



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

NOV 17 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP #4E2998 (RCB #770) Vinclozolin (Ronilan™) in/on tomatoes, cucumbers, and peppers. Amendment of 8/29/86. 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, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Henry Jacoby, Product Manager #21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

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. That amendment did not address the deficiencies cited by RCB in its review of the original submission, which had been rejected (PP #4E2998, memo of J.H. Onley, 3/30/84). The amendment to establish a tolerance on imported green peppers was also rejected because of a number of deficiencies (PP #4E2998, memo of C. Deyrup, 10/17/84). A subsequent amendment, dated 4/4/86, did not fully address the deficiencies cited in RCB's memos of 3/30/84 and 10/17/84 (see memo of C. Deyrup, 7/22/86).

Present Submission

The present submission consists of a cover letter from M. Schreiner, BASF, to H. Jacoby, RD (the letter contains a revised Section B and the petitioner's responses to deficiencies cited in previous reviews), a revised Section F and a Dutch Ronilan FL (flowable) label were also submitted.

The deficiencies which are still outstanding (specified by number and date of the memorandum), will be repeated or summarized below, followed by the Petitioner's Responses and RCB's Comments/Conclusions. Where pertinent, RCB's Comments/Conclusions from previous reviews to these deficiencies will also be summarized.

Deficiency 1, (Memo of J.H. Onley, 3/30/84); Deficiencies 1a and 1b (Memo of C. Deyrup, 10/17/84)

RCB had requested label translations and application instructions for the use of Ronilan in the Netherlands, the Federal Republic of Germany, Spain, Italy, Great Britain, Belgium, Costa Rica, Italy, Jordan, Japan, and Hungary. RCB had not been able to determine from the submissions in which countries Ronilan was to be used.

RCB's Comments/Conclusions, Memo of C. Deyrup, 7/22/86

RCB told the petitioner that the country where vinclozolin was to be used must be specified. RCB also needed to know the details of the proposed use (such as the number of applications permitted per season and the dosage rate) and how this information would be transmitted to the applicators, since it wasn't on the submitted labels. Since the residue data reflected greenhouse use, RCB also needed to know whether the proposed use was limited to greenhouse use. Although the petitioner had submitted a translation of a Dutch label, RCB could not determine whether the translation was of a Ronilan FL label or a Ronilan 50 WP label.

Petitioner's Response, Present Amendment, re: Deficiencies 1, 1a, and 1b

The petitioner states that the application for the vinclozolin import tolerances is for the use of Ronilan on "...tomatoes and peppers treated with Ronilan (Vinclozolin) in greenhouses in the Netherlands only."

According to the petitioner, the translation submitted with the amendment of 7/31/84 was a translation of the Ronilan WP label. The Dutch Ronilan FL label was submitted with this amendment. The petitioner said that the use patterns for Ronilan WP and Ronilan FL are identical.

The petitioner explains that in the Netherlands, use directions are given by the Netherlands Ministry of Agriculture. The Ministry of Agriculture recommends that vinclozolin be applied

2-3 times during the season at a rate of up to 3000 l of a 0.05% spray per hectare. This application rate is equivalent to 0.75 kg a.i./ha. A 3-day PHI is imposed.

RCB's Comments/Conclusions

The petitioner has specified that the proposed use is limited to greenhouse use in the Netherlands.

The petitioner has submitted the Ronilan FL label.. Although no translation was provided, according to the petitioner, the registered use for Ronilan FL is identical to that of Ronilan WP. The Ronilan FL label, like the Ronilan WP label, also does not specify the dosage in terms of weight/unit area, but according to the petitioner, use directions are available from the Ministry of Agriculture.

Since the petitioner has limited the use of Ronilan to the Netherlands, the deficiencies regarding the proposed use in Spain and Italy are moot.

Deficiencies 1 (memo of 3/30/84), 1a, and 1b (memo of 10/17/84) are resolved.

Deficiency 3d (Memo of C. Deyrup, 10/17/84); Deficiency 4a, (Memo of J.H. Onley, 3/30/84)

RCB required residue data from those countries where the petitioner proposed to use Ronilan.

RCB's Comments/Conclusions, Memo of C. Deyrup, 7/22/86

RCB needed to know details of the proposed use, how these details would be transmitted to the applicators, additional residue data reflecting the proposed use on cucumbers grown in the Netherlands, whether open field applications were to be permitted, and additional residue data if the petitioner intended Ronilan to be used in countries from which no residue data had yet been submitted. RCB also wanted to know details of the proposed use on tomatoes grown in Italy. RCB had not been able to assess the residue data in terms of the proposed uses because the details of the proposed use were not on the Dutch labels.

Petitioner's Response, Present Amendment, re: Deficiencies 3d and 4a

The petitioner has withdrawn the proposed tolerance for residues of vinclozolin on cucumbers in a revised Section F. The petitioner's responses to the other problems cited were described under "Petitioner's Response re: Deficiencies 1, 1a, and 1b" above.

RCB's Comments/Conclusions

Since the petitioner has limited application of Ronilan to peppers and tomatoes grown under glass in the Netherlands, and has explained how the applicators will obtain the use directions, the deficiencies related to these issues are now resolved. The deficiencies regarding cucumbers and applications in countries other than the Netherlands are considered moot.

The petitioner has submitted the use directions for tomatoes and peppers; RCB is now able to evaluate the residue data in terms of the proposed use.

Peppers

The proposed use of Ronilan on greenhouse peppers would permit up to 3 applications at a rate of 0.75 kg. a.i./ha per application. A PHI of 3 days is imposed.

The petitioner had submitted residue data on peppers from 4 greenhouse trials conducted in the Netherlands (amendment of 4/4/86). The peppers received 3 treatments at a rate of 0.75 kg. a.i./ha. PHI's of 3 days were imposed in 2 trials, and PHI's of 7 days were observed in the other 2 trials. Although only 2 trials reflect the proposed 3 day PHI, RCB will also consider previously submitted residue data on peppers grown in English greenhouses. England and the Netherlands are separated by about 150 miles, are rather small countries, and are at similar latitudes. The French greenhouse study will not be considered because the amount of sunlight varies widely from one end of France to the other, and RCB is not certain whether the sunlight conditions in Ales, France are appropriate.

The pertinent data are tabulated below.

# Treatments x rate (kg. a.i./ha/application) and country	PHI	Residue level (ppm)
4 x 1.0	0	1.44
England	1	0.75
	3	0.92
	7	1.25
	14	0.54
4 x 0.75	7	0.30-0.34
England	14	0.28-0.75
4 x 0.5	1	2.27
England	7	2.22
3 x 0.75	3	0.60-1.05
Netherlands	7	0.77-1.09

From the above residue data, RCB concludes that the proposed tolerance of 3.0 ppm vinclozolin in/on the pepper varieties examined will be adequate to cover residues expected to arise from the proposed use (see the Other Considerations section of this review for RCB's comments on pepper varieties).

Tomatoes

The proposed use would permit up to 3 applications of Ronilan to greenhouse tomatoes grown in the Netherlands at a rate of 0.75 kg. a.i./ha per application.

The petitioner has submitted residue data from 4 greenhouse trials on tomatoes grown in the Netherlands. These data are tabulated below.

# Treatments x rate (kg. a.i./ha/application)	PHI	Residue level (ppm)
3 x 1.0	3	0.76-1.11
3 x 0.75	3	0.55-0.93
5 x 0.75	3	0.48-0.93

From the above residue data, RCB concludes that the proposed tolerance of 2.0 ppm vinclozolin in/on greenhouse tomatoes grown in the Netherlands will be adequate to cover residues expected to arise from the proposed use.

The problems associated with the residue data reflecting the use of Ronilan on greenhouse tomatoes and peppers grown in the Netherlands have been adequately addressed. Deficiencies 3d (memo of C. Deyrup, 10/17/84) and 4a (memo of J. Onley, 3/30/84) have been resolved.

Deficiency 3e (Memo of C. Deyrup, 10/17/84)

RCB had not been able to judge the appropriateness of the proposed tolerances on peppers.

Petitioner's Response and RCB's Comments/Conclusions

The Petitioner's Response and RCB's Comments/Conclusions are detailed in the preceding sections of this review. Deficiency 3e is unresolved; the petitioner needs to identify the peppers in the field trials (see Other Considerations).

Deficiency 5 (Memo of J. Onley, 3/30/84)

The petitioner's tomato fractionation study showed a maximum Ronilan concentration of about 3X in tomato puree. In view of this, the petitioner should propose a food additive tolerance (which needs to be 3 times the value of the proposed tolerance on whole tomatoes) as follows:

Processed tomato products.....X ppm

Petitioner's Response re: Deficiency 5

The petitioner has submitted a revised Section F in which he proposes a food additive tolerance of 6.0 ppm for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety for processed tomato products.

RCB's Comments/Conclusions

The proposed food additive tolerance is 3 times higher than the tomato tolerance; RCB considers Deficiency 5 resolved.

Other Considerations

- 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. In the revised Section F, the petitioner should also specify that the food additive tolerance on processed tomato products would be covered under 21 CFR 193.137.
- B. The proposed tolerance for processed tomato products satisfies the requirement for a food additive tolerance. The fractionation study submitted with the original petition did not include residue data on tomato pomace, which is an important livestock feed item in the US. At that time, RCB did not request this residue data because pomace derived from treated tomatoes would not be consumed by American cattle.

Since the proposed use involves tomatoes grown in greenhouses, we would not expect these tomatoes to be diverted into animal feed in the Netherlands. If the petitioner ever intends to permit the application of Ronilan to field grown tomatoes, then additional information must be submitted on tomato pomace since these tomatoes could be diverted to animal feed in the Netherlands; residues in exported meat and milk products would be of concern.

However, during the course of RCB's review of BASF's petition for the use of Ronilan on imported grapes (PP #1E2457), the Office of General Counsel (OGC) informed RCB that it was concerned that the establishment of an import tolerance could lead to the issuance of state labels (memo of C.S. Jablon, Attorney, Pesticides and Toxic Substances Division, 9/19/86). The OGC opinion, which involved imported grapes, is also

relevant to imported tomatoes. The OGC stated, "Another consideration which should be taken into account is the special local need registration authority of states under section 24(c) of FIFRA. Once a tolerance is in place, 24(c) registrations will likely be issued in grape growing states to allow growers in those states to compete with the foreign growers... However, the Agency will be hard pressed to deny the 24(c) registrations because of the absence of necessary data in light of the diversion problem [to livestock and processing] when a tolerance has already been issued to allow foreign grapes bearing residues of the pesticide to move in commerce in the United States." A copy of this opinion is attached (Attachment 2).

In other words, the establishment of an import tolerance for residues of Ronilan on tomatoes could also create a regulatory loophole by which any state could then use Ronilan on its tomato crop. Currently, when a tomato tolerance is established in the CFR, this tolerance is established on the commodity "Tomatoes;" it does not specify that the tolerance is for imported tomatoes or fresh market tomatoes.

RCB would be especially concerned if a state like California, which produces over 80% of the tomatoes grown for processing, were to obtain a 24(c) registration. Tomato pomace is an important feed item in CA. Prof. Garrett, professor of animal science, University of California, Davis, said that studies on sheep and cows indicated that tomato pomace is as nutritious as good alfalfa hay (telecon 10/22/86). Furthermore, R. Wakefield, Contadina, and J. Ramsey, Beatrice/ Hunt-Wesson, stated that the tomato pomace from these companies is diverted to livestock. D. Emmrich, Del Monte Inc., also reported that Del Monte analyzes its tomato pomace for pesticide residues and sells the pomace for cattle feed (telecon, 10/27/86). These three companies are leading processors of tomatoes in the US. Since tomato pomace is a waste product, as far as processors are concerned, they are happy to provide feed lot operators and feed companies with pomace for a nominal fee rather paying for disposal in a landfill. In a telecon with S. Buscomb of the California Department of Food and Agriculture (10/24/86), RCB learned that about 60,000,000 pounds of dry tomato pomace are fed to beef cattle each year (there is a state restriction against feeding tomato pomace to lactating cows). J. Dunbar, UC Davis, also said that the feeding of tomato pomace to cattle is a common practice in CA (telecon, 10/24/86). In other words, if CA were to obtain a state label, cattle could be fed tomato pomace without benefit of a feed additive tolerance, if one is needed.

RCB cannot determine whether a feed additive tolerance would be required because the submitted tomato fractionation study did not include pomace. If vinclozolin does concentrate in pomace, animal metabolism studies and feeding studies may also be needed.

In any case, from a residue chemistry point of view, the issuance of a state label solely because of the prior existence of an import tolerance is not scientifically valid; the foreign

use may have nothing to do with the state's use. For instance, there may be no relevance between tomato residue studies in Dutch greenhouses and residue levels expected on tomatoes grown in CA. The issuance of 24 (c) registrations because of established and preexisting import tolerances could then result in widespread use in the US of pesticides when the understanding of the animal metabolism of these pesticides and/or the potential for the occurrence of secondary residues are inadequately understood.

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.

- C. Neither Codex, Mexico, nor Canada has established tolerances for residues of vinclozolin in/on peppers and tomatoes. If the proposed tolerances are established, there will be no compatibility problems.

Recommendations

RCB recommends against the establishment of tolerances for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety on imported tomatoes, peppers, and processed tomato products for reasons given above under Conclusions A and B (see Other Considerations).

cc (Attachment 1 and 2): TOX, PMSD/ISB, PP #4E2998, R.F., Circu,
Reviewer-Deyrup EAB, FDA, Gray/Jablon-OGC
RDI: JHOnley:11/10/86:RDSchmitt:11/10/86
TS-769:RCB:CM#2:RM810:X7484:CDeyrup:cd:11/12/86

Attachment #1

INTERNATIONAL RESIDUE LIMIT STATUS

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-xx
dichloroaniline, expressed as vinclozolin

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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PROPOSED U.S. TOLERANCES:

Petition No. HE 2998

RCB Reviewer C. Deyrup

Residue: Vinclozolin metabolites
containing 3,5 dichloroaniline moiety

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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green peppers	3
tomatoes	2
processed tomato products	6

CANADIAN LIMITS:

☒ No Canadian limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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* NOTES: Although currently no Step 6 limits, 3 ppm on tomatoes
and 2 ppm for sweet peppers expected in 1987.
** Definition which will be proposed at Codex.

Attachment No. 2

September 19, 1986

MEMORANDUM

SUBJECT: Opinion on Enforceability of Labeling Provision
for Vinclozolin (Ronilan) on Grapes

FROM: Cara S. Jablon, Attorney *Cara S. Jablon*
Pesticides and Toxic Substances Division (LE-132P)

TO: Cynthia Deyrup, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

You have requested the opinion of the Office of General Counsel regarding the enforceability and practicality of a labeling provision on cartons of imported grapes which would state "only for use as table grapes, not for processing or feed". This issue has been raised in the context of a tolerance petition for vinclozolin (Ronilan) on fresh grapes imported from Chile.

It is my understanding the Residue Chemistry Branch has non-concurred with the issuance of this tolerance because of the inadequacy of the data on residues of the pesticide in animal commodities. Because it is possible that grapes destined for the table could end up as feed items, Residue Chemistry believes that such studies are necessary to adequately assess the tolerance petition on the fresh commodity. Despite assurances from Chile that the grapes will be for table use only, Residue Chemistry has pointed out that spoiled or surplus grapes could well become feed items. To address this concern, Chile has indicated a willingness to sticker each carton of grapes with the statement:

"Only for use as table grapes, not for processing or feed."

Residue Chemistry apparently has reservations about the enforceability and practicality of this labeling provision.

I share the concerns raised by Residue Chemistry. The proposed labeling provision would not have the effect of law of prohibiting use of the grapes for processing or feed. As far as I can determine, there is no legal requirement under the Federal Food, Drug, and Cosmetic Act that a user follow the proposed prohibitions on the food container. Viewed as a recommendation, moreover, it is certainly possible that this labeling provision would not achieve its goal. Clearly, spoiled or surplus grapes could well be sold for feed or wine production in appropriate situations in spite of the labeling statement.

Another consideration which should be taken into account is the special local need registration authority of states under section 24(c) of FIFRA. Once a tolerance is in place, 24(c) registrations will likely be issued in grape growing states to allow growers in those states to compete with the foreign growers. The use of vinclozolin domestically is far more likely than the foreign use to result in significant quantities of spoiled or surplus grapes which will end up as animal feed or wine without the necessary Agency clearances. However, the Agency will be hard pressed to deny the 24(c) registrations because of the absence of necessary data in light of the diversion problem when a tolerance has already been issued to allow foreign grapes bearing residues of the pesticide to move in commerce in the United States.

It is my understanding that the necessary residue studies are in progress, and could be submitted within two years. In light of the concerns raised by Residue Chemistry, I believe the wisest course to follow is to await the result of the pending residue studies before making a final decision on the merit of the tolerance petition for vinclozolin on table grapes.