Mass Torts Breakout Session II --
Our Food at Risk: Using the Food
Safety & Modernization Act to
Detect Economic Adulteration

Joanne M. Gray¹
Goodwin Procter LLP
New York City, NY

¹ Joanne Gray is a partner and co-chair of the Food and Healthy Living Practice at Goodwin Procter LLP in New York City. She can be reached at jgray@goodwinlaw.com. The author is indebted to Chad Higgins for his assistance in writing this article.
I. Introduction

With the continued globalization of the world economy, including ever-increasing source diversity in the United States food supply, food safety is a growing concern. In addition to monitoring the safety and quality of the actual ingredients, supply, manufacturing and packaging processes of our foods, including those coming into the United States from foreign suppliers, substantial attention and efforts must be directed to the economic adulteration of our food supply. The growing market for diverse foods, especially those with high-quality ingredients, has incentivized actors in the food supply to use lower-cost, lower-quality ingredients, while passing them off as their higher-quality counterparts.

To address food safety and maintain the economic integrity of the market, the food industry and the Food and Drug Administration (“FDA”) have been taking strides to combat economic adulteration in the U.S. food supply. The Food Safety and Modernization Act’s Foreign Supplier Verification Program (“FSVP”) is now a weapon that has been deployed and can be utilized to combat the economic adulteration challenge.

II. What are some examples of economic adulteration in food?

According to a 2011 report, the following are among the most adulterated foods: vanilla extract; maple syrup; coffee; saffron; honey; milk and olive oil. In addition, tea, peanuts, pet food, and organic foods are all subject to economic adulteration. The common forms of adulteration include replacing naturally occurring ingredients with their less expensive synthetic counterparts (vanilla), substituting a product from a country or region different than what is on the label (olive oil), and adding certain chemicals to boost the purported nutrient value (milk and dairy products).

III. What are the consequences of economic adulteration in food?

There are safety concerns with intentional adulteration. In 2007, pet food adulterated with melamine reportedly killed a large number of dogs and cats in the United States. Seafood fraud is common, and beyond the economic fraud issues, it may cause food poisoning or allergic reactions. Beyond these and other potential health risks, the Grocery Manufacturers Association estimates that fraud may cost the global food industry between $10 billion and $15 billion per year, affecting approximately 10% of all commercially sold food products. Fraud resulting in a food safety or public health risk event could have significant financial or public relations consequences for the food industry or a targeted company.

IV. What can be done to combat economic adulteration in food?

The FDA Food Safety Modernization Act (“FSMA”), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011.

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2 http://www.cbsnews.com/media/food-frauds-10-most-adulterated-foods
4 Id.
It primarily aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. One such prevention method is the FSVP rule (21 C.F.R. 1.500, et seq.), which was issued on November 13, 2015 and published on November 27, 2016. This rule has been deployed to protect not only the health and safety of our food supply chain, but also to empower the industry to address economically-motivated adulteration of food.

From the outset, it should be noted that not everyone agrees that the FSVP is appropriate for addressing economically-motivated adulteration. For instance, the Grocery Manufacturers Association (“GMA”) made clear in its public comments to FDA’s proposed rule creating the FSVP that it did not agree with including it within the scope of the program:

Economically motivated adulteration [“EMA”] is not a good fit for the hazard analysis and preventive controls framework for addressing food safety hazards because EMA is, in all but the rarest of circumstances, an issue of product integrity and quality, whereas food safety systems are designed and built to prevent or mitigate food safety hazards. Moreover, whereas traditional food safety hazards are primarily both identified and addressed at the facility level, EMA is typically handled by the corporate parent company. This is where supply chain management programs are typically located and preventive controls to address EMA cannot be applied at the facility level. Further, because food safety-related EMA is extremely rare and because predicting EMA to prevent it is extremely difficult, there will be no measurable benefit to food safety by imposing requirements to consider EMA hazards as part of a food safety plan or foreign supplier verification program.6

The FDA considered this, and other food industry input, but proceeded to include the economically-motivated adulteration analysis requirement in the final rule. To this comment, the FDA responded:

Economically motivated adulteration [“EMA”] can and has resulted in safety concerns, including, as in the case of melamine in infant formula and pet food, the deaths of humans and animals. The fact that a plan for addressing EMA might be developed at the corporate level is irrelevant to whether an importer can determine whether EMA in a particular food is known or reasonably foreseeable. Further, we disagree that economically motivated adulteration requires a completely different approach than unintentional adulteration. Although we acknowledge that many firms currently might not include EMA in their analyses of safety hazards in food, as we stated in the Supplemental Notice, some of the measures that industry uses in supplier verification programs, such as audits and sample testing, are used to guard against EMA. Moreover, we believe that the burden posed by having to analyze potential EMA hazards is limited because, as with hazards that occur naturally or that may be

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unintentionally introduced, we define hazards to include only those agents that have the potential to cause illness or injury. In the EMA context, we anticipate that importers will identify such hazards in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration of a food. Therefore, we conclude it is appropriate that importers consider EMA hazards under the FSVP regulation.7

The FSVP is not specifically designed to counter economically-motivated adulteration. Even so, it is an important tool that regulators and the industry can leverage to address what everyone agrees is a safety risk, and thus it can assist in helping to ensure quality and integrity of imported foods. The following discusses the requirements of the FSVP final rule and how they can be utilized to combat economically-motivated adulteration of food.

The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. Under the rule, importers of food products and dietary supplements are responsible for verifying that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations, as appropriate, and to ensure that the supplier’s food is not adulterated and is not misbranded with respect to allergen labeling.

The FSVP risk factors include the types of hazards, importers, and suppliers involved. The regime is supposed to provide the importer some flexibility in meeting its requirements. Although economic adulteration is not the primary focus of the rule, under this regime, focus on certain economic adulteration controls and enhancements can also be utilized in conjunction with addressing and preventing other hazards.

Importers, subject to certain exceptions, are responsible for:

1) determining known or reasonably foreseeable hazards with each food through a hazard analysis; and

2) evaluating the risk posed by a food, based on the hazard analysis and the foreign supplier’s performance, which must reevaluated at least every three years, or when new information comes to light.

This evaluation must be utilized to determine the risk posed by an imported food and the supplier’s performance to approve suppliers and determine appropriate supplier verification activities, and, if necessary, supplier corrective actions.

Through conducting these already-required risk assessment, supplier evaluation, verification, and corrective activities, the industry can utilize the FSMA to combat economic adulteration. The required elements to be considered include, inter alia, the following economic factors: formulation of the food; condition, function and design of the facility and equipment used to manufacture the food; and the raw materials and other ingredients. To prevent economic

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adulteration, a FSVP should also include safeguards to detect the quality and integrity of the ingredients used.

The hazard analysis is primarily designed to protect against certain health risks, such as controlling for parasites, disease-causing bacteria, chemical and radiological hazards, pesticides, drug residues, natural toxins, food decomposition, unapproved food or color additives, allergens and physical hazards like glass. These may be hazards that are reasonably likely to cause illness or injury, and they may occur naturally or be unintentionally introduced. So the hazard analysis can be utilized to protect against ingredients that are intentionally introduced for purposes of economic gain, such as failing to follow the food product formula by substituting a less costly ingredient. The rule requires importers to evaluate economic adulteration as part of the hazard analysis for a food, so that, if economic adulteration is determined to be a hazard requiring a control for that food or supplier, importers must make sure that appropriate supplier evaluation to prevent the intentional adulteration for economic gain.

In performing the evaluations required under the FSVP, importers have the ability to either conduct their own evaluation of the risk by a food or supplier, or, under certain circumstances, to rely instead on an evaluation conducted by another entity (other than the foreign supplier). The hazard analysis must be well thought out and specific to the risks: Importers must thoughtfully consider all aspects of their hazard analysis, including the nature of the hazard and the entity that will apply the controls for that hazard. Regarding economically-motivated adulteration, importers should consider the foreign supplier’s procedures, processes, and practices related to ingredient supply and integrity. In addition, the importer should also consider the foreign supplier’s food safety performance history and their results from testing foods for hazards, including adulteration issues and the supplier's record of correcting any problems.

In final FSVP rule, the FDA has also sought to create flexibility for the importer as to its foreign supplier verification activities. An importer may rely on another entities’ determination or performance of verification activities. However, an importer must review and assess the results of its own verification activities as well as those of the other entities on which the importer chooses to rely. Verification procedures are primarily to ensure that foods are obtained from approved suppliers, though unapproved suppliers may be used on a temporary basis when the food is subject to verification. Section 1.506 of the final rule provides importers flexibility in determining appropriate supplier verification activities for all hazards, including economic adulteration, consistent with the evaluation of the risk posed by a food and the foreign supplier's performance. These verification activities must be well documented. The FDA’s view of needed records is very clear: if it is not documented, it doesn’t exist.

Importers must develop an FSVP for each food imported and for the foreign supplier of that food. If the importer obtains a certain food from a few different suppliers, a separate FSVP would be required for each of those suppliers.

To address these hazards, importers are responsible for conducting or obtaining documentation of onsite audit of suppliers, sampling and testing of food, review of suppliers relevant food safety records, and other appropriate activities based on supplier performance and the risk associated with the specific food. And, the importers must also review and assess the results of these
verification activities and then take necessary corrective actions. It is important to note that there can be no financial conflicts of interest influencing verification activity results.

To ensure the quality of these oversight responsibilities, importers must establish and follow written procedures to ensure they import only from suppliers approved after a hazard analysis, an evaluation of risk, and that any unapproved suppliers (used only when necessary or temporarily) are subject to adequate verification activities. Qualified individuals must develop and perform these FSVP activities. These individuals must have the appropriate education, training, or experience along with the appropriate language skills to understand the records to be reviewed.

Importers must take corrective actions if the FSVP shows that a foreign supplier is not producing food in compliance with required processes and procedures, with the scope of those corrective actions being dependent upon circumstances. The appropriate corrective measure could be quite severe and may include discontinuing use of the foreign supplier until the cause of noncompliance, adulteration or misbranding has been adequately addressed. Among these controls should also be permanent replacement of suppliers that are determined to be intentionally adulterating products for economic gain. These corrective actions must be properly documented.

Despite the amount of time and efforts devoted to the FSVP regime, important gaps exist within its scope as it relates to economically-motivated adulteration. For instance, some of the most commonly and easily adulterated foods are not covered by FSMA or the FSVP. Juice, fish, and fishery products subject to and in compliance with FDA’s Hazard Analysis and Critical Control Point (“HACCP”) regulations for those products, and certain ingredients for use in juice and fish and fishery products subject to the HACCP regulations are exempted from the FSVP requirements. In addition to juice and seafood, certain meat, poultry and egg products regulated by the U.S. Department of Agriculture at the time of importation are also exempt, along with alcoholic beverages and certain ingredients for use in alcoholic beverages.  

The rule provides that the deadline for compliance is 18 months after the final rule was published, which is the end of May 2017, unless the rule provides otherwise for certain categories of importers.

V. Buyer Beware

A simple “buyer beware” policy should apply to all food companies that import food into the United States: your food supply is always at risk for potential adulteration – whether for economic reasons or otherwise. While the FSVP is not the perfect tool to eliminate all adulteration risk, it does provide the framework for regulators and the food industry to use to help mitigate the risk of adulteration in the imported food supply. Consulting with experienced food lawyers and food safety technical experts is recommended to assist in developing the procedures and processes that you will need to comply with the requirements of the FSVP and to help reduce the risk of product adulteration.

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8 Dietary supplement ingredients that are subject to further processing are exempt from the FSVP so long as certain requirements are met, but the FSVP applies to all finished dietary supplements.