



Chevron Chemical Company

Richmond, California
December 11, 1975

PARAQUAT REGISTRATIONS

J. N. OSPENSON:

This is in response to the information you received indicating that Mr. John B. Ritch, Jr., Director, Registration Division, Office of Pesticide Programs, EPA, during his late November visit with Plant Protection Division in the U.K., told them that ORTHO Paraquat CL has been placed on the list of products which will be denied reregistration under the rebuttable presumption clause of the Section 3 Regulations. As of December 10, 1975 we have been unable to make direct personal contact with Mr. Ritch for confirmation of this information. It certainly is in direct conflict with what we have been told by Registration Division.

On December 9, 1975, D. F. Dye visited Dr. Martin H. Rogoff, Pesticides Science Officer directly under Ritch. Rogoff said that his office has responsibility for development of the Presumptive List; he stated that paraquat is NOT on the list and he has no intention of placing it there. On this matter, I consider Dr. Rogoff a most reliable and responsible source. He could provide no explanation of information reported to have been given to PPD by Mr. Ritch. →

Recommendations for Action

- A. If or when confirmation is obtained that paraquat is on the Presumptive List:
1. The reports on successful medical treatment of human paraquat ingestions, as provided to Dr. Paynter, should be made available to the Office of Special Pesticide Reviews.
 2. A high level medical/toxicological meeting should be set up with this review staff to provide full input into our contention that effective emergency treatments are available.
- B. If confirmed Not on List - No action required.

Background/History - In the winter/spring of 1974, we had several meetings with Mr. Ritch concerning fatalities from accidental ingestion of this product. Out of these meetings came our revised label and public education program highlighting and teaching the product hazards. This program satisfied Registration Division and in so doing squelched any immediate cancellation action by the Office of Pesticide Programs (OPP).

However, the Pesticides Enforcement Division of the Office of General Counsel (OGC), which is administratively separate from OPP, continued to attempt to build a case

12/11/75 Ritch personally confirms that paraquat NOT on R.P. List. J.N.

December 11, 1975

against Paraquat through their Pesticide Episode Review Committee. Thus, there developed an EPA internal conflict which was revealed in some detail in Pesticide Chemical News, November 11, 1974. Again, OPP prevailed and no formal action was taken against Paraquat although OGC obviously was not ready to drop the matter. We, therefore, have been well aware that the legal arm of EPA would jump at any good opportunity to bring formal cancellation action against Paraquat. Many of our registration and marketing decisions during the past 18 months have been influenced by this knowledge as our efforts were designed to build a history of safe use and avoid official citations on technicalities.

On October 16, 1974, EPA published proposed regulations for registration/reregistration under Section 3 of amended FIFRA. These proposed rules contained provisions for presumptive denial of registration (Rebuttable Presumption) based on, among other things, "no known medical treatment to prevent fatality from exposure"; the wording of this part went through several subsequent draft revisions and the impact of this proposal was brought to Mr. Barlow's attention in your memorandum of March 7, 1975 (Attachment A). The problem was recognized as being related specifically to Paraquat and points of rebuttal were outlined. A. P. Brown agreed with the conclusions and presented additional discussion in his memorandum of March 20 to Mr. Barlow (Attachment B).

Pesticide Chemical News on May 21, 1975 published a draft list of Pesticides (developed by Registration Division) for studying the active ingredients which might be classified as "restricted". This list not only indicated that Paraquat would be reregistered, but actually would be "general use" based on our label (Attachment C).

On July 3, 1975, EPA published Section 3 rules and regulations in which the pertinent rebuttable presumption clause stated: "Lack of Emergency Treatment. Has no known antidotal, palliative, or first-aid treatments for amelioration of toxic effects in man resulting from a single exposure". (Part 162.11(a)(3)(C)(iii) CFR.)

On July 16, 1975, Pesticide Chemical News broke an alert that "Paraquat will probably be one of the first, if not the first, pesticides which will have continued registration presumed against under the rebuttable presumption provision of the Section 3 Regulations". This was the information which PPD picked up and which subsequently generated the actions outlined in H. G. Franke's August 20 letter to Alan Calderbank (Attachment D). Again, it must be pointed out that OGC, not OPP, is the arm of the EPA which was trying to "get" Paraquat. Our dealings are with OPP, Registration Division; more specifically, with Toxicology Branch headed by Dr. Paynter under Dr. Rogoff.

In preparing a pesticides programs economic impact report on the proposed guidelines for registration/reregistration, OPP prepared a study guide in which a sample of 641 active ingredients were examined for completeness of the toxicology data on file with EPA towards satisfying the requirements for registration. This study guide, prepared by Rogoff and Paynter, shows Paraquat to satisfy all but one of the toxicology requirements (oncogenic) and that the product could be given interim reregistration with 36 months time allowed to complete the required study (Category II) (Attachment E).

Mr. Dye discussed the Paraquat situation with Dr. Paynter the week of October 13 and was told that OGC had not raised any formal action to presume against Paraquat and further that Toxicology Branch felt well armed to fight in favor of Paraquat registration if and when such action would occur. In other words, OGC had not yet followed up on the story they leaked to Pesticide Chemical News on July 16. However, Mr. Dye the same week also was able to obtain a partial list of products reported to be on a presumptive list developed by OGC. This information was contained in his trip report dated October 29 and indicated that Paraquat was included with the some 100 chemicals on the list. On November 6, Mr. Dye again reconfirmed with Dr. Paynter that Paraquat was not scheduled by OPP for presumption against registration and this was pointed out in his trip report dated November 21, 1975. Note that as of December 9, 1975, Dr. Rogoff says his office has responsibility for the Presumptive List and that OGC is not involved.

I personally attended the NACA Fall Regulatory Conference held in Washington, D.C. on November 5, at which time Mr. Ritch discussed reregistration and rebuttable presumption procedures. The 34,000 registered products will be divided into batches of approximately 1500 each based on certain criteria which make them similar. The products will be categorized into categories I, II, III and IV; category IV will be those products presumed to be not acceptable for reregistration. Products in categories I, II and III will be "called in" for reregistration under a planned program so that the call in packages will include special guidance packages forwarded to all registrants giving detailed instructions and specifying data gaps which must be satisfied for reregistration. Mr. Ritch was very emphatic in stating that, because of the volume of products which must be reregistered, it is imperative that the reregistration proceed on an orderly basis and that registrants not contact Registration Division regarding reregistration of their products. He stated several times "Don't call us, we'll call you". In discussing rebuttable presumption, Mr. Ritch told me that the company holding the registration on a product to be presumed against will be given a chance to rebutt prior to his advising Administrator Train on a recommended course of action. In other words, for rebuttable material, EPA would internally evaluate all information for a determination as to whether or not there is some justification to remove the material from the presumptive list, if they still felt unable to remove it from the list, they would allow the registrant opportunity to come in and discuss the matter and present rebutt arguments. Of course, for any chemical on which it is decided to advise Mr. Train that registration should be denied, there would be notification of the registrant, publication in the Federal Register and formal public hearings if so requested by the registrant.

It has been reported the OPP plans the addition of an Office of Special Pesticide Reviews which would include 6 to 10 project managers. An administrative hearing support staff would also be organized and report to this special office. The project managers would be assigned about 4 chemicals, each which have been presumed against, and they would stay with these chemicals through the hearing if presumption rebuttable failed. Unofficial reports have Mr. James Touhey heading up this office of special pesticide reviews, and reporting directly to Mr. E. L. Johnson, Deputy Assistant Administrator, OPP.



L. R. STELZER

LRS:sag