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M. Wilhite
SRRD
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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: Meeting with Rohm and Haas Co. on the Phase 4 Reregistration Review of Oxyfluorfen.

From: Stephen Funk, Ph.D., Chemist
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C) *S. R. Funk*

Through: Andrew Rathman, Section Head
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To: CBRS File

A meeting was scheduled by SRRD for 12/18/91, 10 AM, Crystal Station, at the request of Rohm and Haas Company to discuss certain aspects of the Phase 4 DCI for oxyfluorfen. The following individuals were present at the meeting:

Robert H. Larkin	Rohm and Haas Co. (Director, Agricultural Chemicals)
Jay A. Holmdal	Rohm and Haas Co. (Product Development Manager)
Bill Lynch	Rohm and Haas Co.
Paul Rybock	Rohm and Haas Co.
Bruce Sidwell	SRRD/ARB
Mark Wilhite	SRRD/ARB
Andrew Rathman	HED/CBRS
Steve Funk	HED/CBRS

Mark Wilhite chaired the meeting. Jay Holmdal presented a brief background on the current uses of oxyfluorfen. About 80% of the product is used on perennial crops (including artichokes and mint, as well as pome fruit, stone fruit, olive, grape, etc.) and for fallow bed treatment. The latter use is confined primarily to California. Dr. Holmdal stressed that the herbicide is used mainly

during crop dormancy or before crop planting and that it is not translocated from the soil to the crop plant. Oxyfluorfen is specific for certain types of weeds (not broad spectrum), but most crops will not survive direct application of the herbicide during the growing season.

After the introduction, the meeting concentrated on issues outlined in a letter of 11/14/91 from Dr. Lynch to Mark Wilhite. The Phase 4 Review acknowledged an alfalfa nature of the residue study (alfalfa tolerance pending) as acceptable for review and requested two additional studies. Grapes, tomato, soybean, and onion were suggested as possible candidates for the 171-4(a) studies. The registrant responded that studies would be conducted on tomato and grape. Application would be made at a 5X rate under normal use conditions, preplant for tomato and dormant for grape. However, the registrant believes that the herbicide will not translocate and that no radioactivity will be found in the tomato or grape plant parts. The registrant is uncertain if such studies will fulfill the metabolism requirements if no residues are found in the plant or crop at harvest.

CBRS asked if Rohm and Haas would consider application at times not specified on the label, i.e., to growing tomato plants or to grape vines after bud break. The Rohm and Haas representatives responded that grape and tomato plants would not survive such a treatment, even at 1X rates. CBRS noted that the herbicide had been successfully applied to alfalfa for the one metabolism study accepted for review. Rohm and Haas Co. responded that alfalfa was unusual. They could offer no possible crop to which the herbicide might be foliarly applied without killing the plant. It was noted that a current label use is for the direct application to onions at low application rates. The representatives agreed that this was a possibility. Given the substantial root structure of tomatoes, Dr. Lynch also thought that pretransplant soil treatment with radiolabeled oxyfluorfen followed by tomato plant introduction might yield some radioactivity in the tomato plant.

It was agreed that radiolabeled studies would be conducted on tomatoes (pretransplant treatment) and onions (foliar treatment). The registrant was asked to provide justification that other crops (e.g., wheat) will not survive directed oxyfluorfen treatment.

The registrant argued that adequate demonstration of lack of translocation of oxyfluorfen will negate the need for processing studies (requested in the Phase 4 DCI) for the following perennial crops: coffee, dates, grapes, olives, and plums. A new stonefruit (cherry) translocation study is planned. It is the registrant's contention that this new study plus the tomato metabolism study (above) and the previously submitted apple translocation study will provide substantial proof of the lack of translocation. It was also indicated that a supplemental academic study on grapes may be submitted.

CBRS responded that translocation studies on three different crops are normally sufficient to establish the degree of translocation of a pesticide for a given use pattern. The use pattern for coffee is application during the growing season. Therefore, a processing study must be done on coffee beans. The registrant indicated that an IR-4 project (University of Hawaii) is underway. Dr. Lynch also stated that a soybean processing study will be conducted.

CBRS agreed to reserve the requirement for the subject processing studies (except coffee) pending an evaluation of the results of the translocation studies. Storage stability study requirements for the subject processed commodities would also be reserved. It was emphasized that the requirements were not waived.

The Phase 4 DCI requested storage stability studies (171-4(e)) for every crop and processed commodity for which a field trial or processing study has been or will be conducted. The registrant raised the issue that this is excessive and that representative storage stability studies from the crop groups for which tolerances exist should be adequate. A protocol based on this approach was reviewed and approved by CBRS, although the crops to be tested were not specifically addressed by CBRS (F. Toghrol, 06/15/89, DEB No. 5374). The registrant now proposes studies on the following raw agricultural commodities:

legume crops-	alfalfa
leafy crops-	cabbage
grain crop-	wheat
root crop-	carrot
nut crop-	almond nut, hull
tree fruit crop-	peach, orange, apple
oil seed crop-	cottonseed
small fruit crop-	strawberry
other matrix-	soil

CBRS stated that the testing of various crop groups (as opposed to every crop with a tolerance) is acceptable, provided variable stability is not encountered. It was suggested that bananas, coffee, and onions be added to the list. Rohm and Haas requested that onions replace carrots on the list, and CBRS agreed. Bananas and coffee are unique in that the use is during the growing season (up to harvest), and onions are unique in that a directed foliar spray is used on the plants. The registrant also asked if one fruit (rather than three) would suffice. CBRS indicated that the original list of three is appropriate.

Dr. Holmdal raised issues on the processing study requirements. He asked if a processing study must be conducted if application at 5X does not yield detectable residues. It was explained that a processing study must be conducted even in the absence of residues unless it can be established that the rate is exaggerated by a factor at least equal to the theoretical maximum concentration

factor due to processing. In many cases, that factor will be greater than 5X. The registrant also asked if a 1X rate is required where a 5X rate is successfully conducted. CBRS indicated that a 1X rate would not be required.

Finally, the registrant objected to the Phase 4 DCI requirement to conduct field trials for an extensive list of crops that the registrant prefers to call "fallow field" uses. These entail application to the ground prior to planting, with a preplant interval as short as 0 days. CBRS maintains that fallow field uses are limited to application of the pesticide at least one year before crop harvest. Because of treatment-to-plant intervals of 0, 30, 60, 90, 120, and 180 days, the application cannot be considered fallow field, and appropriate field trials must be conducted. Dr. Larkin indicated that the registrations were first issued based on crop rotation studies, and that these studies would be submitted for CBRS evaluation. The registrant stated that a 60 day turnaround is needed to start field trials in 1992 if the registrant's position is rejected. CBRS agreed to review the data, but indicated that the turnaround would depend upon the date of receipt by CBRS of the data submission and the magnitude of that submission. CBRS indicated that a time extension would be appropriate if review of the crop rotation data delays the start of trials in 1992.

The registrant was asked if Rohm and Haas would be agreeable to a label limiting the fallow bed uses to California. The registrant indicated that this would be quite acceptable if such an action would help resolve the problem.

The Rohm and Haas personnel raised the issue of the effect of the Craven data review on oxyfluorfen. Mr. Sidwell replied that a DCI would be forthcoming very soon and that nothing more could be discussed until Rohm and Haas Co. receives the document.

cc: RF, List B Oxyfluorfen File, Craven Data Oxyfluorfen File, M. Wilhite (SRRD, H7508W), Circ., S. Funk, C. Furlow (PIB, FOD).

RDI:A. Rathman:12/20/91:E. Zager:12/23/91:

H7509C:CBRS:S. Funk:305-5430:CM#2:RM803-A:SF(1191.15):12/20/91.