

of food that provides for a warning concerning the safety of the food or component of the food.

“(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act [this chapter] not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.”

Amendments by Pub. L. 101-535 not to be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

#### DELAYED APPLICABILITY OF CERTAIN PROVISIONS

Pub. L. 102-408, title III, §310, Oct. 13, 1992, 106 Stat. 2090, provided that: “Notwithstanding any other provision of law, section 403A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(1)) shall not apply with respect to any requirement of any State or political subdivision regarding maple syrup until September 1, 1994.”

### § 343-2. Dietary supplement labeling exemptions

#### (a) In general

A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

- (1) is not false or misleading;
- (2) does not promote a particular manufacturer or brand of a dietary supplement;
- (3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
- (4) if displayed in an establishment, is physically separate from the dietary supplements; and
- (5) does not have appended to it any information by sticker or any other method.

#### (b) Application

Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

#### (c) Burden of proof

In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.

(June 25, 1938, ch. 675, §403B, as added Pub. L. 103-417, §5, Oct. 25, 1994, 108 Stat. 4328.)

### § 343-3. Disclosure

(a) No provision of section 321(n), 343(a), or 348 of this title shall be construed to require on the

label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 343(i)(2) of this title.

(b) In this section, the term “radiation disclosure statement” means a written statement that discloses that a food has been intentionally subject to radiation.

(June 25, 1938, ch. 675, §403C, as added Pub. L. 105-115, title III, §306, Nov. 21, 1997, 111 Stat. 2353.)

#### Statutory Notes and Related Subsidiaries

##### EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

#### § 343a. Repealed. Pub. L. 106-554, § 1(a)(1) [title V, § 517], Dec. 21, 2000, 114 Stat. 2763, 2763A-73

Section, Pub. L. 95-203, §4(c), (d), Nov. 23, 1977, 91 Stat. 1453, 1454, related to distribution of information on health risks of saccharin.

### § 344. Emergency permit control

#### (a) Conditions on manufacturing, processing, etc., as health measure

Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

#### (b) Violation of permit; suspension and reinstatement

The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

**(c) Inspection of permit-holding establishments**

Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

(June 25, 1938, ch. 675, § 404, 52 Stat. 1048.)

**Executive Documents**

## TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

**§ 345. Regulations making exemptions**

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment. This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title.

(June 25, 1938, ch. 675, § 405, 52 Stat. 1049; Pub. L. 101-535, § 5(a), Nov. 8, 1990, 104 Stat. 2362.)

**Editorial Notes**

## AMENDMENTS

1990—Pub. L. 101-535 inserted at end “This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title.”

**Statutory Notes and Related Subsidiaries**

## EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101-535, set out as a note under section 343 of this title.

## CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

**Executive Documents**

## TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

**§ 346. Tolerances for poisonous or deleterious substances in food; regulations**

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(June 25, 1938, ch. 675, § 406, 52 Stat. 1049; Pub. L. 85-929, § 3(c), Sept. 6, 1958, 72 Stat. 1785; Pub. L. 86-618, title I, § 103(a)(1), July 12, 1960, 74 Stat. 398.)

**Editorial Notes**

## AMENDMENTS

1960—Pub. L. 86-618 repealed subsec. (b) which required Secretary to promulgate regulations for listing of coal-tar colors.

1958—Subsec. (a). Pub. L. 85-929 substituted “clause (2)(A)” for “clause (2)” in first sentence.

**Statutory Notes and Related Subsidiaries**

## EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86-618, see section 202 of Pub. L. 86-618, set out as a note under section 379e of this title.

## EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND DESICCANT AMENDMENT OF 1959

Effective date of subsec. (a) as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86-139, Aug. 7, 1959, 73 Stat. 288.