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

JUN 27 1985

MEMORANDUM

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP#4F3101 (RCB #1071). Acephate In Or On Leaf Lettuce. Amendment of 4/17/85.

FROM: W. T. Chin, Ph. D., Chemist  
Tolerance Petition Section II  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

*W. T. Chin*

THRU: Charles L. Trichilo, Ph. D., Chief  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

TO: William Miller, PM #16  
Registration Division (TS-767)

and

Toxicology Branch  
Hazard Evaluation Division (TS-769)

BACKGROUND

The petitioner, Chevron Chemical Company, has previously established a tolerance for the combined residues of the insecticide acephate (O,S-dimethyl acetylphosphoramidothioate) and its metabolite, methamidophos (O,S-dimethylphosphoramidothioate), in or on head lettuce at 10 ppm (methamidophos no more than 1 ppm) (PP#3F1375, 40 CFR 180.108).

The petitioner then submitted PP#4F3101 (Acc. #072685, 5/8/84) containing a volume of residue data generated on leaf lettuce grown in northeastern United States (OH, NY, NJ, VA and MI) and requested to add leaf lettuce to the label of ORTHENE 75S Soluble Powder already established for head lettuce. In other words, the petitioner requested to change the tolerance expression to read "Lettuce", rather than "Lettuce (Head)" thereby covering both head lettuce and leaf lettuce.

RCB recommended against this request because of deficiencies Nos. 3a, 3b and 3c identified in the 8/3/84 memo of K. H. Arne.

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PRESENT CONSIDERATIONS

In response to the above 3 deficiencies, the petitioner submitted the current letter dated on 4/17/85. The deficiencies are restated below and followed by the petitioner's responses and RCB's comments/conclusions.

Deficiency No. 3a

"The proposed use prohibits applications to winter-grown lettuce. This restriction is not practical; it should be removed from the label, and residue data reflecting application to winter lettuce should be submitted."

The petitioner's response to deficiency No. 3a

Winter-grown lettuce: We disagree that the proposed label restriction to Winter-grown lettuce is not practical. The term "winter crop" is one which is firmly established and well recognized in lettuce trade. It describes that portion of the U.S. lettuce crop that is grown in warmer climates, especially California, Arizona, Texas, New Mexico and Florida during the winter months. Seed trade journals as well as USDA and University publications consistently identify the Winter lettuce crop as a discrete entity. Our proposed label twice includes the same restriction against treating Winter lettuce ("Spring, Summer and Fall Crops only", and, "Do not apply to winter crops"). We note that at least one other registered label (Di-Syston 8) contains similar seasonal designations in its lettuce use directions. A copy is attached. From the above examples, we fail to see how such a restriction can be deemed impractical and would welcome any suggestion from the Agency which would describe this restriction less ambiguously.

It is also worth noting that lettuce, once harvested is not stored, to be re-leased to the market as prices warrant. Lettuce spoils so quickly that storage beyond a very brief period is not possible. Thus, Winter grown lettuce (or any lettuce) could not be mixed with Fall, Spring or Summer grown lettuce. This is itself makes the proposed restriction a practical one to implement."

RCB's comments/conclusions on the petitioner's response to deficiency No. 3a

RCB concludes that deficiency No. 3a is justified and, therefore, should remain outstanding because of the following reasons:

1. Lettuce includes head lettuce and leaf lettuce and is a major crop. Both head lettuce and leaf lettuce are planted in all regions of the U. S. A.

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2. The petitioner's request is to change the tolerance rule to read "Lettuce", rather than "Lettuce (Head)". This will mean that the petitioner intends to use the currently established tolerance for head lettuce to cover leaf lettuce.
3. Seasonal designations of leaf lettuce are not RCB's major concern, and the so-called "winter-grown lettuce" may mean either winter grown head lettuce or winter grown leaf lettuce. RCB's major concern is the adequacy of the residue data generated from leaf lettuce grown in all seasons and all major areas in U. S. A.

Deficiency No. 3b

"The submitted residue studies are primarily from the Northeastern United States and do not include experiments from the major lettuce producing states. We require data from California, Texas, and Florida as well as additional data from Northern states (for the reasons listed in 3c). Some experiments should represent applications to winter-grown lettuce; the Imperial Valley of California should be included in these latter."

The petitioner's response to deficiency No. 3b

"Additional Residue Data: The data presented in PP#4F3101 contained residue analyses from the following states: Michigan, New Jersey, Ohio and Virginia. The states which your reviewer lists as deficient are California, Texas and Florida... these are the states where almost all winter lettuce is grown and our label is properly labelled against usage on that winter crop. These analyses reflected treatment at the maximum proposed rate and number of applications. No further data should be required to support this petition because of the 16 trials conducted the maximum residue encountered was 1.9 ppm on leaf lettuce treated at the proposed label rate and harvested 21 days after the last application. This should be sufficient evidence that the tolerance will not be exceeded when Orthene is used to treat leaf lettuce."

RCB's comments/conclusions on the petitioner's response to deficiency 3b

RCB still concludes that it is impractical to use limited residue data of leaf lettuce generated from few northeastern states to reflect other major areas where leaf lettuce is grown. Therefore, deficiency No. 3b is justified and still remain outstanding.

Deficiency 3c

"A storage stability study submitted with PP#3F1375 shows that recoveries of acephate, per se, from lettuce samples stored for six months are adequate, but that for longer intervals (9-12 months) losses of greater than 50% may occur. Residues in stored extracts of lettuce did not decrease as quickly, but some data in the present petition were stored for as long as 17 months before extraction, and only a few samples were stored for less than six months. The additional data requested above (3b) should be from samples that are stored six months or less before analysis."

The petitioner's response to deficiency No. 3c

"Storage Stability Data: The harvest-to-analysis storage time for all of the samples presented in 4F3101 varied from one to seventeen months. See attached Table 1 for a summary of these analyses. We see no pattern in the analytical results from these sixteen tests to suggest that freezer storage of samples for up to seventeen months in any way affects the final measured residue. Indeed, PP#3F1375 which you referred to in your letter, also failed to establish such a degradation effect for lettuce after up to twelve months in storage (see T-2260/1 and T-2260/2 where the samples were actually spiked at 2.5 ppm with no subsequent degradation). (See Table 2 attached.)"

RCB's comments/conclusions on the petitioner's response to deficiency No. 3c

RCB still concludes that deficiency No. 3c is justified and should remain outstanding. Based on the above considerations, RCB concludes that the petitioner's request to change the tolerance rule to read "Lettuce", rather than "Lettuce (Head)", will be appropriate only after the requested residue data from Texas, California and Florida have been received and these data must be from samples that are stored six months or less before analyses.

OTHER CONSIDERATIONS

In accordance with conclusions reached in RCB's third addendum to the Acephate Registration Standard (see the 10/5/84 memo of C. L. Trichilo), it is now recommended that all acephate tolerances be expressed in terms of only acephate per se under 40 CFR 180.108 and 21 CFR 561.20. Residues of methamidophos resulting from the metabolism of acephate are most appropriately placed under the tolerance regulations for methamidophos as a pesticide (40 CFR 180.315 and 21 CFR 561.277). The reason for this is to achieve compatibility with the MRLs of the Codex Alimentarius Commission, if only in terms of residue definition. Such a change

in the residue definition would require deletion of paragraph (d)(8) of 40 CFR 180.3 which states that methamidophos residues may not exceed the higher of the two tolerances established for the use of acephate or methamidophos as a pesticide. A statement should be added to 40 CFR 180.108 explaining that residues of the acephate metabolite methamidophos are regulated under 40 CFR 180.315, the methamidophos section. Also, 40 CFR 180.315 should be subdivided into parts (a) and (b) where (b) includes tolerances reflecting regulation of acephate formulations alone (i.e., methamidophos formulations are not registered for use on these commodities) and where (a) includes tolerances reflecting the situation where both acephate and methamidophos registered on the same crop.

#### RECOMMENDATION

RCB concludes that deficiencies Nos. 3a, 3b and 3c identified in the 8/3/84 memo of K. A. Arne are justified and remain outstanding. Therefore, RCB continues to recommend against establishing a proposed tolerance for the combined residues of acephate and its metabolite, methamidophos, in or on leaf lettuce at 10 ppm (of which methamidophos is no more than 1 ppm).

cc: R.F., Circu., W.T.Chin, TOX, PP#4F3101, PMSD-ISB, EAB, EEB, FDA, Thompson(RTP)NC  
RDI: J.H.Onley(6/26/85), R.D.Schmitt(6/26/85)  
TS-769: RCB:CM#2, RM812,557-7484, W.T.Chin,wc(6/27/85)