percent ADI level, FDA's main concern is with those cases in which a particular substance may be granted exemptions for a number of different types of new uses, each of which results in a dietary exposure at or near the threshold level. In such cases, the dietary exposure resulting from all of the exempted uses could represent a significant increase in the cumulative dietary exposure for the substance and, in cases where the estimated dietary intake from currently regulated uses is close to the ADI, may not be supported by existing safety data. It is possible, however, that once the threshold of regulation process is put into practice, other factors will surface that mitigate the agency's concerns on this issue. If the latter situation proves to be the case, the agency may find it appropriate to reassess the 1 percent of the ADI threshold for regulated direct food additives used in food-contact articles.

9. One comment recommended that FDA publish or otherwise make available the ADI's for currently regulated direct food additives. In cases where such ADI's are not readily available, FDA should consider other sources (e.g., the European Union's Scientific Committee for Foods) or provide guidelines for the calculation of appropriate ADI's.

FDA agrees that the ADI's for currently regulated direct food additives should be made more readily available. Therefore, FDA plans to incorporate this information into its priority based assessment of food additives (PAFA) data base and make this data base accessible to the public (Ref. 2). In the meantime, requestors can obtain this type of information on a specific substance by submitting a written request to FDA's Office of Premarket Approval (HFS–200, 200 C St. SW., Washington, DC 20204). In some cases, especially for those uses of direct additives that result in low dietary exposures such as flavoring agents, FDA may not have an ADI in its files. Therefore, in those relatively few cases where FDA does not have an appropriate ADI for a regulated direct food additive, the agency would consider the use of an ADI value from another appropriate source, such as the Joint World Health Organization/Food and Agriculture Organization (WHO/FAO), Expert Committee on Food Additives, or the European Union's Scientific Committee for Foods, assuming that the data or other information on which that ADI value is based are also available. FDA is revising proposed § 170.39(a)(2)(ii) to state that FDA may use other appropriate sources for ADI values.

FDA disagrees with the comment's suggestion that the agency provide guidelines for the calculation of appropriate ADI's for review under the process specified in this final rule. Regulated direct food additives for which an appropriate ADI does not exist are not suitable candidates for an abbreviated review under the threshold of regulation process. This process is not appropriate for reviewing submissions containing detailed toxicity studies on a substance for the purpose of calculating an ADI value or for verifying an ADI value calculated by the requestor. Such extensive reviews are better handled by the food additive petition process.

10. One comment recommended that FDA expand the proposed threshold of regulation process for regulated direct food additives to include exemptions for direct uses in food, provided the dietary exposures from such uses do not exceed 1 percent of the ADI. The proposed rule limited such exemptions to only those uses that may result in their indirectly becoming components of food (i.e., resulting from their use in food-contact articles).

FDA does not agree that the final rule should be expanded in this manner. There is a fundamental difference in regulatory significance between substances that are deliberately added directly to food to accomplish a technical effect in the food and substances that are used in food-contact articles in a manner such that they may reasonably be expected to become components of food indirectly and to have no technical effect in that food. The purpose of the food additive provisions of the act is to ensure that substances added to food are safe and will have their intended technical effect in the food that is to be consumed (S. Rept. 2422, 85th Cong., August 18, 1958). Thus, given this purpose, there simply would not be circumstances in which a direct additive would be of such little regulatory concern as to justify application to it of the de minimis[4] doctrine that underlies the threshold of regulation concept (see *Monsanto* v. *Kennedy, supra*). For indirect food additives, in contrast, the substance is being used for its technical effect in a food-contact article, not in an article that will itself be consumed.

Moreover, on occasion, it is foreseeable that, while the exact amount of an indirect additive that will get into food is unclear, it will not exceed an extremely small amount. It is in the latter circumstances that it is fair to say that, given the purposes of the Federal Food, Drug, and Cosmetic Act (the act), the use of the substance is of no significant regulatory concern, and thus the use can be exempted from regulation under the food additive provisions of the act. In light of the purposes of the food additive provisions, however, FDA concludes that it is not appropriate to extend the threshold of regulation concept to substances intended for direct use in food.

11. One comment expressed the opinion that the proposed regulation is unduly restrictive for the use of regulated direct food additives in food-contact articles when the direct additive does not have any specific use level restrictions. An example of the type of situation raised by the comment would be flavoring agents where the level of their use in food would be self limiting (i.e., use at high levels would make the food unpalatable, and, therefore, FDA did not find it necessary to impose specific maximum use levels as part of the regulations authorizing the use of such substances). The comment emphasized that, because of the time required to obtain FDA approval (as a result of FDA's current backlog of work), the consumer's access to new packaging technologies is often delayed. Not requiring premarket approval of such substances would save FDA resources, reduce the backlog of work, and enable the consumer to have quicker access to new packaging formulations.

The comment argued that, based on the extremely small levels of dietary exposure that would result from the use of direct additives in food-contact articles, particularly in comparison to the levels of exposure that result from the direct uses of these substances, and based on the fact that direct food additives have been the subject of extensive safety testing, FDA should modify § 174.5(d) (21 CFR 174.5(d)) to allow those direct food additives that are regulated without specific use level limitations to be used as components of food-contact articles. The comment asserted, however, that four restrictions on such use were appropriate: (1) The use of the substance in a food-contact article must not result in a dietary exposure that exceeds 1 percent of the ADI for that substance; (2) the use level must not exceed good manufacturing practice (GMP) or that necessary to accomplish the intended technical effect; (3) the substance must be of a purity suitable for the intended use; and (4) the technical effect for such additives must be as a formulation aid or some other technical effect for which the substance has been listed as a direct

[4] This doctrine is expressed in Latin as de minimis non curat lex (the law does not concern itself with trifles).