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

PM5D/ISB
(Eldridge)
1962

SPECIAL

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DEC 11 1987

MEMORANDUM

SUBJECT: PP#7F3476/FAP#7H5524. RALLY™ (Myclobutanil).
The Regulable Residue in Animal Commodities.
RCB No.: N/A. MRID No.: N/A.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *mjn*

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *RM*

TO: Pam Hurley, Toxicologist
Review Section 2
Toxicology Branch
Hazard Evaluation Division (TS-7669C)

As you know, RCB is in the process of conducting its review of the first permanent tolerance petition for RALLY™ (myclobutanil).

This memo is to formalize RCB's deferral to TOX Branch for a determination, based on toxicological considerations, as to which metabolites, if any, of RALLY™ (myclobutanil) warrant regulation (i.e., inclusion in the tolerance expression) in meat, milk, poultry, and eggs.

You've already received the data RCB has on dairy cow, poultry, and rat metabolism.

If there's any way in which RCB can further facilitate your review, please let me know.

As you're aware, RCB is under timeframe pressures to complete this new chemical priority review, so we would appreciate TOX's decision as soon as you can manage it.

COB/BUD is also awaiting word from RCB about this since they will need to conduct additional method trials if some/all of these metabolites are to be regulated in animal commodities (See Attachment).

Thank you for your continued cooperation.

Attachment: Memo of 12/9/87, A. L. Jennings, Director, BUD, to E. F. Tinsworth, Director, RD

cc: RF, Circ, Reviewer (Nelson), PP#7F3476/FAP#7H5524, PM 21 (Rossi), E. Budd (TOX), H. Jacoby (SPMS), D. Marlow (BUD), ISB/PMSD (Eldridge).

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):
12/10/87.

RDI:SectionHead:RSQuick:12/10/87:DeputyChief:RDSchmitt(byKHArne):
12/10/87.



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

Chuck Trichilo
Bob -

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PESTICIDES AND TOXIC SUBSTANCES

*Please get together with
JOX & advise
on what residues
we are concerned
about.*

DEC - 9 1987

MEMORANDUM

SUBJECT: Rally, Tolerance Method
FROM: Allen L. Jennings, Director
Benefits and Use Division (TS-768)
TO: Edwin F. Tinsworth, Director
Registration Division (TS-767)

Allen L. Jennings
12/11

The purpose of this memo is to let you know that I have a number of problems in completing the lab work on the Rally analytical method. The problems stem from recent changes and additions to the tolerance method.

The meat and milk method was started in the fall shortly after we received the validation request from RCB. The method for apples and grapes was awaiting scheduling when we learned from you in early December that it had become a high priority. We shifted laboratory priorities and are now getting started on the apple and grape residue methods. I was optimistic that we could complete both methods for the parent compound by the end of January.

However, we have just been informed that new methods for the chemical have been received by Registration Division and transmitted to Residue Chemistry. Specifically, I understand that two new methods for certain metabolites have been added for meat and milk as well as for apples and grapes. In addition, modifications have also been made to the apple and grape methodology for the parent compound. Finally, a significant revision was made to meat and milk method by changing the way the Nitrogen-phosphorus and electron capture detectors will be used with the gas chromatograph. While it is not yet totally clear which of these additions and modifications will require lab validation, it is clear that any significant revisions will delay our schedule.

RECEIVED
RCB
12/11

I am willing to further juggle the lab priorities to meet your needs, but I need to know very soon which foods, methods, and combinations of parent and metabolite residues are needed first. Please let me know how you want to proceed.

cc: Jim Akerman