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

(a) A substance used in a food-contact article (e.g., food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if:

(1) The substance has not been shown to be a carcinogen in humans or animals, and there is no reason, based on the chemical structure of the substance, to suspect that the substance is a carcinogen. The substance must also not contain a carcinogenic impurity or, if it does, must not contain a carcinogenic impurity with a TD50 value based on chronic feeding studies reported in the scientific literature or otherwise available to the Food and Drug Administration of less than 6.25 milligrams per kilogram bodyweight per day (The TD50, for the purposes of this section, is the feeding dose that causes cancer in 50 percent of the test animals when corrected for tumors found in control animals. If more than one TD50 value has been reported in the scientific literature for a substance, the Food and Drug Administration will use the lowest appropriate TD50 value in its review.);

(2) The substance presents no other health or safety concerns because:

(i) The use in question has been shown to result in or may be expected to result in dietary concentrations at or below 0.5 parts per billion, corresponding to dietary exposure levels at or below 1.5 micrograms/person/day (based on a diet of 1,500 grams of solid food and 1,500 grams of liquid food per person per day); or

(ii) The substance is currently regulated for direct addition into food, and the dietary exposure to the substance resulting from the proposed use is at or below 1 percent of the acceptable daily intake as determined by safety data in the Food and Drug Administration’s files or from other appropriate sources;

(3) The substance has no technical effect in or on the food to which it migrates; and

(4) The substance use has no significant adverse impact on the environment.

(b) Notwithstanding paragraph (a) of this section, the Food and Drug Administration reserves the right to decline to grant an exemption in those cases in which available information establishes that the proposed use may pose a public health risk. The reasons for the agency’s decision to decline to grant an exemption will be explained in the Food and Drug Administration’s response to the requestor.

(c) A request for the Food and Drug Administration to exempt a use of a substance from regulation as a food additive shall include three copies of the following information (If part of the submitted material is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate in accordance with §10.20(c)(2) of this chapter):

(1) The chemical composition of the substance for which the request is made, including, whenever possible, the name of the chemical in accordance with current Chemical Abstract Service (CAS) nomenclature guidelines and a CAS registry number, if available;

(2) Detailed information on the conditions of use of the substance (e.g., temperature, type of food with which the substance will come into contact, the duration of the contact, and whether the food-contact article will be for repeated or single use applications);

(3) A clear statement as to whether the request for exemption from regulation as a food additive is based on the fact that the use of the substance in the food-contact article results in a dietary concentration at or below 0.5 parts per billion, or on the fact that it involves the use of a regulated direct food additive for which the dietary exposure is at or below 1 percent of the acceptable dietary intake (ADI);

(4) Data that will enable the Food and Drug Administration to estimate
the daily dietary concentration resulting from the proposed use of the substance. These data should be in the form of:

(i) Validated migration data obtained under worst-case (time/temperature) intended use conditions utilizing appropriate food simulating solvents;

(ii) Information on the amount of the substance used in the manufacture of the food-contact article; or

(iii) Information on the residual level of the substance in the food-contact article. For repeat-use articles, an estimate of the amount of food that contacts a specific unit of surface area over the lifetime of the article should also be provided. (In cases where data are provided only in the form of manufacturing use levels or residual levels of the substance present in the food-contact article, the Food and Drug Administration will calculate a worst-case dietary concentration level assuming 100 percent migration.) A detailed description of the analytical method used to quantify the substance should also be submitted along with data used to validate the detection limit.

(iv) In cases where there is no detectable migration into food or food simulants, or when no residual level of a substance is detected in the food-contact article by a suitable analytical method, the Food and Drug Administration will use the validated detection limit of the method used to analyze for the substance.

(5) The results of an analysis of existing toxicological information on the substance and its impurities. This information on the substance is needed to show whether an animal carcinogen bioassay has been carried out, or whether there is some other basis for suspecting that the substance is a carcinogen or potent toxin. This type of information on the impurities is needed to show whether any of them are carcinogenic, and, if carcinogenic, whether their TD50 values are greater than 6.25 milligrams per kilogram bodyweight per day in accordance with paragraph (a)(1) of this section.

(6) Information on the environmental impact that would result from the proposed use of the substance. The request should contain either a claim for categorical exclusion as specified in §25.32 of this chapter or an environmental assessment as specified in §25.40 of this chapter.

(d) Data to be reviewed under this section shall be submitted to the Food and Drug Administration’s Office of Premarket Approval (HFS–200), 5100 Paint Branch Pkwy., College Park, MD 20740.

(e) The Food and Drug Administration will inform the requestor by letter whether the specific food-contact application is exempt from regulation as a food additive or not. Although a substance that migrates to food at a level that results in a dietary concentration at or below the threshold of regulation will not be the subject of a regulation published in the Federal Register and will not appear in the Code of Federal Regulations, the Food and Drug Administration will maintain a list of substances exempted from regulation as food additives under this section on display at the Division of Dockets Management. This list will include the name of the company that made the request, the chemical name of the substance, the specific use for which it has received an exemption from regulation as a food additive, and any appropriate limitations on its use. The list will not include any trade names. This list will enable interested persons to see the types of uses of food-contact materials being exempted under the regulation. Interested persons may also obtain a copy of the list of exempted substances by contacting the Food and Drug Administration’s Office of Premarket Approval (HFS–200), 5100 Paint Branch Pkwy., College Park, MD 20740. For actions requiring an environmental assessment, the agency’s finding of no significant impact and the evidence supporting that finding, contained in the petitioner’s environmental assessment, also will be available for public inspection at the Division of Dockets Management in accordance with §25.51(b)(2) of this chapter. Requests for copies of releasable information contained in submissions requesting exemptions from the food additive regulations will be handled in accordance
§ 170.45 Fluorine-containing compounds.

The Commissioner of Food and Drugs has concluded that it is in the interest of the public health to limit the addition of fluorine compounds to foods (a) to that resulting from the fluoridation of public water supplies, (b) to that resulting from the fluoridation of bottled water within the limitation established in §165.110(d) of this chapter, and (c) to that authorized by regulations (40 CFR part 180) under section 408 of the Act.

[42 FR 14483, Mar. 15, 1977, as amended at 72 FR 10357 Mar. 8, 2007]

§ 170.50 Glycine (aminoacetic acid) in food for human consumption.

(a) Heretofore, the Food and Drug Administration has expressed the opinion in trade correspondence that glycine is generally recognized as safe for certain technical effects in human food when used in accordance with good manufacturing practice; however: