



# Food Code

FDA

U.S. Public Health Service

FDA U.S. FOOD & DRUG  
ADMINISTRATION

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

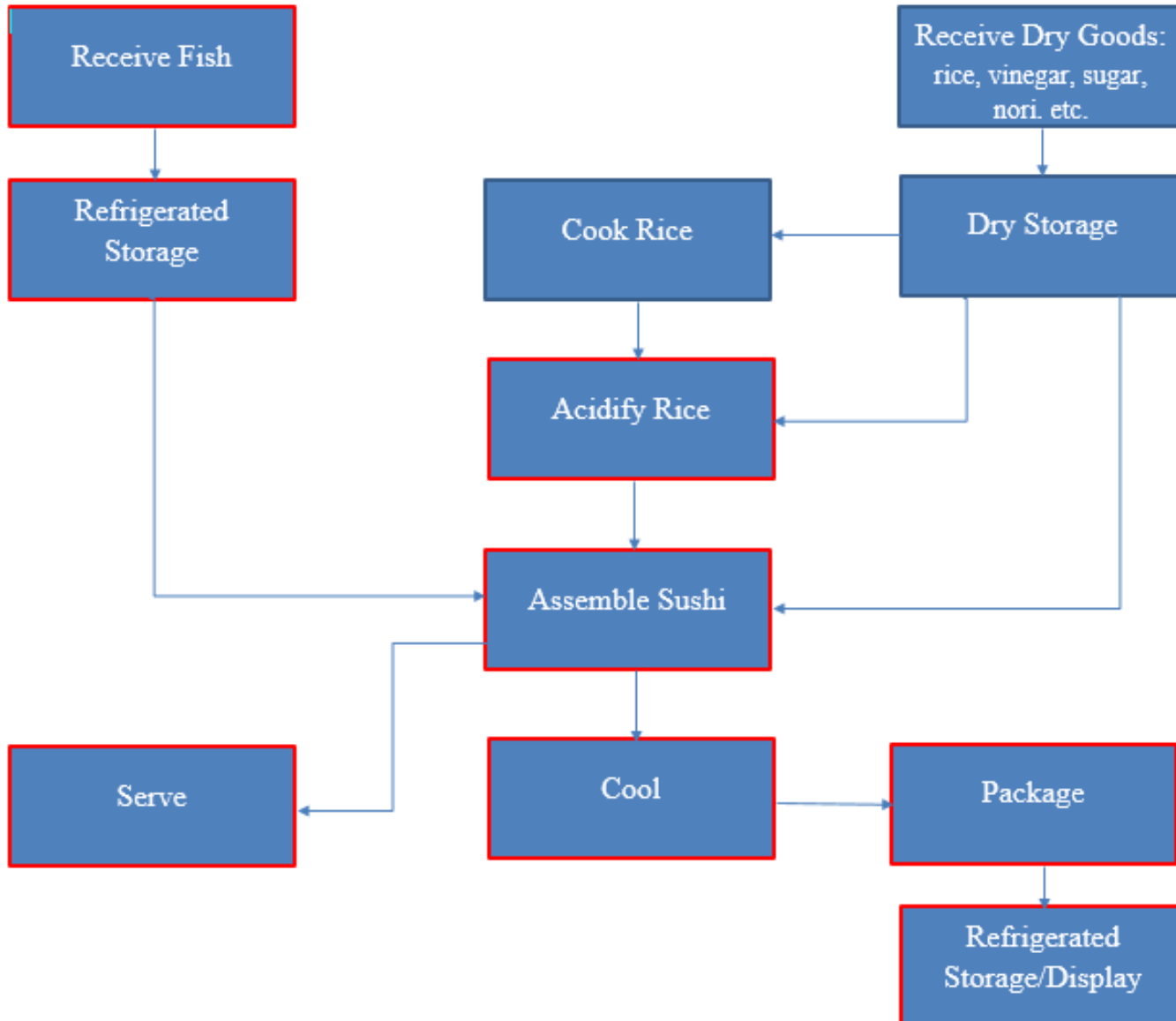
Public Health Service • Food and Drug Administration

College Park, MD 20740

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# SUSHI & THE FOOD CODE

# SUSHI PROCESS FLOW



# Specifications for Receiving

- 3-201.14 Fish.
  - (A) FISH that are received for sale or service shall be:
    - (1) Commercially and legally caught or harvested; or
    - (2) APPROVED for sale or service.

## 3-201.11 Compliance with Food Law.

- (D) FISH, *intended for consumption in raw or undercooked form may be offered for sale or service if:*
  - *obtained from a supplier that freezes the FISH (3-402.11) or*
  - *Frozen on the PREMISES (3-402.11) and records are retained (3-402.12).*
  - Exceptions: Large species of tuna, farm-raised fish, molluscan shellfish, scallop adductor muscle, fish eggs.

## 3-202.11 Temperature

- (A) ...TCS FOOD shall be at a temperature of 5°C (41°F) or below when received.
- (E) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen.

## 3-501.16 Time/Temperature Control for Safety Food, Hot and Cold Holding

- *(A) Except during preparation, cooking, or cooling, or when time is used as the public health control, TCS FOOD shall be maintained:*
  - (1) At 57°C (135°F) or
  - (2) At 5°C (41°F) or less.

## **3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.**

- (A) FOOD shall be protected from cross contamination by:
  - (1) Separating raw animal FOODS during storage, preparation, holding, and display from:
    - (a) Raw RTE FOOD including other raw animal FOOD such as FISH for sushi.
    - (d) Exception: *Frozen, commercially processed and packaged raw animal FOOD.*

# Specialized Processing Methods

- 3-502.11 Variance Requirement.
  - A FOOD ESTABLISHMENT shall obtain a VARIANCE from the RA as specified in § 8-103.10 & § 8-103.11 before:
    - (C) Using FOOD ADDITIVES or adding components such as vinegar:
      - (1)As a method of FOOD preservation rather than flavor enhancement, or
      - (2)To render a FOOD so that it is not TCS;



## 8-103.10 Modifications and Waivers.

- The RA may grant a VARIANCE by modifying or waiving the requirements of this Code:
  - if a health HAZARD or nuisance will not result from the VARIANCE.
  - REGULATORY AUTHORITY shall retain the information specified under § 8-103.11 in its records for the FOOD ESTABLISHMENT.

## 8-103.11 Documentation of Proposed Variance and Justification.

- Before a VARIANCE is APPROVED, the information that shall be provided includes:
  - (A) A statement of the proposed VARIANCE citing relevant Code section numbers;
  - (B) The rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and
  - (C) A HACCP PLAN if required under 8-201.13(A) that includes the information specified under 8-201.14.

## 8-201.13 When a HACCP Plan is Required.

- (A) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant / HOLDER shall submit to the RA a HACCP PLAN if:
  - (1) Submission of a HACCP PLAN is required according to LAW;
  - (2) A VARIANCE is required as specified under 3-401.11(D)(4), **§ 3-502.11**, or 4-204.110(B);
  - (3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE.

## 8-201.14 Contents of a HACCP Plan.

- (A) The name of the PERMIT applicant/holder, the establishment address, and contact information;
- (B) A categorization of the types of TCS foods that are to be controlled under the HACCP PLAN;
- (C) A flow diagram or chart for each specific FOOD or category:
  - (1) Each step in the process;
  - (2) The HAZARDS and controls for each step;
  - (3) The steps that are CCPs;
  - (4) The ingredients, materials, and equipment used in the preparation of that FOOD; and
  - (5) Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved.

## 8-201.14 Contents of a HACCP Plan.

- (D) A CRITICAL CONTROL POINTS summary for each specific FOOD or category type that clearly identifies: <sup>Pf</sup>
  - (1) Each CCP,
  - (2) The CRITICAL LIMITS for each CCP,
  - (3) The method/frequency for monitoring and controlling each CCP by the designated employee or the PIC,
  - (4) The method and frequency for the PIC to routinely verify the employee is following SOPs and monitoring CCPs,
  - (5) Action to be taken by the designated employee or PIC if the CLs for each CCP are not met, and
  - (6) Records to be maintained by the PIC to demonstrate that the HACCP PLAN is properly operated and managed;

# Sample CCP Summary

MENU ITEMS/PRODUCTS:						
HAZARD(S)	CRITICAL CONTROL POINTS (List Only the Operational Steps that are CCPs)	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
<b>PREREQUISITE PROGRAMS</b>						

## 8-201.14 Contents of a HACCP Plan.

- (E) Supporting documents such as:
  - (1) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern;
  - (2) Copies of blank records and forms necessary to implement the HACCP PLAN;
  - (3) Additional scientific data or other information, as required by the RA.
- (F) Any other information required by the RA.

## 8-103.12 Conformance with Approved Procedures.

- If the RA grants a VARIANCE, the PERMIT HOLDER shall:
  - (A) Comply with the HACCP PLANS and procedures that are submitted; and
  - (B) Maintain and provide to the RA, upon request, records specified under § 8-201.14 that demonstrate the following are routinely employed;
    - (1) Procedures for monitoring the CCPs,
    - (2) Monitoring of the CCCPs,
    - (3) Verification of the effectiveness of the operation or process, and
    - (4) Necessary corrective actions if there is failure at a CCP.



## 3-301.11 Preventing Contamination from Hands.

- (A) FOOD EMPLOYEES shall wash their hands.
- (B) FOOD EMPLOYEES may not contact exposed, RTE FOOD with their bare hands.
  - UTENSILS, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT.
  - Exception - washing fruits & veggies.
- (E) FOOD EMPLOYEES not serving a HSP may contact exposed, RTE FOOD with their bare hands if....

## 2-101.11 Assignment.

- PIC requires employees to report health issues related to foodborne illnesses/symptoms/exposures.
- Exclude or restrict
- Report to RA when necessary

## 3-501.14 Cooling.

- (B) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled within 4 hours to 5°C (41°F) or less if prepared from ingredients at ambient temperature.

## 3-602.11 Food Labels.

- (A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 -Food labeling, and 9 CFR 317 Labeling, marking devices, and containers.
- (B) Label information shall include:
  - (1) The common name / descriptive identity statement
  - (2) If made from two or more ingredients, a list of ingredients and sub-ingredients
  - (3) Net quantity of contents
  - (4) The name and place of business of the manufacturer, packer, or distributor.
  - **(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN.**
  - (6) Except as exempted in the Federal FD&C Act § 403(q)(3) -(5), nutrition labeling.

Serve

Refrigerated  
Storage/Display

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## 3-401.11 Raw Animal Foods.

- (D) *A raw animal FOOD such as ....raw FISH,... may be served or offered for sale upon CONSUMER request or selection in a RTE form if:*
  - (1) *the FOOD ESTABLISHMENT serves a population that is not a HSP*
  - (2) *The FOOD, if offered for service from a children's menu, does not contain COMMINUTED MEAT; <sup>Pf</sup> and*
  - (3) ***The CONSUMER is informed as specified under § 3-603.11 ; or***
  - (4) *The REGULATORY AUTHORITY grants a VARIANCE*

Serve

Refrigerated  
Storage/Display

FDA

## 3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed.

- (A) ...if an animal FOOD such as FISH is served or sold raw or undercooked CONSUMERS shall be informed of increased risk by way of a DISCLOSURE and REMINDER
  - using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.
- (B) DISCLOSURE shall include:
  - (1) A description of the animal-derived FOODS or
  - (2) Identification of the animal-derived FOODS by asterisking them to a footnote
- (C) REMINDER shall include asterisking the animal-derived FOODS to a footnote that states:
  - (1) Regarding the safety of these items, written information is available upon request;
  - (2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or
  - (3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.

# Questions?



