MEMORANDUM

SUBJECT: Section 18 - Specific Exemptions for Use of Bifenthrin (Capture) to Control Various Mites on Field Corn in Nebraska and Kansas -- ACTION MEMORANDUM

FROM: Anne E. Lindsay, Director Registration Division

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

APPLICANTS' REQUESTS

Applicants: Nebraska Department of Agriculture. Kansas State Plant Board.

Chemical: Bifenthrin, (2-methyl[1,1'-biphenyl]-3-yl) methyl3-(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: Field corn.

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

Rate: At 0.08 lb. a.i. (5.12 ozs. of product).

Appl.: Two by air (in a maximum of 2 gallons diluent) with a PHI of 30 days.

Acreage: 256,361 acres in 74 counties in Nebraska. 120,000 acres in 43 counties in Kansas.

Poundage: Maximum of 41,081 lbs. a.i. (20,509 gallons of product) in Nebraska.

Maximum of 11,200 lbs. a.i. (5,600 gallons of product) in Kansas.
Use Period: Treatments will be required during the period July 15 to September 15, 1990.

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

According to the Applicants, 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 Applicants indicate 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 Applicants state 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 Applicants, the use of bifenthrin instead of the currently labeled miticides, could prevent an expected yield loss of 15 bu. per acre in Kansas and 20 bu. per acre in Nebraska that would result from use of the registered miticides as a rescue treatment. Kansas anticipates an average production of 148 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 133 bu./acre. At an estimated price for corn of $2.40 per bushel, the 148 bu/acre yield would produce a gross income of $355 per acre and the 133 bu/acre yield from the use of the registered miticides would produce gross revenues of $319/acre. Kansas gives the following production costs per acre for corn: Cash costs $257 to $297, Total costs $319 to $370.

Nebraska estimates with the use of bifenthrin that corn farmers will have gross revenues of $338/acre (130 bu/acre x $2.60 from Table 4 of application) and $286/acre (110 bu/acre x $2.60, Table 4) if the registered miticides are utilized. Nebraska lists in Table 4 of the application cash costs of $162.51 to $177.51.

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 Applicants state 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 methidathion (Supracide) have been requested by and granted to the states of Colorado and Kansas for the past five years and to Nebraska in four of the last five years. In 1986, use of methidathion was allowed in Texas as a possible alternative for Azodrin. In 1989, Kansas requested exemptions for either Supracide or Capture. Colorado and Nebraska requested use of bifenthrin (Capture). Supracide was offered as an alternative but Colorado and Nebraska rejected that use and requested resubmission of their requests for use of Capture. Nebraska, Kansas, Texas, Oklahoma, Colorado and New Mexico were granted the use of bifenthrin in 1989. Applications from Texas and New Mexico for the use of bifenthrin are currently in BEAD review.

On July 17, 1990, the Kansas State Plant Board declared a crisis for the use of bifenthrin on 120,000 acres of field corn. Prior to declaring a crisis, Kansas was aware that the Economic Analysis Branch was unable to conclude from the information provided in their application that corn farmers in Kansas would suffer a significant economic loss if bifenthrin was not available.

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

Biological and Economic Analysis Division (BEAD) reviewed the proposed use of bifenthrin in Nebraska and Kansas. The results of this review 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 in Kansas and Nebraska and in the neighboring states as well. 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 (Cyon) 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 in Nebraska and Kansas continues to be hot, dry and windy.

Economics:

BEAD reviewed the economic information submitted in Nebraska's and Kansas's applications and relevant USDA production and value data for field corn.

Analysis of USDA production data for 1987, 1988, 1989 indicate a slight decline in statewide field corn yields on a per acre basis for Kansas between 1985 and 1989. Statewide corn yields declined by nearly 4.0 percent from 130 bushels per acre in 1985 to 125 bushels per acre in 1989. In comparison, data furnished by the state of Kansas indicate corn yields in the specific impacted area of the state remained fairly constant between 1985 and 1989 averaging 148 bushels per acre.

Analysis of the same USDA data for Nebraska indicate statewide Nebraska field corn yields remained unchanged at 128 bushels per acre in 1985 and 1986, increased in 1987 to 131 bushels per acre, and then declined to 120 bushels per acre in 1989. In comparison, data furnished by Nebraska indicate corn yields in the specific impacted area paralleled the overall trend. In 1985, yields in the impacted areas were estimated at 127 bushels per acre. In 1988, yields were estimated to be 140 bushels per acre, declining to 130 bushels per acre in 1989.

Analysis of the total returns on a per acre basis for both Kansas and Nebraska during the five year period between 1985 and 1989 indicate that the total returns have been sufficient to cover cash costs on a per acre basis. While returns are expected to improve with the use of bifenthrin, analysis of the data provided by the Applicants suggests that net producer returns per acre will not be outside the 5-year average range for either state if bifenthrin is not available. In addition, net producer returns do not reflect the direct effects of governmental programs which would provide additional income to cover costs.

Residue chemistry review:

Dietary Exposure Branch reviewed the current 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.
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. 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.

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 $5.4 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$ 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 $1.3 \times 10^{-8}$.

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:
<table>
<thead>
<tr>
<th>Aerial Application</th>
<th>Lifetime risk</th>
<th>Risk per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixer/Loader</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open System</td>
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<td>$1 \times 10^{-5}$</td>
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<tr>
<td>Closed System</td>
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<td>$1 \times 10^{-7.5}$</td>
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</tr>
<tr>
<td>Flaggers</td>
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<td>$1 \times 10^{-7}$</td>
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**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 the recommended buffer zone may reduce the magnitude and propensity of non-target impacts, it cannot be expected to eliminate them.

Endangered species:

There are several endangered or threatened species that occur in the proposed treatment area in Kansas. In a letter dated May 1, 1990, the Fish and Wildlife Service concluded that the implementation of the following restrictions should result in no adverse effects to the piping plover, interior least tern, bald eagle, black-footed ferret, or other trust resources. The restrictions were as follows:

A one-mile buffer zone for aerial applications of Capture 2E in habitats of endangered species, including Quivira and Kirwin National Wildlife Refuges and Cheyenne Bottoms Wildlife management area.

No aerial applications within one-mile of the following habitats:

- The Cimarron River.
- Active bald or golden eagle nests.
- Prairie dog towns 80 acres or more in size.

No aerial applications within 500 feet of any lake, wetland, flowing river or stream. No aerial spraying when wind speed is 10 mph or greater.

The Endangered Species Specialist in Grand Island Nebraska was contacted by phone. The piping plover and interior least tern are two endangered or threatened species that occur in the proposed treatment area in Nebraska. The Fish and Wildlife Service concluded that the implementation of a one-mile buffer zone for aerial applications of Capture 2E in habitats of endangered species was adequate to protect endangered species.

Ecological Effects Branch deferred to the U.S. Fish and Wildlife Service opinion that the proposed buffer zones are sufficient to protect endangered species.

Based on their review, Ecological Effects Branch concluded that the proposed use of bifenthrin on corn in Nebraska and Kansas 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. Agricultural statistics indicate that Kansas grew 1,200 acres of upland cotton in 1987. Nebraska is not listed as a cotton growing state. The proposed treatment of 120,000 acres of corn in Kansas and 261,000 acres of corn in Nebraska represents a significant increase in the risk to non-target aquatic organisms.

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 requests for a specific exemption from the Nebraska Department of Agriculture and the Kansas State Board of Agriculture for use of bifenthrin (Capture) to control Banks grass mites and two-spotted spider mites on field corn be denied for the following reasons:

The problem with mites in corn remains unchanged from previous years when specific exemptions have been granted for the use of various miticides to control Banks grass mites and two-spotted spider mites on corn in Texas, Nebraska, Kansas, Colorado, New Mexico and Oklahoma. The miticides that are currently registered to control mites of field corn 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. Since the registered alternatives are not satisfactory for rescuing heavily infested corn fields, the question arises will yield losses from mites in corn fields where the registered alternatives have failed be sufficient to cause a significant economic loss as defined in the section 18 regulations. In the past, the Agency has concluded that a significant economic loss was likely to occur and has authorized specific exemptions for the use of various miticides. This year, BEAD has concluded that the economics of corn production this year are such that corn growers in Nebraska and Kansas will not suffer a significant economic loss if a miticide is not made available under the section 18 program to be used as a rescue treatment.
Last year, Nebraska and Kansas were informed in the 1989 authorizing telegrams for this use of bifenthrin on corn that the Agency was not inclined to authorize any future exemptions for this use unless the state could demonstrate that the magnitude of the emergency is such that it clearly outweighs potential risk. I am unable to conclude that the magnitude of the emergency outweighs the potential risk based on EEB's review that concluded the proposed use of bifenthrin on corn provides for a serious risk to non-target organisms and BEAD's conclusion that corn growers are not expected to have an emergency as outlined in the section 18 regulations.

In addition, I recommend applications of bifenthrin under Kansas' crisis exemption be stopped, and that the Kansas State Plant Board's right to declare a crisis for the use of bifenthrin on corn be revoked. According to Section 166.40, a crisis exemption may be issued in situations where an emergency condition exists. Since an emergency situation does not exist in this situation, a crisis declaration was not justified and therefore, Kansas has not complied with the provisions of Subpart C of the section 18 regulations.

Approve: 

Disapprove: 

Date: JUL 27 1990