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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: Biological Evaluation of Public Interest Finding Submitted by Abbott Laboratories in Support of the Conditional Registration of CenTari® Bioinsecticide on Various Crops to Control the Larval Stages of Various Lepidopteran Pests.

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Introduction

Purpose of Review

This analysis was conducted to determine if the conditional registration of CenTari® bioinsecticide for the control of the diamondback moth and other lepidopterous pests on a variety of agricultural crops is in the public interest.

Description of New Pesticide

CenTari is a bioinsecticide containing as its active component a bacterium, Bacillus thuringiensis var. aizawai (B.t.a.). This bacterium is naturally occurring and has activity against infestations by a variety of lepidopterous larvae including diamondback moth (DBM).

Like other Bacillus thuringiensis (B.t.) products, CenTari functions as a stomach poison in susceptible insects. After ingesting a lethal dose of CenTari, the larvae stop feeding within the hour (due to paralysis of the digestive system) and die within several hours to three days (Abbott, 1991).

According to the applicant, B.t.a. is genetically different from Bacillus thuringiensis var. kurstaki (B.t.k.) and contains a totally novel toxin mix thus allowing it to be effective against DBM strains resistant to B.t.k.

The proposed labeling lists many field and row crops as well as tree fruits, ornamental and forestry uses. CenTari is formulated as a 10.3 percent (weight/weight basis) water dispersable granule containing 35,000 diamondback moth units per mg. Application rates for CenTari bioinsecticide vary depending on the severity of the infestation, the insect pest and the type of equipment used. For most row and field crops, the labeling recommends 0.25 to 1 pound of formulated product per acre; for tree fruits and some field crops (primarily for control of armyworm, European corn borer, and Heliothis spp.) label rates range from 0.5 to 2 pounds product per acre.

Description of Data Submitted by Registrant

Efficacy data submitted by Abbott Laboratories in support of conditional registration of CenTari consisted of eighteen (18) small plot studies conducted in the states of Florida, Illinois, Texas, and New York. Of these 18 studies, all evaluated the effectiveness of CenTari against the diamondback moth (DBM). The cabbage looper (CL) was evaluated in eight of the studies, cabbage webworm in one study, and the imported cabbageworm, armyworms, and the cross-striped cabbageworm in two studies. The test cultivars in all these studies consisted of some type of cole crop.

Data submitted from the Experimental Use Permit (EUP) for CenTari showed that a total of about 2,283 acres were used to test the efficacy of this product in controlling various lepidopteran pests (CL, DBM, beet armyworm, and soybean looper). These EUPs were conducted in eleven (11) different states on several different commodities (broccoli, cabbage, cauliflower, lettuce, and cotton).

Even though the registrant claims that a variety of lepidopteran larvae can be controlled with this product, our review will primarily concentrate on the DBM and to a lesser extent the CL. Observations regarding the other pests will be discussed only to the limit allowed by the available data.

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Current Situation

The diamondback moth (DBM), Plutella xylostella (L.) and the cabbage looper Trichoplusia ni (Hbn.) are two of the major pests of cole crops (cabbage, broccoli, collards, cauliflower, kale, kohlrabi) in the United States. The only damaging stage of these pests is the larval stage. The larvae will feed on the leaves and "heads" of the plants rendering the crop unmarketable. According to Abbott (1991), the annual market losses to these crops from damage by the DBM alone could exceed 100 million dollars.

The 1992 Insect Control Guide lists, carbaryl, malathion, diazinon, esfenvalerate (Asana®), endosulfan (Thiodan®), azinphos-methyl (Guthion®), cryolite (Kryocide®), methomyl (Lannate®), methamidophos (Monitor®), fluvalinate (Marvik®), acephate (Orthene®), mevinphos (Phosdrin®), and permethrin (Ambush/Pounce®) as well as various B.t. var. kurstaki products (Cutlass®, Javelin®, Biobit®, Bactospeine®, Larvo-Bt.®, MVP®, and Dipel®) as recommended products for use on cole crops to control the DBM or the CL. These pests, however, are said to show some degree of resistance to many of the products recommended, especially the synthetic products (Shelton and Wyman, 1990; Yu, 1992). Documentation of resistance to some of the B.t. based insecticides are also now being reported (Tabashnik, et al., 1990; Hall, 1990; Leibee, 1990). In general, conventional B.t. products have been the most effective under certain environmental conditions (i.e., warm and dry weather). MVP®, an encapsulated form of B.t. var. kurstaki, was registered for use last year and was claimed to have overcome many of the limitations faced by the conventional B.t. products (i.e., increased residual activity and foliar persistence).

A thorough survey of the Insecticide and Acaricide Tests (1989-1991) revealed only two (2) studies (greenhouse and field plot study) that compared the effectiveness of CenTari with that of the other B.t. products. Data suggested that, in general, control of the DBM and CL in plots treated with the registered B.t. products was as effective as plots treated with CenTari (ABG6305). In addition, in some cases MVP actually provided better control than CenTari; however, this difference was not statistically significant (Eastman et al., 1991; Eastman and Oloumi-Sadeghi, 1991).

Review of Data

Methodology for Review

In order to make an accurate assessment of the performance of CenTari bioinsecticide, several sources were utilized. Product performance data submitted by the registrant as well as other efficacy studies found in the Insecticide and Acaricide Tests, 1989 to 1991 were evaluated to determine the performance of the subject product and its efficacy when compared to other registered products. Information from the product

label, past registration applications, and published state recommendations and other insect control guides were also used in the evaluation of this product. Our objective was to collect and evaluate the best available information on the subject compound, to accurately assess its performance in controlling the insect pests, and to determine if the claim of public interest was supported from the analysis.

Analysis of Data

A). Registrant's Claim: CenTari represents a new active ingredient to which DBM shows no resistance. CenTari is the most effective insecticide against resistant DBM when used in a seasonal pesticide program.

BEAD's Finding: Currently, all the B.t. formulations registered for control of the DBM and CL are based on the delta endotoxin from the B.t. var. kurstaki. Conversely, CenTari is a formulation derived from the active components of B.t. var. aizawai. According to Abbott (1992), B.t. var. kurstaki differs from B.t. var. aizawai by at least two protoxin genes. Thus, BEAD believes that these B.t. formulations represents two different active ingredients.

Efficacy data submitted by the registrants suggest that when CenTari was compared to the conventional B.t. products (Cutlass, Javelin, Dipel, Biobit), CenTari was the most effective product against reducing the larval stages of the DBM and CL. When compared to MVP (6 studies), 50% of the studies indicated that CenTari was the superior product. However, results from the remaining studies suggest that no significant differences in performance was observed. Data also showed that CenTari was significantly more effective than the combination of a B.t. (i.e. Dipel) product and a synthetic product (i.e. Phosdrin, Ambush, Monitor plus Thiodan).

B). Registrant's Claim: CenTari is equally effective to other lepidopteran pests and non-resistant DBM as standard B.t. products.

BEAD's Finding: Very limited data on the efficacy of CenTari against the other labelled lepidopteran pests were submitted. However, analysis of the studies reviewed showed that CenTari was the most effective product at controlling the larval stages of the cabbage webworm, imported cabbageworm, cross-striped cabbageworm and armyworms.

Data provided through the EUP for CenTari show that CenTari provided excellent control of the DBM in eleven (11) states found in all parts of the United States. While resistance has been documented in some of these areas, it has not been documented in all areas. Thus, given the effectiveness of CenTari in the

different states (tested under an EUP), BEAD believes that CenTari is effective against the resistant as well as the non-resistant populations of the DBM.

C). Registrant's Claim: CenTari is compatible in integrated pest management (IPM) programs. Reduction in chemical usage by IPM programs will reduce adverse ecological effects and help revert chemical resistance in the DBM population. As a result additional DBM control from beneficial parasites and predators can be realized.

BEAD's Finding: Since no studies to demonstrate the effects of B.t. on predators and parasite were submitted, no definitive conclusion could be made. However, BEAD assumes that because CenTari, like other B.t. products, are host-specific to certain pests, its effects on non-targets would probably be minimal. Thus, CenTari could be a beneficial part to an integrated pest management program (IPM) and, because of its apparent effectiveness to certain lepidopteran pests, CenTari may indeed reduce the need and dependency on chemical applications. Consequently, over time this reduction in chemical pesticides could lead to the development of less resistant populations.

Major Concerns

Limited data on the efficacy of CenTari to control the DBM and the CL were submitted. Very little information was submitted that reported efficacy of CenTari on other labeled pests. Efficacy data found in Insecticide and Acaricide Tests (Eastman et al., 1991; Eastman and Oloumi-Sadeghi, 1991) suggested that in general control of DBM achieved with CenTari was not statistically significant from the control obtained by other B.t. products. This finding suggests that the data received in the request may not have been a random sample and therefore may not be indicative of what might occur in the field.

Conclusions

The data submitted in support of the conditional registration of CenTari bioinsecticide appears to indicate that this product when used in accordance with the label directions, can be as effective or more effective as the currently registered B.t. products at controlling the DBM and other lepidopterous pests. Based on limited data, BEAD believes that CenTari, with its novel toxin mix, would be a useful addition to currently registered B.t. products for control of resistant DBM populations. Therefore, BEAD believes that, from a benefits perspective, conditional registration of CenTari would be in the public interest.

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