SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

PART 100—GENERAL

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SOURCE: 42 FR 14306, Mar. 15, 1977, unless otherwise noted.

Subpart A—State and Local Requirements

§ 100.1 Petitions requesting exemption from preemption for State or local requirements.

(a) Scope and purpose. (1) This subpart applies to the submission and consideration of petitions under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act), by a State or a political subdivision of a State, requesting exemption of a State requirement from preemption under section 403A(a) of the act.

(2) Section 403A(b) of the act provides that where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency for an exemption. The agency may grant the exemption, under such conditions as it may prescribe by regulation, if the agency finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement.


(2) Agency means the Food and Drug Administration.

(3) Commissioner means the Commissioner of Food and Drugs.

(4) State means a State as defined in section 201(a)(1) of the act (which includes a territory of the United States, the District of Columbia, and Puerto Rico) or any political subdivision of a State having authority to issue food standards and food labeling regulations having force of law.

(5) State requirement means any statute, standard, regulation, or other requirement that is issued by a State.

(c) Prerequisites for petitions for exemption from preemption. The Food and Drug Administration will consider a petition for exemption from preemption on its merits only if the petition demonstrates that:

(1) The State requirement was enacted or was issued as a final rule by an authorized official of the State and is in effect or would be in effect but for the provisions of section 403A of the act.

(2) The State requirement is subject to preemption under section 403A(a) of the act because of a statutory provision listed in that section or because of a Federal standard or other Federal regulation that is in effect, or that has been published as a final rule with a designated effective date, and that was issued under the authority of a statutory provision listed in that section. For the purposes of this subpart, all petitions seeking exemption from preemption under section 403A(a) of the act submitted before May 8, 1992, will be considered timely even though the applicable statutory provisions or regulations are not yet in effect.

(3) The petitioner is an official of a State having authority to act for, or on behalf of, the Government in applying for an exemption of State requirements from preemption.

(4) The State requirement is subject to preemption under section 403A(a) of the act because it is not identical to
the requirement of the preemptive Federal statutory provision or regulation including a standard of identity, quality, and fill. “Not identical to” does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

(i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or

(ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

(d) Form of petition. (1) All information included in the petition should meet the general requirements of §10.20(c) of this chapter.

(2) An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.)

(3) Petitions for exemption from preemption for a State requirement shall be submitted to the Division of Dockets Management in the following form:

(Date)
Division of Dockets Management,
Food and Drug Administration,
Department of Health and Human Services,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

PETITION REQUESTING EXEMPTION FROM PREEMPTION FOR STATE REQUIREMENT

The undersigned submits this petition under section 408(a)(b) of the Federal Food, Drug, and Cosmetic Act to request that the Food and Drug Administration exempt a State requirement from preemption.

The undersigned has authority to act for, or on behalf of, the (identify State or political subdivision of the State) because (document petitioner’s authority to submit petition on behalf of the State).

A. Action Requested

1. Identify and give the exact wording of the State requirement and give date it was enacted or issued in final form.

2. Identify the specific standard or regulation that is believed to preempt the State requirement and the section and paragraph of the act that the standard or regulation implements.

B. Documentation of State Requirement

Provide a copy of the State requirement that is the subject of the application. Where available, the application should also include copies of any legislative history or background materials used in issuing the requirement, including hearing reports or studies concerning the development or consideration of the requirement.

C. Statement of Grounds

A petition for an exemption from preemption should contain the following:

1. An explanation of the State requirement and its rationale, and a comparison of State and Federal requirements to show differences.

2. An explanation of why compliance with the State requirement would not cause a food to be in violation of any applicable requirement under Federal law.

3. Information on the effect that granting the State petition will have on interstate commerce. The petition should contain information on economic feasibility, i.e., whether the State and Federal requirements have significantly different effects on the production and distribution of the food product; comparison of the costs of compliance as shown by data or information on the actual or anticipated effect of the State and Federal requirements on the sale and price of the food product in interstate commerce; and the effect of the State requirement on the availability of the food product to consumers. To the extent possible, the petition should include information showing that it is practical and feasible for producers of food products to comply with the State requirement. Such information may be submitted in the form of statements from affected persons indicating their ability to comply.

4. Identification of a particular need for information that the State requirement is designed to meet, which need is not met by Federal law. The petition should describe the conditions that require the State to petition for an exemption, the information need that the State requirement fulfills, the inadequacy of the Federal requirement in addressing this need, and the geographical area or political subdivision in which such need exists.
D. Environmental Impact

The petition shall contain a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31.

E. Notification

Provide name and address of person, branch, department, or other instrumentality of the State government that should be notified of the Commissioner’s action concerning the petition.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies.

(g) If a State submitted a petition for exemption of a State requirement from preemption under section 403A(a)(3) through (a)(5) of the act before May 8, 1992, that State requirement will not be subject to preemption until:

(1) November 8, 1992; or

(2) Action on the petition, whichever occurs later.

58 FR 2656, Jan. 6, 1993

§ 100.2 State enforcement of Federal regulations.

(a) Under section 307 of the Federal Food, Drug, and Cosmetic Act (the act), a State may bring, in its own name and within its own jurisdiction, proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(j), 403(k), 403(q), or 403(r) of the act if the food that is the subject of the proceedings is located in the State.

(b) No proceeding may be commenced by a State under paragraph (a) of this section:

(1) Before 30 days after the State has given notice to the Food and Drug Administration (FDA) that the State intends to bring such proceeding.

(2) Before 90 days after the State has given notice to FDA of such intent if
§ 100.2

FDA has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding.

(3) If FDA is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

(c) A State may intervene as a matter of right, in any court proceeding described in paragraph (b)(3) of this section.

(d) The notification that a State submits in accordance with paragraph (b) of this section should include the following information and be submitted in the following recommended format:

(Date)
Name of State agency
Post office address
Street address
City, State, and ZIP code
Name of product(s) covered by the notification
Reporting official, title, and telephone no.
FAX No.
Agency contact (if different from reporting official), title, and telephone no.

Director,
Division of Enforcement (HFS–605),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740.

To Whom It May Concern:
The undersigned, [ ]., submits this letter of notification pursuant to section 307(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 337(b)(1)) with respect to [ ] (name of products covered by the notification and the enforcement action that is to be initiated)

Attached hereto, and constituting a part of this letter of notification are the following:

A. The name of the product.
B. The type and size of each product container.
C. Copy of the label and labeling of the product.
D. Manufacturing code (if applicable).
E. Name and address of firm believed to be responsible for violations.
F. Name and address of parent firm (if known).
G. Reason for the anticipated State enforcement action (list specific violations, including sections of the law violated).
H. Name of firm against which action is anticipated (if applicable).
I. Type of enforcement action.

Yours very truly,
Reporting Agency
By (Indicate authority)

(e) The letter of notification should be signed by a State official authorized by the State to institute the contemplated enforcement actions.

(f) The letter of notification should be sent to the Division of Enforcement (HFS–605), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, FAX number 202–205–4642.

(g) FDA will notify the State of the date in which its letter of notification was received by FDA, Center for Food Safety and Applied Nutrition, Division of Enforcement (HFS–605) (within 2 working days after date of receipt). This date will be the date of notification for the purposes of paragraph (b) of this section.

(h) The Director, Division of Enforcement, Office of Field Programs, Center for Food Safety and Applied Nutrition, FDA, will respond to the State’s notification within 30 days of the date of notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or
(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

(1) Information contained in State notification letters shall be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to §§20.61, 20.64, and 20.88 of this chapter.

(j) Definitions. (1) Informal enforcement actions include warning letters, recalls, detentions, or other administrative enforcement actions that pertain to the food in question. (Information collection requirements in this section...
Food and Drug Administration, HHS

were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0275.)

[58 FR 2460, Jan. 6, 1993; 58 FR 17097, Apr. 1, 1993, as amended at 66 FR 56035, Nov. 6, 2001]

Subparts B–E [Reserved]

Subpart F—Misbranding for Reasons Other Than Labeling

§100.100 Misleading containers.

§100.155 Salt and iodized salt.

(a) For the purposes of this section, the term "iodized salt" or "iodized table salt" is designated as the name of salt for human food use to which iodide has been added in the form of cuprous iodide or potassium iodide permitted by §§184.1265 and 184.1634 of this chapter. In the labeling of such products, all words in the name shall be equal in prominence and type size. The statement "This salt supplies iodide, a necessary nutrient" shall appear on the label immediately following the name and shall be in letters which are not less in height than those required for the declaration of the net quantity of contents as specified in §101.105 of this chapter.

(b) Salt or table salt for human food use to which iodide has not been added shall bear the statement, "This salt does not supply iodide, a necessary nutrient." This statement shall appear immediately following the name of the food and shall be in letters which are not less in height than those required for the declaration of the net quantity of contents as specified in §101.105 of this chapter.

(c) Salt, table salt, iodized salt, or iodized table salt to which anticaking agents have been added may bear in addition to the ingredient statement designating the anticaking agent(s), a label statement describing the characteristics imparted by such agent(s) (for example, “free flowing”), providing such statement does not appear with greater prominence or in type size larger than the statements which immediately follow the name of the food as required by paragraphs (a) and (b) of this section.

(d) Individual serving-sized packages containing less than 1⁄2 ounce and packages containing more than 2 1⁄2 pounds...
of a food described in this section shall be exempt from declaration of the statements which paragraphs (a) and (b) of this section require immediately following the name of the food. Such exemption shall not apply to the outer container or wrapper of a multiunit retail package.

(e) All salt, table salt, iodized salt, or iodized table salt in packages intended for retail sale shipped in interstate commerce 18 months after the date of publication of this statement of policy in the Federal Register, shall be labeled as prescribed by this section; and if not so labeled, the Food and Drug Administration will regard them as misbranded within the meaning of sections 403 (a) and (f) of the Federal Food, Drug, and Cosmetic Act.


PART 101—FOOD LABELING

Subpart A—General Provisions

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101.1 Principal display panel of package form food.
101.2 Information panel of package form food.
101.3 Identity labeling of food in packaged form.
101.4 Food; designation of ingredients.
101.5 Food; name and place of business of manufacturer, packer, or distributor.
101.9 Nutrition labeling of food.
101.10 Nutrition labeling of restaurant foods.
101.12 Reference amounts customarily consumed per eating occasion.
101.13 Nutrient content claims—general principles.
101.14 Health claims; general requirements.
101.15 Food; prominence of required statements.
101.17 Food labeling warning, notice, and safe handling statements.
101.18 Misbranding of food.

Subpart B—Specific Food Labeling Requirements

101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.
101.30 Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice.

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Subpart C—Specific Nutrition Labeling Requirements and Guidelines

101.36 Nutrition labeling of dietary supplements.
101.42 Nutrition labeling of raw fruit, vegetables, and fish.
101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.
101.44 Identification of the 20 most frequently consumed raw fruit, vegetables, and fish in the United States.
101.45 Guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

Subpart D—Specific Requirements for Nutrient Content Claims

101.54 Nutrient content claims for “good source,” “high,” “more,” and “high potency.”
101.56 Nutrient content claims for “light” or “lite.”
101.60 Nutrient content claims for the calorie content of foods.
101.61 Nutrient content claims for the sodium content of foods.
101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.
101.65 Implied nutrient content claims and related label statements.
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101.69 Petitions for nutrient content claims.

Subpart E—Specific Requirements for Health Claims

101.70 Petitions for health claims.
101.71 Health claims: claims not authorized.
101.72 Health claims: calcium, vitamin D, and osteoporosis.
101.73 Health claims: dietary lipids and cancer.
101.74 Health claims: sodium and hypertension.
101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.
101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.
101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.
101.78 Health claims: fruits and vegetables and cancer.
101.79 Health claims: Folate and neural tube defects.
101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries.