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

FEB 15 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Iprodione (109801), Reregistration Case No. 2335.
Special Review, Rhône-Poulenc Dietary Risk Assessment.
CBRS No. 16838, DP Barcode No. D222575,
No MRID provided.

FROM: John Abbotts, Chemist *John Abbotts*
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

THRU: Andrew R. Rathman, Section Head
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

TO: Jack Housenger/Vivian Prunier, PM Team 60
Special Review Branch
Special Review and Reregistration Division [7508W]

and Christina Scheltema
Special Review and Registration Section
Risk Characterization and Analysis Branch
Health Effects Division [7509C]

Registrant Rhône-Poulenc AG Company has submitted a dietary risk assessment. Assignment instructions are to review and provide comments, particularly on anticipated residues for peaches, tangelos and tangerines. Please flag any ARs that differ significantly from the Agency's. Expedited Review is requested. CBRS previously determined anticipated residues for iprodione (CBRS 15099, 5/1/95, J. Abbotts). Conclusions and Recommendations below pertain only to this assignment.

Tolerances are established for the combined residues of the fungicide iprodione parent, its isomer, and one metabolite in or on plant commodities, food commodities, and feed commodities (40 CFR 180.399(a) and (c), 185.3750, 186.3750). Tolerances are established for the combined residues of iprodione parent, its isomer, and two metabolites, all expressed as iprodione equivalents, in or on animal commodities (40 CFR 180.399(b)). Chemical structures and full chemical names of residues in tolerance expressions are given in Figure 1. Iprodione is a List B Chemical; Phase 4 Review was completed 3/15/91.

Conclusions

1. Anticipated residues were determined by accounting for percent crop treated data provided by BEAD (CBRS 15099, 5/1/95, J. Abbotts). However, other inputs are involved in estimates of dietary risk. CBRS will limit its evaluation of the Registrant's risk assessment to anticipated residues, and defers to BEAD and other HED Branches, as appropriate, for evaluation of the other inputs.

2. The Registrant's anticipated residues for milk were based on excluding peanut hay and cowpeas from the diet of dairy cattle, and are identical to anticipated residues determined by CBRS for the national milkshed under the same assumptions (CBRS 16636, 2/6/96, J. Abbotts). The Registrant's anticipated residues for red meat commodities are consistent with eliminating peanut hay and cowpeas from the diets of beef cattle and swine.

3. The Registrant's estimated dietary risk from cherries is about half that estimated by the Agency. This difference does not appear to be due to anticipated residues, as those determined by the Registrant and CBRS are both based on monitoring data, and there are no significant differences in the way the two determinations were performed.

4. The Registrant's anticipated residues for fresh peaches, based on the USDA Pesticide Data Program (PDP), are about 60% higher than those determined by CBRS. Despite this difference, the estimated dietary risk from peaches was nearly identical to the Agency's.

5. In Scenarios 1A and 2A, the Registrant uses half the limit of quantitation for anticipated residues in canned peaches. However, the use of this value is not well supported by residue data. Even with this value, the Registrant's estimated dietary risk, cancer, from peaches alone is close to 10^{-6}.

6. The Registrant's anticipated residues for grapes, based on USDA PDP data, are higher than those determined by CBRS. Consequently, the Registrant's estimated dietary risk from grapes is proportionately higher than the Agency's.

7. The Registrant's anticipated residues for wine and sherry were based on data for grapes, adjusted by a processing factor. CBRS anticipated residues were based directly on monitoring data, and are more appropriate (CBRS 15099, 5/1/95, J. Abbotts).

8. The Registrant's anticipated residues for strawberries were somewhat higher than the CBRS value, based on a slightly different data base. Differences in estimated risk are only partially explained by the difference in anticipated residues.

9. The Registrant's anticipated residues for plums and nectarines were based on Cal-EPA monitoring data. CBRS anticipated residues were based on FDA and FOODCONTAM monitoring data, and are more appropriate because they are likely to represent consumption on a wider geographical basis.

10. Upon examination of information pertaining to the production of prune juice, we conclude that anticipated residues for this commodity should be changed from 0.276 ppm (CBRS 15099, 5/1/95, J. Abbotts) to 0.138 ppm.

11. The Registrant's anticipated residues for cotton commodities, 0.05 ppm based on the limit of quantitation, are comparable to anticipated residues determined by CBTS for this proposed use (PP 2F04111, CBTS 14491, 2/9/95, G.J. Herndon).

12. Assignment instructions specifically requested comment on the anticipated residues for tangelos and tangerines. However, iprodione tolerances are not established on these crops, and there is no record of any review by either Chemistry Branch of the field trial data used by the Registrant to determine anticipated residues. Comment therefore is not appropriate.

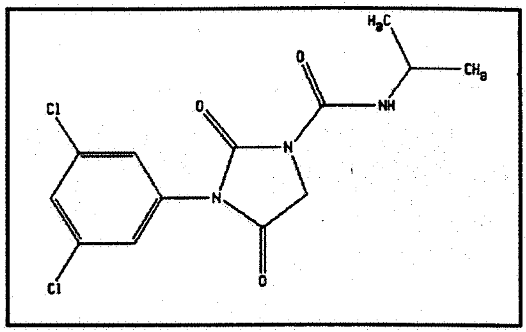
Recommendations

Consistent with Conclusion 2, the Registrant stated its intent in the present submission to prohibit feeding peanut hay and remove cowpeas from iprodione labels as risk reduction measures. Until label amendments are reviewed, accepted by the Agency, and implemented for all applicable labels, CBRS recommends that anticipated residues previously determined for animal commodities remain in effect (CBRS 15099, 5/1/95 and CBRS 16636, 2/6/96, J. Abbotts).

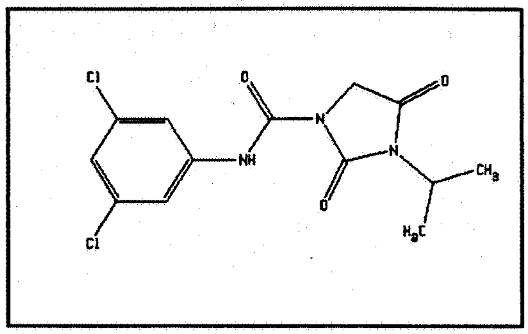
The Registrant contends that data from PDP should be given higher priority than other data bases because of the Program's statistical design. In accordance with Conclusions 4, 6, and 8 above, for some commodities it may be more appropriate for risk assessment to use anticipated residue values higher than those determined by CBRS (CBRS 15099, 5/1/95, J. Abbotts). CBRS anticipated residues should be revised for prune juice (Conclusion 10). For the remaining commodities, revision of CBRS anticipated residues is not warranted or is not expected to have a significant effect on estimated risk.

Figure 1. Iprodione Tolerance Residues:

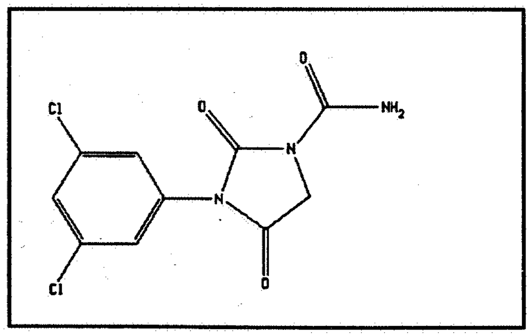
Iprodione parent;
3-(3,5-dichlorophenyl)-
N-(1-methylethyl)-2,4-dioxo-
1-imidazolidine-carboxamide



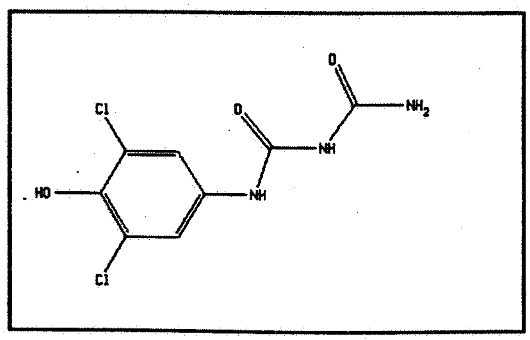
Iprodione isomer, RP30228;
3-(1-methylethyl)-
N-(3,5-dichlorophenyl)-2,4-dioxo-
1-imidazolidine-carboxamide



Iprodione metabolite RP32490
(animals and plants);
3-(3,5-dichlorophenyl)-2,4-dioxo-
1-imidazolidine-carboxamide



Iprodione metabolite RP36114
(animals); N-(3,5-dichloro-
4-hydroxyphenyl)-ureido-carboxamide



Present Submission

The Registrant has submitted the following document:

Chronic Dietary Exposure Assessment: Iprodione Current and Pending Crop Uses, Prepared for Rhône-Poulenc AG Company, TAS, Inc., Washington, D.C., January 30, 1996 (No MRID provided).

The present submission provides dietary risk estimates under four different scenarios: For Scenario 1, exposure was estimated from potential residues in currently registered crops. The analysis for Scenario 2 added estimated exposure from a pending use on cotton. Each of these scenarios was adjusted (Scenarios 1A and 2A) using half the limit of quantitation for residues in commerically-prepared canned peaches, instead of the residue value for raw peaches.

The estimated dietary risk was highest under Scenario 1, and is compared with the most recent estimated Agency risk in Table 1: The present submission provided detailed estimates for each crop contributing greater than 1% of the total dietary exposure; a similar convention has been followed in listing contributors to estimated Agency risk in Table 1:

Table 1. Comparisons of estimated dietary risk, cancer.

Crop/Commodity	Risk estimated by:	
	~~Registrant~~	~~Agency~~
Wine and Sherry	9.22×10^{-8}	3.1×10^{-6}
Potatoes + Carrots	2.59×10^{-7}	2.7×10^{-7}
Cherries including juice	2.96×10^{-7}	5.3×10^{-7}
Peaches including juice	2.27×10^{-6}	2.3×10^{-6}
Blueberries	1.39×10^{-7}	9.2×10^{-9}
Grapes including juice	7.56×10^{-7}	4.9×10^{-7}
Strawberries	7.41×10^{-7}	4.1×10^{-7}
Milk	7.84×10^{-8}	3.4×10^{-6}
Plums and prunes	NR	3.1×10^{-7}
Nectarines	NR	1.2×10^{-7}
Red meat	NR	1.2×10^{-7}
Blackberries	NR	1.0×10^{-7}
Total risk, categories above:	4.63×10^{-6}	1.1×10^{-5}
Overall risk to U.S. population:	5.18×10^{-6}	1.1×10^{-5}

Table notes: Registrant data are taken from the present submission, Scenario 1, p. 27 and Appendix 2; only categories contributing >1% of total exposure were reported. NR = not reported. Agency data are taken from personal communication, V. Prunier, SRRD; only categories contributing $\geq 1.0 \times 10^{-7}$ estimated risk are included.

Inspection of Table 1 leads to some immediate observations: First, the difference in overall risks calculated by the Registrant and the Agency is essentially entirely accounted for by differences in the individual risks estimated for wine and sherry, and milk. Second, the categories listed in Table 1 account for nearly 90% of the overall risk to the U.S. population estimated by the Registrant, and essentially all of the overall risk estimated by the Agency. Any differences in anticipated residues in other crops or commodities are not likely to be significant with regard to risk estimates, and evaluation of the Registrant's anticipated residues will largely be limited to the categories in Table 1.

We note at the outset that estimation of dietary risk depends on several different factors, and anticipated residues represent only one input in the overall estimation. Other parameters, such as assumptions on percent crop treated, dietary consumption, and parameters for toxicology endpoints, are outside the responsibility of CBRS:

Conclusion 1: Anticipated residues were determined by accounting for percent crop treated data provided by BEAD (CBRS 15099, 5/1/95, J. Abbotts). However, other inputs are involved in estimates of dietary risk. CBRS will limit its evaluation of the Registrant's risk assessment to anticipated residues, and defers to BEAD and other HED Branches, as appropriate, in evaluation of the other inputs.

Anticipated Residues

Livestock commodities. In Table 1, perhaps the most significant difference in estimated risks occurs with milk. The present submission includes the following comment (p. 10, footnote):

"RPAC [Registrant] intends to remove cowpeas from the iprodione label. Also a feeding restriction for peanut hay will be implemented; therefore, these feed items were excluded from the calculations."

We note that CBRS recently advised that if peanut hay were excluded from animal diets, anticipated residues for milk would drop from 0.0080 ppm to 0.0003 ppm for the national milkshed, and 0.0009 ppm for a local milkshed. If use on cowpeas were excluded, anticipated residues for a local milkshed would be 0.0007 ppm. (CBRS 16636, 2/6/96, J. Abbotts) In the present submission, anticipated residues for milk under all Scenarios (1, 1A, 2, 2A) were 0.0003 ppm, identical to the provisonal value determined by CBRS for the national milkshed.

The previous assignment to CBRS was to calculate how anticipated residues might change for milk only, but peanut hay also represented a significant dietary burden for beef cattle and hogs (CBRS 15099, 5/1/95, J. Abbotts); eliminating peanut hay should also result in a reduction in anticipated residues for beef and pork commodities. Table 2 compares anticipated residues determined for the applicable commodities by the Registrant and by CBRS:

Table 2. Comparison of anticipated residues, beef and swine.

Commodity	Anticipated residues, ppm determined by:	
	Registrant	CBRS
Meat of cattle, goats, and sheep	0.0002	0.00087
Meat byproducts of cattle, goats, and sheep	0.0018	0.00087
Fat of cattle, goats, and sheep	0.0004	0.0026
Kidney of cattle, goats, and sheep	0.0018	0.0099
Liver of cattle, goats, and sheep	0.0014	0.0082
Meat, organ, other, of cattle, goats, and sheep	0.0018	0.0099
Milk, whole	0.0003	0.0073
Meat of hogs	0.0001	0.00037
Meat byproducts of hogs	0.0005	0.00037
Fat of hogs	0.0001	0.0011
Kidney of hogs	0.0005	0.0043
Liver of hogs	0.0004	0.0035
Meat, organ, other, of hogs	NR	0.0043

Table notes: Registrant data are taken from the present submission, Scenario 1. NR = not reported; in Scenario 1, anticipated residues for meat, organ, other, were reported only for veal.
CBRS data are taken from CBRS 15099, 5/1/95, J. Abbotts.

We note that anticipated residues for milk determined most recently, 0.008 ppm, differ slightly from the value in Table 2 because of changes in livestock feed commodities, Residue Chemistry Guidelines, Table II, September 1995 (CBRS 16636, 2/6/96, J. Abbotts). Other differences in Table 2 may be due to the fact that CBRS calculated anticipated residues separately for meat byproducts and for meats, organ, other, while it appears that the Registrant translated the higher value for liver or kidney to meat byproducts and did not make a separate determination for meats, organ, other except for veal. These considerations lead to the following comment:

Conclusion 2: ~~The Registrant's anticipated residues for milk~~ were based on excluding peanut hay and cowpeas from the diet of dairy cattle, and are identical to anticipated residues determined by CBRS for the national milkshed under the same assumptions (CBRS 16636, 2/6/96, J. Abbotts). The Registrant's anticipated residues for red meat commodities are consistent with eliminating peanut hay and cowpeas from the diets of beef cattle and swine.

Recommendation: Consistent with Conclusion 2, the Registrant stated its intent in the present submission to prohibit feeding peanut hay and remove cowpeas from iprodione labels as risk reduction measures. Until label amendments are reviewed, accepted by the Agency, and implemented for all applicable labels, CBRS recommends that anticipated residues previously determined for animal commodities remain in effect (CBRS 15099, 5/1/95 and CBRS 16636, 2/6/96, J. Abbotts).

Root and tuber vegetables. From Table 1, the combined estimated risks for potatoes and carrots determined by the Registrant and the Agency are virtually identical. The Registrant's anticipated residues were 0.0253 ppm for carrots and 0.0013 ppm for potatoes, based on the USDA Pesticide Data Program (PDP), 1992. Anticipated residues determined by CBRS were based on monitoring data from FDA and the FOODCONTAM data base, both from FY 90-93. Anticipated residues, revised based on new percent crop treated data from BEAD, were 0.022 ppm for carrots and 0.0024 ppm for potatoes (CBRS 16636, 2/6/96, J. Abbotts). The present submission also accounted for percent crop treated in determining anticipated residues from monitoring data. As noted above, the small differences in anticipated residues for these crops did not result in a significant difference between risk estimates of the Agency and the Registrant.

Cherries. As indicated in Table 1, the Registrant's estimated risk from this crop was about half that of the Agency. The Registrant's anticipated residues were 0.318 ppm in cherries, based on FDA monitoring data from 1992 and 1993; based on processing factors, values were 1.27 ppm for dried cherries, and 0.477 ppm for cherry juice. By comparison, CBRS values, based on FDA and FOODCONTAM data, were 0.34 ppm for cherries, 2.07 ppm for dried cherries, and 0.34 ppm for cherry juice (CBRS 15099, 5/1/95, J. Abbotts). Most of the estimated risk from cherries comes from the fresh commodity (Memo, 6/29/95, J. Wintersteen), so the differences in estimated risk do not appear to be due to differences in anticipated residues, leading to the following comment:

Conclusion 3: The Registrant's estimated dietary risk from cherries is about half that estimated by the Agency. This difference does not appear to be due to anticipated residues, as those determined by the Registrant and CBRS are both based on monitoring data, and there are no significant differences in the way the two determinations were performed.

Peaches. The Registrant's anticipated residues for fresh peaches were 0.403 ppm, based on PDP data. The CBRS value was 0.245 ppm, based on FDA and FOODCONTAM data. Despite this difference, the estimated dietary risks were nearly identical (Table 1).

In Scenarios 1A and 2A, the Registrant used half the limit of quantitation, 0.0025 ppm, for residues in canned peaches. The Registrant justified this value by noting that iprodione is not stable in an alkaline environment, and in the preparation of canned peaches, a lye solution is used to remove the peel; detectable residues therefore are not expected in commercially-prepared canned peaches. The Registrant further noted that in FDA market basket surveys from 1982 through 1994, representing 44 samples, no iprodione residues were detected in samples of canned peaches (present submission, p. 8).

We have previously advised that the Registrant submitted a metabolism study in peaches, but no data were provided to indicate the distribution of residues between peel and pulp (CBRS 16038, 9/12/95, J. Abbotts). However, metabolism data on peanuts indicate that TRR in nutmeat, which was not characterized, is approximately one-third the TRR in hulls. These data suggest that some iprodione residues are systemic. Data available to CBRS do not appear to indicate the relative proportion of residues in peaches contained in the peel, or whether the alkali treatment of peaches would be sufficient to eliminate iprodione residues in the pulp.

Furthermore, the present submission (pp. 5,6) notes that monitoring data were used to determine anticipated residues only if the number of samples was 100 or more. This approach is consistent with Agency Guidelines, but the Registrant departed from this standard in using data from 44 market basket samples. Finally, even with the Registrant's values for canned peaches, its estimated risk from peaches alone remains 8×10^{-7} (Appendix 2, Scenarios 1A and 2A). These considerations lead to the following comments:

Conclusion 4: The Registrant's anticipated residues for fresh peaches, based on the USDA Pesticide Data Program (PDP), are about 60% higher than those determined by CBRS. Despite this difference, the estimated dietary risk from peaches was nearly identical to the Agency's.

Conclusion 5: In Scenarios 1A and 2A, the Registrant uses half the limit of quantitation for anticipated residues in canned peaches. However, the use of this value is not well supported by ~~residue data. Even with this value, the Registrant's estimated~~ dietary risk, cancer, from peaches alone is close to 10^{-6}.

Blackberries, blueberries. Table 1 indicates a significant difference between estimated risks for blueberries. In the present submission, the Registrant determined anticipated residues of 0.247 ppm for blackberries, based on data from the Pesticide Residue Information System [FOODCONTAM], and translated this value to other berry crops. CBRS determined anticipated residues of 0.361 for blackberries, based on FDA and FOODCONTAM monitoring data, and separately determined anticipated residues of 0.023 ppm for blueberries, also based on monitoring data.

Because the Registrant did not report a separate estimate for blackberries (see Table 1), the estimated risk from this crop must have been less than 5×10^{-8}. The Registrant's combined estimated risk from blueberries and blackberries therefore could not be more than 1.9×10^{-7}. This compares to a combined Agency risk of 1.1×10^{-7} (Table 1). Any differences in anticipated residues between the Registrant and CBRS therefore do not result in a significant change in estimated risk.

Grapes. The Registrant's anticipated residues on grapes were 0.072 ppm, based on PDP monitoring data. The CBRS value was 0.054 ppm, based on FDA and FOODCONTAM monitoring data. The difference in estimated risk (Table 1) is almost completely explained by the different anticipated residues, leading to the following comment:

Conclusion 6: The Registrant's anticipated residues for grapes, based on USDA PDP data, are higher than those determined by CBRS. Consequently, the Registrant's estimated dietary risk from grapes is proportionately higher than the Agency's.

Wine and sherry. The Registrant's anticipated residues for this category were 0.072 ppm, the same as grapes, adjusted by a processing factor of 0.33. By comparison, the CBRS determination used FDA monitoring data to obtain a value of 0.83 ppm. CBRS specifically noted that values for wine were higher than anticipated residues for grapes adjusted by a processing factor, and the anticipated residues based on monitoring data were more appropriate (CBRS 15099, 5/1/95, J. Abbotts).

Conclusion 7: The Registrant's anticipated residues for wine and sherry were based on data for grapes, adjusted by a processing factor. CBRS anticipated residues were based directly on monitoring data, and are more appropriate (CBRS 15099, 5/1/95, J. Abbotts).

Strawberries. The Registrant's anticipated residues for strawberries, based on FDA monitoring data for 1992 and 1993, were 0.3657 ppm. The Registrant's determination of anticipated ~~residues from PRIS [FOODCONTAM] was 0.1812 ppm. However, the~~ Registrant used PRIS data only if monitoring data were not available from PDP, FDA, or Cal-EPA. CBRS anticipated residues were 0.266 ppm, using monitoring data from both FDA and FOODCONTAM. Adjusting the Agency's estimated risk for differences in anticipated residues alone would give a value of 5.6×10^{-7}, which only explains about half the difference in estimated risks (Table 1).

Conclusion 8: The Registrant's anticipated residues for strawberries were somewhat higher than the CBRS value, based on a slightly different data base. Differences in estimated risk are only partially explained by the difference in anticipated residues.

Plums, nectarines. These are the remaining commodities in Table 1. The Registrant's anticipated residues for plums was 0.0120 ppm, based on data from Cal-EPA. A processing factor of 4 was used for prunes, and 1.4 for prune juice; the latter factor was not explained. CBRS anticipated residues for plums were 0.069 ppm, based on FDA and FOODCONTAM monitoring data; a processing factor of 4 was used for prunes, and the same was used for prune juice (CBRS 15099, 5/1/95, J. Abbotts). The Registrant's anticipated residues for nectarines were 0.0510 ppm, also based on Cal-EPA data. The CBRS value was 0.22 ppm, based on FDA and FOODCONTAM monitoring data.

The Registrant explained that it used Cal-EPA monitoring data only for those crops for which California production represents at least 75% of total U.S. production, and data were available on a minimum of 100 samples. In the absence of a detailed analysis of the different monitoring systems, reasons for the differences in residues attributed to Cal-EPA and other data bases are not clear. The Registrant's report does indicate that for several crops, anticipated residues based on Cal-EPA monitoring data are consistently lower than residues based on monitoring data from FDA and/or PDP (present submission, Table 1, p. 15). In this case, nectarines and plums are not crops sampled by PDP. Compared to Cal-EPA, FDA and FOODCONTAM data bases are likely to represent consumption on a wider geographical basis, and therefore seem more appropriate for determining anticipated residues for estimating dietary risk.

In the Agency's assessment, prune juice accounts for about half the risk from plum/prune commodities (Memo, 6/29/95, J. Wintersteen) Prune juice is produced by leaching dried prunes with water. The reference Fruit and Vegetable Juice: Processing Technology, Avi Publishing Company, Westport CT, 1961, on p. 826 notes that a ton of prunes yields about 500-600 gal of prune juice. Assuming 8 lb per gal, and assuming that all the residues in dried prunes transferred to juice, the minimum dilution factor from prunes to juice would be 2.0, equivalent to a concentration factor of 2.0 from plum residues. The reference cited is somewhat dated, but these theoretical calculations give a processing factor not dramatically different from that of the Registrant. We conclude that this processing factor is more appropriate for prune juice than the value previously used. These considerations lead to the following comments:

Conclusion 9: The Registrant's anticipated residues for plums and nectarines were based on Cal-EPA monitoring data. CBRS anticipated residues were based on FDA and FOODCONTAM monitoring data, and are more appropriate because they are likely to represent consumption on a wider geographical basis.

Conclusion 10: Upon examination of information pertaining to the production of prune juice, we conclude that anticipated residues for this commodity should be changed from 0.276 ppm (CBRS 15099, 5/1/95, J. Abbotts) to 0.138 ppm.

Cotton. In Scenarios 2 and 2A of the present submission, the Registrant included anticipated residues for cotton in its risk assessment, and concluded that the incremental dietary risk from cotton commodities is negligible. Cotton is a proposed use, and CBTS determined anticipated residues for chronic dietary risk from cotton commodities of 0.02 ppm, based on nondetectable residues in cottonseed and no concentration in processed commodities (PP 2F04111, CBTS 14491, 2/9/95, G.J. Herndon). The Registrant used a value of 0.05, the limit of quantitation, for cotton commodities.

Conclusion 11: The Registrant's anticipated residues for cotton commodities, 0.05 ppm based on the limit of quantitation, are comparable to anticipated residues determined by CBTS for this proposed use (PP 2F04111, CBTS 14491, 2/9/95, G.J. Herndon).

Tangelos and tangerines. Instructions for this assignment specifically requested a comment on tangelos and tangerines (see first page of this review). The present submission included anticipated residues on these crops, based on field trials. Field trial data were adjusted by a percent crop treated value of 7% (Appendix 1), and by a processing factor of 7.35 for tangerine juice. Estimated risk for these crops was not reported, implying that it was $< 5 \times 10^{-8}$ (see notes to Table 1).

We note that iprodione tolerances are not established on tangelos or tangerines (40 CFR 180.399). CBTS reviewed a Section 18 request for iprodione use on tangerines and tangelos in FL, but no field trial data on these crops were provided, and residues were estimated by translating data from peaches (CBTS 9308, 3/10/92, R. Lascola). We assume from the title of the present submission (see above) that the Registrant plans to submit its field trial data on tangerines and tangelos in support of a proposed tolerance. These considerations lead to the following comment:

Conclusion 12: Assignment instructions specifically requested comment on the anticipated residues for tangelos and tangerines. However, iprodione tolerances are not established on these crops, and there is no record of any review by either Chemistry Branch of the field trial data used by the Registrant to determine anticipated residues. Comment therefore is not appropriate.

Discussion

The USDA PDP program monitors residues on 12 fruits and vegetables; iprodione tolerances are established for 7 of these. As the Conclusions above indicate, in some cases anticipated residues determined by the Registrant using PDP data were higher than those previously determined by CBRS. In the present submission, the Registrant gave highest priority to residue data from PDP, on the grounds that PDP is based on statistical designs that ensure that the data are representative of potential pesticide residues in the overall U.S. food supply. These considerations lead to the following comment:

Recommendations: The Registrant contends that residue data from PDP should be given higher priority than other data bases because of the Program's statistical design. In accordance with Conclusions 4, 6, and 8 above, for some commodities it may be more appropriate for risk assessment to use anticipated residue values higher than those determined by CBRS (CBRS 15099, 5/1/95, J. Abbotts). CBRS anticipated residues should be revised for prune juice (Conclusion 10). For the remaining commodities, revision of CBRS anticipated residues is not warranted or is not expected to have a significant effect on estimated risk.

cc:Circ, Abbotts, RF, Iprodione List B File, SF
RDI:ARRathman:2/13/96:RBPerfetti:2/13/96:EZager:2/15/96
7509C:CBII-RS:JAbbotts:CM-2:Rm805A:305-6230:2/15/96
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