7-24-84

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

JUL 24 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4G3037. Iprodione on peanuts. Evaluation of analytical methods and residue data. Amendment of 6/15/84.

FROM: Nancy Dodd, Chemist Nancy Dodd
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

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

Rhone-Poulenc Inc. submits a revised Section F in response to an RCB review of PP#4G3037 (N. Dodd, 5/31/84) in which 4 deficiencies were listed.

Deficiency #1:

Residues in peanut hulls resulting from the proposed use may exceed the proposed temporary tolerance of 5.0 ppm. A temporary tolerance of 7 ppm on peanut hulls should be proposed.

Petitioner's response to deficiency #1:

A revised Section F is submitted which proposes a temporary tolerance of 7.0 ppm on hulls.

Conclusion #1:

Deficiency #1 is resolved.

Deficiency #2:

Residues in peanut hay resulting from the proposed use may exceed the proposed temporary tolerance of 110.0 ppm. A temporary tolerance of 150 ppm on peanut forage and hay should be proposed.

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Petitioner's response to deficiency #2:

A revised Section F is submitted which proposes a temporary tolerance of 150 ppm on peanut forage and hay.

Conclusion #2:

Deficiency #2 is resolved.

Deficiency #3:

The proposed temporary tolerance for "nut meat" should be reworded "peanuts" since the shell is removed and discarded from nuts before examination for pesticide residues. The proposed temporary tolerance for "hay" should be reworded "peanut forage and hay."

Petitioner's response to deficiency #3:

A revised Section F is submitted with temporary tolerance proposals for "peanut" and "peanut forage and hay".

Conclusion #3:

Deficiency #3 is resolved.

Deficiency #4:

Since the established tolerances of 0.1 ppm on meat, fat, and meat by-products and 0.02 ppm on milk are exceeded by the proposed use except for hogs and since no tolerances exist for poultry and eggs, temporary tolerances should be proposed. These temporary tolerances should be 0.6 ppm in meat, fat, and meat by-products (excluding liver and kidney) of cattle, hogs, goats, horses, and sheep; 3.0 ppm in kidney of cattle, hogs, goats, horses, and sheep; 2.0 ppm in liver of cattle, hogs, goats, horses, and sheep; 0.4 ppm in milk, 0.05 ppm in meat, fat, and meat by-products of poultry (method sensitivity), and 0.01 ppm for eggs (method sensitivity).

Alternatively, the petitioner may wish to restrict the feed use of peanut vines and hay. If grazing and feeding of peanut vines and hay are restricted, then maximum residues in the feed of dairy cattle from peanut meal, soapstock, and almond hulls and in the feed of beef cattle from peanut meal, peanut hulls, soapstock, and almond hulls would be 0.09 ppm and 0.4 ppm, respectively, and the established tolerances of 0.1 ppm for meat, fat, and mbyp of livestock and 0.02 ppm for milk would be adequate. Method sensitivity temporary tolerances for poultry and eggs would still need to be proposed.

Petitioner's response to deficiency #4:

A revised Section F is submitted which proposes temporary tolerances of 0.6 ppm in meat, fat, and meat by-products (excluding liver and kidney) of cattle, hogs, goats, horses, and sheep; 3.0 ppm in kidney of cattle, hogs, goats, horses, and sheep; 2.0 ppm in liver of cattle, hogs, goats, horses, and sheep; 0.05 ppm in meat, fat, and meat by-products of poultry; 0.01 ppm in eggs; and 0.4 ppm in milk.

Conclusion #4:

Deficiency #4 is resolved.

Conclusions and Recommendations

Since submission of the revised Section F resolves all the deficiencies which were cited in the review of 5/31/84, we recommend that the proposed temporary tolerances be established.

For a future permanent tolerance, the following will be needed:

1. Unknown Z (PP#3F2964/FAP 4H5415), which comprises 26% of the extractable ^{14}C residue in chicken liver and 15.5% of the extractable ^{14}C in chicken kidney, must be identified. RCB needs to know (for TOX Branch) whether Unknown Z is produced in the rat.

2. Additional information is needed concerning the adequacy of the analytical methods for meat, poultry, and eggs. While the methods are adequate for analysis of iprodione and RP32490 in meat, and for iprodione, RP32490, and RP36114 in milk, we need to know whether the other major metabolites (i.e. 3,5-dichloro-4-hydroxyphenylurea, RP44247, and Unknown Z in meat and poultry tissues and RP36112, RP36115, and RP44247 in eggs) are also determined by the analytical methods.

3. RCB defers to TOX Branch as to their concern over residues of the metabolite 3,5-dichloro-4-hydroxyphenylurea, which is the major extractable residue in goat kidney (approx. 23% of the total extractable residue).

4. Peanut processing studies are needed to allow us to determine whether food additive tolerances are needed for crude oil, refined oil, peanut meal, and soapstock.

cc: R.F., Circu, Reviewer, TOX, EEB, EAB, FDA, Robert E. Thompson (RTP) PP#4G3037
RDI:Section Head:EZager:Date:7/19/84:RDSchmitt:Date:7/19/84
TS-769:RCB:Reviewer:N.Dodd:557-7484:LDT:CM#2:RM:810:Date:7/19/84

SECTION F

Iprodione - Peanuts

Petition for Temporary Tolerance

Temporary tolerances are proposed for combined residues of the fungicide Iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboximide], its isomer [3-(1-methylethyl)-N-3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboximide], and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboximide] in or on the following raw agricultural commodities:

Commodity	Temporary Tolerances (ppm)
Peanut	0.1
Peanut Forage and Hay	150
Hulls	7.0

FAT MEAT AND MEAT BY-PRODUCTS

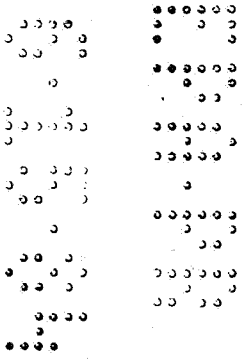
Tolerances are proposed for the combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide and its non-hydroxylated metabolites (expressed as Iprodione equivalents) in or on the following raw agricultural commodities:

Commodity	Temporary Tolerances (ppm)
Meat, fat, and meat by-products (excluding liver and kidney) of cattle, hogs, goats, horses and sheep	0.6
Kidney of cattle, hogs, goats, horses, and sheep	3.0
Liver of cattle, hogs. goats, horses and sheep	2.0
Meat, fat and meat by-products of poultry	0.05
Eggs	0.01

MILK

Tolerance is proposed for the combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide and its non-hydroxylated and hydroxylated metabolites (expressed as Iprodione equivalents) in or on the following agricultural commodity:

Commodity	Temporary Tolerances (ppm)
Milk	0.4



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