UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 2 1993

MEMORANDUM

Subject: Oxyfluorfen (List B, Chemical 111601, Case 2490): Protocol for Coffee Processing Study (171-4(1)). DP Barcode D193009. CBRS No. 12194. MRID No. None.

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In the 90 day response to the Phase 4 Review/DCI for the pre/postemergence herbicide oxyfluorfen (Goal®), or 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-trifluoromethyl) benzene, Rohm and Haas Co. committed to conduct an exaggerated rate field trial (5X) and processing study for the application of oxyfluorfen to coffee (F. A. Fort, CBRS No. 9024, 04/16/92). The registrant previously argued unsuccessfully that the lack of translocation of oxyfluorfen (applied to the ground around trees) negated the need for a coffee processing study (S. Funk, Memorandum of Meeting, 12/31/91). IR-4 now submits a protocol for a coffee processing study. Daniel Kunkel, IR-4 Project Coordinator, notes in a cover letter (05/18/93) that there is concern "...about accounting for the

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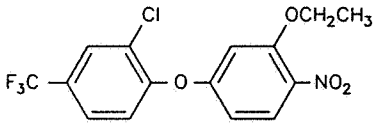
maximum of 6.0 lbs.active per year while at the same time including an exaggerated rate."

The Goal 1.6E label (registration no. 707-174) specifies a maximum single application of 2.0 lbs. a.i./acre and a maximum seasonal use of 6.0 lbs. a.i./acre/year. The PHI is one day, and the herbicide is to be applied in a minimum of 30 gallons of water per acre as a spray directed to the soil and the base of the coffee trees. Contact with coffee foliage is to be avoided.

A tolerance of 0.05 ppm exists (40 CFR §180.381) for residues of oxyfluorfen and its metabolites containing the diphenyl ether linkage in/on coffee beans. There is no food additive tolerance for oxyfluorfen residues in/on processed coffee. The structure of oxyfluorfen is as follows:



Conclusions

The processing study protocol is acceptable, provided the following changes are made:

1. The beans must be harvested at the normal growth stage. Immature beans should not be collected. The timing of the oxyfluorfen application should be adjusted to permit the collection of beans that are typical of coffee beans for processing.

2. The proposed application rate of 7.5 lbs. a.i./acre is a 1.2X exaggeration of the label rate. The maximum theoretical concentration factor for coffee processing (roasting) is 1.2. Therefore, this rate will be acceptable even if no oxyfluorfen residues are found in the treated raw agricultural commodity. The Project Coordinator need not be concerned that this rate exceeds the label rate. The object of the study is not to provide field trial data in support of the oxyfluorfen reregistration (171-4(k)) but to supply coffee beans with an oxyfluorfen residue or beans treated at the maximum theoretical concentration factor to satisfy processing study requirements for reregistration (171-4(l)).

3. The analytical method section of the protocol is acceptable, provided new nature of the residue in plants studies do not reveal

new metabolites that require regulation. The storage fortification samples should be stored with the control and treated samples and prepared and analyzed concurrently with those samples. This will provide adequate storage stability data for the coffee processing study, assuming the interval from harvest to raw and processed sample fortifications is brief, i.e., less than 30 days.

4. The analytical report section of the final submission must provide typical raw chromatographic data (area/height and retention times) for at least one control and treated rac and processed commodity. Copies of the corresponding chromatograms must be submitted. Some calibration data and example standard chromatograms should be provided. Residue levels in all control and treated rac and processed samples should be reported without correction for method recoveries or storage fortification recoveries. Concurrent recovery data should be reported with the appropriate sample results.

5. The proposed performance interval, 3 years, is excessive. CBRS recommends that no more than 2 years be given for conducting all phases of the coffee processing study. The due date should be 09/95.

CBRS notes that both roasted beans and instant coffee are processed commodities (Subdivision O, Table 2). Therefore, the processing study normally must produce instant coffee as well as roasted beans. Oxyfluorfen possesses a solubility in water (0.1 mg/liter) such that an exemption from the instant coffee portion of the study would be appropriate (R. Loranger, 06/10/91, CB Files). Only roasted coffee need be prepared.

Recommendation

CBRS recommends that IR-4 proceed with the processing study after incorporating the changes noted in Conclusion items nos. 1 - 4. CBRS further recommends that the time for conducting the study be limited to 24 months, but realizes that decisions on due dates are in the purview of SRRD.

Detailed Consideration

The field portion of the study is proposed to start 05/93, and the project is scheduled for completion by 05/96. The test site consists of one treated and one untreated plot in Hawaii that have been maintained in good agricultural practices for coffee production. Each plot will contain a minimum of ten trees. The herbicide Goal® 1.6E will be applied in a minimum of 30 gallons of water/acre to the orchard floor beneath the coffee plants.
The protocol specifies one application, 1 day PHI, at a rate of 7.5 lbs.a.i./acre, or 1.2X the maximum seasonal rate. The 1.2X rate corresponds to the maximum theoretical concentration factor due to processing of green coffee beans into roasted coffee (*Pesticide*

Reregistration Rejection Rate Analysis Residue Chemistry: Follow-Up Guidance, EPA 737-R-93-001, 02/93) and is therefore acceptable.

One day after treatment, 8 lbs. of treated and 8 lbs. of untreated beans (fresh samples) will be collected for determination of oxyfluorfen residues in/on fresh beans. An additional 20 lbs. of treated and 20 lbs. of untreated beans will be collected for processing. Each plot will be divided into four subplots to assure random sampling. Beans will be taken from all sections of the trees. The proposal states that the beans need not be ripe. This is unacceptable. The beans must be at the growth stage typical of normal harvesting practice.

Beans are to be placed in plastic bags and shipped in coolers to arrive at the processing facility within 24 hours (Hawaiian Sugar Planters Association, HSPA). Samples for processing are not frozen. Fresh samples are immediately frozen and stored at temperatures < -15° C. The beans for processing are to be roasted by a commercial wet process as soon as possible. Two samples of treated and two samples of untreated processed beans (each about 2 lbs.) are to be retained for analysis. These are placed in plastic bags and maintained at < -15° C. The contemplated interval from sampling or processing to laboratory analyses is not stated.

The protocol outlines the field documentation and processing study documentation.

The analytical laboratory (residue determination) is not specified, but may be HSPA. Samples will be stored whole or macerated, as appropriate. at < -20° C. Extracts may be stored for no more than seven days at 4° C before analysis. Analyses will be conducted by the enforcement method given in PAM II, 180.381. The anticipated starting and completion dates for analytical work are not given.

Some control samples will be fortified in triplicate at two concentration levels to verify accuracy and precision. An acceptable recovery range will be 70% - 120%. Some control samples will be fortified in triplicate at three concentration levels immediately after the arrival of the samples. These storage fortification controls will be stored with the samples and analyzed at the appropriate intervals. One concentration level will be at the method sensitivity.

The final report will include results of the method validation, storage fortification, and control and treated sample residue levels. Representative chromatograms and a complete copy of the method will be included.

cc: List B File, SF, RF, Circ., S. Funk.

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