

(Mar. 16, 1950, ch. 61, §3(a), 64 Stat. 20.)

CODIFICATION

Section was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

EFFECTIVE DATE

Section effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as a note under section 347 of this title.

**§ 347b. Contravention of State laws**

Nothing in this Act shall be construed as authorizing the possession, sale, or serving of colored oleomargarine or colored margarine in any State or Territory in contravention of the laws of such State or Territory.

(Mar. 16, 1950, ch. 61, §6, 64 Stat. 22.)

REFERENCES IN TEXT

This Act, referred to in text, is act Mar. 16, 1950, ch. 61, 64 Stat. 20, which is classified to sections 331, 342, 347 to 347b of this title, and sections 45 and 55 of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Tables.

CODIFICATION

Section was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

EFFECTIVE DATE

Section effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as a note under section 347 of this title.

**§ 348. Food additives**

**(a) Unsafe food additives; exception for conformity with exemption or regulation**

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 342(a) of this title, unless—

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

(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; or

(3) in the case of a food additive as defined in this chapter that is a food contact substance, there is—

(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

(B) a notification submitted under subsection (h) of this section that is effective.

While such a regulation relating to a food additive, or such a notification under subsection (h)(1) of this section relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i) of this section, a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 342(a)(1) of this title.

**(b) Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation**

(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, without 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.

**(c) Approval or denial of petition; time for issuance of order; evaluation of data; factors**

(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