries Service (NMFS/NOAA).

- FDA's HACCP guidelines recommend sensory evaluations for a representative sample from a single lot of fish (FDA Hazards Guide, Chapter 7). The Tuna Council recommends a sample size of 118 tuna per lot (or the entire lot, for lots with less than 118 tuna) as used in the example in the FDA Hazards Guide. This sample should represent one single lot. The individual fish should be selected from throughout the entire lot with attention for possible mishandled fish.
- The FDA Hazards Guide (Chapter 7, page 126) recommends an acceptable level of decomposition in the sample that is less than 2.5% of the fish in the sample from a lot. There should be a minimum of 118 fish in the test pack and the reject % should be calculated based on the actual number of decomposed fish relative to the actual number of fish in the test pack. For example: for a test pack containing 120 fish with 2 rejected fish, the reject % is (2/120)x100 = 1.7%. The calculation should be done using the actual number of fish and not the weight of the fish.

SECONDARY HISTAMINE ANALYSIS (based on results from Sensory Test Pack)

IF the initial histamine analysis indicated an acceptable lot (none of the 18 sampled tuna exceed 30 ppm), BUT the accompanying sensory evaluations from the test pack exceeded the acceptable measure for number of decomposed fish (less than 2.5% in the 118 tuna sample), THEN additional or secondary histamine analysis should be conducted to determine the appropriate disposition for the lot.

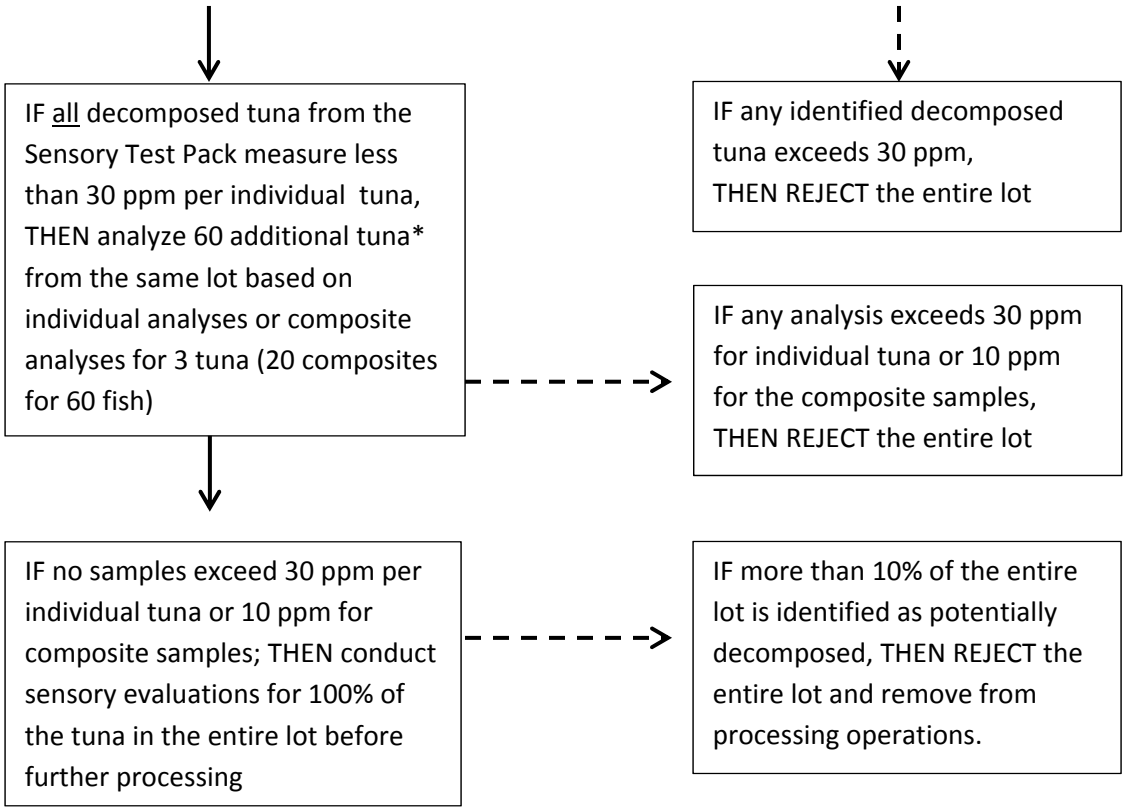
The following illustration provides an outline for the recommended procedures that have been discussed between the Tuna Council and FDA to remain in accordance with their recommendations in the FDA Hazards Guide. These procedures could be part of the corrective actions in a HACCP program.

SECONDARY HISTAMINE ANALYSIS

SUSPECT SENSORY TEST PACK

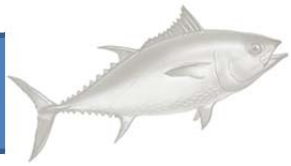
Acceptable tuna lot based only on initial histamine analysis, BUT sensory decomposition exceeds 2.5% of the test pack from the same lot

First, analyze the individual decomposed fish identified during sensory evaluations of the test pack (more than 2.5% of 118 tuna sample per lot)



* The tuna thawed for sensory evaluations should be advanced through processing to avoid any potential increase in histamine levels. Test pack lot identity and segregation should be maintained throughout the subsequent processing steps such that the entire lot can be removed from processing if further analysis indicates potential elevated histamine levels or excessive decomposition.

APPENDIX 4



MONITORING CUMULATIVE TIME

The Tuna Council recommends that facilities develop procedures to effectively monitor cumulative time through multiple process steps. The intent is to establish a procedure that will accurately and precisely monitor the time for each batch of material during production, e.g., from end of pre-cooking to the start of retorting or freezing (loin plant). Below are two examples that can be utilized for tracking fish after being pre-cooked and for tracking frozen loins from thawing to retorting. (Other strategies may be utilized as long as the worst case exposure time is being monitored.)

Example A - Pre-Cooked Fish, Manual System

All fish racks are tagged for identification prior to pre-cooking. For tracking the 12 hour critical limit from the end of pre-cook to the start of retorting or freezing, record the time when the first rack of the pre-cook batch exits the pre-cooker. Ensure all racks can be traced back to the pre-cooker cycle which defines which batch the racks belong to. Place all of the pre-cooker racks from the same pre-cook batch in the same lane or area in the conditioning room.

All fish from the same pre-cooker batch should be processed through skinning and cleaning together to facilitate easy time tracking for the first fish of the batch to the last fish of the batch. Batches must be processed sequentially and the material strictly controlled to prevent mixing of different batches during the cleaning and packing process.

During skinning partially clear the line by having a small physical separation on the cleaning tables between the last fish of the previous batch and the first fish of the current batch being put on the tables.

Total elapsed time is calculated as follows:

- For the end of pre-cooking to the start of freezing or retorting (control of the histamine hazard)
    - Record the time pre-cooker steam is turned off and time when the first pre-cooked rack of fish exits the pre-cooker.
    - Track and monitor the first and last fish from each pre-cooker batch through the skinning, cleaning and packing process.

  - Record the time when the last fish of the batch enters the freezer or retort.

- For the start of skinning to the start of freezing or retorting (control of the *Staphylococcus aureus* hazard)
  - Record the time when the first fish of the batch starts to be skinned.
  - Track and monitor the first and the last fish from the same pre-cooker batch through the skinning, cleaning and packing process.
  - Record the time when the last fish and all associated fish material from the batch enters the freezer or retort.

A production associate will ensure that all fish material associated with the pre-cooker batch, including chunks and flakes generated during cleaning, are loaded into the retort or freezing unit.

Record the time the retort steam is turned on or when the last fish enters the freezer.

Below is an example of a monitoring strategy.

First fish of the batch with tag indicating the time first fish started skinning

Tag on the last fish of the batch to clearly identify when the last fish enters the freezer. This tag follows the same last fish from skinning, cleaning, bagging, sealing and into the freezer.

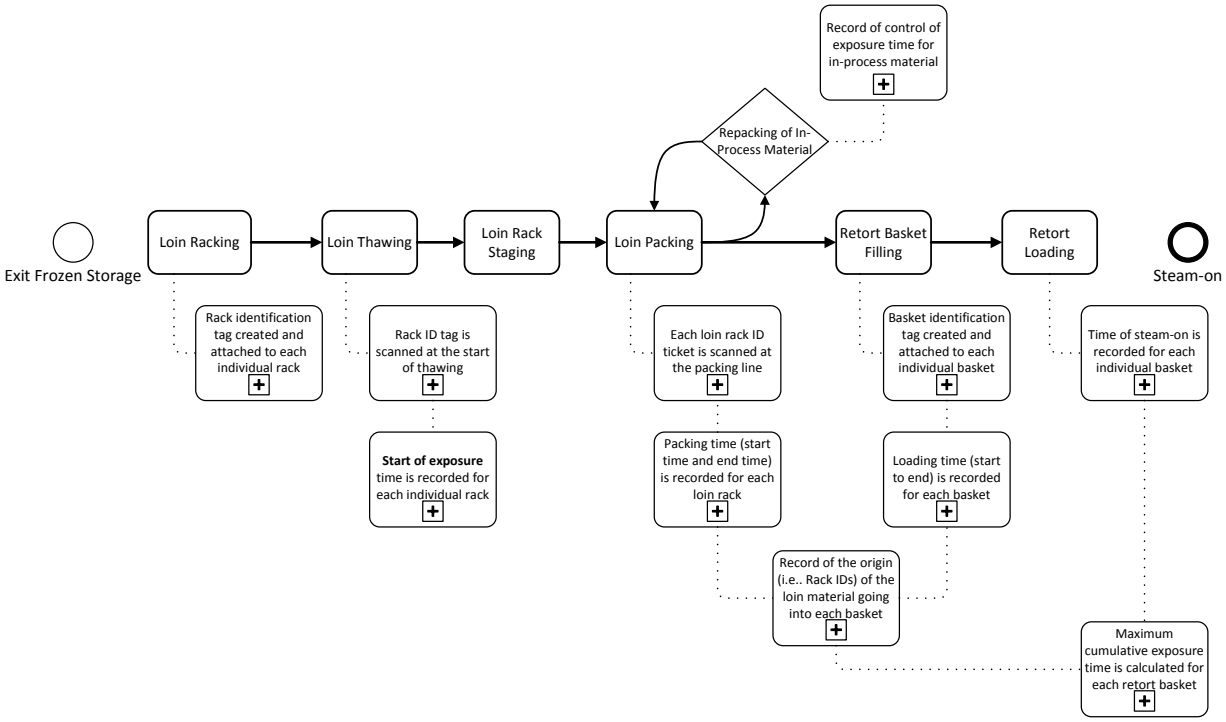
Example B – Frozen Loins to Retorting with Bar Code Scanners / Electronic System

During the racking process each loin rack is tagged for identification. The information regarding the identity of the tuna loins contained in each individual loin rack is entered into a computer inventory control system to assist in creating and maintaining the record of exposure of the tuna loins during processing. The rack identification tags or tickets have unique bar codes that can be scanned allowing computerized tracking of each individual rack. For tracking the exposure time from the start of thawing to the start of retorting, the rack identification tickets are scanned at the different steps in the process. The computer system records and provides real time exposure time information for each individual loin rack during the process.

Right before each rack enters the thawing system, the rack ticket is scanned to record the time the thawing process starts, i.e., the start of exposure time. When the thawed loins are ready for packing, the rack tickets are scanned again to record the time when the loins are packed. As the loin material is canned and loaded into retort baskets, the information regarding the identity of the retort baskets that are being filled is entered into the computer system to allow the system to record which retort basket(s) contain the material from the loins being packed.

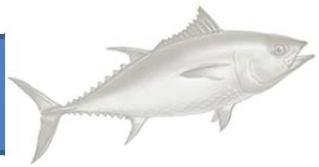
The loaded retort baskets are tagged with bar coded tickets for identification and tracking. The time of start of retorting, i.e., the end of exposure time, is recorded in the computer system for each individual retort basket. The computer system then calculates the maximum time of exposure based on the earliest start of thawing time for any of the material in each retort basket (a retort basket may contain material from several different loin racks, and the racks may have started thawing at different times).

A visual representation of the monitoring strategy is on the following page.



When following the above example, that depicts relying on a computer system to create a record and monitor exposure time, the processor must ensure their computer system is validated, controlled, and verified, and their users trained in accordance with requirements set forth for electronic records in Part 11 of Title 21 of the U.S. Code of Federal Regulations.

APPENDIX 5



COOKER VALIDATION

Verifying Temperature Distributions in Tuna Pre-cookers

Objective: Validate the use of fish pre-cooker exit temperatures (EPIPT) by ensuring that measurements include the slowest heating tuna in every pre-cooker batch. In some cases, EPIPT will be inappropriate, such as when operating pre-cookers designed to initiate cooling before they are opened at the end of the cook cycle. In these situations, time-temperature process schedules must be established. Either case requires an understanding of how every pre-cooker performs. Temperature uniformity inside the pre-cooker is determined by conducting temperature distribution studies.

Temperature Distribution (TD) studies may be carried out for any or all of the following purposes:

- Establish or re-validate an pre-cooker operating procedure that ensures all fish in a pre-cooker will receive the intended minimum process temperature. Ideally, temperature variation should be at a minimum throughout the pre-cooker. To optimize yields and process control, all pre-cookers within a facility should operate as uniformly as possible.
- Determine the location of any persistent cold spot(s) in the pre-cooker.
- If a cold spot is found, it should be considered when selecting fish to be measured for backbone/core temperature at the end of each pre-cook cycle, or when conducting Heat Penetration Tests to establish or validate pre-cook time-temperature process schedules, as appropriate.
- Satisfy HACCP principles 6 and 7 requiring validation, verification and record-keeping if pre-cooking is a CCP in your HACCP plan.

1. Fill out a pre-cooker survey form – an example is at the end of this appendix.
    - Develop and keep on file a drawing of each pre-cooker identifying:
        - Configuration of steam spreader pipes (location, size, number and location of perforations)
        - Dimensions of pipes and types of valves
        - Locations and size of bleeders, vents, and drains
        - Indicate steam flow, e.g. top or bottom

- Steam in
- Steam out

- The survey should identify points in the pre-cooker system that require frequent and regular maintenance to ensure a consistent pre-cook operation.

2. Plan to test the TD of each pre-cooker with a full load of fish representing the most conservative scenario. Some factors to consider:
   - Closest packing density,
   - Most tons of fish per pre-cooker load,
   - Most heat required per unit time, e.g. most steam demand, and
   - Lowest initial fish temperature using properly thawed fish.

3. Inspect each pre-cooker to be sure it is in proper working order at the start of each TD test. Some factors to consider:
   - Clean out the steam spreader holes on blocked steam pipes,
   - Repair any broken steam pipes,
   - Verify that each of the temperature and pressure gauges are working properly,
   - Verify that the automatic steam valve(s) are operating properly, and
   - Verify that the temperature indicating device (TID) or digital temperature gauge (DTG) was calibrated within the past 12 months.

4. As recommended by the Institute for Thermal Processing Specialists (IFTPS), thermocouples used for conducting the TD should be calibrated against a standard reference thermometer or the pre-cooker TID if recently calibrated:
   - Prior to conducting the actual temperature distribution study, standardization or calibration of test equipment should be performed in the pre-cooker selected at the factory, with all leads, extensions and connections assembled as they will be used under actual test conditions.
   - Bundle all thermocouple's (TC's) and locate them in close proximity to the known accurate TID probe, taking care not to inhibit steam flow past the TID probe or TC's.
   - Bring the pre-cooker up to the temperature to be used during the distribution tests and allow the entire system to equilibrate.
   - All TC’s should agree within 0.5°F (0.3°C) of the TID. The range for all TC's should be not more than 1°F (0.6°C).

5. Use a minimum of 24 thermocouples per TD test, 32 or 36 is better.
   - Use of at least 3 thermocouples per pre-cooker trolley is recommended. If sufficient thermocouples are not available, run multiple tests with thermocouples in alternate

positions. For large pre-cookers, multiple runs may be needed for one complete study.

- At least 1 thermocouple must be placed close to the TID or DTG. Pay particular attention to the locations that do not receive direct steam flow.
- Make sure probes do not touch a fish.
- If testing a single lane pre-cooker with steam spreaders on one side, some probes should be placed on the side opposite the spreader.
- If testing a double lane pre-cooker with steam spreaders on the top or bottom, be sure to test the locations between the fish trolleys/racks in the lower areas of the pre-cooker.
- If testing a double lane pre-cooker with steam spreaders in the center of the pre-cooker, be sure to test locations near the outside wall.
- Include probes at the center of trolleys/racks among the fish.

6. Test each pre-cooker at least twice (more if multiple runs are needed to complete a study).
    - Generally pre-cookers are made to a standard design but pre-cookers may not be all uniform.
    - If possible, conduct the TD test in pre-cookers when other pre-cookers are venting to be sure you have an adequate supply of steam.
    - Be certain to test the pre-cooker furthest from the boilers to ensure that steam supplies are adequate when total plant steam demand is high.
    - Make sure to have sufficient steam header pressure and operate under normal conditions.
    - If every pre-cooker configuration is exactly the same design, conduct tests in a minimum of 3 pre-cookers including those that are the furthest from the steam source. Exactly the same design means the same steam and vent valves, same placement, same piping and hole configuration, etc. This is very important especially if the pre-cookers were not built at the same time by the same manufacturer.

7. Documentation to accompany TD data:
    - TID/DTG calibration data,
    - Thermocouple calibration,
    - A map showing the location of each TC for each trolley/rack for each pre-cooker,
    - Pre-cook operating record including vent cycle,
    - All time and temperature raw data,

- Record the minimum and maximum of each TC lead and the TID every 2 minutes for at least the first 15 minutes of the pre-cooker cycle,
- Record the minimum and maximum of each TC lead and the TID every 2 minutes for the entire pre-cook cycle if the factory uses either the ramp up or ramp down pre-cooking technology,
- Report the maximum persistent negative difference between the TID/DTG and the cold spot. (i.e. thermocouple measures lower than TID/DTG),
- Report existence and location of persistent cold spot(s), if found, and
- Trolley/rack loading configurations, and fish size and initial fish temperature.

8. Keep the temperature distribution studies and associated records on file with your HACCP files for validation/verification.
    - Use the TD test to determine which racks/trolleys are at the coldest spot in the pre-cooker. Backbone temperatures of the fish in this location(s) ensure that all of the fish in the pre-cooker has achieved the minimum temperature necessary to stop histamine formation for the validated period.
    - In some cases additional testing may be needed to more accurately identify the cold spot. If a cold spot exists at the end of the normal vent period (at the start of the timed cook), inadequate venting may be responsible.
    - It is recommended to modify the pre-cookers so that all of the cold spots, if there are any, are in the same location. If your company measures backbone temperatures EPIPT, target measurements in the largest fish on racks/trolleys from this same location in the pre-cookers.
    - If any changes are made to the pre-cookers, the TD's need to be re-verified and the records kept on file.

9. Develop a preventative maintenance (PM) program for keeping the pre-cookers in proper working order. The pre-cookers should be maintained in satisfactory operating condition at all times.
    - Keep an organized written record of all PM performed on each pre-cooker.
    - The instruments should be checked for accuracy annually or whenever accuracy is questioned.
    - Pay particular attention to any steam or water spreaders that are located low in the pre-cooker and may become clogged with fish protein, fish oil, or water scale during processing cycles. Use a drill bit to clean each hole, if needed, to make certain the holes are delivering the amount of steam that the pipe is designed for.

10. Other Guides
    - Use the IFTPS guide for conducting temperature distribution studies on retorts as a learning tool
    - Available at http://bit.ly/IFTPS-Still-Steam
    - The GMA Bulletin 26L (*Thermal Processes for Low-Acid Foods in Metal Containers*) is also an excellent guide for the proper installation and operation of food processing equipment involving steam heating.
        - Available at http://bit.ly/GMA-26L

Definitions

- CCP - Critical Control Point
- DTG - digital temperature gauge
- HACCP - Hazard Analysis and Critical Control Points
- IFTPS -Institute for Thermal Processing Specialists (IFTPS)
- TD - Temperature Distribution
- TID - temperature indicating device

PRE-COOKER SURVEY FORM EXAMPLE

Date _____
Factory _____

Pre-cooker ID _____

Type _____ Size _____

1- STEAM SUPPLY

BOILER: Pressure _____ Header size at boiler _____ HP _____

PRE-COOKER: Header pipe size _____ Header pressure _____

Pipe size from header to supply valve _____ (1)

Supply valve size/type _____ / _____

Pneumatic control valve size _____

Bypass valve size/type _____ /_____ Bypass used during venting? Yes / No
(circle one)

Pipe size from control valve to Pre-cooker _____

Steam inlets to Pre-cooker: Number _____ Size _____

Steam spreaders: Number _____ Size _____ (2)

Steam spreader holes: Number _____ Size _____

(1) List smallest pipe size found in this section of the steam supply line.

(2) If multiple steam spreaders are used, note configuration in comments section.

==========

2 - VENTING SYSTEM

Vent holes through Pre-cooker: Number _____ Size _____

Location of vents _____ Venting to manifold or atmosphere
(distance from front of Pre-cooker) (circle one)

Vent valves: Number _____ Size _____ Type _____ Manifold size _____

Spreader pipes: Number of pipes _____ Size of pipe _____

Spreader Holes: Number _____ Size _____

Steam recovery Yes / No Mufflers Yes / No Name & model _____
(circle one) (circle one)

Note *- If more than one Pre-cooker is venting into the same manifold, show configuration and manifold sizes in a diagram in the comments section.*

==========

3 - BLEEDERS

Number of bleeders _____ Size _____ Location _____
(distance from front of Pre-cooker)

Mufflers Yes / No Name & model _____
(circle one)

==========

4 - WATER

Inlet size _____ Type & size of valves _____ / _____

Spreader pipe size _____ Number of holes _____ Hole Size _____

Water level petcock _____ Valve type _____ Location _____

Sanitizer in cooling water Yes / No (circle one)

If Yes, type of sanitizer _____

Source of cooling water _____

==========

5 - AIR

Inlet size _____ Valve types _____ Inlet Location _____

==========

6 – DRAIN

Main drain Size _____ Valve type _____ Location _____

Bypass drain Size _____ Valve type _____ Location _____

==========

7 – PRE-COOKER RACKS/TROLLEYS AND BASKETS

Racks: _____ Baskets per Rack:_____

Basket Dimensions: Length _____ Width _____

Type of Basket:
- Wire Mesh
- Stainless steel
- Open or Closed Bottom

==========

8 - EQUIPMENT

Safety Valves: Number _____ Size _____ Blow-off pressure _____

Thermometers: Number _____ Make _____ ID No.(s) _____

°C/inch _____ Certification date: _____

Pressure gauge: Make _____ Size _____ Range _____

Recorder: Make _____ Serial No. _____ Chart No. _____

==========

9 – COMMENTS

Surveyor _____ Date _____

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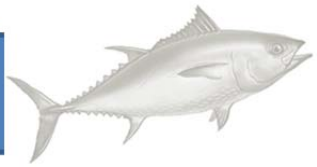
APPENDIX 6



EPIPT MONITORING PROCEDURE

MONITORING PRE-COOKER EXIT FISH TEMPERATURES AS A CCP CONTROL

Prerequisites

- Verify that the temperature distribution of the pre-cooker is uniform during pre-cooking after venting is completed. If there is not a uniform temperature distribution within the pre-cooker, your factory may not be a candidate for using the EPIPT model for using pre-cooking as a CCP.
- If there is a persistent cold spot in the pre-cooker, then the sampling plan must be designed to ensure that the EPIPT monitoring samples include fish from the coldest or slowest heating locations in the pre-cooker.
- Sort all of the fish into uniform size groups, e.g., ± 1 kg, so thawing and pre-cooking times are uniform.
- Schedule the fish into the process so there is no waiting for an open pre-cooker after butchering; the butchered fish should not have to wait for an empty pre-cooker.
- Verify that there is adequate steam capacity in the factory to prevent temperature drops during the pre-cooking cycle. For example, the factory needs enough steam to be able to vent retorts and pre-cookers simultaneously. If the factory is short of steam it may not be a candidate for using the EPIPT model for using pre-cooking as a CCP.

Equipment

- Flashlight
- Clean Gloves that can be washed – no bare hands should touch the fish or racks after pre-cooking.
- A minimum of 8 or more fast responding large face dial thermometers, with divisions that are sufficiently small to show detail in the temperature range around the 60°C (140°F) target. The operators need to work fast so many thermometers as practicable should be used so that multiple fish can be measured at one time.
- Data collection form, clipboard and pen.

Hazard Analysis

The 4th edition of the FDA Hazards Guide advises of a limit of 12 hours to process tuna when the fish is exposed to ambient temperatures greater than 4.4°C (40°F) if any

portion of that time is at temperatures above 21.1°C (70°F). This is to prevent histamine forming bacteria from growing and producing unsafe levels of histamine in the processed tuna loins.

It has been scientifically proven that the most prolific and most heat resistant of the five significant histamine formers, *Morganella morganii*, is reduced by at least 5 log cycles if heated to a cold spot temperature of at least 58°C (137°F), hence a minimum EPIPT temperature of 60°C (140°F) has been proposed by industry (Enache and others 2013; Nolte and others 2012). Also, the work of Kanki and others (2007) indicated that the activity of histidine decarboxylase is substantially reduced at 60°C (140°F). Using pre-cooking as a CCP allows the factory sufficient time to process the fish, both large and small.

Set Critical Limits

A minimum End-Point Internal Product Temperature (EPIPT) of 60°C (140°F) of either the backbone temperature of whole fish or the geometric center of a cut (split fish) portion.

Monitoring Procedures

What will be monitored?

Backbone temperatures of the largest fish within the pre-cooker located in the slowest heating zone – if any.

Sample size – minimum of 24 fish chosen from throughout the pre-cooker; minimum of 1 fish per rack if there are more than 24 racks in a pre-cooker batch. For example, if the factory has a 36 rack pre-cooker it is recommended that management should plan on collecting a minimum of 36 data points per pre-cooker load. Hiring an extra operator or two to help with the data collection and rack pushing is far cheaper than any recovery losses associated with slow data collection techniques.

In practice, it is recommended that the operators check a minimum of 8 fish on the first rack or the first pair of racks if it is a double lane pre-cooker, before proceeding to unload the pre-cooker and collect the EPIPT data. It may also be advisable to test the last racks loaded as well, before proceeding to unload the pre-cooker. Testing the fish at both ends of the pre-cookers will give the operators assurance that the fish are pre-cooked sufficiently, and can be removed from the pre-cooker and moved into the cooling zone. After checking a couple of racks the operators will have a good idea if ALL of the fish will pass the

60°C (140°F) EPIPT (back bone/cold spot) temperature limit. The operators must still plan to measure one or more EPIPTs per pre-cooker rack as the racks are withdrawn from the pre-cookers as the monitoring activity.

How will monitoring be performed?

Measure the backbone temperature of the largest fish at the thickest portion of the round fish or the geometric center of the thickest portion of a split fish.

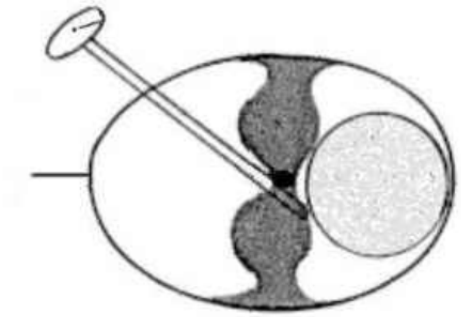
All temperature measurements should be collected within 10 minutes of the pre-cooker doors opening as fish temperatures may be increasing or decreasing over time.

A bi-metallic dial thermometer has a sensing area from the tip to a dimple or circle on the shaft about 1 ½ to 2 inches from the tip; this is the area that holds the bi-metallic coil. It is a good practice to use the same model of thermometer throughout a processing area so everyone using it gets comfortable with the equipment. If the shaft of a bi-metallic thermometer gets bent in any way, dispose of it. It may not measure temperature properly.

An electronic thermometer has a sensing area closer to the tip of the probe. Practically this means the data collection techniques are different, however the fish location for measuring the temperature is the same for both techniques.

When using an electronic thermometer push the probe directly to the backbone in the thickest part of the round fish, generally in the area of the middle of the dorsal fin. If the fish is butchered be sure to go through the top quadrants. Allow the thermometer to equilibrate and record the temperatures.

When using the dial thermometer push the point of the thermometer towards the backbone, touch the backbone and slide the thermometer past the backbone about ½ the distance of the length of the sensing area.



Measuring backbone temperature

How often will monitoring be performed?

Each and every pre-cooker load.

Who will do the monitoring?

Pre-cooker operators and/ or process monitors, fully trained and qualified to use either form of thermometer, electronic or dial and trained in the appropriate monitoring procedure.

Corrective Actions

Take the following corrective actions on all product involved in a critical limit deviation:

If any single temperature is below 60°C (140°F), then leave all remaining racks in the pre-cooker. Push all the racks that were removed from the affected pre-cooker batch back in to the pre-cooker, close and seal the door. Turn the steam back on and continue pre-cooking until the minimum pre-cooker exit temperature of 60°C (140°F) is reached. The time needed for the extended cook will depend on the actual non-compliant exit temperatures, fish size, etc.

Take the following corrective actions to regain control over the operation after a critical limit deviation:

Re-evaluate the pre-cooking times and temperatures for that fish size, and adjust the schedule if necessary. The root cause analysis should include looking at the equipment, steam supply, causes of pre-cooker malfunction, etc. to determine if adjustments or modification are necessary.

Records

The individual temperatures should be recorded on a sheet that is designated strictly for that purpose, and will record the corrective actions, if any on the same sheet.

See Appendix 13 – Example Monitoring Forms for an example EPIPT monitoring form.

Verification

Validate that all of the pre-cookers are operating properly and have a uniform temperature distribution to ensure that all the fish are being evenly heated. Use the references cited to ensure that the proper protocol is being followed.

Before a thermometer is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:

Immersing the sensor in an ice 0°C (32°F), if the device will be used at or near refrigeration temperature;

OR

Immersing the sensor in boiling water 100°C (212°F), if the device will be used at temperatures over 50°C (122°F);

OR

Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to the National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

OR

Following the manufacturer's instructions;

AND

Once in service, check the thermometer daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

AND

Calibrate the thermometer against a known accurate reference device (e.g., a NIST-traceable thermometer), or by an outside lab that performs standard multi-point calibration services at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent

calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and that any critical limit deviations that occurred were appropriately addressed.

References and Resources

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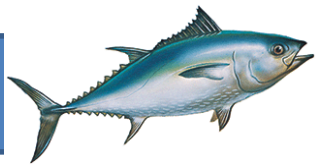
APPENDIX 7



SELF-AUDIT PROGRAM FOR HACCP AND SSOP

The effectiveness of food safety programs is confirmed by the results of HACCP and SSOP (GMP compliance) monitoring and verification procedures. These ongoing programs produce essential records for tracking trends and maintaining control of critical operations. However, processors should remain alert to routines that might lead to complacency over time or missing situations that could compromise food safety. It is useful to conduct periodic reviews of the entire food safety system to ensure that any problems are identified and corrected.

The growth in third party inspection and private standards-setting/auditing programs testify to a growing interest among commercial buyers in substantiated food safety assurance as a supplier certification requirement. These third party programs often go beyond current U.S. regulatory requirements. Regulators perform a verification function when they conduct inspections but these are typically conducted at inconsistent intervals and, of course, have undesirable enforcement implications if problems are revealed. Such problems should be identified and resolved quickly, before outside inspections are conducted, whether by third parties or regulators.

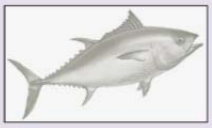
This appendix introduces a self-assessment tool for use by processors or groups responsible for the safety of canned tuna products. Its use at regular intervals is encouraged as a verification step in each company's HACCP and SSOP programs. Screen shots from the Summary and SSOP pages of this tool are printed at the end of this appendix. Its usefulness for self-auditing lies in an active spreadsheet developed to support this handbook.. The spreadsheet can be used on a laptop computer or electronic tablet during audits. Emphasis is placed on evaluating key HACCP and SSOP control procedures pertinent to the tuna industry as outlined in other chapters of this handbook. All of the 8 key sanitation conditions from the FDA HACCP regulation are included since they must be monitored by tuna processors and can be audited along with other food safety control measures with this one tool.

The self-audit tool contains sections for HACCP, SSOPs and other Prerequisite Programs. These major sections contain important points to be confirmed by interviewing responsible personnel, by review of written material and records and/or by direct observation, as appropriate. Related background information and guidance for assessing the degree of compliance is provided in

dialog boxes revealed when the cursor is hovered over scored items of the spreadsheet (indicated by a small red triangle in the upper right corner of the cell).

A minimum passing score of 90 is recommended, although this is somewhat arbitrary and should be determined by management or the responsible auditing group. When used for internal self-assessment, the score should be less important than discovering strengths and weaknesses of the current food safety systems. The first tab ("Summary Page") of the spreadsheet contains a summary of the audit results including an overall score, calculated as a percent of the total number of possible points.

Screen Shot of Summary Page from Self-Audit Tool.



Supplier:		Report Date:	5/23/2013
Plant:		Auditor(s):	
Audit Date:			
Audit Score:	0.00%	Plant Representatives:	
Last Audit Date:			
Previous Audit Score:			

		SCORE SUMMARY			
	Category	Max.	Achieved	Weight (%)	Weighted Score
1.0	HACCP	220	0	37%	0%
2.0	SSOP	510	0	35%	0%
2.1	General Concerns	70	0	6%	0%
2.2	Safety of water and ice.	40	0	3%	0%
2.3	Condition and cleanliness of food contact surfaces.	85	0	4%	0%
2.4	Prevention of cross-contaimination	95	0	4%	0%
2.5	Maintenance of Hand washing, hand sanitizing and toilet facilities.	55	0	4%	0%
2.6	Protection of tuna from adulterants.	30	0	3%	0%
2.7	Proper labeling, storage and use of toxic compounds.	40	0	3%	0%
2.8	Control of employee health conditions.	60	0	5%	0%
2.9	Exclusion of pests.	35	0	3%	0%
3.0	OTHER PREREQUISITE PROGRAMS	335	0	28%	0%
3.1	Product traceability and recovery	40	0	5%	0%
3.2	Allergens	60	0	5%	0%
3.3	Food Defense	95	0	5%	0%
3.4	Other Product Protections	50	0	4%	0%
3.5	Audits	60	0	5%	0%
3.6	Complaint Handling	30	0	4%	0%
	Total Points	1065	0	100%	0.00%

Note 1: Items not applicable are reduced from the total possible points.
Note 2: Items not audited were given all points.

Areas needing improvement

Area	Description

Is a follow up audit required? ☐ Yes ☐ No

Auditor's Signature: X

Plant Representative's signature: X

USER'S GUIDE TO 'TUNA AUDIT' TOOL

This guide serves as quick reference for auditors using the 'TUNA AUDIT' audit tool, an Excel spreadsheet. This tool can be used electronically with scores entered 'real time' while the auditor is evaluating a tuna processing plant. For purposes of simplicity and ease, this spreadsheet has functions added to specific cells that calculate subsection scores and the overall score from the individual scores assigned by the auditor. Self-explanatory dialog boxes pop up when the user/auditor hovers the cursor over a specific item. These dialog boxes provide a quick summary/definition of the items and help the auditor to award appropriate scores.

The audit tool has five tabs (pages):

a. Summary page

This tab auto-summarizes the scores given by the auditor for the various audit segments (HACCP, SSOP, and Other Prerequisite Programs). Scores are automatically weighted to balance the effect of each section on the overall score and are not directly determined by the total number of items and available points in the section. The Summary Page is where plant and auditor information is entered. Space is provided below the summary table for entering comments and suggestions to help plant management focus on important areas needing improvement. Spaces are also provided for the auditor and plant manager to electronically sign the report. Please note that this spreadsheet has functions added to specific cells which require administrative rights to change.

b. HACCP

The HACCP page consists of 12 items relating to the company's development and implementation of HACCP as it applies to the canned tuna industry. Each item should be scored independently. The spreadsheet calculates the available points and total number of points assigned by the auditor and enters the result on this page and on the Summary Page.

c. SSOP

This page consists of 9 sections containing a total of 37 items to score. The page contains a general section on management implementation and oversight of sanitation systems followed by separate sections for each of FDA's eight key sanitation conditions identified in their seafood HACCP regulation, 21 CFR 123. Scores are entered and calculated as described for the HACCP page.

d. Other Prerequisite programs

This page consists of 6 sections containing a total of 29 items to score. Sections are provided on traceability, allergens, food defense, audits, complaint handling, and other product protections. Scores are entered and calculated as described for the HACCP page.

e. Appendices

An appendix tab is provided which currently contains a summary of hazards associated with the production of canned tuna as they relate to the three HACCP models in the Tuna Guide. This provides a quick reference when evaluating a company's hazard analysis and HACCP plan(s).

Using the tuna self-audit tool

The Tuna Council recommends that the following steps be followed when conducting the audit and completing the inspection report.

1. Complete the "boiler plate" information at the top of the Summary Page (first tab at the bottom). This includes the company and facility being audited, the auditor's name, the audit date, previous audit score if applicable, and plant representatives who assist with the audit.

2. Go to each of the subsequent worksheets (click labeled tabs at bottom of page) and score the items according to the order in which the audit is conducted. For example, you might choose to evaluate the company's SSOP programs before proceeding to their HACCP program. Familiarize yourself with the audit contents before using the tool to minimize multiple requests for the same documents or several trips to the same area of the plant.

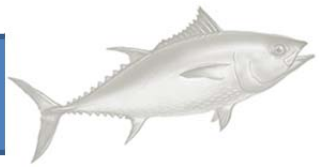
The maximum number of available points is shown for each item to be scored. Use the dialog boxes (hover cursor over the item cell) to assist in assigning points according to expectations. Enter your score in the column labeled "Assigned" under the "Score" heading.

> **Note:** If an item is not appropriate for the facility being audited, enter "na" (no quotes) instead of a numerical score in the "Assigned" column for that item. Entering na reduces the total number of possible points and does not affect the overall score. If an item is not inspected or is not evaluated by the auditor, assign the maximum number of available points for that item. The Tuna Council recommends that a score of zero for any item in bold should result in failure of the audit.

3. Complete the "Comments" cells for as many items as you feel is needed to explain the score given, provide recommendations, or to indicate items that could not be adequately evaluated at the time of the audit.

4. When scoring is completed, return to the summary page. Add major findings as text at the bottom of the page where indicated. Electronically sign the sheet. The overall score and individual section scores are automatically summarized on this page.

APPENDIX 8



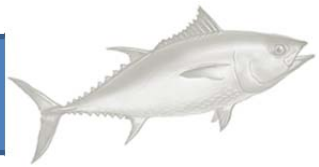
FOOD SAFETY SYSTEM MATRIX

The following matrix is a tool to help processors visualize their comprehensive programs for the management of food safety and product quality incorporating both CCPs and prerequisite programs (PRP). It has processing steps and sections along the vertical axis, and then specific CCPs and PRP along the top of the horizontal axis. The document number and the title for each SOP would be entered and then a check mark can be placed under each CCP and PRP for which the written procedures apply, making it easy to identify the documents where the various control programs can be found.

FOOD SAFETY and QUALITY MANAGEMENT PROGRAM

S O Ps					HAZARDS CONTROL PROGRAMS							PREREQUISITE PROGRAMS														
PART Num.	Section	SOP Num.	Title	Effective Date	Primary Tuna Processors - C C Ps							Premises Buildings & Facilities	Utilities	Site Security & Food Defense	Equipment & Implements	Personnel	Purchasing Receiving Storage & Transportation	Finished Product Specifications, Product Design & Development, Product Inspection, Testing & Approval	Production Specifications & Process Control	Outsourced Processing & Purchased Finished Products	Contracted Services	Contamination Control	Allergen Management	Clean-up, Waste Disposal, Sanitation & Pest Control	Traceability Recall & Non-conforming Products Control	Complaint Handling
					CCP 1 Receiving Elevated Histamine Content Control	CCP 2 Thawing to Precooking Histamine Formation Control	CCP 3 Precooking Control of Histamine Forming Bacteria & Enzyme	CCP 4 End of Precook to Freezing Histamine Formation Control	CCP 5 Skinning to Freezing S. aureus Enterotoxin Formation Control	CCP 6 Metal Inclusion Control	CCP 7 Allergen Control	Condition Inspection/ Monitoring, Product Flow, Employee Traffic Control	Water, Steam, Air, ACHV System Inspection & Evaluation	Standards, Risk-based Food Security Plan, Area Control & Monitoring	Qualification Set-up Maintenance Calibration Maintenance	Training, Hygiene, Conduct & Health	Supplier Approval & Monitoring, Material Spec, Unloading, Storage, Testing	Product Development & Modifications, Product Specs., Product Testing, Evaluation, Approval & Corrective Action	Process Development, Modifications, Process Spec, Process Commissioning Monitoring & Corrections	Outside Processor Approval & Monitoring, Product Testing, Eval, & Approval	Service Supplier Approval & Monitoring, Service Specifications	Control of Sharp Metal Implements, Chemicals, Wood, Glass, Plastic, Metal, Ceramics & Filth	Control of Allergen Materials, Ingredients, & Products, Labeling of Allergens	Unsafe Products or Trademarked Materials Destruction or Disposal Records	Materials, Ingredients, In-process & Re-worked Products Traceability, Systems Tests	Complaint Recording, Investigation, Trend Analysis, Corrective Action
1	Introduction																									
2	Product Design & Development, Finished Product Specifications																									
3	Co-Packing, Outsourced Processing & Purchased Finished Products																									
4	Contracted Services (Standards, Service Provider Approval & Evaluation)																									
5	Material Standards, Supplier Approval (Ingredients, Raw material, Packaging & Non-food Compounds)																									
6	Receiving Unloading, Storage, Incoming Material Evaluation & Approval for Use																									
7	Preparation, Processing																									
8	Packing & Filling																									
9	Sealing																									
10	Freezing																									
11	Packaging, Labeling, Warehousing & Shipping																									
12	Control & Calibration of Process Monitoring Equipment																									
13	Laboratory Procedures & Lab Equipment Maintenance & Calibration																									
14	Quality Control, Product Testing & Evaluation																									
15	Finished Product Approval, Hold & Release Procedures, Tracing & Recalls																									
16	Clean-up, Waste Disposal, Sanitation & Pest Control																									
17	Food Safety & Food Defense																									
18	Internal Audits & Complaint Handling																									
19	Equipment, Facilities, Buildings & Utilities																									
20	Construction, Repair & Maintenance																									
21	Regulatory Compliance, Inspections, Certifications & Third Party Audits																									
22	HR, Personnel, Visitors & Facility Security																									

APPENDIX 9



REFERENCES

Enache, E., A. Kataoka, D. G. Black, L. Weddig, M. Hayman, and K. Bjornsdottir-Butler. 2013. Heat resistance of histamine-producing bacteria in irradiated tuna loins. *J. Food Prot*. 76:1608-1614.

ABSTRACT: Consumption of foods high in biogenic amines leads to an illness known as histamine, or scombrotoxin, poisoning. The illness is commonly associated with consumption of fish with high levels of histamine (≥500 ppm). The objective of this study was to determine and compare the heat resistance of five histamine-producing bacteria in irradiated albacore tuna loins. Heat-resistance parameters (*D*- and *z*-values) were determined for *Morganella morganii, Raoultella planticola, Hafnia alvei,* and *Enterobacter aerogenes*. *D*- or *z*-values were not determined for *Photobacterium damselae,* which was the most heat-sensitive organism in this study. *P. damselae* declined >5.9 log CFU/g after a heat treatment of 50°C for 10 min, 54°C for 3 min, and 56°C for 0.5 min. *M. morganii* was the most heat-resistant histamine-producing bacteria in albacore tuna loins, followed by *E. aerogenes, H. alvei,* and *R. planticola*. *M. morganii* and *E. aerogenes* had the highest $D_{50°C}$, 49.7 ± 17.57 and 51.8 ± 17.38 min, respectively. In addition, *M. morganii* had the highest *D*-values for all other temperatures (54, 56, and 58°C) tested. *D*- and *z*-values were also determined for *M. morganii* in skipjack tuna. While no significant ($P > 0.05$) difference was observed between $D_{54°C}$ and $D_{56°C}$ of *M. morganii* in either albacore or skipjack tuna, the $D_{58° C}$ (0.4 ± 0.17 min) was significantly lower ($P < 0.05$) in skipjack than in albacore (0.9 ± 0.24 min). The *z*-values for all organisms tested were in the range of 3.2 to 3.8°C. This study suggests that heat treatment designed to control *M. morganii* in tuna loins is sufficient for controlling histamine-producing bacteria in canned-tuna processing environments.

Nolte, F., D. G. Black, J. DeBeer, E. Enache. 2014. Use of end point internal product temperature to control histamine formation in tuna at pre-cooking step. *Food Prot. Trends.* 34(2): 94-100.

ABSTRACT: A linear heating and cooling model was developed to determine a critical limit for precooking End Point Internal Product Temperature (EPIPT) in order to achieve a 5-log reduction of the most prolific histamine-forming bacterium, (HFB) *Morganella morganii*. The thermal death time values used in a General Method calculation employed the Trapezoidal rule, where $D_{60^{\circ}C}$ of 0.26m and z = 4.1˚C. Based on the thermal death time values and the General Method calculations, a 60°C pre-cooking EPIPT for tuna of any size will stop histamine formation during and after pre-cooking, until the de-skinning step is reached, thus providing the canned tuna industry with significant extra time to process tuna, especially with the larger sizes. It is also possible to use process lethality as a tool to evaluate a deviation from the process schedule, where a 5-log reduction of HFB can be demonstrated for a pre-cook batch. This information should be of interest to the tuna processing industry and regulatory officials interested in controlling histamine production in these products.

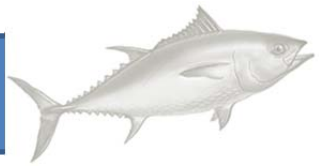
Wu, X. and Y. Su. 2014. Growth of *Staphylococcus aureus* and enterotoxin production in pre-cooked tuna meat. *Food Control* 42: 63-70.

ABSTRACT: This study investigated growth of enterotoxin-producing *Staphylococcus aureus* and time-temperature combinations needed for enterotoxin production in pre-cooked tuna meat. Frozen samples (50 ± 5 g) of pre-cooked albacore tuna (loin, chunk and flake) and skipjack tuna (chunk and flake) were thawed overnight at 5-7°C, inoculated with five strains of *S. aureus* (2–4 log CFU/g), and incubated at 37 and 27°C for up to 36 h. Changes of *S. aureus* populations in samples during incubation were determined by plating on Baird-Parker media. Results indicate that increases in *S. aureus* populations varied among the 5 types of tuna samples. Incubation at 37°C for at least 6 or 8 h was required to allow an increase in *S. aureus* populations by >3 log CFU/g in inoculated albacore or skipjack tuna meat. A similar increase of *S. aureus* counts (>3 log CFU/g) in albacore and skipjack samples required more than 8 and 10 h, respectively, when samples were incubated at 27°C. No enterotoxin was produced in albacore or skipjack tuna meat inoculated with five strains of enterotoxin-producing *S. aureus* and exposed to 37°C for 12 h or 27°C for 16 h. All the samples showed clear sign of spoilage before enterotoxin was detected.

Vogl, F., R. Salazar, F. Nolte, G. Kontoh, G. Ybanez. 2012. Validation for pre-cooking as a control for potential histamine production in tuna loins for subsequent canning. Paper presented at: TAFT 2012. Proceedings of the 4th Trans-Atlantic Fisheries Technology Conference; 2012 Oct 30-Nov 2; Clearwater Beach, Florida.

ABSTRACT: A series of commercial trials involving 30 test variables, 765 fish and a total of 3842 individual histamine tests were designed to demonstrate that pre-cooking tuna is an effective control for potential histamine formation. Long line caught Albacore tuna (*Thunnus alalunga*) sized from 10-20 kg, caught in the South Pacific Ocean were chilled on board and delivered within 3-13 days post harvest from customary fishing vessels. These raw fish were intentionally spoiled to exceed 50ppm histamine to simulate harvest vessel time-temperature abuse beyond worst case conditions, and then frozen to represent standard commercial processing conditions. The fish were thawed and cooked in industrial atmospheric steam pre-cookers using commercial pre-cooking schedules. Results demonstrate that achieving an end point internal product temperature of 60°C controls histamine formation and previous studies have shown that 60°C provides a 5D reduction in *Morganella morganii*, a heat resistant and prolific histamine forming bacteria. No further histamine formation was observed for up to 18 hours. This is more than adequate time to convert pre-cooked fish into frozen tuna loins or canned tuna. These critical limits need to be incorporated as part of a HACCP plan built on a sound foundation of proper GMPs, SSOPs and Pre-requisite Programs.

APPENDIX 10



HACCP FORMS

Hazard Analysis Worksheet					
Firm Name:	**Finished Product Description:**				
Firm Location:	**Method of Storage & Distribution:**				
	Intended Use & Consumer:				
(1) **Processing Step**	(2) List all potential **biological, chemical, and physical food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**

(1) **Processing Step**	(2) List all potential **biological, chemical, and physical food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**

HACCP Plan Form		
Firm Name:	**Finished Product Description:**	
Firm Location:	**Method of Storage & Distribution:**	
	Intended Use & Consumer:	
Signature		**Date**

Critical Control Point		
Significant Hazard(s)		
Critical Limit		
Monitoring	**What**	
	How	
	When	
	Who	
Corrective Action		
Verification		
Records		

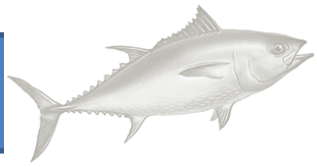
HACCP Plan Form	
Firm Name:	**Finished Product Description:**
Firm Location:	**Method of Storage & Distribution:**
	Intended Use & Consumer:

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

A10-4

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Signature							**Date**		

APPENDIX 11



FDA SEAFOOD HACCP REGULATION

NOTE: The following is an unofficial reprint of the U.S. regulation formatted for easy reading. The regulation is provided for reference only. Please refer to the U.S. Government Printing Office at www.gpo.gov for the most current and official version of the regulation.

Title 21 of the Code of Federal Regulation

Part 123 – Fish and Fishery Products

(Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 241l, 264. **Source:** 60 FR 65197, Dec. 18, 1995, unless otherwise noted.)

Subpart A — General Provisions

§ 123.3 Definitions

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) *Critical control point* means a point, step or procedure in a food process at which control can be applied, and a food-safety hazard can be prevented, eliminated, or reduced to acceptable levels.

(c) *Critical limit* means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food-safety hazard.

d) *Fish* means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to alligators, frogs, aquatic turtles, jellyfishes, sea cucumbers, sea urchins and roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) *Fishery product* means any human food product in which fish is a characterizing ingredient.

(f) *Food safety hazard* means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(g) *Importer* means either the U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom-house broker, the freight forwarder, the carrier or the steamship representative.

(h) *Molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, scallops or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) *Preventive measure* means physical, chemical or other factors that can be used to control an identified food safety hazard.

(j) *Process-monitoring instrument* means an instrument or device used to indicate conditions during processing at a critical control point.

(k) (1) *Processing* means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel.

(iii) The operation of a retail establishment.

(l) *Processor* means any person engaged in commercial, custom or institutional processing of fish or fishery products either in the United States or in a foreign country. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) *Scombroid toxin-forming species* means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n) *Shall* is used to state mandatory requirements.

(o) *Shellfish control authority* means a federal, state or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) *Shellstock* means raw, in-shell molluscan shellfish.

(q) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(r) *Shucked shellfish* means molluscan shellfish that have one or both shells removed.

(s) *Smoked or smoke-flavored fishery products* means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

§ 123.5 Current Good Manufacturing Practice

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices and controls used to process fish and fishery products are safe and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

§ 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan

(a) *Hazard analysis*. Every processor shall conduct or have conducted a hazard analysis to determine whether there are food-safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food-safety hazards can be introduced both within and outside the processing plant environment, including food-safety hazards that can occur before, during and after harvest. A food-safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) *The HACCP plan.* Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together or group kinds of production methods together if the food-safety hazards, critical control points, critical limits and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food-safety hazards that are reasonably likely to occur as identified in accordance with paragraph (a) of this section, and that must be controlled for each fish and fishery product. Consideration should be given to whether any food-safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food-safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food-safety hazards, including as appropriate:

(i) Critical control points designed to control food-safety hazards that could be introduced in the processing plant environment; and

(ii) Critical control points designed to control food-safety hazards introduced outside the processing plant environment, including food-safety hazards that occur before, during and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with § 123.8(a);

(7) Provide for a record-keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d) *Signing and dating the HACCP plan.*

(1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

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

(i) Upon initial acceptance

(ii) Upon any modification and

(iii) Upon verification of the plan in accordance with § 123.8(a)(1).

(e) *Product subject to other regulations.* For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food-safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food-safety hazard. A HACCP plan for such fish and fishery products shall address any other food-safety hazards that are reasonably likely to occur.

(f) *Sanitation*. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §123.11(b) they need not be included in the HACCP plan and vice versa.

(g) *Legal basis*. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

§ 123.7 Corrective Actions

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective-action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with § 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with § 123.10, to determine whether the HACCP plan needs to be

modified to reduce the risk of reoccurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with § 123.8(a)(3)(ii) and the record-keeping requirements of § 123.9.

§ 123.8 Verification

(a) *Overall verification.* Every processor shall verify that the HACCP plan is adequate to control food-safety hazards that are reasonably likely to occur and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) *Reassessment of the HACCP plan.* A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. Reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of § 123.6(c).

(2) *Ongoing verification activities.* Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end product or in-process testing.

(3) *Records review.* A review, including signing and dating, by an individual who has been trained in accordance with § 123.10, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that

appropriate corrective actions were taken in accordance with § 123.7. This review shall occur within one week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) *Corrective actions.* Processors shall immediately follow the procedures in § 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) *Reassessment of the hazard analysis.* Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food-safety hazard now exists. Such changes may include, but are not limited to changes in: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10.

(d) *Recordkeeping.* The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the record-keeping requirements of § 123.9.

§ 123.9 Records

(a) *General requirements.* All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) *Record retention.*

(1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least one year after the date they

were prepared in the case of refrigerated products and for at least two years after the date they were prepared in the case of frozen, preserved or shelf-stable products.

(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least two years after their applicability to the product being produced at the facility.

(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d) *Public disclosure.*

(1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) *Tags*. Tags as defined in § 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of § 123.28(c).

(f) *Records maintained on computers.* The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

§ 123.10 Training

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions.

Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of § 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in § 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in § 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in § 123.8(c); and

(c) Performing the record review required by § 123.8(a)(3); The trained individual need not be an employee of the processor.

§ 123.11 Sanitation Control Procedures

(a) *Sanitation SOP.* Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) *Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food-contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food-contact surfaces, including utensils, gloves and outer garments;

(3) Prevention of cross-contamination from insanitary objects to food, food-packaging material and other food-contact surfaces, including utensils, gloves and outer garments, and from raw product to cooked product;

(4) Maintenance of hand washing, hand sanitizing and toilet facilities;

(5) Protection of food, food-packaging material and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;

(6) Proper labeling, storage and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food-packaging materials and food-contact surfaces; and

(8) Exclusion of pests from the food plant. The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) *Sanitation control records*. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of § 123.9.

(d) *Relationship to HACCP plan.* Sanitation controls may be included in the HACCP plan, required by § 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section, they need not be included in the HACCP plan and vice versa.

§ 123.12 Special Requirements for Imported Products

This section sets forth specific requirements for imported fish and fishery products.

(a) *Importer verification*. Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent

third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.

(d) *Determination of compliance.* There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B – Smoked and Smoke-Flavored Fishery Products

§ 123.15 General

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

§ 123.16 Process Controls

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food-safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Subpart C – Raw Molluscan Shellfish

§ 123.20 General

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

§ 123.28 Source Controls

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in § 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;

(2) The location of harvest by state and site;

(3) The quantity and type of shellfish;

(4) The date of receipt by the processor; and

(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

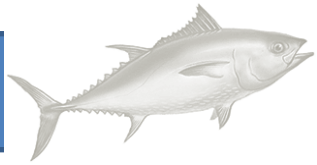
(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with § 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt,

(2) The quantity and type of shellfish, and

(3) The name and certification number of the packer or repacker of the product.

APPENDIX 12



GOOD MANUFACTURING PRACTICE REGULATION

NOTE: The following is an unofficial reprint of the U.S. regulation formatted for easy reading. The regulation is provided for reference only. Please refer to the U.S. Government Printing Office at www.gpo.gov for the most current and official version of the regulation.

Title 21 of the Code of Federal Regulation

Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (GMP's)

(Authority: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264. **Source:** 51 FR 24475, June 19, 1986, unless otherwise noted.)

Subpart A – General Provisions

§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Acid foods or acidified foods* means foods that have an equilibrium pH of 4.6 or below.

(b) *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) *Blanching* except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) *Critical control point* means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) *Food* means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.

(h) *Lot* means the food produced during a period of time indicated by a specific code.

(i) *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective “microbial” instead of using an adjectival phrase containing the word microorganism.

(j) *Pest* refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) *Plant* means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) *Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) *Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) *Safe-moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

(o) *Sanitize* means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) *Shall* is used to state mandatory requirements.

(q) *Should* is used to state recommended or advisory procedures or identify recommended equipment.

(r) *Water activity* (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated

(1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or

(2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B – Buildings and Facilities

§ 110.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant Construction and Design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be

reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 110.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.*

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control.* No pests shall be allowed in any area of a food plant. Guarder guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an

attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C – Equipment

§ 110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D – [Reserved]

Subpart E – Production and Process Controls

§ 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) *Raw materials and other ingredients*.

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations*.

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140°F (60°C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall beperformed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of

undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the a_w of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

[51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

§ 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F – [Reserved]

Subpart G – Defect Action Levels

§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

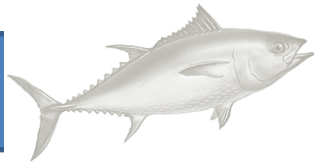
(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[51 FR 24475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

APPENDIX 13



EXAMPLE MONITORING FORMS

CCP – Receiving for Histamine Control
- Lab Histamine Analysis Report
- Fish Reject Results for Lots
- HACCP Test Lot Summary Report

CCP – Thawing to Pre-cook for Histamine Control
- Fish Thawing to Pre-Cooking Tracking Report

CCP – Pre-cooking for Histamine Control
- Exit Cooker Fish Core Temperature Monitoring

CCP – Pre-cooking to Retort or Freezer for Histamine and *S. aureus* Control
- Pre-Cooker Batch Tracking Report - Time

CCP – Metal Detection
- Injection Needle Inspection Report
- Metal Detector Verification Record

CCP – Labeling for Undeclared Allergen Control
- Packing Log Report

QUALITY CONTROL DEPARTMENT

Lab Histamine Analysis Report

Note: This is a HACCP Plan Record

Date of Test: _____

Raw Fish/Hatch #: _____

HACCP Lot # / Supplier: _____

Vessel/Cont#: _____

ID / Sample #	Histamine (ppm)	Lab Technician sign	Comments

HACCP Reviewed By/Date: _____

NB: Minimum 18 samples per HACCP Lot #

***Note: Must be reviewed by a HACCP qualified person within 1 week of test*

QUALITY CONTROL DEPARTMENT
Fish Reject Results for Lots
Note: This is a HACCP Plan Record

Date / Shift: _____

HACCP LOT #: _____

HATCH NO: _____ **Reported By** _____

Bin #	Species	Total # of Fish Examined	# of Fish Rejected for Decomp	% Fish Rejected for Decomposition	(Pass/Fail) Pass < *2.5%* *Fail* ≥ *2.5%*	Comments And Disposition of Rejected Fish

Note: Minimum total number of fish is 118 or entire lot if lot is less than 118

Reviewed By:Date: _____

Note: Must be reviewed by a HACCP qualified person within 1 week of test

QUALITY CONTROL DEPARTMENT
HACCP Test Lot Summary Report
Note: This is a HACCP Plan Record

Test Pack Date: _____ **Recorded By:** _____

HACCP Lot #	Total HACCP Lot Weight	Hatch #	Species	Histamine Sampling (Min 18 or for new Supplier Min 60)		Status of Histamine	Total # of Fish in Test Pack (Min 118 or entire lot if lot is fewer than 118)	No. of Fish Rejected for Decomp	Status of Decomp	Comments and Disposition of Rejected Fish
				No. Samples analyzed	No Samples >30ppm	*Pass/Fail*			*(Pass/Fail) Limit: <2.5%*	

A13-5

Reviewed By/Date: _____

Note: Must be reviewed by a HACCP qualified person within 1 week of test

Quality Control Department

Fish Thawing to Pre-Cooking Tracking Report

Note: This is a HACCP Plan Record

Thaw Batch #

Reported by:		Date/Shift:			Reported by:			Date/Shift:			
Bin #	HACCP Lot #	Species	Fish Size	Time Water on for first bin in the thaw batch	Time Butcher Start	Pre-cooker & Cycle #		Time Pre-cooker Steam On	Thaw Start to Pre-cooker Steam on for the last fish in the thaw batch Hours (Max 12hrs)	Pass/Fail	Comments and Disposition of Rejected Fish

A13-6

Reviewed By/Date:

Note : Must be reviewed by a HACCP qualified person within 1 week of test

QUALITY ASSURANCE DEPARTMENT

Injection Needle Inspection Report

Date/Shift: ___________________________________

FREQUENCIES OF INSPECTIONS: Start of Shift (Pre-Inspection); End of injection Batch not >2hrs; Breaktimes; End of Shift (Post-Inspection), After Machine Jam

Time of Inspection	Thaw Batch No.	Injectors	Injector Needles Condition		Inspected By	Comments
			ACCEPTABLE	NOT ACCEPTABLE	& Verified By (QA)	

NB: Maximum of 2hrs from last inspection time
Pre and Post injector inspection must be done and recorded
***Note: Must be reviewed by a HACCP qualified person within 1 week of test*

HACCP Reviewed By/Date: ______________________

Production Department

Exit Cooker Fish Core Temperature Monitoring

Note: This is a HACCP Plan Record

Date: _____ Shift: _____ SPC Monitor: _____

Batch#		Batch#		Batch#		Batch#		Batch#		Batch#	
Rack #		Rack #		Rack #		Rack #		Rack #		Rack #	
PC #		PC #		PC #		PC #		PC #		PC #	
Cycle#		Cycle#		Cycle#		Cycle#		Cycle#		Cycle#	
Time Start		Time Start		Time Start		Time Start		Time Start		Time Start	
Time End		Time End		Time End		Time End		Time End		Time End	
Spl #	Temp (ºC)	Spl #	Temp (ºC)	Spl #	Temp (ºC)	Spl #	Temp (ºC)	Spl #	Temp (ºC)	Spl #	Temp (ºC)
1		1		1		1		1		1	
2		2		2		2		2		2	
3		3		3		3		3		3	
4		4		4		4		4		4	
5		5		5		5		5		5	
6		6		6		6		6		6	
7		7		7		7		7		7	
8		8		8		8		8		8	
9		9		9		9		9		9	
10		10		10		10		10		10	
11		11		11		11		11		11	
12		12		12		12		12		12	
13		13		13		13		13		13	
14		14		14		14		14		14	
15		15		15		15		15		15	
16		16		16		16		16		16	
17		17		17		17		17		17	
18		18		18		18		18		18	
19		19		19		19		19		19	
20		20		20		20		20		20	
21		21		21		21		21		21	
22		22		22		22		22		22	
23		23		23		23		23		23	
24		24		24		24		24		24	
QA Inspector review		QA Inspector review		QA Inspector review		QA Inspector review		QA Inspector review		QA Inspector review	
Comments		Comments		Comments		Comments		Comments		Comments	

Note : Minimum of 24 temperature readings per cook batch; Must be reviewed by a HACCP qualified person within 1 week.

NB: Notify Supervisor if any of the fish core temperature at exit cooker is <60ºC.

HACCP Reviewer, Reviewed By/Date: _____ Date: _____

Production Manager _____ Date: _____

Quality Assurance Manager _____ Date: _____

Production Department

Pre-Cooker Batch Tracking Report - Time

Note: This is a HACCP Plan Record

Preparation Date: _____ **Production Date:** _____

Pre-Cooker No. & Cook No.	Pre-cooker Steam On	Time End Pre-cook (Doors being opened)	Batch #	Rack #	Time first fish of the pre-cook batch Start Skinning	Time Last fish product of the pre-cook batch enters freezer	CCP - Total time: End Pre-cook to last fish starts freezing or retorting [Max time 12hrs]	CCP - Total time: Start Skinning to Last Fish starts freezing or retorting [Target Max time 2hrs] CL 3hrs	Production / QC Inspector	Comments

NB: Notify Supervisor/Quality Control if any of the Critical Time Limit is deviated; Maximum time from End Pre-cooking to Start Plate Freezing (PF) - 12 hours

Target time in Conditioning Room - 7-9 hours; Max time from start skin to start Freezing or Retorting 2 hours

Note : Must be reviewed by a HACCP qualified person within 1 week.

HACCP Reviewer, Reviewed By/Date: _____ Date: _____

Production Manager _____ Date: _____

Quality Assurance Manager _____ Date: _____

QUALITY ASSURANCE DEPARTMENT

Metal Detector Verification Record

Note: This is a HACCP Plan Record

DATE & SHIFT: _____

LOCATION: _____

METAL DETECTOR ID: _____

Verification of Metal Detector

FREQUENCY: Hourly during production, HACCP requirement is every 2 hours.	METAL PIECES	SIZE
	1.FERROUS	
	2.NON FERROUS	
	3.STAINLESS STEEL	

TIME	Check every bag passes through the metal detector	CALIBRATION RESULTS (Tick Number if OK, cross Number if not ok and record in remarks & corrective actions)	CODE CHECK	INITIAL	REMARKS & CORRECTIVE ACTIONS
		1 2 5 3 4			
		1 2 5 3 4			
		1 2 5 3 4			
		1 2 5 3 4			
		1 2 5 3 4			
		1 2 5 3 4			
		1 2 5 3 4			
		1 2 5 3 4			
		1 2 5 3 4			
		1 2 5 3 4			

Verified by: _____ **Checked by:** _____ **Reviewed by/ Review Date:** _____

Quality Control Department

Packing Log Report

Note: This is a HACCP Plan Record

Production Code: _____ **Date/Shift: _____**

Batch #	Injected/ Non-injected	Species	Pallet No. Inspected	"NON-INJECTED" Final Pallet packaging clearly stated allergen "(Specie) Tuna" [Yes/No]	"BROTH INJECTED" Final Pallet packaging clearly stated allergen "(Specie) Tuna" and "Contains Soy" [Yes/No]	Quality Control Inspector	Comments

Note : Must be reviewed by a HACCP qualified person within 1 week.

NB: Notify Supervisor or QC if final Pallet marking is missing or incorrectly marked

Reviewed by/Date _____