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In 2011, the United States imported 28.2 billion dollars (USD) of food products from Asia, fully 25% of its total supply of imported food. United States federal law invests the U.S. Food and Drug Administration (FDA) with authority to interpret and enforce a complex web of federal law, regulations, and internal compliance policy concerning these food imports. Indeed, in 2011, with the passage of the U.S. Food Safety Modernization Act (FSMA), U.S. FDA possesses even greater authority over to require that suppliers of food and food additives intended for the U.S. market comply with significantly-expanded obligations imposed on manufacturers, distributors, exporters and importers of food and food additives intended for use in the United States.

Legal Structure for Food Additives in the United States

The definition of food under U.S. federal law is quite simple: “articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.” This definition also includes human food, pet food, animal feed, and any substances that could migrate to food contact articles. Significantly more complex, the related definition of food additive includes any substance whose the intended use results, or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.

Premarket Requirements for Food Additives Under U.S. Law

Since 1958, under the U.S. Food Additive Amendments, food additives became subject to FDA approval through the FAP process by which the petitioner (any person) may submit a request, and FDA evaluates whether, to issue a regulation that prescribes the conditions under which the proposed food additive may be safely used. The FAP must include data related to the composition and properties of the substance, amount typically consumed, immediate and long-term health effects, and various other safety
factors. In order to issue a food additive regulation based on the petition, FDA evaluates a built-in safety margin for the proposed substance: some factor that allows for uncertainty related to the amount actually consumed so that that amount that gains approval is substantially lower than the amount that is expected to have an adverse affect on the consumer. As discussed below, the Generally-Recognized-As-Safe (GRAS) Notification and the Food Contact Surface (FCS) Notification regimes currently function as important premarket requirements to ensure the safety of food additives.

What is Included in the Definition of Food Additive?

The definition of food additive includes any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food (and it specifically includes radiation-sources intended for such uses). A substance is a food additive if it is reasonably expected to become a component of food or has a technical effect on the food.

A food additive may be direct or indirect. Direct food additives are substances added directly and intentionally to food whose use has been approved by FDA through the Food Additive Petition (FAP) process or is subject to the Generally-Recognized-As-Safe (GRAS) regime. Note that these direct additives also include substances that are added to food during the processing or manufacturing process but are not intended to have an ongoing technical effect on the food. Indirect food additives are substances that are not intentionally added directly to food but which may reasonably be expected to become a component of food. These additives often include substances used in or on food packaging or the equipment used for processing or handling food.

What is Excluded From the Definition of Food Additive?

The definition of food additive excludes (1) substances excluded by federal law, (2) substances subject to Prior-Sanction, and (3) substances generally recognized as safe (GRAS).

Substances Excluded by Federal Law

Under the U.S. Food Additives Amendments of 1958, many substances, such as pesticide residues on raw agricultural commodities, color additives, new animal drugs, and dietary ingredients, are statutorily excluded from the definition of food additive.

Substances Subject to Prior Sanction

Some food additive substances are exempt from the statutory definition of food additive by prior sanction, because, through scientific procedures, experience based on the common use of the additive in food, or
because the food additive is a substance that was in the U.S. food supply prior to January 1, 1958 (i.e., for which there is a substantial history of consumption by a significant number of consumers). Substances that enjoy prior sanction include, for example, some meats and poultry products or related preservatives (e.g., sodium nitrate and potassium nitrate).

**Substances Generally-Recognized-As-Safe (GRAS)**

As indicated above, "GRAS" is an acronym that means "generally-recognized-as-safe" among qualified experts, as having been adequately shown to be safe under the conditions of its intended use.

While GRAS substances are specifically excluded from the statutory definition of food additive, the regulatory determination of a substance as GRAS functions as a premarket requirement for these substances. The Food Additive Amendments of 1958 established the statutory basis for GRAS as a regulatory mechanism for approving the use of substances in food, and FDA began maintaining a "list" of GRAS substances in the early 1960s. Throughout the 1960s, manufacturers routinely asked FDA to opine on the GRAS 'status' of their substances. During the 1970s, FDA contracted with non-government scientists to evaluate the status GRAS substances, at which time FDA established and maintained an administrative rule-making process by which it "affirmed" the GRAS status of proposed food additives. This process functioned from 1974 to 1990 under which industry submitted GRAS Affirmation Petitions and FDA issued regulations concerning the GRAS status of such substances. The problem, of course, was that most petitions took 4-6 years or longer to evaluate.

In 1997, because this approach was very resource-intensive and required a timely "notice and comment" process in order to issue regulations, FDA proposed the current GRAS "notification" process and began accepting notification filings in 1998. Under this regime, FDA does not affirm the GRAS status of food substances. Instead, FDA merely acknowledges that it possesses "no objections" to the safety determination made by the notifier. Of course, this process itself has not been finalized by regulation and is not currently specifically authorized by statute. (Still, according to FDA’s GRAS Inventory database, since December 31, 2012, at least 451 market participants have submitted GRAS Notifications. Currently, FDA is 30-60 days behind in its publication of received GRAS Notifications.) It is, however, more timely and less resource-intensive: FDA completes its review of most GRAS notifications within six months and does not specifically 'affirm' anything with regard to safety other than that the agency does not object to the notifier's safety determination. Thus, the process is FDA's current attempt to provide an administrative procedure for evaluating the safety of substances intended for consumption in food from outside the FAP approval process specifically articulated under U.S. federal law. However, if the data submitted in the GRAS Notification has not been sufficiently circulated or is not subject to general awareness among qualified experts, then a manufacturer may be required to revert to the FAP process which is both costly and time-consuming.

Notably, because of the empirical nature of safety determinations (i.e., data could arise at any time contradicting established conclusions), no statutory or regulatory definition of "what constitutes safety" exists.

Manufacturers may also 'self-affirm' the GRAS status of their additives by maintaining adequate safety data related to the additive, including ADME (i.e., absorption, distribution, metabolism, bioavailability, and elimination) data, as well as safety data (e.g., human clinical studies, including acute, chronic, mutagenic, genotoxic, and carcinogenic information). Indeed, federal regulations require the same quality and quantity of data in GRAS determinations as that required in the Food Additive Petition process, discussed below.
If a manufacturer chooses not to self-affirm the GRAS status of its food additive, the manufacturer may still submit a "GRAS Notification" to the Office of Food Additive Safety (OFAS), within FDA's Center For Food Science and Applied Nutrition (CFSAN) within FDA. Once submitted, OFAS either (1) does not question the notifier's GRAS determination and issues a "No Objection" letter; (2) concludes that the GRAS notice doesn't include adequate data or information to determine safety, or data or information exists which raises questions concerning safety; or, (3) FDA ceases evaluating the GRAS Notification at the notifier's request. In any case, in the GRAS Notification and "No-Objection Letter" context, then, FDA does not "approve" food additives at all. Instead, FDA merely affirmatively chooses not to dispute the safety findings that the notifier indicates are generally-recognized with respect to the food additive.

**Food Contact Substance (FCS)**

A food contact substance is one that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food. If the FCS use is intended to have a technical effect in the food, then the FCS is also defined as a food additive and is therefore subject to food additive regulation: that is, it must be (a) approved by specific regulation or pursuant to an approved FAP, or (b) exempt from approval because it is specifically-excluded by law, subject to Prior Sanction, or is GRAS. If the FCS use is not intended to have a technical effect in the food, then the FCS is subject to a Food Contact Notification (FCN), which must be submitted 120 days prior to marketing the FCS.

And FCN contains similar data as is normally included in the GRAS Notification. If FDA does not respond to the FCN, then it automatically becomes effective after the 120-day period. If FDA determines that it has safety concerns, the notifier may withdraw the FCN, with prejudicing a future submission. If the notifier does not withdraw the FCN, FDA will issue a Non-Acceptance Letter and does so (1) if FDA believes use of the FCS will increase the cumulative estimated daily intake of the FCS to greater than 3mg/d for non-biocides and 0.5mg/d for biocides, or (2) if a bioassay exists on the FCS which FDA has not reviewed and the bioassay is not clearly negative for carcinogenic effects.

Receiving the automatic effectiveness (Food Contact Notification) and the No-Objection Letter (Generally-Recognized-As-Safe) are proprietary to the applicant. If either notification is withdrawn before FDA's review process is completed, then the information submitted in support of the notification cannot be disclosed to the public. However, if FDA objects because of safety reasons, then the information is publicly available, unless it is confidential trade-secret information.

**Other Requirements on Food Additive Providers**

**U.S. Food Safety Modernization Act (FSMA)**

In 2011, the United States Congress passed the FSMA requiring that FDA implement mechanisms designed to improve food safety in the United States. Now, FDA will require importers to verify that their foreign suppliers comply with U.S. law, and will provide an opportunity for importers to to exchange their operational transparency for expedited review of inbound shipments. The two programs through which FDA intends to fulfill these goals are the Foreign Supplier Verification Program ("FSVP") and the Voluntary Qualified Importer Program ("VQIP").

**Foreign Supplier Verification Program (FSVP)**

FSVP requires importers to perform supplier-verification activities to ensure that imported food additives are safe. Specifically, the program requires importers to create a program and perform risk-based foreign supplier verification activities to verify that imported food additives are produced in compliance with the new Hazard Analysis and Risk-Based
Preventive Controls (HARPC) or Standards for Produce Safety requirements. These verification activities include, but are not limited to lot-by-lot certification of compliance, annual on-side inspections, and periodically testing and sampling shipments. These verification activities are intended to confirm that the imported food additives from a verified foreign food facility are safe.

**Voluntary Qualified Importer Program (VQIP)**

VQIP is a voluntary, user-fee funded program designed to provide an incentive for importers to improve transparency regarding their food safety measures. Under VQIP, FDA will grant importers expedited review of their shipments imported in real time under the program. However, the importer must provide FDA with evidence of adequate food safety measures, prior to approval and prior to importing under the program. The importer becomes eligible for VQIP when (1) FDA determines that the food offered by the importer for importation is safe and (2) the foreign food facility obtains certification by a third-party auditor, which verifies that the facility complies with the relevant food safety regulations.

**Increased Food Facility Registration Requirements**

Under the Bioterrorism Preparedness and Response Act of 2002, all facilities that manufacture, hold, pack, process, or distribute food additives offered for sale in the United States must be registered with FDA as an FDA Food Facility. The facility must also maintain a U.S. Agent to liaise with FDA for matters relating to facility registration. Effective October 2012, under the Food Safety Modernization Act (FSMA), effective foreign food facilities must re-register with FDA every two years.

However, U.S. Federal regulation do not require a foreign facility register if the food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. Thus, many food additive providers may be exempt from FDA Food Facility Registration. Yet, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities are required to register. Any foreign facility that packs or holds food after the last foreign manufacturer/processor of the food must also register.

**Food Additive Facility Compliance and Inspections**

In order to ensure that food additives are prepared, packed, and held under sanitary conditions so as to not become contaminated with filth or rendered otherwise injurious to health, under its "current Good Manufacturing Practices" (cGMPs), U.S. federal regulations impose affirmative obligations on manufacturers of food additives to control risks associated with chemical and microbiological risks. These requirements address personnel practices, plant design, equipment specifications and cleaning, quality control testing, and production controls and distribution.

Under FSMA, food additive facilities are subject to enhanced requirements that include developing a Hazard Analysis and Risk-Based Preventive Controls (HARPC) plan. This will require manufacturers to evaluate and prepare written analyses or known, or reasonably-foreseeable food safety hazards that could affect food (including additives), such as chemicals, allergens, pesticides, and parasites, regardless of whether these contaminants were introduced unintentionally or intentionally. Among other important features, HARPC must include a written food recall plan. While FSMA grants FDA the new authority to mandate a recall if the manufacturer fails to voluntarily conduct a recall of unsafe food that is reasonably expected to cause serious injury or death, new rules under FSMA use the language of "food safety plan" to describe a HARPC plan that additionally includes procedures for monitoring these risks, as
well as corrective action in the event that these risks materialize and a verification process for ensuring the adequacy of these corrective actions.

These registered food facilities are subject to inspection by FDA, at reasonable times, within reasonable limits, and in a reasonable manner. Upon initiating an inspection, FDA personnel must identify itself to the owner, operator, or agent in charge of the facility. During the inspection, FDA officials may request essentially any records, files, papers, processes, except financial and/or sales data, and most personnel data. FDA Inspectors may also collect food samples and labeling.

**Forms and Consequences of Non-Compliance with U.S. Law**

**Forms of Non-Compliance**

U.S. federal law prohibits food additive providers to introduce into United States commerce any food additive that is adulterated: i.e., bears or contains a poisonous or deleterious substance which may render the article injurious to health. This includes, for example, pesticide residues at levels above regulatory tolerances established by the U.S. Environmental Protection Agency (EPA). This does not include substances which, because they may be inherent to the food additive, do not render the article injurious to health (e.g., arsenic in apple extract). This also does not include substances that, while contaminants, are unavoidably necessary to the production of the food additive, so long as the level of the contaminant does not exceed tolerance levels established by FDA. Food additives may also fail to comply with U.S. law and regulation if they contain any filthy, putrid, or decomposed substances. FDA determines whether a food additive contains such an adulterant worthy of enforcement based on the 'defect action' level of the contaminant in the food additive. Food additives may also be adulterated if they are simply otherwise unfit for food (e.g., if they do not meet consumer expectations with respect to appearance, quality, taste, etc.). Importantly, food additive labels must comply with federal law and regulations, especially with respect to their identity, the name of the manufacturer, and the country of origin. Finally, since FDA registered Food Facilities are subject to inspection, its owner/operators must not refuse an FDA inspection that is properly noticed. And FDA inspection of a registered FDA Food Facility often results in inspectional "observations" that amount to allegations that the provider has violated certain of its cGMP obligations relating to the sanitary holding, packing, processing, or preparing of its food additives.

**Consequences of Non-Compliance**

If a food additive provider subject to FDA Food Facility Registration is found to have violated U.S. law or regulations during an inspection, FDA engages certain administrative enforcement strategies which can have significantly negative consequences for these suppliers. First, if an owner, operator, or agent in charge of an FDA registered Food Facility refuses a duly-authorized facility inspection, under FDA’s new authority granted by the FSMA, FDA may suspend the facility’s FDA registration and subject the facility’s imported products to automatic detention without physical examination ("FDA Import Alert," discussed below).

After an FDA Food Facility inspection, FDA issues a "Notice of Inspectional Observations," which are subject to public disclosure. As above, this notice amounts to FDA’s allegations of the extent and manner in which the firm has violated its affirmative legal obligations under U.S. law and regulations. Failure to adequately address these allegations may result in FDA publicly-issuing a "Warning Letter" : it is a formal administrative declaration that FDA believes the provider has violated the law. An FDA Warning Letter amounts, essentially, to a threatening attempt to coerce voluntary compliance ahead of a potential judicial action. FDA can also use its position in American society as the food regulator
to issue negative publicity concerning a food additive provider. When a food additive violates federal law because it is unsafe, FDA often uses its enforcement discretion to persuade such providers to engage in a voluntary recall of the food additive. Under new powers granted to it by FSMA, if the defective food additive subjects the public to reasonably-foreseeable risk of serious adverse health consequences or death—after engaging in an expedited administrative hearing process—FDA may mandate that the provider recall the food additive.

In certain very egregious cases, since the laws governing food additive safety impose criminal penalties, FDA often engages in criminal prosecution against the directors and officers of food additive providers when it appears that the company officials intentionally violated the law and these intentional violations resulted in either large-scale economic fraud or significant health-risks to the public. In addition to subjecting these individuals to imprisonment and/or fines, subsequent to a serious criminal conviction, both individuals and companies responsible for importing food additives can be debarred, i.e., permanently prohibited, from selling food additives into the United States.

Upon importation, FDA may hold or examine a food additive being offered for import into the United States without any reason at all. FDA may stop the article from entering the U.S. if the article merely “appears” to violate federal law or regulations. This allegation may arise from examination of the article, its labeling, or based on some other information (i.e., the compliance history of the importer or manufacturer, the perceived risk-level of the specific food article, or the country or region of origin). In other words, the detention of the food article may occur on the basis of a physical examination or it may occur without physical examination. Upon making this allegation, the importer is given opportunity to present evidence to overcome this allegation. If successful, the article may be released into U.S. commerce. The time-delay, costs (product storage, Customs fees, potential private laboratory costs, etc.) associated with this presentation of evidence to overcome allegations made on the basis of an examination of the article can be significant.

However, under its “Import Alert” regime, when FDA detains food additives automatically without physical examination, the business impact on non-U.S. exporters can be catastrophic. With over 265 FDA Import Alerts, some alerts pertain to all products coming from a particular country, or particular types of products, or non-compliant labeling, or the existence of some adulterant (filth, pesticide or pharmaceutical residue), or the presence of illegal colorants. Becoming exempt from these import alerts involves a complex petitioning process by which a subject firm requests that FDA evaluate evidence submitted in support of the exemption which includes an investigation into the basis for inclusion on the alert, a demonstration of adequate corrective actions, and a record of shipments of the subject article which FDA released into U.S. commerce. Unless this petition is developed, documented, drafted, and prosecuted with expertise, receiving exemption from the import alert remains uncertain.

Conclusion

Navigating the landscape of U.S. federal law and regulations related to food additives is both complex and rewarding for firms that take these obligations seriously. The new world inaugurated by the passage and implementation of FSMA surely will bring opportunities for Asian suppliers, manufacturers, distributors, and exporters of food additives intended for the U.S. market, opportunities to fortify brand strength and to capture market share through investments in regulatory compliance to ensure product quality.