



Reregistration Eligibility Decision (RED)

Benomyl

July 31, 2002

This document serves as and explains EPA's reregistration eligibility decision (RED) for benomyl. Benomyl was scheduled for reregistration in 2002; however, the registrants of benomyl have requested voluntary cancellation. The following provides background information on the pesticide registration, reregistration, and tolerance reassessment, an overview of the uses and health effects associated with benomyl, and a summary of the terms of its cancellation. Because of the voluntary cancellation decision, EPA did not complete risk assessments for benomyl.

Introduction

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.136 *et seq.* The FQPA amendments went into effect immediately. This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of benomyl.

Background

Benomyl was first registered in 1969 by E.I. du Pont de Nemours and Co.(DuPont). EPA issued a Registration Standard for benomyl in June 1987. A June 1992 Data Call-In (DCI) required additional data. DuPont voluntarily canceled registrations for dry flowable (DF) products in 1995. Over the years, DuPont also canceled the following use sites: post harvest use on apples, citrus, pineapple, bananas, pears, and stone fruit;

flowers; ornamentals; bulbs; shade trees; greenhouse, dip treatment for sugarcane, drench treatment for strawberry plants; and turf and residential uses. On April 18, 2001, DuPont requested voluntary cancellation of all its benomyl registrations. EPA published a Federal Register Notice on May 23, 2001 (Federal Register Notice, OPP-66288; FRL-6794-9), announcing receipt of DuPont's request for cancellation and inviting the public to comment during the next 30 days. The Agency considered the comments submitted and on August 8, 2001, the cancellation of benomyl registrations became effective. All other companies holding benomyl product registrations, except one end-use registrant, have requested and obtained voluntary cancellation of their benomyl products. See 6(f) notice in the Federal Register (FR) on October 12, 2001, and cancellation order on January 15, 2002. The remaining end-use registrant requested a voluntary cancellation of its registration on July 31, 2002 (described more fully below). Upon the effective date of the remaining voluntary cancellation request, all benomyl registrations will be canceled.

Uses

Benomyl was registered as a systemic foliar fungicide for control of a wide range of diseases of fruits, nuts, vegetables, and field crops. Benomyl was formulated as a wettable powder (WP) and wettable powder in water soluble film (i.e., packets WSP), both of which contained 50 percent active ingredient. These formulations were applied as delayed dormant, foliar, seed, and seed piece treatments. Application techniques included airblast, aerial, tractor-drawn equipment (groundboom or spreader), chemigation, and hand held equipment. Benomyl was registered for use on the following crops: almonds, apples, anise, apricots, asparagus, avocado, banana, barley, bean vine, blueberries, brassica (broccoli, Brussels sprouts, cabbage, chicory, Chinese cabbage, cauliflower, collards, kale, kohlrabi, mustard greens, rutabagas, and turnips), caneberries (raspberries, blackberries, boysenberries, loganberries, and dewberries), cardoon, carrots, celery, cherries, citrus, conifers, corn, cucurbits (cucumber, melons, pumpkins, and squash), currants, dandelions, dill, figs, grapes, macadamia nuts, mangoes, mushrooms, nectarines, onions, oats, papayas, peaches, peanuts, pears, peas, pecans, peppers, pineapple, pistachio, plums, prunes, rape, rice, rye, soybeans, spinach, strawberry, sugar beets, tomatoes, wheat, and yams.

Health Effects

Benomyl rapidly degrades to carbendizim (MBC) which is also of toxicological concern. MBC is the primary metabolite of thiophanate methyl, another fungicide, and is also registered as an active ingredient.

Effects associated with both benomyl and MBC include liver toxicity, developmental toxicity (such as fetal eye and brain malformations and increased mortality), and reproductive (testicular) effects.

Both benomyl and MBC are also considered possible human carcinogens.

Data Gaps

The following set forth the substantive data gaps for benomyl/MBC:

Toxicology

- Developmental neurotoxicity (DNT) study in rats (benomyl)
- DNT in rats (MBC)
- 21-day dermal in rats (MBC)
- 2-generation rat reproduction and subchronic studies (MBC)

Product chemistry

- UV/Visible Absorption (benomyl tgai)
- Enforcement analytical methods (benomyl tgai)

Residue Chemistry

- Limited or full rotational crop residue studies (or modify labels to prohibit crop rotations)
- Lab validation for residue method used to recover the metabolite 2-AB and an Agency method try-out for use as an enforcement method.
- Multiresidue data for 2-AB, 4-HBC and 5-HBC.
- Storage stability data to support tolerances in plant and animal commodities
- Additional residue data for apricots and nectarines

Occupational Exposure

- Mixer/loader, applicator exposure for commercial seed/seedling treatment uses and dip uses.

Environmental Fate and Effects

There are no outstanding data requirements for benomyl or MBC except for plant toxicity data.

Outstanding plant toxicity studies using benomyl TEP (50% WP):

- 850.4100 - Tier I Seedling Emergence
- 850.4150 - Tier I Vegetative Vigor
- 850.4400 - Tier I *Lemna gibba*
- 850.5400 - Tier I Algal toxicity using: *Pseudokirschneria subcapitata* (*Selenastrum capricornutum*), *Anabaena flos-aquae*, *Navicula pelliculosa*, and *Skeletonema costatum*.

A formulation other than the 50WP may trigger additional ecotoxicity studies for aquatic and terrestrial plants and animals (to be evaluated on a case-by-case basis).

Since the source has been canceled, a generic data exemption no longer applies.

Tolerances

100 tolerances existed for food and feed items such as fruits and nuts, vegetables, soybeans, grains, meat, milk, and eggs. EPA published an FR notice January 15, 2002, proposing to revoke tolerances for benomyl (67 FR1917-02). On July 17, 2002, EPA revoked all tolerances for residues of the fungicide benomyl (67 FR 46900-01). The July 17th notice describes the effective dates for tolerance revocation. These dates allow adequate time for commodities which may contain benomyl residue to clear the channels of trade.

Regulatory Conclusion

The Agency has completed its reregistration eligibility decision for the pesticide benomyl. All registered sources of benomyl have been canceled and all tolerances have been revoked. One end use registration remains; however, on July 31, 2002, the registrant requested that the registration be voluntarily canceled. Once the voluntary cancellation is granted, there will be no registered products containing benomyl.

All Dupont registrations of pesticide products that contain benomyl were effectively canceled on August 8, 2001, and the Agency believed all other registrants' benomyl product registrations were canceled effective January 15, 2002. It has come to the Agency's attention that one end use registration for benomyl still remains. On July 31, 2002, the registrant of the remaining end use registration, Hi-Yield Chemical Company ("Hi-Yield"), requested that its registration (EPA Reg. No. 34911-27) be voluntarily canceled. Hi-Yield has stated that there are no inventories of remaining stocks of this product, therefore, no new existing stocks will be permitted.

The Agency has determined that it is not necessary to assess the risks of benomyl products because there are no tolerances for benomyl and only one inactive end-use product remains, however, this product is being voluntarily canceled. In view of the substantive data gaps, the absence of necessary tolerances, and the absence of a registered source of benomyl manufacturing use product, the Agency finds that benomyl does not meet the statutory requirements of reregistration.

Through the cancellation order dated January 15, 2002, sale and distribution of existing stocks of products already in the channels of trade is permitted until December 31, 2002.

EPA expects that use of any remaining benomyl products will end in 2003 given that production ceased in 2001 and the sale and distribution of benomyl products will end on December 31, 2002.

Lois A. Rossi, Director
Special Review and Reregistration Division