AUG 20 1993

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18 - Specific Exemption Requests from California for the Use of Imidacloprid on Broccoli, Cauliflower, Cabbage, Head Lettuce, Leaf Lettuce, and Rapini, to Control the Sweet Potato Whitefly – ACTION MEMORANDUM – 93-CA-29, & -30

FROM: Lawrence E. Culleen, Acting Director
Registration Division

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

I. APPLICANT'S REQUEST

APPLICANT: California Environmental Protection Agency

CHEMICALS: Imidacloprid (unregistered chemical)

PRODUCTS: Admire®, Unregistered Product, Manufactured by Miles Inc.

SITES: Broccoli, Cauliflower, Cabbage, Lettuce (Head & Leaf), and Rapini

PEST: Sweet Potato Whitefly (*Bemesia tabaci*)

USE PATTERN: 2.5 - 5 dry oz. a.i. (10 - 20 fl. oz. product) per acre; 1 application per crop season (2 crop seasons possible per calendar year); no more than a total of 32 fl. oz. product to be applied per calendar year; applications to be made by one of the following 3 methods: 1) by banding before planting, 2) by in-furrow spray, or banding, at planting, or 3) by drenching after planting; not to be applied to soil within 21 days of harvest.

ACREAGE:	Broccoli, Cauliflower, Cabbage, & Rapini:	22,000 acres
	Lettuce:	40,000 acres
	Total:	62,000 acres

USE SEASON: Present - December 31, 1993

EMERGENCY and ALTERNATIVE CONTROLS: A new strain of sweet potato whitefly (SPWF), referred to as the poinsettia, or B strain, was originally found in greenhouses in 1986, where they occurred in large numbers and were found to be resistant to chemical control. By early spring 1991, SPWF was found on a large number of crops in the Yuma and Imperial Valleys. Since then, the SPWF has steadily spread to new host plants and grown in population size each successive summer and fall, causing severe economic damage to various commodities nationwide. The presence of SPWF on cole crops in California had never been experienced before this. The Applicant states that the Imperial Valley has a much more severe SPWF problem than other areas, thought to be due to the cropping systems, which provide host plants year-round. The SPWF causes damage by piercing and sucking nutrients from the foliage, and indirect damage as a vector of virus. Moreover, it causes quality reduction on crops because of honeydew exudations and subsequent sooty mold growths on the honeydew. When early crops of seedling vegetables emerge from the soil, they are immediately hit by large numbers of adult SPWF. While SPWF feeding does not kill the plants, it essentially stops further development. This damaging behavior continues until well into the fall when lower temperatures and rainfall combine to reduce the SPWF populations.

The Applicant claims that, of the available alternatives, only endosulfan, methamidophos (not available on head lettuce), and acephate (not available on broccoli) can reduce SPWF populations, but do not provide adequate control when the SPWF becomes more numerous.

Cultural practices such as crop rotations and timing of planting and harvesting have become of limited value, as it is important to plant early vegetables since these are the crops that have the greatest profit associated with them. Additionally, as the SPWF continues to expand its range of hosts, the value of cultural controls becomes further compromised.

In California, the Imperial County Whitefly Management Committee has a proposed plan to help control the SPWF. Aspects of the plan include sanitation (i.e., plowing under crops immediately after harvest), crop rotation, host reduction exclusion, repellents, host plant resistance, and studying the biology and migration of the SPWF. The plan also involves the introduction and management of biological control agents. There are currently efforts underway in search of new predators and parasites to control the SPWF, and researchers are also investigating reports of naturally-occurring fungi that

are thought to affect the SPWF in Florida.

The Applicant has requested the use of two different chemicals on these crops. A request for use of bifenthrin which was submitted earlier, is currently pending the Office Director 's signature. Registration Division is recommending that the request be granted. The rationale for requesting use of two chemicals involves the timing during the crop cycle that each of the chemicals can be effectively used. Imidacloprid would be applied only once, at or near planting of the crop. Imidacloprid is a systemic, and would be taken up by the germinating seedling, providing protection for the seedling as it emerges through the soil, during this vulnerable stage of development. Bifenthrin would not be appropriate at this stage, because it is not a systemic, and is used as a foliar spray. At the seedling stage, there is limited leaf area, and foliar sprays at this time would serve no useful purpose. However, the single soil application of imidacloprid will not adequately protect the crop throughout the full season, and imidacloprid cannot be applied also as a foliar spray, later in the season, because the Registrant will not support such use under §18. Since the SPWF is thought to develop resistance to pesticides rather quickly, the Registrant does not want imidacloprid to be used more than once per crop season, in order to forestall resistance development. Therefore, the Applicant has requested use of bifenthrin as a foliar spray, to protect the plants later in the crop season. The Applicant states that bifenthrin provides greater control of the SPWF than the registered alternatives.

ECONOMICS: The Applicant estimates that if only the registered materials are used, SPWF could reduce yields of these crops by up to 75%. It is difficult to estimate what effect this would have on net revenue, as a reduction such as this would likely result in higher market prices. In 1991, SPWF slowed the growth of the early planted broccoli, cauliflower, and lettuce, which resulted in the early and late plantings being harvested together. As a result, the market price dropped, and the net profit was reduced.

II. BACKGROUND

This is the first time that California has requested the use of imidacloprid on these crops under §18. Arizona also requested, and was recently issued (8/5/93) §18 use of imidacloprid for these uses. California also has a request pending for use of bifenthrin (second year for bifenthrin request), to be used as a foliar spray later in the season, on these crops for SPWF control. The decision package for that request was forwarded for the Office Director 's signature on 8/16/93.

PROGRESS TOWARD REGISTRATION: The Registrant, Miles, Inc., has submitted a §3 application to the Agency for use on cotton, which is currently pending. Tolerance petitions (PP#s 3F4169 and 3H5655), for cotton, apple, and potato RACs and processed commodities are currently pending at the Agency, undergoing science review. The Registrant has completed residue testing, and expects to submit tolerance petitions

for cole crops, and head and leaf lettuce, in the near future.

Section 18 Delaney Policy: Imidacloprid is classified as a Group E carcinogen (evidence of non-carcinogenicity for humans), and thus the Delaney clause would not preclude registration of these uses.

RE-REGISTRATION and SPECIAL REVIEW CONSIDERATIONS: Imidacloprid is currently unregistered, so there are no re-registration or special review concerns.

FEDERAL REGISTER NOTICE: Since the use of an unregistered chemical is proposed, publication in the Federal Register of a notice of receipt and solicitation for public comment is required by 40 CFR 166.24. If the Agency issues this exemption, it must be granted within the next 10 days, in order for the materials to be applied at the correct time. Therefore, as allowed by 40 CFR 166.24(c), I recommend that the comment period in this case be eliminated, because the time available to make a decision requires it. It should be noted that notices of receipt were published for the request for these uses from Arizona (7/28/93), and for Arizona 's request for use on cotton (6/10/93), and no comments for either have been received.

III. EPA EVALUATION

BIOLOGICAL and ECONOMIC ANALYSIS: OPP 's Biological and Economic Analysis Division reviewed the requests for these uses from Arizona, and concluded that the situation described in Arizona appears urgent and non-routine, since this new biotype of SPWF is recently-occurring, and it has been demonstrated that this pest can cause extreme yield and quality losses. BEAD also stated that information submitted by Arizona, and the extreme damage observed in Arizona and California in 1991, support the conclusion that no registered alternative will adequately control the SPWF.

BEAD stated that information given with the request demonstrates that bifenthrin, imidacloprid, endosulfan, and acephate are the only insecticides which provided any control of the SPWF, with bifenthrin and imidacloprid being the most effective. When imidacloprid is applied at planting to provide systemic protection, this single application may provide protection for up to 30 - 40 days during the most susceptible stage of growth. Additionally, such an application may prevent early establishment of SPWF populations. However, BEAD states that this at-planting application of imidacloprid may not eliminate the need for foliar applications beyond the 30-40 days, and thus the additional use of bifenthrin would be justified.

Economically, fresh vegetable production in Arizona is very different from many other crops, and Arizona vegetable growers compete in a very volatile and competitive market. According to the Applicant, growers strive for profitable operation in at least one out of every 5 - 7 growing seasons. Given the variability this involves, it is difficult to estimate the likelihood of Arizona growers suffering a significant economic loss; even

a substantial yield loss may not cause growers to fall outside of the historical range. Additionally, this variability makes it difficult to draw any definite conclusions regarding the long-term economic viability of the Arizona vegetable growers. However, BEAD concluded that, considering the damaging potential of the new strain of the SPWF, it is very likely that Arizona vegetable growers could suffer an economic emergency without the use of imidacloprid and bifenthrin.

Because of time constraints, BEAD was not requested to formally review these requests from California. However, BEAD did a cursory examination of the information submitted with the requests, and concluded that the situation in California is essentially the same as that in Arizona. Thus, the conclusions, as outlined above, would be the same for this request for California.

BEAD pointed out that in the Arizona review, it was noted that it was difficult to evaluate the situation economically, since the market for these vegetable crops is extremely variable, and dependent upon various factors such as grading and seasonal pricing. This is true of the situation in California as well. BEAD recommended that, if these uses are requested under §18 in the future, the following information be required in order to adequately evaluate the economics:

- Yield and quality loss estimates without the use of imidacloprid, bifenthrin, or both.

- Seasonal price information by grade to reflect the importance of the harvest dates on annual net revenue.

Requirement for such information is included in the attached correspondence to the state, and will also be required of Arizona, should they request these uses under §18 again.

RESIDUE CHEMISTRY: OPP 's Tolerance Support Chemistry Branch (TSCB) reviewed the proposed use pattern in connection with the request from Arizona, and concluded that the nature of the residue of imidacloprid in/ on tomatoes, eggplants, apples, potato, and corn grain, forage, and silage is adequately understood. TSCB concluded that these data may be translated to these vegetable crops *for the purposes of this §18 use only*, since there are no imidacloprid metabolism studies available for the vegetable crops in question. TSCB estimates that residues of imidacloprid, expressed as the parent compound and its metabolites that contain the 6-chloropyridinyl moiety are not likely to exceed the following levels as a result of the proposed use:

broccoli ..... 1.0 ppm
cauliflower ..... 0.5 ppm
cabbage ..... 2.5 ppm
head lettuce ..... 2.5 ppm
leaf lettuce ..... 2.5 ppm
rapini ..... 2.5 ppm
*milk ..... 0.05 ppm
*meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep ... 0.2 ppm

* Secondary residue estimates are given in association with feeding of products associated with cauliflower and broccoli. There are no animal feed commodities associated with cabbage, head lettuce, or leaf lettuce. There are no poultry feed items associated with any of these vegetables, and therefore secondary residues are not expected to occur in eggs and poultry tissues as a result of the proposed use.

Adequate analytical methods for enforcement purposes are tentatively available (pending validation) from TSCB (Bayer methods 0200 and 00191 [MRID #s 425561-18 and 425561-19]). Analytical reference standards are available only from the Registrant of imidacloprid, Miles, Inc.

**** Note: Craven Laboratories was not involved in generating any of the data used to derive the above imidacloprid reside estimates.**

TOXICOLOGY and EXPOSURE ASSESSMENT: OPP 's Toxicology Branch I (TB-I) reviewed these uses in connection with the Arizona requests, and concluded that the toxicology database is adequate to support this §18 use. There are currently no tolerances established for imidacloprid, as it is an unregistered chemical. The Agency-approved (Peer Review 4/22/93) reference dose (RfD) is set at 0.057 mg/kg/day, based on the NOEL of 5.7 mg/kg/day from a 2-year rat study, and an uncertainty factor of 100.

The margins of exposure (MOEs) for acute exposure to workers, under all scenarios and assuming 100% dermal penetration (which is unlikely to occur), were all acceptable (>100).

Imidacloprid is classified as a Group E carcinogen (evidence of non-carcinogenicity in humans), so there is no cancer risk associated with exposure.

Assuming 100% crop treated, and enforcement level residues in all commodities, dietary exposure is estimated as follows:

POPULATION SUBGROUP	TMRC mg/kg/day	%RfD
Overall U.S. Population	0.001830	3.2
Non-nursing Infants	0.003776	6.6
Children (1-6 yrs.)	0.003132	5.5

All dietary exposure estimate levels are well below levels of concern.

ECOLOGICAL EFFECTS: OPP 's Ecological Effects Branch (EEB) reviewed these uses in connection with the request from Arizona, and stated that imidacloprid is considered moderately toxic to mammals, and slightly - highly toxic to birds, on an acute basis. EEB concluded that the expected environmental residues from the proposed use are not at a level that would be of concern for mammal dietary exposure. However, based on available information, regulatory Levels of Concern (LOCs) are exceeded for songbirds (representative sp., House Sparrow), on an acute basis, for the banded application method only. EEB states that if banding is dropped from the label (and application is limited to in-furrow or drenching), this risk will drop below the level of concern. This was required in the granting of these uses in Arizona. ERMUS staff have consulted with CA-EPA personnel, and they will revise their labeling to eliminate the banding method of application. This restriction is incorporated into the attached correspondence to the state. Reproductive effects are in question regarding waterfowl (representative sp., Mallard Duck); EEB states that further information, requested from the Registrant, will be necessary before this risk can be determined. Imidacloprid is considered to be very highly toxic to bees, both acutely and residually. The label statement regarding risk to bees (included in the proposed labeling) should be strongly adhered to, to mitigate this risk.

Imidacloprid is considered practically non-toxic to freshwater and estuarine fish species; slightly - very highly toxic to freshwater invertebrates; and very highly toxic to estuarine invertebrates. Based upon available data, EEB states that the LOCs are exceeded chronically for estuarine aquatic invertebrates (Mysid spp.); this is not of concern for this proposed use, since the proposed counties of use (Riverside and Imperial) are located inland, away from estuarine or marine habitat.

Endangered or threatened species are not expected to be directly affected by these uses, although the adverse effects to aquatic invertebrates may indirectly affect endangered fish and waterfowl that feed on these organisms.

ENVIRONMENTAL FATE: OPP 's Environmental Fate and Groundwater Branch (EFGB) reviewed these uses in connection with the requests from Arizona, and concluded that the imidacloprid database is sufficient to support these uses under §18. EFGB did note, however, that there is concern for imidacloprid 's potential to leach to ground water and/or be transported to surface waters, and stressed that care should be taken to protect waters during use, particularly in vulnerable areas. EFGB recommended that the following statement be included in the §18 labeling:

> This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

IV. RECOMMENDATION

I recommend that the requests from California for the use of imidacloprid on broccoli, cauliflower, cabbage, head lettuce, leaf lettuce, and rapini be granted. This recommendation is based upon the following:

1. BEAD has concluded that growers are facing a non-routine situation, and the registered alternatives do not provide adequate control of the SPWF. BEAD has also concluded that the use of two chemicals is justified, since the one application of imidacloprid at planting will not protect the crop throughout the season, and application of bifenthrin as a foliar spray would be of no use at the seedling stage when there is limited leaf area. BEAD concluded that, considering the damaging potential of the new strain of the SPWF, it is very likely that vegetable growers could suffer an economic emergency without the use of imidacloprid and bifenthrin.

2. The toxicological database for imidacloprid is adequate to support these uses. These uses are not expected to result in unacceptable risk to human health, and dietary contribution estimates for all population subgroups are well within acceptable limits. The uses proposed are not expected to result in unacceptable risk through occupational exposure.

3. Residues of imidacloprid, expressed as the parent compound and its metabolites that contain the 6-chloropyridinyl moiety are not likely to exceed the following levels as a result of the proposed use:

broccoli	1.0 ppm
cauliflower	0.5 ppm
cabbage	2.5 ppm
head lettuce	2.5 ppm
leaf lettuce	2.5 ppm
rapini	2.5 ppm
*milk	0.05 ppm
*meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep	0.2 ppm

* Secondary residue estimates are given in association with feeding of products associated with cauliflower and broccoli. There are no animal feed commodities associated with cabbage, head lettuce, or leaf lettuce. There are no poultry feed items associated with any of these vegetables, and therefore secondary residues are not expected to occur in eggs and poultry tissues as a result of the proposed use.

4. Levels of concern for songbirds are exceeded on an acute basis from the proposed use. However, elimination of application by banding will reduce this risk below levels of concern, and the Applicant has agreed to so-limit these uses. Endangered or threatened species are not expected to be directly impacted from either use.

5. There is progress toward registration of these uses. This is the first time for a request for these uses of imidacloprid in California. The Registrant, Miles, Inc., has completed residue testing, and expects to submit tolerance petitions for cole crops, and head and leaf lettuce, in the near future.

These uses are not affected by the Section 18 Delaney Policy.

Approve: _____

Disapprove: _____

Date: AUG 20 1993