

Subpart F—Submission of Scientific and Technical Information

§ 177.102 Data and information required to support petition to establish a food additive regulation, to increase a tolerance, or to remove a condition on use.

A petition to establish a food additive regulation, or to modify a food additive regulation by increasing a tolerance for a pesticide residue in or on a processed food or by removing any other condition of use of a food additive, shall include the following data and information:

(a)(1) The name and composition of the food additive that is a subject of the petition, and the chemical composition of each component of the food additive.

(2) The name, chemical identity, and composition of each pesticide residue that is a subject of the petition.

(3) The identity of the processed food(s) in question.

(b) A statement of any conditions of use proposed for the food additive, including all directions, recommendations, and suggestions proposed regarding the use of the food additive, i.e., the amount, frequency, method, and time of application or other use, and a copy of its proposed labeling.

(c) Full reports of investigations made with respect to the toxicity of the food additive and of its safety for the proposed use, including full information as to the methods and controls used in conducting such investigations.

(d) The results of tests to determine the identity and amount of pesticide residues in or on the processed food resulting from the proposed use of the food additive, including a description of the analytical methods used, and a description of practicable methods for measuring such pesticide residues.

(e) Full reports of investigations made with respect to the toxicity of such pesticide residues, including full information as to the methods and controls used in conducting such investigations.

(f) All relevant data bearing on the physical or other technical effects such food additive is intended to produce, and the quantity of such food additive required to produce such effect.

(g) The terms of each food additive regulation proposed.

(h) Any other information relevant to the approval of the petition known to the petitioner that is unfavorable to the petition.

(i) A statement of why, in the petitioner's opinion, it would be reasonable for the Administrator to approve the petition, taking into account the terms of the FFDCA and FIFRA, this part, the petition, the data and information submitted or cited in support of the petition, and other information available to the Agency.

(j) An informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition, and a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice to be furnished to the public under § 177.88 or as part of a proposal under § 177.130. The summary need not refer to any method or process that is entitled to protection as a trade secret under FFDCA section 301(j).

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

§ 177.105 Data and information required to support petition to revoke a food additive regulation, to decrease a tolerance, or to add a condition on use.

A petition to revoke a food additive regulation, or to modify such a regulation by decreasing a tolerance for a pesticide residue in or on a processed food or by adding a condition on the use of a food additive, shall include:

(a) The data and information required by § 177.102(a), (b), (g), (h), and (i).

(b) Such data and information of the types described in § 177.102(c), (d), (e), and (f) as the petitioner chooses to submit.

(c) Information showing what changes, if any, petitioner believes would have to be made in associated registrations of pesticides under FIFRA or in associated tolerance regulations issued under FFDCA section 408 if the petition were granted.

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]