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# 21 U.S. Code § 348

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## Food additives

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### **(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) that is effective.

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under subsection (h)(1) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be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

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