

**IN RE E.I. DU PONT DE NEMOURS
AND COMPANY**

FIFRA Appeal No. 98-2

DECISION AND REMAND ORDER

Decided April 3, 2000

Syllabus

This is an appeal by E.I. du Pont de Nemours and Company (“DuPont”) from an Initial Decision arising out of an administrative enforcement action by the Director of Toxics and Pesticides Enforcement Division, Office of Regulatory Enforcement, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency (“Pesticide Enforcement”). The enforcement action was filed against DuPont for numerous alleged violations of section 12 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (“FIFRA”), 7 U.S.C. § 136j. By the Initial Decision, the Presiding Officer found that, in April 1994, DuPont made a total of 379 shipments of pesticides that were misbranded as defined in FIFRA section 2(q)(1)(F) and (G).

Central to this case and DuPont’s arguments on appeal is the fact that EPA promulgated new pesticide labeling requirements in 1992 as part of the so-called Worker Protection Standard (“WPS”) regulations. The WPS regulations require the labeling for certain pesticide products be modified so as to contain additional warning or caution statements for the protection of pesticide applicators and handlers and so-called early-entry agricultural workers who enter fields within a short time after pesticide application. At issue in this case is the WPS requirement that pesticide products with a potential to cause eye irritation, identified as toxicity category II under the WPS regulations, must bear a protective eyewear warning, but products with a lower eye irritation toxicity level — that of toxicity category III — have no such protective eyewear warning requirement. The Presiding Officer found that the pesticide products at issue in this case are toxicity category II for eye irritation potential but that the labeling used by DuPont failed to contain a protective eyewear warning in the section of the label governing the warnings for early-entry agricultural workers.

DuPont raised four primary arguments on appeal: (1) that the labeling allegedly used by DuPont in April 1994 had been approved by EPA in November 1993; (2) that the WPS labeling requirements do not establish a misbranding standard under FIFRA section 2(q)(1)(F) and (G); (3) the Presiding Officer erred by precluding DuPont from submitting certain evidence proffered to establish that the pesticide products at issue in this case are, in fact, toxicity category III for which the protective eyewear warning is not required by the WPS regulations; and (4) that Pesticide Enforcement failed to submit evidence showing that each of the 379 shipments of pesticide products was in fact sold or distributed bearing the new WPS-modified labeling as alleged in the complaint, rather than the old, previously approved non-WPS labeling.

Held: Affirmed in part, reversed in part and remanded for further proceedings.

1) The Presiding Officer erred on the question of whether DuPont had received approval for its labeling in November 1993. The determination as to whether approval had been granted must be based on the terms of EPA's official letters granting amended registration, which in this case facially granted unqualified approval of the entire labeling and did not indicate that the proposed WPS modifications included in the label were not reviewed or approved. Such approval, however, is not a defense to the misbranding charge; instead it serves as prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of FIFRA.

2) The Presiding Officer did not err in holding that the WPS regulations establish a misbranding standard under FIFRA section 2(q)(1)(F) and (G). EPA satisfied the substantive standard for misbranding under FIFRA section 2(q)(1)(F) and (G) when it promulgated the WPS labeling requirements. Therefore, proof that a pesticide product's label does not contain a warning or use statement that complies with the specific language required by the WPS rule is sufficient to establish that the product is misbranded under FIFRA section 2(q)(1)(F) or (G).

3) The WPS regulations establish different labeling requirements for different categories of pesticide products, based on the product's toxicity through different routes of exposure. Thus, the regulations require, for each pesticide product, that a factual determination of the product's toxicity be made as a predicate to determining the labeling language required by the regulations. The November 1993 approval of the labeling at issue in this case established DuPont's prima facie evidence that such labeling complies with FIFRA's registration requirements and is not misbranded under FIFRA section 2(q)(1)(F) and (G). However, Pesticide Enforcement submitted sufficient evidence to rebut that prima facie case by showing that EPA had mistakenly approved labeling that did not contain a caution or warning statement required by the WPS regulations for pesticide products with eye irritation toxicity category II, which is the toxicity category of DuPont's products as stated in DuPont's own applications for amended registration. However, once Pesticide Enforcement rebutted DuPont's prima facie evidence of compliance, DuPont should have been allowed to submit its additional evidence on toxicity, which DuPont alleges would show that these products are toxicity category III, not toxicity category II as DuPont claims it stated by mistake in its applications for amended registration. This case is remanded to allow DuPont to submit its toxicity evidence and for the Presiding Officer to consider other evidence as to whether the labeling at issue complies with the WPS regulations.

4) DuPont admitted in its answer that the 379 shipments of pesticides identified in the complaint were shipped bearing "WPS language identical to that submitted to EPA on July 14, 1993." This admission removed from controversy in this case any question as to whether the 379 shipments were actually made bearing the WPS-labeling language set forth in DuPont's July 1993 applications for amended registration.

Before Environmental Appeals Judges Scott C. Fulton, Ronald L. McCallum, and Kathie A. Stein.

Opinion of the Board by Judge McCallum:

This is an appeal by E.I. du Pont de Nemours and Company ("DuPont") from an Initial Decision by Administrative Law Judge Edward J. Kuhlmann ("Presiding Officer") arising out of an administrative enforcement action by the Direc-

tor of Toxics and Pesticides Enforcement Division, Office of Regulatory Enforcement, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency (“Pesticide Enforcement”). The enforcement action was filed against DuPont for numerous alleged violations of section 12 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (“FIFRA”), 7 U.S.C. § 136j. By the Initial Decision, the Presiding Officer found that DuPont made a total of 379 shipments of misbranded pesticides in April 1994 as alleged in Pesticide Enforcement’s complaint (Count I of the complaint alleged 32 shipments of misbranded Bladex 4L; Count II alleged 10 shipments of misbranded Bladex 90 DF; Count III alleged 325 shipments of misbranded Extrazine II 4L; and Count IV alleged 12 shipments of misbranded Extrazine II DF). The Presiding Officer assessed a penalty of \$5,000 for each of the 379 shipments made in violation of FIFRA, resulting in an aggregate penalty of \$1,895,000.

DuPont has appealed from both the finding of liability and the penalty assessment. Central to this case and DuPont’s arguments on appeal is the fact that EPA promulgated new pesticide labeling requirements in 1992 as part of the so-called Worker Protection Standard (“WPS”) regulations. As explained in greater detail below, the WPS regulations require the labeling for certain pesticide products to be modified so as to contain additional warning or caution statements for the protection of pesticide applicators and handlers and so-called early-entry agricultural workers who enter fields within a short time after pesticide application. At issue in this case is the WPS requirement that pesticide products with a potential to cause eye irritation, identified as toxicity category II under the WPS regulations, must bear a protective eyewear warning, but products with a lower eye irritation toxicity level — that of toxicity category III — have no such protective eyewear warning requirement. The Presiding Officer found that the pesticide products at issue in this case are toxicity category II for eye irritation potential but that the labeling used by DuPont failed to contain a protective eyewear warning in the section of the label governing the warnings for early-entry agricultural workers.¹

DuPont’s appeal from the Presiding Officer’s finding that DuPont is liable for the sale or distribution of pesticides that were misbranded, as defined in FIFRA section 2(q)(1)(F) and (G), is based on four primary arguments:

- (1) that in November 1993, EPA approved the labeling allegedly used by DuPont in April 1994 on the 379 shipments of the Bladex and Extrazine pesticide products;

¹ As will be discussed below, the labels used by DuPont did contain a protective eyewear warning in the section of the label governing the warnings for pesticide applicators and handlers.

(2) that the WPS labeling requirements do not establish a misbranding standard under the statutory definition of misbranding identified in the complaint, FIFRA section 2(q)(1)(F) and (G);

(3) the Presiding Officer erred by precluding DuPont from submitting certain evidence proffered to establish that the pesticide products at issue in this case are, in fact, toxicity category III for which the protective eyewear warning is not required by the WPS regulations; and

(4) that Pesticide Enforcement failed to submit evidence showing that each of the 379 shipments of pesticide products was in fact sold or distributed bearing the new WPS-modified labeling as alleged in the complaint, rather than the old, previously approved non-WPS labeling.²

Brief of Respondent E.I. Du Pont De Nemours and Company (“DuPont’s Appeal Brief”) at 1.

For the following reasons, we conclude that the Presiding Officer did not err in holding that the WPS regulations established a misbranding standard and in holding that all of the 379 shipments at issue in this case were made bearing the new, WPS-modified labeling, rather than the old, non-WPS labeling. However, we conclude that the Presiding Officer did err on the question of whether DuPont had received approval for its labeling in November 1993 — we conclude that approval was granted and that such approval is *prima facie* evidence that the labeling complies with the WPS regulations. We also conclude that once Pesticide Enforcement had submitted sufficient evidence to overcome the *prima facie* evidence of compliance with the WPS labeling requirements, DuPont should have been allowed to submit its additional evidence on the question of toxicity. Thus, for the following reasons, we affirm in part and reverse in part the Initial Decision and remand for further proceedings.

I. BACKGROUND

A. Statutory Background

FIFRA establishes an elaborate architecture for the regulation of pesticide use in the United States. That architecture, as relevant here, consists primarily of registration of pesticide products under section 3, cancellation of registration

² DuPont also argues that EPA guidance allowed the sale or distribution of products bearing non-WPS labels after April 21, 1994, if those products were “released for shipment” prior to January 1, 1994.

under section 6, and the prohibition under section 12 of certain acts relating to use and sale of pesticides.

Pursuant to sections 3 and 12 of FIFRA, no pesticide may lawfully be sold or distributed unless it is registered with the EPA. FIFRA §§ 3(a), 12(a)(1)(A), 7 U.S.C.A. §§ 136a(a), 136j(a)(1)(A).³ Section 3 of FIFRA establishes stringent requirements for registration of a pesticide. In particular, an applicant for registration must file a copy of the labeling of the pesticide and data supporting the product's safety and efficacy, and the applicant must demonstrate based on scientific evidence that, "its labeling and other material required to be submitted comply with the requirements of this subchapter." FIFRA § 3(c)(5)(B), 7 U.S.C. § 136a(c)(5)(B). EPA will register a pesticide only if it determines that, when considered with any restrictions imposed on it, the pesticide warrants the proposed claims made for it; its labeling and other materials comply with FIFRA's requirements; it will perform its intended purpose without unreasonable adverse effects on the environment; and when used in accordance with common practice, it will not generally cause unreasonable adverse effects on the environment. FIFRA § 3(c)(5), 7 U.S.C.A. § 136a(c)(5).

FIFRA contemplates that a determination made under section 3 may later be reexamined on the grounds that the registered pesticide product does not comply with the applicable registration standards. In particular, section 6 allows EPA to seek to cancel a pesticide products' registration "[i]f it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or * * * generally causes unreasonable adverse effects on the environment[.]" FIFRA § 6(b); *see also CIBA-GEIGY Corp. v. EPA*, 801 F.2d 430, 431 (D.C. Cir. 1986) (noting that EPA may seek to cancel a registration "[w]hen it appears that a registered pesticide no longer conforms to [the registration] standards").⁴ Section 3 itself provides that "[a]s long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter." *Id.* Section 3 further states that "[i]n no event shall registration of an article be construed as a defense for the

³ There are certain exceptions to this general rule that are not relevant here. *See, e.g.*, FIFRA §§ 5, 18, 19 (requirements for experimental use pesticides, exceptions for federal and state agencies and certain storage and transport exceptions).

⁴ Although a cancellation proceeding may be initiated by EPA, the proponent of registration has the burden of proof that the registration of the pesticide product should not be cancelled. 40 C.F.R. § 164.80(b); *see also Stearns Elect. Paste Co. v. EPA*, 461 F.2d 293, 304-05 (7th Cir. 1972); *Dow Chem. Co. v. Ruckelshaus*, 477 F.2d 1317, 1324-25 (8th Cir. 1973) ("Since the registrant has a continuing burden of proof to establish that its product is entitled to registration, *Southern Nat'l Mfg. Co. v. EPA*, 470 F.2d 194 (8th Cir. 1972), if the Administrator has a substantial doubt as to safety, it is his duty * * * to issue the cancellation order. And the cancellation order will remain in effect until the registrant satisfies the Agency that registration is warranted.").

commission of any offense under this subchapter.” FIFRA § 3(f)(2). In terms of actionable offenses, section 12 of FIFRA makes it unlawful, among other things, for any person to “distribute or sell” to any person (1) a pesticide that is not registered, (2) any registered pesticide with claims made for it that are substantially different than were approved as part of the pesticide’s registration, and (3) any pesticide that has been adulterated or misbranded. FIFRA § 12(a)(1)(A), (B), (E), 7 U.S.C. § 136j(a)(1)(A), (B), (E). A pesticide is “misbranded” if, among other things, its labeling does not contain necessary warning or caution statements or directions for use that, if complied with together with other requirements of FIFRA, are “adequate to protect health and the environment.” FIFRA § 2(q)(1)(F)-(G), 7 U.S.C. § 136(q)(1)(F)-(G).

Congress has specifically authorized EPA “to prescribe regulations to carry out the provisions of [FIFRA].” FIFRA § 25(a)(1), 7 U.S.C. § 136w(a)(1). EPA has used this authority to promulgate detailed regulations governing, among other things, (1) the process for pesticide registration and amended-registration, *see* 40 C.F.R. part 152; (2) language that must be included on pesticide labeling, including warning and caution statements and statements regarding use of pesticides, *see* 40 C.F.R. part 156; and (3) procedures governing formal, on-the-record, adjudicatory proceedings for registrants to challenge EPA determinations denying registration or canceling or suspending registration. *See* 40 C.F.R. part 164. Although all of these regulations underlie our decision today (the specific provisions are described in greater detail below), this case initially arises out of EPA’s promulgation in 1992 of the WPS regulations.

B. *Worker Protection Standard (WPS) Regulations and Their Implementation*

In August 1992, EPA promulgated the WPS regulations because it determined that the existing regulations promulgated under FIFRA were not adequate to protect agricultural workers from exposure to pesticides. *See* Worker Protection Standard, 57 Fed. Reg. 38,102 (Aug. 21, 1992) (codified at 40 C.F.R. parts 156 and 170). 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.” *Id.* at 38,105. By the WPS regulations, the EPA established requirements that it determined are “likely to reduce substantially the number of pesticide-related illnesses and injuries to agricultural employees as the result of occupational exposures to pesticides.” *Id.*

The WPS regulations require pesticide registrants, such as DuPont, to “add appropriate labeling statements referencing the [] regulations and specifying application restrictions, restricted-entry intervals (REIs), personal protective equipment (PPE), and notification to workers of pesticide applications,” all to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. *Id.* at 38,102. At issue in this case are the personal protective equip-

ment requirements for early-entry agricultural workers, codified at 40 C.F.R. § 156.212(e) and (j), requiring that the label include a protective eyewear warning for pesticides classified as “toxicity category II” for eye irritation potential. No such warning is required or needed for pesticides classified as “toxicity category III,” the category to which DuPont alleges its products properly belong.

The labeling requirements of the WPS regulations are central to accomplishing the goals of protecting human health and the environment. Indeed, it is not an exaggeration to state that, without compliance by registrants with the labeling requirements, the ability to enforce the measures designed to protect human health and the environment is significantly impaired. For example, an agricultural employer must “[a]ssure that any [applicable] pesticide is used in a manner consistent with the labeling of the pesticide.” 40 C.F.R. § 170.7. FIFRA further provides that it is unlawful for any person “to use any registered pesticide in a manner inconsistent with its labeling.” FIFRA § 12(a)(2)(G), 7 U.S.C. § 136j(a)(2)(G). Obviously, if the labeling does not accurately state the applicable requirements, then the applicable requirements cannot be effectively implemented by pesticide users such as agricultural employers and workers.⁵

The WPS regulations contemplated a phase-in of the new labeling requirements in that the new WPS labeling was allowed, but not required, on affected pesticide products sold or distributed between April 21, 1993 and April 21, 1994, and was required for all affected products sold or distributed after April 21, 1994. 40 C.F.R. § 156.200(c)(2)-(3).⁶ Because regulations promulgated under FIFRA only allow the sale or distribution of pesticide products bearing labeling that has been approved by the EPA, during the transition period of April 21, 1993, through April 21, 1994, registrants were allowed to sell or distribute pesticides bearing either non-WPS labeling that had been approved as part of the product’s earlier registration or new WPS compliant labeling that had been approved by EPA or was otherwise authorized to be used.

The WPS regulations are designed to augment the existing FIFRA regulations, which provide a comprehensive system for the registration of pesticide products and the labeling of those products. Specifically, the new WPS labeling

⁵ It is important to note that negative consequences may flow from both over-protective and under-protective labeling: for example, labeling with instructions for too little protection may increase worker injuries and, conversely, labeling with instructions for protection greater, or different, than that required by the regulations may result in employers bearing possibly inappropriate costs, as well as causing confusion in the minds of users over the significance and meaning of label warning and caution statements.

⁶ The labeling provisions of the WPS regulations became effective on October 20, 1992. 40 C.F.R. § 156.200(c)(1).

requirements amend 40 C.F.R. part 156, which contains general provisions governing pesticide label content and requires use of specific label language. Although the WPS regulations require pesticide registrants to add appropriate language to pesticide labels, the WPS regulations did not modify the previously existing requirements for registration of pesticides and pesticide labels set forth in 40 C.F.R. part 152.⁷ Significantly, those existing regulations prohibit the use of modified labeling prior to EPA approval of an application to amend the pesticide's registration:

Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration * * *. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.

40 C.F.R. § 152.44(a).⁸ Because these regulations only allow the sale or distribution of pesticide products bearing labeling that has been approved by EPA as part of the product's registration, the only products that were allowed to be sold during the transition period contemplated by the WPS regulations of April 21, 1993 through April 21, 1994, were products bearing non-WPS labeling that had been approved as part of the product's earlier registration or products bearing new WPS-compliant labeling that had been approved as a registration amendment.

Nevertheless, in the implementation of the WPS labeling requirements, EPA recognized that prior review of all labeling amendments would prevent rapid implementation of the new WPS labeling requirements. EPA recognized that a "large number of products will be affected by the new requirements," 57 Fed. Reg. at 38,105, and that it could not quickly perform product-by-product reviews of all pesticides subject to the WPS regulations. EPA was expecting between 6,000 and

⁷ The WPS regulations did add a specific provision applicable to the WPS labeling requirements for "modification on special review," which is otherwise generally governed by 40 C.F.R. part 154. See 40 C.F.R. § 156.204(a). In addition, the WPS regulations specifically state that other modifications, waivers, or alternative labeling statements may be approved by the Agency under the authorities granted by FIFRA §§ 3, 6, and 12, and that "[a] registrant who wishes to modify any of the statements required in §§ 156.206, 156.208, 156.210, or 156.212 must submit an application for amended registration unless specifically directed otherwise by the Agency." *Id.* § 156.204(b).

⁸ This restriction is consistent with the legislative policy underlying FIFRA that the question of a product's compliance with the Act be resolved before the pesticide can be marketed by the registrant. This policy was first established by the 1964 amendments to FIFRA (as enacted in 1947), which amendments shifted the burden of proof on the question of compliance to the applicant by eliminating the option for registration "under protest," see H. Rep. 88-1125 (1964), and was carried over into the present version of FIFRA as part of the overhaul of FIFRA in 1972, see H. Rep. No. 92-511 at 20 (1971) (noting that the burden of proof remains with the applicant as existed under the old FIFRA).

8,000 WPS label amendment applications. Transcript of Hearing (Aug. 20-26, 1997) (“Hearing Tr.”), vol. II at 45. Stated simply, EPA noted that it could not “through a product-by-product review, quickly or adequately reduce the incidence of pesticide-related injuries and illnesses.” 57 Fed. Reg. at 38,106. Accordingly, EPA issued a series of guidance documents to aid in the efficient and expeditious implementation of the new labeling requirements. *See* 57 Fed. Reg. at 38,141-42; PR-Notice 93-7 (April, 1993); PR-Notice 93-11 (August, 1993).

The initial source of guidance appeared in the preamble to the final WPS rule and provided an overview of the options available to registrants for coming into compliance with the new labeling requirements. It also advised that a “PR-Notice” would be issued to provide more detailed guidance. 57 Fed. Reg. at 38,141-142.⁹ Subsequently, PR-Notice 93-7, issued in April 1993, provided guidance as to the exact language to be added to pesticide labeling and other options for compliance.¹⁰ PR-Notice 93-11, issued a few months later, in August 1993, provided supplemental guidance regarding issues that had arisen after the issuance of PR-Notice 93-7, and offered a “registrant-verification” option for registrants to use modified labeling prior to obtaining EPA approval. As is relevant to the present case, in order to qualify for the “registrant-verification” option under PR-Notice 93-11, “the registrant [had to] certif[y] in the WPS amendment application submitted to EPA that the labeling instructions in PR-Notice 93-7 are followed exactly.” PR-Notice 93-11, *supp. A* at 1.

The registrant-verification option as implemented by PR-Notice 93-11 does not fit within any of the authorized exceptions to the regulatory prohibition under 40 C.F.R. § 152.44(a) against the sale or distribution of products bearing modified labeling prior to the approval of an application for amended registration.¹¹ Thus, the guidance in PR-Notice 93-11 regarding registrant-verification would appear to have been a statement by EPA regarding its intention to use its discretion not to enforce technical violations of section 152.44(a) where the guidance of PR-

⁹ To the extent any conflict exists among these documents, we would generally interpret the subsequent, more detailed guidance as controlling.

¹⁰ Other options included deletion of uses for which WPS compliance is required and cancellation of registration. PR-Notice 93-7 at 8.

¹¹ The exceptions to the regulatory prohibition established in section 152.44(a) that are set forth in section 152.44(b) would appear not to be applicable. Those exceptions allow EPA in its discretion not to require the submission of an application for amended registration. In contrast, the exercise of the registrant-verification option as contemplated by PR-Notice 93-11 was premised upon the prior submission of an application for amended registration, which would still be reviewed by EPA, albeit after the registrant was permitted to begin using the modified labeling.

Notice 93-7 is “followed exactly.” PR-Notice 93-11, supp. A at 1.¹²

Both the preamble and PR-Notice 93-7 stated that the registrant is required to file an application for amended registration. 57 Fed. Reg. at 38,143-144; PR-Notice 93-7 at 8. Because the new WPS labeling requirements may prescribe multiple statements on an individual product depending upon a pesticide’s toxicity level and the various potential routes of exposure, PR-Notice 93-7 required each applicant to specifically state in the application the toxicity category applicable for the pesticide through each route of exposure. PR-Notice 93-7, supp. II at 4, 5-6, supp. III at 7.¹³ This case, however, concerns a single route of exposure, referred to as “eye irritation potential.” PR-Notice 93-7 set forth detailed guidance specifying the exact language required in the amended labels for each toxicity category indicated by the applicant for each route of exposure. For toxicity category II for eye irritation potential, PR-Notice 93-7 stated that the label must contain in the Agricultural Use Requirements Box (for the protection of early-entry agricultural workers) and in the “Hazards to Humans (and Domestic Animals)” section of the label (for the protection of handlers and applicators, among others) a statement requiring use of protective eyewear. Protective eyewear is not required in either section of the label for pesticides with toxicity category III for eye irritation potential.¹⁴

Registrants who elected to add WPS-compliant language to their labels (in contrast to those who elected to delete agricultural uses from their labels to escape WPS coverage) were required to submit a copy of their proposed amended label and were allowed to elect between two different types of certification statements to include with the application. The first certification statement included the following key language:

I certify that the revised labeling being submitted for this product is in complete accordance with the labeling requirements of PR-Notice 93-7 * * *. Where exact language is specified in the PR-Notice I have used that language exactly, in the location specified.

¹² Similarly, EPA’s guidance discussed in the following paragraph (which advised applicants to state in their amendment applications the toxicity of their products through the different routes of exposure, without providing studies to support the toxicity statement) would appear to have been an exercise of discretion in implementing the registration regulations.

¹³ PR-Notice 93-7 directed the registrant to “[u]se data in your files to determine the Toxicity Category of your end-use product for each route of entry.” PR-Notice 93-7, supp. III at 7. It also advised where a registrant might obtain data if the registrant did not have the data in its files. *Id.*

¹⁴ This guidance provided in PR-Notice 93-7 as to the exact language for each toxicity category simply restates the exact language requirements of the regulations. 40 C.F.R. § 156.212(e).

PR-Notice 93-7, supp. II at 5. (As discussed below, DuPont submitted this certification statement for each of its four products.) PR-Notice 93-11, which was issued several months after PR-Notice 93-7, stated that applicants who had provided this certification statement of having followed the labeling requirements in PR-Notice 93-7 exactly may elect to use the self-verification option.

The second certification statement allowed the pesticide registrant to indicate that deviations from the language required by PR-Notice 93-7 were being requested. PR-Notice 93-7 stated that applications certifying exact compliance with the language requirements of PR-Notice 93-7 would be reviewed on an expedited basis. It also specifically warned that “[m]ost label changes require Agency approval before product may be sold or distributed bearing the new label. If any changes to your label are neither reviewed nor accepted, sale or distribution of product bearing a label including such changes will probably be in violation of FIFRA, and could subject you to enforcement action.” PR-Notice 93-7, supp. II at 6-7. PR-Notice 93-11 stated that prior approval would not be required if the applicant elected the self-verification option. In addition to the warning in PR-Notice 93-7, the preamble to the WPS regulation also warned 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. at 38,144.

C. Factual and Procedural Background

As of the effective date of the WPS regulations, October 20, 1992, the four pesticide products at issue in this case (Bladex 4L, Bladex 90 DF, Extrazine II 4L, and Extrazine II DF) were registered with the EPA, and DuPont had been selling and distributing those pesticides with EPA-approved labels. After receiving PR-Notice 93-7, DuPont acknowledged that these pesticides were subject to the new WPS requirements. To come into compliance, DuPont filed registration-amendment applications, dated July 14, 1993. Each of DuPont’s applications for amended registration indicated that the pesticide had an eye irritation potential of toxicity category II.¹⁵ Each application also contained a certification statement,

¹⁵ The applications for Bladex 4L and Bladex 90 DF specifically stated category II for eye irritation potential. Although the applications for Extrazine II DF and Extrazine II 4L failed to state a toxicity category for eye irritation potential, PR-Notice 93-7 clearly stated that treatment equivalent to toxicity category II would be required if the toxicity category for eye irritation potential is left blank and the product’s “signal” word is “warning.” PR-Notice 93-7, supp. III at 9-10 (guidance for worksheet Blocks 6, 8 and 10); *see also* 40 C.F.R. § 156.212(d). As part of the original registration of the product, a signal word is assigned under 40 C.F.R. § 156.10(h) based on the highest hazard through any of the identified routes of exposure. The signal word for the Extrazine products is “warning” and, therefore, DuPont’s applications, which certified exact compliance with PR-Notice 93-7, necessarily contemplated treatment equivalent to toxicity category II for eye irritation potential. For ease of reference, we will refer to DuPont’s applications as having specified toxicity category II for eye irritation potential for all four pesticides.

certifying that the revised labeling being submitted was in complete compliance with PR-Notice 93-7. Complainant's Exhibits ("CX") 6 through 9. However, despite DuPont having specified toxicity category II for eye irritation potential for all four pesticides, it is undisputed that DuPont's proposed amended labels did not state in the Agricultural Use Requirements Box that use of protective eyewear is required.

At approximately the same time that DuPont submitted its applications for amended registration seeking approval of label modifications to comply with the WPS regulations, DuPont also submitted separate applications for amended registration in order to participate in an unrelated voluntary label amendment program run by the EPA, known as the voluntary cyanazine-exposure reduction program. Hearing Tr. vol. III at 58-85. DuPont had originally submitted its applications for approval of wording changes required for the cyanazine-reduction program and certain other changes in June 1993. *Id.* at 58-59. After receiving comments on the draft cyanazine-reduction amendments and after submitting revised drafts during August through October 1993, DuPont received preliminary approval from EPA's Special Review and Reregistration Division for DuPont's proposed cyanazine-reduction modifications. *Id.* at 59-67; Respondent's Exhibit ("RX") 92 (letter from Peter Caulkins, Acting Director of EPA's Special Review and Reregistration Division, to Tony Catka (Oct. 19, 1993)). The preliminary approval included instructions that DuPont should submit the proposed cyanazine-reduction label changes to EPA's Registration Division for final approval. *Id.* On October 28, 1993, after receiving this preliminary approval, DuPont submitted to EPA's Registration Division for final approval, its proposed amended labels containing both the cyanazine-reduction modifications and the proposed WPS modifications. Hearing Tr. vol. III at 67-68. Five business days later on November 4, 1993, the Registration Division issued letters for each amended label stating that approval had been granted and providing copies of the modified labeling stamped as approved (the "November 1993 Letters"). *Id.* at 84-85. (The exact scope of the approval granted by the November 1993 Letters was a matter of dispute early in this case and will be considered as the first issue in our discussion below.)

Subsequently, on March 11, 1994 and March 14, 1994, EPA's Registration Division sent Notices of Serious Error to DuPont, which were received by DuPont in mid-March 1994. CX 22 through 25. Those notices stated that EPA had reviewed DuPont's July 14, 1993 registration-amendment applications, i.e., the ones by which DuPont had requested approval of the proposed WPS label amendments and had certified were in complete compliance with PR-Notice 93-7. *Id.* The Notices of Serious Error, among other things, stated that DuPont's proposed label amendments were not in compliance with PR-Notice 93-7. *Id.* at 1. In particular, the Notices of Serious Error stated that "EPA has determined that one or more of the errors on the labeling you submitted to the Agency is categorized as '*serious*' as defined in PR-Notice 93-11." *Id.* The Notices of Serious Error also stated in bold letters that "YOU MUST NOT SELL OR DISTRIBUTE (INCLUDING RE-

LEASE FOR SHIPMENT) ANY PRODUCT BEARING THE SUBMITTED LABELING.” *Id.*

Notwithstanding its receipt of the March Notices of Serious Error, DuPont thereafter between April 1, 1994, and April 26, 1994,¹⁶ proceeded to sell or distribute pesticides bearing the WPS label modifications that DuPont had submitted with its July 1993 applications for amended registration.¹⁷

EPA’s investigation of DuPont’s sales began after DuPont informed EPA that notwithstanding the Notices of Serious Error, it had continued to sell and distribute pesticides bearing the modified labels. Pesticide Enforcement ultimately filed the complaint commencing this action in October 1994. The complaint alleged that DuPont made the 379 shipments between April 1, 1994, and April 26, 1994, bearing the July 14, 1993 proposed amended WPS labels. The complaint further alleged (1) that the Notices of Serious Error had informed DuPont that its proposed amended labels were not approved; (2) that the proposed amended labels were not adequate to protect health and the environment; (3) that a pesticide is misbranded if its label does not contain a caution or warning statement of the kind described in FIFRA section 2(q)(1)(F)-(G); (4) that DuPont sold and distributed pesticides bearing the proposed amended labels; and (5) that such conduct violated FIFRA section 12(a)(1)(E), which prohibits the distribution or sale of misbranded pesticides.

DuPont’s answer acknowledged that the 379 shipments were made on or about the dates alleged in the complaint and that the WPS language in the labels of those shipments was “identical to that submitted to EPA on July 14, 1993.” Affirmative Defenses ¶ 2; *accord* Answer ¶¶ 13, 23, 33, 43. DuPont nevertheless denied that its conduct amounted to the distribution or sale of a misbranded pesticide, and, among other things, DuPont alleged that its July 1993 applications for amended registration covering the proposed WPS changes to its labels had been approved by the November 1993 Letters.

¹⁶ In point of fact, it appears DuPont may have begun to sell and distribute all four pesticide products bearing amended labels earlier — sometime after DuPont submitted its applications for amended registration. Thus, Pesticide Enforcement has stated that it could have brought more than 379 counts in this case, but that it “chose to limit its action to those shipments made after March 31, 1994, the date of [DuPont’s] response to the Notices of Serious error.” Complainant’s Brief in Support of Proposed Findings of Fact, Conclusions of Law, and Order (Nov. 14, 1997) at 42 n.64.

We also note that the last day of the alleged violations corresponds to when DuPont and EPA’s Registration Division reached agreement on a procedure for DuPont to use stickers and brochures to correct the labeling on future sales of existing product. Post-Hearing Brief of Respondent at 29-30.

¹⁷ On appeal, DuPont argues, however, that Pesticide Enforcement failed to prove that all of the 379 shipments at issue in this case were made actually bearing the WPS label modifications that DuPont had submitted with its July 1993 applications. This issue will be considered in the last part of our discussion below.

In February 1995, DuPont filed a motion seeking dismissal of the complaint on the grounds of the alleged approval of its WPS label amendment applications by the November 1993 Letters. DuPont argued that because the WPS label changes had been approved by the November 1993 Letters, the subsequent Notices of Serious Error were “null and void” as improper attempts to change the terms and conditions of the Bladex and Extrazine products’ registrations without following the procedures required for cancellation of the approved registration. Respondent’s Motion to Dismiss Based on Threshold Legal Issues (Feb. 27, 1995). The Presiding Officer denied DuPont’s motion to dismiss by order dated March 6, 1997 (the “March 1997 Order”).

Thereafter, an evidentiary hearing was held, at which time DuPont sought to submit both documentary evidence and witness testimony to show that the Bladex and Extrazine pesticide products should not be categorized as toxicity category II for eye irritation potential, but instead should be categorized as toxicity category III. This evidence would have provided DuPont with the factual foundation necessary to argue that the WPS regulations do not require these pesticide products to bear a protective eyewear warning in the Agricultural Use Requirements box of the label. However, the Presiding Officer would not admit DuPont’s proffered evidence, holding that because the proffered evidence had not been submitted in connection with DuPont’s applications for amended registration, it is not relevant to this proceeding. Thereafter, the Presiding Officer issued the Initial Decision finding DuPont liable for 379 sales or distributions of misbranded pesticides and assessing a penalty of \$5,000 for each such sale or distribution, resulting in an aggregate penalty of \$1,895,000.

II. DISCUSSION

Pesticide Enforcement’s complaint alleged that DuPont violated the prohibition in FIFRA section 12(a)(1)(E)¹⁸ against the sale or distribution¹⁹ of pesticides that are “misbranded,” as that term is defined in FIFRA section 2(q)(1)(F) and (G),²⁰ which provide as follows:

¹⁸ Section 12(a)(1)(E) provides that “it shall be unlawful for any person in any State to distribute or sell * * * any pesticide which is * * * misbranded.” FIFRA § 12(a)(1)(E), 7 U.S.C. § 136j(a)(1)(E).

¹⁹ The phrase “distribute or sell,” and other grammatical variations thereof including “distributed or sold,” are defined by the regulations to mean, among other things, “shipping.” 40 C.F.R. § 152.3(j). Accordingly, DuPont’s admission that it made the 379 “shipments” as alleged in the complaint (Affirmative Defenses ¶ 2; *accord* Answer ¶¶ 13, 23, 33, 43) establishes that it distributed or sold those pesticides.

²⁰ The term “misbranded” is defined in FIFRA section 2(q), 7 U.S.C. § 136(q), which sets forth numerous provisions that define compliant and noncompliant pesticide labeling and packaging.

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(F) 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 * * * are adequate to protect health and the environment;

(G) the labeling accompanying it 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)(F)-(G), 7 U.S.C. § 136(q)(1)(F)-(G).²¹

The complaint alleged that the Bladex and Extrazine products were misbranded because the labeling omitted a protective eyewear warning in the Agricultural Use Requirements box of the label. As explained earlier, statements specifying personal protective equipment must be added to a pesticide's label as a result of the WPS rulemaking and for pesticides with a toxicity category II for eye irritation potential, the WPS regulations require that a protective eyewear warning be included in both the Hazards to Humans (and Domestic Animals) section and the Agricultural Use Requirements box of the label. *Id.* § 156.212(e). A protective eyewear statement, however, shall not be used for pesticides with a toxicity category III for eye irritation potential. *Id.*

The issues raised by DuPont on appeal primarily concern the proper burdens or presumptions governing proof in a penalty action as to whether a particular warning or direction for use is required under the definition of "misbranded" set forth in FIFRA section 2(q)(1)(F) and (G). The principal issues argued by the parties concern whether DuPont was properly precluded from introducing its proffered evidence regarding whether the Bladex and Extrazine pesticide products are, in fact, toxicity category II for eye irritation potential or whether they should be categorized in the lower toxicity category III, for which EPA concedes there is no requirement for the products' label to contain a protective eyewear warning.

DuPont's arguments concerning evidentiary burdens and presumptions, stated very briefly, are as follows: (1) it was denied due process when the Presiding Officer would not consider its toxicity evidence; and (2) the Presiding Officer erroneously treated DuPont's application for amended registration (which, as noted, identified these pesticides as toxicity category II) as "conclusive and irrefutable" proof of the pesticides' toxicity category. DuPont also argues that EPA

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The complaint, however, specifically identified only section 2(q)(1)(F) and (G) as implicated in this case.

²¹ Although the complaint cites the misbranding definition in FIFRA section 2(q)(1)(F), both Pesticide Enforcement and the Presiding Officer relied primarily on FIFRA section 2(q)(1)(G).

guidance permitted it to use non-complying labels if the products were “released for shipment” prior to January 1, 1994, and that Pesticide Enforcement failed to show that these products were released for shipment after that date.

However, before we discuss these arguments, we must first consider two additional arguments raised by DuPont that are logically antecedent to the toxicity question and the “released for shipment” argument. DuPont contends in its proposed alternative findings of fact that the Presiding Officer erred in holding that the WPS label modifications proposed by DuPont were not approved by the November 1993 Letters. Notice of Appeal of Appellant E.I. du Pont de Nemours and Company at 3. DuPont also argues that the Presiding Officer erred in relying upon the WPS labeling requirements as establishing a misbranding standard under FIFRA section 2(q)(1)(F) and (G). DuPont’s Appeal Brief at 33-35.²²

In the following discussion, we consider the issues in this order: in Part A, we consider the scope of approval granted by the November 1993 Letters; in Part B, we consider whether the WPS regulations established misbranding standards that implement the statutory definition; in Part C, we consider the evidence of misbranding submitted by Pesticide Enforcement and whether DuPont was properly precluded from submitting its toxicity studies; finally, in Part D, we consider DuPont’s arguments regarding the alleged failure of proof as to the labeling actually used on the 379 shipments and DuPont’s “release for shipment” argument. For the following reasons, we affirm the Presiding Officer’s determination that the WPS regulations establish a misbranding standard and his rejection of DuPont’s failure-of-proof and “release for shipment” arguments. However, we reverse the Presiding Officer’s conclusion that the approval granted by the November 1993 Letters did not encompass the proposed WPS label modifications and we conclude that DuPont is entitled to submit its toxicity studies. We therefore remand this matter for consideration of DuPont’s toxicity evidence and for consideration of an additional issue discussed below as to an internal inconsistency in the use of protective eyewear warnings that is apparent on the face of DuPont’s labels.

²² DuPont has argued that “[t]he record * * * reveals bias on the ALJ’s part in EPA’s favor.” DuPont’s Appeal Brief at 8 n.4, 14. This argument is rejected first because DuPont did not raise the issue of bias before the Presiding Officer, see *In re Woodcrest Mfg, Inc.*, 7 E.A.D. 757 (EAB July 23, 1998), *aff’d Woodcrest Mfg., Inc. v. EPA*, No. 3:98 CV 0456 AS (N.D. Ind. Dec. 14, 1999), and second, none of the parts of the transcript cited by DuPont reflect anything other than the Presiding Officer’s efforts at courtroom administration and diligent discharging of his fact finding responsibilities. What DuPont characterizes as “coaching” of witnesses appears instead to be proper effort to obtain clarification from witnesses of what otherwise would have been ambiguous answers.

A. *Whether the November 1993 Letters Approving DuPont's Amended Registration Authorized Use of the Labels as Approved*

In its list of Proposed Alternative Findings of Facts, DuPont has requested that we find that “[f]or each of the Bladex and Extrazine products, Respondent received letters dated November 4, 1993 from EPA stating that the proposed labeling — which did not include protective eyewear warnings in the Agricultural Use Requirements box — was ‘acceptable.’” DuPont’s Notice of Appeal at 3. In its appeal brief, DuPont states further that “[t]he letters containing EPA’s approval were unconditional.” DuPont’s Appeal Brief at 10. Thus, although not specifically identified in its listing of issues on appeal and discussed only in passing in DuPont’s appeal briefs,²³ DuPont nevertheless seeks to challenge the Presiding Officer’s determination that the November 1993 Letters did not authorize DuPont’s use of the WPS portions of the labels.

As noted in our summary of the procedural background, DuPont originally raised the question of approval in the form of a motion to dismiss. DuPont argued that the November 1993 Letters approved the WPS label amendments and that the “approval was unconditional and unqualified and did not indicate in any way that any additional approval would be required by the Agency.” Respondent’s Motion to Dismiss Based on Threshold Legal Issues at 26 (Feb. 27, 1995). DuPont also argued that “Once EPA has approved the terms and conditions of registration — i.e., the label — it cannot change the terms and conditions without following the procedures for canceling the registration pursuant to FIFRA § 6(b).” *Id.* at 28. DuPont also asserted that “The Agency’s unconditional approval of DuPont’s WPS labeling on November 4, 1993 bars the Agency from bringing this enforcement action because an EPA-approved label cannot be misbranded.” *Id.*

Pesticide Enforcement responded to DuPont’s request for dismissal based on the November 1993 Letters by filing the affidavit of Robert J. Taylor (“Mr. Taylor”), who stated that his responsibilities included both final review of the cyanazine-reduction amendments to the Bladex and Extrazine labels submitted on October 28, 1993, and issuance of the November 1993 Letters. Taylor Aff. ¶¶ 1, 6, 9. Mr. Taylor stated that he did not review the proposed WPS label modifica-

²³ In its October 27, 1999 supplemental brief on appeal, DuPont asserts without any additional explanation that EPA unconditionally approved DuPont’s label amendment applications on “November 29, 1993.” Supplemental Brief of Respondent E.I. Du Pont De Nemours and Company at 8 n.5, and 11-13 (Oct. 27, 1999). The assertion of an approval on November 29, 1993, appears to be a typographical error as an allegation of approval on that date does not appear anywhere in DuPont’s prior briefs to this Board and does not appear in DuPont’s post-hearing briefs before the Presiding Officer. *See e.g.*, Post-Hearing Brief of Respondent at 19-21, 59-62 (Nov. 14, 1997); Respondent’s Proposed Findings of Fact and Conclusions of Law ¶¶ 135-151. However, to the extent that DuPont is seeking to raise a new argument on appeal, it must be rejected on the grounds that it was not first argued to the Presiding Officer and therefore has been waived.

tions. *Id.* ¶ 8. With respect to the allegation that the November 1993 Letters stated unconditional approval of the proposed labeling, Mr. Taylor stated that “it was neither necessary nor required to specify that my acceptance did not apply to [DuPont’s] verified WPS statements.” *Id.* ¶ 9. Mr. Taylor also stated that he discussed the proposed amendments with Tony E. Catka, DuPont’s Product Registration Manager, and that “Mr. Catka also stated that he understood I would not review WPS statements for the four cyanazine-reduction pesticide label amendments that DuPont submitted in October 1993.” *Id.* ¶ 10.

DuPont did not respond to the Taylor Affidavit by filing any affidavit or by providing any reference to EPA’s guidance documents or any other information in the record of this case to show any error in Mr. Taylor’s statements. Instead, it argued that any discussions between Mr. Taylor and Mr. Catka “are irrelevant since they were merged into the Agency’s formal approval of DuPont’s labels on November 4, 1993 without qualification, and the terms of the Agency’s official written registration approval speak for themselves.” Respondent’s Reply In Support of Its Motion to Dismiss at 8 n.2 (Apr. 25, 1995).

In the March 1997 Order, the Presiding Officer concluded that “The filings submitted on this issue establish that respondent was aware that the process which considered its amendments for cyanazine containing products did not approve the WPS amendment that was self-certified in July 1993.” March 1997 Order at 7. Further, the Presiding Officer concluded that “The evidence does not support a claim that complainant changed the conditions of respondent’s registration without a hearing.” *Id.* Thus, in the March 1997 Order, the Presiding Officer rejected DuPont’s argument that its proposed WPS label modifications had been approved by the November 1993 Letters.

Upon review, we conclude that the Presiding Officer erred when he determined in the March 1997 Order that the November 1993 Letters did not stand as approval of DuPont’s proposed label modifications, including their WPS components. We also conclude, however, that denial of DuPont’s motion to dismiss was nevertheless proper.

The Taylor Affidavit established that EPA’s Registration Division did not, in fact, perform a review of the WPS label modifications in connection with the issuance of the November 1993 Letters. The Taylor Affidavit also established that Tony E. Catka “stated that he understood [Mr. Taylor] would not review [the] WPS statements for the four cyanazine-reduction pesticide label amendments that DuPont submitted in October 1993.” Taylor Affidavit ¶ 10.²⁴ The Presiding Of-

²⁴ The Taylor Affidavit also set forth Mr. Taylor’s testimony that DuPont was aware that EPA did not intend the November 1993 Letters to grant approval of DuPont’s proposed WPS modifications.
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ficer's March 1997 Order, in effect, concluded that Mr. Taylor's uncontroverted testimony on these matters would be sufficient to entitle Pesticide Enforcement to judgment that the November 1993 Letters did not approve DuPont's proposed WPS labeling modifications. We disagree. Communications by EPA registration personnel, or other factual circumstances, not referenced on the face of EPA's formal letters granting amended registration, cannot modify or alter the clear, unambiguous terms of EPA's formal approval.

The November 1993 Letters, on their face, approved DuPont's applications for amended registration and stamped as approved DuPont's modified labels without comment.²⁵ Those modified labels contained the proposed WPS language that is at issue in this proceeding. Nothing on the face of the November 1993 Letters or any of the enclosures gave any indication that the approval was less than full approval of the entire labeling. Specifically, the November 1993 Letters stated in full as follows:

The labeling referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable. Please submit five (5) copies of your final printed labeling before you release the product for shipment. A stamped copy of labeling is enclosed for your records.

Each of the four letters contained a copy of the specific product's labeling with an official EPA stamp marked "ACCEPTED" and identified the EPA registration number for the product.

While the Taylor Affidavit was sufficient to establish that EPA did not *intend* to grant approval of the proposed WPS modifications to DuPont's labels and that EPA had not yet performed a review of the WPS portions of the labeling, such facts cannot change the unqualified approval granted by the November 1993 Letters. A program that is responsible for the issuance of thousands of licenses — in this case, testimony established that EPA's pesticide program was expecting more than 8,000 WPS amendment applications — cannot be operated based on recollections of conversations and other circumstances that are not recorded on the face of the official license or registration. If we were to allow such evidence to modify the otherwise clear terms of a registration approval, it would create an unacceptable level of uncertainty potentially undermining reliance by

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As discussed in the text, these facts cannot change the terms of the formal approval granted by the November 1993 Letters. However, these facts may be relevant to the penalty assessed for any violation found on remand (but we do not decide this issue at this stage of this case).

²⁵ Where an approval is qualified, EPA's registration division stamps the labeling as "accepted with comments." *See, e.g.*, Notices of Serious Error, att. II.

both registrants and EPA on the requirements incorporated in the registrations of numerous other products. Therefore, we hold that the question of whether the registrations for DuPont's Bladex and Extrazine pesticide products had been amended to include DuPont's proposed WPS modifications must be based on the terms of EPA's official correspondence. Here, the November 1993 Letters on their face granted unqualified approval of the entire labeling and did not indicate that the proposed WPS modifications were not reviewed or approved. Accordingly, we hold that, although EPA may not have intended to grant approval of DuPont's proposed WPS label modifications, nevertheless, it did in fact grant that approval when it sent the November 1993 Letters.

DuPont argued in its motion to dismiss that since its proposed WPS labeling was approved in November 1993, it was entitled to dismissal of this action. Specifically, DuPont argued that "[t]he Agency's unconditional approval of DuPont's WPS labeling on November 4, 1993 bars the Agency from bringing this enforcement action because an EPA-approved label cannot be misbranded." Respondent's Motion to Dismiss Based on Threshold Legal Issues at 26 (Feb. 27, 1995). DuPont's argument in its motion to dismiss, however, is mistaken as to the effect that the November 1993 approval has on this action. FIFRA specifically states that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." FIFRA § 3(f)(2). Instead, "registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter." *Id.* More generally, as noted in our discussion of the statutory background, FIFRA contemplates that a determination made under FIFRA section 3 may later be reexamined on the grounds that the product does not comply with the registration standards.

Notwithstanding its arguments in its motion to dismiss, during oral argument DuPont conceded that registration approval may be challenged in a misbranding enforcement action. In particular, during oral argument Judge McCallum posed the following hypothetical and DuPont's counsel responded as follows:

JUDGE McCALLUM: * * * [I]f the Agency granted the application and it contained what EPA later thought was a toxicity characterization that * * * minimized the toxicity of the product, then the statute clearly provides a process for the Agency to come back in and make a determination that [the product] causes unreasonable adverse effects on the environment. * * * [I]t is a cancellation proceeding.

MR. BARRETT: Or it is a misbranding proceeding.

* * * * *

[I]n *Ciba-Geigy Corporation v. EPA*, * * * the Agency itself took the position that it could take action against products that met your description of being unsafe because it didn't have the correct warnings, under either the misbranding provisions or the registration provisions. There are two separate enforcement tracks.

Transcript of Oral Argument at 15-16 (Sept. 29, 1999) (discussing *CIBA-GEIGY Corp. v. EPA*, 801 F.2d 430 (D.C. Cir. 1986)); see also Supplemental Brief of Respondent E.I. Du Pont De Nemours and Company at 10 (Oct. 27, 1999) ("This construction makes sense as a matter of public policy * * *"). Accordingly, as DuPont concedes, even if particular labeling has been approved during the registration process, the registration approval does not bar EPA from charging that the labeling is misbranded. We agree.

For the foregoing reasons, DuPont was not entitled to rely on the registration approval granted by the November 1993 Letters as a defense to this misbranding enforcement action. DuPont, nevertheless, was entitled under FIFRA section 3(f)(2) to rely on the approval granted by the November 1993 Letters as prima facie evidence that its labeling complies with the applicable requirements. However, the evidence submitted at the evidentiary hearing showing that DuPont's own applications for amended registration characterized these products as toxicity category II was sufficient, in the circumstances of this case, to overcome the prima facie evidence of compliance established by the November 1993 Letters. Accordingly, while we conclude that the Presiding Officer erred in finding that DuPont's proposed WPS label modifications had not been approved by the November 1993 Letters, we also conclude that denial of DuPont's motion to dismiss was proper.

B. *Whether the WPS Regulations Establish a Misbranding Standard*

Next, we turn to the standards for proof of "misbranding" that governs this enforcement action and DuPont's argument that the Presiding Officer erred when he concluded that "the WPS rule establishes a standard for misbranding under [FIFRA] section 2(q)(1)(G) [and that] [p]roof that Respondent failed to include a warning or caution statement required by the WPS rule on the labels of the Bladex and Extrazine products is sufficient to establish that the labels were misbranded under FIFRA § 2(q)(1)(G)." DuPont's Appeal Brief at 33, quoting *Init. Dec.* at 14 (modifications made by DuPont).

DuPont correctly notes that the analysis must begin with the statutory standard set forth in the definition of "misbranded." For the violations at issue here the

substantive standard is found in the requirement that the directions for use and warning or caution statements must be adequate to “protect health and the environment.” FIFRA § 2(q)(1)(F)-(G), 7 U.S.C. § 136(q)(1)(F)-(G).²⁶ The Presiding Officer correctly held that EPA satisfied the substantive standard for misbranding under FIFRA section 2(q)(1)(F) and (G) when it promulgated the WPS labeling requirements. Init. Dec. at 11-14. EPA’s intent to establish such a standard is evident from the following excerpt from the notice of proposed WPS rulemaking:

FIFRA section 2(q)(1) provides that pesticide labeling must contain both necessary directions for use and warnings or caution statements which, if complied with, are adequate to protect health and the environment. The Agency proposes to find that worker protection standards are necessary to protect health of agricultural workers and pesticide handlers, and therefore should be required to be placed on pesticide labeling.

53 Fed. Reg. 25,970, 25,998 (July 8, 1988).

In its appeal brief, DuPont also argues that EPA did not have the authority to issue a misbranding standard by regulation. Specifically, DuPont argues that “The ALJ’s conclusion is based on the flawed supposition that EPA is authorized under FIFRA to make a generalized — rather than a product-specific — risk determination of the warning labels that are required to protect human health.” DuPont’s Appeal Brief at 33. DuPont, thus, argues that the question of whether particular labeling language “is adequate to protect health and the environment” within the meaning of FIFRA section 2(q)(1)(F) and (G) must be made on a product-specific basis without reference to regulations specifying labeling requirements for toxicity categories. This argument was stated in greater detail in DuPont’s post-hearing brief, where DuPont argued that “Complainant cannot rely on the WPS rule to establish misbranding because nothing in that rule sets a standard for misbranding.” See Post-Hearing Brief of Respondent at 36. DuPont argued further that the EPA did not provide notice that the WPS regulations would define conduct that would constitute misbranding. *Id.* at 36-41. These arguments must be rejected.

As noted by the Presiding Officer, DuPont primarily relies upon the opinion of the Administrator in *In re Stevens Industries, Inc.*, 1 E.A.D. 9 (Adm’r 1972), for its argument that EPA cannot make a generalized risk determination, but instead that a product-specific finding is required under FIFRA section 2(q)(1)(F)

²⁶ The phrase “protect health and the environment” is defined to mean “protection against any unreasonable adverse effects on the environment,” *id.* § 2(x); and that phrase is further defined as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” *Id.* § 2(bb).

and (G). Init. Dec. at 11. The Presiding Officer held, at pages 11-13 of the Initial Decision, that DuPont's reliance on *Stevens Industries* is misplaced. First, the Presiding Officer correctly observed that *Stevens Industries* was decided before Congress enacted FIFRA section 25(a), which authorizes the Administrator to promulgate regulations under FIFRA, and that *Stevens Industries* did not purport to apply a duly promulgated regulation.²⁷ Second, the Presiding Officer also noted that the Agency specifically determined as part of the WPS rulemaking, at 57 Fed. Reg. at 38,105, that it has the authority to promulgate regulations establishing disclosure and warning requirements, including the warning regarding protective eyewear at issue here, based on "a generalized risk determination * * * where reaching individualized risk determinations would unnecessarily impair the Agency's ability to carry out its statutory duty to protect agricultural workers." Init. Dec. at 12 (noting that the Agency relied upon *Associated Builders and Contractors, Inc. v. Brock*, 862 F.2d 63, 68 (3d Cir. 1988), in making this rulemaking determination). The Presiding Officer also held that nothing in the statutory text of FIFRA section 2(q)(1)(F) or (G) precludes the establishment of misbranding standards by regulation. Upon review, we find no error in the Presiding Officer's analysis of these issues and hereby reject DuPont's arguments to the contrary.

DuPont's argument that it did not have notice that the WPS regulations created a misbranding standard is also rejected. This contention fails to recognize that the regulatory labeling requirements in the WPS were promulgated to interpret and implement the statutory misbranding definition and, therefore, establish the standard for compliance with the statute. The Presiding Officer correctly observed that both the proposed rulemaking and notice of final rulemaking gave specific notice to registrants that a failure to comply with the WPS rule could result in a misbranding charge. Init. Dec. at 10, citing 53 Fed. Reg. 25,970, 26,001 (July 8, 1988) (proposed), 57 Fed. Reg. 38,102, 38,144 (April 21, 1992) (final). In addition, we note that notice of the fact that the Part 156 regulations establish misbranding standards is given by the registration regulations, *see* 40 C.F.R. § 152.112(f) (referencing Part 156 as a misbranding standard), by the notice of proposed rulemaking that resulted in the creation of Part 156, 49 Fed. Reg. 37,960 (Sept. 26, 1984) (stating that "[t]he statutory standard that is the basis

²⁷ For the same reasons, we reject as inapplicable two cases cited by DuPont for the first time on appeal. DuPont's Appeal Brief at 16-17 (citing *Continental Chemiste Corp. v. Ruckelshaus*, 461 F.2d 331 (7th Cir. 1972), and *Stearns Elec. Paste Co. v. EPA*, 461 F.2d 293, 306 (7th Cir. 1972)). Both cases, like the *Stevens Industries* case, did not involve application of regulations promulgated, pursuant to FIFRA § 25(a)(1), interpreting and elaborating upon the definition of "misbranded." In addition, the *Continental Chemiste* case is inapplicable because it involved a question of the relationship between two different statutory schemes, not the relationship between FIFRA and regulations promulgated under FIFRA. *Continental Chemiste* addressed the question of whether a pesticide could be found to be misbranded under FIFRA if it may cause certain foods to become "adulterated" within the meaning of the Food, Drug and Cosmetic Act. It is also worth noting that the *Stearns Electric* court specifically stated that the issue being considered did not involve interpretation or application of a regulation. *Stearns Elec.*, 461 F.2d at 304.

for Agency regulation of pesticide labeling is contained in section 2(q) of FIFRA”), and the notice of proposed WPS rulemaking. 53 Fed. Reg. 25,970, 25,998 (July 8, 1988) (“FIFRA section 2(q)(1) provides that pesticide labeling must contain both necessary directions for use and warnings or caution statements which, if complied with, are adequate to protect health and the environment. The Agency proposes to find that worker protection standards are necessary to protect health of agricultural workers and pesticide handlers, and therefore should be required to be placed on pesticide labeling.”).

For all of these reasons, we hold that the Presiding Officer did not err when he concluded that “the WPS rule establishes a standard for misbranding under [FIFRA] section 2(q)(1)(G).” Init. Dec. at 14. We therefore hold that proof that a pesticide product’s label does not contain a warning or use statement that complies with the specific language required by the WPS rule is sufficient to establish that the product is misbranded under FIFRA section 2(q)(1)(F) or (G). Next, we turn to the question of whether Pesticide Enforcement’s evidence proves that the labels at issue in this case failed to comply with the specific labeling requirements of the WPS rule and whether DuPont should have been allowed to submit its toxicity evidence to contradict Pesticide Enforcement’s evidence.

C. Compliance with the WPS Rule: Toxicity Issue and Related Matters

As noted in the foregoing discussion, the WPS labeling regulations specify the particular label language that may be necessary to protect health and the environment and which EPA has determined must be included on the labeling of pesticide products intended for agricultural uses. The regulations, however, do not require the same label language for all pesticide products falling within the scope of the WPS regulations. Instead, the regulations establish different labeling requirements for different categories of pesticide products, based on the product’s toxicity through different routes of exposure. Thus, the regulations require, for each pesticide product, that a factual determination of the product’s toxicity be made as a predicate to determining the labeling language required by the regulations. In particular, the regulations state as follows:

The requirement for personal protective equipment is based on the acute toxicity category of the end-use product for each route of exposure as defined by § 156.10(h)(1). * * * 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.

40.C.F.R. § 156.212(d)(2).²⁸ Thus, whether a particular label warning is required under the WPS regulations is dependent upon the toxicity of the pesticide product determined first by “obtainable” data and, only if data is not obtainable, then by the signal word assigned to the product as part of its original registration.²⁹

The particular warning at issue in this case concerns protection against eye irritation. For pesticides with a toxicity category II for eye irritation potential, the WPS regulations require that a protective eyewear warning be included in two different sections of the label: (1) the Hazards to Humans (and Domestic Animals) section for warning to handlers and applicators; and (2) the Agricultural Use Requirements box for warning to agricultural and early entry workers. 40 C.F.R. § 156.212(e), (j). Protective eyewear statements, however, are not to be used in either section of the label for pesticides with a toxicity category III for eye irritation potential. *Id.*

As noted above in Part I.A of our discussion, DuPont was entitled to rely upon the November 1993 Letters, which granted registration approval of its labels, as prima facie evidence that its labels comply with the applicable registration requirements, including the subsidiary issue of compliance with the WPS labeling standards. However, the un rebutted Taylor Affidavit raised initial questions regarding the weight that should be given the November 1993 approval — it established that the approval was the result of a mistake; EPA had not performed a sufficient review of the WPS portions of the labels as of November 1993. More significantly, at the evidentiary hearing, Pesticide Enforcement sought to establish a prima facie case of non-compliance with the WPS labeling standards by introducing into the record DuPont’s July 1993 applications for amended registration and the related EPA guidance which, collectively, show that DuPont characterized these products as being toxicity category II for eye irritation potential.³⁰ In particular, EPA’s guidance required the applicant to “[u]se data in your files to determine the toxicity category of your end-use product for each route of entry.” PR-Notice 93-7, supp. III, at 7. Therefore, DuPont’s applications set forth its statement regarding the eye irritation toxicity category of the Bladex and Extrazine

²⁸ Section 156.212(d)(2) defines the personal protective equipment requirements for pesticide applicators and handlers. Section 156.212(j)(1) states, with limited exceptions, that the personal protective equipment required for early-entry workers shall be the same personal protective equipment listed for applicators and handlers. Section 156.212(c) states that the list of personal protective equipment for applicators and handlers shall appear in the “Hazards to Humans (and Domestic Animals)” section of the labeling and the list of personal protective equipment for early-entry workers shall appear in the Directions for Use section of the labeling under the heading Agricultural Use Requirements.

²⁹ The product’s signal word is assigned under 40 C.F.R. § 156.10(h) based on the highest hazard through any of the identified routes of exposure.

³⁰ See *supra* n.15.

products. At a minimum, this evidence would generally constitute an admission by DuPont that its pesticide products are toxicity category II and must bear protective eyewear warnings under the WPS regulations. *See LWT, Inc. v. Childers*, 19 F.3d 539 (10th Cir. 1994) (admission made by party in pleadings in one action is admissible as evidence in another case).³¹ As such, this evidence, which was admitted without objection, established Pesticide Enforcement's prima facie case that the products are toxicity category II (the evidence of this fact also established a prima facie case under the WPS labeling requirements that a protective eyewear warning was required in both sections of the label).

It is undisputed that DuPont's WPS label modifications submitted with its July 1993 applications for amended registration (which are in the record of this case, *See* CX 6, CX 7, CX 8, CX 9) do not contain a protective eyewear warning in the Agricultural Use Requirements box. Thus, Pesticide Enforcement's evidence established a prima facie case of misbranding based on non-compliance with the WPS regulations. (The labels, however, do contain a protective eyewear warning in the Hazards to Humans section of the label, which creates an internal inconsistency on the face of the labeling. We will return to this issue at the end of our discussion in this part.)

The question presented by the parties in this case, however, is whether DuPont is permitted to introduce other evidence to rebut Pesticide Enforcement's prima facie case by showing that DuPont's own statements in its applications for amended registration are, in fact, incorrect. At the evidentiary hearing, DuPont sought to rebut Pesticide Enforcement's prima facie case by proffering evidence, in the form of both testimony and toxicity studies, which it contended would prove that its pesticides belong in toxicity category III for eye irritation potential, rather than category II. DuPont's proffered evidence, thus, would provide DuPont with a factual predicate for arguing that a protective eyewear warning is not required on the pesticides' labels. The Presiding Officer, however, refused to admit this evidence. *Init. Dec.* at 21-22. Upon review, we conclude that the Presiding Officer erred by excluding DuPont's proffered evidence.

As discussed above, EPA issued the November 1993 Letters approving DuPont's proposed labels, including the WPS modifications, without comment.³²

³¹ Under the Administrative Procedure Act, a licensing proceeding is an adjudicative proceeding. 5 U.S.C. § 551(6), (7). FIFRA registration proceedings are licensing proceedings commenced by the submission of an application.

³² Pesticide Enforcement argues that "the Agency classified each of Respondent's four products as Toxicity Category II for eye irritation." Pesticide Enforcement's Brief at 10. However, the Taylor Affidavit shows that EPA had not reviewed DuPont's WPS label modifications as of November 1993. Indeed, in this case, it is Pesticide Enforcement, not DuPont, that seeks to challenge the conclusion produced by the registration process.

Once EPA discovered that the approval granted in November 1993 was based on an insufficient review and that a more complete review would have led to the conclusion that DuPont's proposed modifications did not conform to the WPS labeling standards based on the toxicity identified in DuPont's applications, EPA was entitled to proceed under either of the two enforcement tracks identified in Part I.A of our discussion: cancellation under FIFRA section 6, or misbranding enforcement under FIFRA section 12.³³ Had EPA elected to enforce the WPS labeling standards by cancellation, DuPont would have been entitled to full due process, including a formal evidentiary hearing pursuant to FIFRA section 6 and 40 C.F.R. part 164. There is nothing in the statute or regulations that would require DuPont, in such a cancellation proceeding, to defend the terms of its product's registration solely based on information it submitted in connection with its application for registration or amended registration. To the contrary, subsequently developed data regarding both adverse effects and benefits are considered as a matter of course in cancellation proceedings. *See, e.g., In re CIBA-GEIGY Corp.*, 3 E.A.D. 232 (Adm'r 1990) (cancellation of certain diazinon registrations); *In re Stevens Indus., Inc.*, 1 E.A.D. 9 (Adm'r 1972) (cancellation of certain DDT registrations).

In this case, EPA did not elect to proceed by cancellation of the registration approval it had granted in November 1993, but instead it chose to commence this misbranding enforcement action under FIFRA section 12. The choice of this procedural vehicle for enforcing the registration standards, however, should not — absent clear indications to the contrary — limit the evidence that DuPont may submit to demonstrate compliance with those standards. Indeed, we have found nothing to suggest the contrary in this case. In a case like this where Pesticide Enforcement is alleging misbranding notwithstanding the registrant's use of an approved label, the statute contemplates a showing that the label is not protective of health and the environment. The submission of the applications for amended registration, while instructive and sufficient to meet Pesticide Enforcement's prima facie burden on this point, is not dispositive where the respondent has sought to introduce other evidence relevant to the inquiry contemplated by the statute and implementing regulations.³⁴ Accordingly, we hold that the Presiding

³³ FIFRA contains a third enforcement option: issuance of a "stop sale, use, or removal" order under FIFRA section 13. This enforcement vehicle is not at issue in this case because, among other things, DuPont was not charged with violation of any such order under FIFRA section 12(a)(1)(I), 7 U.S.C. § 136j(a)(1)(I).

³⁴ Pesticide Enforcement argues that the toxicity determination in this case was made by the WPS rule based on the Bladex and Extrazine products' signal word because "Respondent did not propose an alternative classification" in its applications for amended registration. Pesticide Enforcement's Brief at 10. Here, however, registration approval was granted upon insufficient review and Pesticide Enforcement has challenged DuPont's labels in a separate enforcement proceeding. The WPS rule simply does not limit the data that DuPont may use in defense of the registrations that were approved in November 1993.

Officer erred when he precluded DuPont from submitting its toxicity evidence, which was proffered by DuPont to show that its products, in fact, are toxicity category III for eye irritation potential. We therefore remand this case for further proceedings to consider DuPont's proffered evidence and any admissible rebuttal evidence that may be submitted by Pesticide Enforcement.

In addition, on remand, the Presiding Officer may consider, as part of the questions of the evidence bearing upon the labels' alleged compliance with the WPS-labeling standards, whether the labels at issue in this case show a facial non-compliance with the language requirements of the WPS regulations in that the labels contain an internal inconsistency. As noted above, DuPont's proposed amended labels submitted with its July 1993 applications for amended registration are in the record of this case. *See* CX 6, CX 7, CX 8, CX 9. It is undisputed that these labels do not contain a protective eyewear warning in the Agricultural Use Requirements box. It is also apparent from a review of the labels that they do contain such a warning in the Hazards to Humans (and Domestic Animals) section. Thus, the labels contain an internal inconsistency in that a protective eyewear warning is used in one part of the label and omitted in another. This is facially inconsistent with the specific language required by the WPS regulations, which require the same level of eye protection warning in both parts of the label. 40 C.F.R. § 156.212(e), (j). DuPont has not shown that it had approval for this deviation from the regulation's exact language requirements as required by 40 C.F.R. § 156.204(b). DuPont should be afforded an opportunity to address this issue, which arises directly from the same facts and circumstances and legal standards identified in the complaint and the evidence established at trial.

D. DuPont's "Released for Shipment" Argument

DuPont argues that Pesticide Enforcement failed to prove that the 379 shipments were made bearing the unapproved amended labels, and it argues that Pesticide Enforcement failed to prove that use of those labels was unauthorized because PR-Notice 93-11 allowed DuPont to sell pesticide products with "non-complying" labels if those products were "released for shipment" prior to January 1, 1994. The Presiding Officer correctly rejected both of these arguments. We hereby adopt the Presiding Officer's analysis and conclusions set forth at pages 25 through 27 of the Initial Decision. In particular, we note that DuPont admitted in its answer that the 379 shipments of pesticides identified in the complaint were shipped bearing "WPS language identical to that submitted to EPA on July 14, 1993." DuPont's Affirmative Defenses ¶ 2. This admission removed from controversy in this case any question as to whether the 379 shipments were actually made bearing the WPS-labeling language set forth in DuPont's July 1993 applications for amended registration. Thus, because DuPont's answer admitted that the 379 shipments were made bearing the WPS language that DuPont had submitted with its July 1993 applications, Pesticide Enforcement was not required to make any further proof at trial. The trial exhibits consisting of DuPont's July 1993 ap-

plications and proposed modified labeling were sufficient to establish the label language used by DuPont on the 379 shipments at issue in this case.

DuPont's "release for shipment" argument also must be rejected both for the reasons stated in the Initial Decision and for the additional reason that the release for shipment option under PR-Notice 93-11 only authorized continued use, after April 21, 1994, of previously approved, non-WPS labeling, and only if the pesticides bearing that non-WPS labeling had been released for shipment prior to January 1, 1994. The released for shipment option set forth in Supplement C to PR-Notice 93-11 did not purport to change the requirement under 40 C.F.R. § 152.44(a) that labeling modifications be approved before the modified product may legally be sold. Instead, by the "released for shipment" option, EPA sought to provide manufacturers assurance that they could continue production until January 1, 1994, of products bearing previously approved, although not WPS compliant, labeling and be able to sell those products even if the sales had not occurred prior to April 21, 1994. Thus, the released for shipment option did not authorize use of modified labeling that was only partially, but not fully, compliant with the new WPS standards as argued by DuPont.³⁵ Accordingly, we reject DuPont's argument that Pesticide Enforcement was required to show when the products in the 379 shipments were released for shipment.

III. CONCLUSION

For the foregoing reasons, we hereby remand this case for further proceedings consistent with this decision.

So ordered.

³⁵ In essence, DuPont's argument, if accepted, would mean that EPA granted DuPont the right to use any misbranded labeling, including false and misleading labeling, so long as the products bearing that labeling were released for shipment prior to January 1, 1994. That result is absurd and was not intended.