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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
BEFORE THE ADMINISTRATOR

In the Matter of )  
 )  
Microft Systems ) Docket No. FIFRA-93-H-03  
International )  
Holdings, S.A. and )  
Alfred Waldner Company, )  
 )  
Respondents )

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ORDER ON DEFAULT

On September 10, 1993, the Complainant moved for a Default Order against the Respondent, Microft Systems International Holdings, S.A. (Microft), pursuant to 40 CFR Part 22.17 for failing to file a pre-hearing exchange as ordered by the ALJ. If granted, the Default Order will constitute an admission of the facts alleged in the complaint.

The initial complaint, filed on December 28, 1992, alleged that Respondent Microft falsified registration information submitted to the Agency on May 5, 1989, in violation of § 12(a)(2)(Q) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S. C. § 136j(a)(2)(Q)). Respondent, through Todhunter, Mandava & Associates, its agent in the United States, had filed two applications for registration of pesticides: Insecticide 2000 Concentrate and Insecticide 2000 Ready-To-Use. Insecticide 2000 Ready-To-Use is a diluted form of "Insecticide 2000 Concentrate," which is also referred to as "Clean Kill Insecticide."

Complainant avers that the Respondent falsified its applications by claiming the formulation for Insecticide 2000 is the same as Clean Kill Insecticide Concentrate. Clean Kill Insecticide Concentrate allegedly contains only permethrin as its active ingredient, while Insecticide 2000 Concentrate allegedly contains both permethrin and bioresmethrin. The complaint proposed a penalty of \$5000, the maximum allowed under FIFRA for a single violation.

Alfred Waldner Company (Waldner), an Austrian corporation and successor to Microft, filed an answer through Science Regulatory Services International (SRSI),<sup>1/</sup> on January 19, 1993, denying the allegations in the complaint and asserting that the claims in its registration were truthful when made.

By letter, dated April 22, 1993, the ALJ, absent a settlement of this matter, ordered the parties to exchange pre-hearing information on or before July 9, 1993.

Complainant filed its pre-hearing exchange on the due date as extended, July 16, 1993. Respondent, which through its agent, SRSI, had been directed to supply two items of information, did not file any pre-hearing exchange and, indeed, has made no response to the ALJ's directive to the date of this order. SRSI was directed to state whether it had received any replies or correspondence concerning this matter from Alfred

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<sup>1/</sup> SRSI was formerly Todhunter, Mandava & Associates, Respondent's previous agent in the United States.

Waldner Company, Mr. Otmar Hofer of Hofer Real,<sup>2/</sup> or Dr. Erwin Annau of Microft System International Holdings, S.A. since sending them a copy of the complaint and to furnish a statement or affidavit from Dr. Waldner as to whether he or his company had a pesticide product containing only permethrin at the time of the registrations at issue.

Simultaneously with the filing of its pre-hearing exchange, Complainant filed a motion to amend the complaint so as to include the Alfred Waldner Company (Waldner) as a party respondent, because the answer indicated that Microft Systems International Holdings, S.A. was no longer in existence and its interest in Insecticide 2000 products had been sold to Waldner. As indicated above, the answer to the complaint was filed on behalf of Waldner. Accordingly, there is no prejudice in granting the motion to amend and an order, issued contemporaneously, grants the motion to amend so as to include Waldner as a party respondent.

On September 10, 1993, Complainant filed two motions, a motion to supplement its pre-hearing exchange<sup>3/</sup> and a motion for a default order pursuant to Rule 22.17 of the Consolidated Rules of Practice (40 CFR Part 22). The latter motion was based on Respondent's failure to comply with the ALJ's order, as

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<sup>2/</sup> Mr. Otmar Hofer is a business agent for Alfred Waldner Company.

<sup>3/</sup> Complainant's motion to supplement its pre-hearing exchange is granted.

amended, that pre-hearing exchange information be filed on or before July 16, 1993. Respondent did not acknowledge or respond to either motion.

In accordance with Rule 22.17(a) "(a) party may be found in default. . . (2) after motion or sua sponte, upon failure to comply with a prehearing or hearing order of the Presiding Officer. . . ." A default by respondent constitutes for purposes of the pending action only, an admission of all facts alleged in the complaint and a waiver of respondent's right to a hearing on such factual allegations.

Based on the allegations in the complaint, the answer filed on behalf of the Alfred Waldner Company and the pre-hearing information and exhibits filed by Complainant, I make the following:

#### Findings of Fact

1. Respondents are Microft Systems International Holdings, S.A. (Microft), a Lugano, Switzerland corporation and its successor in interest, Alfred Waldner Company (Waldner), an Austrian corporation.
2. Microft and Waldner are persons and registrants as defined by FIFRA (7 U.S.C. §§ 136(s) and 136(y)).
3. On or about August 12, 1988, Microft authorized Todhunter, Mandava & Associates, presently SRSI, to act as its registration agent pursuant to 40 CFR § 152.50(b).

4. On or about May 5, 1989, Microft, through its registration agent, submitted two applications for the registration of pesticides: "Insecticide 2000 Concentrate" and "Insecticide 2000 Ready-To-Use." Supporting data for the applications included toxicity studies on a product identified as "Clean-Kill Insecticide Concentrate." The products were conditionally registered on October 29, 1990, "Insecticidal 2000 Concentrate" being assigned EPA Registration No. 62212-1 and "Insecticidal 2000 Ready-To-Use" being assigned EPA Registration No. 62212-2. Registrations for these pesticides were transferred to Respondent, Alfred Waldner Company, on January 26, 1993, and assigned EPA Registration Nos. 66410-1 and 66410-2, respectively.
5. The applications for the registration of the pesticides referred to in finding 4 and the labels thereof represent that the active ingredients for the products are permethrin and bioresmethrin.
6. On October 24, 1991, a conditional registration for the pesticide "BEP Insecticide," EPA Registration No. 64321-1, was granted to Bio Environmental Products Corporation, West Redding, Connecticut. The label for BEP Insecticide states that the active ingredient is "permethrin."
7. Although the complaint alleges that "Clean-Kill Insecticide Concentrate" (EPA Registration No. 66410-1, formerly Reg. No. 62212-2) is marketed in the United States under the

name "BEP Insecticide," BEP Insecticide is a dilute form of Clean-Kill Insecticide Concentrate.

8. Permethrin is the only active ingredient in Clean-Kill Insecticide Concentrate and in BEP Insecticide. Clean-Kill Insecticide Concentrate contains 25% permethrin, while the concentration of permethrin in BEP Insecticide is 1/100 of that amount or .25%.
9. An undated statement entitled "Certified Summary Of Acute Toxicology Of Insecticide 2000," submitted by SRSI on behalf of Microft in support of the applications for registration referred to in finding 4, contains the following:

Clean-Kill Insecticide Concentrate is the European trade name for Insecticide 2000, a resmethrin, pyrethrin based insecticide. The formulation is identical. Insecticide 2000 Ready-to-Use is a diluted version of Insecticide 2000 Concentrate.

10. In a statement, dated February 3, 1993, Mr. Hubert Steuerer, Director of Jesmond Limited, London, certified, inter alia, that "Clean-Kill" and "Bio-Kill" are registered trademarks of the Jesmond Group and refer to one and the same formulation of a permethrin based aqueous emulsion insecticide; that BEP Bio Environmental Products Corporation, Wilmington, DE, a wholly owned subsidiary of Jesmond Holding AG, Zug, Switzerland, submitted an application for registration of BEP Insecticide on

October 19, 1990; that the formula for the Bio-Kill/Clean-Kill batch which had been supplied to RCC, a research and consulting firm, in order to perform a.m. toxicity studies in 1986 fully complies with the formula, data and documents in the application for registration of "BEP Insecticide;" that BEP Insecticide ("Bio-Kill/Clean-Kill) is a ready-to-use permethrin based emulsion insecticide which contains 0.25% permethrin, but no other active ingredient; and that Jesmonds' Bio-Kill/Clean-Kill Insecticide has never contained resmethrin.

11. The complaint alleges that the statement submitted by SRSI, quoted in finding 9, is false and in violation of FIFRA § 12(2)(Q). In its letter answer, Respondent (Waldner) has denied this allegation, alleging that Clean Kill Insecticide was indeed formulated from bioresmethrin and permethrin and that this product was at various times in its development referred to as Clean Kill Insecticide and/or Clean Kill Insecticide 2000. Dr. Alfred Waldner, the principal owner of Alfred Waldner Company, allegedly was formerly employed by the firm which was developing the Clean Kill product. The answer further alleges that this unnamed firm predated Microft and sold and assigned its rights in the product to Waldner.
12. In further support of the denial of the allegations in the complaint, SRSI alleges that data submitted in support of the applications for registration of Insecticide 2000

Concentrate and Ready-To-Use included the results of analysis of a sample of the product obtained from Microft which confirmed the presence of permethrin and bioresmethrin. Additionally, SRSI states that as part of label changes required by the Agency for approval of Insecticide 2000 products, a limitation on indirect food contact uses was imposed due to the lack of a tolerance for bioresmethrin. This assertedly was not a problem for the then intended use of Insecticide 2000, but did lock Waldner out of the large and lucrative agricultural market.

13. SRSI asserts that it strains credulity to believe that Waldner, if his company already had a permethrin only product (as now alleged by the Agency) would not have simply said so and developed the product for the U.S. agricultural market. SRSI alleges that it had every reason to believe that its original statement regarding the identity of Clean-Kill Insecticide and Insecticide 2000 was accurate. Moreover, SRSI points to circumstances indicating that toxicology studies submitted to the Agency in support of the registration of BEP Insecticide may have been altered or misrepresented.
14. Among items of information Waldner was directed to supply by the ALJ's letter, dated April 22, 1993, was a statement or affidavit from Dr. Waldner as to whether he or his company had a pesticide product containing only permethrin at the time of the registrations at issue. The due date,

as extended, for supplying this information was July 16, 1993. Waldner has not supplied this information to the date of this order and has not responded in any manner to Complainant's motion for default.

15. Under date of July 10, 1993, Hofer Real submitted a Pesticides Report for Pesticide-Producing Establishments on behalf of Microft for the products "Insecticide 2000 Concentrate" and "Insecticide 2000 Ready-To-Use" in accordance with 40 CFR Part 167, Subpart E. The report indicates that there was no production of either pesticide in the calendar year 1992.
16. On January 13, 1993, Waldner through SRSI paid the annual pesticide maintenance fee for the pesticides referred to in finding 15 of \$1,950. At that time, the registrations were held by Microft.
17. AD&B report reflecting data through July 29, 1993, states that Waldner's sales for a period not stated, totaled \$1,260,000 in U.S. currency.

#### C O N C L U S I O N S

1. Microft and Waldner are persons and registrants as defined by FIFRA §§ 2(s) and 2(y) and are thus subject to the Act.
2. Respondents, having failed to comply with a pre-hearing order of the ALJ, are in default in accordance with Rule 22.17 of the Consolidated Rules of Practice (40 CFR Part 22).

3. Pursuant to Rule 22.17, a finding of default constitutes an admission of all facts alleged in the complaint. Among the facts alleged in the complaint, which are deemed admitted by Respondents' default, is that the statement, quoted in finding 9, submitted in support of registrations of the pesticides "Insecticide 2000" and "Insecticide 2000 Ready-To-Use" is false.
4. Under § 12(Q) of FIFRA it is unlawful to falsify all or any part of any information submitted to the Administrator relating to the testing of any pesticide, including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed.
5. Respondents, having violated FIFRA as alleged in the complaint, are jointly and severally liable for a penalty in accordance with FIFRA § 14 (7 U.S.C. § 1361(a)).
6. A penalty of \$5,000 is considered appropriate and will be assessed against Respondents

#### D I S C U S S I O N

As set forth in the findings of fact, Respondents appear to have a reasonable basis for the belief that the statement to the effect that Clean Kill Insecticide Concentrate and Insecticide 2000 Concentrate are identical, which the complaint alleges to be false, was accurate. Accordingly, the first matter warranting discussion is whether this "good faith defense," if

established, would operate to relieve Respondents of liability or whether it may only be considered in mitigation of the proposed penalty. Although specific authority for the conclusion that FIFRA is a strict liability statute appears to be sparse, see In Re Harmack Grain Co. Inc., Docket No. IF&R-VIII-180C (Accelerated Decision, May 2, 1986), court decisions imply that the Act imposes strict liability. See, e.g., George's Pest Control v. U.S. EPA, 572 F.2d 204 (9th Cir. 1977); Aeromaster, Inc. v. U.S. EPA, 747 F.2d 748 (8th Cir. 1985) and Panhandle Co-op Association, v. EPA, 771 F.2d 1149 (8th Cir. 1985). I conclude that FIFRA is a strict liability statute and that "good faith" is only to be considered in determining the amount of the penalty. Be that as it may, the finding of default precludes Respondents from raising or presenting facts to contradict the allegations of the complaint. See, e.g., In Re Buerge Feed and Seed, FIFRA Appeal No. 88-1 (CJO, August 31, 1988). Accordingly, Respondents violated FIFRA § 12(2)(Q) and may be assessed a penalty therefor in accordance with § 14(a)(1) of the Act.

Respondent Waldner is the successor of Microft. Waldner recognized its interests herein by filing an answer to the complaint. In Oner II, Inc. v. U.S. EPA, 597 F.2d 184 (9th Cir. 1979), the court held that imposing liability on a successor corporation was proper in view of FIFRA's purpose to regulate pesticides for the protection of the environment. This rule

will be applied here and it is concluded that Waldner is jointly and severally liable for the violation found.

The only remaining question is whether the proposed penalty of \$5,000 is appropriate. Although Rule 22.17 (40 CFR Part 22) provides in part that [upon a finding of default] "the full amount of the penalty proposed in the complaint shall become due and payable without further proceedings. . .", courts have, nevertheless, held that the factors in FIFRA § 14(a)(4) must be considered. Katzson Brothers, Inc. v. U.S. EPA, 839 F.2d 1396 (10th Cir. 1988). "Gravity of the violation" is among the factors required to be considered by the cited section of the Act in determining the amount of any penalty. The first step in determining the "gravity" of the violation is to determine the actual or potential harm to human health or the environment which could result from the violation or the importance of the requirement to achieving the goals of the statute (Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act, July 2, 1990, at 21).

The Notice of Warning issued to SRSI on December 28, 1993, stated, inter alia, that the Clean-Kill studies should not have been used to support the registration of Insecticide 2000 products and had the Agency been aware of this fact when the applications for registration were submitted, it could not have granted the registrations. This, then, is a case where, unbeknownst to the Agency, studies for a pesticide containing only permethrin as an active ingredient were used to support the

registration of pesticides containing permethrin and bioresmethrin as active ingredients. Under such circumstances, the potential for harm would appear to be obvious. Moreover, central to the purpose of FIFRA that pesticides be regulated is that data supporting pesticide registration be accurate. It is concluded that prima facie the maximum penalty permitted by the Act is appropriate.

Next for consideration are adjustment factors such as culpability and the size of Respondents' business. While, if the defense is credited, SRSI had every reason to believe that the statement to the effect that the formulation for Clean Kill Insecticide Concentrate was identical to Insecticide 2000 was accurate when made, Respondents' default has precluded the presentation of facts which might verify this contention.

Although financial information in the record is scanty, the fact that Waldner has paid the \$1,950 registration maintenance fee and is reported to have had sales in excess of \$1,200,000 in U.S. currency in a recent reporting period makes it unlikely that imposition of a penalty in the amount of \$5,000 would adversely effect its ability to continue in business.

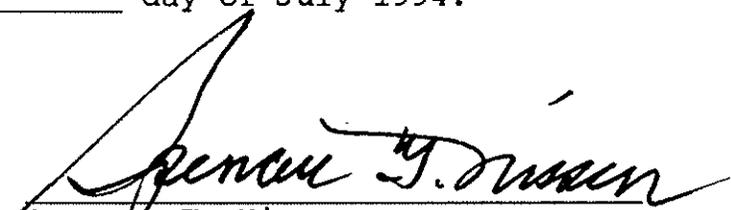
It is concluded that the penalty of \$5,000 proposed in the complaint is appropriate and will be assessed.

ORDER

Microft Systems International Holdings, S.A. and its successor Alfred Waldner Company, having violated FIFRA § 12(a)(2)(Q) as alleged in the complaint, a penalty of \$5,000 is assessed against these companies jointly in accordance with § 14(a)(1) of the Act (7 U.S.C. § 1361(a)(1)). Payment of the full amount of the penalty shall be made by sending a cashier's or certified check payable to the Treasurer of the United States to the following address within 60 days of the date of this order:<sup>4/</sup>

Hearing Clerk  
U.S. EPA Headquarters  
P.O. Box 360277M  
Pittsburgh, PA 15251

Dated this 15<sup>th</sup> day of July 1994.

  
Spencer T. Nissen  
Administrative Law Judge

Enclosure  
Order Granting Motion to Amend Complaint

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<sup>4/</sup> In accordance with Rule 22.17(b) this default order constitutes an initial decision, which unless appealed to the EAB in accordance with Rule 22.30 or unless the EAB elects, sua sponte, to review the same as therein provided, will become the final order of the EAB in accordance with Rule 22.27(c).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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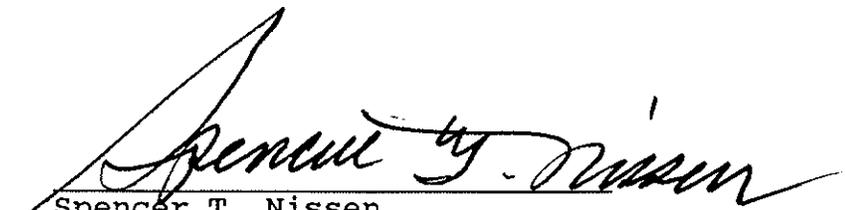
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ORDER GRANTING MOTION TO AMEND COMPLAINT

Counsel for Complainant having by motion, dated July 16, 1993, moved to amend the complaint so as to add Alfred Waldner Company as a party respondent, and it appearing that the Alfred Waldner Company has filed an answer as successor in interest to Microft Systems and that no prejudice from the amendment will result, the motion is granted and Alfred Waldner Company is a party respondent herein.

Dated this 15<sup>th</sup> day of July 1994.

  
Spencer T. Nissen  
Administrative Law Judge

CERTIFICATE OF SERVICE

I do hereby certify that the foregoing **Order on Default** was filed in re Microft Systems International; Docket No. FIFRA-93-H-03 and copies of the same were mailed to the following:

(Interoffice)

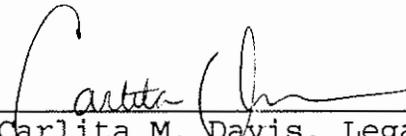
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Dated: July 18, 1994