

FDA HACCP: Considerations, Preparations and Expectations

I. Introduction

“Hazard Analysis Critical Control Point (HACCP)” requirements have been in affect since late 1997.¹ Beginning with their application to seafood products, these regulations now apply to fruit and vegetable juices.² These regulations apply to foreign processors entering products into the U.S. market as well as domestic processors. Therefore, it is important for foreign and U.S. processors to understand the regulatory environment that exists for imported products and domestic products; how to prepare for FDA inspections at the border and in domestic and foreign processing plants; and what to expect during and after FDA inspections at the border and in domestic and foreign processing plants.

I am going to provide you the overlay of the legal rights and obligations as they affect the cast of characters that exist in the world of FDA imposed HACCP requirements. This includes an analysis of foreign manufacturers, U.S. importers and domestic processors. The legal rights and obligations as they apply to your company and FDA are critical to ensuring that your company and your foreign suppliers safely navigate the regulatory waters.

II. Considerations

A. Imported or Purely Domestic

The first consideration is whether you are a foreign processor or a domestic processor utilizing foreign imported product or a purely domestic processor utilizing U.S. suppliers of U.S. grown products. On one hand, imported products are held to a higher standard of FDA scrutiny. The reason for this is that FDA resources are unable to handle the existing domestic inspection requirements and currently inspects less than one-two percent of all imported products.³ On the other hand, FDA rarely inspects foreign processors because FDA resources are strained and FDA does not have the type of foreign regulatory systems in

¹ Title 21, Code of Federal Regulations (C.F.R.), Part 123; published in the Federal Register of December 18, 1995 (60 Fed. Reg. 65096-65202).

² FDA Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6138 (Jan. 19, 2001).

³ Food Safety Overview of Food Safety and Inspection Service and Food and Drug Administration Expenditures Before the S. Comm. On Agriculture, Nutrition, and Forestry, 106th Cong. (2000) (statement of Lawrence J. Dyckman, Director, Food and Agriculture Issues Resources, Community, and Economic Development Division), *available at* <http://www.gao.gov/archive/2000/rc00300t.pdf>; see also, Caroline Smith DeWaal, Kristina Barlow & Giselle Hicks, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net*, at 2 (Center for Science in the Public Interest 7th ed. 2005), <http://www.cspinet.org/foodsafety/OutbreakAlert2005.pdf>.

place such as those that USDA has (e.g. providing for foreign certification of facilities and equivalence standards). If any facet of your company's operation involves imports then you should incorporate the considerations for imported products into the preparation of your HACCP plan.

B. Imported Products

Imported products are most vulnerable to FDA regulation. The reason for this is that because the FDA does not have the resources to police the products being imported from foreign countries, the agency uses Import Alerts as a mechanism to target countries, shippers and foreign manufacturers. A good illustration is the current Import Alert 16-131.

Import Alert 16-131 imposes obligation upon importers to mandatory testing of all aquacultured products arising out of China.⁴ The Import Alert covers various aquacultured products including catfish, eel and shrimp. China is the third largest importer of farmed seafood into the U.S.,⁵ so, many of you in this audience are likely aware and affected by this Import Alert. If your company imports Chinese processed seafood covered under this Import Alert, you are paying \$3000-\$5000 dollars per typical container to secure FDA release of the product. The time that it takes to secure final results of third party laboratory testing and subsequent FDA review can and usually does take anywhere from 2-6 weeks.

However, the laboratory delays and the costs associated with storage and testing are only the beginning of considerations that your company should be thinking about. Among other considerations are the laboratory methods used by the third party laboratory and whether that laboratory is credible. FDA currently has no authority to inspect or certify third party laboratories.⁶ Notwithstanding, the importer must be aware of the laboratory methods that are applicable to a third party testing facility. Our firm recently encountered a third party laboratory that was conducting test methods utilizing a modified sampling methodology whereby they conducted a composite sampling versus an individual sampling, as required by the applicable FDA Laboratory Information Bulletin (LIB). Neither the foreign

⁴ U.S. Food and Drug Administration (FDA) Import Alert 16-131, "Detention without Physical Examination of Aquacultured Catfish, Basa (*Pangasius* sp), Shrimp, Dace, and Eel Products from the People's Republic from China Due to the Presence of New Animal Drugs and/or Unsafe Food Additives". available at http://www.fda.gov/ora/fiars/ora_import_ia16131.html.

⁵ Transcripts of FDA Press Conference on Seafood Imported from China, available at <http://www.fda.gov/bbs/transcripts/transcript062807.pdf>.

⁶ See ORA Laboratory Manual, Section 7, available at http://www.fda.gov/ora/science_ref/lm/vol3/section/07.pdf; see also 69 Fed. Reg. 23460, Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food (citing FDA's proposed rule to regulate third party laboratories tasked with sampling and analyzing FDA regulated food imports).

manufacturer nor the importer was aware of the failure of the third party laboratory to follow methods recognized by FDA's Center for Food Safety and Applied Nutrition (CFSAN) until problems arose.⁷

C. Purely Domestic

FDA inspections of domestic processors are much more involved than inspections at the border. On the domestic level, FDA will enter your facility or farm and conduct an extensive evaluation of your HACCP plan and typically review the processing of anywhere from one to three different products that are currently being processed. These domestic inspections should be taken very seriously because the Consumer Safety Officer (CSO) is there for a single purpose: to collect evidence in support of an administrative action, civil enforcement action or potential criminal investigation. Unlike imported products, FDA will be focused on the details of your HACCP plan and will assess the critical control points and monitoring steps and their actual application to the products under review. The consequence of being unprepared can result in an FDA pressured recall, civil seizure action, injunction action, and a criminal prosecution.

It is also important to consider whether the FDA is working in concert with the state or in its own capacity. FDA requirements are generally much different in scope than those of individual states. Your company should be cognizant of any state/FDA partnership agreement or Memorandum of Understanding (MOU). FDA does not have current MOUs with most states; however, the unsuspecting processor could experience what appears to be a minor FDA administrative action (e.g. untitled letter or warning letter) to ultimately develop into what I like to analogize as an inoperable regulatory cancer.

As an example, our firm encountered a seafood company that was ultimately placed in bankruptcy due to its failure to recognize the jurisdictional limits of the state and the FDA. This particular company was a seafood company and had received notice of violations in an FD-483, Inspectional Observations, over the course of a couple of inspections, each over a year apart. In each instance, the company responded in a timely manner to the alleged violations contained in the FD-483. During this time, the state was working in concert with the FDA to obtain samples at retail outlets and conducting its own inspections at the company's processing plant. The company had no indication from the FDA that there was a "serious" problem; in fact, FDA never issued its typical "untitled letter" or even a warning letter. The company was notified by the state that retail samples collected by the state were found to contain listeria and as a result the state requested a voluntary company initiated recall. The company complied with the state's request and days later was shocked to find a joint state/FDA inspection in which the state and FDA effectively worked together to close the firm under the state's embargo powers.

⁷ See FDA Laboratory Methods available at <http://www.cfsan.fda.gov/~comm/labmeth.html>.

The state was unable to maintain an embargo without additional evidence. The reality is that neither the state nor the FDA had the requisite evidence to support an injunction or even a state administrative action that would impose a monetary fine. The company never considered the importance of the significant jurisdictional and evidentiary distinctions that exist between the state and the FDA. As a result, FDA worked with the state's evidence to persuade the company to enter into a consent decree. That consent decree included terms and obligations that no company should agree to and the company ultimately went bankrupt in an effort to try to cooperate with the FDA, an agency that had not taken any action for over 7 months. As a domestic processor, it is paramount that you take into consideration the state and federal agencies that regulate you and the legal rights and obligations that exist for your company and the state and federal regulators with whom you interact.

III. Preparations

A. Imported Products

It is important for any company dealing in imported products to track FDA Import Alerts as diligently as it would in determining market demands or accessing product price points. Importing FDA regulated products carries risk that your company should be prepared to address. The most important preparations your company can make include addressing the following issues:

- **Is there an existing FDA Import Alert?** FDA's Import Alerts identify products that may be Detained Without Physical Examination (DWPE). FDA claims its authority to DWPE, and thus issue Alerts, on the basis of section 801(a), which states, "If it appears from the examination of such samples *or otherwise* that (1) such article has been manufactured, processed, or packed under insanitary conditions . . . then such article shall be refused admission...."⁸ According to FDA, Congress authorized the agency to refuse admission of regulated articles based on information, *other than the results of examination of sample*.⁹ Information that identifies that past entries, of similarly manufactured and/or processed product from a foreign source, offered for import have been in violation of the FDCA, among other things, may cause an article to "appear" adulterated, misbranded, or otherwise in violation of the FDCA, as described in section 801(a).
- **What are the requirements of the Import Alert?** FDA currently places the burden on the importers¹⁰ to demonstrate that the products they want

⁸ 21 U.S.C. § 381 (FDCA § 801).

⁹ See FDA REGULATORY PROCEDURES MANUAL, *supra* note 19, ch. 9, subch. Automatic Detentions.

¹⁰ See Treas. Reg. § 48.0-2(a)(4)(i) (1988) (defining importer as any person bringing an article into the United States from outside the United States ...).

to bring into the United States comply with FDA rules and regulations. The agency accomplishes this through Import Alerts (Alerts). For example, if FDA becomes aware that a product appears to violate the agency's rules and regulations, the product may be put on an Alert. This means that future shipments of that product will not be allowed entry into the United States unless the importer demonstrates that the product is in compliance with the FDCA.¹¹ Through Alerts, FDA shifts the burden of determining compliance onto the importer.

- **Will the foreign manufacturer incur the costs associated with requirements imposed by the Import Alert?** Importers and foreign manufacturers should address this issue prior to importing products affected by Import Alerts. If you are a foreign manufacturer, selecting and paying for the third party testing of your product will establish privity with the laboratory and provide for greater control over testing. Our firm has seen large foreign companies who export products affected by Import Alerts suffer greatly due to a lack of control over independent third party laboratories. Without cooperation from the importer, the foreign manufacturer has no control over the methodology used by the laboratory, release of testing to the FDA and there is no privity in the case that a laboratory has acted negligently thus causing damages.
- **Are there any records that the foreign manufacturer maintains that would help overcome the appearance of a violations alleged in the Import Alert?** Not all import Alerts require testing and even if the Import Alert does require testing there is no legal requirement, at least for the majority of Alerts, that mandates following testing procedures in order to overcome the appearance of a violation. Most importers and foreign manufacturers do not understand this and many times testing is the preferred option even though it is costly.
- **If testing is required under the Import Alert, what third party laboratory will your company use?** It is extremely important to ensure that the third party laboratory is credible and is following “approved” FDA methodology. No matter what lab you use, always review the third party laboratory results prior to issuance to FDA. Currently, FDA has no jurisdiction over third party labs. Although FDA has issued a proposed rule,¹² there is no requirement that a third party laboratory must withhold lab results from the importer prior to issuance to FDA. Reviewing the laboratory results will protect your company from unacceptable methodologies and mistakes.

¹¹ FDA has argued that Import Alerts are guidance documents that instruct FDA field staff to exercise discretion when determining whether to detain a shipment. *See infra* note 57. Whenever FDA issues an Alert, however, it is likely that the product subject to the Alert will be detained because FDA's field staff is required to follow guidance documents. *See* 21 U.S.C. § 371(h) (FDCA § 701(h)).

¹² *See* 69 Fed. Reg. 23460, Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food (citing FDA's proposed rule to regulate third party laboratories tasked with sampling and analyzing FDA regulated food imports).

- **How will your company or your supplier ensure that you do not get added to an Import Alert or fail to get added to an exemption list?**
There is no consistency to the structure and format of Import Alerts. Some Alerts are country wide and provide for placement on an exemption list while others identify specific companies and shippers. We recommend that you consult legal counsel if you find your company or supplier on an Alert.
- **How can your company incorporate the liability of Import Alerts as a Critical Control Point (CCP) in your company's HACCP plan?**
Preparation for Import Alerts is crucial to any food company that is exporting to the U.S. I have experienced the affect of Import Alerts first hand and on many occasions companies go out of business. If you are an importer, you should always have secondary supply sources.

B. Domestic Processing

Preparation for FDA inspections should include a standard operating manual that addresses your company's policies concerning state and FDA inspectional procedures. The manual should include clear procedures concerning state and FDA (federal) inspectional authorities and explain your company's procedures for handling state and FDA inspections. The standard operating manual should identify at least three trained company representatives that will be trained and prepared to accommodate any state inspector of FDA investigator. Preparations for domestic inspections should address the following issues:

- **What are the FDA and state inspectional authorities?** Understanding FDA and state inspectional authority is paramount to the training of your company's representatives. The Food Drug and Cosmetic Act (FDCA) provides that any "refusal to permit entry or inspection" is a criminal offense.¹³ The FDCA gives the FDA authority "to inspect, at reasonable times and with reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein."¹⁴
- **What records may be provided to FDA?** The FDCA does not specifically address FDA's right of access to HACCP records. However, FDA's own HACCP regulations require that "all records" and "all plans and procedures" required by the regulations "shall be available for official review and copying"- i.e., including review and copying by an FDA inspector conducting an establishment inspection – "at reasonable times."¹⁵ This means that, in general, all HACCP records need to be available for review by an FDA inspector.¹⁶ However, there is some legal

¹³ 21 U.S.C. § 331(f).

¹⁴ 21 U.S.C. § 374(a)(1) (emphasis added).

¹⁵ 21 C.F.R. § 123.9(c)

¹⁶ The FDA regulations provide that if a processing facility is "closed for a prolonged period between seasonal packs," or if "record storage capacity is limited on a processing vessel or at a

debate over whether FDA's proclaimed access to HACCP records comports with section 704(a)(1) of the FDCA.¹⁷ Section 704 makes specific reference to FDA access of drug and device manufacturing records whereas no such provision appears in reference to foods. If your company has cause to withhold HACCP records in a given situation, your company should contact legal counsel because there is a grey area that exists in terms of whether your company is legally required to provide access to such records. Shipping records must only be provided upon written request of an FDA inspector.¹⁸ Records submitted to FDA under written request may be used in civil proceedings against the person or company providing them but not in a criminal prosecution. If FDA requests shipping records, your trained company representative should always ask for a written request for records. Some records are required to be maintained under the Bioterrorism Act. However, as a general rule, the company manual should always establish a policy that any shipping records may be provided to FDA by written request only to provide the greatest degree of insulation from their use in a criminal prosecution. Your trained company representatives should contact legal counsel if FDA persists or reacts in an adversarial manner to this policy.

- **How does your company preserve confidentiality of records?** All companies should be cautious of the records that are provided to the FDA should be marked "confidential" and any copies of such records provided to regulators should be copied and indexed by the company representative overseeing the inspection. FDA has a reputation for committing error in the disclosure of confidential records.¹⁹ FDA may disclose your HACCP records that document adverse events. Our firm has witnessed this first hand where FDA utilized customer records and state inspection and analytical results to support the threat of an injunction against a seafood processor. This publicly available information was so damaging to the company and was shown in the press. Notwithstanding the nature of the information as "trade secret or confidential commercial or financial information" and thereby exempt from release to the public, the company went bankrupt before any redress could be obtained.
- **What happens when FDA samples product?** All FDA inspectors are authorized to collect samples.²⁰ Physical sample collection under FDA's Compliance Policy Guidance Manual (CPGM) is rare. However, FDA routinely takes samples of labeling, and state inspectors routinely take unfinished and finished product samples. Always take duplicative samples

remote processing site," records may be transferred to some other reasonably accessible location at the end of a seasonal pack "but shall be immediately returned for official review upon demand." 21 C.F.R. § 123.9(b)(3). Maintenance of records on computers can be acceptable. 21 C.F.R. § 123.9(f).

¹⁷ 21 U.S.C § 374(a)(1).

¹⁸ 21 U.S.C. § 373.

¹⁹ *Jerome Stevens Pharm.*, 402 F.3d at 1252; see Ralph C. Nash & John Cibinic, *Government Disclosure of a Trade Secret: A Tort Claim?*, 9 NASH & CIBINIC REP. 6, 28 (Jun. 2005).

²⁰ 21 U.S.C. §§ 372(b), 374(c), (d).

of any physical product testing or labeling. Always ask for a “Receipt for Samples” (FD- 484) for any samples taken during the inspection. As part of company policy, the trained company representative should verify that duplicative lots have been sampled by your company for future analysis should FDA identify any violative conditions with product sampled.

- **What about photographs?** FDA inspectors are trained to take photographs during inspections. Photographs are “one of the most effective and useful forms of evidence of violations.”²¹ There are two judicial decisions that FDA inspectors rely upon to persuade the use of photographs. In *United States v. Acri Wholesale Grocery Co.*, the court held that when a company fails to object to FDA’s request to take photographs, those photographs may be used as evidence against your company in a criminal prosecution.²² In *Dow Chemical Co. v. United States*, the authority of the Environmental Protection Agency (EPA) to take photographs of company property from an airplane in public airspace was held lawful.²³ No FDA regulated companies have been subject to judicial action for refusing to allow FDA to take photographs. Your company should make it very clear that photographs are not allowed as a matter of company policy. FDA inspectors are not regularly trained to take photographs and the photographs will likely over emphasize whatever adverse condition that the FDA inspector identifies.
- **What is the difference in detention and seizure authority as to the FDA and state?** FDA has no authority to detain or embargo seafood products that appear be in violation of the FDCA except for under the Bioterrorism Act. FDA does have authority to seize products but it requires a litany of events that will not likely occur under 2-3 days during an inspection. More commonly, FDA will ask the state to place embargoes on products that are believed to be adulterated or misbranded.²⁴
- **What is the scope of the inspection?** Trained company representatives should ascertain the scope of the state or FDA inspection from the moment the FD-482 is issued. Understanding whether the inspection is “directed” or routine will enable your company to provide the necessary information to the agency inspecting.
- **Have you reviewed the company policies with the inspector?** It is important that companies educate inspectors on the company’s policies concerning photographs and dissemination of information by company employees. All questions should be directed to the trained company representative. Accompany the FDA or state inspector to ensure that the inspector is never unattended by a trained company representative.

²¹ FDA Investigations Operations Manual Subchapter 520, Section 523, “Photographs-Photocopies” (September 2007).

²² *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S.D. Iowa 1976).

²³ *Dow Chemical Co. v. United States*, 476 U.S. 227 (1986).

²⁴ See, e.g., *United States v. An Article of Food . . . 345/50-Pound Bags*, 622 F.2d 768, 769 at note 1 (5th Cir. 1980).

Always keep a detailed record of all that the inspector says or does. This information may become important in the future, especially if FDA to engage in enforcement action based upon inspectional findings.

- **What if FDA asks for a signed affidavit?** Never sign or initial “affidavits” or other documents. As a former FDA investigator, I can tell you that we were trained to gather evidence at all times including admissions of accuracy via affidavits. Any admissions in the statement can and will be used in some form or fashion against you or your company whether in an administrative or judicial action. Your company should include a policy not to read or sign affidavits and this should be a part of your manual.
- **How do you handle an FD-483?** FDA may issue inspectional observations at the conclusion of the inspection.²⁵ The FD-483 will identify the violations that the FDA inspector believes to exist at your processing plant. All items on the FD-483 should be discussed in detail and any corrective actions that can be taken to immediately correct any violations should be initiated. It is extremely important to discuss any violations that you do not understand or may disagree with before the conclusion of the inspection. The FDA inspector will generate an Establishment Inspection Report (EIR) which includes a section discussing corrective actions and firm responses to FD-483 observations. Your comments during the discussion of the FD-483 will be captured in the EIR and may affect whether the inspection is ultimately identified as No Action Indicated (NAI), Voluntary Action Indicated (VAI) or Official Action Indicated (OAI). The classification of the inspection will guide when the FDA will inspect in the future as well as whether future administrative enforcement actions or criminal investigations will occur.

III. Expectations

A. Imported Products

If your company imports a product that is not on Import Alert, you can expect that the FDA field staff at the port of entry then decide whether to 1) release the shipment for entry, 2) examine the shipment for possible refusal due to violations of FDA laws and regulations, or 3) detain it until the broker furnishes additional information.²⁶ If you are dealing with a product subject to an Import Alert you can expect that your product will be detained. If it is a country wide Alert, your

²⁵ 21 U.S.C. § 374(b), states, “Upon completion of any such inspection . . . and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate any food . . . in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”

²⁶ See FOOD AND DRUG ADMIN., INVESTIGATIONS OPERATIONS MANUAL, ch. 6, *Imports* (2007), available at http://www.fda.gov/ora/inspect_ref/iom/contents/ch6_toc.html.

product will be not be released, if at all, for anywhere from 1-6 weeks depending upon FDA resources and laboratory testing time. If you are attempting to get on an exemption list, you can expect 30-90 days before that occurs.

B. Domestic Products

Once the FDA inspection ends, trained company representatives should meet with quality assurance personnel to review the inspectional results and implement corrections and improvements. These actions should be carefully documented and a written response should be promptly sent to the FDA field office within days of the inspection. This allows for your company to establish views on possible incorrect observations and to establish voluntary corrective actions on the record prior to issuance of an untitled letter or warning letter, which may not be issued if you have promptly responded subsequent to the inspection.

Most districts will forward a copy of the EIR but this is not always the case. It is important to ensure that your company maintains records of all EIRs. Some EIRs will be different than others as a result of the nature of the inspection and seriousness of adverse observations. If a district office fails to supply the EIR, which does occur, you may request release under the Freedom of Information Act. Your company should always review the EIR after an inspection to ensure that FDA has redacted the document of any trade secret or confidential information. The same is true for analytical results. Your company should obtain FDA's analytical results and methodology if possible. FDA retains a portion of the sample collected and that may be made available to your company should enforcement actions be contemplated by the agency.²⁷

IV. Conclusion

I appreciate the opportunity to share my experiences and legal insight today. I will now take any questions that you may have. Thank you.

²⁷ 21 U.S.C. § 372(b).