US EPA ARCHIVE DOCUMENT

R.F.
3-16-87

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

MAR 16 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP #4E2998. (RCB #1952) Vinclozolin (Ronilan) in or on Peppers and Tomatoes. Amendment of 1/12/87. No Accession No.

FROM: Cynthia Deyrup, Ph.D., Chemist Cynthia Deyrup
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: Lois Rossi, Product Manager #21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Note: The FDA (Paul Corneliussen) should be notified that there is a potential for the occurrence of illegal residues of vinclozolin on imported tomatoes and processed tomato products from Italy.

Background

BASF Corporation had proposed the establishment of permanent tolerances for residues of the fungicide vinclozolin [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] and its metabolites containing the 3,5-dichloroaniline moiety in/on imported tomatoes at 2.0 ppm and imported cucumbers at 1.0 ppm. The amendment of 7/31/84 also proposed to establish a tolerance for vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in/on imported green peppers at 3.0 ppm.

Present Submission

The present submission consists of a revised Section F and a cover letter from J.R. Graham, (BASF, 1/12/87) to L. Rossi,

RD. The remaining deficiencies will be cited below, followed by the petitioner's response and RCB's Comments/Conclusions. The following deficiencies were described under Sections A and B of Other Considerations in RCB's review of 11/17/86.

Deficiency A

While reviewing the current amendment, it was noted that Section F proposes a tolerance for residues of Ronilan on "Peppers." The residue data reflected analyses on "Green Peppers" and "Peppers." The petitioner will need to identify the varieties of peppers used in the greenhouse trials. If the petitioner's intent is to propose a tolerance on peppers, residue data on all varieties of peppers, including pimentos and bell and hot and sweet peppers are required [40 CFR 180.1(h)]. Alternatively, if the residue data reflect greenhouse trials on bell peppers, the petitioner has the option of proposing a tolerance on bell peppers in a revised Section F.

Petitioner's Response

The petitioner explains that the residue data on peppers reflected analyses on bell peppers. The revised Section F proposes a tolerance of 3.0 ppm for residues of vinclozolin and its metabolites bearing the 3,5-dichloroaniline moiety on bell peppers imported from the Netherlands.

RCB's Comments/Conclusions

The proposed tolerance reflects the commodity which was actually the subject of the greenhouse trials. Deficiency A is resolved.

Deficiency B

RCB was concerned that the establishment of an import tolerance on tomatoes grown in Dutch greenhouses could lead to the issuance of 24(c) registrations. If a state such as California were to be issued a 24(c) registration, RCB felt that treated tomato pomace would probably be fed to livestock. Also, since the Office of General Counsel has stated that establishment of an import tolerance could make it difficult to deny 24(c) registrations, RCB concluded that such registrations would not be supportable from a residue chemistry point of view; there may be no relevance between residue studies conducted in Dutch greenhouses and residue levels expected in the open fields in the US. RCB concluded," Thus, additional residue data on domestic tomatoes, processing studies, and animal feed and metabolism studies, if needed, should be required before Ronilan is used on US tomatoes. To avoid these problems, we suggest adding to the CFR language which stipulates that import tolerances may not be used to justify the issuance of a 24(c) label. Similar wording is now used for tolerances with regional registration in the US. RCB suggests that RD contact the Office of General Counsel on the feasibility of such an addition to the CFR."

Petitioner's Response

The petitioner has submitted a revised Section F from which the proposed tolerance on tomatoes has been withdrawn.

RCB's Comments/Conclusions

Withdrawing the proposed tolerance on tomatoes addresses RCB's concerns regarding the issuance of state labels and problems associated with that possibility. Deficiency B is resolved. [However, since Ronilan is registered for use on Italian tomatoes, there is a distinct possibility that processed tomatoes bearing illegal residues of Ronilan are entering the US (see Other Considerations)].

Other Considerations

In its review of the amendment of 4/4/86, RCB noted that the petitioner did not submit a revised Section F proposing a food additive tolerance on processed tomato products. The petitioner's fractionation study had shown that there is a 3 fold concentration of residues in processed tomato products relative to the raw agricultural commodity. In the 4/4/86 review, RCB (memo of C. Deyrup) pointed out, "Ronilan is already registered for use on tomatoes in Italy, which is the major exporter of processed tomato commodities to the US and accounts for about 1/3 of the processed tomato commodities which are imported. The most recent figures indicate that about 120 million pounds of processed tomatoes (canned, paste, etc.) were imported from Italy (telecon of 7/3/86 with D. Hodgen, International Trade Association, US Department of Commerce)."

In its review of the amendment of 11/17/86 (memo of C. Deyrup), in which the petitioner had submitted a revised Section F, RCB had suggested adding to the CFR language which stipulates that import tolerances may not be used to justify the issuance of a 24(c) label. In this way a tolerance could have been established which would cover residues in processed tomatoes (which in all likelihood would come from Italy instead of the Netherlands). The petitioner has withdrawn tomatoes from the petition and has thereby resolved the remaining deficiencies A and B; but imported processed tomatoes bearing residues of Ronilan could now be subject to seizure.

In view of Italy's importance as an exporter of processed tomatoes to the US and the registered use of Ronilan on Italian tomatoes, RCB suggests that the FDA monitor processed tomatoes from Italy for illegal residues of Ronilan. The Agency would appreciate any information that the registrant can provide on the extent that Ronilan is used on Italian tomatoes.

Neither Codex, Canada, nor Mexico has established tolerances for

residues of vinclozolin on bell peppers. Codex has proposed an MRL (maximum residue level) of 2.0 ppm vinclozolin and its 3,5-dichloroaniline containing metabolites on sweet peppers; this level is unlikely to change. Therefore there could be a future compatibility problem.

Recommendations

TOX and EAB considerations permitting, RCB recommends that the proposed tolerance of 3.0 ppm vinclozolin/metabolites be established on bell peppers.

Note to PM: RCB's position regarding the need for monitoring tomatoes and processed tomato products from Italy would probably be of interest to the registrant, and he should be so informed. RCB would also appreciate any information the registrant can provide on the extent that Ronilan is used on Italian tomatoes.

cc: TOX, PMSD/ISB, PP #4E2998, R.F., Circu, Reviewer-Deyrup
EAB, FDA
RDI: JHOnley:3/11/87:RDSchmitt:3/11/87
TS-769:RCB:CM#2:RM810:X7484:CDeyrup:cd:3/11/87

Attachment #1

INTERNATIONAL RESIDUE LIMIT STATUS

J. Kier 3/6/87

CHEMICAL Vinclozolin

CODEX NO. none

CODEX STATUS:

☑ No Codex Proposal *
Step 6 or above

Residue(if Step 8): sum of vinclozolin and all metabolites containing 3,5-dichloroaniline, expressed as vinclozolin **

Crop(s)	Limit (mg/kg)
sweet peppers	2 *

PROPOSED U.S. TOLERANCES:

Petition No. 4E2998

RCB Rewiewer C. Deyrup

Residue: Vinclozolin + metabolites containing 3,5 dichloroaniline moiety

Crop(s)	Limit (mg/kg)
Bell peppers	3

CANADIAN LIMITS:

☑ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

* proposal by 1986 JMPR, will be considered by Codex at step 3. The Codex commodity definition includes bell peppers. Codex proposal will be temporary because ADI is temporary, but numerical level unlikely to change.

** Definition proposed by 1986 JMPR.

* NOTES