

(c) Any petitioner who has a food additive petition pending before the agency and who subsequently submits a premarket notification for a food contact substance (FCN) for a use or uses described in such petition shall be deemed to have withdrawn the petition for such use or uses without prejudice to a future filing on the date the FCN is received by the Food and Drug Administration.

[42 FR 14489, Mar. 15, 1977, as amended at 67 FR 35731, May 21, 2002]

§ 171.8 Threshold of regulation for substances used in food-contact articles.

Substances used in food-contact articles (e.g., food-packaging or food-processing equipment) that migrate or that may be expected to migrate into food at negligible levels may be reviewed under §170.39 of this chapter. The Food and Drug Administration will exempt substances whose uses it determines meet the criteria in §170.39 of this chapter from regulation as food additives and, therefore, a food additive petition will not be required for the exempted use.

[60 FR 36596, July 17, 1995]

Subpart B—Administrative Actions on Applications

§ 171.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409(c)(2) of the Act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that 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 prior to the forwarding of the order to the FEDERAL REGISTER for publication shall notify

the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(b) The regulation shall describe the conditions under which the substance may be safely used in any meat product, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*).

(c) If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

[42 FR 14489, Mar. 15, 1977, as amended at 65 FR 51763, Aug. 25, 2000]

§ 171.102 Effective date of regulation.

A regulation published in accordance with §171.100(a) shall become effective upon publication in the FEDERAL REGISTER.

§ 171.110 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409 (c), (d), or (h) of the Act shall be governed by part 12 of this chapter.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977]

§ 171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data

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shall be furnished in the form specified in §§ 171.1 and 171.100 for submitting petitions.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977]

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

Subpart A—General Provisions

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172.5 General provisions for direct food additives.

Subpart B—Food Preservatives

- 172.105 Anoxomer.
- 172.110 BHA.
- 172.115 BHT.
- 172.120 Calcium disodium EDTA.
- 172.130 Dehydroacetic acid.
- 172.133 Dimethyl dicarbonate.
- 172.135 Disodium EDTA.
- 172.140 Ethoxyquin.
- 172.145 Heptylparaben.
- 172.150 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.
- 172.155 Natamycin (pimaricin).
- 172.160 Potassium nitrate.
- 172.165 Quaternary ammonium chloride combination.
- 172.170 Sodium nitrate.
- 172.175 Sodium nitrite.
- 172.177 Sodium nitrite used in processing smoked chub.
- 172.180 Stannous chloride.
- 172.185 TBHQ.
- 172.190 THBP.

Subpart C—Coatings, Films and Related Substances

- 172.210 Coatings on fresh citrus fruit.
- 172.215 Coumarone-indene resin.
- 172.225 Methyl and ethyl esters of fatty acids produced from edible fats and oils.
- 172.230 Microcapsules for flavoring substances.
- 172.235 Morpholine.
- 172.250 Petroleum naphtha.
- 172.255 Polyacrylamide.
- 172.260 Oxidized polyethylene.
- 172.270 Sulfated butyl oleate.
- 172.275 Synthetic paraffin and succinic derivatives.
- 172.280 Terpene resin.

Subpart D—Special Dietary and Nutritional Additives

- 172.310 Aluminum nicotinate.
- 172.315 Nicotinamide-ascorbic acid complex.

- 172.320 Amino acids.
- 172.325 Bakers yeast protein.
- 172.330 Calcium pantothenate, calcium chloride double salt.
- 172.335 D-Pantothenamide.
- 172.340 Fish protein isolate.
- 172.345 Folic acid (folacin).
- 172.350 Fumaric acid and salts of fumaric acid.
- 172.365 Kelp.
- 172.370 Iron-choline citrate complex.
- 172.372 N-Acetyl-L-methionine.
- 172.375 Potassium iodide.
- 172.380 Vitamin D₃.
- 172.385 Whole fish protein concentrate.
- 172.395 Xylitol.
- 172.399 Zinc methionine sulfate.

Subpart E—Anticaking Agents

- 172.410 Calcium silicate.
- 172.430 Iron ammonium citrate.
- 172.480 Silicon dioxide.
- 172.490 Yellow prussiate of soda.

Subpart F—Flavoring Agents and Related Substances

- 172.510 Natural flavoring substances and natural substances used in conjunction with flavors.
- 172.515 Synthetic flavoring substances and adjuvants.
- 172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.
- 172.530 Disodium guanylate.
- 172.535 Disodium inosinate.
- 172.540 DL-Alanine.
- 172.560 Modified hop extract.
- 172.575 Quinine.
- 172.580 Safrole-free extract of sassafras.
- 172.585 Sugar beet extract flavor base.
- 172.590 Yeast-malt sprout extract.

Subpart G—Gums, Chewing Gum Bases and Related Substances

- 172.610 Arabinogalactan.
- 172.615 Chewing gum base.
- 172.620 Carrageenan.
- 172.623 Carrageenan with polysorbate 80.
- 172.626 Salts of carrageenan.
- 172.655 Furcelleran.
- 172.660 Salts of furcelleran.
- 172.665 Gellan gum.
- 172.695 Xanthan gum.

Subpart H—Other Specific Usage Additives

- 172.710 Adjuvants for pesticide use dilutions.
- 172.712 1,3-Butylene glycol.
- 172.715 Calcium lignosulfonate.
- 172.720 Calcium lactobionate.
- 172.723 Epoxidized soybean oil.
- 172.725 Gibberellic acid and its potassium salt.
- 172.730 Potassium bromate.