



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

OCT 2 1990

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Section 18 - Specific Exemption for Use of
Bifenthrin (Capture) to Control Various Mites on
Seed Corn in Texas -- ACTION MEMORANDUM

FROM: Anne E. Lindsay, Director
Registration Division

Anne E. Lindsay

TO: Douglas D. Campt, Director
Office of Pesticide Programs

APPLICANT'S REQUEST

Applicant: Texas Department of Agriculture.

Chemical: Bifenthrin, (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl cyclopropanecarboxylate.

Product: Capture 2 EC Insecticide/Acaricide, manufactured by FMC Corporation (EPA Reg. No. 279-3069).

Site: Seed corn.

Pests: Banks Grass Mite [Oligonychus pratensis (Banks)],
Two-spotted Spider Mite [Tetranychus urticae Koch].

Rate: At 0.08 to 0.1 lb. a.i. (5.12 to 6.4 fl. ozs. of product).

Appl.: Maximum of four by air (in a maximum of 2 gallons diluent) or through chemigation equipment. A maximum of 0.4 lb. a.i. (25.6 fl. ozs.) may be applied per acre per growing season. A PHI of 30 days is proposed.

Acreage: Texas: 2,000 acres of seed corn in Hidalgo County in the Lower Rio Grande Valley.

Poundage: Texas: Maximum of 800 lbs. a.i. (400 gallons of product).

Use Period: Treatments will be required during the period September 15, 1990 to December 24, 1990.

REG. ALT.: Currently the following chemicals are recommended by the Applicant for control of mites on corn: oxydemeton methyl (MetaSystox-R), disulfoton (Di-Syston), dimethoate (Cygon), propargite (Comite), phorate (Thimet), carbofuran (Furadan), and terbufos (Counter).

According to the Applicant, propargite (Comite) is effective as a preventative or prophylactic treatment but cannot be used as a rescue treatment once high mite populations have developed in the field. The Applicant indicates that the primary purpose of this request is to provide a method for rescue treatments of heavily infested fields when the registered pesticides fail to control the pests. Dimethoate provides good control of banks grass mite, but not of two-spotted spider mites. Carbofuran and terbufos only suppress mite populations. The Applicant states that disulfoton, phorate, and oxydemeton methyl provide extremely variable control and are not considered satisfactory as a rescue treatment.

ECONOMICS: Based on information supplied by the Applicant, the use of bifenthrin instead of the currently labeled miticides, could prevent an expected yield loss of 15 bu. per acre that would result from use of the registered miticides as a rescue treatment. Texas anticipates an average production of 45 bu./acre with the use of bifenthrin. Use of the current miticides, with its 15 bu/acre anticipated yield reduction, would give an average yield of 30 bu./acre. At an estimated price for seed corn of \$90 per bushel, the 45 bu/acre yield would produce a gross income of \$4,050 per acre and the 30 bu/acre yield from the use of the registered miticides would produce gross revenues of \$2,633/acre. Texas gives the total production costs per acre for seed corn of: \$697 for the registered miticides to \$714 for four applications of bifenthrin.

EMERGENCY: The currently available chemicals provide adequate control in most fields. However, in certain parts of the state or in specific fields the registered alternatives will fail to provide an adequate level of control and a miticide will be needed as a rescue treatment. The Applicant states that since the registered alternatives are not satisfactory for rescuing heavily infested corn fields, bifenthrin is needed.

BACKGROUND

Previous Section 18's: Section 18s for use of a miticide on field corn have been requested by and granted to Texas in nine of the last ten years. In 1984, use of a miticide was not requested. In

1981, 1984 and 1989, Texas requested exemptions for a miticide on seed corn (Azodrin & Capture). On June 25, 1990, the Texas Department of Agriculture requested a specific exemption for the use of bifenthrin on field corn in northern Texas. On July 6, 1990, Texas declared a crisis for the use of bifenthrin on field corn in northern Texas. On August 1, 1990, Texas requested that their specific exemption be amended to authorize treatment of 2,000 acres of seed corn in Hidalgo county. On August 13, 1990, Texas withdrew the request to treat 415,286 acres of field corn in northern Texas because all applications had been completed under the crisis exemption. This leaves the request to treat 2,000 acres of seed corn still pending.

Progress Towards

Registration: On August 5, 1988, the Agency issued a conditional registration for use of bifenthrin on cotton with a final expiration date of October 31, 1992. In order to evaluate the effects of bifenthrin on fish and aquatic organisms and its fate in the environment, several data requirements must be fulfilled during the period of conditional registration. Such requirements include an aquatic field test which has been submitted and is expected to be reviewed by 1/91 and a repeat confined crop rotation study in wheat due 10/91.

A tolerance petition for bifenthrin on corn has been submitted to the Agency. Until the data necessary to evaluate the effects of bifenthrin on aquatic organisms has been submitted and evaluated, progress on the registration is not expected.

A Registration Standard has been completed for bifenthrin for greenhouse ornamental only. Bifenthrin is not a Special Review Chemical.

EPA EVALUATION

The Biological Analysis Branch has previously reviewed the proposed use of bifenthrin on field corn and the Economic Analysis Branch reviewed the current economic data submitted by the Applicant. The results of these reviews are discussed below.

Biological:

Pest problems are often directly associated with weather conditions. This is especially true of mites on corn. Hot, dry and windy conditions exacerbate mite population expansion and growth. Mite populations left unchecked under such circumstances quickly "explode". Furthermore, because of the short life cycle and high reproductive capacity, selection for resistance can occur rapidly. Rescuing a heavily infested corn crop is difficult with any pesticide.

Two species of mites are important pests of corn. They are the Banks grass mite and the two-spotted spider mite. The Banks grass mite normally appears first in the season, feeds primarily on the lower leaves of the corn plant and is moderately susceptible to the currently registered insecticides/miticides. The two-spotted spider mite tends to appear later in the season, increases rapidly, feeds on the entire plant, and is much more difficult to control.

The registered alternatives proparagite and dimethoate are fairly soft on beneficial organisms, and as such they fit into IPM programs of mite control better than other miticides. Proparagite is used primarily as a prophylactic treatment for mites in corn. It has ovicidal properties which other miticides do not have and can be used very effectively for early season treatment. Depending upon precision of application and the cooperation of the weather, a single treatment can sometimes provide sufficient suppression to make further treatment during the critical part of the season unnecessary. Proparagite cannot be used to rescue a heavily infested crop.

Dimethoate (Cygon) has been the most relied upon material for corn growers in recent years. It is reportedly still somewhat effective against the banks grass mite but is largely ineffective on the two-spotted spider mite. Other miticides listed for corn; carbofuran, disulfoton, oxydemeton-methyl, and phorate have resistance problems and must be used repeatedly to achieve adequate control. Capture, according to data submitted and telephone conversations with on-site entomologists, provides control for a longer period of time and therefore, is less likely to require repeat applications.

BEAD concluded mites would be a significant problem for corn growers if the weather continues to be hot, dry and windy.

Economics:

BEAD reviewed the economic information submitted in Texas's application and relevant USDA production and value data for field corn. BEAD concluded that field corn growers would suffer a significant economic loss if the registered miticides fail and an effective rescue treatment is unavailable.

Residue chemistry review:

Dietary Exposure Branch reviewed the request for the use of bifenthrin on field corn in Nebraska. Residue levels were projected for field corn grain at no greater than 0.05 ppm, silage 2.0 ppm, fodder 4.0 ppm, milk 0.1, meat 0.1 ppm, and meat byproducts and meat fat 0.5 ppm. Residues on seed corn are expected to be similar.

Toxicology Review and Dietary Risk Assessment

The following analysis provided by the Dietary Risk and Evaluation Section assumes all the secondary residues in meat and milk have come from the use on corn. Uncertainties associated with animal diets, the percentage of the crop that is treated, and local versus national exposures make a meaningful partitioning of the secondary residues among the conditional registration on cotton and the proposed section 18 on corn impractical.

The current reference dose for bifenthrin is based on a 1-year dog feeding study with a NOEL of 1.5 mg/kg and a safety factor of 100 giving a reference dose of 0.015 mg/kg/day. Based on the TMRC and 100% of the crop treated, the percent of the reference dose utilized for the conditionally registered use on cotton plus the proposed use on corn utilizes 10.4% of the reference dose. The DRES subgroup with the highest exposure is non-nursing infants less than one year old. The conditionally registered use plus the proposed use on corn utilizes 45.9% of the reference dose for this subgroup.

With the use of anticipated residues and percent crop treated data to conduct an Anticipated Residue Contribution (ARC), dietary exposure for both uses is calculated to be 0.16% of the reference dose for the U.S. population and 0.51% of the reference dose for non-nursing infants.

In late 1985, 6(a)(2) data concerning a mouse oncogenicity study was received. HED conducted a peer review of bifenthrin; it was classified as class C in terms of its oncogenic potential, primarily on the basis of the mouse study in which a dose-related occurrence of leiomyosarcomas in the urinary bladder of male mice was observed. A potency estimate, Q^* of 5.4×10^{-2} (mg/kg/day)⁻¹ in human equivalents, has been calculated. The rat oncogenicity study was negative.

The dietary carcinogenic risk for the overall U.S. population calculated by multiplying the ARC exposure analysis for both the corn and cotton use by the Q^* for bifenthrin, and based on 70-year exposure was determined to be approximately 1.3×10^{-6} .

Risk to Applicators:

The lifetime cancer risks to applicators from the use of bifenthrin on corn based on 5 days of exposure per year for a working life of 35 years and 55.4% dermal absorption are as follows:

Aerial Application	Lifetime risk	Risk per year
Mixer/Loader		
Open System	$1 \times 10^{-3.5}$	1×10^{-5}
Closed System	1×10^{-6}	$1 \times 10^{-7.5}$
Pilots	1×10^{-6}	$1 \times 10^{-7.5}$
Flaggers	1×10^{-5}	1×10^{-7}

Ecological Effects and Environmental Fate Review

Based on the estimated exposure and the available acute and chronic avian toxicity data, bifenthrin is not expected to pose a direct or dietary hazard to avian wildlife. Because of the extreme toxicity to aquatic organisms, waterfowl that use small ponds, prairie potholes, marshes, or other wetlands as feeding grounds may be indirectly affected through adverse effects to aquatic food organisms.

Use of bifenthrin is not expected to pose a direct or dietary hazard to mammalian wildlife.

Bifenthrin is extremely toxic to aquatic organisms. Mortality has been demonstrated in both field and laboratory studies. Information submitted under Section 6(a)(2) report reductions of aquatic invertebrates and gizzard shad under field use patterns.

Aquatic organisms are especially sensitive and would be substantially harmed by exposure to bifenthrin which would result from off-target transport. Aquatic species will be exposed to bifenthrin in two ways: runoff and spray drift. Exposure from runoff is expected to exceed laboratory demonstrated effect concentrations even though bifenthrin has a high binding affinity for soils.

Bifenthrin is extremely persistent in the environment. A potential chronic hazard to aquatic life may occur. A significant problem with bifenthrin is that there is no fully validated method to measure the low concentrations of bifenthrin in the environment which affect aquatic organisms. These low concentrations are at or below the level of detection making demonstration of the cause-and-effect relationship needed for enforcement activities almost impossible.

Bioaccumulation data (BCF 8,720x after 42 days and 53% of the bifenthrin present in the fish 42 days post-exposure) plus bifenthrin's extreme persistence in the environment indicates that the concentration of bifenthrin could reasonably be expected to accumulate in aquatic environments from two applications and to bioaccumulate in aquatic organisms.

EEB concluded that the proposed restriction of no applications of bifenthrin within 500 feet of any lake, wetland, flowing river or stream may afford some attenuation of off-target drift loadings, but whether this will mitigate potential adverse effects is not known. EEB felt that while the recommended buffer zone may reduce the magnitude and propensity of non-target impacts, they cannot be expected to eliminate them.

Based on their review, Ecological Effects Branch concluded that the proposed use of bifenthrin on corn in Texas provides for serious risks to non-target organisms. Serious impacts to aquatic organisms near corn agriculture may occur. The greatest problems foreseen with bifenthrin are its extreme toxicity to aquatic organisms, its persistence in the environment, and its potential to bioaccumulate.

Incremental risk:

Bifenthrin is conditionally registered for use on cotton. According to the Texas Department of Agricultural, 100,000 acres of cotton were grown in Hidalgo County last year. The proposed treatment of 2,000 acres of seed corn represents an insignificant increase in the risk to non-target aquatic organisms when compared to the risk from the use of bifenthrin and other synthetic pyrethroids on the 100,000 acres of cotton being grown in Hidalgo County.

Endangered species:

The Endangered Species Specialist in Corpus Christi was contacted by phone about the treatment of 2,000 acres of seed corn in Hidalgo County in the Lower Rio Grande Valley. The Endangered Species Specialist was not aware of any endangered aquatic species in Hidalgo County.

Environmental fate:

Review of the environmental fate data for bifenthrin indicates that the data necessary to support a section 18 for the use of bifenthrin on corn have been submitted except for rotational crop data that has been partially satisfied. Data currently available support a 30-day rotational crop interval after the last bifenthrin application for leafy vegetables, root vegetables and small grains. Residues were found in straw derived from wheat planted 120-days after the last bifenthrin application. Straw derived from wheat planted in corn fields treated with bifenthrin should be prohibited from use for food or feed.

RECOMMENDATION:

I recommend that the request for a specific exemption from the Texas Department of Agriculture for use of bifenthrin (Capture) to control Banks grass mites and two-spotted spider mites on seed corn be granted for the following reasons:

1. An emergency situation as defined in the section 18 regulations appeared to exist based on BEAD's review of the information submitted by the Applicant. In addition, the problem with mite damage to corn appears to be substantially unchanged from the situation in Texas last year and in Kansas, and Nebraska this year where the use of bifenthrin on field corn was authorized.

2. Residue levels for the proposed use were projected for field corn grain at no greater than 0.05 ppm, silage 2.0 ppm, fodder 4.0 ppm, milk 0.1, meat 0.1 ppm, and meat byproducts and meat fat 0.5 ppm. Similar levels are expected in seed corn.

3. The percent of the reference dose utilized for the conditionally registered use on cotton plus the proposed use on corn is 10.4%. The DRES subgroup with the highest exposure is non-nursing infants less than one year old. The conditionally registered use plus the proposed use on corn utilizes 45.9% of the reference dose for this subgroup.

With the use of anticipated residues and percent crop treated data to conduct an Anticipated Residue Contribution (ARC), dietary exposure for both uses is calculated to be 0.16% of the reference dose for the U.S. population and 0.51% for non-nursing infants.

The dietary carcinogenic risk for the overall U.S. population calculated by multiplying the ARC exposure analysis for both the corn and cotton use, by the Q* for bifenthrin, and based on 70-year exposure, was determined to be approximately 1.3×10^{-6} .

The actual increase in dietary risk from the proposed treatment of 2,000 acres of seed corn is expected to be insignificant when compared to the dietary risk from the registered use on cotton and treatment of 416,000 acres of field corn under Texas's crisis declaration.

4. The cancer risks to applicators from the use of bifenthrin on corn based on 5 days of exposure per year for two years of exposure and 55.4% dermal absorption were estimated to be approximately 1×10^{-8} to 1×10^{-7} .

5. This use of bifenthrin is not expected to pose a direct or dietary hazard to avian or mammalian wildlife.

The proposed buffer zones and other use restrictions in the authorizing telegram should be sufficient to protect aquatic organisms. The proposed treatment of 2,000 acres of seed corn represents an insignificant increase in the risk to non-target aquatic organisms when compared to the risk from the use of bifenthrin and other synthetic pyrethroids on 100,000 acres of cotton being grown in Hidalgo county.

Approve: _____

Dusan H. Woyten

Disapprove: _____

Date: _____

10/2/90