In the Matter of:

JAMES BYRON, **ARB CASE NO. 14-087**

COMPLAINANT, **ALJ CASE NO. 2014-FDA-001**

v. **DATE: September 28, 2016**

I.E.H. LABORATORIES,

RESPONDENT.

BEFORE: THE ADMINISTRATIVE REVIEW BOARD

Appearances:

For the Complainant:

Jeffery S. Gulley, Esq.; *Government Accountability Project,* Washington, District of Columbia; and **Thad M. Guyer, Esq. and Stephani L. Ayers, Esq.; *T.M. Guyer and Ayers & Friends, PC*; Medford, Oregon**

For the Respondent:

Sarah E. Bouchard, Esq. and Lauren E. Marzullo, Esq.; *Morgan, Lewis & Bockius, LLP*; Philadelphia, Pennsylvania

For the Assistant Secretary of Labor for Occupational Safety and Health as Amicus Curiae:

M. Patricia Smith, Esq.; Jennifer S. Brand, Esq.; William C. Lesser, Esq.; Megan E. Guenther, Esq.; and Erin M. Mohan, Esq.; *U.S. Department of Labor,* Washington, District of Columbia

Before: Paul M. Igasaki, *Chief Administrative Appeals Judge*; E. Cooper Brown, *Administrative Appeals Judge*; and Luis A. Corchado, *Administrative Appeals Judge.* Judge Brown, concurring.

DECISION AND ORDER OF REMAND

This case arises under the employee protection provisions of the Food, Drug, and Cosmetic Act (FDCA), added by Section 402 of the Food Safety and Modernization Act of 2011

(FSMA),[1] and the implementing regulations at 29 C.F.R. § 1987 (2015). James Byron filed a complaint with the Department of Labor's Occupational Safety and Health Administration (OSHA) alleging that I.E.H. Laboratories (I.E.H.) retaliated against him for engaging in FSMA-protected activities. On February 24, 2014, I.E.H. filed a Motion to Dismiss that the Administrative Law Judge (ALJ) treated as a motion for summary decision. After going through a commendable analysis, the ALJ granted the motion and dismissed the complaint by Decision and Order Granting Motion to Dismiss and Denying Motion for Attorney's Fees dated July 30, 2014 (D. & O.). The ALJ based his dismissal solely on the grounds that the FSMA whistleblower provision does not cover companies engaged in testing samples of food and, therefore, does not cover I.E.H. Byron appealed the ALJ's decision to the Administrative Review Board.

We are required to apply a murky statute to resolve the sole issue on appeal: whether the FSMA whistleblower provision protects I.E.H. whistleblowers who raise concerns about its testing of food samples to check for threats to public health. The ALJ found that Congress intentionally excluded all testing activities from whistleblower protection, even where a food manufacturer performed in-house food testing. We disagree and conclude that Congress intended whistleblower protection to apply to I.E.H. because it performed the testing, in question, on samples of food to detect threats to public safety arising during the manufacturing, processing, or importation process. In addition, Section 402 covers I.E.H.'s testing in this case because it performed these tests as an accredited and regulated entity. Accordingly, as explained below, we reverse the ALJ's ruling and remand the case for further proceedings consistent with our decision.

BACKGROUND[2]

Respondent operates a food testing laboratory accredited by the FDCA. It performs laboratory testing of foods nationally and internationally under contracts with food manufacturers, processors, and importers. Respondent performs microbial testing, testing for certain allergens, and import detention testing of detained shipments. To perform the tests, I.E.H. uses representative food samples from food lots and from detained food shipments. While the food samples may not be intended for consumption, the food lots and shipments from which they come are intended for consumption. I.E.H.'s clients determine whether the food lot or shipment will enter into commerce and may also use the results of the tests to demonstrate to the FDA that detained food shipments are safe for release.

In 2010, I.E.H. hired Byron as its Vice President of International Business Development and Technology Transfer. On several dates in August and September 2011, Byron raised concerns directly to the CEO about I.E.H.'s salmonella testing method. Following a phone call

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[1] 21 U.S.C. §§ 301 *et seq*. (1938). Section 402 is codified at 21 U.S.C. § 399d (2011).

[2] The facts for the Background section are taken from the undisputed facts and, for the purposes of determining whether summary decision is proper, they are viewed in the light most favorable to the party opposing summary decision, i.e., Byron.

to the CEO on October 4, 2011, during which Byron asked for an update on the work to validate the testing method, the CEO terminated Byron's employment. Byron filed a complaint with the Department of Labor on October 21, 2011. OSHA denied the complaint, and Byron requested a hearing before an ALJ.

On February 23, 2014, prior to any hearing, Respondent filed a Motion to Dismiss requesting dismissal of Byron's complaint. Byron filed his "Opposition to Respondent's Motion to Dismiss" supported by a sworn declaration. After permitting oral argument, the ALJ issued a Decision and Order Granting Motion to Dismiss and Denying Motion for Attorney's Fees (D. & O.) dated July 30, 2014. The ALJ concluded that I.E.H. is not a covered entity under the Act and thus dismissed the claim. Byron appealed the ALJ's ruling to the Board.

JURISDICTION AND STANDARD OF REVIEW

The Secretary of Labor has delegated authority to the ARB to issue final agency decisions for the Department in cases brought under the FSMA.[3] The ARB reviews ALJ summary decisions de novo, using the same standard that ALJs must apply.[4] Summary decisions are permitted where "there is no genuine issue as to any material fact and [the] party is entitled to summary decision."[5] The ARB views the record on the whole in the light most favorable to Byron, the non-moving party.[6] "[A] 'genuine issue' exists if a fair-minded fact-finder (the ALJ in whistleblower cases) could rule for the nonmoving party after hearing all the evidence, recognizing that in hearings, testimony is tested by cross-examination and amplified by exhibits and presumably more context."[7] In ruling on a motion for summary decision, neither the ALJ nor the Board weighs the evidence or determines the truth of the matters asserted.[8] Denying summary decision because there is a genuine issue of material fact simply means that an

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[3] Secretary's Order No. 2-2012 (Delegation of Authority and Assignment of Responsibility to the Administrative Review Board), 77 Fed. Reg. 69,378 (Nov. 16, 2012); 29 C.F.R. § 1987.110(a).

[4] *Franchini v. Argonne Nat'l Lab.*, ARB No. 11-006, ALJ No. 2009-ERA-014, slip op. at 5 (ARB Sept. 26, 2012).

[5] 29 C.F.R. § 18.40(d) (2012). After the ALJ's decision, this regulation was amended, effective June 18, 2015, and similarly provides, "The judge shall grant summary decision if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to decision as a matter of law. The judge should state on the record the reasons for granting or denying the motion." 29 C.F.R. § 18.72(a) (2015). The amendment makes clear that the movant has a heavy burden to establish that there is no genuine issue of material fact. Upon remand, failure to meet that burden under the new regulations should result in a denial of the motion for summary judgment.

[6] *Franchini*, ARB No. 11-006, slip op. at 5.

[7] *Id.* at 6 (citations omitted).

[8] *Id.*

evidentiary hearing is required to resolve some factual questions; it is not an assessment on the merits of any particular claim or defense.[9]

DISCUSSION

This matter arises under statutes and regulations pertaining to food safety. The Federal FDCA authorizes the Food and Drug Administration (FDA) to regulate the safety of food in interstate commerce.[10] Chapter 9 of the FDA regulates food safety from the time it is imported, manufactured, or processed until it is packaged and distributed for public consumption. On January 4, 2011, Congress enacted the FDA Food Safety Modernization Act to substantially amend the FDCA and add "employee protections" (Section 402) as part of the final subchapter (Miscellany) in Chapter 9.[11] Congress delegated to the Secretary, who in turn delegated to the OSHA, the responsibility for enforcing the FSMA's whistleblower protection provision.[12] Section 402 of the FSMA provides that:

> [n]o entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food may discharge an employee or otherwise discriminate against an employee" 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 [FDCA]."

Section 402(a)(codified at 21 U.S.C. § 399d(a)(1))(the "FSMA whistleblower statute"). Byron alleges that I.E.H. violated the FSMA whistleblower statute when it terminated his employment.

I.E.H. moved to dismiss Byron's claim on two grounds. First, I.E.H. argues that the service it provides, testing samples of food, is not listed as one of the covered activities in the FSMA whistleblower statute. Second, I.E.H. argues that it discards the samples of food that it tests and, therefore, it does not test food intended for public consumption, a requirement of the whistleblower statute. Byron countered by arguing that I.E.H.'s testing was a necessary part of some of the covered categories in FSMA (food manufacturing, processing, and importing food) and making food safe for public consumption. In his sworn statement, Byron described how I.E.H.'s testing played an integral part in the regulated business processes identified in the FDCA and FSMA.

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9 *Id.*

10 21 U.S.C. §§ 301 *et seq.*

11 Pub. L. 111-353, 124 Stat. 3885 (Jan. 4, 2011).

12 *See* Secretary's Order No. 1-2012 (To Delegate Authority and Assign Responsibility to the Assistant Secretary for Occupational Safety and Health), 77 Fed. Reg. 3,912 (Jan. 25, 2012).

The ALJ considered Section 402's language and concluded that Respondent is not a covered entity under this whistleblower provision. The ALJ reasoned that Congress deliberately chose not to include "testing" within the FSMA coverage by providing that the FSMA applied to entities "engaged in manufacture, processing, packing, transporting, distribution, reception, holding, or importation." He reached this conclusion by concluding first that Congress used "unambiguous" terms (e.g., "processing") to describe eight "categories" and these categories did not expressly include "testing." In addition, the ALJ found that Congress provided a means to address complaints concerning testing under Section 202 of the FSMA (codified at 21 U.S.C. § 350k), and thus he did not need to construe Section 402 as covering "testing" of food.[13] Yet, the ALJ acknowledged that: (1) "portions of the FSMA . . . could be read to suggest that testing is included in section 399d's [section 402 of FSMA] coverage of manufacturing, processing and holding" food and (2) "legislative history tends to support the Complainant's contention that Congress intended entities engaged in testing to be covered by section 399d . . . ." D. & O. at 8-9. We disagree with the ALJ's final conclusion as to the coverage of section 402 in this case where I.E.H. tested food samples to detect the presence of contaminants that could injure the health of consumers.[14] Because statutory interpretation is a question of law, we engage in our own analysis of Section 402.

Statutory principles of interpretation

In applying any statute, like the courts, "our task is to give effect to the will of Congress."[15] Understanding Congressional intent begins with the statute, and we attempt to apply the plain meaning of the words used.[16] Some rules of statutory interpretation serve as aids to finding Congressional intent.[17] Importantly, the whistleblower provision must be applied in context and in light of the whole statute.[18] Often courts assume that, when Congress includes

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[13] However, the ALJ acknowledged that the floor statements before Congress discussing implementation of the Act focus on the importance of preventive controls and tend to support the contention that Congress intended entities engaged in testing to be covered by Section 399d.

[14] We restrict our discussion as to whether Respondent was an entity engaged in manufacturing, processing, and importation of food, as these were the categories of employers Complainant identified before the ALJ. *See* Complainant's Opposition to Respondent's Motion to Dismiss. But our limited focus should not be understood to limit the discretion the ALJ may have in this case to consider any of the other activities the FSMA protects.

[15] *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 567, 570 (1982).

[16] *See Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999).

[17] I 2A SUTHERLAND STATUTORY CONSTRUCTION § 47:23 (7th ed.).

[18] *See King v. Burwell*, __ U.S. __, 135 S. Ct. 2480, 2489 (2015)(Court "must the read words 'in their context and with a view to their place in the overall statutory scheme'" and "construe statutes, not isolated provisions.")(citations omitted); *Owass. Indep. Sch. Dist*., 534 U.S. 426, 434 (2002)(consider "entire legislative scheme"). *See also Smith v. U.S.*, 508 U.S. 223, 233 (1993)("Just as a single word cannot be read in isolation, nor can a single provision of a statute.").

some classifications in a series, it does so to the exclusion of others.[19] In a similar vein, courts also often follow the maxim that words are known by their associates or accompanying words.[20] We keep these principles in mind, but cautiously,[21] as we attempt to decipher what Congress intended in making the whistleblower statute applicable to entities "engaged in manufacturing, processing, importing" or any other of the eight stages of moving food in the commerce chain.

FSMA's Focus

Looking at FSMA as a whole statute makes clear that (1) protecting the consumer from food contamination was the overarching Congressional focus and purpose for enacting FSMA and (2) shoring up food testing efforts was critical to achieving that purpose. The catalyst that sparked Congress to pass FSMA was a series of incidents in which tainted food sickened and killed thousands of Americans.[22] Congress sought to immediately stop risks of serious injury or death. As indicated by the title and section headings, Titles I and II focus on "improving capacity to prevent" and "*detect* and respond" to food safety problems, respectively. (Emphasis added.) Title II specifically focuses on "Laboratory accreditation for *analyses* of foods,"[23] "tracking, "tracing," "surveillance," and "detention" of food and "enhancing food safety."[24] Title III focuses on "improving the safety of imported food" by specifically creating a "verification program,"[25] requiring "certifications for food," and establishing "independent third-

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[19] *Ron Peterson Firearms LLC*, 760 F.3d 1147, 1158 (10th Cir. 2014)(The strength of this maxim varies by context).

[20] *See Babbitt v. Sweet Home, Chapter*, 515 U.S. 687, 694 (1995).

[21] *See Helvering v. Stockholms Enskilda Bank*, 293 U.S. 84, 88-89 (1934), which cautions as follows:

> To ascertain the meaning of the words of a statute, they may be submitted to the test of all appropriate canons of statutory construction, of which the rule of *ejusdem generis* is only one. If, upon a consideration of the context and the objects sought to be attained and of the act as a whole, it adequately appears that the general words were not used in the restricted sense suggested by the rule, we must give effect to the conclusion afforded by the wider view in order that the will of the Legislature shall not fail.

[22] 155 Cong. Rec. S2692-01, (Mar. 3, 2009)(statement of Senator Durbin)("Every year, more than 76 million Americans become sick because of a food-borne illness, 325,000 are hospitalized, and 5,000 die").

[23] *See* Section 202 (emphasis added).

[24] *See* Sections 204, 205, 207, 210.

[25] *See* Section 301.

party auditors,"[26] among other things. Title IV, FSMA's last part, added a few "miscellaneous provisions" that included the whistleblower provision.

Consistent with the title and section headings, FSMA's substantive provisions flesh out Congress's goal of strengthening the ability to thoroughly detect public health threats. In strengthening detection methods, FSMA expressly focuses on a total of eight major stages of the moving food from raw materials through processing and ultimately into the consumers' hands: manufacture, processing, packaging, transporting, distribution, reception, holding, or importation.[27] Testing was addressed in each of the Titles and with respect to each of the eight stages of the food commerce chain as reflected in the following examples: [28]

Title I

Section 103—requires "preventive controls" that included "testing" at "critical points" and keeping records of such controls.

Title II

Section 201—requires "testing" seafood imports.

Section 202—extensively discusses "testing procedures" and requires the Secretary of Health and Human Services (Secretary of HHS) to create a "program for the testing of food by accredited laboratories" and model standards for "analytical testing methodology."

Section 205—requires the Secretary of HHS to establish a working group of experts that included "food testing industries."

Sections 206 and 209—contains additional provisions about testing and training on "testing" procedures (among other processes).

Title III

Section 301—requires "testing" and "sampling" of imported shipments.

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[26] *See* Section 307.

[27] Some FSMA provisions expressly mentioned 4 of these stages, while other provisions mentioned 5, 6, 7, or all 8 stages in the commerce chain of moving food to the consumer. *See, e.g.,* Sections 101(a)(lists 7 of the 8); 102(b)(1)(lists 5); 103(a)(lists 4); 210(a)(lists 6); 303(b)(lists 4).

[28] There are many more examples we could list and, if this matter returns to us again, we may take the opportunity to add to this list.

Section 302—lists "testing" as a relevant eligibility factor in the "voluntary qualified importer program," (VQIP) that offers expedited review and entry of food.[29]

This consistent and repetitive reference to testing throughout FSMA and with respect to all the stages of food movement convinces us that Congress viewed "testing" as a part of the eight stages of movement and not as a separate category. As referenced above, Congress expressly wanted "critical points" in manufacturing and processing to include "preventive controls," specifically "preventive controls" that a person would employ who is knowledgeable about safe manufacturing, processing, packing, and holding food.[30] We are also convinced that Congress intended to create and monitor third party testing laboratories when it passed FSMA. Having looked at the overall structure and themes of FSMA Titles I through III, we turn to Title IV, where the whistleblower provision is found, comprising the bulk of Title IV.

In turning to the text in Section 402, we note first that Congress placed the whistleblower protection in the last Title as a miscellaneous provision, more like a catch-all provision in the FSMA. Second, and most telling, Congress repeatedly used broad terms throughout the whistleblower provision that demonstrate a Congressional intent to create broad coverage as opposed to limited coverage. For example, in the whistleblower provision, Congress used the general term "entity" (rather than "facility" or "food facility") to focus on participants in the food chain commerce and not simply factories or warehouses.[31] Additionally, Section 402 expressly includes all eight stages in the food commerce chain that FSMA addresses in various combinations throughout FSMA.[32] Unfortunately, the words manufacturing and processing are inexact words and not defined in FSMA. But contrary to the ALJ's and I.E.H.'s views, we see this series of words as a list of general and broad terms attempting to focus on the continuum of movement of food throughout commerce, not as a list excluding critical discrete aspects of these stages.[33] As discussed earlier in looking at FSMA as a whole, Congress addressed the discreet

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[29] The FDA can also require in specific circumstances that food offered for import be accompanied by a certification from an accredited third-party certification body. 21 U.S.C. § 384a(a), (c)(4); *see also* 21 C.F.R. § 1.600 *et seq*. (2016) I.E.H. contends that it is "one of very few food testing companies that has received accreditation" by the FDA in advance of the statutory requirements. See Affidavit of Dr. Mansour Samadpour.

[30] *See* Section 103(o)(1), (3).

[31] For example, consider Sections 103 (preventive controls and testing at "facilities"); 210 (Secretary to make grants to eligible "entities" to enhance food safety); and 303 (Secretary could require an "entity" to provide a certification before permitting the importation of food).

[32] In fact, in only one other instance does FSMA lists all eight stages together as it does in the whistleblower provision. *See* Section 206.

[33] The ALJ noted the common definitions of "manufacture" and "processing" broadly include a series of actions or operations. D. & O. at 4, n.5. Our task in this case is to determine whether Congress viewed "testing" as an action or aspect of one or more of the eight stages, not to determine every action or aspect included or not included in these stages.

act of "testing" as part of manufacturing and processing, not as a major movement stage.[34] We also see the undefined phrase "engaged in" as another general and broad phrase that can be understood to mean "being involved in or part of."[35] In passing FSMA, Congress viewed "testing" food as it moved through the food commerce chain as "engaging in" or participating in manufacturing, processing, and/or importation of food.[36] Our conclusion comports with the principle that whistleblower provisions "should be liberally interpreted to protect victims of discrimination and to further [their] underlying purpose of encouraging employees to report perceived . . . violations without fear of retaliation."[37]

We succinctly dispense with two additional arguments the Respondent raises. First, Respondent argues that "in-house" testing would be protected under Section 402, Conference Call Transcript at 9, but not third-party testing. It seems illogical that, as food moved from raw materials to the consumers' hands, the extent of whistleblower protection for disclosing the same exact health threat arising from testing would depend on who tested the food. Second, Respondent argues that Congress excluded "testing" from the whistleblower provision because such protection allegedly exists in Section 202 (21 U.S.C. § 350k). But, contrary to the ALJ's finding, FSMA Section 202 does not provide a separate means to address retaliation against whistleblowers in testing laboratories. This provision merely requires testing laboratories to "ensure that . . . procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited"[38] and does not prevent retaliation against an employee for making such a complaint.

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[34] See supra 7-8.

[35] ROGET'S II, THE NEW THESAURUS (Expanded Edition)(1988), p. 344. Thought not relevant here, other general phrases or terms used in the whistleblower provision include "related to" and "unfavorable" employment actions.

[36] We find unpersuasive I.E.H.'s additional argument that it is not covered under FSMA because it discarded the samples of food it tested and, therefore, the samples were not "food intended for public consumption," a required element in the whistleblower provision. To begin with, one would expect tested food samples to be destroyed. In addition, we find that the plain and straightforward meaning of food includes test samples of the food. In our view, saying that food samples are not food because they are destroyed is an unjustifiable, hyper-technical dissection of Congress's intent as to the meaning of "food."

[37] See *Fields v. Florida Power Corp.*, ARB No. 97-070, ALJ No. 1996-ERA-022, slip op. at 10 (ARB Mar. 13, 1998) (decision under the Energy Reorganization Act, 42 U.S.C.A. § 5851 (*citing English v. General Elec. Co*., 496 U.S. 72 (1990) and *Bechtel Constr. Co. v. Secretary of Labor*, 50 F.3d 926, 932 (11th Cir. 1995) ("it is appropriate to give a broad construction to remedial statutes such as nondiscrimination provisions in federal labor laws")). *See also Haley v. Retsinas*, 138 F.3d 1245, 1250 (8th Cir.1998)(courts tend to construe ambiguous whistleblower statutory language "in favor of protecting the whistleblower").

[38] Codified at 21 U.S.C. § 350(k)(6)(A)(iii).

Ultimately, given our review of the FSMA and the whistleblower provision, we reach three inescapable conclusions. Congress considered testing as a significant aspect in protecting our food and part of the manufacturing, processing and importation stages. Congress also intended to regulate accredited testers through FSMA. The whistleblower provision was written broadly with these goals in mind and with the intent of protecting employees engaged in activities that affected the safety of food as it moved from raw materials to the consumers' hands. If we found that "testing" was not covered by the whistleblower provision, including testing performed by I.E.H., we would substantially contravene Congress's fundamental purpose in passing FSMA.[39] Therefore, based on the undisputed facts, we conclude that Section 402 covers I.E.H. in this case because the testing in question was performed on samples of food to detect public health threats arising during the manufacturing, processing or importation process. In addition, Section 402 covers I.E.H.'s testing in this case because it performed these tests as an accredited and regulated entity. Therefore, we reverse the ALJ's rejection of whistleblower protection coverage in this case.

CONCLUSION

For the reasons discussed above, the ALJ's Decision and Order Granting Motion to Dismiss and Denying Motion for Attorney's Fees is **REVERSED**, and the case is **REMANDED** for further proceedings consistent with this opinion.

SO ORDERED.

LUIS A. CORCHADO
Administrative Appeals Judge

PAUL M. IGASAKI
Chief Administrative Appeals Judge

E. Cooper Brown, Administrative Appeals Judge, *concurring*:

I join with the majority in reversing and remanding the ALJ's Decision and Order herein appealed. Because this case affords the Administrative Review Board its first opportunity to

[39] One Representative stated that "[a]nother 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 (Dec. 21, 2010)(statement of Representative Lee).

address the scope of employer coverage under the whistleblower protection provisions of the Food Safety and Modernization Act of 2011, I write separately to specifically address the errors of statutory construction by which the ALJ concluded that 21 U.S.C.A. § 399d does not cover an independent third party laboratory that performs testing under contract for food manufacturers, processors or importers.

21 U.S.C.A. § 399d(a) prohibits any entity "engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food" from retaliating against an employee engaged in whistleblowing activity as defined therein. In support of his holding that Section 399d(a) unambiguously exempts food testing from coverage, the ALJ concluded that the definitions of the eight listed categories covered thereunder clearly did not include testing; that applying the statutory maxim *expressio unius est exclusio alterius* to the eight enumerated activities set forth in section 399d(a) results in the conclusion that Congress intended that the whistleblower protection provision exclude entities engaged in testing; and that because "test" or "testing" is mentioned elsewhere in the Food Safety and Modernization Act, but not in section 399d, Congress acted purposefully in excluding testing from coverage. However, as herein demonstrated, none of these canons of statutory construction inescapably leads to the ultimate conclusion reached by the ALJ upon which he dismissed Mr. Byron's complaint.

The ALJ appropriately followed the Supreme Court's directive that "[i]n determining the meaning of a statutory provision, 'we look first to its language, giving the words used their ordinary meaning.'"[40] Given that the terms manufacture," "processing" and "importation" are not defined by statute or implementing regulation, the ALJ resorted to their common, ordinary definitions as found in the dictionary.[41] Based on a narrow interpretation of those definitions, the ALJ concluded that they "do not indicate that they include 'testing.'" D. & O. at 4.

The common and ordinary definitions of the terms "manufacture," "processing" and "importation" do not, however, support the ALJ's narrow interpretation. The definitions set forth in the dictionary do not unambiguously exclude "testing" or, for that matter, any other particular act. "Manufacture" is defined, *inter alia*, as "something made from raw materials," "the process of making wares," "the act or process of producing something." See www.merriam-webster.com/dictionary/manufacture. The definition of "process" includes, "a series of actions or operations conducing to an end." See www.merriam-webster.com/dictionary/processing. "Importation" is defined as "the act or process of

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[40] *Lawson v. FMR LLC*, 134 S. Ct. 1158, 1165 (2014) (quoting *Moskal v. United States*, 498 U.S. 103, 108 (1990)). "[T]he meaning of the statute must, in the first instance, be sought in the language in which the act is framed, and if that is plain, . . . the sole function of the courts is to enforce it according to its terms." *Caminetti v. U.S.*, 242 U.S. 470, 485 (1917).

[41] In giving words in a statute their "common and ordinary" meaning, "absent an indication Congress intended them to bear some different import," it is a well-accepted practice to resort to the dictionary definition. *See, e.g., Williams v. Taylor*, 529 U.S. 420, 431-432 (2000); *Commodity Trend Serv., Inc. v. Commodity Futures Trading Com'n.*, 233 F.3d 981, 989 (7th Cir. 2000).

importing." See www.merriam-webster.com/dictionary/importation.[42] The definitions of the terms are highly abstract, generalized descriptions suggesting, with respect to each, multiple step processes carried out in furtherance of a particular end, which foreseeably could include testing.[43]

As additional support for a narrow interpretation of the terms "manufacturing" and "processing," the ALJ cited an FDA regulatory definition for "manufacturing/processing" found at 21 C.F.R. § 1.227(b)(6). See D. & O. at 4, n.5. Much ink is spilled by both parties in their respective briefs on appeal as to whether the cited regulatory definition is appropriate or whether, as Complainant argues, broader and more expansive regulatory definitions that expressly include the term "test" or "testing" are appropriate.[44] The more important point, that both sides miss, is the fact that these conflicting regulatory definitions underscore the ambiguity found in the common dictionary definitions of the terms "manufacture," "processing," and "importation."

Nor is the ambiguity resolved, as the ALJ and Respondent would have it, by invocation of the maxim *expressio unius est exclusio alterius* (the mention of some implies the exclusion of others not mentioned). The Supreme Court has repeatedly admonished that the canon "does not apply to every statutory listing or grouping; it has force only when the items expressed are members of an 'associated group or series,' justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence." *Barnhart v. Peabody Coal Co*., 537 U.S. 149, 168 (2003). Moreover, the canon is "only a guide, whose fallibility can be shown by contrary indications that adopting a particular rule or statute was probably not meant to signal any exclusion of its common relatives." *United States v. Vonn*, 535 U.S. 55, 65 (2002). "As with all aids for interpretation, *expressio unius* is a rule of statutory construction and not a rule of law, is subordinate to the primary rule that legislative intent governs the interpretation of a

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42 *Cf. Bilski v. Kappos*, 561 U.S. 593 (2010), a patent law case in which the Supreme Court, relying in part upon its earlier resort in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), resorting to the dictionary for their ordinary common meaning, viewed the terms "manufacture" and "process" as "expansive," thus indicating that "Congress plainly contemplated that the patent laws would be given wide scope." 561 U.S. at 601.

43 An expansive interpretation of the terms "manufacturing" and "processing" as those terms are found at 21 U.S.C.A. § 399d(a) to include "testing" is consistent with the FDA's broad definition of the terms in numerous contexts. *See, e.g.*, 21 C.F.R. § 207.3(a)(8) (defining "manufacturing" and "processing" of drugs to include "manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process"); 21 C.F.R. § 600.3(u) (defining the "manufacture" of biologics to include "filling, testing, labeling, packaging, and storage"); 21 C.F.R. § 607.3(d) (defining the "manufacture" of blood products to include "collection, preparation, processing or compatibility testing" including any "manipulation, sampling, testing, or control procedures applied to the final product"); and 21 C.F.R. §§ 1271.3(e) and 1271.3(f) (defining "manufacture" and "processing" of human cell and tissue products to respectively include "screening or testing of the cell or tissue donor" and the "testing for microorganisms, preparation, sterilization, steps to inactive or remove adventitious agents, preservation from storage, and removal from storage").

44 See footnote 4, *supra*.

statute, and is, consequently, overcome by a strong indication of contrary legislative intent." Singer & Singer, 2A SUTHERLAND STATUTORY CONSTRUCTION, § 47.23 (7th Ed.) (citations omitted).[45]

The *expressio unius* maxim "properly applies only when in the natural association of ideas in the mind of the reader that which is expressed is so set over by way of strong contrast to that which is omitted that the contrast enforces the affirmative inference that that which is omitted must be intended to have opposite and contrary treatment." *Ford v. United States*, 273 U.S. 593, 611 (1927). Under this canon of statutory construction the presumption is that "when a legislature has enumerated a list or series of related items, the legislature intended to exclude *similar items* not specifically included in the list." *Christian Coalition of Florida, Inc. v. United States*, 662 F.3d 1182, 1193 (11th Cir. 2011). As the Third Circuit has explained:

> The canon applies only when the expressed and unmentioned items are part of a "commonly associated group or series," [citing *Vonn*, 535 U.S. at 65], "justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence." [citing *Barnhart*, 537 U.S. at 168]. In other words, the expressed item and the unmentioned item should be understood to go "hand in hand," thus supporting a sensible inference that Congress must have meant to exclude the unmentioned item. [citing *Barnhart, supra*].

Perlin v. Hitachi Capital America Corp., 497 F.3d 364, 370 (3d Cir. 2007). "The canon depends on identifying a series of two or more terms or things that should be understood to go hand in hand, which [is] abridged in circumstances supporting a sensible inference that the term left out must have been meant to be excluded." *Chevron U.S.A. Inc. v. Echazabal*, 536 U.S. 73, 81 (2002).

In the instant case, Congress has under section 399d identified a series of eight integrally related activities undertaken by the food industry involving the production and movement through commerce of food destined for public consumption. Respondent argues that the testing conducted by independent laboratories such as Respondent is an activity distinguishable from these activities; that "testing is not a necessary, integral or essential part of food manufacturing and processing" or its importation. Respondent's Response to Amicus, at pp. 6-7. Respondent's argument that the excluded activity (i.e. testing) is *dissimilar* from the series of *related* activities set forth at section 399d in and of itself defeats the *expressio unius* maxim's utility in the present case, for it disallows any possibility of a contrary indication from the omission that would, in turn, justify the inference that food testing was excluded by deliberate choice. The obvious and necessary association of the eight identified categories of food production and movement through commerce to the consumer, on the one hand, and testing, on the other, are not, in the

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[45] Moreover where, as here, a statute implemented by an administrative agency employs broad terms, the *expressio unius* maxim is generally considered "an especially feeble helper in an administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved." *Cheney R.R. Co. v. I.C.C.*, 902 F.2d 66, 68-69 (D.C. Cir.1990). *Accord Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014).

natural association of the words, so set over against each other by way of strong contrast that a negative inference can be drawn from the omission of the word "testing" in section 399d. For this reason alone, the *expressio unius* canon of statutory construction is of little, if any, guidance in interpreting section 399d's coverage.

The foregoing is not the only reason for rejecting the maxim's applicability. As the Assistant Secretary for OSHA points out in his amicus brief, the ALJ's analysis mistakes generality for negative implication. Where Congress has chosen broad activities (e.g., manufacturing and processing), rather than more specific ones, to formulate the statutory provision governing whistleblower protection, Congress's "failure to mention" a specific activity —in this case "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). The ALJ's ruling depends critically on whether section 399d's failure to identify "testing" together with the other eight activities creates a negative implication that testing is never a part of the manufacturing, processing, or importation of food under any circumstances. "The force of any negative implication, however, depends on context. [The Supreme Court has] long held that the *expressio unius* canon does not apply 'unless it is fair to suppose that Congress considered the unnamed possibility and meant to say no to it,' . . . and that the canon can be overcome by 'contrary indications that adopting a particular rule or statute was probably not meant to signal any exclusion.'" *Marx v. General Revenue Corp*., 133 S. Ct. 1166, 1175 (2013). In the present case, as hereinafter demonstrated, context persuasively supports the conclusion that Congress did not intend to deny whistleblower protection under section 399d to employees of independent testing laboratories such as Respondent notwithstanding omission of the term "testing" from the listing of covered employer activities.[46]

Another form of *expressio unius* relied upon to no avail by the ALJ is "where 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 purposely in the disparate inclusion or exclusion." *Russello v. United States,* 464 U.S. 16, 23 (1983); *United States v. Wong Kim Bo,* 472 F.2d 720, 722 (CA5 1972). Under this variation of the *expressio unius* maxim, "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." *Hamdan v. Rumsfeld*, 548 U.S. 557, 578 (2006).

Citing this familiar principle of statutory construction, the ALJ concluded that the omission of "testing" from amongst the eight enumerated activities listed in section 399d(a), but its express mention elsewhere in the statute (*i.e*. 21 U.S.C.A. § 305k), was further evidence that Congress purposefully excluded testing from coverage under the FMSA's whistleblower protection provision. The Assistant Secretary argues (Amicus Brief, pp 10-11) that Congress's use of the term "testing" elsewhere in the statute while choosing broader coverage terms in section 399d does not tell us anything about whether or not Congress intended to exclude those

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[46] "An inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent. *Burns v. United States*, 501 U.S. 129, 136 (1991).

engaged in independent food testing under contract from liability for retaliation against whistleblowers. I agree.

One need look no further than 21 U.S.C.A. § 350g to see that Congress, in enacting the FMSA, considered "testing" to be a necessary facet of the safe manufacture, processing, and distribution of food for public consumption. As the ALJ noted (D. & O. at 6-7), section 350g includes "testing" within the "manufacture" and "processing" of food in requiring the establishment of "preventative controls" for assuring food safety. Section 350g requires owners and operators of food manufacturing and processing facilities, and their agents, to identify and evaluate a broad range of food safety hazards, including "biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives," and to implement "preventative controls" regarding such hazards. 21 U.S.C.A. § 350g(a)-(c). To verify the absence of these food safety hazards and the effectiveness of established preventative controls, the use of "environmental and product testing programs" are prescribed. *Id*. § 350g(f)(4). "Preventative controls" are defined at section 350g(o)(3) to include, among other procedures, practices, and processes, the FDA's current "Good Manufacturing Practices" (GMPs) found at 21 C.F.R. § 110.80, which includes, as part of food manufacturing and processing, "[c]hemical, microbial, or extraneous-material testing procedures . . . where necessary to identify . . . possible food contamination."

Similarly, under the FMSA testing of food samples from detained international food shipments is a facet of the importation of food for public consumption. As previously noted, "importation" is defined in the dictionary as "the act or process of importing." "Importing," in turn, is ordinarily defined as "to bring a product into the country to be sold." www.merrian-webster.com/dictionary/importing. Under 21 U.S.C.A. § 384a(a)(1), food importers are generally required to perform "risk-based foreign supplier verification activities" in order to assure that imported food is, among other things, "produced in compliance with the requirements of section 350g of this title."[47] The statutorily prescribed foreign supplier verification activities include "periodically . . . testing shipments." 21 U.S.C.A. § 384a(c)(4). As with food manufacturing and processing, the FMSA thus makes safety verification, including food testing, part and parcel of the importation of food into the United States.

In rebuttal to the foregoing statutory inclusion of testing within the meaning of food manufacturing and processing, and in further support of his conclusion that 21 U.S.C.A. § 399d(a) does not cover testing laboratories, the ALJ focuses upon 21 U.S.C.A. § 350k, asserting that this section provides "a means outside the whistleblower process [of section 399d] to address complaints concerning testing." D. & O. at 9-10. What the ALJ fails to appreciate is that section 350k is not an employee protection provision, and thus that his comparison is misplaced. As the Assistant Secretary points out (Amicus Brief at 11-12), the section mandates the development of accreditation standards for food testing laboratories that ensure, among other things, that laboratories have procedures in place to address complaints about an accredited laboratory's testing practices. Section 350k says nothing about what happens when an employee who raises such a complaint is retaliated against. Simply put, section 350k does not displace the

[47] The "importation or offering for importation of a food" is prohibited if the importer "does not have in place a foreign supplier verification program." 21 U.S.C.A. § 331(zz).

whistleblower protection that is afforded under section 399d, and thus provides no credible basis for rejecting the coverage of food testing under the whistleblower protection provision.

In fact, and again as the Assistant Secretary notes (Amicus Brief at 12-13), in *Lawson v. FMR LLC*, 134 S. Ct. 1158 (2014), a case arising under the whistleblower protection provisions of the Sarbanes-Oxley Act (SOX), 18 U.S.C.A. § 1514A, the Supreme Court rejected similar reasoning to that expressed by the ALJ in his focus upon section 350k. In *Lawson* the employer argued that SOX's whistleblower coverage did not extend to mutual fund investment advisors and accountants and lawyers employed by contractors for publicly-traded companies who reported fraudulent activities because separate provisions of SOX imposed targeted reporting and specified fiduciary obligations on these professionals intended to address fraudulent stock market activities. The Supreme Court concluded to the contrary, explaining that the separate requirements actually "indicate why Congress would have wanted to extend [whistleblower] coverage" beyond publicly-traded companies in order to protect these professionals. *Id.* at 1171-72. Because no other provision of SOX protected these professionals from retaliation by their immediate employers for engaging in statutorily-obligated activities, refusing to afford them whistleblower protection under 18 U.S.C.A. § 1514A would leave them "vulnerable to discharge or other retaliatory action" for taking action contemplated by law. *Id.* This the Supreme Court in *Lawson* refused to do, and held that SOX's whistleblower protection provision applied. The situation confronting employees of accredited testing laboratories under contract with any of the entities listed under section 399d is no different. The existence of procedures for evaluating and responding to complaints regarding activities for which a laboratory is responsible, required under section 350k, does not afford a laboratory employee protection against retaliation should he or she make such a complaint. Only section 399d affords such protection.

FMSA's legislative history lends support for the conclusion that Congress intended to cover independent laboratories engaged in food testing under section 399d. After conceding as much,[48] the ALJ nevertheless rejected the proposition that the legislative history "compels a conclusion that section 399d should be read to include the word 'testing'" based on the circuitous logic that section 399d(a) "does not expressly include 'testing' as one of the listed activities covered by the statute and the fallacious reasoning that "Congress provided a means outside of section 399d to address complaints concerning testing." D. & O. at 9.

Multiple floor statements by members of the House and Senate at the time of its passage indicate that Congress passed the FMSA in response to several high profile food safety incidents that had, in turn, resulted in foodborne illness outbreaks. *See* 156 Cong. Rec. H8861-01 (Dec. 21, 2010); 156 Cong. Rec. S8259-02 (Nov. 30, 2010). While there are no congressional committee reports accompanying passage of the FMSA, the congressional record nevertheless contains floor statements showing the concerns and intent of individual members in supporting passage of the legislation. These statements, including in particular explanatory statements of

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[48] The ALJ acknowledged that "an argument can be made that the legislative history [of the FMSA] tends to support Complainant's contention that Congress intended entities engaged in testing to be covered by section 399d." D. & O. at 9.

Senator Dick Durbin, the legislation's sponsor in the Senate, are indicative of Congress's intent in passing the FMSA.[49]

Senator Durbin emphasized the importance of the FMSA in requiring the food industry to identify food safety hazards and establish preventative measure addressing such hazards. 155 Cong. Rec. S2692-3 (Mar. 3, 2009); 155 Cong. Rec. S11396 (Nov. 17, 2009). The importance of the preventative measures contained in the legislation, including the importance of testing, was repeated by numerous members of the House and Senate during floor debate. For example, Representative Henry Waxman (Senator Durbin's counterpart in the House) noted that the FMSA "will fundamentally shift our food safety oversight system to one that is preventative in nature as opposed to reactive"). 156 Cong. Rec. H8861, H8885 (Dec. 21, 2010). Representative Danny Davis, another key supporter, highlighted the legislation's requirement that food producers "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) (emphasis added).

Moreover, like similar whistleblower statutes, the whistleblower protections established by section 399d were designed to protect employees in furtherance of the FMSA's food safety goals. Whistleblower protection was clearly regarded as a key element for ensuring the safety of food intended for public consumption. As Repredentative Jackson Lee noted on the House floor: "ensur[ing] the protection of whistleblowers that bring attention to important safety information pertaining to food regulation and food safety" was an "important component" of the FMSA. 156 Cong. Rec. H8861-01, at H8889 (Dec. 21, 2010). "It is most vital," stated the Congressman, "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." *Id.*

Having concluded that "manufacturing," "processing" and "importing," as those terms appear in section 399d(a), encompass the testing of food, the question ultimately remains as to whether Respondent is engaged in any or all of these activities and thus subject to section 399d's prohibitions.

Citing the common dictionary definition of "engage," the ALJ rejected the argument that the prohibitions of section 399d extend to Respondent because the statutory requirement that an entity be "engaged in" one of section 399d(a)'s listed activities neither expanded that list nor expanded the definitions of the section's enumerated activities. D. & O. at 5, n.8. Reaching this

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[49] "[C]ourts today do find that certain kinds of statements made during legislative debates are compelling evidence of legislative intent. So, for example, courts look to explanatory statements by a bill's sponsor, see *National Woodwork Mfrs. Ass'n v. N.L.R.B.*, 386 U.S. 612 (1967); *N. L. R. B. v. Fruit and Vegetable Packers and Warehousemen, Local 760*, 377 U.S. 58 (1964), or by the standing committee member charged to present the bill and lead debate. See *Johansen v. U.S.*, 343 U.S. 427 (1952); *Singer v. U.S.*, 323 U.S. 338 (1945). . . . Courts admit a legislator's statements from floor debates when they provide information about contemporary conditions and events, *see U.S. v. Henning*, 344 U.S. 66 (1952), and help establish what problems or evils the legislature was trying to remedy. *See National Woodwork Mfrs. Ass'n v. N. L. R. B*, 386 U.S. 612 (1967); *Galvan v. Press*, 347 U.S. 522 (1954)." 2A SUTHERLAND STATUTORY CONSTRUCTION § 48:30. *See also*, *id.* at §§ 48:14, 48:15.

conclusion not only ignores the expansive definition of the terms listed in section 399d(a),[50] it ignores the fact that the definition of "engage" encompasses not only the concept of "to do" but also the concept of "taking part in." *See* www.merriam-webster.com/dictionary/engage, "to do or take part in something," and WEBSTER'S NEW INT'L DICTIONARY, p. 751 (3d Ed. 1993), defining "engage" to include "take part; participate." *See also*, BLACK'S LAW DICTIONARY 528 (6th Ed.1990) ("To employ or involve one's self; to take part in; to embark on.").

The parties embrace case law interpreting "engage" to require that one's involvement be "integral" or "essential" to the activity in question, and then argue over whether or not Respondent's food testing program meets that definitional standard. Both parties read more into the definition of "engage" than is appropriate, creating a heightened standard that does not exist. As courts that have been called upon in various contexts to interpret the common ordinary meaning of "to engage in" have recognized, it is the concept of "to take part in" or "to be involved in" that is the primary focus. *See, e.g., Serrato-Navarrete v. Holder*, 601 Fed Appx. 734, 2015 WL 1037309 (10th Cir. 2015); *Toler v. State Farm Mut. Auto. Ins. Co.*, 64 Fed. Appx. 388, 2003 WL 21235465 (4th Cir. 2003); *B. & H. Passmore Metal & Roofing Co. v. New Amsterdam Cas. Co*., 147 F.2d 536, 539 (10th Cir. 1945); *Goldsmith v. New York Life Ins. Co*., 69 F.2d 273, 275 (8th Cir. 1934); *Louis-Charles v. Sun-Sentinel Co*., 595 F. Supp. 2d 1304, 1307 (S.D. Fla. 2008).

Based on the common ordinary definition of the term "engage," the protection afforded by section 399d applies if an entity charged with whistleblower retaliation either *takes part in* or *is involved in* any of the eight listed categories of activity. Whether Respondent takes part in, or is involved in the activities of manufacturing, processing, or importation of food, and thus covered under section 399d(a), is ultimately a question of fact. Before turning to that question, however, there is one remaining legal issue that Respondent raises that must be addressed—*i.e.* whether the testing that Respondent conducts involves the testing of "food" within the meaning of FMSA's whistleblower protection provision.

The ALJ did not reach the issue of whether or not the items Respondent tests constitute "food" within the meaning of section 399d(a). *See* D. & O. at 4, n.4. Nevertheless, on appeal Respondent argues that as a matter of law the food samples it tests are not "food" within the meaning of section 399d(a) because the samples are destroyed after testing and not distributed for public consumption. In support of its argument, Respondent cites the statutory definition of "food" found at 21 U.S.C.A. § 321(f) ("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.").[51] Because the food samples that are tested are not distributed to the public for consumption but destroyed upon completion of the testing, Respondent asserts, the samples are not "food" within the meaning of section 321(f) and thus Respondent's activities as an independent testing laboratory are not covered by section 399d.

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50 *See* discussion, *infra*.

51 The regulatory definition of "food" found at 29 C.F.R. § 1987.101(h) merely repeats the statutory definition: "Food means articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article."

Section 321(f)'s rather circuitous definition is, as the Seventh Circuit has noted, "not too helpful." *Nutrilab v. Schweiker*, 713 F.2d 335, 337 (7th Cir. 1983). Nevertheless, in striving to ascertain what constitutes "food" within the meaning of this statutory definition, courts have uniformly rejected the essence of Respondent's argument, i.e., that the definition of "food" hinges upon its intended use. In *Nutrilab*, the court noted that "defining food as articles intended by the manufacturer to be used as food is problematic," pointing out that where Congress meant to define a substance under the Federal Food and Drug Act in terms of its intended use, "it explicitly incorporated that element into its statutory definition" (citing 21 U.S.C.A. §§ 321(g)(1)(B) and (g)(1)(C)), whereas section 321(f) omits any reference to intent. 713 F.2d at 337. Thus, the court opined, "a manufacturer 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." *Id*. "The test for determining whether an item is a food under the Act cannot be one of intended use. . . . It must of necessity be one which regards items as food which are generally so regarded when sold in a food form. . . . So long as the product retains a semblance of the identity it possessed as a food, the product must be considered as a food." *U.S. v. Tech. Egg Prods.*, 171 F. Supp. 326, 328 (D. Ga. 1959) (citations omitted). *Accord United States v. Thirteen Crates of Frozen Eggs*, 208 F. 950, 952 (S.D.N.Y. 1913), *aff'd*, 215 F. 584 (2d Cir. 1914) ("The character of the thing does not depend on the intent or purpose of the owner."). *See also, U.S. v. 52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940).

Ultimately, as the Seventh Circuit advised in *Nutrilab***,** "[i]n the absence of clear cut Congressional guidance, it is best to rely on statutory language and common sense." 713 F.2d at 337. Here, the statutory language and common sense lead to the inescapable conclusion that the samples that Respondent tests are "food" within the meaning of the FMSA. One need look no further than 21 U.S.C.A. § 350k to recognize the illogic of Respondent's argument. The laboratory accreditation provision repeatedly refers to "food sampling," "food testing," and the "testing of food." It is a fundamental of statutory construction that "[a] term appearing in several places in a statutory text is generally read the same way each time it appears." *Ratzlaf v. United States*, 510 U.S. 135, 143 (1994). Consistent with this maxim, "food" as that term is found in section 350k is to be read the same as it is found in section 399d. Surely there can be no argument but that section 350k's references are to food that is intended for public consumption. Otherwise, why the need for testing? Indeed, Respondent does not dispute that the lots from which samples are taken for purposes of testing are food for public consumption. Yet, Respondent would have this Board ignore the definition of "food" as that term is understood under section 350k when interpreting the same term as it is found in FMSA's whistleblower protection provision. Logic and *Ratzlaf* dictate a more consistent approach. Thus, regardless of Respondent's destruction of food samples upon completion of testing, the fact that the samples are from food lots intended for public consumption but not as yet distributed dictates but one conclusion: that the food samples that Respondent tests are "food" within the statutory meaning of that term.

Having concluded that section 399d applies to an entity that either takes part in or is involved in any of the eight categories of activity listed therein, and that food samples such as those tested by Respondent are "food" within the meaning of FMSA's definition of that term notwithstanding that the samples themselves are destroyed and not distributed to the public for

consumption, the question ultimately remains as to whether Respondent is, by its actions, a covered entity subject to section 399d's prohibitions against whistleblower retaliation.

The uncontroverted evidence of record that is before the Board pertaining to the testing that is conducted by Respondent demonstrates that the testing performed by Respondent is performed as part of and in furtherance of its clients' manufacturing, processing, or importation of food. In summation, that evidence establishes that the testing Respondent performs is performed on a relatively routine basis in furtherance of its clients' manufacturing, processing, and importation of food. The testing conducted by Respondent is of samples taken from food lots intended for public consumption. The tests Respondent performs include testing to detect harmful microbes such E.coli, Listeria, or Salmonella, as well as testing for common allergens in food. Respondent's clients rely on the results of Respondent's testing to determine whether or not food lots intended for distribution to the public are safe and unadulterated and thus can be released into commerce, or whether additional processing or labeling is required.[52]

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[52] Because this case comes before the Board on appeal from the summary decision of the ALJ, the uncontroverted evidence of record is viewed in the light most favorable to Complainant Byron, the party opposing summary judgment. That evidence was presented by the parties through their respective affidavits. The uncontroverted evidence set forth in the affidavits of Dr. Mansour Samadpour (Feb. 13, 2014, and Mar. 21, 2014), submitted on behalf of Respondent, establish that Respondent is an independent, third party laboratory that performs sample testing and consulting for clients in the food industry; that the testing that Respondent conducts on food samples is at the request of its clients; that upon receipt of food samples from a client, Respondent performs the tests, which the client specifies and subsequently reports the results of the testing directly to the client; and that food samples tested by Respondent are destroyed after testing.

Similarly, from the uncontested declaration under oath of Complainant Byron (Mar. 4, 2014), it is further established that Respondent performs laboratory testing services domestically and internationally under contracts with numerous food manufacturers, processors, and importers; that Respondent's testing services include routine laboratory testing of food lots to detect harmful microbes such as E.coli, Listeria, and Salmonella, as well as common allergens in foods; that many food manufacturing and processing companies perform this sort of routine testing using their own personnel and facilities, while other companies outsource the testing to third party laboratories such as Respondent; that most food manufacturing and processing companies, and especially those dealing with high risk foods, view the testing as an absolute necessity to prevent shipping unsafe food to their customers; that in some cases Respondent performs its food testing from laboratories within the manufacturing or processing client's facilities; that Respondent also has freestanding laboratories that receive and test samples sent by, or collected from, its clients; that representative samples of food lots are taken and analyzed in the laboratory as the lots are produced; that until the testing is completed and the results known, the food lots are held by the company and not distributed; that Respondent's clients rely on the test results to determine whether lots of food are safe and ready for delivery, or adulterated, in which case the food may either be destroyed or reprocessed/reconditioned to render it safe; that manufacturers rely upon the results of allergy testing to determine whether information about potential allergens needs to be included on the food's labeling; that Respondent also performs testing of food shipments suspected of being contaminated and thus detained by FDA and denied release to the importer; and that the importer uses the results of Respondent's tests of detained shipments to demonstrate to the FDA that the detained lots are safe and suitable for release.

Respondent argues that interpreting whistleblower protection under the FMSA to include independent food testing laboratories "would lead to the absurd result of covering virtually every employer in any industry allied with food," citing as example everything from architectural and construction firms that design or construct food manufacturing facilities to sanitation service providers to companies that provide products that are used by any of the eight listed food industry categories under section 399d(a). Respondent's assertion ignores the central and critical role food testing plays in the overall scheme under the FMSA of detecting and preventing food safety hazards before food reaches the public, *see* 155 Cong. Rec. S6255 (Mar. 3, 2009) (Statement of Senator Durbin), as opposed to activities that are incidental to the food industry activities listed under section 399d.[53]

The actual absurdity would result from affirming the ALJ's ruling. The critical role that food testing is intended under the FMSA to play in protecting the public's food supply would readily, and quite easily, be defeated by the ALJ's narrow reading of the FMSA whistleblower protection provision. Respondent readily concedes the anomalous result: that testing conducted "in-house" by food manufacturers, processors, and importers would be covered, whereas food testing contractually out-sourced to independent laboratories would not. See Respondent's Response Brief at 16-17. Sanctioning such a dichotomy would assuredly undermine if not totally frustrate the role Congress intended food testing to play under the FMSA. It would provide a valuable incentive for out-sourcing all testing in order to escape the prohibitions of section 399d, leaving those best-situated to "blow the whistle" on contaminated and unsafe foods without legal protection from retaliation.

By protecting employees who typically stand in the best position to witness violations of the Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 301 *et seq*., from threats and reprisals for reporting violations of the Act, section 399d implicitly serves the FMSA's purposes of improving food safety. Given Congress's recognition of the critical role that testing such as that undertaken by Respondent plays in achieving this purpose, it is reasonable to conclude that Congress intended for the protections afforded by FMSA's whistleblower protection provisions to apply to employees such as Complainant.

E. COOPER BROWN
Administrative Appeals Judge

53 *Cf. Lawson v. FMR LLC*, 134 S. Ct. at 1173 (addressing a similar argument raised in defense against extending SOX whistleblower protection to independent contractors, the Supreme Court stated: "if contractors were taken off the hook for retaliating against their whistleblowing employees, just to avoid the unlikely prospect that babysitters, nannies, gardeners, and the like will flood OSHA with 1514A complaints, Congressional purpose under SOX would be defeated.").