12/15/94

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
Ortex Products of California, (Inc.)	)	Docket No. FIFRA-09-0829-C-93-04
	)	
Respondent	)	

INITIAL DECISION
DISMISSING REMAINING COUNTS IN COMPLAINT

The U.S. Environmental Protection Agency, Region IX, (EPA) brings this action against Ortex Products of California (Respondent or Ortex) pursuant to section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 to 136y. Respondent is charged with failing to submit an annual pesticide producing establishment report (Count I), six labeling violations (Counts II through VII) and two counts of distribution or sale of an adulterated pesticide (Counts VIII and IX). For these nine alleged violations, Complainant proposes to assess a penalty of $44,000.

Respondent denied all of the alleged violations and requested a hearing. The parties exchanged prehearing documents and a hearing was held on February 10 and 11, 1994.

Respondent is a registered pesticide producing establishment, and is the registrant for the pesticide products Pool Aid 1" Chlorinating tablets (Pool Aid 1" tablets) and Pool Aid Jumbo Chlorinating tablets (Pool Aid Jumbo tablets). (Answer ¶¶ 5, 15, 26.)

Counts II through IX are based upon observations made and samples taken during inspections in May, June and July 1991, of Barth Valley Pool & Supplies, 2615 East Main Street, Pullayup, Washington (Barth Valley); The Watermill, Inc., 12301 Lake City Way, NE, Seattle, Washington; and Aqua-Rec's Swimming Hole, 1221 Regents Boulevard, Fircrest, Washington (Aqua-Rec). The allegations of labeling violations, Counts II through VII, state that an inspector observed that the the labels on drums of Pool Aid 1" and Jumbo tablets were cut off, in violation of section 12(a)(2)(A) of FIFRA.

Count I was withdrawn from the complaint upon motion of the Complainant, dated February 28, 1994. All of the labeling violations were dismissed at the hearing by the Judge, on grounds of Complainant's failure to establish a prima facie case. Only two

counts remain at issue.

Counts VIII and IX allege that on or about September 10, 1990, Ortex offered for sale Pool Aid 1" tablets and Pool Aid Jumbo tablets, respectively, to Barth Valley. It is alleged that during the inspection of Barth Valley on June 17, 1991, samples of each of such tablets were collected. The labeling of Pool Aid 1" and Jumbo tablets state that they contain 90% available chlorine. A laboratory analysis of the samples revealed the 1" tablets to contain 73% available chlorine, and the Jumbo tablets to contain 72.9% available chlorine. Thus, Respondent is charged in each of those two counts with offering for sale an adulterated pesticide, in violation of FIFRA section 12(a)(1)(E). EPA proposes a penalty of $9,000 for those violations.

Section 136(c)(1) of FIFRA provides as follows:

> The term "adulterated" applies to any pesticide if . . . its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold * * * *

FIFRA 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 adulterated or misbranded."

Findings of Fact

1. Respondent produces, distributes and sells Pool Aid 1" and Jumbo tablets (Answer ¶¶ 13, 24.)

2. Respondent received on or about August 15, 1990, 51 drums of granular Neochlor 90 from Mitsubishi International Corporation (Mitsubishi). Respondent compressed some portion of the Neochlor 90 into tablets of various sizes and shapes. Mitsubishi, through its agent, Del Cal, Inc, ordered and paid for the Neochlor 90 to be shipped to Ortex for tabletization, and then to be shipped and sold to The Watermill. From Respondent's facility, on September 10, 1990, 1" and 3" tablets of Neochlor 90 were shipped on behalf of Mitsubishi Corporation to The Watermill, Inc., and to Barth Valley. (Tr. 199-206, 235-236, 238-239, 241-243; Respondent's Exhibits ("R-") 3, 7, 8, 9.)[1]

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[1] There is a discrepancy between the names and addresses of the facilities inspected on June 17 and 19, 1991, and the facilities referred to by Respondent in its answer. Inspections occurred at Barth Valley Pool & Supplies, 2615 East Main Street, Puyallup, Washington, and The Watermill, Inc., 12301 Lake City Way N.E., Seattle, Washington. The facilities to which Respondent

(footnote continued)

3. Shikuko Chemicals Corporation of Japan (Shikuko), the manufacturer and registrant of Neochlor 90, sold that product to Mitsubishi. (Tr. 200, 202; Complainant's Exhibits ("C-") 5, 6, 7, 18.)

4. The products which were sampled at the inspection of Barth Valley on June 17, 1991, were 1" and 3" tablets of Neochlor 90, not Pool Aid 1" and Jumbo tablets. The containers from which the samples were taken had partial labels on them which were identified as Shikuko labels. (Tr. 40-41, 45-54, 64-65, 78-79, 81-82, 88-89, 136-138; C-4, 5, 6, 7, 22, 25, 26.)

5. Samples gathered from an inspection at Aqua-Rec, but originating from the same production lot of tablets shipped from Ortex, had available chlorine of over 90% (C-5, 6, 12, 13.) The laboratory analysis for those samples reported available chlorine in an amount which is greater than what is chemically possible (Tr. 220-221.)

6. No record showing the chain of custody, such as a transmittal sheet for the samples taken at Barth Valley, was produced for the record. (Tr. 58-60, 86-87; Respondent's post-hearing brief at 10.)

7. The laboratory report of the samples taken from Barth Valley states that the substance tested was granular, not tablet. The inspector, Hugh Watson, testified that he took at least two 1" tablets and placed them, whole, into a sample container, and broke one 3" tablet apart inside the sampling container. (Tr. 57-58, 87-90; C-5, 6.)

8. Complainant has not provided Respondent with a portion of any of the product samples for an independent analysis. (Respondent's post-hearing brief at 16-18; Respondent's Request for Production of Documents for Inspection, Copying and Testing; and Complainant's response thereto (R-23, 24).)

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asserts the products were shipped are Barth Valley Pool, 3624 96th Avenue East, Puyallup, Washington, and The Watermill, Inc., 25001 73rd St., N.E., Bothell, Washington. The parties have not raised an issue about this discrepancy, however.

Confusion over the identity and registrant of the product arises from the absence of and discrepancies in records and labels at the Barth Valley facility, which repackaged the products. (C-22, Tr. 33-33, 36-38, 41-42.) The inspector, Hugh Watson, testified that Barth Valley apparently took Neochlor 90 out of a container with Shikuko's registration number and repackaged the product in a container with Ortex's registration number. (Tr. 101-104.)

9. There is no evidence showing that the product which was sampled during the inspection of Barth Valley was adulterated at the time it was shipped from Ortex's facility to Barth Valley and The Watermill, on or about September 10, 1990.

Conclusions of Law

1. Complainant has not demonstrated the chain of custody for the samples taken from Barth Valley.

2. Complainant has not established by a preponderance of the evidence that the product sampled was adulterated.

3. Complainant has not established that Respondent sold or distributed a pesticide which was adulterated.

4. No violation will be found based upon an issue upon which Respondent did not have notice and a fair opportunity to defend at the hearing.

Discussion

Complainant has not carried its burden to prove by a preponderance of the evidence that the violation occurred as set forth in the complaint. It has not been demonstrated that Respondent sold or distributed an adulterated pesticide. Complainant also cannot prevail under a theory of Respondent's liability as a producer of the pesticide at issue, as set forth in its final brief dated May 13, 1994.

Complainant's position in the complaint, hearing, and its post-hearing brief is that Respondent offered for sale Pool Aid 1" and Jumbo Chlorinating tablets which were adulterated. The claim of adulteration is based on the discrepancy between the laboratory analysis and the labeling claim of Pool Aid 1" and Jumbo Chlorinating tablets of available chlorine. The theory of liability is that Ortex as the registrant is responsible for the integrity of the Pool Aid product as represented in its labeling claim. (Complainant's post-hearing brief at 4, 6.)

However, the testimony and evidence shows that the products from which samples were taken were tablets of Neochlor 90. The issues in this proceeding are therefore based on Neochlor 90 which Respondent converted from granular into tablet form.[2]

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[2] The fact that the complaint did not allege and was not amended to allege that the pesticide products at issue were tablets (footnote continued)

Nevertheless, the laboratory analysis was not shown to be reliable. In light of all of the testimony and evidence, it has not been demonstrated that samples that were taken during the inspection of Barth Valley had a strength or purity below a professed standard of quality as expressed on any labeling.[3] **Therefore, it has not been shown by a preponderance of the evidence** that the Neochlor 90 product which Respondent tabletized was adulterated.

Assuming that the test results were reliable, Complainant has not established that Respondent is liable for selling or distributing an adulterated pesticide. Adulteration of a product is premised on the assertion of purity or strength on the labeling under which it is sold. FIFRA § 2(c). Respondent could only have sold or distributed an adulterated pesticide if, at the time of sale or distribution, such labeling expressed the strength of the product. The only labeling existing at the time the products were shipped from the Ortex facility to Barth Valley was the Shikuko labeling. Complainant has not demonstrated or even alleged that Respondent was legally responsible for adulteration based on Shikuko's labeling.

Consequently, in its final brief, Complainant seems to change the theory of its case. While Complainant concludes that Respondent is liable as charged in the complaint, its arguments tend to support a different conclusion.

Complainant argues that Ortex was a pesticide producer and that it failed to properly label the pesticide which it tabletized. A producer is any person who "processes any pesticide." FIFRA § 2(w). Complainant asserts, without citing to authority, that Ortex's conversion of the granular pesticide into tablet form constitutes "processing" a pesticide. By virtue of being a

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of Neochlor 90, does not preclude the Judge from ruling on the unpleaded allegation. The parties clearly consented to litigate, and did litigate, the issues of whether the Neochlor 90 tablets were adulterated and whether Respondent was liable for selling or distributing them. See note 5, *infra*.

[3] For example, no transmittal sheet was produced to establish the chain of custody, and there is a discrepancy in the description of the substance sampled, tablets, and the description of the substance tested, granular. Findings of Fact 6, 7. A presumption of regularity in the discharge of official duties by public officers applies only where there is no evidence indicating that any tampering with exhibits has occurred. United States v. Aviles, 623 F.2d 1192, 1197-1198 (7th Cir. 1980). Similarly, such a presumption should not apply where the description of the product sampled does not match that of the product tested.

producer, Respondent became subject to FIFRA labeling requirements, Complainant argues. Regulations under FIFRA require that the product label must show "clearly and prominently" the "name and address of the producer." 40 C.F.R. § 156.10(a)(1)(ii). Also, the regulations require that the "product must meet all label claims." 40 C.F.R. § 156.10(g)(6)(ii).[4]

Complainant asserts that when the tablets were delivered to Barth Valley, the label required by law to be on the package is Respondent's label. Complainant alleges that Respondent's delivery of the tableted product to Barth Valley constitutes distribution of the product, as defined in section 2(gg) of FIFRA. A distributor is responsible for assuring that the product distributed is registered, under section 12(a)(1)(A) of FIFRA, Complainant asserts, which is shown by meeting the label requirements of 40 C.F.R. § 156.10. The product registration number must be on the label, as well as the product ingredient, which is the basis for a finding of adulteration.

Complainant concedes that the label of Barth Valley, as the seller of the product at issue, is the "label under which it is sold" as referenced in the definition of "adulterated." However, the Ortex label should be the same except for the name, address, and establishment number representing that Barth Valley repackaged the product, Complainant states.

Liability for the violations alleged may not be based on an allegation that Ortex should have provided its own labeling as the producer of the products. A pesticide can only be adulterated if the labeling under which it is sold exists. For Ortex to be liable for selling or distributing such a pesticide, said labeling must exist at the time Ortex sold or distributed it. The issue of whether or not Respondent "processed" or "produced" the product need not be reached. Complainant's attempt to blend that issue with its theory of liability is untenable.

Taking the assertion that Respondent is a producer as a basis for a violation of the labeling requirements, at 40 C.F.R. § 156.10, however, creates a new theory of liability. Complainant seems to suggest such a violation in its final brief, although no motion has been made to amend the complaint. However, before addressing such a violation on the merits, the threshold question is whether the Judge may consider the unpleaded issue based upon

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[4] However, that requirement only applies to pesticides which change in chemical composition significantly. 40 C.F.R. § 156.10(g)(6).

the evidence admitted at the hearing.[5]

Due process requires an administrative agency to provide the respondent with a clear statement of the theory on which the agency will proceed with the case. It may not change theories without giving the respondent reasonable notice of the change. Yellow Freight System Inc. v. Martin, 954 F.2d 353, 357 (6th Cir. 1992), citing, Bendix Corp. v. FTC, 450 F.2d 534, 542 (6th Cir. 1971). However, no violation of due process occurs if the parties fairly and fully litigated the issue at a hearing. Yellow Freight, 954 F.2d at 358. For an issue to be fully litigated, the respondent must have impliedly consented to litigate the issue. That is, the Judge cannot base his decision upon an issue that was tried inadvertently. Id.

> Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue. . . . Also, evidence introduced at a hearing that is relevant to a pleaded issue as well as an unpleaded issue cannot serve to give the opposing party fair notice that the new, unpleaded issue is entering the case. Id. (Citations omitted.)

Even where the trier of fact finds that sufficient evidence exists to establish an unpleaded violation, the respondent in those cases must have had notice of the new violation and a fair opportunity to defend before such a violation may be found. Carlisle Equipment Co. v. U.S. Secretary of Labor and Occupational Safety, 24 F.3d 790, 795 (6th Cir. 1994) (evidence understood by all as being introduced to show an element of the pleaded violation did not fairly serve as notice that a new violation was entering the case.) Cf., Galindo, *supra* (parties clearly understood unpleaded issue was before the court where record was "replete with direct references" to the unpleaded issue, counsel expressly addressing it in arguing motion to dismiss and in closing argument).

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[5] Where an applicable provision does not appear in the administrative procedural rules, 40 C.F.R. Part 22, the Judge may look to federal court practice for guidance. Federal Rule of Civil Procedure 15(b) allows the amendment of pleadings to conform to the evidence when the parties explicitly or impliedly consent to the trial of the issues. A formal amendment need not be made; a court may amend the pleadings merely by entering findings on the unpleaded issues. Galindo v. Stoody, 793 F.2d 1502, 1513 n. 8 (9th Cir. 1986).

Consent may be implied if, during the trial, a party acquiesces in the introduction of evidence which is relevant only to the new theory. DCPB, Inc. v. City of Lebanon, 957 F.2d 913, 917 (1st Cir. 1992); H.B. Fuller Company v. Kinetic Systems, Inc., 932 F.2d 681, 685 (7th Cir. 1991)(implied consent found where parties explicitly referred to the new issue and counsel did not object).

Consent was not found in cases where the opposing party could have presented additional evidence had he known sooner the substance of the new issue, or if he could have raised different defenses. In re Ravinius, 977 F.2d 1171, 1175 (7th Cir. 1992); Burdett v. Miller, 957 F.2d 1375, 1380 (7th Cir. 1992).

At the hearing, counsel for Respondent objected to testimony which would relate to issues, including label requirements for pesticide producers, which were beyond those presented in the complaint. (Tr. 104, 194, 195, 207, 210, 244-246.) Respondent did not acquiesce in the introduction of evidence which was relevant only to allegations that it was a producer or that it was responsible for labeling the product.

Moreover, such allegations were not raised until Complainant's final brief. Yet, Complainant was aware of the factual predicate for the new allegations early in this proceeding but did not seek leave to amend its complaint. In its answer, Ortex stated that the products shipped to Barth Valley were Neochlor 90 which Ortex had converted into tablets. (Answer ¶¶ 20, 29.) It was clear from the inspection report and the laboratory analysis report that the products which were sampled were not labeled by Ortex. (C-5, 6, 22 pp. 4-5.)

Respondent did not have an adequate opportunity to defend the new allegations, and would be unduly prejudiced by raising them this late in the proceeding. DCPB, Inc., 957 F.2d at 917, 918 ("We think that prejudice is an almost inevitable concomitant in situations where . . . the late amendment attempts to superimpose a new (untried) theory on evidence introduced for other purposes"); Grand Light and Supply Co. v. Honeywell, Inc., 771 F.2d 672, 680 (2d Cir. 1985). Therefore, it is not appropriate to decide the issue of whether Respondent is liable for failure to provide labeling for the pesticide product which it converted from granular to tablet form.

ORDER

The remaining counts of the complaint in this proceeding are dismissed, with prejudice, in their entirety.[6]

Jon G. Lotis
Chief Administrative Law Judge

Dated: December 15, 1994
Washington, D.C.

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[6] 40 C.F.R. § 22.27(c) provides that the 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 proceedings unless (1) an appeal to the Environmental Appeals Board is taken from it by a party to the proceedings, or (2) the Environmental Appeals Board elects, sua sponte, to review the initial decision." Under 40 C.F.R. § 22.30(a), the parties have twenty (20) days after service of this Initial Decision to appeal it.