Public Law 95-203
95th Congress

An Act

Nov. 23, 1977
[S. 1750]

To require studies concerning carcinogenic and other toxic substances in food, the regulation of such food, the impurities in and toxicity of saccharin, and the health benefits, if any, resulting from the use of nonnutritive sweeteners; to prohibit for 18 months the Secretary of Health, Education, and Welfare from taking certain action restricting the continued use of saccharin as a food, drug, and cosmetic; to require certain labels and notices for foods containing saccharin; and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Saccharin Study and Labeling Act.
21 USC 301 note.

SECTION 1. This Act may be cited as the "Saccharin Study and Labeling Act".

Study.
21 USC 343 note.

SEC. 2. (a)(1) The Secretary of Health, Education, and Welfare (hereinafter in this Act referred to as the "Secretary") shall arrange, in accordance with subsection (b), for the conduct of a study, based on available information, of—

(A) current technical capabilities to predict the direct or secondary carcinogenicity or other toxicity in humans of substances which are added to, become a part of, or naturally occur in, food and which have been found to cause cancer in animals;

(B) the direct and indirect health benefits and risks to individuals from foods which contain carcinogenic or other toxic substances;

(C) the existing means of evaluating the risks to health from the carcinogenicity or other toxicity of such substances, the existing means of evaluating the health benefits of foods containing such substances, and the existing statutory authority for, and appropriateness of, weighing such risks against such benefits;

(D) instances in which requirements to restrict or prohibit the use of such substances do not accord with the relationship between such risks and benefits; and

(E) the relationship between existing Federal food regulatory policy and existing Federal regulatory policy applicable to carcinogenic and other toxic substances used as other than foods.

(2) The Secretary shall arrange, in accordance with subsection (b), for the conduct of a study to determine, to the extent feasible—

(A) the chemical identity of any impurities contained in commercially used saccharin,

(B) the toxicity or potential toxicity of any such impurities, including their carcinogenicity or potential carcinogenicity in humans, and

(C) the health benefits, if any, to humans resulting from the use of nonnutritive sweeteners in general and saccharin in particular.

National Academy of Sciences, conduct of studies.

(b)(1) The Secretary shall first request the National Academy of Sciences (hereinafter in this section referred to as the "Academy"), acting through appropriate units, to conduct the studies, required by subsection (a), under an arrangement whereby the actual expenses incurred by the Academy directly related to the conduct of such studies will be paid by the Secretary. If the Academy agrees to such request, the Secretary shall enter into such an agreement with the Academy.

Agreement.

(2) If the Academy declines the Secretary's request to conduct any such study under such an arrangement, then the Secretary shall enter into a similar arrangement with another appropriate public or nonprofit private entity to conduct such study.

(3) Any arrangement entered into under paragraph (1) or (2) of this subsection for the conduct of a study shall require that such study be completed and reports thereon be submitted within such period as the Secretary may require to meet the requirements of subsection (c).

Reports to congressional committees.

(c)(1) Within 12 months of the date of the enactment of this Act the Secretary shall report to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives (A) the results of the study conducted pursuant to subsection (a)(2) (including supporting data and other materials provided by the entity which conducted the study), and (B) any action proposed to be taken on the basis of the results of the study.

(2) Within 15 months of the date of the enactment of this Act the Secretary shall report to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives (A) the results of the studies (including supporting data and other materials provided by the entity which conducted the study) conducted pursuant to subsection (a)(1), (B) the recommendations, if any, of such entity for legislative and administrative action, and (C) such recommendations for legislative action as the Secretary deems necessary.

"Saccharin."

(d) For purposes of this section and section 3, the term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

21 USC 348 note.

SEC. 3. During the 18-month period beginning on the date of the enactment of this Act, the Secretary—

(1) may not amend or revoke the interim food additive regulation of the Food and Drug Administration of the Department of Health, Education, and Welfare applicable to saccharin and published on March 15, 1977 (section 180.37 of part 180, subchapter B, chapter 1, title 21, Code of Federal Regulations (42 Fed. Reg. 14638)), or

(2) may, except as provided in section 4 and the amendments made by such section, not take any other action under the Federal Food, Drug, and Cosmetic Act to prohibit or restrict the sale or distribution of saccharin, any food permitted by such interim food additive regulation to contain saccharin, or any drug or cosmetic containing saccharin,

21 USC 301.

solely on the basis of the carcinogenic or other toxic effect of saccharin as determined by any study made available to the Secretary before the date of the enactment of this Act which involved human studies or animal testing, or both.

Labeling.
21 USC 343.

SEC. 4. (a)(1) Section 403 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new paragraph:

"(o)(1) If it contains saccharin, unless, except as provided in subparagraph (2), its label and labeling bear the following statement: 'USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS'. Such statement shall be located in a conspicuous place on such label and labeling as proximate as possible to the name of such food and shall appear in conspicuous and legible type in con-

trast by typography, layout, and color with other printed matter on such label and labeling.

"(2) The Secretary may by regulation review and revise or remove the requirement of subparagraph (1) if the Secretary determines such action is necessary to reflect the current state of knowledge concerning saccharin.". Regulation.

(2) The amendment made by paragraph (1) shall apply only with respect to food introduced or delivered for introduction in interstate commerce on and after the 90th day after the date of the enactment of this Act. Effective date. 21 USC 343 note.

(3) The Secretary shall report to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives any action taken under section 403(o)(2) of the Federal Food, Drug, and Cosmetic Act. Report to congressional committees. 21 USC 343 note. *Supra.*

(b)(1) Section 403 of the Federal Food, Drug, and Cosmetic Act is amended by adding after paragraph (o) the following new paragraph: Retail establishments, notice, display. 21 USC 343.

"(p)(1) If it contains saccharin and is offered for sale, but not for immediate consumption, at a retail establishment, unless such retail establishment displays prominently, where such food is held for sale, notice (provided by the manufacturer of such food pursuant to subparagraph (2)) for consumers respecting the information required by paragraph (o) to be on food labels and labeling.

"(2) Each manufacturer of food which contains saccharin and which is offered for sale by retail establishments but not for immediate consumption shall, in accordance with regulations promulgated by the Secretary pursuant to subparagraph (4), take such action as may be necessary to provide such retail establishments with the notice required by subparagraph (1).

"(3) The Secretary may by regulation review and revise or remove the requirement of subparagraph (1) if he determines such action is necessary to reflect the current state of knowledge concerning saccharin. Notice requirement, review, revision or removal.

"(4) The Secretary shall by regulation prescribe the form, text, and manner of display of the notice required by subparagraph (1) and such other matters as may be required for the implementation of the requirements of that subparagraph and subparagraph (2). Regulations of the Secretary under this subparagraph shall be promulgated after an oral hearing but without regard to the National Environmental Policy Act of 1969 and chapter 5 of title 5, United States Code. In any action brought for judicial review of any such regulation, the reviewing court may not postpone the effective date of such regulation.". Hearing. 42 USC 4321 note. 5 USC 500 *et seq.* Judicial review.

(2) The amendment made by paragraph (1) shall apply with respect to food which is sold in retail establishments on or after the 90th day after the effective date of the regulations of the Secretary of Health, Education, and Welfare under paragraph (p)(4) of the Federal Food, Drug, and Cosmetic Act. Effective date. 21 USC 343 note. *Supra.*

(3) Section 201 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following: "Saccharin." 21 USC 321.

"(z) The term 'saccharin' includes calcium saccharin, sodium saccharin, and ammonium saccharin.".

(c) The Secretary may by regulation require vending machines through which food containing saccharin is sold to bear a statement of the risks to health which may be presented by the use of saccharin. A regulation under this subsection shall require such statement to be located in a conspicuous place on such vending machine and as proxi- Vending machines, health risk statement, requirements. 21 USC 343a.

mate as possible to the name of each food containing saccharin which is sold through such machine. Any food containing saccharin which is sold in a vending machine which does not meet any applicable requirement promulgated under this subsection shall, for purposes of the Federal Food, Drug, and Cosmetic Act, be considered a misbranded food.

21 USC 301.

Information, availability and distribution.

(d) The Secretary shall (1) prepare information respecting the nature of the controversy surrounding the use of food containing saccharin, and (2) provide for the distribution of such information for display by retail establishments where such food is sold but not for immediate consumption. The Secretary may review and revise such information if he determines such action is necessary to reflect the current state of knowledge concerning the risks to health presented by the use of saccharin.

SEC. 5. (a) Section 204(d) of the National Research Act (Public Law 93-348) is amended by striking out "36-month period" each place it appears and inserting in lieu thereof "42-month period".

42 USC 289*l*-1 note.

(b) Section 211(b) of such Act is amended by striking out "January 1, 1978" and inserting in lieu thereof "November 1, 1978".

42 USC 218 note.

Approved November 23, 1977.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 95-658 accompanying H.R. 8518 (Comm. on Interstate and Foreign Commerce) and No. 95-810 (Comm. of Conference).

SENATE REPORTS: No. 95-353 (Comm. on Human Resources) and No. 95-369 (Comm. on Commerce, Science, and Transportation).

CONGRESSIONAL RECORD, Vol. 123 (1977):

Sept. 14, 15, considered and passed Senate.

Oct. 17, considered and passed House, amended, in lieu of H.R. 8518.

Nov. 3, House agreed to conference report.

Nov. 4, Senate agreed to conference report.