

Oregon Department of Agriculture Food Safety Program

The Step by Step Guide to the Licensed Processing of Juice Products

On January 19, 2001, the FDA published a final rule in the Federal Register that requires processors of juice to develop and implement Hazard Analysis and Critical Control Point (HACCP) systems for their processing operations (66 FR 6138). To help the industry understand key aspects of the juice HACCP regulation, the FDA has published several guidance documents that included information on important aspects of the juice HACCP regulation such as effective dates, use of the label warning statement, and training.

The intent of this handout is to provide the basic requirements and guidance for food processors wishing to enter the business of processing juice products for wholesale business. This “Step by Step Guide” contains tools to get you started, links for informational resources, and important contact information to help you along the way to becoming a licensed processor of juice products. Failure to adhere to these requirements may lead to the foods being deemed adulterated and subjected to a state or federal recall.

Oregon juice processors are subject to Oregon’s food statutes and administrative rules. Additionally, firms are held to the Juice HACCP regulations set-forth by 21 Code of Federal Regulations (CFR).

WHAT ARE JUICE PRODUCTS? *See 21 CFR 101.17(g) CFR Title 21-Juice.*

“**Juice**” means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree as stated in the CFR.

WHAT DOES PROCESSING AND PROCESSORS MEAN? *See 21 CFR 120.3 (j) and (k)*

“**Processing**” means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

- (i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and
- (ii) The operation of a retail establishment.

“**Processor**” means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

STEP 1: CONTACT THE OREGON DEPARTMENT OF AGRICULTURE (ODA) FOOD SAFETY PROGRAM

Call the Food Safety Program at (503) 986-4720 to locate an inspector in your facility zip code. Review the following regulations:

- **21 CFR Part 117:** Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (Juice processors are exempt from Subparts C & G if

they follow the Juice HACCP regulations. Juice processors still must meet the requirements of subparts A, B, and F (for the records required by subpart A). [21 CFR Part 117](#)

- **21 CFR Part 120:** Hazard Analysis Critical Control Point (HACCP) Systems
<https://oda.fyi/CFRTitle21-120>.

STEP 2: CONTACT THE INSPECTOR AND PROVIDE A DETAILED DESCRIPTION OF YOUR PRODUCT

Your facility will need an ODA's **Food Processor License**.

*Please note that ODA's food licenses are valid from July 1st until June 30th of the following year.
ODA's Licensing Department does not prorate fees based on the time of year the firm is licensed.*

Provide the following information to your local inspector.

- Product Name
- Source of Juice Product (i.e. types of fruits, vegetables, botanical roots)
- Describe the Food and Process (i.e. refrigerated, frozen, raw, pasteurized)
- Method of Receiving, Storage and Distribution (i.e. whole fruit, pureed, stored and distributed under refrigeration)
- Finished Packaging Type (i.e. bottles, sealed glasses, bags)
- Intended Use and Consumer (i.e. ready-to be consumed by general public).

STEP 3: PROVIDE A HAZARD ANALYSIS AND A JUICE HACCP PLAN ACCORDING TO YOUR PRODUCT AND PROCESS

If the beverage or beverage components are available for wholesale customers such as retail stores, juice bars, and distributors, the manufacturing firm must have and implement a juice HACCP plan. The plan is specific to the product, process and facility. For all wholesale juicing operations, regulations require juice to be processed in a manner that prevents and controls potential hazards. At a minimum, juices must be pasteurized or go through an approved HACCP-based 5-log pathogen reduction process. Examples of approved, non-pasteurization 5-log reduction methods include, but are not limited to, ultraviolet irradiation, pulsed-light, or citrus fruit surface-sanitation treatments.

Hazard Analysis Overview The juice hazard analysis (HA) is a process of collecting and evaluating information on hazards associated with juice, to determine which hazards are reasonably likely to occur and must be addressed in a HACCP plan. A firm is required to produce a written HA for each type of juice you process to determine whether there are food hazards that are reasonably likely to occur and to identify measures that you can apply to control those hazards. The regulation requires a written HA for each type of juice unless different types of juice have identical hazards and control measures and then they may be grouped in one hazard analysis.

Submit your juice HACCP plan to the ODA Juice HACCP inspector to review and comment. If you do not identify any hazards, you will be asked to provide a HA. Your HA must be developed by an appropriately trained individual (or individuals). If you do not know how to conduct a HA or develop a juice HACCP plan, you must attend and pass a recognized juice HACCP course as required in [21 CFR 120.13: Training](#). This person may be your employee or a hired outside expert.

Suggested Juice HACCP Training Programs are;
[Cornell University Juice HACCP Course](#)
[University of Florida Juice HACCP Course](#)

<https://ucfoodsafety.ucdavis.edu/training/haccp-juice-haccp-training>

STEP 4: CREATE A LABEL FOR YOUR PRODUCTS

All juice products must, at a minimum, be labeled with a common or usual name of the product, list of ingredients, net weight, company name, and address of the manufacturer.

- See the ODA Food Safety labeling handout as a guide to developing your label.
[ODA Food Labeling Requirements and Guidelines](#)
- Submit your food label(s) for ODA Juice HACCP inspector to review and comment.

STEP 5: SCHEDULE A CONSULTATION WITH THE ODA JUICE HACCP INSPECTOR

Plan review of your facility is not required but highly recommended. Your facility must be inspected and approved prior to being licensed for processing. Plan reviews and consultations are a free of charge service.

The consultation visit will include an evaluation of the food preparation area to ensure that it meets all applicable health, food safety, construction and sanitation requirements per OAR Division 25, and if applicable the Code of Federal Regulations: [OAR 603-025](#)

STEP 6: PROVIDE THE TOOLS AND DEVELOP PRODUCTION RECORDS SHOWING ADHERENCE TO THE PROCESS

You will need special equipment to accurately monitor your critical control points (CCPs).

You may need the following:

- Thermometer
- Continuous time/temp monitoring device (if the ingredients or finished product will be refrigerated)
- Clock or Timer
- Metal Detector

You will need to develop the following records [21CFR120.12](#):

- Production Logs for monitoring critical control points (i.e. pasteurization or cooling time/temp, refrigerated storage temp)
- Standard Sanitation Operating Procedures (SSOP) [21CFR120.6](#)
- Corrective Action [21CFR120.10](#)
- Calibration [21CFR120.11](#)
- Consumer Complaint [21CFR120.11](#)

STEP 7: RECALL PLAN

A recall plan is not required to obtain a license approval for juice processing, however the ODA strongly encourages the development of a recall plan. Should you lose the 21 CFR 117 Qualified Facility Exemption under Subpart E, a recall plan is required.

STEP 8: REQUEST A FINAL ON-SITE PROCESS REVIEW AND INSPECTION FOR LICENSING

After you demonstrate completion of all the aforementioned requirements, call your inspector to arrange an initial approval inspection to license your firm.

For all new and existing structures with plumbing changes, **a final plumbing approval from your local authority will be required** prior to the initial licensing inspection. It is your responsibility to be in compliance with all county and municipal land use or zoning laws, ordinances, and building codes. **Approval by ODA does not grant approvals for other regulatory agencies.**

STEP 9: REGISTER YOUR FACILITY WITH THE FDA ACCORDING TO BIOTERRORISM ACT OF 2002

The **Public Health Security and Bioterrorism Preparedness and Response Act of 2002** (the Bioterrorism Act) directs the Food and Drug Administration (FDA) as the food regulatory agency of the Department of Health and Human Services to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies. To carry out certain provisions of the Bioterrorism Act, the FDA established regulations requiring that food facilities register with the FDA and that the FDA be given advance notice on shipments of imported foods.

Register as soon as you have been licensed by the ODA. [FDA Registration of Food Facilities](#)

STEP 10: MAINTAIN ACCURATE RECORDS *See 21CFR 120.12*

Keep all your records together in one place, preferably in a binder. Requirements for retaining records are identified in the regulations. You may receive a visit from FDA or ODA inspectors at any time during your business hours about once per year to observe your process, inspect your facility, and review processing records.

JUICE HACCP RESOURCES

On August 31, 2001, the FDA published "**The Juice HACCP Regulation Questions and Answers**," a document that addressed important aspects of the regulation in a simple question and answer format. As a follow-up to that first set of questions and answers, this document contains a second set of questions and answers designed to further clarify the juice HACCP regulation and to address frequently asked questions.

Additional information on juice HACCP is available at www.cfsan.fda.gov under "Program Areas" and "HACCP." The information available at this website includes the juice HACCP regulation, the August 31, 2001, publication, "The Juice HACCP Regulation Questions and Answers," and additional guidance FDA has issued related to the juice HACCP regulation.

FDA's guidance documents do not establish legally enforceable responsibilities. Instead, the Guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency Guidances means that something is suggested or recommended, but not required.

- Food and Drug Administration (FDA) website: www.fda.gov
- 21 CFR Part 120: Hazard Analysis and Critical Control Point (HACCP) Systems
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=120>
- Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition, March 2004

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first>

- Guidance for Industry: Juice HACCP and the FDA Food Safety Modernization Act, August 2017
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-haccp-and-fda-food-safety-modernization-act>
- Guidance for Industry: Questions and Answers on Juice HACCP Regulation, September 2001
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-juice-haccp-regulation>
- Guidance for Industry: Questions and Answers on Juice HACCP Regulation, September 2003
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-juice-haccp-regulation-2003>
- Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices, June 2007
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-refrigerated-carrot-juice-and-other-refrigerated-low-acid-juices>
- Letter to State Regulatory Agencies and Firms That Produce Treated (but not Pasteurized) and Untreated Juice and Cider, September 2005
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/letter-state-regulatory-agencies-and-firms-produce-treated-not-pasteurized-and-untreated-juice-and>
- Guidance for Industry: Recommendations to Processors of Apple Juice or Cider on the Use of Ozone for Pathogen Reduction Purposes, October 2004
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-processors-apple-juice-or-cider-use-ozone-pathogen-reduction>
- Lists of Foreign Processors of Juice Approved by their Governments
<https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/lists-foreign-processors-juice-approved-their-governments>
- Guidance for Industry: Bulk Transport of Juice Concentrates and Certain Shelf-Stable Juices, April 2003
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-bulk-transport-juice-concentrates-and-certain-shelf-stable-juices>
- CPG Sec 510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin, November 2005
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-510150-apple-juice-apple-juice-concentrates-and-apple-juice-products-adulteration-patulin>

For more information contact the Oregon Dept. of Agriculture • Food Safety Program
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