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

SEP 12 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Registrations/Tolerances for Esfenvalerate.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

Mike Flood

THROUGH: Robert S. Quick, Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

Robert S. Quick

TO: George LaRocca, PM 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

E. I. du Pont de Nemours and Company, Inc. and IR-4 have been submitting petitions for new tolerances for esfenvalerate, S-alpha-cyano-(3-phenoxyphenyl)-methyl S-4-chloro-alpha-(1-methylethyl)-benzeneacetate, with registration applications for Asana® XL Insecticide, which contains 8.4% esfenvalerate. Additionally, the company has obtained Asana® registrations for the crops having tolerances in 40 CFR 180.379. However 40 CFR 180.379 lists tolerances for fenvalerate, a racemic mixture of four isomers, of which esfenvalerate is one. DuPont is withdrawing its registrations of Pydrin®, whose active ingredient is fenvalerate, and CBII (CBRS) is recommending that the existing tolerances be revoked. The question arises about what will happen to the Asana® registrations when the fenvalerate tolerances are revoked.

Because recommended use levels of fenvalerate are typically 4 times corresponding use levels of esfenvalerate, tolerances established on the basis of fenvalerate residue data will certainly be high enough to support corresponding residue levels of esfenvalerate, but these tolerances will almost certainly be too high once all fenvalerate formulations are no longer in use. In support of new uses for esfenvalerate, DuPont has submitted bridging data, which allow use of fenvalerate residue data in setting of tolerances for esfenvalerate. For example, in PP#0F3852 (esfenvalerate for use in/on alfalfa and head lettuce), we concluded that the average ratio of Asana® residue levels/Pydrin® residue levels for alfalfa forage and hay from

five bridging trials was 0.3. This means that fenvalerate residue data can be used in establishing tolerances for esfenvalerate -- for alfalfa forage and hay -- by applying the factor of 0.3 to the tolerances which would be obtained solely from Pydrin® data.

In general, we intend to convert a fenvalerate tolerance to a corresponding esfenvalerate tolerance by applying the average bridging factor (within a given crop group) to the relevant fenvalerate tolerance. **To establish new tolerances for esfenvalerate by converting existing tolerances for fenvalerate, additional bridging data are needed.** Presently, we require at least three bridging studies per crop group. As more bridging data become available, this requirement may be modified. However, if the bridging data do not show a consistent ratio for esfenvalerate/fenvalerate residue levels, then esfenvalerate data for all relevant major crops (or crop groups) will be needed.

Is DuPont aware that bridging data are necessary to support the uses of esfenvalerate that were registered in the absence of any esfenvalerate data? If these data are not forthcoming, CBTS will recommend that these registrations of esfenvalerate be cancelled when the fenvalerate tolerances are revoked as a part of reregistration.

Additional Observations

1. Although fenvalerate is a List B chemical, du Pont is not supporting any food use, so no review of existing data was carried out by CB II. When and if tolerances for esfenvalerate are to be obtained by application of bridging factors to corresponding fenvalerate tolerances, the adequacy of the fenvalerate residue data base will be examined.

2. Bridging data should reflect application of all formulations of esfenvalerate. (PP#0F3852, for use of esfenvalerate in/on alfalfa and head lettuce, requested registration for only one formulation: ASANA® XL Insecticide 0.66 EC.)

3. We have recommended that tolerances for new uses of esfenvalerate be placed in the same CFR section as fenvalerate but in a new subsection in which it would be stated that esfenvalerate, the S,S-isomer, is the principal isomer in the residue (40 CFR 180.379 -- PP#0F3852, M.Flood, memo of 4/10/91).

4. Current analytical methods for both fenvalerate and esfenvalerate involve measurement of peak areas of four isomers, of which esfenvalerate is one (the S,S-isomer). An individual bridging factor, therefore, is

directly proportional to the ratio of the the sum of the peak areas for esfenvalerate to the corresponding sum of the peak areas for fenvalerate. It is important that this convention be consistently maintained in determination of all the bridging factors, whether or not a method is developed which would completely separate the esfenvalerate isomer from the other three.

The regulatory issues surrounding fenvalerate/esfenvalerate are complex. It is important that DuPont be aware of our interpretation of these issues. We recommend that a meeting be held between representatives of DuPont and EPA.

cc: SF, RF, Fenvalerate Rereg. File, Circu., MikeFlood, E.Haeberer, Hoyt Jamerson (H7505C).

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:557-4362:typist(mtf):8/15/91.
RDI:Branch Senior Scientist:RALoranger:9/9/91.