7/13/77

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE REGIONAL ADMINISTRATOR

In the Matter of Kemin Industries, Inc., Respondent.	)	I. F. & R. Docket No. VII-223C

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 November 10, 1976, the Chief, Pesticides Branch, United States Environmental Protection Agency, Region VII (Complainant), issued a Complaint together with Notice of Opportunity for Hearing, charging Kemin Industries, Inc. (Respondent) with violation of the Act.

The Complaint charged Respondent with violation of Sec. 12 of the Act, 7 U.S.C. 136j, by holding for sale on or about March 3, 1976, in Des Moines, Iowa, a pesticide labeled Dry Powder Mold Curb, which pesticide was not in compliance with the provisions of FIFRA as follows:

1. Misbranded in that the label of the sampled product stated in part:

"* * *

DRY POWDER

MOLD CURB

* * *

ACTIVE INGREDIENTS: 20%

Propionic Acid

INERT INGREDIENTS: 80%

* * *"

whereas, when tested, the product failed to contain 20% Propionic Acid. [12(a)(1)(E), 7 U.S.C. 136j(a)(1)(E); 2(q)(1)(A), 7 U.S.C. 136(q)(1)(A)].

2. Adulterated in that its strength or purity fell below the professed standard or quality under which it was sold. [12(a)(1)(E), 7 U.S.C. 136j(a)(1)(E); 2(c)(1), 7 U.S.C. 136(c)(1)].

(PROPOSED PENALTY $5,000)

(When tested one subsample from a 50-pound drum coded "602 8385", was found to contain only 8.19% Propionic Acid.)

A civil penalty has been proposed by Complainant in accordance with the Civil Penalty Assessment Schedule (39 FR 27713) which permits an assessment of $5,000.00.

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).

The Respondent, through counsel, filed an Answer which denies that the product was misbranded and asserts that the product contained the labeled amount of propionic acid and also denies that the product was adulterated in that its strength or purity fell below the professed standard or quality under which it was sold.

In its prehearing response and during the formal hearing, Respondent asserts, and the Complainant agrees, that the sole issue to be resolved is the question relating to the test method used to determine the amount of propionic acid contained in the Dry Powder Mold Curb.

The proceedings were conducted pursuant to the applicable Rules of Practice, 40 CFR 168.01 et seq. At my request, the parties, pursuant to Section 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 Des Moines, Iowa, on May 12, 1977, just prior to the formal hearing at which certain stipulations were agreed upon by the parties as follows:

1. The product was obtained by Complainant in accordance with law by an authorized employee thereof. EPA Exhibits 1-7.
2. Eugene Wilson, Product Supervisor, EPA, would testify that if the amount of propionic acid contained in Mold Curb is 60 percent defective, the product would not be effective.

3. The proposed civil penalty was properly computed in accordance wit the EPA Guidelines. And further, that the Respondent is in Category V, with annual gross sales of over $1,000,000.00 and payment of the penalty will not affect its ability to remain in business. Further, Respondent objected to admission of a Dun & Bradstreet report, EPA Exhibit 14, and said objection was sustained upon good cause shown.

4. Respondent withdrew its Exhibits B and D-L submitted with prehearing response.

The Complainant was represented by Daniel J. Shiel, Esq., and Respondent was represented by John F. Lemker, Esq.

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

Respondent relies heavily in its brief upon the fact that the Complainant's analytical procedure used in this matter to determine the propionic acid content of Dry Powder Mold Curb is invalid and not binding upon Respondent because it was not promulgated in accordance with the Administrative Procedure Act (APA), 5 U.S.C. 551 et seq., in that (1) it is a rule as defined in 5 U.S.C. 551 and was not exempt from the promulgation requirements of 5 U.S.C. 553, and (2) independent of 553 requirements, it was not published pursuant to 5 U.S.C. 552(a)(1) and, therefore, is not binding.

A similar question arose in a matter[1/] before the undersigned in which I held:

> "The test methods or protocols which form the basis for the intent to cancel the registration of Registrant's product were not established under the informal rule-making requirements of APA and are, therefore, invalid and unenforceable."

Based upon this finding it was ordered that the Notice of Intent to Cancel Registration of Cowley's Original Rat and Mouse Poison for failure to meet efficacy requirements was vacated. In reversing this Initial Decision and remanding for a decision on the merits, the Administrator stated:

> "In this case, the 90% standard has not been treated as a 'rule' in the APA sense. In fact, Registrant was afforded the full procedural rights of adjudication under the APA to contest 90% standard. The cases relied upon by the ALJ and Registrant simply do not preclude an agency from enforcing a proposed standard through case-by-case adjudication under the APA so long as the reasonableness and appropriateness of such standard are at issue in each adjudication.
>
> "While rulemaking may be preferable to adjudication for issues such as the 90% standard, an agency's choice to proceed through adjudication does not render its action statutorily or constitutionally infirm. The choice (absent explicit statutory requirements) is within the discretion of the agency. N.L.R.B. v. Bell Aerospace Co., 416 U.S. 267, 290-295 (1974); S.E.C. v. Chenery Corp., 332 U.S. 194, 203 (1974."[2/]

1/ In the Matter of S. L. Cowley & Sons Mfg., Co., Inc., FIFRA Docket No. 341.

2/ On remand I found on the merits in favor of EPA. The Administrator then affirmed and cancelled the registration. The matter is now pending in the United States Court of Appeals for the District of Columbia Circuit, No. 77-1164.

Since this ruling by the Administrator sets forth the policy of the Environmental Protection Agency in the area of rulemaking by adjudication, I feel that it is encumbent upon me to follow that policy.

Therefore, in order to resolve this matter we must look to the proof as to the validity of the two test methods as described at the hearing.

Findings of Fact

1. Respondent is a corporation with its place of business located at 2104 Maury, Des Moines, Iowa. Its gross sales exceed $1,000,000.00 annually and the assessment of the proposed penalty will not effect its ability to continue in business.

2. On or about March 3, 1976, Respondent held for sale or distribution at its producer establishment in Des Moines, Iowa, the pesticide Dry Powder Mold Curb, EPA Reg. No. 8596-6.

3. That the active ingredient listed on the label is 20% propionic acid.

4. That no propionate salts were listed as either active or inactive ingredients on the label of said pesticide.

5. That the inert ingredients included a listing of, among others, Sodium Chloride and Calcium Silicate.

6. When tested at the EPA Denver Chemistry Laboratory, a sample of said pesticide was found to contain only 8.19% propionic acid.

7. That the method of analysis utilized by the EPA Denver Chemistry Laboratory, which did not include acidification of the sample prior to injection in the gas chromatograph, detects and reports only the propionic acid present in the sample under the conditions which the product was held for sale or distribution and intended use.

8. Said method, without preacidification, is the correct test method to be used to determine the percentage of active propionic acid contained in Dry Powder Mold Curb.

9. The product Dry Powder Mold Curb was misbranded in that it failed to contain 20% propionic acid.

10. The product Dry Powder Mold Curb was adulterated in that its strength or purity fell below the professed standard of quality under which it was sold.

11. For the above-mentioned violations, Findings 9 and 10, 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).

12. 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.

Discussion

The Cowley matter and the instant proceeding differ in that Cowley did not effectively rebut the test method used to determine the efficacy of its product. Here Respondent did contest the procedures (test method) utilized by Complainant to determine the propionic acid content of Dry Powder Mold Curb.

The method used by Complainant provides a result indicating propionic acid content of 8.19%.

The method used by Respondent provides a result indicating propionic acid content of 20%, the percentage of active ingredient stated on the product's label.

The question then to be resolved is which test method is proper. Complainant offered the expert testimony of Martin Byrne, an analytical chemist employed by Complainant at its Pesticide Formulation Laboratory in Denver, Colorado. Respondent offered the expert testimony of two witnesses, Dr. Walter Langston, owner of an analytical, biological laboratory in Leawood, Kansas and Dr. Milton S. Feather, a professor of biochemistry at the University of Missouri at Columbia, Missouri.

All of the experts testified that gas chromatographic analysis was the proper method to be utilized. The difference in testimony of the experts, however, related to one step in the testing procedure just prior to the actual gas chromatography test. Complainant extracts the propionic acid from the inert ingredients by use of a solvent component prior to injecting the acid into the gas chromagraphic equipment. Respondent subjects the product to a preacidification which

frees propionic acid from its substrate which is then injected into the test equipment. Therefore the only difference between Complainant's test method and Respondent's test method is in the preparation of the sample before it is injected into the gas chromatographer.

Complainant contends that preacidification is improper since it results in reporting not only propionic acid but also propionic salts. Propionic salts are not listed on the label as being active ingredients. And that the product would be adulterated and misbranded if it were found that propionic salts had been substituted wholly or in part for propionic acid.

Respondent contends that preacidification is required to free acids which might be bound to a substrate. In addition, Respondent cites the appropriateness of using Association of Official Agricultural Chemists (AOAC) procedures for the type of determinations required in the instant proceeding. This method does require preacidification in the test method to determine the content of mold inhibitors such as sodium propionate in bread, fish, and eggs. A determination is first made as to the amount of propionic acid and then this figure is converted to the percentage of actual mold inhibitor.

While I find it very difficult to decide which test method is appropriate, I must decide in favor of the method used by Complainant. When using this method you are determining the amount of free propionic acid which is the active ingredient both listed on the label

and which performs its function as a mold curb. When using preacidification where salts are present, as here, you are actually creating a chemical reaction between the salts and the added acid which effectively changes the active chemical content of the product by increasing the amount of propionic acid above that which was originally a part of the formulation of the product and also in excess of the amount of propionic acid which will be effective as a mold curb without acidification.

While the test method proposed by Respondent may produce a result indicating 20% propionic acid, such test result does not bear any relationship to the actual amount of propionic acid which is active at the time of use.

Since it is intended to assess only a nominal penalty due to the direct conflict in testimony at the hearing from Complainant's and Respondent's witnesses and the fact that at the point of hearing, either party might have been correct, the gravity of the violation, while having been considered, does not bear directly upon the amount of the penalty proposed.

While it would appear that the Respondent may have acted in good faith in its use of its test method, there was an effort on the part of the parties, prior to complaint, to agree on a test method which apparently was not pursued by Respondent.

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

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 civil penalty of $500.00 is assessed against Respondent, Kemin Industries, Inc., for the violation which has been established on the basis of the Complaint issued on November 10, 1976.

Edward B. Finch
Administrative Law Judge

September 15, 1977

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).)