ADMINISTRATIVE REVIEW BOARD
UNITED STATES DEPARTMENT OF LABOR
WASHINGTON, D.C.

JAMES BYRON, Complainant,	)	ALJ Case No. 2014-FDA-00001
v.	)	ARB Case No. 14-087
I.E.H. Laboratories Respondent.	)	

BRIEF OF THE ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH AS *AMICUS CURIAE*

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STATEMENT OF INTEREST

Pursuant to 29 C.F.R. 1987.108(a)(1) and the Administrative Review Board's ("Board") order of September 3, 2014, the Assistant Secretary of Occupational Safety and Health submits this brief as *amicus curiae*.

The Occupational Safety and Health Administration ("OSHA") is responsible for enforcing the FDA Food Safety Modernization Act ("FSMA" or "Act") whistleblower protection provision. See Secretary's Order 1-2012 (Jan. 18, 2012), 77 Fed. Reg. 3912 (Jan. 25, 2012). The Secretary of Labor's procedural regulations grant the Assistant Secretary the right to participate as *amicus curiae* in a FSMA whistleblower protection case "at any time at any stage of the proceeding." 29 C.F.R. 1987.108(a)(1).

The Assistant Secretary has a significant interest in the scope of coverage under the FSMA whistleblower provision. OSHA believes that the ALJ in this case erred by

concluding that the provision exempts entities that engage in food testing. For the reasons set forth more fully below, the Assistant Secretary respectfully urges the Board to hold, as a matter of law, that the FSMA whistleblower protection provision covers laboratories that test food samples because they are engaged in the manufacture, processing, importation, holding, or reception of food. Accordingly, the Assistant Secretary asks the Board to reverse the ALJ's decision and remand for further proceedings.

STATEMENT OF THE ISSUE

Whether the ALJ erred in holding that the FSMA whistleblower provision categorically exempts from coverage entities that test food?

STATEMENT OF THE CASE

A. Statutory Background

The Federal Food, Drug, and Cosmetic Act ("FD&C") has since 1938 authorized the Food and Drug Administration ("FDA") to regulate the safety of food in interstate commerce. See 21 U.S.C. §§ 301 et seq.. On January 4, 2011, Congress enacted the "FDA Food Safety Modernization Act," which substantially amended the FD&C by authorizing the FDA to require comprehensive, prevention-based controls across the food supply. See Pub. L. 111-353, 124 Stat. 3885.

The FSMA also amended the FD&C to add an employee (or "whistleblower") protection provision, administered by the Secretary of Labor. Id. § 402; 21 U.S.C. § 399d. This provision covers employers that are "engaged in the manufacture, processing,

packing, transporting, distribution, reception, holding, or importation of food." 21 U.S.C. § 399d(a). It protects employees against retaliation if they report to their employer, the federal government, or a state attorney general, information relating to violations or perceived violations of "any order, rule, regulation, standard, or ban under the FD&C," including any new obligations arising from the FSMA. 21 U.S.C. § 399d(a)(1). Section 399d further protects employees if they testify, participate, or assist in proceedings concerning such a violation, or if they object to or refuse to participate in possible violations. Id. § 399d(a)(2)-(4).

B. Procedural History

James Byron filed a complaint with OSHA in October 2011, alleging that Respondent, International Environmental Health Laboratories ("I.E.H."), terminated him in violation of 21 U.S.C. § 399d. Following an investigation, OSHA determined that I.E.H. is a covered entity within the meaning of the FSMA whistleblower protection provision, but that the evidence was insufficient to establish that I.E.H. had retaliated against Mr. Byron for engaging in protected activity. Pet'r App at 47. Accordingly, the Assistant Secretary dismissed Mr. Byron's complaint. Id.

Mr. Byron requested a hearing before an Administrative Law Judge ("ALJ") in October 2013, and, in December 2013, ALJ Paul Almanza issued initiating orders. Id. at 49. On February 24, 2014, I.E.H. filed a motion to dismiss the case, arguing that the FSMA whistleblower protection provision does not apply to food testing laboratories. Id.

at 1; id. at 50.[1] I.E.H. also argued that it does not handle "food" as defined by the FSMA, because the food samples it tests are not distributed for consumption. Id. at 7. Following further briefing and oral argument by the parties, ALJ Almanza issued a Decision and Order granting I.E.H.'s motion on July 30, 2014. Id. at 58.

C. Brief Statement of Facts

The summary decision record contains one affidavit from each of the parties, setting forth the following facts: I.E.H. performs laboratory testing services under contracts with food manufacturers, processors, and importers. Id. at 44. These services include tests to detect harmful microbes such as E.coli, listeria, and salmonella. Id. While I.E.H.'s clients outsource this sort of work, other food manufacturers and processors conduct similar tests using their own personnel. Id.

To perform the tests, I.E.H. uses representative food samples from food lots and from detained food shipments. Id. at 44-45. After testing the samples, I.E.H. destroys them. Resp't App at 2. I.E.H.'s clients then determine whether the food lot or shipment will enter into commerce. Id. In addition, I.E.H.'s importer clients use the results of I.E.H.'s tests to demonstrate to the FDA that detained food shipments are safe for release. Pet'r App at 45. In some cases, I.E.H's clients send food samples to I.E.H. to be tested, and "I.E.H. receives these samples" in its laboratories. Resp't App at 1; see also Pet'r

[1] I.E.H. additionally argued that the case should be dismissed because Mr. Byron failed to timely request an ALJ hearing, id. at 1; however, that issue is not before the Board on review.

App at 44. Other times, I.E.H. employees conduct testing within facilities carrying out other steps in the manufacture and processing of food. Id.

Mr. Byron worked for I.E.H. as the Vice President of International Business Development and Technology Transfer. Id. Mr. Byron alleges that I.E.H. terminated him in retaliation for raising concerns about and objecting to salmonella testing practices. Id. at 47.

D. ALJ's Decision

Stating that "section 399d unambiguously excludes entities engaged in testing from its coverage," id. at 54, the ALJ dismissed Mr. Byron's whistleblower complaint. In reaching this conclusion, the ALJ noted that "testing" is "not found in the eight enumerated activities listed in section 399d," and that the definitions of these eight activities did "not indicate that they include 'testing.'" Id. at 53.

The ALJ also noted that "Congress expressly mentioned testing," in 21 U.S.C. § 350k (section 202 of the FSMA), which establishes a "broad food testing program through accreditation of laboratories." Id. The ALJ concluded that the existence of 350k demonstrates that Congress "knew how to, and did enact statutory language explicitly covering testing," id. at 58, and therefore did not intend for any of the terms in 399d(a) to encompass testing. Id. at 54.

At the same time, the Decision and Order acknowledges provisions of the Act that "arguably indicate[] that under the FSMA, manufacture and processing"—two of the eight activities enumerated in 399d—"necessarily include testing." Id. at 54 (citing

provisions at 21 U.S.C. § 350g). The ALJ did not expressly reconcile these provisions with his conclusion that the text of 399d is unambiguous, but stated that even assuming it was ambiguous, he would not conclude that the employee protection provision covers I.E.H. Id. 54-58.

Turning to the legislative history of the FSMA, the ALJ's Decision and Order highlights a number of Congressional statements showing that "outbreaks of foodborne illness" inspired the passage of the FSMA, and that Congress saw "mandating preventative controls" as a "key purpose" of the legislation. Id. at 56-57. The ALJ concluded, however, that the existence of 350k "accounts for the intent of these individual legislators concerning the importance of testing." Id. at 57. The ALJ also relied on 350k to reject the argument that the "broader statutory context" of the FSMA dictates that 399d should be read to cover entities engaged in testing. Id. The ALJ did so notwithstanding his statement that "[g]iven the FSMA's goal of protecting American consumers from adulterated food and the emphasis Congress placed on preventative controls," it "would arguably be incongruous to read the statute to exclude entities engaged in testing" from coverage. Id.

Finally, the ALJ noted that because he had found "testing" was not one of the activities that would make I.E.H. a covered employer under the FSMA, he did not need to reach I.E.H.'s argument that it did not handle "food" because the laboratory destroys the samples it tests, and they are not consumed. Id. at 52 n.4.

JURISDICTION AND STANDARD OF REVIEW

The Secretary of Labor has delegated to the Board authority to issue final agency decisions under the FSMA's whistleblower provision. See 29 C.F.R. § 1987.110. The Board reviews the ALJ's decision granting summary decision de novo. Cobb v. FedEx Corporate Services, Inc., ARB No. 12-052, 2013 WL 6971136, at 4 (ARB Dec. 13, 2013). An ALJ may enter summary decision if the pleadings, affidavits, and other evidence show that there is no genuine issue as to any material fact and the moving party is entitled to prevail as a matter of law. Id.; 29 C.F.R. § 18.40(d). The Board will affirm an ALJ's recommended grant of summary decision only "if, upon review of the evidence in the light most favorable to the non-moving party," it concludes "without weighing the evidence or determining the truth of the matters asserted, that there is no genuine issue as to any material fact and that the ALJ correctly applied the relevant law." Cobb, 2013 WL 6971136, at 4.

SUMMARY OF ARGUMENT

The ALJ erred as a matter of law when he held that the FSMA whistleblower protection provision excludes entities that test food. Far from "unambiguously" exempting food testing, Congress based FSMA whistleblower coverage on a sweeping list of highly generalized activities. Whistleblower protection applies if an employer engages in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food. The ordinary meanings of these terms leave wide room for interpretation, and therefore, must be understood in light of the FSMA's overall statutory scheme and overarching purpose: to prevent outbreaks of foodborne illness.

Notwithstanding the ALJ's reliance on the laboratory accreditation provision at 21 U.S.C. § 350k, moreover, section 399d is the only provision in the statute that protects employees who report or assist in prosecuting potential violations of food safety rules.

Viewing the evidence in the light most favorable to Mr. Byron, as is required on a motion for summary decision, I.E.H. engages in one or more of at least five of the broad categories of food-related activities listed in 399d(a). First, the record indicates that I.E.H. engages in both the "reception," and "holding" of food, thus triggering whistleblower protection for its employees. Additionally, when an entity tests representative samples from yet-to-be-distributed food lots, it engages in the "manufacture," and "processing" of food as defined by the ordinary meanings of those terms. Likewise, when an entity tests samples from food shipments pending admission into the United States, it is involved, or engages, in the importation of food. This reading is underscored by the FSMA's statutory scheme, which made safety verification a mandatory part of food manufacturing, processing, and importation.

Construing the terms "manufacture," "processing," and "importation," to encompass testing for salmonella, E.coli, and other harmful microbes, also best effectuates the FSMA's overall food safety goals. Employees who test food as a part of food manufacture, processing, or importation are well-positioned to recognize a safety breach before contaminated food enters the stream of commerce. Given food testing employees' critical role in stopping foodborne illness outbreaks before they start, it is reasonable to infer that Congress intended the terms "manufacture," "processing," and

"importation" to be interpreted to protect the ability of these employees to report and help prosecute potential food-safety violations without fear of retaliation.

Finally, I.E.H.'s assertion that it destroys food samples after it tests them is irrelevant to the issue of coverage under 399d. As courts construing the term "food" under the FD&C have long recognized, companies "cannot avoid the reach of the FDA by claiming that a product which looks like food and smells like food is not food because it was not intended for consumption." Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 337 (7th Cir. 1983).

ARGUMENT

I. The ALJ Erred in Holding that the FSMA's Whistleblower Provision Excludes Entities that Test Food from Its Coverage.

A. Nothing in the text of the FSMA's whistleblower provision exempts entities that primarily test food for safety.

The FSMA provides whistleblower protection to employees of entities that are "engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food." 21 U.S.C. § 399d(a). Section 399d does not contain an exception for entities that test food, nor does it contain any other exemption or limitation. Rather, based on the plain language, the protection applies if an entity is "engaged in"—i.e., it is involved in activities that fall within—any of the eight highly general categories of activities listed. This is true whether or not the qualifying activity is the entity's primary activity.

Nevertheless, the ALJ concluded that the FSMA whistleblower protection provision unambiguously excludes entities that engage in food testing. Pet'r App at 52.

The ALJ based this conclusion in part on the fact that "testing" is not one of the eight activities listed in 399d(a). Id. This analysis mistakes generality for negative implication. Cf. Burns v. United States, 501 U.S. 129, 136 (1991) ("An inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent"). "Many statutes," however, "use broad terms that require interpretation in order to determine whether the broad term encompasses more specific categories of conduct." Whitmore v. Kraft Foods Global, 798 F.Supp.2d 917, 922 (N.D. Ill. 2011). Furthermore, when a statute implemented by an administrative agency employs broad terms, the *expressio unius* canon, on which the ALJ relied, is a "feeble helper," as Congress is presumed to have left to "reasonable agency discretion questions that it has not directly resolved." Adirondack Medical Center v. Sebelius, 740 F.3d 692, 697 (D.C. Cir. 2014). Simply that 399d omits specific mention to "testing," does not unambiguously equate to non-coverage, because testing can fall within the range of broad activities listed.

Likewise, that Congress used the specific terms "testing," and "sampling" in a separate section of the FSMA providing detailed instructions relating to accreditation of those activities, but chose broader terms to define the scope of whistleblower coverage, does not demonstrate its intent to exclude entities that engage in "testing" from the scope of these broader terms. To the contrary, this choice of language is a familiar pattern in the FD&C. For example, the statute uses the narrower terms "labeling" and "packaging" in provisions specifically concerning those activities. See 21 U.S.C. § 343 (establishing packaging and labeling requirements, including that food be labeled with detailed

nutrition information); see also 21 U.S.C. § 347(b) (establishing specific labeling and packaging requirements for oleomargarine). But where the broader terms "manufacturing" and "processing" appeared in the FD&C prior to the FSMA, the FDA has defined them to include both "labeling" and "packaging." See 21 C.F.R. § 1.227(b)(6). Given that Congress likewise chose broad activities (e.g. manufacture and processing), rather than more specific ones (e.g. labeling or packaging) to formulate the whistleblower provision, "its failure to mention" another specific activity—testing—"does not tell us anything about whether it intended that practice to be covered." Jackson v. Birmingham Bd. of Educ., 544 U.S. 167, 175 (2005) (holding that Title IX's "broadly written general prohibition on discrimination," encompasses "retaliation," even though the statute does not expressly mention retaliation, unlike other statutes which spell out in great detail the conduct that constitutes discrimination).

B. Section 350k of the FSMA does not displace whistleblower coverage for employees of food testing laboratories.

The ALJ also erred in concluding that 399d does not cover testing entities because section 202 of the FSMA, 21 U.S.C. § 350k, provides "a means outside the whistleblower process to address complaints concerning testing." Pet'r App at 54. Section 350k, titled "Laboratory accreditation for analyses of foods," is not an employee protection provision. Instead, it requires the Secretary of Health and Human Services ("HHS") to recognize

bodies that will accredit food testing laboratories. 21 U.S.C. § 350k(a)(1).[2] As part of this program, the FSMA directed HHS to develop model accreditation standards, which must include (among other criteria) methods to ensure that laboratories have procedures "to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited." Id. § 350k(a)(6)(A)(iii)(emphasis added).

But while section 350k contemplates that there may be complaints about testing practices, it says nothing about what happens when objectors are employees who suffer retaliation for raising food-safety concerns to their employer. Nor does section 350k address retaliation for the reporting of food safety violations to FDA or to a state attorney general, activity which 399d is expressly designed to protect. Nor, unlike 399d, does 350k address retaliation for an employee's participation in FDA proceedings to resolve food safety violations. Section 350k does not, accordingly, displace whistleblower coverage for employees of food testing laboratories.

The Supreme Court roundly rejected similar reasoning in its recent decision in Lawson v. FMR LLC, 134 S.Ct. 1158, 1171-72 (2014). Lawson addressed whether Sarbanes-Oxley whistleblower coverage extends to employees of contractors to publicly traded companies. One of the bases for the employer's arguments that the whistleblower provision did not apply was that Congress had chosen to protect against fraud through separate provisions that required accountants and lawyers for publicly-traded companies

[2] Whenever the Act or HHS requires testing to address an identified or suspected food safety problem, the owner or consignee of the food use an accredited in-house laboratory or hire an accredited third-party laboratory to conduct the tests. Id. § 350k(b)(1)(A).

to report misconduct, and that required mutual fund investment advisers to comply with certain fiduciary requirements. Id. at 1171-72. The Supreme Court rejected these arguments and drew the opposite conclusion from the targeted reporting requirements and direct regulation of investment advisers. Id. at 1171-72. These separate requirements, the Court explained, "indicate why Congress would have wanted to extend [whistleblower] coverage" to these professionals. Id. (emphasis added). As with testing employees in the present case, moreover, no other provision of the statute afforded outside accountants, attorneys, or investment advisors protection from retaliation by their employers if they made the reports the statute specifically anticipated. Id. at 1171-72 (noting both with respect to outside attorneys and accountants and to investment advisers that "separate regulation does not remove the problem" because only 18 U.S.C. § 1514A affords whistleblower protection). The Supreme Court therefore refused to leave these employees "vulnerable to discharge or other retaliatory action" for taking steps contemplated by the law. Id. The Board should do the same here.

II. There is a Genuine Dispute of Fact as to Whether I.E.H. Engages in At Least Five of the Enumerated Activities Triggering Coverage under the FSMA Whistleblower Provision.

Construing the declarations in the summary decision record in its favor, and as a matter of law, there is a genuine dispute of material fact as to whether I.E.H. engages in at least five of the activity categories covered by section 399d(a), including manufacture, processing, importation, reception, and holding.

A. When an entity tests samples from a food lot for harmful microbes, it engages in the manufacture and processing of food.

The ordinary meanings of the terms "manufacturing" and "processing," along with the FSMA's statutory scheme and guiding purpose, compel the conclusion that an entity engages in the "manufacture" and "processing" of food when it tests a sample from a food lot for harmful microbes.

The terms "manufacture" and "processing" are extraordinarily expansive, indicating that Congress intended them to have a broad reach. Cf. Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (in a patent law case, describing the terms "processes" and "manufactures" as "expansive," and noting that this word choice supported Congress' intent to give a statutory provision a broad scope). In addition, the ordinary meanings of these terms encompass multiple more-specific actions. As the ALJ noted, Merriam-Webster defines "processing," as "a series of actions or operations conducing to an end." Pet'r App at 52 n.5; see also www.merriam-webster.com/dictionary/processing. And to engage in "manufacture" is to engage in "the act or process of producing something." See Pet'r App at 52 n.5; www.merriam-webster.com/dictionary/manufacture. Because these definitions are highly generic, moreover, they leave open the specific actions or operations that comprise any particular process. Contrary to the ALJ's conclusion, Pet'r App at 52, nothing about the ordinary definitions of these terms indicates that they do not include testing.

Instead, common sense suggests that quality control steps—such as testing for harmful microbes—are among the multiple actions that comprise the processing and

manufacture of food. In many contexts, ranging from drugs, 21 C.F.R. § 207.3(a)(8), to biologics, id. § 600.3(u), the FDA, through its regulations, defines the terms manufacture and processing to include testing, sampling, and other quality controls. See Pet'r Br. at 16 (citing examples). And indeed, even prior to the passage of the FSMA, the FDA advised that good food manufacturing practices include "[c]hemical, microbial, or extraneous-material testing procedures . . . where necessary to identify sanitation failures or possible food contamination." 21 C.F.R. § 110.80.[3]

The structure and content of the FSMA, which imposed new preventative mandates for the safe manufacture and processing of food, further confirms this reading.

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[3] In the Decision and Order, the ALJ focused on the FDA's regulatory definitions for the terms "manufacturing" and "processing" with respect to food facility registration requirements enacted as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. These definitions are not controlling with respect to section 399d, and are of limited assistance in determining the scope of whistleblower coverage under the FSMA.

The food facility registration regulatory definitions are aimed at enabling the FDA to "act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply." Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 FR 58894-01. The scope of the regulatory definitions is limited, moreover, because the statutory registration requirement applies to entities only if they qualify as a "facility," which is a statutory term of art, and only if they perform manufacturing, processing, or certain other activities with food that will be consumed in the United States. See 21 U.S.C. § 350d; see also 68 FR 58894-01. Food samples used for testing, however, are not typically consumed. The food facility registration regulations also define "food" more narrowly than it is defined under the FD&C. See 21 CFR 1.227(b)(4).

Finally, as Mr. Byron notes in his brief, the FDA uses broader definitions of the terms manufacture and processing in many other contexts, and such definitions generally list testing as one of the activities included in the definitions of manufacture and processing. See Pet'r Br. at 16.

Section 103 of the FSMA not only requires owners and operators of food manufacturing and processing facilities to identify and evaluate food safety hazards, and to identify and implement controls to prevent the hazards, 21 U.S.C. § 350g(a)-(c), but also to "verify" that the preventative controls "are effectively and significantly minimizing or preventing the occurrence of identified hazards." Id. § 350g(f)(4). To verify that hazards are not present, facilities may use "environmental and product testing programs" and other appropriate means. Id. In other words, the FSMA made verifying the effectiveness of food safety controls—through food testing or through other methods—a required step in the series of actions that comprise the "manufacture" and "processing" of food.

Reading the terms "manufacture" and "processing" to encompass "testing," also best addresses the "mischief" Congress sought to resolve with the FSMA. Lawson, 134 S. Ct. at 1161; see also Pub. Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 455 (1989) ("[S]tatutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.") Congress passed the Act in the wake of several high profile food safety incidents, including a multi-state salmonella outbreak. See Congressional Research Service, The FDA Food Safety Modernization Act (P.L. 111-353), February 18, 2011 at 2. Although there are no reports on the bill that became law, multiple floor statements emphasize members' deep concern over these

foodborne illness outbreaks. See 156 Cong. Rec. H8861-01 (Dec. 21, 2010); 156 Cong. Rec. S8259-02 (Nov. 30, 2010).[4]

The FSMA addresses such food crises by "fundamentally" shifting the "food safety oversight system to one that is preventive in nature as opposed to reactive." 156 Cong. Rec. H8861-01 (Dec. 21, 2010) (statement of Rep. Waxman); see also id. (statement of Rep. Pallone) ("[M]ost notably, the bill emphasizes prevention and safety that helps ensure that food is safe before it's distributed, before it reaches store shelves, before it reaches the kitchens of American families."). Congress sought to accomplish this preventative goal by requiring, "food producers to come up with strategies to prevent contamination and then continually test to make sure these strategies are working." 156 Cong. Rec. E2249 (Dec. 22, 2010) (statement of Rep. Davis); see also 156 Cong. Rec.

[4] For example, see 156 Cong. Rec. H8861-01 (Dec. 21, 2010) (statement of Rep. Dingell) (explaining that the FSMA addresses the "shameful" situation in which "48 million Americans are sickened by bad food, some 128,000 are hospitalized, and 3,000 are killed yearly"); (statement of Rep. Stupak) (noting that the House Oversight and Investigations Committee had "held over 13 hearings on food-borne illnesses from spinach, peanut butter, jalapenos, and most recently tainted eggs"); id. (statement of Rep. Waxman) ("Food-borne illness outbreaks can strike each and every one of us. In recent years, foods we never would have imagined to be unsafe, everything from spinach to peanut butter, have sickened an untold number of Americans. It is time, once and for all, to enact this legislation."); id. (statement of Rep. Pallone) ("Every time we have a food safety crisis, be it eggs or spinach or peppers or peanuts, we shake our heads at the vulnerability of our food supply and bemoan the fact that we don't have the tools to protect it. And these aren't isolated instances."); id. (statement of Rep. Jackson-Lee) (discussing recent salmonella outbreak); id. (statement of Rep. DeLauro) (describing constituent sickened by E.coli); see also 156 Cong. Rec. S8259-02 (Nov. 30, 2010) (statement of Sen. Whitehouse) ("I have been appalled by the stories of deaths and serious illnesses from seemingly benign foods such as peanut butter and spinach."); id. (statement of Sen. Leahy) (discussing a recent salmonella outbreak); id. (statement of Sen. Casey) (describing how E.coli killed one of his constituents).

H8861-01 (Dec. 21, 2010) (statement of Rep. Waxman) (explaining that companies "that process or package foods will be required to implement preventive systems to stop outbreaks before they occur"). Thus, not only does the FSMA make hazard control and verification mandatory steps in the manufacture and processing of food, but Congress intended that these operations be at the center of the Act's overall food safety scheme.

Like the other federal whistleblower statutes it mirrors, section 399d is designed to achieve the FSMA's greater safety goals, as well as to protect employees. See Cobb v. FedEx, ARB No. 12-052, 2013 WL 6971136, at * 10 (ARB Dec. 13, 2013). The legislative history indicates that Congress regarded whistleblower protection as a key element of ensuring the safety of food entering the stream of commerce. As one representative noted shortly before FSMA became law: "Another important component of this legislation would ensure protection of whistleblowers that bring attention to important safety information pertaining to the food regulation and food safety. It is most vital that we afford those people who may know information about certain food the opportunity to inform authorities about any concerns they may have with their consumption." 156 Cong. Rec. H8861-01, 2010 WL 5173366, at H8889 (Dec. 21, 2010) (statement of Rep. Jackson Lee).

Employees who test food lots for harmful microbes—like salmonella—are particularly well-positioned to have information about violations that might lead to a wide-spread foodborne illness outbreak. Indeed, as Mr. Byron points out, employees using laboratory equipment to perform microbial testing will frequently be the only individuals with knowledge that a particular food lot is unsafe, because harmful microbes

cannot be detected by the naked eye. Pet'r Br. at 24. These individuals' ability to report potential violations is crucial to the FSMA's objective of ensuring food safety through prevention.

This critical role for food testing employees does not depend, of course, on whether the employee works for a vertically integrated food business or for a third-party that specializes in testing. But construing the terms "manufacture" and "processing" to exclude the testing component of these activities would yield precisely this uneven result—exposing some food testing employees to retaliation, while shielding others, depending on their employer's additional activities. Although the food testing employees of a vertically integrated food business would likely still be protected, if the same food business outsources its testing work to a third-party contractor, the contractor's employees would be left vulnerable to retaliation for reporting safety concerns. This would be true even if the employees conduct testing activities in the exact same manner at the same facility where the food business' other manufacturing and processing activities occur. Such an outcome is not only at cross-purposes with the FSMA, but also results from an unnecessarily restrictive reading of the FSMA whistleblower provision's broad coverage of entities engaged in the manufacture and processing of food.

B. When an entity tests samples from detained international food shipments, it engages in the importation of food.

The statutory text, the FD&C's statutory scheme, and the preventative goals of the FSMA also dictate that an entity engages in the importation of food when it tests samples from detained international food shipments. The dictionary defines "importation," as

"the act or practice of importing something." See www.merriam-webster.com/dictionary/importation. Importing something, in turn, ordinarily means to "bring a product into the country to be sold." www.merriam-webster.com/dictionary/importing. Section 301 of the FSMA, generally requires that importers[5] of food establish "risk-based foreign supplier verification activities." See 21 U.S.C. § 384a(a); id. § 331(zz) (prohibiting the "importation or offering for importation of a food if the importer . . . does not have in place a foreign supplier verification program"). These activities may include "periodically sampling and testing shipments." Id. § 384a(c)(4). Thus, as with food manufacture and processing, the FSMA makes safety verification, which may include the type of testing performed by I.E.H., part and parcel of bringing foreign food into the stream of commerce in the United States.

Reading the phrase "engaged in . . . importation" in 399d to encompass the testing of foreign food shipments not yet admitted into the United States is also consistent with the FSMA's goal of preventing food-borne illness from imported food. During floor debate prior to the passage of the FSMA, members of Congress expressed serious concerns about the safety of global food supply chains. See, e.g. 156 Cong. Rec. H8861-01 (Dec. 21, 2010) (statement of Rep. Dingell) (noting that many food scandals "of the most appalling character" have occurred "mostly with regard to imported food: bad

[5] For the purposes of this provision, the term "importer" means the United States owner or consignee of the article of food at the time of entry of such article into the United States, or the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States. 21 U.S.C. § 384a(a)(2).

seafood and shellfish from China, unsafe leafy vegetables like spinach and celery from China, bad berries and fruit from Chile and . . . peppers from Mexico.") In keeping with its focus on prevention, the FSMA sought to ameliorate these dangers by requiring importers "to demonstrate that the food they bring into the country is safe." Id. (statement of Rep. Waxman).

Whistleblowers play an important role in effectuating this scheme. When contaminated food enters the country, employees who test the food shipment for safety, are, of course, among the most likely to have knowledge of the threat. Whether they are employed by the owner or consignee of the food, or by a third-party, these individuals' ability to report potential violations that arise during the importation of food —without fear of reprisal—is key to Congress' goal of preventing food incidents stemming from global supply chains.

C. When I.E.H. receives food samples from its clients, it engages in the reception and holding of food.

Even aside from its testing activities, however, the summary decision record indicates that I.E.H. employees are covered by the whistleblower provision because I.E.H. engages in the reception and holding of food. Like the other terms in the whistleblower coverage provision, the common definition of the word "reception" is highly generalized. The dictionary defines reception as "the act or action or an instance of receiving," and to "receive" as "to get or be given (something)." See www.merriam-webster.com/dictionary/reception and www.merriam-webster.com/dictionary/receive. The term "holding" is nearly as sweeping, and per its dictionary definition means "to

have possession or ownership of or to have at one's disposal." See www.merriam-webster.com/dictionary/hold (emphasis added). Given the ordinary meaning of the term, I.E.H. engages in "reception," when "I.E.H's clients send samples," and "I.E.H. receives these samples." Resp't App at 1 (Affidavit of Dr. Mansour Samadpour). Likewise, while these food samples are in I.E.H's possession and at its disposal, I.E.H. engages in the holding of food.

D. Food samples handled by I.E.H. constitute "food" under the FSMA and FD&C.

In its Motion to Dismiss, I.E.H. argued that the samples it tests from food lots and food shipments are not food, because it destroys the samples after testing. Pet'r App at 50. Courts have long rejected such arguments. The case law makes clear that companies "cannot avoid the reach of the FDA by claiming that a product which looks like food and smells like food is not food because it was not intended for consumption." Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 337 (7th Cir. 1983); see also United States v. Technical Egg Products, Inc., 171 F. Supp. 326, 328 (N.D. Ga. 1959) (holding that inedible incubator reject eggs were food) (citations omitted); see also United States v. Thirteen Crates of Frozen Eggs, 208 F. 950, 953 (S.D.N.Y. 1913) aff'd, 215 F. 584 (2d Cir. 1914) (holding that decomposed eggs were "food" under the Pure Food and Drug Act of 1906, even though their owner did not intend to sell them for consumption, but for other purposes).

The FD&C's definition of the term "food" "omits any reference to intent." Nutrilab, 713 F.2d at 337; see also 21 U.S.C. § 321(f) (providing that the "term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and

(3) articles used for components of any such article"); see also 29 CFR 1987.101(h) (adopting, for the purpose of the Secretary of Labor's regulations, the FD&C's definition of food). Accordingly, the test for whether something is food under the FD&C does not look to the "intended" use of a particular item of food, but "regards items as food which are generally so regarded when sold in a food form." Technical Egg Products, Inc., 171 F. Supp. at 328. "So long as the product retains a semblance of the identity it possessed as a food," courts consider it "food." Id.

Furthermore, I.E.H.'s argument that samples (taken for testing purposes from food that would otherwise be consumed) fall outside the statutory definition of "food," is impossible to square with Congress' use of the term "food" elsewhere in the FSMA. The laboratory accreditation provision, in particular, repeatedly refers to "food sampling" and "food testing," and "testing of food." See 21 U.S.C. § 350k. [6] I.E.H. would have the Board conclude that these samples are "food" for purposes of laboratory accreditation, but not for the broad remedial purposes of the FSMA whistleblower protection provision. This cannot be correct. See Ratzlaf v. United States, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it

[6] Indeed, even prior to the FSMA's passage, the FDA treated food samples imported for "quality assurance, research or analysis purposes only," and "not for human or animal consumption," as "food," for the purposes of enforcing the FD&C's requirements for submitting prior notice for food imported or offered for import into the United States. See Compliance Policy Guide, Guidance for FDA and CBP Staff, Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm.

appears.") Regardless of whether it destroys the food samples, when an entity takes or receives a sample from a not-yet-distributed food lot or a not-yet-admitted food shipment and uses this sample for testing purposes, it is variously engaged in the reception, holding, manufacture, processing, or importation of "food." If its employees blow the whistle on unsafe practices, the FSMA protects them against retaliation.

CONCLUSION

For these reasons, the Assistant Secretary respectfully urges the Board to reverse the ALJ's holding that the FSMA whistleblower provision categorically excludes entities engaged in food testing. Instead, the Board should hold that testing laboratories are covered by the FSMA whistleblower protection provision when they test food as part of food manufacture, processing or importation and when they hold or receive food. The Board should remand this case to the ALJ for further proceedings consistent with that holding.

Dated: October 14, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that copies of this BRIEF OF THE ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH AS AMICUS CURIAE have been served via first class mail on the following individuals this 14th day of October, 2014:

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