UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF

RHÔNE-POULENC AG COMPANY DOCKET NO. FIFRA-95-H-01

RESPONDENT

ORDER DENYING MOTION TO DISMISS

The complaint in this proceeding under Section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA or the Act), 7 U.S.C. § 1361(a), issued on October 7, 1994, charged Respondent, Rhône-Poulenc AG Company, Inc. (Rhône-Poulenc) with forty-six counts of violating FIFRA Section 12(a)(1)(E), 7 U.S.C. § 136(a)(1)(E), by selling or distributing a misbranded pesticide.[1/] The complaint alleges that, after receiving notice that its proposed amended label contained serious errors requiring correction before sale or distribution, Respondent shipped its registered pesticide product, CHIPCO® RONSTAR® 50 WP Herbicide, EPA Reg. No. 264-472, (RONSTAR) with the erroneous labeling, on forty-six separate occasions.

The alleged serious errors were outlined in a letter to Respondent, dated December 10, 1993 (Motion to Dismiss, Ex.4) and included the omission from the Personal Protective Equipment (PPE) section of the label instructions to "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." Another alleged serious error involved the omission of "Protective Eyewear" from the PPE and "Agricultural Use Requirement" Sections of the label. The PPE Section of Respondent's label, but not the Agricultural Use Requirements Section, required "(a)pplicators or other handlers" to wear ". . . goggles or face shield, . . . " A fourth alleged serious error involved the use of "chemical resistant shoes, shoe coverings or boots plus socks" in the PPE Section of the label rather than "Chemical-resistant footwear plus socks" required by PR Notice 93-7, Supplement Three-A.[2/] Complainant proposes to assess Respondent a civil penalty of $5,000 for each count, the maximum permitted by the Act, for a total of $230,000.00. (7 U.S.C. § 1361(a)).

Respondent filed an answer on October 28, 1994, in which it admitted to shipping RONSTAR on the forty-six distribution dates alleged in the complaint, admitted that the proposed amended label was affixed to the pesticide product at the time of each shipment, but denied that the product was misbranded. Respondent asserted seven affirmative defenses and requested a hearing. Respondent's affirmative defenses are that: 1) forty-two of the counts are based on shipments prior to April 21, 1994, but the alleged labeling errors pertained to worker protection statements that were not mandatory until after April 21, 1994; 2) the complaint failed to "state with specificity the factual basis for the alleged violations;" 3) the complaint failed to "explain the reasoning behind the proposed penalty" and the penalty calculation failed to comply with EPA's guidelines for assessing civil penalties; 4) RONSTAR was used on turf (e.g. golf courses), a use not within the scope of 40 CFR Part 156; 5) the RONSTAR label was not "misbranded" because the alleged errors did not create a potential for harm to users, the labels were not inadequate to protect health and the environment, and the alleged errors cannot be "serious" because workers were not required to adhere to the label statements until January 1, 1995; 6) the RONSTAR label was not misbranded because the allegedly defective statement regarding protective eyewear for early reentry was not necessary; and, 7) omission of a statement to discard drenched clothing was not serious error because it is extremely unlikely that a RONSTAR applicator could become drenched [with concentrate].[3/]

In response to new regulations and EPA guidance documents requiring label modifications, Rhône-Poulenc, on July 27, 1993, submitted an application to amend the RONSTAR label.[4/] Although the label contains an EPA date stamp "accepted with comments", the letter, dated December 10, 1993, referred to above, notified Rhône-Poulenc that serious errors were found on the proposed label and that the registrant "must not sell or distribute (including release for shipment) any product bearing the submitted labeling."[5/] Rhône-Poulenc replied on January 4, 1994, informing the Agency that none of the product with the unacceptable labeling had been distributed or sold, but labels had been printed and 27,000 pounds released for shipment.[6/] Rhône-Poulenc asserted that the submitted label was more restrictive than PR Notice 93-7 nd that its label posed no serious [risk] of harm to workers or the environment. Therefore, Rhône-Poulenc proposed to continue to use the existing label until August 1994, when the next label printing was scheduled. Respondent pointed out that the product was currently sold without WPS labeling, and, anticipating the need to sell the product with WPS labeling very soon, requested an expedited response. EPA made no response until March 1, 1994 when an EPA representative verbally

advised Rhône-Poulenc to correct the label prior to sale and distribution due to the "serious error." (Motion to Dismiss at 10).

By letter to EPA dated March 1, 1994, Rhône-Poulenc proposed to correct the labeling by opening the boxes already released for shipment, stickering the bags of RONSTAR with wording to indicate that the label was no longer in effect, and including replacement labels in the box (Motion to Dismiss, Ex.6). The March lst letter requested immediate approval and informed EPA that this plan was being implemented. EPA made a verbal reply, on or about March 15, 1994, proposing that the registrant place the new labels on each RONSTAR bag. (Motion to Dismiss at 11). Rhône-Poulenc's representative, Lizbeth Simila, indicated that she would check on the acceptability and feasibility of EPA's proposal. (Id.).

Meanwhile, Rhône-Poulenc's "Materials and Distribution Department" shipped quantities of RONSTAR with the unapproved labels on multiple occasions from January 27, 1994 through May 5,1994.[7/] On May 11, 1994, Ms. Simila verbally notified EPA of the shipments, and on May 13, 1994, wrote to EPA, explaining that approximately 10,650 pounds of RONSTAR with unacceptable labeling remained in Rhône-Poulenc's warehouse and at the distributor level. The May 13th letter requested approval of Rhône-Poulenc's stickering proposal, because it was the quickest and most feasible way to bring the product into compliance, and indicated that the issue needed to be resolved before May 16th.[8/]

On May 18, 1994, Ms. Simila allegedly attempted to call EPA six times before reaching an Agency official, who informed her that EPA would send a response the following day. EPA's response, dated May 19, 1994, denied continued use of the unaccepted labeling until the next printing due to the serious errors identified in the December 10, 1993 letter, but authorized sale and distribution of the remaining incorrectly labeled product, provided the registrant: 1) developed revised labeling; 2) developed a sticker indicating that the label was no longer in effect and instructing users to follow labeling received at sale; 3) notified state agencies and regional EPA offices that the Agency required the warning sticker and replacement labeling; and, 4) submitted verification that these requirements had been satisfied to EPA's Office of Compliance Monitoring in Washington, DC (Motion to Dismiss, Ex.9). Respondent complied with each of these requirements.[9/]

As indicated previously, the complaint seeks a penalty for each distribution of RONSTAR having the unapproved label. Respondent's Motion to Dismiss, dated June 26, 1995, argues that the complaint should be dismissed for three reasons: l)

the RONSTAR labels were not misbranded prior to April 21, 1994, because the regulations did not require the allegedly erroneous or omitted language until after April 21, 1994; 2) there is no basis for Complainant's allegation that the controverted language caused the potential for "serious harm;" and 3) Complainant is barred from bringing this action because it has not strictly complied with the Paperwork Reduction Act (PRA).

Complainant filed a response to the motion, on August 14, 1995, asserting that the new rules were enforceable any time products containing the new language were sold or distributed after April 21, 1993. Complainant alleges that labels containing the new language prior to April 21, 1994, were required to either be approved by EPA, or self-verified by the registrant that the labeling followed the Agency's guidance documents exactly. Complainant contends that FIFRA prohibits pesticide registrants from selling or distributing pesticide products containing labeling with partial, incomplete or incorrect compliance with the new rules; that the omission of protective eyewear comprised "serious error" resulting in clear potential for exposure and harm to workers; that the PRA is an affirmative defense which must be raised in the answer; and that, in any event, Complainant fully complied with the PRA. Respondent filed a Motion for Leave to Reply and a Reply in Support of its Motion to Dismiss, dated August 23, 1995 (Reply); and Complainant filed a Motion for Leave to Respond, dated September 1, 1995, and a Response to the Reply on September 25, 1995 (Response to Reply) . These additional pleadings are accepted and will be considered herein.

For the reasons hereinafter appearing, Respondent's motion to dismiss will be denied.

Discussion

EPA promulgated a final rule, on August 21, 1992, revising 40 CFR Part 170 (Worker Protection Standards For Agricultural Pesticides) and adding Subpart K (Worker Protection Statements) to 40 CFR Part 156 (Labeling Requirements For Pesticides And Devices). (57 Fed. Reg. 38101 et seq. (Aug. 21, 1992) The new rules expanded the scope of the worker protection requirements and required statements on product labels pertaining to general worker protection, entry intervals, personal protective equipment, and posting of treated areas. (57 Fed. Reg. at 38103).

Subpart K of Part 156 became effective on October 20, 1992, sixty days after publication of the final rule. In order to ensure that new Worker Protection

Standard (WPS) labeling was not available to users before EPA and cooperating organizations could disseminate information necessary for compliance, the rule instituted a phased implementation plan.[10/] It precluded registrants from selling or distributing pesticide products with labels reflecting the new WPS requirements prior to April 21, 1993.[11/] After April 21, 1994, compliance with Subpart K was mandatory. (57 Fed. Reg. 38106; 40 CFR § 156.200(c)). Use of WPS language during the period April 21, 1993, through April 21, 1994, was, therefore, optional.

The issue presented by Respondent's first ground for dismissal (ante at 7) is whether a product having a label not in exact compliance with WPS may be considered misbranded during the optional period. It is concluded that this issue is not dependent upon whether WPS labeling is optional and must be answered in the affirmative.

FIFRA § 3(c), Procedure for registration, provides in pertinent part: "(1) Statement required. Each applicant for registration of a pesticide shall file with the Administrator a statement which includes ... (C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for use;..." In conformance with this statutory requirement, the regulation, 40 CFR § 152.50(e), provides that each application for new registration must be accompanied by five legible copies of draft labeling and that each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes.

Section 152.44 provides in pertinent part: "(e)xcept 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." Section 152.46 lists modifications to registration not requiring amended applications and includes (a)(1) "A revision of the label language consistent with part 156 of this chapter and involving no change in the statement of ingredients, precautionary statements of (sic) directions for use." These provisions are complimented by § 156.10(a), which provides that "[e]very pesticide products [sic] shall bear a label containing the information specified by the Act and the regulations in this part." Additionally, § 156.10(a)(6) provides that, with an exception not here relevant, "...final printed labeling must be submitted and accepted prior to registration..."

The changes to the RONSTAR label at issue here involved "Precautionary Statements" and "Directions For Use" and clearly required EPA approval in accordance with §§ 152.44 and 152.46. Under FIFRA §§ 2 (q) (1) (F) and 2 (q) (1) (G) a pesticide is misbranded if the labeling accompanying it does not contain directions for use and warning or cautionary statements which, if complied with, are adequate to protect health and the environment. (supra note 1). The Agency has determined that labels for the pesticide at issue must contain specified "Worker Protection Statements" to protect health and the environment. (40 CFR Part 156). In view of these statutory and regulatory provisions, the facts that use of WPS label language was at the option of the registrant during the period April 21, 1993, through April 21, 1994, and was not mandatory until after April 21, 1994, are not relevant to whether RONSTAR was misbranded because deviations from specified WPS label language precautionary statements and directions for use required EPA approval.

The Agency's two guidance documents, PR Notice 93-7, dated April 20, 1993, and PR Notice 93-11, dated August 13, 1993, reinforce the foregoing conclusion. PR Notice 93-7 was concerned primarily with determining what products were subject to WPS and the procedures for submitting an application for amended registration to conform to WPS.[12/] This Notice, inter alia, summarized the requirements of WPS; provided that previously accepted statements on current labeling which conflict with WPS-required statements must be deleted, unless they provide a greater level of protection than WPS-required statements;[13/] and provided for alternate certifications on applications to amend pesticide registration, one where Supplement Three to the Notice was followed exactly and one where deviations from the exact language and/or its location on the label were proposed.[14/] Although Respondent certified that its revised labeling for RONSTAR was in complete accordance with PR Notice 93-7 (letter, dated July 27, 1993, Ex.3), this certification, as we have seen (ante at 2), was inaccurate in several respects.

PR Notice 93-11, issued after Respondent submitted its application for amended labeling, provided that the instructions in this notice supplement instructions in PR Notice 93-7, but that instructions in PR Notice 93-7 remain applicable except where modified or superseded herein (Id. at 5). PR Notice 93-11 states that under certain conditions EPA will allow registrants to self-verify revised labeling and, on the basis of the registrant verification, to sell or distribute product with revised labeling that has not yet been stamped as accepted by EPA (Id. at 5; Supplement A at 1) The Notice made it clear that for the registrant-verification option to be available, nothing less than complete and exact compliance with PR Notice 93-7 would suffice.[15/] The only alternative

was for Respondent to submit an application for amended registration and obtain EPA approval. Here, although Rhône-Poulenc submitted an application for amended registration, it was on notice prior to the shipments in question that EPA considered its label unacceptable.

PR Notice 93-11 also contained a "Released-For-Shipment by January 1, 1994 Option." (Id., Supplement C at 1). This option allowed product within the scope of PR Notice 93-7, which was released for shipment prior to January 1, 1994, to be sold or distributed after April 21, 1994, without labeling complying with PR Notice 93-7, provided certain conditions, including notification to EPA were met. While Rhône-Poulenc has not alleged that the product here involved was released for shipment prior to January 1, 1994, nor that it complied with the conditions for the availability of this option, it does argue that the fact that this option was developed to deal only with non-complying products after April 21, 1994, demonstrates the absence of a need to deal with non-complying products prior to the mentioned date. (Motion to Dismiss at 19, note 11). This argument is rejected because the "released for shipment option" applied only to products lacking WPS language and because the warning in PR Notice 93-7 (supra note 12), identifying label changes without EPA approval as probable violations of FIFRA, is not conditioned on the April 21, 1994 date, after which compliance with WPS was mandatory.

Because the Worker Protection Statements of Part 156 do not modify in any way §§152.44 and 152.46, which specify the circumstances, including label changes, under which an application for amended registration and EPA approval is required, Respondent's argument that nothing in the regulation concerning effective dates (40 CFR § 156.200(c)) bars a registrant from putting some, but not all, WPS language on its label during the option period, April 21, 1993 through April 21, 1994 (Motion to Dismiss at 14, 15), is wide of the mark and is rejected. Similarly, Respondent's assertion (motion to Dismiss at 18), that EPA's policy notices do not change the effective date of WPS, is accurate, but beside the point, because the issue is the sale or distribution of a pesticide which is misbranded because it lacks EPA approved labeling, rather than the effective date of WPS. For this reason, Respondent's contention that the requirement for "protective eyewear" and for a statement that clothing or other absorbent materials which have been "drenched or heavily contaminated with concentrate" be discarded could not give rise to a misbranding charge prior to April 21, 1994, the effective date of WPS (Motion to Dismiss at 21), is also rejected.

As indicated previously (ante at 13), PR Notice 93-11 made it clear that nothing less than complete and exact compliance with PR Notice 93-7 would enable a registrant to sell or distribute product with revised WPS labeling without EPA approval. Because this position merely reinforces §§ 152.44 and 152.46, i.e., label revisions involving changes in ingredients, precautionary statements or directions for use require EPA approval, Respondent's argument that the PR Notices are an attempt to advance the effective date (April 21, 1994) of WPS without fair warning (Motion to Dismiss at 22), is erroneous and is rejected. The issue is not the date after which compliance with WPS was mandatory, but the sale or distribution of a pesticide, which is misbranded, because it lacks EPA authorized label changes.

More telling is Respondent's contention that the alleged errors and omissions are not serious (Motion to Dismiss at 25). PR Notice 93-11 announces that EPA would limit enforcement actions for minor errors in registrant-verified labels to a response such as requiring correction at the next printing of the label. (Id. Supplement A at 3). Referring to errors in registrant-verified labeling, the Notice states that "..it is clear that some types [of errors] would be serious, possibly requiring such enforcement responses as stop sale orders, recalls, or civil penalties." (Id. Supplement A at 3). The Notice further states "(i)n general, errors will be regarded by EPA as serious when they create a potential for harm to workers, handlers, other persons, or the environment, or when the errors prevent achievement of basic goals of WPS or FIFRA." (Id.). Examples of serious errors include "PPE that is missing, or is incorrect and judged by EPA to be significantly underprotective or risk-inducing." (Id.)

Respondent emphasizes the quoted language and asserts that there is no potential for the clothing of mixers and handlers to become heavily contaminated with RONSTAR, because the concentrate is a wettable powder which is poured directly into a large tank for mixing.[16/] Respondent says that there,is virtually no potential for the clothing of applicators to become drenched or heavily contaminated, because the product is sprayed on the ground to control preemergent.weeds. Because of the use pattern, Respondent maintains that there is no likelihood of eye exposure during any early reentry which might occur. Moreover, Respondent asserts that its label requirement of "goggles and face shield" is more restrictive and thus more protective than the "protective eyewear" language required by EPA. Respondent says it retained the "goggles and face shield" language on its label because PR Notice 93-7 directed that label language which was more restrictive than WPS be retained. Respondent persuasively argues that there is no substantial difference in meaning between

use of the language chemical-resistant shoes, shoe coverings or boots plus socks" on its label rather than "chemical-resistant footwear plus socks" demanded by EPA. (Motion to Dismiss at 27).

In view of the foregoing, there are only two possible bases for the Agency's claim of serious error: 1) the omission of "(d)iscard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate" from the PPE section, and 2) the omission of "protective eyewear" from the Agricultural Use Requirements section of Respondent's label.[17/] Although Complainant continues to use the term "serious errors" when referring to Respondent's label, it appears to have abandoned all but the omission of "protective eyewear" as a basis for the claim of misbranding (Partial Prehearing Exchange, June 8, 1995; Response to Motion to Dismiss, August 14, 1995). Furthermore, the discussion above indicates that the likelihood of the clothing of applicators or other handlers becoming drenched or heavily contaminated with concentrate under the conditions of use of RONSTAR is remote. Be that as it may, the WPS requirement that clothing and other absorbent materials, which have been drenched or heavily contaminated with concentrate bearing the signal words "Danger" or "Warning" on the label, not be reused has been promulgated through notice and comment rulemaking and may not be challenged herein. Nevertheless, whether the omission of language reflecting this requirement from the label of RONSTAR is a serious error within the meaning of PR Notice 93-11 is a factual issue inappropriate for resolution on a motion to dismiss.

As to the second basis for serious error, Respondent points out that the Agency has recently determined that the omission of a protective eyewear requirement for early entry is not serious error for "limited contact tasks" (60 Fed. Reg. 2843, January 11, 1995). In the cited Federal Register, EPA requested comments on a proposed exception to WPS which would allow, under specified conditions, workers to perform "limited contact tasks" for up to three hours per day during a restricted entry interval. "Limited contact task" was defined as "..a non-hand labor task that is performed by workers that results in minimal contact with treated surfaces (including but not limited to soil, water, air, surfaces of plants, and equipment), and where such contact with treated surfaces is limited to the forearms, hands, lower legs, and feet" (Id. at 2845). Because RONSTAR is sprayed on the ground to control preemergent weeds, Respondent alleges that any reentry to areas sprayed with this product would be within the "limited contact task" definition (Motion to Dismiss at 28). The proposal included the following: "EPA considered requiring that protective eyewear be included in the minimum PPE requirement if required on the product labeling for

early entry because of concern about workers rubbing or wiping residues into their eyes from hands, gloves, or sleeves. EPA decided not to propose a requirement for eyewear as part of the minimal set at this time because performance of limited contact tasks should result in minimal worker contact with treated surfaces" (60 Fed. Reg. 2846). This exception was essentially finalized as proposed (60 Fed. Reg. 21955, May 3, 1995). Regarding protective eyewear, the Agency stated: "EPA has carefully considered comments supporting required eyewear and reviewed information in its possession that indicates a relatively low incidence of eye injuries to field workers by pesticides. EPA has concluded that rather than create a universal standard for eyewear to be used under the limited contact exception, the use of protective eyewear should be consistent with PPE required on the labeling. Where eyewear is required on the label for early entry, it is also required for this exception" (Id. at 21957).

Referring to the quoted language, Respondent says that the Agency appears to be saying that, although protective eyewear is not generally necessary to prevent a serious risk, in certain situations it should be used as a precautionary measure during early reentry (Motion to Dismiss at 29). Respondent argues that this statement does not detract from the Agency's admission that there is generally no "serious" risk, if protective eyewear is not used. According to Respondent, there is no possible "serious" risk of eye exposure under the conditions of use of products subject to this action. Although Respondent's argument that there is no "serious" risk within the meaning of PR Notice 93-11 from the failure to use protective eyewear during early reentry may have merit, this issue should not be decided without a full exposition of the evidence.

The motion to dismiss insofar as based upon the contention that the WPS label language was not effective until after April 21, 1994, must and will be denied.

Paperwork Reduction Act

In its motion to dismiss, Respondent asserted for the first time that EPA is precluded from assessing penalties in this action, because it did not strictly comply with the display requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. §§ 350l-3520 (1986) (Motion to Dismiss at 30). The PRA prohibits a federal agency from requiring private entities to collect and report information to the agency, unless the "information collection request" (ICR) is approved by the office of Management and Budget (OMB) and bears a control number to be displayed on the ICR.[18/] Respondent argues that the PRA bars the complaint because: 1) EPA did not submit an application to OMB for approval of

the WPS labeling requirements until nearly eight months after publishing the final rule in the Federal Register; 2) PR Notice 93-7 never became effective because the Agency issued PR Notice 93-7 before the WPS rules had an effective control number; and 3) EPA did not timely publish the OMB control number in the Code of Federal Regulations. (Motion to Dismiss; Reply). Complainant counters that the PRA is an affirmative defense waived by Respondent when not raised in the answer; the PRA does not bar this action because EPA fully complied with the PRA prior to the violations alleged in the complaint; and at all times relevant to the complaint, the WPS labeling requirements incorporated a valid and effective OMB-approved control number that had been properly displayed and codified in EPA's regulations. (Response to Motion to Dismiss; Response to Reply.)

Complainant's argument that the PRA defense was waived because it was not raised in the Answer is rejected. Although the PRA is an affirmative defense, it is now well established that the defense may be raised in pleadings subsequent to the Answer.[19/] There is no demonstrated prejudice to Complainant in this case, where the PRA defense was raised before either party submitted a complete prehearing exchange, before the ALJ assigned a hearing date, and each party was granted ample time to prepare its case.

Respondent's allegation that the PPA precludes penalty assessment in this action is without merit because the complaint does not allege that Respondent committed a reporting or record keeping violation subject to the PRA. It is, therefore, not necessary, for resolution of this case, to determine whether EPA, in fact, complied with the PRA.

The Supreme Court, in Dole v. Steelworkers, 494 U.S. 26, 32 (1990), held that the Paperwork Reduction Act of 1986 does not apply to agency regulations requiring disclosure of information to third parties because such disclosures are not "information collection requests."[20/] The Court concluded that the PRA required OMB approval of regulations requiring regulated entities to provide information to a federal agency, either directly or indirectly.[21/] The Court held that the PRA did not apply to the Department of Labor's (DOL) hazard communication standard, which required chemical manufacturers to label containers of hazardous chemicals with warnings and provide data sheets to commercial purchasers listing physical characteristics and hazards of each chemical, medical conditions aggravated by exposure, symptoms caused by overexposure, and other data.[22/] "[A] Government-imposed reporting requirement customarily requires reports to be made to the Government, not training and labels to be given to someone else altogether." (Dole, 494 U.S. at 36). EPA's

WPS labeling requirements, like DOL's hazard communication standard labeling requirements, are not "information collection requests" and do not require OMB approval.[23/]

In addition to requiring statements on the product label, EPA required registrants to submit an application for amended registration to incorporate mandatory label changes. (ante at 9-10). EPA obtained OMB approval, OMB Control Number 2070-0060, for the requirement that registrants submit forms and data relating to pesticide registration, and submit an application for an amendment to include voluntary changes to the original submission and label revisions. The WPS required an amendment to OMB approval because the requirement for submittal to EPA of an application to amend registrations of products subject to WPS was not voluntary.[24/] A complaint which alleged a violation of FIFRA § 12(a)(2)(B), i.e., "to refuse to prepare, maintain, or submit any records...", and proposed to assess a penalty therefor, would allege a violation subject to the PRA. This complaint, however, alleges sale and distribution of a misbranded pesticide because the product's label lacked information considered necessary for the protection of third parties. (Dole, supra). The complaint is not based upon a failure to submit information to the Agency, but upon an alleged failure to comply with a substantive rule. Respondent's argument that the PRA precludes assessment of any penalty herein is, therefore, rejected.

Order

Respondent's Motion to Dismiss is denied. The parties will submit prehearing exchanges in accordance with Rule 22.19(b) and the ALJ's letter, dated March 17,1995, on or before December 27, 1996.

Dated this 15th day of November 1996.

Spencer T. Nissan
Administrative Law Judge

CERTIFICATE OF SERVICE

I do hereby certify that the foregoing ORDER DENYING MOTION TO DISMISS was filed in re Rhone-Poulenc Ag Company; Docket No. FIFRA-95-H-01 and copies of the same were mailed to the following:

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Dated: November 18, 1996

[1/] FIFRA § 12(a)(1)(E) states: "Except as provided by subsection (b) of this section, it shall be unlawful for any person in any State to distribute or sell to any person --...any pesticide which is adulterated or misbranded." 7 U.S.C., § 136j(a)(1)(E). A pesticide is misbranded if, inter alia, ". . any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness ... as to render it likely to be read and understood... the labeling ... 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 ... the label does not contain a warning or caution statement which may be necessary and if complied with.. is adequate to protect health and the environment" 7 U.S.C.§ 136(q)(1)(E),(F)and(G).

[2/] The December 10th letter points out that the requirement under PPE must state: "Applicators and other handlers must wear..." and instructs Respondent to cross-out its lead-in statement and replace it with the correct one. The lead-in statement of the PPE Section of Respondent's label contains precisely the quoted language and it appears that the letter was not drafted with specific reference to Respondent's label.

[3/] Respondent's Answer and Request for Hearing, undated, stamped "Received" by the EPA Hearing Clerk on October 28, 1994, (Answer). Complainant contends that the WPS does apply to RONSTAR, even though it is intended for use on turf, because Respondent's registration covers other uses that require WPS compliance. Respondent's motion to dismiss does not rely on its fourth affirmative defense and this order does not address the issue.

[4/] FIFRA and EPA's implementing regulations require registration of pesticide products. 7 U.S.C.§136a (a); 40 CFR § 152.15. A "pesticide product" is "a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold." 40 CFR § 152.3 (t). "A registrant may distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency." 40 CFR § 152.130. A pesticide registration, therefore, includes EPA approval of the pesticide substance along with the proposed packaging and labeling in which the product will be distributed or sold. See, In re Monsanto Co., I.F.& R.-VII-1193C-93P, 11(Dec. 6, 1995).

[5/] Motion to Dismiss, Ex. 4. The December 10th letter also instructed Rhône-Poulenc, within one year from the date of the letter, and before the next label printing, to make all specified changes and send EPA one copy of the final printed label before selling or distributing any product bearing the label, as amended.

[6/] Letter from Lizbeth R. Simila to Michael Wood, dated January 4, 1994 (Motion to Dismiss, Ex. 5). "A product is 'packaged, labeled, and released for shipment' by a producing establishment when the product has been produced, packaged, and labeled and it is the intent of the producer to introduce such product into commerce." (PR Notice 93-11, Supplement C).

[7/] Counts VI, VII, VIII, and XL concern shipments made after April 21, 1994.

[8/] The May 13th letter indicated that EPA had proposed an alternative method -- affixing the labels in a pouch with a trimmed copy of the label, but that Respondent's proposed method would take less time to implement and was preferred in light of the need to bring the released product into compliance immediately.

[9/] Motion to Dismiss at 12; letter, dated June 14, 1994, Ex.13. In another letter dated May 19, 1994, EPA requested information regarding each shipment of RONSTAR sold or distributed from December 10, 1993 until May 19, 1994 which bore the unapproved labeling. The requested information included amounts and dates the product was shipped, locations to which and from which it was shipped, and locations of producing establishments (Motion to Dismiss, Ex. 10). Rhône-Poulenc submitted this information on June 8, 1994 (Motion to Dismiss, Ex. 12).

[10/] 57 Fed. Reg. at 38141 ("Otherwise, users could face the dilemma of being required to comply with provisions [of the rule] without the necessary information on how to do so"); 40 CFR § 156.200(c).

[11/] ".... the new labeling may not be used until April 21, 1993. At that time, specified selected provisions of the regulation [Part 170] will become enforceable to support new instructions to users on the labeling." 57 Fed. Reg. at 38106.

[12/] PR Notice 93-7 supports the conclusion reached above, i.e., that the label changes at issue here require EPA approval, providing in pertinent part (Supplement Two) at 6, 7: "Most 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 a product bearing a label including such changes will probably be in violation of FIFRA, and could subject you to enforcement action." PR Notice 93-11 quoted the above language from PR Notice 93-7 and stated "These statements refer to nonWPS changes (such as adding a new crop or use-site) made to a label through a WPS amendment, and do not invalidate the registrant-verification process" (Id. at 5).

[13/] Supplement Two, § III at 2. Although Respondent asserted that its label was more restrictive than the WPS label in its January 4, 1994 letter, this argument has not been advanced as a ground for the motion to dismiss.

[14/] PR Notice 93-7 provides, Supplement Two at 5: "Certification when Supplement Three is followed exactly: I certify that the revised labeling being submitted for this product is in complete accordance with the labeling requirements of PR Notice 93-7, which reflects the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). Where exact language is specified in the PR Notice I have used that language exactly, in the location specified. I further certify that no revisions are being submitted other than those directed by PR Notice 93-7. I understand that it would be a violation of FIFRA if I or my supplemental registrants were to sell or distribute this product after April 21, 1994, without amended labeling complying with the requirements of 40 CFR part 156, subpart K."

[15/] PR-Notice 93-11, Supplement A at 1 provides in pertinent part: 1. What labeling qualifies for registrant-verification?

The option of registrant-verification is available for the following types of amended labeling:

Complete and exact compliance- labeling for which the registrant certifies in the WPS amendment application submitted to EPA that the labeling instructions in PR Notice 93-7 are followed exactly .....

[16/] Motion to Dismiss at 26. "Concentrate" literally applies only to the pesticide product undiluted by water or other liquid. Although this, as a practical matter, limits the possibility of clothing being drenched or heavily contaminated with concentrate to liquid pesticides, this result was intended, because 40 CFR § 170.240(f)(2), upon which the label provision is based, provides in part "(c)overalls or other absorbent materials that have been drenched or heavily contaminated with an undiluted pesticide... shall not be reused."

[17/] The first paragraph of "Agricultural Use Requirements" of the EPA approved label (Worksheet Section F, Part 2, Supplement Three-A, PR Notice 93-7) provides: "Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in

this box only apply to uses of this product that are covered by the Worker Protection Standard." Through a typographical error, Respondent's label used the word "expectations" rather than "exceptions". Complainant has not, and cannot contend that this error is serious.

[18/] 44 U.S.C. § 3507 (1986). Section 3507(f) provides: "(a)n agency shall not engage in a collection of information without obtaining from the Director a control number to be displayed upon the information collection request." A penalty may not be assessed for failure to maintain or provide information to an agency unless the information request displays a current control number assigned by the Director. 44 U.S.C. § 3512. Congress enacted substantial revisions to the PRA on May 22, 1995, P.L. 104-13, and OMB modified its implementing regulations on August 29, 1995, 60 Fed. Reg. 44978. The 1995 PRA amendments became effective on October 1, 1995, 44 U.S.C. § 3530(a) (1995), and therefore, were not in effect at any time relevant to these proceedings.

[19/] In re Zaclon Inc., RCRA-V-W-92-R-9, 13 (Initial Decision, March 19, 1996)(dismissing complaint because of PRA noncompliance where Respondent raised the PRA by motion dated one week prior to the hearing); ROI Development Corp., RCRA (3008) VIII-90-12, 20 (Initial Decision, March 31, 1994)(rejecting argument that respondent had waived the PRA, because it was not included in its answer); In re Bickford, TSCA-V-C-052-92 (Initial Decision, Oct. 18, 1995) (raising PRA issues, sua sponte, after the hearing). The 1995 PRA amendments resolve this question, stating, "The protection provided by this section may be raised in the form of a complete defense, bar or otherwise at any time during the agency administrative process or judicial action applicable thereto." 44 U.S.C. § 3512(b)(1995).

[20/] By holding that the language, structure and purpose of the statute revealed that Congress did not intend the PRA to encompass labeling, employee training, and other third-party disclosure rules (Dole at 35), the Supreme Court invalidated OMB's regulation which defined a "collection of information" to include disclosure and labeling requirements. (5 CFR § 1320.7 (c) (1)). Until Congress amended the Act in 1995, the Dole opinion prevented OMB from requiring agencies to obtain OMB approval for label requirements even though OMB did not change its regulations to comply with the Court's decision.

[21/] "The terms 'collection of information' and 'information collection request', when considered in light of the language and structure of the Act as a whole, refer solely to the collection of information by, or for the use of, a federal

agency; they cannot reasonably be interpreted to cover rules mandating disclosure of information to a third party." Dole 494 U.S. at 41.

22/ "An agency charged with protecting employees from hazardous chemicals has a variety of regulatory weapons from which to choose: It can ban the chemical altogether; it can mandate specified safety measures, such as gloves or goggles; or it can require labels or other warnings alerting users to dangers and recommended precautions. An agency chooses to impose a warning requirement because it believes that such a requirement is the least intrusive measure that will sufficiently protect the public, not because the measure is a means of acquiring information useful in performing some other agency function."' Id. at 33 - 34.

23/ The 1995 PRA, P.L. 104-13 (May 22, 1995) overturned the Supreme Court's interpretation in Dole that Agency third-party disclosure requirements are not within the scope of the Act. (44 U.S.C. § 3502(3)(A) (1995); See H.R. Rep. No. 104-13, 104th Cong., lst Sess., 1995 U.S.C.C.A.N. 164)). The new definition of "collection of information" includes "requiring the disclosure to third parties or the public... of facts or opinions by or for an agency..." 44 U.S.C. § 3502(3)(1995).

24/ EPA submitted an application to OMB to amend ICR 277, (ICR 277.05), on April 20, 1993, requesting a one-time increase in the burden for OMB control number 2070-0060. OMB approved the revision on April 21, 1993 (Motion to Dismiss, Ex. 4), which EPA displayed in the June 6, 1993 Federal Register (58 Fed. Reg. 31383), and the July 1, 1993 CFR (40 CFR § 9.1).