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HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

DATE: 9/25/97

SUBJECT: HED Metabolism Assessment Review Committee Meeting of  
9/4/97. Isoxaflutole. PP#6F04664. Chemical 123000.  
Barcode D238728.

FROM: George F. Kramer, Ph.D., Chemist *George F. Kramer*  
RAB1/HED (7509C)

THRU: Melba Morrow, Branch Senior Scientist *Melba Morrow*  
RAB1/HED (7509C) 9/25/97

TO: HED Metabolism Committee Members<sup>1</sup>.

QUESTIONS DISCUSSED

1. Is there any scientific objection to establishing the animal tolerances and conducting risk assessment in terms of isoxaflutole and its metabolite RPA 202248?
2. Are additional isoxaflutole metabolites at the levels reported in animal commodities of special toxicological concern? If so, which one(s)? Do they warrant inclusion in the tolerance

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<sup>1</sup>Robert Fricke, Karl Baetcke, Paul Chin, Leung Cheng, Kit Farwell, Mike Ioannou, George Kramer, Richard Loranger, Christine Olinger, Randolph Perfetti, Alberto Protzel, Catherine Eiden.

regulation? Separate regulation? Inclusion in the dietary  
 risk assessment? Additional metabolism studies?  
 Toxicological studies?

INDIVIDUALS IN ATTENDANCE

METABOLISM COMMITTEE: (Signatures indicate concurrence unless  
 otherwise stated)

Randolph Perfetti

*R. B. Perfetti*

Robert Fricke

*Robert Fricke*

Karl Baetcke

*Karl Baetcke*

Richard Loranger

*Richard Loranger*

Alberto Protzel

*Alberto Protzel*

Byong-Han Chin

*Byong-Han Chin*

Leung Cheng

*Lee Cheng*

George Kramer

*George Kramer*

Christine Olinger

*Christine Olinger*

SCIENTISTS: Non-Committee members responsible for the data  
 presentation (signatures indicate technical  
 accuracy of the report)

George F. Kramer

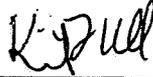
*George F. Kramer*

Sanjiv Diwan

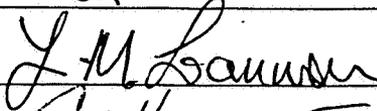
*Sanjiv Diwan*

**METABOLISM COMMITTEE MEMBERS IN ABSENTIA:** (Signatures indicate concurrence with the overall conclusions of the Committee.)

Kit Farwell



Mike Ioannou



Catherine Eiden



**MATERIAL REVIEWED**

The Committee reviewed the RAB1 briefing paper, which included the isoxaflutole metabolic pathways in corn, rotational crops and animals (goat and hen) and the magnitude of the residue data. The Committee also reviewed tox data on the metabolism of isoxaflutole in rats and environmental fate data on the metabolism of isoxaflutole in the environment.

**CONCLUSIONS REACHED**

It was concluded that the identified metabolites RPA 207048 and RPA 205834 are likely to be of comparable toxicity to the parent. Since RPA 207048 and RPA 205834 are a major portion of the residue in animal commodities, these metabolites need to be included in the risk assessment. However, since another major metabolite, RPA 202248 is measured by the proposed enforcement method, RPA 207048 and RPA 205834 need not be included in the tolerance expression for animals. The Committee also decided that the residues of concern in drinking water are isoxaflutole and its metabolites RPA 202248 and RPA 203328.

cc: PP#6F04664, G. Kramer (RAB1), B. Madden (RCAB)  
 RDI: M. Morrow (9/8/97), R. Loranger (9/5/97)  
 G.F. Kramer:804V:CM#2:(703)305-5079:7509C:RAB1