# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

#### BEFORE THE ADMINISTRATOR

In the matter of	)
Chemarmor,	) Docket No. FIFRA-8-99-71 ) FIFRA-8-2000-41
Respondent	)
<u>II</u>	NITIAL DECISION

By: Carl C. Charneski Administrative Law Judge

Issued: October 2, 2001 Washington, D.C.

**Appearances** 

For Complainant:

Dana J. Stotsky, Esq. Eduardo Quintana, Esq. United States Environmental Protection Agency Region 8 Denver, CO

For Respondent:

Kathleen Dwire President of Chemarmor Missoula, MT

#### I. Statement of the Case

These consolidated cases arise under the Federal Insecticide, Fungicide, and Rodenticide Act, commonly referred to as "FIFRA." 7 U.S.C. § 136 *et seq.* The United States Environmental Protection Agency ("EPA") charges Chemarmor, a pesticide manufacturer, with three counts of violating FIFRA. In two of the counts, EPA alleges that Chemarmor sold a pesticide after being ordered by the Agency to stop all sales of the product. This is a violation of FIFRA Section 12(a)(2)(I). 7 U.S.C. § 136j(a)(2)(I). In the remaining count, EPA alleges that as manufactured, the chemical composition of this pesticide differed from the chemical composition that the Agency had approved in the FIFRA registration process. This is a

violation of FIFRA Section 12(a)(1)(C). 7 U.S.C. § 136j(a)(1)(C). For these violations, EPA seeks civil penalties totaling \$9,900. *See* EPA Br. at 11 n.2.

Chemarmor disputes EPA's charges that it violated FIFRA. A hearing in this matter was held on August 8-9, 2000, in Missoula, Montana.

For the reasons set forth below, Chemarmor is found to have violated FIFRA as alleged by EPA in each of the three counts. A civil penalty of \$ 4,500 is assessed for these violations.

#### II. Facts

Chemarmor manufactures pesticides in Missoula, Montana. CX 14; Resp. Br. at 2. By all accounts, it is a small business. One of the pesticides that Chemarmor produces is Bear Pause Attack Deterrent ("Bear Pause"). This product is contained in an 8-ounce, aerosol cannister and it is intended to be used by an individual for self-defense in the event of a grizzily bear attack. CXs 14, 20 & 36; RX 18. Bear Pause is the pesticide that is involved in all three violations at issue in this case.

On September 22, 1998, Chemarmor submitted an application to EPA for the registration of Bear Pause. CX 41. In the registration application, Chemarmor represented in its Confidential Statement of Formulation that the active ingredient in Bear Pause is "capsaicin." CX 18. Capsaicin is an oleoresin extract of the Capsicum red pepper and it has a Chemical Abstract Service ("C.A.S.") Number of 404-86-4. CX 10; RX 18; Resp. Br. at 2.

Thereafter, on October 30, 1998, EPA issued to Chemarmor a Stop Sale, Use or Removal Order ("SSURO") directed at Bear Pause. CX 36. In the SSURO, EPA ordered Chemarmor "to stop the sale, use or removal of the Bear Pause Attack Deterrent product immediately" unless certain conditions were met. If the prescribed conditions were met, Chemarmor would be allowed to sell, distribute and produce Bear Pause, but only until January 15, 1999. The order added: "No further sales, distributions, and productions of the Chemarmor Bear Pause Attack Deterrent … may occur after this date *unless the product has been registered with the U.S. EPA.*" CX 36 (*emphasis added*).<sup>1</sup>

The SSURO was issued pursuant to Section 13(a) of FIFRA. 7 U.S.C.§ 136k(a). This order informed the respondent that it is unlawful to sell a pesticide that is not registered under Section 3 of FIFRA. 7 U.S.C. § 136a.

On March 23, 1999, EPA issued to Chemarmor a registration for the pesticide

<sup>&</sup>lt;sup>1</sup> Chemarmor was allowed to sell Bear Pause until January 15, 1999. Tr. 193-94. Two of the counts at issue in this case involve its sale of Bear Pause after this date.

Bear Pause. CX 41; Resp. Br. at 2.<sup>2</sup> Prior to the issuance of this registration, however, Chemarmor sold one case (*i.e.*, 12 cans) of Bear Pause to The Trailhead sporting goods store on February 8, 1999, and one case to the Sportsman's Surplus sporting goods store on February 11, 1999. CX 39; Resp. Br. at 3; Tr. 172. These pre-registration sales are the basis for the two counts under Section 12(a)(2)(I).

Also, in October of 1999, EPA Region 8 received information from EPA Headquarter's Office of Pesticide Programs that the active ingredient in Bear Pause might be something other than capsaicin. Specifically, one of Chemarmor's competitors complained to EPA that the respondent was manufacturing Bear Pause using "synthetic capsaicin" as the active ingredient, and not "capsaicin," as was listed by respondent in registering the pesticide. Tr. 198. EPA's subsequent investigation into this complaint led to the present charge that Chemarmor violated Section 12(a)(1)(C) of FIFRA.

#### III. Discussion

### A. The Stop Sale Violations

It is a violation of FIFRA Section 12(a)(2)(I) to breach the terms of a Section 13 "stop sale" order. Here, Chemarmor does not dispute the fact that the Section 13 "stop sale" order was properly issued. This order clearly instructed Chemarmor not to sell Bear Pause after January 15, 1999. CX 36. The respondent, however, admits that on February 8, 1999, it sold Bear Pause to The Trailhead, and that on February 11, 1999, it sold Bear Pause to Sportsman's Surplus. Jt. Ex. 1. These sales occurred after the January 15, 1999, stop sale date of the SSURO, and before March 23, 1999, when Bear Pause finally received its FIFRA registration. See CX 41; Resp. Br. at 3. Accordingly, EPA has proven the two Section 12(a)(2)(I) violations alleged. As discussed below, respondent's explanation that it believed that the product Bear Pause was actually registered with EPA when these sales were made is not a defense to the charges of violation.

In seeking to avoid liability here, Chemarmor argues that it was misled by EPA into thinking that Bear Pause was registered when it was sold to The Trailhead and to Sportsman's Surplus. As noted, Chemarmor submitted its FIFRA application for Bear Pause on September 22, 1998. CX 41. After EPA issued the "stop sale" order on October 30, 1998, but before the February, 1999, sales to The Trailhead and to Sportsman's Surplus, Chemamor received a correspondence from Daniel Peacock of EPA. Peacock is an EPA biologist who oversaw the FIFRA registration process for Bear Pause. Tr. 25-26. It is this correspondence upon which respondent bases its defense to the Section 12(a)(2)(I) charges.

Specifically, in a letter dated February 3, 1999, Peacock informed Chemarmor: "We

<sup>&</sup>lt;sup>2</sup> The EPA Registration Number is 71768-1.

are prepared to issue a conditional registration for [Bear Pause] as soon as you submit the ... information requested in our January 29, 1999, letter." CX 36.3 Chemarmor maintains that in response to Peacock's letter, it submitted the requested information to EPA prior to its sale of Bear Pause to The Trailhead and Sportsman's Surplus on February 8 and 11, 1999, respectively. In light of Peacock's February 3 letter, Chemarmor states that it was the company's understanding that Bear Pause was officially registered upon its submission of the requested material to EPA. Chemarmor states further that it didn't learn that EPA believed otherwise until Peacock left a telephone message on February 17 informing the respondent that Bear Pause was not in fact registered. Resp. Br. at 5; Resp. R.Br. at 1-3.

Chemarmor's reliance upon Peacock's letter of February 3 is misplaced. First, even though EPA concedes that this letter could have been clearer (Tr. 234), the fact remains that fairly read the letter does not state that Bear Pause would be considered registered upon the respondent's mere submission of certain material. The letter simply pointed out deficiencies in Chemarmor's registration application and how these deficiencies could be corrected.

Second, Chemarmor's reading of the Peacock letter is not a reasonable one considering the whole context of the application process. In that regard, in seeking FIFRA registration, Chemarmor submitted a written registration kit for EPA's review. As is evident from the substance of Peacock's February 3 letter, on December 27, 1998, Chemarmor submitted to EPA a Confidential Statement of Formula, and January 29, 1999, EPA made a separate informational request from respondent. These written exchanges between an applicant seeking to register a product under FIFRA, and the reviewing Agency authorized to grant such a registration, are evidence of the formal process that one would expect for obtaining permission to market a pesticide to the public. Chemarmor's belief that a product (*i.e.*, Bear Pause) could be registered upon the submission of purportedly supporting material, without allowing EPA the opportunity to review the sufficiency of its submission, is inconsistent with the very application process in which Chemarmor was engaged in this case.

Finally, it would simply turn the FIFRA registration process on its head to allow the party seeking registration effectively to determine that its product is registered because, in its view, it has submitted all the necessary supporting information. Congress has placed that authority squarely with EPA, and no one else. 7 U.S.C. § 136a.

# B. The Chemical Composition Violation

FIFRA Section 12(a)(1)(C) provides that it shall be unlawful to sell "any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under

<sup>&</sup>lt;sup>3</sup> EPA had requested two acute toxicity studies, information on the product's spray pattern, and a revised label. *Ibid.* 

section 136a of this title." 7 U.S.C. § 136j(a)(1)(C). EPA alleges that Chemarmor violated Section 12(a)(1)(C) because it manufactured the pesticide Bear Pause using "synthetic capsaicin" as the product's active ingredient, instead of "capsaicin" which had been approved by EPA in the FIFRA registration process. Indeed, Chemarmor does not dispute that capsaicin was identified as the active ingredient in the chemical composition of Bear Pause when the pesticide received its FIFRA registration. Also, Chemarmor admits that at all times that it subsequently produced this pesticide, synthetic capsaicin (also known as vanillyl pelargonamide, or "VP") was the active ingredient, and not capsaicin. Jt. Ex. 1.

Based upon a strict reading of the statute, it is held that EPA has proven a violation of Section 12(a)(1)(C). As explained below, capsaicin is the active ingredient that was approved by EPA in the FIFRA registration process, and not synthetic capsaicin. Respondent's substitution of this active ingredient in the manufacturing process is a violation of FIFRA.<sup>4</sup>

The chemical name for capsaicin is "8-methyl-n-vanillyl-6-nonenamide." It has an Empirical Formula of  $C_{18}H_{27}N0_3$  and a Chemical Abstracts Service Number of 404-86-4. CX  $10.^5$  Also, capsaicin has a Formula Weight of 305.42. Synthetic capsaicin, however, has an Empirical Formula of  $C_{17}H_{27}NO_3$ ; its Chemical Abstracts Number is 2444-46-4 and its Formula Weight is 293.4. CX 38; Tr. 35. In addition, a comparison of the structural formulas of these chemicals shows that capsaicin has an extra double bond and an extra carbon. Tr. 37; CX 38.

Clearly, capsaicin is a unique substance different from synthetic capsaicin. It may well be that synthetic capsaicin is as effective a repellent as capsaicin, as respondent claims its

 $<sup>^4</sup>$  In defending against this charge, Chemarmor has argued that there is no Section 12(a)(1)(C) violation because the synthetic capsaicin actually used in the manufacturing of Bear Pause is the equivalent of capsaicin. Therefore, Chemarmor maintains that the chemical composition of the manufactured pesticide is the same as the chemical composition of the pesticide approved by EPA.

Given the holding here, it is not necessary to resolve Chemarmor's claims concerning capsaicin and synthetic capsaicin. Moreover, whether the properties of capsaicin and synthetic capsaicin are such that the two are essentially the same and may be used interchangeably is a difficult issue that could not be decided on the present record. As noted *infra*, that is a question that might be better left to the FIFRA registration process.

<sup>&</sup>lt;sup>5</sup> Chemical Abstract Service numbers are used to reference specific chemicals. They are prepared by the American Chemical Society's division of Chemical Abstract Service. Tr. 47.

evidence shows. Whether synthetic capsaicin can do the same job as capsaicin in deterring an attacking bear, however, is not the issue here. That is an issue that can be revisited by Chemarmor and EPA through the FIFRA registration process; this time respondent can list synthetic capsaicin as the active ingredient in its statement of formula. *See, e.g.*, Tr. 49-51. The issue presented here is a narrower one -i.e., whether capsaicin and synthetic capsaicin are the same for purposes of FIFRA registration. The answer is that they are not and the fact that they are not supports a finding of a Section 12(a)(1)(C) violation.

### C. <u>Civil Penalty</u>

Section 14 of FIFRA authorizes the assessment of a civil penalty for a violation of this Act. 7 U.S.C. § 136l. In particular, Section 14(a)(4) sets forth the road map for deciding the penalty amount. It states:

In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

# 7 U.S.C. § 136l(a)(4) (emphasis added).

In evaluating the evidence in light of this statutory criteria, it is determined that the appropriate penalty for each of the two Section 12(a)(2)(I) violations is \$2,000 and that the appropriate penalty for the Section 12(a)(1)(C) violation is \$500. This penalty assessment is explained below.<sup>7</sup>

<sup>&</sup>lt;sup>6</sup> See, e.g., EPA Br. at 13, "Respondent has put on an impressive after-the-fact argument that these differences are slight, that pungencies and mean pain potentials are equivalent, that the world's chemical nomenclature is strewn with equivalencies between capsaicin and VP...."

<sup>&</sup>lt;sup>7</sup> It is worth noting that while EPA did submit into evidence a Penalty Calculation Narrative (CX 5), and while one of its witnesses did offer testimony as to the penalty (Tr. 220-232), the Agency's post hearing briefing of this issue consisted of little more than one page and contained no citations to the record. EPA Br. at 11-12.

#### Size of the Business

In calculating its proposed penalty in this case, EPA determined that Chemarmor was a small business. Tr. 219-220. Inasmuch as respondent does not dispute this determination, it is found that Chemarmor is in fact a small business, with annual sales not exceeding \$160,000. Tr. 245; *see* Tr. 216 & EPA Br. at 11 n.2.

# Ability to Continue in Business

What limited evidence there is on this penalty criterion supports a finding that the imposition of a \$4,500 penalty will not put the respondent out-of-business. The evidence addressing this criterion is basically the same, sparse evidence that addressed the size of the business criterion. In addition, while Chemarmor's president, Kathleen Dwire, testified to the "tremendous financial burden" that this case has placed on the company, her testimony lacked specifics and was not supported by any documentation. Tr. 355.

### **Gravity of the Violations**

Insofar as the two Section 12(a)(2)(I) violations are concerned, the record establishes that respondent was moderately negligent. Chemarmor offered no reasonable explanation for its sale of Bear Pause on two occasions prior to this product being registered under FIFRA. Its interpretation of Peacock's letter -i.e., its belief that the mere submission of supporting information constitutes registration under FIFRA -i.e. is not an acceptable excuse for sale of an unregistered pesticide. The statute is clear in its requirement that a pesticide cannot be sold until it is properly registered. Determination of when a pesticide is registered lies with EPA, not with the registrant. Chemarmor is in the pesticide manufacturing business and it should have known how to comply with the registration provisions of the Federal Insecticide, Fungicide, and Rodenticide Act. Chemarmor should have known that the mere submission of information to EPA does not mean that the pesticide has met with the Agency's approval and that it is deserving of registration.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> Arguing that Chemarmor's negligence was considerably greater, EPA cites to the testimony of Peacock that he received an "e-mail" from respondent during the week of February 17, 1999, indicating that the company was aware that Bear Pause was not yet registered. EPA also cites to the testimony of Ron Stewart of the Montana Department of Agriculture concerning a conversation that he had with Kathleen Dwire of Chemarmor. According to EPA, Dwire informed Stewart sometime after February 11, 1999, that she knew that Bear Pause was not registered. EPA Br. at 8.

Contrary to EPA's assertion, this testimony does not show that respondent knew that Bear Pause was not registered when it was sold on February 8 and 11. In that regard, Dwire testified that she was informed by EPA sometime around February 16 or 17, 1999, that Bear

Aside from the issue of negligence, the gravity criterion also includes a consideration of the seriousness of the violation. In that regard, the sale of an unregistered pesticide is normally a serious violation because it may expose the public and the environment to a product that is not safe. For example, the selling of unregistered pesticides prevents the EPA from performing its important regulatory duties of evaluating the efficacy and overall safety of a pesticide before the product is offered to the public. Fortunately, in this case, there has been no showing by EPA that the Bear Pause Attack Deterrent sold to The Trailhead and to Sportsman's Surplus posed any such danger. Indeed, the fact that EPA allowed Chemarmor to continue to sell Bear Pause for approximately two and one-half months after the "stop sale" order was issued strongly suggests that the Agency did not believe that this pesticide posed a serious hazard. See EPA Br. at 4 n.1; see, also, Tr. 42.

Accordingly, the evidence in this case supports the assessment of a \$2000 civil penalty for each Section 12(a)(2)(I) violation.

The gravity surrounding the Section 12(a)(1)(C) violation is a little more difficult to gauge. While manufacturing a pesticide using a different chemical composition than the one approved by EPA would seem to warrant a significant penalty, the facts of this case don't support such an assessment. As earlier noted, the respondent offered evidence that synthetic capsaicin is as good as, if not better than, capsaicin. While this argument is not a defense to the charge of a violation, it is an appropriate consideration in determining the penalty.

In that regard, without concluding whether or not Chemarmor's claims are correct, the fact is that it presented evidence concerning the efficacy of synthetic capsaicin. For its part, EPA provided no such evidence. Indeed, in its post hearing brief EPA seems to conceded the expertise in this area to Chemarmor. Given this fact, and given the fact that there has been no showing that Chemarmor operated in bad faith in substituting synthetic capsaicin for capsaicin, the unique facts of this case justify a penalty in the lower range.

Accordingly, considering the facts surrounding this violation, a penalty of \$500 is warranted. This penalty assessment recognizes that respondent's substitution of synthetic capsaicin during the manufacturing process was wrong. It also recognizes that EPA did not carry its burden of proof to show that the gravity of this violation was of such a nature that a significant penalty should be assessed. Indeed, as noted, EPA barely addressed this point in its brief.

Pause was not registered. Insofar as the e-mail to Peacock is concerned, the record shows that it was sent after Dwire learned that Bear Pause was not registered, not before. Tr. 339-340. Also, EPA's assertion that Stewart's conversation with Dwire occurred sometime after February 11, 1999, is too imprecise to be of any importance. Indeed, it appears that this conversation occurred after February 17. *See* Tr. 145-146; *see, also,* CX 36.

# **ORDER**

It is held that Chemarmor committed two violations of Section 12(a)(2)(I) and one violation of Section 12(a)(1)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act. 7 U.S.C. §§ 136j(a)(2)(I) & 136j(a)(1)(C). Accordingly, pursuant to FIFRA Sections 14(a)(1) and 14(a)(4), 7 U.S.C. §§ 136l(a)(1) and 136l(a)(4), Chemarmor is directed to pay a civil penalty of \$4,500 for these violations within 60 days of the date of this order. 9

This decision will become a final order of the Environmental Appeals Board unless it is appealed to the Board, or unless the Board elects to review this decision *sua sponte*, as provided by 40 C.F.R. 22.27(c) & (d), and 40 C.F.R. 22.30.

Carl C. Charneski Administrative Law Judge

<sup>&</sup>lt;sup>9</sup> Payment of the civil penalty may be made by mailing, or presenting, a cashier's or certified check made payable to the Treasurer of the United States, addressed to Mellon Bank EPA Region 8 (Regional Hearing Clerk), P.O. Box 360859, Pittsburgh, PA 15251-6859.