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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR 77 JUL 11 A 9: 33

Ciba-Geigy Corporation,

Claimant

v.

Industria Prodotti Chimici,

Respondent

FIFRA COMP. Docket No. 7

Clarification of Scope of Proceeding and Request to File

I

This is a proceeding under section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136a(c)(1)(D), Supp V, 1975), instituted by a claim for compensation filed by Ciba-Geigy Corporation by letter dated June 17, 1974 against Industria Prodotti Chimici for test data allegedly produced by Ciba-Geigy Corporation and purportedly utilized or to be utilized in the registration under the act of Industria Prodotti Chimici's product Atrazine Technical pursuant to an application for registration therefor filed December 27, 1973. Notice of such application, which had been assigned EPA File Symbol 33660-R, was published in the Federal Register May 9, 1974 (39 F.R. 16512). The application and the notice described a technical product containing 96 percent 2-chloro-4-ethylamino-6-isopropylamino-s-triazine and 4 percent inert ingredients.

Pursuant to the authorization and direction of the Acting Administrator, dated October 13, 1976 (41 F.R. 46020), in part, making effective that portion of section 3(c)(1)(D) of the act relating to the determination of claims, the Director of the Agency's Registration Division certified and forwarded the file in this proceeding December 21, 1976 to the Office of Administrative Law Judges and the file and Rules of Procedure promulgated herein were subsequently served upon the parties. After correspondence with the parties, Claimant filed, pursuant to the request of the Administrative Law Judge, a document as to why an accelerated decision should not be issued against it and Respondent filed a reply thereto.

II

Claimant's claim of June 17, 1974 states that the "application giving rise to our claim is designated EPA File Symbol 33660-R as published in the Federal Register, Vol. 39, No. 91, Page 16512, May 9, 1974" and lists extensive data for which compensation is claimed, which data had been submitted to the Agency beginning in 1959 and continuing through 1973. Subsequent to such claim, Respondent, by letter dated May 5, 1975 to the Agency, requested that the Registration Division "withdraw from our registration application data that can be subject of a compensation claim" and "proceed with registration of our product under 2(a) considering that all data we hereby submit to your review are our own data specifically carried out to support our application."

On July 19, 1976, a registration was issued for Respondent's product, EPA Reg. No. 33660-1, the Notice of Registration therefor containing the following notation:

Note that this submission was processed and accepted under the 1947 Federal Insecticide, Fungicide, and Rodenticide Act. At such time as re-registration is required or amendments are proposed, the Registration, Re-registration and Classification Procedures, as published in the Federal Register on July 3, 1975, will be applied. Refer to Section 162.23 of that document. Refer also to PR Notice 75-1 and 75-4.

Douglas D. Campt, then Associate Director for Registration, Registration Division, sent Claimant the following letter dated July 20, 1976, with respect to EPA Reg. No. 33660-1:

In a letter dated June 17, 1974, your firm submitted a claim for reasonable compensation for data to be used in support of registration for the above product in accordance with Section 3(c)(1)(D) of the Federal Insecticide Fungicide Rodenticide Act, as amended. The claim was in response to a notice of application in the May 9, 1974 Federal Register. On June 10, 1976, an additional notice of application appeared in the Federal Register of June 10, 1976 based on the revised method of support and the required offer to pay reasonable compensation in accordance with the November 28, 1975 amendment to the Act.

This letter is to notify you that registration has been issued to Industria Prodotti Chimici for Atrazine Technical not using any data submitted by Ciba-Geigy but relying only on necessary data submitted by the registrant.

Pursuant to our request, Douglas D. Campt, now Acting Director, Registration Division, filed in the proceeding a memorandum, dated May 2, 1977, listing the data used to register Atrazine Technical, EPA Reg. No. 33660-1. Such memorandum lists the data submitted by Respondent herein and does not indicate reliance upon any data submitted by Claimant.

In response to inquiries suggested by Campt's letter to Claimant of July 20, 1976, Claimant contends that if the registration involved herein "was issued in accordance with applicable regulatory requirements, that registration was necessarily issued in reliance upon chronic toxicology data on atrazine which in all probability had been developed and submitted only by CIBA-GEIGY. CIBA-GEIGY also believes that the IPC registration also relied upon other data which CIBA-GEIGY developed and submitted on atrazine, as well as upon the highly confidential formula of CIBA-GEIGY's atrazine" Counsel for Claimant then sets forth the reasons for such beliefs.

It is apparent therefrom that Claimant is contending that the registration in issue was subject to regulations published July 3, 1975 (40 F.R. 28242) with respect to the registration, re-registration and classification of pesticides, which became effective August 4, 1975. Claimant further contends that the new regulations effective August 4, 1975 "require the submission of certain test data not previously required to secure a registration, including chronic toxicology data, which is very expensive and may require two to three years to develop." After describing examples of chronic toxicology data previously submitted by Claimant, it states that such data has only been submitted to EPA by it and that it is highly unlikely that Respondent submitted its own chronic toxicology data.

Claimant further states that even if Respondent's application for registration had been subject to the data requirements of the regulations in effect prior to August 4, 1975, it would have had to

rely on acute and subacute toxicology studies on atrazine, as well as fish and wildlife studies, which had been submitted to EPA only by the Claimant. Also, it is alleged that it would have been necessary to consider or compare the chemical composition of the technical atrazine produced by Claimant and Respondent, with special attention given to the nature and amount of the impurities contained in each product.

In a letter dated May 16, 1977, in response to Campt's May 2, 1977 memorandum counsel for Claimant, in effect, iterates his earlier position by stating that "although Mr. Campt's May 2nd letter does not indicate that chronic toxicology data was relied upon for IPC's registration, the agency's failure to require the submission of chronic toxicology data would have violated its own registration regulations. IPC's application was subject to these regulations, which had an effective date of August 4, 1975, since the record indicates that IPC resubmitted its application for registration on April 15, 1976, and that its acute toxicity data was received by the EPA on April 22, 1976. Therefore, the Administrator would have had to consider Ciba-Geigy's chronic toxicology data to lawfully issue the atrazine registration to IPC..."^{1/}

We have set forth in some detail the major contentions of Claimant in order to place this controversy in proper perspective. Section 3(c)(1)(D) of the act in effect at the time of the filing of Ciba-Geigy

^{1/} We note in this connection that the data submitted April 22, 1976 constituted a resubmission of data previously sent by Respondent May 5, 1975, which data had apparently been misplaced by the Agency.

Corporation's claim provided, in part, 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. . . . If the parties cannot agree on the amount and method of payment, the Administrator shall make such determination. . . ."

(Pub. L. No. 92-516, 86 Stat. 973.) The November 28, 1975 amendment to section 3(c)(1)(D) merely reemphasized in this connection that this is a proceeding to determine the "compensation for producing the test data to be relied upon. . . ." (Pub. L. No. 94-140, 89 Stat. 755).

This then is a proceeding to fix the amount and method of payment for producing the test data to be relied upon. It is not a proceeding to determine what test data should have been relied upon or what test data was required to have been relied upon pursuant to the act and the regulations issued thereunder. Stated another way, this is not a forum or proceeding to invalidate a registration that has been issued or to substitute our judgment as to the data to be relied upon in the issuance of a registration. Instead, it is our function and the limited scope of this proceeding to determine the compensable data of a claimant actually relied upon in the registration of a respondent's product and the reasonable compensation for producing such test data.^{2/}

By reason of the foregoing, we are not to determine herein whether the regulations effective August 4, 1975 should have been applicable to the application in issue. It is clear that such regulations were

^{2/} We need not now consider the legal effect of Respondent's contention that the Agency was without authorization to consider any of Claimant's data.

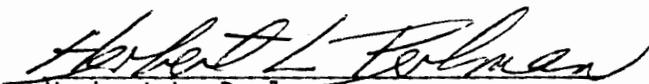
not so applied. Nor are we involved herein with the question of whether the formula for, and the impurities contained in, the atrazine technical produced by Claimant were considered by the Administrator in registering Respondent's product. Claimant must look elsewhere for relief with respect to such considerations or claims.

This leads us not to the matters contained basically in the letters of Claimant's counsel dated March 14, 1977 and May 16, 1977, but to counsel's letter of June 20, 1977, and specifically to page 2 thereof. We hereby request that Mr. Campt, Acting Director, Registration Division, file by August 1, 1977 an explanation of the alleged inconsistency between his memorandum of May 2, 1977 and the Notice of Pesticide Registration dated July 19, 1976, wherein it is stated that some of the data listed in the May 2, 1977 memorandum "is being forwarded for review and the results will be made a part of the record for this product." Also, Mr. Campt is requested to comment on the allegation that a report on Acute Toxicity of Atrazine to Mudcrab was submitted on April 26, 1973 by Claimant "to support the registration of Atrazine Technical." Further, the record does not contain a copy of the September 2, 1976 letter of Robert Taylor, Product Manager, referred to by the parties and the Acting Director is requested to supply such letter for the record.

It should now be stated, perhaps, that at this preliminary stage of the proceeding the record is devoid of any indication that any compensable data owned by Claimant was relied upon in the registration of Atrazine Technical produced by Respondent. In fact, Respondent specifically restricted from its data submission for registration

"data that can be subject of a compensation claim" and, in reality, appears to have proceeded on the basis of data resulting from tests conducted on its behalf. While some confusion exists by virtue of language contained in the Notice of Registration dated July 19, 1977, such language does not indicate a reliance on data submitted by Claimant in the registration involved. It further appears that Claimant's major concerns are beyond the scope of this proceeding.

Subsequent to the submission requested herein from Mr. Camp, a prehearing conference will be held with respect to the matters set forth above and additional issues, including the legal consequences of the January 1, 1970 date contained in the 1975 amendment to the act upon Claimant's claim and the type of data contained in such claim.


Herbert L. Perlman
Chief, Administrative Law Judge

July 11, 1977