UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 6/11/99

SUBJECT: PP#6E04629, PP# 6E04760, PP# 8E05009, PP# 8E04993, PP# 8E05064, PP# 8F5014, PP# 9E5069, PP# 9E5084. **FQPA Human Health Risk Assessment for Bifenthrin** - Proposal for Tolerances of Residues in/on Globe Artichoke, Cucurbits, Eggplants, Legume Vegetables, Peas and Beans, Sweet Corn, Head and Stem Brassica Vegetables, and Canola.

DP Barcode:	D255756	PRAT Case:	none
Submission No.:	509111	Caswell No.:	463E
Chemical No.:	128825	Class:	Insecticide
Trade Name:	Brigade® WSB	EPA Reg No.:	279-3108
	Capture® 2EC		279-3069
40 CFR:	§180.442		

TO: G. LaRocca /PM Team 13
IRB/RD (7505C)

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1.0 EXECUTIVE SUMMARY

General Background:

PP# 6E04629 Interregional Research Project No. 4 (IR-4), State Agricultural Experiment Station, Rutgers University, New Brunswick, NJ on behalf of the IR-4 Project and the Agricultural Experiment Station of California requests the establishment of a tolerance for residues resulting from the use of the insecticide/miticide bifenthrin (2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate), in or on **globe artichoke at 1.0 ppm**.

PP# 6E04760 IR-4, on behalf of the Agriculture Experimental Stations of Arkansas, Florida, Illinois, Mississippi, North Carolina, Oklahoma, and Puerto Rico, has proposed permanent tolerances for residues of the insecticide bifenthrin in or on **cucurbits vegetables at 0.4 ppm**.

PP# 8E05009 IR-4, on behalf of the Agriculture Experimental Stations of Oklahoma, South Carolina, and Wisconsin, has proposed permanent tolerances for residues of the insecticide bifenthrin in or on **eggplant at 0.05 ppm**.

PP# 8E04993 IR-4, on behalf of the Agricultural Experiment Stations of Illinois, Minnesota, Mississippi, Tennessee, and Wisconsin, requests the establishment of a tolerance for residues of the insecticide/miticide bifenthrin *per se* in or on the raw agricultural commodities in Crop Subgroup 6-A (40 CFR 180.41), edible-podded **legume vegetables, at 0.5 ppm.**

PP# 8E05064 IR-4, on behalf of the Agricultural Experiment Stations of Delaware, Georgia, Illinois, Minnesota, Mississippi, Oregon, Washington, and Wisconsin, requests the establishment of a tolerance for residues of bifenthrin *per se* in or on the raw agricultural commodities in Crop Subgroup 6-B (40 CFR 180.41), **succulent shelled peas and beans, at 0.05 ppm.**

PP# 8F5014 FMC Corporation, has proposed a tolerance for residues of the insecticide bifenthrin on the raw agricultural commodity (RAC) **sweet corn at 0.05 ppm** and to increase the tolerance on **corn forage to 3.0 ppm.**

PP# 9E5069 IR-4, on behalf of the Agriculture Experimental Stations of Arizona, Arkansas, California, Florida, Georgia, and Mississippi has proposed a tolerance on **cabbage at 4.0 ppm,** and **head and stem brassica vegetables except cabbage at 0.6 ppm.**

PP# 9E5084 IR-4, on behalf of the Agriculture Experimental Stations of Idaho and Washington, has also proposed a tolerance on **rapeseed at 0.05 ppm.**

Bifenthrin is a non- systemic insecticide/miticide in the class of synthetic pyrethroids. It is registered for uses on a variety of crops for the control of various insect pests. It is also registered for residential use on outdoor lawn/ gardens, inside households, pets and as a termiticide.

HED has evaluated the toxicological, product/residue chemistry and exposure databases for bifenthrin. On 7/17/97 and 7/24/97, the HED HIARC Committee met to determine appropriate toxicological endpoints for risk assessment purposes and to evaluate the Food Quality Protection Act (FQPA) aspects of ten pyrethroid chemicals including bifenthrin. For detailed information, see memo of 11/14/97, P. Hurley, *et. al.*, *Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids*, D238737.

FQPA safety factor **The FQPA Safety Factor for enhanced sensitivity of infants and children was reduced to 1x** (Ad hoc HED FQPA Safety Factor Committee. Memo of 11/16/98, P. Hurley, *et. al.*, D248723).

Acute Dietary Exposure **Acute RfD: 0.01 mg/kg/day.** This acute RfD (RfD = NOAEL ÷ UF) is based on a developmental toxicity study in the rat with a maternal NOAEL of 1.0 mg/kg bwt/day and an uncertainty factor (UF) of 100. The FQPA Safety Factor for enhanced sensitivity of infants and children was reduced to 1x. The acute population adjusted dose (**aPAD**) is determined by dividing the acute RFD by the FQPA factor: **aPAD** = 0.01 / 1 = **0.01 mg/kg /day**. Since the HED FQPA Safety Factor Committee determined to remove the 10X safety factor, the acute RfD is identical to the aPAD. This aPAD applies to all population subgroups.

Chronic Dietary Exposure **Chronic RfD: 0.015 mg/kg/day.** This chronic RfD (RfD = NOAEL ÷ UF) is based on a 1-year oral feeding study in dogs with a NOAEL of 1.5 mg/kg/day and an uncertainty factor (UF) of 100. The FQPA Safety Factor for enhanced sensitivity of infants and children was reduced to 1x. The chronic population adjusted dose (cPAD) is determined by dividing the chronic RfD by the FQPA factor: **cPAD** = 0.015 / 1 = **0.015 mg/kg/day**. Since the HED FQPA Safety Factor Committee determined to remove the 10X safety factor, the chronic RfD is identical to the cPAD. This cPAD applies to all population subgroups.

Short- and Intermediate- Term Occupational and Residential Dermal Exposure For the **short- and intermediate- term dermal endpoints**, the HED HIARC Committee selected the maternal NOAEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats (same study as for acute dietary exposure). The dermal absorption rate is 25% and a **MOE of 100**, which includes FQPA considerations, was recommended.

Chronic Occupational and Residential Dermal Exposure For the **chronic dermal endpoint**, the HED HIARC Committee recommended using the NOAEL of 1.5 mg/kg/day based on a 1-year oral study in dogs (same study as for chronic dietary exposure). The dermal absorption rate is 25% and a **MOE of 100**, which includes FQPA considerations, was recommended.

All Time Periods Occupational and Residential Inhalation Exposure. No appropriate inhalation studies are available. The HED HIARC Committee recommended using the maternal NOAEL of 1.0 mg/kg/day from the oral development toxicity study in rats. This risk assessment should be

inclusive of dietary and inhalation exposure components. For inhalation exposure,100% absorption should be assumed.

Cancer

Bifenthrin has been classified as a Group C Carcinogen (HED Carcinogenicity Peer Review Committee, 4/29/92). A cancer risk assessment using the RfD approach is required.

Risk Assessment Conclusions:

Acute Aggregate Risk (Food + Water)

Acute aggregate risk estimates do not exceed HED's level of concern. The acute dietary risk (food only) estimates used a probabilistic (Monte Carlo) analysis. This analysis is highly refined in that it used percent crop treated for registered uses and anticipated residues for all uses. It is estimated that the acute exposure to bifenthrin from food for the most highly exposed population subgroup (Children 1-6 years) will utilize **96%** of the **aPAD** (99.9th percentile). An acute dietary exposure (food plus water) of 100 % or less of the **aPAD** is needed to protect the safety of all population subgroups. EFED supplied surface and ground water modeling estimate for acute exposure (0.1 µg/L), this estimate does not exceed our calculated Drinking Water Level Of Comparison (DWLOC) for any subpopulation. Therefore, HED does not expect the acute aggregate exposure estimates to exceed our level of concern.

Chronic Aggregate Risk (Food + Water + Residential)

Chronic aggregate risk estimates do not exceed HED's level of concern. The Dietary Exposure Evaluation Model (DEEM) chronic dietary risk estimates (food only) are based upon anticipated residues for most of the commodities, although 100 % crop treated was used for all crops but hops and cottonseed. The chronic exposure to bifenthrin from food for the most highly exposed population subgroup (Children 1-6 year) will utilize **6.7%** of the **cPAD**. A chronic dietary exposure (food plus water) of 100% or less of the cPAD is needed to protect the safety of all population subgroups. EFED supplied surface and ground water modeling estimate for chronic exposure (0.032 µg/L), and this estimate does not exceed our calculated DWLOCs for any subpopulation. Although the registered termiticide use of bifenthrin constitute a chronic exposure scenario, the exposure from this termiticide use is negligible considering the application technique of the termiticide use (buried underground) and the fact that vapor pressure of bifenthrin is extremely low (1.8×10^{-7} torr). Therefore, HED does not expect the chronic aggregate exposure estimates to exceed our level of concern. HED concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to bifenthrin residues.

Short- and Intermediate- Term Aggregate risk (Residential + Chronic Food + Chronic Water)

Bifenthrin's registered residential uses constitute short- and intermediate- term exposure scenarios; MOEs of 100 have been selected for short- and intermediate-term dermal and inhalation exposures. The routes of exposure from these registered residential uses include dermal and inhalation for adults, and dermal, inhalation, and oral (nondietary) for infants and children. The calculated MOEs for dermal, inhalation, and oral (nondietary) are all greater than 100 for adult, infant, and children. EFED's chronic water estimate (0.032 µg/L) is well below our DWLOCs for any population. HED concludes that there is a reasonable certainty that no harm will result to adults, infants and children from short- and intermediate- term aggregate exposure to bifenthrin.

Cancer

As the HED Carcinogenicity Peer Review Committee recommended the RfD approach (4/29/92), a quantitative (q*) dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of bifenthrin are adequately addressed by the DEEM chronic exposure analysis using the chronic RfD. For the U.S. population, only **2.4%** of the **cPAD** (RfD) is occupied by chronic food exposure. Based on a comparison of the calculated DWLOCs and the estimated exposure to bifenthrin in drinking water (0.032 µg/L), HED does not expect the chronic aggregate exposure to exceed 100% of the chronic RfD (cPAD) for adults. Thus, HED concludes with reasonable certainty that the carcinogenic risk is within acceptable limits.

Occupational Exposure

There are potential exposures to bifenthrin during mixing, loading, and application activities. The MOEs for these activities do not exceed HED's level of concern. A risk assessment for post-application exposure was conducted. The MOEs calculated using Tier 1 are all below 100 on the day of application, which exceeded HED's level of concern. Further refinement of the calculation for MOEs can be reached using chemical specific dislodgeable foliage residue data, and these data are currently under review by HED's contractor. In the meantime, to bring the MOEs up above100, HED recommends that restricted entry intervals (REI's) of 5 days for artichoke and head & stem brassica, 9 days for eggplants, cucurbits, peas & beans, and 18 days for sweet corn be placed on the label.

As a result of the longer REI needed to address post-application risks to workers there are crops for which the preharvest interval (PHI) now is less than the REI. Since these crops are primarily hand harvested, the PHI can not in most cases be less than the REI. Therefore, although the tolerances and proposed PHI's are appropriate based on the available residue data, HED recommends that the label be revised for the crops eggplant, cucurbits, beans/peas, and sweet corn to emphasize that in those cases where hand-harvesting occurs the PHI needs to be as long as the REI (i.e., 9 days for eggplant, cucurbits, and beans/peas; 18 days for sweet corn). In the meantime, HED will continue to assess the available foliar dislodgeable residue data on strawberries to determine if shorter REI's can be set with MOE's that do not exceed our level of concern.

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Recommendations:

HED concludes that there is a reasonable certainty that no harm will result to the U.S. Population including infants and children from acute, short- and intermediate- term and chronic aggregate exposure to bifenthrin residues. Pending on the submissions of the following:

- Revise Section F of PP# 8E04993 to increase the proposed tolerance on edible-podded legume vegetables (Crop Subgroup 6-A) to 0.6 ppm.

- Revised Section B clarifying the intended use pattern for head and stem Brassica vegetables (PP#9E5069).

- Revised Section F listing canola not rapeseed (PP#9E5084).

HED has no objection to the establishment of permanent tolerances for the residues of bifenthrin, expressed as parent, in or on **the following RACs:**

Petition #	Crop Group or Crop:	Recommended Tolerance Level: (ppm)
PP#6E04629	globe artichoke	1.0
PP# 6E04760	cucurbits	0.4
PP# 8E05009	eggplant	0.05
PP# 8E04993	edible-podded legume vegetables	0.6
PP# 9E05064	succulent shelled peas and beans	0.05
PP#8F5014	sweet corn	0.05
	corn forage	3.0
PP#9E5069	head and stem brassica (5A) except cabbage	0.6
	cabbage	4.0
PP#9E5084	canola	0.05

Data Needs:

Data required for petition PP# 8F5014:

a. 21-Day dermal toxicity study **in rats** (Guideline 82-2)
b. Acute neurotoxicity study in rats (Guideline 81-8)

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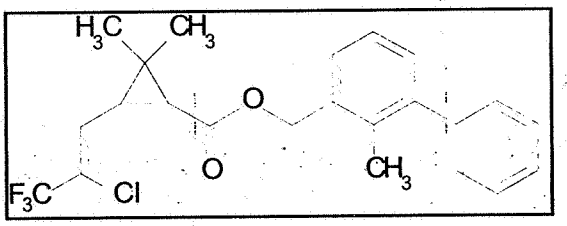
c. Subchronic neurotoxicity study in rats (Guideline 82-5)

Since corn is a major food crop (and will also result in increased bifenthrin residues in milk), the above studies are required to be performed and submitted to support PP#8F5014 (FMC Corporation petition for a tolerance on sweet corn and to increase the tolerance on corn forage). Since these are confirmatory toxicology studies, they need not be submitted prior to establishment of the requested tolerances, but should be submitted within a reasonable period of time.

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

The chemical structure of bifenthrin is as follows:



Product chemistry for bifenthrin has been previously reviewed by HED. It was concluded that the data were satisfactory to support a Section 3 registration. (Memo of 1/10/91, N. Dodd, 6F3454).

3.0 HAZARD CHARACTERIZATION

3.1 Hazard profile

A detailed discussion on the hazard assessment for bifenthrin can be found in Attachment 6 of HED memo of 11/14/97, P. Hurley, *et. al., Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids*, D238737.

3.2 FQPA Consideration

HED Ad hoc FQPA Safety Factor Committee determined that the FQPA safety factor for enhanced sensitivity of infants and children should be reduced to 1X for bifenthrin (see HED memo of 11/16/98, P. Hurley, *et. al.*, D248723).

3.3 Dose Response Assessment

Detailed information on the dose response assessment for bifenthrin is contained in the HED memo of 11/14/97, P. Hurley, *et. al., Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids*, D238737.

Table 1 summarizes the regulatory endpoints selected by the HED HIARC Committee for various exposure scenarios.

Table 1. Summary of Toxicological Endpoints for Bifenthrin [1]

Exposure Scenario	Route of Exposure and Dose for Risk Assessment	Endpoint for Risk Assessment	Study and Toxicological Effect
Acute Dietary (All populations)	Oral NOAEL =1.0 mg/kg/day UF=100 **Acute RfD**: 0.01 mg/kg/day.	Acute Population Adjusted Dose (aPAD) **aPAD** =acute RfD = **0.01 mg/kg/day**	Developmental Toxicity, Rats - tremors in dams during & post dosing
Chronic Dietary (All populations)	Oral Dietary Exposure NOAEL=1.5 mg/kg/day UF = 100 **Chronic RfD**: 0.015 mg/kg/day	Chronic Population Adjusted Dose (cPAD) **cPAD** = chronic RfD = **0.015 mg/kg/day**	Chronic Oral, Dogs - tremors in both sexes
Short Term Dermal (1-7 days) (Occupational/Residential)	Dermal Exposure Oral NOAEL =1.0 mg/kg/day (Use dermal absorption rate = 25%)	**MOE = 100**	Developmental Toxicity, Rats - tremors in dams during & post dosing
Intermediate-Term Dermal (one week to several months) (Occupational/Residential)	Dermal Exposure Oral NOAEL =1.0 mg/kg/day (Use dermal absorption rate=25%)	**MOE = 100**	Developmental Toxicity, Rats - tremors in dams during & post dosing
Chronic Dermal (several month to lifetime) (Occupational/Residential)	Dermal Exposure Oral NOAEL =1.5 mg/kg/day (Use dermal absorption rate=25%)	**MOE=100**	Chronic Oral, Dogs - tremors in both sexes
All time periods: inhalation (Occupational/Residential)	Inhalation Exposure Oral NOAEL = 1.0 mg/kg/day (Use inhalation absorption rate=100%)	**MOE=100** Risk assessment should be inclusive of dietary & inhalation exposure components	Developmental Toxicity, Rats - tremors in dams during & post dosing (No appropriate inhalation studies available.)
Cancer	Dietary/Dermal/Inhalation Exposure Group C Carcinogen	use RfD approach.	Carcinogenicity, Mice - Urinary bladder tumors in male mice

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[1] HED memo of 11/14/97, P Hurley, *et. al., Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids*, D238737.

4.0 EXPOSURE ASSESSMENT

Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin in or on a variety of plant raw agricultural commodities at levels ranging from 0.5 ppm in cottonseed to 10.0 ppm in dried hops, and various animal commodities ranging from 0.05 ppm in eggs to 1.0 ppm in cattle fat.

4.1 Summary of Registered Uses

Bifenthrin is a non- systemic insecticide/miticide in the class of synthetic pyrethroids. It is registered for uses on a variety of crops for the control of various insect pests. It is also registered for residential use on outdoor lawn/ gardens, inside households, pets and as a termiticide.

Brigade® WSB, (EPA Reg. No. 279-3108), has been proposed for use on globe artichoke. This product contains 10% by weight of the active ingredient (ai) bifenthrin. The product is formulated as a wettable powder in translucent water soluble bags.

Capture® 2EC (EPA Reg. No. 279-3069) is an emulsifiable concentrate which contains 25.1% active ingredient bifenthrin (2 lbs a.i. per gallon) and proposed for use on the remaining crops in these petitions. Capture® 2 EC is a Restricted Use pesticide (application limited to certified applicators).

Proposed use on Globe Artichoke:
Brigade® WSB is to be applied to globe artichoke for the control of cribrate weevil and artichoke plume moth at the rate of 16 oz of product per acre per application (0.10 lbs ai/A). Applications are to begin when the pest population reaches damaging thresholds and applications may be repeated on a 15 day interval. Applications may be made by ground equipment in a minimum of 75 gallons of spray per acre or by air equipment in a minimum of 10 gallons per acre. A 5 day preharvest interval (PHI) must be observed. The following restrictions are included on the proposed label: I. Do not exceed 0.10 lbs ai/A between bud formation and harvest; ii. Do not exceed 0.5 lbs ai per acre per season.

It was concluded the directions for use of Brigade® WSB (EPA Reg. No. 279-3108) on globe artichoke are adequate. (Memo of 3/8/96, W. Wassell, D221188).

Proposed Use on Cucurbits
Capture® 2EC is to be foliarly applied to cucurbits by ground or air for the control of squash bugs, aphids, leafhoppers, cucumber beetles and whiteflies. Apply Capture®2EC at the rate of 0.04 to 0.1 lbs a.i. per acre, with spray intervals no less than 7 days apart. Do not make more

than two applications after bloom. Maximum application is 0.3 lbs a.i. per acre per season, and the preharvest interval (PHI) is 3 days.

Proposed Use on Eggplant

Capture® 2EC is to be foliarly applied to eggplant by ground or air for the control of mites, whiteflies, lygus bugs, and colorado potato beetles. Apply Capture®2EC at the rate of 0.1 lbs a.i. per acre, with spray intervals no less than 7 days apart. Do not make more than two applications after bloom. Maximum application is 0.2 lbs a.i. per acre per season, and the PHI is 7 days.

It was concluded the directions for use of Capture®2EC on cucurbits and eggplants are adequate. (Memo of 5/20/99, Y. Donovan, D239894).

Proposed Use on Legume Vegetables and Peas and Beans

Capture® 2 EC is to be used by certified applicators for control of various insect pests in the production of edible-podded legume vegetables (Crop Subgroup 6-A) and succulent shelled peas and beans (Crop Subgroup 6-B). Apply 0.033 - 0.10 lb ai (2.1 - 6.4 fl oz of product) per acre, depending on the pest species to be controlled. Apply in a minimum of 2 gallons of finished spray per acre by air or in a minimum of 10 gallons per acre with ground equipment. When applying by air, 1 - 2 quarts of emulsified oil may be substituted for 1 - 2 quarts of water in the finished spray. Thorough coverage of the foliage is essential to achieve control.

Do not apply more than 0.2 lb ai (12.8 fl oz of product) per acre per season. Do not make applications less than 7 days apart. Do not apply within 3 days of harvest.

It was concluded that the proposed directions for use of Capture®2EC on Crop Subgroups 6-A and 6-B are adequately described. (Memo of 5/18/99, M. Nelson, D247316).

Proposed Use on Sweet Corn

Capture®2EC is to be applied to sweet corn at 0.033 - 0.1 lb ai/A. Two applications may be made depending on infestation level and pest to be controlled. A maximum of 0.2 lb ai/A/season may be applied with a 1-day PHI.

Proposed Use on Head and Stem Brassica Vegetables

Capture®2EC is to be used at rates up to 0.1 lb ai per application with a maximum yearly application of 0.5 lb ai and 7-day PHI. However, there is no indication of maximum number of applications nor spray intervals. The field trial data show a use pattern of 5 applications at the maximum use rate and 7-day pretreatment intervals.

Proposed Use on Canola

Capture®2EC is to be applied to canola at the rate of 0.04 lb ai/A by ground or air at first flower. A second application may be made after 14 days. Maximum application is 0.08 lb ai/A/season, and the PHI is 35 days.

The proposed directions for use of Capture® 2EC on corn and canola are adequate. However, the petitioner should submit a revised Section B clarifying the intended use pattern on head and stem Brassica vegetables (Memo of 5/25/99, W. Cutchin, D248814).

4.2 Dietary Exposure

Residue chemistry data for the proposed use of bifenthrin on **globe artichoke** have been previously reviewed by HED. It was concluded the submitted field trial data are adequate to support the requested tolerance level of 1.0 ppm for residues of bifenthrin in/on globe artichoke when Brigade® WSB is used as proposed. TOX considerations permitting, HED recommends for the establishment of the proposed tolerance for residues of bifenthrin in/on globe artichoke at 1.0 ppm. (Memo of 3/8/96, W. Wassell, D221188).

Residue chemistry data for the proposed use of bifenthrin on **cucurbits, eggplants, edible-podded legume vegetables, succulent shelled peas and beans, sweet corn, head and stem Brassica vegetables, and canola** have been previously reviewed by HED. Below are summaries from these reviews (Memo of 5/20/99, Y. Donovan, D239894. Memo of 5/18/99, M. Nelson, D247316. Memo of 5/25/99, W. Cutchin, D248814. Memo of 6/10/99, R. Loranger, D256765).

1. The manufacturing process of technical grade bifenthrin as well as the physical/chemical properties have been adequately described. (see HED memo of 1/10/91, N. Dodd, 6F3454).

2. The proposed directions for use of Capture® 2EC on cucurbits, eggplants, legume vegetables, peas and beans, corn, and canola are adequate. However, the petitioner should submit a revised Section B clarifying the intended use pattern for head and stem Brassica vegetables.

3. The nature of bifenthrin residues in plants and in animals is adequately understood. The residue of concern is bifenthrin *per se*.

4. Adequate enforcement methods are available for determination of the regulated bifenthrin residue in plants and in animals. EC-GLC methods have been submitted (7/89) for publication in the Pesticide Analytical Manual, Volume II, to enforce tolerances for residues of bifenthrin in/on plant (RAN-0140) and animal (P-1031) commodities. Residues of bifenthrin are recoverable under Protocols D and E of the multiresidue methods.

5a. The analytical method used in data collection for bifenthrin in cucurbit and eggplant samples is a modified version of the method entitled: "Analytical method for the determination of bifenthrin in/on various crops and soils" by J.E. Ridler, FMC Corporation Method P-2132M,

April 24, 1989. HED concludes that this method has been adequately validated for collection of residue data for bifenthrin in/on cucurbits and eggplant.

5b. EC-GLC data collection methods for succulent peas and beans (P-1089 and P-2132M) similar to RAN-0140 were validated in these current petitions on succulent peas and beans. Recoveries were 71-119%. The limit of quantitation is 0.05 ppm.

5c. The data gathering method for sweet corn used here, FMC Method P-2550M, has been submitted for inclusion in PAM II. The data gathering method for head and stem Brassica vegetables and canola, P-2132M, is a variation of two other methods which have been submitted for inclusion in PAM II.

6a. Data pertaining to the stability of residues of bifenthrin on cucurbits and on eggplants were submitted. Fortified field trial sample were analyzed after extended period of frozen storage at -20°C. The average relative recoveries for the subject crops are as follow: cucumbers - 95% (360-361 days), cantaloupe - 90% (366-369 days), squash - 91% (358-359 days), and eggplants - 88% (131-136 days). Based on the available storage stability data. RAB2 concludes that the stability studies of bifenthrin in/on cucurbits and eggplant are adequate and that samples stored at the above storage intervals are stable.

6b. Frozen storage recovery data (up to 196 days) on bifenthrin-fortified succulent peas and beans adequately validate the storage interval (up to 178 days) of the field-treated residue samples.

6c. No new corn storage stability data were submitted with this corn petition (PP#8F5014). Previously submitted data indicated that bifenthrin was stable on corn commodities for up to 49 months. The data submitted here with the corn field trials indicate that the corn samples were analyzed within 6 months of harvest. The corn storage stability database is adequate to support the residue data submitted.

6d. Limited storage stability studies were submitted for broccoli, cauliflower, and cabbage, which indicate that bifenthrin is stable on head and stem Brassica vegetables for up to 294 days. The data submitted here with the field trials indicate that the longest storage interval between harvest and analysis was 246 days for cauliflower. These submitted storage stability studies and the existing storage stability database are adequate to support the residue head and stem Brassica vegetable data submitted.

6e. A limited storage stability study submitted here indicates that bifenthrin is stable on canola for up to 136 days. The data submitted here with the canola field trials indicate that the canola samples were analyzed within 4 months of harvest. The submitted canola storage stability study and the existing storage stability database is adequate to support the canola residue data submitted.

7a. From reviewing the studies submitted by the petitioner on cucumbers, cantaloupe, summer squash, and eggplant, HED concludes that the number of the crop field trials and the geographic representation of the major cucurbits and eggplant growing regions of the U.S. in the submitted field trials are adequate. The HED recommended tolerance for cucurbits is **0.4 ppm**, and for eggplants is **0.05 ppm**.

7b. An adequate number of geographically representative field trials reflecting the proposed use pattern were submitted for representative commodities of Crop Subgroups 6-A (edible-podded legume vegetables) and 6-B (succulent shelled peas and beans). The **appropriate tolerance levels are 0.6 ppm and 0.05 ppm**, respectively. **A revised Section F is needed to raise the Crop Subgroup 6-A tolerance proposal to 0.6 ppm.**

7c. The residue data, the geographic diversity, and number of the residue field trials are adequate data to support the proposed bifenthrin tolerance in/on **sweet corn at 0.05 ppm** and raising the existing **corn forage tolerance to 3.0 ppm**, in/on **cabbage at 4.0 ppm** and **head and stem Brassica (5A) except cabbage at 0.6 ppm**.

The residue data from the submitted field trials indicate that the proposed use on canola will not exceed the proposed bifenthrin tolerance at 0.05 ppm. However, the petitioner has requested this tolerance in terms of rapeseed while the submitted field trials were conducted only on canola. Current HED policy indicates that a rapeseed tolerance would include canola but a canola tolerance would not include rapeseed. **Since the submitted residue field trials were conducted only on canola, the petitioner should submit a revised Section F listing a tolerance in/on canola at 0.05 ppm.**

8. There are no processed commodities requiring residue data associated with all the subject crops except canola. The processed commodity study submitted here on canola is adequate. Neither of the canola processed commodities, meal or oil, showed detectable residues in spite of the 3x treatment level. No separate tolerances for the residues of bifenthrin on canola processed commodities will be required.

9. Rotational Crop restrictions follow the registered label use for Capture® 2EC. Leafy vegetables and root crops may be rotated 30 days following the final application of bifenthrin. Crops for which bifenthrin tolerances exist may be rotated at any time. All other crops may be rotated seven months following the final application of bifenthrin. Straw may not be used for food or feed.

10. There are no animal feed items associated with cucurbits, eggplants, legume vegetables, peas and beans, and head and stem Brassica.

Sweet corn forage is a feed item for cattle. Comparing the livestock dietary burden, including the proposed increased tolerance on sweet corn forage, to the cattle feeding study indicates that the existing tolerance for animal commodities are adequate.

Canola meal is a feed item for cattle, poultry, and swine. The processing study submitted here indicates that detectable residues in canola meal are not likely. Therefore, feeding canola meal made from treated canola is not likely to produce detectable residues in animal commodities.

11. International Tolerance Status: There are no established tolerances for all subject crops.

4.2.1 Food Exposure

Acute Dietary Exposure and Risk. **aPAD = 0.01 mg/kg bwt/day.**

Acute dietary (food) risk assessment was conducted by Novigen Science, Inc. In this acute analysis, Monte Carlo analysis (Tier 3) was used. For those foods identified by EPA as single-serving commodities, Monte Carlo simulation is based on iterative sampling from individual residue values from field trial data reflecting maximum application rates and minimum preharvest intervals. For those considered to be blended or processed, mean field trial residues were calculated, substituting those samples for which residues were reported at or below the limit of detection (LOD) with ½ of the LOD. It was assumed that 100% crop treated for all pending registrations: citrus, snap beans, peas, lima beans, canola, sweet corn, cucurbits, eggplant, and brassica vegetable. Secondary residues for meat and milk were derived from the total dietary burden and tissue- to- feed ratio, using the highest ratio for meat, and the average ratio for milk.

HED concludes that the data files used in this analysis are adequate.

This analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. Resulting exposure values (at the 99.9th percentile) and percentage of the aPAD utilized are shown in Table 2. The most highly exposed population subgroup (Children 1 to 6 year) utilizes **96%** of the aPAD. This is a highly refined assessment since % crop treated was used for registered crops and anticipated residues for all crops; it is unlikely that it can be significantly further refined at this time.

Table 2. **Acute** Dietary (Food Only) Exposure Analysis by DEEM for Bifenthrin

Population Subgroup	Exposure @ 99.9th Percentile (mg/kg bwt/day)	Percent aPAD[1]
U.S. Population (48 states)	0.0053	53%
All infants (< 1 yr)	0.0063	63%
Female 13 +	0.0035	35%
Non-nursing infants (< 1 yr)	0.0058	58%

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Table 2. **Acute** Dietary (Food Only) Exposure Analysis by DEEM for Bifenthrin		
Population Subgroup	Exposure @ 99.9th Percentile (mg/kg bwt/day)	Percent aPAD[1]
Children (1-6 yrs)	0.0096	**96%**
Children (7-12 yr)	0.0062	62%

[1] Percentage Acute PAD (% aPAD) = $\frac{\text{Exposure X 100\%}}{\text{aPAD}}$

The subgroups listed above are: (1) the U.S. population (48 states), (2) Female 13 + , and (3) those for infants and children.

It was determined that an acute dietary exposure (food plus water) of 100 % or less of the aPAD is needed to protect the safety of all population subgroups.

Chronic Dietary Exposure and Risk. **cPAD = 0.015 mg/kg bwt/day.**

In conducting this DEEM analysis for chronic dietary (food only) risk assessment, Novigen used anticipated residue values which were determined from field trial data conducted at maximum label conditions of maximum application rates and minimum preharvest intervals. Mean anticipated residue values were calculated substituting half of the LOD for those samples for which residues were reported below the LOD. It was assumed that 100% crop treated for all crops except hops at 43%, cottonseed-oil and cottonseed-meal at 4%. Secondary residues for meat and milk were derived from the total dietary burden and tissue- to- feed ratio, using the average ratio for meat and milk.

HED concludes that the data files used in this analysis are adequate.

The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. Summaries of the Anticipated Residue Concentration (ARC) and their representations as percentages of cPAD for the general population and subgroups of interest are in Table 3. The most highly exposed population subgroup (Children 1-6 years) will utilize **6.7%** of the cPAD. This chronic risk assessment should be viewed as partially refined.

Table 3. **Chronic** Exposure Analysis by the DEEM System for Bifenthrin		
Population Subgroup	Exposure (mg/kg/day)	Percent cPAD[1]
U.S. Population (48 States)	0.00036	2.4%

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Table 3. **Chronic** Exposure Analysis by the DEEM System for Bifenthrin		
Population Subgroup	Exposure (mg/kg/day)	Percent cPAD [1]
Children (1-6 years old)	**0.0010**	**6.7%**
Female 13+	0.00037	2.5%

[1] Percentage cPAD = $\frac{\text{Exposure X 100\%}}{\text{cPAD}}$

The subgroups listed above are: (1) the U.S. population (48 states); (2) female 13+; (3) highest exposed population subgroup that includes infants and children.

It was determined that a chronic dietary exposure (food plus water) of 100 % or less of the cPAD is needed to protect the safety of all population subgroups.

4.2.2 Drinking Water

The Environmental Fate and Effects Division (EFED) provided HED with estimated environmental concentrations (EECs) of bifenthrin residues. The estimated acute and chronic drinking water concentrations generated with the PRZM I/EXAMS model are 0.10 ppb and 0.032 ppb, respectively, using the highest application rate of 0.5 lbs a.i./A on cotton. (EFED memo of 3/11/99, J. Melendez, D248839).

Acute

For purposes of this acute risk assessment, the estimated acute maximum concentration for bifenthrin in surface and ground waters (0.10 ppb = 0.10 µg/L) should be used for comparison to the back-calculated DWLOCs for the acute endpoint. These DWLOCs for various population categories are summarized in Table 4.

Table 4. Drinking Water Levels of Comparison for **Acute** Exposure to Bifenthrin[1]					
Population Category[2]	aPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC[4,5,6] (µg/L)	EEC[7] (µg/L)
U.S. Population (48 states)	0.01	0.0053	0.0047	165	0.10
Females 13 +	0.01	0.0035	0.0065	200	0.10
Children (1-6 year)	0.01	0.0096	0.0004	4	0.10

[1] Values are expressed to 2 significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = [aPAD or cPAD (mg/kg/day) - Food Exposure (mg/kg/day)].
[4] DWLOC(μg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/μg) x water consumed daily (L/day)].
[5] HED Default body weights are: General U.S. Population, 70 kg; Males (13^{+} years old), 70 kg; Females (13^{+} years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7]EEC: Estimated Environmental Concentration. (Acute value).

Chronic

For purposes of chronic risk assessment, the estimated chronic maximum concentration for bifenthrin in surface and ground waters (which is 0.032 ppb = 0.032 µg/L) should be used for comparison to the back-calculated human health DWLOCs from the chronic (non-cancer) endpoint. These DWLOCs for various population categories are summarized in Table 5.

Table 5. Drinking Water Levels of Comparison for **Chronic** Exposure to Bifenthrin[1]

Population Category[2]	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC [4,5,6] (µg/L)	EEC[7] (µg/L)
U.S. Population (48 states)	0.015	0.00036	0.015	530	0.032
Female 13+	0.015	0.00037	0.015	450	0.032
Children (1-6 years)	0.015	0.0010	0.014	140	0.032

[1] Values are expressed to 2 significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = aPAD or cPAD (mg/kg/day) - Food Exposure (mg/kg/day).
[4] DWLOC(μg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/μg) x water consumed daily (L/day)].
[5] HED Default body weights are: General U.S. Population, 70 kg; Males (13^{+} years old), 70 kg; Females (13^{+} years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7]EEC: Estimated Environmental Concentration. (Chronic 56-day value).

Short- and Intermediate- Term

For purposes of short- and intermediate- term risk assessment, the estimated chronic maximum concentration for bifenthrin in surface and ground waters (which is 0.032 ppb = 0.032 µg/L) should be used for comparison to the back-calculated human health DWLOCs from the short-

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and intermediate- term endpoints. Notice that the values for MOE_{water} are from **Section 5.0.3** below (Short- and Intermediate-Term Aggregate Risk).

Adult : $MOE_{water} = 120$
Children(1-6): $MOE_{water} = 130$
Infant(<1 yr): $MOE_{water} = 120$

The maximum water exposure can be calculated by dividing the acute NOAEL(1.0 mg/kg/day) by MOE_{water}. Hence, the DWLOCs can be calculated and then compared to EFED's chronic water estimate. Table 6 summarizes the DWLOCs for various population categories.

Table 6. Drinking Water Levels of Comparison for **Short- and Intermediate-Term** Exposure to Bifenthrin[1]

Population Category[2]	MOE_{water}	Acute NOAEL (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC [4,5,6] (µg/L)	EEC[7] (µg/L)
Adult (male)	120	1.0	0.0083	290	0.032
Adult (female)	120	1.0	0.0083	250	0.032
Child (1-6)	130	1.0	0.0077	77	0.032

[1] Values are expressed to 2 significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Short- Intermediate-term) (mg/kg/day) =Acute NOAEL / MOE_{water}.
[4] DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/µg) x water consumed daily (L/day)].
[5] HED Default body weights are: General U.S. Population, 70 kg; Males (13^{+} years old), 70 kg; Females (13^{+} years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7] EEC: Estimated Environmental Concentration. (Chronic 56-day value).

Cancer
Same as chronic.

4.3 Occupational Exposure

4.3.1. Handler

There is a potential for exposure to Bifenthrin during mixing, loading, and application activities. Bifenthrin has two formulations: (1) Capture 2EC(Liquid) EPA Reg. No. 279-3069, and (2) Brigade WSB(Water Soluble Bag, WSB) EPA Reg. No. 279-3108. An exposure/risk assessment using applicable endpoints selected by the HIARC (11/14/97) was performed. The MOEs for Capture 2EC range from **290** for **aerial mixer/loader** to **3200** for **aerial applicator**. The MOEs

for Brigade WSB range from **2100** for **ground applicator** to **3300** for **ground mixer/loader**. These MOEs DO NOT exceed HED's level of concern. Exposure assumptions and estimates for occupational handlers for Capture 2EC and Brigade WSB are summarized in Tables 7, 8, 9, and 10, respectively. HED's worker exposure estimates are based on surrogate data from the Pesticide Handlers Exposure Database (PHED) as presented in the PHED Surrogate Guide(9/98).

The minimum level of PPE for handlers is based on acute toxicity for the end-use product. The Registration Division (RD) is responsible for ensuring that PPE listed on the label is in compliance with the Worker Protection Standard (WPS).

Table 7. Occupational Exposure Assumptions for Capture 2EC(Liquid)

PARAMETER	ASSUMPTION
Pesticide Handlers Exposure Database (PHED), Version 1.1, Unit of Exposure From Surrogate Exposure Guide (8/98)	Mixer/Loader [all liquids, open mixing/loading]: Dermal = 23.0 µg/lb ai handled (High conf. run), Inhalation = 1.2 µg/lb ai handled (High conf. run)
	Applicator - Ground [groundboom: open cab]: Dermal = 14.0 µg/lb ai applied (Mid conf. run), Inhalation = 0.74 µg/lb ai applied (High conf. run)
	Applicator - Air [aerial - fixed wing: liquid formulations]: Dermal = 2.2 µg/lb ai applied (Low conf. run), Inhalation = 0.068 µg/lb ai applied (Mid conf. run)
Work Clothing and PPE	Single layer, gloves, protective eyeware for mixer/loaders
Percent Absorption	Dermal: 25 % Inhalation: 100 %
Application Type	Ground boom Aerial spray
Maximum Application Rate	0.1 lb ai/A
Acres Treated/Day (Y.NG,BEAD)	Ground: 80 acres Air: 350 acres
Worker Weight	70 kg (default value)

Table 8. Occupational Exposure and Risk Assessment for Capture 2EC(Liquid)[a]

Worker	Dermal Daily Dose[b] (ug/kg/day)	Inhalation Daily Dose[b] (ug/kg/day)	Total Daily Dose (ug/kg/day)	Short-Term[c]/ Intermediate-Term[d] MOE
Ground Mixer/ Loader	0.66	0.14	0.8	1300

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Table 8. Occupational Exposure and Risk Assessment for Capture 2EC(Liquid)[a]				
Worker	**Dermal Daily Dose[b] (ug/kg/day)**	**Inhalation Daily Dose[b] (ug/kg/day)**	**Total Daily Dose (ug/kg/day)**	**Short-Term[c]/ Intermediate-Term[d] MOE**
Ground Applicator	0.40	0.085	0.48	2100
Aerial Mixer/Loader	2.9	0.60	3.5	290
Aerial Applicator	0.28	0.034	0.31	3200

[a] MOEs are expressed to two significant figures.

[b] Daily Dose (DD) = PHED unit exposure x % absorption x application rate x acres treated/day ÷ kg body weight.

[c] Short-Term Occupational Exposure MOE = NOEL/DD (where NOEL = 1.0 mg/kg/day).

[d] Intermediate-Term Occupational Exposure MOE = NOEL/DD (where NOEL = 1.0 mg/kg/day).

Table 9. Occupational Exposure Assumptions for Brigade WSB(Water Soluble Bag)	
PARAMETER	**ASSUMPTION**
Pesticide Handlers Exposure Database (PHED), Version 1.1, Unit of Exposure From Surrogate Exposure Guide (8/98)	Mixer/Loader [all liquids, open mixing/loading]: Dermal = 9.8 µg/lb ai handled (Low conf. run), Inhalation = 0.24 µg/lb ai handled (Low conf. run)
	Applicator - Ground [groundboom: open cab]: Dermal = 14.0 µg/lb ai applied (Mid conf. run), Inhalation = 0.74 µg/lb ai applied (High conf. run)
Work Clothing and PPE	Single layer, gloves, protective eyeware for mixer/loaders
Percent Absorption	Dermal: 25 % Inhalation: 100 %
Application Type	Ground boom
Maximum Application Rate	0.1 lb ai/A
Acres Treated/Day (Y. NG,BEAD)	Ground: 80 acres
Worker Weight	70 kg (default value)

Table 10. Occupational Exposure and Risk Assessment for Brigade WSB(Water Soluble Bag)[a]				
Worker	**Dermal Daily Dose[b] (ug/kg/day)**	**Inhalation Daily Dose[b] (ug/kg/day)**	**Total Daily Dose (ug/kg/day)**	**Short-Term[c]/ Intermediate-Term[d] MOE**
Ground Mixer/Loader	0.28	0.027	0.31	3300

Table 10. Occupational Exposure and Risk Assessment for Brigade WSB(Water Soluble Bag)[a]				
Worker	**Dermal Daily Dose[b] (ug/kg/day)**	**Inhalation Daily Dose[b] (ug/kg/day)**	**Total Daily Dose (ug/kg/day)**	**Short-Term[c]/ Intermediate-Term[d] MOE**
Ground Applicator	0.40	0.085	0.49	2100

[a] MOEs are expressed to two significant figures.
[b] Daily Dose (DD) = PHED unit exposure x % absorption x application rate x acres treated/day ÷ kg body weight.
[c] Short-Term Occupational Exposure MOE = NOEL/DD (where NOEL = 1.0 mg/kg/day).
[d] Intermediate-Term Occupational Exposure MOE = NOEL/DD (where NOEL = 1.0 mg/kg/day).

4.3.2 Post-Application

Previous Section 18s have been granted for the use of bifenthrin on citrus in Florida and on sorghum in Kansas/Texas. However, the postapplication exposure/risk assessments were not required for these two Sections 18s because: (1)bifenthrin was applied to the soil beneath citrus trees and the chemical would not be found on tree foliage at significant levels; and(2) sorghum crops, like many small grains, are harvested mechanically and therefore postapplication exposure to the bifenthrin would be negligible.

This Section 3 action on bifenthrin involves:(1) foliage applications, (2) aerial spray, and (3) hand harvesting of vegetable crops. Therefore, there is a potential for postapplication exposure and a risk assessment is required.

To estimate post-application exposures, a default transfer coefficient (Tc) of 2,500 cm^2/hr was used for harvesting(hand) artichokes, head & stem brassica; 4,000 cm^2/hr for harvesting (hand)eggplants, cucurbits, peas and beans; and 10,000 cm^2/hr for harvesting (hand) corns. These defaults were established by the HED Exposure SAC (5/7/98, policy #3). The short/intermediate -term MOEs for post-application exposure on day 0 are 16 for artichokes, head & stem brassica, 39 for eggplants, cucurbits, peas and beans, and 62 for corns. It would take 5 days for artichokes, head & stem brassica, 9 days for eggplants, cucurbits, peas and beans, and 18 days for corns to reach an acceptable level of exposure(MOE>100). Since these Tier 1 calculated MOEs are smaller than 100 on the day of application, they **exceed HED's level of concern. Further assessment/ refinement based on the chemical specific Dislodgeable Foliar Residue study may be required. Currently, dislodgeable foliar residue data for bifenthrin on strawberries are still under review by the contractor. Hence, the postapplication exposure data could possibly be refined after the dislodgeable foliar residue data are validated.** A summary of the Postapplication Exposure and Risk Assessment is included as **Table 11.**

The current label has a 12-hr restricted entry interval(REI). The technical material has an acute oral LD50= 70.1 mg/kg which is in the range of Toxicity Category II. Per the Worker Protection Standard(WPS), a 24-hr REI is required for chemicals classified under Toxicity Category II. However, based on the Tier 1 calculated MOEs for postapplication exposure in Table 5, HED recommends that a REI of 5-days be required for artichokes, head & stem brassica; 9-days for eggplants, cucurbits, peas and beans; and 18-days for corns. As mentioned before, the REI could possibly be refined using chemical specific Dislodgeable Foliar Residue data that are currently under review by the contractor. The RD should ensure the correct REI appears on the label.

Table 11. Postapplication Occupational Exposure and Risk Assessment

Transfer Coefficient (Tc)	[4]DFR_t	[5]DD_t	[6]Short Term MOE	[7]Intermediate Term MOE
2,500[1]	t=0: 0.224 t=5: 0.132	t=0: 0.016 t=5: 0.009	**t=0: 62** **t=5: 106**	**t=0: 62** **t=5: 106**
4,000[2]	t=0: 0.224 t=9: 0.087	t=0: 0.026 t=9: 0.010	**t=0: 39** **t=9: 101**	**t=0: 39** **t=9: 101**
10,000[3]	t=0: 0.224 t=18: 0.034	t=0: 0.064 t=18: 0.010	**t=0: 16** **t=18: 104**	**t=0: 16** **t=18: 104**

[1] Tc = 2,500 cm^2/hr for harvesting(hand) artichokes, head & stem brassica
[2] Tc = 4,000 cm^2/hr for harvesting(hand) eggplants, cucurbits, peas & beans
[3] Tc = 10,000 cm^2/hr for harvesting(hand) corns
[4] DFR_t =AR x F x $(1-D)^t$ x 4.54E8 ug/lb x 24.7E-9 acre/cm^2
where: DFR_t = dislodgeable foliage residue on day "t" (ug/cm^2)
AR = application rate (0.1 lb ai/acre)
F = fraction of ai retained on foliage (0.2, unitless)
D = fraction of residue that dissipates daily (0.1, unitless)
t = postapplication day on which exposure is being assessed (day 0, day 5, day 9, day 18)
[5] DD_t = (DFR_t x 0.001 mg/ug x Tc x % dermal absorption x ET) / BW
where: DD_t = Daily Dose on day "t" (mg/kg/day)
DFR_t = dislodgeable foliage residue on day "t" (ug/cm^2)
Tc = transfer coefficient (cm^2/hr)
% absorption = 25% dermal absorption
ET = exposure time (8 hr/day)
BW = body weight (70 kg)
[6] Short-term MOE = NOEL ÷ DD (NOEL = 1.0 mg/kg/day)
[7] Intermediate-term MOE = NOEL ÷ DD (NOEL = 1.0 mg/kg/day)

HED's worker exposure estimates are based on surrogate data. The unit exposure values are considered to be central tendency. The application rates, treatment variables, etc used in this assessment are upper percentile values. Therefore, the potential dose is characterized as central to high-end.

HED notes that as a result of the longer restricted entry intervals (REI's) needed to address post-application risks to workers there are crops for which the preharvest interval (PHI) now is less than the REI. Since these crops are primarily hand harvested, the PHI can not in most cases be less than the REI. Therefore, although the tolerances and proposed PHI's are appropriate based on the available residue data, HED recommends that the label be revised for the crops eggplant, cucurbits, beans/peas, and sweet corn to emphasize that in those cases where hand-harvesting occurs the PHI needs to be as long as the REI (i.e., 9 days for eggplant, cucurbits, and beans/peas; 18 days for sweet corn). In the meantime, HED will continue to assess the available foliar dislodgeable residue data to determine if shorter REI's can be set with MOE's that do not exceed our level of concern.

4.4 Residential Exposure

Bifenthrin is currently registered for the following residential uses: **on lawn for flea infestation control, and as a termiticide.** These registered uses constitute short- and/or intermediate-term, and chronic exposure scenario.

A residential exposure assessment for the **lawn care** uses of **bifenthrin** was conducted in conjunction with the "Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids" (P. Hurley, *et. al.*, 11/14/97, D238737). Their exposure data (mg/kg/day) are summarized in Table 12 below:

Table 12. Bifenthrin: Post-Application Exposure Estimates for Turf Use (mg/kg/day)

Scenario	Individual	Inhalation	Dermal	Oral
Lawn Application	Adult	not conducted	not conducted	not conducted
Post-Application Lawn	Adult	1.94E-05	2.32E-03	not conducted
Post-Application Lawn	Child (1-6)	4.80E-05	4.39E-03	4.76E-04
Post-Application Lawn	Infant (<1)	5.96E-05	4.55E-03	5.07E-04

The applicator's exposure assessment was not conducted. This product is a restricted use pesticide, and therefore, required to be applied by professional LCOs only. This scenario is considered out of our scope for purposes of residential exposure. The termiticide use is addressed below in Section 5.0.2.

5.0 AGGREGATE RISK ASSESSMENT AND RISK CHARACTERIZATION

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational

exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from ground or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor and/or outdoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

5.0.1 Acute Aggregate Risk (Food + Water)

Using the Monte Carlo analysis, it is estimated the acute exposure to bifenthrin from food for the population subgroup (US Population- all season) will utilize **53%** of the aPAD, and for the most highly exposed population subgroup that includes children (Children 1-6 year) will utilize **96%** of the **aPAD**, as shown in Table 2. It was determined that an acute dietary exposure (food plus water) of 100 % or less of the **aPAD** is needed to protect the safety of all population subgroups.

Despite the potential for exposure to bifenthrin in drinking water, HED does not expect the aggregate exposure to exceed 100% of the aPAD for adults, infants and children. As seen in Table 4, EFED's maximum concentration of bifenthrin in surface and ground water for acute exposure is below the DWLOC. HED concludes that there is a reasonable certainty that no harm will result to adults, infants and children from acute aggregate exposure to bifenthrin residues.

5.0.2 Chronic Aggregate Risk (Food + Water + Residential)

Using the refined exposure assumptions described above, it is estimated that the chronic exposure to bifenthrin from food for the most highly exposed population subgroup (Children 1-6 year) will utilize **6.7%** of the cPAD, as shown in Table 3. It was determined that a chronic dietary exposure (food plus water) of 100% or less of the cPAD is needed to protect the safety of all population subgroups.

Despite the potential for exposure to bifenthrin in drinking water, HED does not expect the aggregate exposure to exceed 100% of the cPAD, as indicated in Table 5, EFED's maximum concentration of bifenthrin in surface and ground water for chronic exposure is very small compared to the DWLOC. Although the registered termiticide use of bifenthrin constitutes a chronic exposure scenario, the exposure from this termiticide use is negligible considering the application technique of the termiticide use (buried underground) and the fact that vapor pressure of bifenthrin is extremely low (1.8×10^{-7} torr). Therefore, HED concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to bifenthrin residues.

5.0.3 Short- and Intermediate-Term Aggregate Risk (Residential + Chronic Food + Chronic Water)

In general, the short- and intermediate-term aggregate risks are estimated by combining exposure from food (chronic), water and residential uses. When all the acceptable MOEs are at the same

level, the aggregate risks for population subgroups can be estimated by calculating aggregate Margin of Exposure values ($MOE_{aggregate}$).

$$MOE_{aggregate} = \frac{1}{\frac{1}{MOE_I} + \frac{1}{MOE_D} + \frac{1}{MOE_O} + \frac{1}{MOE_{FOOD}} + \frac{1}{MOE_{WATER}}} \quad (1)$$

where I = inhalation, D = dermal, O = non-dietary oral, MOE_{FOOD} = the oral NOAEL selected for the short- (and in this case, intermediate-) term dermal and inhalation endpoints ÷ the exposure from the chronic DEEM run.

As residue values in water from monitoring data are not available, therefore, the DWLOCs have to be back calculated.

In the case of bifenthrin, the registered residential use sites include outdoor lawn/gardens, inside households and termiticide. These uses constitute a short, and intermediate term exposure scenario. Endpoints have been selected for short- and intermediate-term dermal and inhalation exposures, and the acceptable MOEs for short- and intermediate-term exposures are all at 100 (see Table 1). For adults, the routes of exposure from these registered residential uses include dermal and inhalation, and for infants and children, the routes of exposure include dermal, inhalation, and oral (nondietary).

According to our HED most recent aggregate risk assessment guideline, exposures with toxicological endpoints selected from similar toxicological effects should be aggregated. Since the toxicological effects through the inhalation, dermal, chronic food, and oral non-dietary routes are similar (see Table 1), short- and intermediate-term aggregate risk assessment for bifenthrin will include inhalation, dermal, oral non-dietary, chronic food, and water exposure routes. A worst case scenario estimate of exposures from residential uses of bifenthrin (turf use) has previously been calculated. The residential exposures for different population subgroups are summarized in Table 12 under **section 4.4** above. MOEs for different population subgroups are calculated by dividing the oral NOAEL by exposure, and the results are summarized in Table 13.

Table 13. Short- and Intermediate- Term Risk: MOEs from Exposure of Turf Use and Chronic Food.[1,2]

Pop. Subgroup	Residential Exposure(from bifenthrin turf use, see Table 7)						Dietary Exposure (from chronic food)	
	Inhalation (mg/kg/ day)	MOE_I[3] (Oral eq.)	Dermal (mg/kg/ day)	MOE_D[4] (Oral eq.)	Oral (mg/kg/ day)	MOE_O[5]	Chronic Food (mg/kg/ day)	MOE_{FOOD}[6]
Adult	1.94E-05	52000	2.32E-03	1700	not conducted	N/A	0.00036	4200
Child (1-6)	4.80E-05	21000	4.39E-03	900	4.76E-04	2100	0.0010	1500

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Table 13. Short- and Intermediate- Term Risk: MOEs from Exposure of Turf Use and Chronic Food.[1,2]								
Pop. Subgroup	Residential Exposure(from bifenthrin turf use, see Table 7)						Dietary Exposure (from chronic food)	
	Inhalation (mg/kg/ day)	MOE_I[3] (Oral eq.)	Dermal (mg/kg/ day)	MOE_D[4] (Oral eq.)	Oral (mg/kg/ day)	MOE_O[5]	Chronic Food (mg/kg/ day)	MOE_{FOOD}[6]
Infant (<1)	5.96E-05	17000	4.55E-03	900	5.07E-04	2000	0.00048	3100

[1] acute NOAEL = 1.0 mg/kg/day. chronic NOAEL = 1.5 mg/kg/day.
[2] All MOEs are expressed to 2 significant figures.
[3] MOE_I: MOE from inhalation = (acute NOAEL) / (Inhalation exposure x 100%).
[4] MOE_D: MOE from dermal absorption = (acute NOAEL) / (Dermal exposure x 25%)
[5] MOE_O: MOE from incidental oral = (acute NOAEL) / (Incidental oral exposure).
[6] MOE_{FOOD} : MOE from chronic food = (chronic NOAEL) / (Chronic food exposure).

As Table 13 indicated, all MOEs are greater than 100, which is the level of concern for inhalation, dermal absorption, and incidental oral.

Substituting the above MOE_I, MOE_D, MOE_O, and MOE_{FOOD} values into equation (1), and assume that $MOE_{aggregate}$ is at the minimum acceptable level of 100, the minimum MOE_{water} can be calculated for each individual. Below is a step-by-step calculation to determine the MOE_{water} for **Children (1-6 year)**:

$$MOE_{aggregate} = \frac{1}{\frac{1}{MOE_I} + \frac{1}{MOE_D} + \frac{1}{MOE_O} + \frac{1}{MOE_{FOOD}} + \frac{1}{MOE_{WATER}}} \quad (1)$$

$$100 = \frac{1}{\frac{1}{21000} + \frac{1}{900} + \frac{1}{2100} + \frac{1}{1500} + \frac{1}{MOE_{WATER}}} \quad (2)$$

$$100 = \frac{1}{0.0023 + \frac{1}{MOE_{WATER}}} \quad (3)$$

$$0.0023 + \frac{1}{MOE_{WATER}} = \frac{1}{100} \quad (4)$$

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$$\frac{1}{MOE_{WATER}} = \frac{1}{100} - 0.0023 \quad (5)$$

$$\frac{1}{MOE_{WATER}} = 0.0077 \quad (6)$$

$$MOE_{WATER} = 130$$

Using the same calculation as above, substituting the MOEs for adult and infant into the above equation (1), the MOE_{water} for adult and infant can be determined. Therefore, the minimum MOEs for water for these population subgroups are:

Adult : $MOE_{water} = 120$
Children(1-6): $MOE_{water} = 130$
Infant(<1 yr): $MOE_{water} = 120$

Despite the potential for exposure to bifenthrin in drinking water, HED does not expect the aggregate exposure to exceed our level of concern. As indicated in Table 6 under **section 4.2.2** (Drinking Water), EFED's maximum concentration of bifenthrin in surface and ground water for chronic exposure is very small compared to the DWLOCs. Therefore, HED concludes that there is a reasonable certainty that no harm will result to adults, infants and children from short- and intermediate- term aggregate exposure to bifenthrin residues.

5.0.4 Determination of Cancer Risk

Bifenthrin has been classified as a group C carcinogen, using the RfD approach. Based on the recommendation that the RfD approach be used, a quantitative (q*) dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of bifenthrin are adequately addressed by the DEEM chronic exposure analysis using the cPAD (RfD). For the U.S. population, only 2.4% of the cPAD (RfD) is occupied by chronic food exposure. As stated previously, based on a comparison of the calculated DWLOCs and the estimated exposure to bifenthrin in drinking water (0.032 ppb), HED does not expect the aggregate exposure to exceed 100% of the chronic cPAD (RfD) for adults. Thus, HED concludes with reasonable certainty that the carcinogenic risk is below HED's level of concern.

5.0.5 Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public

interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

5.0.6 Cumulative Exposure To Substances with a Common Mechanism of Toxicity

Bifenthrin is a member of the Synthetic Pyrethroids. Other members of this class include cyfluthrin, cypermethrin, lambda-cyhalothrin, zeta-cypermethrin, deltamethrin, esfenvalerate, fenpropathrin, tefluthrin and tralomethrin.

HED does not have, at this time, available data to determine whether bifenthrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, HED has not assumed that bifenthrin has a common mechanism of toxicity with other substances.

6.0 DATA NEEDS

There are no data gaps pertaining to product chemistry.

RAB2 has previously concluded that data pertaining to residue chemistry are as follow:

- Revise Section F of PP# 8E04993 to increase the proposed tolerance on edible-podded legume vegetables (Crop Subgroup 6-A) to 0.6 ppm.

- Revised Section B clarifying the intended use pattern for head and stem Brassica vegetables (PP#9E5069).

- Revised Section F listing canola not rapeseed (PP#9E5084).

Data pertaining to toxicity studies are as follow:

According to the HED memo of 11/14/97, *Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids*, by P. Hurley et al., the four toxicology studies listed below are considered to be data gaps which "should be considered before permanent tolerances are granted" (p. 15). Further, when required, studies 1, 2 and 3 (below) should be "considered as confirmatory in nature" and study 4 (below) should "only be required if effects observed (e.g. lesions of the CNS) in the acute and 90-day neurotoxicity studies indicate concerns for increased sensitivity of the infant or neonate" (quoted from HED memo of 11/12/97, *Clarification of Data Requirements for Pyrethroids and Documentation of Decision Logic Applied to Determination of Appropriate Uncertainty Factors for Infants and Children*, by K. Baetcke et al.).

1. 21-Day dermal toxicity study **in rats** (Guideline 82-2)

2. Acute neurotoxicity study in rats (Guideline 81-8)
3. Subchronic neurotoxicity study in rats (Guideline 82-5)
4. Developmental neurotoxicity study in rats (Guideline 83-6)

Since corn is a major food crop (and will also result in increased bifenthrin residues in milk), studies 1, 2 and 3 (above) are required to be performed and submitted to support PP#8F5014 (FMC Corporation petition for a tolerance on sweet corn and to increase the tolerance on corn forage). Since these are confirmatory toxicology studies, they need not be submitted prior to establishment of the requested tolerances, but should be submitted within a reasonable period of time.

These studies are not required to support the other (E) petitions discussed in this memo since these requests are for tolerances on minor food crops.

Attachments: 1. HIARC report on bifenthrin (11/14/97).
2. DEEM summaries from Novigen.
3. EFED memo of 3/11/99, D247317.

cc with Attachments: Y.W. Donovan.

cc without Attachments: Shih-Chi Wang, RAB2 reading file, PP#6E04629, PP# 6E04760, PP# 8E05009, PP# 8E04993, PP# 8E05064, PP# 8F5014, PP# 9E5069, PP# 9E5084.