

the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce.

(b) Procedure

The Secretary may not take any action under subsection (a) of this section with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(c) Applicability

Subsection (a) of this section shall apply with respect to offenses or acts regardless of when such offenses or acts occurred.

(d) Judicial review

Any person that is the subject of an adverse decision under subsection (a) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(June 25, 1938, ch. 675, §308, as added Pub. L. 102-282, §4, May 13, 1992, 106 Stat. 160.)

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102-282, see section 7 of Pub. L. 102-282, set out as a note under section 335a of this title.

§ 336. Report of minor violations

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(June 25, 1938, ch. 675, §309, formerly §306, 52 Stat. 1045; renumbered §309, Pub. L. 102-282, §2, May 13, 1992, 106 Stat. 150.)

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.

§ 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforce-

ment, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary 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.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

(June 25, 1938, ch. 675, §310, formerly §307, 52 Stat. 1046; Sept. 3, 1954, ch. 1263, §37, 68 Stat. 1239; Pub. L. 101-535, §4, Nov. 8, 1990, 104 Stat. 2362; renumbered §310, Pub. L. 102-282, §2, May 13, 1992, 106 Stat. 150.)

AMENDMENTS

1990—Pub. L. 101-535 substituted “(a) Except as provided in subsection (b) of this section, all” for “All” and “any proceeding under this section” for “any such proceeding” and added subsec. (b).

1954—Act Sept. 3, 1954, struck out reference to section 654 of title 28.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective 24 months after Nov. 8, 1990, except that such amendment effective Dec. 31, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, see section 10(a)(1)(C) 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.

SUBCHAPTER IV—FOOD

§ 341. Definitions and standards for food

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for

any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

(June 25, 1938, ch. 675, § 401, 52 Stat. 1046; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919; Pub. L. 103-80, § 3(h), Aug. 13, 1993, 107 Stat. 776.)

AMENDMENTS

1993—Pub. L. 103-80 substituted “or reasonable standards of fill of container. No definition” for “and/or reasonable standards of fill of container: *Provided*, That no definition”.

1956—Act Aug. 1, 1956, designated provisions constituting subsec. (a) as entire section and repealed subsec. (b) which provided the procedure for establishment of regulations and is covered by section 371(e) of this title.

1954—Act Apr. 15, 1954, designated existing provisions as subsec. (a) and added subsec. (b).

SAVINGS PROVISION

Section 3 of act Aug. 1, 1956, provided that: “In any case in which, prior to the enactment of this Act [Aug. 1, 1956], a public hearing has been begun in accordance with section 401 of the Federal Food, Drug, and Cosmetic Act [341 of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by such section, or has been begun in accordance with section 701(e) of such Act [section 371(e) of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by section 403(j), 404(a), 406(a) or (b), 501(b), 502(d), 502(h), 504 or 604 of such Act [section 343(j), 344(a), 346(a) or (b), 351(b), 352(d), 352(h), 354, or 364 of this title], the provisions of such section 401 or 701(e), as the case may be, as in force immediately prior to the date of the enactment of this Act [Aug. 1, 1956], shall be applicable as though this Act [amending this section and section 371(e) of this title] had not been enacted.”

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.

FOOD SAFETY AND SECURITY STRATEGY

Pub. L. 107-188, title III, § 301, June 12, 2002, 116 Stat. 662, provided that:

“(a) IN GENERAL.—The President’s Council on Food Safety (as established by Executive Order No. 13100 [set out below]) shall, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. Such strategy shall address threat assessments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

“(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of implementing the strategy developed under subsection (a), there are authorized to be appropriated \$750,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.”

FOOD SAFETY COMMISSION

Pub. L. 107-171, title X, § 10807, May 13, 2002, 116 Stat. 527, provided that:

“(a) ESTABLISHMENT.—

“(1) IN GENERAL.—There is established a commission to be known as the ‘Food Safety Commission’ (referred to in this section as the ‘Commission’).

“(2) MEMBERSHIP.—

“(A) COMPOSITION.—The Commission shall be composed of 15 members (including a Chairperson, appointed by the President[]).

“(B) ELIGIBILITY.—

“(i) IN GENERAL.—Members of the Commission—

“(I) shall have specialized training or significant experience in matters under the jurisdiction of the Commission; and

“(II) shall represent, at a minimum—

“(aa) consumers;

“(bb) food scientists;

“(cc) the food industry; and

“(dd) health professionals.

“(ii) FEDERAL EMPLOYEES.—Not more than 3 members of the Commission may be Federal employees.

“(C) DATE OF APPOINTMENTS.—The appointment of the members of the Commission shall be made as soon as practicable after the date on which funds authorized to be appropriated under subsection (e)(1) are made available.

“(D) VACANCIES.—A vacancy on the Commission—

“(i) shall not affect the powers of the Commission; and

“(ii) shall be filled—

“(I) not later than 60 days after the date on which the vacancy occurs; and

“(II) in the same manner as the original appointment was made.

“(3) MEETINGS.—

“(A) INITIAL MEETING.—The initial meeting of the Commission shall be conducted not later than 30 days after the date of appointment of the final member of the Commission.

“(B) OTHER MEETINGS.—The Commission shall meet at the call of the Chairperson.

“(4) QUORUM; STANDING RULES.—

“(A) QUORUM.—A majority of the members of the Commission shall constitute a quorum to conduct business.

“(B) STANDING RULES.—At the first meeting of the Commission, the Commission shall adopt standing rules of the Commission to guide the conduct of business and decisionmaking of the Commission.

“(b) DUTIES.—

“(1) RECOMMENDATIONS.—The Commission shall make specific recommendations to enhance the food safety system of the United States, including a description of how each recommendation would improve food safety.

“(2) COMPONENTS.—Recommendations made by the Commission under paragraph (1) shall address all food available commercially in the United States.

“(3) REPORT.—Not later than 1 year after the date on which the Commission first meets, the Commission shall submit to the President and Congress—

“(A) the findings, conclusions, and recommendations of the Commission, including a description of how each recommendation would improve food safety;

“(B) a summary of any other material used by the Commission in the preparation of the report under this paragraph; and

“(C) if requested by 1 or more members of the Commission, a statement of the minority views of the Commission.

“(c) POWERS OF THE COMMISSION.—

“(1) HEARINGS.—The Commission may, for the purpose of carrying out this section, hold such hearings, meet and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable.

“(2) INFORMATION FROM FEDERAL AGENCIES.—

“(A) IN GENERAL.—The Commission may secure directly, from any Federal agency, such information as the Commission considers necessary to carry out this section.

“(B) PROVISION OF INFORMATION.—

“(i) IN GENERAL.—Subject to subparagraph (C), on the request of the Commission, the head of a Federal agency described in subparagraph (A) may furnish information requested by the Commission to the Commission.

“(ii) ADMINISTRATION.—The furnishing of information by a Federal agency to the Commission shall not be considered a waiver of any exemption available to the agency under section 552 of title 5, United States Code.

“(C) INFORMATION TO BE KEPT CONFIDENTIAL.—

“(i) IN GENERAL.—For purposes of section 1905 of title 18, United States Code—

“(I) the Commission shall be considered an agency of the Federal Government; and

“(II) any individual employed by an individual, entity, or organization that is a party to a contract with the Commission under this section shall be considered an employee of the Commission.

“(ii) PROHIBITION ON DISCLOSURE.—Information obtained by the Commission, other than information that is available to the public, shall not be disclosed to any person in any manner except to an employee of the Commission as described in clause (i), for the purpose of receiving, reviewing, or processing the information.

“(d) COMMISSION PERSONNEL MATTERS.—

“(1) MEMBERS.—

“(A) COMPENSATION.—A member of the Commission shall serve without compensation for the services of the member on the Commission.

“(B) TRAVEL EXPENSES.—A member of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an executive director and such other additional personnel as are necessary to enable the Commission to perform the duties of the Commission.

“(2) STAFF.—

“(A) IN GENERAL.—The Chairperson of the Commission may, without regard to the civil service laws (including regulations), appoint and terminate the appointment of an executive director and such other additional personnel as are necessary to enable the Commission to perform the duties of the Commission.

“(B) CONFIRMATION OF EXECUTIVE DIRECTOR.—The employment of an executive director shall be subject to confirmation by the Commission.

“(C) COMPENSATION.—

“(i) IN GENERAL.—Except as provided in clause (ii), the Chairperson of the Commission may fix the compensation of the executive director and other personnel without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, relating to classification of positions and General Schedule pay rates.

“(ii) MAXIMUM RATE OF PAY.—The rate of pay for the executive director and other personnel shall not exceed the rate payable for level II of the Executive Schedule under section 5316 of title 5, United States Code.

“(3) DETAIL OF FEDERAL GOVERNMENT EMPLOYEES.—

“(A) IN GENERAL.—An employee of the Federal Government may be detailed to the Commission, without reimbursement, for such period of time as is permitted by law.

“(B) CIVIL SERVICE STATUS.—The detail of the employee shall be without interruption or loss of civil service status or privilege.

“(4) PROCUREMENT OF TEMPORARY AND INTERMITTENT SERVICES.—The Chairperson of the Commission may procure temporary and intermittent services in accordance with section 3109(b) of title 5, United States Code, at rates for individuals that do not exceed the daily equivalent of the annual rate of basic pay prescribed for level II of the Executive Schedule under section 5316 of that title.

“(e) AUTHORIZATION OF APPROPRIATIONS.—

“(1) IN GENERAL.—There is authorized to be appropriated such sums as are necessary to carry out this section.

“(2) LIMITATION.—No payment may be made under subsection (d) except to the extent provided for in advance in an appropriations Act.

“(f) TERMINATION.—The Commission shall terminate on the date that is 60 days after the date on which the Commission submits the recommendations and report under subsection (b)(3).”

EX. ORD. NO. 13100. PRESIDENT'S COUNCIL ON FOOD SAFETY

Ex. Ord. No. 13100, Aug. 25, 1998, 63 F.R. 45661, as amended by Ex. Ord. No. 13286, §16, Feb. 28, 2003, 68 F.R. 10623, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

SECTION 1. *Establishment of President's Council on Food Safety.* (a) There is established the President's Council on Food Safety (“Council”). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, and Homeland Security, the Director of the Office of Management and Budget (OMB), the Administrator of the Environmental Protection Agency, the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, the Assistant to the President for Domestic Policy, and the Director of the National Partnership for Reinventing Government. The Council shall consult with other Federal agencies and State, local, and tribal government agencies, and consumer, producer, scientific, and industry groups, as appropriate.

(b) The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy shall serve as Joint Chairs of the Council.

SEC. 2. *Purpose.* The purpose of the Council shall be to develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report “Ensuring Safe Food from Production to Consumption” and other input from the public on how to improve the effectiveness of the current food safety system. The Council shall make recommendations to the President on how to advance Federal efforts to im-

plement a comprehensive science-based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety.

SEC. 3. *Specific Activities and Functions.* (a) The Council shall develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science-based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short-term and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council shall consult with all interested parties, including State and local agencies, tribes, consumers, producers, industry, and academia.

(b) Consistent with the comprehensive strategic Federal food safety plan described in section 3(a) of this order, the Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sustain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food safety. The Council shall also ensure that Federal agencies annually develop a unified budget for submission to the OMB for the President's Food Safety Initiative and such other food safety issues as the Council determines appropriate.

(c) The Council shall ensure that the Joint Institute for Food Safety Research (JIFSR), in consultation with the National Science and Technology Council, establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs. The JIFSR shall report to the Council on a regular basis on its efforts: (i) to develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative and such other food safety activities as the JIFSR determines appropriate; and (ii) to coordinate efficiently, within the executive branch and with the private sector and academia, all Federal food safety research.

SEC. 4. *Cooperation.* All actions taken by the Council shall, as appropriate, promote partnerships and cooperation with States, tribes, and other public and private sector efforts wherever possible to improve the safety of the food supply.

SEC. 5. *General Provisions.* This order is intended only to improve the internal management of the executive branch and is not intended to, nor does it, create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. Nothing in this order shall affect or alter the statutory responsibilities of any Federal agency charged with food safety responsibilities.

§ 342. Adulterated food

A food shall be deemed to be adulterated—

(a) **Poisonous, insanitary, etc., ingredients**

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.¹ (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a sub-

stance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) **Absence, substitution, or addition of constituents**

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) **Color additives**

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

(d) **Confectionery containing alcohol or non-nutritive substance**

If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall

¹ So in original. The period probably should be “; or”.