7-30-86

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

JUL 30 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP6F3366/FAP6H5496: Iprodione in or on Potatoes.
No EPA ACCESSION NUMBER. [RCB # 1008, 1009]
Amended Section F, letter of 5/23/86.

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
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

In our previous review of subject petition, several deficiencies were noted. We shall repeat the deficiency, give the petitioner's response, and finally, give our comments or conclusions.

1. Residue data from potato processing studies utilizing potatoes bearing residues near the tolerance level are needed to determine the adequacy of the proposed food additive tolerance levels. Exaggerated application rates may be necessary to obtain potatoes with adequate residues for processing studies.

Petitioner's response: The petitioner has submitted a discussion in support of the previously submitted potato processing study. We shall attempt to paraphrase and reply to each argument.

A) The submitted residue data for processed potato fractions are from 2X exaggerated rate, and higher exaggeration rates would create a "highly artificial situation" without assuring residues would approach tolerable levels.

B) All residue trial samples would have to be analyzed before the processing study could begin, creating a storage stability problem and a need for storage stability data.

C) The cost of the study imposes an undue economic burden on the petitioner.

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D) The petitioner contends that combined residues did not exceed 0.1 ppm in "tubers".

E) The petitioner contends that this data request is not consistent with a previous iprodione petition on grapes. The petitioner states that in the case of grapes, residue levels did not approach tolerance levels and yet the Agency was able to determine residue levels in grape processing fractions.

F) The petitioner claims to have put forth good faith effort to completely assess the residue picture during potato processing.

G) The petitioner contend that the TAS shows a conversion factor of 6.5 for whole fresh potatoes to dry potatoes.

Our comments and conclusions:

We have considered the petitioner's arguments and we are not persuaded. Our specific comments are below:

a) We are not requesting a "highly artificial situation". We are requesting a situation where field grown potatoes bearing iprodione residues at or near the proposed tolerance level are processed.

b) It is reasonable to expect that some potatoes would be analyzed prior to the initiation of the processing study. However, it is not necessary to analyse "all" samples.

c) The claim of "undue economic burden" is outside the purview of RCB and we will not comment. We note, however, that the scientific validity of a study is not dependent upon its cost.

d) The petitioners contention that combined residues did not exceed 0.1 ppm is not true. We find that combined iprodione residues in raw agricultural commodity potatoes were as high as 0.22 ppm (CA, 4 lb., 12 days); 0.21 ppm (ND, 4 lb., 14 days); 0.17 ppm (NJ, 4 lb., 14 days); and 0.16 ppm (ME, 4 lb., 30 days).

[The petitioner appears to be operating under the misconception that cull potatoes are not subject to the tolerance. That conception is incorrect. 'Cull' potatoes for animal feed purposes are 'potatoes' subject to the tolerance.]

e) Residue levels in raw agricultural commodity grapes (see PP3F2964 FAP4H5415, memo of R. Cook, 2/21/84), while less than the tolerable level, were in fact far higher (about 1.7 to 2.4 ppm) than the limit of detection. On the other hand, in the potato processing study, we are considering residues at the limit of detection (0.05 ppm) being processed into potato fractions. We are hesitant to use these small and somewhat questionable residue levels (<0.05 to 0.06 ppm, in the potatoes processed but up to 0.22 ppm in other field samples) as a basis for food additive tolerances. Thus, the grape processing study is not an appropriate precedent for the potato study.

f) While we agree that the petitioner has attempted to resolve the residue picture during processing, our conclusions will not be based upon the amount of effort, but only on the results of that effort, i. e., our conclusions will be based upon the residue data presented.

g) The 6.5 conversion factor is a calculated factor based upon weight comparison. This conversion factor does not consider differences in residue levels occuring in peel versus pulp. Thus, actual residue data on potato processing fractions are necessary.

2. A revised Section F including the term "(expressed as iprodione equivalents)" is needed. Further, the food additive tolerances should be proposed in terms of "Potatoes, processed (including chips)." rather than as "Chips" and "Flakes".

Petitioner's response:
A revised section F is submitted, including the term "(expressed as iprodione equivalents)". The food additive tolerances are proposed in terms of "Potatoes, processed (including chips)."

Our comments or conclusions: This deficiency is resolved by the submission of the tolerance in terms of "Potatoes, processed (including chips)" and the revised Section F including the term "(expressed as iprodione equivalents)".

Additional note: In conference with the petitioner on 5/23/86, the proposed tolerance level of 3.5 ppm was discussed; this reviewer suggested that a level of 4 ppm may be more appropriate. The petitioner has resubmitted a proposal for food additive tolerance level of 4 ppm.

Conclusions:

1. We have considered the petitioner's arguments and we are not persuaded. Deficiency # 1 remains outstanding.

2. We acknowlege receipt of the booklet describing in general the potato processing industry and practices. The information will be maintained in our reference files.

Recommendations:

We recommend against the establishment of the proposed tolerances, for the reason cited in Conclusions 1. For a favorable recommendation, the petitioner should be advised that the following information is needed.

1. Residue data from potato processing studies utilizing potatoes bearing residues near the tolerance level are needed to determine the adequacy of the proposed food additive tolerance levels. Exaggerated application rates may be necessary to obtain potatoes with adequate residues for processing studies.

cc: R.F., Circu, R. W. Cook, PP#6F3366/FAP6H5496, PMSD(ISB), TOX, FDA.
TS-769:RCB:Reviewer:RWCook:Date:7/28/86:CM#2:RM:810:557-7377
RDI:Section Head:RSQuick:Date:7/28/86