



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

JUN 3 1986

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Parathion - Monsanto response to 3(c)(2)(B)
letter of 1/28/86 extension request
[No Accession No., RCB No. 944]

FROM: Susan V. Hummel, Chemist
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Residue Chemistry Branch
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THRU: Edward Zager, Section Head
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TO: Ed Allen, PM#12
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Registration Division (TS-767)

Monsanto Company has responded to the Parathion Data Call-In letter dated January 28, 1986; in their letter dated May 6, 1986.

Plant Metabolism

Monsanto agrees to conduct plant metabolism studies on wheat and cotton, and proposes to start these studies in November, 1986. They request a 12 month extension to complete these studies. Monsanto requests a minor use waiver for metabolism studies on potatoes. No economic justification for the minor use waiver was submitted.

Plant metabolism data are required on diverse crops from a minimum of three crop groups, more if the metabolism in these three studies is substantially different. Therefore, plant metabolism data are needed for the root crop potatoes, as well as wheat and cotton. A waiver of the requirement for plant metabolism data on potatoes is not appropriate. The time allotted to conduct these studies is given in PR Notice 85-5; 18 months is considered sufficient to plan, initiate, and complete metabolism studies. Therefore, no extension of time is appropriate.

Animal Metabolism

Monsanto agrees to conduct animal metabolism studies in goats and chickens. This is acceptable. Monsanto requests an 18 month extension of time to conduct these studies. They state that the animal metabolism studies cannot be initiated until the plant metabolism is known, and until the radiolabeled plant metabolites can be synthesized. This is incorrect. The feeding of plant metabolites is ordinarily not needed. Ordinarily, the parent compound (parathion) should be fed. Feeding of parathion is required since finite residues of parathion have been found in animal feed items. Additional animal metabolism studies may be required if significant plant metabolites are not also found to be animal metabolites. Additional time will be granted to conduct animal metabolism studies of parathion plant metabolites, if needed. Animal metabolism studies of parathion, per se, can be conducted at the same time as the plant metabolism studies; 18 months is considered sufficient to conduct these studies; therefore, no time extension is appropriate at this time.

Analytical Methodology

Monsanto states that the Data Call-In letter did not require new analytical methodology. We remind the registrant that validated analytical methodology must be submitted to support all metabolism and residue studies.

Storage Stability

Monsanto states that they did not conduct the residue trials for the commodities referenced in the Data Call-In Notice, and cannot provide storage stability data to support these data. However, Monsanto states that they will provide storage stability data to support the residue studies required by this Data Call-In Notice. This is acceptable.

Magnitude of the Residue

Monsanto states that the major crops on which ethyl parathion is used are grain sorghum, wheat, peaches, cotton, nut crops, and corn. They state that the emulsifiable concentrate formulation is used on these crops, and that a wettable powder is also used on peaches and nut crops.

Monsanto agrees to conduct residue studies on the crops above, and they request an 18 month extension of time to conduct these studies. Monsanto requests a minor use waiver for all other crops. No economic justification was submitted for any of these crops.

RCB agrees that some of the crops listed are minor crops. Most, however, are major crops. A waiver of all residue chemistry data requirements even for minor crops is not appropriate. Some residue data are needed even for minor crops, since the level of residue present in the crop is necessary to accurately set tolerances and to accurately assess dietary exposure.

As part of the EPA Minor Use Policy, the crop grouping scheme (40 CFR 180.34(f)) for establishing crop group tolerances was implemented to ease the residue chemistry data requirements for minor crops (48 FR 29855, 6/29/83 and 51 FR 11341, 4/2/86). The crop grouping scheme enables the establishment of tolerances for a group of crops based on residue data for certain crops that are representative of the group. In most cases, acceptable residue data for the representative crops are adequate to support a crop group tolerance. Once a crop group tolerance is established, the tolerance level applies to all raw agricultural commodities in the group, unless a crop is specifically excluded from the crop group tolerance.

Assuming maximum parathion uses are similar and residues in representative crops do not vary by more than a factor of five, the crop grouping scheme should ease residue chemistry data requirements for the crops on which parathion is registered. Even though a waiver of residue chemistry data is not appropriate, an extension of deadlines for the residue chemistry data is appropriate to ensure that the plant metabolism is fully known, and to allow for a full regimen of parathion treatment on each crop. These revised deadlines are given below for the seven crops for which Monsanto agreed to conduct studies and by crop group. The representative commodities are listed.

<u>Crop</u>	<u>Revised Due Date</u>
alfalfa	1/88
corn	9/87
cotton	1/88
sorghum	9/87
nut trees group	5/88
peaches	12/87
wheat	12/87

<u>Crop Group</u>	<u>Revised Due Date</u>
Root and Tuber Vegetables	9/87
Carrots	
Potatoes	
Radishes	
Sugar Beets	

<u>Crop Group</u>	<u>Revised Due Date</u>
Leaves of Root and Tuber	
Vegetables	9/87
Turnips	
Sugar Beets	
Bulb Vegetables	2/88
Green Onions	
Bulb Onions	
Garlic	
Leafy Vegetables(except Brassica)	
Celery	3/88
Leaf Lettuce	9/87
Head Lettuce	9/87
Spinach	9/87
Brassica Vegetables	
Cabbage	9/87
Broccoli	1/88
Kale (substituting for	9/87
mustard greens)	
Legume Vegetables	
soybeans	3/88
dry beans	9/87
peas (succulent and dry)	12/87
snap beans	3/88
Foliage of Legume Vegetables	
Bean vines and hay	
(dry beans)	9/87
(snap beans)	3/88
Pea vines and hay	12/87
Soybean forage and hay	3/88
Fruiting Vegetables (except curcurbits)	
peppers	1/88
tomatoes	9/87
Curcurbits	9/87
cucumbers	
melons	
summer squash	
Citrus Fruits	9/87
Grapefruit	
Oranges	
Lemons	

<u>Crop Group</u>	<u>Revised Due Date</u>
Pome Fruits	4/88
Apples	
Pears	
Stone Fruits	2/88
Apricots (substituting for Peaches)	
Plums (fresh prunes)	
Sweet and Sour Cherries	
Small Fruits	3/88
Cranberries	
Gooseberries (substituting for blueberries)	
Grapes	
Strawberries	
Cereal Grains	
Field Corn	9/87
Sweet Corn	9/87
Rice	3/88
Sorghum	9/87
Wheat	12/87
Forage, Fodder, and Straw of Cereal Grains	
Corn	9/87
Rice	3/88
Wheat	12/87
Grass Animal Feeds	12/87
Bermudagrass	
Bluegrass	
Bromegrass or Fescue	
Non-grass Animal Feeds	12/87
Clover	
Alfalfa	
Miscellaneous Commodities	
Artichokes	3/88
Avocados	3/88
Dates	5/88
Figs	2/88
Hops	3/88
Mangoes	3/88
Okra	9/87
Olives	4/88
Peanuts	3/88
Pineapples	3/88

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<u>Crop Group</u>	<u>Revised Due Date</u>
Miscellaneous Commodities	
Rape	9/87
Sunflower	3/88
Tobacco	3/88

Processing studies will be due six months after the above deadlines for the associated raw agricultural commodity.

We recommend that all crops for which Monsanto has not agreed to conduct studies be removed from the product labels. We note that Monsanto has agreed to conduct studies on grain sorghum, and not sweet sorghum. We are unsure if Monsanto has agreed to conduct studies on alfalfa, since a minor use waiver was requested for alfalfa.

cc: R.F., circu, parathion S.F., parathion S.R.F. (Hummel)
parathion Reg Std F. (Boodee), S. Hummel, TOX, EAB, D.
Giamporcaro (SRB), PMSD/ISB
RDI: EZ:6/02/86:RDS:6/02/86
TS-769:RCB:RM 810:CM#2:SVH:svh:6/02/86