

Public Law 85-929

AN ACT

September 6, 1958
[H. R. 13254]

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

Food Additives
Amendment of
1958.
52 Stat. 1041.
21 USC 321.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Amendment of 1958".

SEC. 2. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end of such section the following new paragraphs:

Definitions.

"(s) The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

"(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following).

"(t) The term 'safe', as used in paragraph (s) of this section and in section 409, has reference to the health of man or animal."

71 Stat. 441.

Insanitary in-
gredients.
21 USC 342.

SEC. 3. (a) Clause (2) of section 402 (a), as amended, of such Act is amended to read as follows: "(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;"

(b) Section 402 (a), as amended, of such Act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: "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 409."

21 USC 342.

(c) The first sentence of section 406 (a) of such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

21 USC 346.

SEC. 4. Chapter IV of such Act is amended by adding at the end thereof the following new section:

21 USC 341 et seq.

"FOOD ADDITIVES

"Unsafe Food Additives

"SEC. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

"(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

"Petition To Establish Safety

"(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

"(2) Such petition shall, in addition to any explanatory or supporting data, contain—

"(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

"(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

"(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

"(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

"(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

"(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, with-

out disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

“(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

“(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

“Action on the Petition

“(c) (1) The Secretary shall—

“(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

“(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

“(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

“(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

“(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

“(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

“(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

“(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

“(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

“(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

“(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

“(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

“(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

“Regulation Issued on Secretary’s Initiative

“(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

“Publication and Effective Date of Orders

“(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

“Objections and Public Hearing

“(f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

“(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

“(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

“Judicial Review

“(g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place

of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

"(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

"(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.

"(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

"(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

"Amendment or Repeal of Regulations

"(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

"Exemptions for Investigational Use

"(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

21 USC 331.

SEC. 5. Section 301 (j) of such Act is amended by inserting "409," after "404."

Effective dates.

SEC. 6. (a) Except as provided in subsections (b) and (c) of this section, this Act shall take effect on the date of its enactment.

Ante, p. 1784.

(b) Except as provided in subsection (c) of this section, section 3 of this Act shall take effect on the one hundred and eightieth day after the date of enactment of this Act.

(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act shall take effect—

Ante, p. 1784.

(1) either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such additional

period (but not later than two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act becomes effective,

Ante, p. 1785.

whichever date first occurs.

SEC. 7. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following).

71 Stat. 441.

SEC. 8. The annual rate of basic compensation of the Commissioner of Food and Drugs shall be \$20,000.

Compensation of Commissioner.

SEC. 9. Section 208 (g) of the Public Health Service Act, as amended (42 U. S. C. 210 (g)), is amended by striking out the phrase "in the professional and scientific service" and inserting in lieu thereof the phrase "in the professional, scientific, and executive service" and by striking out the phrase "of specially qualified scientific or professional personnel" and inserting in lieu thereof "of specially qualified scientific, professional, and administrative personnel".

69 Stat. 407, 70 Stat. 430, 741.

Approved September 6, 1958.

Public Law 85-930

AN ACT

To extend the Renegotiation Act of 1951 for six months, and for other purposes.

September 6, 1958
[H. R. 11749]

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

SECTION 1. SIX-MONTH EXTENSION.

Section 102 (c) (1) of the Renegotiation Act of 1951, as amended (50 U. S. C., App., sec. 1212 (c) (1)), is amended by striking out "December 31, 1958" and inserting in lieu thereof "June 30, 1959".

Renegotiation Act of 1951, extension.
69 Stat. 447.

SEC. 2. APPLICATION TO NATIONAL AERONAUTICS AND SPACE ADMINISTRATION.

(a) **IN GENERAL.**—Section 103 (a) of the Renegotiation Act of 1951 (50 U. S. C., App., sec. 1213 (a)) is amended by inserting "the National Aeronautics and Space Administration," after "General Services Administration,". Section 103 (b) of such Act is amended by inserting "the Administrator of the National Aeronautics and Space Administration," after "the Administrator of General Services,".

70 Stat. 786.

(b) **EFFECTIVE DATE.**—The amendments made by subsection (a) shall apply only with respect to contracts entered into by the National Aeronautics and Space Administration and to contracts transferred to such Administration from a Department (as defined in section 103 (a) of such Act) under section 301 or section 302 of the National Aeronautics and Space Act of 1958, and to related subcontracts.

Ante, p. 432, 433.

Approved September 6, 1958.