12/9/76

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE REGIONAL ADMINISTRATOR

In the Matter of

Sidmar Enterprises Inc.	)	I. F. & R. Docket No. I-31C
	)	
Respondent	)	Initial Decision

Preliminary Statement

This is a proceeding under section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended,[1/] 7 U.S.C. 136 l(a), for assessment of civil penalties for violations of said Act. The proceeding was initiated by complaint issued on February 26, 1976 by the Director, Enforcement Division, EPA, Region I charging respondent with several violations of the Act. It is alleged, in substance, that respondent in violation of 7 U.S.C. 136j(a)(1)(E), offered for sale on March 4, 1975, the pesticide Sanityze 72 that was adultered within the meaning of 7 U.S.C. 136(c)(1) and misbranded within the meaning of 7 U.S.C. 136(q)(1)(A).[2/]

1/ The Federal Insecticide, Fungicide, and Rodenticide Act, originally enacted in 1947, was extensively amended on October 21, 1972. The legislative mechanism used to amend FIFRA 1947 was designated Federal Environmental Pesticide Control Act of 1972, 86 Stat, 973, Public Law 92-516, referred to as FEPCA. Section 2 of FEPCA contains the entire Act as amended and appears in 7 U.S.C. 136 et seq. and will hereinafter be referred to as FIFRA.

2/ It is also alleged that the product was misbranded under 7 U.S.C. 136(q)(1)(D) in that it did not bear the registration number of the producer's establishment. No penalty was proposed to be assessed for this minor violation because it "is not considered to be a charge which would warrant a civil complaint by itself" (Tr. 43). See Guidelines for Assessment of Civil Penalties, Sec. IB(3)(a).

It is also alleged that respondent in violation of 7 U.S.C. 136j(a)(2)(B) refused to keep records required by 7 U.S.C. 136f(a) and regulations thereunder, 40 CFR 169.2.

It is alleged that the label of the product represented that it contained 4.5% didecyl dimethyl ammonium chloride (DDAC) whereas it contained approximately 2.38% of this ingredient, and that this resulted in the product being adulterated [7 U.S.C. 136(c)(1)] and misbranded [7 U.S.C 136(q)(1)(A)].

It is also alleged that the product was misbranded [7 U.S.C. 136(q)(1)(A)] in that it was represented to be effective against Staphylococcus aureus at a dilution of one ounce per gallon and against Pseudomonas aeruginosa at a dilution of two ounces per gallon whereas at these dilutions the product would not be effective.

Penalties totaling $6,510 were proposed to be assessed - $2,520 for adulteration[3/] and $3,990 for refusal to keep records.

The respondent filed an answer and requested a hearing which was held in Boston, Massachusetts, on August 17, 1976. The complainant was represented by Janet E. LaBella, attorney in EPA Region I and respondent was represented by M. M. Eisenberg and Sidney T. Small (non-lawyers), officers of the respondent company.

The respondent challenges the proposed penalty for adulteration as being excessive. It also claims that it did not violate the record-keeping provision and that no penalty is assessable.

3/ No penalties were proposed to be assessed for the misbranding violations but they will be considered insofar as they affect the gravity of the violation relating to adulteration. See 7 U.S.C. 136 l(3).

The complainant has filed proposed findings of fact and conclusions and a brief in support thereof. The respondent has submitted written arguments in support of its position. These have been duly considered.

Findings of Fact

1. The respondent Sidmar Enterprises Inc., is a corporation, formerly located in Medway, Massachusetts, now located at Kleen Way, Holbrook, Massachusetts. Sidmar has several divisions and wholly owned subsidiaries. At the times here material Greenwood Chemical Co. was a division of Sidmar. Subsequently this division became a separate corporation under the name of Greenwood Chemical Co., Inc. and is now a subsidiary of Sidmar. Sidmar has gross sales in excess of one million dollars a year.

2. On February 12, 1975, Greenwood Chemical Division, division of Sidmar, manufactured a batch of 550 gallons of pesticide called Sanityze 72. The product was shipped in drums, each containing 55 gallons. The label of the product represented it to be a cleaner, disinfectant, deodorizer, fungicide for hospital and institutional uses. The label of the product represented that it contained as one of the active ingredients didecyl dimethyl ammonium chloride (DDAC) in the amount of 4.5%. The label of the product further represented that it disinfects when used as directed. A sample of the product was collected by an inspector of the Environmental Protection Agency

at the premises of respondent in Medway, Massachusetts, on March 4, 1975 at which time the product was being held for and offered for sale.

3. The directions for hospital and nursing home use on the label of the product called for a dilution of two ounces per gallon of water and at this dilution represented, among other things, that it would be effective against the pathogens Pseudomonas aeruginosa and Staphylococcus aureus. The directions for use in schools, and institutional and industrial uses called for a dilution of one ounce per gallon of water and at this dilution represented, among other things, that it is effective against Staphylococcus aureus.

4. The product did not contain 4.5% of the active ingredient DDAC but contained approximately 2.38% of this ingredient. When used at a dilution of two ounces per gallon the product was not effective against Pseudomonas aeruginosa. When used at a dilution of one ounce per gallon the product was not effective against Staphylococcus aureus.

5. The product was adulterated within the meaning of 7 U.S.C. 136(c)(1) in that its strength fell below the professed standard of quality as expressed on the label under which it was sold.

6. The product was misbranded within the meaning of 7 U.S.C. 136(q)(1)(A) in that its label bore statements which were false and misleading.

7. On October 25, 1974 the Regional Office of Environmental Protection Agency in Boston (Region I) sent by certified mail to respondent a

copy of the regulations relating to keeping of books and records of pesticide production and distribution. These regulations were issued on September 13, 1974 and were published in the Federal Register on September 18, 1974, 39 F.R. 33514 et seq. The respondent received these regulations within a few days of mailing in the regular course of mail. The regulations came to the attention of the president of respondent company and were read by him.

8. Under section 169.2(a) of these regulations the respondent was required to maintain production records showing product name, EPA Registration Number, amounts per batch, and batch identification of all pesticides produced. Under section 169.2(d) of these regulations the respondent was required to maintain records with information regarding shipment of pesticides.

9. The respondent did maintain certain records regarding shipment of pesticides but from the date it received the copy of the regulation as set forth in Finding 7 until the date of inspection on March 4, 1975 it refused to keep production records as required by section 169.2(a) of the regulations. The respondent's refusal to keep such records was in violation of 7 U.S.C. 136j(a)(2)(B).

10. The respondent is subject to the imposition of civil penalties under 7 U.S.C. 136 l(a)(1) for violations of 7 U.S.C. 136j(a)(1)(E) and 136j(a)(2)(B).

Discussion and Conclusions

At the hearing a stipulation was submitted in which, for the purpose of this action only, it was agreed that the product in question is a pesticide and that it was offered for sale by respondent on March 4, 1975. In the stipulation the respondent did not dispute the allegations relating to adulteration and misbranding by reason of deficiency of the active ingredient DDAC (Allegations A.1. and A.2.) and did not dispute the allegations relating to ineffectiveness of the product against Staphylococcus aureus (at a one ounce per gallon dilution, Allegation A.3.) and against Pseudomonas aeruginosa (at a two ounce per gallon dilution, Allegation A.4.). There was no stipulation regarding the allegations relating to the refusal to keep records (Allegation B.1.) and the respondent contested this charge claiming that it did keep records required by 7 U.S.C. 136f and the regulations thereunder.

With regard to the adulteration and misbranding charges, the only question is the appropriateness of the penalty that should be imposed. The complaint proposes to impose a civil penalty of $2,520 for adulteration and no penalty is proposed for the misbranding violations.

The proposed penalty is based on the civil penalty assessment schedule for violations of 7 U.S.C. 136 l published in the Federal Register on July 31, 1974, 39 F.R. 27711. Under the schedule for a business with gross sales of over one million dollars the penalty for chemical deficiency of a product that is partially inefficacious is $2,800. In proposing the amount of penalty it was reduced from the scheduled

amount by 10% because of mitigating factors. [See Guidelines, Section I(C)(2).] The Guidelines provide that in negotiating for settlement the respondent may present mitigating factors which may warrant the lowering of the proposed penalty by as much as 40%.

In determining the amount of penalty to be assessed, 7 U.S.C. 136 l (a)(3) requires that there shall be considered the appropriateness of the penalty to the size of respondent's business, the effect on respondent's ability to continue in business, and the gravity of the violation. Section 168.60(b) of the rules of practice provides that in evaluating the gravity of the violation there shall also be considered respondent's history of compliance with the Act and any evidence of good faith or lack thereof.

In considering the size of respondent's business it was determined that it was in the category of businesses with gross sales of over one million dollars a year. The respondent argues that it should have been put in the category of businesses with gross sales between $400,000 and $700,000. It argues that the gross sales of Greenwood Chemical Inc. for current year are approximately $650,000.

As above noted at the time of the violations in question, Greenwood was not a separate corporation but was a division of Sidmar and the respondent has acknowledged that annual gross sales of Sidmar are in excess of one million dollars. The respondent in the case is Sidmar and not Greenwood. The complainant properly placed the respondent in the proper category as to size of business.

The respondent makes no claim that it is unable to pay the proposed penalty or that payment thereof will effect its ability to continue in business. It argues that assessment of the penalty will affect its cash flow. The effect that payment of a penalty has on the cash flow of a company is not one of the elements to be considered in imposing a civil penalty in a case of this type.

The critical area for determining the amount of the penalty for adulteration is the evaluation of the gravity of the violation. In previously decided civil penalty cases under FIFRA it has been held that gravity of the violation should be considered from two aspects - gravity of harm and gravity of misconduct.

The deficiency of the active ingredient DDAC came about when the product was being formulated. The respondent's supplier of this ingredient furnished it as a 50% active material. At the time the batch in question was formulated the respondent's employee who usually formulated the finished product was out of work because of illness. The substitute formulator was inexperienced and erroneously took the ingredient as being 100% active and thus resulted in a deficiency of this active ingredient of approximately 50%. There was no intent on the part of the formulator or the respondent to make a finished product which was deficient in this ingredient. There was, however, negligence on the part of the employee. Even more important, there was negligence on the part of the respondent in having an inexperienced and unqualified employee perform this important function. As a result of this negligent conduct,

550 gallons of this partially ineffective product found its way into the channels of commerce.

As soon as the president of the company received a report of analysis of the product he realized what had occurred and he took steps to remedy the situation. There is no evidence that respondent did not act in good faith and it readily admitted the deficiency. The gravity of misconduct was of a moderate degree.

Now, as to gravity of harm. This product is labeled as a disinfectant for hospital and institutional use. For hospital and nursing home use the directions call for dilution of two ounces per gallon of water. At this level it is represented as effective against Pseudomonas aeruginosa. The respondent in the stipulation did not contest the allegation that at this dilution it would not be so effective. In tests by EPA at a dilution of two ounces per gallon the produce failed to kill this pathogen in 11 out of 30 trials. Thus, it was effective against this pathogen in about 1/3 of the tests. It is to be noted that no penalty was proposed to be assessed for this violation. The witness for complainant who had primary responsibility for recommending the proposed penalty testified that under guidance from EPA headquarters "we are not to assess a penalty for civil complaint for failure to kill Pseudomonas because the test is not as reliable as the test for Staphylococcus aureus".

The complainant presented an expert witness who testified regarding adverse effects that would result from ineffectiveness of this product

against Staphylococcus aureus. There was no evidence as to adverse effects by reason of the ineffectiveness of this product against Pseudomonas aeruginosa. I must, therefore, conclude that complainant places little, if any, weight in this case relating to gravity of harm because of the inefficacy of this product against this pathogen.

The evidence shows that at the recommended dilution for hospital use - two ounces per gallon of water - the product was effective against Staphylococcus aureus. At the institutional or household dilution - one ounce per gallon water - it was ineffective against this pathogen.

The complainant's expert witness testified that there are various strains of the Staphylococcus organism and that testing on the strain of Staphylococcus aureus would be typical of the effect on other strains of this organism. Staphylococcus organisms are found in the natural environment on surfaces such as walls, floors, ceilings, etc., and on the skin of humans, in the intestinal tract, and on clothing. It is readily deposited by air currents and by way of hands from person to surface. Individuals have their particular indigenous strain of the organism and have a resistance to that strain. When an individual picks up a strain to which he is not resistant infection may result, particularly where there is a break in the skin. Certain strains of the organism may cause intestinal problems. However, despite the possibilities of infection from a strain of this organism, the testimony on behalf of complainant was that the potential for and severity of injury from use of this partially ineffective product was slight.

Considering the gravity of misconduct which is moderate, and gravity of harm, which is slight, relating to the distribution of this batch of Sanityze 72, I am of the view that the penalty should be reduced considerably[4/] from the amount set forth in the complaint and conclude that an appropriate penalty for the adulteration charge is $1,000.[5/]

Turning now to the charge for refusal to keep records. There are two aspects to this charge - (1) did the respondent keep the required records, and (2) did the respondent refuse to keep such records.

Section 8(a) of FIFRA, 7 U.S.C. 136f(a), states in pertinent part:

> "Requirements - The Administrator may prescribe regulations requiring producers to maintain such records with respect to their operations and the pesticides and devices produced as he determines are necessary for the effective enforcement of this Act. (Emphasis added)

Regulations under this section were promulgated on September 13, 1974 (40 CFR, Part 169) and were published in the Federal Register on September 18, 1974, 39 F.R. 33514 et seq. Section 169.2 provides in pertinent part:

> All producers of pesticides . . . subject to this Act . . . shall maintain the following records:
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> (a) Records showing the product name, EPA Registration Number, . . . amounts per batch and batch identification (numbers, letters, etc.) of all pesticides produced . . . The batch identification shall appear on all production control records. These records shall be retained for a period of two (2) years.
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> . . .

4/Section 168.46(b) of the Rules of Practice provides that the Administrative law Judge may in his discretion increase or decrease the assessed penalty from the amount proposed to be assessed in the complaint.

5/A separate penalty could properly have been imposed for the misbranding charge for lack of efficacy. However, lack of efficacy (gravity of harm) is taken into account in assessing the penalty for adulteration.

> (d) Records showing the following information regarding the shipment of all pesticides and devices.
> (1) Brand name of pesticide or device.
> (2) Name and address of consignee . . .
> (3) Name of originating carrier.
> (4) Date shipped or delivered for shipment, and
> (5) Quantities shipped or delivered for shipment.
> Shipping and receiving documents such as invoices, freight bills, receiving tickets, etc., which provide the required information will be considered satisfactory for the purposes of this section. These records shall be retained for a period of two (2) years.

Under these quoted provisions the respondent was required to keep production control records and shipping records.

Sanityze 72 was packaged in 55 gallon drums and a batch code number was stenciled on each drum showing date of manufacture. When a drum of the product was sold the individual who shipped the product inserted the batch number of the product on the invoice to the consignee. In addition, there was a card for each of respondent's customers and when a sale of any product was made to that customer an entry would be made on the card showing the sale of the named product with a reference to the invoice number. To ascertain the batch number that was sold would require reference to the customer's card and the pulling of the appropriate invoice.

The respondent did not keep production records which showed that at a particular time a batch[6/] with a batch identification number was produced. The testimony from respondent's president was to the effect

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6/ Batch is defined in section 169.1(b) of the regulations as follows:
> The term "batch" means a quantity of a pesticide product made in one operation or lot or if made in a continuous or semi-continuous process or cycle, the quantity produced during an interval of time to be specified by the producer.

that the company had no separate records showing that a batch of the product was produced at a particular time and that in order to ascertain the batch number that was made at a particular time one would have to go through the invoices to find out to whom portions of that particular batch were sold.

On the basis of the testimony from the respondent's president, I must conclude that the respondent did not keep the production records required by section 169.2(a).

The respondent argues that it is sufficient if it keeps normal commercial records and that it is not required to keep separate records for EPA (Tr. 26). As authority for this contention respondent cites the preamble to the record-keeping regulations (section 169.2) as it appeared in 39 F.R. 33513. The pertinent portions of the preamble are as follows:

> It has been alleged [by industry] that promulgation of the regulations as proposed would mean that numerous records, in addition to those already kept by producers, would be required and that a special set of records for the exclusive use of EPA would have to be maintained.
>
> . . .
>
> The Agency has carefully evaluated these comments. Inquiries indicate that as a general matter such records as are specified in section 169.2, as revised, are already kept by most producers. Moreover, no producer will be required to keep a duplicate set of records for purposes of furnishing information to EPA. To the extent information required to be maintained by the regulations is kept in company records presently maintained as part of business operations, no change will be necessary. (Emphasis added)

The invoices and customer card records kept by respondent were not sufficient to meet the requirements of section 169.2(a).

We now come to the question as to whether or not respondent refused to keep production records.

The respondent received in the course of the mail a copy of the record-keeping regulations that was mailed to it on October 25, 1974. The president of the company read the regulations. Thus, the respondent had actual notice of the record-keeping requirements.[7/]

"Refuse" is defined "to show or express positive unwillingness to do or comply with (as something asked, demanded, expected)".[8/]

While refusal often implies a precedent demand this is not required. As was said in Mackey v. United States, 290 Fed. 21 (6th Cir. 1923), "'To refuse' does not necessarily imply a precedent demand deliberately denied." When a party has knowledge of certain requirements "refuse" may also merely mean a passive failure to act. Halprin v. Babbit, 303 F.2d 139, 140 (1st Cir. 1962).

The respondent had actual knowledge of the record-keeping requirements and its failure to keep the required records was refusal to do so. The fact that respondent was under the erroneous impression that the

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7/It is not necessary to decide in this case whether publication in the Federal Register would have been sufficient notice on which to base a charge of "refusal". Publication in the Federal Register "is sufficient to give notice of the contents of the document to a person subject to or affected by it". 44 U.S.C. 1507. See Federal Crop Ins. Corp. v. Merrill, 332 U.S. 380, 385; Kempe v. U.S., 151 F.2d 680, 684 (8th Cir. 1945); Wolfson v. U.S., 492 F.2d 1386, 1392 (Ct. Cl. 1974).

8/ Webster's Third New International Dictionary.

records it kept were sufficient to comply with the regulations goes to the respondent's good faith and the severity of the sanction and not to question as to whether there was a violation.

The purpose of the record-keeping requirements is explained in the preamble to the regulations as promulgated, 39 F.R. 33513.

> Most of the required records (those pertaining to production, shipment, inventory, batch identification and quantity) will enable the Agency to identify, track and isolate violative batches or shipments of pesticides. In this way, the effectiveness of EPA stop sale, use or removal orders and seizures pursuant to section 13 of the Act, in addition to recalls, will be greatly enhanced, while the producer and the Agency will be spared actions against non-violative shipments.

The failure of respondent to keep the required production records would impede effective enforcement of some of the provisions of the Act.

In this case there was no deliberate flouting of the law and the respondent acted under a misconception of the requirements. The failure to keep records resulted in no immediate harm to the users of the pesticide or to the public. Considering the good faith of respondent and lack of history of prior violations, I am of the view that an appropriate penalty is $2,000 rather than the amount set forth in the complaint.

I have considered to entire record in the case and the arguments of the parties and based on the Findings of Fact, and Discussion and Conclusions herein it is proposed that the following order to issue.

FINAL ORDER[9/]

Pursuant to section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended [7 U.S.C. 136 l(a)(1)] civil penalties totaling $3,000 are hereby assessed against respondent, Sidmar Enterprises Inc. for the violations which have been established on the basis of the complaint issued on February 26, 1976.

Bernard D. Levinson
Administrative Law Judge

December 9, 1976.

9/ 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 168.40(c).]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE REGIONAL ADMINISTRATOR

In the matter of

Sidmar Enterprises Inc.	)	
	)	I. F. & R. Docket No. I-31C
Respondent	)	

Corrections and Addendum to Initial Decision

The following corrections are hereby made to the Initial Decision of the undersigned issued this day:

Page 9, line 14 Change "produce" to "product".

Page 9, " 15 Change "effective" to "ineffective".

Page 15, 3rd line from bottom, change "to" to "the".

Page 15, last line, change "to issue" to "be issued"

The following footnote, number 5a, is added on page 11, line 7 at the word "records".

5a/ Section 12(a)(2)(B) of the Act, 7 U.S.C. 136j(a)(2)(B) provides in pertinent part:

"It shall be unlawful for any person to refuse to keep any records required pursuant to section 8 . . ."

Bernard D. Levinson
Administrative Law Judge

December 9, 1976