Public Law 86-618

AN ACT

July 12, 1960 [S. 2197]

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

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 "Color Additive Amendments of 1960".

Color Additive Amendments of 1960.

> 5 2 Stat. 1040; 72 Stat. 1784. 21 USC 321.

TITLE I—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

DEFINITIONS

SEC. 101. Section 201, as amended, of the Federal Food, Drug,

and Cosmetic Act is further amended as follows:

(a) Paragraph (s) of such section (defining the term "food additive") is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

"(3) a color additive; or".

(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

"(u) The term 'safe', as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal."

(c) There is inserted, immediately after paragraph (s) of such sec-

tion, the following new paragraph:

"(t) (1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color

thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely

for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays.
"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

COLORS OR COLORED ARTICLES—WHEN DEEMED TO BE ADULTERATED OR MISBRANDED FOODS, DRUGS, OR COSMETICS

Food

Sec. 102. (a) (1) Clause (2) (A) of section 402(a), as amended, of such Act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than

52 Stat. 1040. 21 USC 342.

[74 STAT.

one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive".

52 Stat. 1046. 21 USC 342. (2) Section 402(c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

52 Stat. 1058. 21 USC 376. "(c) If it is, or it bears or contains, a color additive which is unsafe

within the meaning of section 706(a)."

(3) Section 403 of such Act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Drugs

52 Stat. 1049. 21 USC 351. (b) (1) Clause (4) of section 501(a) of such Act (relating to drugs deemed adulterated by reason of uncertified coal tar color) is amended to read as follows: "(4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a)."

52 Stat. 1050. 21 USC 352.

21 USC 376.

(2) Section 502 of such Act (relating to the circumstances under which drugs are deemed misbranded) is amended by adding at the

end thereof the following new paragraph:

"(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 706."

Cosmetics

52 Stat. 1054. 21 USC 361.

21 USC 376.

21 USC 362.

(c) (1) Section 601(e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal tar color) is amended to read as follows:

"(e) If it is not a hair dye and it is, or it bears or contains, a color

additive which is unsafe within the meaning of section 706(a)."

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by

adding at the end thereof the following new paragraph:

"(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a))."

REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

Sec. 103. (a) Such Act is further amended by—

(1) repealing subsection (b) of section 406 and striking out the subsection designation "(a)" after "Sec. 406." in such section;

(2) repealing section 504;(3) repealing section 604; and

(4) amending section 701(e) by (A) striking out "406 (a) or

21 USC 346.

21 USC 354.

21 USC 354. 21 USC 364.

21 USC 371.

(b)" and inserting in lieu thereof "406"; (B) striking out "504, or 604,"; and (C) inserting the word "or" after "501(b),". (b) Section 706 of such Act is amended to read as follows:

52 Stat. 1058. 21 USC 376.

"LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

"When Color Additives Deemed Unsafe

"Sec. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 1049, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 1054, 10

501(a)(4), or section 601(e), as the case may be, unless-

"(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

"(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f)

of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

"Listing of Colors

"(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

"(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be em-

ployed for such general use.

"(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use

or uses for which it is suitable and may safely be employed.

"(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive

21 USC 342, 361.

21 USC 321.

may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: Provided, however, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

"(5)(A) In determining, for the purposes of this section, whether

a proposed use of a color additive is safe, the Secretary shall consider,

among other relevant factors-

"(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food,

drugs, or cosmetics because of the use of the additive;

"(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dve and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such

article because of the use of such additive.

"(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

"(C) (i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof

21 USC 371.

and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or

proposal.

"(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

"(iii) Where—

"(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

"(II) a request has been made for referral of such proposal to

an advisory committee:

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

"(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the

procedure to be followed by the committee.

"(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration

within the meaning of this Act.

"(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

"(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

"(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

"(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

"Certification of Colors

"(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement pot to be necessary in the interest of the protection of the public health: Provided, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

"Procedure for Issuance, Amendment, or Repeal of Regulations

"(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b) (5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

"(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior

52 Stat. 1055. 21 USC 371. referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, 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;

"(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b) (5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

"(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject

to the requirements of section 409(f)(2); and

"(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

60 Stat. 241.

72 Stat. 1787. 21 USC 348.

72 Stat. 1788. 21 USC 348.

"Fees

"(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

"Exemptions

"(f) The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic 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."

CONFIDENTIALITY OF TRADE SECRETS

Sec. 104. Section 301(j), as amended, of such Act, prohibiting disclosure of trade secrets, is amended by striking out "or 704" and inserting in lieu thereof "704, or 706".

52 Stat. 1042. 21 USC 331.

CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

Sec. 105. Such Act is further amended by-

(a) striking out, in section 301(i) thereof (relating to forgery or unauthorized use of certain identification devices), "404, 406 (b), 504, 506, 507, or 604", and inserting in lieu thereof "404,

506, 507, or 706";

(b) (1) striking out, in clause (3) of section 303(c) (relating to color manufacturer's guarantee), the word "coal-tar" wherever it appears in such clause, and (2) inserting after the word

52 Stat. 1042. 21 USC 331.

52 Stat. 1043. 21 USC 333. "color", wherever it appears in such clause, the word "additive";

52 Stat. 1047. 21 USC 342.

(c) striking out "harmless coloring" in section 402(d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

TITLE II-EFFECTIVE DATE, TRANSITIONAL PROVI-SIONS, AND EFFECT ON OTHER LAWS

DEFINITIONS

52 Stat. 1040. 21 USC 301.

SEC. 201. As used in this title, the term "basic Act" means the Federal Food, Drug, and Cosmetic Act; the term "enactment date" means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

EFFECTIVE DATE

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

PROVISIONAL LISTINGS OF COMMERCIALLY ESTABLISHED COLORS

Sec. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

52 Stat. 1058.

(2) For the purposes of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

(b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date, and

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date, was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date, be deemed to be provisionally

listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

(d) (1) The Secretary shall, by regulations issued or amended from

time to time under this section-

(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

(B) provide for the provisional listing of the color additives

and particular uses thereof specified in subsection (c);

(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act;

(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b) (2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is neces-

sary to protect the public health.

(2) (A) Except as provided in subparagraph (C) of this paragraph, regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act, but for the purposes of the application of section 706(e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits

5 2 Stat. 1049, 1052, 1055, 1047. 21 USC 346, 354, 364, 342.

> 52 Stat. 1058. 21 USC 376.

to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act, shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended.

(B) If the Secretary, by regulation-

(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant

to paragraph (1) (E) of this subsection; or

(ii) has, pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing)

which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a)(2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally

or in writing, act upon such proposal by published order.

(C) Any person adversely affected by an order entered under sub-paragraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

(D) On and after the enactment date, regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 of the basic Act.

52 Stat. 1055. 21 USC 371.

A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706 (b) or (c) of the basic Act.

(3) For the purpose of enabling the Secretary to carry out his functions under paragraphs (1) (A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act, afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1) (A), or for determining the prevailing level or levels of use thereof prior to the enactment date with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1) (C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS INSPECTION ACTS

Sec. 204. Nothing in this Act shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following), or the Poultry Products Inspection Act (21 U.S.C. 451 and the following). Approved July 12, 1960.

71 Stat. 441.

Public Law 86-619

AN ACT

To make uniform provisions of law with respect to the terms of office of the members of certain regulatory agencies.

July 12, 1960 [S. 1965]

Regulatory agen-

cies.
Terms of office

of members. 46 Stat. 797.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the second sentence of the first section of the Federal Power Act (16 U.S.C. 792) is amended to read as follows: "Their successors shall be appointed each for a term of five years from the date of the expiration of the term for which his predecessor was appointed and until his successor is appointed and has qualified, except that he shall not so continue to serve beyond the expiration of the next session of Congress subsequent to the expiration of said fixed term of office, and except that any person appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the unexpired term."

Sec. 2. The first sentence of subsection (c) of section 4 of the Communications Act of 1934 (47 U.S.C. 154(b)) is amended to read as follows: "The Commissioners first appointed under this Act shall continue in office for the terms of one, two, three, four, five, six, and seven years, respectively, from the date of the taking effect of this Act, the term of each to be designated by the President, but their successors shall be appointed for terms of seven years and until their successors are appointed and have qualified, except that they shall not continue to serve beyond the expiration of the next session of Congress subsequent to the expiration of said fixed term of office; except that any person chosen to fill a vacancy shall be appointed only for the unexpired term of the Commissioner whom he succeeds."

48 Stat. 1067.