

Food Processing and Distributing

Requirements for Licensing

You have indicated an interest in starting a business processing and distributing food. The attached sheet gives you an outline of the information that is required for the Health District to license and permit your proposed business.

It is not possible for the Health District or state Food Protection program to act as your consultant for bottling, sealing, packaging, or food processing procedures. You must propose a process for review, or hire a consultant to assist you.

This information is sent to the Food and Drug Administration (FDA) for review. The FDA will determine if their agency will regulate your business based on the product, the volume, and the estimated percentage of the interstate commerce. It is necessary that the Health Department get this determination from the FDA (or USDA with Meat Processors) before proceeding with facility and licensing review.

You must register your food processing facility with the FDA. The following website was created to facilitate making submissions of registrations, listings and other notifications to the FDA; <https://www.access.fda.gov>

If the FDA or USDA answers that they will NOT assume jurisdiction for your food business, then your plans will be submitted and reviewed by the Health Department. Your application will be approved or denied a food license under the *Idaho Food Code*. The Idaho Food Code can be accessed on the internet at: <https://www.cdh.idaho.gov/eh-food-forms.php>.

You may obtain *A Comprehensive Guide for Idaho Specialty Food Processors* from the Idaho Department of Agriculture, P.O. Box 790, Boise ID 83701-0790. You can also telephone that agency at 332-8530 or find them on the Internet at: <https://agri.idaho.gov>.

The following rules from the Idaho Food Code specifically pertain to food processing and labeling requirements.

Specialized Processing Methods

3-502.11 Variance Requirement.*

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before:

- (A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;
- (B) Curing FOOD;
- (C) Using FOOD ADDITIVES or adding components such as vinegar:
 - (1) As a method of FOOD preservation rather than as a method of flavor enhancement, or
 - (2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS;
- (D) Packaging FOOD using a REDUCED OXYGEN PACKAGING method *except as specified under § 3-502.12 where a barrier to ***Clostridium botulinum*** in addition to refrigeration exists;*
IDAPA 16.02.19.351. Modifications to Section 3-502.11. Sections 3-502.11(E) and (F) are not adopted
- (G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE.

Clostridium botulinum Controls

3-502.12 Reduced Oxygen Packaging, Criteria.*

- (A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form shall ensure that there are at least two barriers in place to control the growth and toxin formation of ***C. botulinum***.
- (B) A FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:
 - (1) Identifies the FOOD to be PACKAGED
 - (2) Limits the FOOD PACKAGED to a FOOD that does not support the growth of ***Clostridium botulinum*** because it complies with one of the following:
 - (a) Has an a_w of 0.91 or less,
 - (b) Has a PH of 4.6 or less,
 - (c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the U.S.D.A. using substances specified in 9 CFR 318.7 Approval of substances for use in the preparation of products and 9 CFR 381.147 Restrictions on the use of substances in POULTRY products and is received in an intact package, or
 - (d) Is a FOOD with a high level of competing organisms such as raw MEAT or raw POULTRY;

- (3) Specifies methods for maintaining FOOD at 5°C (41°F) or below;
- (4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
- (a) Maintain the FOOD at 5°C (41°F) or below, and
 - (b) For FOOD held at refrigeration temperatures, discard the FOOD if within 14 calendar days of its packaging it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;
 - (5) Limits the refrigerated shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;
 - (6) Includes operational procedures that:
 - (a) Prohibit contacting FOOD with bare hands,
 - (b) Identify a designated area and the method by which:
 - (i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, and
 - (ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, and
 - (c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and
 - (7) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:
 - (a) Concepts required for a safe operation,
 - (b) EQUIPMENT and facilities, and
 - (c) Procedures specified under Subparagraph (B)(6) of this section and ¶ 8-201.14(D).
- (C) *Except for FISH that is frozen before, during, and after packaging*, a FOOD ESTABLISHMENT may not package FISH using a REDUCED OXYGEN PACKAGING method.

Food Processing Plants

IDAPA 16.02.19.355: Food processing plants, establishments, canning factories or operations must meet the requirements in Chapters 1 through 8 of the 2001 Food Code, and Subsections 355.01 through 355.05 of these rules.

01. **Thermal Processing of Low-Acid Foods.** Low-acid food products processed using thermal methods for canning must meet the requirements of 21 CFR 113.
02. **Bottled Water Processing.** Bottled drinking water processed in Idaho must meet the requirements of 21 CFR 129. Bottled drinking water must also meet the quality monitoring requirements in 21 CFR 165.
03. **Approval of Process Methods.** A variance by the regulatory authority must be approved and granted for specialized processing methods for products listed in 3-502.11.
04. **Labels.** Proposed labels shall be submitted to the regulatory authority for review and approval prior to printing.
05. **Testing.** The license holder is responsible for chemical, microbiological or

extraneous material testing procedures to identify failures or food contamination of food products being processed or manufactured by the license holder.

06. Quality Assurance Program. The license holder or his designated person must develop and submit to the regulatory authority for review and approval a quality assurance program or HACCP plan that covers the food processing operation. The program must include the following:

- a. An organizational chart that identifies persons responsible for quality control operations.
- b. A process flow diagram outlining the processing steps from the receipt of the raw materials to the production and packaging of finished product(s) or group of related products.
- c. A list of specific points in the process which are critical control points that must have scheduled monitoring.
- d. Product codes that establish and identify the production date and batch.
- e. A manual covering sanitary maintenance of facility and hygienic practices to be followed by employees.
- f. A records system allowing for review and evaluation of all operations including the quality assurance program results. These records must be kept for a period of time that exceeds the shelf life of the product by six (6) months or for two (2) years, whichever is less.

3-6 FOOD IDENTITY, PRESENTATION, AND ONPREMISES LABELING

Subparts

3-601 Accurate Representation

3-602 Labeling

3-603 Consumer Advisory

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and Standards of Identity or Composition, and the general requirements in 21 CFR 130 - Food Standards: General and 9 CFR 319 Subpart A - General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

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 of the FOOD, or absent a common name, an adequately descriptive identity statement;
- (2) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the FOOD;
- (3) An accurate declaration of the quantity of contents;
- (4) The name and place of business of the manufacturer, packer, or distributor; and
- (5) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3)-(5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.
- (6) For any salmonid FISH containing canthaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

- (1) The manufacturer's or processor's label that was provided with the FOOD; or
- (2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

- (1) *A health, nutrient content, or other claim is not made;*
- (2) *There are no state or local LAWS requiring labeling; and*
- (3) *The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.