



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

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SEP 29 1989

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: FAP8H5564, Fenvalerate and Esfenvalerate in Food Handling Establishments - Amendment to Petition to amend 40 CFR 185.1300 - DEB 5638 No MRID NO

FROM: R. W. Wisco, Chemist
DEB/HED (100-115)

THRU: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (H7509C)

Edward J. Gage, for

TO: G. L. Lawrence, PM-15
Registration Division (H7505C)

and
Toxicology Branch
Health Effects Division (H7509C)

The petitioner has submitted an amendment to FAP8H5564, which seeks to amend 40 CFR 185.1300 and further to establish permanent tolerances under 40 CFR 186.1300 in feed handling establishments, and a cover letter (dated July 20, 1989) explaining previous submissions.

The petitioner has responded to several questions about the previously submitted study. The test material was made in advance of the test and used throughout the 30 day study. The exhaust system in the test room is a built-in system which was turned on just after the 30 minute exposure interval. The food samples were removed just after the ventilation was turned on. Ventilation exhaust remained on until the next spraying several days later.

Deficiencies Outstanding:

1. Tolerances for residues of fenvalerate and esfenvalerate in the raw agricultural commodities poultry meat and eggs are required before the requested feed additive tolerances can be established.
2. Section B should be revised to exclude use in feed handling/warehouse establishments and Section F should delete the 40 CFR 186.1300 proposal for the feed additive tolerance.

Conclusions and Recommendations:

It is recommended that tolerances for residues of esfenvalerate be established in all food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food handling establishments where food and food products are held, processed or prepared, provided the use is limited to maximum application rates dosages, dilutions, and treatment intervals conforming to the submitted Section B (Proposed Directions) and Section F (Proposed Tolerances) submitted in this amendment.

It is recommended that tolerances not be established in feed and feed handling establishments (i.e. ~~40~~ CFR 186.1300) due to the lack of established tolerances on the raw agricultural commodities poultry and eggs.

Revised Sections B and F should be submitted as indicated above.

The petitioner should be informed that future residue trials must be conducted at maximum treatment rates, not at "normal" or "light infestation" rates.

Deficiency 1:

1. The petitioner should submit revised Section F clearly indicating by correct chemical name the chemical for which regulation is sought (i.e., § 40 CFR 185.1300(a)(3) and 186.1300(a)(3) should specify as (S)-cyano(3-phenoxyphenyl)-methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzeneacetate.

The petitioner has resolved this deficiency by submitting the corrected Section F.

Deficiency 2:

2. The submitted residue data do not reflect the proposed use as space spray since application rates in the submitted study were less than the maximum permitted by the proposed food additive regulation at 40 CFR 185.1300. Residue data reflecting the maximum proposed application rate are needed and should include data on a food service establishment.

Upon reconsideration of the previously submitted residue data, we are not requesting additional residue data at this time, providing the recommended maximum application rates, dilution rates, dosages, and timing of application remain as proposed herein.

Deficiency 3:

3. The submitted labeling differs significantly from the accepted labeling in that surface spray is recommended for retreatment at 7 day intervals in restaurants while accepted labeling specifies 14 day retreatment. The petitioner is advised to submit revised labeling conforming to accepted labeling or submit residue data reflecting the 7 day retreatment interval.

The petitioner has submitted revised labeling reflecting a 14 day retreatment interval for the surface spray, which is now consistent with the previously accepted labeling. This deficiency is resolved.

Deficiency 4:

4. The petitioner should submit revised labeling which clearly indicates retreatment intervals in food areas for space sprays and contact sprays. There are 4 different retreatment restrictions on the label:

- Repeat as necessary (Space Spray)
- Repeat every 3 days (Space Spray)
- Repeat every 7 days (Surface Spray)
- Repeat every 14 days (Surface Spray)

Dosage and dilution rates for uses in food areas must be clearly indicated. Under "General" three dilution rates are given, yet under Surface Spray there is no mention of specific dilution to use under specific circumstance. For example, instructions to "Use a dosage of one (1) gallon of 0.025% active ingredient spray per 1000 square feet for maintenance control" are specific to dosage and dilution.

The revised labeling submitted by the petitioner resolves this deficiency.

5. The label instruction allowing mixture of Evercide® Residual Insecticide Concentrate 2457 with methoprene and hydroprone must be removed or modified to clearly and specifically prohibit use of such mixtures in food handling establishments. Neither methoprene nor hydroprone are permitted in food areas under current regulation. Pyrethrin-containing products are permitted in food handling areas but not feed handling areas, except when used in certain multiwall paper bags or cotton bags for dried feeds.

If the use of such mixtures is intended in non-food areas, such as lawn flea control, Asian cockroach control, etc., label instructions should be clear and explicit to authorize use in these areas but to prohibit use in food areas.

The revised label includes instructions to use methoprene and hydroprone spray only in areas where these products are permitted. This deficiency has been resolved.

6. We note that we have recommended favorably for the establishment of feed additive tolerances for fenvalerate under FAP3H5383 (see 3/16/84 and 5/11/84) and more recently under FAP6H5503 (see 11/17/86). We further note that such feed additive regulations have not been promulgated. We continue to recommend establishment of tolerances for residues of fenvalerate in animal feedstuffs as a result of use in feed handling establishments, although we cannot recommend for the currently proposed feed additive regulation until other problems associated with the use of esfenvalerate are resolved. Additionally, tolerances are necessary in 40 CFR 180.379 for poultry meat and eggs to cover possible esfenvalerate residues in animal feeds from use in feed handling establishments.

This deficiency is not resolved. Sections B and F should be revised to delete use directions and 40 CFR 186.1300 regulation proposals that would encompass feed handling establishment uses.

7. The proposed expression of the tolerance in 185.1300(a) and 186.1300(a) should be revised to delete the phrase "...of all isomers..." to read "...for residues of the insecticide cyano...". Additionally, in the same regulations at the newly proposed (a)(3), the phrase should read "Application of (S)-cyano(3-phenoxyphenyl) methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzeneacetate...."

The petitioner has submitted the revision. This deficiency is resolved.

cc: FAP8H5564, [redacted], Circ, Cook, PMSD/ISB
RDI: Section Head: RSQuick:9/22/89:RALoranger:9/25/89