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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJ: Parathion Data Call In

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and

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This memo addresses the question raised by the Office Director at the 10/10/85 Parathion briefing about when a DCI should be issued in order to avoid missing a growing season.

The following summarized data will be requested by the Registration Standard. The nature of the residue in plants and animals is not adequately understood. Data reflecting the distribution and metabolism of [^{14}C]ring-labeled parathion and complete ^{14}C -residue identification are needed for the following raw agricultural commodities (r.a.c.'s) following various foliar/soil treatments: cottonseed and forage, wheat grain and forage, and potatoes. Animal metabolism studies are needed utilizing ruminants and poultry dosed with radiolabeled parathion in order to identify residues in muscle, fat, kidney, liver, milk and eggs. No tolerances presently exist for parathion residues in animal tissues. Adequate residue methods are available for field residue data collection and for enforcement purposes of established parathion tolerances as they are currently expressed (the parent compound, per se). However, if additional metabolites are identified by plant metabolism studies and/or in proposal of tolerances for animal products, then new analytical methodology may need to be developed.

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Data gaps in the Registration Standard exist for storage stability of parathion in/on plant commodities. Although sufficient residue data are available to determine the adequacy of established tolerances for parathion in/on seven r.a.c.'s, data are needed on an additional approximately 88 r.a.c.'s. Data are also needed to determine whether tolerances are required for residues in 23 processed products. Finally on at least 20 feed items data are needed to establish tolerances or request an exemption therefrom.

It must be noted that the above data would have to be generated in a sequential manner. Execution of field residue studies would be contingent upon completing metabolism studies and developing any new analytical methodology for estimating residues of toxicological interest. Thus, the majority of the field residue studies will probably be carried out during the 1987 growing season rather than the 1986 growing season.

According to PR Notice 85-5 the following time frames are allowed for the generation of residue chemistry data:

Plant and Animal Metabolism Studies	18 mos.
Residue Analytical Methodology	15 mos.
Field Trials	18 mos.
Processed Food/Feed Studies	24 mos.
Animal Tissues Residue Studies	18 mos.

Conclusion

As long as the Registration Standard goes out this year, then the registrants will have sufficient time to begin field studies by the summer of '87 and there will be no need for a separate DCI. Any delay beyond Jan. '86 in the release of these data requests will not permit the statutory minimum of 15/18 months for metabolism studies and analytical methodology development prior to the summer of 1987.

Recommendation

RCB recommends that either the Registration Standard or a separate residue chemistry 3(c)2(b) DCI letter be issued no later than the end of calendar year 1985.

cc: Steve Shatzow, OPP Office Director
Special Review File (Reiter)
Reviewer
Reading File
Subject File (Parathion)
Circulation
PMSD/ISB

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