The Regulation of Food Packaging

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While there is general familiarity with food laws in the legal community, the laws and regulations governing food packaging are often less understood, even though they may have a significant impact on a food company’s success in marketing new products. This article explains how food packaging is regulated in the United States and how the U.S. regulatory scheme compares to other jurisdictions throughout the world; in addition, we provide insight to how many of the current food packaging regulations came about, including some recent updates to food packaging laws and regulations.

Food packaging serves a range of critical functions beyond containment of food and beverages. These range from providing physical protection and slowing product deterioration to offering convenience and transmitting information. More advanced food packages can include susceptors to aid in the browning of foods cooked in microwave ovens, features that interact chemically or biologically with their contents to extend shelf-life, and the ability to monitor the condition of the food. The evolution of regulations governing the composition and use of food packaging has included changes to accommodate these advances.

The Basics

But let’s start with the basics. Most food packaging regulatory systems include general safety requirements that are intended to preserve the physical, chemical, and sanitary integrity of the contents of food packages. These requirements generally prohibit the transfer of substances from the packaging to the food that may be deleterious to human health or bring about an unacceptable change in composition, taste, or odor of food.

Most global food packaging regulatory systems are based on similar scientific principles, but the approach used by different jurisdictions can vary considerably. These different approaches can also impact the data that is required to clear a substance for use in food packaging. For example, in the U.S., substances that may not reasonably be expected to become components of food and are not likely to present any public health problem can be cleared based on analytical chemistry data and extrapolations that show such components present no cause for toxicological concern due to minimal dietary exposure. Conversely, in the European Union (EU), just about all food packaging materials need to be explicitly cleared based on a toxicological evaluation and published regulations, regardless of exposure.

The Beginning of Food Packaging Regulation in the U.S.

Formal regulation of food packaging in the U.S. began with the passage of the Food Additives Amendment of 1958. This amendment added, among other things, a new section to the Federal Food, Drug, and Cosmetic Act (FFDCA) that defined the term “food additive” as: “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of
any food..." unless that substance is Generally Recognized as Safe (GRAS) or subject to one of a number of exceptions or exclusions listed in the Act.[1]

This definition is responsible for a distinctive feature of the U.S. food packaging regulatory scheme that is not common to other jurisdictions, namely that all food contact substances[2] that may reasonably be expected to migrate to food are regulated as food additives similar to the manner in which something added directly to food, such as a sugar substitute or an emulsifier, is regulated. Importantly, under Section 409 of the Act; a food additive that is not the subject of a regulation, or otherwise cleared by FDA for its intended use, is considered to adulterate food. No showing of the potential for harm is necessary under such circumstances to establish adulteration.

There are three exceptions under the Act, which, for purposes to this article, are important. The first is commonly referred to as the “prior sanctioned” substance exception. Prior to 1958, some companies that manufactured food packaging materials would inquire with FDA or the U.S. Department of Agriculture (USDA) whether it would have an objection to the use of a particular material to package food. This was often done to assure customers as to the safety of the product when used with food. If FDA or USDA did not object to the use of the substance in question, the agency that received the request would issue a “no objection” letter. When the Food Additives Amendment was passed in 1958, the subjects of these letters became known as “prior sanctioned” substances and were exempted from the food additive requirements for further clearance or authorization by FDA. It was a kind of grandfathering provision.

Substances that are “generally recognized as safe” (GRAS) are also exempted from the definition of a food additive. A GRAS substance is one that is “generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.”[3] These substances do not need clearance or authorization by FDA prior to being placed on the market for use. However, FDA has always allowed manufacturer or users to submit the basis for a GRAS determination to FDA for review. In this respect, FDA issued a final rule on its GRAS notification process in August 2016.[4] The final rule outlines the types of data that can be used to support a GRAS conclusion.

The third class of substances exempted by the food additive definition of importance here are those which may be used in food packaging, or are otherwise in contact food, but are not reasonably expected to become components of food. Such substances are not by definition “food additives,” and may be used without prior authorization or clearance by FDA. Additional history on the underpinnings for this so-called “no migration” exemption is discussed further below.

A subset of the no migration exclusion is the “functional barrier doctrine.” Food contact substances that are separated from food by a functional barrier that prevents migration of those substances are not considered food additives. To use this doctrine, it is necessary to establish that the functional barrier actually prevents migration. The composition and thickness of the material separating the substances from the food, in addition to its physical and chemical characteristics, are important factors in making this type of determination. Other factors to consider are the time and duration of exposure to the food and the type of food.
The Food Additive Petition Process

The Food Additives Amendments of 1958 included a process to petition FDA to allow the use of an additive in food by way of the issuance of a “Food Additive Regulation.” The food additives petition process involves clearing food additives (including food packaging materials that meet the definition of a food additive) through a notice and comment rulemaking process. A food additive petition requires detailed information about the identity and composition of the substance of interest and a description of how it is made, in addition to information on its intended use—such as food types, temperature conditions, and duration of contact with food—and chemistry and toxicology data supporting the safety of that food additive for the intended use. Once a food additive is cleared through this process, FDA publishes a regulation.[5] These clearances are generic and can be relied on by anyone as long as any limitations and specifications listed in the regulation are met.

Shortly after the food additive petition process was put in place, FDA announced in 1961 that it would no longer provide “no objection” letters on the basis of migration data. After that announcement, there was some disagreement on whether a company could make a self-determination that a substance was not a food additive based on “no detectable migration” and, thereby, avoid the need to submit a food additive petition prior to using that substance in food packaging.

Prior to that time, FDA had not provided definitive criteria on how to determine whether a substance may be reasonably be expected to become a component of food. However, guidance on this issue came from two main sources. First, FDA circulated a proposal in 1969 that it would not require a food additive regulation for substances without toxicological concern migrating to food in quantities no greater than 50 parts per billion (ppb). While this proposal was never formally adopted by FDA, it did take on a life of its own, and became known as the “Ramsey Proposal.”

Second, in *Monsanto v. Kennedy,*[6] which FDA a regulatory determination by FDA which prohibited the marketing of beverage bottles made from a certain type of polymer, the U.S. Court of Appeals for the District of Columbia found that for FDA to classify a substance as a food additive, Congress must have intended the agency “to determine with a fair degree of confidence that a substance migrates into food in more than insignificant amounts.” The court remanded the matter to FDA for further consideration under this standard.

FDA eventually adopted a rule that in a way addressed this issue. In 1995, the agency amended the food additives regulations to formally establish a process for determining when the migration of a food contact substance to food is “so trivial as not to require regulation of the substance as a food additive.”[7] The Threshold of Regulation (TOR) Rule permits FDA to exempt a food contact material from regulation based on exposure and toxicology. The dietary exposure of the material must be less than 0.5 ppb or, if it is already cleared for use as a directive additive, exposure from the food contact use must be less than 1% of the Accepted Daily Intake (ADI). With respect to toxicology data, the food contact material cannot be carcinogenic or have any impurities that are potent carcinogens.

Once FDA receives a request to exempt the use of a food contact substance from regulation as a food additive based on insignificant migration to food, it will review the data and, if the TOR criteria is met, the agency will issue a TOR exemption letter.[8] These letters are not proprietary and, therefore, anyone can rely on them.
When FDA first developed regulations governing the safe use of polymers to be used in contact with food, it focused on what might migrate from the polymer into the food. This led to regulation of polymers as a whole rather than the complex variations in the polymerization process and has become known as the “basic polymer doctrine.” Under this doctrine, substances such as catalysts, chain transfer agents, and initiators used in accordance with good manufacturing practices are considered part of the basic polymer and are implicitly cleared along with the polymer. These substances need to be integral to the polymerization process, used in small quantities, washed out or become a part of the polymer backbone, and not affect the suitable purity of the polymer.

One final feature of food packaging regulation in the U.S. that should be mention is the so-called “housewares exemption.” Under this exemption, which arose out of the legislative history of the 1958 Act, and recognized by FDA officials in the ensuing years on several occasions, substances that are used in contact with food as part of a houseware product are excluded from the need for FDA premarket clearance. Housewares are generally considered to be articles sold empty and used by consumers in the home or by a commercial establishment to hold, prepare, or serve food. However, substances in housewares are not exempt from the general safety provisions of the FFDCA.

**The Food Contact Notification Program**

A significant development in the regulation of food packaging in the U.S. took place when the Food Contact Notification (FCN) program became effective in January 2000. Since its inception, it has become the preferred method for clearing food contact substances. A major advantage of the FCN program over the food additive petition process is expediency. While it can take two to four years or more to clear the use of a food additive through the petition process, an FCN becomes effective in 120 days from the time FDA accepts the notification, unless the agency objects in writing. Another major difference between FCNs and food additive regulations is that FCNs are proprietary to the manufacturer of the substance and its customers.

The data requirements for an FCN are similar to those for a food additive petition but some differences exist. Both require the notifier to determine the amount of a food contact substance that is expected to enter the human diet, i.e., the Estimated Dietary Intake (EDI). This can be calculated by multiplying the amount of the substance that is expected to migrate to food by the approximate fraction of the daily diet expected to contact materials containing that substance. One difference between data requirements for petition and FCNs is FCNs must include the cumulative estimated dietary intake (CEDI) from all potential sources, not just from the food contact substance that is the subject of the FCN. The type and amount of toxicology data required to clear the food contact substance for its intended use will depend on the nature of that substance and its CEDI.

An additional requirement for FCNs, TOR requests, and food additive petitions are they must include information about the potential environmental impact of their use in order for FDA to issue a finding of no significant impact, or, if needed, complete an environmental impact statement. This requirement stems from the National Environmental Policy Act (NEPA) which requires federal agencies to assess the potential environmental impact of “major” actions.

**Food Packaging Regulation in the EU and Other Jurisdiction**

In today's global economy, different systems for regulating food packaging in different jurisdictions can impact
trade between countries. As a result, some countries have revised or are in the process of revising their laws and regulations governing food packaging to better align with other jurisdictions, especially the EU.

To understand the difference between the U.S. and European food regulatory systems, let’s start with a brief overview of food packaging regulations in the EU. The Framework Regulation[12] governs all food contacts materials in the EU, including containers for transporting food, machinery to process food, and housewares. It also establishes safety standards and authorizes the European Commission (EC) to adopt measures for specific food contact materials or substances.

EU’s most comprehensive legislation on a specific category of food contact materials, to date, is the Plastics Regulation.[13] This regulation includes a positive list (also known as the Union list) of monomers and other starting substances, additives (other than colorants), and some polymer production aids that may be used in the production of food contact plastics. The Plastics Regulation also establishes an overall migration limit (OML) of 10 mg/dm$^2$ for all plastic substances in contact with food, unless their use is subject to an exemption. Specific migration limits (SMLs) and residual quantity in the material (QM) limits for certain substances also are specified.

The Plastics Regulation is “harmonized,” i.e., it essentially preempts the Member States of the EU from imposing additional or different requirements on plastics intended to be used with food except under very narrow circumstances. Plastics are one of the few types of food contact material so far subject to the harmonization in Europe.[14] Member States do retain regulatory authority over other types of materials (e.g., paper, metal, coatings, etc.).

The use of positive lists in the regulation of food packaging materials is becoming more widespread. Under a positive list system, all substances need to be explicitly cleared based on a toxicological evaluation and published in regulations, regardless of exposure, and use of substances not on mandatory “positive lists” is generally prohibited. These lists generally apply to specific categories of food contact materials, such as monomers or additives.

Following are some of the jurisdiction that incorporate (or are in the process of incorporating) positive lists in their food packaging regulations.

- **MERCOSUR** (Mercado Común Del Sur or the “Common Market of the South”) is the largest trading bloc in South America, with Brazil, Argentina, Paraguay, Uruguay, and Venezuela as members. This group issues GMC resolutions that must be adopted by member countries to become law. MERCOSUR’s resolutions on “Positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment that come into contact with food”[15] and “Positive List of Additives for Plastic Materials Intended for the Manufacture of Packages and Equipment in Contact with Foods”[16] are based on clearances in the EU’s Plastic Regulation.

- The GCC (Gulf Cooperation Council) Standardization Organization (GSO) develops standards and technical regulations for the GCC Member States (the Kingdom of Bahrain, the State of Kuwait, the Sultanate of Oman, the State of Qatar, the Kingdom of Saudi Arabia, and the United Arab Emirates) and Yemen, which cover, among other things, food contact materials. The implementation of these standards is voluntary in the GCC Member States. GSO 1863/2013 establishes a list of authorized monomers, other starting substances, macromolecules obtained from
microbial fermentation, additives, and polymer production aids (PPA) that may be used in the manufacture of plastic packages.


- Japan is in the process of transitioning to a positive list system for regulating food contact materials, which is expected to become effective in April 2020. A proposed positive list of 32 resins is based on the existing positive lists developed by the Japan Hygienic PVC Association and the Japan Hygienic Olefin and Styrene Plastics Association.

Food Packaging in the Spotlight

Greater attention has been paid to food packaging over the last few years, with part of that attention in the form of increased scrutiny concerning the safety of food contact materials. Some of the concern stems from advances in technology and the need for FDA to review some of the decisions it made prior to those advances, but it is also due to attacks by environmental groups and other self-defined “public interest” organizations on the safety of food packaging materials. One example is perfluorinated substances.

A petition to delist three perfluoroalkyl ethyl compounds used in water and grease repellant coatings for paper and paperboard to package aqueous and fatty foods was submitted to FDA in March 2015. In reviewing the petition, FDA could not determine the dietary exposure from food contact use of the substances. In addition, there were no toxicological studies showing reproductive or developmental toxicity for the three substances, but recently available data did show toxicity of similarly structured substances. As a result, FDA concluded that there was no longer a reasonable certainty of no harm for the food contact use of the three substances and amended the food additive regulations in January 2016 to no longer permit their use. Interestingly, the three substances had not been used in the U.S. since 2011; the groups that submitted the petition indicated that they were concerned about food packaging made with these substances being imported from other countries.

The use of food contact substances can also be banned in individual states or local jurisdictions. In March 2018, the governor of Washington State signed a bill[18] banning food packaging that contains perfluoroalkyl and polyfluoroalkyl substances. The ban will become effective in 2022 unless the state Department of Ecology cannot identify safer alternative by then. In San Francisco, a ban on the sale of food service wares that contains fluorinated chemicals will become effective in 2019. Needless to say, food packaging materials are also subject to the warning requirements of California’s Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986).

As food packaging continues to receive more attention especially with regards to the safety of individual components, the food and food packaging industries will need to keep abreast of the latest science and how it fits in with the statutory and regulatory requirements designed to assure the safety of packaging materials for use with food.

[2] A food contact material is defined in the FDCA Sec. 409(h)(6) as: “any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in food.”


[9] The Food and Drug Administration Modernization Act (FDAMA) of 1997 introduced this program.

[10] FDA has only once attempted to complete an environmental impact statement for a food packaging material, and it gave up on that effort after a decade worth of work.


[14] The EU also has harmonized sector-specific food contact legislation for ceramics, regenerated cellulose film, and recycled plastics.

[15] GMC Resolution No. 02/12.

[16] GMC Resolution No. 32/07.
