Safety and Food Packaging

FDA/Michael Ermarth

The Food and Drug Administration (FDA) is responsible for ensuring the safety of all food packaging, including components of packaging materials that are expected to migrate into food. The agency refers to these materials as "food contact substances." Examples include coatings on cans, plastics, paper, and sealants for lids and caps.

The Office of Food Additive Safety in FDA's Center for Food Safety and Applied Nutrition is charged with ensuring that food contact substances are safe. "Safe" is defined in the law as a reasonable certainty that a substance is not harmful under the intended conditions of use. FDA regulates components of food packaging under the laws governing the use of food additives.

Requiring High Safety Standards

Manufacturers are required to obtain approval from FDA for all packaging components that may migrate to food before they can be marketed unless those components are considered "generally recognized as safe" (GRAS).

To obtain approval for a new food contact substance, manufacturers submit detailed information to FDA about the substance and its impurities. This includes safety and chemical information, as well as potential environmental effects. FDA does not approve food contact substances if they have been shown to cause cancer in humans or animals.

Though packaging components that are considered generally recognized as safe for use in food or food packaging do not require FDA approval under the law, they are required to meet the same safety standards as other food contact substances.

These same standards also are required for other components of packaging that were authorized informally ("prior sanctioned") before FDA gained premarket approval authority over food contact substances in 1958.

Evaluating Consumer Exposure

Safety assessments ensure that consumers are only exposed to food contact substances at levels far below those that might have any health consequences.

As part of the review process, FDA scientists consider the amount of a substance that's expected to migrate into food relative to its safety profile. Agency scientists assess the amount of a substance migrating into food using a variety of data and information, including:

Conducting migration testing: FDA scientists have developed tests to assess the migration of compounds from a food contact substance into food. These migration tests mimic the conditions under which food is prepared and stored in contact with packaging materials. Migration tests also model the most severe conditions of use of the material.

Assessing cumulative dietary exposure: FDA scientists consider other

uses of a food contact substance and/or its components to determine a cumulative dietary exposure. Additionally, when FDA scientists assess consumer exposure they assess exposure to the food contact substance and all of its components that may migrate to food from the proposed use.

Reviewing stability data: Data on the relative stability of food contact substances are an important part of FDA's safety review of new packaging and other food contact materials. FDA requests stability data from manufacturers to ensure that breakdown of the food contact substance does not occur under the conditions of use. If it does occur, all breakdown products from the food contact substance must be appropriately identified and quantified. Approval is only granted with appropriate limitations and specifications to ensure that the food contact substance is safely used.

Evaluating research: FDA reviews all pertinent safety data. Agency toxicologists perform searches for additional data in the published literature and within FDA's own files. Any and all relevant data are then considered in determining whether the intended use of the food contact substance is safe.

If Concerns are Raised Later

As with any FDA regulated product, safety assessments of food contact substances are made in the context of the science at the time the decision is made. For this reason, FDA scientists also monitor new information that may relate to the safety of already authorized food contact substances.

When the science evolves or new information becomes available that causes FDA to question a previous safety decision, the agency may take one or more of several actions:

- contacting the manufacturer and ensuring that corrective action is taken
- removing the food contact substance from the market completely or imposing limits to ensure its safe use
- requiring that industry develop data or information to address a concern
- imposing additional limitations or specifications to ensure safe conditions of use
- prohibiting the use of a food contact substance that is no longer considered safe

The specific action that FDA takes generally depends on the likely public health risk. Any imminent danger to health is acted upon immediately with a recall or regulatory action.

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Bisphenol A (BPA)

A draft brief published in April 2008 by the National Toxicology Program, a part of the National Institutes of Health (NIH), raised concerns about the safety of products containing Bisphenol A (BPA). BPA is a chemical used in plastic containers for certain food and drinks, including baby bottles. The NIH draft brief indicated that some studies in animals suggest that BPA may cause developmental effects in infants and children.

FDA has been reviewing emerging literature on BPA on a continuous basis for years. Agency experts believe there is a large body of evidence indicating that FDA-regulated products containing BPA are safe. Current evidence indicates that exposure levels to BPA from food contact materials, including for infants and children, are below those that may cause health effects. But as a science-based agency, FDA continues to consider new research.

In light of recent concerns, FDA formed an agency-wide BPA task force in April 2008 to spearhead review of research and new information on BPA for all FDA-regulated products. In June 2008, FDA announced that a subcommittee of FDA's Science Board will hold a public meeting on the safety of BPA in plastics and review the agency task force report.

According to FDA, there is no reason to recommend that consumers stop using products that contain BPA while the agency carries out its assessment process. But concerned consumers should know that several alternatives to polycarbonate baby bottles exist, including glass baby bottles. If FDA's review of data leads to a determination that uses of BPA are not safe, FDA will take action to protect the public health.

For more information about the public meeting on BPA safety, on September 16, 2008, visit *http://edocket.access.gpo.gov/2008/E8-18864.htm*. The meeting documents, including the draft assesment of BPA released on August 15, 2008, are available at *www.fda.gov/ohrms/dockets/ac/oc08.html#ScienceBoard*

For More Information

Food Ingredients and Packaging: Consumer Information
www.cfsan.fda.gov/~dms/opa-bckg.html

Food Contact Substance Program
www.cfsan.fda.gov/~dms/opa-notf.html

FDA's Bisphenol A (BPA) Web page
www.fda.gov/oc/opacom/hottopics/bpa.html

GRAS: Time Tested and Trusted Food Ingredients
www.fda.gov/fdac/features/2004/204_gras.html