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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Fenvalerate and Esfenvalerate Tolerances. Memorandum Dated 4/6/91 from R. Cool, RD.

DEB # 7860. HED Project # 1-1046

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CBTS has been asked to comment on various issues concerning fenvalerate and esfenvalerate. IR-4 has recently submitted petitions proposing tolerances for esfenvalerate, and CBTS' evaluations have raised several questions of interpretation.

Fenvalerate, Pydrin®, is a racemic mixture of four optical isomers [RS-alpha-cyano-(3-phenoxypenyl)-methyl RS-4-chloro-alpha-(1-methylethyl)-benzeneaceate. Esfenvalerate, Asana®, is enriched in the S,S-isomer, the isomer possessing insecticidal action. E. I. du Pont de Nemours and Company, Inc. is replacing its registrations for Pydrin® with registrations for Asana®. Because esfenvalerate contains up to 85% of the S,S-isomer, lower application rates can produce the required action. The analytical method, a capillary GC method, measures the sum of the four isomers and is the same for both fenvalerate and esfenvalerate.

Since use levels of esfenvalerate are lower (typically one fourth to one third) those for fenvalerate and the analytical method determines total isomers, current tolerances for fenvalerate will certainly cover residues expected from esfenvalerate.

CBTS has dealt in detail with the issue of fenvalerate/esfenvalerate in its 4/10/91 memo for PP#0F3852 (esfenvalerate for use in/on alfalfa and head lettuce).

The Minor Use Section, Registration Division poses three questions.

1. Can fenvalerate data be used in support of tolerances for esfenvalerate? If so, can we provide IR-4 with guidance as to when to submit existing fenvalerate data in support of esfenvalerate tolerances, and when fenvalerate data would not be acceptable? Is the registrant aware that additional esfenvalerate data are likely to be required to convert existing tolerances for fenvalerate?

CBTS Response

Fenvalerate data can certainly be used in support of tolerances for esfenvalerate. However exclusive use of such data will generally result in higher tolerances and anticipated residues than are necessary, and the acceptable daily intake may be exceeded. For this reason, petitioners have argued that residue levels for esfenvalerate can be accurately estimated from corresponding fenvalerate levels by applying a relative use correction factor. For example, if proposed use levels of esfenvalerate on a given rac are 1/4 the corresponding use levels for fenvalerate, esfenvalerate levels should be 1/4 the levels observed in existing fenvalerate residue data. It is CBTS's position that while esfenvalerate levels will certainly be lower, there are currently insufficient data which would allow us to quantitatively predict such levels. Although fenvalerate does contain the S,S-isomer, the enriched product could well produce different residue levels.

If a petitioner requests a lower tolerance than that supported by fenvalerate data alone, some bridging data are necessary in the absence of complete esfenvalerate residue data. By "bridging data" we mean residue data generated from field trials done with esfenvalerate and fenvalerate concurrently, in adjacent locations, and reflecting identical use patterns but with the appropriate lower amount of active ingredient for esfenvalerate. Presently, we require at least three bridging studies per crop group. As more bridging data become available, we may modify or even drop this requirement. Especially for minor uses, we will be as flexible as possible. For example, there may be bridging data for a crop from field trials conducted under a different use pattern than the one currently sought. These data could still be useful in deriving an appropriate scaling factor for the fenvalerate residue data on the crop. Because fenvalerate/esfenvalerate are basically non systemic, we can be flexible in translating bridging data from one crop group to another.

We emphasize that if residue data are available from fenvalerate field trials only and if we are unable to translate

bridging data from field trials on other crops, a tolerance for esfenvalerate can still be obtained but it will be identical to the tolerance for fenvalerate.

2. A recently received petition from IR-4 proposes that the established tolerance for fenvalerate on artichokes be increased because of a revision in the use pattern. The tolerance was originally established on the basis of Pydrin® data, and is now listed as the tolerance for esfenvalerate. The residue data in the petition reflect application of Asana®.

   Should IR-4 propose an increase in the fenvalerate tolerance or should IR-4 propose a tolerance for residues of esfenvalerate on artichokes? Should the Agency establish any new tolerances for fenvalerate?

3. Should tolerances for esfenvalerate be established under §180.379 or should a separate section be established under part 180 for esfenvalerate tolerances?

CBTS Response

In our recent memo for PP#0F3852 we concluded (Conclusion 6):

> Because DuPont is in the process of withdrawing its registrations of fenvalerate and CBRS will recommend that existing tolerances be revoked, new tolerances for esfenvalerate should be placed in a new subsection of 40 CFR 180.379. This should facilitate the eventual transfer of tolerances from fenvalerate to esfenvalerate. However, we do not recommend that new animal tolerances be placed in the new subsection at this time.

With respect to the petition for esfenvalerate in/on artichokes, residue data reflecting application of Asana® would support a tolerance for esfenvalerate. The tolerance would be listed in a new subsection of §180.379. If these residue data support a lower tolerance than that currently listed for fenvalerate -- this could occur because of the lower use level of esfenvalerate relative to fenvalerate, even though the use pattern is more severe -- the use could be registered with the current tolerance for fenvalerate and later transferred with the lower tolerance to the new subsection when tolerances for fenvalerate are revoked. In our 4/10/91 memo we concluded that it is not necessary that an enforcement method be available to distinguish between residues resulting from application of fenvalerate or esfenvalerate.

CBTS does not recommend that EPA establish new tolerances for fenvalerate. It is our understanding that current registrations for fenvalerate are being withdrawn.

cc: SF, RF, Circu., C.Furlow(PIB/FOD, M.Flood, E.Haeberer, G.LaRocca(H7505C).

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:557-4362:typist(mtf):5/16/91.
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