Jap#6H1946

Petitions Control Branch and Division of Toxicological Evaluation

January 20, 1966

Pesticides Branch, Division of Food Standards and Additives AF 8-176

FAP #6H1946. Synergized pyrethrins in food-storage and food-processing areas. Prefile review.

The use of synergized pyrethrins in food-storage and food-processing areas has been permitted in the past under an extension of the Statute (Section 121.91) with tolerances of 3 ppm for pyrethrins and 20 ppm each for piperonyl butoxide and MCK 264 (M-Octylbicycloheptene dicarboximide). The last extension to 12/31/65 was granted under FAY #15.

The McLaughlin-Gormley-King Company originally requested a permanent regulation in FAP #404; but none was issued because of deficiencies in the pharmacological support and descriptions of the analytical methods (see our memo of 7/9/65 in FAP #404).

In this resubmission the petitioner proposes a regulation to permit the use of synergized pyrethrins in food-storage and food-processing areas, with limits of:

1 ppm pyrethrins

10 ppm piperonyl butoxide

10 ppm MGK 264

for residues in milling fractions derived from cereal grains, and of:

3 ppm pyrethrins

10 ppm piperonyl butoxide

10 ppm MGK 264

for residues in other foods (except meats, dairy products, and other fatty foods). (We understand that studies are underway to support the inclusion of fatty foods.)

Use

This resubmission proposes the use of various spray and aerosol formulations, the maximum concentrations being 0.5% for pyrethrins, 1.0% for piperonyl butoxide and 1.67% for MGK 264. Space spray formulations are to be used at rates up to 2.6 ozs/1000 cu.ft. Surface applications are to be limited to the following amounts per square foot: pyrethrins - 3 mg; piperonyl butoxide - 10 mg; and MGK 264 - 10 mg.

The new Section F contains various use restrictions, at least some of which might be covered by a statement in the regulation to the effect that the labeling shall conform to that registered by the USDA; but this can be decided at the time of our final review.

The labels in Section B should all conform to the requirements of Section F. This is not always the case. We presume that the petitioner has expressed his intended use in Section F. On that basis, the proposed labels have the following deficiencies:

- 1. All but label #7 fail to state that the pesticide is not to be used in plants processing fatty foods.
- 2. Labels #2 and #6 merely state "do not apply directly to food." It would be more proper to suggest the removal or covering of food and food processing equipment.
- 3. All but label #7 fail to include the proposed 48-hour delay where washing of food processing surfaces is not feasible.
- 4. Labels #2 and #6 recommend surface applications at rates higher than the maxima in Section F for food processing or storage equipment. The labels should make it clear that these rates are not to be used on surfaces that would come in contact with food.

In addition, comments in the petitioner's letter of 12/30/65 appear to be inconsistent with Section F. The letter states that despite the exception of fatty foods in the proposed tolerances, he sees no reason why the sprays could not be used in warehouses and meat processing plants, provided food is removed or covered during application. The letter further points out that the Meat Inspection Division of USDA permits the use of these sprays in meat processing plants, provided processing surfaces are washed after spraying.

However, the use precautions indicated above are identical to those for foods where tolerances are proposed. In addition the use approved by the Meat Inspection Division of USDA was at a time before the tolerances under the extension of the Statute had expired. Thus the uses of the preceeding paragraph might now result in illegal residues.

Residue Methods and Residue Data

The descriptions of the analytical methods have been reorganized and clarified. We now consider them adequate for final review. The residue data also are adequate for final review.

Recommendations

1. The petitioner should be advised that the labels in Section B are not in conformity with the restrictions of Section F. If the deficiencies enumerated above were corrected, we would be able to recommend in favor of filing.

2. The petitioner should also be advised that, even were the proposed regulation to issue, if any residues result in meat from the uses mentioned in his letter of 12/30/65, such residues would now be illegal.

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cc: BSSE BTK FSA/OD FSA/PB FAP #6H1946~ FAP #404

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