Regulatory Implications For UV/EB-Cured Coatings Used In Packaging Children's Products

About UV/EB

The Consumer Product Safety Commission (CPSC) does not expressly regulate packaging materials. It may, however, regulate consumer products packaging if the package itself has a practical use (e.g., buckets) or has some play value to children. As discussed below, the regulatory program administered by the Food and Drug Administration (FDA) for food packaging provides useful guidance concerning the exposure of children to hazards in packaging. Based on these regulations the use of such packaging materials in food applications, properly cured UV/EB coatings can be used safely in packaging of children's products.

Although not required by any regulations, it may be appropriate for a manufacturer to review any testing that has been performed on its UV/EB-cured coatings for food and drug packaging purposes to determine the exposure and risks associated with residues or other components, and to consider conducting tests if there is insufficient data. Given the recent attention by the Clinton Administration and others on health and environmental risks to children, particularly concerning exposure to chemicals, and given the potential for liability under programs such as California's Proposition 65, a cautious approach may be warranted even if not required.

This article will first discuss the regulations over which the CPSC has jurisdiction. Those regulations are focused on the products themselves rather than the packaging, but the CPSC would likely exercise jurisdiction over packaging materials if such packaging were to present a risk of injury through exposure to a toxic substance. This article examines the procedure for determining the safe use of UV/BE-cured coatings in food contact applications, and includes a brief discussion concerning the suffocation hazard posed by thin plastic film bags, steps taken by industry to educate the public about the risk, and local regulations requiring warning labels.

A. Regulation of Children's Products by the Consumer Product Safety Commission

The CPSC has jurisdiction over implementation of several product safety statutes, including the Consumer Product Safety Act, the Flammable Fabrics Act, the Federal Hazardous Substances Act, and the Poison Prevention Act. These statutes are all focused on the safety of consumer products; that is, items likely to be found in and around the home. At present, none of these regulations specifically addresses the composition of packaging for children's products, although a number of regulations specify the type of safety packaging or labeling required on products that are inherently dangerous for children (e.g., household cleaners, drain openers) even though they are not intended for use by children.

The Federal Hazardous Substances Act, among other things, governs toys and other products intended for use by children that present chemical, electrical, mechanical, or thermal hazards that may cause injury in normal or reasonably foreseeable use and handling, including foreseeable ingestion by children. Products intended for children are banned under the Act in one of two ways. An article that is intended for children is a banned hazardous substance under the Act if it is toxic, corrosive, an irritant, or a strong

sensitizer, or if it is flammable or combustible or generates pressure through decomposition, heat, or other means. A toy or other article intended for children is banned by statute if it contains a hazardous substance in a manner that makes the substance accessible to a child using the product. These products are banned automatically and do not require a specific regulation. For example, the Act has been invoked to ban children's wearing apparel treated with the chemical flame retardant (2,3-dibromo-propyl) phosphate, also known as TRIS, because of the potential health risk to children caused by the substance's toxicity. Some articles intended for children of a specified age are expressly exempt from these regulations because of their function, such as chemistry sets and fuels for propulsion of model rockets.

The second way a product intended for children is banned is through a specific regulation. This method is required for products that pose a mechanical, electrical, or thermal hazard. Unfortunately, there is no comprehensive list of articles that are banned in this manner, although some articles are listed in the regulations. The CPSC also has issued a specific ban on toys and other articles intended for use by children that bear lead-containing paint, defined as a coating in which the lead content exceeds 0.06 percent of the weight of the total non-volatile content of the paint.

The CPSC has established regulations setting forth tests for determining whether a substance is toxic or an irritant. Toxic is defined under the Act as any substance "which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." In addition, the regulations describe a procedure for evaluating the type of foreseeable use and abuse a product will be exposed to by children to determine if latent hazards become exposed.

Because the statute defines the scope of the Act's provisions as encompassing any "article intended for use by children," the CPSC could consider a package within its jurisdiction. For example, in 1994, the CPSC initiated a rulemaking proceeding covering 5-gallon buckets because of a number of reported drownings of small children. A package could be considered a banned hazardous substance under the Act if the package contained a hazardous substance that was accessible to children in foreseeable use and abuse. A package, therefore, must not contain a hazardous or toxic substance that can be absorbed through physical contact, inhalation, or ingestion.

Although the CPSC would assert jurisdiction over a package under its statutory authority, it would only do so if it became aware that a package presented a potential hazard. Because there are no prescriptive CPSC regulations on how to determine the potential toxic hazards associated with a package, individual manufacturers should rely on determinations made under the regulatory scheme for food packaging administered by the Food and Drug Administration (FDA) for their specific packaging products

B. Regulation of Food Packaging by the Food and Drug Administration

Children's products can be safely packaged with materials bearing UV/EB-cured coatings so long as there is no reasonable expectation that a toxic or hazardous substance from the packaging could be absorbed, inhaled, or ingested through ordinary or foreseeable contact with the package or that such a substance could become a component of the children's product contained in the package. This article analyzes the issue from this perspective because, although children's toys and other products are generally not

intended for ingestion, children, particularly very young ones, often put objects in their mouths. Also, children frequently put their hands in their mouths, so any hazardous residue on the package or the product contained therein could be inadvertently ingested, inhaled, or absorbed.

The use of UV/EB coatings as components of food packaging is permitted by FDA under certain conditions and in compliance with certain regulations. Because not all packaging is expressly "approved" by FDA, and since materials, processes, and quality control vary from manufacturer to manufacturer, each manufacturer must perform its own analysis to determine whether its packaging is safe for food use. Therefore, individual manufacturers may wish to conduct risk assessments to determine whether there is any likelihood of exposure to a hazardous substance either directly from the packaging or through migration from the packaging to the product using the same techniques employed in food packaging regulation, which is summarized below.

Substances used in food contact articles must be the subject of a food additive regulation if they are reasonably expected to migrate to food under the intended conditions of use unless the quantity migrating is insignificant, the substance is generally recognized as safe (GRAS), or is the subject of a prior sanction. If the substance is not reasonably expected to become a component of food under the intended conditions of use, it is not considered to be a food additive and may be used without the need for a permissive food additive regulation. This determination usually entails an analysis, often conducted for the manufacturer by an outside entity, to evaluate a package's safety.

Most coatings substances intended for use in food packaging applications are either covered by an applicable FDA regulation or are "exempt" from the pre-clearance requirements of the Federal Food, Drug and Cosmetic Act (FFDCA). FDA's regulation of food packaging is based on Section 201(s) of the FFDCA, which defines a food additive, in relevant part, as "[A]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component . . . of any food . . . if such substance is not generally recognized . . . to be safe under the conditions of its intended use". This definition is repeated in Section 170.3(e) of the Food Additive Regulations which adds other explanatory information:

A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component . . . directly or indirectly of the food packed in the container . . . . If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive.

Over the years, indirect food additives regulations have been issued in response to individual food additive petitions. Because this process is time-consuming, however, coatings manufactures, whenever possible, establish that the subject material is exempt from the definition of a food additive and, thus, from the requirements for filing a food additive petition.

One of the most important means of establishing satisfactory FDA status for a food-contact component is to establish a rational basis on which to conclude that there is no reasonable expectation of the substance becoming a component of food. For most substances, a finding of "non-detected" in a properly conducted migration study is considered to be a sound basis for concluding that the substance

is not a food additive. A properly conducted migration study is one which accurately simulates the conditions of actual use, utilizing analytical methods sensitive to the equivalent of 50 parts per billion (ppb) of the substance in food. In some cases, however, it may be necessary to base a "no-migration" determination on being able to say "non-detected" with a method sensitive to 10 or even 1 ppb because of the toxicological nature of the material being used, such as a heavy metal, or because of the high exposure of the end product, such as soda or milk containers. Of course, carcinogenic constituents must be evaluated separately using risk assessment techniques.

Another important concept is the "basic resin" or "basic polymer" doctrine. This doctrine is based on the principle that the Food Additive Regulations clear substances on a generic rather than a proprietary basis. Under this principle, as long as the basic resin is listed in a regulation, is manufactured in accordance with good manufacturing practices, and complies with any applicable limitations such as stated extraction requirements, it is covered by that regulation even though different manufacturers may make the resin by different processes, including using different catalysts or initiators, reaction control agents, chain transfer agents, and the like. Under this doctrine, substances such as catalysts, chain regulators, and other materials required to produce the basic resin which is regulated or otherwise permitted for use are considered a part of it and do not require independent regulatory pre-market clearance. This regulatory approach is premised on the fact that, when a substance is used only in a small quantity and either becomes part of the resin during polymerization or is washed from the resin at the conclusion of polymerization, its potential for becoming a component of food in more than insignificant amounts is virtually non-existent. In other words, there is no reasonable expectation of migration of these types of substances to food; thus, they are not food additives as that term is defined in Section 201(s) of the Act.

In the case of radiation-cured coatings, the typical components can be categorized as base resins, reactive diluents, and, in the case of UV-curable coatings, photoinitiators. Certain resins are already permitted for use in food-contact coatings. Thus, depending upon the specific resin used by a coatings manufacturer and the compounds that are formed after reaction with the diluents or photoinitiators, a radiation-cured coating could be approved for use through this method. Depending upon the specific chemical composition of a manufacturer's radiation-cured coating, it could be either exempt from the food additive regulations because there is no expectation of migration or cleared for use because it is covered by an existing regulation by analogizing to an approved compound with a similar molecular composition.

C. Regulation of Suffocation Hazards Presented by Plastic Bags

From time to time, the CPSC has expressed an interest in the issue of plastic bag warnings. The issue stems from reports in the late 1950s of children suffocating after coming in contact with ultra-thin plastic garment bags of the type used by dry cleaners. Since that time, the concern has expanded to include other bags such as disposable trash bags. A voluntary industry effort to educate the public and to include warning labels on plastic bags has resulted in no nation-wide regulation or ban of plastic bags. Some jurisdictions, however, have adopted regulations mandating that warning labels be placed on bags meeting certain specifications. The majority of those jurisdictions have adopted language similar to the

voluntary industry guideline and the New York City and Chicago ordinances. Plastic bags that are thinner than 1 mil (1/1,000 of an inch), longer than 25 inches, and which have an opening greater than 7 inches, should bear a label warning against choking hazards. This requirement should enter into the overall safety assessment of packaging for children's products.

D. Conclusion

Under the CPSC's statute and regulations, the CPSC would consider the packaging for children's articles within its jurisdiction, but the Commission would only act if it became aware of a potential safety issue. Although the regulations do not specifically cover packaging, the prudent course would be for manufacturers to submit their packaging to the same standards as children's products and food contact packaging, since it is foreseeable that children would have access to the packaging and would have the opportunity for contact with any hazardous substances present through ingestion, inhalation, or absorption. In a similar vein, using the FDA indirect food additive regulations as an analogy, it is possible that otherwise benign packaging might react with a certain type of toy coating. Therefore, it is always advisable to determine what type of product is intended to be packaged using a UV/EB-cured coating and whether there is a likelihood of interaction between the package coating and the product.