#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

#### BEFORE THE ADMINISTRATOR

In the Matter of
Ciba-Geigy Corporation,
Claimant,

٧.

Farmland Industries, Inc.,

Respondent.

) FIFRA COMP. Dockets Nos. 33, 34 & 41

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#### **APPEARANCES:**

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#### INITIAL DECISION

August 19, 1980

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#### INITIAL DECISION

This is a proceeding under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), Section 3(c)(1)(D), to determine what Farmland Industries, Inc. should pay to Ciba-Geigy Corporation as "reasonable compensation," because test data produced by Ciba-Geigy was used by Farmland to register three pesticides. The pesticides are Co-op Atrazine Tech (Brand of Technical Atrazine) (EPA Reg. No. 1990-376), registered on Sept. 17, 1975, Co-op Atrazine 80W, 80% Wettable Powder Herbicide (EPA Reg. No. 1990-377), registered on Aug. 5, 1975, and Co-op Liquid Atrazine (EPA Reg. No. 1990-381), registered on Nov. 19, 1975. All three products contain the chemical atrazine as the active ingredient.

<sup>1/</sup> Compensation is governed by the original version of Section 3(c)(1)(D), enacted as part of the Federal Environmental Pesticide Control Act of 1972, Pub. L. 92-516, 86 Stat. 979-980 (1972). The current version of Section 3(c)(1)(D), as amended, is at 7 U.S.C.A. 136a (c)(1)(D)(Supp. 1979). References to Section 3(c)(1)(D) will be to the original version, a copy of which is attached as an appendix to the decision.

The authority for conducting these proceedings is the notice of the Acting Administrator of the United States Environmental Protection Agency, dated October 13, 1976, 41 Fed. Reg. 46020 (Oct. 19, 1976.). Originally instituted as three separate claims proceedings, the matters were consolidated by order of the Chief Administrative Law Judge dated May 12, 1977.

After lengthy prehearing proceedings, a hearing was held in Washington, D.C., for one day in December 1979, and for eight days in February, 1980, a total of nine days in all. Both parties thereafter submitted proposed findings of fact and conclusions of law and briefs.

Certain information furnished in confidence has been deleted from the text of this decision which is released to the public. The deletions are denoted by an asterisk. The pertinent portion of the text with the confidential information included is contained in a separate in camera appendix.

The decision rendered herein is based upon consideration of the entire record. In the findings of fact and in the opinion which follow, those "background" facts deemed pertinent to the parties' respective positions on the issues, are set forth in the findings of fact. The opinion contains

<sup>2/</sup> The Administrator of the EPA, by notice dated November 14, 1973, had previously established procedures for asserting claims for compensation and for registering pesticides when the applicant was relying on data against which claims had been asserted. 38 Fed. Reg. 31862 (Nov. 19, 1973).

<sup>3/</sup> The compensation claim for Atrazine Tech was assigned FIFRA COMP. Docket No. 33, that for Atrazine 80% was assigned FIFRA COMP. Docket No. 34, and that for Co-op Liquid Atrazine was assigned FIFRA COMP. Docket No. 41. In accordance with procedures established by the Acting Administrator in his notice dated October 13, 1976, supra, I was designated by the Chief Administrative Law Judge as the presiding officer in each proceeding. Identical rules of procedure were issued for each proceeding and consolidation was effected pursuant to these rules.

<sup>4/</sup> The hearings were held in camera at the request of Ciba-Geigy. Subsequently, Ciba-Geigy consented to the public disclosure of the transcript of the December 1979 hearing. The transcripts of the hearings held in February 1980 are still kept in camera.

additional findings of fact on disputed factual issues and also the conclusions of law and the determination of reasonable compensation. Factual findings proposed by the parties which are inconsistent with this decision are rejected.

#### I. FINDINGS OF FACT

#### A. The Parties

- 1. Ciba-Geigy Corporation, a New York Corporation, is the wholly-owned United States subsidiary of Ciba-Geigy Limited of Basle, Switzerland. It is a diversified corporation engaged in the development, manufacture, and sale of various types of chemicals, including agricultural chemicals. The present corporation was formed in 1970 by the merger of Ciba Corporation with Geigy Chemical Corporation in October 1970. F. Ex. 13, p. 2;

  Tr. Vol. 3 at 89; CG Ex. 19 at 2.
- 2. Since 1950, Ciba-Geigy has been actively engaged in a pesticide research and development program, on which it has expended many millions of dollars. During this period it has developed approximately 18 new pesticides, for all of which United States patents were obtained. Research and development has been devoted not only to discovering new pesticides but to expanding uses for existing pesticides on the market. CG Ex. 19 C, pp. 3-4; Tr. Vol. 2 at 54-55; Tr. Vol. 6 at 18.

<sup>5/</sup> Farmland's motion to admit into evidence Farmland's Exhibits 21 through 30, 32, 35, 36, 39, 43 and 44 is granted. The motion is denied with respect to Farmland's proposed Exhibits 31, 33, 34, 37, 38, 40, 41 and 42, since these documents are already in the record as pleadings and orders, and are not factual in nature.

<sup>6/</sup> The record is cited as follows: References to the transcript of testimony are prefixed by the abbreviation "Tr." followed by the volume and page number, e.g., Tr. Vol. 2 at 76; References to Ciba-Geigy's exhibits are identified as "CG" Ex. \_\_\_\_", and references to Farmland's exhibits are identified as "F. Ex. \_\_\_\_". Reference to an exhibit attached to a main exhibit is sometimes identified by enclosing the attached exhibit in parentheses, e.g., CG Ex. 1 (Ex. 2). Pursuant to prehearing order, direct testimony was submitted in written form and included as exhibits. All Ciba-Geigy exhibits except CG Exs. 1-14 (excluding Ex. 3a - 3 ss) have been placed in the record in camera. Farmland's Exhibits 3-6, 12 are also in camera.

- 3. Farmland Industries, Inc. is a Kansas Corporation headquartered in Kansas City, Missouri. It is a regional manufacturing and marketing cooperative doing business in fifteen mid-western states. It markets, and, in some cases produces, a variety of products used in agriculture, including feed, fertilizer, petroleum products and agricultural chemicals. Tr. Vol 8 at 34-35, Vol. 9 at 70; F. Ex. 13, p. 3.
- 4. Farmland's sales from all its business operations have ranked it among the 100 largest corporations in the United States. Only a small part of these sales, however, are accounted for by its agricultural chemical business. Its activities appear to have been confined to the distribution of pesticides prior to its construction of an atrazine manufacturing plant in 1976. Farmland does little in the way of research and development in pesticides. CG Exs. 25, 42; Tr. Vol. 8 at 34-35, Vol. 9 at 102.

#### 8. Atrazine and Ciba-Geigy's Role in Marketing Atrazine

- 5. Atrazine is a widely used herbicide effective for control of most broadleaf and grass weeds infesting corn, sorghum, sugar cane, and non-crop sites. CG Ex. 19, p. 6-7. By far the major use of Atrazine has been on corn. The second largest use has been to control weeds in sorghum. CG Ex. 20, 4.
- 6. Atrazine was developed by Ciba-Geigy's parent corporation who obtained a United States patent on it on June 23, 1959. Ciba-Geigy was then given an exclusive license by the parent to make, use, and sell Atrazine for herbicidal purposes for seventeen years, or until June 1976. Atrazine was produced first at Ciba-Geigy's manufacturing facility in McIntosh, Alabama, and subsequently at another manufacturing plant in St. Gabriel, Louisiana. The St. Gabriel plant's production capacity varies with the atrazine products produced, but it can produce in excess of \* pounds of atrazine products per year. CG Ex. 23, p. 1; Tr. Vol. 3 at 12-13, 92-93.

- 7. The two principal formulations of atrazine, are "80 W", which is a wettable powder consisting of 80% active ingredients, and atrazine "4L", which is a liquid formulation consisting of 4 pounds active ingredients per gallon. Technical atrazine is the basic active ingredient in the formulation of atrazine pesticides. CG Ex. 19 at 7.
- 8. With the enactment of the original FIFRA in 1947, it became necessary to federally register a pesticide in order to commercially market it in the United States (except that intrastate sales were excluded from Federal registration prior to 1972). FIFRA was first administered by the United States Department of Agriculture, but with the creation of the United States Environmental Protection Agency in December 1970, administration of the Act was transferred to that agency. Reorg. Plan No. 3, 84 Stat. 2086.

In general, to obtain a registration, the applicant must submit data to show that the pesticide is safe and effective when used according to the instructions on its labelling. The actual data requirements have changed over the years as pesticides have come into ever-wider use and their environmental as well as their health effects have become known. F. Ex. 10, p. 54; CG Ex. 19 (Ex. AA). In addition, a pesticide applied to a food or to a feed crop cannot be registered until a tolerance setting the maximum amount of pesticide that can

<sup>7/</sup> C1ba-Geigy's 80W, sold under the name AATREX<sup>R</sup> 80W (EPA Reg. No. 100-439) is comparable to Farmland's CO-OP ATRAZINE 80W, and C1ba-Geigy's 4L sold under the name AATREX<sup>R</sup> 4L is comparable to Farmland's Co-op Liquid Atrazine.

<sup>8/</sup> See Act of June 25, 1947, ch. 125, Sec. 4, 61 Stat. 167, and amendment added by the Federal Environmental Pesticide Control Act of 1972, Pub. L. 92-516, 86 Stat. 973.

<sup>9/</sup> Thus, beginning in 1970, evidence was required to show that the pesticide was not only safe to humans, but also that it would not be harmful to the environment. CG Ex. 19 (Ex. AA). See also the EPA's statement explaining the regulations for enforcing FIFRA issued on June 26, 1975 (40 Fed. Reg. 28242, 28248): "The data requirements for registration of a pesticide have been increasing slowly and steadily over the past 25 years."

be on the article of food or feed has been established pursuant to the Federal Food Drug, and Cosmetic Act, 21 U.S.C. 346, 346a and 348, as amended. Tr. Vol. 1 at 87.

- 9. Ciba-Geigy appears to have obtained its first registration of atrazine about the time the patent was issued. In November 1958, Ciba-Geigy received a registration for the formulation 50W, which was for non-selective or industrial weed control on non-cropped land. In January 1959, a similar registration was granted for 80W, by referring to data submitted in support of the 50W registration. CG Exs. 26 and 27; Tr. Vol. 6 at 49-51. In March 1959, data was submitted to support a proposed registration of 50W for weed control on corn. Submission a, CG Ex. 3a. It would appear that the same data submission was used to also obtain a registration for the pre-emergence use of 80W on corn. Tr. Vol. 6 at 49-51.
- 10. The potential of atrazine as a commercially successful pesticide was early recognized by Ciba-Geigy. After atrazine had been put on the market, Ciba-Geigy continued to study ways to fully exploit the product and to maximize the profits on it. Tr. Vol. 6 at 19-22. Several new and amended registrations were obtained over the next 14 years, with data being submitted to support each registration. CG Ex. 19A (Exs. E, F, G).
- 11. One line of effort by Ciba-Geigy was to expand atrazine's uses to additional crops. Thus, in 1961, data was submitted to support a registration of 80W for weed control on sugarcane. Submission f, CG Ex. 3f. In 1963, data was submitted to support a registration of 80W for weed control on sorghum. Submission n, CG Ex. 3n. Registrations were also obtained

of the EPA in December 1970. Reorg. Plan No. 3, 84 Stat. 2086.

11/ "Submission" refers to the lettered data submissions described in the compensations claims filed by Ciba-Geigy in connection with the Farmland registrations. See CG Ex. 19A (Exs. E, F and G).

12/ In the case of 80W, however, a separate submission of data was made in 1960, to support a registration on post-emergence weed control on corn. Submission d, CG Ex. 3d.

<sup>10/</sup> The functions of administering tolerances for pesticides was transferred from the Secretary of Health, Education and Welfare (now Secretary of Human and Health Sciences) to the EPA on the organization of the EPA in December 1970. Reorg. Plan No. 3, 84 Stat. 2086.

for use of 80W on macadamia nuts, and on pineapple, on supporting data submitted in 1962. Submissions k and r, CG Exs. 3k and 3r. The major uses for atrazine, however, have turned out to be for weed control on corn and sorghum. Tr. Vol. 6 at 19; CG Ex. 20, p. 4.

- 12. Ciba-Geigy also applied for and obtained the establishment of tolerances on corn, sorghum, and certain other crops after discovering that there were detectable residues in or on these crops. The first tolerances, on corn and sorghum, were established in 1967. CG Ex. 19 (Exs. W, Z); CG Exs. 3 aa and 3 cc; CG Ex. 28.
- 13. In addition to expanding atrazine's uses on crops, Ciba-Geigy also devoted its efforts to finding new uses for atrazine on weeds, to enlarge the geographical areas of use, and to find more effective methods and conditions of application. For example, in 1961 data was submitted to support a registration for the use of 80W for the control of quackgrass and northern scrubgrass. Submission g., CG EX. 3g. In 1965, data was submitted to support the use of 80W for controlling weeds in forests and Christmas tree plantations in the Northwest. Submission s, CG Ex. 3s. In 1967, Ciba-Geigy submitted data to demonstrate the feasibility of the aerial application of 80W. Submission y, CG Ex. 3y. Also in 1967, Ciba-Geigy submitted data to support the post-emergence application of 80W with emulsifiable oil and water on corn and sorghum. Submission bb, CG Ex. 3 bb.
- 14. CG has also devoted efforts to finding additional formulations for atrazine. For example, in 1969, Ciba-Geigy submitted data to support a registration of atrazine 4L, a liquid formulation of atrazine, which is the other principal formulation of atrazine, besides 80W. Submission ee, CG Ex. 3ee; CG Ex. 19 p. 7, and Ex. T.
- 15. In 1973, Ciba-Geigy submitted data to support a registration for technical atrazine. This registration appears to have been obtained in

order to permit Ciba-Geigy to sell atrazine to others for the purpose of making formulated products. Submission ss, CG Ex. SS; CG Ex. 19, p. 7.

- 16. All of these efforts were successful in providing a wide market for atrazine. In 1975, when Farmland's registrations were granted, Ciba-Geigy sold some \* pounds of atrazine (80W equivalent). CG Ex. 20, p. 5.
- 17. In addition to marketing atrazine itself, Ciba-Geigy, between 1973 and 1975, granted non-exclusive licenses to 14 companies to make and sell atrazine products under the United States patent. In exchange for the license, the licensee agreed to pay a royalty rate per pound of atrazine sold. CG Ex. 19B, pp. 7-8.

#### C. Farmland's Distribution and Sale of Atrazine Products

- 18. Between 1970 and 1973, Farmland was a major distributor of Ciba-Geigy's atrazine products. F. Ex. 6, p. 2; F. Ex. 13, p. 3. In 1973, Farmland concluded that it was unprofitable to continue as a distributor of Ciba-Geigy's atrazine products and attempted to find alternative sources of supplies of atrazine. F. Ex. 6, p. 2; Tr. Vol. 9 at 22-24.
- 19. In March, 1973, Farmland made an agreement with Soluja Ltee, a Canadian corporation, to purchase from Soluja six million pounds of imported 80W atrazine or its equivalent in technical atrazine between June 1973 and August 1976. The atrazine was to be distributed by Farmland pursuant to a supplemental registration obtained under a registration held by Soluja.

  The arrangement with Soluja was performed only in part, however. In March 1974, Soluja refused to make any further sales of atrazine to Farmland.

  CG Ex. 23 (Exs. 1-2).

<sup>13/</sup> A supplemental registration permits a distributor of a registered pesticide to market that pesticide product under the distributor's brand name. See 40 CFR 162.(b)(4).

- 20. When Farmland began selling atrazine pursuant to its supplemental registration from Soluja, it was sued by Ciba-Geigy for patent infringement. This suit was settled in 1974 by Farmland accepting a non-exclusive, non-transferable license from Ciba-Geigy to make, use, and sell atrazine in exchange for Farmland's agreeing to pay \$500,000 to Ciba-Geigy, and a royalty of 27.5 cents for each pound of technical atrazine sold through June 1976, when Ciba-Geigy's patent would expire. Total royalties paid by Farmland under this agreement. amounted to \$1,589,176. F. Ex. 6, p. 4; CG Ex. 23 (Exs. 3-6); Tr. Vol. 9 at 24.
- 21. Farmland, in late 1973 or early 1974, began considering construction of its own atrazine manufacturing plant and distribution under its own label. It investigated a water-processing method of producing atrazine owned by Hilton-Davis Corporation. Being satisfied with this process and believing that an investment in an atrazine plant would be profitable, Farmland's Board of Directors, on January 29, 1975, authorized the construction of an atrazine plant in St. Joseph, Missouri, with a planned annual capacity of 10 million pounds of atrazine. The initial authorization was for a commitment of \$13.3 million toward the construction cost and \$1 million toward working capital. In February 1975, Farmland contracted to purchase from Hilton-Davis technical know-how and expertise in producing atrazine. Hilton-Davis was to be paid \$750,000 as a royalty following the commencement of production at the plant. Tr. Vol. 9 at 25-28, 30-33, 80; F. Ex. 6, pp. 3-4.

22. The plant started manufacturing in late 1976. Farmland's sales of atrazine, for its fiscal years 1976-1978, were as follows:

	Production Expressed in 80W Equivalent (includes Liquid)
Fiscal 1976 (Sept. 1, 1975 to Aug. 31, 1976)	6,555,000
Fiscal 1977	8,456,000
Fiscal 1978	8,394,000
	23,405,000

The 23.4 million pounds does not include atrazine sales by Farmland's subsidiaries, Missouri Chemical or Technec during this period, which could have amounted to as much as another 5.2 million pounds. Farmland Ex. 44, CG Ex. 20, p. 5.

#### D. Farmland's Registration of its Atrazine Labels

- 23. In conjunction with its decision to produce its own atrazine, Farmland, in January 1975, applied for registration of its technical and 80W labels. In May 1975, Farmland applied for registration of its liquid atrazine label CG Ex. 19A (EXS. B, C, D).
- 24. Applications for registration in 1975 had to comply with the EPA's procedure then in effect for carrying out the provisions of Section 3(c)(1)(D). These procedures were set out in an "Interim Policy Statement" dated November 14, 1973, 38 Fed. Reg. 31862 (Nov. 19, 1973), and required that all applications for registration contain the following:

<sup>14/</sup> This 5.3 million pounds is based on Ciba-Geigy's estimate since Farmland refused to furnish the actual atrazine sales by Missouri Chemical and Technec. According to Ciba-Geigy's estimates, Farmland sold 8,760,000 lbs. in 1976, and 10,000,000 lbs. in each of the years 1977 and 1978. CG Ex. 20, p. 5.

- 1. An express written offer to pay reasonable compensation "to the extent provided under Section 3(c)(1)(D)" for use of any test data submitted to EPA in connection with an application for registration for the first time on or after October 21, 1972.
  - 2. Any one of the following:
    - (a) All required supporting data;
    - (b) Specific references to all required data to be considered in support of the application;
    - (c) A request that registration proceed on the basis of use patterns, efficacy and safety previously established under FIFRA (which meant that registrations had been previously approved for a similar product and for similar labelling).

The requirements in Paragraph 2 were commonly referred to as the "2(a)", "2(b)", or "2(c)" methods of support. F. Ex. 21; Interim Policy Statement, 38 Fed. Reg. at 31863.

If an applicant followed the 2(c) procedures (sometimes referred to as a "me-too" applicant), his application was published by the EPA in the <u>Federal Register</u>. Any person who had submitted data to the EPA to support an application for registration and believed that the data was now being relied on in the 2(c) application was required to file a claim for compensation for that data within 60 days following the <u>Federal Register</u> publication, if he wished to preserve his rights to

<sup>15/</sup> The EPA originally construed Section 3(c)(1)(D) as applying only to test data submitted on or after October 21, 1972, the date of the enactment of the Federal Environmental Pest Control Act of 1972. That construction is no longer being followed by the EPA and has not been followed in this decision. See <a href="infra">infra</a> at 47-49.

compensation under Section 3(c)(1)(D). If a claim for compensation was filed, the applicant under 2(c) could not obtain a registration until he either made a revised application under 2(a) or 2(b) above (i.e., provided supporting data or specific references to supporting data), or acknowledged in writing that his application relied on the data identified by the claimant and requested the EPA to consider that data in support of the application. Interim Policy Statement, 38 Fed. Reg. at 31863.

25. Farmland's applications were each accompanied by an offer to pay compensation in the form required by the EPA and were processed under the \$\frac{16}{2}\$ (c) method. Ciba-Geigy filed timely compensation claims with respect to all three applications, the identical test data being cited in each claim. By three letters to EPA, one dated July 24, 1975, and two dated July 31, 1975, Farmland expressly acknowledged that its applications for registration of its technical, 80W and liquid atrazine relied upon the data identified by Ciba-Geigy in its claim letters. Each letter contained a request that EPA consider these data in support of Farmland's application for registration and that the EPA proceed to registration. By letters dated July 28, 1975, and August 6, 1975, EPA notified both companies that it would continue processing Farmland's applications by relying on data cited by Ciba-Geigy in its claims. CG Exs. 7, 19A (Exs. E-K); F. Exs. 24, 25, 28-30.

<sup>16/</sup> Farmland initially applied for registration of its technical and 80W atrazine by attempting to rely on data filed by Soluja Ltee, since that company had given Farmland permission to use the data. Farmland, however, was unable to proceed with registration on this basis because it discovered that Soluja Ltee's own data on file with the EPA was insufficient to support the registrations. CG Exs. 1, 7; F. Ex. 24; Tr. Vol. 9 at 91-93.

- 26. The EPA approved, on September 17, 1975, Farmland's registration of technical atrazine; on August 5, 1975, Farmland's registration of atrazine 80W; and on November 19, 1975, Farmland's registration of liquid atrazine. CG Ex. 19, p. 8.
- 27. The label for Farmland's 80W atrazine is identical to the label for Ciba-Geigy's 80W atrazine approved in 1969, except that the following uses on Ciba-Geigy's label are not on Farmland's label: chemical fallow, turf grasses, macademia nuts, pineapples and lay-by in corn. CG Ex. 19, p. 9 and Exs. 0 and Q thereto.
- 28. The label for Farmland's liquid atrazine is identical to Ciba-Geigy's 4L label registered in 1973, except for the deletion of pre-emergence broadleaf control in farrow irrigated bedded sorghum in Arizona and California. CG Ex. 19, p. 9 and Exs. P and R thereto.

#### E. The EPA's Data Requirements

29. In 1975, the EPA's data requirements for registration and for obtaining tolerances, in part, were contained in agency memoranda, some published, in part, were dependent on oral requirements handed down by people who had previously been reviewers, and, in part rested on the judgment of the individual data reviewer. Tr. Vol. 1 at 51-52, 75-76, 97-100, 132-33, 136, 146; CG Ex. 38 (letter of EPA dated Nov. 15, 1979).

<sup>17/</sup> Farmland's label also did not contain a use for atrazine 80W on rangeland. Ciba-Geigy in its compensation claim has included data submitted to the EPA to support this use of 80W. A rangeland use was not on the Ciba-Geigy 80W label registered in 1969, but Ciba-Geigy claims compensation for the data because of its asserted relevancy to the claims on the Farmland label.

- 30. The EPA, in general, in 1975, required the following kinds of data in support of a pesticide such as atrazine which is used on food and feed crops:
- (1) product chemistry data which included such matters as the basic manufacturing process, and the product's chemical characteristics;
- (2) performance data (also referred to as "efficacy data") showing that the product was effective in controlling the target pest and would not injure the crops to which it was applied; (3) data relating to the effects of the pesticide's residues, metabolites or degradation products on the environment; and (4) toxicological data relating to whether the pesticide has any toxic effects on humans. Tr. Vol. 1 at 18, 123-125, 153 CG Ex. 19, pp. 11, 28-31.
- 31. The following types of data in 1975 were required to obtain a tolerance:
  - Product chemistry data on the chemical and its physical properties, including information on the composition of impurities;
  - (2) Plant and animal metabolism data showing what happens to the pesticide in crops treated with it and in animals fed with the treated crop;
  - (3) Analytical methodology to determine residues in plants and animals;
  - (4) Field residue trial data to determine the level of residues of the product in the treated area or in other areas; and
  - (5) toxicological data relating to whether the pesticide has any toxic effect on humans. Tr. Vol. 1 at 88-94, 126-130.

- 32. At the time the Farmland registrations were issued, the EPA had no published guidelines specifying the type and quantity of performance data which an applicant must submit and no standardized procedures to guide Agency reviewers in reviewing the data. It was initially up to the applicant to submit whatever performance data it thought would support the registration. An Agency reviewer would then decide whether the data submitted was sufficient to support the registration. If it was not, the applicant would be requested to submit additional data. The Agency reviewer usually confined his review to the data submitted with the application and did not search the Agency's files in order to examine data submitted in previous applications unless the applicant specifically referred to such data. Tr. Vol. 1 at 52-56, 75-76, 175-176, 198-99.
  - 33. In 1975, the supporting toxicological data required to register a pesticide or to obtain a tolerance for it was governed by internal administrative practices. There was no published regulation or rule specifically identifying the data which should be submitted. Tr. Vol. 1 at 135-36.

In general, to register a pesticide, five basic acute toxicity studies were needed for both the technical and the formulated product.

<sup>18/</sup> Acute studies were concerned with finding the lethal dose of the pesticide for 50 percent of an animal group, expressed as an "LD-50" or "LC-50", and also with whether exposure to the pesticide caused eye or skin irritation. Tr. Vol. 1 at 24.

Then, depending on the use pattern for a particular formulation, subacute studies (21-day dermal, 90-day oral, 14-21 day inhalation) could also be required. Tr. Vol. 1 at 124-26.

To obtain a tolerance for pesticides like atrazine, which resulted in the presence of non-negligible residues on food and feed products, chronic or long-term animal feeding studies were required. Tr. Vol. 1 at  $\frac{19}{127-30}$ ; CG Ex. 13.

34. Environmental effects data demonstrating that the pesticide was not harmful to fish and wildlife was required when the pesticide was used outdoors. The specific supporting data which would be needed was left to the judgment of the Agency reviewer. CG Ex. 19, pp. 29-30.

#### F. The Agency's Review of Applications under 2(c)

35. Under the 2(c) method of support, the Agency reviewed the proposed labelling to determine whether the directions for use, limitations and precautionary statements were the same as those previously registered for the same product. The Agency did not go back to the data that had been submitted to support the previous registrations and actually attempt to match it with the statements in the proposed labelling.

<sup>19/</sup> If extensive toxicity were disclosed in the sub-acute studies, such as the presence of neoplasms, chronic or long-term studies would be required to obtain a registration regardless of whether a tolerance was sought. Tr. Vol. 1 at 126.

The reason for this appears to have been that the Agency's records of approved labelling did not show what test data supported the labelling. The Agency, therefore, could only have identified the relevant data by  $\frac{20}{20}$  searching its voluminous files. Since the manpower and time required to do such a search probably made the task extremely burdensome, if not impracticable, the Agency, in reviewing an application under 2(c), did not attempt to identify in the record of that registration, and did not tell the parties, what previously submitted data the Agency had considered in support of the application. Instead, the EPA adopted the procedures in the Interim Policy Statement described above (Fdg. 24) so that data owners would be able to protect their compensation rights and 2(c) applicants would be alerted to their possible liability under Section 3(c)(1)(D). Tr. Vol. 1  $\frac{21}{2}$  at 140-51.

<sup>20/</sup> For example, the Agency keeps a compendium of registrations granted on food products, which shows the approved crop uses, tolerances, dosage rates, and limitations on use, but does not show what test data provides the basis for the Agency's approval. Tr. Vol. 1 at 147; CG Ex. 38 (attachment to EPA's letter of Nov. 15, 1979, giving the information in the compendium for atrazine).

<sup>21/</sup> As the EPA stated in its interim policy statement on stressing the need for data owners to file timely claims for compensation, "It must be recognized that in the case of a product proceeding to registration under Section 2(c), it may be impossible to determine in the future what specific data, if any, were considered by EPA in support of the application for registration." 38 Fed. Reg. at 31863. See also, Tr. Vol. 1 at 150-51.

#### Opinion

Ciba-Geigy in this proceeding claims compensation from Farmland in the amount of \$8.11 million for Farmland's use of Ciba-Geigy's test data. Farmland contends that \$49,500 is all that it should be required to pay. The amount that is found to be reasonable compensation, for the reasons set forth in this opinion, is \$245,419.

The wide gulf between the parties stems primarily from their disagreement over what is meant by "reasonable compensation," and how it should be determined. This issue is considered in Part A of this opinion. To a lesser extent the difference between the parties also results from their dispute over what data Ciba-Geigy should be compensated for, and this issue is considered in Part B. Part C sets forth the amount which is determined to be reasonable compensation.

<sup>22/</sup> Section 3(c)(1)(D) excludes from mandatory licensing data which was protected from disclosure by former FIFRA, Section 10, Pub. L. 92-516, 86 Stat. 989 (1972)(current version at 7 U.S.C.A. 136h). That section prohibited the Administrator from disclosing information which in his judgment contains or relates to trade secrets or confidential information. Where the EPA has, nevertheless, considered trade secret or confidential information in granting a me-too registration, the proper remedy for the data originator may still be compensation. See Amchem Prods., Inc. v. GAF Corp., 594 F.2d 470, 482, rehrg. denied, 602 F. 2d 724 (5th Cir. 1979). Ciba-Geigy claims that most of its data constitutes confidential or trade secret information. It has not made the claim an issue to be decided on the merits, however, stating that the determination of whether its data are confidential or trade secret "would appear to fall outside the scope of this proceeding." Post-trial brief at 80, n. 66. Accordingly, in determining compensation, I have not considered any of the data to be trade secret or confidential information protected by Section 10, and it has not been necessary for me to reach the question of how compensation should be determined for test data qualifying as trade secret or confidential information protected by Section 10, when such data has been used to grant a me-too registration.

# A. The Meaning of "Reasonable Compensation" and How It Should Be Determined

Ciba-Geigy arrives at its \$8.11 million claim by using a formula for determining the value of the data under which Farmland pays the cost of reproducing Ciba-Geigy's test data in 1975, amounting to \$2.6 million, plus a royalty on Farmland's gross sales of atrazine for the first three years following EPA registration, totalling \$5.5 million. This formula, derived from criteria used in licensing technical know-how, Ciba-Geigy argues, conforms to what Congress intended in Section 3(c)(1)(D) by providing that a data owner be compensated for the use of his data. Farmland, on the other hand, argues that it should have to pay only some proportionate share of Ciba-Geigy's actual costs in producing the data, and this is all Congress meant by "reasonable compensation."

FIFRA itself does not expressly define the term "reasonable compensation," so the answer cannot be found in the "plain words" of the statute. "Reasonable," as any dictionary will show, is a flexible word which can have several different meanings. Nor has the term been defined in any administrative regulation or rule. The EPA has taken the position that it would not be practicable to establish a precise formula for determining reasonable compensation and that what is reasonable is to be governed by the particular circumstances of each 23/case. So far as the case law is concerned, it has been stated in a few

<sup>23/</sup> See proposed regulations for determining compensation for use of test data under former Section 3(c)(1)(D), 42 Fed. Reg. 31284 (June 20, 1977).

court decisions that Congress intended reasonable compensation to be a reasonable share of the cost of producing the data, but none of these cases have been concerned with determining reasonable compensation, so the statements are no more than dictum. This case, then, appears to be the first pronouncement of what is reasonable compensation under Section 3(c)(1)(D).

#### 1. The Legislative History

The legislative history of Section 3(c)(1)(0) begins with a proposal by the National Agricultural Chemicals Association ("NACA"), while Congress was considering amendments to the 1947 FIFRA, that FIFRA be amended to provide that data submitted in support of an application could not, without the permission of the applicant, be considered by the EPA in support of any other application for registration. This proposal, known as "the exclusive use of data," was in H.R. 10729, the bill amending FIFRA, as it was first passed by the House. That provision was also in H.R. 10729 as it was first reported out by the Senate Committee on Agriculture and Forestry.

25/ Hearings on H.R. 26 and 4152 (and other bills) Before the House Comm. on Agriculture, 92d Cong., 1st Sess. 331 (1971).

26/ While there was some objection to the measure in the House, it survived untouched with apparently little need for any defense by its supporters. See H.R. Rep. No. 92-511, 92d Cong., 1st Sess. 69-75; 117 Cong. Rec. 40061 (1971).

27/ See S. Rep. No. 92-838, 92d Cong., 2d Sess. 19. The Senate version further provided that tests submitted by one applicant could be used by the EPA without the permission of the applicant to determine the adequacy of another's data. Id.

<sup>24/</sup> The question seems to have arisen in considering the relationship between the data compensation provisions of Section 3(c)(1)(0) and the protection afforded trade secrets in Section 10. See Chevron Chemical Co. v. Costle, 443 F. Supp. 1024, 1031 (N.D. Cal. 1978) (holding that test data could be trade secrets or privileged or confidential information protected by FIFRA, Section 10(b)); Amchem Prods. Inc. v. GAF Corp., 594 F. 2d 470, 481, reh'g. denied, 602 F.2d 724 (5th Cir. 1979) (holding that reliance on trade secret data to grant a registration did not necessarily invalidate the registration).

In the Senate, the exclusive use of data encountered strong opposition from the Senate Committee on Commerce, which also considered K.R. 10729, and proposed several amendments to it. One of these amendments was to delete the exclusive use of data, because the Commerce Committee feared that it would create barriers to entry in the pesticides industry, since competition may not be able to afford the sometimes costly safety and efficacy tests, and that it would also result in the diversion of funds into unnecessary duplicative testing.  $\frac{28}{}$ The Committee on Agriculture and Forestry issued a supplemental report in answer to these and other objections raised by the Commerce Committee to H.R. 10729. In the report, it was stated that the purpose of the exclusive use of data was "to give manufacturers an incentive to undertake the research necessary to develop better and safer pesticides." The report went on to explain that without the exclusive use of data, there would be no incentive to undertake the costs of testing products which were not patentable or on which the patent had expired, since there was nothing to prevent a competitor from registering The report further stated that the Committee on a similar product. Agriculture and Forestry did not believe that there would be any great

<sup>28/</sup> S. Rep. No. 92-970, 92d Cong., 2d Sess. 12-19 (1972).

<sup>29/</sup> S. Rep. No. 92-838 (Part II, Supp. Rept.), 92d Cong., 2d Sess., 11-12 (1977)

diversion of funds to duplicate testing, but rather that the exclusive use of data was likely to result in equitable sharing of research costs, as it would be more reasonable for the parties to share in the costs than for each to undertake to do its own testing.

A compromise amendment to Section 3(c)(1)(D) was finally agreed to in the Senate, which in pertinent part, read as follows:

[D]ata submitted in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay a reasonable share of the cost of providing the test data to be relied upon and such data is not protected from disclosure by section 10(c). If the parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstances....(emphasis added)31/

<sup>30/</sup> Id. at 12. The Committee included in its report NACA's arguments about the need to have the exclusive use of data in order to foster research and development. NACA also referred to the fact that the EPA "as a matter of practice" has considered data submitted by one applicant to support the registration of the same or similar product by another applicant. NACA objected to this practice as without statutory authority and expressed concern that the new policy of H.R. 10729 requiring publication of data (except trade secrets) would substantially aggravate this situation. Id. at 18. NACA disavowed any intention to use the exclusive use of data as a means of extending either directly or indirectly the protection received by a registrant under a patent. Id. at 15.

<sup>31/</sup> H.R. 10729, as amended by the Senate, on September 26, 1972, at 78-79; See also 118 Cong. Rec. 32257 (1972); S. Rep. No. 92-838 (Part II) supra, n. 29, at 69-73.

The following statement of "legislative intent" accompanied this compromise substitute:

The change back to section 3(c)(1)(D) as reported by the Agriculture Committee with additions has essentially 2 purposes:

- (1) To authorize the Administrator to require a description of <u>all</u> relevant tests and their results and
- (2) To prevent unnecessary repetitive testing by subsequent applicants.

Thus, all data either voluntarily submitted hereunder or required to be submitted by the Administrator may be used by the Administrator in making determinations of the adequacy of the test data submitted in connection with other applications. As concerns use of such data in support of another application without permission of the originator of the test data, however, it is recognized that in certain circumstances it might be unfair or inequitable for government regulation to require a substantial testing expense to be borne by the first applicant, with subsequent applicants thereby gaining a free ride. On the other hand, unnecessary duplicative testing would represent a wasteful, time-consuming, and costly process resulting in a substantial misallocation of resources. Thus it was decided that fairness and equity require a sharing of the governmentally required cost of producing the test data used in support of an application by an applicant other than the originator of such data. If no agreement can be reached, the Administrator is vested with authority to determine the reasonable share of the cost of the test data used, including subsequent reallocations upon requests for use of such data by additional applicants.32/

<sup>32/118</sup> Cong. Rec. 32258 (1972); S. Rep. No. 92-838 (Part II) supra, n. 29, at 72-73.

Ciba-Geigy argues that the purpose of the compromise was "to protect proprietary rights and promote research." There is no specific mention of these goals in the legislative explanation of the compromise substitute. The only possible recognition of proprietary rights would appear to be in the exclusion from mandatory licensing of test data determined by the EPA to be trade secrets or privileged or confidential information protected from disclosure by FIFRA, Section 10(b). Otherwise, what is expressed is the goal of having all registrants of the same or similar product equitably share in the costs of providing the necessary test data; instead of either making the first registrant bear the entire testing cost or requiring subsequent registrants to do unnecessary duplicative testing to show what had already been established, that the product and its labelling met FIFRA's requirements. Undoubtedly, the compromise does reflect the concern that manufacturers would be unwilling to invest in substantial testing expenses, if the data could then be used without cost by competitors, but the Senate compromise went no further in protecting the manufacturer's interest than assuring that all competitors would share in the costs on some reasonable basis.

H.R. 10729 was then sent to conference to have the differences between the House and Senate ironed out. The Conference Committee reported out H.R. 10729, with the wording of Section 3(c)(1)(D) changed from "reasonable share of the cost of producing the test data" to "reasonable compensation for producing the test data." A change was also made in the judicial review obtainable for the EPA determination of reasonable compensation.

<sup>33/</sup> H.R. 10729, as passed by the Senate, provided that the order of the Administrator determining compensation was to be reviewed in the court of appeals as a final order under the judicial review provisions. The Conference changed this to provide that judicial review was to be by appeal to the federal district court and the amount of payment determined by the court could not be less than that determined by the Administrator. H.R. Rep. No. 92-1540, 92d Cong., 2d Sess. 9, 31 (1972).

The only explanation for these changes was the following:

...It[the Conference Bill] provides for mandatory licensing of test data. The conferees concluded that the Administrator is in the best position to determine the proper amount of reasonable compensation for producing the test data that should be accorded the originator of such data. It was consequently concluded that an appeal of such determination by the originator of such data to the District Court should not result in a lowering of the Administrator's determination. It was also concluded that the pendency of such proceeding before the Administrator or the Court should not stay or delay use of such data (section 3(c)(1)(D)).34/

A further explanation of the Conference substitute was given by Senator Miller, one of the Senate Conferees, during the debate on the conference report:

One of the most difficult areas to be negotiated here had to do with test data use in submitting an application for a certificate. I believe the protection afforded the owner of test data represents an adequate protection, and while I understand that some people who own test data do not wish to have it made available under any circumstances at all, this position would constitute a considerable cost to the Government, and a proper reimbursement approach seemed to be in order.

What we have provided in this particular conference report has been a procedure whereby, through the use of the courts, the owner of the test data can, if he is not satisfied with the award made by the EPA, try to obtain additional amounts of money representing the just compensation due him, and in the meantime he will have the added protection of being able to receive the amount of the award made by the EPA.

I think this is about the best protection that could be afforded to the owner of test data.35/

Section 3(c)(1)(D) was subsequently enacted into law in the form recommended in the Conference Report.

<sup>34/</sup> H.R. Rep. No. 92-1540, supra, n. 33, at 31.

<sup>35/ 118</sup> Cong. Rec. 33922 (1972).

### 2. The Measure of Compensation for Data - Cost of Production or Value as Property

It is Ciba-Geigy's position that the changes by the Conference Committee to Section 3(c)(1)(D), which Congress accepted and which became the law, evidence an intent to abandon a cost-sharing approach in favor of one which would give greater recognition to the value of Ciba-Geigy's property rights in the data. Farmland, on the other hand, argues that Congress never intended to change the standard from some reasonable share of Ciba-Geigy's cost. It relies for this argument both on the legislative history of the 1972 Act, and on statements made during Congress' consideration of subsequent amendments to FIFRA. The later interpretations of reasonable compensation by Congress in considering amendments to Section 3(c)(1)(D), however, are of doubtful weight because they were not addressed to any administrative or judicial construction of what constitutes reasonable compensation. Cf., NLRB v. Bell Aerospace Co., 416 U.S. 267, 275 (1974); Amchem Prods., Inc. v. GAF Corp., 594 F. 2d 470, 477-78 rehrg. denied, 602 F. 2d 724 (5th Cir. 1979).

<sup>36/</sup> Section 3(c)(1)(D) was amended in 1975 and 1978. In the amendments added in 1975, Pub. L. 94-140, 89 Stat. 751-755, Congress limited compensation to data submitted after January 1, 1970, gave both parties the same rights on judicial review, and further provided that registration was not to be delayed pending determination of reasonable compensation. 89 Stat. at 752. In the amendments added in 1978 (The Federal Pesticide Act of 1978), Pub. L. 95-396, 92 Stat. 819, Congress made supporting data submitted with respect to new pesticides registered after September 30, 1978 (except "defensive data" used to maintain the registration) subject to exclusive use for ten years after registration, and compensable for an additional 5 years thereafter; made other data submitted after December 31, 1969, compensable for 15 years (except safety data supporting a registered product made from that pesticide); and provided for disputes over compensation to be settled by binding arbitration. 92 Stat. at 821-24. It is true that there were statements during Congressional consideration of these amendments that Section 3(c)(1)(D) dealt with cost-sharing. See e.g., S. Rep. No. 94-452, 94th Cong., 1st Sess. 10 (1975), S. Rep. No. 95-334, 95th Cong., 1st Sess. 31 (1977). Nevertheless, Congress avoided any reference to costsharing in the amendments themselves, except to provide in the Federal Pesticide Act of 1978 for a procedure whereby registrants may jointly agree to develop or to share in the cost of developing additional data which the EPA has determined is necessary to maintain an existing registration. FIFRA. Section 3(c)(2)(B), 7 U.S.C.A. 136(a)(C)(2)(B). Thus, cost-sharing was mentioned only as procedure to be followed when the parties agreed upon it.

Turning first to Ciba-Geigy's position, Ciba-Geigy argues that Congress, by providing that the me-too applicant first offer to pay compensation, expected the parties in the first instance to negotiate over what is reasonable This may be true and it may also be true, as Ciba-Geigy further compensation. appears to argue, that if the parties do negotiate and have agreed upon a basis for determining compensation but not on the amount, the EPA's role is not to question the basis on which the parties have been bargaining, which may be on some grounds other than reasonable share of the cost, but simply to start with the difference between the parties and attempt to arrive at a reasonable resolution of this difference. But such arguments are not helpful in this case because the parties never bargained over the amount of compensation and there has never been any meeting of the minds between the parties as to what they should be bargaining over in determining reasonable compensation.  $\frac{37}{}$ Instead, they have taken entirely different positions towards what constitutes reasonable compensation.

<sup>37/</sup> There were some preliminary discussions between Farmland and Ciba-Geigy over compensation in June and the early part of July 1975. These, however, appear to have dealt mainly with the question of whether Farmland did not have a right to Ciba-Geigy's data for registration purposes under the patent license agreement. Ciba-Geigy denied that there was any such right, or that any such right was intended, since Farmland never raised the matter of using Ciba-Geigy's data for registration purposes during the patent license negotiations, and the patent license agreement did not include any rights to use Ciba-Geigy's data. CG Ex. 23, pp. 5-6, and Exs. 7 and 8 thereto. The discussions never reached the point of negotiating over the amount of compensation, assuming some compensation was payable, one possible reason being that Ciba-Giegy was unwilling to name an amount at that time. CG Ex. 23 (Ex. 8).

Ciba-Geigy, nevertheless, in pursuing its theory that reasonable compensation should be determined by reference to negotiations between the parties and not by cost, has attempted, as a starting point for determining reasonable compensation, to construct a situation where Ciba-Geigy as "willing seller", and Farmland as "willing buyer", would initially be negotiating reasonable compensation in 1975, when the registrations were obtained. According to Ciba-Geigy's expert witness, Dr. Stobaugh, Farmland, in making a rational business decision in 1975, between whether to do its own testing or pay Ciba-Geigy for the use of data, could have paid up to

\* for the data on the basis of its expected profits from atrazine. The data would have had this value to Farmland, because Farmland would have saved about \$2.7 million in not doing its own testing, and, also, since it was able to enter without having to take three years to do its own testing, would have expected to receive a "pre-tax incremental cash flow" (i.e., additional cash receipts attributable to atrazine sales) of \* which it would not have received if it had done its own testing.

On the other hand, according to Dr. Stobaugh, Ciba-Geigy would not have been willing to sell its data for a payment of less than \* spread over a three-year period, because that represents the incremental cash flow lost by Ciba-Geigy as a result of Farmland's early entry into the market by being able to use Ciba-Geigy's data. The amount proposed

<sup>38/</sup> Tr. Vol. 4 at 56; CG Ex. No. 15, pp. 13-18; CG Ex. 16, pp. 44-48. The \$2.7 million (actually \$2.6 million) is based upon Ciba-Geigy's actual testing costs adjusted to costs in 1975. CG Ex. 19A (Ex. A, p. 12). The \* is the amount Dr. Stobaugh stated Farmland could have paid and not, as Ciba-Geigy asserts (post-trial brief at 107), the amount it would have "willingly" paid, since the figure assumes that all cash profit generated by atrazine sales during the three-year period would have been paid over to Ciba-Geigy. See Tr. Vol. 4 at 56. Dr. Stobaugh believed that giving Ciba-Geigy about one-half the profit would be a reasonable royalty. Tr. Vol. 4 at 58-59. The alternative amount of \$13.06 million, which Ciba-Geigy asserts, on the basis of Dr. Lipschutz's calculations, Farmland would have "agreed" to, also appears to assume that Farmland would have been willing to give up all its profits for the three-year period. Post-trial brief at 109. Dr. Lipschutz would have also allowed Farmland about one-half its estimated profit. FOOTNOTE CONTINUED ON NEXT PAGE

by Ciba-Geigy of \$8.11 million is then offered as a reasonable compromise which fairly accounts for the benefit gained by Farmland and the loss suffered by Ciba-Geigy, and one which the EPA should accept in its role as arbiter between the parties.

Ciba-Geigy's estimate of what Farmland would have been willing to pay  $\frac{39}{}$  for the data in 1975, is, of course, pure speculation. But I have a more basic problem with Ciba-Geigy's approach than determining how plausible are its estimates. Ciba-Geigy's formula is really a rough marginal analysis

38/ CONTINUED:

CG Ex. 16, p. 47.

Besides the cash flow generated by early entry, Ciba-Geigy argues that another benefit to Farmland from purchasing the data would be that Farmland saves the risk of failure in producing satisfactory data. Dr. Stobaugh and Mr. Goldscheider also mention benefits to be gained by obtaining production and marketing experience sooner than if Farmland had to wait three years. CG Ex. 15, p. 4, CG Ex. 22, p. 13. But there is nothing in the record to indicate what value could or should be attributed to these unmeasureable and intangible benefits, in and of themselves.

39/Farmland has refused to produce the investment proposal for its atrazine plant which was presented to Farmland's directors in January 1975. F. Ex. 44. Ciba-Geigy has requested, therefore, that in the alternative, I draw the inference, pursuant to Section 15(b) of the rules of procedure, that Farmland's projected atrazine sales, return on investment, and profits in the investment proposal show, as Ciba-Geigy claims, that it would have been more economically advantageous for Farmland to pay Ciba-Geigy \$8 million for the data than to enter the market by doing its own testing. The proposal, however, could not have considered the \$8.11 million payment, since Farmland's plans to build its own atrazine plant seem to have been made on the assumption that it could rely on Soluja Ltee's data, which Soluja Ltee had made available to Farmland without charge. Tr. Vol. 9 at 91-94; F. Exs. 19, 22 23. Consequently, while Farmland's refusal to produce its investment proposal would support the inference that Farmland anticipated substantial profits from its atrazine sales, the inference that Farmland would have been willing to pay Ciba-Geigy over \$8 million for test data instead of either doing its own testing, or possibly simply abandoning its plans to build an atrazine plant would be too tenuous. To draw such an inference, I would have to conjecture not only what projections Farmland's officials would have made if they included the \$8 million cost in their plans, but also what decision Farmland's directors would have reached if they had to take into account such payment. See Tr. Vol. 9 at 96-98.

for finding the point at which the gain to Farmland in purchasing data from Ciba-Geigy arguably exceeds the gain to be realized by Farmland in producing 40/
its own data. As calculated by Ciba-Geigy, the value arrived at of \$8.11 million would divert to Ciba-Geigy's benefit the money that would otherwise be spent for unnecessary and duplicate testing, and, in addition, saddle Farmland with the expense of paying a royalty on its sales for two and one-half to three years after the patent period, which the royalty Ciba-Geigy was getting from its licensees under the patent. The effect of the formula, therefore, is not only to make Farmland bear the full expense of Ciba-Giegy's testing costs but also to extend the rewards for Ciba-Geigy's research and development of atrazine beyond the period allowed by the patent grant. The data, in short, does not come cheap, and meeting federal testing requirements is made more expensive for Farmland than for Ciba-Geigy on the rationalization that it is more profitable for Farmland to purchase data than to produce it.

<sup>40/</sup> The gain to Farmland in entering the atrazine market is estimated by Ciba-Geigy to be about a 20% return on its investment. CG Ex. 16, pp. 44-48. Since Farmland would appear to save nothing in testing costs under the formula (there being no reason to assume that Ciba-Geigy's \$2.6 million is less than what Farmland would have had to pay to produce its own data), the marginal analysis is really directed to what value should be placed on Farmland's entry into the market earlier than if it had to produce its own data.

<sup>41/</sup> The \$5.51 million charge for early entry amounted to 10% of Farmland's gross sales during 1976, 1977, and 1978. See Ciba-Geigy's post-trial brief at 69-70. The royalty Ciba-Geigy was charging its licensees in 1975 was F. Ex. 5, pp. 54-55.

The exclusionary effect of such a formula cannot be ignored, although it may not give the absolute power to exclude which Ciba-Geigy had under its patent. The \$8.11 million payment increases Farmland's initial investment cost in becoming an atrazine producer from \$13 million to \$21 million, an increase of about 62%. Regardless of how sanguine Farmland's management were about their prospective profits from atrazine in 1975, the magnitude of the additional cost is such that the testimony of Farmland's official that Farmland would have reconsidered its decision to produce its own atrazine if it meant incurring this additional \$8.11 million cost cannot be discounted. The models presented by Drs. Stobaugh and Lipschutz to show that in 1975, it would have been more economically advantageous for Farmland to pay \$8.11 million for Ciba-Geigy's tests than for Farmland to do its own testing, simply elide over a third possibility that Farmland would not have been willing to either risk a \$21 million investment, or take what Ciba-Geigy asserts is the more

<sup>42/</sup> See Tr. Vol. 9 at 96-98. The asserted reasonableness of \$8.11 million is calculated on the basis of Farmland's actual sales of 28 million pounds (as estimated by Ciba-Geigy) over the first three years of operation at the prices in effect during that period (the price having dropped from \$2.33 a pound in 1976 to \$1.66 a pound in 1978). I am assuming that this \$8.11 million approximates what Ciba-Geigy would have requested as a payment in any negotiation with Farmland in 1975, on the basis of Farmland's anticipated sales. I am further assuming that Ciba-Geigy's evaluation of the data is based on what Farmland as a willing buyer would have paid when Farmland was considering entry into atrazine production, and is not based upon the fact that a higher price than Ciba-Geigy would otherwise have requested was justified by the situation in which Farmland found itself after it had constructed its atrazine plant and had discovered that Soluja Ltee's data, which it had intended to rely upon, was not adequate to support its registrations.

costly alternative of waiting three years while it produced its own tests. It seems fair to assume, since Farmland's entry admittedly threatened a loss of business to Ciba-Geigy, that if, in any negotiations in 1975, Farmland, concluding that purchasing the data from Ciba-Geigy made entry too costly, had abandoned plans for producing its own atrazine, Ciba-Geigy not only would have been totally unconcerned about this happening, but might well have welcomed it.

It may still be true that Farmland in 1975 would have been willing to pay more than \$49,500 for the data. I find, however, that trying to decide how high a price the data originator can charge before it becomes more economically advantageous for the user to do its own testing is not the way reasonable compensation is to be determined under Section 3(c)(1)(D). Such a formula differs from the exclusive use of data in that some concessions are made to the data user in order to discourage duplicative

<sup>43/</sup> Although atrazine had an established market, entry into the market was not risk-free. In fact, Farmland lost money on its atrazine sales during two out of the first three years of operations. F.Ex. 11 (Ex. 1). Dr. Lipschutz would apparently concede that Ciba-Geigy's formula has an exclusionary effect for new entrants who are "so inefficient" that they cannot consider entering the market for the registered pesticide if they have to pay to develop their own registration data. CG Ex. 16, p. 34, n. 13. The only efficiencies apparent are those of scale, i.e., expected pesticide sales must be large enough to justify testing costs. Ciba-Geigy developed its data during the 17 years it had a virtual monopoly through its patent on atrazine. Its expected sales were undoubtedly large enough to justify testing costs totalling \$2.6 million (in 1975 dollars). Farmland would have been asked to pay a sum over three times as large for its much smaller volume of sales.

testing, but the user's right to obtain the data is really subordinated to the claimed need to protect the profits of the data owner in order to encourage further research and development in pesticides. This was also the justification made for exclusive use of data. Such approach construes too narrowly Congress' purpose in rejecting exclusive use for data which is neither confidential nor trade secret and less likely to represent an innovative contribution to pesticide research and development. Cf. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 476 (1974). In providing for the mandatory licensing of such data, it would appear that Congress was concerned with minimizing the burden on pesticide producers and distributors of meeting expensive governmentally imposed testing requirements, and not with adding to the profits of data owners by allowing them to charge the maximum price for data the user will pay. Understandably, Congress saw it as a needless waste of resources to insist that the EPA wear blinders in evaluating the registerability of a pesticide and require expensive testing when it already had in its files proof that the pesticide was safe and effective. At the same time, Congress was unwilling to have a system in which all the data costs would be borne by the first registrant who sought to register a new pesticide or a new or more efficient use for an existing pesticide, because of the dampening effect such a system could have on pesticide research and development. The purpose of reasonable compensation, therefore, is to spread the burden of meeting costly testing requirements fairly and equitably among all producers who benefit from the test data. The patent laws and exclusive

<sup>44/</sup> Supra, at 21-22.

rights to test data that are confidential or trade secrets, are to be the 45/
means for rewarding invention and innovation in pesticide research.

This seems a more reasonable interpretation of what Congress intended by reasonable compensation than that given by Ciba-Geigy which would make any amount of compensation reasonable that can be shown to offer the buyer some advantage, no matter how slight or questionable, over doing its own testing. Under Ciba-Geigy's construction of Section 3(c)(1)(D), the buyer appears to gain little, if anything at all, by the right to obtain use of the data through mandatory licensing when it cannot conclude a mutually agreeable price with the data owner. To accept Ciba-Geigy's construction would be contrary to the principle that a statute should not be construed to produce an absurd or negative result. See United States v. Mendoza, 565 F.2d 1285 (5th Cir. 1978); Application of the United States, 563 F.2d 637, 642 (4th Cir. 1977).

It is to be noted that my construction of Section 3(c)(1)(D) is similar to that reached by the court in <u>Mobay Chemical Corp.</u> v. <u>Costle</u>, 12 Envir. Rep. Cas. (BNA) 1572 (W.D. Mo., 1978) (three judge court), <u>appeal dismissed</u>, 439 U.S. 320 (1979). Mobay dealt with the question of whether the 1975

<sup>45/</sup> Ciba-Geigy argues that Section 3(c)(1)(D) was enacted because Congress was "painfully aware" of the inadequacy of the patent laws in 1972. Post-trial brief at 132. Insofar as concern was expressed about the inadequacy of the patent law, it was in connection with opposing the proposal to delete the provision making all data subject to exclusive use. See <a href="supra">supra</a> at 21. There is no evidence in the legislative history that Congress believed that patent rights, or in their absence exclusive use of data, would be inadequate to maintain research and development in pesticides. It is to be noted that in amending Section 3(c)(1)(D) in the Federal Pesticide Act of 1978, <a href="supra">supra</a>, at 27. Congress appears to have considered the protection given both by the patent laws and by exclusive use as an adequate reward for a registrant's innovation. See statement by Senator Leahy on consideration of the conference report on S. 1678, <a href="Senate Comm">Senate Comm</a>. on Agriculture, Nutrition, and Forestry, Federal Pesticide Act of 1978, <a href="95th Cong">95th Cong</a>, 2d Sess. 2-3 (Committee Print 1979).

amendment to FIFRA, which required compensation only for data submitted on or after January 1, 1970, and imposed no restrictions on the use of data submitted prior to 1970, amounted to an unconstitutional taking of property. In ruling that there was no unconstitutional taking of property, the court found that Section 3(c)(1)(D) was for the public purpose of fairly allocating the burden of producing governmentally mandated data, and was not concerned with insuring maintenance of competitive commercial positions of the original submitters of data.

<sup>46/</sup> Mobay v. Costle, supra, 12 Envir. Rep. Cas (BNA) at 1578. Supreme Court dismissed the direct appeal in Mobay for lack of a substantial question on the constitutional validity of the statute, finding that plaintiff was really attacking agency practice under the statute. 439 U.S. at 320-21. Dismissal, accordingly, would not appear to affect the merits of the district court's decision in refusing to enjoin the agency from considering pre-1970 data without payment of compensation. See R. Stern and E. Gressman, Supreme Court Practice 50-51 The same reasoning that upheld the constitutional validity (3rd Ed. 1962). of the statute as construed by the three-judge court seems equally applicable But Cf.. Chevron Chemical v. Costle, to agency practice under the statute. No. 79-532 (D. Del. June 5, 1980), where in sustaining the Agency's right to consider pre-1970 data under the 1978 amendments to FIFRA, the court held that it would not reach the question of whether doing so without payment of compensation would be an unconstitutional taking of property, since the question should be considered in a claim filed under the Tucker Act. Slip op. at 8-9. In Union Carbide Agricultural Products Co., Inc., v. Costle, 481 F. Supp. 195 (S.D.N.Y. 1979), appeal pending No. 79-6200 (2d Cir., filed 1979), cited by Ciba-Geigy, the court did grant a preliminary injunction on constitutional grounds against the EPA disclosing and using trade secret and confidential data submitted to the EPA prior to October 1, 1978, finding that such data was property within the intendment of Fifth Amendment protection. 481 F. Supp. at 199. The case, however, is probably distinguishable since Section 3(c)(1)(D) applies only to use of the data, and disclosure of the data is not necessary in order for the Agency to consider it in evaluating the safety and efficacy of the me-too registrant's products.

Ciba-Geigy disavows any intention to protect its profits or competitive position and argues that it is seeking only to protect its property rights in the test data. It asserts that to require it to accept less than the fair value would be confiscatory, would give Farmland a "free ride," and would discourage research and development in pesticides.

The only "proprietary right" given up by Ciba-Geigy in the data is the right to exclusive use of the data in obtaining a federal registration, since Ciba-Geigy still retains possession of the data and the full use of it. Ciba-Geigy assumes that aside from Section 3(c)(1)(D), it has some inherent property right to prevent the EPA from considering the data in granting registrations to others. Such an assumption seems unfounded. Instead, it would appear that whatever right of compensation Ciba-Geigy has attaches because of Section 3(c)(1)(D). On this point, I am fully in agreement with the following reasoning of the court in Mobay Chemical Corp. v. Costle, supra, 12 Envir. Rep. Cas. (BNA) at 1579-80:

[The] sole property interest which plaintiff claims is diminished by the 1970 cutoff data of Sec. 3(c)(1)(D)is an alleged right to exclusively use the data; that is, to prevent others from using it. Defendant responds that plaintiff does not possess such a right, under the Constitution or the common law. Whether or not plaintiff possesses a right to exclusive use of its property within the bundle of rights which make up property ownership, this Court finds that the interference of Sec. 3(c)(1)(D)with that alleged "right" does not rise to the level of a taking of plaintiff's property. This Court simply cannot reasonably conclude that the Administrator's mere consideration of data which is required by and which he already possesses pursuant to a lawful regulatory scheme in order to determine the registrability of a pesticide product--that is, to assure its efficacy and safety prior to its transportation in interstate commerce--without

disclosing the contents of that data to any other person and without diminishing in any manner the originator's use of its own data violates the Fifth Amendment to the United States Constitution. (footnote omitted) 47/

In short, it is most doubtful what the "fair market value" of the exclusive right to use the data would be absent Section 3(c)(1)(D). If, as appears, the right to reasonable compensation is a legislative grant, then whether the compensation is "confiscatory," because less than what the data owner thinks it can obtain, is irrelevant,

Perhaps trade secret or confidential data involving special techniques in analyzing, testing, or producing atrazine, may have a "proprietary" value which is diminished by using the data to register the products of another registrant. Whether or not this would justify valuing such data differently from other data in determining compensation is not an issue in this case. See supra at 18.

<sup>47/</sup> The case of Kaiser Aetna v. United States, U.S., 62 L. Ed. 2d 332 (1979), is readily distinguishable. In that case, the government action created a public right of access to what hitherto had been a private pond, thereby significantly interfering with the enjoyment and use of the pond by the owners who had developed it in order to exploit it as a private marina. The EPA's consideration of Ciba-Geigy's data to grant registrations to others in no way interferes with Ciba-Geigy's use of the data to obtain registrations or for other business purposes, such as to support advertising claims or to defend against product liability claims, and it is for such uses that the data really appears to have been developed by Ciba-Geigy, and not for the purpose of selling the data to others. Further, not every regulation of property which affects in some way the value of the property rises to the level of a taking of property requiring the payment of compensation. See South Terminal Corp. v. EPA, 504 F. 2d 646, 678-79 (1st Cir. 1974); Mobay Chemical Corp. v. Costle, supra.

<sup>48/</sup> Certainly this would appear to be true in the case of data which is not protected by Section 10 as trade secret or confidential, and therefore presumably would have been publicly available once it was filed with the EPA, since Ciba-Geigy does not claim that any of it is subject to copyright protection. An example is the efficacy data obtained through research done by research cooperators at land-grant universities or colleges, with the financial support of Ciba-Geigy alone or in combination with other pesticide companies for which Ciba-Geigy claims compensation. Ciba-Geigy does not have any ownership rights in such data and the information would appear to be available to the public. See Tr. Vol. 2 at 56, 153-54, Vol. 6 at 38-42. For the reasons stated below at 56, I find that such data is nevertheless compensable to the extent that Ciba-Geigy contributed to its production.

unless Congress intended compensation to be awarded on that basis. I find nothing in the legislative history or in the statute to warrant ascribing such an intention to Congress.

In any event, I am not persuaded that Ciba-Geigy has shown that \$8.11 million is a reasonable price for the data so that Farmland would have been willing to pay this price rather than do its own testing. Dr. Stobaugh and Dr. Lipshutz have made plausible arguments as to why, from the viewpoint of Ciba-Geigy, it would have been to Farmland's economic advantage to pay \$8.11 million. But Ciba-Geigy's interest really lies in protecting its profits in atrazine and not in making a sale of its data. Whether Farmland would have been persuaded by the arguments made by Dr. Stobaugh and Dr. Lipschutz to pay \$8.11 million is another matter, depending on how it weighed the relative advantages and disadvantages and how it wished to allocate its resources. It would be presumptuous of me, assuming I could intelligently do so, to "second-guess" the decision-making of Farmland's management if they had been presented with the option of Farmland paying \$8.11 million or doing its own testing. I seriously question whether Congress ever intended reasonable compensation to be determined in such a fashion.

<sup>49/</sup> The economic loss to Ciba-Geigy caused by mandatory licensing, which is stressed by Ciba-Geigy and its expert witnesses as making the \$8.11 million reasonable from the standpoint of Ciba-Geigy, is not the inability to recover its testing costs, but the loss of sales and profits caused by Farmland's entry as a producer. See Ciba-Geigy's post-trial brief at 110-15. Indeed, the \$8.11 million would amount to more than 300% profit on the cost of producing the data, using 1975 costs. Moreover, the actual cost of the data may well have been recouped in the sales of atrazine. Ciba-Geigy admits the price paid by distributors for atrazine may include some part of the value of the research data. Reply brief at 39.

<sup>50/</sup> The certified public accountant who audited Farmland's books and appeared to be familiar with the financial analyses used by companies to make investment decisions never heard of the "net incremental pretax cash flow" analysis used by Dr. Stobaugh. Tr. Vol. 8 at 130.

Similarly, Mr. Goldschieder has given some logical rules for bargaining in negotiating licensing agreements involving technology transfers. Assuming the analogy to licensing of "know-how" is apt, even though no technical information is actually disclosed to Farmland, Mr. Goldschieder's testimony does not really help in deciding where the bargain will actually be struck.

Ciba-Geigy argues that the fact that Farmland was willing to pay a 10% fee for selling atrazine while the patent was in effect is proof of the market value of the data. But Farmland could not have sold atrazine either as a distributor or otherwise without the license. It does not necessarily follow that Farmland would have been willing to pay a 10% royalty for the privilege of selling atrazine produced by it sooner than it would otherwise be able to do. Nor is the fact that Farmland made a choice to go ahead with registration by relying on Ciba-Geigy's data any indication of what sum it would have been willing to pay. The law at the time as to what constituted reasonable compensation was unknown, and, in fact, this is the first case to pass upon the question. That it may have been willing to proceed on the risk of having to pay some compensation does not mean that it would have proceeded with registration if it knew that it would have had to pay \$8.11 million.

<sup>51/</sup> It may be true that Farmland, if it had negotiated with Ciba-Geigy before proceeding with registration, could have found out what Ciba-Geigy's asking price was although Ciba-Geigy was unwilling to name an asking price in July 1975, and, in fact, apparently did not decide upon its formula of reproduction cost plus a royalty until 1978 or 1979. See CG Ex. 23 (Ex. 8); Tr. Vol. 8 at 6. Ciba-Geigy admits, however, that any bargaining would have been fruitless, because the price at which it would have been willing to sell the data was far greater than Farmland would have been willing to pay. Post-trial brief at 112. It could well be that Farmland surmised as much from the few conversations it appears to have had with Ciba-Geigy, see CG Ex. 23 (Exs. 7 & 8), and decided to rely on compensation as determined by the EPA. It is to be noted that at that time the EPA construed compensation as applying only to data submitted to the EPA on or after October 21, 1972. FOOTNOTE CONTINUED ON NEXT PAGE

I find, accordingly, that Ciba-Geigy's formula of total cost plus a royalty payment for the privilege of early entry is not an appropriate method for determining reasonable compensation. It is premised on the claim that Congress' predominant concern in enacting Section 3(c)(1)(D) was to protect the data originator's "proprietary right" to profit from the data. I find nothing in the legislative history to support this claim. What the legislative history indicates is that Congress was as much concerned with not imposing unnecessary testing costs as with compensating data producers. I must, therefore, reject a method which subordinates the interest of the data user to the interest of the data originator.

It remains then to examine the cost-sharing formula proposed by Farmland. Farmland contends that compensation should be determined by apportioning the original cost of the data according to the respective market shares of the parties. In 1975, converting production figures in the record to their dollar value, Farmland asserts that its market share was 6.4%. Farmland should, therefore, pay 6.4% of the original cost of such data is as properly compensable. According to Farmland, compensation so computed would amount to \$49.500.

The EPA also stated that the purpose of Section 3(c)(1)(D) was to assure a "degree of protection" for the data developer's investment in procuring the data, but that it was not intended "to limit fair economic competition nor extend existing protecting of inventions beyond that already provided by patent and similar laws." Interim Policy Statement, 38 Fed. Reg. 31862 (Nov. 19, 1973). Regardless of whether the EPA's interpretation of Section 3(c)(1)(D) was correct, there is nothing in the statement to indicate that compensation would be as large as that claimed by Ciba-Geigy. To the contrary, the EPA's interpretation would seem to lend more support to Farmland's position on compensation than to Ciba-Geigy's.

<sup>52/</sup> See Ciba-Geigy's post-trial brief at 74, 82.

<sup>53</sup>/ Farmland's proposed conclusions of law at 10-12.

For reasons hereafter noted, I find this method more in line with what Congress intended than Ciba-Geigy's method. As proposed, however, it seems slanted in favor of the data user. I am, accordingly, making the following modifications in the method:

First, I agree with Ciba-Geigy's contention that compensation should not be based on original cost but on cost adjusted to account for inflation between the time the cost was incurred and 1975, when the registrations were granted. Contrary to what Farmland contends (proposed findings at 87), this would not result in an inflationary windfall to Ciba-Geigy, but would merely insure that Farmland's payment of what is determined to be a fair share of the cost is equal in value to what Ciba-Geigy spent.

Second, I agree with Ciba-Geigy that it would be unfair to apportion 54/
costs on the basis of Farmland's 1975 sales. EPA granted Farmland's atrazine registrations in the second half of 1975. The major selling season for atrazine, however, would appear to be the spring which is the growing season for the major crops (corn and sorghum) on which atrazine is used.
Ciba-Geigy asserts that 1976 production figures should be used. Instead,
I find that sales data for 1977 and 1978 more accurately reflect what

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<sup>54/</sup> I also agree with Ciba-Geigy that production figures are more accurately stated in pounds rather than in dollars as Farmland has done.

Farmland's market share is likely to be. As so computed, Farmland's  $\frac{55}{5}$  share of the cost is 9.5%. Reasonable compensation, accordingly, will be assessed by taking 9.5% of the 1975 cost of the data subject to compensation as determined below. Although referred to herein, as "cost-sharing", it is not strictly such since it is based on cost adjusted for inflation.

Another method for determining Farmland's share of the cost, which should be considered although not proposed by either party, is to divide the cost equally among all data users. In this case, Ciba-Geigy has identified 25 other companies against whom it has filed claims besides Farmland.

<sup>55/</sup> Farmland's atrazine sales for 1977 and 1978, including sales by its subsidiaries, as estimated by Ciba-Geigy, were 20,000,000 lbs. Total atrazine sales by all companies including Farmland and Ciba-Geigy as estimated by Ciba-Geigy for that period would come to 211,444,000 lbs. CG Ex. 20, p. 5. Logically, the universe for determining proportionate shares should be confined to sales by all users of Ciba-Geigy's data. In this case, however, using total sales is probably justified because the sales by companies other than Farmland and Ciba-Geigy may well include sales by companies who also relied on Ciba-Geigy's data. While the record does not disclose whether there was atrazine data in the EPA's files from other companies, Ciba-Geigy appears to have been the only company to have submitted a substantial amount of atrazine data. One other company, Soluja Ltee, filed a claim for compensation for the atrazine data. The record shows that Soluja Ltee had little or no data on file with the EPA. See. Tr. Vol. 1 at 150-151, Vol. 9 at 93; CG Ex. 23 (Ex. 1). In fact, Ciba-Geigy has filed a claim against Soluja Ltee for use of its data. F. Ex. 39.

<sup>56/</sup> See infra, at 47-58.

<sup>57/</sup> F. Ex. 13, pp. 27-28; F. Ex. 39. In addition, there may be companies who have used the data with Ciba-Geigy's consent and who have paid no compensation. Ciba-Geigy has refused to produce information about the companies who have been permitted to use the data without payment of compensation on the grounds that the information is privileged and its relevancy has not been shown. F. Ex. 13, p. 28. Such information has not been found to be relevant in determining compensation by apportioning costs on the basis of market shares. Whether it would be relevant if compensation were to be determined by an equal division of costs among all users has not been considered.

Conceivably, Farmland's share could be determined by assuming that the cost should be divided equally between Farmland, Ciba-Geigy, and these 25 other companies so that Farmland will pay a twenty-seventh share of the  $\frac{58}{}$  Cost. Alternatively, the cost could be divided equally between Farmland and Ciba-Geigy, on the assumption that as claims are determined against other users, the payments made by each user will be pro-rated to make an equal division of costs between that user and the other users who have paid compensation.

There are, of course, practical problems in dividing the costs in this  $\frac{59}{}$  fashion. Aside from this, however, it seems more equitable to pro-rate the costs according to the benefit each user derives or expects to derive from the data, and sales would appear to be a good measure of the benefit. Considering the benefit to the user in apportioning the cost of the data, however, is a

<sup>58/</sup> There is no way of knowing, however, whether these will be all the companies that will rely on the data. Even as to these 25 companies, whose compensation presumably is still to be determined, it is not known whether the same quantity of data, or a lesser quantity, or a greater quantity will have been relied on in each case, and this probably cannot be known until the claims have been decided. Assessing the cost on a straight, per-capita, basis, when all companies have not used the data to the same extent, would have the inequitable result of making a company which has used only a small part of the data pay as much as a company which has relied on a large amount of the data. Also, many of these companies are apparently formulators only and not basic manufacturers or importers, and this could also present a problem since Ciba-Geigy has indicated that it might seek compensation against such companies on a different basis. Tr. Vol. 8 at 8-9.

<sup>59/</sup> See testimony of Dr. Lipschutz, CG Ex. 16, pp. 23-25.

different matter than utilizing the benefit to the user as a justification  $\frac{60}{}$  for awarding compensation in excess of cost, as Ciba-Geigy has done.

Ciba-Geigy argues that limiting compensation to some share of cost is not reasonable under Section 3(c)(1)(D) because it does not compensate a data originator either for its risks in undertaking research and development, which risk the data user is spared, or for the expense of maintaining the specialized facilities which it devotes to doing research and development, which expense a company such as Farmland does not have. The costs do take into account the employment of Ciba-Geigy's resources to produce the data, including research and development overhead. No allowance is made for a profit to reward research and development or the acquisition of "know-how" over and above that realized from the sale of the pesticide itself, but it does not follow that this offends Section 3(c)(1)(D), simply because it may have an effect on a company's commitment to do future

<sup>60/</sup> Dr. Lipschutz argues that sales-based cost sharing would have to be carried out on a post-assessment basis, taking each firm's total sales over some assumed compensable life of the data. CG Ex. 16, p. 26. Perhaps this would be a more accurate way of doing it, but it seems to be needlessly complicated. When there is sales data in the record, as there is in this case, I do not see why the allocation cannot be based on this data unless there is reason to believe that it unfairly favors either the data user or the data originator. There is no reason to distrust Farmland's 1977 and 1978 sales of 10,000,000 lbs. per year, because that is the capacity of its plant. While the total annual sales may thereafter change, up or down, with corresponding changes in the market shares, that is a risk that both companies share, and therefore one which it does not seem unfair to impose on them. It is to be noted that Dr. Lipschutz had no problem in advocating a prospective approach in his calculations of reasonable compensation.

<sup>61/</sup> See CG Ex. 17.

research and development, as Ciba-Geigy argues it will do. Future research and development in atrazine, or for that matter in any pesticide, will undoubtedly be governed by the relationship which the costs invested in the work bear to the expected profit to be gained from its results, such as a new pesticide or an improved way of using it. Cost-sharing affects the cost side of the equation, specifically the cost of meeting governmentally imposed testing requirements. Reducing the costs to the data originator of doing the testing to meet registration requirements by apportioning these costs fairly among all users of the data, should certainly provide more incentive to the data originator to incur such costs than if the costs had to be borne entirely by the data originator with its competitors getting a "free ride."

On the profit side of the equation there are the competitive advantages to be gained from patents and the exclusive use of trade secrets where  $\frac{62}{}$  applicable. If, notwithstanding these incentives, cost-sharing does have some adverse incremental affect on research and development by lowering the data-originator's expectation of profit which could be gained from the sale of the data, this is counter-balanced by the elimination of unnecessary testing costs thereby reducing the total amount of resources expended

<sup>62/</sup> Ciba-Geigy argues that the large profits it admittedly made on atrazine during the years of patent protection are irrelevant to consideration of compensation under Section 3(c)(1)(D). They are not irrelevant, however, if compensation is being justified on the ground that the patent system no longer adequately rewards research and development in pesticides. Certainly, the profits made by Ciba-Geigy on atrazine would seek to disprove any claim that the research and development efforts resulting in the data at issue in this case were not adequately rewarded. See testimony of Dr. Oscar H. Johnson, F. Ex. 4, pp. 9-14. Dr. Johnson's estimate of Ciba-Geigy's profits on atrazine does not appear to be seriously disputed.

in meeting government testing requirements. Cost-sharing, therefore, does appear to carry out Congress' purpose in enacting Section 3(c)(1)(D), since it recognizes both the private interest of the data producer and the equally important public interest of keeping costs of entry into the pesticide business attributable to government regulation as low as possible.

The cost-sharing standard applied here does not ignore the change made in Section 3(c)(1)(D), as finally enacted, by substituting "reasonable compensation" for "reasonable share of the cost." The reading that seems to most accord with the legislative history is that Congress did not intend to repudiate cost-sharing, but to permit the Administrator to determine whatever compensation seemed reasonable under the circumstances, which could be a share of the cost, or less than or greater than a share of the cost, when the parties could not agree upon compensation. The compensation awarded here is not strictly cost-sharing but costs adjusted to protect Ciba-Geigy against the inflation intervening between the time the costs were incurred and the time the data was used. I have found no basis in this record, however, for awarding compensation in an amount greater than 9.5% of these adjusted costs. Compensation in this amount is found to be eminently fair and reasonable under the circumstances presented in this case.

data originator's right of judicial review by providing that his right of compensation should not be reduced on appeal to the District Court. But this is to be considered in conjunction with the conferee's explanation that they concluded that the Administrator is in the best position to determine the proper amount of reasonable compensation." See p.25 supra. In other words, the change in judicial review was probably to protect the data originator against the Administrator setting too low a compensation. Certainly, it cannot be deduced from this procedural change that Congress intended to limit the Administrator to the fair market value method advocated by Ciba-Geigy.

## B. Data Subject to Compensation

Ciba-Geigy has claimed compensation for data included in 43 separate  $\frac{64}{}$  data submissions made to the EPA between March 1959 and November 14, 1973. Each data submission was to support a specific registration action.  $\frac{\text{i.e.}}{65}$ , to obtain a new or amended registration or a tolerance.

Farmland first contends that data submitted prior to October 21, 1972, is not subject to compensation even if it was considered by the EPA in granting Farmland's registration, and has requested that I reconsider my decision of June 29, 1979, reversing an earlier decision and holding that data submitted prior to October 21, 1972, is compensable.

I so ruled, after the EPA's interpretation in its Interim Policy Statement, 38 Fed. Reg. 31862 (1973), that Section 3(c)(1)(D) applied only to data submitted after October 21, 1972, which interpretation I had relied on in my prior ruling, had been rejected in two court decisions.

Amchem Prods. Inc. v. GAF Corp., 594 F.2d 470, reh'g. denied, 602 F.2d 724 (5th Cir. 1979), and Rohm & Haas Co. v. Costle, Civ. Action Nos. 78-6, 78-12, 78-3606 (E.D. Pa.) (Bench opinion).

<sup>64/</sup> CG Ex. 19A (Ex. A). Although three Farmland registrations are involved, Ciba-Geigy has counted a test only once even though it was claimed in connection with more than one registration.

<sup>65/</sup> Tr. Vol. 2 at 70.

<sup>66/</sup> Neither of the court decisions was appealed by the EPA. In the case of Dow Chemical Co. v. Velsicol Chemical Corp., FIFRA COMP. Docket Nos. 4 through 18, the Administrator, on May 29, 1980, on the basis of these two court decisions, reversed his previous decision of May 25, 1977, insofar as it limited compensation to post-October 21, 1972 data.

me that my former decision was wrong and I note that the Administrator has  $\frac{67}{}$  reached the same conclusion. I therefore adhere to my decision that data submitted prior to 1972 is compensable.

Farmland argues that even if the court decisions are correct, applying them to Farmland would be an "impermissible retroactive action," since Farmland in obtaining its registrations had justifiably relied on the EPA's then interpretation of Section 3(c)(1)(D) in its Interim Policy Statement that Farmland would only have to pay compensation for data submitted on or after October 21, 1972. The argument appears to be based on a misunderstanding of the effect to be given to EPA's interpretation of Section 3(c)(l)(D) in its Interim Policy Statement. An agency interpretation of law is not conclusive on judicial review and will be given only such weight as the court is persuaded it should have. Skidmore v. Swift & Co., 323 U.S. 134, 139-40 (1944). Farmland, in 1975, when it elected to proceed with registration in reliance on Ciba-Geigy's data, may have acted on the expectation that the EPA had correctly interpreted Section 3(c)(1)(D), as applying only to data submitted after October 21, 1972. It should also have recognized, however, that Ciba-Geigy was claiming compensation for data submitted prior to October 21, 1972, and that there was a risk that the EPA's interpretation may not be correct, particularly as there was no judicial pronouncement on the question, so that Farmland could be held liable to pay for all data relied on. In short, Farmland would not have been justified in assuming that its reliance on the EPA's interpretation of Section 3(c)(1)(D), exonerated Farmland from all liability to pay for

<sup>67/</sup> See <u>supra</u>, n. 66. 68/ See 38 Fed. Reg. 31862 (1972).

data submitted prior to October 21, 1972, if the interpretation turned out to 69/
be wrong. Making Farmland pay for pre-October 21, 1972, then, produces no inequitable result, since it is an eventuality which Farmland should have foreseen, and is unobjectionable, even if imposing such liability at this point does have a "retroactive" effect. See Automobile Club of

Mich. v. Commissioner, 353 U.S. 180 (1957); Cf. Bradley v. Richmond

School Board, 416 U.S. 696 (1972). Indeed, if there is any inequitable result, it would be to continue to adhere in this administrative proceeding to a ruling which on reconsideration is found to be wrong and unlikely to be sustained on judicial review.

The parties also disagree in several respects over which data was, in the words of Section 3(c)(1)(D), "considered by the Administrator in support of [Farmland's] ...application for registration." The problem arises because the EPA made no record of what data was considered, and, in fact, did not actually consult or look at any of  $\frac{70}{}$  Ciba-Geigy's data. The largely informal data requirements and review procedures of the EPA at the time have also constributed to the problem.

<sup>69/</sup> The cases cited by Farmland are inapplicable. Gelpcke v. Dubuque, 68 U.S. 175 (1863), and Chevron Oil Co. v. Huson, 404 U.S. 97 (1971), are cases dealing with the retroactive effect of overruling a line of judicial decisions. Lemon v. Kurtzman, 411 U.S. 192 (1973), concerns the retroactive effect of declaring a statutory provision unconstitutional. There is an obvious difference between reliance on judicial decisions or on a statute and reliance on an agency's untested legal interpretation. See Skidmore v. Swift & Co., 323 U.S. 134, 139-40 (1944). Power Reactor Development Co. v. International Union, 367 U.S. 396 (1961) dealt with an administrative ruling to which the Court gave great weight because Congress had considered the ruling on several occasions and appeared to have acquiesced in it. 367 U.S. at 408-9. There has been no similar Congressional approval of the EPA's interpretation. See Amchem Prods., Inc. v. GAF, supra, 594 F. 2d at 482-83.

<sup>&</sup>lt;u>70</u>/ See Finding 35, <u>supra</u>, at 16.

<sup>71/</sup> See Findings 29-34, supra, at 13-16.

Farmland argues that compensation should be limited to data submitted for registrations of AATREX 80W, AATREX 4L and TECHNICAL ATRAZINE, the products corresponding to Farmland's products, which were for the same uses as were on Farmland's labels, and as to such data only so much as was necessary to support Farmland's registrations. Ciba-Geigy argues, on the other hand, that all data which contained information relevant to Farmland's labelling should be made compensable, because it was supportive of Farmland's labelling, and because Farmland acknowledged reliance on Ciba-Geigy's data and requested the EPA to consider the data in Farmland's registrations without any qualification.

The written statement which Farmland made acknowledging reliance on Ciba-Geigy's data and requesting the EPA to consider the data in support of Farmland's registrations was filed with the EPA pursuant to its requirements in its Interim Policy Statement for processing registrations under the 2(c) method of support. The procedure appears to have been designed to give the EPA the right to review all of the data cited by the claimant which was pertinent to the registerability of the products.

It must be pointed out, however, and Ciba-Geigy does not dispute, that the only data involved in determining Farmland's liability is data which is pertinent to the registerability of the products. The conditions which made it difficult for the EPA to identify the actual supporting test data (Finding 35, <a href="mailto:support">suppar</a>), made it virtually impossible for Farmland to refer, in support of its applications, to specific data previously filed by Ciba-Geigy, except with

<sup>72/</sup> See Interim Policy Statement, 38 Fed. Reg. 31803 (1973); Tr. Vol. 9 at 66, 99-100; F. Ex. 6, pp. 5-6.

the consent and cooperation of Ciba-Geigy. If Farmland had desired to look at Ciba-Geigy's data in the EPA files, it would have had to file a request for it under the Freedom of Information Act, and risk a lawsuit by Ciba-Geigy Consequently, it would be unfair to enjoin disclosure of the information. to Farmland, and certainly not intended by it when it acknowledged reliance on the Ciba-Geigy data and requested the EPA to consider this data, to construe its conduct as admitting reliance on all data regardless of its relevancy to Farmland's registrations.

The criteria for determining what efficacy data was pertinent to the registerability of Farmland's products, and so compensable, was set out by the EPA's Registration Division, in a statement it furnished reconstructing what data in certain data submissions would have been considered by the EPA as having supported Farmland's registrations in 1975. how it selected the data, the Registration Division said that it relied on the following:

- Types of formulations (i.e., wettable powder, liquid, and tank mixes).
- Crops treated.
- 3. Specific areas or states in which the product was tested.
- 4. Methods and rates of application.
- Stage of crop development at time of application.

74/ CG Ex. 8. The Registration Divison's review was confined to those data submissions identified in Ciba-Geigy's claim letters as oo/pp,

rr, and ss (CG Ex. 3 oo/pp, 3 rr, and 3 ss).

<sup>73/</sup> Tr. Vol. 1 at 49. As already stated, the question of whether Ciba-Geigy's test data would be protected from disclosure by former FIFRA Section 10, 86 Stat. 989 (current version at 7 U.S.C.A. 136h) is not an issue in this case. It is to be observed, however, that the test data were only made available to Farmland under a stringent protective order and that most of the data (except for grant research data) has been claimed by Ciba-Geigy to constitute confidential or trade secret information. See Ciba-Geigy's post-trial brief at 80, n. 66. Under FIFRA, Section 10(c), 7 U.S.C. 136h(c), before the EPA can release data claimed to be confidential, it has to give the data owner advance notice and the data owner can then seek a court determination on whether the data is protected by Section 10(b), before it is released.

Neither party appears to have any quarrel with this criteria in general, but their application to specific data is disputed.

Farmland argues that Ciba-Geigy has not shown that the EPA would have reviewed data in submissions made to register a formulation or crop use different than that registered by Farmland and that all data in such submissions should be excluded even though otherwise relevant to Farmland's atrazine labels.  $\frac{75}{}$ This argument appears to be based on the type of data review normally made by the Agency when data was submitted to it by a registrant. In such cases, the data reviewer would usually confine his review to the submissions made to support the application before him, and would not examine previously submitted data unless it was referred to or was necessary to fill gaps in the data submissions in hand.  $\frac{76}{}$ The argument is defective because what is involved here is not a review of a data submission by Farmland, which presumably would be complete in itself, or even a review of specific data references by Farmland, which it considered as adequately supporting its registrations. In those instances, the EPA reviewer may well have limited his review to the data submitted or referred to, so long as the data was adequate to support the labelling. Here, however, Farmland has, in effect, placed all relevant data in Ciba-Geigy's cited submissions before the EPA for review. Ciba-Geigy has shown that the data it has claimed in submissions not specifically

<sup>75/</sup> Thus, Farmland would exclude all data in Ciba-Geigy's submissions made to support granular formulations, and formulations consisting of a mixture of atrazine with another product not in Farmland's labelling, would exclude 80W data used to support the registration of Farmland's liquid atrazine, and would also exclude data in Ciba-Geigy's submissions to support 80W registrations for uses on chemical fallow, turf grasses, macademia nuts, pineapples, lay-by in corn, and range grasses, which crops were not on Farmland's labelling. See Fdg. 27, supra, at 13.

<sup>&</sup>lt;u>76</u>/ See Tr. Vol. 1 at 31, 53-56, 162, 175-76.

pertaining to the products and uses registered by Farmland are relevant to the Farmland registrations. Since Farmland could not have complained if this data had been reviewed, I find that it should be made compensable.

For similar reasons, I also find that Ciba-Geigy has established its right to compensation of all data submissions oo/pp, rr and ss (CG Exs. 3 oo/pp, 3 rr, and 3 ss) claimed by it, even though the Registration Division in its reconstruction omitted some of the data as data it would have considered in registering Farmland's products. The Registration Division, for example, excluded certain data from states different from those specified on Farmland's labels for 80W, and also excluded data on wettable powder in considering the data to support Farmland's liquid (4L) registration. It appears, however, that the Registration Division did overlook the relevancy of this data. Ciba-Geigy has shown, for example, that in the few instances where it included data on states not on Farmland's 8DW label, the data concerned post-emergence tests which would not be affected by soil conditions

<sup>77/</sup> For example, formulations of wettable powder other than 80W appear to be relevant to the efficacy of 80W. See CG Ex. 26, Tr. Vol. 1 at 169. Data relating to the efficacy of 80W was used by Ciba-Geigy to show the efficacy of 4L, on the grounds that the two formulations are biologically equivalent, and biological equivalency does not appear to have been questioned by the EPA. See CG Ex. 19, pp. 16-18; Tr. Vol. 1 at 29-31. Data comparing the performance of a wettable powder with a granular or tank mix formulation would contain data showing the performance of wettable powder. See Tr. Vol. 2 at 22. Data relating to the effectiveness of 80W in controlling weeds on crops not on Farmland's labels, would contain information relevant to controlling these same weeds in crops on Farmland's label or to the non-selective weed control claims on Farmland's labels. See Tr. Vol. 1 at 32-36.

<sup>78/</sup> While Farmland could not as a practical matter have referred to specific items of data cited by Ciba-Geigy, because it did not know what the data submissions contained, it was put on notice by Ciba-Geigy's claim letters that certain submissions referred to products or uses not on Farmland's labelling. See CG 19A (Exs. E-G). Farmland, however, did not disavow any reliance on such submissions in its statement to the EPA. In fairness to Farmland, it is doubtful whether the EPA would have accepted such qualified reliance on the data claimed by Ciba-Geigy, but this would only seem to support the conclusion that the EPA wanted to preserve its right to consider all pertinent data relating to the registrations.

<sup>79/</sup> See CG Ex. 8.

and where the climate was similar to the climate of states on Farmland's  $\frac{80}{}$  label. Ciba-Geigy has also shown that data on the 80W formulation is also relevant to the liquid (4L) formulation. The data, therefore, was relevant and could have been considered by a reviewer, and this appears to be the proper test for determining compensability under the registration procedure used by Farmland.

Farmland also claims that the EPA would not have considered tests using atrazine on sweet corn in registering Farmland's products because it asserts that the EPA did not consider sweet corn to be a crop on Farmland's label. There was originally some confusion within the EPA as to whether the term "corn" on a label meant all corn or only field corn. As of July 1, 1975, however, the EPA had established the policy that "corn" meant all corn including sweet corn. There is some ambiguity in the evidence as to when this policy was put into effect. Farmland, however, does not claim that it intended to exclude sweet corn as a crop on Farmland's label, or that its 80W is not being used on sweet corn. Consequently, any ambiguity should be resolved in favor of Ciba-Geigy. I find, accordingly, that data on sweet corn was relevant to Farmland's label and is compensable.

81/ Supra, n. 77.
82/ See Tr. Vol. 1 at 163-65, 202-04, CG Exs. 14, 29. Some divisions within the EPA construed word "corn" as meaning all corn, while others construed the word as meaning only field corn. Tr. Vol. 1 at 163-65.

<sup>80/</sup> See CG Ex. 19, pp. 20-21.

<sup>83/</sup> CG Exs. 9, 19 (Ex. V), 29. Mr. Taylor from the EPA's Registration Division appeared at first to be under the impression that in 1975 when the Farmland registrations were granted, the herbicide division followed the policy that "corn" meant field corn. Tr. Vol. 1 at 163-65. The letter from Mr. Campt, Director of the Registration Division, however, suggests that the policy had been changed by July 1, 1975, to make the term "corn" mean all corn, and when Mr. Taylor was further questioned on the matter, he admitted that he could not really recall when the change in policy had taken place with respect to processing applications for registration. See CG Ex. 29; Tr. Vol. 1 at 202-04.

Farmland also appears to question the compensability of data submitted to obtain tolerances, since it argues that tolerances are not required by FIFRA but by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C., § 346a, and once established need not be re-established in subsequent registrations of the same pesticide. The tolerances show that atrazine can be safely used on corn, sorghum, sugarcane, and perennial rye grass so long as there are no residues which exceed the limits set by the tolerance. These crops are crops in Farmland's 80W or liquid labels. It is undisputed that Farmland could not have registered its products for use on each of these crops unless tolerances had been established for such uses. The supporting data for these tolerances, therefore, is relevant to the safety of Farmland's products and should be made compensable as data relied on by Farmland and considered by the EPA.

<sup>84/</sup> Farmland's proposed findings, Paras. 7-10. Farmland does not elaborate on what specific data submitted to support a tolerance it would exclude, but presumably the argument relates to data which would be required to obtain a tolerance but not necessarily required to register a product.

<sup>85/</sup> See CG Ex. 19, p. 26; 21 U.S.C. 346(a). The tolerances were established after it was discovered that there were detectable residues on these crops. See Ciba-Geigy's Reply Brief App. A, p. 4; CG Ex. 28.

<sup>86/</sup> See CG Ex. 19 (Exs. Q and R).

<sup>87/</sup> See Tr. Vol. 1 at 87.

<sup>88/</sup> The record does indicate that the data requirements for a tolerance were not identical to the data requirements for registration. For example, it is not clear to what extent the chronic animal studies submitted to support a tolerance would also have been required to support a registration. See Fdg. 33, supra at 15; CG Ex. 19A (Ex. A7). Whether or not data required for a tolerance but not for a registration must be regarded as compensable under Section 3(c)(1)(D) where it is clear that it was not relied on by the me-too registrant in procuring its registration is not decided here. In this case, Farmland, in representing what data it relied on and requested the EPA to consider, made no exception for data submitted in support of a tolerance, although Ciba-Geigy's claim letter did inform Farmland that compensation was being claimed for data submitted in support of tolerance petitions. See CG Ex. 19A (Exs. E-G, items 6 aa, 6 cc, 6 rr). Consequently, the tolerance data, in effect, was submitted in support of Farmland's registrations, and so far as relevant, must be held to be compensable. See Tr. Vol. 1 at 136.

Farmland also guestions Ciba-Geigy's right to compensation for efficacy data obtained through grants to researchers in land-grant universities and colleges. Compensation under Section 3(c)(1)(D), depends on whether the data was submitted in support of an application for registration and then relied on by a subsequent applicant. That is the situation with respect to this data. in Section 3(c)(1)(D), of course, is that there must be some grounds for awarding compensation for the data, and the ground that is stressed in the legislative history is the expense incurred by the data originator in developing the data. The grants by Ciba-Geigy to university and college researchers would appear to be as much a cost of generating data as the costs incurred in testing done internally. It is true that Ciba-Geigy has no ownership or "proprietary " right in the data so obtained.  $\frac{90}{}$ But the legislative concern about the dampening effect on pesticide research if the data originators are not compensated for their research efforts would seem to be equally applicable to this kind of research as well as to the data obtained from private research. Although these grants do not cover the cost or even the major part of the cost of the agricultural research done by these university and college researchers. it does appear that they do play an important part in the decision to do the specific research on efficacy which the data originator desires for its product, and this seems to be the kind of research at issue here. Accordingly, I find that Ciba-Geigy is entitled to compensation for the data it obtained from research done by university and college researchers, which it has included in its claim.

<sup>89/</sup> Ciba-Geigy appears to construe Farmland's objection as being directed only to data produced by researchers which was published. But the objection appears to relate to all data produced by researchers. See, for example, Farmland's objection to the grant data in Submission b, which seems to be made solely on grounds that it was produced by researchers. Farmland's Proposed Finding of Fact 95, and F. Ex. 3. In any event, publication by the researcher would not affect Ciba-Geigy's right to compensation, since Section 3(c)(1)(D) does not make any exception for published data.

<sup>90/</sup> See Tr. Vol. 6 at 40-42.

<sup>91/</sup> See Tr. Vol.6 at 36-42.

Finally, Farmland contends that it should not have to pay for data in four submissions which were not listed in the claims Ciba-Geigy filed 92/ in July 1975, pursuant to the EPA's interim policy. Farmland first received notice that Ciba-Geigy was claiming compensation for these four submissions in Ciba-Geigy's amended Confidential Exhibit 1 to Ciba-Geigy's Rule 2 Statement, which was filed September 14, 1979. Ciba-Geigy argues that these submissions were omitted by mistake from its claim letter, but that nevertheless they should be subject to compensation because they were on file with the EPA and contained scientifically supportive data.

Compensable data in this case has been determined by reference to the interim policy procedures. These procedures were designed to insure that the data considered in support of a "me-too" registration under 2(c) be identified if compensation was being claimed. An essential part of this procedure was that the party seeking compensation file a notice of claim specifying the data for which it wished to assert a right of compensation. The notice then served as the basis for determining the data which the  $\frac{93}{2}$ 

<sup>92/</sup> These are submissions a plus, q plus, s plus and x plus.

<sup>93</sup>/ See 38 Fed. Reg. 31862. On the importance of filing a claim, the EPA said (38 Fed. Reg. at 31863):

<sup>....</sup>In the case of any application proceeding under 2(c), if no notice of claim for compensation is given or if notice of claim is received by the Administrator after the 60-day period, the Administrator will not at any time accept a request to make a determination of reasonable compensation with respect to the claim under Sec. 3(c)(1)(0). It must be recognized that in the case of a product proceeding to registration under 2(c), it may be impossible to determine in the future what specific data if any were considered by EPA in support of the application for registration.

Ciba-Geigy does not quarrel with the reasonableness of these procedures, and, in fact has relied on them. It cannot, however, claim the benefit and yet escape the liabilities resulting from its own failure to comply with the procedures. The claim letter and the acknowledgement made by Farmland in response to it have been the means for determining what data Farmland can reasonably be held liable for under the circumstances where the EPA did not actually examine any data. There is no basis in these procedures either for charging Farmland with liability for data which it did not acknowledge reliance upon, or for assuming that the EPA would have considered data not specifically referred to by Ciba-Geigy in its claims if it had actually reviewed the data.

I find, accordingly, that Farmland is not liable to pay compensation for any of the data claimed in submissions a plus, q plus, s plus and x plus.

I have examined the other objections made by Farmland to the data and have found them without merit. In all such cases, the data claimed has been shown to be relevant and properly included as compensable data.

## C. <u>Determination of Reasonable Compensation</u>

Compensation, accordingly, is fixed at 9.5% of Ciba-Geigy's 1975 cost for the data claimed, totalling \$2,636,024, less the 1975 cost of submissions a plus, s plus, q plus and x plus, amounting to \$52,667. The compensation thus computed amounts to \$245,419.

<sup>94/</sup> Farmland's argument that the EPA would only examine other data in its files when there was a need to do so because of "data gaps" in the submissions specifically being relied on is well taken with respect to data neither cited by Ciba-Geigy in its claim for compensation nor acknowledged by Farmland as data it was relying on. Ciba-Geigy does not claim compensation for these four submissions because they were necessary to fill a "data gap," but only because they were "scientifically relevant."

<sup>95/</sup> See CG Ex. 19, pp. 13-31; Tr. Vol. 2 at 19-46.

<sup>96/</sup> See CG Ex. 19 (Ex. A), p. 12; Ciba-Geigy's reply brief, Appendix, p. 15.

<sup>97/</sup> \$2,636,024 - \$52,667 = \$2,583,357 X .095 = \$245,419.

In this proceeding under the Federal Insecticide, Fungicide and Rodenticide Act, Section 3(c)(1)(D), as amended by the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 979-80, it is hereby determined that the amount of \$245,419, is reasonable compensation for test data produced by Ciba-Geigy Corporation and submitted in support of applications for registration by Ciba-Geigy, and subsequently relied upon by Farmland Industries, Inc., in support of its applications for CO-OP ATRAZINE 80W 80% WETTABLE POWDER HERBICIDE (EPA Reg. No. 1990-377); CO-OP ATRAZINE TECH (Brand of technical atrazine) (EPA Reg. No. 1990-376); and CO-OP LIQUID ATRAZINE (EPA Reg. No. 1990-381). Said amount of \$245,419, shall be paid by Farmland to Ciba-Geigy within thirty (30) days from the date this order becomes final as provided in the rules of procedure issued herein.

Gerald Harwood Administrative Law Judge

August 19, 1980

<sup>98/</sup> Pursuant to Section 29(c) of the rules of procedure issued herein, this order becomes the final order of the Administrator within forty-five (45) days after transmission thereof by the Hearing Clerk to the Administrator unless (1) an appeal is taken by a party to the Administrator pursuant to Section 22 of the Rules; or (2) the Administrator elects, sua sponte, to review the initial decision.

## APPENDIX

Federal Insecticide, Fungicide and Rodenticide Act,
Section 3(c)(1)(D), as amended by the Federal Environmental
Pest Control Act of 1972, Pub. L. No. 92-516, Section 2,
86 Stat. 979-980:

3(c)(1)...Each applicant for registration of a pesticide shall file with the Administrator a statement which includes

(D) if requested of the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 10(b). If the parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstances. The Administrator's determination shall be made on the record after notice and opportunity for hearing. If the owner of the test data does not agree with said determination, he may, within thirty days, take an appeal to the federal district court for the district in which he resides with respect to either the amount of the payment or the terms of payment, or both. In no event shall the amount of payment determined by the court be less than that determined by the Administrator....