

LABELING GUIDANCE FOR FOODS IN RETAIL ESTABLISHMENTS

In today's regulatory landscape, keeping well-informed of ever-changing labeling requirements set forth by the Federal Food and Drug Administration (FDA) and the Kentucky Department of Public Health (KDPH) is paramount. Failing to do so could potentially jeopardize your business.

FDA and KDPH labeling requirements undergo frequent updates, and staying informed can be challenging. The consequences of incorrect labels are significant, ranging from customer complaints and product recalls to legal repercussions. Therefore, ensuring compliance with these evolving requirements is not just a matter of good practice; it's a safeguard for the integrity and sustainability of your business.

This document is a summary of the FDA's and KDPH's requirements.

PACKAGED FOODS:

The term "Packaged" is defined in the 2013 FDA Food Code as:

- (1) "**Packaged**" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a retail food facility or a food processing plant that has been prepared in advance and packed in a way that extends its shelf life.
- (2) "**Packaged**" **does not** include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

If a **Time/Temperature Controlled for Safety (TCS) food** is packaged, and **NOT made or prepared** by the retail food facility or food establishment **then it must be fully labeled** with ingredients (including sub-ingredients), and all other required labeling information, as listed above.

LABELING GUIDE BY FOOD TYPE:

2013 FDA Food Code 3.602.11 (A)(B) – ALL Packaged Foods

Food packaged **IN** a retail food facility or a food processing plant shall be labeled with:

- 1) Common name of the food
- 2) Ingredients (including sub-ingredients) in descending order of predominance by weight. This includes a declaration of artificial colors, flavors, and chemical preservatives if contained in the food.
- 3) Accurate declaration of net quantity of contents
- 4) Name and place of business of the manufacturer, packer, or distributor
- 5) Major food allergens if applicable
- 6) Nutrition labeling if not exempt in the Food Drug & Cosmetic Act
- 7) Disclosure of canthaxanthin or astaxanthin for salmonid fish

2013 FDA Food Code 3-602.11 (C) Bulk Foods – consumer self-dispensing

Bulk foods available for consumer self-dispensing (e.g., self-dispensing bins of dried grains, nuts, beans, spices, and flours) must be prominently labeled with the following:

- 1) Manufacturers or processor's label provided with the food; OR
- 2) A card/sign/poster/book at point-of-sale (POS) with all information for displayed foods; OR
- 3) Other methods of notification at POS such as a sign stating "ingredients available upon request," with directions on where to look/inquire. This other method must include a Common Name, Ingredients (including sub-ingredients), and Nutritional labeling information, if not exempt.

2013 FDA Food Code 3-602.11 (D) Bulk, Unpackaged Foods – portioned to customer request

Unpackaged products (e.g., bakery products) and unpackaged foods (e.g., service counter foods – deli meats, cheese, salads) that are manufactured or prepared on-premise or in a satellite food facility owned by the same owner do **NOT** need to be labeled IF:

- 1) No health, nutrient content, or other claim is made; AND
- 2) Ingredients are available upon request

Unpackaged foods **NOT** prepared or manufactured **ON the premise** (or satellite facility) must have an acceptable form of labeling that includes:

- 1) Common name of the food
- 2) Ingredients (including sub-ingredients) in descending order of predominance by weight. Includes a declaration of artificial colors, flavors, and chemical preservatives if contained in the food.
- 3) Accurate declaration of net quantity of contents
- 4) Name and place of the business of the manufacturer, packer, or distributor
- 5) Major Food Allergens if applicable
- 6) Disclosure of canthaxanthin or astaxanthin for salmonid FISH

FDA EXEMPTIONS:

The following exemptions apply to this code section:

- 1) **Self-service bulk Foods**, such as bulk candy bins, that have alternative labeling requirements (2013 FDA Food Code 3- 602-11(C)).
- 2) **Packaged Food**, such as bakery products, that are made or prepared AND packaged on the premise of the retail food facility or satellite food facility/processing plant owned by the same owner and sold retail to customers.
- 3) **Unpackaged Food**, such as deli salads, meats, and cheeses, which is portioned to a consumer request and is made on the premise of the food facility or another food facility/processing plant owned by the same owner and makes no health claims (2013 FDA Food Code 3-602.11 (D)).

A card, sign, or similar must be displayed indicating “ingredients/allergens are available upon request” with directions on where to inquire/look if necessary. The information listed above must be available at the bakery or its satellite facility at all times.

KDPH EXEMPTION for PACKAGED (Grab-N-Go) FOODS:

Packaged or re-packaged food, as defined above, that is not made or prepared in the retail food facility would typically require full labeling. KDPH will **EXEMPT** a packaged food product from being fully labeled if **ALL** the following apply:

- 1) The item is made or assembled in the retail food facility or a satellite facility with the **same owner**
- 2) The item is a single serving and packaged
- 3) The item is marked with the date of preparation
- 4) The item is sold within 24 hours or discarded
- 5) The service case has a placard, poster, card, book, or similar, displayed with or near the food item, and which includes the common name, all ingredients and sub-ingredients, and major allergens
- 6) The packaging itself contains a label with the common name, general ingredients (not sub-ingredients), name and address of the store, net quantity, and major allergens

2013 FDA Food Code 3-203.11 and 3-203.12 Molluscan Shellfish

All individual packages of molluscan shellstock must have original shellstock tags attached until empty. The tag must include:

- 1) The dealer's name/address,
- 2) Shellfish permit #,
- 3) Growing area identification,
- 4) Date of harvest,
- 5) Type and quantity of shellstock

Individual packages of fresh or raw frozen shucked shellfish (oysters, clams, & mussels) must have:

- 1) Name/address and permit # of the SP or RP for the shellfish
- 2) Packages less than ½ gallon: "sell by" date or "best if used by" date and for greater than ½ gallon: date shucked

Frozen molluscan shellfish must be labeled "frozen" and include a year's date. Shellstock tags shall be maintained for **90 days**. The facility must have accurate records of the sources and quantity of all lots of shellfish, in chronological order, correlated to the dates during which shellstock is sold or served.

ADDITIONAL FOOD LABELING RESOURCES:

- [Labeling for Retail Food – Examples: https://www.lfchd.org/wp-content/uploads/2023/12/Labeling-for-Retail-Food-Examples.pdf](https://www.lfchd.org/wp-content/uploads/2023/12/Labeling-for-Retail-Food-Examples.pdf)
- Food Labeling Guide: <https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf>
- Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5): <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5>
- Labeling & Nutrition Guidance Documents & Regulatory Information: <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/labeling-nutrition-guidance-documents-regulatory-information>
- The FDA obtains its labeling requirements as specified in law, including the Code of Federal Regulations (CFR):
 - 21 CFR 101 – Food Labeling: <https://www.ecfr.gov/compare/2023-05-24/to/2023-05-23/title-21/chapter-I/subchapter-B/part-101> and
 - 9 CFR 317 – Labeling, marking devices, and containers: <https://www.ecfr.gov/current/title-9/chapter-III/subchapter-A/part-317>