

ENVIRONMENTAL PROTECTION AGENCY

[OPP-68017; FRL-5755-7]

Termilind Limited; Notice and Order of Revocation of Registrations**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice; Notice and Order of Revocation of Registrations and Final Determination Governing Sale and Use of Existing Stocks.

SUMMARY: In March of 1996, EPA issued registrations for two end use naphthaleneacetic acid (NAA) products, Alphaspra 200 (EPA Registration Number 67223-2) and Alphaspra 800 (EPA Registration Number 67223-1) to Termilind Limited (Termilind). On August 2, 1996, Amvac Chemical Corporation (Amvac) filed a petition to cancel the Termilind registrations based upon assertedly false certifications that Termilind would use Amvac-registered material to formulate its products. Amvac filed a second petition in October of 1996 asking EPA to deny Termilind's application for a technical NAA registration based upon an assertion that Termilind misappropriated data to support the application. EPA has determined that Termilind submitted misleading materials in support of its applications for end-use registrations, and that the registrations would not have been granted absent this misleading information. On August 6, 1997, EPA issued a Decision granting Amvac's petition in this regard and revoking the end-use registrations. In that same Decision, EPA denied Amvac's petition to deny Termilind's application for technical registration. The revocation Decision, and a subsequent determination concerning the sale and distribution of existing stocks of the revoked products, are published in this Notice.

DATES: The revocation Decision was effective as to Termilind on August 6, 1997. The Decision and existing stocks determination are effective as to all other persons on November 19, 1997. Any person interested in requesting an informal hearing should submit such a request by January 20, 1998.

ADDRESSES: Request for a formal hearing should be addressed to: Robert Perlis, Office of General Counsel (2333), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: James J. Jones, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 401

M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 713, 1921 Jefferson Davis Hwy., Arlington, VA, 703-305-5446, e-mail: jones.james@epamail.gov. **SUPPLEMENTARY INFORMATION:** Unit I. of this document contains the Agency's August 6, 1997 decision on the petition to revoke the registrations, and Unit II. consists of the Agency's existing stocks determination.

I. Decision on Amvac's Petition to Revoke Termilind Limited's Registrations

Petitioner Amvac Chemical Corporation (Amvac) seeks immediate revocation of respondent Termilind Limited's (Termilind) registrations for two end use naphthaleneacetic acid (NAA) registrations, Alphaspra 200 (EPA Registration No. 67223-2) and Alphaspra 800 (EPA Registration No. 67223-1). Amvac also seeks revocation of Termilind's technical NAA registration, (EPA Registration No. 67223-22). Amvac claims that the end use registrations were obtained through willful misrepresentation of the source of technical NAA, and that the technical registration was obtained through the submission of data "stolen" or "misappropriated" from Amvac. Amvac asserts, as well, that the willful nature of Termilind's acts authorizes summary revocation of the subject registrations without resort to the procedural requirements of section 6(b), the cancellation provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). We grant the petition with respect to the two end use registrations, and deny the petition with respect to the technical registration.

Legal Background

The sale, distribution and use of pesticides in the United States is regulated by the Federal Insecticide, Fungicide, and Rodenticide Act. 7 U.S.C. 136-136y. Under FIFRA, with certain limited exceptions, a pesticide may not be sold or distributed unless it is registered. *Id.* 136a(a), 136j(a)(1)(A). In order for a pesticide to qualify for registration, the Environmental Protection Agency (EPA) must determine that it will not cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice. *Id.* 136a(c)(5)(C)-(D). To make this finding, EPA reviews data on product chemistry, toxicology, and environmental fate, among other subjects. See 40 CFR part 158 (data requirements for registration). The data reviewed must be supplied by the registrant; it is not generated by the Agency. *Id.* Because the volume of data received and reviewed by the Agency is extremely large, EPA is unable to investigate each statement, study and item of data received for potential fraud or misrepresentation. Thus, to a great degree, the Agency must rely on the good faith and integrity of registrants if it is to fulfill its mandate of protecting human health and the environment from unreasonable risk.

A registrant can fulfill its obligation to submit much of the data required for

registration by formulating its product with an existing registered pesticide purchased from another producer. See 7 U.S.C. 136a(c)(2)(D); 40 CFR 152.85 (Formulators' exemption).¹ The premise behind the formulators' exemption is that the purchase price of the registered material compensates the original registrant for the cost of data generation. See *id.*

In the case of certifying eligibility for the formulators' exemption, good faith on the part of applicants is critical. When an applicant certifies that it will formulate its product using a registered pesticide as the active ingredient, it is excused from the requirement of submitting data pertaining to the safety of that ingredient. See *id.* Instead, the Agency bases its risk analysis of that ingredient on the data received from the registrant of the original product. If the applicant does not then use the registered product cited, the risk assessment performed by the Agency, and any safety finding premised upon it, are unreliable—they may not reflect the nature or contents of the new product. Thus the Agency's ability to carry out its mandate of protecting human health and the environment is undermined.

Regulatory History

Termilind cited Amvac Chemical Corp. of Los Angeles California as the source of the technical NAA active ingredient in

¹ 7 U.S.C. 136a(c)(2)(D) reads as follows:

Exemption—no applicant for registration who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is subject of the application shall be required to --

- (i) submit or cite data pertaining to such purchased product; or
- (ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

40 CFR 152.85 reads as follows:

(a) FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to the safety of any ingredient (or mixture of ingredients) contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another producer.

(b) If the product contains one or more ingredients eligible for the formulators' exemption, the applicant need not comply with the requirements of §§ 152.90 through 152.96 with respect to any data requirements pertaining to the safety of any such ingredient, provided that he submits to the Agency a certification statement containing the following information . . .

- (1) Identification of the applicant, and of the product by EPA registration number or file symbol;
- (2) Identification of each ingredient in the pesticide that is eligible for the formulators' exemption, and the EPA registration number of the product that is the source of that ingredient;
- (3) A statement that the listed ingredients meet the requirements for the formulators' exemption;
- (4) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Statement of Formula; and
- (5) The name, title and signature of the applicant or his authorized representative and the date of signature.

(c) An applicant for amended registration is not required to submit a new formulators' exemption statement, if the current statement in Agency files is complete and accurate.

applications for two end use NAA registrations submitted to EPA in September 1995. Termilind also certified to EPA that it was eligible for the formulators' exemption. On the basis of that information, EPA granted the two registrations in March of 1996.

In July 1996, EPA Region X issued a Stop Sale, Use, or Removal Order (SSURO) prohibiting the sale or distribution of Termilind's two end use NAA products. Records obtained by EPA from an Oregon Department of Agriculture investigation revealed that technical NAA product had been shipped from Seoul, South Korea by Inchema Company, to Oregon California Chemicals Inc. (Or-Cal), a contractor for Termilind. EPA issued the SSURO on the grounds that the Agency believed that "the supplier of [NAA] for the [end use products] is different than what was listed in [Termilind's] confidential statement of formula [CSF] for these products" in violation of FIFRA section 12(a)(1)(C) (unlawful to distribute or sell pesticide composition of which differs at time of distribution from composition described in CSF). 7 U.S.C. 136j(a)(1)(C). The order remained in effect until September 23rd, when Termilind amended the CSFs of the two products to reflect the use of its own technical NAA, which was registered by EPA that same month. This matter was followed up with a Warning Letter, mailed to Termilind on December 16, 1996, in which Region X confirmed the Agency's conclusion that a violation of FIFRA section 12(a)(1)(C) had occurred. *Id.*

On August 2, 1996, Amvac submitted its first petition for revocation, which concerned the two Termilind end use registrations. In the petition, Amvac claimed that the registrations were issued based on "false certifications to EPA. . . that Termilind's two products would be formulated from Amvac's EPA-registered technical naphthalene acetic acid (NAA) and thus qualify for the formulators' exemption." Amvac stated that it was the only source of registered technical NAA, and that although Termilind cited Amvac as its source of technical NAA in the registration materials submitted for two end use products, neither Amvac nor any of its distributors had sold any technical NAA to Termilind. Amvac claimed, as well, that neither it nor its distributors had discussed sales of technical NAA with Termilind.

In early October, shortly after the SSURO was lifted, Amvac submitted a second petition for revocation, this one concerning the registration of Termilind's technical NAA product. In that petition Amvac asserted that "Termilind willfully misappropriated confidential business information (CBI) to obtain the Technical Registration," and requested that the registration be revoked on that basis.

Amvac asserts that in 1994 it entered into an arrangement with Shin Young C-Tech Co., Ltd. (C-Tech), a South Korean company, and its U.S. agent, Inchema, Inc., whereby C-Tech/Inchema would manufacture technical NAA for Amvac. In its second petition, Amvac stated that it supplied CBI to C-Tech/Inchema for the purposes of carrying out this business arrangement. The CBI was allegedly the subject of a confidentiality agreement,

pursuant to which C-Tech/Inchema was forbidden to disclose it to third parties for any purpose. It is this CBI which Amvac claims Termilind "misappropriated" and submitted to EPA in support of a technical NAA registration.

Amvac failed to serve copies of either petition on Termilind, arguing in each that the willful nature of Termilind's conduct warranted summary revocation, without prior notice or an opportunity to be heard. Amvac cited section 558 of the Administrative Procedures Act (APA) as authority for this proposition.²

EPA forwarded copies of the two petitions to Robert Fisher, Termilind's regulatory agent. A copy of the first petition was mailed to Mr. Fisher on September 5, 1996; a copy of the second was sent on November 25. Termilind did not respond to either petition. On December 6, EPA formally invited Termilind to respond to the allegations contained in the two petitions and set a deadline of December 20 for receipt of a response.

After receiving and reviewing Termilind's response, EPA determined that further development of both legal and factual issues was warranted prior to issuing a decision. EPA sent an identical set of questions to each party and, again, invited them to respond. Via the same letter EPA established a series of procedures to govern communications between Agency personnel and representatives of Amvac or Termilind concerning the merits of the ongoing dispute.

In addition to petitioning EPA to revoke Termilind's registrations, Amvac has also initiated legal proceedings against Termilind in the United States District Court for the District of Oregon, seeking, among other things, a preliminary injunction to enjoin Termilind from maintaining any registrations for products containing NAA, and to prohibit Termilind from selling, marketing or distributing any product containing NAA. By order dated January 17, 1997, Amvac's motion was denied. The issue of whether Termilind misappropriated CBI owned by Amvac and submitted such in support of its technical NAA registration is still before the District Court.

Based on the materials submitted by both parties in response to the questions posed by the Agency, EPA makes the following findings of fact:

Findings of Fact

(1) Respondent Termilind Ltd. is a person and a registrant as defined by FIFRA. (7 U.S.C. 136(s), (y))

(2) Petitioner Amvac Chemical Corp. is a person and a registrant as defined by FIFRA. (7 U.S.C. 136(s), (y))

² Section 558(c) of the APA reads in pertinent part:

Except in cases of willfulness or those in which public health, interest or safety requires otherwise, the withdrawal, suspension, revocation, or annulment of a license is lawful only if, before the institution of agency proceedings therefor, the licensee has been given--

(1) notice by the agency in writing of the facts or conduct which may warrant the action; and

(2) opportunity to demonstrate or achieve compliance with all lawful requirements.

(3) Jerry Fitzsimmons is the president of Termilind, Ltd. (Affidavit of Jerry Fitzsimmons, November 6, 1996, at 1)

(4) J. R. Fisher is the principal of Fisher and Associates, a regulatory agent providing services to companies seeking registration of products with EPA. (Affidavit of J. R. Fisher, November 6, 1996, at 1)

(5) J. R. Fisher has been a regulatory agent providing services to companies seeking registration of products with the EPA since 1981. (Affidavit of J. R. Fisher, December 31, 1996, at 2)

(6) J. R. Fisher prepared and submitted the application materials for Termilind's end use registrations. (Affidavit of J. R. Fisher, December 31, 1996, at 4)

(7) Shin Young C-Tech Co., Ltd. (C-Tech) is a South Korean company. (Affidavit of Eric Wintemute at 4)

(8) Inchema, Inc. is the United States Agent for C-Tech. (Affidavit of Eric Wintemute at 5)

(9) In or about July 1995, J. R. Fisher and Jerry Fitzsimmons met with Hans Wessel and Steve Shim of Inchema regarding the purchase of technical NAA. (Affidavit of J. R. Fisher, December 31, 1996, at 2)

(10) Inchema had manufactured technical NAA for Amvac. (Affidavit of Eric Wintemute at 5)

(11) Amvac rejected the last batch of NAA produced by Inchema/C Tech. (Affidavit of J. R. Fisher, November 6, 1996, at 2)

(12) Termilind was aware that the technical NAA it purchased from Inchema/C-Tech had been rejected by Amvac. (Affidavit of J. R. Fisher, November 6, 1996, at 2)

(13) Termilind cited Amvac Chemical Corp. of Los Angeles California as the source of the technical NAA active ingredient in its applications for two end use NAA registrations, submitted to EPA in September 1995. (Affidavit of J. R. Fisher, November 6, 1996, at 2; Warning Letter issued to Termilind Ltd. by EPA Region 10, December 16, 1996) These registrations were granted in March of 1996. (Alphaspra 800, EPA Registration No. 67223-1 granted March 15, 1996; Alphaspra 200, EPA Registration No. 67223-2 granted March 26, 1996)

(14) Termilind certified that it was eligible for the formulators' exemption, 7 U.S.C. 136a(c)(2)(D); 40 CFR 152.85. (Formulators' exemption statement submitted by Termilind)

(15) Termilind cited Amvac's product labels and material safety data sheet in applications for end use NAA registrations submitted to EPA in September 1995. (Affidavit of J. R. Fisher, December 31, 1996, at 3)

(16) Termilind had Inchema/C-Tech formulate unregistered technical NAA into end use product for import into the United States. These products bore Termilind's EPA registration number for the end use NAA product Alphaspra 800. (Affidavit of J. R. Fisher, November 6, 1996, at 2; affidavit of J. R. Fisher, December 31, 1996, at 4)

(17) Termilind did not obtain samples of, or perform any tests upon, the technical NAA product used to formulate the Alphaspra 800. (Affidavit of J. R. Fisher, December 31, 1996, at 3).

(18) Under 19 CFR 12.112, "an importer desiring to import pesticide or devices into

the United States shall submit to the Administrator a Notice of Arrival of Pesticides and Devices . . . prior to the arrival of the shipment in the United States." (emphasis added). Termilind did not submit the required Notice of Arrival of Pesticides and Devices until 3 months after the shipment of NAA product had arrived in the United States from Korea. The Notice was filed only after EPA Region X discovered NAA product shipped from Korea in the possession of Or-Cal, a Termilind licensee. (Notice of Arrival submitted July 13, 1996)

(19) Termilind sold pesticide products formulated with unregistered Inchema/C-Tech NAA in the United States. (Stop Sale, Use, Or Removal Order issued to Termilind Ltd. by EPA Region 10, July 3, 1996; Warning Letter issued to Termilind Ltd. By EPA Region 10, December 16, 1996)

(20) Termilind never purchased or attempted to purchase Amvac's registered technical NAA from Amvac or any of its distributors. (Petition for revocation submitted to EPA by Amvac October 9, 1996 at 4)

Decision

I.

In its second petition, dated October 9, 1996, Amvac claims that Termilind's technical registration was obtained through the submission of data "stolen" or "misappropriated" from Amvac. On that basis, Amvac asserts that the Agency must revoke the technical registration. We deny this petition on jurisdictional grounds.

EPA does not have the powers of a court of general jurisdiction. Beyond the limited realm of data compensation, see 7 U.S.C. 136a(c)(1)(F); 40 CFR 152.99, the Agency has neither the expertise nor the authority to adjudicate conflicts regarding ownership of intellectual property. As noted above, this very matter is currently before the Federal District Court for the District of Oregon. A court of general jurisdiction is a more appropriate forum for the resolution of disputes of this nature. Accordingly, Amvac's second petition, seeking revocation of Termilind's technical registration, is denied.

II.

Amvac also seeks immediate revocation of Termilind's two end use registrations, claiming that they were obtained through willful misrepresentation of the source of the technical NAA used as the active ingredient in the products. But for the misrepresentation, Amvac contends, the registrations would not have been granted; thus they are void *ab initio*. Amvac also asserts that in light of Termilind's willful behavior, the Agency has inherent power to revoke these registrations without resort to section 6 of FIFRA. We agree.

As an initial matter, we must first address whether Termilind's conduct was willful. Willful misconduct had been defined as "an intentional misdeed or such gross neglect of a known duty as to be the equivalent thereof." *Hutto Stockyard, Inc. v. USDA*, 903 F.2d 299, 304 (4th Cir. 1990 (quoting *Capitol Packing Co. v. United States*, 350 F.2d 67, 78-79 (10th Cir. 1965)); see also *Capital Produce*

Co. v. United States, 930 F.2d 1077, 1079 (4th Cir. 1991). Termilind has not claimed that the material it purchased bore an Amvac EPA approved label identifying it as a registered product. Termilind did not purchase the material from Amvac or an Amvac distributor. Moreover, Termilind conceded that it was aware that the material had been rejected by Amvac. Nevertheless, Termilind identified Amvac's registered technical NAA as its source of active ingredient. Furthermore, Termilind certified that it was eligible for the formulators' exemption. This behavior constitutes willful misrepresentation.

Termilind cannot plausibly claim that its conduct was innocent. Its regulatory agent, J. R. Fisher, had 15 years experience in providing services to clients seeking registration of products with the EPA; he cannot credibly argue ignorance of the law in Termilind's defense. Moreover, common sense dictates that material purchased from a party other than the registrant or its distributors, that is known to have been rejected by the registrant, is not that registrant's registered material. Termilind does not claim that the material it purchased bore Amvac's label or EPA registration number. Under no view of the facts was it reasonable for Termilind to represent the product purchased from Inchema/C-Tech as Amvac registered material. Nevertheless, Termilind cited Amvac's product labels and material safety data sheet in its applications for end use registrations. This conduct was consistent with an intent to deceive the Agency about the origin of its technical material, as was Termilind's failure to submit a timely Notice of Arrival of Pesticides and Devices when the NAA material arrived from Korea. If the Notice had been filed in a timely fashion it might have drawn attention to the fact that Termilind, though citing Amvac Chemical Corp. of Los Angeles, California as its source of registered technical material, was receiving shipments of NAA product from Korea. We conclude that Termilind's misrepresentation was willful.³

We next address the Agency's authority to revoke a registration summarily, without resort to section 6 of FIFRA, where the registration was procured through willful misrepresentation.⁴ As a general rule, it is well accepted that "every tribunal, judicial or administrative, has some power to correct its own errors or otherwise appropriately to modify its judgement, decree or error." *Alberta Gas Chemicals, Ltd. v. Celanese Corp.*, 650 F.2d 9, 13 (2d Cir. 1981) (quoting K. Davis, Administrative Law Treatise

³As the above definition notes, "willful" behavior encompasses conduct that is grossly negligent as well as conduct that is intentional. Thus, even if Termilind did not act with intent to deceive the Agency, but was merely grossly neglectful of its statutory duties, the outcome would be the same.

⁴Petitioner claims pursuant to section 558(c) of the Administrative Procedure Act that in light of Termilind's willful misrepresentation, the Agency can revoke the registrations summarily without providing notice or opportunity for comment. As this decision documents, the Agency has given Termilind an opportunity to respond to Petitioner's allegations and to submit supplemental briefing. Thus, the Agency has given Termilind more process than section 558(c) requires.

section 18.09 at 606 (1958); *Bookman v. United States*, 453 F.2d 1263, 1265 (Ct. Cl. 1972) (same); see also *Trujillo v. General Electric Co.*, 621 F.2d 1084, 1086 (10th Cir. 1980) (Administrative agencies have inherent authority to reconsider their decisions since power to decide carries with it power to reconsider) (quoting *Albertson v. Federal Communications Comm'n.*, 182 F.2d 397, 399 (D.C. Cir. 1950)). Moreover, the Supreme Court and other courts have recognized that administrative agencies have implied authority to reconsider and correct errors, even where the applicable statute and regulations do not explicitly grant such powers. *Gun South Inc. v. Brady*, 877 F.2d 858, 862 (11th Cir. 1989) (listing cases). Courts have relied on this implied power in holding that agencies have the authority to revoke licenses improperly granted. See, e.g. *Kudla v. Mode*, 537 F.Supp 87, 89-90 (E.D. Mich. 1982) (improperly granted license revoked where licensee had failed to pass qualifying examination; procedural protections afforded by statute do not attach unless requirements for obtaining license have been met).

More specifically, courts have recognized that agencies have the inherent authority to correct errors and reverse judgements induced by fraud or misrepresentation. *Alberta Gas*, 650 F.2d at 13 ("It is a well established principle that an administrative agency may reconsider its own decisions". . . It is hard to imagine a clearer case for exercising this inherent power than when a fraud has been perpetrated on the tribunal in its initial proceeding") (citations omitted); see also *Hand v. Matchett*, 957 F.2d 791, 794 (10th Cir. 1992) (self evident that university has inherent authority to revoke improperly awarded degree where fraud shown); *Colonial Penn Insurance Co. v. Coil*, 887 F.2d 1236, 1240 (revoking insurance settlement procured through fraud); *In Re Berman*, 97 S.E. 2d 232, 235 (N.C. 1957) (board has inherent power, independent of statutory authority, to revoke license improperly issued due to fraud or misrepresentation); *Schireson v. Shafer*, 47 A.2d 665, 667 (Pa 1946) (where license was procured by fraud licensing authority may revoke it regardless of fact that fraud is not specified as ground for revocation in statute); cf. *Hazel-Atlas Glass Co. V. Hartford-Empire Co.*, 322 U.S. 238, 246 (1943) (reversing judgment in patent infringement suit where both Patent Office and Court of Appeals were influenced by fraudulent misrepresentations -- "Public welfare demands that the agencies of public justice be not so impotent that they must always be mute and helpless victims of deception and fraud.") (overruled on other grounds). In the instant case, this rule supports the proposition that EPA has inherent authority to revoke Termilind's end use registrations. Indeed, courts have recognized that administrative agencies, as guardians of the public interest, have a duty to make corrections where they have relied on erroneous information. *Green County Planning Bd. v. Fed. Power Comm'n.*, 559 F.2d 1227, 1233 (2d Cir. 1976; *Hudson River Fishermen's Ass'n v Federal Power Comm'n.*, 498 F.2d 827, 833 (1974); *Borlem S.A. Emprederimentos Indutriaes v. U.S.*, 718 F. Supp 41, 47 (CIT 1989).

Termilind claims that revocation is the equivalent of cancellation and can only be accomplished through section 6 of FIFRA. In essence, Termilind asserts that a registrant that has submitted false or misleading application materials, and thereby induced the Agency to grant a registration erroneously, has the same interest in the wrongly obtained registration, and is entitled to the same procedural protections, as a registrant that acted in good faith to meet the requirements for registration. We find it implausible that Congress intended applicants who obtained registrations through fraud to receive the procedural protections of section 6.

Likewise, we find Termilind's argument that the Agency does not have the authority to revoke registrations obtained through fraud or misrepresentation, because FIFRA does not specifically describe such a procedure, equally unpersuasive. As the legal analysis above establishes, Agencies have inherent authority to redress fraud or misrepresentation. See also *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 843, 844 (1984) ("Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency."). Moreover, this conclusion is consistent with the Agency's statutory duty under FIFRA to protect man and the environment from the unreasonable adverse effects of pesticide use. As noted above, Congress established a scheme in FIFRA that requires registrants to supply the data necessary to establish and maintain FIFRA registrations. The Agency, therefore, must be able to rely on applicants to act with goodwill and integrity in submitting the required data. In order to protect the integrity of the FIFRA process and the safety of pesticide users and the public, the Agency must have a swift and sure method of responding when the submission of fraudulent or misleading application materials is discovered. If unscrupulous applicants receive the same procedural protections as honest ones, there is little incentive to be honest. Instead, the dishonest applicants who obtain speedy registration through fraud or misrepresentation are rewarded for their deception. Such an interpretation of FIFRA is contrary to the EPA's mandate to protect public health and the environment.

We wish to emphasize that the quality of the evidence available to the Agency in this case was critical to the outcome. Sworn statements of the parties were included in the record, and based on these, the Agency was able to make the factual findings necessary to underpin a revocation action with confidence. The Agency is very unlikely to take similar actions in future cases unless allegations of misrepresentation are supported by reliable and persuasive evidence.

III.

As noted above, Amvac's petition to revoke Termilind's technical registration is denied on the basis that, beyond its role in resolving

data compensation disputes, the Agency has neither the expertise nor the jurisdictional competence to adjudicate complicated issues regarding ownership of intellectual property rights. Nevertheless, the Agency does intend to go forward with a Notice of Intent to Cancel Termilind's technical registration, but on alternative grounds.

Although there is no explicit fitness criterion among the requirements for obtaining or holding a registration under FIFRA, as a general matter, determining the "fitness" of an applicant to hold a license or registration is recognized as a legitimate end of licensing schemes. See *Payne v. Fontenot*, 925 F. Supp. 414, 423 (M. D. La. 1995) (licensing body may require certain standards of applicant; qualifications to hold license must have rational connection to applicant's fitness). Furthermore, prior to granting a registration, the Agency is required to determine that a pesticide will not "generally cause unreasonable adverse effects on the environment" when used in accordance with widespread and commonly recognized practice. 7 U.S.C. 136a(c)(5). As a practical matter, in making such a determination the Agency must rely on data and certified statements submitted by the registrant. The Agency's ability to make an accurate finding is therefore directly related to the reliability of the material submitted. If the Agency knows that a registrant has a history of willful misrepresentation, the reliability of the materials submitted by that applicant is subject to question. The Agency's ability to make an accurate finding that the statutory standard for registration has been met is undermined under such circumstances. A "fitness" or "reliability" criterion can therefore properly be implied as a component of the "unreasonable adverse effects" standard. Cf. *Cooley v. Fed. Energy Regulatory Comm'n*, 843 F.2d 1464, 1471 (D.C. Cir. 1988) ("Nothing in [Federal Power Act] explicitly requires a finding of fitness." Commission is charged with considering all relevant public interest factors; fitness of licensee-applicant is public interest factor); see also *Delaware River Development Corp.*, 10 F.P.C. 540, 550 (1951) ("ethical and moral fitness" considered in public interest determination to grant permit); see generally *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 843, 844 (1984) ("Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.").

Denial of a license on fitness grounds is not uncommon. See, e.g. *RKO General, Inc., v. Fed. Communication Comm'n*, 670 F.2d 215, 232 (D.C. Cir. 1981) (F.C.C. did not abuse its discretion in denying license renewal for lack of candor; "[T]he Commission must rely heavily on the completeness and accuracy of the submissions made to it, and its applicants, in turn have an affirmative duty to inform the Commission of the facts it needs in order to fulfill its statutory mandate."); see also *ALRA Laboratories, Inc., v. Drug Enforcement Agency*, 54 F.3d 450, 452 (7th. Cir 1995) (DEA did not abuse its

discretion when it denied application for new license to manufacturer and distributor of controlled substances where manufacturer had not complied with recordkeeping requirements, had shipped contaminated products, had his inventory seized and was closed for 6 months, and was under indictment); *Dep't Transp. Fed. Highway Admin. v. Interstate Commerce Comm'n*, 733 F.2d 105, 113 (D.C. Cir. 1984) (I.C.C.'s order granting certificate vacated where evidence inadequate to establish applicant's fitness). The licensing body is in the best position to make determinations regarding applicant fitness, and its decisions are entitled to deference. *Ramachar v. Sobol*, 838 F. Supp. 100, 108 (S.D.N.Y. 1993) (licensing authority entitled to deference in assessing risks posed by licensee). Furthermore, when making licensing decisions "an Agency rationally may conclude that past performance is the best predictor of future performance." *ALRA*, 54 F.3d at 452; *Matsun Gyogyo Co.*, 2 O.R.W. 349 (NOAA 1980) (past violations should be significant factor in determining whether to issue new permit); see also *Dep't Transp. Fed. Highway Admin.*, 733 F.2d at 112 (statements of good intentions in future of limited value in assessing what applicant's future conduct will be).

FIFRA itself does not limit the criteria that the Agency may consider in making a safety calculus. Instead, as described above, the statute dictates that the Agency must affirmatively find that a product will not cause unreasonable adverse effects before a registration may be granted. Common sense dictates that the Agency must be permitted to consider all relevant criteria when performing its analysis. As the discussion above illustrates, the integrity or reliability of a registrant is highly germane to the Agency's ability to make an accurate finding; if the Agency has reason to suspect that materials submitted by a registrant are untrustworthy, an affirmative safety finding cannot be made.

In this case the Agency has determined that Termilind has submitted misleading materials in support of its applications for registration. The Agency is therefore unable to rely on the veracity of unsubstantiated materials submitted by Termilind. Under these circumstances the Agency cannot affirmatively find that Termilind's technical product will not generally cause unreasonable adverse effects on the environment. Accordingly, it is the Agency's intention to undertake a section 6 cancellation of Termilind's technical NAA product in separate proceedings.

Order

For the reasons discussed above, EPA hereby revokes Termilind's registrations for Alphaspra 200 (EPA Registration No. 67233-2) and Alphaspra 800 (EPA Registration No. 67223-1). Existing stocks of these products must be used in a manner consistent with label directions.

Dated: August 6, 1997

/s/ Lynn R. Goldman
Assistant Administrator for Prevention,
Pesticides and Toxic Substances

II. Existing Stocks Determination

On August 6, 1997, in response to a petition filed by Amvac Chemical

Corporation ("Amvac"), EPA revoked the registrations issued to Termilind Limited ("Termilind") for Alphaspra 200 (EPA Registration No. 67223-2) and Alphaspra 800 (EPA Registration No. 67223-1) after determining that Termilind had intentionally or willfully misidentified in its application materials the source material from which it intended to formulate the two products. In the Order attached to the Revocation Determination, the Agency allowed use of existing stocks of the revoked registrations, provided that such use is consistent with existing label directions. The Order was silent on the question of whether existing stocks could be sold or distributed.

EPA subsequently issued three clarifications addressing the existing stocks issue. On August 18, 1997, the Acting Associate General Counsel for Pesticides and Toxic Substances (Kevin Lee) explained in a letter to counsel for Amvac that inasmuch as the Order resulted in the termination of the registration of the products and did not authorize any sale or distribution of the products, such further sale or use was unlawful under section 3(a) of FIFRA (which generally prohibits the sale and distribution of unregistered pesticides). On August 20, 1997, the Agency issued a clarification to the Order which specifically provided that "no person may sell or distribute stocks of Alphaspra 200 and Alphaspra 800." This clarification was followed by a second clarification issued on August 22, 1997, which stated that the revocations "shall be effective for dealers and distributors upon publication in the **Federal Register**." Under the terms of this last clarification, the Agency would not consider sale or distribution of existing stocks by dealers and distributors to be unlawful until the Revocation Determination was published in the **Federal Register**.

On August 18, 1997, Termilind filed a request for Reconsideration and Stay of the Revocation Order. As part of that request, Termilind asserted that EPA should permit sale and distribution of existing stocks of the revoked products in a manner consistent with EPA's Statement of Policy related to existing stocks issued in the **Federal Register** of June 26, 1991 (56 FR 29362). Amvac filed a brief response to Termilind's request on August 26, 1997, arguing, without responding to any of the specific assertions made by Termilind, that reconsideration would not be appropriate.

On August 29, 1997, EPA indicated in a letter to counsel for Amvac and Termilind that the Agency intended to carefully consider and resolve finally

the existing stocks issues raised by the Revocation Order. This Determination reflects the Agency's resolution of these existing stocks issues.

A. Legal Authority

Under section 6(a)(1) of FIFRA, the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under section 3, 4, or 6 of FIFRA, to such extent, under such conditions, and for such uses as the Administrator determines is not inconsistent with the purposes of FIFRA. As noted above, EPA issued a Policy Statement in 1991 outlining the policies that would generally be followed in making such existing stocks determinations. The legal issue presented is whether section 6(a)(1) and the Policy Statement apply to the situation addressed in the Revocation Determination.

The Agency concluded in its Revocation Determination that it has the inherent authority to correct an erroneous registration decision induced by fraud or willful misrepresentation, and that such authority is inherent in the authority to issue registrations in the first place. The Agency's authority to issue pesticide registrations stems from section 3 of FIFRA. It thus seems to follow that the inherent authority to revoke a registration induced by fraud or misconduct also stems from section 3 of FIFRA. The question then becomes: Is the revocation a "cancellation under section 3" for purposes of section 6(a)(1) of FIFRA?

The Agency has concluded that there is no meaningful distinction between a revocation and a cancellation, and that the revocation of Termilind's registration was a cancellation under section 3 giving the Agency authority over the sale and use of existing stocks. Whether the action is called a revocation or cancellation, the defining element of the action is the termination of a license (or in this case, pesticide registration) previously issued by the Agency. Cancellation is the term used in FIFRA for the termination of a registration; the word "revocation" does not appear in the statute in this context.

Moreover, in this particular case, the license issued by the Agency does not just confer something of value to the licensee (registrant); a pesticide registration allows a pesticide product to enter the stream of commerce where the interests of third parties come into play. When a pesticide registration terminates, for whatever reason, the termination can have immediate consequences for all these third parties. Unless the Agency has determined

otherwise under section 6(a)(1) or has issued a regulation under section 3(a) of FIFRA, existing stocks of an unregistered pesticide may be used by any person with impunity, without regard to any conditions that would have applied to the use while the product was still registered.⁵ Sale and distribution of an unregistered pesticide, on the other hand, is unlawful under FIFRA unless the Agency allows such sale or distribution pursuant to section 6(a)(1). Such a prohibition on sale or distribution would also apply to commercial "for-hire" applications of the unregistered product.⁶ A determination that a revocation is not a cancellation under section 3 would leave the Agency essentially powerless to effectively condition the use of existing stocks (even if such conditions were necessary to prevent unreasonable adverse effects on the environment), and would also leave the Agency powerless to authorize the sale of existing stocks, even by third parties who had no involvement in the activities giving rise to the revocation and even where there are no health, safety, or environmental reasons to disallow continued sales and where a revocation may trigger the otherwise unnecessary disposal of existing stocks of the revoked product. The Agency is declining to interpret FIFRA in a manner that would suggest that Congress intended to give the Agency the authority to terminate registrations without giving the Agency authority to deal with the existing stocks consequences of such terminations. The Agency concludes that a revocation of a registration based upon misconduct in the inception of the registration is a cancellation under FIFRA section 3, and provides the Agency authority under section 6(a)(1) to regulate the sale, distribution, and use of existing stocks of a revoked product.

B. Provisions for Existing Stocks

For the reasons stated above, the Agency concludes that it has the authority under FIFRA section 6(a)(1) to issue an order regulating the sale, distribution, and use of existing stocks of revoked products. Under that section, such sale or use may be permitted to the extent, and under such conditions, as

⁵ Such use need not be consistent with the terms of the previously-approved labeling of the product. Section 12(a)(2)(G) makes it a violation of FIFRA to use any registered pesticide in a manner inconsistent with its labeling; there is no similar provision making it unlawful to use an unregistered pesticide in a manner inconsistent with its labeling.

⁶ FIFRA section 2(gg) exempts from the definition of sale or distribution only the commercial application of registered pesticides.

will make the sale and use consistent with the purposes of FIFRA.

The Agency set forth in its Policy Statement on existing stocks the general policies it will apply when making decisions under section 6(a)(1). In particular, the Agency concluded that it will focus on two issues in making existing stocks determinations: whether the sale or use of existing stocks may pose unreasonable adverse effects on the environment, and whether the registrant (or conceivably some other party) has failed to comply with an obligation of registration. As a general matter, the Agency concluded in the Policy Statement that existing stocks determinations where the Agency has significant risk concerns will be made on a case-by-case basis, with sale and use generally allowed only if supported by a risk/benefit balancing. In situations where there are no significant risk concerns, the Policy would generally allow non-registrants to sell, distribute, and use existing stocks until such stocks are exhausted (provided that all existing label directions are met). The sale and distribution of existing stocks by registrants under the Policy generally hinges upon whether (and when) the registrant failed to comply with an obligation of registration. The Policy is silent on whether supplemental distributors (under 40 CFR 152.132) should be treated like registrants or like other distributors of pesticide products.⁷

The first issue of concern under the Policy Statement is whether the Agency has risk concerns with the existing stocks of the revoked products. This is an issue that has been discussed by both parties in various papers related to Amvac's Petition. The Agency expressed a concern in its Revocation Order related to Termilind's technical registration that the Agency has difficulty finding that a product will not result in unreasonable adverse effects on the environment if a registrant makes false statements to the Agency. In such circumstances, the Agency cannot rely on scientific data submitted by a registrant or on the registrant's compliance with its obligations under section 6(a)(2) to submit additional adverse effects information to the Agency. Where the Agency is unable to rely on material submitted by a registrant, the Agency cannot make the affirmative findings necessary to a determination that a product will not

cause unreasonable adverse effects on the environment.

This particular concern with Termilind's registrations does not apply with much, if any, force to the existing stocks issue presented here. While the source used by Termilind to manufacture its end-use products was not the source originally identified by Termilind in its applications, the identity of the source is not in dispute. The papers filed with the Agency by both sides provide the Agency with ample confidence that the existing stocks were manufactured with NAA source material supplied by Inchema. The question then becomes whether the Agency has confidence that the material supplied by Inchema was NAA of sufficient quality to allow the Agency to conclude that the existing stocks of revoked material can be used without causing unreasonable adverse effects on the environment.

The Agency has concluded, based on a number of factors, that there is reasonable assurance that the Inchema material is of sufficient quality to resolve any possible concerns associated with the sale, distribution, or use of existing stocks. Sampling performed of Termilind material did not reveal any problems with the product. While Amvac declined to accept the Inchema NAA provided to Termilind, the Agency is unaware of any allegations by Amvac that Inchema NAA lacks sufficient quality to support a registration.⁸ There has been no material presented by Amvac to challenge Termilind's assertion that Amvac's refusal to accept the Inchema NAA was based upon anything other than a dispute over price. The Agency previously accepted the quality of Inchema NAA as a source for Termilind's products when it approved amendments to Termilind's registrations to correctly reflect the source of NAA used in those products. Based on all these factors, the Agency has no reason to suspect that the NAA products made by Termilind differ meaningfully in quality from other NAA products on the market, and does not believe that sale or use of existing stocks of such products would result in unreasonable adverse effects on the environment.⁹

⁸Indeed, Amvac's allegations that Inchema has misappropriated Amvac proprietary technology, as well as Amvac's previous use of Inchema as a source of its own NAA and the absence of any submittals by Amvac under section 6(a)(2) of FIFRA discussing quality problems associated with Inchema's production of NAA, seem to suggest that Amvac has no dispute with the quality of material produced by Inchema.

⁹Indeed, the only difference between a risk/benefit balancing for NAA generally and a balancing for the existing stocks is that a ban on

The only reason to disapprove the sale, distribution, or use of existing stock is to punish the misconduct that resulted in the registration of the products in the first place, and to deter future such misconduct. As noted earlier, this particular situation was not addressed in the Policy Statement, and the Agency has concluded that the Policy Statement does not provide significant guidance on how to deal with misconduct similar to Termilind's. It is clear that prohibiting sale, distribution, and/or use of existing stocks may result in hardships on relatively "innocent" third parties. On the other hand, allowing continued sale, distribution, or use of existing stocks would be "unfair" to registrants of competing registered products (such as Amvac in this case) that presumably are complying with the provisions of FIFRA, and would tend to minimize the repercussions to Termilind in this case and serve as less of a disincentive for others to include incorrect or false information in their applications for registration.

After considering carefully these issues, the Agency has determined that it is appropriate to prohibit all further sale or distribution by any person of the revoked products, except the application of existing stocks by for-hire applicators so long as the applicator does not deliver any unapplied pesticide to the person for whom the application is performed. The Agency reached this determination based primarily on the nature of the misconduct in this particular case and its conclusion that the use by pesticide registrants of source material different than the source material identified in the statement of formula submitted to the Agency is a very serious matter. In general, where the Agency revokes a registration because of misconduct involved in its inception, the Agency believes it inappropriate to allow the company involved in the misconduct to derive any benefit from its actions. The only way for the Agency to maximize the likelihood that Termilind will not profit at all from its actions is to prohibit all sale and distribution of the revoked products. In addition, the Agency believes it appropriate to send the strongest possible message to any company that may be considering the use of unregistered source material in its production of registered product notwithstanding the fact that the

existing stocks would require that the stocks be disposed of. Legal or illegal disposal of existing stocks could have financial and/or environmental consequences that tip the risk/benefit balance even further towards allowance of the use of existing stocks.

⁷ It should also be noted that the Policy Statement does not address the issue of what existing stocks provisions are appropriate for situations such as the one involving Termilind, where the Agency concludes that a registration would not have been issued in the first place in the absence of misconduct by the applicant for registration.

registration is predicated on use of a registered source material. Put simply, the Agency generally does not intend to allow resale by any person of pesticide products that were not produced in compliance with FIFRA.

The Agency does intend to allow continued use of the revoked products, including use by for-hire applicators, provided that such use is consistent with the labeling of the products. The Agency does not believe that a prohibition on further use would be realistically enforceable in the absence of the devotion of significant resources to such enforcement, and given the conclusion reached on the likelihood of no unreasonable adverse effects on the environment, the Agency does not believe this issue merits the expenditure of such significant resources. The Agency is also concerned that a prohibition on use could lead to

unnecessary and unsupervised disposal of revoked products by users.

The Agency recognizes that in data suspension cases under section 3(c)(2)(B) of FIFRA, adversely affected persons have a right to a hearing on existing stocks issue. While no such right is provided for revocations such as the one involved here, the Agency believes it appropriate in this particular case, given the novelty of the issues and the absence of any guidance for revocations in the existing stocks Policy Statement, to provide any person adversely affected by this existing stocks determination with an informal hearing opportunity before the Agency if such person wishes to seek reconsideration of this determination. If this opportunity for an informal hearing is pursued, the Agency will consider all issues raised relevant to the existing stocks determination. Any person interested in

requesting an informal hearing should submit such a request within 60 days, in writing, to Robert Perlis, Office of General Counsel (2333), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Requests should include the nature of the person's objection to the determination, the nature of the proposed changes to the determination, and the bases for the objections and changes.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: October 31, 1997.

Lynn R. Goldman,

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Pesticides and Toxic Substances.*

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