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

JUN 6 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: June 1, 1994 Meeting with FMC concerning sulfentrazone in soybeans.

FROM: G.F. Kramer Ph.D., Chemist
Tolerance Petition Section III
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: P.V. Errico, Section Head
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: Chemistry Branch Files

Attendees:
J. Mayes, RD/FHB
R. Loranger, HED/CBTS
G. Kramer, HED/CBTS
C. Chukwunenye, FMC
D. Shaw, FMC
J. Becker, FMC
R. Cook, FMC
E. Cherry, FMC

FMC is proposing temporary tolerances for hydroxymethyl-sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide), the major metabolite of sulfentrazone (2-(2,4-dichloro-5-methylsulfonylamidophenyl)-4-difluoromethyl-2,4-dihydro-5-methyl-3H-1,2,4-triazol-3-one). Sulfentrazone is the a.i. in a new herbicide developed for preemergent use on soybeans. FMC requested this meeting to discuss issues related to rotational crops and our recent review of the EUP/temporary tolerance petition (Memo, G. Kramer 4/25/94). The registrant reports that residues of sulfentrazone and three metabolites have been detected in rotational crops in limited field

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trials, thus necessitating rotational crop tolerances. The registrant is planning rotational crop residue trials for corn and wheat. In response to questions posed by the registrant, CBTS supplied the following information:

1) The location of the rotational crop field trials should include the areas where corn and wheat is rotated with soybeans. If, in the future, the registrant seeks to register sulfentrazone for use on a target crop grown in different regions than soybeans, then further rotational crop field trials may be required. This situation can be avoided by initially performing the rotational crop field trials in all areas where the rotational crop is grown.

2) Processing studies do not appear to be required for wheat since the TRR in barley grain in the confined rotational crop study was <0.01 ppm. For corn, phytotoxicity limits the ability to perform exaggerated rate trials. CBTS indicated that it would be satisfactory to process grain from a 1X study. The grain sample may be composited from different trials.

3) The rotational crop label restrictions can be seasonal; i.e., "Do not rotate until the following spring." However, a minimal interval such as 8 months should also be included. The minimum interval should be also be represented in as many of the rotational crop field trials as possible.

4) The number of rotational crop field trials should be the same as for target crops. The forthcoming field trial document recommends at least 20 trials each for corn and wheat, with two samples per site.

5) Label restrictions such as "Rotate only to soybeans, wheat and corn" are acceptable for a soybean herbicide. The first crop following the primary crop is the "rotational" crop. The rotational crop label restrictions thus do not apply to crops planted two years after application.

6) A recovery of 50% for a sulfentrazone metabolite in the rotational crop analytical enforcement methodology may be acceptable if the precision is sufficient.

7) Petitions without data and tolerance requests for soybean hay and forage will be accepted as long as the studies were initiated within 6 months of the issuance of the revised Table II. The registrant is planning to submit a Section 3 registration this summer with data for soybean seed only. Field trials to generate data for hay and forage are planned for 1995.

The following points were made in response to questions concerning our recent review of the EUP/temporary tolerance petition (Memo, G. Kramer 4/25/94):

1) In metabolism studies, storage stability is probably not an issue for bound residues. However in cases where such residues are released (e.g. by acid hydrolysis) and subsequently stored in some type of solvent for an extended period, stability of these released residues should be assessed.

2) Characterization of polar metabolites should include chromatographic separation. If no single compound comprises >10% of the TRR or 0.05 ppm, then further identification work is not necessary.

3) Bound residues have been characterized by mild acid and various enzymes. Refluxing in concentrated acid will not be required if the registrant can demonstrate that sulfentrazone would be degraded under these conditions.

4) Demonstration that the radioactivity is extracted from the labelled samples by the proposed analytical enforcement method may fulfill the requirements for radiovalidation.

5) Feeding studies may not be necessary if the metabolism study is done using a greatly exaggerated rate based on the estimated dietary burden and estimated residues in milk and tissues (by extrapolation) will be well below the detection limit of the analytical method. This decision would be reevaluated once data for hay and forage is submitted.

6) Whether a change in the enforcement method necessitates a new ILV and PMV is made on a case by case basis.

7) An actual PHI (in days) should be proposed. The proposed PHI can be based on the shortest PHI represented in the residue field trials.

cc: S.F., Kramer, circ., R.F., PP#3G4272, J. Mayes (RD-7505C)
RDI: P.V. Errico (6/2/94), R.A. Loranger (6/2/94)
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