

8/2/96

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF)	
)	
MICROFT SYSTEMS INTERNATIONAL)	DOCKET NO. FIFRA-93-H-03
HOLDINGS, S.A. AND)	
ALFRED WALDNER COMPANY,)	
)	
)	
RESPONDENTS)	

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ORDER ON MOTIONS

By an order, dated December 13, 1994, the default order issued, July 15, 1994, in this proceeding under Section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 1361, was set aside. The ALJ determined that there was a strong probability of a different result at least as to the amount of the penalty, if a hearing were held.

The complaint, issued on December 28, 1992, alleged that Respondent, Microft Systems International, S.A., falsely certified that five acute toxicity studies submitted to support the registrations of two pesticides, Insecticide 2000 and Insecticide 2000 Ready To Use, were on a product containing permethrin and bioresmethrin as active ingredients. This certification was allegedly false in violation of FIFRA § 12(a)(2)(Q).^{1/} For this

^{1/} Section 12(a)(2)(Q) of FIFRA states:

It shall be unlawful for any person ... to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used,
(continued...)

alleged violation, it was proposed to assess Microft a penalty of \$5,000.

Microft's registration agents, Science Regulatory Services International (SRSI), filed a letter-answer, on January 19, 1993, on behalf of Alfred Waldner Company (Waldner), successor to Respondent's interest in the pesticides at issue.^{2/} Respondent denied liability, denied that the certification was false, and maintained that the toxicity studies were conducted on a substance (Clean Kill Insecticide and/or Clean Kill Insecticide 2000) containing the same active ingredients as the products proposed for registration. The answer alleged, inter alia, that Mr. Alfred Waldner was formerly employed at the firm which was developing the Clean Kill product, that this product was formulated

^{1/} (...continued)
observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter.

7 U.S.C. § 136j(a)(2)(Q).

^{2/} Letter from SRSI to Headquarters Hearing Clerk, dated January 19, 1993, incorporating by reference letter from SRSI to Michael F. Wood, Director, Compliance Division, dated January 6, 1993 (R's answer). SRSI, located in Washington, DC, was formerly called Todhunter, Mandava & Associates. Id. Microft was a Lugano, Switzerland corporation, which, on May 6, 1991, transferred all of its interest in EPA labels, registrations and the data in support of the registration for EPA Reg. Nos. 62212-1 and 62212-2 to Alfred Waldner Company (Waldner), located in Vienna, Austria (Complainant's Prehearing Exchange [CPH] Ex. 16). Sometime thereafter, Microft ceased operations (R's answer at 1). Complainant's motion to add Waldner as a party respondent was granted by an order issued contemporaneously with the default order.

from bioresmethrin and permethrin, and that the firm sold or assigned rights in the product to Waldner.

SRSI submitted applications on behalf of Microft, dated May 5, 1989, to register the pesticide products, Insecticide 2000 Concentrate and Insecticide 2000 Ready to Use. On October 29, 1990, EPA approved the applications, assigning EPA Registration Nos. 62212-1 and 62212-2, respectively.^{3/} SRSI filed an application, dated July 28, 1992, to transfer the registrations from Microft to Waldner, which EPA approved on January 26, 1993, assigning Registration No. 66410-1 to Insecticide 2000 and Reg.No. 66410-2 to Insecticide 2000 Ready To Use.

It is undisputed that the mentioned pesticide registrations issued to Microft/Waldner by EPA were for products containing two active ingredients: permethrin and bioresmethrin. Complainant alleges that five (RCC) toxicity studies Respondent submitted with its registration application were conducted on a substance that contained permethrin, but not bioresmethrin, as an active ingredient. The default order referred to above was issued because Waldner did not respond to the ALJ's letter-order, dated April 22, 1993, which, as extended, required the parties to exchange prehearing exchange information on or before July 16, 1993. Waldner did not respond to Complainant's motion for a

^{3/} CPH, ex. 3. The registrations were approved, contingent upon submission of a Dermal Sensitization Study and a Storage Stability Study for registration number 62212-1, an Acute Dermal Study for registration 62212-1, and label changes not here relevant.

default order, filed September 10, 1993. Waldner was found to be in default and the full amount of the proposed penalty assessed (Order on Default, July 15, 1994). The order was served under date of July 18, 1994.

On August 5, 1994, Mr. Otmar Hofer of Hofer-Real, Wien, Austria, business agent for Waldner, filed a document entitled "Appeal for Temporary Stay of Order on Default". Among other things, the "appeal" alleged that SRSI no longer represented Waldner. The ALJ ruled that Waldner's "appeal" would be treated as a motion to set aside the default order pursuant to Rule 22.17(d) (40 CFR Part 22) and Waldner was directed to provide certain information in order to determine whether "good cause" to set aside the default order existed (Order, August 10, 1994). Waldner by Hofer-Real (Otmar Hofer) responded under date of September 23, 1994, identifying the firm which produced Clean Kill Insecticide 2000 as "Steuerer GesmbH", probably intended to be "Steurer GesmbH" (Steurer Ltd.), and alleging that Mr. Waldner was the general representative [of that firm] for the whole area. In 1985, Mr. Steuerer [despite an agreement with Waldner] allegedly granted another person exclusive rights [for the sale of Clean Kill] for the above country [apparently Austria], which led to many disputes. Mr. Steuerer and Waldner assertedly went their separate ways in 1987 and Waldner, with the RCC studies and the know-how obtained from Steuerer to support his activities [as a representative of Steuerer-GesmbH], applied for registration under the name of Microft Systems International. The Hofer letter identified a Dr. Berger,

living in Vienna, as the [former] chief chemist and finally the producer of Clean Kill Insecticide 2000 for Steurer GesmbH. Dr. Berger allegedly confirmed that "we" worked with two active Pyrethroids, but was not willing to write out an affidavit, because he was so disappointed with Mr. Steuerer that he would never have anything to do with him.

The mentioned Hofer letter referred to and enclosed two pages from an "Opinion on Insecticide 2000" from the Higher Federal School And Test Institute For The Chemical Industry (Test Institute For Biochemistry And Insecticides), dated June 7, 1984. The "Opinion" referred to a request from Steurer Ges.m.b.H. (Steurer Ltd.) and the receipt of test material on May 6, 1984. Mr. Waldner is quoted as suggesting that a sample of the material could be obtained from the Test Institute and analyzed for active ingredients.^{4/} The Hofer letter also refers to an opinion on Insecticide 2000, requested by Steurer Ges.m.b.H, from the Austrian Foodstuffs Research Institute, dated October 12, 1984, a copy of which is enclosed in German. This Institute allegedly received a sample of Insecticide 2000 "around October 1984" and it is averred that EPA could request a sample for analytical purposes from that organization.

^{4/} This course seemingly is equally open to Waldner. It is noted, however, that the signature page of the "Opinion" contains a note to the effect that test materials are kept in official custody on these premises for six months, provided the samples have adequate storage life (CPH Ex. 10). While this does not preclude samples being in storage at some other location, for all that appears, neither party has made any effort to ascertain whether the sample still exists or to have it analyzed.

Alfred Waldner's affidavit, dated September 19, 1994, states that Hubert Steuerer under the [business] name(s) of "Steurer Ltd." and "Jesmond Ltd." was the manufacturer of the product "Insecticide 2000" at the time of the expert opinion from the High Federal School and Test Institute for Chemical Industry referred to above, which he identified by number. He asserts that the product contained Permethrin and Bioresmethrin or Bioallethrin. Additionally, he states that this product was sold internationally for many years under [the names] "Insecticide 2000", "Clean-Kill Insecticide 2000", "Clean Kill", and "Bio-Son."

Attached to the Hofer letter was a statement by Professor Fritz Schreiner, dated September 20, 1994, who describes himself as a scientist and an expert in pest control.^{5/} Professor Schreiner states flatly that Insecticide 2000 contains two active ingredients: Permethrin and Bioresmethrin. He further states that Insecticide 2000, which contains the active ingredients Permethrin 0.175% and Biomesremethrin 0.075%, is less toxic than a product which contains only Permethrin 0.25%.^{6/} He asserts that a toxicological study, comparing Insecticide 2000 with this other

^{5/} Mr. Hofer's letter states that Professor Schreiner was in "my" office on September 20, 1994, and "looked technicalwise" over the registration matter.

^{6/} Support for Professor Schreiner's opinion is found in the fact that bioresmethrin ($C_{22}H_{26}O_3$) is described as a synthetic insecticide of the pyrethrin type. Bioresmethrin is biodegradeable and has a low toxicity, is nonpersistent, and can act as a synergist. Hawley's Condensed Chemical Dictionary, Eleventh Ed. (1987).

product, presumably a Permethrin only insecticide, would show the great toxic difference. Referring to the existing [RCC] studies (identified infra), Professor Schreiner says that we can scientifically expect that these studies would show less suitable data if made with a Permethrin only ingredient. On the supposition that the existing studies were made with a Permethrin only product, he opines that a study with two active ingredients would show better figures and data. He declares that the chemical data which underly the studies and [Waldner] registrations are definitely correct.

By a letter addressed to SRSI, Waldner's domestic registration agent, dated July 20, 1994, the Director of the Registration Division informed Waldner that EPA had received information alleging that false claims were made regarding the applicability of data submitted in support of registrations for Insecticidal 2000 Concentrate (EPA Reg. No. 66410-1, formerly 62212-1) and Insecticidal 2000 Ready To Use (EPA Reg. No. 66410-2, formerly 62212-2). The letter pointed out that the Certified Summary of Acute Toxicology of Insecticidal 2000, submitted in support of the registrations, stated that the substance tested, Clean-Kill Insecticide Concentrate, was identical in formulation to Insecticidal 2000 and that it has now been alleged that Clean-Kill Insecticide Concentrate contained only one active ingredient, permethrin, while Insecticidal 2000 products contain both permethrin and bioresmethrin. Waldner was informed that if this allegation were accurate, there was no basis for the registrations.

Waldner was directed to submit any information it may have to demonstrate that the data submitted in support of the cited registrations were accurate by August 15, 1994, and warned that, if it failed to do so, the registrations would be revoked. The registrations were revoked by a notice published in the Federal Register on September 28, 1994.^{7/} By a letter addressed to the Hearing Clerk, via Complainant's counsel, dated October 5, 1994, Otmar Hofer referred to his response to the order in Docket No. FIFRA-93-H-03 and argued that the revocation should not be effective, because this matter was still pending. No action has been taken on this letter.

BEP REGISTRATIONS

On October 24, 1991, EPA granted an application by Bio Environmental Products Corporation, West Redding, Connecticut, for registration of a product identified as "BEP Isecticide", EPA Reg.

^{7/} 59 Fed. Reg. 49395, September 28, 1994. The notice cited the Administrative Procedure Act (5 U.S.C. § 558) as legal authority for the revocation and stated, inter alia, that it has subsequently been established that the toxicological studies submitted by Microft/Waldner to support the registration of Insecticidal 2000 Concentrate and Insecticidal 2000 Ready To Use were sponsored by Jesmond Ltd. and were conducted on a substance containing permethrin as the single active ingredient. If the finding that the referenced studies submitted by Microft/Waldner were conducted on a substance containing permethrin as the sole active ingredient is based upon the default order, this finding is open to question, because Rule 22.17(a) (40 CFR Part 22) provides that default by respondent constitutes an admission of all facts alleged in the complaint for the purpose of this proceeding only. (emphasis added).

No. 64321-1 (CPH Ex. 3). Bio Environmental Products Corporation (BEP) is a wholly owned subsidiary of Jesmond Holding AG, Zug, Switzerland.^{8/} In support of the application for registration, BEP submitted five toxicological studies which had been performed for Jesmond in 1986 by Research & Consulting Company AG (RCC), Itingen, Switzerland. These studies were assigned Project Nos. 064372, 064383, 064394, 064405, and 064416.

In connection with BEP's application for registration, Mr. Richard Glaser, identified simply as Director, certified that the RCC toxicology reports contained in BEP's application were conducted using a concentrate formulation containing 25% permethrin (Certification, dated October 5, 1990, CPH Ex. 4). The certification further states that this concentrate was diluted 1:100 with water to give BEP Insecticide a concentration of 0.25% permethrin.

Mr. Hubert Steuerer, identified as Director, has submitted identical statements on the letterhead of Jesmond Limited and Jesmond Holding AG, dated February 3, 1993, to the effect that Jesmond is the sole legal proprietor of the toxicity studies (as indicated on enclosure 1) performed by Research & Consulting Company (RCC) Itingen, Switzerland, for "our" product Clean-Kill

^{8/} Statement of Hubert Steuerer, Director, on behalf of Jesmond Limited, dated February 3, 1993 (CPH Ex. 6). According to Mr. Steuerer, Jesmond Holding AG, Zug, is the sole proprietor of all shares of Jesmond Limited, London (letter from Jesmond Holding AG to counsel for Complainant, dated July 2, 1993, CPH Ex. 13). Jesmond Holding AG (Jesmond Intertrading AG, Zurich) was formerly known as Alpha-Intertrading, Zurich. These related companies will be referred to as "Jesmond".

Insecticide/Bio-Kill Insecticide (CPH Ex. 13, Annex 1). Although it does not appear that there was an enclosure to either of the mentioned statements, evidence that Jesmond sponsored the studies and that the studies are those identified in the BEP application, i.e., Nos. 064372, 064383, 064394, 064405 and 064416, is included with Jesmond's letter, dated July 2, 1993 (CPH Ex. 13, Annex 2). Mr. Steuerer averred that "Clean-Kill" and "Bio-Kill" are both registered trademarks of the Jesmond Group [identified supra note 8] and refer to one and the same formulation of a Permethrin based aqueous emulsion insecticide. He further stated that the formula of the Bio-Kill/Clean-Kill batch supplied to RCC in 1986 (Jesmond Bio-Kill/Clean-Kill Batch No. 03/8503) to perform the a.m. toxicity studies fully complies with the formula, data and documents in the application for registration of BEP Insecticide. Mr. Steuerer alleged that the Bio-Kill/Clean-Kill batch supplied to RCC was a sample out of Bio-Kill concentrate production Lot No. 03/8503 and contained 25% Permethrin. Certificates of analysis and samples from that batch are assertedly available on request. Mr. Steuerer denies that Jesmond's Bio-Kill/Clean-Kill insecticide has ever contained Resmethrin and asserts that, therefore, Jesmond Bio-Kill Batch No. 03/8503 supplied to RCC to perform the a.m. studies did not contain Resmethrin.

RCC has stated that at the time the studies identified above were performed, it did not analyze the chemical composition of the substance tested (letter from RCC to Complainant's counsel, dated June 8, 1993, CPH Ex. 8). RCC explains that such analysis

was not then required and that a data sheet without analytical information, but dated and signed by the sponsor, was provided along with the test substance. RCC says that "(e)xplicitly no analysis was requested by the sponsor." According to RCC, at the time the studies were performed, it did not learn of the chemical composition of the substance tested from any other source.

Jesmond's letter to EPA counsel, dated July 2, 1993 (CPH Ex. 13), repeats the assertion that the Clean-Kill batch which was furnished to RCC to perform the toxicity studies in question here was taken from Jesmond's production Lot No. 03/8503. Jesmond avers that Lot No.03/8503 was toll-manufactured in the factory of Cooper France, Paris. For that production, Cooper France allegedly used technical permethrin (PE Batch No. 10070) produced by the Wellcome Foundation Ltd., UK. It should be noted that the RCC Report (Project 064383) states "Batch Number unknown; information in sponsors' files" (CPH Ex. 12 at 11). A certificate of analysis by the Wellcome Foundation, dated June 28, 1985 (CPH Ex. 13, Annex 3), indicates, inter alia, that Lot No. 10070 was manufactured on June 27, 1985, and that the content of Cis-Permethrin was 26.8%.

PENDING MOTIONS

The order setting aside the default order, referred to at the outset of this order, directed the parties to submit a schedule for suggested further proceedings on or before January 13, 1995. The order noted that setting aside the default order did not reinstate Waldner's registrations which had been canceled (Id. note

9). Complainant filed a response on January 26, 1995, noting that it had expended substantial resources on this proceeding without any commensurate expenditure by Respondent or any progress toward resolution of this matter. Complainant alleged that, because Respondent had yet to comply with the initial prehearing exchange order, it would be prejudiced if it were directed to participate in a further prehearing exchange.^{9/} Complainant suggested that an order directing the parties to participate in a conference call may expedite resolution of this matter.^{10/} Additionally, Complainant pointed out that Respondent no longer has a domestic registration agent as required by 40 CFR § 152.50(b) and, alluding to difficulties in communication caused by the absence of such an agent, moved that Respondent be directed to engage a domestic registration agent. Waldner has not responded to the ALJ's order that the parties submit a schedule for suggested further proceedings nor to the suggestion and motion in Complainant's response to the order.

On June 3, 1996, Complainant filed a motion for an order requiring Respondent to admit or deny some 20 factual allegations. Waldner has not responded to this motion and by motions, dated July 18 and July 22, 1996, Complainant has requested an immediate ruling on its request for admissions. For the reasons hereinafter

^{9/} Because the default order based upon the initial prehearing order has been set aside, the initial order is no longer extant.

^{10/} This suggestion is denied, because it is unlikely to be productive at the present time.

appearing, Complainant will be directed to supplement its prehearing exchange, Waldner will be directed to appoint a domestic agent for registration matters,^{11/} and Complainant's motion for an order compelling Respondent to admit or deny factual allegations will be granted in part. Additionally, Respondent's letter, dated October 5, 1994 (ante at 8), arguing that the revocation of its registrations should be stayed, should be treated as an objection to the revocation/cancellation and the Hearing Clerk will be directed to forward the letter to the Director of the Registration Division and the Office of General Counsel.

Order Directing Complainant To Supplement The Record

The order on default contains a finding (No. 8) that "permethrin is the only active ingredient in Clean-Kill Insecticide Concentrate and BEP Insecticide." Additionally, the order setting aside the default order recites that it is established that permethrin is the only active ingredient in "Clean-Kill Insecticide" and "BEP Insecticide". The facts summarized herein, however, indicate that RCC, the firm which conducted the studies at issue, did not test, or learn from any other source, the chemical composition of the substance upon which the studies were based and

^{11/} Respondent's letter, dated October 5, 1994, indicates that it was furnished a copy of the Federal Register notice of the revocation of its registrations by Prentiss Inc., N.Y. At one time Waldner apparently had a business relationship with Prentiss or contemplated such a relationship (handwritten notes by Dr. John A. Todhunter, SRSI, dated October 22, 1991, and Dr. Todhunter's letter to Otmar Hofer, dated January 30, 1992; CPH Ex. 10, Attachments D & E).

that there is no documentation in the record which ties the Welcome Foundation permethrin analysis to the batch delivered to RCC for the purpose of conducting the studies. The studies contain a notation "batch number unknown, information in the sponsors' files" (ante at 11). It is therefore apparent that whether the SRSI certification that the identified RCC studies were on a product (Clean-Kill Insecticide Concentrate) identical to Insecticide 2000 Concentrate, and thus contained both permethrin and bioresmethrin as active ingredients, is false depends entirely on the credibility of Jesmond/Steuerer. In this regard, Mr. Waldner's affidavit states that Hubert Steuerer under the business names of "Steurer Ltd. and Jesmond Ltd." was the manufacturer of Insecticide 2000 at the time of the expert opinion from the "High Federal School and Test Institute for Chemical Industry" (1984) and that this product contained permethrin and bioresmethrin or bioallethrin.

Mr. Waldner's assertion that Steurer Ges.m.b.H. (Steurer Ltd.) manufactured Insecticide 2000 is supported by the Food Research Institute Opinion which as translated and supplemented indicates that Insecticide 2000 manufactured by Steurer Ges.m.b.H. has been admitted for sale in Austria (CPH Ex. 9). Mr. Waldner further states that this product was sold internationally for many years under the names "Insecticide 2000", "Clean Kill-Insecticide 2000", "Clean Kill" and "Bio-Son". It should be emphasized that the mentioned Test Institute and Food Research Institute opinions were requested by "Steurer GesmbH" (Steurer Ltd.), the firm which formerly employed Mr. Waldner. It should also be noted that

Jesmond (by Hubert Steuerer) acknowledges that it is internationally marketing "Clean-Kill" and "Bio-Kill", which are asserted to be different brand names for the same pesticide (Jesmond letter, dated July 2, 1993, CPH Ex. 13, Annex 2). See also Jesmond's statements, dated February 3, 1993, signed by Mr. Steuerer (CPH Ex. 13, Annex 1). The notary's attestation attached to the mentioned statements identifies Hubert Steuerer as an Austrian citizen, which lends credence to the notion that Mr. Steuerer may have done business under the name Steurer GesmbH (Steurer Ltd.).

Mr. Waldner's affidavit indicates that "Steurer Ltd." and "Jesmond Ltd." are different names for the same entity or, at the minimum, closely related companies. Other evidence suggesting that there is or was a relationship between Steurer Ltd. and Jesmond Ltd., the sponsor of the studies, is found in RCC's assertion that on May 26, 1986, it received a letter from Steuer-und Rechtsberatung, Zurich, signed by Mr. R. Schnider, who is identified as study monitor on the RCC studies, stating that "Clean-Kill" is an identical product to "Bio-Kill", having an identical substance composition, and requesting that copies of the reports be sent to that firm.^{12/}

^{12/} CPH Ex. 8. In its answer filed on behalf of Waldner, SRSI alleged that the RCC studies may have been altered to support the BEP registration, pointing out that the initial studies were on a product identified as "Bio-Kill Insecticide", that "Clean-Kill Insecticide" is identified as the test substance in the studies submitted to support the BEP registration and that there are fewer pages in the Clean-Kill studies. Jesmond, however, asserts that these are one and the same studies, emphasizing that the RCC
(continued...)

There appears to be no dispute but that "Insecticide 2000," the subject of the 1984 Test Institute and Food Research Institute opinions, contained both permethrin and bioresmethrin as active ingredients and that Insecticide 2000 was manufactured by Steurer GesmbH (Steurer Ltd.). There is evidence mentioned above supporting Mr. Waldner's assertion that Steurer Ltd. and Jesmond Ltd. are either different names for the same company or closely related companies. Accordingly, Mr. Steurer's assertion that "Jesmonds' Bio-Kill/Clean-Kill insecticide has never contained Resmethrin" (statements, dated February 3, 1993) may be literally accurate and, yet, misleading, because "Clean Kill Insecticide" and "Clean Kill Insecticide 2000" produced by Steurer Ltd., a closely related company, did contain Resmethrin as Waldner alleges.^{13/} Jesmond says that certificates of analysis for production Lot No. 03/8503, samples of which were supplied to RCC, and samples from that batch are available on request. Complainant will be directed

^{12/} (...continued)

project numbers identifying the studies are identical (CPH Ex.13, Annex 2). Additionally, Complainant avers that review of the complete RCC reports submitted by Jesmond/BEP in support of the registration of BEP Insecticide reveals that RCC changed the name of the test substance and the name of the sponsor and documented those changes (CPH at 9-12). Absent other evidence, these explanations dispel the notion that the RCC studies were altered to support the BEP registration.

^{13/} Waldner's answer alleges that, because no tolerance has been established for bioresmethrin, Insecticide 2000 may not be used on products which may result in indirect food contact. Dr. Todhunter's notes and his letter to Otmar Hofer (supra note 11) indicate that Waldner contemplated developing a permethrin only product. This consideration would provide a motive for an applicant for registration to represent a permethrin/bioresmethrin product as containing only permethrin.

to supplement the record with a copy of the referenced certificates of analysis and with the result of analysis of a sample from the batch identified by Jesmond.^{14/}

Because there exist disputed issues of material fact, in particular as to the chemical composition of the substance tested by RCC, this case cries out for an evidentiary hearing. It may be possible, however, to resolve the question of liability through the information and documents Complainant acquires from Jesmond pursuant to this order. In view thereof, and in view of the substantial logistical difficulties and expense in conducting a meaningful hearing, no attempt will be made to schedule a time and location for such a hearing at this time.

Complainant's Motion for Order Directing Respondent to Obtain a U.S. Agent

Section 152.50(b) of the FIFRA regulations requires a pesticide registrant not residing in the United States to designate a person residing in the United States to act as his agent on all registration matters. 40 CFR § 152.50(b). While violation of this requirement could subject the registrant to civil penalties and provide a basis for cancellation of a registration, no such issues are before me. Complainant's motion, however, raises the question of the ALJ's authority to order Respondent to designate such an agent.

^{14/} The Agency may wish to obtain a sample of BEP Insecticide and analyze its chemical composition.

FIFRA § 25(a)(1) authorizes the Administrator, in accordance with procedures set forth in § 25(a)(2), to prescribe regulations to carry out the provisions of this subchapter, i.e., Subchapter II-Environmental Pest Control [The Environmental Pesticide Control Act of 1972]. The cited regulation was issued pursuant to this and other authority granted the Administrator by the Act (40 Fed. Reg. 28242, July 3, 1975). The General Counsel has opined that the [Administrator's] conclusion effective enforcement of the Act requires foreign registrants to have a domestic agent for registration matters is reasonable and that promulgation of such a regulation would be within the Administrator's authority (General Counsel's Opinion, June 23, 1972). Moreover, although nothing in FIFRA § 14(a) provides that the hearing, or the opportunity therefor, provided by § 14 (a)(3) must be "on the record", FIFRA civil penalty proceedings have been regarded as subject to the Administrative Procedure Act since the rewrite of FIFRA occasioned by the enactment of the Federal Environmental Pesticide Control Act of 1972.^{15/} Under the APA (5 U.S.C. § 556(c)), an employee (ALJ) presiding at a hearing is authorized, subject to published rules of the agency and within its powers, to inter alia: "... (6) hold conferences for the settlement or simplification of the issues by consent of the parties; ... (8) require the attendance at any conference held pursuant to paragraph

^{15/} See Part 168-Rules of Practice Governing Proceedings Conducted In The Assessment Of Civil Penalties Under The Federal Insecticide, Fungicide, And Rodenticide Act, As Amended, 39 Fed. Reg. 27656, July 31, 1974.

(6) of at least one representative of each party who has the authority to negotiate concerning resolution of issues in controversy; (9) dispose of procedural requests and similar matters; (11) take any other action authorized by agency rule consistent with this subchapter." Rule 22.04(c) of the Consolidated Rules of Practice (40 CFR Part 22), authorizes the presiding officer (ALJ) to, inter alia, (2) Rule upon motions, requests, and offers of proof, dispose of procedural requests, and issue all necessary orders; ... (8) Require parties to attend conferences for the settlement or simplification of issues, or the expedition of the proceedings; ... (10) Do all other acts and take all measures necessary for the maintenance of order and for the efficient, fair and impartial adjudication of issues arising in proceedings governed by these rules.

The Part 22 rules are intended to be a delegation to an ALJ presiding in a particular proceeding of all the adjudicative powers personally held by the Administrator. In re Arrcom, Inc., Drexler Enterprises, Inc., RCRA (3008) Appeal No.86-6, 2 E.A.D. 203 (CJO, May 19, 1986), petition for reconsideration denied, sub nom. Arrcom, Inc. et al., 1988 RCRA Lexis 36 (March 8, 1988). The requirement of 40 CFR § 152.50(b) that an applicant for registration not residing in the United States must designate an agent residing in the United States to act on behalf of the registrant "on all registration matters" encompasses enforcement matters relating to that registration. In re Health Care Products, Inc. et al., I.F.&R. Docket No. VIII-90-279C et al. (Pearlstein,

J.) (Orders On Motions, June 13, 1996). It is concluded that the ALJ does have the authority to require Respondent to designate a person residing in the United States as its agent for the purpose of this proceeding and Respondent will be ordered to designate such an agent.

Complainant's Motion to Compel Admission/Denial

Complainant's "Motion to Compel Respondent to Admit or Deny Factual Allegations," dated June 3, 1996, will be accepted as a Motion for Discovery pursuant to Rule 22.19(f). The motion requests responses to some twenty factual assertions. Complainant refers to FRCP Rule 36 as the legal basis for the motion.^{16/} Although not specifically provided for in the Part 22 Consolidated Rules of Practice, it has been held that requests for admissions are an appropriate form of discovery.^{17/}

Rule 22.19(f) provides that "...further discovery, under this section, shall be permitted only upon determination by the Presiding Officer: (i) That such discovery will not in any way unreasonably delay the proceeding; (ii) That the information to be

^{16/} FRCP 36 provides, "[a] party may serve upon any other party a written request for the admission, for purposes of the pending action only, of the truth of any matters within the scope of [those matters eligible for discovery] set forth in the request that relate to statements or opinions of fact or of the application of law to fact, including the genuineness of any documents described in the request." Fed. R. Civ. Proc. 36 (1993).

^{17/} See, e.g., In re Safety Kleen Corp., RCRA-1090-11-10-3008(a) (ALJ, December 6, 1991); In re Tri-State Mint, Inc., et. al. EPCRA-VIII-89-05 (ALJ, July 3, 1990).

obtained is not otherwise obtainable; and (iii) That such information has significant probative value." 40 CFR § 22.19(f)(1). Requiring responses to Complainant's requests for admission/denial will not unreasonably delay this proceeding, because a hearing has yet to be scheduled. Moreover, if certain facts are admitted, or deemed to be admitted, resolution of this matter may be expedited. The probative value of the information appears to be obvious. For the reasons stated below, however, Complainant's motion will be granted in part and denied in part.

Factual Allegation No. 1 asserts that the firm Steurer Ges.m.b.H. of Vienna, Austria, is not a parent, subsidiary, predecessor, successor or agent of Jesmond. Mr. Waldner's affidavit and the Test Institute and Food Research Institute opinions indicate that Steurer Ges.m.b.H. is simply another name for Steurer Ltd. (Jesmond Ltd.). Other evidence strongly suggesting a relationship between Jesmond and Steurer is detailed above. Waldner clearly has a different version of these relationships and may not be directed or presumed to admit facts he disputes. Moreover, information as to the relationship, if any, between Mr. Hubert Steuerer and Jesmond to Steurer Ltd. should be readily obtainable from Jesmond/BEP. Request No. 1 will be denied.

Factual Allegation Nos. 2 through 7 assert (2) that Hubert Steuerer has no affiliation with Steurer Ges.m.b.H; (3) that Jesmond was the sponsor of the tests; (4) that Jesmond provided the test samples to RCC; (5) that Jesmond, as sponsor of the tests, knows the chemical composition of the test samples; (6) that at the

time Jesmond sponsored the tests, Hubert Steuerer was an official of Jesmond; and (7) that Hubert Steuerer has direct and first-hand knowledge of the chemical composition of the test samples. These are all matters within the knowledge of Hubert Steuerer and Jesmond and are not appropriately addressed to Waldner. This information should be "otherwise obtainable" from Jesmond/BEP. Request Nos. 2 through 7 will be denied.

Factual Allegation Nos. 8-12 and 15 state: (8) that Alfred Waldner and Steuerer and/or [Steurer Ltd.] Jesmond severed business relations in 1984; (9) that Alfred Waldner was not employed by or affiliated with Jesmond in 1985 or thereafter; (10) that Alfred Waldner did not participate in the tests at RCC; (11) that Alfred Waldner did not participate in Jesmond's decision to sponsor the tests at RCC; (12) that Alfred Waldner did not participate in the selection or the collection of the test samples for use in the tests at RCC; (13) that Alfred Waldner has no direct or first-hand knowledge of the source or the chemical composition of the test samples; and (15) Respondent cannot produce any documentary evidence of the chemical composition of the test samples. Otmar Hofer's letter, dated September 23, 1994, on behalf of Waldner states that Mr. Steuerer and Waldner went their separate ways in 1987. Accordingly, Waldner has already submitted a statement of the year the business relationship with Mr. Steuerer was severed and Waldner may not be directed or presumed to make an admission to the contrary. Moreover, information to dispute Waldner's statement is seemingly readily obtainable from

Steuerer/Jesmond/BEP. Request Nos. 8 & 9 will be denied. If Waldner and Steuerer severed their business relationship in 1987 as Waldner alleges, Waldner may have information within the scope of Request Nos. 10-13 and 15. In any event, these are matters within Waldner's personal knowledge and he will be directed to admit or deny Request Nos. 10-13 and 15.

Allegation Nos. 14 and 16 through 20 state: (14) Respondent cannot produce any witness who has direct or first-hand knowledge of the chemical composition of the test samples; (16) Respondent cannot produce any witness who has direct or first-hand knowledge of the chemical composition of the insecticide product marketed by Jesmond under the trade names "Clean-Kill" or "Bio-Kill" in 1984 or later; (17) Respondent cannot produce any documentary evidence of the chemical composition of the insecticide product marketed by Jesmond under the trade name "Clean-Kill" or "Bio-Kill" in 1984 or later; (18) Respondent cannot produce any witness who has more accurate and more reliable information about the identity of the test samples used in the tests at RCC than the information provided by Hubert Steuerer; (19) Respondent has no evidence concerning the formulation of the insecticide product marketed by Jesmond under the trade name "Clean-Kill" or "Bio-Kill" since the date on which Alfred Waldner and Steuerer and/or Jesmond severed relations; and (20) since 1985, the insecticide product marketed by Jesmond under the trade name "Clean-Kill" or "Bio-Kill" has contained only permethrin as an active ingredient. Respondent will be directed to admit or deny Request Nos. 14, 16, 17, and 19

and to furnish the names of any witnesses and to produce any documents which would support or explain the denial of these allegations.^{18/} Request No. 18 will be denied as improper, because it in effect asks Respondent to acknowledge the credibility of Hubert Steuerer which is open to question, and Request No. 20 will be denied, because it is contrary to Waldner's previous pleadings and assertions herein.

Respondent's Motion for Stay of Pesticide Revocation

As indicated (note 7 and accompanying text), Waldner's registrations have been revoked upon the ground data and representations submitted in support of the registrations had been falsified. The notice of revocation cited the Administrative Procedure Act (5 U.S.C. § 558(c)), rather than FIFRA § 6 as the legal authority for the revocation (cancellation). Waldner, by letter, dated October 5, 1994, moved for a stay of the revocation, arguing in effect that, because the penalty proceeding was still pending, there had been no final determination that the data submitted in support of its registrations were false as alleged in the complaint. To the extent the Agency's determination that data submitted in support of the registrations were false rests upon the default order, that determination is open to question, because default constitutes an admission of facts alleged in the complaint

^{18/} The Hofer letter, dated September 23, 1994, states that Waldner was trying to locate Mr. Puha, a former employee of Steuerer GesmbH, in order to obtain his affidavit, but that he (Waldner) had been unable to do so. No explanation of the testimony and evidence Mr. Puha was expected to offer has been provided.

for the purpose of that proceeding only (supra note 7). In any event, the default order has been set aside and the findings therein are of no force or effect. Moreover, in view of the express procedures in FIFRA § 6 for the suspension and cancellation of pesticide registration, it is questionable whether the APA may be relied upon as an independent basis for the revocation (cancellation). The validity of the revocation is not before me and it is my determination to regard Waldner's letter of October 5, 1994, as an objection to the revocation (cancellation) pursuant to 40 CFR Part 164, the Rules of Practice Governing Hearings Under FIFRA. The Hearing Clerk will be directed to forward a copy of Waldner's letter, dated October 5, 1994, to the Director of the Registration Division and to the Office of General Counsel.

ORDER


1. Complainant is directed to supplement its prehearing exchange with a copy of the certificates of analysis of the batch which Jesmond alleges was furnished to RCC for the purpose of conducting the 1986 toxicology studies at issue herein and with the result of analysis of the chemical composition of the sample which Jesmond alleges is available upon request. If Complainant elects to comply with the suggestion (supra note 14) that a sample of BEP Insecticide be obtained and analyzed, the result of that analysis should also be included in Complainant's supplemental prehearing submission.

2. Waldner is directed to admit or deny Factual Allegation Nos. 10, 11, 12, 13, 14, 15,16, 17, and 19 as listed in Complainant's Motion To Compel, dated June 3, 1996. Waldner is directed to explain any denials of the listed allegations and to identify any witnesses and furnish a copy of any documents which may explain or support denial of these allegations. If Mr. Puha (supra note 18) has information or evidence, which supports Waldner's position herein, further efforts to locate Mr. Puha may be warranted. If Waldner fails to admit or deny the listed factual allegations within the time set forth in this order, these allegations will be deemed to have been admitted.
3. In accordance with 40 CFR § 152.50(b), Waldner is directed to designate an agent residing in the United States for registration matters and to inform the Agency, counsel for Complainant, and the ALJ of the name and address of that agent.^{19/}
4. Responses to this order shall be filed with the Hearing Clerk and served on the opposing party and the ALJ on or before September 30, 1996.

^{19/} In a letter addressed to Complainant's counsel, dated July 12, 1996, Mr. Otmar Hofer stated that he no longer represented Microft Systems International Holdings S.A. and Mr. Waldner.

The Hearing Clerk is directed to forward a copy of Waldner's letter, dated October 5, 1994, to the Director of the Registration Division and to the Office of General Counsel.

Dated this 2nd day of August 1996.


Spencer T. Nissen
Administrative Law Judge

CERTIFICATE OF SERVICE

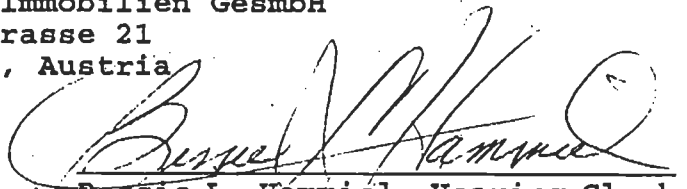
I do hereby certify that the foregoing Order On Motions was filed in re Microft Systems International Holdings, S.A. & Alfred Waldner Company; Docket No. FIFRA-93-H-03 and copies of the same were mailed to the following:

(Interoffice)

Scott Garrison, Esq.
Toxics & Pesticides Enforcement Div. (2245A)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

(1st Class Mail)

Otmar Hofer
Hofer Real Immobilien GesmbH
Oberlaaerstrasse 21
A-1100 Wien, Austria



Bessie L. Hammiel, Hearing Clerk
U.S.E.P.A. (1900)
401 M Street, S.W.
Washington, D.C. 20460

Dated: August 5, 1996