



FDA Authority to Oversee Private Laboratories that Analyze Imported FDA-Regulated Food

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Summary

Industry observers have raised concerns about perceived gaps in food import safety over the past few years. One particular area of concern focuses on imported goods that are released into the United States market after the Food and Drug Administration (FDA) detains them under an import alert. Generally, these goods may be released into the market after an importer “provides evidence that the entry is in compliance with federal laws and regulations.” Currently, the FDA does not have express statutory authority to regulate the private labs that test these imported goods for compliance, although the FDA has authority over the importer and imported products. This report focuses on obstacles to and legislative proposals for FDA regulation of the private laboratories that analyze imported FDA-regulated goods. It will provide background to that relationship, as well as present information about agency and Bush Administration proposals and legislative responses from the 110th Congress (particularly the Dingell Draft, S. 2418, H.R. 5904, and H.R. 5827) to the lack of regulation.

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Background

Industry observers have raised concerns about perceived gaps in food import safety over the past few years. One particular area of concern focuses on imported goods that are released into the United States market after the Food and Drug Administration (FDA) detains them under an import alert. Generally, these goods may be released into the market after an importer “provides evidence that the entry is in compliance with federal laws and regulations.”¹ The proof can be provided by private laboratories that have tested samples of the detained imported goods, and importers can present results indicating that the goods are FDA-compliant. Currently, the FDA does not have express statutory authority to regulate the private laboratories that sample or test these imported goods, although the FDA regulates the importer and imported products. This report focuses on proposals for FDA regulation of the private laboratories that analyze imported, FDA-regulated goods. It will provide background to the relationship between the FDA and the private laboratories, as well as information about agency and Bush Administration proposals and legislative responses in the 110th Congress (particularly the Dingell Draft, S. 2418, H.R. 5904, and H.R. 5827) to the current lack of regulation.

The FDA and Private Laboratories

Administrative responsibility for regulation of certain types of imported food is delegated to the FDA under Chapter VIII of the Federal Food, Drug and Cosmetic Act (FFDCA).² Generally, the FFDCA provides that an article must be refused admission into the United States, with some exceptions, on the following bases:

[i]f it appears from the examination of [samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States] or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions ..., or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505.³

Under the FFDCA, the FDA can automatically detain a product without physically examining it.⁴ Automatic detention occurs as a result of the issuance of import alerts, which “identify problem commodities and/or shippers and/or importers and provide guidance for import coverage,” such as if “those products or shippers ... have met the criteria for automatic detention.”⁵ Importers

¹ FDA, Regulatory Procedures manual, Ch. 9-5: Release Notices, http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-5.html [hereinafter Release Notices]; FDA, Office of Regulatory Affairs, III-07, ORA Laboratory Manual (2003), http://www.fda.gov/ORA/science_ref/lm/vol3/section/07.pdf.

² 21 U.S.C. § 381(a); FFDCA § 801(a).

³ *Id.* Section 505 of the FFDCA refers to the FDA’s process for approving new drugs.

⁴ The FDA states that Congress’s use of the term “or otherwise” gives the FDA the authority to forego the physical inspection and detain the item. See FDA Regulatory Procedures Manual, Ch. 9-6: Detention without Physical Examination, http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-6.html.

⁵ FDA, Regulatory Procedures manual, Ch. 9-13: Import Information Directives, http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-13.html. Import alerts list reasons for detaining a product. For example, in 2007, the FDA issued Import Alert # 16-131, which covered farm-raised catfish, basa, shrimp, dace, and eel from China. These fish are to be automatically detained at the U.S. border due to the presence of unapproved antimicrobial drug residues.

whose products have been detained because of import alerts can petition for the release of their products by presenting testimony from private, or third-party, laboratories that shows that their products are compliant.⁶ In order to do this, they submit either their products or samples of their products for testing to the private laboratories. For the products to be released, the private laboratories must then present test results that indicate that the products do not violate the FDA's entry standards. The test results can be returned to the importer, who will give it to the FDA, or the lab can turn in the results directly to the FDA. The FDA may then use this data "to determine whether the imported food complies with the [FFDCA] and can be released into the United States."⁷

The FDA has recognized these private laboratories as an integral part of food import safety.⁸ According to the FDA, the third-party labs help ensure that the food reaching the market complies with agency standards and allow agency laboratory resources to be devoted to other regulatory matters.⁹ However, there has been criticism regarding the autonomy given to the importers and private laboratories. Such criticism varies from the manner in which the samples are collected for testing to the reporting of test results by the importers to the FDA. For example, at a 1998 hearing before a Senate Governmental Affairs subcommittee, a former customs broker testified regarding the abuses of the private laboratory system in relation to the product samples given to the private laboratory. He recounted how some importers selected samples for testing that were from shipments that had not been detained or they submitted multiple samples for testing until a sample was found to be compliant.¹⁰ As the FDA has noted, "[b]oth of these activities permit importers to market adulterated or misbranded foods in the United States, representing a health hazard."¹¹

Another example occurred early in 2008, when the chairman of a private laboratory that samples and tests FDA-regulated goods testified at a House Energy and Commerce subcommittee hearing. His testimony concerned encounters with importers who deleted information from test results that evidenced FDA violations and then submitted the altered results to the FDA, as well as suggestions for improving the FDA's regulation of imported foods via the use of laboratories and existing FDA programs.¹² Additionally, he stated that the FDA should be able to visit and audit laboratories at their physical location at any time. Currently, the FDA may conduct voluntary, on-site assessments of such laboratories.¹³ Recent agency, administration, and legislative proposals address various ways to curb the potential for such abuses by monitoring private laboratories.

⁶ Release Notices, *supra* note 1.

⁷ Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food, 69 Fed. Reg. 23460, 23461 [hereinafter Proposed Rule](proposed Apr. 29, 2004)(to be codified at 21 C.F.R. pt. 59).

⁸ *Id.* at 23460.

⁹ *Id.*

¹⁰ The Safety of Food Imports: Fraud and Deception in the Food Import Process—Part III: Hearing Before the Subcomm. on Investigations of the S. Comm. on Governmental Affairs, 105th Cong. 28-29 (Sept. 10, 1998) (statement of "Mr. Broker," Confidential Informant/Former Customs Broker), <http://hsgac.senate.gov/hearings1998.htm>; see also Proposed Rule, *supra* note 7, at 23463; Contaminated Food: Private Sector Accountability: Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 110th Cong. (Feb. 26 2008)(statement of David A. Eisenberg, Chairman, Anresco, Inc.) [hereinafter Anresco statement], at 7, http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.022608.Eisenberg-Testimony.pdf.

¹¹ Proposed Rule, *supra* note 7, at 23462.

¹² Anresco statement, *supra* note 10, at 5.

¹³ FDA, Office of Regulatory Affairs, III-07, ORA Laboratory Manual 10 (2003), http://www.fda.gov/ORA/science_ref/lm/vol3/section/07.pdf. The FDA arguably possesses the authority to inspect such laboratories, under 21 (continued...)

Agency and Bush Administration Proposals

The FDA Office of Regulatory Affairs publishes a Laboratory Manual with a section on Private Laboratory Guidance.¹⁴ The Guidance “seeks to establish a uniform, systematic, and effective approach to ensuring that private labs performing analyses on FDA-regulated imported commodities submit scientifically sound data.”¹⁵ To that end, the Guidance provides recommendations on sampling techniques, information regarding the training and experience of private lab analysts, considerations for reviewing the analytical packages, and suggested criteria for collecting audit samples.¹⁶ In general, a guidance document is a type of policy statement, “issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.”¹⁷ General statements of policy do not “impose any rights and obligations,”¹⁸ nor do they “establish a ‘binding norm’ ” because they are “not finally determinative of the issues or rights to which [they are] addressed.”¹⁹

In April 2004, the FDA proposed a rule to regulate imported food product sampling services and private laboratories.²⁰ It was withdrawn without comment on August 5, 2005.²¹ Some of the recommendations from the FDA’s Laboratory Guidance were put forth in the proposed rule.²² The proposed rule would have required “samples to be properly identified, collected and maintained.”²³ The proposed sampling requirements outlined specific provisions for identification, collection, and documentation from the time the sample was collected to the time the sample was delivered to a private laboratory. Particularly, the proposed rule placed an emphasis on an “independent” execution of the sampling, to ensure that the sampling and the tests

(...continued)

U.S.C. § 374(a), but has not chosen to assert it. That statute authorizes the FDA “(A) to enter, at reasonable times, any factory, warehouse, or establishment in which food ... [is] manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction ... ; and (B) to inspect, at reasonable times and within 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. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in [FFDCA § 414; 21 U.S.C. § 350c] when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.” 21 U.S.C. § 374(a).

¹⁴ FDA, Office of Regulatory Affairs, III-07, ORA Laboratory Manual 10 (2003), http://www.fda.gov/ORA/science_ref/lm/vol3/section/07.pdf.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Tom C. Clark, Attorney General, Attorney General’s Manual on the Administrative Procedure Act, at 30 n.3 (1947), <http://www.law.fsu.edu/library/admin/1947iii.html> [hereinafter AG Manual]; *see, e.g.*, Chamber of Commerce v. United States Department of Labor, 174 F.3d 206, 212 (D.C. Cir. 1999) (“In *American Bus Association v. United States*, we held that the question whether a rule is a policy statement is to be determined by whether it (1) has only a prospective effect, and (2) leaves agency decisionmakers free to exercise their informed discretion in individual cases.”) (internal citations omitted).

¹⁸ Community Nutrition Institute v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987) (internal quotations omitted).

¹⁹ Pacific Gas & Electric Co. v. Federal Power Commission, 506 F.2d 33 (D.C. Cir. 1974).

²⁰ Proposed Rule, *supra* note 7, at 23463.

²¹ 70 Fed. Reg. 64553, 64590 (Oct. 31, 2005).

²² Both the proposed rule and the Guidance have nearly identical requirements for proper sample collection and review of analytical packages.

²³ Proposed Rule, *supra* note 7, at 23460.

are conducted without the importer's influence. It went further to require "laboratories to use validated or recognized analytical methods, and to submit analytical results directly to FDA."²⁴ It purposefully omitted a laboratory accreditation requirement.²⁵

In November 2007, the FDA prepared a report entitled, the *Food Protection Plan*.²⁶ The FDA's plan is integrated with a separate plan prepared for President Bush by the Interagency Working Group on Import Safety called an *Action Plan for Import Safety*.²⁷ Both reports highlight how the Bush Administration would like to improve food import safety. The *Food Protection Plan* recommends legislation that would give the FDA the authority to accredit private laboratories.²⁸ The *Action Plan for Import Safety* notes that the FDA plans to issue guidance "that would set standards for the sampling and testing of imported products, including the use of accredited private laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved."²⁹

Legislative Proposals from the 110th Congress

Several bills introduced in the 110th Congress addressed the issue of private laboratory regulation. One common theme among these legislative proposals is the accreditation or certification of private laboratories.

The Food and Drug Administration Globalization Act (Dingell Draft)

Representative Dingell of the House Committee on Energy and Commerce began circulating a bill in draft form in April 2008.³⁰ The draft sought to alter the FFDCA in a variety of ways, including by requiring new sampling and testing protocols for food shipments. The Dingell draft would have added a new section to the FFDCA dedicated to the testing of food shipments. The new section would have addressed three areas of food shipment testing: (1) testing in facilities that manufacture, process, pack, or hold food that *would not have been certified* under the provisions that the bill would have established (in which case accredited laboratories would conduct sampling and testing of *each* shipment and *simultaneously* submit the sampling results electronically to the Health and Human Services (HHS) Secretary and the facility owner); (2) testing in like facilities that *would have been certified* under the bill's provisions (accredited laboratories would conduct sampling and testing of shipments "on a *periodic* basis specified by the Secretary" and submit the sampling results electronically to the HHS Secretary and the facility owner); and (3) accreditation of laboratories by the HHS Secretary "for the purpose of

²⁴ *Id.*

²⁵ *Id.* at 23464.

²⁶ Department of Health and Human Services, Food and Drug Administration: Food Protection Plan 1 (2007) [hereinafter Food Protection], <http://www.fda.gov/oc/initiatives/advance/food/plan.html>.

²⁷ *Id.* at 3; Interagency Working Group on Import Safety: Action Plan for Import Safety (2007) [hereinafter Import Safety], <http://www.importsafety.gov/report/actionplan.pdf>.

²⁸ Food Protection, *supra* note 26, at 3.

²⁹ Import Safety, *supra* note 27, at 50.

³⁰ FDA Legislation, <http://energycommerce.house.gov/FDAGlobalAct-08/index.shtml>.

conducting sampling and testing.”³¹ The section would have required the Secretary to establish a standard for accreditation and mandated that all certified and non-certified facilities submit all their samples to accredited labs only. The accredited labs would then return the results simultaneously to the FDA and to the importer.

Ending Agricultural Threats: Safeguarding America’s Food Supply for Everyone (EAT SAFE) Act of 2007 (S. 2418)

The EAT SAFE Act was introduced by Senator Casey in December 2007. The bill would have required private laboratories that conduct tests on FDA-regulated imports to be certified by the agency under a fee-funded certification and audit process developed by the FDA. Laboratories would have had to submit to the agency the results of all tests conducted.

Safe Food Enforcement, Assessment, Standards, and Targeting (FEAST) Act of 2008 (H.R. 5904)

The Safe FEAST Act was introduced in April 2008 by Representative Costa. In particular, it would have allowed the HHS Secretary to recognize “qualified” laboratories to test imported foods, once the laboratories have established, to the recognizing agency’s satisfaction, that they maintain internal quality systems and meet other criteria. The Secretary would also have been required to establish a registry of such laboratories.³² Alternative laboratories would have been allowed to test samples as well, but additional requirements, such as the submission of evidence to the Secretary to establish the laboratory’s qualifications and the submission to the FDA of all testing results and data, would have been imposed on such laboratories.

Keeping America’s Food Safe Act of 2008 (H.R. 5827)

This bill was introduced by Representative Roskam in April 2008. Among other things, the bill would have required the addition of a section to the FFDCFA that would have required the HHS Secretary to certify all private laboratories and sampling services that test imported FDA-regulated goods.³³ Laboratories would have had to allow audits and submit all test results directly to the FDA. In addition, importers, laboratories, and sampling services would have faced civil penalties for knowingly falsifying test results.

³¹ FDA Legislation, § 107, http://energycommerce.house.gov/FDAGlobalAct-08/Dingel_60AXML.pdf (emphasis added).

³² H.R. 5904, § 8: Recognition of Qualified Laboratories for Analyses of Imported Foods.

³³ H.R. 5827, § 2: Certification of Private Laboratories and Sampling Services.

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