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

5-3-85

MAY 3 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: No EPA ACCESSION NUMBER. [RCB # 761, 777]
PP4F3129/FAP4H5440: Iprodione in or on Peanuts and Peanut
Fractions, Meat, Milk, Kidney and Liver, and Eggs.
Amended Section F.

TO: H. Jacoby, PM 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

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

FROM: R. W. Cook, Chemist *RWCook*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

In our previous review of subject petition (R. W. Cook, 2/15/85), we noted several deficiencies. Primarily, the deficiencies pertained to Section F. The petitioner has now submitted revised Section F addressing those deficiencies. We shall repeat the deficiency, provide the petitioners response, and then give our comments or conclusions.

Deficiency #1:

1. Proposed tolerances for eggs of 0.01 ppm, and meat, fat, and meat by-products of poultry at 0.05 ppm are not appropriate since tolerances are established at 0.8 ppm for eggs and 0.4 ppm for poultry meat and meat byproducts, 2 ppm for poultry fat, and 3 ppm for poultry liver. The proposal at 2 ppm in liver of cattle, goats, hogs, horses, and sheep is not correct since tolerance is established at 3 ppm. These inappropriate proposals should be withdrawn. A revised Section F is needed.

Petitioners response:

The petitioner has submitted a revised Section F withdrawing these inappropriate tolerance proposals.

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For the record, the following tolerance levels are currently established:

Eggs = 0.8 ppm;
Poultry meat and meat byproducts = 0.4 ppm;
Poultry fat = 2 ppm
Liver of cattle, goats, hogs, horses, poultry, and sheep = 3 ppm.

Our conclusions/comments: This deficiency in regard to inappropriate tolerance levels is resolved.

Deficiency #2:

2. A revised Section F proposing tolerances in the following terms is needed for iprodione residues in raw agricultural commodities of animal origin:

"for combined residues of iprodione and its metabolites containing the 3,5-dichloroaniline moiety (expressed as iprodione equivalents)."

TOX considerations permitting, a tolerance 0.5 ppm is appropriate for combined residues of iprodione (as above) in milk, and in the meat, fat (except poultry fat) and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep. A revised Section F is needed.

Petitioners response:

A revised Section F is provided proposing tolerances for the combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolites containing the 3,5-dichloroaniline moiety (expressed as iprodione equivalents) in or on milk at 0.5 ppm and in or on meat, fat and meat byproducts (excluding liver and kidney) of cattle, hogs, goats, horses, and sheep at 0.5 ppm.

The petitioner should be informed that we consider both hydroxylated and non-hydroxylated metabolites to be included within the term "3,5-dichloroaniline moiety".

In our previous review, Conclusion 5 read in part:

"...0.5 ppm ... the meat, fat (except poultry fat) and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, poultry, and sheep."

The underlined phrases should have been carried into our Recommendations.

We conclude that this deficiency is not fully resolved. However, see our comment below about clarification of the tolerance expression.

Deficiency #3:

Tolerances are proposed for combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (expressed as iprodione equivalents) in or on soapstock at 10 ppm.

Our conclusions/comments:

The previously proposed FA tolerance for crude peanut oil has been removed as we recommended. This deficiency has been resolved.

Recommendations:

In our previous review (2/15/85), we recommended for a revision of the expression of the tolerance for reasons of clarity and brevity. The primary reason was to avoid the use of the vague terms such as 'hydroxylated' and 'non-hydroxylated' metabolites as currently in 40 CFR 180.399. Upon considerable reflection, we have concluded that the previously recommended expression is not as clear as it should be. Therefore, to resolve this, the compounds covered by the tolerance should be listed in 40 CFR 180.399(a) and (b).

For plant substrates, the tolerance expression in 180.399(a) should list combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide.

For meat and milk, the tolerance expression in 180.399(b) should list combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolites 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and N-(3,5-dichloro-4-hydroxyphenyl)-ureidocarbamide, all expressed as iprodione equivalents.

We could recommend for the establishment of the proposed tolerances pending revision of the tolerances as we have suggested.

OTHER CONSIDERATIONS:

International Tolerances:

There are no Codex, Canadian, or Mexican tolerances for residues of iprodione in or on peanuts or peanut byproducts. Therefore, we do not anticipate any compatibility problems. A Codex sheet was attached to our previous review.

Clarification of CFR Listing:

In our previous review (2/15/85), we recommended for a revision of the expression of the tolerance for reasons of clarity and brevity. The primary reason was to avoid the use of the vague terms such as 'hydroxylated' and 'non-hydroxylated' metabolites as currently in 40 CFR 180.399. Upon considerable reflection, we have concluded that the previously recommended expression is not as clear as it should be. Therefore, to resolve this, the compounds covered by the tolerance should be listed in 40 CFR 180.399(a) and (b).

For plant substrates, the tolerance expression in 180.399(a) should list combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide.

For meat and milk, the tolerance expression in 180.399(b) should list combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolites 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and N-(3,5-dichloro-4-hydroxyphenyl)-ureidocarboxamide, all expressed as iprodione equivalents.

cc: R.F., Circu, R. W. Cook, FDA, PP#4F3129/FAP4H5440, TOX
EEB, EAB, Robert E. Thompson, M. J. Bradley
TS-769:RCB:Reviewer:RWCook:Date:5/1/85:CM#2:RM:810:557-7377
RDI:Section Head:RSQuick:Date:5/1/85:RDSchmitt:Date:5/1/85