

E, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the notice of filing.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977; 42 FR 55207, Oct. 10, 1977; 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 54 FR 18281, Apr. 28, 1989; 62 FR 40600, July 29, 1997]

**§ 570.38 Determination of food additive status.**

(a) The Commissioner may, in accordance with § 570.35 (b)(4) or (c)(5), publish a notice in the FEDERAL REGISTER determining that a substance is not GRAS and is a food additive subject to section 409 of the act.

(b)(1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the act. Any petition shall include all relevant data and information of the type described in § 571.130(b) of this chapter. The Commissioner will place all of the data and information on which he relies on public file in the Dockets Management Branch and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Dockets Management Branch. Copies of all comments shall be made available for examination in the Dockets Management Branch.

(3) The Commissioner will evaluate all comments received. If he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the act, he will publish a notice thereof in the FEDERAL REGISTER. If he concludes that there is convincing evidence that the substance is GRAS, he will publish an order in the FEDERAL REGISTER listing the substance in this subchapter E as GRAS.

(c) A FEDERAL REGISTER notice determining that a substance is a food additive shall provide for the use of the additive in food or food-contact surfaces as follows:

(1) It may promulgate a food additive regulation governing use of the additive.

(2) It may promulgate an interim food additive regulation governing use of the additive.

(3) It may require discontinuation of the use of the additive.

(4) It may adopt any combination of the above three approaches for different uses or levels of use of the additive.

(d) If the Commissioner of Food and Drugs is aware of any prior sanction for use of the substance, he will concurrently propose a separate regulation covering such use of the ingredient under this subchapter E. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under this subchapter E., incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977; 42 FR 55207, Oct. 14, 1977; 54 FR 18281, Apr. 28, 1989]

**PART 571—FOOD ADDITIVE PETITIONS**

**Subpart A—General Provisions**

Sec.  
571.1 Petitions.