IN RE MICROBAN PRODUCTS COMPANY

FIFRA Appeal No. 02-07

FINAL DECISION

Decided May 12, 2004

Syllabus

The United States Environmental Protection Agency, Office of Enforcement and Compliance Assurance, Toxics and Pesticides Enforcement Division ("Pesticide Enforcement") appeals Administrative Law Judge ("ALJ") William B. Moran's September 13, 2002 Decision Upon Remand. The ALJ found Microban Products Company ("Microban") not liable for any of the alleged violations of section 12(a)(1)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136j(a)(1)(B). Section 12(a)(1)(B) makes it unlawful to distribute or sell a pesticide if any claims made as a part of its distribution or sale substantially differ from claims made for it as part of its registration statement. Pesticide Enforcement has alleged thirty-two violations of section 12(a)(1)(B) based upon thirty-two shipments of Microban Plastic Additive "B" ("Additive 'B'") to Hasbro, Inc. ("Hasbro") and its contractors and has proposed a total civil penalty of $160,500.

This case was previously before the Environmental Appeals Board ("Board") following Pesticide Enforcement's appeal of the ALJ's November 5, 1999 Initial Decision Regarding Penalty and associated February 18, 1999 Order Determining Number of Violations and Ruling on Respondent's Motion for Accelerated Decision as to Penalty. The ALJ, in those orders, had concluded that Microban committed five violations of FIFRA section 12(a)(1)(B) based upon five documents in which he had found Microban to have made unapproved claims and assessed a $25,000 civil penalty. On appeal, the Board held that the ALJ had erred in his interpretation of section 12(a)(1)(B) of FIFRA because a "unit of violation" must be based, not upon the number of documents containing unapproved pesticidal claims, but rather upon the number of proven distributions or sales of the pesticide, which in turn must be shown to be "linked" to one or more of the unapproved claims. The Board therefore reversed the ALJ's decision and remanded the matter back to the ALJ for further proceedings. *In re Microban Prods. Co.*, 9 E.A.D. 674 (EAB 2001). On remand, the ALJ, after holding a supplemental hearing, found that none of the unapproved claims were linked with the pesticide's distribution or sale in a manner that would give rise to a violation of FIFRA section 12(a)(1)(B).

The issue currently presented for resolution by the Board is whether the ALJ committed error on remand in concluding that Microban did not violate section 12(a)(1)(B) of FIFRA. Pesticide Enforcement argues that the ALJ erred in finding that claims that substantially differ from the registration of Additive "B" were not a part of the sale or distribution of that pesticide product. Pesticide Enforcement argues that these claims should be considered as a part of the distribution or sale because those claims were made in the following three ways: in a presentation to Hasbro that was found to have been intended to induce Hasbro's purchase of that pesticide, in suggestions to Hasbro for a Draft Label

when a purpose of the document was to induce Hasbro's purchase of the product, and in a Questionnaire ("Q & A document") for training of Hasbro's employees when a purpose of the document was to induce sale of the product. Pesticide Enforcement also contends that the ALJ erred in failing to find that the License and Supply Agreement between Microban and Hasbro and, in particular, Exhibit E, contained unapproved claims made as part of the distribution or sale of Additive "B."

Held: The Board reverses the ALJ's liability determination, finding Microban liable for thirty-two violations of FIFRA, and assesses a civil penalty of $160,500 for these violations. In particular, the Board concludes that:

(1) Pesticide Enforcement proved by a preponderance of the evidence that there was a sufficiently close link between the unapproved claims made by Microban in the presentation it made to Hasbro and the thirty-two distributions or sales (in the form of shipments) of Additive "B" subsequently made to Hasbro and/or its contractors. The claims were therefore made as part of the distribution or sale of the pesticide. Consequently, Microban is liable for thirty-two violations of FIFRA section 12(a)(1)(B).

(2) Although the evidence surrounding the presentation to Hasbro and the resulting distribution or sale of Microban's Additive "B" is, in and of itself, sufficient to support a finding of all thirty-two of the alleged violations of FIFRA, the Board also considers whether there was a sufficiently close link between the distribution or sale of Additive "B" and the unapproved claims in the Draft Label suggestions and the Q & A document. The Board finds that Pesticide Enforcement proved by a preponderance of the evidence that the unapproved claims made by Microban in its suggestions for a Draft Label and in its Q & A document were sufficiently linked to the later distribution or sale of Additive "B" to Hasbro. The claims were therefore made as part of the distribution or sale of the pesticide. Accordingly, based on the timing of these two documents and the subsequent distribution or sale (in the form of shipments) of Additive "B" to Hasbro and/or its contractors, this would independently support a finding that Microban is liable for twenty-nine of the thirty-two violations of FIFRA section 12(a)(1)(B).

(3) The ALJ did not err in concluding that any unapproved claims which may have been made in the License and Supply Agreement, including Appendix E, should not be considered as "unapproved claims" in determining violations in the case.

(4) Because the ALJ's liability decision is reversed and Microban is held liable for thirty-two violations of FIFRA, a penalty assessment is needed. Although the Board often remands the case back to the ALJ to determine an appropriate penalty, the Board may assess a penalty directly. Based upon information already in the record, in particular the transcript of the 1999 penalty hearing and the ALJ's findings following that hearing, the Board assesses the statutory maximum penalty per violation, which results in a total civil penalty of $160,500.

Before Environmental Appeals Judges Ronald L. McCallum, Edward E. Reich, and Kathie A. Stein.

Opinion of the Board by Judge McCallum:

On November 12, 2002, the United States Environmental Protection Agency ("U.S. EPA"), Office of Enforcement and Compliance Assurance, Toxics and Pesticides Enforcement Division ("Pesticide Enforcement") filed an appeal in

the above-referenced matter with the Environmental Appeals Board ("Board"). *See* Brief in Support of Appellant's Notice of Appeal of the Decision Upon Remand ("Second Appeal"). Pesticide Enforcement seeks review of Administrative Law Judge ("ALJ") William B. Moran's September 13, 2002 Decision Upon Remand, which found Microban Products Company ("Microban" or "Respondent") not liable for any violations of section 12(a)(1)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136j(a)(1)(B). That section makes it unlawful to distribute or sell a pesticide if any claims made as part of its distribution or sale differ from claims made for it as part of its registration statement. *Id*.

This case was most recently before the ALJ following this Board's review and remand of his 1999 decision in which he had concluded that Microban had committed five violations of FIFRA section 12(a)(1)(B) based upon five documents in which he found Respondent to have made unapproved claims. *See In re Microban Prods. Co.*, 9 E.A.D. 674 (EAB 2001) ("*Microban I*"); *see also* Order Determining Number of Violations and Ruling on Respondent's Motion for Accelerated Decision as to Penalty (ALJ Feb. 18, 1999) ("1999 Liab. Dec.") (decision finding five violations). In our decision remanding this matter, we held that the "unit of violation" under section 12(a)(1)(B) of FIFRA must be based, not upon the number of documents containing unapproved pesticidal claims, but rather upon the number of proven distributions or sales of the pesticide, which in turn must be shown to be "linked" to one or more of the unapproved claims. *Microban I*, 9 E.A.D. at 686. On remand, the ALJ, after holding a supplemental hearing, found that none of the unapproved claims were proven to be linked with the pesticide in a manner that would give rise to a violation of FIFRA section 12(a)(1)(B). Decision Upon Remand ("Remand Dec.") at 13.

The issue currently presented for resolution by the Board is whether the ALJ committed error in concluding that Microban did not violate section 12(a)(1)(B) of FIFRA. For the reasons outlined below, we find that the ALJ committed error and reverse his Decision Upon Remand. After reviewing the record, we find Microban liable for thirty-two violations of FIFRA section 12(a)(1)(B) and assess a penalty of $160,500.

I. *BACKGROUND*

A. *Statutory Background*

FIFRA is a federal statute regulating the manufacture, sale, distribution, and use of pesticides by means of a national registration system. 7 U.S.C. §§ 136-136y. Section 12(a)(1)(B) makes it unlawful for any person to distribute or sell any registered pesticide if any claims made as a part of the pesticide's distribution or sale are different from the approved claims under the product's

registration. *Id*. § 136j(a)(1)(B). FIFRA defines "distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver." *Id*. § 136(gg). In addition, EPA's regulatory definition of "distribute or sell and other grammatical variants of the term * * * such as 'distribution or sale'" includes "the acts of distributing, selling, offering for sale, holding for sale, [and] shipping * * * to any person in any State." 40 C.F.R. § 152.3.

B. *Factual Background*[1]

1. *Registration of Additive "B" and Communications with EPA*

Microban is a corporation with its principal place of business in North Carolina.[2] Answer to Second Amended Complaint ("Answer") ¶ B.1. As a corporation, Microban is a "person" as that term is defined by FIFRA section 2(s), 7 U.S.C. § 136(s). *See id.*; *see also* Order on Motions for Discovery, Filing of Sur-Reply and Partial Accelerated Decision ("Partial Accel. Dec.") at 14 n.9 (ALJ Sept. 18, 1998).

Microban produces a product called Microban Plastic Additive "B" ("Additive 'B'") which was registered by the EPA under section 3 of FIFRA, 7 U.S.C. § 136a, on August 15, 1983.[3] Complainant's Motion for Accelerated Decision as to Liability ("Mot. for Accel. Dec."), Ex. 2 (Notice of Pesticide Registration for Microban (Aug. 15, 1983)); Answer ¶ B.1. The claims made by Microban for Additive "B" as part of the statement required in connection with its registration application include the following: "A preservative, bacteriostatic[4] agent for use in the manufacture of polymer plastic and latex." Mot. for Accel. Dec., Ex. 1 (EPA-Approved Microban Label (Aug. 15, 1983)); *see also* Answer ¶ B.6. In ap-

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[1] The factual background associated with this case was previously described in our decision remanding this matter. *See Microban I*, 9 E.A.D. at 676-78. Nevertheless, because we review the ALJ's decision *de novo*, we are again providing the relevant factual background of the case. This section has been updated, however, to include certain facts that might not have been included in our first decision, as well as information that might have been developed in the record subsequent to our decision remanding the case. Because certain portions of the record have been claimed as Confidential Business Information ("CBI") by Microban, the only information in the record to which we cite in support of our factual findings is from non-CBI sources, such as the non-CBI version of the complaint, the answer, and party briefs.

[2] North Carolina is, of course, a "State" as that term is used in FIFRA. *See* 7 U.S.C. §§ 136(aa), 136j(a)(1).

[3] Microban Plastic Additive "B" is registered under the EPA registration number 42182-1. Mot. for Accel. Dec., Ex. 2.

[4] The term "bacteriostatic" refers to an agent that inhibits the growth or multiplication of bacteria. *See* Dorlands Illustrated Medical Dictionary 182 (27th ed. 1988).

proving the registration of Additive "B," EPA stated in the Notice of Pesticide Registration issued to Microban that:

> This product is being accepted as a preservative and bacteriostatic agent effective only against *non-health related* organisms which may contribute to deterioration of the treated articles or to control odors by such organisms.

Mot. for Accel. Dec., Ex. 2 (emphasis added).

In 1984, EPA sent Microban a letter reiterating that "bacteriostatic claims are not acceptable for the control of microorganisms infectious for man." Mot. for Accel. Dec., Ex. 3 (Letter from William E. Campbell, Jr., Microbiologist, Disinfectants Branch, EPA Registration Division, to William L. Morrison, Microban Products Co. (Dec. 20, 1984)). In the letter, EPA referred Microban to certain Agency guidance that distinguishes between microorganisms infectious to man and microorganisms of economic or aesthetic (i.e., bacteriostatic) significance. *Id.* (citing U.S. EPA, Requirements for Antimicrobial Pesticides: Determination of Health-Related and Non-Health-Related Uses, DIS/TSS-16 (June 26, 1979) ("DIS/TSS-16")). Such guidance indicates that:

> Since elimination or significant reduction in numbers of microorganisms * * * must be demonstrated before a product is considered acceptable for claims against microorganisms infectious for man[,] * * * products bearing claims for effectiveness at the bacteriostatic level (inhibition of growth) will not be accepted for such situations. Bacteriostatic claims will only be permitted for products expressly recommended for control of microorganisms of economic or aesthetic significance (e.g. slimeforming bacteria, odor-causing bacteria).

DIS/TSS-16, at 1.

In 1987, following submission of data by Microban, EPA informed Respondent that "the data which you have submitted do not support health-related efficacy claims. The *only claim* which may be made is that the product is bacteriostatic *with respect to bacteria not infectious to man*." Mot. for Accel. Dec., Ex. 4 (Letter from Jeff Kempter, Product Manager, EPA Office of Pesticide Programs Registration Division, to William L. Morrison, President, Microban Products Company (July 10, 1987)) (emphasis added). EPA also provided Microban with a list of non-health-related claims that were acceptable for use in conjunction with the sale and distribution of its Additive "B." The acceptable claims included: (1) provides a hygienic surface; (2) inhibits growth of bacteria; (3) resists bacterial growth; (4) inhibits/controls growth of odor-causing bacteria and mildew

(fungus); and (5) resists mildew and bacteria growth. *Id*.; *see also* Transcript of May 26, 1999 Hearing ("Tr.") at 46-47. The letter further indicated that "[i]n order to substantiate any claim for * * * activity against bacteria which are infectious to man, you must submit data conducted in accordance with the type of protocol we previously recommended to you." Mot. for Accel. Dec., Ex. 4. There is no evidence in the record that Microban submitted acceptable efficacy studies that were approved by EPA and/or that EPA ever approved language allowing Microban to make claims for bacteria that are infectious to man.

On August 2, 1996, EPA sent Microban a letter regarding its use of Additive "B" as a preservative in air filters. Mot. for Accel. Dec., Ex. 5 (Letter from Walter C. Francis, Acting Product Manager, EPA Office of Pesticide Programs Registration Division, to Barnwell S. Ramsey, Microban Products Co. (Aug. 2, 1996)). In that letter, the Agency noted that citation to *Staphylococcus aureus* "constitutes a health related use pattern." *Id*. at 2. The Agency further explained that "[c]urrently, only non-public health claims are accepted [by] the Agency for bacteriostatic preservatives. * * * Products bearing labeling claims to control specific microorganisms directly infectious for man, or indirectly infectious for man (i.e., by transmittal) such as *Staphylococcus aureus* * * * are considered to be directly related to human health." *Id*. at 2-3 (emphasis omitted).

2. *Relationship Between Microban and Hasbro*

In May 1995, Microban and Hasbro, Inc. ("Hasbro"),[5] a manufacturer of plastic toys, began discussing the incorporation of Additive "B" into Hasbro's plastic toy products. *See* Respondent's Reply to Complainant's Appeal as to the Number of Violations ("Resp't Reply to First Appeal") at 3; Tr. at 361-63. Microban made a presentation to Hasbro regarding Microban's corporate capabilities on May 31, 1995. Tr. at 364. This presentation, memorialized in a document entitled "Presentation to Hasbro, Inc.," included the statement that Additive "B" was "the ultimate in germ-fighting protection." Mot. for Accel. Dec., Ex. 14 (Presentation to Hasbro Inc. (May 31, 1995)) ("Hasbro Presentation"). The Hasbro Presentation also included a picture of toys labeled with the terms "*E. Coli*" and "*Staph.* [*Staphylococcus*] *Aureus*."[6] *Id*.; Tr. at 364.

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[5] Hasbro is a "person" as that term is defined by FIFRA section 2(s), 7 U.S.C. § 136(s). Answer ¶ B.1.

[6] The Hasbro Presentation also contained a reference to a Time Magazine story about "Killer Microbes," as well as charts that appear to show increasing public interest in "HIV/AIDS" and other "Germs." We note that, although there may be some microorganisms for which there is a question as to whether, in fact, they are infectious to man, in this case, the ALJ took official notice of the fact that "*E. Coli*" (*Escherichia coli*), "*Salmonella*," "Staph." (*Staphylococci*), and "Strep." (*Streptococci*) are widely recognized as microorganisms infectious to man. Order on Motion (ALJ Apr. 3, 1998); Order Reaffirming Taking of Judicial Notice (ALJ June 29, 1998).

Thereafter, on April 12, 1996, Microban and Hasbro entered into a multi-year License and Supply Agreement ("Agreement") whereby Hasbro would incorporate Microban's Additive "B" into certain Hasbro plastic toys, games, and juvenile products.[7] *See* Answer ¶ B.38.a; *see also* Transcript of April 26, 2001 Hearing ("Suppl. Tr.") at 55-56; Resp't Reply to First Appeal at 3. As part of this Agreement, Hasbro agreed to purchase a minimum quantity of Additive "B," pursuant to which a number of shipments, including the thirty-two that are the subject of this case, were made. Respondent's Reply to EPA's Appeal of the Decision on Remand ("Resp't Reply to Second Appeal") at 15 & n.11. The Agreement also contemplates that Microban would, for the term of the Agreement, provide marketing assistance to Hasbro, and that Hasbro would provide Microban with samples of products and marketing materials for approval by Microban prior to commercial sale of the products. *See* Tr. at 355-56, 368-71. Pursuant to the Agreement, Microban made more than thirty-two shipments of Microban Plastic Additive "B" to persons designated by Hasbro, predominantly to Hasbro contractors, for incorporation into Hasbro's plastic toys, games, and juvenile products.[8] Resp't Reply to First Appeal at 3; Suppl. Tr. at 10; *see also* Answer ¶ B.25 (admitting that Respondent sent thirty-two shipments to Hasbro or to Hasbro contractors pursuant to its contract).

On October 28, 1996, Microban commented on a draft label for Hasbro plastic toys containing Additive "B." Mot. for Accel. Dec., Ex. 16 (Facsimile from Stephen F. Smith, Microban Marketing Manager, to Carolyn Beeley, Hasbro Toy Group (Oct. 28, 1996)) (hereinafter "Draft Label"); Tr. at 368-71. Microban suggested that the Hasbro toy labels state, "Only Playskool has the exclusive Microban germ-fighting technology built right into the toy. This unique technology inhibits the growth of germs on toys to help provide a healthier (or better) environment for your child." Draft Label at 3.

Subsequently, in January 1997, Microban participated in a media training session for Hasbro employees. Answer ¶¶ B.16, B.38.b. Microban produced a question and answer document about Microban products for use at the training

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[7] Microban asserts that the entire License and Supply Agreement is CBI protected from disclosure. Respondent's Reply to EAB Order Regarding CBI Documents at 3 (Nov. 30, 2000); *see* 7 U.S.C. § 136h(b); 40 C.F.R. § 22.22(a)(2). While no determination has been made as to that claim, all information referenced in this decision regarding the License and Supply Agreement is drawn from non-CBI sources in the record. *See supra* note 1.

[8] Microban also asserts that the thirty-two invoices documenting such shipments are CBI protected from disclosure under FIFRA. This decision does not recite any of the specific information provided in these invoices, such as the date, destination, or price of the shipments. For purposes of this opinion, it is important to know generally that thirty-two shipments of Microban Plastic Additive "B" to Hasbro's contractors occurred beginning sometime in October of 1996 and extending through January of 1997, as alleged in the Second Amended Complaint. Second Am. Compl. ¶¶ 32-33; *accord* Resp't Reply to First Appeal at 3; Tr. at 8.

session.[9] *See id*. ¶ B.38; Mot. for Accel. Dec., Ex. 12 (Facsimile from Stephen F. Smith, Microban Marketing Manager, to Gary Serby, Hasbro (Jan. 13, 1997)) (hereinafter "Q & A Doc."); Tr. at 380-82. The Q & A document provides:

> Microban antimicrobial protection is being introduced into consumer products to address the growing public concern over the prevalence of germs and bacteria, such as E. coli, Salmonella, Staph and Strep.
>
> * * * *
>
> Microban protection has been shown to be effective in virtually eliminating the growth of most common household germs, including E. coli, Salmonella, Staph. and Strep. as well as mold and fungus.

Q & A Doc. at 1, 3.

3. *Enforcement Activities*

In April and May of 1997, Pesticide Enforcement's duly designated officers conducted two inspections of Microban. Answer ¶ B.23. Pesticide Enforcement requested information from Microban regarding the sale and distribution of Additive "B" to Hasbro. *See id*. ¶ B.24. Respondent provided Pesticide Enforcement with copies of invoices for more than thirty-two shipments of Additive "B" to Hasbro. *Id*. ¶ 32; Resp't Reply to First Appeal at 3; *see also* 1999 Liab. Dec, 1999 EPA ALJ LEXIS 4, at *13 (noting that EPA did not include twenty-two additional sales invoices in the complaint).

Included in the information provided to Pesticide Enforcement was an undated promotional brochure that states: "Microban has been proven to safely reduce the growth of many common harmful bacteria (including E. coli, Salmonella, Staph. and Strep.) by 99.9 percent." Mot. for Accel. Dec., Ex. 7, at 6 (Microban Products Company Brochure (undated)) ("Brochure"); *see also id.* at 3. The document also refers to "germ-related illnesses" and explains that "[e]very year in the U.S., there are approximately 80 million cases of food-borne illness

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[9] Microban argues that this document is "a training tool used in a media training exercise conducted by an independent media training expert." Answer ¶ B.16. No matter who conducted the training exercise, it is clear from the facsimile itself that an individual in *Microban's* marketing department sent the document via facsimile *to Hasbro*. Furthermore, Microban admits that the training session was "requested, arranged, and paid for by Hasbro" and was apparently for Hasbro employees. *Id*. ¶ B.38.d; *see also* Tr. at 381-82 (testimony of Glenn Cueman, president and CEO of Microban) (stating that there were many people from Hasbro in attendance at the training session, including Hasbro product managers and some senior executives).

(commonly referred to as food poisoning)." *Id.* at 5. According to evidence elicited at the second hearing, the Brochure had been printed in June of 1996. *See* Suppl. Tr. at 73 (testimony of Mr. Ramsey). However, although EPA learned that Hasbro was in possession of a copy of this document, no evidence was presented with respect to when or how Hasbro obtained the Brochure and, more specifically, whether Hasbro was in possession of the Brochure prior to any of the thirty-two shipments at issue in this case.

Microban also provided to Pesticide Enforcement an undated document titled, "Facts about Microban® Antimicrobial Protection," which states that:

> Microban protection is being introduced into consumer products to address the growing public concern over the prevalence of germs and bacteria, such as E. coli, Salmonella, Staph. and Strep. *Independent laboratory tests have shown conclusively that Microban can safely reduce the presence of bacteria on these products by 99.9 percent.*

Mot. for Accel. Dec., Ex. 13, at 1 (Facts about Microban Antimicrobial Protection (undated)) ("Fact Sheet"). As with the Brochure, no evidence was presented regarding when the Fact Sheet was sent to Hasbro or whether Hasbro was in possession of it prior to any of the thirty-two shipments of Additive "B."

Relying upon the inspections and the information collected, Pesticide Enforcement charged Microban with thirty-two violations of FIFRA section 12(a)(1)(B) based upon thirty-two shipments of Additive "B" to various destinations.

C. *Procedural Background*

1. *Early Proceedings*

On December 5, 1997, Pesticide Enforcement filed a Complaint against Microban alleging, in a single count, that Microban committed thirty-two violations of FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), based on the thirty-two sales or distributions of Additive "B," and alleging that Microban "in each instance sold or distributed a registered pesticide with claims that were substantially different from claims made in connection with its registration." Compl. ¶ 32. For these violations, Pesticide Enforcement proposed a civil penalty of $160,500. *Id.* (Penalty Calculation Worksheet).

Pesticide Enforcement filed an Amended Complaint on December 16, 1997, which restated the FIFRA section 12(a)(1)(B) violations, but also included an "Al-

ternative Pleading" alleging thirty-two violations of FIFRA section 12(a)(1)(A)[10] under the theory that the ten percent active ingredient form of Additive "B" was an unregistered pesticide. Am. Compl. ¶¶ 31-36. This Amended Complaint was filed as a matter of procedural right pursuant to 40 C.F.R. § 22.14(c). The ALJ subsequently granted Pesticide Enforcement leave to file a Second Amended Complaint. Order on Motion at 12 (ALJ Apr. 3, 1998). In its Second Amended Complaint, Pesticide Enforcement realleged violations of FIFRA sections 12(a)(1)(B) and 12(a)(1)(A), but also provided a more detailed factual basis in support of its allegations that the claims made by Microban in its Q & A document, its Hasbro Presentation, and its comments on Hasbro's Draft Label[11] substantially differed from "those claims made in connection with the registration of Microban Plastic Additive 'B', EPA Reg. No. 42182-1."[12] Second Am. Compl. ¶¶ 23-25, 28.

On September 16, 1998, the ALJ issued a partial accelerated decision as to liability. The ALJ's analysis began with the rudiments, i.e., that Microban and Hasbro were "persons" and that Microban was located in a "State," required elements of a FIFRA section 12(a)(1)(B) violation. Partial Accel. Dec. at 14 n.9. The ALJ then indicated that a finding of liability for violating FIFRA section 12(a)(1)(B) could be found by "holding up, on the one hand, the terms of EPA's registration approval and then, * * * determining whether Microban made any claims as a part of its distribution or sale which substantially differ from those made in connection with its registration approval."[13] *Id*. at 14. In order to make this comparison, the ALJ considered five documents that Pesticide Enforcement had included in its Motion for Partial Accelerated Decision: (1) the Microban Brochure; (2) the Microban Fact Sheet; (3) the Hasbro Presentation; (4) suggested

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[10] With certain limited exceptions, FIFRA section 12(a)(1)(A) makes it unlawful for any person to distribute or sell an unregistered pesticide or a pesticide whose registration has been canceled or suspended. 7 U.S.C. § 136j(a)(1)(A).

[11] These documents are described in more detail above in Part I.B.2.

[12] Pesticide Enforcement also alleged that Microban had "use[d] the term 'germs' to connote microorganisms infectious to man," relying on two documents as the basis for this allegation: Microban's Q & A document and Exhibit E of Microban's License and Supply Agreement with Hasbro. Second Am. Compl. ¶ 26. Pesticide Enforcement did not, however, explicitly allege that the claims in the License and Supply Agreement substantially differed from those claims made in connection with the registration of Additive "B," nor did it raise this issue in its Motion for Accelerated Decision. *See id.* ¶ 28 (citing only the claims listed in paragraphs 23, 24, and 25 as substantially differing from the registration claims); *see also id.* ¶ 26 (containing no allegations that the claims discussed in paragraph 26 were part of Respondent's sale and distribution and/or that they differed from the claims made in connection with the registration of Additive "B"); Mot. for Accel. Dec. at 7.

[13] The ALJ noted that Microban had not asserted that its product was unregistered. Partial Accel. Dec. at 2 n.3. Consequently, Pesticide Enforcement's "protective" alternative cause of action, *see supra* note 10 and accompanying text, which was based upon a theory that Respondent's product was an unregistered pesticide sold or distributed in violation of FIFRA section 12(a)(1)(A), was not viable. *See* Partial Accel. Dec. at 2 n.3.

language from Microban to Hasbro on a Draft Label; and (5) the Q & A document. *Id*. at 15-16. The ALJ concluded that the claims made in these five documents "'substantially differ' from those approved with Microban's registration and did so as a part of its distribution or sale."[14] *Id.* at 16. Because he still had some remaining questions about what the precise number of violations in the case should be, the ALJ did not decide this issue at that time but instead directed the parties to submit briefs addressing that issue.

On February 18, 1999, following receipt of the parties' briefs, the ALJ ruled that Microban committed five violations of FIFRA section 12(a)(1)(B). *See* 1999 Liab. Dec., 1999 EPA ALJ LEXIS 4, at *16. In doing so, the ALJ rejected Pesticide Enforcement's argument, i.e., that there were thirty-two violations based on the number of shipments to Hasbro's contractors, as overreaching and likely to produce unreasonable results. *Id*. at *5-10. The ALJ also disagreed with Microban's construction, i.e., that the five documents are linked to a single sale to Hasbro (presumably referring to the License and Supply Agreement) and thus amount to no more than a single violation, as too narrow a reading of the statute and at odds with the purpose of FIFRA section 12(a)(1)(B). *Id.* at *9-10. He instead concluded that Microban had committed five violations of FIFRA section 12(a)(1)(B), one for each of the five documents containing claims that substantially differed from the statements made in connection with the registration for Additive "B." *Id*. at *16. After finally determining liability in the matter, the ALJ concluded that a number of factual issues remained in dispute with respect to the appropriate penalty that should be assessed for the five violations. *See id*. at *18-23. Accordingly, the ALJ denied Pesticide Enforcement's request for an accelerated decision as to the penalty and instructed that a penalty hearing be scheduled.

Subsequently, on November 4, 1999, following the penalty hearing, the ALJ issued an initial decision in which he imposed a $25,000 penalty for the five violations of FIFRA section 12(a)(1)(B). Initial Decision Regarding Penalty ("Init. Dec. Regarding Penalty") at 3.

2. *First Appeal*

On December 6, 1999, Pesticide Enforcement filed an appeal with the Board, seeking review of the ALJ's initial decision with respect to the number of violations and the corresponding penalty. Pesticide Enforcement argued that FIFRA section 12(a)(1) makes each act of selling or distributing a pesticide prod-

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[14] We agree with and affirm the ALJ's analysis in the Partial Accelerated Decision with respect to the question of whether the claims in the five documents differed from the statement approved in the registration of Microban's Additive "B." Insofar as any of the language in the Partial Accelerated Decision conflicts with *Microban I* or this decision, however, it is overruled.

uct in a prohibited manner an independent offense. Complainant's Appeal as to the Number of Violations ("First Appeal") at 2-3.

In response, Microban argued that the ALJ erred "by mechanically counting the number of documents containing claims that he found to be unauthorized * * * [and] should have concluded that the 32 shipments constituted only one sale or distribution and that the 5 documents were a part of the one sale or distribution." Resp't Reply to First Appeal at 12. Microban also argued that the ALJ's decision correctly found that EPA failed to allege or offer any evidence that the unauthorized claims were made as "a part of" each of the thirty-two shipments made by Microban. *Id.* at 4-8 (relying on the ALJ's statement in the Initial Decision that "based on the present record the five offending documents were not particularly tied to the thirty-two sales or distributions"). Nonetheless, Microban did not appeal the penalty imposed.

The Board remanded the case because the ALJ placed undue emphasis on the number of documents containing unapproved claims rather than focusing on the number of sales or distributions in determining the number of violations. *Microban I*, 9 E.A.D. 674, 689 (2001). The Board held that the plain language of FIFRA section 12(a)(1)(B) makes it clear that the "unit of violation" under the statute must be based on the number of proven distributions or sales of the registered pesticide by Microban to Hasbro, and that a distribution or sale is unlawful "if claims made for it as a part of its distribution or sale substantially differ from any claims * * * in connection with its registration." *Id.* at 683-84.

The Board also found deficiencies in the ALJ's analysis of the nexus between unapproved claims and Microban's thirty-two shipments of Additive "B" to Hasbro's contractors. *Id.* at 686. The Board noted that the ALJ had "made findings that '[t]he five documents which form the heart of EPA's case in this instance *were not particularly tied* to the thirty-two Microban sales or distributions. Rather they *existed independently* of any particular sale or distribution.'" *Id*. at 687. This statement appeared inconsistent with the overall findings of the ALJ in holding Respondent liable for violations of FIFRA section 12(a)(1)(B) as well as inconsistent with the language of that FIFRA provision. *See id*. The Board also noted that it seemed from the facts that "some or all of the unapproved claims may have had some connection to the nascent, and ultimately, ongoing contractual relationship that existed at times between Microban and Hasbro involving the distribution or sale of Microban Additive 'B.'" *Id*. at 688. As this was a mixed question of law and fact, the Board ordered the ALJ to examine all the surrounding facts and circumstances concerning the offending documents and the dealings between the parties before making a determination regarding the number of violations. *Id.* In particular, the Board instructed the ALJ to determine: (1) whether certain unapproved claims were made "as a part of" thirty-two shipments of Microban's Additive "B"; and (2) whether the License and Supply Agreement between Microban and Hasbro contained unapproved claims that were made "as part of a distribution

or sale" of Additive "B." *Id.* at 689. The Board likewise remanded the ALJ's penalty determination "without opinion for assessment of a penalty consistent with the conclusion of the further proceedings." *Id.*

3. *Case on Remand*

On remand, the ALJ held a supplemental hearing at which EPA presented testimony by Dr. Brenda Mosley, the EPA case development officer who worked on this matter. Suppl. Tr. at 18-38. At the end of EPA's case, the ALJ noted that "it is a little perplexing to me in that the information that Dr. Mosley has just recited is everything that was already in front of me. And, you know, it was in front of the [B]oard as well. So it seems to me that the [B]oard wouldn't have needed to remand this case if, globally, the statements that have be[en] reidentified by Dr. Mosley — if those statements were enough." *Id.* at 39. Thereafter, Microban moved for a directed verdict, which the ALJ denied with reservations. *Id.* at 51.

At the conclusion of the hearing, after Microban presented testimony by its vice president, Barnwell Ramsey, who had also testified at the first hearing, the ALJ instructed the parties, in their briefs, to address the concerns expressed by the Board in its remand. *Id.* at 76-77. The ALJ also remarked that he wondered "what the [B]oard was looking for. If it was all there in front of them, I don't know why they just didn't wrap it up. * * * [I]t seems to me they were looking for something more." Suppl. Tr. at 76-77.

After receiving and reviewing the parties' briefs, the ALJ found Microban not liable for any violations of FIFRA section 12(a)(1)(B). *See* Remand Dec. at 13-14. He determined that, according to the evidence, none of the five documents in question had been included in the thirty-two shipments of Additive "B," and he found EPA's arguments that they were created close in time to the shipments and that their purpose was to induce sales of Additive "B" unconvincing. *Id.* He found that EPA did not address each specific shipment nor did it produce information individually connecting any unapproved claim(s) to a particular shipment. *Id.* The ALJ also stated that the supplemental hearing had produced no new evidence and remarked that "the Board must have found the record incomplete or it would have resolved these questions without the need for remand." *Id.* at 13.

The ALJ noted additional concerns in his Decision Upon Remand with respect to two of the five documents — the Brochure and the Fact Sheet. Regarding the Microban Brochure, which was printed after Hasbro and Microban had entered into the License and Supply Agreement and therefore could not have induced the agreement itself, the ALJ pointed out that there was insufficient evidence to show when or how Hasbro received the brochure. *Id.* at 8. As for the Fact Sheet, the ALJ noted that although the document had a copyright date of 1996, "[t]he record does not reveal when a document bearing the title 'Facts about

Microban' was provided to Hasbro or whether Hasbro receive[d] the version entered into evidence." *Id.* at 9. In addition to these concerns, the ALJ also noted that the Brochure and the Fact Sheet were not mentioned in the Second Amended Complaint.[15] *Id.* at 8-9.

The ALJ also considered the License and Supply Agreement and concluded that the Agreement could not be used as a basis for EPA's FIFRA section 12(a)(1)(B) claim because it was not considered in the determination of the violations, nor was it included in EPA's complaints for this purpose. *Id.* at 10-11. The ALJ alternatively concluded that even if he did consider it, EPA had not shown the unapproved claims in Appendix E were connected to the distribution or sale of Microban's Plastic Additive "B." *Id.* at 11.

In sum, the ALJ concluded that Pesticide Enforcement had not demonstrated a particularized link between the thirty-two invoices and the unapproved claims in the Presentation, the Q & A document, and the Draft Label. *Id.* With respect to the Brochure and Fact Sheet, because of the evidentiary and pleading problems mentioned above, he essentially held that they could not be used to establish a violation. *Id.* at 8-9. He also found that the License and Supply Agreement could not be used as the basis for a violation. *Id.* at 10-11. Thus, he found no violations of FIFRA section 12(a)(1)(B).

On November 12, 2002, Pesticide Enforcement filed this appeal. Pesticide Enforcement argues that the ALJ erred in finding that claims that substantially differ from the registration of Microban's Additive "B" are not a part of the sale or distribution of that pesticide product. *See* Second Appeal at 6. Pesticide Enforcement contends that those claims should be considered part of the distribution or sale because those claims were made (1) in a presentation to Hasbro that has been found to be intended to induce Hasbro's purchase of that pesticide, (2) in suggestions to Hasbro for a Draft Label when a purpose of the document was to induce Hasbro's purchase of the product, and (3) in a Q & A document for training of the

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[15] While it is true that the Brochure and the Fact Sheet were not mentioned in the Second Amended Complaint, we do not believe this would necessarily be fatal as the claims made in these two documents were referred to and relied upon as containing unapproved claims by Pesticide Enforcement in its Motion for Accelerated Decision. *See* Mot. for Accel. Dec. at 7-11. Microban, in its response to the Motion for Accelerated Decision, did not question the inclusion of the claims in these two documents in Pesticide Enforcement's motion, but instead argued that the claims in the two documents did not substantially differ from the claims approved by EPA. *See* Resp't Opp'n to Mot. for Accel. Dec. at 16-21. The claims in these two documents have been in debate in this case since that time and Microban has not questioned their authenticity. On several occasions, we have interpreted the Consolidated Rules of Practice, 40 C.F.R. part 22, to allow amendment of pleadings to conform with the evidence. *E.g., In re H.E.L.P.E.R., Inc.*, 8 E.A.D. 437, 449 (EAB 1999) (discussing this principle of law in detail and citing numerous Board and federal court cases). Accordingly, we do not agree with the ALJ insofar as he held that the close-in-time argument should be dismissed based on the ground that the two documents were not specifically mentioned in the complaint.

purchaser's employees about the pesticide when a purpose of the document was to induce sale of the product. *Id*. at 5-6. Pesticide Enforcement also contends that the ALJ erred in failing to find that the License and Supply Agreement between Microban and Hasbro and, in particular, Exhibit E, contained unapproved claims made as part of the distribution or sale of Additive "B." Respondent filed a reply to this second appeal on December 20, 2002. Resp't Reply to Second Appeal.

II. *DISCUSSION*

A. *Standard of Review*

The standard of review for the Board is *de novo*, giving the Board the authority to either adopt, modify, or set aside the ALJ's findings of fact or conclusions of law. 40 C.F.R. § 22.30(f). Although the Board has stated that it will generally give deference to findings of fact based upon the testimony of witnesses as the ALJ is in a better position to assess witness credibility, *e.g.*, *In re CDT Landfill Corp.*, 11 E.A.D. 88, 100 n.23 (EAB 2003); *In re Chempace Corp*., 9 E.A.D. 119, 134 (EAB 2000); *In re Ocean State Asbestos Removal, Inc.*, 7 E.A.D. 522, 530 (EAB 1998), the Board is not bound by these findings. *In re Bricks, Inc.*, 11 E.A.D. 224, 233 (EAB 2003); *In re Everwood Treatment Co.*, 6 E.A.D. 589, 612 n.39 (EAB 1996), *aff'd*, No. 96-1159-RV-M, 1998 U.S. Dist. LEXIS 927 (S.D. Ala. Jan. 21, 1998); *see also* Administrative Procedure Act, 5 U.S.C. § 557(b) ("On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision * * * .").

In reviewing penalty appeals, the Board applies the "preponderance of the evidence" standard established by 40 C.F.R. § 22.24(b). *E.g.*, *Ocean State*, 7 E.A.D. at 529-30. That section provides that "[e]ach matter of controversy shall be decided by the [ALJ] upon a preponderance of the evidence." 40 C.F.R. § 22.24(b). The Board has often stated that the "preponderance of the evidence" standard requires that "a fact finder should believe that his factual conclusion is more likely than not." *Ocean State*, 7 E.A.D. at 530 (citing *In re Echevarria*, 5 E.A.D. 626, 538 (EAB 1994)); *accord In re The Bullen Cos.*, 9 E.A.D. 620, 632 (EAB 2001); *In re Great Lakes Div. of Nat'l Steel Corp.*, 5 E.A.D. 355, 363 n.20 (EAB 1994) (preponderance of the evidence standard means that a fact is more probably true than untrue). Thus, in reviewing an appeal, if the ALJ's findings of fact are not supported by a preponderance of the evidence in the record, the Board is not bound by those findings. *Bricks*, 11 E.A.D. at 233 (citing 40 C.F.R. § 22.30(f)); *see also W.F. Bolin Co. v. NLRB*, 70 F.3d 863, 872 (6th Cir. 1995) (stating that an ALJ's "opportunity to observe a witness's demeanor 'does not, by itself, require deference with regard to his or her derivative inferences'" (quoting *Penasquiotos Vill., Inc. v. NLRB*, 565 F.2d 1074, 1079 (9th Cir. 1977))). In the present case, we examine whether the evidence on the record shows that EPA's

allegations of Microban's thirty-two violations of FIFRA section 12(a)(1)(B) were more likely than not true.

B. *Liability Under FIFRA*

As we articulated in *Microban I*, the elements of a FIFRA section 12(a)(1)(B) violation are four-fold. "First, there must be a person charged with the violation. Second, that person must be located in a state. Third, that person must have distributed or sold a registered pesticide to another person. Fourth, there must be 'claims made [for the registered pesticide] *as a part of its distribution or sale* [that] substantially differ from any claims made for it as a part of the statement required in connection with its registration.'" *Microban I*, 9 E.A.D. at 687 (citing 7 U.S.C. § 136j(a)(1)(B)) (alteration in original). The first three elements are largely undisputed.[16] *See id.* at 687 & nn.13-17. As for whether the claims in the five documents "differed" from those made in the registration statement, we have previously affirmed the ALJ's findings and conclusions with respect to that particular issue.[17] Thus, the key remaining question is whether the unapproved claims were made "as part of" the distribution or sale of Additive "B."

1. *Were the Unapproved Claims Made "As a Part of" the Distribution or Sale of the Pesticide?*

a. *Meaning of Statutory Term "As a Part of"*

In *Microban I*, we explained that the FIFRA section 12(a)(1)(B) statutory phrase "as a part of" requires that "a nexus exist between the unapproved claims and the distribution or sale of the pesticide." 9 E.A.D. at 688. We further noted that:

> The Chief Judicial Officer in *In re Sporicidin International, Inc.* [3 E.A.D. 589 (CJO 1991)] ruled that a "sufficiently close link" existed between the claims and sales and distributions of pesticides in that case. He construed the statutory phrase broadly, and *ruled that claims and corresponding distributions or sales need not be contemporaneous*. It follows, therefore, that a rigid test, applicable to all situations, for determining whether claims have

[16] With respect to the third element, there appears to be a dispute as to whether there were one or thirty-two "distributions or sales" as that term is meant in the statute. *See* discussion *infra* Part II.B.1.c.i.

[17] *Microban I*, 9 E.A.D. at 687 n.18; *see also supra* note 14 and accompanying text. For the ALJ's analysis as to whether the claims in the five documents differed from those made in the registration statement, see Partial Accelerated Decision at 1-23.

> been made as a part of the distribution or sale of a pesticide is not contemplated as part of the statutory scheme. Rather, it is necessary to examine all of the surrounding facts and circumstances to make such a determination.

9 E.A.D. at 688 (citations and footnotes omitted) (emphasis added). Because the record before us at the time of *Microban I* did not contain a sufficient factual and legal analysis of whether the unapproved claims were made as part of the distribution or sale of Additive "B," we remanded the issue back to the ALJ in order for him to more fully consider the question.

b. *Assumptions and Conclusions in Remand Decision*

In his Decision Upon Remand, the ALJ found no violations under FIFRA section 12(a)(1)(B) because Pesticide Enforcement had not demonstrated that there was a "particularized link" between the unapproved claims[18] and any of the thirty-two invoices. *See* Remand Dec. at 13. This conclusion was apparently influenced by a misreading of the Board's remand decision as calling for more evidence than was eventually adduced at the supplemental evidentiary hearing on remand. The ALJ,[19] and perhaps even Microban,[20] were under the impression that the Board had remanded the case because there was insufficient evidence in the record as it stood at the time of *Microban I* to support a finding of liability under the Board's interpretation of FIFRA section 12(a)(1)(B). This, however, is an incorrect reading of the Board's previous decision.

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[18] Although the ALJ previously found from the evidence submitted to him at the accelerated decision stage that there were *five* documents containing unapproved claims, in his Decision Upon Remand he ultimately refers only to "the unapproved claims cited in paragraphs 23, 24, and 25 of the Second Amended Complaint." *See* Remand Dec. at 13. These paragraphs refer only to claims in *three* documents: the Hasbro Presentation, the Q & A document, and the Draft Label language. Second Am. Compl. ¶¶ 23-25. This reference to what amounts to only three documents containing unapproved claims was apparently due to the ALJ's conclusion that the evidence regarding when and how Hasbro obtained the other two documents, the Brochure and the Fact Sheet, was deficient as well as the fact that neither of these documents was cited in the Second Amended Complaint. *See supra* Part I.C.3; *see also supra* note 12.

[19] It is apparent from the ALJ's statements at the supplemental hearing and in his Decision Upon Remand that he was under the impression that the Board remanded the case, at least in part, to bolster the record. For example, as we noted earlier, at the hearing the ALJ remarked, "[I]t is a little perplexing to me in that the information that Dr. Mosley has just recited is everything that was already in front of me. And, you know, it was in front of the [B]oard as well. So it seems to me that the [B]oard wouldn't have needed to remand this case if * * * those statements were enough." Suppl. Tr. at 39. Likewise, in his recent decision, the ALJ stated that "[i]t was unlikely that the Board would have needed to remand the case if it had sufficient information before it to resolve the case." Remand Dec. at 13.

[20] *See, e.g.*, Resp't Reply to Second Appeal at 9. *But see* Second Appeal at 4.

Although in *Microban I* we stated that there were certain deficiencies in the ALJ's *findings and associated analysis* of the nexus between the unapproved claims and the thirty-two shipments of Additive "B,"[21] nowhere did we state that the factual record was deficient or even that another supplemental evidentiary hearing was necessary.[22] *See Microban I*, 9 E.A.D. at 686-89. Rather, because the ALJ had based his Initial Decision Regarding Penalty on an incorrect interpretation of the statute, the other findings appeared to us to be both deficient and inconsistent.[23] *See id.* In addition, the penalty had been based on the ALJ's initial interpretation of FIFRA section 12(a)(1)(B) and thus needed to be reassessed in light of our interpretation of the statutory provision. Accordingly, we remanded the case to the ALJ both to allow for a trial court level reassessment of Respondent's liability (and penalty, if appropriate) using the appropriate standard and to provide the parties an opportunity to supplement the record, if they believed they had additional evidence that they had not presented because the original proceedings had proceeded based upon an incorrect reading of the statute.

The record on remand suggests that, because the ALJ inaccurately interpreted *Microban I* as indicating that the factual record contained insufficient evidence to sustain a finding of liability under section 12(1)(1)(B), and because no new information was presented at the supplemental hearing, the ALJ felt compelled to find no liability in this matter. He also appears to have read the statutory term "as a part of" very narrowly, in fact, substantially more narrowly than he had in his 1998 Partial Accelerated Decision.[24] *Compare* Remand Dec. at 8-9, 12-13 *with* Partial Accel. Dec. at 15-20. As we already indicated above, *Microban I* does not stand for the proposition that the original record was insufficient. Furthermore, as we pointed out in *Microban I*, the term "as a part of" has been construed

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[21] This deficiency was understandable, as it was a direct result of the ALJ's erroneous interpretation of FIFRA section 12(a)(1)(B), which we overruled.

[22] We did not, however, rule out a hearing.

[23] For example, in one of the ALJ's orders, he made findings that "[t]he five documents which form the heart of EPA's case * * * were not particularly tied to the thirty-two Microban sales or distributions." 1999 Liab. Dec., 1999 EPA ALJ LEXIS 4, at *15; *see also* Init. Dec. Regarding Penalty at 2. As we mentioned in *Microban I*, this statement directly conflicts with the findings necessary to impose a penalty under section 12(a)(1)(B), which the ALJ did impose in his Initial Decision. 9 E.A.D. at 687-88. Moreover, in an earlier order, the ALJ noted that "Microban's argument also ignores that the sales picture is actually a mural, which includes more than the actions which result in the closing of a present sale with Hasbro. Selling a product is an ongoing effort which involves current and future sales and secondary sales efforts * * *." Partial Accel. Dec. at 20. This statement also appeared to us to be inconsistent with his statement that the five documents were not particularly tied to the subsequent sales.

[24] Although the ALJ had previously indicated that claims need not be contemporaneous with the distribution or sale, *e.g.*, Partial Accel. Dec. at 19, in his decision not to impose liability, he appears to have found the fact that the documents did not physically accompany the shipments very important, *see* Remand Dec. at 12-13.

broadly, not narrowly. 9 E.A.D. at 688; *accord In re Sporicidin Int'l, Inc.*, 3 E.A.D. 589 (CJO 1991). Based on the record below, we find that the ALJ erred in assuming that the record was incomplete and, consequently, erred in his analysis of liability in this case on remand. Rather than remand the case for a second time with further instructions, we have reviewed the record to determine whether Pesticide Enforcement met its burden of proof to establish liability.

c. *Post-Remand Board Consideration of "as a Part of Its Distribution or Sale" Issue*

Upon examination of all the surrounding facts and circumstances of this case, as recounted in Part I.B above, we conclude below that there is a "sufficiently close link" between at least some of the unapproved claims and the "distribution or sale" of Additive "B." Because the Hasbro Presentation was made prior to all thirty-two of the shipments at issue in this case, and thus could potentially establish a link to all of them, we first consider the connection between it and the shipments. We then consider separately the link between the shipments and both the Q & A document and Microban's suggested Draft Label language. We do not, however, further consider the Brochure and the Fact Sheet because we agree with the ALJ that, as to those two documents, there is insufficient evidence in the record establishing when Hasbro received them. *See supra* notes 15, 18 and accompanying text. Without a time frame establishing "receipt" of the documents containing the unapproved claims, it is possible that Microban sent them to Hasbro after the thirty-two shipments at issue in this case. Consequently, there is inadequate evidence to demonstrate that the unapproved claims were linked with the distribution or sale of the pesticide.

i. *Hasbro Presentation*

It is clear that the intent behind Microban's 1995 Hasbro Presentation, which contained unapproved claims, was to induce the sale of Additive "B" to Hasbro.[25] Subsequent to the presentation, Hasbro entered into a sales agreement with Microban (the License and Supply Agreement) in which it agreed to purchase a minimum amount of pesticide and pursuant to which, at a minimum, thirty-two shipments of the pesticide were made to Hasbro and/or its contractors. *See* Resp't Reply to Second Appeal at 15 & n.11.

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[25] Even Microban seems to recognize this fact. For example, in its recent reply brief, Microban acknowledges that "[a]t best, the presentation document could be said to have *induced* Hasbro to purchase Additive B." Resp't Reply to Second Appeal at 15 n.11 (emphasis added). Additionally, at the first hearing, the president and CEO of Microban stated that a purpose of the meeting between Microban and Hasbro was to determine "where there were proper opportunities for us to sell our products." Tr. at 361-62 (testimony of Glenn Cueman).

Microban argues that, when there is a sale and later shipments made pursuant to that sale, unless the unapproved claims are *attached* to the subsequent shipments, there can only be one violation of FIFRA — for the sale. *See, e.g.*, *id*. at 14 (emphasizing the fact that none of the five documents at issue were sent with the thirty-two shipments to any of Hasbro's contractors); Resp't Reply to First Appeal at 11 (suggesting that the claim must physically accompany the shipment).[26] This argument is contrary to the conclusions in *In re Sporicidin International, Inc*., 3 E.A.D. 589 (CJO 1991). As the Chief Judicial Officer[27] in that case explained, FIFRA is a remedial statute and, as such, "should be construed liberally so as to effectuate its purposes." *Id*. at 604. Therefore, "[b]roadly construing the phrase 'part of its distribution or sale' so as not to require a contemporaneous sale

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[26] In an earlier reply brief in this matter, Microban relied upon a 1973 Office of General Counsel ("OGC") memorandum for its assertion that "unapproved claims must 'accompany' a sale or distribution of a pesticide product to support an independent violation of section 12(a)(1)(B)." Resp't Reply to First Appeal at 11 (relying on *Authority to Regulate Advertising of Pesticide Products*, 1 Op. Off. Gen. Counsel 439 (1973)). Microban argued that "[a]s a critical part of this legal opinion, OGC interpreted the scope of Section 12(a)(1)(B) to be limited: '"Distribution or sale" may only connote claims made in graphic or written material accompanying the pesticide.'" *Id*. at 11 (alteration in original). Microban did not raise this specific point before us in its current reply brief; therefore, the argument must be deemed to have been abandoned. Nonetheless, because of the ostensible relevance of the memorandum, as earlier portrayed by Microban, we examined it to satisfy our own concerns that it might have some bearing on the issues raised on appeal. We address it here.

Upon review of the OGC memorandum, we find that Microban has misread and misrepresented the significance of the quoted passage. The memorandum in question was written shortly after the enactment of the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 975 (1972) (which significantly amended FIFRA), and was focused on EPA's authority to regulate the advertisement of pesticide products in light of the Federal Trade Commission's ("FTC") general advertising authority. *See* 1 Op. Off. Gen. Counsel at 439. The memorandum explores two theories under which EPA could potentially establish concurrent jurisdiction with FTC to regulate advertising of pesticide products. *Id.* at 439-41. The memorandum suggests that while, on one hand, section 12(a)(1)(B) of FIFRA "*may* apply to 'claims' made in advertising," on the other hand, the language in other statutory provisions "*perhaps* indicate[] that the words of art 'distribution or sale' [used in 12(a)(1)(B)] should be read more narrowly than advertising in general. 'Distribution or sale' *may* only connote claims made in graphic or written material accompanying the pesticide." *Id.* at 440 (emphasis added). Thus, contrary to Microban's assertion, not only is the cited statement not a "critical" part of the opinion, but the statement is acknowledged by the memorandum to be one of the possible interpretations of the newly amended Act. *Id*. Furthermore, in 1989, the Agency interpreted these same advertising-related statutory provisions in a different manner from the Agency's 1973 theory cited by Respondent above. *See* 40 C.F.R. § 168.22(a) (interpreting the claims referenced under 12(a)(1)(B) to "extend[] to advertisements in any advertising medium to which pesticide users or the general public have access"). Thus, Microban's argument is inapposite here.

[27] The Chief Judicial Officer was a predecessor to the Board, making final agency decisions pursuant to Agency regulations and delegations from the Administrator. *See* Changes to Regulations to Reflect the Role of the New Environmental Appeals Board in Agency Adjudications, 57 Fed. Reg. 5320, 5320 (Feb. 13, 1992). The Chief Judicial Officer's decisions, as final agency decisions, are cited and relied upon by the Board. *See, e.g.*, *In re Chem Lab Prods., Inc.*, 10 E.A.D. 711, 728 (EAB 2002); *In re Carroll Oil Co.*, 10 E.A.D. 635, 652 (EAB 2002); *In re Everwood Treatment Co.*, 6 E.A.D. 589, 601 (EAB 1996), *aff'd*, No. 96-1159-RV-M, 1998 U.S. Dist. LEXIS 927 (S.D. Ala. Jan. 21, 1998).

or distribution furthers the overall purposes of FIFRA." *Id.* Here, as in *Sporicidin*, "[c]ommon sense suggests that a claim followed by a sale evinces nothing more than a normal cause-and-effect relationship, and that a time interval spanning the two events is common."[28] *Id.* at 603. Following from this general principle, the fact that the sales agreement (i.e., the License and Supply Agreement) was entered into sometime after the presentation, and the shipments resulting from the agreement occurred sometime after that,[29] does not change the underlying fact that a connection existed between the unapproved claims and the "distribution or sale" of the pesticide. Furthermore, Microban presented no evidence that it corrected or redacted the unapproved claims it had made to Hasbro in its presentation prior to entering into the sales agreement or prior to making any shipments of the pesticide. In fact, the weight of the evidence (for example, the Q & A document, the Draft Label language) demonstrates that Microban, in its ongoing relationship with Hasbro, continued making these types of unapproved claims throughout the time it was shipping the pesticide.

Indeed, later in its brief, Microban acknowledges that it is possible, "using EPA's argument[s]," to find a violation of FIFRA based upon the Presentation to Hasbro and the resulting License and Supply Agreement. Resp't Reply to Second Appeal at 15 nn.11, 20; *see also* Resp't Reply to First Appeal at 12-13. Microban, however, disputes the number of violations that would result based upon the facts in this case and claims that, *at best*, these facts would establish *only one* violation of FIFRA, not thirty-two, as sought by Pesticide Enforcement. Resp't Reply to Second Appeal at 20 (emphasis added). Microban contends that, once the sales agreement was signed, Hasbro was obligated to take the amount of Additive "B" set forth in the agreement regardless of how the pesticide was shipped. *Id*. at 20-21. Thus, Microban argues, the fact that Hasbro requested delivery in at least thirty-two shipments was "mere happenstance" and does not alter the fact that there was only one sale. *Id*. at 21.

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[28] Microban's activities in this case are very similar to those of the respondent in *Sporicidin*, who was found liable for violations of FIFRA section 12(a)(1)(B). *See* 3 E.A.D. at 589. In that case, the company's vice president brought promotional literature on its products Sporicidin and Permacide, which included unapproved claims, to a hospital where it was read on many occasions by hospital staff, some of whom were in a position to approve the use of such disinfectant products. *Id*. at 604 & n.34. These visits began in the early part of 1987, and deliveries of Sporicidin were received by the hospital in June, July, and September of that year. *Id*. At least one sample of Permacide was also brought to the hospital in late 1987 or early 1988. *Id.* The Chief Judicial Officer concluded that "[u]nder these circumstances, there is a sufficiently close link between respondent's claims for Sporicidin and Permacide and the subsequent sale or distribution of stocks of these pesticides to satisfy the requirements of FIFRA § 12(a)(1)(B)." *Id.*

[29] We do not believe the issue should necessarily turn on *when* the shipments were made pursuant to the sales agreement. In other words, we believe the same result should occur no matter whether the thirty-two shipments had been sent by Microban on the very same date as the signing of the sales agreement, or whether the shipments resulting from the sale were made some time after entry into the agreement.

Microban's position appears to us, at bottom, to be that the Agency should only consider the sale of a pesticide and should ignore the shipments of the pesticide resulting from that very sale.[30] Microban's position, however, is not consistent with the language of the Act itself, which is the primary consideration in interpreting any statute. *E.g.*, *United States v. James*, 478 U.S. 597, 604 (1986); *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 756 (1975); *see also Microban I*, 9 E.A.D. 674, 682 (EAB 2001) (stating that "the starting point in any exercise of statutory construction is the statute itself"). The plain language of FIFRA authorizes the Agency to consider each shipment as a violation of the Act. The relevant section of FIFRA provides that "*it shall be unlawful for any person in any State to distribute or sell* to any person * * * (B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration." 7 U.S.C. § 136j(a)(1)(B) (emphasis added). FIFRA defines the terminology "to distribute or sell" to include *both* a sale and a shipment of a pesticide. *Id.* § 136(gg) ("'to distribute or sell' means to distribute, *sell*, offer for sale, hold for distribution, hold for sale, hold for shipment, *ship*, deliver for shipment, release for shipment, or received and (having so received) deliver or offer to de-

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[30] In its previous reply brief, Microban also relied upon certain facts in *Sporicidin* to suggest that there was only one "sale or distribution" of Microban Additive "B" to Hasbro. Resp't Reply to First Appeal at 10-11. Microban argued that "in *Sporicidin*, EPA alleged only one violation of Section 12(a)(1)(B) involving three shipments of a pesticide" and the Chief Judicial Officer found only one violation of FIFRA. *Id.*

First, we note that in *Sporicidin*, there were at least three sales *and* three corresponding shipments of Sporicidin as well as at least one shipment of Permacide to the hospital, but defendant was only charged and found liable for two violations (one for making claims in connection with Permacide's distribution or sale that differed from claims accepted in connection with its registration and one for making claims in connection with Sporicidin's distribution or sale that differed from claims accepted in connection with its registration). 3 E.A.D. at 594, 604; *accord In re Sporicidin Int'l*, Dkt. No. FIFRA-88-H-02, 1988 WL 236319 (ALJ Nov. 1, 1988). The Agency, therefore, did not allege violations for each shipment made by the respondent, nor did it allege violations for each sale. The reason for this, however, is not contained in either the ALJ's decision or the Agency's final decision. It is also noteworthy that the charges that were brought by EPA in that case were based on a previous enforcement policy. *Sporicidin*, 3 E.A.D. at 605 (citing a 1974 FIFRA enforcement policy). That policy does not contain similar detailed guidance to the language quoted below from the 1990 enforcement policy with respect to how many charges to list in a complaint and whether to allege violations for each sale and/or each shipment. *See* EPA Guidelines for the Assessment of Civil Penalties, 39 Fed. Reg. 27,711 (July 31, 1974). Finally, in a particular matter, the Agency also retains the discretion to seek to impose liability for less than the maximum number of possible violations. *E.g.*, *In re Chempace Corp.*, 9 E.A.D. 119, 129-30 & n.16 (EAB 2000). In fact, in the current case, Pesticide Enforcement listed thirty-two shipments in its amended complaint even though it apparently had obtained evidence that there were at least 54 shipments made to Hasbro. *See* 1999 Liab. Dec., 1999 EPA ALJ LEXIS 4, at *13 (stating that EPA had decided not to charge Microban for twenty-two additional shipments for which the Agency had invoices). Without more information about the rationale behind the number of violations charged in the *Sporicidin* matter, no definitive explanation can be given for why the Agency charged only two violations of the Act in that case. Accordingly, we find unconvincing Microban's reliance on *Sporicidin* for its position on this issue.

liver") (emphasis added). Thus, in interpreting this provision in *Microban I*, we explained that "a single shipment (a form of distributing or selling) of a registered pesticide constitutes one violation of FIFRA section 12(a)(1)(B), *if* the elements of paragraph (B) are satisfied. Multiple shipments are potentially multiple violations, once again, *if* the elements of paragraph (B) are satisfied with respect to each shipment."[31] 9 E.A.D. at 684.

We have just concluded above that the elements of paragraph (B) have been satisfied with respect to each of Microban's thirty-two shipments, i.e., that there was a sufficiently close link between the unapproved claims in the Hasbro Presentation and the distribution or sale of Additive "B." Consequently, under the plain language of the statute, each shipment of Additive "B" constitutes one violation of FIFRA. Our analysis need go no further as, where Congress' intent is clearly evinced by the plain language of the statute, no additional means of statutory interpretation need be undertaken. *E.g., Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."); *accord Yellow Transp. Inc. v. Michigan*, 537 U.S. 36, 45 (2002); *Barnhart v. Walton*, 535 U.S. 212, 217-18 (2002); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125-26, 132 (2000).

We do note, however, as we pointed out in *Microban I*, that linking the number of violations to the number of distributions or sales — and here, more particularly, the number of shipments — is consistent, not only with FIFRA's plain language, but with the consumer protection goals of FIFRA. 9 E.A.D. at 686. In fact, as we recounted in *Microban I*, consumer protection from false and/or misleading claims is one of the longstanding goals of FIFRA and its predecessor, the Federal Insecticide Act of 1910, ch. 191, 36 Stat. 331 (repealed 1947). 9 E.A.D. at 686 & n.12 (quoting *In re Ankiewicz*, 8 E.A.D. 218, 242 (EAB 1999) (McCallum, J., concurring)).

The Agency's penalty policy for violations of FIFRA is also consistent with the plain language of the statute. *See* U.S. EPA, Office of Compliance Monitoring & Office of Pesticides & Toxic Substances, *Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)* (July 2, 1990) ("ERP"). The ERP states that "[a] violation is independent if it results from an act (or failure to act) which is not the result of any other charge for which a civil penalty is to be assessed, or if the elements of proof for the violations are differ-

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[31] This interpretation of the statute likewise means that each sale of a registered pesticide can potentially be a violation of FIFRA, if the elements of paragraph (B) are satisfied. This reading of the statute, however, does not change the fact that each shipment of a registered pesticide can also be a violation if the elements of paragraph (B) are satisfied.

ent. * * * Consistent with the above criteria, the Agency considers violations that occur from each shipment of a product * * * or each sale of a product * * * to be independent offenses of FIFRA." ERP at 25. The ERP further indicates, in a footnote, that "[i]ndependent violations which can be documented as both per sale and per shipment are to be calculated only as either per sale or per shipment, whichever is more appropriate based on the supporting documentation, and whichever approach yields the highest civil penalty."[32] *Id.* at 25 n.*. Thus, in the case of a FIFRA section 12(a)(1)(B) violation, the ERP authorizes the Agency to charge violations of *either* the sale(s) or the shipment(s) of a pesticide (but not both). In this case, Pesticide Enforcement, within its discretion, alleged violations based on the number of shipments rather than on the one sale.

In conclusion, we find it more likely than not that there is a sufficiently close link between the unapproved claims made by Microban in the Hasbro Presentation and the thirty-two distributions or sales of Additive "B" made to Hasbro and/or its contractors. Thus, Microban is liable for thirty-two violations of FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B).

ii. *Q & A Document and Suggested Draft Label Language*

Even though we have already concluded that the evidence surrounding the Hasbro Presentation and the resulting distribution or sale of Microban's Additive "B" is, in and of itself, sufficient to support a finding of thirty-two violations of FIFRA, we will also consider whether there was a "sufficiently close link" between the unapproved claims in two other documents — the suggested Draft Label language and the Q & A document — and the "distribution or sale" of Additive "B."

In the remand decision, the ALJ noted that the purpose of both the Q & A document and the suggested Draft Label language, by their very nature, was to induce the purchase of Additive "B." Remand Dec. at 9. He found, however, that only some of the shipments followed Microban's Draft Label language suggestions and that only eleven shipments were sent after the date of the Q & A document. *Id*. He also found that neither of these documents "physically accompanied" the shipments. *Id*. Pesticide Enforcement argued that, despite the fact that these two documents did not accompany the shipments, the sequence of events beginning with the Agreement, continuing through the creation and exchange of the two documents between Microban and Hasbro, and finishing with the later ship-

[32] The ERP provides the following example to explain this principle: "[I]f Person A has a violation involving 1 sale and 2 shipments, and Person B has a violation involving 2 sales and 1 shipment, both persons would be charged for 2 violations of FIFRA (Person A is charged for 2 shipments and Person B is charged for 2 sales)." ERP at 25 n.*.

ments of the pesticide as envisioned by the Agreement, constituted a "sufficiently close link" between the unapproved claims and the distribution and sale of Additive "B." Despite this argument, the ALJ held that neither of these two documents were particularly linked to Microban's distribution or sale of Additive "B." *Id*. at 13. In its reply to the appeal, Microban maintains that the ALJ's analysis on this issue was correct. Resp't Reply to Second Appeal at 7-18. We disagree.

The evidence in this case indicates that, as part of the Agreement between Microban and Hasbro, Microban agreed to help Hasbro with its marketing of the products that would contain Microban's Additive "B." Tr. at 355-56, 368. As part of this ongoing buyer-seller relationship, Microban provided Hasbro with Draft Label suggestions and the Q & A document. *Id*. at 368, 380-81. These two documents also contained unapproved claims. *See supra* note 14 and accompanying text. As the ALJ found, Microban intended these documents to maintain the buyer-seller relationship between itself and Hasbro and to induce the continued purchase of the product by Hasbro. Moreover, because the Agreement specified only a minimum amount that had to be purchased, Resp't Reply to Second Appeal at 15 & n.11, Microban had an incentive to continue to promote sales in excess of that minimum amount. Finally, as we have discussed above, *see supra* Part II.B.1.c.i, claims and corresponding distributions or sales need not be contemporaneous.[33]

These facts are very similar to those in *Sporicidin*. In that case, the respondent handed out informational packets, which contained the unapproved claims, "to *current users of* disinfectant products (including Sporicidin), including individuals who [we]re in a position to influence the * * * decision whether to purchase them." *In re Sporicidin, Int'l, Inc.*, 3 E.A.D. 589, 603 (CJO 1991) (emphasis added). Based on this evidence, the Chief Judicial Officer stated, "This evidence warrants the conclusion that respondent's dissemination of the Bionetics reports [containing unapproved claims] was intended to persuade * * * staff of the value of the products and to encourage their purchase and use." *Id*. The Chief Judicial Officer also noted that "'[d]istribution' includes both marketing and merchandising a commodity." *Id*. at 605. Consequently, the fact that respondent gave the unapproved claims to persons already using the product did not lessen the connection between the unapproved claims and the later sale and distribution of the product to those same users.[34] *See id.* at 604-05.

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[33] This is not to say that once a respondent makes an unapproved claim, the number of violations that can be charged is unlimited. Rather, the key issue is whether or not there is a sufficient *link* between the unapproved claims and the distribution or sale of the pesticide.

[34] We note that, in this case, if the documents containing unapproved claims were also part of an effort to induce sales over the specified minimum amount, the fact that no such sales beyond that amount apparently occurred is not material.

We likewise hold, based on the surrounding facts and circumstances in this case, that it is more likely than not that Microban's unapproved claims in both the Q & A document and the Draft Label were sufficiently linked to the later distribution or sale of Additive "B" to Hasbro. In an ongoing buyer-seller situation such as this, where the seller uses unapproved claims in its continued "sales" and marketing of its product to maintain its buyer and to ensure its buyer continues to order shipments pursuant to a current agreement and to enter into additional and/or future sales agreements, we find such evidence to be sufficient to demonstrate that a nexus exists between the unapproved claims and the distribution or sale of the pesticide. Although shipments made prior to Microban's furnishing these documents to Hasbro obviously cannot be considered as linked to the unapproved claims in the two documents, any shipments made after Hasbro received the documents would be sufficiently linked for the purposes of liability. According to the record, twenty-nine shipments occurred after Microban provided Hasbro with suggested language on its draft label and eleven shipments occurred after the Q & A document. Thus, we conclude that there is a sufficiently close link between the unapproved claims made by Microban in the Draft Label and the Q & A document and, at a minimum, twenty-nine distributions or sales of Additive "B" made to Hasbro and/or its contractors.

2. *Were There Unapproved Claims in the Agreement That Were Made "As a Part of" the Distribution or Sale of Additive "B"?*

Based on the record, we find no error in the ALJ's conclusion, *see* Remand Dec. at 10, that any unapproved claims that may have been made in the Agreement, including Appendix E, should not be considered as "unapproved claims" in determining violations in the case. The ALJ found that the Second Amended Complaint limited the substantially differing claims upon which the alleged violations were based only to those claims found in the Hasbro Presentation, the Q & A document, and the Draft Label suggestions. *Id*. Thus, he agreed with Microban that Pesticide Enforcement's arguments regarding Appendix E to the License and Supply Agreement — i.e., that the claims in Appendix E were incorporated by reference into each of Hasbro's purchase orders and thus were made as part of the distribution or sale — were untimely raised. *Id.*; *see also supra* note 12. We agree with his conclusion on this particular issue.

C. *Penalty Assessment*

In his most recent decision, the ALJ did not assess a penalty against Microban because he found Respondent not liable for any of the thirty-two violations alleged by Pesticide Enforcement. *See Remand Dec*. at 14. In an earlier decision, however, the ALJ had assessed a $5,000 fine per violation of FIFRA following a lengthy, two-day hearing on the question of the appropriate penalty in this matter. Init. Dec. Regarding Penalty at 3 (Nov. 8, 1999). Because we reverse the latest order of the ALJ in this decision and find Microban liable for thirty-two

counts, a penalty assessment is needed for these thirty-two violations. In cases such as these, the Board often remands the case back to the ALJ to determine an appropriate penalty. In the interest of expediting this matter, however, which has been in litigation since 1998 and twice before the Board, we will assess the penalty directly, relying upon the record and, in particular, the transcript of the 1999 penalty hearing and the ALJ's findings following that hearing. *See* 40 C.F.R. § 22.30(f) (authorizing the Board to "assess a penalty that is higher or lower than the amount recommended" by the ALJ or to remand the case for further action); *see also In re Tifa Ltd.*, 9 E.A.D. 145, 160-61 (EAB 2000) (assessing a penalty directly for the counts that were reversed on appeal in the interest of expeditiously settling the matter and because the factual record was fully developed); *In re Commercial Cartage Co.*, 7 E.A.D. 784, 804 (EAB 1998) (reversing the ALJ's liability determination as to one of the counts and assessing a penalty directly rather than remanding in the interest of expediting the matter, which had been before the Board two times and had been pending for five years).

EPA's regulations provide that a penalty should be "based on the evidence in the record and in accordance with any penalty criteria set forth in the Act." 40 C.F.R. § 22.27(b). The regulations also instruct the ALJ to "consider any civil penalty guidelines issued under the Act." *Id*. Although these directives are addressed specifically to the imposition of penalties by ALJs, the Board takes not only the statutory penalty criteria but generally any relevant penalty policies[35] into account when assessing a penalty. *E.g.*, *Tifa*, 9 E.A.D. at 161; *Commercial Cartage*, 7 E.A.D. at 805; *see also In re Antkiewicz*, 8 E.A.D. 218, 239 (EAB 1999) (considering the statutory factors as well as the FIFRA penalty policy in assessing a penalty).

Under FIFRA, the maximum civil penalty that may be assessed against any registrant for each offense is $5,000.[36] 7 U.S.C. § 136l(a)(1). Section 14(a)(4) of FIFRA enumerates three civil penalty factors that must be considered in assessing a penalty: "[1] the appropriateness of such penalty to the size of the business of the person charged, [2] the effect on the person's ability to continue in business, and [3] the gravity of the violation." 7 U.S.C. § 136l(a)(4); *accord Tifa*, 9 E.A.D. at 161.

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[35] Penalty policies are not binding upon ALJs or the Board because the policies, not having been subjected to the rulemaking procedures of the Administrative Procedure Act, 5 U.S.C. §§ 551-706, lack the force of law. *E.g.*, *In re CDT Landfill Corp.*, 11 E.A.D. 88, 119 n.57 (EAB 2003); *In re City of Marshall*, 10 E.A.D. 173, 189 n.29 (EAB 2001).

[36] Pursuant to the regulations implementing the Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, the maximum daily penalty amount allowed under section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), has increased to $5,500 for violations occurring after January 30, 1997. 40 C.F.R. § 19.4 (2003). In this case, one violation occurred after January 30, 1997. *See* Second Am. Compl. at 15 n.2; Tr. at 8 (noting that one of the thirty-two alleged violations occurred after the maximum penalty amounts changed). Thus, for this one violation, a maximum penalty of $5,500 may be assessed.

As mentioned *supra* Part II.B.1.c.i, EPA has issued a penalty policy with respect to the assessment of administrative penalties for violations of FIFRA. *See generally* ERP. The ERP recommends computing the penalty via a five-stage process. *Id*. at 18. These steps are: (1) determine the gravity of the violation; (2) determine the size of business category for the violator; (3) use the FIFRA penalty matrices to determine the dollar amount associated with that gravity level and that size of business category; (4) further adjust the gravity of the base penalty by considering the specifics of the pesticide involved, such as toxicity, the actual or potential harm to human health and/or the environment, the compliance history of the violator, and the culpability of the violator; and, finally, (5) consider the effect of the calculated payment on the ability of the violator to continue in business. *Id*.

In this case, Pesticide Enforcement proposed a total penalty of $160,500, which was based on thirty-one violations at $5,000 per violation and one violation at $5,500. Second Am. Compl. at 15; *see supra* note 36. Pesticide Enforcement considered the statutory penalty factors as well as the ERP criteria in arriving at this figure. *See* Second Am. Compl. at 14-15 & attach. (Penalty Calculation Worksheet); *see also* Tr. at 262-63.

In its post-penalty hearing brief, Microban argued that a penalty of no more than $1,000 per violation should be imposed. Resp't Reply to Compl't Proposed Findings of Fact and/or Conclusions of Law at 9. Microban disputed the gravity of the violation, arguing that: (1) its Additive "B" should not be considered a toxicity "1" pesticide and given a gravity adjustment value of "2"; (2) the gravity adjustment value for "potential serious or widespread harm to human health" is overinflated and based on "purported consumer views"; (3) the gravity adjustment value of "3" for "potential serious widespread harm to the environment" is similarly overinflated as Respondent has not undermined the credibility of the Agency's pesticide registration program, as Pesticide Enforcement has asserted; and (4) Respondent did not knowingly or willfully violate FIFRA and therefore the gravity adjustment value of "4" for culpability is too high. *Id*. at 1-9.

As the ALJ observed in his penalty assessment, it is indisputable from the evidence that Microban is a large company with gross revenues above a million dollars during the period of time covered by the complaint. Init. Dec. Regarding Penalty at 3; Tr. at 271. Furthermore, as the ALJ noted, Microban conceded that imposition of the fine proposed in the Second Amended Complaint would not have an effect on its ability to remain in business. Init. Dec. Regarding Penalty at 4 (citing Tr. at 10). We agree with the ALJ's conclusion that "with regard to the first two statutory criteria, the former criterion, which points to the imposition of a higher penalty for large companies, directs that such an enhanced penalty be imposed against the Respondent, while the latter criterion, as applied to the facts of this case, directs that there be no reduction in the penalty on that account, as the penalty will not impair Microban's ability to continue in business." *Id*. In fact,

using the first three steps of the ERP results in a base penalty of $5,000.[37] Thus, as the ALJ correctly concluded in his penalty assessment discussion, the key factor here is the gravity of the violations.

The ALJ determined that the gravity of the violation warranted a high penalty. *Id*. at 4. Looking closely at his analysis, it is evident that the main reason the ALJ found the gravity to be significant is because he determined that Microban's culpability was high. *See id*. (stating that the documents containing unapproved claims "blatantly departed from the scope of the approval" given to Microban by EPA in its registration and that Microban's departures from the approved registration language was "egregious"). The ALJ also noted that he could not "ignore, in terms of evaluating the gravity of the departures, the fact that Microban's version of the 1983 EPA registration approval conveniently omitted the critical limiting language that it was accepted only against non-health-related organisms. The redacted approval may have been sent out to potential customers." *Id*. at 5 (citations omitted). The ALJ, describing certain of Microban's arguments on this point as "disingenuous at best," also found that EPA did not, as Microban viewed it, change its position about claims it had approved for Microban and that EPA clearly informed Microban of what was allowed at the outset of the registration process.[38] Finally, the ALJ concluded that Microban's actions "interfered with the agency's ability to carry out its statutory mandate of protecting human health and consequently did harm to the regulatory program," warranting a substantial penalty.[39] *Id*. at 5-6 (citing Tr. at 80-83, 275). For all of these reasons, he imposed the statutory maximum per violation. We agree with his determination with respect to the gravity of the violations and thus also agree that the statutory maximum is appropriate for each of the thirty-two violations in the case. Thus, a penalty of $5,000 per violation is assessed (except for the sole violation that occurred after the statutory maximum was amended, for which a penalty of $5,500 is assessed), for a total penalty of $160,500.

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[37] Using the ERP, the "level" of this type of violation (step 1) is "2" and the size of business category (step 2) is "I." Plugging these two values into Table 1 of the ERP (step 3) results in a dollar amount associated with this gravity and this size of business of $5,000. *See* ERP at 18-20 & app. A.

[38] We agree with the ALJ's statement in an earlier decision that "[c]learly these documents show a consistency on Microban's part to achieve via a backdoor route what EPA had not approved: associating the effectiveness of the product against health related organisms." Partial Accel. Dec. at 18.

[39] This is consistent with Board precedent, as we have previously stated that harm to a regulatory program is sufficient to justify a substantial penalty. *E.g.*, *In re Arapahoe County Weed Dist.*, 8 E.A.D. 381, 392 & n.14 (EAB 1999) (harm to FIFRA program); *In re Predex Corp.*, 7 E.A.D. 591, 601 (EAB 1998) (same); *In re Green Thumb Nursery, Inc.*, 6 E.A.D. 782, 800-01 (EAB 1996) (same); *see also In re Phoenix Constr. Servs.*, 11 E.A.D. 379, 395-400 (EAB 2004) (holding that a substantial penalty may be assessed due to harm to the Clean Water Act section 404 permit program); *In re Friedman*, 11 E.A.D. 302, 345-46 (EAB 2004) (holding that harm to the asbestos regulatory program can result in a significant penalty).

We further find that, although the ALJ predominantly relied on the statutory criteria and not the penalty policy in his 1999 penalty assessment,[40] applying his general findings and rationale to the ERP would similarly result in a $5,000 (or $5,500) penalty per violation. Although, as we indicated earlier, the FIFRA penalty policy is not binding, *see supra* note 35, we consider it below because, as we have stated on several occasions, "penalty policies serve to facilitate the application of statutory penalty criteria and, accordingly, offer a useful mechanism for ensuring consistency in civil penalty assessments." *In re CDT Landfill Corp.*, 11 E.A.D. 88, 117 (EAB 2003); *accord Friedman*, 11 E.A.D. at 341-42 n.42; *In re Chempace Corp.*, 9 E.A.D. 119, 131 (EAB 2000); *In re DIC Americas, Inc.*, 6 E.A.D. 184, 189 (EAB 1995) (citing *In re Great Lakes Div. of Nat'l Steel Corp.*, 5 E.A.D. 355, 374 (EAB 1994)).

Under step 4 of the ERP, to warrant a reduction in the base penalty generated in step 3 (i.e., $5,000 or $5,500 for the last violation), the sum total of all gravity adjustment values must be less than "8." As the ALJ found, see discussion above, and we likewise find, the evidence demonstrates that Microban has a high culpability in this matter. Under the ERP, this level of culpability would lead to a gravity adjustment value of "4" for the "culpability" criterion.

The ALJ also found that Microban's actions harmed the regulatory program. The ERP's two gravity adjustment criteria that deal specifically with harm, i.e., the "harm to human health" and the "environmental harm" criteria, do not explicitly mention "harm to the regulatory program," nor do they equate a value for such harm. We have, however, previously affirmed a presiding officer's assignment of a value of "3" to *both* the "environmental harm" and "harm to human health" criteria where the risks to the environment and to human health were unknown and respondent's actions were harmful to the FIFRA regulatory program. *In re Sultan Chemists, Inc.*, 9 E.A.D. 323, 351 (EAB 2000), *aff'd*, 281 F.3d 73 (3d Cir. 2002). *But see In re Predex Corp.*, 7 E.A.D. 591, 601 (EAB 1998) (affirming an ALJ's decision to impose a nominal penalty where the respondent acted in good faith, there was no harm to human health or the environment, but there was harm to the regulatory program). The result in *Sultan* is generally consistent with our cases, cited above, in which we have found "harm to the regulatory program" to justify a substantial penalty. *See supra* note 39 and accompanying text; *see also In re Safe & Sure Prods., Inc.*, 8 E.A.D. 517, 529-30 (EAB 1999) (stating that "even if Respondents' products posed no risk to health or the environment, Respondents' failure to register its establishment or pesticide products 'deprives the Agency of necessary information and therefore weakens the statutory scheme,'" thus justifying a substantial penalty).

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[40] The ALJ did not use the ERP *per se* in his analysis because he found that some of Pesticide Enforcement's gravity determinations under that policy were overstated. *See* Init. Dec. Regarding Penalty at 3 & n.7.

Looking more closely at the ERP with respect to the "harm to human health" gravity adjustment criterion, the policy assigns a value of "3" for "potential serious or widespread harm to human health" or where the "harm to human health is unknown," and assigns a value of "1" where there is "minor potential or actual harm to human health, neither serious nor widespread." ERP app. B-1. Pesticide Enforcement argues that "[u]nsubstantiated public health claims made about antimicrobial pesticides pose a serious risk to human health because consumers may rely on products whose claims have not been supported by test results that show effectiveness against human pathogens. Relying on unsupported claims, consumers may fail to take protective measures that they might otherwise take and thereby expose themselves to pathogens." Compl't Br. in Support of Proposed Findings of Fact and/or Conclusions of Law at 4-5. Pesticide Enforcement further argues that, because Microban's pesticide is incorporated "into nationally-marketed products, even if a small fraction of U.S. consumers are misled, this creates the *potential* for *widespread* harm, which fully justifies the assignment of a gravity value of '3.'"[41] *Id*. at 3. Pesticide Enforcement also points out that any harm that arises because of these claims could be very serious, possibly fatal. Compl't Reply to Resp't Proposed Findings of Fact and/or Conclusions of Law at 3. Microban responds to this argument by claiming that the pesticide itself is not toxic to humans through contact with the toys containing it. Resp't Reply to Compl't Proposed Findings of Fact and/or Conclusions of Law at 4-5 (citing statements by EPA witnesses and counsel). Respondent also asserts that Pesticide Enforcement's arguments about the potential for widespread harm are merely opinion and speculation. *Id.* Although Microban has provided evidence that toys containing its pesticide are not inherently toxic, they have not provided evidence showing that the unapproved claims would not cause harm.

Based on the information cited by Pesticide Enforcement, in particular Microban's survey, we find that there is some evidence of potential serious or widespread harm due to Microban's violations. Even if a small percentage of the population is misled by the claims disseminated by Microban, this could cause serious harm to those individuals and their families. Thus, we conclude that, at a minimum, the "harm to human health" factor should merit at least a value of "3" based on the more than minor potential for harm as well as the harm to the regulatory program. In fact, if we were to conclude that the level of harm due to Respondent's violations is unknown, the value would still be "3." *See In re Ankiewicz*, 8 E.A.D. 218, 240 (EAB 1999).

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[41] Pesticide Enforcement relies on a Microban-sponsored consumer survey that indicates that a percentage, albeit small (2%), of consumers incorrectly believe that products treated with Additive "B" do not need normal washing and cleaning to remove pathogens. *See* Compl't Reply to Resp't Proposed Findings of Fact and/or Conclusions of Law at 3 & n.7 (citing Ex. 115). Pesticide Enforcement suggests that even this relatively low percentage is surprising, as the questions in the survey are worded in a manner allegedly favorable to Microban. *Id.*

Starting with a value of "4" for culpability and a value of "3" for human health, even assuming the lowest values for all other categories, including a value of "1" for both "environmental harm" and "toxicity," the lowest total gravity adjustment value would be a "9" and therefore would not lead to a downward adjustment of the base penalty. Accordingly, using the ERP, the resultant final penalty per violation would be $5,000 (or $5,500 for the violation occurring after January 30, 1997), with a total penalty of $160,500 — the same penalty we found appropriate above.

III. *CONCLUSION*

For the foregoing reasons, the ALJ's decision on remand is reversed. We find Microban liable for thirty-two violations of FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), and assess a total penalty of $160,500 against Respondent. Payment shall be made within thirty (30) days of this final order, by cashier's check or certified check payable to the Treasurer, United States of America, and forwarded to:

United States EPA - Washington
Hearing Clerk
Post Office Lock Box 360277M
Pittsburgh, PA 15251-6277

So ordered.