## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

#### BEFORE THE ADMINISTRATOR

In the Matter of Predex Corporation

Respondent

UN 30 10 11

Docket No I.F. & R.-V-004-93

### ORDER GRANTING IN PART MOTION FOR ACCELERATED DECISION

The complaint in this proceeding under Section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA or the Act), 7 U.S.C. §  $136\underline{1}(a)$ , issued on May 12, 1993, charged Respondent, Predex Corporation, with: 1) violating Section 12(a)(1)(A) of FIFRA, 7 U.S.C. §  $136\underline{j}(a)(1)(A)$ , by selling or distributing an unregistered pesticide and 2) violating Section 12(a)(2)(L) of FIFRA, 7 U.S.C. §  $136\underline{j}(a)(2)(L)$ , by producing a pesticide in an unregistered establishment.<sup>1/</sup> For these alleged violations, Complainant proposes to assess Respondent a civil penalty totaling \$4,200.<sup>2/</sup>

<sup>1/</sup> FIFRA § 12(a)(1)(A) provides "It shall be unlawful for any person ... to distribute or sell to any person ... any pesticide that is not registered under section 136a of this title..."

FIFRA §12(a)(2)(L) provides "It shall be unlawful for any person ... who is a producer to violate any of the provisions of section 136e of this title." Section 136e(a) provides "No person shall produce any pesticide subject to this subchapter ... unless the establishment in which it is produced is registered with the Administrator." 7 U.S.C. § 136e(a).

2/ Section 14(a)(1) of the Act, 7 U.S.C. § 136<u>1</u>(a)(1), authorizes assessment of penalty up to \$5,000 for each offense. The complaint proposed a penalty of \$7,000 -- \$3,500 for each (continued...) Respondent answered on June 8, 1993, denying that product and establishment registration were required, and requested a hearing. In accordance with an order of the ALJ, dated November 17, 1993, the parties have exchanged pre-hearing information. On July 6, 1994, the parties filed Joint Stipulations of Fact and Law. The stipulations provide, inter alia, that Respondent produced and maintained for distribution a product called "PRED-X" at its establishment and that neither the product nor the establishment were registered with EPA pursuant to FIFRA. The first issue, therefore, is whether PRED-X is a pesticide triggering FIFRA registration requirements.

Complainant filed a Motion for Accelerated Decision, Or In The Alternative, for Partial Accelerated Decision, on October 31, 1994.<sup> $\frac{3}{}$ </sup> Complainant asserted that it was entitled to judgment as a matter of law, because the label and advertising for PRED-X made pesticidal claims, the product's name implied that it was a pesticide, users of PRED-X expected it to deter predators, PRED-X was not an exempted deodorant, and, therefore, PRED-X was subject to pesticide registration. Complainant alleged that the penalty was computed in accordance with the Enforcement Response Policy for

 $\frac{2}{}$  (...continued)

offense. On April 1, 1994, Complainant filed a motion to reduce the total proposed penalty to \$4,200, because of information it had received regarding the size of Respondent's business and ability to pay.

<sup>3</sup>/ The motion was refiled on November 1, 1994, because the initial motion had overlooked including a copy of the Joint Stipulations of Fact and Law.

FIFRA (July 2, 1990) (ERP) and moved that judgment be entered for the amount of the penalty claimed.

Respondent filed a response on December 14, 1994, in which it asserted that PRED-X was not intended for a pesticidal purpose, was a deodorant exempt from FIFRA registration requirements, and that questions of material fact remained. As to the amount of the penalty, Respondent asserted that Predex Corp. was essentially shut down by a cease and desist order [issued by the Colorado Department of Agriculture] before "start up" costs were recouped and argued that it should be able to present evidence as to how the penalty would affect its business.

The ALJ may render an accelerated decision as to all or any part of the proceeding, provided no genuine issue of material fact exists and a party is entitled to judgment as a matter of law. 40 CFR § 22.20(a). In considering a motion for accelerated decision, the ALJ must view the evidence in the light most favorable to the nonmoving party.<sup>4</sup> The evidence of the nonmovant is to be believed and all justifiable inferences are to be drawn in his favor.<sup>5</sup> The

<sup>5/</sup> In re Adolph Coors Company, RCRA-VIII-90-09 (ALJ, March 1, 1991); See also Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574 (1986) ("if--there is any evidence in the record from any source from which a reasonable inference (in the nonmoving party's) favor may be drawn, the moving party simply cannot obtain summary judgment.")

<sup>&</sup>lt;sup>4</sup>/ <u>In re J & L Specialty Products Corp.</u>, NPDES Appeal No. 92-22 (EAB, Feb. 2, 1994)("[T]he standards for addressing summary judgment motions under Rule 56 of the Federal Rules of Civil Procedure are useful in addressing requests for evidentiary hearings), <u>citing In re Mayaguez Regional Sewage Treatment Plant</u>, NPDES Appeal No. 92-23 (EAB, Aug. 23, 1993) and <u>Anderson v.</u> <u>Liberty Lobby, Inc.</u>, 477 U.S., 225, 255 (1986).

facts enumerated below, therefore, incorporate facts stipulated by the parties and assume Respondent's factual assertions to be true. For the reasons stated below, Complainant's Motion for Accelerated Decision will be granted as to liability and denied as to the penalty.

### Discussion

# **Liability**

Respondent operated a business located at 700 Garfield Ave., Duluth, Minn, 55802, where it produced and distributed a product called "PRED-X". PRED-X consisted of a tag, to be attached to the ear of ewes, lambs, and calves, that contained an odorous substance. The substance masked the natural scent of an animal so that predators, such as coyote or fox, would not detect the animal's scent and therefore would not "find" it.<sup>6/</sup> If a predator

<sup>6</sup>/ Respondent's Response to Motion for Accelerated Decision Or In The Alternative Partial Accelerated Decision ("R's Response").

Respondent agrees with US EPA biologist, William W. Jacobs that, over time, predators may begin to "associate the odor of the masking agent with the prey and learn that food can smell like PRED-X, too." Respondent's Response, <u>citing</u> Letter to Rob Forrest, dated Jan. 31, 1994, appearing in the record as exhibit S to the Joint Stipulations of Law and Fact. Regardless of whether PRED-X achieved its intended goal, if it was intended for a pesticidal purpose, Respondent could not legally distribute or sell it without applying for, and receiving, EPA registration The registration applicant must submit efficacy and approval. toxicity data, which is reviewed by EPA during the registration 7 U.S.C. § 136a(c)(1)(F); 7 U.S.C. § 136a(2); 40 CFR § process. 152 subpart E; 40 CFR § 158. If a vertebrate pesticide does not perform its intended purpose or is unreasonably adverse to the (continued...)

discovered the presence of livestock by means other than smell, PRED-X would not prevent the predator from attacking.<sup>7/</sup> PRED-X worked more effectively at night than during the day when a predator could more readily see its prey.<sup>8/</sup> Masking a sheep's scent so it is undetectable to coyotes theoretically reduces predation, because the predator would not discover the animal and would pursue other food sources. PRED-X's objective is to "guard" or "protect" livestock against predation without injuring the predator.<sup>2/</sup>

The PRED-X label contained the following statements:

"Over the past two years I have used the PRED-X ear tags on 1258 ewes and lambs and have had zero predation by coyotes or fox, although I live in an area with high fox populations." Rock Thompson, South Dakota.

"I put these ear tags to a severe test. In the spring I lost two calves from calving problems on the range. One I left out unprotected and by the third night it was eaten by coyotes. On the other I put a PRED-X ear tag. This calf was never touched and rotted down." Larry Licking, Carter County, Montana.

6' (...continued) environment, then registration will likely be denied. 7 U.S.C. § 136a(c)(5); 40 CFR § 152.112. If the substance complies with EP A's standards, the registration will likely be granted. Id.

 $\mathcal{U}$  R's Response.

<u>8</u>/ Id.

<sup>9</sup> R's Response. Respondent states, "The intent of PRED-X is to prevent detection of one animal by another...it has no affect on the coyote, other than making it think there is no lamb present." Respondent compares his product to taking the lamb off the range and putting it into a barn. Respondent's analogy is not persuasive. Corralling sheep behind a fence or in a barn does not pose the same potential hazards as introducing a new substance into the environment without EPA review.'\* "In 1991, I used the PRED-X ear tags on 175 ewes...Only one lamb, not tagged, that strayed far from the rest of the sheep was killed by a coyote that year. PRED-X really works." Delane Nixon, Harding County, South Dakota. $\frac{10}{}$ 

Complainant contends that these testimonials on the label indicated public understanding of the intended use of the product and demonstrated that the product was intended for use, and was in fact used, as a pesticide.<sup>11/</sup> Complainant also referenced the product's name and advertisements to support its position that PRED-X was intended for a pesticidal purpose.<sup>12/</sup> Respondent acknowledged that these testimonials appeared on the product's label, but asserted that neither the label, advertising, nor name of the product demonstrated a pesticidal purpose. Gregory Bambenek, President of Predex Corp., explained, "[W]e have never made repellency or pesticide claims in our advertising or labeling," but admitted that "the testimonials that we used might have been misconstrued as a claim of repellency."<sup>13/</sup> Dr. Bambenek changed the label to remove

 $\frac{10}{5}$  See, Joint Stipulations of Law and Fact, Number 13 and copies of the labels submitted as exhibits A and B.

 $\frac{11}{}$  C's Motion for Accelerated Decision.

<sup>12</sup>/ One advertisement states: "No Loss to Predators. Guard Your Flock with the New PRED-X Protectant Ear Tags...At last you can protect lambs and calves against predators...Field tests show 100% stoppage of coyote and fox predation on lambs and ewes...Proven effective for six months - zero predation from coyote and fox." Complainant's ("C's") Prehearing Exchange, exhibit C-5.

13/ Letter, dated October 2, 1992, to Steven D. Blunt, Sr. Agricultural Specialist, State of Colorado, Dept. of Agriculture. (continued...)

the testimonials and declared, "I feel that all claims that could be construed to be pesticidal are now removed from the label."<sup>14/</sup> The revised label stated:

Field tests have shown this ear tag to be an effective deodorant cover scent for lambs and calves. It covers up and counteracts the natural odor of lambs and calves. This makes it more difficult for predators to find them, especially at night...The sense of smell is a very important sensory system in predators. PRED-X ear tags camouflage lambs and calves natural odor.

Any pesticide, even one that is nontoxic and harmless to the environment, may not be sold unless it has been registered with EPA.<sup>15/</sup> It is EPA's responsibility to review and analyze data and labeling submitted with the registration application to ensure that the environment is adequately protected by general or restricted use of the product.<sup>16/</sup>

A determination whether the product is intended for use against pests does not end with a review of the product's label. "Industry claims and general public knowledge can make a product pesticidal notwithstanding the lack of express pesticidal claims by the producer itself. Labeling, industry representations, advertising materials, effectiveness and the collectivity of all the circumstances are therefore relevant." <u>N. Jonas & Co. v.</u> <u>U.S.</u>, 666 F.2d 829, 833 (3d Cir. 1981).

<u>14</u>/ <u>Id</u>.

<sup>15/</sup> FIFRA § 3a; 7 U.S.C. § 136a. The only pesticides authorized for sale or distribution are ones whose use does not cause unreasonable adverse effects to the environment.

<sup>16</sup>/ FIFRA § 3a; 7 U.S.C. § 136a: "To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered." EPA may deny or cancel registration to products that are found to (continued...)

 $<sup>\</sup>frac{13}{}$  (...continued)

Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest..."<sup>17/</sup> The statute defines "pest" to include any form of "terrestrial or aquatic plant or animal life" which the Administrator declares, after notice and "injurious to opportunity for hearing, is health or the environment." 7 U.S.C. § 136(t); 7 U.S.C. § 136w(c)(1). FIFRA regulations further explain that any vertebrate animal other than man is a pest "under circumstances that make it deleterious to man or the environment." 40 CFR § 152.5. Thus, whether a vertebrate animal is a pest may depend upon the circumstances. Predators, such as coyote and fox, are clearly "deleterious to man and the environment," when they kill livestock, and are, therefore, pests under these circumstances. $\frac{18}{}$  Because predatory behavior against livestock is the basis for the deleterious condition that defines the animal as a "pest," any product that is intended to prevent, destroy, repel, or mitigate either the predator or its predatory

16/ (...continued)
have an unreasonable adverse effect on the environment. 7 U.S.C.
§ 136a(c)(6); 7 U.S.C. § 136d.

 $\frac{17}{}$  Section 152.3(s) of the Regulation provides essentially the same definition: "Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest..." 40 CFR § 152.3(s).

<sup>18</sup>/ <u>See, generally, Nat'l Cattleman's Assoc. v. U.S. E.P.A.</u>, 773 F.2d 268 (10th Cir. 1985) (upholding all but one of EPA's restrictions on the registered use of Compound 1080, a pesticide used to control predation of livestock).

behavior against livestock is a pesticide that requires registration before it may be distributed or sold.<sup>19/</sup>

Evidence of the intended pesticidal purpose of a product is demonstrated by: 1) what the distributor or seller claims, states or implies, 2) whether the substance has any commercially viable use other than as a pesticide, and 3) whether the distributor or seller knows that the product will be used, or is intended to be used as a pesticide. $\frac{20}{}$ 

<sup>19/</sup> Respondent compares its product to camouflage duck hunting jackets and deer hunting scents used to camouflage human scent, attract deer, or discourage retreat. R's Response and exhibits. Although these products may operate to mask humans from detection, they are not subject to FIFRA unless they are intended for use as a pesticide. Cover scents used to attract deer are generally not intended to destroy, repel, prevent, or mitigate a pest. If the cover scent were simultaneously intended to protect the hunter from, for example, mosquito stings, then it would require EPA registration under FIFRA, because mosquitoes are not within the proviso exempting "viruses, bacteria, or other micro-organisms in or on living man or other living animals" from the definition of a pest (FIFRA § 2(t)).

<sup>20/</sup> A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):

(1) That the substance ... can or should be used as a

pesticide;... or

(b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose ...; or

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

40 CFR §152.15.

PRED-X does not destroy and arguably does not repel a predator.<sup>21/</sup> It is, however, intended to lessen the likelihood of a predator detecting the presence of domestic livestock for its prey and, thus, engaging in the behavior that defines it as a pest. It mitigates predation of lambs and calves by masking their scent.<sup>22/</sup> Admissions in Respondent's pleadings, the PRED-X label and advertising expressly state this intended purpose.<sup>23/</sup> Because PRED-X's intended purpose is to prevent or mitigate the activities of a pest, a livestock predator, PRED-X is a pesticide and may not be sold or distributed until it has been registered by EPA.

Respondent's contention that PRED-X is a deodorizer that is exempt from FIFRA's registration requirements is without merit. The regulation provides that deodorizers are not considered pesticides "unless a pesticidal claim is made on their labeling or in connection with their sale and distribution." 40 CFR § 152.10. A deodorizer is, therefore, subject to FIFRA requirements if, in

Webster's Third International Dictionary, defines mitigate as, "...to make less severe: alleviate, lessen, temper." Because PRED-X makes it less likely that a predator will detect the presence of sheep or other domestic animals, it decreases the number of such animals killed by predators.

21/ R's answer to the complaint and R's Response. See, description of Pred-X, supra.

<sup>&</sup>lt;sup>21</sup>/ Webster's Third International Dictionary defines repellant as, "serving or tending to drive away or ward off; arousing aversion or disgust: repugnant." PRED-X does not drive predators away nor does it repulse them. A predator will not be repelled or deterred from attacking an animal having a PRED-X ear-tag, if the predator discovers the animal's presence.

addition to deodorizing, it is also intended for use as a pesticide. A deodorizer that is not intended for pesticidal use, and whose label and advertising make no pesticidal claims, but that inadvertently has a pesticidal effect in addition to its intended use, would arguably be exempt from FIFRA requirements. This is not, however, Respondent's product. Even if it were a deodorizer, PRED-X was also intended for use as a pesticide to mitigate predation and this intended use appeared on its labels and advertising. Furthermore, Webster's Third International Dictionary defines "deodorizer" as, "any of various preparations or solutions (as a soap or disinfectant) that destroy or mask unpleasant odors."<sup>25/</sup> PRED-X does not counteract unpleasant odors, therefore, it does not operate as a deodorizer.<sup>25/</sup> PRED-X does not, therefore, fall within the section 152.10 exception for deodorizers.

Respondent's express statements regarding the purpose of PRED-X are sufficient to conclude that it is a pesticide. Remaining disputed facts, such as whether the name of the product, "PRED-X," also demonstrates a pesticidal purpose, are therefore not material and need not be resolved. Because no material facts remain in

<sup>25</sup>/ PRED-X has an odor that is extremely offensive to humans and masks an odor that coyote find appealing. <u>See</u>, Joint Stipulations of Law and Fact, Exhibit K, magazine article entitled, "PRED-X: It Stinks ... But It Works."

<sup>24/ &</sup>quot;Deodorizer" is defined as a "deodorant." The definition provided above appears under the "deodorant" heading. A deodorant that also acts as a disinfectant would be subject to FIFRA, provided it was not intended for use on viruses, bacteria or other micro-organisms on man or other living animals (FIFRA § 2(t)).

dispute regarding the issue of liability, the issue can be decided on the written record. PRED-X is a pesticide which must be registered under section 3 of FIFRA, 7 U.S.C. § 136a, before it is distributed or sold..<sup>26/</sup> Respondent admitted to distributing and selling PRED-X without having first registered it. Respondent also admitted to producing PRED-X at its unregistered establishment. An accelerated decision as to liability will, therefore, be granted in Complainant's favor as to both counts in the complaint.<sup>27/</sup>

### **Penalty**

Complainant's motion also requests an accelerated decision for the amount of the penalty claimed, \$4,200. For the reasons hereinafter appearing, this portion of the motion will be denied.

<sup>27</sup>/ <u>In re Holmquist Grain & Lumber</u>, FIFRA Appeal No. 83-3 (CJO, April 25, 1985) (holding that sale of unregistered pesticide and production in an unregistered establishment constitute two separate violations because one requires proof of the pesticide's unregistered status and the other requires proof of pesticide production).

<sup>26/</sup> Misunderstanding the purpose of EPA's list of active ingredients, Respondent argued that PRED-X was not a pesticide because its active ingredients were not currently registered by EPA's list of registered active ingredients, is a list of EPA. ingredients that have already received EPA approval for pesticidal use. Any active ingredient not approved for pesticidal purpose would not appear on EPA's list and, therefore, may not be used in a new pesticide formulation without EPA registration. 40 CFR § 152.113 et. seq. Furthermore, any registered active ingredient may not be included in a pesticide for "new uses" not previously considered unless the pesticide is approved and registered for the new use. Id. Because Respondent's active ingredients were not previously registered with EPA, Respondent may not distribute or sell these ingredients for a pesticidal purpose without submitting the necessary data to EPA for review.

Complainant alleges that no issues of material fact remain regarding the penalty, because the penalty was calculated in accordance with the Enforcement Response Policy for FIFRA (ERP) (July 2, 1990). Complainant points out that the proposed penalty was reduced from the \$5,000 maximum permitted by the statute for a single violation to \$2,100 for each of the two counts. Respondent, on the other hand, maintains that the penalty should be zero because it attempted, in good faith, to comply with the law and, because any penalty assessment would have an adverse effect on its ability to remain in business. According to Respondent, its good faith efforts to comply with the law included consultations with and government "experts," several private including EPA representatives, who allegedly advised it that PRED-X did not require registration and was non-lethal and environmentally friendly.

FIFRA section 14(a)(3) provides that "no penalty [for FIFRA violations] shall be assessed unless the person charged shall have been given notice and opportunity for hearing on such charge in the county, parish, or incorporated city of the residence of the person charged." This right to a hearing is reinforced by the Rules of Practice, 40 CFR § 22.15, which provide, inter alia, that a person contending the amount of a proposed penalty is inappropriate shall file an answer and that a hearing on the issues raised by the complaint and answer shall be held at the request of the respondent. Respondent's answer clearly requested a hearing and,

absent a waiver,<sup>28</sup>/ or some compelling reason, not shown here, this right may not be disregarded.

FIFRA section 14(a)(4) provides that determination of the penalty amount must 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." 7 U.S.C. 1361(a)(4). The first two factors are frequently considered as one under the rubric of "ability to pay", while the "gravity of the violation" is considered from two aspects, gravity of the harm or potential harm, and gravity of the misconduct. See, e.g., In re James C. Lin and Lin Cubing, Inc., FIFRA Appeal No. 94-2 (EAB, December 6, 1994). It is obvious that the effect of a proposed penalty on a firm's ability to continue in business or its "ability to pay" involve factual questions and that, unless the facts relating thereto permit but one conclusion, an accelerated decision on such an issue is simply inappropriate. Matsushita Electric Industrial Co. (note 3 supra). Moreover, it is not uncommon for a substantial period of time to elapse between an initial and a final penalty calculation, during which time a firm's financial condition may have changed for better or for worse. $\frac{29}{}$ 

<sup>29</sup>/ Because PRED-X is the subject of a cease and desist order in at least the State of Colorado, it would not be (continued...)

 $<sup>\</sup>frac{28}{}$  Although para 43 of the parties' stipulations, providing that the parties seek to present arguments to this tribunal and to receive a ruling as to the appropriate penalty amount based on the facts of this matter, might be construed as a waiver of the right to a hearing, neither party has so regarded it and I decline to do so.

This time lapse does not, of course, lessen in any manner the oblgation to consider the statutory factors in determining a penalty.

The remaining factors, gravity of the harm or potential for harm and gravity of the misconduct, are also not normally amenable to determination on summary judgment. This is because there may be, and frequently are, factual questions relating to the harm or potential harm from the misuse or possible misuse of a particular See, e.g., In re Haveman Grain Company, Inc., and Dan pesticide. Haveman, Docket No. I.F.& R.-VII-1211C-93P (Order Granting In Part Motion For Accelerated Decision, July 7, 1995). Here, no claim has been made that use of PRED-X presents any particular hazards or risks to the environment and it is noted that, in determining gravity adjustments for penalty calculation purposes, Complainant used a value of "1", i.e., "minor potential or actual harm to the environment, neither widespread nor substantial". For purposes of the ERP, "minor harm" refers to actual or potential harm which is, or would be of short duration, no lasting effects or permanent damage, effects are easily reversible, and harm does not, or would not result in significant monetary loss (ERP, Appendix B Footnotes). Respondent is entitled to present evidence that even this definition overstates the risk from use of the product at

29/ (...continued) surprising if Respondent's financial condition had deteriorated since the revised penalty calculation was made. issue here, because the ERP categorization of risk is subject to challenge. $\frac{30}{}$ 

The second aspect of "gravity of the violation" is gravity of "Gravity of the misconduct" may not be separated the misconduct. from lack of culpability or Respondent's good faith, which is inherently a factual matter. Haveman Grain Company, supra. In case of dispute or where the facts are unclear, "good faith" is simply not a matter appropriate for resolution on summary judgment. Here, Complainant assessed the culpability value under the ERP at level 2, which corresponds to circumstances where the violator's Respondent claims to have relied upon culpability is "unknown." the advice of "experts", including representatives of EPA, in concluding that PRED-X did not require registration and believes that it "did everything that was necessary to abide by the law". Respondent asserts that "if what [it did] was wrong, it was not on purpose."<sup>31</sup>/ Respondent argues that the culpability factor should be determined to be level 0. A culpability assessment at level 0 would reduce the total gravity adjustment criteria from a value of 5, as asserted by Complainant, to a value of 3. The enforcement

30/ See, e.g., In re Employers Insurance Company of Wausau and Group Eight Technology, Inc., Docket Nos. TSCA-V-C-62-90 and TSCA-V-C-66-90 (Initial Decision, September 29, 1995) (assumptions, findings and conclusions upon which penalty policy rests must be supported by evidence), presently on appeal to the EAB.

31/ R's Response.

remedy for a total gravity value of 3 would be "no action, Notice of Warning, or 50% reduction of matrix value" (ERP, Appendix C).

While inaccurate advice from EPA or other experts that PRED-X was not a pesticide requiring registration would not preclude a determination that Respondent was liable for the sale and distribution of an unregistered pesticide and for the production of a pesticide in an unregistered establishment as alleged in the complaint, such advice is clearly relevant to a determination of the amount, if any, of an appropriate penalty. Respondent has not, claim with affidavits however, supported this or other documentation and Respondent will be ordered to produce any letters, notes, memoranda, telephone logs, calendars, or other documents which summarize advice received and the facts upon which the advice was based. $\frac{32}{}$  After Respondent complies with this order, Complainant will furnish written statements from Ms. Ann Brown and Mr. Gary Kuyava stating the substance of any advice rendered to Respondent as to whether PRED-X was a pesticide.

For the reasons stated, Complainant's motion for judgment for the amount of the penalty claimed will be denied.

<sup>&</sup>lt;sup>32/</sup> In its prehearing exchange, Respondent stated that the first production of PRED-X was on April 10, 1992, that Ann Brown of EPA, who was contacted on November 21, 1991, supplied respondent with a registration kit, that Dr. Don Gables of FDA and Dr. Jim Davis of USDA were contacted on May 2, 1990, and that Gary Kuyava of the Minnesota Department of Agriculture was contacted on May 3, 1990. Additionally, advice that PRED-X did not require registration was allegedly obtained from Dr. Charles Yeager, Registration Consulting Associates, Auburn, California, an expert with over 40 years of experience in pesticide regulations, at a date not stated.

## <u>ORDER</u>

- 1. Complainant's Motion for Accelerated Decision that Respondent violated the Act by the distribution and sale of an unregistered pesticide and by the production of a pesticide in an unregistered establishment is granted.
- 2. Complainant's motion for judgment for the amount of the penalty claimed is denied.
- 3. On or before March 15, 1996, Respondent is ordered to provide copies of any letters, notes, memoranda, telephone logs, calendars, or other documents which summarize or confirm advice assertedly received from the representatives of EPA, FDA, USDA, and the Minnesota Department of Agriculture identified above. On or before April 12, 1996, Complainant will furnish written statements from Ms. Ann Brown and Mr. Gary Kuyava concerning advice furnished Respondent as to whether PRED-X is a pesticide requiring registration.<sup>33/</sup>

Dated this day of February 1996.

т. Nissen Spen Er

Administrative Law Judge

<sup>33/</sup> After the parties have supplied the information and documents required by this order, I will be in telephonic contact with the parties for the purpose of scheduling a hearing on this matter, which will be held in Duluth, Minnesota.

## CERTIFICATE OF SERVICE

This is to certify that the original of this ORDER GRANTING IN PART MOTION FOR ACCELERATED DECISION, dated February 16, 1996, in re: <u>Predex Corporation</u>, Dkt. No. IF&R-V-004-93, was mailed to the Regional Hearing Clerk, Reg. V, and a copy was mailed to Respondent and Complainant (see list of addressees).

indon Helen F. Handon

Legal Staff Assistant

## DATE: February 16, 1996

#### ADDRESSEES:

Gregory Bambenek, M.D. President Predex Corporation 700 Garfield Avenue Duluth, MN 55802

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Ms. Jodi L. Swanson-Wilson Regional Hearing Clerk U.S. EPA, Region V 77 West Jackson Boulevard Chicago, IL 60604