

(1) Reports in scientific literature indicate that adverse effects were found in cases where high levels of glycine were administered in diets of experimental animals.

(2) Current usage information indicates that the daily dietary intake of glycine by humans may be substantially increasing due to changing use patterns in food technology.

Therefore, the Food and Drug Administration no longer regards glycine and its salts as generally recognized as safe for use in human food and all outstanding letters expressing sanction for such use are rescinded.

(b) The Commissioner of Food and Drugs concludes that by May 8, 1971, manufacturers:

(1) Shall reformulate food products for human use to eliminate added glycine and its salts; or

(2) Shall bring such products into compliance with an authorizing food additive regulation. A food additive petition supported by toxicity data is required to show that any proposed level of glycine or its salts added to foods for human consumption will be safe.

(c) The status of glycine as generally recognized as safe for use in animal feed, as prescribed in §582.5049 of this chapter, remains unchanged because the additive is considered an essential nutrient in certain animal feeds and is safe for such use under conditions of good feeding practice.

**§ 170.60 Nitrites and/or nitrates in curing premixes.**

(a) Nitrites and/or nitrates are food additives when combined in curing premixes with spices and/or other flavoring or seasoning ingredients that contain or constitute a source of secondary or tertiary amines, including but not limited to essential oils, disodium inosinate, disodium guanylate, hydrolysates of animal or plant origin (such as hydrolyzed vegetable protein), oleoresins of spices, soy products, and spice extractives. Such food additives may be used only after the establishment of an authorizing food additive regulation. A food additive petition submitted pursuant to §§171.1 and 171.100 of this chapter, supported by data demonstrating that nitrosamines are not formed in curing premixes con-

taining such food additives, is required to establish safety.

(b) Nitrites and/or nitrates, when packaged separately from flavoring and seasoning in curing premixes, may continue to be used under prior sanctions in the commercial curing of meat and meat products and poultry products and in accordance with the provisions of §§172.170 and 172.175 of this chapter that apply to meat curing preparations for the home curing of meat and meat products, including poultry and wild game. To assure safe use of such ingredients the labeling of the premixes shall bear instructions to the user that such separately packaged ingredients are not to be combined until just prior to use. Encapsulating or coating some or all of the ingredients does not constitute separate packaging.

**Subpart D—Premarket Notifications**

SOURCE: 67 FR 35729, May 21, 2002, unless otherwise noted.

**§ 170.100 Submission of a premarket notification for a food contact substance (FCN) to the Food and Drug Administration (FDA).**

(a) An FCN is effective for the food contact substance manufactured or prepared by the manufacturer or supplier identified in the FCN submission. If another manufacturer or supplier wishes to market the same food contact substance for the same use, that manufacturer or supplier must also submit an FCN to FDA.

(1) An FCN must contain all of the information described in §170.101.

(2) An FCN may incorporate by reference any information in FDA's files provided that the manufacturer or supplier is authorized to reference the information. The FCN must include information establishing that the manufacturer or supplier is authorized to reference information in FDA's files.

(3) Any material submitted in or referenced by an FCN that is in a foreign language must be accompanied by an English translation verified to be complete and accurate.

(b) FDA may choose not to accept an FCN for either of the following:

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(1) A use of a food contact substance that is the subject of a regulation in parts 173 through 189 of this chapter; or

(2) A use of a food contact substance that is the subject of an exemption under the threshold of regulation process described in §170.39.

(c) A petition must be submitted under §171.1 of this chapter to authorize the safe use of a food contact substance in either of the following circumstances, unless FDA agrees to accept an FCN for the proposed use.

(1) The use of the food contact substance increases the cumulative dietary concentration to a certain level. For a substance that is a biocide (e.g., it is intended to exert microbial toxicity), this level is equal to or greater than 200 parts per billion in the daily diet (0.6 milligram (mg)/person/day). For a substance that is not a biocide, this level is equal to or greater than 1 part per million in the daily diet (3 mg/person/day); or

(2) There exists a bioassay on the food contact substance, FDA has not reviewed the bioassay, and the bioassay is not clearly negative for carcinogenic effects.

(d) A manufacturer or supplier for which a notification is effective must keep a current address on file with FDA.

(1) The current address may be either the manufacturer's (or supplier's) address or the address of the manufacturer's (or supplier's) agent.

(2) FDA will deliver correspondence to the manufacturer's or supplier's current address.

### **§ 170.101 Information in a premarket notification for a food contact substance (FCN).**

An FCN must contain the following:

(a) A comprehensive discussion of the basis for the manufacturer's or supplier's determination that the use of the food contact substance is safe. This discussion must:

(1) Discuss all information and data submitted in the notification; and

(2) Address any information and data that may appear to be inconsistent with the determination that the proposed use of the food contact substance is safe.

(b) All data and other information that form the basis of the determination that the food contact substance is safe under the intended conditions of use. Data must include primary biological data and chemical data.

(c) A good laboratory practice statement for each nonclinical laboratory study, as defined under §58.3(d) of this chapter, that is submitted as part of the FCN, in the form of either:

(1) A signed statement that the study was conducted in compliance with the good laboratory practice regulations under part 58 of this chapter; or

(2) A brief signed statement listing the reason(s) that the study was not conducted in compliance with part 58 of this chapter.

(3) Data from any study conducted after 1978 but not conducted in compliance with part 58 of this chapter must be validated by an independent third party prior to submission to the Food and Drug Administration (FDA), and the report and signed certification of the validating party must be submitted as part of the notification.

(d) Information to address FDA's responsibility under the National Environmental Policy Act, in the form of either:

(1) A claim of categorical exclusion under §25.30 or §25.32 of this chapter; or

(2) An environmental assessment complying with §25.40 of this chapter.

(e) A completed and signed FDA Form No. 3480.

### **§ 170.102 Confidentiality of information in a premarket notification for a food contact substance (FCN).**

(a) During the 120-day period of the Food and Drug Administration (FDA) review of an FCN, FDA will not disclose publicly any information in that FCN.

(b) FDA will not disclose publicly the information in an FCN that is withdrawn prior to the completion of FDA's review.

(c) Once FDA completes its review of an FCN, the agency will make its conclusion about the FCN publicly available. For example, if FDA objects to a notification 90 days after the date of receipt, the agency would make available its objection at that time.