

5/10/76

ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE REGIONAL ADMINISTRATOR

In re)	I. F. & R. Docket Nos.
)	VII-92C
Fleming & Company,)	VII-135C
)	
Respondent)	Initial Decision

Preliminary Statement

These are two proceedings under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended [7 U.S.C. 136 1(a)], 1973 Supp., for the assessment of civil penalties for violations of said Act. The Respondent in each of the proceedings is the same and by order of the Chief Administrative Law Judge, dated August 14, 1975, the proceedings were consolidated.^{1/}

Case No. VII-92C was initiated by complaint dated January 24, 1975 issued by the Chief, Pesticides Program Branch, EPA, Region VII charging Respondent with a violation of Section 3 of the FIFRA [7 U.S.C. 135a(a)] by shipping from St. Louis, Missouri to Melrose Park, Illinois, on or about November 27, 1974, the pesticide Impregon Diaper Disinfectant

^{1/} Pursuant to Section 168.22(a) of the applicable Rules of Practice, 40 CFR 168.22(a), 39 F.R. 27658 et seq.

Concentrate (Impregon) that was not registered under Section 4 of FIFRA (7 U.S.C. 135b).^{2/} A civil penalty of \$4,675 was proposed.

This complaint also charged that the pesticide was misbranded in that it did not bear a required warning or caution statement. On motion of Complainant this misbranding charge was dismissed without prejudice.

Case No. VII-135C was initiated by complaint dated July 25, 1975, issued by the said Chief, Pesticides Program Branch, charging Respondent with a violation of Section 12(a)(2)(I) of FIFRA, as amended, [7 U.S.C. 136j(a)(2)(I)] in that it made a shipment of the pesticide, Impregon, on April 18, 1975, in violation of a "Stop Sale, Use, or Removal Order" that was issued on April 10, 1975. A civil penalty of \$5,000 was proposed.

The Respondent filed answers to the complaints and in each instance requested a hearing.

A prehearing conference was held in the cases in St. Louis on January 21, 1976, and a Report and Summary thereof was issued by the undersigned on March 2, 1976, and a copy thereof is made part of the record as ALJ Ex. 1. The parties were afforded an opportunity to

^{2/} FIFRA was originally approved on June 25, 1947, and was amended on several occasions prior to October 21, 1972. Extensive amendments were made by the Federal Environmental Pesticide Control Act of 1972 (FEPCA) P.L. 92-516, 86 Stat. 973. Section 4(b) of FEPCA provides:

The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act and the regulations thereunder as such existed prior to the enactment of this Act shall remain in effect until superseded by the amendments made by this Act and regulations thereunder . . .

submit objections or suggested additions or amendments to the Report and Summary, (ALJ letters of March 2 and 24, 1976, marked ALJ Exs. 2 and 3) and none were submitted.

Subsequent to the prehearing conference an oral deposition of Thomas E. Fleming, owner of Respondent corporation, was taken on February 18, 1976, by counsel for Respondent with cross examination by counsel for Complainant, and the parties have agreed to make the deposition part of the record, and it is marked as Resp. Ex. 10.

The parties agreed that an oral hearing in the case was not necessary (See ALJ Ex. 3 and letter dated March 22, 1976, from counsel for Complainant, marked ALJ Ex. 4). The parties filed briefs which have been duly considered by the undersigned.

The misbranding charge in Docket No. VII-92C having been withdrawn, it is to be observed that in neither of the cases are charges made of inefficacy, harm to users, or adverse effects on the environment.^{3/} The question in Docket No. VII-92C is whether there is any basis for finding that the product was registered and the question in Docket No. VII-135C is whether there was a violation of the "Stop Sale, Use, or Removal Order."

^{3/} As will hereinafter appear, where appropriate, these elements may properly be considered in assessing the "gravity of the violation."

Findings of Fact

1. The Respondent, Fleming & Company, is a Missouri corporation now located in Fenton, Missouri, and at all times here material had a place of business in St. Louis, Missouri. Thomas E. Fleming is the President of Respondent and is its principal or sole share-owner.

2. On November 27, 1974, Respondent shipped from St. Louis, Missouri, to Melrose Park, Illinois, a quantity of the pesticide called Impregon Diaper Disinfectant Concentrate (Impregon).

3. The said pesticide (economic poison) was not registered as required by Section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 135(b)] as continued in effect by Section 4(b) of the Federal Environmental Pesticide Control Act of 1972, P.L. 92-516, 86 Stat. 973.

4. On April 24, 1970, a criminal prosecution was brought against Respondent in the United States District Court, Eastern District of Missouri, Eastern Division [70 CR 83(A)] charging four interstate shipments of Impregon (between August 1967 and March 1970) and alleging that the product was not registered (Counts 1, 3, 5, 7) and in each instance was misbranded (Counts 2, 4, 6, 8). There was trial before the Court sitting without jury and on June 24, 1971, the Court found the defendant not guilty on all Counts.

5. In 1973 a second criminal prosecution, in seven Counts, was instituted against Respondent in the United States District Court, Eastern District of Missouri [73 CR 284(3)]. Six of the Counts charged interstate shipments of Impregon (between July 1971 and October 1972) that was not registered as required by FIFRA; one Count charged misbranding of the product. The Respondent (defendant in the criminal proceeding) moved to dismiss the prosecution based on the acquittal of June 24, 1971, in the previous case. On September 6, 1974, the Court granted the motion to dismiss holding the plaintiff was "estopped from re-litigating the issue of non-registration". The Government appealed the order of dismissal to the 8th Circuit but subsequently withdrew its notice of appeal and the appeal was dismissed on November 14, 1974.

6. In September 1970 the Respondent filed with the Department of Agriculture (predecessor of Environmental Protection Agency for registration of pesticides) an application for registration of Impregon. The application was denied in January 1971 and Respondent filed objections and requested a hearing. It filed another application for registration in June 1972 and that was denied in August 1972. Again Respondent filed objections to the denial and requested a hearing. The hearing requests were merged and a hearing in the matters was held before an Administrative Law Judge. The Respondent contended that the product should be deemed registered by operation of law by virtue of

the above-mentioned finding of not guilty of June 24, 1971. The ALJ in a Recommended Decision of May 15, 1973, rejected this contention and concluded that Respondent was not entitled to registration of Impregon. The EPA decision of July 10, 1973, affirmed the ALJ's Recommended Decision. The Respondent did not seek to obtain judicial review of the Agency decision.

7. On April 9, 1975, the Regional Administrator of EPA (Region VII, Kansas City, Missouri) pursuant to Section 13(a) of FIFRA, as amended [7 U.S.C. 136k(a)] issued to Respondent an order not to sell, use, or remove the pesticide Impregon Diaper Disinfectant Concentrate. The order stated that the product was in violation of FIFRA in that it was not registered and was misbranded. The order further stated that it shall pertain to all quantities of the above-named pesticide within the ownership, control, or custody of Respondent.

8. Notwithstanding the above order of April 9, 1975, the Respondent on April 18, 1975 shipped and sold a quantity of said pesticide to a customer in Rutherfordton, North Carolina. The said sale and shipment was a deliberate and intentional violation of the above mentioned order of April 9, 1975.

9. The Respondent has been in business since 1960. Its annual sales are in excess of one million dollar . The assessment of the civil penalties hereinafter set forth would be burdensome to the company but would not put it out of business.

Discussion and Conclusions

With regard to the non-registration charge (Docket No. VII-92C), the Respondent, in its brief, states its position as follows: "Any and all proceedings subsequent to the lawsuit filed by the United States of America in the Federal District Court in St. Louis, Missouri, Cause No. 70 CR 83(A), should be barred by the application of res judicata or collateral estoppel."

With regard to the charge of violating the "Stop Sale, Use, or Removal Order" (Docket No. VII-135C) it is Respondent's position that it did not violate the order and that violation of such an order requires an intentional act, an intent to violate, and that Respondent at no time either knowingly or intentionally violated the order.

At the outset it must be recognized that these proceedings are civil proceedings for the imposition of a penalty. Clearly, section 14(a) of the Act (7 U.S.C. 136 1) which authorizes imposition of civil penalties is, as it states, a civil penalty provision and is not a punitive provision. When H.R. 10729, the bill that contained this provision and which was subsequently enacted, was being considered, the House Committee on Agriculture in H.R. Rep. No. 92-511, 92d Cong., 1st Sess. (1971) stated (p. 24):

H.R. 10729 contains provisions for civil penalties. Such provision is not included in existing FIFRA . . .

Civil penalty provisions are considered a necessary part of a regulatory program such as pesticide control. While the criminal provisions may be used where circumstances warrant, the flexibility of having civil remedies

available provides an appropriate means of enforcement without subjecting a person to criminal sanctions.^{4/}

When Congress has characterized the remedy as civil and the only consequence of a judgment for the Government is a money penalty, the courts will accept the characterization by Congress. United States v. J. B. Williams Co., Inc., 498 F.2d 414, 421 (2d Cir. 1974).

The Non-registration Charge (Docket No. VII-92C)

A. Background

In 1960 the Respondent began marketing Impregon and, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as it was then in effect,^{5/} applied to the Department of Agriculture^{6/} for registration of the product. Although the Respondent's application was not approved, it continued to market the product. In November 1969 or thereabouts, the Department of Agriculture directed Respondent to withdraw the product from the market. This directive was based on information concerning the toxicity of tetrachlorsalicylanilide (TCSA) which is an active ingredient of Impregon. The Respondent was advised at that time that the product was not registered. The Respondent continued to market the product.

^{4/} The Report of the Senate Committee on Commerce on H.R. 10729, S. Rep. No. 92-270, 92d Cong., 2d Sess. (1972), p. 39, contains identical language.

^{5/} Act of June 25, 1947, 61 Stat. 167, 7 U.S.C. 135-135k.

^{6/} Reorganization Plan No. 3 of 1970, Section 2(a)(8)(i), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, 5 U.S.C. Appendix II, transferred to the Administrator of the Environmental Protection Agency the functions of the Secretary of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act.

B. The 1970 Criminal Prosecution

On April 24, 1970, a criminal prosecution was brought against Respondent in the United States District Court, Eastern District of Missouri, Eastern Division [70 CR 83(A)] charging four interstate shipments of Impregon (between August 1967 and March 1970) and alleging that the product was not registered (Counts 1, 3, 5, 7) and in each instance, was misbranded (Counts 2, 4, 6, 8). There was trial before the Court sitting without jury and on June 24, 1971, the Court found the Respondent not guilty on all Counts. The Remarks by the Court issued from the bench are in the record. (Resp. Ex. 3). The Court found (Resp. Ex. 3, p. 3) that in the early 1960's the Respondent applied for registration with the Pesticides Registration Division of the Department of Agriculture and that registration was refused; that the product was not registered; that following refusal of the Department of Agriculture to register the product the Respondent and representatives of the Department had a conference and that Respondent insisted that the product be registered "whether they had the right or not."^{7/} (Resp. Ex. 3, p. 5).

C. Refusal to Register After Hearing

In September 1970 the Respondent filed with the Department of Agriculture an application for registration of Impregon. The application

^{7/} In acquitting the defendant the trial judge relied, in part, on a provision that existed in Section 4c of the 1947 Act, 61 Stat. 163, which permitted registration under protest, i.e., the applicant could insist on marketing his product even where registration was denied. This provision was repealed in 1964 and all existing registrations under protest were terminated, Act of May 12, 1964, sections 3 and 7, 78 Stat. 190. Aside from this the judge's remarks basically indicate that he was dissatisfied with the sufficiency of the evidence offered by the Government. The acquittal should be construed simply to mean that the burden of proof required in a criminal case had not been met. See infra p.13.

was denied in January 1971 and Respondent filed objections and requested a hearing. It filed another application for registration in June 1972 and this was denied in August 1972. Again Respondent filed objections to the denial and requested a hearing.^{8/} The hearing requests were merged and a hearing in the matters was held before an Administrative Law Judge. The Respondent contended that the product should be deemed registered by operation of law by virtue of the judgment in the above mentioned criminal case in the Eastern District of Missouri. The ALJ rejected this contention. His Recommended Decision concluded that Petitioner (Respondent herein) is not entitled to registration of Impregon (Comp. Ex. 2, p. 12). The EPA final decision of July 10, 1973 (Comp. Ex. 3) affirmed the ALJ's Recommended Decision. The Respondent did not seek to obtain judicial review of the Agency decision as permitted by section 16(b) of FIFRA, as amended, 7 U.S.C. 136n(b).

D. The 1973 Criminal Prosecution

In 1973 (date not shown) a second criminal prosecution was instituted against Respondent by a seven Count indictment in the United States District Court, Eastern District of Missouri. Six of the Counts charged interstate shipments of Impregon (between July 1971, and October 1972) that was not registered as required by FIFRA; one Count charged misbranding of the product. The Respondent (defendant in the criminal proceeding)

^{8/} See FIFRA, as amended, sections 6(b)(2) and (d), 7 U.S.C. 136d (b)(2) and (d).

moved to dismiss the Information based on the acquittal of June 24, 1971, in the previous criminal case.

On September 6, 1974, the Court (a different judge) granted the motion to dismiss holding the plaintiff was "estopped from re-litigating the issue of non-registration."

The Government appealed the order of dismissal to the 8th Circuit but subsequently withdrew its notice of appeal and the appeal was dismissed on November 14, 1974.

In urging the defense of res judicata or collateral estoppel. The Respondent in its brief states its position as follows:

It is the position of Respondent that any and all proceedings subsequent to the lawsuit filed by the United States of America in the Federal District Court in St. Louis, Missouri, Cause No. 70 CR 83(A), should be barred by the application of res judicata or collateral estoppel. This includes the decision handed down by Judge Abraham Gold, dated May 15, 1973, and the second lawsuit instituted by the United States of America in 1973 against Respondent, which was dismissed by the trial court, and the appeal, which was voluntarily dismissed by plaintiff.

The Respondent relies solely on the case of George H. Lee Company v. Federal Trade Commission, 113 F.2d 583 (8th Cir. 1940) and cases cited therein.

The Lee case was a civil action by the Federal Trade Commission charging misleading and false statements in advertising. In an earlier

civil seizure action under the Food and Drug Act it had been decided that substantially the same statements were not false and misleading. The court held that on the matter of false representations, the Government had its day in court and could not collaterally attack the decree entered in the earlier case.

The Lee case and the other case cited by Respondent are not at all in point. Each of those cases involved civil actions only - both the first action, which was in favor of the party being sued, and the subsequent action which was held to be barred by the previous determination.

In the instant case the first action which is the basis for the claim of res judicata or collateral estoppel was a criminal action and the present action is a civil action.

It is firmly established that when the first suit is a criminal prosecution resulting in an acquittal, no preclusive effect is to be attributed to the judgment in a subsequent civil proceeding involving the same or similar conduct.

A leading case on this point is Helvering v. Mitchell, 303 U.S. 391 (1938). Mitchell had been tried and acquitted on a criminal charge of willfully attempting to evade payment of his income tax. Thereafter suit was brought to collect the taxes owed plus a 50 per cent penalty for fraudulent evasion. The acquittal in the criminal case was held not to be a bar to the collection of the penalty. The Supreme Court said:

The difference in degree of the burden of proof in criminal and civil cases precludes application of the doctrine of res judicata. The acquittal was "merely * * an adjudication that the proof was not sufficient to overcome all reasonable doubt of the guilt of the accused." Lewis v. Frick, 233 U.S. 291, 302. It did not determine that Mitchell had not willfully attempted to evade the tax. That acquittal on a criminal charge is not a bar to a civil action by the Government, remedial in its nature, arising out of the same facts on which the criminal proceeding was based has long been settled. Stone v. United States, 167 U.S. 178, 188; Murphy v. United States, 272 U.S. 630, 631, 632. Cf. Chantangco v. Abaroa, 218 U.S. 476, 481-482. (Emphasis added).

See also One Lot Emerald Cut Stones, etc. v. United States, 409 U.S. 232, 235 (1972); United States v. National Association of Real Estate Bds., 339 U.S. 485, 493-494 (1950); Murray & Sorenson, Inc. v. United States, 207 F.2d 119, 122 (1st Cir. 1953); United States v. Gramer, 191 F.2d 741, 743 (9th Cir. 1951); Glup v. United States, 523 F.2d 557, 561 (8th Cir. 1975).

Acquittal in a criminal prosecution is considered merely an adjudication that proof was not sufficient to overcome all reasonable doubt of guilt. As to the issues raised, an acquittal does not constitute an adjudication on the "preponderance of the evidence" standard which applies in civil proceedings. United States v. Burch, 294 F.2d 1, 3 (5th Cir. 1961); Helvering v. Mitchell, supra at 397. Although the proof offered in the criminal case might have been insufficient to meet the guilt beyond a reasonable doubt requirement, it could nevertheless be sufficient to support a judgment of civil liability. United States v. National Ass'n of Real Estate Bds., 339 U.S. 485, 493 (1950). The

Complainant's evidence as to non-registration is sufficient to sustain a judgment of civil liability in the present proceeding.

The Respondent has admitted that Impregon is not registered with EPA.^{9/} Further proof of such non-registration is not necessary. It might be noted, however, that the Recommended Decision of the ALJ after public hearing on the issue as to whether EPA should register Impregon concluded that the product should not be registered.^{10/} His decision was affirmed by the Judicial Officer, acting for the Administrator on July 10, 1973. The Respondent could have sought judicial review in a Court of Appeals^{11/} but elected not to do so. The proper forum to challenge the Agency action refusing to register the product would have been the Court of Appeals.

E. The "Stop Sale, Use, or Removal Order"

On April 9, 1975, the Regional Administrator of EPA (Region VII, Kansas City, Missouri) issued to Respondent a "Stop Sale, Use, or Removal Order" which was received by Respondent on April 10, 1975.^{12/} The text of the order was as follows (Comp. Ex. 4):

By the authority vested in me pursuant to Section 13(a) [7 U.S.C. 136k(a)] of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136), you are

^{9/} ALJ Ex. 1, p. 2, para. No. 5.

^{10/} The ALJ rejected the defense of res judicata and collateral estoppel. See Comp. Ex. 2, p. 7.

^{11/} 7 U.S.C. 136n(b).

^{12/} See ALJ Ex. 1, p. 5, para. 13.

hereby ordered not to sell, use, or remove the pesticide IMPREGON DIAPER DISINFECTANT CONCENTRATE.

This product is in violation of Section 12 of the FIFRA (7 U.S.C. 136j) in that it is not registered and is misbranded. The label failed to bear a warning or caution statement which is necessary to protect health and the environment.

This order shall pertain to all quantities of the above named pesticide within the ownership, control, or custody of the above named company. Said pesticide shall not be sold, used, or removed other than in accordance with the provisions of this order or of such further orders as may be issued in connection with the pesticide.

Any person violating the terms or provisions of this order shall be subject to the penalties prescribed in Section 14 of the Act.

On April 18, 1975, the Respondent made a shipment of four bottles of Impregon from its place of business in St. Louis, Missouri, to Rutherfordton, North Carolina. The Impregon that was shipped was merchandise that had previously been sold by Respondent to a customer and was returned for relabelling or resale. The account of the customer who returned the merchandise was credited for its value. The returned units were not placed in the Respondent's current stock of Impregon but were shipped to the customer in Rutherfordton for which the customer was charged by invoice that Respondent issued and which the customer paid.

Mr. Fleming, in his deposition (Resp. Ex. 10, p. 12), testified that he did not knowingly or intentionally violate the "Stop Sale, Use, and Removal Order" of April 9, 1975.

The Respondent has admitted that it made a shipment of Impregon to Rutherfordton, North Carolina, on or about April 18, 1975 (ALJ Ex. 1, p. 5, para. 14). The Respondent argues that this admission does not constitute a violation of the "Stop Sale Order". In support of this contention Respondent adopts the deposition testimony of Thomas E. Fleming.

The testimony of Mr. Fleming in the light most favorable to Respondent shows that four units of Impregon were returned to Respondent by a customer for relabeling or resale; the customer's account was credited with the returned merchandise; the returned goods were not put in the company's current stock; said merchandise was shipped to the customer in Rutherfordton and the customer was charged for the merchandise and paid for it.

Irrespective of the source of the Impregon in question, it was in the custody and control of Respondent. The Respondent removed the Impregon from its control and custody, sold it to the customer in North Carolina, and received payment. This was a removal and sale in deliberate violation of the Stop Sale, Use, and Removal Order of April 9, 1975.

Despite the assertion of Mr. Fleming (Resp. Ex. 10, p. 12) that he did not knowingly or intentionally violate the Stop Sale, Use, or Removal Order, I find that the sale and shipment to the customer in North Carolina was a knowing and intentional violation of said Order. The language of the Order prohibiting sale and removal was clear and unequivocal.

Even if the sale and removal was not a knowing and intentional violation, the Respondent would not be excused from the consequences of his conduct. Knowledge or intent are not required elements in a violation for the assessment of a civil penalty under Section 14(a). In statutes that are designed for social betterment or for the welfare of the public (as in FIFRA), the Congress has often authorized the imposition of penalties even though there is no intent to violate and no awareness of wrongdoing. U.S. v. Dotterweich, 320 U.S. 277 (1943); U.S. v. Balint, 258 U.S. 250 (1922). See also Morrisette v. U.S. 342, U.S. 246, 256 (1952).

It is to be observed that under Section 14(b) of FIFRA, as amended, 7 U.S.C. 136 1(b), a criminal violation is not established unless the person charged "knowingly violates". Significantly, the word "knowingly" is omitted in Section 14(a), 7 U.S.C. 136 1(a), the civil penalty provision.

The Amount of the Civil Penalties

A. General

Section 14(a)(1) of FIFRA, as amended [7 U.S.C. 136 1(a)(1)] provides, in pertinent part, that any wholesaler, dealer, retailer or other distributor who violates any provision of this Act may be assessed a civil penalty of not more than \$5,000 for each offense. The Respondent falls within one or more of the categories described.

Section 14(a)(3), 7 U.S.C. 136 l(a)(3) provides, in pertinent part, as follows:

In determining the amount of the penalty the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation.

The Environmental Protection Agency has published Guidelines for Assessment of Civil Penalties under Section 14(a) of FIFRA. These appear in 39 F.R. 27711 et seq., July 31, 1974.

Section 168.46(b) of the Rules of Practice provides as follows:

In determining the dollar amount of the recommended civil penalty assessed in the initial decision, the Administrative Law Judge shall consider all elements regarding the appropriateness of civil penalty set forth in §168.60(b). In determining the appropriate penalty to be assessed, the Administrative Law Judge may consult and rely upon the Guidelines for the Assessment of Civil Penalties, published in the Federal Register at 39 F.R. 27711. The Administrative Law Judge may at his discretion increase or decrease the assessed penalty from the amount proposed to be assessed in the complaint.

In the Guidelines the Agency has utilized five gradations as to size of a Respondent's business. The largest size, Category V, includes those firms whose gross sales exceed one million dollars. The Respondent has stipulated that its annual sales are in excess of one million dollars (ALJ Ex. 1, p. 5, para. 16). The Respondent represented that payment of the penalties would be burdensome but has acknowledged that assessment of the penalties (totaling \$9,675) would not put it out of business (ALJ Ex. 1, p. 5, para. 17).

For a non-registration violation where registration has previously been denied, the Guidelines set forth a \$5,000 penalty for firms in Category V (39 F.R. 27713). For violation of a Stop Sale, Use, or Removal Order, the Guidelines set forth a \$5,000 penalty for firms in all categories - the smallest and largest (39 F.R. 27717).

The Respondent, whose annual sales are in excess of one million dollars must be considered as a firm of very substantial size. The payment of the proposed penalties would not effect its ability to continue in business. The remaining consideration in determining the appropriateness of the penalty is the gravity of the violation.

Aside from the general purposes of the Act, there is nothing therein that would assist in interpreting what Congress intended in the term "gravity of the violation." So far as the undersigned can determine there is nothing in the legislative history to shed light on this subject. See In re Amvac Chemical Corporation, Notices of Judgment under FIFRA, No. 1499, issue of June 1975.

With regard to "gravity of violation" the undersigned in the Amvac case stated his views (which have been adopted by other Administrative Law Judges) as follows:

It is our view that in considering appropriateness of the penalty to the "gravity of the violation" the evaluation should be made from two aspects -- gravity of harm and gravity of misconduct. As to gravity of harm there should be considered the actual or potential harm or damage, including severity, that resulted or could result from the particular violation. This must

be viewed in the light of the purposes of the Act which includes protecting the public health and environment and affording to users the protection and benefits of the Act. Further, the Act provides enforcement officials with the means for preventing the marketing of violative products and also the means for obtaining speedy remedial action when necessary.

As illustrative of the degrees of gravity of harm, it is apparent that a violation involving the marketing of a highly toxic pesticide that is not registered is much more serious than a violation in which the label of a registered pesticide fails to bear the registration number.

As to gravity of misconduct, matters which may be properly considered include such elements as intention* and attitude of respondent; knowledge of statutory and regulatory requirements; whether there was negligence and if so the degree thereof; position and degree of responsibility of those who performed the offending acts; mitigating and aggravating circumstances; history of compliance with the Act; and good faith or lack thereof. It is observed that the Rules of Practice specify these last two elements as those that may be considered in evaluating the penalty (section 168.53(b)).

In grading the gravity of the various violations enumerated in the Act, shipment of an unregistered pesticide may be considered to be a serious violation. It is obvious that when an unregistered pesticide is distributed the protective and enforcement purposes of registration are defeated.

*Although intent is not an element of an offense in a civil penalty assessment case (Cf. U.S. v. Dotterweich, 320 U.S. 277), intent to violate may be an aggravating factor.

B. The Non-registration Charge

The product that was involved in the hearing for cancellation was Impregon, which contained 2% tetrachlorosalicylanilide (TCSA)

(Comp. Ex. 2, p. 8). TCSA is an active ingredient of the product in the present case and also constitutes 2% of the product. (ALJ Ex. 1, p. 3, para. 7). The Respondent admitted the photosensitivity of TCSA and acknowledged that it is a known sensitizing agent. (ALJ Ex. 1, p. 3, para. 7).

Impregon is represented as a diaper disinfectant concentrate. The directions for use in the present case are the same as they were in the proceedings for cancellation. The ALJ in that case made the following pertinent findings of fact (Comp. Ex. 2, p. 11):

7. Impregon contains tetrachlorosalicylanilide (TCSA), the most potent known photosensitizer; and when light comes in contact with this chemical on the skin the resulting reactions, as shown by tests and experiments, include redness, heat, swelling, pain and blisters.

8. Photosensitization can be activated by the amount of light which can pass through window glass or the amount of light emitted by some artificial indoor light sources.

9. Photosensitivity can be activated by a concentration of TCSA much less than that recommended in the labelling for the use of Impregon.

From a gravity of harm point of view, serious damage could result from the use of Impregon. Consideration must be given to the fact that the product is to be used in treating diapers which come in direct contact with the tender skin of infants. The gravity of harm in the present case is of a high degree.

The gravity of misconduct in the non-registration case is also of a high degree. The Respondent's first application for registration of

Impregon was denied in January 1971. The acquittal in the first criminal case was in June 1971. It is apparent that Respondent did not consider this acquittal as tantamount to registration by operation of law, as it now contends. If this was Respondent's honest belief, what was the purpose of the second application for registration in June 1972?

The decision of the ALJ rejected Respondent's position that the acquittal operates as registration by operation of law on the basis of res judicata or collateral estoppel. When the Agency affirmed the decision of the ALJ, the Respondent did not seek court review. The Agency decision not to register Impregon stands as the effective action in the matter. The Respondent's shipment of Impregon on November 27, 1974, as charged, must be considered as an intentional violation of that provision of the Act that prohibits shipment of non-registered pesticides.

The gravity of the violation in the non-registration charge is of a high degree. Considering all of the factors that the statute requires to be considered, the undersigned is of the view that the penalty as proposed in the Complaint, namely \$4,675, is appropriate.

C. Violation of the Stop Sale, Use, or Removal Order

The harm or injury that could result from the distribution of Impregon has already been covered. As noted, serious injury could result from the use of this product.

The "Stop Sale, Use, or Removal" provision in Section 13(a) of Act, 7 U.S.C. 136k(a), was a new enforcement tool that was added by the 1972 amendments. It appears that this provision has special significance in the enforcement program. Even without this provision, sale and distribution of pesticides that are in violation of the Act is prohibited. The purpose of this provision is to authorize "the Administrator to issue a 'stop sale, use, or removal' order to any person possessing a pesticide or device if he believes that the pesticide or device is or will be sold in violation of the Act . . ."^{13/} (Emphasis added).

In view of the Respondent's history relating to the sale and distribution of Impregon, it is apparent that the Environmental Protection Agency had reason to believe that this non-registered product would be sold in violation of the Act. Accordingly, the very strongly worded order of April 9, 1975, was issued. Within 10 days of the Order, the Respondent, in contemptuous disregard of the terms of the Order, made a sale and shipment of the product. This is gravity of misconduct of the highest degree.^{14/} When such conduct is considered in connection with

^{13/} Report of Senate Committee on Commerce, S. Rep. No. 92-970, 92 Cong., 2nd Sess. (1972) p. 40.

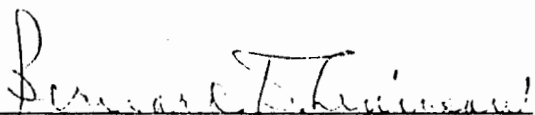
^{14/} It is to be observed that for violation of a Stop Sale, Use, and Removal Order, the Guidelines consider the maximum of \$5,000 as an appropriate penalty for a business of any size, even one in the category whose annual gross income is less than \$100,000 (39 F.R. 27717).

the serious harm that could result from use of this product, the imposition of the maximum penalty of \$5,000 for this violation is appropriate.

Having considered the entire record in the case and based on the Findings of Fact, and Conclusions and Discussion herein, it is proposed that the following order be issued.

FINAL ORDER ^{15/}

Pursuant to section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended [7 U.S.C. 136 1(a)(1)] civil penalties totaling \$9,675 are hereby assessed against Respondent, Fleming & Company. The penalty for the non-registration violation set forth in I.F. & R. Docket No. VII-92C is \$4,675 and the penalty for the violation set forth in I.F. & R. Docket No. VII-135C is \$5,000.


Bernard D. Levinson
Administrative Law Judge

May 10, 1976

15/ Unless appeal is taken by the filing of exceptions pursuant to section 168.51 of the Rules of Practice, or the Regional Administrator elects to review this decision on his own motion, the order shall become the final order of the Regional Administrator. (See section 168.46(c)).