

Regulatory Review for Food Packaging

The Federal Food, Drug, and Cosmetic Act requires that all food packaging must be safe and suitable for its intended use. Food packaging, including can coating materials, is evaluated by the U.S. Food and Drug Administration (FDA) prior to commercialization. The FDA Office of Food Additive Safety (OFAS) is responsible for these evaluations. OFAS has over 125 full-time scientists and other employees that focus specifically on food safety, food packaging, and food processing.

Food Packaging Regulated as Food Contact Substance

For food packaging, the FDA OFAS safety review requires proof that there is a reasonable certainty of no harm from the intended food packaging. Under FDA regulations, food packaging is considered a food contact substance, and is reviewed and regulated as such. That is because all packaging of food or beverage products will migrate a small or trace amount of that packing material into the food or beverage.

Typical exposures from food contact materials are very low. For these materials, the FDA safety evaluation occurs under the food contact notification process. FDA also has a food additive petition process for indirect additives that is used for circumstances in which high exposures are expected. FDA reserves the right to determine which process should be used for new food contact materials, but for the most part, the food contact notification process has been the primary means in which FDA authorizes new food contact substances since its inception back in 1999.

Information Required in Food Contact Notification

Under the food contact notification process, a manufacturer of a new food contact substance, or a party wishing to use an existing food contact substance in a new manner, must submit a complete data package to FDA for review that must include:

- A comprehensive summary of the intended use of the new food contact substance, including any impurities;
- All relevant chemical information on the food contact substance;
- Intended conditions of use of the food contact substance, which includes food types to be used with and maximum temperatures allowed;
- Intended technical effect information, including information on how much the new substance is required to achieve the technical effect;

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- Potential consumer intake (exposure) information, including all data used to estimate daily intake of food contact substance and impurities;
- Toxicity Information; and
- Information on the food contact substance environmental assessment or a claim for categorical exclusion.

The submitter must also provide a declaration that it has considered all chemical and toxicology data available and, based on the sponsor's determination, the material is safe as defined under FDA standards.

FDA Review of Food Contact Notification

After FDA receives a food contact notification, it will conduct an initial review to ensure the data package is complete. At that time, FDA sends a letter to the sponsor indicating that the review process had begun. FDA has 120 days, or about four months, to review the information submitted and determine if it agrees with the sponsor's conclusion of safety. In its review, FDA evaluates all the data submitted under robust scientific procedures.

If FDA concludes that there is a reasonable certainty of no harm caused by the intended use, it will allow the food contact notification to become effective. If FDA identifies concerns with the submission, it can invite the sponsor to withdraw the notification pending further consultation or it can object to the notification. In either case, the food contact substance is not approved and cannot be used commercially under the conditions of the notification.

It is important to note that new food contact notifications are exclusive to the sponsor and the use. Only the sponsor that submitted the notification has permission to market the substance and only in the use notified. FDA posts an inventory of food contact notifications in effect on its website. This robust regulatory scheme ensures that all substances used in food packaging are evaluated under a rigorous scientific process to establish their safety *prior* to being placed on the market.

Post Notification FDA Engagement

After a food contact notification is approved, FDA will continue to monitor and evaluate public information and data regarding the safety of approved substances. During these evaluations, FDA considers the utility of the new data to human health effects by determining if the study design and execution are relevant to potential human exposures, as well as sample size, statistical significance of results, and other scientific criteria. While FDA will consider all data, the reality is that some studies are more relevant for determining human health effects than others are and should be given a higher weight within the larger assessment.