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WASHINGTON, D.C. 20460

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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No.: 476-2178. Phosmet.  
Protocol for a Stored Sweet Potato Residue Study.  
RCB #: 2603. MRID#: None.

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) *RK*

TO: Hoyt Jamerson, PM 43  
Registration Support & Emergency Response Branch  
Registration Division (TS-767C)

By letter dated June 17, 1987, IR-4 has submitted a draft protocol for conducting a residue study on unwashed sweet potatoes treated postharvest with phosmet prior to storage.

This study is required by the Guidance Document for the Reregistration of Pesticide Products Containing Phosmet as the Active Ingredient (9/86), which specifically states:

"Data depicting residues in or on unwashed sweet potatoes treated postharvest with the 5% D [Dust formulation] at 0.2 oz ai/50 lb [the registered use] must be submitted. Samples must be collected immediately after treatment and at regular (weekly) intervals thereafter until residues begin to decline. An appropriate tolerance revision must be proposed." [Table A, "Generic Data Requirements for Phosmet", §158.125 Residue Chemistry, Footnote 10.]

IR-4's draft protocol deviates from the Guidance Document in that IR-4 proposes to collect weekly samples only for 21 days (0, 7, 14, and 21), then at days 30 and 60. IR-4 requests the Agency's decision as to "whether additional weekly samples will be necessary to meet the Standard."

IR-4 also asks if the current method of analysis "meets the requirements for plant metabolism when considering this use pattern of phosmet." If not, IR-4 indicates this project will be put on hold until the data gaps in plant metabolism have been met.

### Discussion

The available residue chemistry data on phosmet-treated stored sweet potatoes are discussed (pp. 48-49) in the Residue Chemistry Chapter (3/26/86) prepared for the Phosmet Registration Standard.

Those data indicated extreme variability in residue values and the tendency for residues to apparently increase over time.

Based on those findings, the requirement for additional data from a stored sweet potato residue study conducted as described in the Guidance Document (quoted above) was imposed.

In light of the above, it is our considered opinion that the study should be run as the Guidance Document directs. IR-4 should be advised that weekly sampling throughout the entire course of the study is required, and that such sampling should continue as long as is necessary to unequivocally demonstrate that residues are on the decline (i.e., longer than 60 days, if necessary).

IR-4 should also be advised that storage conditions should reflect standard practice as to temperature, humidity, containers, etc., and these should be fully documented in the study report.

Because considerable variability in residue values may be encountered, IR-4 should be counselled to collect (and separately analyze) the 3-4 replicates/interval/method of treatment, as is currently being proposed.

We note that a concurrent storage stability study is planned, which we consider advisable.

As to IR-4's query as to the adequacy of the current enforcement methodology for residue analysis for this study, IR-4 should be advised that it would be prudent for them to delay the conduct of this residue study on stored sweet potatoes pending resolution of the plant metabolism data gaps on phosmet raised in the Guidance Document. [Ref. Table A, §158.125 Residue Chemistry, Footnote 3.]

We advise this since the Guidance Document clearly states:

"If the requested data regarding the nature of the residue in plants and animals reveal additional metabolites of toxicological concern, additional analytical methods for data collection and enforcement may be required." [Table A, §158.125 Residue Chemistry, Footnote 6.]

### Conclusions

1. Because of the variability in residue values which have previously been reported on phosmet-treated stored sweet potatoes, IR-4 should be advised that weekly sampling throughout the entire course of the study is required.
2. Weekly sampling should continue as long as necessary to unequivocally demonstrate that residues are on the decline (i.e., longer than the proposed 60 days, if necessary).
3. IR-4 should also be advised that storage conditions should reflect standard practice as to temperature, humidity, containers, etc., and these should be fully documented in their study report.
4. Because variability in residue values may be encountered, IR-4 should be counselled to collect (and separately analyze) the 3-4 replicates/interval/method of treatment, as currently proposed.
5. We note that a concurrent storage stability study is planned, which we consider advisable.
6. IR-4 should be advised that it would be prudent for them to delay the conduct of this residue study on stored sweet potatoes pending resolution of the plant metabolism data gaps on phosmet raised in the Guidance Document.

### Recommendations

IR-4 should be advised of the comments expressed in Conclusions 1-6 of this review.

cc: RF, Circ, Reviewer (M. Nelson), PM#43, Phosmet Registration Standard file, PP#3F1328, PMSD/ISB (Eldridge).  
TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):8/18/87.  
RDI:SectionHead:RSQuick:8/18/87:DeputyChief:RDSchmitt:8/18/87.