9-23-86.

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

SEP 23 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

EXPEDITE

SUBJECT: PP #1E2457. (RCB #1376) Vinclozolin (Ronilan) in or on Grapes. Amendment of 8/11/86. 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)

This review has been expedited as per the request of J. Akerman, Acting Director of Registration Division (memo to J. Melone, 9/8/86).

Background

BASF Wyandotte Corporation had proposed a tolerance of 6 ppm for residues of the fungicide vinclozolin [Ronilan; 3-(3,5-dichlorophenyl)-5ethenyl-5-methyl-2,4-oxazolidinedione] and its metabolites containing the 3,5-dichloroaniline moiety in or on table grapes.

RCB had questioned the petitioner's contention that imported table grapes would be used solely for that purpose and had therefore requested a grape fractionation study, and, since processed commodities from grapes may be fed to livestock, ruminant and poultry metabolism and feeding studies (see RCB's 4/27/81 review of PP #1E2457).

Present Consideration

The present amendment consists of a letter from M. Schreiner of BASF Canada, Inc., a letter from J.G. Morris, University of California, Davis, a letter from H.F. Felipe Erråzuriz (Ambassador of Chile), and an article on the feeding of winery pomace to cattle. A letter from L.E. Chase, Cornell University, was also supposed to be enclosed but was missing.

Petitioner's Response re: the requirement for processing and poultry and livestock metabolism and feeding studies

The petitioner has submitted a letter from J.G. Morris, professor of animal science and physiological science at the University of California, Davis. Prof. Morris writes that the University of California has conducted trials evaluating winery pomace for feeding to beef cattle. The article by M. Prokop (the journal reference from which it came was not given) describes trials comparing the nutritive values of grape, grape-apple-pear, and apple pomace. The source of the pomace was the Gallo winery. The article states that CA wineries produce 50,000-80,000 dry tons of grape pomace annually. The feeding study results indicate that diets containing 20% pomace were not as nutritious as a diet in which the 20% pomace is replaced by additional barley and that grape pomace was less nutritious than apple or grape-apple-pear pomace. The petitioner therefore contends that grape pomace is not generally fed to cattle.

The petitioner argues that table grapes are not used for processing and that it is economically unlikely for Chilean table grapes to be processed.

In order to ensure that Chilean table grapes be for fresh market use only, it is proposed that boxes containing Chilean grapes bear a label stating "Only to be used as table grapes, not for processing or feed."

It is not clear who is proposing the label instructions. In his letter to Mr. Jacoby, Mr. Schreiner says, "...the Chilean Embassy in Washington will be sending a letter to you explaining on how the Chilean exporters will make sure that all fruit importers into the USA in addition be told that Chilean table grapes are for fresh fruit consumption only but not for processing." Sr. Erråzuriz states in his letter to Mr. Jacoby, "The BASF company has also said that they will instruct all grape producers purchasing the Ronilan product that all grapes sent to the United States must carry a label on each box with the following words: 'Only to be used as table grapes, not for processing or feed.' The Chilean Exporters Association has also expressed its agreement to this measure."

RCB's Comments/Conclusions

RCB contacted the following importers and wholesalers:

W.H. Kopke, NY
J. Vandenburg, NY
Weinstein's, MD
Fava Fruit, MD
Grower's Coop, NY
Venture Vineyards, NY
De Carlo Fruit Co., NY
Cal Fruit, CA
Granada Marketing, CA
Pando Brothers, CA
Horton Fruit, KY

RCB was concerned that spoiled grapes may be fed to livestock. According to several of the wholesalers, produce which is spoiled is sometimes given away to hog farmers. Although this practice is not unusual for lettuce, none of the wholesalers could recall ever giving away grapes to farmers. Supermarket distributors (Giant and Safeway) said that they returned the grapes to the importer if they were unsatisfied with the grapes. However, in the past, rejected produce had been given to pig farmers; again, the produce involved was not grapes.

RCB has been informed that grapes are stored at 33-34° and keep quite well under those conditions. According to W.H. Kopke Co. and J. Vandenberg, only a very small number of boxes would have to be discarded. However, Mr. Morelli (USDA) said that grapes which have been shipped late in the growing season have a higher sugar content and are more apt to spoil.

According to Mr. Hollinger of Market News, the Chilean grapes consist of the following varieties:
Perlettes
Thompson Seedless
Flame Seedless
Ribiers
Exotic
Black Beauty
Calmerias

Mr. Morelli of the USDA said that Almerias, Emperors, Pink Muscatels, and King Rubies are also imported. Mr. Hollinger said that the major import is probably the Thompson Seedless. According to M. Bregande (Welch's), Prof. Poole (Cornell University), E. Smith (Grower's Coop, producer of grape concentrate for Ocean Spray), and Mr. Morelli, all of these varieties could be used for juice and/or wine. Although these varieties are not well suited for the production of juice, Thompson Seedless grapes are frequently used as a blender in the production of wines (M. Morelli, Prof. Poole, M. Bregande). Welch's sometimes adds California concentrates to some of its products; Mr. Bregande said

that the Thompson seedless is the most popular grape for processing into grape concentrates in CA. It is therefore apparent that the above table grapes could be used in processing.

RCB asked the above distributors and importers whether grapes which had to be discounted (because of deterioration) were ever sold to processors. Most of the distributors said that these grapes would not be sold to processors because the number of cases involved would be too small. However, one distributor (name confidential) said that in the past, they have taken domestic grapes to a near-by winery. RCB was told that if the grapes are dumped, it is necessary to pay to use the landfill, whereas if the winery takes the grapes, they pay the distributor. In order to deliver the grapes to the winery, the distributor has to take them out of the boxes. Since Chilean grapes come in 18 lb. containers rather than the 23 lb. containers used for domestic grapes, the distributor said that he might opt to dump Chilean grapes, boxes and all, rather than take them to the winery, because the empty 18 lb. boxes are not as useful to him as the domestic boxes. As yet, this distributor has only taken domestic grapes to the winery. However, it is apparent that grapes may be taken to a processor rather than to a landfill. In the above case, the grapes were taken to a winery, but Prof. Poole and Mr. Bregande felt that these grapes could also be processed to a poor grade of concentrate, which could then be used for coolers or added to livestock feed. Such grapes could not be used for juice, because the deterioration would lead to an off-taste in the juice.

At the present time, Chilean grapes would not be diverted to processing within the United States because grape crushing takes place from September to November on both the East and West coasts according to Prof. Poole, Mr. Wideman of Welch's, and Mr. Morelli. Chilean grapes generally enter the US from December to May. However, since grape processors may purchase grapes on the open market in addition to contracting for them (Welch's, Pando Brothers), whether or not the proposed box label is enforceable is of paramount importance. According to the Office of General Counsel, this label is not enforceable (see attached 9/19/86 memorandum of Attorney C.S. Jablon). It would not be possible to ensure that grapes not be taken out of their labeled boxes and sold to a winery or any other processor.

Even if it is assumed that Chilean table grapes are not being diverted to major US processors now, that situation could change. In 1985, 195,838 metric tons of grapes were imported by the US, of which 169,475 metric tons of grapes came from Chile (Foreign Agricultural Service, USDA). According to Mr. Morelli, who cited "Fruit Catalogue" (published by Corporacion de Fomento de la Produccion Chile, 1984), by 1991, Chile expects to export 246,000 tons to the US. According to a 1986 projection by the Chilean Fruit Producers Federation (provided by B.J. Obbink, president of the California Table Grape Commission),

Chile expects to ship about 0.8 billion pounds of table grapes to the US by 1990 (see attached article). One criterion for determining whether the use of a pesticide constitutes a minor use (in which case the requirements for registration may be less stringent) is the production of the crop involved. A crop may be considered a minor crop if less than 100 million pounds are produced per year. The projected Chilean imports would amount to half a billion to almost one billion pounds of grapes. Under these circumstances, it could become economically feasible to process the grapes.

RCB needs processing studies not only because imported grapes may find their way into the US processing chain but because Chile is already exporting processed grape products to the US. In 1985 Chile exported to the US about 395,000 pounds of raisins and 59,717 liters of grape juice concentrate (R. Gifford, Foreign Agricultural Service, USDA; US Imports for Consumption and General Imports, Dept. of Commerce, Bureau of the Census, 1985). The Chilean label submitted with the amendment of 7/31/81 permits application to "Uvas de Mesa" and "Uvas Viniferas." Since the proposed use of Ronilan on grapes does not limit the use to table grapes (and RCB doubts the practicality of such a restriction, in any case), in order to determine whether food additive tolerances are needed on processed grape commodities, appropriate data need to be submitted. RCB considers it likely that processed grape exports could increase as the Chilean grape production increases.

RCB appreciates the assistance of Mr. Gifford in obtaining import statistics of processed commodities imported from Chile.

Grapes treated with Ronilan could also be processed into wine in Chile and then exported to the US. Chilean wines are a major commodity; since 1981 Chile has exported more than 1,000,000 liters of wine to the US each year. Although the EPA does not regulate wines, future cooperation between the EPA and the Bureau of Alcohol, Tobacco, and Firearms with regard to pesticide residues in wines could have beneficial results.

The petitioner contends that the grape pomace is not very nutritious and is not often fed to livestock. The Registration Guidelines, Subdivision O: Residue Chemistry, specify that grape pomace may be fed to cattle and poultry. Furthermore, the article provided by the petitioner states that CA produces up to 80,000 tons of dry grape pomace per year. Although pomace is not expected to be as nutritious as barley, RCB has always considered grape pomace a feed item.

After consultation with the OGC (Ed Gray, Office of General Counsel) RCB became concerned that the establishment of a tolerance for the use of Ronilan on imported grapes could lead to state labels (24 c's) which would then permit the use of Ronilan on domestic grapes. RCB estimates that it only

reviews about 10% of the state labels issued (A. Rathman, RCB). Therefore it would be possible for an important grape producing state to obtain a state label, even though the major data gaps (processing, animal metabolism and feeding studies) have not been addressed.

RCB notes that processing, metabolism and secondary residue data were first requested from the petitioner (BASF) in conjunction with this petition almost 6 years ago.

RCB continues to recommend against the establishment of a tolerance for residues of vinclozolin (Ronilan) and its metabolites containing the 3,5-dichloroaniline moiety for the following reasons:

1. It is OGC's opinion that the proposed label is unenforceable (see attached memo of C. Jablon, OGC, 9/19/86).

2. Processing studies are needed because:

   i. Processors may buy grapes on the open markets, and suppliers in the past have sold grapes to processors rather than dumping them;

   ii. The projected increases in imported grapes make it more feasible that diversion of imported grapes to processors could occur; and

   iii. Chile is currently exporting processed grape commodities to the US (raisins and grape juice concentrate; wine).

3. The establishment of the tolerance could permit the issuance of CA and/or NY Section 24c labels even though the major data gaps in the subject petition have not yet been resolved.

4. Imported grapes may be diverted to processing and the resulting pomace may be fed to livestock. Therefore ruminant and poultry metabolism and feeding studies are needed.

Contacts

Granada Marketing (209) 627-5977
Pando Brothers (805) 725-3755
Cal Fruit (213) 629-2100
De Carlo Fruit (716) 824-0110
Venture Vineyards (607) 582-6774
Growers' Coop (716) 326-3161
Horton Fruit (502) 969-1371
Weinstein's (301) 799-5800
Fava Fruit (301) 799-5500

W.H. Kopke (516) 328-6800
J. Vandenburg (212) 409-9110
M. Morelli, USDA (202) 447-2011
M. Bregande, Welch's (716) 326-5174
J. Wideman, Welch's (716) 326-3131
R. Gifford, Foreign Agricultural Service, USDA (202) 447-6877
Prof. Poole, Cornell University (315) 787-2238
California Grape and Tree Fruit League (209) 226-6330
California Table Grape Commission (209) 224-4997

Attachment 1: International Residue Limit Status
Attachment 2: Memo of C. Jablon, OGC, 9/19/86
Attachment 3: Productive Potential and Commercialization of Chilean Table Grapes

cc (Attachments 1 and 2): TOX, PMSD/ISB, PP #1E2457, R.F., Circu, Reviewer-Deyrup
EAB, FDA, Gray/Jablon-OGC, Phillips-BUD, G. Greene-OCM, Barton-HED
cc (Attachments 1, 2, and 3): PM #21
RDI: JHOnley:9/22/86:RDSchmitt:9/22/86
TS-769:RCB:CM#2:RM810:X7484:CDeyrup:cd:9/22/86

Attachment No 2

September 19, 1986

MEMORANDUM

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

FROM: Cara S. Jablon, Attorney
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.