3/27/77

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE REGIONAL ADMINISTRATOR

In the Matter of Mid-American Research Chemical Corporation, Respondent.	)	I.F. & R. Docket No. VII-261C

INITIAL DECISION

Preliminary Statement

This is a proceeding under Sec. 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 l(a)), 1973 Supp., for the assessment of a civil penalty for violation of the Act.

On June 10, 1977, the Chief, Pesticides Branch, United States Environmental Protection Agency, Region VII (Complainant), issued a Complaint together with Notice of Opportunity for Hearing, charging Mid-American Research Chemical Corporation (Respondent) with violation of the Act. The Complaint was amended on August 3, 1977, to read as follows:

> "1. Misbranded in that the labeling bore a statement as to the safety of the product which is false or misleading. (12(a)(1)(E), 7 U.S.C. 136j(a)(1)(E); 2(q)(1)(A), 7 U.S.C. 136(q)(1)(A).
>
> (Product labeling entitled "ROOT CONTROL" contained the statement "SAFE". This claim did not appear on labeling accepted January 15, 1976, in connection with registration of the product and is an unwarranted claim as to

the product's safety. This claim is inconsistent with the precautionary statements on the product's label, which are "DANGER: KEEP OUT OF REACH OF CHILDREN," "CAUTION: Keep out of reach of children", "Harmful if swallowed", "Do not reuse container", and "Destroy when empty".)

2. Misbranded in that the labeling stated in part "E.P.A. APPROVED". (12(a)(1)(E), 7 U.S.C. 136j(a)(1)(E); 2(q)(1)(A), 7 U.S.C. 136(q)(1)(A))

(Such a statement is false and misleading in that it implies that the product is recommended or endorsed by the Environmental Protection Agency. The Environmental Protection Agency neither recommends nor endorses the use of this or any other pesticides.)"

The Amended Complaint alleged that the statements "SAFE" and "E.P.A. APPROVED" made in labeling are prohibited under Sec. 162.10(a)(5) of the Sec. 3 Product Registration Regulations, 40 CFR Part 162, and that no such claims appeared on labeling accepted in connection with this product's registration nor would they have been accepted if they appeared on labeling submitted for acceptance. Complainant considers that such claims differ in substance from those accepted.

A civil penalty has been proposed by Complainant in accordance with the Civil Penalty Assessment Schedule (39 FR 27713) which permits an assessment of $1,800.

It should be noted that neither the ALJ nor the Regional Administrator is bound by the amount of proposed penalty in the Complaint. See 40 CFR 168.46(b) and 168.60(b)(3).

Respondent, through its President, Mr. C. R. Lambert, filed an Answer denying that the words "EPA Approved" and "Safe" are on the labels actually affixed to "Root Control". Complainant agrees.

Respondent further alleges that these words, while appearing on a "brochure" sent to prospective customers, do not constitute labeling as contemplated by the Act and Regulations. Complainant disagrees.

Therefore, since both parties agree that these statements appeared on literature used to promote the sale of "Root Control," the only issue to be resolved is whether or not this literature constitutes "labeling" and, if so, the use of these statements constitute violations of said Act and Regulations since they are proscribed by the Regulations and were not approved at the time of registration.

The proceedings were conducted pursuant to the applicable Rules of Practice, 40 CFR 168.01 et seq. At my request, the parties, pursuant to Sec. 168.36(e) of the Rules, corresponded with me for the purpose of accomplishing some of the purposes of a prehearing conference (see Sec. 168.36(a) of the Rules).

A prehearing conference was held in Columbus, Nebraska, November 22, 1978, just prior to the formal hearing at which certain stipulations were agreed upon by the parties as follows:

1. EPA exhibits 1-6 were admitted into evidence without objection, except that Respondent desired to characterize EPA Ex. 4 as a "brochure" as opposed to Complainant's characterization as "labeling".

2. Objection was sustained regarding the admission into evidence of EPA Exh. 7, a Dun and Bradstreet Report, since Respondent admitted its gross annual sales are in excess of one million dollars and less than two million dollars.

3. Complainant did not call any witnesses and rested its case based upon EPA Exhibits 1-6.

4. The proposed civil penalty was properly computed in accordance with the EPA Guidelines. And further, that the Respondent is in Category V, with annual gross sales of over one million dollars and payment of the penalty will not affect its ability to remain in business.

The Complainant was represented by Daniel J. Shiel, Esq., and Respondent was represented by its President, C. Ronald Lambert.

The parties have filed briefs in support of proposed findings of fact and conclusions of law, which I have carefully considered.

Findings of Fact

1. Respondent is a corporation with its place of business located at Box 458, Columbus, Nebraska 68601. Its gross annual sales exceed $1,000,000 and the assessment of the proposed penalty will not affect its ability to continue in business.

2. That the Respondent held the pesticide MARC 70 ROOT CONTROL for sale or distribution as alleged in the Complaint. (EPA Ex. 2.)

3. That the brochure entitled, in part, "ROOT CONTROL" was available at Respondent's establishment at which the product was held for sale or distribution. (EPA Ex. 2.)

4. That a copy of the brochure was given to an EPA inspector, at the inspector's request, along with a sample of the pesticide. (EPA Ex. 2.)

5. That the brochure bears the statements "Safe" and "EPA Approved" made with respect to the pesticide in question. (EPA Ex. 4.)

6. That none of the labeling accepted in connection with this product's registration bears the statements "Safe" and "EPA Approved." (EPA Exs. 5 and 6.)

7. That the labeling accepted in connection with product registration bears the following cautionary statements:

Keep out of reach of children

Harmful if swallowed

Do not reuse containers

Destroy when empty (EPA Exs. 5 and 6, Tr. 25.)

8. That the brochure was used by Respondent to promote the sale of this product and that distribution of the brochure did result in some sales of the product. (Answer, Tr. pp. 15, 18, and 20, MARC Ex. 1.)

9. For the above-mentioned violations, Findings 5 and 6, the Respondent is subject to a civil penalty under Sec. 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 l(a).

10. Taking into consideration the size of Respondent's business, the effect on Respondent's ability to continue in business, and the gravity of the violation, it is determined that a civil penalty of $500.00 is appropriate.

Labeling is defined in Sec. 2(p)(2) of FIFRA as ". . . all labels and all other written, printed, or graphic matter. . . accompanying the pesticide. . . at any time . . . ." The factual record indicates that the brochure was available at Respondent's establishment at which the pesticide was held for sale or distribution, and that a copy of it was given to the EPA inspector at the time he collected a sample of the pesticide. (EPA Ex. 2.) In interpreting similar provisions under the Federal Food, Drug and Cosmetic Act (FFDCA), reviewing courts have consistently held that there need be no physical attachment of the printed material to the product for it to "accompany" the product and therefore be labeled.[1/] The leading cases involving interpretations of labeling under the FFDCA are United States v. Kordel, 335 U.S. 345 (1948), 69 S.Ct. 106 and United States v. Urbuteit, 335 U.S. 355 (1948), 69 S.Ct. 112.

1/ Sec. 201(m) of the FFDCA defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." (Emphasis added.)

In Kordel, the alleged misbranding consisted of statements in circulars or pamphlets distributed to consumers by vendors of the products relating to their efficacy. Some counts charged that the literature and product were shipped in the same carton. The remaining counts involved literature that was shipped separately from the product and at different times. The court looked first to the purpose of the act, which was to protect consumers who were unable to protect themselves. It did not wish to "create an obviously wide loophole" by holding that a product would be misbranded if the literature were shipped in the same container but would not be misbranded if shipped before or after the product. The court concluded that "the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported."

In Urbuteit, the Supreme Court found machines to be misbranded because of statements made in a leaflet shipped separately from the machines. In so holding, the court said ". . . the common sense of the matter is to view the interstate transaction in its entirety--the purpose of the advertising and its actual use."

These principles have been consistently followed in cases involving determinations as to where literature accompanies a product so as to be labeling. See, for example, United States v. 353 Cases . . . Mountain Valley Mineral Water, 247 F.2d 473 (8th Cir. 1957); United States v. 47 Bottles, More or Less . . . "Jenasol RJ Formula "60", 320 F.2d 564 (3rd Cir. 1963).

In the Mountain Valley Mineral Water case the court held that:

> "Where pamphlets, concerning mineral water, were seized in place of business of water distributor, pamphlets were printed for use in promotion and sale of water, were useful for no other purpose, and president of company, which bottled the water, testified that he knew of no sales literature which was not approved advertising matter, pamphlets constituted "labeling" within section of food, drug, and cosmetic act providing that labeling means all printed matter upon article or accompanying it in the sense of supplementing or explaining it, even though there was evidence that pamphlets had not been used by distributor in connection with selling of water."

In following this reasoning, I must reject Respondent's contention that these brochures were not technical, that is, not necessary to a correct application and use of the product. Their use in promotion of the product is sufficient to be considered "labeling". In fact, in Mountain Valley the pamphlets had not been distributed.

It may be ironic, but the actual statements complained of here are specifically proscribed by the Regulations.

Sec. 162.10(a)(5) of the Regulations for the Enforcement of FIFRA, 40 CFR Part 162, sets forth as examples of statements or representations in labeling which constitute misbranding as follows:

> ". . .(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
> . . .(ix) claims as to the safety of the pesticide or its ingredients, including statements such as "safe", . . . with or without such a qualifying phrase as "when used as directed. . . ."

While Respondent argues that the phrase "EPA Approved" is intended only to mean that the product is registered as required, such an interpretation cannot be applied to the ordinary meaning placed upon this phrase by users of the product.

The statement "EPA Approved" clearly indicates that the product is recommended or endorsed by the Environmental Protection Agency, an agency of the Federal Government, and as such contravenes the Regulations cited above.

Additionally, the claim that the product is "Safe" is specifically identified as false or misleading in subsection (ix), above. Further support that this pesticide is not "safe" is evidenced by the cautionary statements on its label. Thus, these statements are false or misleading.

The remaining factor for consideration is the gravity of the violation. Sec. 168.60 of the Rules of Practice, 40 CFR Part 168, provides that the Respondent's history of compliance with FIFRA and any evidence of good faith or lack thereof are to be considered as in evaluating the gravity of the violation. Respondent has been cited for no other violations under FIFRA or its predecessor statutes and there is no evidence indicating a lack of good faith by the Respondent.

In addition to these two factors, the gravity of the violation has been evaluated on the basis of the gravity of the harm and the

gravity of the misconduct. In the gravity of harm category, I believe there to be little probability of adverse effects as a result of this violation. The record contains no evidence of any actual harm having occurred. The greatest potential for harm would be from the likelihood that the precautionary statements found on the label would be ignored because of the claim that the product is "safe". The very nature of these precautionary statements indicate there is some possibility for harm to man or the environment if the product is not used properly.

I associate a high gravity of misconduct with Respondent's representation that this product is "Safe" and "EPA Approved". As discussed above, the applicable regulations[2/] used the claim that a product is "Safe" as an example of misbranding. Also the statement implying that a product is recommended or endorsed by an agency of the Federal Government was given as an example of misbranding. The statement that a product is "EPA Approved" clearly implies that it is recommended or endorsed by EPA. EPA does not recommend or endorse any pesticides.

While the legal principles applied here in order to find that a civil penalty is appropriate may not have been clear to Respondent,

2/ 40 CFR 162.14(a)(5), (6), November 25, 1971;
40 CFR 162.10(a)(5)(v) and (ix), July 3, 1975.

it serves to emphasize clearly the obligation imposed upon persons subject to the Act to be certain of their responsibilities under law before proceeding as here. I would assume a request for approval of the instant brochure would have eliminated the basis for this proceeding.

Conclusions

I have taken into account all of the factors that are required to be considered in determining the appropriateness of the penalty. I am of the view that a penalty of $500.00 is appropriate.

The proposed Findings of Fact and Conclusions submitted by the parties have been considered. To the extent that they are consistent with Findings of Fact, and Discussion and Conclusions herein, they are granted, otherwise they are denied.

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

FINAL ORDER[3/]

Pursuant to Sec. 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 l(a)(1)), a

3/ Unless appeal is taken by the filing of exceptions pursuant to Sec. 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 Sec. 168.46(c).)

civil penalty of $500.00 is assessed against Respondent, Mid-American Chemical Corporation, for the violation which has been established on the basis of the Amended Complaint issued on August 3, 1977.

Edward B. Finch
Administrative Law Judge

March 27, 1977