

6/4/75

ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE REGIONAL ADMINISTRATOR

In re)
Elco Manufacturing Company,) I. F. & R. Docket No. III-33C
Respondent)

INITIAL DECISION

of
Frederick W. Denniston
Administrative Law Judge

By Complaint dated February 26, 1974, as amended by Motion approved November 8, 1974, the Director of the Enforcement Division, Environmental Protection Agency, Region III, alleged that Elco Manufacturing Company had violated the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973; 7 U.S.C. 136 et seq.) (FIFRA herein). Specifically, it was alleged that Elco held for sale the products Dursban Insecticide 1E and Dursban Insecticide 2E which had improper labels, and a civil penalty of \$5,000 was proposed to be assessed.

Following a prehearing exchange of proposed evidence, hearing was held in Pittsburgh, Pennsylvania on November 26, 1974. Proposed Findings and Briefs were filed on March 3, 1975 and replies on March 17, 1975.

With its Proposed Findings, Respondent submitted an Errata proposing corrections of the transcript, to which no objections have been filed. Those proposed changes should be granted, except as to Item 14, which should be Page 226, line 23 - Change "remun-erazation" to "a summarization."

Pursuant to permission granted at the hearing (Tr. p. 215), Respondent also tendered with its Proposed Findings, a statement of gallons of Dursban 1E and 2E sold from 1969 through 1974. This statement is received as a late-filed exhibit and Respondent's Exhibit No. 12 is assigned thereto.

Respondent has been represented by Eugene B. Strassburger III, of Strassburger & McKenna, of Pittsburgh, Pennsylvania, and Complainant by Peter J. Smith of Philadelphia, Pennsylvania.

Findings of Fact

1. Pursuant to a prior telephonic communication, Sherman Latchaw, Consumer Safety Officer in EPA, Region III, visited the establishment of Elco Manufacturing Company, Sharpsburg, Pennsylvania, on August 21, 1973, for the purpose of conducting an establishment inspection pursuant to Section 9(a) of FIFRA [7 U.S.C. 136g(a)].

2. Mr. Latchaw conferred with Mr. Harry Katz, President of Elco, who supplied copies of 20 to 30 existing product labels which Latchaw compared with copies of the EPA approved labels. This took about 2 to 3 hours. There were no discrepancies between the approved labels for Dursban 1E and Dursban 2E, and those supplied by Mr. Katz.

3. At Latchaw's request, Katz then took the former into the warehouse area so that he could draw physical samples and inspect all products packaged, labeled and readied for shipment. A Notice of Inspection form was given to Katz at the same time stating the reason for the inspection was to obtain "samples of any pesticides or devices, packaged, labeled, and released for shipment and samples of any containers or labeling for such pesticides or devices."

4. Latchaw was then taken, by his request, to the warehouse area to obtain the physical samples, by Katz or one of his employees. Within 25 to 50 feet of the office approximately six stacked cartons were pointed out to Latchaw as containing Elco Dursban 1E and 2E. Samples were also taken of other products which are no longer here in issue.

5. After opening the cartons, Latchaw removed two one-gallon bottles each of Elco Dursban 1E and 2E. One of each was bagged and sealed for submission to the EPA Chemical Laboratory; a duplicate of

each was also bagged and sealed and given to Mr. Katz as a duplicate sample. Latchaw prepared a Receipt for Samples covering ten items, including the Elco Dursban 1E and 2E, which included the following statement which was called to the attention of Mr. Katz:

The undersigned acknowledges that the following samples were obtained from pesticides or devices that were packaged, labeled, and released for shipment; or having been shipped, are being held for distribution for sale.

Mr. Katz indicated there would be no charge for the samples taken. He insisted, however, that one of the products listed was not held for sale and at his request Latchaw noted on the receipt as to that item, "Not for sale." Mr. Katz then signed the receipt.

6. Later the same day, Latchaw compared the labels on the two Dursban samples and found they did not agree with the accepted registered labels. Each of the labels on the samples omitted portions of the precautionary instructions and failed to include portions of the directions for use contained on the approved labels.

7. On the next day, August 22, 1973, Mr. Latchaw returned to Elco's establishment and informed Mr. Katz of the different labels, who, after inspecting a jug of the Elco Dursban, obtained a correct label and placed it on that jug, explaining that it was not on the jug because it was a larger label and looked too awkward. Mr. Katz, although expressing concern over the prospect of a possible fine for a violation, did not contend the labels on the bottles were merely

for identification purposes, or that the two products were not offered for sale, shipment, or delivery. Neither Mr. Katz nor any Elco employees indicate the labels on the samples were for training purposes or that they were not the correct labels for those products.

8. The approved labels of both Dursban products contained the following precautionary statements, which are wholly lacking on the sample labels:

WARNING

May be fatal if swallowed. May be absorbed through skin. May be injurious to eyes and skin.

Do not get on skin or in eyes. Wash thoroughly after handling. Do not wear contaminated clothing. Avoid Breathing vapors or spray mist. Keep away from food, feedstuffs and water supplies. Keep container closed. Keep away from heat and open flame.

Flush contaminated eyes with plenty of water and get medical attention.

Note to physician: Active ingredient is a cholinesterase inhibitor. Treat symptomatically. Atropine is an antidote.

Keep Out of Reach of Children and Animals
Combustible Liquid.

9. Dursban is in EPA's toxicity category II, because of its acute oral toxicity (LD50) of 50 to 500 milligrams. The LD50 is the amount of a single dose of the chemical necessary to kill 50% of any test animal population. This is determined from toxicity data submitted by the company submitting the chemical for evaluation by

EPA. In the case of Dursban, the data was submitted by the Dow Chemical Company.

10. The toxicity of Dursban is the result of its physiological effect. Specifically, Dursban is an organic phosphate compound that acts on the nervous system as a cholinesterase inhibitor. Cholinesterase is an enzyme in the nervous system. It is responsible for the breakdown of acetylcholine, another enzyme which is necessary in the transmission of impulses through the nervous system. Inhibition of cholinesterase causes a buildup of acetylcholine. The symptoms of such a buildup include convulsions, respiratory inhibition and cardiac arrest.

11. The absence of precautionary statements relating to the toxicity of these products would probably leave the user unable to determine the toxicity category of these products. Furthermore, it is the policy of EPA to require such precautionary labeling even if the products are intended for use by pest control operators only. This is because EPA does not assume that operators would necessarily have more knowledge concerning a particular product's toxicity than the general public.

12. For the foregoing reasons, the labels on the samples did not sufficiently provide for the protection of human health.

13. The approved labels also contain "Directions for use" of both products on lawns and turf for the control of chinch bugs and web worms,

together with application rates and dilution tables, which directions and use are not contained on the sample labels. The dilution rates for Dursban 1E and 2E are different due to their different degrees of concentration. Improper dilution or use of an improper rate of application could result in the products being ineffective and in the possibility of unnecessary environmental contamination from repeated efforts by the user to obtain desired results.

Discussion and Conclusions

The defense of Elco in essence, is that the labels on the samples taken were merely for "tagging" purposes and were not the labels placed on deliveries when sales are made; that the samples taken were not being held for sale; and that the registered label is placed on all containers prior to sale and delivery.

Elco and Mr. Katz, its President, have exercised leadership in organizing a training program for the Western Pennsylvania Pest Control Association. Mr. Katz and other Elco employees have conducted training courses for the Association, instructing in correct labeling of products, among other things. According to Katz, the labels on the samples were printed for use in the training sessions, and to reduce the size, certain portions of the approved labels were omitted. As difficulty was experienced in identifying bottles of the Dursban product, because markings

rubbed off, and because the training labels were available, the latter were utilized as "tags" or identification, according to Katz. Such use was further justified by Katz as being due to the fact that the approved label was so large it protruded freestanding 1 1/2 inches above the body of the jug,^{1/} and became messy if the contents were poured in or out, as was sometimes done.

Partial corroboration of Katz' testimony is found in the testimony of four pest control operators in the area who obtained their supplies by purchase of Elco Dursban 1E or 2E, and represented a substantial portion of Elco's total sales of these products. In a general way they confirmed the use of the constructed label at training sessions but insisted the registered label was on the deliveries they received. None, however, was in a position to account for all their receipts of deliveries. Other Elco employees testified the correct registered label was on shipments when they went out; but again, they were unable to speak as to all shipments.

Finally, Katz justified the delivery of the samples to Latchaw and the signing of the receipt for samples, as having been done with the "understanding" that Latchaw knew the correct labels were to be affixed to the products before sale and delivery because Latchaw had reviewed the labels as part of his initial review during the inspection.

^{1/} An attempt by Complainant to show that such a label would not be approved was ruled irrelevant; in any event, the question is mooted by the fact that Respondent has ceased formulation of the two products.

Unfortunately, these explanations do not agree with what occurred contemporaneously with the events and must be rejected. While the language of the Receipt for Samples is ambiguous it reproduces Section 9(a) of FIFRA which uses the words "held for ... sale" as does Section 12(a)(1). In any event, the purpose of the samples taken was clearly obvious to Katz who insisted on a write-in on the receipt of "Not for Sale" with respect to another unrelated product covered by the receipt. Moreover, the reaction of Katz to the return visit of Latchaw fully accepted the concept that a violation had occurred.

Accordingly, Respondent's proposed finding No. 28, that Dursban was never held for sale without the proper label attached is unsupported by the record and must be rejected.

It is concluded, therefore, that Respondent did hold for sale Elco Dursban 1E and 2E, as alleged.

The Penalty: Complainant has computed proposed assessments by use of the Civil Penalty Assessment Schedule designed to produce comparability of penalties. 39 F.R. 27711.

Complainant proposes to assess two separate amounts against each of the two products, of \$1,250 each, for a total of \$5,000. Respondent contends generally that this is excessive and proposes in the alternative \$500, in the event it is found to have violated the Act.

Under the heading of Labeling Violations, Section One (2) Deficient Precautionary Statements: Lacks Required Precautionary Labeling, - for a Category II concern as is Respondent, the penalty of \$1,250 is prescribed where (A) Adverse Effects are Highly Probable. This would properly apply to each of the two products and would amount to \$2,500. As to the second charge, resulting from the elimination of the Lawn and Turf usages and accompanying dilution and use directions, Complainant proposes application of Section Three of the Labeling Use Violations - 1. Inadequate Directions for Use, A. Likely to Result in Mishandling or Misuse, for which Category 2 specifies \$1,250. In this instance, however, the use itself was not specified on the incorrect label, and it is not perceived how this could lead to a likelihood of mishandling or misuse. It would therefore appear more appropriate to apply "C. Not likely to result in mishandling or misuse" for which a penalty of \$300 is prescribed, or \$600 for the two products.

The resulting figure accordingly is \$3,100 but in view of mitigating circumstances here present, in the judgment of the Presiding Officer, this figure should be lowered by the 40% negotiating margin approved by the Schedule for settlement purposes. Here, the violations are clearly the result of carelessness rather than by venality or intent to deceive or defraud and Respondent's past record and immediate correction when advised of the violations, indicate exemplary conduct on its part. Moreover, Respondent has shown leadership in instructing other users in the pesticide field.

Ultimate Conclusion

It is found that Respondent violated the provisions of FIFRA as charged and that a civil penalty of \$1,860 should be assessed against it.

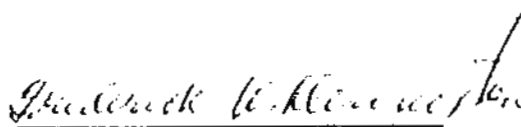
ORDER^{2/}

1. Pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973; 7 U.S.C. 136 1(a)), a civil penalty of \$1,860 is hereby assessed against Respondent Elco Manufacturing Company.

2. Payment of the full amount of the civil penalty assessed shall be made within sixty (60) days of the service of the final order upon Respondent by forwarding to the Regional Hearing Clerk a cashier's check or certified check payable to the United States of America in such amount.

3. The corrections proposed by Respondent of the transcript of the November 26, 1974 hearing are approved and the transcript is CORRECTED accordingly, except that at page 226, line 23, "remunerazation" should be changed to "a summarization"

4. The late-filed exhibit of Dursban sales, is identified as Respondent's Exhibit No. 12, and is received in evidence.


Frederick W. Denniston
Administrative Law Judge

June 4, 1975

^{2/}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)).