

About the Author



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Utilizing the Newly Proposed Imported Food Safety Rules as a Risk Management Tool

The announcement by the U.S. Food and Drug Administration (FDA) in late July of proposed regulations intended to strengthen the oversight of foods imported for consumption in the U.S. has generated a great deal of publicity and comment in the media—often on the part of importers and other affected suppliers who are concerned about the increased time, cost and paperwork that compliance with the new rules would require. Given the degree to which imported food products have become a significant component of the U.S. food supply and the number of disease outbreaks linked to imported food products, however, the development of regulations and a framework to insure the safety of food products imported into the U.S. is inevitable. As a result, rather than resisting regulation as an onerous burden on their business, imported food suppliers should recognize the ultimate benefit of these regulations as a potential risk management tool that will mitigate the potential for the significant liability that can result from the importation of hazardous food products. In addition, given the intent of these regulations to prevent the importation of hazardous products by focusing on the foreign sources of those products rather than hoping to identify hazardous foods as they enter the U.S.—or worse, after domestic shipment to distributors, retailers and consumers—compliance with the proposed regulations should also mitigate the significant monetary and reputational cost of a recall.

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In announcing the food import regulations, dubbed the Foreign Supplier Verification Programs (FSVP), FDA stated that it was following one of the mandates of the 2011 Food Safety Modernization Act to insure that food imported into the U.S. meets the same level of public health protection as food that is produced domestically. FDA reported that about 15 percent of the U.S. food supply is now imported from farms and producers around the world, and for some commodities, that percentage is significantly larger, especially with respect to produce. Although Congress directed FDA to increase its own inspection of foreign food facilities, the realities of its limited resources prompted FDA to utilize its additional authority to require industry to share the responsibility for insuring that foreign food suppliers produce and provide safe food products.

In essence, the FSVP regulations require food importers to engage in the type of hazard recognition and assessment, and in the type of recordkeeping, which any responsible supplier of consumer goods should perform with respect to its products. Generally speaking, manufacturers, distributors and sellers of consumer products are under a common law duty to provide products that are not unreasonably dangerous and to warn consumers of potential dangers associated with the use of their products. In the event of a claimed injury, accurate recordkeeping that documents the steps taken to insure the safety of the product as well as steps taken to insure that the product was manufactured in compliance with its design and safety specifications is important evidence demonstrating that the manufacture took appropriate steps to comply with its duty to supply safe products. In addition, Consumer Product Safety Act regulations require the prompt reporting and correction of potential safety hazards, and under certain circumstances, the recall of products that impose a risk of injury. While the cost and inconvenience of these regulations may seem at first to be unduly burdensome, in practice, this regulatory scheme has spared many manufacturers and importers from what could have otherwise developed into substantial liabilities for personal injuries.

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The same rationale can be applied with respect to the FSVP regulations that FDA proposes for food importers, who are likely the most vulnerable members of the imported food commerce stream when it comes to personal injury litigation in the U.S. Because the foreign producers of imported foods are likely acting wholly outside the U.S. and are not the entities shipping their products here, those foreign suppliers are also likely insulated from exposure to direct liability in the U.S. for the production of contaminated or otherwise hazardous food products. As a result, the importers of those products will be the primary, and perhaps only, targets of any litigation arising from the consumption of those products. Given the potential for widespread illness or death resulting from the consumption of hazardous food products, the potential risk of an importer incurring substantial liabilities is not inconsequential.

In addition, even if the hazardous potential of a food product is identified after importation but before there are any incidents of serious injury, the cost of a recall of those products both monetarily and to the reputation of the importer is one that could have been avoided if adequate measures were taken at the foreign source of those products.

However, by engaging in the hazard assessment and verification process proposed by FDA to evaluate both products available for import and the suppliers of those products, food importers can mitigate the risk of substantial injury liability resulting from consumption of the products they import and distribute in the U.S., as well as the risk of incurring substantial recall costs. Not only should effective compliance

with the FSVP regulations help an importer minimize or eliminate the risk that a food product it imports will be an actual or potential cause of harm, but the recordkeeping requirements of those regulations will insure that the importer can demonstrate its efforts to prevent the possibility that products it imports are hazardous. Even if after full compliance with the FSVP regulations a harmful food product slips through the cracks and causes injury, the extent to which an importer complied with the regulations should help reduce its ultimate litigation exposure.

Government proposals for new regulations inevitably result in resistance from the business community, but there seems no question that imposition of regulations designed to insure the safety of imported food products cannot be avoided. Rather than fight those regulations as an imposition, the food industry, and especially importers of foreign food products, can view compliance as a beneficial risk management tool that should ultimately reduce their exposure to personal injury or recall liabilities.

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