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

7-30-84

JUL 30 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3E2939 Chlorothalonil on Cranberries. Comments
on Amendment of April 27, 1984 (Acc. No. 253191)

FROM: Martin F. Kovacs, Jr., Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: Hoyt Jamerson, Minor Uses Officer
Process Coordination Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

In our previous review of this petition (memo of January 13, 1984, M. Kovacs), we recommended against the establishment of tolerances for combined residues of the fungicide chlorothalonil (tetrachloroisophthalonitrile) and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile in or on the raw agricultural commodity cranberries at 2.0 ppm. For a favorable recommendation, we indicated the following would be needed:

1. In the absence of submitted residue data for the impurities HCB and PCBN on cranberries following the proposed use of BRAVO 500 formulations, we calculated maximum theoretical residues of HCB and PCBN on cranberries of <0.002 ppm and <0.05 ppm respectively. Unless TOX Branch objects, we (RCB) consider these calculated maximum impurity levels of no concern. However, if TOX Branch is concerned, then the petitioner must provide RCB with either (1) assay data on the BRAVO 500 formulations used in the residue trials submitted, all reflecting impurity levels of HCB and PCBN

IMPURITY (NPD IS NOT INCLUDED)

at less than [REDACTED] respectively or as an alternative (2) reanalyses of selected cranberry samples for residues of both HCB and PCBN all treated at the maximum proposed use rate. If reanalyses of these samples reveals finite residues of HCB and PCBN at levels of concern to TOX Branch then these residues may need to be included in a revised tolerance expression for cranberries.

2. Because of the need for an explanation by the petitioner as to the reason for high control or check values of chlorothalonil residues in the NJ and WA residue trials, resolution of questions relating to the inclusion of HCB and PCBN in the tolerance expression, and submission of chromatograms depicting residues of chlorothalonil in the WA trial (Check Samples #823-826), we cannot conclude that adequate analytical methodology is available to enforce the proposed tolerance on cranberries at this time.
3. We reserve our final conclusion regarding the adequacy of the proposed tolerance for use of chlorothalonil on cranberries grown in MA, NJ and WI until the petitioner provides information regarding the mode of application (i.e., ground vs aerial) used in the submitted residue studies. If the submitted residue data were obtained by ground application only then Section B must be revised to reflect this use pattern.
4. We reserve our final conclusion regarding the adequacy of the proposed tolerance for use of chlorothalonil on cranberries grown in WA until conclusion 3 above has been resolved and in addition until the petitioner either (1) submits to RCB representative chromatograms of all previous sample analyses including calculations and representative chromatograms of check samples (see our conclusion 2 above) and reanalyzes all samples collected in that residue trial or (2) conducts additional residue studies in WA at the maximum proposed use rates and minimum PHI's permitted on the label. If new residue data are submitted, the mode of application (i.e., ground vs. aerial) must be specified and all sample analyses (including check samples) submitted should include representative chromatograms.

The petitioner has now responded to the deficiencies, respectively, as follows:

1. The petitioner has not responded to this deficiency per se, however, the final resolution of this deficiency is predicated upon an opinion from TOX Branch as to their concern, if any, regarding the maximum calculated residue levels of HCB and PCBN on cranberries resulting from the proposed use. In the absence of such an opinion from TOX Branch, RCB must therefore conclude that deficiency No. 1 (Conclusion 1a of the M.F. Kovacs 1/13/84 review of PP#3F2939) has not been resolved.
2. In response to deficiency No. 2 (Conclusion 3 of the M.F. Kovacs 1/13/84 review of PP#3F2939) the petitioner has submitted chromatograms of the requested WA residue trial check samples #823-826. In addition, the petitioner has submitted copies of letters from two IR-4 cooperators who conducted the residue trials in WA and NJ. Dr. A. Y. Shawa of Washington State University stated in his 3/5/84 letter to Dr. M. E. Burt, IR-4 Project, Cook College Rutgers University, that high control or check values in the submitted WA residue trial was presumably due to air movement at time of application which was responsible for drift of spray to the control plots and in addition ~~juvenile berries which were present at time of application would have~~ been contaminated. In a 3/3/84 letter to Dr. Burt from Allan W. Stretch, USDA, ARS, NER, Blueberry and Cranberry Research Center, Rutgers University, Dr. Stretch stated that the plot diagram used in the NJ residue trial indicated that only 1 of the 10 6' X 6' check plots in the trial was located at a distance of more than 2' from any of the treated 6' X 6' cranberry plots, thereby contributing to some spray drift into check plots in the absence of barriers. In addition, Dr. Stretch indicated that treated plots were handpicked and no washing of hands was done between plots, thereby also contributing to an additional source of contaminated checks.

Our Comments/Conclusions on Deficiency No. 2

Our examination of the petitioner's submitted check sample chromatograms (#823-826) from the WA residue trial clearly indicate a well defined peak at the RT of chlorothalonil in all 4 samples at calculated concentrations ranging from 0.70 to 1.90 ppm and averaging 1.37 ppm. The explanations provided in the letter submitted by the IR-4 project cooperators from both WA and NJ as to the reasons for the high check values observed appear to be reasonable. Based on this information, RCB concludes that the reported high check values are indicative of errors in either experimental design or procedure and in no way reflect upon the adequacy of the enforcement analytical methodology. If TOX renders an opinion that HCB and PCBN are not of toxicological concern for the proposed use, then RCB could conclude that adequate analytical methodology is available to enforce the proposed tolerance on cranberries. However, as we have previously noted above, final resolution of deficiency No. 2 is also contingent upon resolution of deficiency No. 1.

3. In response to deficiency No. 3 (Conclusion 4a of the M.F. Kovacs 1/13/84 review of PP#3F2939) the petitioner surveyed all cooperators participating in the MA, NJ and WA residue trials as to the mode of chlorothalonil application (i.e. ground vs aerial) used in their respective trials. In all cases, the cooperators reported that applications were made by ground equipment only.

The petitioner takes issue with EPA's statement that "if the residue data were obtained by ground application only, then Section B of the petition must be revised to reflect this use pattern". In support of his rebuttal to EPA's statement above, the petitioner has included in his submission the results of prior studies that demonstrate no differences in residues obtained when chlorothalonil was applied either aerially or by ground equipment to the same crop.

In a study entitled "Fungicide Application Through Sprinkler Irrigation Systems", by G.M. McMaster and D.R. Douglas presented at the December 15-18, 1975 meeting of the American Society of Agricultural Engineers, chlorothalonil was applied to potato fields at 5 Idaho locations via either solid set sprinkler irrigation systems, ground rig or aerial methods at the

manufacturers recommended rates and potato foliage was assessed for early blight symptoms, 3-4 weeks following application and analyzed for residue deposits of chlorothalonil (ug/cm^2) at 1 to 2 days following application. Overall, surface area residues on potato foliage following sprinkler, ground rig and aerial applications were (0.1 to 0.8) average 0.37 ug/cm^2 (1.4 to 10.1) average 4.27 ug/cm^2 and (0.1 to 6.3) average 3.97 ug/cm^2 respectively. The study results indicated no significant difference in total amount of chlorothalonil surface residues on potato foliage following either ground or aerial applications.

In the current submission the petitioner also cites a summary table obtained from a Florida celery study demonstrating relative chlorothalonil deposits (mg/mm^2) after (time not specified) application of BRAVO 6F at 1 1/2 pts/A by ground rig, or by fixed wing aircraft equipped with either micronair units or with a conventional spray boom. Here again, no significant difference was observed between surface area residues of chlorothalonil on celery following ground rig and fixed wing applications i.e. (0.097 to 0.130) average 0.114 mg/mm^2 and (0.056 to 0.160) average 0.115 mg/mm^2 respectively.

Citing the results of the aforementioned studies the petitioner contends that crop residues of chlorothalonil resulting from aerial applications may be expected to be present at lower levels than those from ground applications with the results translatable from both potato foliage and celery to cranberries. Accordingly, the petitioner further states that chlorothalonil residues from aerial applications can be expected to be within the established tolerance limits (on cranberries) when applied according to approved directions for use.

Our Comments/Conclusions on Deficiency No. 3

RCB disagrees with the petitioner's conclusions that the results of the cited chlorothalonil residue deposit studies on both potato foliage and on celery can form a basis for predicting expected chlorothalonil residues on cranberries following aerial applications. The commodities tested, potatoes and celery, are

both botanically quite dissimilar from cranberries, belong to different crop groupings for tolerance purposes as defined in 40 CFR §180.34(f) and in addition represent widely differing crop cultural practices. For these reasons, RCB cannot conclude as the petitioner has, that the surrogate residue data submitted on both potato foliage and celery demonstrate that residues of chlorothalonil on cranberries resulting from aerial applications can be expected to be at the same or lower levels than those actually observed following ground applications.

Accordingly, since the previously submitted residue data on cranberries in PP#3E2939 reflected ground applications only either Section B must be revised to reflect this use pattern and the requested additional residue studies from WA (see our comments/conclusions under Deficiency No. 4 below) must reflect this use pattern or as an alternative additional residue studies must be submitted from WA, WI, MA and NJ reflecting both aerial and ground applications to cranberries.

RCB concludes that deficiency No. 3 (Conclusion 4a of the M.F. Kovacs 1/13/84 review of PP#3F2939) has not been resolved.

4. In response to Deficiency No. 4 (Conclusion 4b of the M. F. Kovacs 1/13/84 review of PP#3F2939) the petitioner has chosen not to address item (2) that is, to conduct additional residue studies in WA at the maximum proposed use rates and minimum PHI's permitted on the label. Instead, the petitioner has attempted to address Conclusion 4b (1) via submission of the requested check sample chromatograms (#823-826) from the WA residue trial (see RCB's comments/conclusions on Deficiency No. 2 (conclusion 3) discussed above regarding its evaluation of these submitted chromatograms). However, the petitioner has not complied with our additional requests in conclusion 4b to submit to RCB representative chromatograms of all previous sample analyses (including calculations) and reanalyses of all samples collected in the WA residue trial. In regard the latter, the petitioner has merely stated that "Regarding the reanalysis of the Washington check samples 823-826, it is unlikely that the results would be significantly different upon reanalysis".

Our Comments/Conclusions on Deficiency No. 4

Notwithstanding the petitioner's failure to comply with RCB's original request (see Conclusion 4b (1) of RCB's M.F. Kovacs 1/13/84 review of PP#3E2939) to submit representative chromatograms of all previous sample analyses and reanalyses of all samples collected in the WA residue trial, based on RCB's evaluation of the check sample chromatograms submitted by the petitioner (#823-826) together with the letter of 3/5/84 from Mr. A.Y. Shawa of Washington State University to Dr. M.E. Burt (IR-4) documenting drift of chlorothalonil spray from treated to control plots in the WA residue trial, RCB can now conclude that no credence can be placed on the accuracy of the submitted chlorothalonil residue data previously reported in PP#3E2939 on cranberries as "uncorrected" residues. Accordingly, the previously submitted WA residue data reflecting ground applications only at 1 or 2X the maximum recommended application rate and at a 100 day PHI (50 days recommended on the proposed label) will not support the proposed tolerance of 2.0 ppm for residues of chlorothalonil and its metabolites on cranberries. Therefore, RCB now reiterates its original conclusion 4b (2) of the aforesaid review i.e. that the petitioner conduct additional residue studies in WA at the maximum proposed use rates and minimum PHI's permitted on the label. In addition, in the absence of a revised Section B, the requested additional residue data from WA should reflect both ground and aerial applications. All sample analyses, including check samples, should include representative chromatograms.

RCB concludes that Deficiency No.4 (Conclusion 4b of the M.F. Kovacs 1/13/84 review of PP#3F2939) has not been resolved.

Recommendations

RCB continues to recommend against establishment of a tolerance for combined residues of the fungicide chlorothalonil and its metabolite 4-OH chlorothalonil in or on the raw cranberries at 2.0 ppm.

✓ A favorable tolerance consideration is contingent upon TOX Branch expressing no concern regarding maximum calculated residues of the impurities HCB at ≤ 0.002 ppm and PCBN at ≤ 0.05 ppm on cranberries following the proposed use of BRAVO 500 formulation (see conclusion 1a of our M. F. Kovacs 1/13/84 review of PP#3F2939). If TOX Branch expresses concern over these calculated maximum residue levels of HCB and PCBN on cranberries, then either requirement (1) or (2) under Conclusion 1a above must be satisfied by the petitioner.

For further tolerance consideration, the petitioner should revise Section B to reflect ground application only or as an alternative, additional residue studies must be submitted from WA, WI, MA and NJ reflecting both aerial and ground applications to cranberries. The petitioner should conduct additional residue studies in WA at the maximum proposed use rates and minimum PHI's permitted on the label, and in the absence of as revised Section B, as recommended above, the submitted data should reflect both ground and aerial applications. The petitioner should also submit the results of sample analyses to include check samples and representative chromatograms.

The International Residue Limit (IRL) Status sheet is attached. According to it there are no Canadian or Mexican tolerances for chlorothalonil residues on cranberries. The Step 9 Codex IRL temporary limit of 5.0 ppm for residues of chlorothalonil only on cranberries has been proposed pending WHO full ADI. In addition, as recommended by 1983 JMPR the previously included 4-OH metabolite portion of the tolerance expression has been deleted based on the conclusion that the 4-OH residues are only a maximum of 10% of the total residue. The level of the proposed Codex temporary limit (5.0 ppm) although incompatible with the 2.0 ppm tolerance proposed in this petition is more than adequate to cover the submitted residue data. However, after questions relating to the residue data submitted in this petition have been resolved, and more importantly, until currently outstanding deficiencies cited in our M.F. Kovacs 11/7/83 review of PP#3F2875 re the nature of the residue in both plants and animals (see also Chlorothalonil Registration Standard dated 11/4/83) have been resolved, we cannot at this time, for the sake of compatibility with the Codex IRL revise U.S. chlorothalonil tolerances to express results as "chlorothalonil only."

cc:R.F., Circu, Reviewer, TOX, EAB, EEB, PP#3E2939
FDA, Robert Thompson
RDI:J. Onley:7/6/84:R.D. Schmitt:7/6/84
TS-769:M. Kovacs:wh:CM#2:RM810:X7484:

INTERNATIONAL RESIDUE LIMIT STATUS

MURPHY HOUSE

CHEMICAL Chlorothalonil

PETITION NO. 3E7934

CCPR NO. 81

(AMENDMENT)

7. Joes 7/9/84

Codex Status

Proposed U. S. Tolerances

No Codex Proposal
Step 6 or above

FOR Sec. 180.275

Residue (if Step 9): _____

Chlorothalonil 1/

Residue: Chlorothalonil AND

METABOLITE *

Crop(s) Limit (mg/kg)^{2/}

cranberries 5.

Crop(s) Tol. (ppm)

CRANBERRIES 2.0

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue: _____

Residue: _____

Crop Limit (ppm)

Crop Tolerancia (ppm)

1/ "non-substantial" amendment recommended by 1983 JMPR. Previously included 4-OH Metabolite. Change as result of indicator compound concept.

2/ Temporary limits pending WHO full ADI.

Notes: * 4-Hydroxy-2,5,6-Trichloroisophthalonitrile