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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Data Requirements to Support Regional Registration of Chlorothalonil on collards, turnip greens and mustard greens in Georgia.

TO: Susan Stanton, Environmental Scientist
Emergency Response and Minor Use Section
Registration Support Branch
Registration Division/OPP

FROM: Debra Edwards, Chief
Chemistry Branch - Tolerance Support
Health Effects Division/OPP

Debra Edwards
10/13/93

CBTS/HED has been asked to provide input on the residue chemistry data that would be needed to permit evaluation of a tolerance petition and application for regional registration of chlorothalonil on collards, turnip greens and mustard greens in Georgia. The following data would be needed:

1. Three field trials on mustard greens would be needed from different production areas within the state. At least two composite samples (may be from the same plot at each location) must be collected from each trial site.
2. Two field trials on turnips would be needed from different production areas within the state. At each of the two trial sites, there should be four independent plots (two at the 1x application rate and two at the 2x application rate). At least one composite sample must be collected from each plot at each trial site. Both turnip trials should include analyses of roots and tops unless documentation can be provided to assure the Agency that use can be limited to varieties grown solely for tops.
3. The Agency's Good Laboratory Practices regulations must be followed in the generation of these data. Field trials must reflect the proposed use, i.e., maximum permissible number of applications, minimum interval between



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applications, minimum preharvest interval allowed, and maximum label rate (except in two plots each at the two turnip trials where a 2x rate must be represented). If registration is requested for more than one formulation class (e.g., WP, EC), residue trials or side-by-side comparison trials must be conducted for each type of formulation. To ensure the integrity of residue levels, samples should be frozen upon harvesting and should be retained in a frozen condition until analysis. Samples should not be washed prior to analysis. A complete sample history must be provided.

4. The method used to generate all residue data must be submitted along with method performance data for the substrates analyzed (fortification/recovery data, control sample analyses). If this method has been significantly modified from currently accepted PAM I or PAM II (FDA's Pesticide Analytical Manual) methodology, the petitioner will need to comply with the Agency's requirement for Independent Laboratory Validation (PR Notice 88-5) and the method will then need to undergo Agency method validation prior to acceptance.
5. Because cancer risk from existing uses of chlorothalonil is currently estimated to be in the 10^{-6} range, we advise that the petitioner also provide data on the effects of consumer washing and cooking on residue levels. This information need not be provided for each sample, but should be submitted for at least 2 or 3 samples and should indicate residue levels both before and after washing and cooking.

In addition, "reduction of residue" studies would provide valuable information for use in exposure estimation. Several studies in which duplicate or triplicate samples are collected with analysis also in duplicate or triplicate are recommended. We suggest that samples be collected at different points in the harvest and transportation process. The following possible sampling points for fresh market greens are suggested:

- a. whole plant which could be harvested from field trial (raw agricultural commodity)
- b. part of plant typically harvested (if different)
- c. plant after hydrocooling
- d. plant after transportation to grocery store
- e. plant after misting in grocery store

For processing greens, the following sampling points in addition to a and b above are suggested:

- a. after transport to the processing plant
- b. after washing

- c. after blanching
- d. after chilling/washing
- e. after chopping and freezing

6. It should be noted that there is no guarantee that generation of these data will result in an Agency decision to grant a permanent tolerance or regional registration for use of chlorothalonil on turnips, mustard greens or collards in Georgia. Rather, these data will allow the Agency to complete an evaluation of such applications and, if the data requested in #5 are submitted, will permit a realistic estimation of human dietary exposure from the proposed use.

cc: Chlorothalonil SF, Reading File, Circu