food-contact articles. Thus, allowing individual manufacturers to make their own determinations would increase the likelihood of inconsistent decisions.

For example, 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 validated detection limit of the method used to analyze for the substance would need to be considered in order to estimate the dietary concentration from the intended use. Qualified experts may disagree not only on the specific numeric value for this detection limit but also on what percentage of the detection limit should be used in such situations to estimate actual migration (e.g., 100 percent versus 50 percent). Qualified experts may also disagree on the appropriate consumption factor to use in estimating dietary concentrations. Different conclusions on the environmental effects resulting from the use of a food-contact article may also arise from such independent determinations. The agency believes that having all such exemption decisions made by a review team consisting of a small number of agency personnel will help lessen the likelihood of inconsistent decisions on these matters.

Having such determinations made by FDA will also mean that the agency will have more complete information on what materials industry is actually using in food-contact articles. As a result, FDA will be able to make more informed decisions in the event that data become available that raise significant concerns about whether the continued use of a component of a food-contact article is safe.

Although only the Commissioner of FDA has the statutory authority to exempt a substance from regulation as a food additive in those cases where the use of the substance meets the ''food additive'' definition in section 201(s) of the act, FDA emphasizes that nothing in this final rule limits the use of a substance exempted by FDA from regulation to only the manufacturer who submitted the request for an exemption. Other manufacturers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued.

Consistent with this fact, FDA plans to give general notice by means of the **Federal Register**, should it ever decide to revoke an exemption. The notice will state that continued use of such a substance would constitute the use of an unapproved food additive, unless a petition is filed, and the substance is listed for use in FDA's regulations. It will also set out the reasons for FDA's decision to revoke the exemption, thereby providing manufacturers with the opportunity to submit relevant data to the agency and to request that the exemption be reinstated.

FDA does not believe, however, that it would be practical to routinely provide notice in the **Federal Register** of its intent to revoke an exemption. Such a process would only unduly delay and burden the revocation process. It would be inconsistent with the intent of the threshold of regulation process to minimize the use of agency and industry resources for those substances whose use in food-contact articles poses only negligible safety concerns. Accordingly, FDA is revising § 170.39(g) to make clear that the agency plans to provide notice in the **Federal Register** after it has decided to revoke an exemption issued for a specific use of a substance in a food contact article.

FDA has decided, however, not to include in § 170.39 a statement that only the Commissioner can make threshold of regulation determinations. It is not the agency's usual practice to enumerate in its regulations those regulatory decisions that are reserved to the agency. Therefore, the agency is not doing so here.

Scope of the Exemption

14. Two comments recommended that FDA expand its proposed threshold of regulation to enable the agency to exempt entire classes of compounds. Under the scheme suggested by these comments, FDA would review one or more compounds within a given class, and, if it determined that these individual chemicals qualified for an exemption, the agency would exempt all of the chemicals within the class. One of these comments expressed the view that many manufacturers do not use their proprietary chemicals for food-contact applications because of FDA's requirement that they be regulated based on their chemical identity, and that the use of such an approach would remove impediments that stifle innovation in the food industry.

FDA disagrees with this approach for a number of reasons. Because the level of migration, and resulting dietary concentration, of the chemical depend on both its molecular weight and chemical properties, it would be impossible to predict whether the use of all compounds within a class would result in dietary concentrations below the threshold based on the migration properties of just one or two sample chemicals. For example, polymeric materials manufactured from the same monomer but having significantly different molecular weights would belong to the same class of chemicals but would be expected to have different migration properties. Similarly, the intrinsic toxic potencies for chemicals within a certain class may vary significantly. For example, the polychlorinated dibenzo-*p*-dioxins are a class of 75 congeners that exhibits a wide range of toxicity depending on the degree of chlorination and the location of the chlorine atoms within the chemical structure. As a result, the likelihood that a substance poses a health hazard is not necessarily determinable based on the information about the toxicity of other chemicals that are in the same class. In addition, it would be difficult to predict the environmental impact that would result from the manufacture, use, and disposal of all substances within a class based on the impact of one or two chemicals. Therefore, FDA does not believe that it is possible, based on the review of one or more compounds within a given class, to justify an exemption for all other chemicals belonging to the same class.

For the foregoing reasons and because the dietary concentration of a specific chemical is dependent on the conditions of its use (e.g., type of use, temperature, food type, and contact time), FDA concludes that to adequately safeguard the public health, it is necessary to limit exemptions under § 170.39 to those conditions of use of a chemical that it has evaluated.

15. One comment recommended that rather than require a submission for each chemical and each proposed use, FDA should publish guidelines based on categories of uses that would provide performance standards that could be used by manufacturers to guide customers on how to stay below the threshold exposure.

As discussed earlier, the dietary concentration resulting from the use of a substance in a food-contact article may vary considerably depending on the type of use and the conditions of use. Therefore, it would not be feasible to establish guidelines for use with respect to all possible food-contact articles under all possible conditions. Interpretation of such complicated guidelines by individual manufacturers and customers would inevitably lead to confusion and inconsistencies.

The process specified in this final rule, as part of which a small team of agency personnel will review each request for an exemption, will result in more consistent decisions. Having all such determinations made by FDA