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

SEP 8 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6F3337 (RCB #988) - Metalaxyl on Strawberries - Evauation of Amendment Dated April 11, 1986 (Accession No. 260659)

FROM: Michael P. Firestone, Ph.D., Chemist
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

Michael P. Firestone

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Henry M. Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

Ciba-Geigy Corporation has submitted a letter dated April 11, 1986 in response to Deficiency 3 cited in RCB's review of the original petition for a metalaxyl on strawberries tolerance (see M. Firestone memo of February 21, 1986).

Deficiency 3 will be restated below, followed by the petitioner's response and RCB's comments/conclusions.

Deficiency 3

The residue data do not support the proposed metalaxyl use on strawberries for the following reasons:

a. Three out of seven field studies (including both non-CA studies) do not reflect the proposed zero-day PHI; CA = 68 days, MD = 40 to 54 days, LA = 21 to 35 days.

b. No field trials were conducted in the Pacific Northwest (Oregon or Washington), the Northeast (New York, Pennsylvania, or New Jersey), the Midwest (Michigan or Ohio), or Florida, areas in which strawberry agricultural practices are expected to vary.

Thus, the petitioner will need to conduct additional field trials in the States of Oregon or Washington; New York, Pennsylvania, or New Jersey; Michigan or Ohio; and Florida, which reflect the maximum proposed use (3 applications at 1.0 lb ai/A) and minimum PHI (zero-days).

At this time, RCB can reach no conclusion regarding the adequacy of the proposed 5 ppm metalaxyl tolerance for strawberries.

Petitioner's Response

"In rereviewing our Section D submittal, it became apparent to us that we did not indicate very clearly the two distinct use patterns for metalaxyl on annual and periennial strawberries. Although our directions for use in the proposed labeling clearly distinguished between the two, the presentation of our residue studies did not.

When taking this into consideration, it is true we do not have enough residue trials to support a national tolerance for the use of metalaxyl on both perennial and annual straberries. CIBA-GEIGY plans to conduct the necessary trials in the locations recommended by RCB during the coming year. These trials will be run using the rates and preharvest intervals which are necessary for the two different types of strawberries.

Generally, annual strawberries are grown in California, Florida, and Louisiana, while perennial strawberries can be found in the northeast, northwest, midwest and parts of the southeast. When using metalaxyl on annual strawberries, a 0-day PHI is necessary, since an application can be made during the harvest season. In the case of perennial strawberries, two applications are recommended; one at dormancy break and the other in the fall after harvest. No preharvest interval is needed because the applications occur either way before or after harvest.

Currently, there is a Section 18 Emergency Use Exemption in effect in California for the use of metalaxyl on strawberries to control red stele (Phytophthora fragariae). In the RCB review enclosed with your letter of March 21, it was noted that RCB had considered whether the proposed use of metalaxyl on strawberries would qualify for a regional tolerance based on the new minor use policy recently published in the Federal Register. The review went on to say RCB could not recommend for a regional tolerance because of the deficiencies in our data and the inappropriateness of using raspberry data (the only berry crop for which metalaxyl has an established tolerance) since residues in raspberries are one tenth of those expected in strawberries.

CIBA-GEIGY respectfully requests that RCB reexamine our data in light of the following, and reconsider the regional tolerance approach for use in California only, until we can generate the necessary data to register the use nationally:

1. If you examine the residue data in our Section D (EPA Accession No. 260659), you will find that we conducted a total of ten trials in California. Several of these were conducted with the use pattern for perennials and four with the use pattern for annuals (0-day PHI). The other trials do not clearly support either use.

2. The four trials which were conducted with the use pattern for annuals all were run at a 0-day PHI. Three applications at up to 1.0 lb. ai/A/application were made in three of these trials. One trial consisted of four applications at 1.0 lb. ai/A/application. This trial would represent a worst case scenario because only 3.0 lbs. ai/A/application are allowed by the proposed labeling.

3. CIBA-GEIGY feels that these four trials in California more then adequately support the request for a regional tolerance for use in California only. The maximum total residues of metalaxyl and its metabolites were calculated to be 3.43 ppm. Therefore, the requested tolerance of 5.0 ppm is still appropriate for this request."

RCB's Comments/Conclusions re: Deficiency 3

In RCB's February 21, 1986 review of the original petition, the following was stated regarding regional registration of metalaxyl on strawberries:

"RCB has considered whether the proposed use of metalaxyl on strawberries could qualify for a tolerance with regional registration based on EPA's Revised Draft Policy Statement on Minor Uses of Pesticides (OPP-30099 - see s. Schatzow memorandum of December, 24, 1985), in lieu of the relevancy of the residue data generated only in California.

Although strawberries are not included in the list of minor crops automatically considered for a pesticide tolerance with regional registraion, the Agency will consider other crops (such as strawberries) for tolerances based on geographically limited residue data on the basis of the following criteria:

1. Likelihood of expanded use,

2. Quality of the available residue data,

3. Availability of data on similar crops,

4. Variability of the residue data base, and

5. Toxicity of the pesticide.

On the basis of the above criteria for a tolerance with regional registration in the State of California only, RCB finds that it cannot translate raspberry residue data (the only berry crop for which a metalaxyl tolerance exists) since residues in/on strawberries are likely to be 10 times higher than those in/on raspberries. Also, metalaxyl is a systemic pesticide. Judgement on matters relative to Criteria No. 1 (Likelihood of expanded use) above should be referred to the Benefits and Use Division."

RCB now reiterates its earlier conclusion that granting a tolerance with regional registration is not appropriate in the case of metalaxyl on strawberries grown in the State of California only.

Thus, Deficiency 3 remains pending at this time.

Other Considerations

An International Residue Limit Status sheet is attached to RCB's February 21, 1986 review of the orginal petition. Since Codex, Canada and Mexico have no established limit/tolerance covering residues of metalaxyl in/on strawberries, there are no compatibility problems.

Recommendation

At this time, RCB recommends against the establishement of the proposed metalaxyl tolerance covering residues in/on strawberries for the reason cited in Deficiency 3; i.e., the need for geographically representative residue data reflecting the proposed use.

cc: R.F., Circu, EAB, EEB, MPFirestone, FDA, PMSD/ISD, PP#6F3337
RDI: JHOnley-8/25/86:RDSchmitt-8/25/86
RCB:TS-769:MPFirestone:CM#2:Rm800b:557-1991:typed by gm