food additive (e.g., a substance approved for use as a stabilizer and thickener in food would be allowed to be used as a stabilizer and thickener in the manufacture of food-contact articles). The comment cited FDA's approach to handling generally recognized as safe (GRAS) substances as a precedent for this approach. Under 21 CFR 186.1(a), ingredients affirmed as GRAS for direct use in part 184 (21 CFR part 184) are also affirmed as GRAS for use as indirect human food ingredients in accordance with § 184.1(a).

The agency notes that the issue raised by this comment is outside the scope of the proposed threshold of regulation process. The comment is about whether the uses in question should be approved as food additive uses, not about whether they should be exempted from regulation under the food additive provisions of the act.

Although outside the scope of this rulemaking, FDA would like to comment on the merits of the approach recommended in this comment because the agency is always interested in evaluating ways that may help it to more effectively implement the food additive provisions of the act. FDA's main concern with the recommended approach is that those direct food additives that are regulated without specific use level limitations, and which meet the other restrictions specified in this comment, could be used as components of food-contact articles without any further safety review by FDA. Although it is true that the dietary exposure resulting from the use of a substance added directly to food is usually much higher than that resulting from the use of that substance as a component of a food-contact article, the existing safety data in FDA files used to support the direct additive use may not always be adequate to support even a modest increase in the dietary exposure resulting from its use as an indirect food additive.

Some direct food additives have been regulated for uses in which only a narrow margin exists between the cumulative estimated dietary exposure and the acceptable dietary exposure. Many other direct additives have been regulated for uses for which, initially, the margin between the estimated daily intake and the ADI was reasonably broad, but as the substance has been subsequently regulated for other uses, the margin has become quite narrow. Because existing safety data may not be adequate to support the use of direct additives as components of food-contact articles in all cases, such uses must be evaluated on a case by case basis, either as the subject of a food additive petition (if the dietary exposure is likely to be greater than 1 percent of the ADI) or as a request for an exemption from regulation (if the dietary exposure is likely to be below the 1-percent ADI threshold of regulatory concern).

Another agency concern with the recommended approach is that some of the direct food additives may also have been regulated at a time when FDA did not conduct reviews on the possible environmental effects resulting from such uses. (FDA regulations for considering the environmental effect of its actions in accordance with the National Environmental Policy Act (NEPA) were established on March 15, 1973.) It may be possible that the manufacture, use, and disposal of food-contact articles containing regulated direct food additives may have an adverse impact on the environment. Therefore, the potential environmental effects resulting from the intended use of a direct food additive in a food-contact article need to be evaluated by FDA either as part of a review of a petition or as part of a review of an exemption from regulation request. Further discussion of this issue is found later in this final rule in the agency's response to comments 28 and 29.

For the reasons listed above, FDA has concluded that the use of a regulated direct food additive in a food-contact article should either be the subject of a specific food additive regulation authorizing such use or be exempted from regulation as a food additive by FDA under the procedures specified in this final rule. Application of the Food Additive Definition

12. Two comments expressed the opinion that the *Monsanto* decision gives FDA the flexibility to consider those substances migrating out of food-contact articles in trivial amounts not to be food additives. These comments went on to say that the Delaney Clause (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), which prohibits the use of known carcinogens as food additives, would therefore not apply.

FDA disagrees with the comments. It is true that *Monsanto* stated that the Commissioner has discretion to implement the statutory scheme established by the Food Additives Amendment, and that this discretion includes the option of declining to define a substance as a food additive (613 F.2d at 956). However, the court also said that the Commissioner's discretion is limited (id.). The Commissioner's exercise of discretion must be consistent with the statutory scheme. He cannot exercise his discretion to vitiate that scheme. Under the Food Additives Amendment, a carcinogenic additive is deemed to be unsafe, no matter how low the exposure to the additive or how low the risk from the additive (see *Public Citizen* v. *Young*, 831 F.2d 1108, 1122 (D.C. Cir. 1987), cert. denied, 485 U.S. 1006 (1988)). Given these facts, FDA has formulated the threshold of regulation regime to exempt substances from regulation as food additives based on the level of dietary exposure but has conditioned that exemption on such substances not having been shown to be carcinogens. No other approach would be consistent with the act.

13. Three comments recommended that FDA clarify whether companies can make their own threshold of regulation determinations. The comments stated that, in those cases where the use of the substance meets the definition of a ''food additive'' in section 201(s) of the act (21 U.S.C. 321(s)), individual manufacturers should be able to make their own determination as to whether the use of a substance in a food-contact article meets the criteria for an exemption from regulation. One of the comments requested that the agency's position on this issue be explicitly stated in the final regulations.

According to *Monsanto*, only the Commissioner has the statutory authority to exempt a substance from regulation as a food additive. A substance that meets the definition of a food additive in section 201(s) of the act must, therefore, either be the subject of a regulation authorizing its use or be exempted from regulation by FDA under the process specified in new § 170.39, unless the use of the substance conforms to an exemption for investigational use issued under section 409(i) of the act.

From a policy standpoint, the procedure outlined in this final rule, whereby FDA makes all exemption decisions, offers a number of advantages over an approach that allows individual manufacturers to make their own threshold of regulation decisions. One advantage is that the agency's determination as to whether a substance used in a food-contact article meets the criteria for an exemption from regulation as a food additive will be binding on the agency. Thus, manufacturers of food-contact articles will be able to rely on these determinations and market their products without fear of regulatory action.

This approach also will result in more consistent decisions. Qualified experts may disagree on what specific assumptions are appropriate for estimating the dietary concentrations resulting from the use of substances in