# UNITED STATES FOOD SAFETY LAW DEVELOPMENTS OF INTEREST FOR EUROPEAN FOOD COMPANIES

*food safety*

MAILE HERMIDA, ANNA GLINKE

The food safety laws in the United States have changed significantly in recent years. The FDA Food Safety Modernization Act (FSMA) was signed into law in 2011, after which the U.S. Food and Drug Administration (FDA) spent several years developing and finalizing implementing regulations. Most of the regulations under FSMA are now being enforced, and FDA is focusing considerable efforts on its inspectional activities. The FSMA regulations apply to food companies that sell FDA-regulated food in the United States, with very few exceptions, so companies in Germany and Austria are covered by these new requirements as applicable to their operations. In this article, we survey the key requirements under the FSMA regulations, provide updates on FDA's implementation and inspection activities, and conclude with recommendations for actions to take to ensure you are in compliance. Note that FDA does not regulate meat and poultry products, so U.S. requirements for those foods are beyond the scope of this article.

## I. Background on FSMA

Congress enacted FSMA in response to a number of significant food safety issues in the United States and increasing globalization of the food system. About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. The goal of FSMA is to shift the focus from responding to foodborne illness to preventing it.

FDA has finalized seven major rules to implement FSMA. The underlying focus of the regulations is on ensuring that all of the parties in the global food supply chain are responsible for managing the food safety risks within their control.

## II. Overview of Key Regulations

Below is a summary of each of the seven major FSMA regulations, their requirements, and how they affect companies in Germany and Austria that sell food in the United States.

### *1. Preventive Controls for Human Food*

In general, the Preventive Controls for Human Food (PCHF) rule applies to all facilities that are required to register with FDA. These facilities must develop and implement a Food Safety Plan (FSP). This is similar to, but has some key differences from, a HACCP plan.

A food safety plan must have the following components:

- *Hazard Analysis* The hazard analysis must identify and evaluate known or reasonably foreseeable biological, chemical, and physical hazards. If any of these hazards is determined to be significant enough that it is a "hazard requiring a preventive control," then the facility must identify and implement preventive controls to significantly minimize or prevent the identified hazards.

- *Preventive Controls* The rule includes several types of preventive controls:
  - Process controls (e.g., cooking, refrigerating, and acidifying foods);
  - Food allergen controls (i.e., controls for allergen cross-contact and to ensure allergens are appropriately listed on labels);
  - Sanitation controls (i.e., procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to minimize or prevent hazards such as environmental pathogens); and
  - Other Controls (i.e., controls that are not described above but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented).


- ***Management Components*** To ensure that the controls are being met, facilities must implement procedures for monitoring, corrective actions, and verification of the preventive controls. Verification includes activities such as calibration, validation, records reviews, environmental monitoring, and product testing, as appropriate.

- ***Supply Chain Program*** If a supplier is responsible for controlling a "hazard requiring a preventive control," then a supply chain program is required. FDA has issued detailed requirements for how to adequately perform supplier verification in these situations, which differ significantly from the way that companies have historically performed supplier verification voluntarily. Careful attention is needed for this part of the regulation. In particular, be aware that just obtaining your supplier's third-party audit certificate is not sufficient to be in compliance.

- ***Recall Plan*** If the hazard analysis identifies a hazard requiring a preventive control, the facility must have a written recall plan that describes the procedures to perform a recall of the product. The recall plan must include procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks, and to appropriately dispose of recalled product.

There also are significant recordkeeping requirements related to the Food Safety Plan, as well as requirements for reanalysis.

You also should be aware that there are some significant differences between FDA's expectations and the standards under European and law. For example, FDA has a very strict policy for listeria in ready-to-eat foods. The supplier verification regulations are another area with significant differences that warrants careful attention.

In addition to issuing the above regulations, FDA "modernized" the current Good Manufacturing Practice (cGMP) regulations. In particular, the regulations now specifically address allergen cross-contact and include a provision for holding and distribution of human food by-products that are used for animal food.

Finally, there are new training requirements for all personnel, and specialized training requirements for personnel with responsibility for development and implementing the Food Safety Plan. First, all employees who manufacture, process, pack, or hold food must be qualified to perform their assigned duties. This means that they must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold food that is clean and safe. Individuals also must receive training in the principles of food hygiene and food safety. Second, whoever is responsible for preparing the Food Safety Plan and performing certain key activities under the plan must be a "Preventive Controls Qualified Individual" (PCQI). This status can be attained either by attending a training program equivalent to a standardized curriculum developed by FDA (such as the training programs offered through the Food Safety Preventive Controls Alliance), or based on education and experience.

The compliance dates for the PCHF regulation have passed, and FDA is actively performing inspections. These inspections are occurring domestically and internationally. Note that foreign inspections are preceded with written notice, and are scheduled in advance. There can be significant consequences related to refusal or failure of a foreign inspection, including delayed or rejected imports to the United States. If an inspection results in a Form 483, this means that FDA has identified deficiencies during the inspec-

tion. It is imperative to respond in writing to a Form 483 within 15 business days of when it is issued, and advisable to work with experienced legal counsel to ensure that your response is sufficient.

*2. Preventive Controls for Animal Food* The Preventive Controls for Animal Food (PCAF) rule is parallel to the PCHF rule, except that the rule applies to food made for animals. You should be aware that FDA expects that animal food will be free of pathogens, just like human food. However, the allergen requirements for human food do not apply to animal food. Instead, FDA is focused on issues of specific interest for animals, such as nutrient deficiencies or toxicities (e.g., inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep). As part of this rulemaking, FDA also issued cGMP regulations for animal food. Most of the compliance dates for the PCAF regulation have passed, and FDA has started conducting inspections.

*3. Intentional Adulteration* This rule represents the first time that companies are required to create a Food Defense Plan to address intentional adulteration. With some exceptions, this rule applies to both domestic and foreign companies that are required to register with the FDA. The Food Defense Plan must identify vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions and verification. Reanalysis is required every three years or when certain criteria are met, including mitigation strategies that are determined to be improperly implemented. More details are provided below:

- *Vulnerability Assessment* Facilities must identify vulnerabilities and actionable process steps for each type of food manufactured, processed, packed or held. For each point, step, or procedure in the facility's process, these elements must be evaluated:
  - The severity and scale of the potential impact on public health. This would include such considerations as the volume of product; the number of servings, the number of exposures; how fast the food moves through the distribution system; potential agents of concern and the infectious/lethal dose of each; and the possible number of illnesses and deaths.
  - The degree of physical access to the product. Issues to be considered would include the presence of such physical barriers as gates, railings, doors, lids, seals, and shields.
  - The ability to successfully contaminate the product.

- *Mitigation Strategies* Mitigation strategies should be identified and implemented at each actionable process step to provide assurances that vulnerabilities will be minimized or prevented. The mitigation strategies are tailored to the facility and its procedures.

- *Mitigation Strategy Management Components* These are steps that must be taken to ensure the proper implementation of each mitigation strategy. Specifically, there are requirements related to food defense monitoring, food defense corrective actions, and food defense verification.

The first compliance date for the Intentional Adulteration rule is July 26, 2019, which applies to the largest companies. FDA was scheduled to begin routine inspections of larger businesses in March 2020, but these inspections were delayed in response to the COVID-19 pandemic. Routine inspections for smaller businesses will begin in March 2021. When routine inspections begin, FDA has said they will consist of "quick checks" that will occur during regularly scheduled food safety inspections. These "quick checks" allow FDA to verify that the facility has satisfied the basic requirements of the rule by preparing a Food Defense Plan and may also provide some educational materials. Note that there are numerous training programs available for the various aspects of this regulation. Because this is a complex regulation that does not mirror any preexisting regulations, it is prudent to pay careful attention to these requirements and developing an implementation strategy.

*4. Foreign Supplier Verification Program* The Foreign Supplier Verification Program (FSVP) requires someone in the United States to verify the safety of the food being imported. FSVP cannot be performed by someone outside of the United States. The legal responsibility for FSVP falls on the person in the U.S. who owns the food, has purchased the food, or has agreed in writing to purchase the food – i.e., the "importer." Note that "importer" for FSVP is defined differently than the term "importer of record," which is used in other U.S. regulations. This identity of the FSVP importer party will vary depending on your own situation.

*The FSVP importer must do the following:*

- *Hazard Analysis* The importer is required to identify and evaluate – based on experience, illness data, scientific reports and other information – the known or reasonably foreseeable hazards for each type of food it imports to determine if there are any hazards requiring a control. The importer can rely on another entity (such as the foreign supplier) to conduct the hazard analysis, so long as the importer reviews and assesses the relevant documentation.

- *Evaluation of Food Risk and Supplier Performance* The importer must evaluate (1) the hazard analysis, (2) the entity that will be significantly minimizing or preventing the hazards (e.g., whether the hazard is controlled by the foreign supplier or the supplier's own supplier), (3) the foreign supplier's procedures, processes, and practices related to the safety of food, (4) applicable FDA food safety regulations, and information regarding the foreign supplier's compliance, (5) the foreign supplier's food safety history, including the responsiveness of the foreign supplier in correcting past problems, and (6) other factors as necessary, including storage and transportation practices. The importer can rely on another entity (other than the foreign supplier) to perform this evaluation, so long as the importer reviews and assesses the relevant documentation.

- *Verification Activities* Based upon the evaluation of risk that was conducted, the importer must establish and follow written procedures to ensure that it only imports from approved foreign suppliers. The importer also must conduct appropriate supplier verification activities. The verification activity options include:
  - Annual on-site audits of the supplier's facility. Note that an on-site audit can be a second-party audit or a third-party audit. Such audits are generally required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard);
  - Sampling and testing (e.g., performing testing upon receipt of the food, or receiving a Certificate of Analysis); or
  - A review of the supplier's relevant food safety records.

An importer can rely on another entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities, so long as the importer reviews and assesses the relevant documentation.

- *Corrective Actions* Importers must promptly take appropriate corrective actions if they determine that there is a food safety problem or the foreign supplier is out of compliance. The appropriate corrective measure will depend on the circumstances, but could include discontinuing use of the foreign supplier.

Note that there are a number of exemptions from the FSVP regulations, as well as modified requirements for certain types of food. For example, the FSVP regulations do not apply to foods produced under FDA's seafood or juice HACCP regulations.

Upon entry to the U.S., FDA determines who is responsible for FSVP as the importer based on the "unique facility identifier" (UFI) provided on the import documentation. The importer must obtain and provide a Data Universal Numbering System (DUNS) number, which serves as their UFI for FSVP.

Most of the compliance dates have passed for FSVP, and FDA is actively performing inspections of the FSVP importers. Note that because these inspections occur in the United States and FSVP importers must be domestic, FDA will never perform an FSVP inspection of a foreign company or outside of the U.S.

*5. Produce Safety* FDA's Produce Safety rule established, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption in the United States. The rule applies to all produce that will be consumed in the United States, regardless of whether it is grown domestically or internationally. There are two key exemptions from the rule:

- Produce commodities that FDA has identified as rarely consumed raw – i.e., asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts; and
- Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

*The following is a summary of the key substantive requirements under the rule:*

- *Agricultural Water* The rule establishes requirements for agricultural water related to water quality and testing. FDA is currently reconsidering these requirements, however, and has extended the compliance dates for this part of the rule.
- *Biological Soil Amendments* The rule has requirements relating to the use of raw manure and stabilized compost as biological soil amendments.
- *Domesticated and Wild Animals* The rule includes standards related to intrusion by domesticated and wild animals at farms. Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated. However, farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas.
- *Worker Training and Health and Hygiene* Requirements for health and hygiene include taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons, using hygienic practices when contacting produce or food-contact surfaces, and taking measures to prevent visitors from contaminating produce and/or food-contact surfaces.
- *Equipment, Tools and Buildings* The rule establishes standards related to equipment, tools and buildings to prevent these sources, and inadequate sanitation, from contaminating produce. This section of the rule covers, for example, greenhouses, germination chambers, and other such structures, as well as toilet and hand-washing facilities. Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance, and cleaning of equipment and tools.
- *Sprouts* There are specific requirements to help prevent the contamination of sprouts, which are particularly at risk for microbial contamination.

The compliance dates have passed for most farms and FDA has started performing inspections until the spring of 2019 to allow time for more guidance, training, technical assistance, and planning.

*6. Accredited Third-Party Certification* The rule on Accredited Third-Party Certification establishes a voluntary program for the accreditation of

third-party certification bodies, also known as third-party auditors, to conduct food safety audits and issue certifications of foreign entities and the foods for humans and animals they produce. FSMA specifies two uses for certifications under this program:

- Certifications may be used by importers to help establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which is a fee-based program that offers expedited entry reviews.
- FDA can also require in specific, limited circumstances that a food offered for import be accompanied by a certification from an accredited third-party certification body.

This rule is unlikely to affect most foreign companies, unless they are producing food that will be imported under VQIP.

*7. Sanitary Food Transportation* FDA's Sanitary Food Transportation rule aims to prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food. The rule establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of that food. The requirements do not apply to transportation by ship or air because of limitations in the law. The rule only applies to transportation within the United States, and thus only applies to U.S. transport legs for imported food.

## III. Forthcoming FSMA Regulations

FDA is in the process of implementing two additional regulations. When finalized, these regulations also will affect German and Austrian businesses selling food to the United States.

*1. Laboratory Accreditation* On November 4, 2019, FDA issued the Laboratory Accreditation for Analyses of Foods Proposed Rule. The key components of the Proposed Rule mirror Section 202 of FSMA. First, it would require that certain food testing must be performed by laboratories accredited by an FDA-recognized accreditation body. Second, results of testing conducted under the rule would be required to be sent directly to FDA. Third, it would establish model laboratory standards. Finally, it would establish a public registry of accreditation bodies and accredited laboratories. The Proposed Rule would apply to an "owner or consignee" that is required to use an accredited laboratory to conduct food testing under the regulation. FDA defines this term to mean "any person with an ownership or consignment interest" in the food product or environment that triggers the need for testing under this proposed regulation. As part of a settlement agreement with a consumer group seeking to compel FDA to satisfy its obligations under FSMA, the agency has agreed to issue a Final Rule by February 4, 2022.

- *Use of Accredited Laboratories* Use of an accredited laboratory would be required when testing is conducted on behalf of an owner or consignee in the following situations: (1) for nine specific existing regulatory testing requirements that apply to bottled water, shell eggs, and sprouts; when FDA issues a "food testing order"; (2) to address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing prior to the issuance of a mandatory food recall order, as part of a corrective action plan after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order; (3) in support of admission of an article of food under section 801(a) of the Federal Food, Drug, and Cosmetic Act, which allows FDA to refuse admission of food for reasons including if the food "appears" to be adulterated, misbranded, or manufactured, processed, or packed under insanitary conditions; (4) as required by FDA in a food testing order, which is a new regulatory tool the agency proposes establishing under the rule; or (5) to support removal from import alert through successful consecutive testing.

*2. Traceability* FSMA also requires FDA to issue a proposed rule addressing traceability. Specifically, FSMA requires FDA to designate a list of "high-risk" foods, and then engage in rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold designated high-risk foods. The designation for high-risk foods must be based on:

- the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention (CDC);
- the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;
- the point in the manufacturing process of the food where contamination is most likely to occur;
- the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
- the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
- the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

The purpose of the recordkeeping requirements is to facilitate the quick identification of recipients of food to prevent or mitigate a foodborne illness outbreak. FDA will issue the list of high-risk foods and a Proposed Rule by September 8, 2020, and a Final Rule by November 7, 2022. Once the Final Rule is issued, FDA will publish on its website the list of high-risk foods.

## IV. Recommended Action Steps

FSMA is a significant development that all German and Austrian companies selling food in the US need to understand. Below we set out key recommen-

dations to help you with FSMA compliance.

*All FSMA Rules* Work with experienced legal counsel or consultants to ensure you understand FDA's expectations and how they apply for your operation. Ignorance or misunderstandings are not excuses that will help you when FDA comes to inspect.

*Preventive Controls for Human Food and Preventive Controls for Animal Food:*

- Ensure that someone in your company is a Preventive Controls Qualified Individual, or identify a PCQI to assist you with your Food Safety Plan as a consultant.
- Develop a Food Safety Plan, which may involve performing a gap analysis to identify opportunities to modify your HACCP plan to comply with FSMA.
- For human foods, put a strong emphasis on environmental monitoring for pathogens, if you make ready-to-eat foods, and allergen controls, if you make foods containing any of the "big 8" allergens in the United States (i.e., milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybean).
- Review your supplier verification program to assess whether it is consistent with the requirements in the regulations. In particular, be aware that just having a third-party audit of your supplier is not sufficient to be in compliance.
- Stay abreast of FDA's guidance documents, as the agency is exercising "enforcement discretion" for some provisions of the regulations through guidance and also has issued recommendations to assist with compliance.

*FSVP*:

- Ensure you know who is responsible for performing FSVP for the foods you are sending to the United States. You will need to work with this entity to ensure they have the necessary information to verify the safety of your products. Be aware that just providing them with a third-party (e.g., GFSI) audit is not enough for the FSVP importer to be in compliance.

*Intentional Adulteration:*

- Carefully review the regulation and FDA's guidance documents to become familiar with the agency's expectations.
- Participate in the various available training programs to develop the necessary expertise to build your Food Defense Plan.
- Develop and implement a Food Defense Plan.

*Produce Safety:*

- Review FDA's regulations and guidance to ensure you understand the regulation.
- Attend training programs related to the regulation to deepen your understanding of the rule.
- Train personnel on FDA's expectations.
- If you qualify for an exemption based on commercial processing of your produce, ensure you meet the requirements under the rule related to the exemption.

*Accredited Third-Party Certification:*

- Consult with your U.S. importer as to whether they are considering participating in VQIP and/or may require your facility to obtain a certification under this program.

*Sanitary Food Transportation:*

- If you are shipping food to the U.S. that will be further transported in the same shipping container once it arrives, be sure you are familiar with the requirements under this rule and how it applies to your shipments once they are in U.S. commerce.

*Laboratory Accreditation*

- Keep an eye out for FDA's final regulation, and assess the implication of the final regulation's requirements for your testing programs.

*Traceability*

- Monitor for FDA's release of the list of designated high-risk foods and Proposed Rule. Even if the foods you produce are not designated as high-risk under the proposal, it will be prudent to monitor FDA's recordkeeping requirements for those foods, because they could ultimately serve as the foundation for traceability throughout the entire food system.

*Zusammenfassung* Der Food Safety Modernization Act (kurz: „FSMA") stellt die größte Reform des US-amerikanischen Lebensmittelsicherheitsrechts seit den 1930er Jahren dar. Das Gesetz ist im Jahr 2011 in Reaktion auf eine Reihe von Lebensmittelskandalen, bei denen auch Verbraucher zu Schaden gekommen waren, verabschiedet worden. Mittlerweile sind fast alle Übergangsfristen abgelaufen. Der FSMA verpflichtet Lebensmittelunternehmen in größerem Umfang als bislang zur Einrichtung von präventiven Kontrollmechanismen, und er erweitert die Eingriffsbefugnisse der Food and Drug Administration („FDA") erheblich. US-amerikanische Lebensmittelunternehmen müssen im Rahmen eines „Foreign Supplier Verification Program" auch gewährleisten, dass ihre Lieferanten die neuen Vorschriften beachten. Europäische Unternehmen, die Lebensmittel in die USA exportieren, müssen daher ihre Prozesse überprüfen und an ihren Produktionsstandorten einen Mitarbeiter zum „Preventive Controls Qualified Individual (PCQI)" ausbilden, der für die Beachtung des FSMA verantwortlich ist. Die FDA führt auch bereits Inspektionen in europäischen Betrieben zur Überprüfung der FSMA-Compliance durch. Bei einem Verstoß drohen Abmahnungen und Importwarnungen, die das US-Geschäft empfindlich treffen können. Dieser Beitrag erläutert die neuen Regelungen und gibt Empfehlungen zur Umsetzung in europäischen Unternehmen.

*Maile Hermida, Attorney at law, Hogan Lovells US LLP, Washington*

*Rechtsanwältin Dr. Anna Glinke, Hogan Lovells International LLP, Düsseldorf*

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