

GUIDANCE FOR LABELING PACKAGED FOODS IN RETAIL FOOD FACILITIES

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 and sub-ingredients** in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the food;
 - (3) An accurate declaration of the net quantity of contents;
 - (4) The name and place of business of the manufacturer, packer, or distributor; and
 - (5) The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient.
 - (6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(g)(3)-(5), nutrition labeling as specified in 21 CFR 101-Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling*.
 - (7) For any salmonid FISH containing canthaxanthin or 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 or canthaxanthin.

EXEMPTION:

The following **exemption** applies to this code section:

- 1) **Self-Service Bulk Foods**, such as bulk candy bins, that have alternative labeling requirements (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. This exemption includes 'bake-off' items (3-602.11(D) and 3 PA. C.S.A. §5729(b)(1)).
- 3) **Unpackaged Food**, such as deli salads, meats and cheeses, which is *portioned to a consumer request* and is made (including slicing) on the premise of the food facility or another food facility/processing plant owned by the same owner and makes no health claims (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.

PACKAGED FOODS:

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

- (1) "**Packaged**" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a Food Facility or a Food Processing Plant.
- (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 food is considered packaged, including baked goods, and **NOT** made or prepared by the retail food facility or food establishment, it must be **fully** labeled with ingredients (including sub-ingredients), and all other required labeling information, as listed above.

EXEMPTION – 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 fully labeled. PDA will **EXEMPT** a packaged food product from being fully labeled if **ALL** the following apply:

- 1) Item is made or assembled in the retail food facility
- 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 included 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

***3-602.11(B) FOOD LABELS – Nutritional Labeling Exemptions:**

(6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(g)(3)-(5), nutrition labeling as specified in 21 CFR 101-Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling*.

<i>Summary of Exemption</i>	<i>Regulation #</i>
Manufactured by small business	21 CFR 101.9(j)(1) and 101.9 (j)(18)
Food served in restaurants, etc. of delivered to homes ready for immediate consumption	21 CFR 101.9(j)(2)
Delicatessen-type food, bakery products and confections that are sold directly to consumers from the location where prepared	21 CFR 101.9(j)(3)
Foods that provide no significant nutrition such as instant coffee (plan, unsweetened) and most spices	21 CFR 101.9(j)(4)
Infant formula, and infant junior foods for children up to 4 years of age (modified label provision for these categories)	21 CFR 101.9 (j)(5) and 101.9(j)(7)
Dietary supplements (must comply with – 21 CFR 101.36)	21 CFR 101.9(j)(6)
Medical foods	21 CFR 101.9 (j)(8)
Bulk foods shipped for further processing – or packaging before retail sale	21 CFR 101.9 (j)(9)
Fresh produce and seafood (a voluntary nutrition labeling program covers these foods)	21 CFR 101.9(j)(10) and 101.45
Packaged single-ingredient fish or game meat may be labeled on basis of 3-ounce cooked portions (as prepared). Custom processed fish and game are exempt from nutrition labeling.	21 CFR 101.9(j)(11)
Certain egg cartons (nutrition information inside lid or insert)	21 CFR 101.9(j)(14)
Packages labeled “This unit not labeled for retail sale” within multiunit package, and outer wrapper bears all required label statements	21 CFR 101.9(j)(15)
Self-service bulk foods-nutrition labeling by placard, or on original container displayed clearly in view	21 CFR 101.9(a)(2) and 101.9(j)(16)
Donated food that is given free (not sold) to the consumer (*unless the donated food is later placed on sale)	21 CFR 101.9(a)
Game meats may provide required nutrition information on labeling in accordance with 21 CFR 101.9(a)(2) (eg. counter cards)	21 CFR 101.9(j)(12)

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LABELING GUIDE BY FOOD TYPE:

ALL Packaged Foods – 3.602.11 (A)(B)

Food packaged **IN** a retail food facility 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 canthaxanthin for salmonid fish

EXEMPTION – 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 fully labeled. PDA will **EXEMPT** a packaged food product from being fully labeled if **ALL** the following apply:

- 1) Item is made or assembled in the retail food facility
- 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 included 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

Bulk Unpackaged Foods – consumer self-dispensing - 3-602.11 (C)

Bulk foods available for consumer self-dispensing must be prominently labeled in plain view with:

- 1) Manufacturer's 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 method of notification at POS such as, sign stating "ingredients available upon request," with directions on where to look / inquire. This other method must include Common Name, Ingredients (including sub ingredients) and Nutritional labeling information, if not exempt.

Note: section 3-306.13 stipulates which foods may be offered for self-service.

Bulk, Unpackaged Foods – portioned to customer request 3-602.11 (D)

Unpackaged food products (ex: bakery items, deli service counter foods – deli meats, cheese, salads, meat or seafood service counter foods – stuffed flounder, crab cakes, stuffed chicken breast, seasoned meats) that are manufactured or prepared on premise (including 'slicing'), or satellite food facility owned by the same owner, do **NOT** need labeled IF:

- 1) No health, nutrient content or another 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 canthaxanthin for salmonid FISH

Molluscan Shellfish – 3-203.11 and 3-203.12

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 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 are sold or served.

Other Labeling Information:

- 'Packaged' is defined in the Food Code
- When a booklet is used for labeling reference, a sign at the bulk food or deli display will need to indicate where the booklet may be found, if, not displayed at bulk or deli food display
- **Allergens:** All packaged and labeled items should visibly declare if there are **allergens** present in the product in plain language. Allergens that **MUST** be noted are: **tree nuts (specify type), peanuts, egg, milk, soy, fish, shellfish, and wheat.** (Ex: "Contains: wheat, peanut and egg")
- **Sub-ingredients:** ingredients for the full label must list ALL ingredients for the individual products used in the making of the final product. (Ex: if you used Lebanon bologna, then all ingredients on the bologna packet must be listed on your label)
- All products made in PA at a Registered Food Establishment can use the statement: "**Reg Penna Dept Agr**"
- **Out of state sales:** any product being sold or distributed over state lines should use full labeling and the manufacturer or distributor of the products should contact their local Food and Drug Administration (FDA) office for guidance on labeling and shipping of these products.

Meat and Poultry that is Packaged but not Ready-To-Eat – 3-201.11 (F)

Meat and Poultry that is not ready-to-eat and is in a packaged form when offered for sale, or otherwise offered for consumption, shall be labeled with safe handling instructions as specified in 9CFR 317.2(i) and 9CFR 381.125(b). (**In addition to general 'packaged food requirements')

Note: Some Meat and Poultry packaged directly in a USDA inspected facility may contain a "Sell By", "Use By", or other type of date. These dates are not 'enforceable' and products CAN legally be sold after those dates, unless the product can be deemed 'unwholesome' or 'adulterated'.

Eggs – 3-201.11 (G) & PA Egg Refrigeration Law

Egg Refrigeration Law: §88.4(a) & (b) - Each consumer receptacle and case of consumer receptacles shall be labeled by the processor with (1) The plant at which the eggs were processed; (2) The date of process, (3) The flock of origin of the eggs. These items may be incorporated as a code approved by the Department.

Egg Refrigeration Law: §88.5 – Small flock producers (in lieu of (a) & (b) requirements above) must label with Producer Name and Address, 'Date of Lay'.

Egg Refrigeration Law: §88.4(c) – All packaged/cartoned Eggs must be labeled “Keep Refrigerated”
3-201/11 (G): Eggs that have not been specifically treated to destroy all viable Salmonellae shall be labeled with safe handling instructions as specified in 21CFR 101.17(h).

(**In addition to general packaged food requirements)

Fluid Milk – 3-201.13 & PA Milk Sanitation Regulations 7Pa. Code 59.a

PA Milk Sanitation Regulations §59a.14 – **Milk** or milk products be labeled with “Keep Refrigerated” (or “Keep Refrigerated after Opening” if aseptically packaged). Milk or milk products should be labeled “Grade A.” (unless it is not, eg. Raw Milk). Milk or milk products should have a processing plant ‘code’ or identifier.

(**In addition to general packaged food requirements)

PA Milk Sanitation Regulations §59a.15 – **Pasteurized Milk** must be labeled with a “Sell By” Date which is 17 days from processing. Exempt products would be those that are cultured, HTST, Ultra, or Aseptic pasteurized, or sold on the premises of the processor.

PA Milk Sanitation Regulations §59a.411 – Raw Milk, if packaged by the producer, must be labeled as “Raw Milk”, and include the Name & Address of the Producer, Fluid Volume, “Keep Refrigerated” and a 17 day “Sell By” date, Raw Milk must also have a consumer advisory on the label, such as: “Raw milk has not been processed to remove pathogens that can cause illness. The consumption of raw milk may significantly increase the risk of foodborne illness in persons who consume it-particularly with respect to certain highly susceptible populations such as preschool-age children, older adults, pregnant women, persons experiencing illness, and other people with weakened immune systems.

Infant Formula – Federal Law

Federal Law requires that all powdered, concentrate, or ready to consume infant Formula contain a “Use By” date. The products cannot be sold after that date. “Infant Formula” does not include products that are commonly known as “Pureed Baby Foods.”

(**In addition to general packaged food requirements)

*This guidance document in no way takes the place of the official Laws and Regulations that govern these products.
If you have additional questions, please contact the Department at 717-787-4315.*