# Guidance Document for Retail Sushi HACCP Standardization

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# Prepared By the CFP Council III Retail Sushi HACCP Standardization Committee

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# Introduction

## Preface

Council III of the Conference for Food Protection created the Standardization of HACCP Plans for Sushi at Retail Committee in response to Issue 2020-III-017. The committee was charged with:

1. Reviewing current industry practices, collecting available guidance documents, and current state codes pertaining to the production of sushi prepared at retail establishments.
2. Updating the current CFP guidance document for the production of sushi prepared at retail establishments.
3. Referencing the guidance document in the Food Code Annex, or wherever the committee deems appropriate.
4. Identifying whether the Food Code adequately addresses sushi production at retail as a whole

The committee reviewed the current CFP guidance document related to sushi created by the 2016-2018 Special Process Controls Committee titled "Single Hazard Special Process HACCP Template" and it was determined that the information prepared by the committee is not easily integrated into the existing document. This document was created to supplement the templates and guidance provided for acidified rice in that document. This document is intended to provide guidance for food service operators and regulators, is not binding and does not replace regulatory provisions.

*Note: This summary was developed around the 2017 FDA Model Food Code. Not all jurisdictions will have adopted this version of the Food Code, however, the references will be similar among versions of the Food Code. Be sure to verify your regulatory authority's requirements.*

## Sushi Background

The word "sushi" describes the specific preparation of the rice used in formed sushi-making. Sushi rice is a specific variety of rice that has its own unique flavor and ability to stick together to form finished products when combined with vinegar or other acidic products. In its conventional usage, sushi is described as cooked rice that has been acidified with vinegar solutions and formed with raw or cooked fish other seafood, imitation crabmeat, shellfish and fish egg, surimi, fresh chopped vegetables, produce, pickles, tofu, etc.

Sushi products may be formed manually using mats made of bamboo or plastic, specialized tools, or mechanically using sushi forming machines. Popular product forms can include:

- Nigiri, small balls of rice with raw or cooked fish or shellfish, optionally held in place with strips of dried seaweed (nori).
- Maki Rolls, layers of rice and nori sheets rolled with a bamboo or plastic mat to form cylinders that contain various seafood, vegetables, and other ingredients, [i.e., California roll cucumber, avocado and surimi or imitation crab, Philly roll with cream cheese, Tekka maki raw tuna)]; and
- Hand rolls, cone shaped rolls formed by a sheet of nori filled with various ingredients."

Sashimi is a separate food from sushi, even though the two are often used interchangeably. Sashimi, loosely translated, means "pierced body "and it refers to a delicacy of thinly sliced fish or other types of meat. Sashimi is eaten plain, without rice or other foods. Sashimi-grade fish is not a regulatory term but is used as a culinary one. Some of the most popular varieties of sashimi include salmon, fatty tuna, yellowtail, and squid.

An example of a food flow diagram that outlines the entire process of preparing sushi can be found in Appendix A.

## Existing Problem

Due to the number and types of local regulatory agencies responsible for food safety across the country, there is inconsistent interpretation and enforcement of existing Food and Drug Administration (FDA) Model Food Code, herein called Food Code, provisions for specialized processes. Establishments that operate in multiple jurisdictions with separate regulatory agencies may be asked to provide different documentation for the same food item produced the same way. Examples of these inconsistencies include, but are not limited to:

- When a full HACCP plan and/or variance may be needed
- Procedures for variance submittal
- pH value for acidification of rice
- Provisions for submitting sample to lab for pH verification
- Final cooling temperature of rice
- Labeling provisions
- Additional regulatory provisions, such as when seafood HACCP is needed

## Audience and Benefits of Document

This document provides standardized information for reference and use by both regulatory agencies and retail food establishments that make and sell sushi. Providing standardized guidance for sushi and acidified rice should not only shorten plan review and approval times but would greatly reduce the number of HACCP plans that each retail food establishment or sushi company must create and maintain.

The goal of this guidance is to help jurisdictions achieve a more standardized review of HACCP Plans. Uniform criteria for retail sushi HACCP plans allow for more consistent oversight for regulatory agencies and allows for training of food safety regulators on established critical control points across all facilities. Furthermore, this approach would help ensure that risks associated with the production of sushi at retail and food establishments were properly identified and addressed.

## Purpose and Limitations of Guidance Document

This guidance document addresses the specialized process of acidifying rice to make it a non-time/temperature control for safety (TCS) food. This process needs a variance in the current version of the Food Code. This document does not address seafood HACCP for fish used as an ingredient in sushi. Seafood HACCP is needed for approved suppliers, and since provisions for approved suppliers are outlined in the Food Code, adherence to regulation is sufficient for retail HACCP.

# Sushi Preparation Food Code References

The application of the Food Code provisions to sushi will vary depending on methods the establishment utilizes to prepare sushi products. Just like all TCS food, the Food Code provisions for parasite destruction, consumer advisory, cold holding, and cooling need to be considered for all sushi operations. Depending on the establishment's operation, time as a public health control or the special process of acidification of rice may also need to be addressed. The establishment's choice of sushi products served, and methods of operation will guide their best approach to meeting the Food Code provisions.

***References for all sushi operations:***
*Parasite Destruction §3-402.11*
*Cooling §3-501.14*
*Temperature Control §3-501.16*
*Consumer Advisory §3-603.11*

***Additional Considerations for some operations:***
*Date Marking §3-501.17*
*Time as a Public Health Control §3-501.19*
*Special Process (Acidification) §3-502.11*
*Labeling §3-602.11*

## References that Apply to all Sushi Operations

### Parasite Destruction §3-402.11

Sushi products that include raw or undercooked fish may have naturally occurring parasitic hazards that need to be controlled. The Food Code outlines that fish that will be served raw or undercooked to be frozen to specific time and temperature parameters found in §3-402.11, unless an exemption is met. Exemptions include molluscan shellfish, shucked scallop adductor muscle, select tuna species [*Thunnus alalunga, Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus, Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern)], and fish raised under specified aquaculture practices. Retail establishments commonly rely on suppliers to address parasite controls. Documentation of proper parasite control is needed which may include in-house freezing records or letters of guarantee from suppliers.

### Cooling §3-501.14

TCS foods held in the Danger Zone have the potential to cause foodborne illnesses. To help control these foodborne illnesses, the Food Code outlines rapid cooling of TCS foods, such as cooked rice, cooked fish products, and assembled finished products. TCS food must be rapidly cooled using a two-tiered cooling system that includes cooling TCS from 135°F (57°C) to 70°F (21°C) within 2 hrs., then to 41°F (5°C) within a total of 6 hours.

Sushi usually contains multiple components that include both TCS and non-TCS ingredients. The TCS ingredients and TCS containing finished products must be rapidly cooled to prevent foodborne illness. Sushi rice when acidified below 4.2 is not considered a TCS food. However, the finished, assembled sushi roll containing TCS foods must be rapidly cooled in accordance with §3-501.14.

### Temperature Control §3-501.16

Cold holding may occur at several different steps in the production of sushi products. This commonly includes cold holding of fish, some sushi ingredients and sauces, non-acidified cooked rice, and the assembled sushi product if not immediately served. Keeping TCS food at or below 41°F (5°C) reduces opportunity for pathogen growth and/or toxin formation. Keeping TCS foods at 135°F (57°C) or above additionally controls pathogen growth. In sushi operations, hot holding may not be a feasible option due to quality.

### Consumer Advisory §3-603.11

The Food Code outlines that the consumer be informed about the risks of consuming undercooked or raw animal foods, including raw or undercooked fish often found in sushi. The consumer advisory outlines 1) **disclosure** identifying any raw or undercooked animal foods and 2) **reminder** of risks associated with consuming undercooked or raw animal foods such as fish. Consumer advisories are commonly placed on menus, signage at place of order, or on label of packaged product.

## References for Some Operations (based on preparation methods)

### Date Marking §3-501.17

Date marking in the Food Code applies to ready-to-eat, TCS foods held cold for more than 24 hours within the establishment. Food components that go into finished sushi products, as well as the completed rolls, may need date marking if held over 24 hours. Fish used in sushi products is considered ready-to-eat even if it remains in an undercooked or raw form. Date marking for these ready-to-eat fish components would begin when removed from manufacturers' packaging or removal from in-house freezing for parasite destruction step. When food items are combined, the oldest date needs to be used for the new item. Many sushi products are prepared and sold to consumers the same day, so date marking may not apply.

However, all sushi operations should review use of components that were opened in advance and possible end of day carry-over to determine if the Food Code date marking provisions would apply.

### Time as a Public Health Control §3-501.19

Time as a public health control (TPHC) is an option under the Food Code §3-501.19. This can allow use of food products for up to four hours after being cooked without temperature control or control of pH, with any remaining product being discarded. This practice needs written procedures, labeling food when removed from temperature control, and discarding unlabeled products and any remaining at the end of four hours. This option does not allow for saving or restarting once a TPHC procedure is started. This approach works frequently for finished sushi rolls intended for immediate consumption. However, retail establishments packaging sushi for to-go service methods will find TPHC impractical.

### Special Process - Acidification of Rice §3-502.11

Acidification of TCS foods with the intent of making them non-TCS is considered a special process in the Food Code. In the case of sushi rice, this process takes a TCS food (cooked rice) and adds acid (typically vinegar) to drop the pH and allow the cooked rice to be held without time or temperature controls. This acid addition needs to adjust the equilibrium pH to less than 4.2 to control the identified hazards.

Addition of vinegar for flavor only, when pH is not monitored, is not considered a special process and rice must be temperature controlled just like any other TCS food. It is also important to remember once the acidified rice is combined with other sushi ingredients the final product would be considered TCS again requiring time and temperature control.

Retail food operations who wish to handle food outside the Food Code parameters can do so by use of a Variance and HACCP Plan. HACCP plan (discussed following sections) specifies the process and how food safety hazards will be controlled. The Food Code §8-103.11 outlines provisions for obtaining a regulatory variance, and §8-201.14 identifies elements of HACCP plans. The variance issued by the regulatory authority allows the establishment to implement a reviewed HACCP plan which controls food safety hazards in an alternate manner. The Food Code §8-103.10 has additional information about variances.

### Labeling §3-602.11

Sushi that is packaged for retail sale, for example clam shell packaged sushi products in a consumer display case, will also need labeling. Package labeling is needed to allow the consumer to make informed decisions on food selections and avoid major food allergens. The definition of “packaged” is included in the Food Code and excludes over wraps or carry-out containers facilitating service of food upon consumer request. Basic elements needed on the label include identity statement, ingredient list, net quantity, major allergens, and name and place of business. In addition to the Food Code, labeling may meet 21 CFR 101.

## When a Variance and HACCP Plan is Needed

Based on the food process the establishment has chosen, a variance and HACCP Plan may be needed for a retail sushi establishment. As noted above, the Food Code outlines a variance and HACCP when acidifying rice to render it non-TCS; however, regulations will vary with jurisdictions. In determining whether a HACCP Plan is needed, the establishment needs to consult with the regulatory authority for specific procedures for receiving a variance. This document is intended for retail food service establishments and does not cover food processing plants. Example scenarios to help determine whether a food business is a retail food establishment, or a food processing plant can be found in Appendix B. A decision tree is included in Appendix C to assist in determining if a variance and HACCP approval is needed. The sections below provide guidance for creating the HACCP plan for acidified rice only.

# Contents of a Sushi Rice HACCP Plan

There are seven principles of HACCP: Hazard Analysis, Determine Critical Control Point, Establish Critical Limit, Establish Monitoring Procedures, Establish Corrective Action, Verification and Record Keeping. A Sushi Rice HACCP Plan should address each of these principles. Additional items are outlined for a HACCP Plan as stated in §8-201.14, such as general information regarding the operation, recipes, flow diagrams, sample blank log forms, and Standard Operating Procedures.

- **General Information:** General information should be included on the plan to include the owner/operator's name, location of business, Person-In-Charge (PIC), and contact information.
- **Recipe(s)**: Included in your HACCP Plan should be the recipe for your sushi rice. Include each different sushi rice recipe, including alternative grains such as quinoa, brown rice, or similar.
- **Flow Diagram or Chart**: A flow diagram will visually explain the exact process of preparing the sushi rice. Your plan should include a flow diagram or chart. The first step in the flow of food should be receiving ingredients and the last step is consumption or sale of sushi rice. An example food flow can be found in Appendix D.
- **Sample log form**s: A copy of the blank logs should be attached to the HACCP plan. There should be at least one log for each of the critical control points.
- **Standard Operating Procedure**s: Standard operating procedures (SOPs), are written procedures that provide specific instructions on performing food safety tasks related to the HACCP plan.

## Hazard Analysis

A hazard analysis identifies the known or reasonably foreseeable hazards associated with a specific food. There are two main biological hazards associated with sushi rice held at room temperature: *Bacillus cereus (B. cereus) and Staphylococcus aureus (S. aureus)*. If they are allowed time to grow in the rice, both bacteria can form toxins that cause vomiting and diarrhea. *B. cereus* is a spore forming bacteria often associated with rice. The spores may be present in rice and other grains, and then survive the cooking step. *S. aureus* is associated with food preparation environments and may be introduced to sushi rice due to the amount of handling throughout the sushi preparation process. These bacteria can produce toxins when left for too long in temperature danger zone, of above 41°F- below 135°F (5°F - 57°C). These bacteria are commonly associated with unacidified or improperly acidified sushi rice because it is typically kept in the temperature danger zone. A full hazard analysis for sushi rice process can be found in Appendix D.

## Control Measure

Control measures are those processes or procedures put into place to control, reduce, or inactivate pathogens. The main control for the growth of *B. cereus* and *S. aureus*, aside from time/temperature control, is acidification. In the preparation of sushi rice, vinegar is typically mixed thoroughly into cooked sushi rice to reduce the pH of the rice to less than 4.2. This pH threshold meets the definition of a non-TCS food, found in Table B of the FDA Model Food Code (note that water activity of cooked rice is greater than 0.88, and so is not a factor in this determination). This control is effective only when the pH of the rice is correctly monitored by using a pH meter. Colorimetric methods for the determination of pH may be allowed in some instances when the pH is 4.0 or lower.

## Critical Control Point (CCP)

The critical control point, or CCP, is the point in the flow of the process at which there is control over the identified hazard, typically the growth of pathogens. If not done correctly, pathogens could grow and/or produce toxins, resulting in consumer illness. The step in which vinegar is added to the rice is the critical control point for sushi rice. This is the step where the two hazards of concern, *B. cereus and S. aureus*, must be controlled to prevent illness.

## Critical Limit(s)

Critical limits are those measurable parameters and values that are based on science that demonstrate a critical control point is effective controlling the identified hazard. In the case of acidified sushi rice the critical limit is a pH of below 4.2 to be considered non-TCS. When using FDA Interaction Table B, rice acidified to below 4.2 would not need further evaluation and would be considered non-TCS. Cooked short grain white rice has available water measurement (known as water activity, $a_w$) of approximately 0.98.

**Alternative grains such as brown rice or wild rice, quinoa, couscous, cauliflower rice, are sometimes proposed to be used instead of sushi rice. Any alternate grains must meet this same pH critical limit unless alternate science is provided.**

## Monitoring

A HACCP Plan must include information on how the production of the acidified rice will be monitored. An example monitoring procedure is included in this document. When preparing the sample, 21 CFR 114.90 states that a ratio of 10-20 mL of water to 100 grams of product should be used. Both the acidification of the rice and the final pH of the rice should be monitored. The plan will indicate what is being monitored, how it will be monitored, what is the frequency of monitoring, and who will do the monitoring. With sushi rice, monitoring should be done by a trained individual using a calibrated pH meter.

## Corrective Action

Corrective actions are steps taken when a critical limit is not met during the preparation process. It is important that any time a corrective action is needed it must be recorded on a log sheet. If the pH of the measurement is 4.2 or greater; then repeat the measurement with a new sample. If that sample reads 4.2 or greater; add more vinegar to the acidified rice. Mix well and repeat the pH measurement. Repeat this corrective action until the pH is below 4.2. The rice can also be held using time as a public health control, cooled, and held cold, or discarded as a corrective action. Additional long term corrective actions should be applied, including reviewing the process, adjusting recipe, or substituting vinegar type. Note all corrective actions applied in a corrective action log.

Verification vs Validation

Verification and Validation are not the same thing. **Verification** is making sure the HACCP Plan is working as written. **Validation** is making sure the HACCP Plan will work to control the hazards identified based on science. Most sushi rice HACCP plans are written based on already validated science (i.e., pH below 4.2), because of this, scientific validation is not required. If a method is used that is not already recognized in the scientific literature as controlling the identified hazard, a validation (other science or challenge studies) may be required.

## Verification

The Person-in-Charge (PIC) is responsible for reviewing and signing the sushi rice acidification log and making sure the HACCP plan is being followed as written. This is considered a verification of the HACCP plan. The HACCP plan should indicate who will do the verification, the frequency of the verification and what verification activities are taking place. The PIC should also observe employees performing the pH measurement and recording data periodically. All verification activities should be noted in the appropriate log notes along with the signature of the PIC performing the verification activities. An example checklist can be found in Appendix E that can help with verification activities.

## Record Keeping

Records (logs or log forms) are an integral part of the HACCP Plan and should be kept for all monitoring of critical control points. These records include pH meter calibration logs, sushi rice pH measurement logs, corrective action logs, PIC verification logs, and training logs.

*Note: Once records are created, they must be kept for at least six months or as otherwise specified by the jurisdiction based on inspection frequency and made available to the Regulatory Authority upon inspection request.*

## Training

Any employee involved in the acidification of rice should be trained to show that they understand the hazards and controls associated with making acidified rice. The training plan must address any food safety issues of concern as stated in §8-201.14(F) (1) and should include training on all facility standard operating procedures. The PIC must review sections relating to the flow diagram, hazards, control measures, CCPs, critical limits, verification and record keeping. Hands-on training is essential. A blank training log form should be attached to the HACCP Plan. The training sessions must be recorded in the log, and must include date, employees present, and instructor.

## Standard Operating Procedures

Standard operating procedures, or SOPs, are an important part of a HACCP Plan. These are specific written instructions that give details on how to perform tasks associated with food safety and the sushi rice HACCP Plan. SOPs should already align with the regulation unless a variance is in place. SOPs should include pH meter calibration, cleaning and sanitizing food contact surfaces, personal hygiene and employee health policies, hand washing, eliminating bare hand contact, and proper chemical storage. Many of the SOPs needed for sushi rice acidification are contained within the Food Code, but should include the following (these are examples only, additional SOPs may be needed):

- **Bare hand contact:** Clarify that bare hand contact with ready to eat (RTE) food is not permitted at any time and what is done with RTE food touched with bare hands
- **Employee health policy:** Address the symptoms of foodborne illness, pathogens associated with illness, symptom and illness reporting requirements, exclusion/restriction plan, return to work criteria, etc.
- **Personal hygiene:** Address wounds/sores, jewelry, fingernails, hair restraints, clothing (i.e., uniform, apron), tasting food, eating/drinking, what is done when employees do not follow the personal hygiene information
- **Hand washing:** Clarify when, how, and where to wash hands, and any corrective actions
- **Labeling:** Include details of all applicable dates (packaging, expiration), consumer advisory (if applicable), and what is done with food that is not labeled or is incorrectly labeled
- **Cleaning and sanitizing food contact surfaces:** Specify how to properly clean and sanitize food contact surfaces, and what to do with food contact surfaces that have not been properly cleaned and sanitized
- **Thermometer use and calibration:** Address the method and frequency of thermometer calibration and what is done with thermometers that cannot be calibrated, and provide details of documenting thermometer calibration
- **pH meter use and calibration:** Address the method and frequency of pH meter use; calibration, verification of accuracy of calibration and what is done with pH meters that cannot be calibrated and provide information on calibration and use logs.
- **Cold holding:** Address proper cold holding temperatures and corrective actions if food is found to be out of temperature, including allowances for cooling or discarding food
- **Transporting:** Address proper cold holding temperatures and applicable corrective actions if food is found to be out of temperature, including allowances for cooling or discarding food

## Example Standard Operating Procedures

The following are examples of standard operating procedures that can be used for thermometer calibration, pH meter calibration, and pH monitoring. Be sure to follow any manufacturer's instructions related to specific equipment. *****These are only examples; sushi operations may choose another SOP to align with business needs. *****

## Standard Operating Procedure for Thermometer Calibration

- Thermometers used for specialized processes should meet the same provisions as outlined in the Food Code Sections 4-201.12, 4-203.11 and 4-302.12.
- All thermometers must be accurate to +/-2 degrees Fahrenheit.
- Thermometers must be calibrated according to the Food Code Section 4.502.11(B). Thermometers should be calibrated at least once per day and whenever they are exposed to extreme temperatures or dropped.
- The ice water calibration method is the most common and reliable, and is outlined below:
- Fill a cup with ice, preferably crushed, with enough ice so the thermometer remains upright.
- Add cold water to the cup and stir, allowing the temperature to equilibrate.
- Place the thermometer probe in the cup. Temperature should read at 32°F, if it does not, adjust the thermometer according to manufacturer's instructions.
- When taking product temperature, the probe should be placed in the thickest portion of the food. For rice and other grains, it is recommended to stir first before taking temperature.

## Standard Operating Procedure for pH meter Calibration

- The pH meters used for sushi rice should be designed for food and not designed simply for water or liquids. Appropriate meters will be portable, able to be calibrated and read to at least two decimal points
- pH should be calibrated daily and according to the manufacturer's instructions. Typically, pH meters come with 2-3 buffer solutions which are typically pH 4, pH 7 and pH 10. These solutions may be in aqueous or powder form and will come with any applicable mixing and handling instructions.
- The following outlines a basic calibration procedure, but always follow specific manufacturer's guidance.
    1. Prepare buffer solutions according to the package instructions.
    2. Remove the electrode from the storage solution, rinse thoroughly with distilled water and carefully blot (do not wipe) dry with a lint-free wipe.
    3. Turn the pH meter on and submerge the probe in the pH 7 solution, gently moving the probe around until the pH reading stabilizes. Select the calibrate button and then rinse the probe with distilled water and blot dry.
    4. Repeat step 3 with the pH 4 buffer solution.
- After calibration is complete, check the pH in the 4.0 buffer solution to make sure it reads correctly. The reading should be within 0.1 pH units of its true value (for example, the 4.0 buffer should read between 3.9 and 4.1).
- If results aren't within 0.1 pH unit of the true value for the buffer, the meter must be recalibrated.
- Record the calibration in your pH meter calibration log. You are now ready to test product samples.
- A second pH meter will ensure acidification operation can continue if there is failure of the pH meter. Having an additional pH meter for use as a backup is recommended.

### Standard Operating Procedure for pH monitoring

- Each batch of acidified rice must be measured for pH as follows.
- Prepare rice and acidify according to the approved recipe. Allow rice to sit so vinegar can uniformly penetrate the rice. The pH is typically measured within 30 minutes or within timeframe specified in HACCP plan.
- Prepare and calibrate the pH meter according to the manufacturer's directions. Record the calibration of the pH meter in the log. Calibration should be done daily or as needed to maintain calibration.
- One quarter cup of rice should be collected from various locations in the batch of sushi rice. Press the rice down during sampling in the measuring cup so that it is flat and level. Repeat the procedure so there are two different samples.
- Add ¾ cup of distilled water to the ¼ cup of sushi rice for each sample. Mix the rice and water until a consistent slurry develops. The cooked and acidified grains will need to be crushed, mashed or blended with distilled water to reach a semi-liquid consistency.
- Insert the pH electrode into the first rice slurry and press the button to measure the pH. The electrode should be fully submerged in the sample and should be gently and slowly stirred until the probe reading is complete.
- Record your measurement on in your log, including the signature of the person who performed the acidification/monitoring. Take the pH of the second sample. Record it.
- **If either sample has a pH of 4.2 or above, corrective action is needed**.

## Prerequisite Programs

### PARASITE DESTRUCTION

- Raw, ready-to-eat seafood, except for those exempt under §3-402.11(B), need freezing utilizing one of the following options: frozen and stored at a temperature of -20 ˚C (-4 ˚F) or below for a minimum of 168 hours (7 days) in a freezer, frozen at -35 ˚C (-31 ˚F) or below until solid and stored at -35 ˚C (-31 ˚F) or below for a minimum of 15 hours; or frozen at -35 ˚C (-31 ˚F) or below until solid and stored at -20 ˚C (-4 ˚F) or below for a minimum of 24 hours.
- In addition to exempt tuna species, some aquacultured fish products that have met specific provisions in §3-402.11(B) are exempt from freezing.
- The Food Code outlines that "If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under § §3-402.11" be provided. A similar written agreement is needed to verify aquacultured fish products have met exemption provisions.
- Either purchase specifications or a letter of guarantee would be an acceptable way to verify the parasite destruction provisions.
- A document containing the following information would meet the provisions for verifying parasite destruction.
- Name of processing facility, or other entity, that has documented and carried out the freezing process.
- Draft date (within one year of purchase)
- Seafood item name
- Clear description of master cartons, or packaging, logo/brand reference to aid in cross referencing the letter to the item.
- One of the following specifications, depending on whether fish has been frozen or is exempt from parasite destruction

    - For fish that has been frozen: specific freezing process (one of the above) used to destroy parasites
    - For exempt/aquacultured fish: specifics on feed type and farm type (open water, net-pens, ponds, tanks, etc.)

- Where freezing is not applied for raw ready-to-eat seafood, and a parasite destruction exemption exists, documentation shall be secured from the supplier/processor to include, at a minimum, the following:
- Additionally, fish served raw in sushi products should be labeled as "ready-to-eat." Retail sushi operations should read packaging and labels as all fish and fish products are not intended for raw consumption. If the label or package does not state information about whether it is intended for raw consumption, the sushi operator should verify the intended use with the supplier.

## REFERENCES


- FDA Food Code 2017: §3-402.11 Parasite Destruction
- Fish and Fish Products Hazards and Controls Guidance – June 2022 Edition
- FDA Appendix 1 - https://www.fda.gov/media/99581/download


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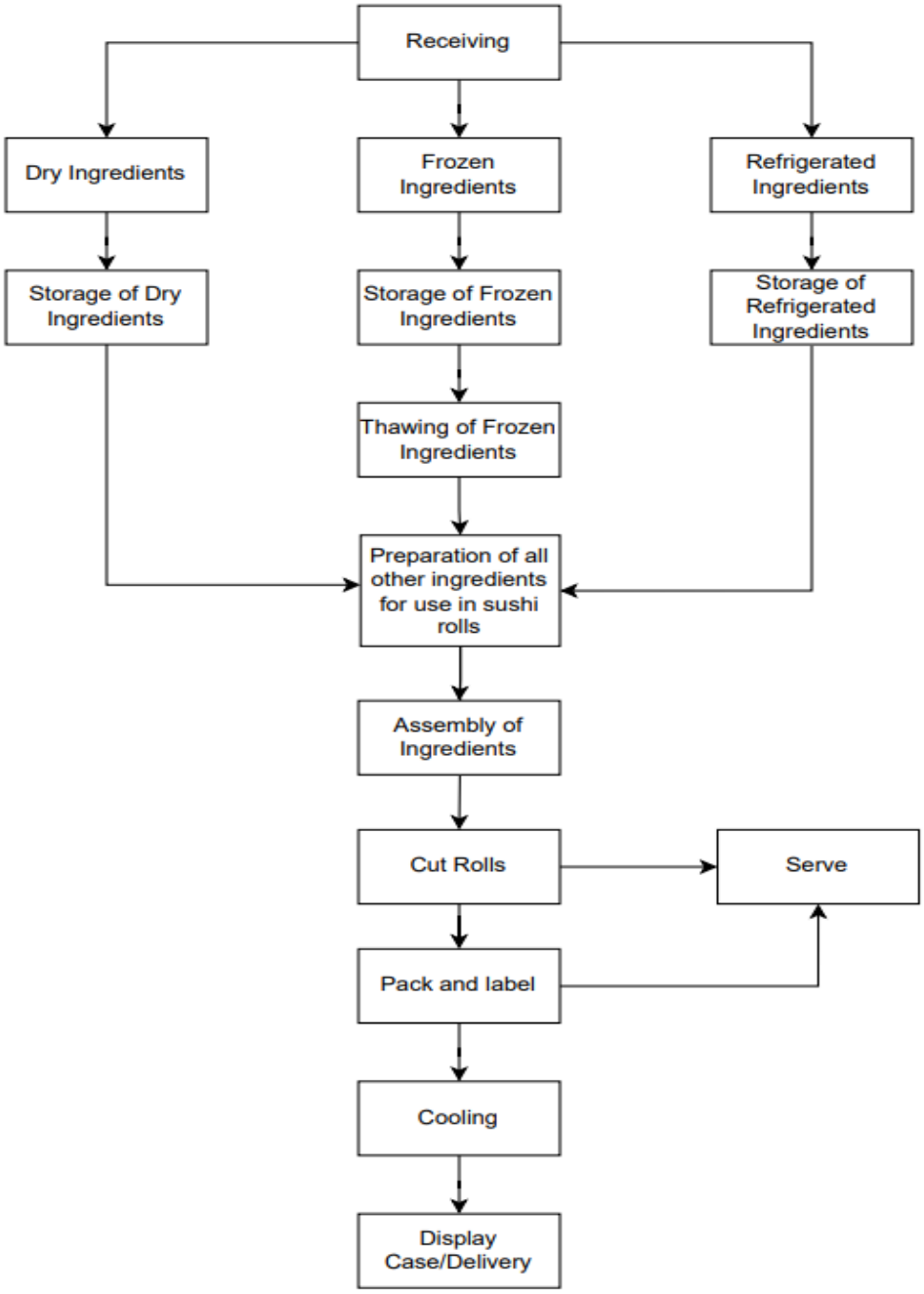
- 2021-2022 CFP Executive Board
- Members of Retail Sushi HACCP Standardization Committee


## Appendix

A – Food Flow Diagram for Sushi Process
B – Example Permitting Scenarios
C – Decision Tree
D – Food Flow Diagram and Hazard Analysis for Sushi Rice
E – Sample Validation and Verification Checklist

## Appendix A: Food Flow Diagram for Sushi Process

This food flow diagram is designed to illustrate the entire process for preparing sushi products and is not intended to be submitted with the HACCP Plan. **This food flow includes many steps that do not need to appear in the food flow diagram for the sushi rice HACCP plan. The only components of this food flow diagram that are needed in a HACCP Plan are receiving, storing, preparation, and service.** An example of the food flow diagram that should be submitted with a HACCP plan can be found in Appendix D.



## Appendix B: Examples permitting scenarios and how to interpret

### Definitions:

I. ***Retail Food Establishments*** are sushi producers that prepare sushi products for direct distribution to the end consumer. The distribution methods may include but are not limited to dine in restaurant, to-go distribution, delivery, mobile food establishments, and vending machines, and can be fixed or temporary facilities or locations. Additional specifics of the retail food establishment definition can be found in FDA Food Code 1-201.10.

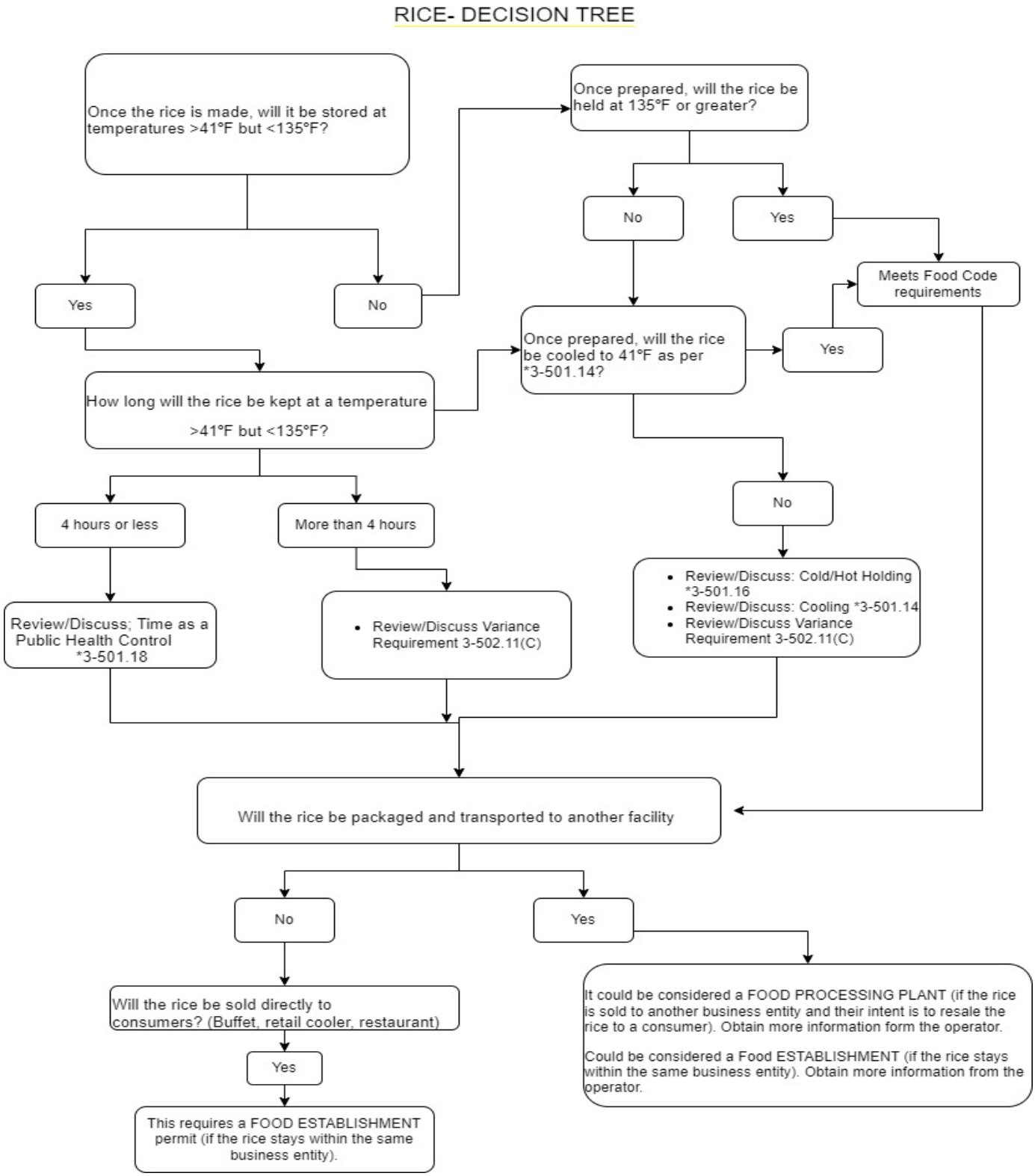
II. ***Food Processing Plants*** are commercial sushi operations that manufacture, package, label, or stores sushi and provides it for sale or distribution to other business entities. These sushi operations are generally offsite from a retail food establishment and sell or distribute to a business (Food Establishment) prior to distribution to the end consumer.

### Examples:

1. Sushi is prepared in a restaurant and offered for sale to the consumer either for dine in, take out, or other third-party delivery service. These operations would be **Retail Food Establishments**.
2. Sushi is prepared in retail grocery store by a third-party vendor and the grocery store does not take ownership of the product. The vendor is leasing space, the sushi producer provides finished sushi to the end consumer, and the grocery store takes payment. These operations would be **Retail Food Establishments**.
    - Distribution often includes stocked refrigerators, 3rd party delivery services, and/or vending machines. The sushi establishment does not need to collect money directly for sale of its products.
3. Sushi is prepared at an off-site commissary and delivered to other retail stores or businesses that do not produce onsite. These operations are **Food Processing Plants**.
    - Sushi products made at a food processing plant may be produced at a central commissary location and distributed to other Food Establishments not operated by the company. In this instance, there is a business that receives the products as an intermediary before the final consumer receives the sushi or sushi product.
4. Sushi is produced by a chain operation at a grocery store and distributes it to another kiosk owned by the same operation. These operations would be **Retail Food Establishments**.
    - Sushi products may be prepared or produced at a central commissary location and delivered to other operations owned by the same company. Ownership of the product cannot change, but the product may be made in a different location than where it is offered for sale to the consumer.
5. Sushi is prepared at a preparation site/kitchen/commissary and ends up in university campus/hospital/airport. These operations are **Food Processing Plants**.
    - This would apply to sushi provided to locations such as universities, airports, etc. where the sushi company does not retain ownership of the product. These end locations may have a retail establishment component, but the sushi prepared for service within these locations is considered from a food processing plant, unless the distribution is via vending machine or other direct to consumer Food Establishment criteria.

## Appendix C: Decision Tree

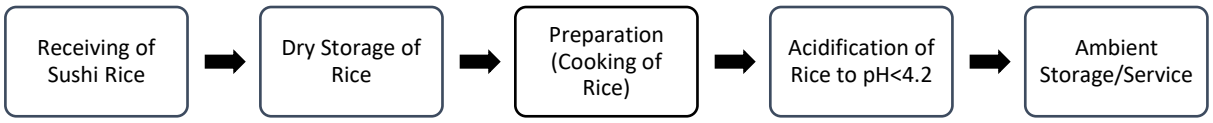
The decision tree is based off the 2017 FDA Model Food Code is intended to provide operators with specific food safety guidance based on the process used by an operator for holding rice. It also includes information about permitting/licensing based on how it will be served/sold.



## Appendix D: Food Flow and Hazard Analysis for Sushi Rice

### Food Flow Diagram for Sushi Rice

This is an example of a food flow diagram that should be submitted with a sushi rice HACCP Plan. All steps related to the preparation and acidification of rice are included. Please note that food flow diagrams do not have to follow this format, they just must contain the appropriate information.




### Hazard Analysis for Sushi Rice

This chart outlines the steps in sushi rice preparation and the hazards associated with them. The CCP has also been identified. This information can be used in assembling the HACCP Plan.

| **PROCESS** | **RECOMMENDATIONS/POLICIES** | **HAZARDS** | **CCP? IF YES, CRITICAL LIMITS** |
|---|---|---|---|
| Receiving | ●All food products received from approved suppliers/distributors | ●B: Microbial pathogens<br>●C: Chemical contamination of products<br>●P: Pest contamination | ●No; have prerequisite receiving program Rejection process/segregation of rejected products SOP |
| Food storage | ●Any dry storage foods will be stored away from any chemicals and in a dry, clean, 6" off floor location that is not exposed to other contamination. | ●B: Potential growth or survival of pathogens | ●No; Food Code parameters met for cold storage and dry storage |
| Preparation | ●Rinse/soak rice to remove any foreign debris<br>●Cook rice to desired temperature, 135°F for rice that will be hot held | ●B: Potential growth of *B. cereus, S. aureus, C. perfringens* | ●Follow Food Code parameters for proper cooking and holding of rice. |
| Acidification | ●Acidify rice after cooking, prepare sample for pH measurement and take pH<br>●Calibrate pH meter according to manufacturer's specs | ●B: Potential growth of *B. cereus, S. aureus* and *C. perfringens* if held at room temp | ●CCP<br>pH<4.2 |
| Display/Serve | ● Display and serve sushi using no bare hand contact with ready-to-eat foods.<br>● Food should be stored according to time/temperature provisions during display | ●B: Potential growth or survival of pathogens | ●Follow Food Code parameters for employee health, no bare hand contact, and holding temperatures for TCS ingredients |

## Appendix E: Checklist HACCP Plan Review and Verification

| **HACCP Plan Contents** | **Observed** |
|---|---|
| List of all ingredients, equipment, and packaging to be used including recipes and/or formulations | |
| Food flow diagram (page 15 Appendix D of guidance document) | |
| Hazard Analysis (*B. cereus, S. aureus* is pathogen of concern) | |
| Critical control points labeled (acidification step as CCP) | |
| Critical limit given (pH of rice below 4.2) | |
| Monitoring procedures (pg. 9-10) | |
| Corrective actions provided (pg. 7) | |
| Record keeping procedures (pg. 8) | |
| Employee training program | |
| Written prerequisite programs and SOPs | |
| **Notes:** | |

| **Verification Activities** | **Observed** |
|---|---|
| Approved equipment used | |
| Proper ingredients and formulation used | |
| Identification of employees involved in process | |
| Proper pH meter calibration observed | |
| Observation of pH sample preparation and pH meter use | |
| Corrective actions observed or discussed with trained employees | |
| Review of pH logs and corrective actions log | |
| Review and verification of adequate training program | |
| Observation of prerequisite programs/SOPs | |
| **Notes:** | |