



**Issue Date: 30 July 2014**

CASE NO: 2014-FDA-00001

*In the Matter of:*

**JAMES BYRON,**  
*Complainant,*

v.

**I.E.H. LABORATORIES,**  
*Respondent.*

**DECISION AND ORDER GRANTING MOTION TO DISMISS  
AND DENYING MOTION FOR ATTORNEY'S FEES**

*Procedural and Factual Background*

This proceeding arises from a claim of retaliatory employment action under section 2012 of the Food, Drug, and Cosmetic Act ("FDCA"), added by section 402 of the FDA Food Safety and Modernization Act ("FSMA"), Pub. L. 111-353, and codified at 21 U.S.C. § 399d.

The Complainant, James Byron, filed his complaint with the Occupational Safety and Health Administration ("OSHA") in October 2011. He alleged that he was fired by Respondent, I.E.H. Laboratories, in a retaliatory employment action after raising concerns about testing practices he believed were in violation of food safety law and regulations. In particular, Complainant alleged he repeatedly raised concerns with manipulations of salmonella testing procedures to result in more favorable outcomes. He claimed that Respondent, an independent food testing company, violated the whistleblower protections of 21 U.S.C. § 399d when it fired him after he made these complaints to the company's president.

In the Secretary's Findings issued in August 2013, OSHA dismissed the complaint. OSHA found that Respondent was a covered entity within the meaning of 21 U.S.C. § 399d, as it was engaged in manufacturing and processing food, but that there was insufficient evidence to establish a violation of section 399d.

Complainant requested a hearing before a Department of Labor administrative law judge in October 2013. I issued a Notice of Assignment, Order to Meet and Confer, and Pre-Hearing Order on December 24, 2013.

On February 24, 2014, Respondent filed its Motion to Dismiss (the “Motion”).<sup>1</sup> Respondent states that it is an accredited, independent laboratory that conducts testing for food industry clients. Affidavit of Dr. Mansour Samadpour, Exhibit A to Motion, at ¶¶ 2, 4. Respondent argues that it is not a covered entity under section 399d for several reasons.<sup>2</sup> First, Respondent argues that it is not covered by the plain language of the FSMA, which applies to entities “engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food.” 21 U.S.C. § 399d. Since there is no direct reference to testing in the list of activities engaged in by covered entities, Respondent argues that it is not a covered entity under section 399d. Additionally, Respondent interprets the express mention of testing in other portions of the FSMA as a sign that section 399d’s omission of this term was intentional. Respondent also contends that it is not testing food, as that term is defined as articles used for food or drink for humans or animals. Respondent states that it tests only product samples, which are then destroyed and never enter the food stream for human or animal consumption. In sum, Respondent argues that “because ... [it] is not covered by the FSMA’s whistleblower protections, DOL lacks subject matter jurisdiction over this dispute and the Complaint should be dismissed.” Motion, at 8.

Complainant filed his Memorandum in Opposition to the Motion (the “Opposition”) on March 5, 2014. Complainant states that he was employed by Respondent, that Respondent “performs laboratory testing services domestically and internationally under contracts with numerous food manufacturers, processors, and importers,” that some food manufacturing and processing companies “outsource [testing] to a third-party like” Respondent, that Respondent’s “customers rely on the test results it generates to determine whether lots of food are safe and ready for delivery, or adulterated,” and that food “importer[s] use[] the results of ... [Respondent’s] tests of detained shipments to demonstrate to the FDA that the detained lots are safe and suitable for release.” Declaration of Complainant James Byron, Exhibit A to Opposition, at ¶¶ 1, 4, 7, and 9. Complainant contends that the testing services Respondent provides “are an “integral and necessary part of the manufacture, processing, and importation of food,” Opposition, at 12, as Complainant states that Respondent’s clients rely on the test results to determine whether food lots are adulterated and that the results are also used by food importers seeking FDA approval to release their products into the American market. *Id.* at 11. Complainant thus argues that Respondent is “engaged in” manufacturing and processing activities, making it a covered entity. *Id.* at 12. Complainant also contends that employee protections under the FSMA are not impacted by whether an entity is the primary manufacturer or producer or a third party subcontractor such as Respondent, since Complainant reads the provision as applying to any entity engaged in the production and movement of food. The Respondent’s narrow view of the provision, Complainant argues, would frustrate the Act’s purpose of improving food safety by protecting whistleblowers. *Id.* at 14-15.<sup>3</sup>

---

<sup>1</sup> Technically, the Motion is better considered a motion for summary decision under 29 U.S.C. § 18.40. The Motion also includes a request for attorney’s fees, which I briefly address in the conclusion section of this Decision and Order.

<sup>2</sup> Respondent had also argued that Complainant’s request for a hearing was untimely, but that argument was withdrawn and thus is not discussed further.

<sup>3</sup> On March 13, 2014, Complainant filed a notice of appearance of counsel and a Restated Complaint. In my order of April 14, 2014, I stated that the Restated Complaint does not affect the Motion.

On March 24, 2014, Respondent filed its Request for Leave to File Reply and Reply (the “Reply”) and a Motion for Protective Order, requesting a stay of discovery until I ruled on the Motion. On April 9, 2014, Complainant filed a Memorandum in Opposition to the Motion for Protective Order and a Response to the Reply (the “Response”). In my order of April 14, 2014, I granted leave to file the Reply and granted the requested protective order. Not having previously ruled on whether I would consider the Response, I now decide that under the circumstances of this particular case I will consider it, even though no leave was requested to file it. *See* 29 C.F.R. § 18.6(b).

In its Reply, Respondent argues that the language of section 399d provision is clear and unambiguous, making the principles of broad construction Complainant argues for inapplicable. Reply, at 2-3. Respondent also counters the argument that its services are “integral and necessary” to manufacturing, processing, and importing food, on the grounds that the case Complainant cites for this proposition, *Cobb v. Fedex Corporate Services, Inc.*, ARB No. 12-052, ALJ No. 2010-AIR-024 (ARB Dec. 13, 2013), is distinguishable. Respondent also argues that an overly broad reading of section 399d “would lead to the absurd result of covering virtually every employer in every industry allied with food.” Reply, at 4.

In his Response, Complainant argues that the statutory language should be interpreted broadly to give it the full effect Congress intended. Response, at 3-4. The relevant inquiry, Complainant argues, is not “whether a particular step in the manufacturing process is listed ... [in the plain language of section 399d], but rather whether that particular activity [here, testing] is carried out by an entity in furtherance of the ‘manufacture, processing, ... or importation of food.’” *Id.* at 4.

Respondent requested oral argument on the Motion, which was held by conference call on May 6, 2014. Counsel for both parties participated in the call; while Complainant was not present, his counsel consented to proceed without Complainant’s participation in the call. Hrg. Tr. at 10:5-15 (May 6, 2014).

#### *Issue*

Whether Respondent is a covered entity under 21 U.S.C. § 399d.

#### *Analysis*

Before turning to the merits, I note that in situations not specifically addressed by the rules of practice and procedure applicable to hearings before Department of Labor administrative law judges, the Federal Rules of Civil Procedure apply. 29 C.F.R. § 18.1(a). As the administrative rules only refer to motions for summary decision and not specifically to motions to dismiss for lack of subject matter jurisdiction, to the extent the administrative rules do not address an issue concerning the Motion, the Federal Rules of Civil Procedure for a motion to dismiss for lack of subject matter jurisdiction apply. *See* 29 C.F.R. §§ 18.40, 18.41; Fed. R. Civ. P. 12(b)(1). In ruling on the Motion, I view the facts in the light most favorable to the Complainant, the party opposing the Motion. *Cobb*, slip op. at 2 n. 2.

Ultimately, the resolution of the issue at hand turns on whether the eight enumerated activities in section 399d(a) – “manufacture, processing, packing, transporting, distribution, reception, holding, or importation” – encompass the activity Respondent engages in, testing.<sup>4</sup> As this is a question of statutory interpretation, the Supreme Court’s recent guidance in *Lawson v. FMR LLC*, 134 S. Ct. 1158 (2014), is instructive. In *Lawson*, the Court considered whether employees of private companies contracted to manage and advise mutual funds were covered by the Sarbanes-Oxley Act’s whistleblower protection provision. The Court’s opinion outlined the basic considerations when undertaking interpreting a statute. First, a court must look to the actual text of the statute. *Id.* at 1165. Then, a court may look to sources beyond the text, such as legislative history, to inform its analysis. *Id.* at 1169. Additionally, a court may look to is the broader context within which the statute was enacted. *Id.* at 1171-1175. Each of these aspects will be considered in turn below.

### The Statute’s Unambiguous Text Does Not Cover Respondent

Considering the plain meaning of the text is the initial step in interpreting a statute. In *Lawson*, the Court noted, “[i]n determining the meaning of a statutory provision, ‘we look first to its language, giving the words used their ordinary meaning.’” 134 S. Ct. at 1165 (quoting *Moskal v. United States*, 498 U.S. 103, 108 (1990) (citations and internal quotation marks omitted)). The relevant portion of the FSMA, 21 U.S.C. § 399d(a), prohibits any “entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food” from taking retaliatory action against an employee who engages in specified protected activity. The FDCA does not define “manufacture,” “processing,” or “importation,” *see* 21 U.S.C. §§ 321 and 341, and the dictionary (and, with respect to “manufacture” and “processing,” the regulatory) definitions of these terms do not indicate that they include “testing.”<sup>5,6</sup>

---

<sup>4</sup> As a determination of whether section 399d covers entities engaged in testing resolves the Motion, I do not reach the issue of whether or not the items Respondent tests constitute “food.” *See* Motion, at 7-8.

<sup>5</sup> “Manufacture” is defined as “something made from raw materials by hand or by machinery,” “the process of making wares by hand or by machinery especially when carried on systematically with division of labor,” “a productive industry using mechanical power and machinery,” and “the act of process of producing something.” *See* [www.merriam-webster.com/dictionary/manufacture](http://www.merriam-webster.com/dictionary/manufacture) (last visited July 29, 2014). The definition of “process” includes, “a series of actions or operations conducing to an end; *especially*: a continuous operation or treatment especially in manufacture.” *See* [www.merriam-webster.com/dictionary/processing](http://www.merriam-webster.com/dictionary/processing) (last visited July 29, 2014). The regulatory definition of these terms is: “Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.” 21 C.F.R. § 1.227(b)(6). “Importation” is defined as “the act or practice of importing” and in turn the relevant definition of “import” is “to bring from a foreign or external source: as ... to bring (as merchandise) into a place or country from another country.” *See* [www.merriam-webster.com/dictionary/importation](http://www.merriam-webster.com/dictionary/importation) and [www.merriam-webster.com/dictionary/import](http://www.merriam-webster.com/dictionary/import) (last visited July 29, 2014). The Department of Labor’s regulations at 29 C.F.R Part 1987 do not define these terms, nor does the preamble to the interim final rule provide any guidance as to their meaning. *See* 29 C.F.R. § 1987.101; Procedures for Handling Retaliation Complaints under Section 402 of the FDA Food Safety Modernization Act, 79 Fed. Reg. 8619, 8621 (Feb. 13, 2014).

<sup>6</sup> Moreover, while in this Decision and Order I focus on “manufacture,” “processing,” and “importation,” I recognize that one could conceivably argue that “holding” is broad enough to include “testing.” The dictionary definition of this term includes “to have possession or ownership of or have at one’s disposal,” *see* [www.merriam-](http://www.merriam-)

Respondent is correct that “testing” is not found in the eight enumerated activities listed in section 399d(a). Applying the maxim *expressio unius est exclusio alterius* (mention of one is the exclusion of the other) results in a conclusion that section 399d(a) does not apply to entities engaged in testing. The Supreme Court has noted that “[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion and exclusion.” *Russello v. United States*, 464 U.S. 16, 23 (1983) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)).<sup>7</sup>

Congress expressly mentioned testing in other parts of the FSMA and excluded it in section 399d. For example, the FSMA directs the Food and Drug Administration (“FDA”) to establish a broad food testing program through accreditation of laboratories. *See* 21 U.S.C. § 350k. The words “test” or “testing” are found eighteen times in this section. Obviously, Congress was aware of testing when it passed the FSMA and knew how to include testing in that legislation. This raises the question of why Congress did not specifically include testing in the list of covered activities in section 399d(a). In its requirements for the model laboratory standards it directed the FDA to create, Congress included “methods that ensure that ... procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited.” 21 U.S.C. § 350k(a)(6)(A)(iii). As section 350k provides for a mechanism outside the whistleblower process to address complaints about testing, the FSMA’s scheme as a whole is consistent with an interpretation of section 399d that does not cover entities engaged in testing.<sup>8</sup>

I thus find that section 399d’s meaning is unambiguous – it does not include “testing” among the eight activities covered. “In interpreting a statute, our inquiry must cease if the statutory language is unambiguous.” *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 131 S. Ct. 1885, 1893 (2011) (citation and internal quotation marks omitted). In reaching this conclusion, however, I recognize that the Supreme Court has also said that the relevant section must be read within the context of the entire statute:

---

webster.com/dictionary/hold (last visited July 29, 2014) and the regulatory definition is: “Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.” 21 C.F.R. § 1.227(b)(5). I conclude that the definitions of “holding” do not indicate the term includes “testing.”

<sup>7</sup> *See also Hamdan v. Rumsfeld*, 548 U.S. 557, 578 (2006) (“A familiar principle of statutory construction ... is that a negative inference may be drawn from the exclusion of language from one statutory provision that is included in other provisions of the same statute.”).

<sup>8</sup> To the extent Complainant believes the statute’s use of “engaged in” is broad enough to cover an entity such as Respondent that “performs laboratory testing services ... under contracts with ... food manufacturers, processors, and importers,” Declaration of Complainant James Byron, Exhibit A to Opposition, at ¶1, Complainant places too much weight on those two words. The relevant definitions of “engage” are “to begin and carry on an enterprise or activity – used with *in* <engaged in trade for many years>” and “to do or take part in something – used with *in* <engage in healthy activities> <engage in bad conduct>.” *See* www.merriam-webster.com/dictionary/engage (last visited July 29, 2014). Section 399d’s use of “engaged in” merely means that the statute applies to entities that “do or take part in” the enumerated activities. These two words, “engaged in,” do not expand the list of enumerated activities, nor do they expand the definitions of the terms used in that list.

In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context. It is a “fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” A court must therefore interpret the statute “as a symmetrical and coherent regulatory scheme,” and “fit, if possible, all parts into a harmonious whole.”

*Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000) (internal citations omitted). As outlined above, Congress has in section 350k provided a means outside the whistleblower process to address complaints concerning testing. A reading of section 399d that is limited to the statutory text is thus consistent with the FSMA as a whole. Simply put, even though Congress did not include “testing” in the activities covered under section 399d, Congress established another process to address complaints regarding testing. *See* 21 U.S.C. § 350k(a)(6)(A)(iii). Considering both sections 350k and 399d together, I find that Congress enacted a coherent statutory scheme that provides whistleblower protections to employees of entities engaged in the activities listed in section 399d and that separately requires procedures to be established to address complaints concerning testing in section 350k. Accordingly, I find that section 399d unambiguously excludes entities engaged in testing from its coverage.<sup>9</sup>

Even if Section 399d Were Ambiguous,  
I Would Conclude That It Does Not Cover Respondent

Even though I have found that section 399d unambiguously excludes “testing” as one of the covered activities, I recognize that one could argue that the statute is ambiguous. I thus continue the statutory interpretation analysis to address the meaning of section 399d even if one were to conclude that it is ambiguous.

One could argue that section 399d is ambiguous because under the FSMA, “testing” is included within “manufacture” or “processing” despite the dictionary definitions of those terms. For example, section 350g, which covers hazard analysis and risk based preventative controls and was added to the FDCA along with section 399d as part of the FSMA, arguably indicates that under the FSMA, manufacture and processing necessarily includes testing. This section states, in relevant part, that:

---

<sup>9</sup> *Cobb* does not compel a different conclusion because it is distinguishable. In *Cobb*, the statutory text was far broader than the text at issue here – in that case, the statute covered “an entity ‘undertaking by any means, directly or indirectly, to provide air transportation.’” *Cobb*, slip op. at 8. In finding that the statute applied to the respondent in that case, the Administrative Review Board particularly focused on the statute’s expansive language: “the key words are ‘undertaking by any means’ to ‘indirectly’ provide air transportation. The repeated use of broad language in the AIR 21 statute indicates Congress’s intent that the definition of ‘air carrier’ be broadly construed.” *Id.*, slip op. at 10 (emphasis in original). Moreover, the ARB cited the statute’s coverage of “contractors and subcontractors” as indicating Congressional intent that the AIR 21 whistleblower statute be applied broadly, as well as citing precedent that whistleblower statutes are meant to be broadly construed. Unlike in *Cobb*, here the relevant statute does not include extremely broad language such as “by any means, directly or indirectly,” nor does it explicitly cover contractors or subcontractors. *Cf.* H.R. 2749, 111th Cong., § 212, discussed in n. 10, *infra*. Most importantly, unlike in *Cobb*, as discussed above Congress here provided an alternate means, outside the whistleblower provision, to address complaints concerning the activity at issue.

The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, *identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards* . . . monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

21 U.S.C. § 350g(a) (emphasis added). In addition to enacting preventive controls to keep food from becoming adulterated, the statute specifically uses the word “testing” in requiring that entities verify that the preventive controls they implement are “effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other means.” 21 U.S.C. § 350g(f)(4). The FDA is required to promulgate regulations that “establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventative controls, and documenting the implementation of the preventive controls under this section.” 21 U.S.C. § 350g(n)(1).

“Preventive controls” are “reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ” that are “consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.” 21 U.S.C. § 350g(o)(3). The argument that testing is included within section 399d’s coverage of “manufacture [or] processing” essentially is that as entities engaging in manufacturing or processing must have preventive controls, and preventive controls include testing, then testing is part of manufacturing or processing.

Examples of procedures and practices constituting preventive controls include, among others, “Current Good Manufacturing Practices (cGMPs) under part 110 of title 21, Code of Federal Regulations” issued by the FDA and “[s]upplier verification activities that relate to the safety of food.” 21 U.S.C. §§ 350g(o)(3)(F) and (G). An argument can certainly be made that testing of the type done by Respondent is a part of supplier food safety verification, making testing a part of manufacturing and processing. Similarly, the FDA’s regulations at 21 C.F.R. Part 110, entitled Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, suggest that testing is part of manufacturing and processing, as well as holding:

All operations in the . . . *preparing, manufacturing, packaging, and storing* of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. . . . All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. *Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination.*

21 C.F.R. § 110.80 (emphasis added).

These portions of the FSMA, along with section 350g's reference to FDA regulations that include testing as a part of Current Good Manufacturing Practices, could be read to suggest that testing is included in section 399d's coverage of manufacturing, processing, and holding, despite the statutory text omitting the word, "testing." Accordingly, although I have found section 399d unambiguously excludes testing from its coverage, I nevertheless consider the legislative history, Congressional purpose, and broader context surrounding the FSMA to determine whether section 399d would cover entities engaged in testing, assuming *arguendo* the statute were ambiguous.

### Legislative History and Congressional Purpose

As outlined above, I am considering section 399d to be ambiguous for the limited purpose of considering whether the statute would cover entities engaged in testing if the statute were ambiguous. If a statute's meaning cannot be discerned from its text, courts look to the legislative history and Congressional purpose in enacting the statute. *See, e.g., Lawson*, 134 S. Ct. at 1169-70. Legislative reports are evidence of Congressional intent. Floor statements of individual legislators "should not be given controlling effect, but when they are consistent with the statutory language and other legislative history, they provide evidence of Congress' intent." *Brock v. Pierce Cnty.*, 476 U.S. 253, 263-65 (1986) (discussing House and Senate reports as evidence of legislative intent and qualifying, as quoted above, statements of individual legislators as evidence of such intent).

In this case, there are no reports on the bill that became law,<sup>10</sup> but the Congressional Record contains floor statements showing individual members' intent concerning the FSMA. Many members shared stories of constituents who were sickened or killed by unsafe food, and outbreaks of foodborne illnesses from contaminated peanut butter and spinach appear to have provided the impetus for the bill's introduction.<sup>11</sup>

The floor statements, in particular those by Sen. Dick Durbin, focus on the importance of preventive controls. When introducing the bill in the Senate, Sen. Durbin explained that the bill "requires the food industry to have in place plans that address identified hazards with the right preventative measures." 155 Cong. Rec. S2692-3 (March 3, 2009). In later debate, he noted that,

---

<sup>10</sup> The bill that became law was S. 510/H.R. 2751, 111th Cong. There is a committee report on H.R. 2749, the Food Safety Enhancement Act of 2009, which was passed by the House on July 30, 2009, but was not passed by the Senate. H. Rep. No. 111-234 (2009). H.R. 2749's provision covering testing by accredited laboratories would not have specifically required that a procedure be established to address concerns with testing. H.R. 2749, 111th Cong., § 110 (*see* H. Rep. No. 111-234 at 19, 51). Moreover, H.R. 2749's whistleblower provision would not have been limited to entities engaged in specific enumerated activities, but rather would have applied to any "person who submits or is required under this Act to submit any information related to a food, or any officer, employee, contractor, subcontractor, or agent of such person...." *Id.* at § 212 (emphasis added; *see* H. Rep. No. 111-234 at 33, 57). The scheme H.R. 2749 would have established – extending whistleblower protections to employees of contractors, subcontractors, and agents of entities required to submit information under the FDCA, but not specifically providing a separate means outside the whistleblower provision to address complaints concerning testing – would have been consistent with a Congressional intent that entities engaged in testing such as independent third party laboratories should be covered by the whistleblower provision. As H.R. 2749's scheme was not enacted into law, however, I need not discuss it further.

<sup>11</sup> *See* Proceedings and Debates of the 111th Congress, 156 Cong. Rec. H8861-91 (Dec. 21, 2010).

“[e]xperts agree that individual businesses are in the best position to identify and prevent food safety hazards... That is why the bill asks each business to identify the food safety hazards at each of its locations and then implement a plan that addresses these hazards.” 155 Cong. Rec. S11396 (Nov. 17, 2009). These statements single out mandating preventive controls as a key purpose of the FSMA.

Other legislators also focused on the preventive measures in the bill. “Companies that process or package foods will be required to implement preventative systems to stop outbreaks before they occur ... it will fundamentally shift our food safety oversight system to one that is preventative in nature as opposed to reactive,” said Rep. Henry Waxman. 156 Cong. Rec. H8885 (Dec. 21, 2010). Rep. Danny Davis highlighted that the bill specifically “requires 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).

While an argument can be made that the legislative history tends to support Complainant’s contention that Congress intended entities engaged in testing to be covered by section 399d, the floor statements of individual legislators do not necessarily resolve the issue. This is because, regardless what may have been the intent of individual members, the statute as enacted does not include “testing” as one of the listed activities covered by the statute, even though other parts of the FSMA include that word and thus indicate that Congress specifically included testing under FSMA provisions when it intended to do so. Moreover, as outlined above, in section 350k Congress provided a means outside of section 399d to address complaints concerning testing, so FSMA accounts for the intent of these individual legislators concerning the importance of testing even though section 399d does not cover testing. Accordingly, I do not believe the legislative history compels a conclusion that section 399d should be read to include the word, “testing.”

#### Broader Context

Looking at the broader statutory context for the act from which a specific section of text is derived can also inform a court’s analysis. “[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.” *Brown & Williamson Tobacco Corp.*, 529 U.S. at 133. The Supreme Court provided some guidance regarding elements of that broader context to consider in *Lawson*. In that case, the Court interpreted Sarbanes-Oxley’s whistleblower protections so as to avoid isolating an entire industry, in that case the mutual fund industry, from a statute meant to address a broad swath of the financial services sector. 134 S. Ct. at 1171-72. The present case arguably provides an analogous situation, with Respondent essentially arguing that the testing industry should be exempted from the scope of the whistleblower protections. Given the FSMA’s goal of protecting American consumers from adulterated food and the emphasis Congress placed on preventive controls, as well as the FSMA provisions discussed above that suggest testing is considered part of manufacturing, processing, or holding, it would arguably be incongruous to read the statute to exclude entities engaged in testing from the coverage of section 399d.

As outlined above, however, Congress provided a means outside the whistleblower process to address complaints concerning testing, by requiring that FDA develop model

standards for accredited testing laboratories that “shall include ... methods to ensure that ... procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited.” 21 U.S.C. § 350k(a)(6)(A)(iii). Because Congress provided a separate means in section 350k to address complaints concerning testing, the broader context of the FSMA does not compel a conclusion that section 399d should be read to cover entities engaged in testing.

## **CONCLUSION**

Complainant and Respondent each have raised persuasive arguments for their interpretations of FSMA to either include or exclude entities engaged in testing from the scope of section 399d. Recognizing that Congress knew how to, and did, enact statutory language explicitly covering testing elsewhere in the FSMA, and recognizing that Congress provided a separate means to address complaints concerning testing in section 350k, I conclude that the eight listed activities in section 399d(a) – “manufacture, processing, packing, transporting, distribution, reception, holding, or importation” – do not include “testing.” Accordingly, I find that Respondent is not a covered entity under 21 U.S.C. § 399d and GRANT Respondent’s Motion to Dismiss.

Respondent has also moved for attorney’s fees on the grounds that Complainant’s claim was frivolous, in part because “it is clear that ... [Respondent] is not a covered employer under the plain language of the FSMA.” Motion, at 8. As should be apparent from the discussion above, while I have ruled against Complainant on Respondent’s Motion to Dismiss, Complainant’s argument that Respondent is a covered entity under section 399d was well-supported and well-argued. His claim was thus far from frivolous. Accordingly, Respondent’s Motion for Attorney’s Fees is DENIED.

**SO ORDERED.**

**PAUL R. ALMANZA**  
Administrative Law Judge

Washington, D.C.