UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF:	)	
	)	
	)	
E.I. DU PONT	)	
DE NEMOURS & CO., INC.	)	DOCKET NO. FIFRA-95-H-02
	)	
Respondent	)	

INITIAL DECISION [(1)]

This is a civil administrative proceeding instituted pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. The complaint was issued on October 7, 1994, by the Director of Toxics and Pesticides Enforcement Division in the Office of Regulatory Enforcement (Complainant). The Complainant alleges that Respondent violated section 12 of FIFRA, 7 U. S. C. § 136j when it sold and distributed misbranded registered pesticides Du Pont Bladex 4L Herbicide (EPA Reg. No. 352-470), Du Pont Bladex 90 DF Herbicide (EPA Reg. No. 352-495), Du Pont Extrazine II 4L Herbicide (EPA Reg. No. 352-500) and Du Pont Extrazine II DF Herbicide (EPA Reg. No. 352-577). The complaint alleges that, between April 1, 1994 and April 26, 1994, Respondent made 32 shipments of misbranded Bladex 4L (Count I), 10 shipments of misbranded Bladex 90 DF (Count II), 325 shipments of misbranded Extrazine II 4L (Count III) and 12 shipments of misbranded Extrazine II DF (Count IV). [(2)]

According to the complaint, each shipment (379 in all) of Bladex 4L, Bladex 90 DF, Extrazine II 4L and Extrazine II DF constituted a violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E) because the Respondent sold and distributed pesticides that were misbranded. Complainant found that Respondent's July 14, 1993 proposed amended labels for Bladex 4L, Bladex 90 DF, Extrazine II 4L and Extrazine II DF "contained error(s) which may create a potential for serious harm to workers, handlers, other persons or the environment, or prevent the achievement of the basic goals of FIFRA." Respondent submitted the proposed label changes in response to the Worker Protection Standard, 57 Fed. Reg. 38102 (1992) (codified at 40 C.F.R. §§ 156 and 170), and its associated labeling guidance. The proposed amended labels, the complaint states, were "not adequate to protect health or the environment."

The complaint points out that Respondent had been sent a Notice of Serious Error for the proposed labels for Bladex 4L, Bladex 90 DF, Extrazine II 4L and Extrazine II DF on March 11 and 14, 1994. The Notices of Serious Error informed the Respondent that approval of its amendment to the Extrazine and Bladex labels would be granted only if Respondent made changes to comply with the Worker Protection Standard rule. In addition, Respondent was directed not to sell or distribute (including release for shipment) any product bearing the proposed amended labels Respondent submitted to the Agency on July 14, 1993. All of the shipments cited in the complaint were shipped subsequent to the Notices of Serious Error.

The complaint points out that a pesticide is misbranded pursuant to FIFRA § 2(q)(1)(F) "if the labeling accompanying the pesticide does not contain directions for use which are necessary for effecting the purpose for which the product is intended and, if complied with, together with any requirements imposed under section 3(d) of the Act, are adequate to protect the health and the environment." In addition, the complaint cites FIFRA § 2(q)(1)(G) which defines a pesticide as misbranded "if the label does not contain a warning or a caution statement which may be necessary and if complied with, taken together with any requirements imposed under section 3(d) of the Act, is adequate to protect the health and the environment." The Complainant requests assessment of a penalty of $5,000 per violation, or $1,895,000 for the 379 violations.

In answer to the complaint, Respondent admitted that it is a person as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s); that it is a registrant as that term is defined by section 2(y) of FIFRA, 7 U.S.C. § 136(y); that it produces Bladex 4L, Bladex 90 DF, Extrazine II 4L and Extrazine II DF and that the Bladex and Extrazine products are registered with U.S. EPA as herbicides under the registration numbers cited in the complaint; that it submitted, on July 14, 1993, the proposed amended labels for Bladex 4L, Bladex 90 DF, Extrazine II 4L and Extrazine II DF in response to the WPS and the associated labeling guidance; and that Complainant issued to Respondent a "Notice(s) of Serious Error" on March 11, 1994 and March 14, 1994 which directed Respondent not to sell or distribute (including release for shipment) any product bearing the submitted labeling.

Respondent stated in its answer that it did not believe the Notices of Serious Error were legally binding because the labels had been approved by EPA on November 4, 1993 and the WPS labeling requirements did not have to "implemented" until April 21, 1994. Respondent denied that the labels were not adequate to protect the health and the environment. Respondent conceded in its answer that it shipped Bladex 4L, Bladex 90 DF, Extrazine II 4L and Extrazine II DF "on or about the dates alleged and in the amounts alleged" in the complaint with WPS labels submitted to the Agency in July 1993. However, Respondent denied that the shipments were misbranded as alleged in paragraph 14 of the complaint. Respondent stated in its answer that it would demonstrate 15 defenses to the allegations in the complaint.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Respondent violated FIFRA § 12(a)(1)(E) by selling and distributing misbranded pesticides as alleged in the complaint.

Misbranding Under FIFRA § 2(q)(1)(G)

The complaint charges Respondent with violating FIFRA § 12(a)(1)(E). Section 12(a)(1)(E) states that "it shall be unlawful for any person in any State to distribute or sell to any person . . . any pesticide which is . . . misbranded." 7 U.S.C. § 136j(a)(1)(E). Misbranding is defined in FIFRA § 2(q). Section 2(q)(1)(G) of FIFRA, the section that Complainant charges Respondent has violated, [(3)] classifies a pesticide as misbranded if "the label does not contain a warning or caution statement which may be necessary and if complied with . . .is adequate to protect health and the environment." An examination of the definition of the phrase "protect health and the environment," [(4)] establishes its meaning as "protect against any unreasonable risk to man or the environment." In other words, to sustain a charge of misbranding under section 2(q)(1)(G), Complainant must show that the products at issue bore labels that lacked a warning or caution statement

that "may" have been necessary and if complied with was adequate to "protect against any unreasonable risk to man or the environment."

In the instant case, Complainant alleges that Respondent sold and distributed the Bladex and Extrazine products with labels that did not include a warning or caution statement required by the WPS rule. Specifically, Complainant charges that Respondent failed to include on the labels a statement that protective eyewear was required personal protective equipment ("PPE") for early entry workers. The WPS rule is an Agency determination that protective eyewear and other early entry PPE were necessary to mitigate "unreasonable risks" to agricultural workers from on the job pesticide exposures.(5) To address these unreasonable risks, the Agency, "drawing on its expertise in regulating pesticides" determined that early entry PPE and seven other simple measures were "likely to reduce substantially the number of pesticide-related illnesses and injuries to agricultural employees." 57 Fed. Reg. 38,102, 38,105.

PPE requirements for early entry workers are determined based upon the toxicity category of the pesticide. For pesticides in toxicity categories I and II for eye irritation, 40 C.F.R. § 156.212(e) directs that protective eyewear is to be worn as PPE by applicators and other handlers. 40 C.F.R. § 156.212(j)(1) directs that if protective eyewear is required for applicators and handlers it is also required for early entry workers. Pursuant to 40 C.F.R. § 156.212(c)(2) protective eyewear for early entry workers is to be listed in the Agricultural Use Requirements box on the labels affixed to pesticides in toxicity categories I and II.

To come into compliance with the new WPS rule registrants were required to amend the labels of affected products. The WPS rule and its associated labeling guidance, PR Notices 93-7 and 93-11 provided several options for registrants seeking to come into compliance with the rule's requirements. For the Bladex and Extrazine products, Respondent chose the "complete and exact compliance" self-verification option detailed in PR Notice 93-11. Under this option Respondent was required to certify that the labeling instructions in PR Notice 93-7 were followed exactly. This allowed Respondent to sell or distribute product with revised labeling that had not yet been stamped as accepted by EPA, subject to final review and approval by the Agency. If Respondent felt that the requirements of PR Notice 93-7 and the WPS rule resulted in a label that was overprotective, it had the option of proposing a deviation from the labeling changes pursuant to 40 C.F.R. § 156.204(b).

Respondent's Misbranded Labels

On July 14, 1993, Tony Catka, Respondent's product registration manager for its Extrazine and Bladex products, submitted proposed WPS label amendments for the Bladex and Extrazine products. CX 6-9. As required, Mr. Catka included with each WPS label amendment application an indication of the product's toxicity. 40 C.F.R. 156.212(d); CX 20 at Supp. 2, pp. 4, 5-6. For the two Bladex products, Mr. Catka stated that the acute toxicity category for eye irritation potential was category II. CX 8-9 at 3. Mr. Catka testified that at the time he was preparing the proposed WPS label amendments he could not locate eye irritation studies for the two Extrazine products and so left the toxicity category for eye irritation blank. Tr. III-54-55; CX 6-7 at 3. Accordingly, pursuant to 40 C.F.R. § 156.212(d)(2) and PR Notice 93-7, the Extrazine products were defaulted to category II, which equated to the products' signal word of "Warning."(6) The label amendments included what Mr. Catka characterized as Respondent's "Certification of exact compliance statement including toxicity category values," as well as a certification that the information contained in each of the label amendment applications was "true, accurate and complete." CX 6-9 at 2.

EPA reviewed the label amendment applications submitted by Respondent. Based on Respondent's certifications, EPA, on March 11, 1994, issued to Respondent a Notice of Serious Error concerning Respondent's proposed amended label for Bladex 4L. On March 14, 1994, EPA issued similar Notices of Serious Error to Respondent concerning Respondent's proposed label amendments for Bladex 90 DF, Extrazine II DF and Extrazine II 4L. These notices stated that the proposed labels contained one or more serious errors "that may create a potential for harm to workers, handlers,

other persons, or the environment," or "prevent the achievement of the basic goals of FIFRA." CX 22-25 at 1. The notices also informed Respondent that EPA could approve the proposed amended labels only if specified changes were made and stated that Respondent "**MUST NOT SELL OR DISTRIBUTE** (INCLUDING RELEASE FOR SHIPMENT) **ANY PRODUCT BEARING THE SUBMITTED LABELING**." CX 22-25 (emphasis in original). Respondent received these notices on March 16, 1994 and March 22, 1994 respectively. Tr. III-90-91 (Catka).

Upon receiving the Notices of Serious Error, Respondent sought to contact EPA for clarification of the substance of the errors. Throughout the remainder of March and April Mr. Catka, and his supervisor Richard Holt, exchanged telephone calls and letters with James Tompkins (at the time Deputy Branch Chief in the Registration Support Branch of the Registration Division of the Office of Pesticide Programs at EPA's Headquarters), Dean Ziegel (an attorney with the Toxics Peticides Enforcement Division in the Office of Regulatory Enforcement, at the time a case development officer in the Office of Compliance Monitoring) and others at the Agency involved in the WPS label amendment process in an effort to resolve the labeling errors. However, despite the fact that the Notices of Serious Error instructed Respondent not to sell or distribute the Bladex and Extrazine products bearing the submitted labels, Respondent continued to ship the products throughout the month of April.

At hearing and in its pleadings Respondent has made an array of legal and factual arguments contesting Complainant's misbranding charges. These arguments are aimed on the one hand at Complainant's use of the WPS rule as a standard for misbranding and on the other at what it asserts is Complainant's lack of proof of its charges. These arguments will be considered in turn below.

Respondent challenges the use of the WPS rule as a standard for misbranding primarily on two grounds. First, Respondent asserts that the WPS rule was promulgated pursuant to FIFRA's use provision, section 12(a)(2)(G), 7 U.S.C. 136j(a)(2)(G), and that nothing in the WPS final rule or in the notice of proposed rulemaking provided notice that the Agency was intending to establish a standard for misbranding (citing 57 Fed. Reg. 38,102).[(7)] Because, Respondent asserts, Complainant's effort to enforce the WPS rule as a misbranding standard is undertaken without adequate notice to regulated parties that the WPS establishes such a standard, and without providing regulated parties an opportunity to comment on the standard, Complainant's action is contrary to fundamental due process and the Administrative Procedure Act. Respondent cites a line of fair notice cases involving administrative agencies in support of its argument. See, e.g., Rollins Environmental Services v. EPA, 937 F.2d 649 (D.C. Cir. 1991), Gates and Fox Co., Inc. V. OSHRC, 790 F.2d 154 (D.C. Cir. 1986); Diebold v. Marshall, 585 F.2d 1327 (6th Cir. 1978); In re: CWM Chemical Services, Inc., et al., TSCA Appeal No. 93-1, 6 E.A.D. 1 (Order on Interlocutory Appeal, EAB, May 15, 1995).

Respondent Had Adequate Notice of the Misbranding Standard

Respondent's arguments on this point are not persuasive. An examination of the WPS Final Rule as published in the Federal Register demonstrates that the Agency did provide notice to registrants that a violation of the WPS rule could lead to a charge of misbranding. Subsection B (Registrant Compliance) of part VI of the preamble to the final rule clearly puts registrants on notice that failure to comply with the WPS rule could result in a misbranding charge. Subsection B(1)(d)(vi) states that "[i]f, after a certification is reviewed, the Agency determines that the registrant has incorrectly labeled the product, the product may be deemed to be misbranded in violation of FIFRA section 12(a)(1)(E). . . ." 57 Fed. Reg. 38,102, 38,144. Similar language was included in the notice of proposed rule. 53 Fed. Reg. 25,970, 26,001 (July 8, 1988). The fact that the possibility of a section 12(a)(1)(E) misbranding charge was noted in both the proposed rule and the final rule put Respondent on notice of the conduct required under the rule.

This distinguishes the case at bar from the line of due process fair notice cases cited by Respondent. Those cases establish that an Agency must provide notice of the particular conduct required or prohibited by a regulation before it can impose civil or criminal sanctions for a violation of that regulation. Here, as just

described, such notice was provided. Moreover, the Notices of Serious Error constitute "pre-enforcement warning" to Respondent that failure to comply with the WPS rule could lead to an enforcement action under FIFRA § 2(q)(1)(F) and (G). See General Electric Co. v. U.S. EPA, 53 F.3d 13324 (D.C. Cir. 1995) (Agency's pre-enforcement contact with regulated party may provide notice for due process purposes); B.J. Carney Inds., Inc, CWA Appeal No. 96-2, (Remand Order, EAB, June 9, 1997) slip op. at 33 (same).

Complainant's Enforcement Action Is Consistent With the Statutory Scheme

Respondent's second argument is that EPA failed to make the product specific determination of unreasonable risk which it argues is necessary to establish a substantive standard for misbranding under FIFRA §§ 2(q)(1)(F) or (G). Respondent asserts that extensive FIFRA case law establishes this proposition and relies in particular on In the Matter of Stevens Industries, Inc., et al., 1 E.A.D. 9 (Opinion of the Administrator, June 2, 1972). Moreover, Respondent argues, the FIFRA statutory scheme as a whole demonstrates that Congress did not intend for the Agency to set standards for misbranding under section 2(q)(1)(G) by regulation. Respondent points to section 2(q)(1)(B), which specifically references Agency regulations, as proof that if Congress had intended for the Agency to set 2(q)(1)(G) misbranding standards by regulation it would have specifically provided for such action in the statute.

Respondent's reliance on Stevens Industries for the proposition that the Agency must make a product-specific finding of unreasonable risk is misplaced. In Stevens Industries the Agency was not enforcing a standard established by a duly promulgated regulation. The significance of this difference is amplified by the fact that FIFRA § 25(a), 7 U.S.C. 136w(a),[(8)] which explicitly authorizes the Agency to "prescribe regulations to carry out the provisions of this subchapter" had not yet been enacted when the Administrator issued his decision in Stevens Industries.[(9)] Moreover, a reading of the plain language of sections 2(q)(1)(F) and (G) does not support Respondent's interpretation. Neither section makes mention of a need for a specific risk determination. The Agency, in promulgating the WPS rule, made a finding of generalized unreasonable risk of pesticide related injury to agricultural employees and determined that PPE, including protective eyewear was necessary to mitigate those risks for early entry agricultural workers. 57 Fed. Reg. 38102, 38,105. The Agency relied on Assoc. Builders and Contractors, Inc. v. Brock, 862 F.2d 63, 68 (3d Cir. 1988), as legal authority for the proposition that a generalized risk determination is sufficient in instances where reaching individualized risk determinations would unnecessarily impair the Agency's ability to carry out its statutory duty to protect agricultural workers.

Respondent's argument that the FIFRA statutory scheme does not contemplate the establishment of misbranding standards by regulation under section 2(q)(1)(G) is also unavailing. Contrary to what Respondent argues, the specific reference to standards established by the Administrator in section 2(q)(1)(B) is not indicative of an intent to limit the Agency's authority under section 2(q)(1)(G). Rather, in light of the broad regulatory authority granted under section 25(a) and FEPCA's legislative history,[(10)] the language of section 2(q)(1)(B) indicates a congressional intent to impose a limit on only section 2(q)(1)(B).

Respondent's Challenge to the WPS Rules Is Untimely

In essence, Respondent, although it disclaims such an intent, is challenging the WPS rule itself. As just explained, the WPS rule provided notice to registrants that failure to comply with the rule could lead to charges of misbranding. With notice of that possibility, if Respondent believed that a generalized determination of unreasonable risk was not an adequate ground to support a charge of misbranding, it had the opportunity to challenge the rule in court at the time it was promulgated. Similarly, if Respondent believed, as it argues here, that Associated Builders is inadequate legal authority for the Agency's actions the proper time and place to raise that issue was in a challenge to the rule, not an enforcement action. It is well settled that challenges to a rule in an enforcement proceeding

are disfavored and Respondent has provided no reason to entertain such a challenge in this case. In re Norma Echevarria et al. d/b/a Echeco Environmental Services, CAA Appeal No. 94-1, 5 E.A.D. 626, 634 (Final Decision, EAB, Dec. 21, 1994); In re Woodkiln, CAA Appeal No. 96-2, 1997 EPA Lexis 14, at *34-35 (Final Decision, EAB, July 17, 1997); B.J. Carney Inds., Inc., CWA Appeal No. 96-2, slip op. at 32, 1997 EPA Lexis 7 (Remand Order, EAB, June 9, 1997).

To summarize, it is held that the WPS rule establishes a standard for misbranding under section 2(q)(1)(G). Proof that Respondent failed to include a warning or caution statement required by the WPS rule on the labels of the Bladex and Extrazine is sufficient to establish that the labels were misbranded under FIFRA § 2(q)(1)(G).

2. Complainant Has Demonstrated that the Products Cited in the Complaint Were Misbranded.

Complainant Correctly Relied on Respondent's Designation of Toxicity Categories In Its Amendments to the Bladex and Extrazine Registrations.

Respondent's second line of argument focuses on what it terms Complainant's "lack of proof," in particular Complainant's use of the label amendment applications submitted by Respondent to establish the toxicity categories for the Bladex and Extrazine products. First, Respondent asserts that Complainant bears the burden of demonstrating that the labels on the Bladex and Extrazine products violated the WPS rule and that in order to carry this burden Complainant must show that the repondent's products at issue fell into toxicity category II for eye irritation. Respondent contends that Complainant introduced no independent document stating that the Bladex and Extrazine products fall into toxicity category II and that the testimony of Complainant's own witness, toxicologist Dr. William Dykstra, demonstrated that these products are in fact in toxicity category III for eye irritation. (11)

Respondent's arguments are unfounded. First, it is found that EPA properly relied upon Respondent's label amendment applications in reaching a determination that the Bladex and Extrazine products were misbranded. As Dr. Dykstra (a toxocologist in the Health Effects Division in the Office of Pesticide Programs) testified, given the large number of WPS label submissions it was essential to the success of the program that EPA rely on the representations of Respondent and other registrants and assume that they had performed a proper review of relevant studies.(12) Tr. I-252-53. This did not, as Respondent argues, constitute an improper delegation of the Agency's duty to determine the toxicity categories.(13) Respondent acknowledged at the hearing that the toxicity categories for the Bladex and Extrazine products were determined by the Agency as part of the initial registration process.(14)

In the event that the WPS rule and its labeling guidance, PR Notices 93-7 and 93-11, resulted in label language that a registrant believed to be overprotective, the WPS rule provided a procedure for registrants to follow. As part of the WPS label amendment process registrants were instructed to review toxicity data in their files. (15) After that review they could either certify that the Agency's determinations had not changed, or propose changes through a regulatory waiver/modification procedure. (16) Respondent did not avail itself of the opportunity to request a waiver or modification. Under the circumstances the Agency had no duty, as Respondent tries to suggest, to review data and verify Respondent's certifications or to request additional data.

Second, the testimony of Dr. Dykstra on the issue of the appropriate toxicity categories for the Bladex and Extrazine products relied on by Respondent is irrelevant because it does not relate to the determination of the toxicity categories at the time the label amendment applications were submitted. Moreover, even assuming that Dr. Dykstra's testimony on this issue is relevant, Respondent mischaracterizes it.

It is correct, as Respondent states, that Dr. Dykstra testified that technical cyanazine falls into category III for eye irritation, and that technical atrazine is classified in category IV.[(17)] Tr. I-257-58. However, after making the statements relied upon by Respondent, Dr. Dykstra went on to state that the toxicity categories for technical cyanazine and atrazine do not necessarily correspond to the toxicity categories for a product formulation made up of technical cyanazine and/or atrazine and other inert ingredients. Tr. I-255-56. Specifically, Dr. Dykstra testified that it may be that the inert ingredients cause eye irritation that does not occur with the technical ingredients alone and that "you have to be really specific . . . because it really comes down to the results of these particular studies done with that particular product." Tr. I-256, 306 Further, on cross examination, in response to the question "there is no reason to believe that Bladex or Extrazine would be in any other than tox [sic] category III or IV; right?" Dr. Dykstra replied "Well I don't agree with that. . . ." Tr. I-255.

Similarly, Respondent quotes Dr. Dykstra as stating that "all of the studies that were handed in at pretrial, which I looked over, were of Toxicity Category III." Tr. I-262. This quote is offered as proof that Dr. Dykstra considered the Bladex and Extrazine products to be in toxicity category III. However, Dr. Dykstra later testified that he neither did scientific analysis of these studies nor prepared any reports on them and characterized his review of them as "cursory." Tr. I-299.

Finally, Respondent's assertion that Dr. Dykstra agreed that Bladex 4L is in category III for eye irritation also mischaracterizes Dr. Dykstra's testimony. Respondent's counsel asked Dr. Dykstra to "assume" that the study he was looking at was done with Bladex 4L after he told counsel that he had "no way of knowing" whether the pesticide that was the subject of the study counsel directed him to look at was identical in composition to Bladex 4L, "or even what the inert ingredients [were] for this [pesticide]." Tr. I-295-96. Taken as a whole, Dr. Dykstra's testimony, even if accepted as relevant, does not reflect his agreement with Respondent's claim that the Bladex and Extrazine products did not belong in toxicity category II.

The Record Does Not Support Respondent's Claim that It Mistakenly Misclassified the Toxicity Categories for the Bladex and Extrazine Products.

Respondent next argues that the certifications on its label amendment applications cannot be used to establish its liability because the toxicity classifications for the Bladex and Extrazine products are incorrect and/or the result of errors corrected in testimony at the hearing. Specifically, Respondent points to the testimony of Tony Catka, Respondent's Product Registration Manager for the Bladex and Extrazine products. Mr. Catka testified that he knew Bladex 4L was actually in category III for eye irritation but that when he reviewed the final draft of the label amendment application he did not enter that information on the application form that was filed. This error caused Bladex 4L to be erroneously listed as toxicity category II. Tr. III-44-45, 152. As for Bladex 90 DF, Mr. Catka testified that he made a mistake in reading the summary of a Bladex 90 DF eye irritation study when he filled out the label amendment form. Tr. III-47. In the case of the Extrazine products, Mr. Catka testified that the toxicity category designation was left blank because he could not locate eye irritation studies for them. Because the toxicity category was left blank, their classification was determined by the default procedure. Tr. III-51, 55-56. Mr. Catka testified that he subsequently located relevant studies and that they demonstrate that the Extrazine products are properly classified in toxicity category III. Tr. III-56.

Respondent submits that Complainant cannot rely on the admitted errors of Mr. Catka in recording the toxicity categories of the Bladex label applications and the blank statement on the Extrazine label amendments to prove that its products were in category II. Respondent argues that it is entitled to correct Mr. Catka's errors through the presentation of testimony at hearing. In support of its argument, Respondent cites a series of Clean Water Act cases which provide that a Respondent may, as a defense to liability in an enforcement action, demonstrate that errors were made in compiling the reports that establish the basis for the alleged violations. See, e.g., In the Matter of American Cyanamid Co. et al., NPDES Appeal

Nos. 92-18, 92-8, 4 E.A.D. 790, 797 n.6 (Order Denying Review, EAB, Sept. 27, 1993); Public Interest research Group v. Yates Industries, 757 F.Supp. 438, 447 (D.N.J. 1991); Friends of the Earth v. Facet Enterprises, Inc., 618 F.Supp. 532, 536 (W.D.N.Y. 1984).

This defense is not supported by the record. In their communications with the Agency subsequent to receiving the Notices of Serious Error, neither Mr. Catka nor Mr. Holt, Mr Catka's supervisor, ever suggested that the Bladex and Extrazine products belonged in a toxicity category other than II. These communications contradict Mr. Catka's hearing testimony that he "knew" that Bladex 4L was category III at the time he filled out the label amendment applications and undermine Respondent's contention that the Bladex and Extrazine products were given incorrect toxicity category designations.

In a March 31, 1994 letter from Mr. Catka to Mr. Michael Wood, Director of the Compliance Division, Mr. Catka makes no mention of his knowledge that Bladex 4L, or any of the other pesticides at issue here, were category III and therefore did not need a protective eyewear statement for early entry agricultural workers; Mr. Catka merely states his belief that workers would be protected by the language proposed on July 14, 1993. CX 11, Exhibit B. The proposed label changes attached to this letter indicate that protective eyewear is to be included on the amended label for each of the four products at issue.

Nor does Mr. Catka make any mention of his knowledge concerning Bladex 4L in his April 7, 1994 letter to Mr. Tompkins and Mr. Ziegel. CX 11, Exhibit C. In that letter, Mr. Catka explained why Respondent believed that, in practical terms, the labels it submitted in July of 1993 would provide adequate protection to early entry workers.[(18)] Mr. Catka did not dispute that the Bladex and Extrazine products belonged in toxicity category II and in fact stated that "[i]t is correct that the WPS tox [sic] category for eyes is Category II in Box 10 of the worksheet for each of the subject products." CX 11, Exhibit C at 2. Mr. Catka testified that at no time between October 1993 and the end of April 1994 did he inform the Agency that it had in its data base studies which demonstrated that the Bladex and Extrazine products were in toxicity category III. Tr. III-185. Mr. Catka also testified that he did not come to the conclusion that Bladex 90 DF was category III until some time after the label problems with EPA arose and that he did not reach the conclusion that the Extrazine products were category III until sometime in 1997, more than two years after the complaint was brought. Tr. III-56.

Finally, Mr. Catka testified that he understood -- and the evidence supports his understanding-- all four products to be toxicity category II at the time he filled out the labels. Tr. III-151. In other words, contrary to Respondent's characterization of Mr. Catka's actions in filling out the label amendment applications as "mistakes," Mr. Catka made no mistake in certifying the Bladex and Extrazine products as toxicity category II.[(19)] Only for Bladex 4L did Mr. Catka conceivably make a mistake and his testimony on this point lacks credibility in light of his actions subsequent to receiving the Notices of Serious Error as described above. When the label amendment applications were completed they were accurate and Respondent has made no showing to the contrary.[(20)]

Respondent's effort to prove that the toxicity categories were incorrect through its submission of studies which it asserts prove that the Bladex and Extrazine products do not belong in category II is rejected on similar grounds. Respondent has made no showing that these studies were submitted to the Agency for consideration during the course of the label amendment process. Furthermore, respondent's assertion and proffered testimony that these studies place the Bladex and Extrazine products in a lower toxicity category is speculative; respondent does not know how the Agency would classify these products if theses studies were presented for formal review. As respondent itself points out, only the Agency is permitted to change a registration after reviewing an application for amendment.

Respondent's Labels on the Extrazine and Bladex Products Did Not Have the Required Protective Eyewear Statement. Therefore, They Were Inadequate to Protect Against

Any Unreasonable Risk of Eye Injury.

Remaining to be decided under FIFRA § 2(q)(1)(G), then, is whether the Bladex and Extrazine products lacked the required language on their labels and whether the protective eyewear statement, if complied with, was adequate to protect human health and the environment. James Tompkins, Deputy Branch Chief, Registration Support Branch, Registration Division, Office of Pesticides Programs, testified at the hearing that Respondent failed to list protective eyewear for early entry workers in the Agricultural Requirements box for each of its four July 14, 1993 label amendment submissions. Tr. I-101-02. Mr. Tompkins testimony is supported by the label amendment submissions themselves, which were entered into evidence as Complainant's exhibits 6 through 9. See CX 6-9 at 7. Moreover, Respondent, in its answer states that the Bladex and Extrazine products at issue bore labels with WPS language "identical to that submitted to EPA on July 14, 1993." See Respondent's Answer at 3, ¶ 13; 4 ¶ 23; 5 ¶ 33; 7 ¶ 43; and 7 ¶¶ 2-3.[(21)] Accordingly, it is found that the Bladex and Extrazine shipments named in the complaint were shipped with labels lacking the required protective eyewear statements.

The final element of misbranding under section 2(q)(1)(G) is a showing that the protective eyewear statement, if complied with, was adequate to protect against an unreasonable risk of eye injury to early entry agricultural workers exposed to category II pesticides. The adequacy of the required label warnings in the instant case is determined pursuant to the WPS rule. In promulgating the WPS rule, the Agency made a generalized determination of unreasonable risk and determined that protective eyewear would be adequate to protect against unreasonable risks for pesticides in category II for eye irritation. 57 Fed. Reg. 38,102, 38,117, 38,119-20. Because the Bladex and Extrazine products are category II pesticides, the WPS rule's protective eyewear statement requirement, if complied with, was adequate to protect against any unreasonable risk of eye injury to early entry agricultural workers.

Respondent contests this element of the misbranding charge on the ground that, because Complainant cannot rely on the WPS rule as a misbranding standard, Complainant must prove that the Bladex and Extrazine labels were not adequate to protect health and the environment. Respondent asserts that because the Agency did not present factual evidence that the products as labeled were inadequate to protect health or the environment, Complainant cannot satisfy the statutory standard for misbranding. Because the premise of Respondent's argument -- that the WPS rule does not establish a standard for misbranding -- has been rejected this argument must fail.

Respondent makes the additional argument that Complainant raises a new theory of misbranding in its post-hearing brief. Specifically, Respondent objects to Complainant's interpretation of the section 2(q)(1)(G) as requiring a showing that protective eyewear labeling "may" have been necessary to protect health and the environment and not a showing that protective eyewear labeling "was not adequate to protect health and the environment." Respondent complains that because this interpretation of the statute was not laid out in the complaint or at hearing, its due process right to a full and fair challenge has been violated.

This argument too, is rejected. First, the statute itself provides notice of this "theory" of liability. Section 2(q)(1)(G) clearly states that a pesticide is misbranded if "the label does not contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." FIFRA § 2(q)(1)(G), 7 U.S.C. 136(q)(1)(G). Second, although Complainant incorrectly stated in its complaint at paragraph 10 that Respondent's label was not adequate to protect health and the environment, Complainant quoted the correct language from section 2(q)(1)(G) in paragraph 11 of the complaint. Accordingly, Respondent had adequate notice and opportunity to challenge this theory.

Respondent's Shipment of Misbranded Pesticides

Respondent's shipping records (Complainant's Exhibit 11, Exhibit F) establish that

Respondent shipped the misbranded pesticides at the times and in the quantities alleged in the complaint. Respondent corroborates this conclusion in its answer. Respondent represented that it "shipped Bladex 4L bearing the label approved by EPA on November 4, 1993 on or about the dates alleged and in the amounts alleged in [the complaint]", Answer at 2, ¶ 13, and identical admissions were made with regard to the other three pesticides at issue. Answer at 4, ¶ 23 (Bladex 90 DF); 5, ¶ 33 (Extrazine II DF); and 7, ¶ 43 (Extrazine II 4L).

Respondent does not directly dispute these facts, instead Respondent asserts that it elected the "released for shipment" option detailed in PR Notice 93-11 and that Complainant must show, as part of its prima facie case, that Respondent's products were released for shipment after January 1, 1994. Released for shipment is defined in PR Notice 93-11 to mean "the product has been produced, packaged, and labeled and it is the intent of the producer to introduce such product into commerce" as demonstrated by the fact that the "product is stored [at the production facility] in an area where finished products are held for shipment in the ordinary course of business (warehouse, loading docks, *etc.*)." CX 21, Supp. C, at 4. Respondent contends that it chose the released for shipment option and that Complainant could have determined through investigation whether the shipments in question comprised "released for shipment" pesticides that were exempt from the WPS label requirement or shipments that were not exempt but did not avail itself of this opportunity. Consequently, Respondent argues, Complainant has introduced no evidence showing that any of the products subject to the complaint were released for shipment after January 1, 1994. In the absence of such evidence, Respondent urges, Complainant's case must fail.

Under the circumstances of this case, Respondent's "release for shipment" argument is disingenuous. The Notices of Serious Error directed Respondent to stop selling or distributing any product bearing the proposed amended labels including product that had been released for shipment unless it included approved WPS labeling. Respondent concedes that it ignored this prohibition. Moreover, there is no evidence in the record substantiating Respondent's claim that some of the product in the lists provided to the Agency could have been exempt from the WPS.

In any event, it was Respondent's obligation to provide relevant distribution and sales information in response to the Agency's requests; Respondent should have investigated the facts it provided. When the Agency wrote to Respondent on April 26, 1994 and May 6, 1994, the request to Respondent was that it provide shipping information for the Bladex and Extrazine products that contained WPS labeling. CX 10, CX 36. The record reflects that the sales and distribution listed in the complaint were those supplied by Respondent in response to the Agency's request for WPS-labeled product sold or distributed after the Notices of Serious Error had been received by the Respondent in March 1994. Without some concrete evidence that the information supplied was in error, it would be conjectural to assume that the distribution and sales listed in the complaint were excepted from the WPS rule. This is particularly the case here where Respondent represented in its answer that the sales and distribution items in the complaint had the noncompliant label prepared in July 1993.

3. The Appropriate Penalty

Pursuant to section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4), the Complainant proposes that a penalty of $1,895,000 should be assessed against the Respondent for the 379 misbranding violations. Section 14(a)(4) requires that the Agency consider in determining the amount of the penalty the gravity of the violation, the appropriateness of the penalty to the size of the business, and the effect on the entity's ability to continue in business. In addition, the Consolidated Rules of Practice direct the presiding officer to consider any civil penalty guidelines issued under the statute and whether the Respondent exhibited good faith or lack thereof. 40 C.F.R. §§ 22.14(c), 22.35(c).

In arriving at its proposed penalty amount, Complainant applied the Agency's FIFRA Enforcement Response Policy, dated July 2, 1990 (FIFRA ERP) to the facts of this case. Under FIFRA ERP violations of section 12(a)(1) (E) misbranding, as defined by sections 2(q)(1)(F) and (G), are assigned a gravity level of 2. Misbranding is

considered a more serious violation because the Agency's regulatory program relies on the accuracy of labeling information to protect humans and the environment from unreasonable risks of harm. Respondent's business had 1993 gross revenues of more than $37 billion and 1996 gross revenues of $42 billion. CX 32 at 1; CX 33 at 1; CX 34 at 1. This places Respondent's business in category I, the largest of the three possible categories in FIFRA ERP.[(22)] The policy categories follow the precept that the larger a business, the larger the penalty necessary to achieve a deterrent effect. FIFRA ERP at 20.

The FIFRA ERP civil penalty matrix provides that the base penalty for a gravity level 2 violation committed by a category I business is $5,000, which is the statutory maximum for any single violation of FIFRA. Numerical adjustments may be made upward or downward to the gravity-based penalty depending on the specific characteristics of the pesticide involved, the actual or potential harm to human health, actual or potential harm to the environment, compliance history of the violator and culpability of the violator. Complainant urges that, based on its analysis of the facts and circumstances of this case, no downward adjustment of the penalty is warranted and further, that the full penalty must be imposed if it is to have any deterrent effect because Respondent made over $9.4 million from its sale of misbranded pesticides.

Respondent's Violation Was Serious and a Substantial Penalty is Appropriate

Respondent takes the position that under the circumstances the appropriate sanction is a warning, as provided for in section 14(a)(4) of FIFRA,[(23)] and not a civil penalty. A warning is adequate, Respondent argues, because its actions did not result in any real or potential harm to human health or the environment, and it exercised due care.

In support of its claim that its actions presented no risk of actual or potential harm, Respondent points to Complainant's stipulation that "For purposes of the penalty only [the Bladex and Extrazine products] are in Toxicity Category III for purposes of eye irritation, and do not pose any risk of harm to human health or the environment." Tr. III-21.[(24)] Respondent adds that "[t]he fact that EPA allowed DuPont to continue shipping product with allegedly noncompliant labeling after April 22 also shows that the Agency had no concern about any harm to health or the environment." Respondent's Brief in Support at 51.

Due care, Respondent argues, is demonstrated by the resources it devoted to its WPS compliance efforts. These efforts included creating a WPS implementation team, training its registration managers to ensure they understood the procedures for preparing the label amendments, and taking measures to see that compliance deadlines were met and that its dealers and farmers were aware of the WPS program and its requirements.

In addition, Respondent asserts, Complainant's reliance on "harm to the regulatory program" as the basis for its gravity determination is misplaced. According to Respondent, harm to the regulatory program has been found generally only where a violator's actions place it beyond the purview of the regulatory process and under FIFRA only where a respondent has failed to register a pesticide product or establishment. Respondent submits that this case does not present such a situation.

Issuance of a warning would not be appropriate on this record. The record supports the classification of Respondent's violations as gravity level 2. Complainant's stipulation as to the toxicity category and actual risk of harm presented by the Bladex and Extrazine products for penalty purposes explicitly excepted harm to the regulatory program from its scope. The EAB has recognized that a violation that undermines a regulatory program may be a serious violation even in the absence of actual or potential harm to the health of specific individuals or components of an ecosystem. Green Thumb Nursery, Inc., FIFRA Appeal No. 95-4a (Final Order, EAB, March 6, 1997) at 25-29 (failure to register pesticide was harmful to the FIFRA regulatory program and the public, even where there was no individualized and specific injury to health or the environment); Everwood Treatment Company, Inc.,

RCRA Appeal No. 95-1, (Final Order, EAB, September 27, 1996) at 17-21, decision upheld, Everwood Treatment Co., Inc. v. U.S. E.P.A., 1998 U.S. Dist. Lexis 927 (D. Ala. 1998) (where violation created adverse effect on the RCRA program, the potential for harm was considered "major" even where there was no evidence of actual harm)[(25)]; Harmon Electronics, Inc., RCRA (3008) Appeal No 94-4 (Final Order, EAB, March 24, 1997) at 65-69, appeal docketed (W.D. Mo.) (violations posed a serious threat to regulatory program and therefore merited a substantial penalty).

Actions like those taken by Respondent in this case -- shipping pesticides with labels found by the Agency to contain serious errors after being expressly told not to do so -- interfere with the Agency's ability to carry out its statutory mandate to protect human health and the environment and thus present a clear threat to the FIFRA regulatory scheme. Consequently, Respondent's effort to distinguish the instant case from others in which harm to the regulatory program has been found must fail. As Complainant points out, the Agency's FIFRA regulatory program "has to rely on registrants selling only products bearing labeling that complies with the terms of registration and with EPA guidance." Tr. II-37 (True). In this case, the Agency determined that PPE statements were necessary to mitigate unreasonable risks of harm to agricultural workers. 57 Fed. Reg. 38105-06. The WPS rule specifies which statements must be included on a product label. 40 C.F. R. § 156.212(e). Several witnesses testified that the labeling requirements go to the heart of the WPS program and that, if they are disregarded, the purpose of the WPS (and FIFRA) is defeated. Tr. II-90-91 (Ziegel); Tr. II-190, 262 (Hellyer); Tr. I-107 (Tompkins); Tr. II-36-37 (True). Louis True, formerly the Acting Director, Special Review and Registration Division, Office of Pesticide Programs, testified that Respondent's sales of pesticides with noncompliant labeling were "inimical to the regulatory program, not just with respect to Worker Protection Standard labeling implementation but to all label improvement programs of which the WPS implementation was one. That is[,] all of the processes the agency uses to make mass changes to labels, changing many labels at once." Tr. II-36.

Moreover, Respondent's assertion that the Agency's decision to allow it to continue shipping the misbranded products demonstrates that the Agency did not believe any harm would come from such sales is based on unreliable evidence. Respondent's claim that the Agency's gave it oral permission to continue shipping on April 22,1994 [(26)] conflicts with the Agency's contrary position issued four days later. On April 26, 1994, the Agency wrote to Respondent and granted it permission to continue shipping Bladex and Extrazine products but only on condition that Respondent develop supplemental labeling for the products and make it available to all purchasers of misbranded product. See CX 10.

Respondent's argument that it exhibited due care is also not supported by the record. Most significantly, Respondent failed to heed the Agency's direction to cease its sales and shipment of the Bladex and Extrazine products. Respondent's knowing violation of an agency order demonstrates a failure to exercise due care. In addition, Respondent's failure to prepare any instructions about what should be done if the WPS labels were found to contain serious errors also exhibits a lack of due care. As Respondent's witnesses testified, the label amendment process of the WPS program was complicated. See, e.g., Tr. IV-36-38 (Baer). In a situation where a registrant self-verifies a complicated label amendment subject to Agency approval, prudence suggests that preparations should be made for the eventuality that approval may not be granted.

Respondent's Actions Do Not Warrant a Low Gravity Assessment for Good Faith

Respondent offers several arguments in support of its contention that it acted in good faith and that the gravity of its violations should therefore be lowered. First, Respondent contends that it had a good faith belief that its amended labels had been accepted in November of 1993 and that the March notices were a mistake. According to Respondent, in response to its submission on October 28, 1993 of a revised label containing both WPS language and language relating to a voluntary cyanazine exposure reduction program, it received a response unconditionally accepting both the WPS and cyanazine language.

Assuming that Respondent believed that its WPS language had been approved, its receipt of the Notices of Serious Error in March of 1994 should have disabused it of this belief.[(27)] The notices were clear on the issue of further distribution or sales of the Bladex and Extrazine products and the violations charged in the complaint all took place after Respondent received the notices. Moreover, Mr. Holt testified that in his 28 years with Respondent he has never encountered a situation in which a letter from EPA telling the company to stop selling something turned out to be the result of an Agency mistake. Tr. V-69 (Holt).

Furthermore, Respondent's argument that its continued shipments in April cannot be considered in bad faith because it informed the Agency in a March 31, 1994 letter of its plans and the Agency did not reiterate its order to cease shipments is without merit. Respondent relies on the testimony of Mr. Ziegel to support its argument that the Agency was aware of Respondent's plans to continue shipping and tacitly approved of its actions. Mr. Ziegel's testimony, however, does not support this conclusion. Mr. Ziegel testified that he believed the letter reflected Respondent's desired distribution plan contingent upon a timely resolution of the labeling problems and that "We never dreamed that DuPont would go ahead and [continue shipping] until the labeling was finally resolved. . . ." Tr. II-108-13, 173-74.

Respondent also asserts that the violations giving rise to this enforcement action arose as a consequence of inadvertent mistakes and that this should be considered a mitigating factor. As already discussed in determining liability, Respondent has not shown that its toxicity category certifications were erroneous at the time it completed its label amendment applications.

Respondent also points to a host of compliance efforts that, it asserts, made it an industry leader in implementation of the WPS. These efforts, Respondent maintains, should be taken as an indication of its good faith interest in complying with the WPS program. These efforts, while commendable, do not offset Respondent's decision to defy the agency's orders in the Notices of Serious Error.

Respondent argues further that its cooperative attitude in working out acceptable label language with the Agency demonstrates its good faith. Testimony does indicate that Respondent did cooperate with the Agency in reaching agreement on compliant label language. Tr. II-114-16 (Ziegel); Tr. III-142 (Catka). However, the circumstances of the case, including Respondent's culpability and the economic benefit it derived from sales of misbranded product argue against any reduction in the penalty amount.

Finally, Respondent asserts that it relied on Agency assurances at a public meeting that it would be given notice and an opportunity to reply if a label was found to contain errors before any action such as a stop sale or distribution order was issued. This verbal assurance, however, was not part of the written result of that public meeting, PR Notice 93-11. This fact vitiates Respondent's argument that it was entitled to rely on any verbal assurances. Moreover, it distinguishes the instant case from those cited by Respondent as they do not address a situation in which a verbal assurance is not subsequently included in written guidance on the issue. See In the Matter of Hanlin Chemicals, Docket Nos. I. F. & R III-425C, TSCA-III-651, EPCRA-III-091 (Initial Decision, Nov. 9, 1995); In the Matter of Aquarium Products, Inc., I. F. & R. Docket No. III-439-C (Initial Decision, June 30, 1995); In the Matter of N. Jonas & Co., Inc., I. F. & R Docket No. III-121C, 1978 FIFRA Lexis 17 (Initial Decision, July 27, 1978)

The Circumstances Do Not Merit a Reduction in Penalty

Respondent argues that Complainant has erred in its application of its own penalty policy to the facts of this case because it failed to make any downward adjustment in its penalty calculation for lack of harm, culpability and other factors. The record shows, however, that Complainant did correctly apply the FIFRA ERP to the facts of the case and that no downward adjustment is warranted.

In particular, Respondent complains that an adjustment for lack of harm to health

and the environment is required based on Complainant's stipulation. However, as Respondent acknowledges, the stipulation of no harm did not extend to harm to the regulatory program and Complainant's analysis of this issue explicitly excluded actual harm to the environment or human health from consideration. As already discussed, Respondent's actions posed a threat to the FIFRA regulatory program and thus created the potential for serious or widespread harm to human health and the environment by preventing achievement of the basic goals of the WPS and FIFRA.

Respondent's culpability is established by its decision not to cease shipments of the Bladex and Extrazine products in April 1994 despite its receipt of the Notices of Serious Error on March 16 and 22, 1994. Tr. III-90-91 (Catka); Tr. V-85 (Holt). These notices, in bold type, directed Respondent not to sell or distribute (including release for shipment) any product bearing the submitted label. CX 22-25 at 1.

The remaining factors given consideration under the FIFRA ERP and not already considered elsewhere, voluntary disclosure and compliance history, do not argue for a reduction in Respondent's penalty. Respondent did not voluntarily disclose its violations as that term is used in the penalty policy. First, Respondent did not disclose its violations before their discovery by the Agency, Respondent provided the sales and distribution records on which the Complaint is based only after the Agency made written requests for the information on April 26 and May 6, 1994. Second, Respondent's failure to immediately take steps to come into compliance, including steps requested by the Agency to mitigate the violation is evidenced by Respondent's knowing disregard of the Notices of Serious Error. Respondent's compliance history shows one prior violation of FIFRA § 12(a)(1)(B) (CX 35) which resulted in a consent order finalized on May 21, 1991, within 5 years of the present violation.

Finally, Respondent argues that justice requires the consideration of other mitigating factors in the fashioning of any penalty. These factors include mistakes contained in the Notices of Serious Error and confusion caused by the notices, and EPA delay in meeting with Respondent to discuss the label problems. A consideration of Respondent's arguments on these points, however, does not lead to the conclusion that a penalty reduction is warranted.

The errors contained in the notices, which related to a label statements pertaining to the type of gloves to be worn and the removal of contaminated clothing, were not significant and any confusion caused by the notices did not justify Respondent's refusal to abide by their clear directive not to sell or distribute the Bladex and Extrazine products. Moreover, in its communications with the Agency at this time Respondent never told anyone at the Agency that it believed that its products had been erroneously classified in toxicity category II or submitted any toxicity studies to the Agency for review. Consequently, when, at Respondent's product registration manager Tony Catka's request, Mr. Tompkins reviewed Respondent's four WPS labels against PR Notice 93-7's decision logic, his review was confined to whether PR Notice 93-7 required protective eyewear for early entry and he concluded that it did. CX 19 at 6, ¶¶ 30, 32, 34; Tr. I-124-27 (Tompkins).

Respondent's Economic Benefit From Noncompliance

A primary purpose of FIFRA penalties is to deter future violations. Johnson Pacific, Inc., FIFRA Appeal No. 93-4, 5 E.A.D. 696, 707 (Final Order, EAB, Feb. 2, 1995); Sav-Mart, Inc., FIFRA Appeal No. 94-3, 5 E.A.D. 732, 738-39 (Final Order, EAB, Mar. 8, 1995). Effective deterrence of future violations includes recovery of a Respondent's economic benefit when necessary to take "away the economic incentive to violate the law." B.J. Carney Inds., Inc., CWA Appeal No. 96-2, (Remand Order, EAB, June 9, 1997) at 49. Although not explicitly provided for in FIFRA ERP, the EPA General Enforcement Policy #GM-22 describes Agency policy for recovery of a violator's economic benefit from "selling products without required labeling or warnings." CX 37 at 10. In the instant case a reasonable approximation of Respondent's economic benefit yields a figure several times the proposed penalty. This provides additional support for assessment of the full proposed penalty.

In arguing against recovery of its economic benefit by Complainant, Respondent

incorrectly maintains that Complainant offered no method for quantifying economic benefit. Complainant calculated that Respondent realized a profit of $9.4 million from illegal sales of the counts in the Complaint in the following manner. See CX 40. The lowest possible price of each product was subtracted from the average cost per gallon or per pound. Those totals were then multiplied by the quantity shipped, to equal the profit per product. The profit for each of the four products was then combined to equal total profit (economic benefit) of $9,430,521.50.(28) In making this calculation, Complainant was guided by the EPA General Enforcement Policy which sets forth the Agency's policy for the recovery of economic benefit. See CX 37 at 10-14.

Respondent also claims that there would not have been any loss if it had complied with the stop sale orders because it would have sold the product after the labels were approved in late April. This was the case the Respondent represents because it had "pushed" product into the lower levels of the channels of distribution before April 1, 1994. Tr. V-139-40, 152 (Bader). This argument lacks credibility in light of Respondent's previous representations about the seasonal window for the sale of products, and the severe economic impact of any disruption to the supply sequence during March and April.(29) In addition, even if Respondent could have sold the products in May or June, it had no assurance that the labels would be approved by that time.

Respondent also objects that Complainant's economic benefit calculation does not represent Respondent's profit because the products were shipped, but not necessarily sold. This argument too conflicts with Respondent's written correspondence with the Agency in which it represented that the products had been sold before shipment. See CX 29 at 3; CX 11 at Ex. B, p. 2. In any event, as Complainant observes, even if the product was not sold the shipment of the product set in motion a process that would culminate in sale and yield an economic benefit for Respondent.

In sum, Respondent has not shown that Complainant's calculation is not a reasonable approximation of its benefit from the unlawful sales of the Bladex and Extrazine products.

ACCORDINGLY, IT IS ORDERED that, pursuant to section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4), the Respondent IS ASSESSED a penalty of $1,895,000 for 379 violations of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

Payment of the full amount of the civil penalty assessed must be made within sixty (60) days of the service date of the final order by submitting a certified check or cashier's check payable to Treasurer, United States of America, and mailed to:

U. S. EPA-Washington
(Hearing Clerk)
Mellon Bank
P.O. Box 360277M
Pittsburgh, PA 15251

A transmittal letter identifying the subject case and the EPA docket number, plus respondent's name and address must accompany the check.

Failure by respondent to pay the penalty within the prescribed statutory time frame after entry of the final order may result in the assessment of interest on the civil penalty. 31 U.S.C. § 3717; 4 C.F.R. § 102.13.

Pursuant to 40 C.F.R. § 22.27 (c), this initial decision shall become the final order of the Environmental Appeals Board within forty-five (45) days after its service upon the parties and without further proceeding unless (1) an appeal to the Environmental Appeals Board is taken from it by a party to this proceeding or (2) the Environmental Appeals Board elects, sua sponte, to review this initial decision. If an appeal is taken, it must comply with § 22.30. A notice of appeal and an accompanying brief must be filed with the Environmental Appeals Board and all other parties within twenty (20) days after this decision is served upon the parties.

_____

Edward J. Kuhlmann
Administrative Law Judge

April 30, 1998
Washington, D. C.

1. Robert W. Darnell, Esq. and Mark Garvey, Esq. represented the Complainant. Kenneth W. Weinstein, Esq., Cara S. Jablon, Esq. and Lora A. Brzezynski, Esq. represented the Respondent.

2. The complaint was amended once, on April 16, 1997, to correct an error in the original complaint. The shipping data in Count IV and Count III were reversed. The Respondent did not object to the amendment. References to complaint in this decision are to the April 16, 1997 amended complaint. On October 28, 1994, the Respondent answered the complaint; its answer was not amended after Complainant amended the complaint in 1997.

3. The complaint charges Respondent with violating FIFRA §§ 2(q)(1)(F) and (G). In its post-hearing brief Complainant states that while either provision is sufficient to establish liability under section 12(a)(1)(E), it will focus its discussion on section 2(q)(1)(G) because it applies most directly to the instant case.

4. The phrase "protect human health and the environment" is defined in section 2(x) of FIFRA as "protection against any unreasonable adverse effects on the environment." The phrase "unreasonable adverse effects on the environment," in turn, is defined in section 2(bb) as "any unreasonable risk to man or the environment."

5. In the Preamble to the WPS final rule EPA estimated "that at least tens of thousands of acute illnesses and injuries . . .occur annually to agricultural employees as the result of occupational exposures to pesticides . . . ." 57 Fed. Reg. 38,102, 38,105 (1992). The WPS rule was an effort to reduce the number of such injuries suffered by agricultural workers.

6. 40 C.F.R. 156.212(d)(2) states that: "The requirement for personal protective equipment is based on the acute toxicity category of the end-use product for each route of exposure . . . . If data to determine the acute toxicity of the product by a specific route of exposure . . . are not obtainable, the toxicity category corresponding to the signal word of the end-use product shall be used to determine personal protective equipment requirements for that route of exposure."

7. Complainant maintains that this defense and others raised by Respondent for the first time at hearing should be excluded from consideration on procedural grounds because they are affirmative defenses and were not raised in Respondent's answer as required under the Consolidated Rules. See Complainant's Brief in Support at 15-16, Complainant's Reply Brief at 4, 6-7. Respondent replies that the defenses at issue are not affirmative defenses, but rather, are legal defenses and that, in any event, Complainant has suffered no prejudice as a consequence of the defenses raised by Respondent at hearing. See Respondent's Reply Brief at 21-26. While Respondent's arguments may have come very late and were disruptive to the conduct of an efficient hearing, Complainant has not demonstrated that it has been unduly prejudiced.

8. FIFRA § 25(a), 7 U.S.C. § 136w, is cited in the Legal Authority section of the Preamble to the final WPS rule. 57 Fed. Reg. 38,102.

9. Section 25 of FIFRA was passed as part of the Federal Environmental Pesticide Control Act of 1972 ("FEPCA"). Act of Oct. 21, 1972, Pub. L. No. 92-516, 86 Stat.

973 (1972). FEPCA represented a comprehensive revision of FIFRA which, among other additions, made explicit for the first time that FIFRA's purpose was to protect man and his environment. In considering the authority conferred on EPA under FEPCA the D.C.Circuit observed that prior to FEPCA EPA's field re-entry requirements had been "merely informational until FEPCA made them enforceable" and specifically cited FIFRA § 25 as authority for the regulations promulgated by EPA. Organized Migrants in Community Action, Inc. v. Brennan, 520 F.2d 1161, 1166 & n.8 (D.C. Cir. 1975).

10. The Senate report on FEPCA includes the following passage: "The Committee believes there can be no question . . . but . . . that the bill requires the Administrator to require that the labeling and classification of pesticides be such as to protect farmers, farm workers, and others coming in contact with pesticides or pesticide residues." S. Rep. No. 838, 92d Congress, 2d. Sess. at 14 (1972) (Agriculture and Forestry), reprinted in 1972 U.S.C.C.A.N. 4023, 4063 (quoted at 57 Fed. Reg. 38,102-03).

11. Respondent submits that Complainant's lack of proof is further underscored by a stipulation entered into by Complainant that "[f]or purposes of penalty only, the four pesticide products at issue in this Complaint . . . are in Toxicity Category III for purposes of eye irritation, and do not pose any risk to human health or the environment." Tr. III-21. Respondent argues that Complainant's position is untenable, that the Bladex and Extrazine products cannot be category II for one purpose and category III for another. This argument is rejected. A stipulation entered into strictly for penalty purposes does not establish the stipulated fact for purposes of liability and Respondent cites no authority for such a proposition.

12. It is common for the Agency to rely on certifications made by registrants in making determinations in pesticide registration-type procedures. As the Agency recently explained in the context of a registration revocation proceeding, "prior to granting a registration, the Agency is required to determine that a pesticide will not 'generally' cause unreasonable adverse effects on the environment. . . . As a practical matter, in making such a determination the Agency must rely on data and certified statements submitted by the registrant." 62 Fed. Reg. 61,890, 61,893 (1997) (Notice and Order of Revocation of Registrations and Final Determination Governing Sale and Use of Existing Stocks).

13. Respondent's argument is that, regardless of what it certified on its label amendment applications, the applications cannot be used to establish its liability because a registrant's assessment of a toxicity category is not proof of what the toxicity category actually is; only the Agency has the authority to determine toxicity categories. Therefore, Respondent asserts, Complainant cannot rely on Respondent's certifications to establish Respondent's liability because to do so would constitute an improper delegation of the Agency's authority.

14. At the hearing Respondent stated that each toxicity category determination "was made for each of these chemicals when they were registered. It's not a new determination that the registrant was making [when it certified the toxicity categories]." Tr. I-303.

15. PR Notice 93-7 instructs registrants to:

> Use data in your files to determine the toxicity Category of your end-use product for each route of entry. If you do not have all the data, you may be able to obtain it from one of the following sources. . . .

CX 20 at Supp. 3, page 7.

16. Pursuant to 40 C.F.R. § 156.204(b), registrants could file a request for modification or waiver of any WPS requirement with data in support thereof. See also CX 20 (PR Notice 93-7) at Supp. 2, pp. 4-5. Given that the modification/waiver provision expressly directed registrants to submit data in support of any request, Respondent's contention that it had no duty to submit additional data in the absence of a formal request by the Agency because the Agency had already made toxicity category determinations for the Bladex and Extrazine products is contrary to established Agency practice. The Agency's requirements for changing the existing toxicity categories follows well established principles. The proponent of a waiver

or modification of an existing rule or finding always bears the burden of submitting support for varying an established ruling. 40 C.F.R. § 156.204(B).

17. Cyanazine and atrazine are the active ingredients in the Bladex and Extrazine products at issue.

18. According to Mr. Catka's letter the July 14, 1993 label language was adequate in a practical sense for two reasons. First, because the Bladex and Extrazine products are applied pre-emegence or early post-emergence to corn and cotton crops there was no need for workers to enter the fields during the restricted reentry period and if they did, the chance of the pesticides reaching their eyes was very slight. Second, given the agricultural practices associated with the use of the Bladex and Extrazine products just described, the diluted form in which the products are applied further reduces the risk to any early reentry workers.

19. Mr. Catka explained that he followed the WPS guidelines in the Agency instructions for making determinations about what was required to be included on the labels for the Bladex and Extrazine products. He stated that because the old labels on Extrazine and Bladex required a face mask, the WPS guidelines required a statement that protective eyewear had to be included on new labels, if they were to be in compliance with the new WPS rules. Tr. III-40-53. It was not until four years after he had completed EPA Form 8570-1 that Mr. Catka claimed he had made a mistake. The "mistake," however, is that Respondent now believes it should have made the special showing required to change the toxicity designations for the Bladex and Extrazine herbicides. Respondent's argument does not establish mistake but, instead, indicates that Respondent, in hindsight, wishes it had followed the procedures for changing the existing toxicity designations for Bladex and Extrazine. Respondent's testimony and brief are filled with endless speculation about the conclusions it believes the Agency would have reached if it had followed that course. Which, of course, it did not do.

20. Respondent's effort to analogize its situation to that presented in American Cyanamid and the other Clean Water Act ("CWA") National Pollution Discharged Elimination System cases cited fails for this reason. Those cases addressed situations involving actual mistakes, such as incorrect calculations or typographical errors. Here, as just explained, respondent has made no showing that any "mistakes" of the sort considered in the cited CWA cases occurred.

21. Respondent's Tenth Affirmative Defense does not give cause to disturb the conclusion to be drawn from these admissions. In paragraph three of the tenth affirmative defense Respondent quotes language from its April 28, 1994 letter to EPA which states "we do not track product sold or distributed from our warehouses by date of manufacture, so it is not possible to know which product label would have been on product sold or distrubuted after March 11, 1994" and "product labeling for some of the product campaigns in 1993 did not use our WPS labels." Respondent made these statements in the context of its released for shipment defense, not in opposition to the admissions noted above. Moreover, Respondent did not contest Complainant's charge that the protective eyewear statements were missing from the labels of the product shipped and introduced no evidence on this issue in its pre-hearing submissions or at the hearing itself.

22. Respondent does not dispute its category I designation for business size, and does not argue that it is unable to pay the proposed penalty or that assessment of the proposed penalty will affect its ability to remain in business. Therefore, these issues will not be discussed further.

23. FIFRA § 14(a)(4) provides that when a violation occurs even though the Respondent exercised due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of a penalty.

24. Respondent also relies on the testimony of Dr. Dykstra and proffered testimony. Respondent's interpretation of Dr. Dykstra's testimony was considered and rejected in the liability portion of this decision and will not be discussed further here. As for Respondent's proffered testimony, this evidence was excluded from the record of the hearing and thus will not be addressed here.

25. In granting the Agency's motion for summary judgment, the district court explicitly adopted the finding of the magistrate judge that:

> 'Everwood's claim that the EPA must prove an environmental impact is irrelevant in light of the fact that the EAB found it to have committed a major violation in undermining the goals and purposes of the RCRA program.'

_1998 U.S. District Lexis 927, at *7.

26. This claim, offered for the first time at the hearing, is supported only by the vague recollection of Mr. Holt. Holt testified that on April 22 he received permission orally from an unnamed higher up at the Agency who might have been Doug Campt, the director of the Office of Pesticide Programs at that time. Mr Holt's testimony is not credible in light of the Agency's action of April 26, 1994.

27. The following quote from Respondent's letter of April 28, 1994, for which Respondent has offered inconsistent and conflicting explanations, indicates that Respondent knew that its WPS label language had not been approved in November of 1993: "Thus, as of November 1993, we felt obligated to use these approved labels for our subsequent production, even though we knew the WPS process was still in progress." CX 29 at 3.

28. This amount was calculated from information supplied by the Respondent.

29. In its April 28, 1994 letter to the Agency Respondent represented that "the bulk of our triazine products are ordered, sold and distributed in late 1993 and 1st Qtr 1994 for early spring applications. The months of March and April are the months in which our production is running at maximum capacity and a large portion of our triazine products are being distributed in the channels of trade. The sheer volume of the production and distribution chain makes it exceedingly difficult to make changes in the supply sequence during this peak season. Any disruption would necessarily have a severe economic [impact] on all businesses in the distribution channel down to the farmer level." CX 29 at 3 (emphasis added).