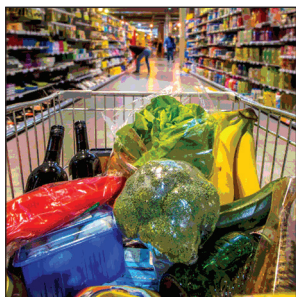


Ensuring the Safety of Food Contact Materials: GMPs and Beyond



Requirements for food companies to ensure the safety of food packaging

The U.S. Food and Drug Administration (FDA) announced in January 2018 that it was exercising enforcement discretion with respect to the Food Safety Modernization Act (FSMA) Foreign Supplier Verification Program (FSVP) requirements for importers of food contact substances (FCSs). The news was met with a sigh of relief by the industry. The reasons for FDA's decision centered on the vastly different hazard profiles and risks presented between FCSs and traditional food.

In meetings and through written correspondence, food packaging industry representatives had pointed out to FDA that requiring importers of FCSs to comply with the FSVP regulation would impose a burden that is not commensurate with the risk presented. Many importers of FCSs source materials from hundreds of suppliers through a complex supply chain; yet, packaging materials do not have a history of being a source of foodborne illnesses.

FDA cited its premarket review and oversight of FCSs, and the regulatory framework for these substances as reasons for exercising enforcement discretion with regards to FCSs and the FSVP regulation.

There are some overriding requirements that apply to both conventional food and food packaging. Chief among these is the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act) prohibition on the adultera-

tion of food. Section 402 of the act defines "adulterated food" as food that:

- Contains any poisonous or deleterious substances "which may render" food injurious to health;
- Contains an uncleared food additive;
- Consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food;
- Is prepared, packed, or held under insanitary conditions where it may have become contaminated with filth or may have been rendered injurious to health;
- Is in a container that is composed, in whole or part, of any poisonous or deleterious substance "which may render" food injurious to health.

The FD&C Act defines "food" to include food additives and defines a "food additive" as "any substance the intended use of which results, or may reasonably be expected to result...in its becoming a component or otherwise affecting the characteristics of any food," unless the substance is generally recognized as safe or the subject of an exemption. This can include substances that are added directly to food and that may become a component of food indirectly, such as through packaging materials.

Prior to 2000, the only means to obtain FDA clearance for FCSs that were food additives was through the submission of a food additive petition. Once submitted, it would then take an average of 2 to 4 years for FDA to promulgate and publish a formal regulation.

During a congressional hearing held in 1958 on the FD&C Act, it was pointed out that with respect to packaging materials, FDA was being called upon to spend an inordinate amount of resources on a potential hazard that time had shown was virtually no hazard at all.¹ Industry kept pressing the point with the U.S. Congress and FDA, which finally paid off with the enactment of

the Food and Drug Administration Modernization Act of 1997 (FDAMA), which introduced a new framework for obtaining FDA clearance of FCSs.

More specifically, FDAMA authorized the Food Contact Notification (FCN) program. This program allows a manufacturer or supplier of an FCS to submit an FCN that includes the identity and intended use of the new FCS, along with data supporting the conclusion that the substance is safe for its intended use. If FDA does not object to an FCN submission within 120 days, then the new FCS, or materials made with it, may be marketed.

So, what does this have to do with Good Manufacturing Practices (GMPs)? Well, just as hazard and risk are important elements in determining how food packaging and other contact materials

should be regulated and the extent of public resources that should be expended on them, so too are these important considerations in assessing the type and nature of GMP controls needed to ensure the safety of FCSs.

As a precursor to this discussion, it is important to note that even if an FCS is cleared by FDA and complies with the specifications and limitations set out in an applicable regulation of an FCN, its use will violate the FD&C Act if it does not also comply with the GMP regulation for food packaging materials, “General provisions applicable to indirect food additives.”²² This regulation is central to ensuring the safety of FCSs in the U.S.

Good Manufacturing Practices

GMPs ensure that products meet food safety, quality, and legal requirements. Since the hazard profiles and risk presented for conventional food and FCSs are very different, FDA has issued separate GMP regulations for

them. Current GMPs for food³ describe the methods, equipment, facilities, and controls for producing food and prescribe the minimum sanitary and processing requirements for producing safe and wholesome food.

Pursuant to FSMA, the current GMP requirements for human food were updated in 2015. Among the changes were new requirements to establish Hazard Analysis and Risk-Based Preventive Controls for food products, which

“There are some overriding requirements that apply to both conventional food and food packaging.”

shift the focus from responding to foodborne illness to preventing it. Since FCSs are rarely the cause of foodborne illness, GMPs for them, which only specify generic requirements, were not updated under FSMA.

The most critical GMP requirement for packaging materials is that they be suitably pure for their intended use. This means that

the FCS may not impart anything to food that can make it harmful or deleterious to health, or impart an off-taste or -odor to food. While rare, off-taste and -odor issues in food packaging do arise. In 2010, Kellogg voluntarily recalled 28 million boxes of cereal due to complaints of off-taste and smell. It was postulated that the wax paper liners in the cereal boxes were releasing hydrocarbons, including methylnaphthalene. Kellogg filed suit against its supplier of the liners to recover the damages it incurred due to the faulty liners, and the liner manufacturer then interpleaded its coating supplier as the liable party.

An important part of suitable purity involves the need to ensure that residual components of starting materials are sufficiently low that their presence will not result in a health or safety concern. Most of these concerns center upon harm from chronic exposure to certain substances that may be suspected of carcinogenic potential or other such health hazards. In evaluating these impurities,

the toxicity profile of the impurity and its dietary exposure must be considered.

Oftentimes, with materials cleared by FDA by way of an FCN, these issues are considered and dealt with by the inclusion of specifications in the FCN itself. Sometimes, where FCSs may be cleared by a regulation, this is not the case as the substance may not have been recognized as a carcinogen at the time it was regulated, and even if it had been, some of the specifications may have been set so long ago as to now be woefully out of date. A dated regulation does not relieve a manufacturer’s responsibility to ensure a suitably pure product.

In addition to purity requirements, the GMP requirements for food packaging apply to the use level of an additive. This means that an FCS may be used only in an amount necessary to achieve its function or purpose, and must also not contain impurities at levels sufficient to adulterate the food.

The GMP regulation for FCSs specifies general rather than the detailed requirements specified for conventional food. The procedures that a manufacturer of FCSs should follow to ensure compliance with the GMP regulation will vary based on the specific product and the manufacturing process. For example, a GMP program for a manufacturing facility that produces defoamers for food contact paper products will differ from one for a plant that produces trays for microwaveable foods.

A well-designed GMP program will address the entire production cycle of FCSs and products. This should include raw materials, manufacturing equipment and procedures, personnel, testing procedures to ensure product purity, and quality control of finished products, along with record-keeping. Other considerations for an effective GMP program are discussed below.

Assessment of raw materials should include confirmation that specifications are met. This may include obtaining certificates from suppliers that show that raw materials are cleared for their intended use by FDA or test results, such as migration testing. In addition,

suppliers should be contractually obligated to notify their customers of any significant changes. The impact of any changes in raw materials or processes should be evaluated before they are implemented. Finally, food contact and nonfood contact materials should be stored separately.

Manufacturing procedures should be written out and available at workstations. The written procedures

should include specific raw materials and amounts, identification of critical points in production that need monitoring, and required testing. Procedures that should be taken to correct any deviations should also be specified. All employees should be trained in GMPs, and details of the training should be specified.

The process for the management of changes—such as the source of raw materials, a product formula, or the production process—should be written out. It is important to clearly document the management hierarchy so it is clear who may approve specific types of changes.

Documentation and record keeping are critical to demonstrating that a manufacturer is conforming to its Standard Operating Procedures. Including all the factors mentioned above in a GMP manual will minimize the chance for errors.

Customer Requirements

As discussed above, GMPs should ensure that FCSs meet legal prerequisites for safety and quality, and while this article focuses on U.S. legal requirements in our global economy, GMP requirements of other countries may need to be considered as well. In the European Union, for example, food contact materials are subject to the Framework Regulation (EC) No. 1935/2004 and the GMP Regulation (EC) No. 2023/2006.

The Framework Regulation specifies that food contact materials and articles must be manufactured in accordance with GMPs, so that they do not transfer their constituents to foodstuffs in quantities that could endanger human health or bring about an unacceptable change in the composition of the food or its organoleptic properties.

Once legal safety requirements are met, customers may require further assurance that FCSs and products are safe and of a certain quality. For instance, many food manufacturers, especially large international ones, are mandating that their packaging suppliers be Global Food Safety Initiative (GFSI) certified.

GFSI was founded in 2000 due to concerns about overlapping audit systems and inconsistencies between

them. GFSI establishes requirements for food safety management schemes and provides a framework against which these schemes can be benchmarked. The organization does not undertake any accreditation or certification activities.

Several certification programs for manufacturers and converters of packaging and packaging materials are currently recognized by GFSI, namely, the British Retail Consortium, FSSC22000, IFS PACsecure, and the Safe Quality Food program.⁴ The GFSI-benchmarked food packaging standards establish a minimum set of requirements. One of these requirements is to have a Hazard Analysis and Critical Control Points (HACCP) program in place. Unlike GMP inspections that can be flexible, GFSI-benchmarked audits are defined by the owners of the standard.

A HACCP plan can be included in a company's GMPs. Its basis is to identify, evaluate, and control hazards. For packaging, these can include foreign objects or chemical contamination.

The seven principles of an HACCP program are:

- Conduct a Hazard Analysis;
- Identify the Critical Control Points (CCPs) where control can be applied to prevent, eliminate, or reduce a hazard;
- Determine limits for each CCP;
- Establish monitoring to ensure that limits are being met at each Control Point;
- Establish corrective actions when limits are not met;
- Establish record-keeping procedures;
- Verify that the program is working.

In summary, FDA's GMP regulation for indirect additives is fairly general and includes the following requirements for food contact materials and their components: They should be suitably pure and comply with other provisions of the FD&C Act; they must not render food unfit for consumption; and they should not be used at a level greater than necessary to achieve the intended technical effect.

This being said, as greater attention is focused on the role of packaging in food safety, whether justified or not, food manufacturers may require their packaging supplier to establish compliance with food safety certification programs that go beyond current requirements. But that is a subject for another day. ■

George G. Misko, Esq., is a partner in the Washington, DC, office of Keller and Heckman LLP. He can be reached at misko@khlaw.com.

References

1. See *Food Additives: Hearings on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food Before a Subcommittee Of the House Committee On Interstate & Foreign Commerce*, 85th Cong. 44 (1958); at 447 (testimony of Jerome H. Heckman, Society of the Plastics Industry).
2. 21 C.F.R. Section 174.5.
3. 21 C.F.R. Part 117.
4. See www.mygfsi.com/certification/recognised-certification-programmes.html. Keller and Heckman does not endorse any specific certification or audit program.

"The most critical GMP requirement for packaging materials is that they be suitably pure for their intended use."