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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

DECISION MEMORANDUM

**SUBJECT:** Registration of Mefenoxam

**FROM:** Donald R. Stubbs, Chief *Donald R. Stubbs*  
Fungicide Herbicide Branch (7505C)

**TO:** Stephen L. Johnson, Director  
Registration Division (7505C)

**REGISTRANT:** Ciba-Geigy Corporation

**CHEMICAL:** Mefenoxam (R)-2{(2,6-dimethylphenyl)-methoxyacetyl-amino}-  
propionic acid methyl ester

**USES:** Control of Diseases in Food and Non-Food Crops and as a Seed  
Treatment

**TYPE OF REGISTRATION:** Time-Limited

BACKGROUND

On September 6, 1995, Ciba-Geigy Corporation requested registration of mefenoxam technical (CGA 329351) and 13 end-use products that contain mefenoxam as an active ingredient. Mefenoxam is the R enantiomer of metalaxyl. Mefenoxam is a fungicide used for control of diseases in food and non-food crops and as a seed treatment. The technical and 13 end-use products will have a time-limited registration of one-year.

Based on information submitted and reviewed, EPA has determined that under the terms of registration this isomer of metalaxyl presents fewer risks than currently registered metalaxyl products and should serve as an efficacious replacement for the currently registered product at all current use sites. Because the registrant has agreed to voluntarily cancel the currently registered metalaxyl product upon the registration of this reduced risk product, the Agency believes this registration action will serve to reduce risk to human health and the environment. For this reason, the Agency believes this action is consistent with the fundamental purpose of FIFRA -- to prevent unreasonable adverse effects to the environment from the use of pesticides.

The terms of registration provide that the registration shall expire, without opportunity for hearing in one year. Additionally, EPA may, by order and without hearing, cancel the registration if EPA determines, based on the review of data submitted in support of this product, upon comments submitted pursuant to section 3(c)(4) of FIFRA, or upon any other information that this product no longer meets the requirements of section 3(c)(5).

EPA approved these terms of registration because the Agency has not completed a full review of all information submitted to support this registration, and because the 30-day period for comment under section 3(c)(4) has not expired. While the Agency does not believe it is likely that it will review or receive information to demonstrate that this product does not meet the requirements of 3(c)(5), the Agency believes such limitations are appropriate where additional information could further refine the nature of the risks and benefits of the pesticide and thus give rise to the need for regulatory action.

These terms will allow the Agency to respond expeditiously should any data or comment from the public indicate that this product may present unreasonable adverse effects. Any additional information received and reviewed will also be taken into account to support this product registration beyond the one-year term.

The public comment provisions of section 3(c)(4) state that the Agency shall provide 30 days in which any Federal Agency or interested person may comment on the receipt of an application for a product containing a new active ingredient or a product that includes a changed use pattern of an active ingredient contained in currently registered products. Although section 3(c)(4) does not by its terms preclude registration action under section 3 prior to the expiration of the 30-day comment period, EPA believes that 3(c)(4) was intended to provide the public with an opportunity to inform and influence EPA registration action, and therefore the Agency generally will provide the public with the full 30-days' notice prior to the issuance of a registration.

The Agency believes, however, that in certain circumstances, for good cause, it is appropriate to issue a registration prior to the expiration of the 30-day period. In the present situation, the Agency has registered mefenoxam for the purpose of achieving risk reduction in 1996. Were the Agency to have waited until March 27 to take this action Ciba-Geigy would not have agreed to voluntarily cancel the existing metalaxyl registration and any risk reduction resulting from the removal of metalaxyl from the market would not have been available. For this reason, the Agency believes that granting this registration advances the public interest and therefore represents a circumstance where it is appropriate to depart from the general practice of providing 30-days' notice prior to registration.

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**CONDITIONS OF REGISTRATION:**

This time-limited registration is subject to the following terms:

1. This registration shall expire on March 5, 1997 without opportunity for hearing.
2. EPA may, by order and without opportunity for hearing, cancel this registration prior to March 5, 1997 if the Agency determines, based upon comments submitted pursuant to section 3(c)(4) of FIFRA, or upon any other information that this product no longer meets the requirements of section 3(c)(5).
3. The registrant must submit to the Agency a written request to voluntarily cancel Metalaxyl Technical and its end use products within 10 business days from the date of this registration.
4. The registrant must 1) submit and/or cite all data required for registration/reregistration of the product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and 2) submit acceptable responses required for reregistration of your product under FIFRA section 4.
5. Any outstanding data requirements cited in the Metalaxyl Reregistration Eligibility Document (RED) also apply to Mefenoxam. These studies may be conducted on either Metalaxyl or Mefenoxam.

**RECOMMENDATION:**

I recommend that you concur with the time-limited registration of this fungicide under Section 3(c)(5) of the Act.

CONCUR

DO NOT CONCUR

DATE

Peter Coulter

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