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

JUN 14 1994

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: The HED Chapter of the Reregistration Eligibility Decision Document (RED) for Fenamiphos, Case #0333

From: Jane Smith, Chemist
John Redden, Biologist
Chemical Coordination Branch
Health Effects Division 7509C

Thru: Debra Edwards, Ph.D., Branch Chief
Chemical Coordination Branch
Health Effect Division 7509C
and
Penelope Fenner-Crisp, Ph.D., Director
Health Effects Division 7509C

To: Lois Rossi, Chief
Reregistration Branch
Special Review and Reregistration Branch 7508W

The Human Health Assessment for the Reregistration Eligibility Document for fenamiphos is attached. This chapter includes the Hazard Assessment from Patricia McLaughlin in Toxicology Branch II, the Occupational/Residential Exposure Assessment from Laura Morris in OREB, the Dietary Exposure Assessment, Product Chemistry and Tolerance Reassessment from Christine L. Olinger in Chemistry Branch II, and the Dietary Risk Assessment from Jennifer M. Wintersteen in DRES.

USE INFORMATION

Fenamiphos (O-ethyl-O-(3-methyl-4-methyl-thiophenyl)-isopropylphosphoramidate) is a systemic nematicide/insecticide used for the control of nematodes, thrips, beetles, aphids, and root borers on terrestrial food crops and non-food sites. Fenamiphos is labelled for use on terrestrial food, non-food, and food and feed crops. Use sites are quite varied and include: low, mid-height, and orchard type agricultural crops; turf uses; and ornamental uses. More specifically, agricultural use sites include: low crops ; mid-level crops ; and orchard type crops. Turf use sites include commercial/industrial lawns; ornamental

lawns and turf; sod farms and golf courses. All uses appear to be outdoors except for some of the ornamental uses which may be inside of greenhouses. There are no residential turf uses allowable for fenamiphos at this time for any label or end-use-product.

CHEMISTRY ASSESSMENT

The Chemistry data base for fenamiphos is substantially complete, there are uncertainties associated with the exposure/risk assessment as outlined below.

- Results from a poultry feeding study would provide a more accurate estimate of potential exposure. Residues in poultry commodities were estimated from the total radioactive residue values found in the poultry metabolism study.

- It is very unlikely that the outstanding storage stability data will significantly alter the exposure/risk assessment.

- The anticipated residue values are the best estimates that can be provided using the currently available residue data. These values have an inherent uncertainty associated with variations in analytical methods, geographical representation of field trials, seasonal variation of residue levels, etc.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.349(a) for the following commodities: apples; bananas; Brussels sprouts; cabbage; cherries; cotton, seed; eggplant; garlic; grapefruit; grapes; lemons; limes; okra; oranges; peaches; peanuts; peanuts, hulls; pineapples; raspberries; strawberries; and tangerines; see Table X in the HED Product and Residue Chemistry Chapter for modifications in commodity definitions and Table XI for recommendations for harmonizing U.S. tolerances with Codex MRLs.

TOXICOLOGY ASSESSMENT

The toxicological data base for fenamiphos is adequate and will support reregistration eligibility. The chemical was classified as "Group E" for carcinogenic potential based on adequate negative studies in two animal species.

The toxicological endpoint for determining intermediate term or **repeated dermal exposure** to workers (rather than acute) is based on cholinesterase inhibition as reflected in the 21-day dermal study in rabbits. The maternal toxicity exhibited in the rabbit developmental study, consisting of salivation, ataxia, diarrhea, reduced weight gain, and mortality, is supporting evidence. Both have NOELs of 0.5 mg/kg/day (MRID#s 154497, 403476-02). In order

to assess **acute dietary risk**, the toxicological concern is cholinesterase inhibition. The endpoint for short term exposure is the maternal toxicity in the developmental study having a NOEL of 0.5 mg/kg/day (MRID 403476-02).

In addition, fenamiphos has been implicated in a handler exposure poisoning incident which resulted in hospitalizing the worker. The Agency is expecting additional human incident data concerning possible worker exposure poisoning. Due to the lack of sufficient data at this time, the Agency can not adequately evaluate the potential hazards associated with the use of this chemical which may result in human poisoning.

DIETARY RISK

All published tolerances are being supported in reregistration except soybeans and cocoa beans. For chronic exposure, the ARC for the U.S. population from the published uses of fenamiphos being recommended for reregistration is 1.0×10^{-5} mg/kg bwt/day, which represents 10% of the RfD. The proposed tolerances being recommended for reregistration contribute 2.0×10^{-6} mg/kg bwt/day, or 2% of the RfD. Pending tolerances for fenamiphos contribute an additional 4.8×10^{-5} mg/kg bwt/day, an exposure representing 48% of the RfD.

The ARC from published uses for the most highly exposed population subgroup, non-nursing infants less than one year of age, is 4.0×10^{-5} mg/kg bwt/day (40% of the RfD). The ARC for new tolerances recommended in reregistration contributes less than 1.0×10^{-6} mg/kg bwt/day (0.2% of the RfD). The ARC for pending tolerances contributes 1.9×10^{-4} mg/kg bwt/day (189% of the RfD).

The dietary MOE's for acute high end exposure are unacceptable for the following subgroups:

- U.S. population - 48 states;
- Infants (< 1 year);
- Children (1-6 years);
- Females (13+ years); and
- Males (13+ years).

WORKER RISK

The acute dermal LD_{50} for technical fenamiphos classifies the chemical in Toxicity Category I. Based on this classification, the criteria as established by Worker Protection Standard (WPS) for Agricultural Pesticides--40 CFR Parts 156 and 170--should be followed.

Personal Protective Equipment (PPE)

The Agency is requiring PPE for applicators, mixer/loaders and other handlers as well as early entry workers consistent with the PPE level required for pesticides classified as Toxicity Category I for acute dermal toxicity. It should be noted that PR Notices 93-7 and 93-11 indicated that fenamiphos is classified as Toxicity Category II, and that existing data indicate fenamiphos should be classified as a Toxicity Category I pesticide (for acute dermal toxicity).

Post Application/Re-Entry Exposure

The Agency recommends a 48 hour restricted entry interval (REI) for all sites (unless otherwise noted) within the scope of the WPS as a conservative measure to mitigate risk to workers entering treated areas after application. During the REI, the Agency will allow workers to enter areas treated with fenamiphos only for the few narrow exceptions allowed in the WPS.

There are several sites for which the Agency requests data and /or further clarification of the use patterns which may affect exposure potential. For these sites, the 48 hour REI should be used in the interim, until receipt and evaluation of the requested data. These data are considered confirmatory.

Margins of exposure are acceptable (i.e.>100) except for the below:

- Open mixing granulars - MOE equals 5;
- Open mixing Emulsifiable concentrations (EC) - MOE equals 0.1;
- Open mixing for chemigation [only EC] - low pressure MOE equals 0.1, high pressure MOE equals 0.8;
- Ground boom application - MOE ranges from 16.7 to 3.1; and
- Granular application - broadcast MOE ranges from less than 0.01 to 0.02, banding MOE equals 50.

Inhalation exposure is estimated to be less than 5%. Therefore, this route of exposure does not impact on the MOE.

Data Requirements

The registrant must submit 61-2: Starting materials and manufacturing process, 61-3: Discussion of formation of impurities, 62-1: Preliminary analysis, 62-2: Certification of ingredient limits, and 62-3: Analytical methods to verify the certified limits for the 85% T (EPA Reg. No. 3125-269); 61-1: Product identity and disclosure of ingredients for the 72.3% FI (EPA Reg. No. 3125-33); and either certify that the suppliers of starting materials and the manufacturing process for the fenamiphos products have not changed since the last comprehensive product chemistry review or submit a complete updated product

chemistry data package. These data are considered confirmatory.

Data pertaining to the nitrcsamine content of some fenamiphos products are outstanding, but nitrosamine content is not expected to be of dietary concern since nitrosamines have not been detected in previously submitted studies for some other products.

Additional confirmatory data must be submitted (see Table B of Product and Residue Chemistry Chapter for specifics) for the following: Animal metabolism (171-4(b)); Residue analytical methods (171-4(c/d)); Storage stability (171-4(e)); Magnitude of the residue in meat, milk, poultry, and eggs - eggs, and the fat, meat, and meat byproducts of poultry (171-4(j)).

In the event that the required storage stability data are found to alter the exposure/risk assessment, additional data may be requested for (see Table B of Product and Residue Chemistry Chapter for specifics): Magnitude of the residue in meat, milk, poultry, and eggs, milk and the fat, meat and meat byproducts of cattle, goats, hogs, horses, and sheep (171-4(j)).

A food additive tolerance for pineapple juice must be proposed. As there are no registered uses of fenamiphos on soybeans, the Agency recommends that the established tolerance for soybeans be revoked.

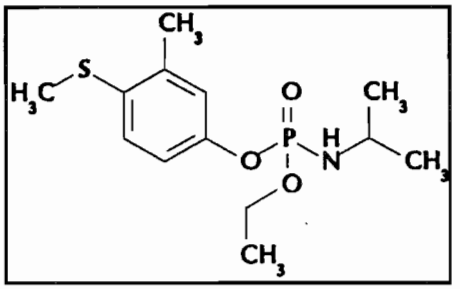
Based on the use information and data available, post-application exposure data are required to support the reregistration of fenamiphos for the uses that may involve human contact with treated soil. The data to support guidelines 132-1(b): Soil residue dissipation, 133-3: Dermal exposure and 133-4: Inhalation exposure include: pre-transplant strawberries and asparagus, ornamental non-flowering plants, ornamental herbaceous plants, sod farm turf, ornamental woody shrubs and vines, and all nursery stock. The data are considered confirmatory because the recommended interim 48-hour REI is expected to offer adequate margins of exposure for these uses.

cc: Patricia McLaughlin (TBI)
Laura Morris (OREB)
Christine L. Olinger (CBII)
Jennifer M. Wintersteen (DRES)

A. PRODUCT CHEMISTRY

DESCRIPTION OF CHEMICAL

Fenamiphos (O-ethyl-O-(3-methyl-4-methyl-thiophenyl)-isopropylphosphoramidate) is a systemic nematicide/insecticide used for the control of nematodes and thrips on terrestrial food crops and non-food sites.



Empirical Formula:	$C_{13}H_{22}NO_3PS$
Molecular Weight:	303.4
CAS Registry No.:	22224-92-6
Shaughnessy No.:	100601

IDENTIFICATION OF ACTIVE INGREDIENT

Technical fenamiphos is an off-white to tan waxy solid with a melting point of 49°C and a vapor pressure of 4.7×10^{-5} mm Hg at 20°C. Fenamiphos is soluble in dichloromethane, 2-propanol, and toluene, only slightly soluble in n-hexane, and insoluble in water.

MANUFACTURING-USE PRODUCTS

A search of the OPP Reference Files System (REFS) conducted 5/26/93 identified two fenamiphos manufacturing-use products (MPs), an 85% technical (T; EPA Reg. No. 3125-269) and a 72.3% formulation intermediate (FI; EPA Reg. No. 3125-333), both registered to Miles, Inc. (formerly Mobay Corp.). Although REFS lists the label claim as 85% for the Miles technical (EPA Reg. No. 3125-269), the Registration Standard (1987) refers to the product as a 90% T, and the Registration Standard Update (2/92) refers to the product by the reported nominal concentration (92.5%).

REGULATORY BACKGROUND

The Fenamiphos Guidance Document (6/87) required all updated

generic and product-specific product chemistry data for the Miles, Inc. fenamiphos MPs. In response, Miles, Inc. submitted new data that revised the database for product chemistry. These data were reviewed in the Fenamiphos Registration Standard Update (2/92), and additional data were then required under Guideline Reference Nos. 61-2, 61-3, 62-1, 62-2, and 62-3 for the 85% T, and under Guideline Reference Nos. 61-1, 62-1, 62-3, and 63-17 for the 72.3% FI.

Product Chemistry Data Requirements

Data requirements and data gaps are given in the product chemistry data summary tables (pp. 3-6) of the Chemistry chapter. The registrant must submit 61-2: Starting materials and manufacturing process, 61-3: Discussion of formation of impurities, 62-1: Preliminary analysis, 62-2: Certification of ingredient limits, and 62-3: Analytical methods to verify the certified limits for the 85% T (EPA Reg. No. 3125-269); 61-1: Product identity and disclosure of ingredients for the 72.3% FI (EPA Reg. No. 3125-33); and either certify that the suppliers of starting materials and the manufacturing process for the fenamiphos products have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package. These data are considered confirmatory.

Data pertaining to the nitrosamine content of some fenamiphos products are outstanding, but are not expected to be of dietary concern since nitrosamines have not been detected in previously submitted studies for some other products.

B. Human Health Assessment

1. Toxicology Assessment

a. Acute Toxicity

Table I: Acute Toxicity

Test	Result	Category
Acute Oral LD_{50} (rat)[1]	2.7 mg/kg M 3.0 mg/kg/F	I
Acute Dermal LD_{50} (rabbit)[2]	225 mg/kg M 178.8 mg/kg F	I
Acute Inhalation LC_{50} (rat)[3]	0.1 mg/L	II
Eye Irritation (rabbit)[4]	mild irritation	III
Dermal Irritation (rabbit)[4]	not irritating	IV
Skin Sensitization (guinea pig)[5]	negative	-

[1] 81-1; MRID# 33831
[2] 81-2; MRID# 37962
[3] 81-3; MRID# 154492
[4] 81-4, 81-5; MRID# 82111
[5] 81-6; MRID# 148464

The LD_{50} for 99.7% fenamiphos from an acute oral Sprague-Dawley rat study was 2.7 mg/kg and 3.0 mg/kg in males and females, respectively (Guideline 81-1). Similar oral LD_{50} values were obtained with fenamiphos in mice, rabbits, cats, dogs, and hens. In contrast, oral LD_{50} values for most metabolites of fenamiphos exceeded 1000 mg/kg (EPA Document Number 1310; MRID No. unavailable).

The LD_{50} for technical fenamiphos from an acute dermal study in New Zealand white rabbits was 225 and 178.8 mg/kg in males and females, respectively (Guideline 81-2). The LC_{50} for a rat inhalation study with 89.9% fenamiphos in THO/W74 rats of both sexes was 0.1 mg/L for a 4-hour exposure (Guideline 81-3). Ocular application of fenamiphos to rabbits produced mild chemosis and iritis with category III toxicity (Guideline 81-4).

(8)

A primary dermal irritation study indicated that fenamiphos was not a skin irritant (Guideline 81-5). No dermal sensitization occurred with 90.2% fenamiphos in guinea pigs (Guideline 81-6). Fenamiphos was not neurotoxic when administered in a single oral dose to hens in an acute delayed neurotoxicity study (Guideline 81-8; MRID No. 57606).

b. Subchronic Toxicity

Fenamiphos was administered in the diet for three months to rats in two studies. One study employed doses of 0, 4, 8, 16, or 32 ppm to Wistar rats. Plasma and red cell cholinesterase inhibition were found at 8 ppm (the LOEL, 0.4 mg/kg/day) and above. The NOEL was 4 ppm (0.2 mg/kg/day) (guideline 82-1; MRID# 117403). When Fisher 344 rats were given doses of 0, 0.36, 0.6, or 1.0 ppm, the NOEL was 1 ppm (0.05 mg/kg/day, highest dose tested) (guideline 82-1; MRID# 133475).

There were two feeding studies in beagle dogs of three months' duration. One used doses of 0, 1, 2, or 5 ppm and found a NOEL of 1.0 ppm (0.025 mg/kg/day). The LOEL was 2 ppm (0.05 mg/kg/day), based on dose-related plasma cholinesterase inhibition to this level. Erythrocyte cholinesterase inhibition and growth depression occurred at 5 ppm (guideline 82-1; MRID 111667). In a second study, the doses were 0, 0.6, 1.0, or 1.7 ppm. The NOEL was 1.0 ppm (0.23 mg/kg). The LOEL was 1.7 ppm (0.439 mg/kg/day for females and 0.358 mg/kg/day for males), based on depressed plasma cholinesterase activity (guideline 82-1; MRID 256002; EPA document TOX DER# 1310).

In a New Zealand rabbit dermal study, doses of 0, 0.5, 2.5, or 10 mg/kg/day were applied for 21 days. Slight erythema of abraded skin lasting 3 to 6 days, plus inhibition of plasma, red cell and brain cholinesterase, occurred at doses of 2.5 (LOEL) and 10 mg/kg/day. Body weight gain was reduced at 10 mg/kg/day. No effects on cholinesterase occurred at a dose of 0.5 mg/kg/day, which was the NOEL (guideline 82-2; MRID# 154497).

c. Chronic Toxicity

In a two-year chronic toxicity-carcinogenicity study in Fischer 344 rats, the dietary doses were 0, 2, 10, and 50 ppm, equivalent to 0, 0.12, 0.6, and 3.36 mg/kg/day for females and 0, 0.098, 0.46, and 2.45 mg/kg/day for males. The LOEL was the lowest dose, 2 ppm, for plasma and red cell cholinesterase inhibition; a NOEL was not established. The NOEL for systemic effects was 10 ppm. The systemic LOEL was 50 ppm, based upon reduction in body weight gain and food consumption, as well as decreased liver and increased lung weights. No dose-related neoplastic or nonneoplastic histopathological lesions occurred at any doses (guidelines 83-1, 83-2; Accession# 263729).

(9)

A combination of a one-year dog feeding study and a six-month dog feeding study demonstrated a NOEL for cholinesterase inhibition at 0.01 mg/kg/day (0.5 ppm). The LOEL was 0.03 mg/kg/day (1 ppm) for plasma cholinesterase inhibition. The systemic NOEL was 0.08 mg/kg/day (3 ppm). The systemic LOEL was 0.3 mg/kg/day (12 ppm) based on anemia in males. The beagle dogs were given 0, 1.0, 3.0 or 12.0 ppm fenamiphos in the one-year study and 0 or 0.5 ppm in the six-month study (guideline 83-1; MRID# 421836-01; 42684801).

d. Carcinogenicity

Long-term carcinogenicity studies have been conducted with fenamiphos in rats and mice. As indicated above, no compound-related neoplasms were observed after feeding at levels of 0, 2, 10, or 50 ppm to male and female Fischer 344 rats for two years. Also, no carcinogenic effects were observed in a second two-year study in Wistar rats that tested at dietary levels of 3, 10, and 30 ppm (0.15, 0.5, and 1.5 mg/kg/day) (EPA Document TOX DER# 1314; MRID No. unavailable).

An 18-month carcinogenicity study with CD albino mice employed dietary doses of 0, 2, 10, and 50 ppm (0, 0.2, 1.0, and 5.0 mg/kg/day). No compound-related neoplasms were observed. Body weight was reduced at the highest dose level (guidelines 83-1, 83-2; MRID# 98614).

The high dose levels tested in rats and mice were considered adequate for carcinogenicity testing in rats and mice. The treatment did not alter the spontaneous tumor profile in these strains of rats and mice. The chemical was classified as "Group E" based on adequate studies in two animal species.

e. Developmental Toxicity

Charles River rats were given 0, 0.25, 0.85, or 3.0 mg/kg/day of fenamiphos by gavage on gestation days 6-15. The maternal toxicity LOEL was 3 mg/kg/day, the highest dose tested, based upon increased mortality, cholinergic signs of toxicity accompanied by reductions in plasma and erythrocyte cholinesterase, and reductions in body weight gain and food consumption. The maternal NOEL was 0.85 mg/kg/day. No compound-related developmental effects were reported for external, visceral or skeletal observations at levels up to and including 3 mg/kg/day, the developmental NOEL (guideline 83-3; MRID# 412254-01).

In Chinchilla rabbits, doses of 0, 0.1, 0.5, or 2.5 mg/kg/day were given by gavage on gestation days 6-18. The maternal effects were mortality, salivation, ataxia, diarrhea, reduced weight gain and decreased food consumption. The maternal LOEL was 2.5 mg/kg/day and the NOEL was 0.5 mg/kg/day. The developmental NOEL was 2.5 mg/kg/day, the highest dose tested

(guideline 83-3; MRID# 403476-02).

f. Reproductive Toxicity

A three-generation study in Strain FB 30 rats used dietary doses of 0, 3, 10, or 30 ppm. The reproductive NOEL was 30 ppm (1.5 mg/kg/day, highest dose tested). For adult toxicity, the NOEL was 10 ppm (0.5 mg/kg/day) and the LOEL was 30 ppm based on reduced weight gain observed in the F2 males (guideline 83-4; MRID# 37979).

A two-generation study in Sprague-Dawley rats used doses of 0, 2.5, 10, or 40 ppm fenamiphos in the diet (equivalent to 0, 0.2, 0.73, or 3.2 mg/kg/day for females and 0, 0.17, 0.64, or 2.8 mg/kg/day for males). The parental NOEL was 2.5 ppm for males and below this level for females. The parental LOELs were 10 ppm for males and at 2.5 ppm for females, based on reduced body weight and weight gain, as well as plasma and red cell cholinesterase inhibition. The reproductive NOEL was 40 ppm, the highest dose (guideline 83-4; MRID# 419089-01).

The HED RfD Committee determined (5/20/93) that there was no evidence to suggest that the chemical was associated with significant developmental or reproductive toxicity under the testing conditions.

g. Mutagenicity

Fenamiphos was not mutagenic in studies designed to detect gene mutations. These were the CHO/HGPRT assay in vitro (MRID # 159127) and the Ames reversion assay with S. typhimurium (MRID# 403190-01). Structural chromosomal aberrations were not found in the dominant lethal test in mice (MRID# 86981). The B. subtilis rec assay and the unscheduled DNA synthesis assay in primary rat hepatocytes were negative (EPA document TOX DER# 5682 and MRID# 406491-01) (These studies fulfill guidelines 84-2 and 84-4).

h. Metabolism

Metabolism studies in Wistar rats indicated no major differences between oral and intravenously (i.v.) administered fenamiphos. Orally administered compound was rapidly absorbed, and compounds given by both routes were immediately metabolized and excreted. The major metabolites were sulfoxides and sulfates, nine of which were found in urine, with only a single major one in feces. Within 48 hours after oral or i.v. dosing with radiolabelled compound, 93 to 100% was found in urine, 1.5 to 3.8% in feces, and less than 0.1% in CO_2. At 48 hours, tissue levels of radioactivity were highest in liver, kidneys and skin. Based on the data, a metabolic pathway was proposed for fenamiphos (guideline 85-1; MRID# 411949-02).

i. Reference Dose

The Health Effects Division RfD Peer Review Committee met on May 20, 1993 and determined the RfD for fenamiphos was 0.0001 mg/kg/day based on results of a long-term feeding study in beagle dogs. The NOEL was 0.01 mg/kg/day for plasma cholinesterase inhibition, which was observed at 0.03 mg/kg/day. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability (U.S. EPA, 1993).

The regulatory value of 0.0005 mg/kg/day was established for this chemical by the World Health Organization (WHO) in 1987.

2. Exposure Assessment

a. Dietary

An OPP Reference Filing System (REFS) search conducted 5/26/93 revealed that there are two end-use products (EPs) of fenamiphos presently registered to Miles, Inc. (formerly Mobay Corporation) which may be used on food/feed crops grown in the U.S.; these EPs include a 15% G (Nemacur®15%; EPA Reg. No. 3125-236, dated 12/10/91) and a 3 lb/gal EC (Nemacur®3; EPA Reg. No. 3125-283, dated 2/27/92) formulations. The registrant has recently submitted copies of 10% G labels with English translations from Costa Rica, Ecuador, Guatemala, and Philippines which use fenamiphos on bananas targeted for export to the U.S. market.

A comprehensive summary of the registered food/feed use patterns of fenamiphos, based on these product labels, is presented in Tolerance Reassessment Summary (Table X; Appendix I). The conclusions regarding the reregistration eligibility of fenamiphos on the crops listed in Table IX (Appendix I) are based on the use patterns registered by the basic producer, Miles, Inc and summarized in the tolerance reassessment summary of this document.

The qualitative nature of the residue in plants is adequately understood. Studies with a variety of plants including beans, cabbage, carrots, mustard, oats, peanuts, pineapples, potatoes, soybeans, sugar beets, tobacco, tomatoes, and wheat indicate that fenamiphos is readily absorbed from soils, foliage, and fruits and translocated throughout the plant. Metabolism involves the oxidation of fenamiphos to fenamiphos sulfoxide and/or fenamiphos sulfone, subsequent hydrolysis to fenamiphos sulfoxide phenol and fenamiphos sulfone phenol, and the formation of the glucoside or other conjugates. The terminal residues of concern are fenamiphos, fenamiphos sulfoxide, and fenamiphos sulfone. (GLN 171-4 (a))

The qualitative nature of the residue in animals is not

adequately understood. Additional data are required to upgrade the previously submitted study pertaining to laying hens, and Miles Inc. had committed to submit these data by October 1993; they are currently outstanding. The nature of the residue in ruminants is adequately understood. The major residues identified in ruminant tissues and milk consisted of fenamiphos sulfoxide phenol, fenamiphos sulfoxide, fenamiphos sulfoxide phenol sulfate, fenamiphos sulfone phenol sulfate, fenamiphos phenol sulfate, des-isopropyl fenamiphos sulfoxide (in milk only), and des-isopropyl fenamiphos sulfone (in muscle only). Currently, the terminal residues of concern are fenamiphos, fenamiphos sulfoxide, fenamiphos sulfone, des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide, and des-isopropyl fenamiphos sulfone. The proposed metabolic pathway in ruminants is similar to that of plants with the exception of an additional de-isopropylation step of fenamiphos sulfoxide. No changes in the tolerance expression for animals are currently required.

The major residues identified in poultry tissues and eggs consisted of fenamiphos, fenamiphos sulfoxide phenol, fenamiphos sulfone phenol, fenamiphos phenol, fenamiphos sulfoxide, fenamiphos sulfone, and des-isopropyl fenamiphos sulfoxide (in liver only). Although the metabolism is not adequately understood in poultry, the information in the submitted metabolism study gives a reasonably reliable indication of the residues in poultry tissues and eggs. The total radioactive residue values from the metabolism study should be used when conducting the dietary risk assessment. (GLN 171-4 (b))

Adequate enforcement methods are available for the determination of residues of fenamiphos and its cholinesterase-inhibiting metabolites in/on plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists two GLC methods, each with thermionic detection (TD) and a limit of detection of 0.01 ppm. Method I (Miles, Inc Method 25402) is available for the determination of the combined residues of fenamiphos and its sulfoxide and sulfone metabolites, measured as sulfone, in/on plant commodities. Method II is available for the determination of the combined residues of fenamiphos, its sulfoxide and sulfone metabolites, des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide, and des-isopropyl fenamiphos sulfone in animal tissues and milk. The requirement for radiolabeled validation of the current enforcement methodology using representative samples from metabolism studies is waived because the enforcement analytical method has been validated and much is known about metabolism.

Residue data submitted in response to the Guidance Document and in support of petitions for the establishment of new tolerances were collected using modifications of the available PAM Vol. II methods. These modified methods, along with other methods listed in PAM Vol. II, are adequate for fenamiphos data collection and tolerance enforcement.

The FDA Pestrak database (PAM Vol. I, Appendix II) contains data concerning the applicability of all FDA multiresidue methods for recovery of fenamiphos and its sulfoxide and sulfone metabolites. Fenamiphos and its sulfoxide and sulfone metabolites are completely recovered through the Luke Method (232.2). Data pertaining to the multiresidue method testing of the des-isopropyl metabolites are no longer required. (GLNs 171-4 (c) and (d))

The qualitative nature of the residue in animals (poultry) has not been adequately described. If the requested data on poultry metabolism indicate the presence of additional metabolites of toxicological concern, relevant additional analytical methods and data may be required.

For plant commodities, storage stability data are adequate for Chinese cabbage (bok choy), eggplant, kiwifruits, non-bell peppers, and peanuts and their processed commodities. Storage stability data are also available for several commodities for which no tolerance has been established including corn, broccoli, potatoes, and carrots. Data have generally demonstrated stability of fenamiphos and metabolites for intervals up to 1170 days on some commodities.

The Agency has agreed to Miles' proposal to use storage stability studies with asparagus, bananas, garlic, and the processed commodities of cottonseed and grapes as representative data to fulfill the outstanding requirements for storage stability data on asparagus, bananas, Brussels sprouts, garlic, okra, and strawberries and the processed commodities of cottonseed, grapes, and pineapples. The data are currently outstanding. The representative data must be consistent with the storage intervals of commodities from magnitude of the residue and metabolism studies for both the commodities tested and commodities to which these data will be translated. Because all previous storage stability studies for both registered and unregistered commodities provide preliminary evidence of stability of fenamiphos residues in plant commodities, the outstanding data are considered confirmatory and the existing information sufficient to support the magnitude of residue studies and the tolerance reassessments.

No storage stability data for animal commodities are available; these data remain outstanding and are considered confirmatory. Samples from the cattle feeding studies were stored for a short interval prior to extraction, but the extracts were stored for an extended period. Submission of data pertaining to the storage stability in the extracts has been required. Because available storage stability data in plant commodities indicate that residues are generally stable, and that the samples in the feeding studies were stored as extracts which are likely to be more stable, the information available is sufficient to support

the cattle feeding studies. The additional data are required to confirm the conclusions that the existing animal commodity tolerances (which exclude poultry) are adequate. Storage stability data must be submitted for eggs. Adequate storage study data must be available to support the new poultry feeding study described under 171-4 (j). (GLN 171-4 (e))

All data for magnitude of the residue in plants have been evaluated and deemed adequate to reassess the tolerances for residues of fenamiphos; no additional data are required regarding this guideline. Field trials were performed representing the various conditions under which the pesticide could be applied. The geographical representation for each commodity is generally adequate and a sufficient number of trials reflecting representative formulation classes were conducted. The recently submitted fenamiphos labels from countries which use fenamiphos on bananas targeted for export to the U.S. market are supported by adequate residue data.

Magnitude of the residue and pyrolysis studies have been submitted for tobacco. Sufficient data are available to assess residue levels of fenamiphos and metabolites in tobacco. (GLN 171-4 (k))

All data requirements for magnitude of the residue in processed food/feed have been evaluated and deemed adequate to determine the extent to which residues of fenamiphos concentrate in food/feed items upon processing of the raw agricultural commodity. Existing food/feed additives tolerances have been reassessed and found appropriate. Residues tend to concentrate in dried, processed feed items (grape pomace, apple pomace, citrus pulp, pineapple bran, and raisin waste) and in citrus molasses. Residues also concentrate in raisins, citrus oil, and pineapple juice. A food additive tolerance for pineapple juice must be proposed. (GLN 171-4 (l))

Ruminant feeding studies are adequate to satisfy ruminant feeding study data requirements. Two studies were conducted where cattle were fed fenamiphos or fenamiphos sulfoxide at levels ranging from 0.3 to 3 times the maximum dietary burden. Residues were generally non-detectable in tissues and milk with the exception of one liver sample from the 3x cow, where residues of 0.012 ppm were found. The storage stability data to support this study remain outstanding. Because existing data provide preliminary evidence of stability of the residues, the available information is adequate to conclude that the established tolerances on livestock commodities (except poultry) are appropriate.

New poultry feeding studies are required as the existing studies have been recently evaluated and found inadequate considering the new metabolism study and proposed poultry feed item tolerance revisions. Poultry feeding studies have been submitted previously

but they are inadequate for tolerance assessment since the dosing period was inadequate. New studies must be submitted for an appropriate tolerance level determination. The total radioactive residue levels from the poultry metabolism study will be used to provide a reasonably reliable estimate of the residue levels to be used for this risk assessment. (GLN 171-4 (j))

Data pertaining to rotational crop studies are currently under review by the Agency. A preliminary review of the data indicates that residues of regulated metabolites in rotated crops are greater than 0.01 ppm at the currently established plant-back interval of 4 months. Residues in one commodity at a plant-back interval of 8 months were non-detectable. The registrant may choose to do one of the following: (1) provide limited rotational crop data at an interval greater than 4 months and increase the plant-back interval to an interval at which residues are non-detectable; or (2) if the registrant intends to keep a plant-back interval of 4 months, rotational crop tolerances must be proposed and extensive rotational crop data must be provided. These conclusions may change upon full review of the data. (GLNs 165-1 and 165-2)

b. Occupational and Residential

Mixer/Loader/Applicator Exposure

Based on the use patterns, several exposure scenarios are plausible as defined by the types of application equipment and procedures that might be employed by fenamiphos handlers. Each scenario is presented in Table II **Summary Exposure Values** along with a corresponding exposure assessment. Each scenario was defined by the types of potential mixing/loading and application equipment that could be employed based on the major use groups for fenamiphos. Exposure values were calculated based on the Pesticide Handlers Exposure Database (PHED). No chemical specific mixer/loader/applicator exposure data were submitted in support of the reregistration of fenamiphos. Mixer/loader/applicator (M/L/A) exposure data were not required by the 1987 Registration Standard for Products Containing Fenamiphos.

Additionally, Table III Exposure Scenario Descriptions for Fenamiphos have been provided to clarify Table II Summary Exposure Values. This Table summarizes the caveats and parameters specific to each exposure scenario. This Table also includes a description of the sources for each data point as well as general information pertaining to the techniques used to calculate the corresponding exposure values. The "Data Source" indicates the derivation of the measurements. The "Clothing Scenario" represents the clothing worn by test subjects during the generation of the referenced exposure values. "Equipment" describes the application techniques used to generate the

referenced data. The "Formulation" represents which end-use products are addressed. "Standard Assumptions" represent the use scenarios employed by EPA to estimate daily exposure levels. [Note: Use assumptions are based on the maximum rates allowable by the current fenamiphos labels.] The "Comments" section includes any other critical descriptions of the data including information pertaining to the quality of the exposure data (i.e., notations are only included to indicate if the data are in any way considered circumspect).

Mixer/loader exposure during chemigation and ground applications is of concern. Applicator exposure is a concern when using ground equipment applications (e.g., broadcast, banding, injection applications, etc.).

Data Quality is a critical parameter in the interpretation of the results of any exposure assessment. As indicated above, only PHED exposure data were used to develop the exposure assessments in the Summary Exposure Values Table. Data contained in PHED are assigned grades (A through E) based on the overall quality of the analytical recovery data generated concurrently with actual data points (i.e., laboratory recovery, field recovery and stability data). All PHED-based exposure assessments were based on the surrogate unit exposure values currently being used as a standard source of exposure values. All values were defined using high quality data and a large number of replicates to calculate exposures if the data were available. However, if not available, rangefinder exposure values were calculated using all data available in PHED.

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
Mixer/Loader Exposure Levels											
Open Mixing Granulars (I)	Nemacur 10 G Nemacur 15 G	All open mixing operations	Variable, see below	Variable, see below	10.0*	100 Acres	0.006	2.4×10^{-3}	0.1	4.0×10^{-2}	5.0
Open Mixing Emulsifiable Concentrates (II)	Nemacur 3	All open mixing operations	Variable, see below	Variable, see below	20.0	80	0.15	4.0×10^{-4}	4.0	1.1×10^{-2}	0.1
Open Mixing For Chemigation (III) [Only ECs are used for chemigation]	Nemacur 3	Low Pressure	Variable	Pome/Stone/Citrus Fruits, Grapes, Kiwi, Pineapple, Tree Nuts, Leather Leaf Fern, Deciduous Fruit Trees	9.0 lb/acre	200			4.5	1.2×10^{-2}	0.1

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
		Solid Set (on LUIS report)	Variable	Ornamental Non-Flowering Plants	12.0 lb/acre	20			0.6	1.6×10^{-3}	0.8
Applicator Exposure Levels											
Groundboom Application (IV)	Nemacur 3	In-Furrow	At/Pre-Plant	Cotton, Ornamental Herbaceous Plants	12.0 lb/acre	80	0.01	1.3×10^{-3}	0.16	2.1×10^{-2}	3.1
			Post-Plant	Ornamental Herbaceous Plants	12.0 lb/acre				0.16	2.1×10^{-2}	3.1
		Banding	At/Pre-Plant	Beets, Cotton, Asparagus, Peanuts	2.7 lb/acre				0.04	4.7×10^{-3}	12.5
			Pre-Transplant	Strawberry, Asparagus	2.7 lb/acre				0.04	4.7×10^{-3}	12.5

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
			At/Post-Transplant	Eggplant	2.0 lb/acre				0.03	3.5×10^{-3}	16.7
				Apple, Cherry, Citrus, Deciduous Fruit Trees, Grapes, Nectarine, Peaches, Tree Nuts	10.0 lb/acre				0.13	1.7×10^{-2}	3.8
			Bearing/Foliar	Grapes[H], Citrus[I]	10.0 lb/acre				0.13	1.7×10^{-2}	3.8
Groundboom Application (cont.) (IV)	Nemacur 3	Banding (cont.)	Fall	Ornamental Herbaceous Plants	12.0 lb/acre				0.16	2.1×10^{-2}	3.1

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
			Nonbearing Nursery-stock	Tree Nuts, Unspecified Deciduous Fruit Trees	9.0 lb/acre				0.12	1.6×10^{-2}	4.2
			No Timing Specified	Citrus, Cotton	10.0 lb/acre				0.13	1.7×10^{-2}	3.8
			Dormant, Post-Harvest	Asparagus, Raspberry	6.0 lb/acre				0.08	1.0×10^{-2}	6.3
			Post-Plant, Pre-Emergent	Asparagus	2.0 lb/acre				0.03	3.5×10^{-3}	16.7
		Soil Injection	At/Pre-Plant	Cotton	3.0 lb/acre				0.04	5.2×10^{-3}	12.5
		Broadcast/ Spray	At/Pre-Plant	Tobacco, Pineapple	20.0 lb/acre				0.27	3.5×10^{-2}	1.9

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
			Non-Bearing	Grapes, Kiwi, Unspecified Orchards	9.0 lb/acre				0.12	1.6×10^{-2}	4.2
			Post-Harvest (Ratoon)	Pineapple	10.0 lb/acre				0.13	1.7×10^{-2}	3.8
			Post-Plant, Pre-Emergent	Pineapple	3.0 lb/acre				0.04	5.2×10^{-3}	12.5

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
			Foliar	Sod Farm Turf[i], Ornamental Woody Shrubs and Vines, Ornamental Lawns and Turf, Golf Course Turf[k], Pineapple[k]	10.0 lb/acre				0.13	1.7×10^{-2}	3.8

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
Granular Application (V)	Nemacur 10G & 15G	Broadcast	Foliage on Plant[I]	Ornamental Herbaceous Plants, Commercial and Industrial Turf, Golf Course Turf, Ornamental Lawns and Turf, Ornamental Non-Flowering Plants	10.0 lb/acre	50	3.59	6.8×10^{-1}	29.91	5.7	0.02
			At/Pre-Plant	Pineapple	20.0 lb/acre	50	3.59	6.8×10^{-1}	59.8	11.3	< 0.1

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
			Post-Plant	Ornamental Herbaceous Plants (Protea), Ornamental Woody Shrubs and Vines	9.75 lb/acre	10			5.8	1.1	< 0.1
			Nursery Stock	Ornamental Shade Trees, Ornamental Herbaceous Plants, Ornamental Woody Shrubs and Vines	10.0 lb/acre	10			6.0	1.1	< 0.1

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
	Nemacur 10G & 15G	Banding	At/Pre-Plant	Iris, Lily, Narcissus,	10.0 lb/acre	5	0.001	1.0×10^{-7}	0.0008	8×10^{-8}	625
				Cotton, Cabbage, Pepper, Chinese Cabbage, Okra, Peanuts	0.17 lb/1000 row (3.0 lb/acre on 30" rows)	69			0.003	3×10^{-7}	167
			1 Year Stock	Iris, Lily, Narcissus	10.0 lb/acre	5			0.0008	8×10^{-8}	625
			Pre-Emergent, Post-Plant	Cabbage, Brussel Sprouts	0.17 lb/1000 row (3.0 lb/acre on 30" rows)	69			0.003	3×10^{-7}	167

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
Granular Application (V)	Nemacur 10G & 15G	Banding (cont.)	At/Post-Transplant	Strawberries (Production and Nonbearing Nursery Stock), Cabbage, Brussel Sprouts, Eggplant, Citrus Fruit[I], Ornamental Herbaceous Plants	10.05 lb/acre	69			0.01	1×10^{-6}	50.0
			Pre-Transplant	Strawberries (Production and Nonbearing Nursery Stock)	2.0 lb/acre	69			0.002	2×10^{-7}	250

Table II. Summary Exposure Values for Fenamiphos[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (mg/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (mg/kg/day)	MOE Dermal
			Any Time[I]	Citrus Fruits	10.05 lb/acre	69			0.01	1×10^{-6}	50.0
	Nemacur 15 G	In-Furrow	At/Pre-Plant	Cotton, Garlic	4.5 lb/acre	69			0.005	5×10^{-7}	100
			Post-Plant	Ornamental Herbaceous Plants	12.0 lb/acre	10			0.002	2×10^{-7}	250

A The EPA Reg. Nos. for the fenamiphos formulations considered in this table include: (1) Nemacur 3: 3125-283; (2) Nemacur 10G: 3125-237; and (3) Nemacur 15G: 3125-236. For post application exposure considerations, any crop with a pre-harvest interval of $\leq$ 30 days is noted on an individual basis.
B Denotes fenamiphos formulation for which this exposure scenario is applicable.
C Application type refers to the category as referred to in the LUIS system nomenclature (e.g, banding or broadcast).
D Values are defined based on the maximum application rate for the corresponding application target(s).
E Values represent the maximum number of acres which can be treated on a daily basis.
F See Table III. Exposure Scenario Descriptions For Fenamiphos below for information concerning the source of the data points used in this exposure assessment.
G Daily Exposure (mg/kg/day) = [(Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre) * Max. Treated)/60 kg]
H MOE values calculated using the following equation: MOE = NOEL/Exposure, NOEL = 0.50 mg/kg/day based on 21-day dermal study

on rabbits and the maternal toxicity from a
developmental study. (MRID #s 154497 and 403476-02).
i LUIS reported application time as "foliar" which was interpreted to mean treatments anytime foliage was available on the target of interest. No applications of fenamiphos are directly to foliar surfaces for any target/treatment scenario.
j 2 day Pre-Harvest Interval is established for this use.
k 30 day Pre-Harvest Interval is established for this use.

* For use on pineapples it is assumed that a maximum of 50 acres may be treated at the maximum rate of 20 lb ai/acre.

[Note: Based on label statements, discrepancy exists for the maximum application rate using the banding technique. Also, there is an issue concerning the dermal absorption of granular formulations (data are not documented to support the fact that granulars may not be as readily absorbed dermally as liquid formulations).]

Table III. Exposure Scenario Descriptions For Fenamiphos*

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario	Equipment	Formulation	Standard Assumptions* (8 hour workday)	Comments
Mixer/Loader Exposure Levels						
Open Mixing Granulars (I)	PHED	Coveralls, gloves	PHED Open Mixing Category	Granular	Based on various broadcast applications for which up to 1000 lb ai/day can be used.	Dermal data: All grade data/0-14 replicates Inhalation: All grade data/14 replicates
Open Mixing Emulsifiable Concentrates (II)	PHED	Long Sleeves, Long Pants, No Gloves	PHED Open Mixing Category	All Liquids	Based on broadcast preplant treatment of pineapples	50% protection factor applied to unit exposure data as no data were available for the WPS clothing scenario (coveralls over normal work clothing and gloves)
Open Mixing For Chemigation (III) [Only ECs are used]	PHED	Long Sleeves, Long Pants, No Gloves	PHED Open Mixing Category	All Liquids	See chemigation for Nemacur 3	Dermal: Grades A&B/14+ replicates for each body part. Inhalation: Grades A&B/40 replicates. 50% protection factor applied to unit exposure data as no data were available for the WPS clothing scenario (coveralls over normal work clothing and gloves)
Applicator Exposure Levels						
Groundboom Application (IV)	PHED	Long Sleeves, Long Pants, No Gloves	PHED Groundboom Category/Open Cab	All Formulations		Dermal: Grades A, B, C/6+ replicates Inhalation: Grades A, B, C/56 replicates 50% protection factor applied to unit exposure data as no data were available for the WPS clothing scenario (coveralls over normal work clothing and gloves)

Granular Application (V) Broadcast	PHED	Coveralls, gloves	PHED Solid Broadcast Spreader	Granular		Data based on combined mixer/loader/applicator activities. However, no adjustments to exposure data were completed based on the nominal exposures noted for the open mixing of granules (Scenario 1) -- these values were nominal in comparison. Dermal: Grades C&E/5+ replicates. Inhalation: Grades C&E/19 replicates.
Granular Application (V) Banding and In-Furrow	PHED	Total Deposition	PHED Granular Category	Granular		Dermal and Inhalation: Grades A & B/2 replicates 50% protection factor applied twice to unit exposure data as no data were available for the WPS clothing scenario (coverall over normal work clothing and gloves)

* Standard Assumptions are all based on an 8 hour workday. Use data were not available to justify many scenarios. Additionally, all standard assumptions were based on the maximum application rate allowable by each end-use product label.

Based on the toxicological endpoints and the significant potential for exposure, fenamiphos meets EPA's criteria for the requirement of mixer/loader/applicator exposure data.

In addition, fenamiphos has been implicated in a handler poisoning incident which resulted in hospitalizing the worker. The Agency is awaiting additional human incident data. The data would allow the Agency to evaluate the potential hazards associated with the use of this chemical which may result in human poisoning.

Post Application/Re-Entry Exposure

As previously stated, fenamiphos is applied to the soil and to be effective, it should be incorporated or irrigated into the soil immediately after treatment. With the exception of pineapples, fenamiphos is not applied to foliage (even though foliage may be present during application), and human post-application exposure to foliage should be minimal. Post-application exposure is a concern for human activities which may involve contact with the soil after treatment (i.e., applied prior to transplanting strawberries). The Registration Standard (1987) indicated that reentry data were required. About a year later, the registrant requested a waiver of the data requirements and the proposed 48 hour reentry interval for the golf course use. The Agency granted a waiver for both the data requirement and the 48 hour restricted entry interval for the golf course use.

The Agency has reviewed a foliar dislodgeable residue study submitted on pineapples in support of reregistration requirements [guideline #132-1(a)]. The study entitled, "Foliar Residue Following Application of NEMACUR to Pineapples" MRID # 419017-01 was submitted by Mobay Corporation. The study was conducted on 3 sites in Hawaii using Nemacur 3 (EC). Based on the data analysis and toxicology data, a 17 day restricted entry interval was proposed by the registrant. The study is considered acceptable. However, the following study deficiencies were noted: 1) only one fortification level, instead of a range of levels, was used to generate laboratory data; 2) incomplete weather data, 3) tank mix samples were not collected, and 4) sprayer calibration data were not provided. Nevertheless, the Agency concurs with the registrant's proposed restricted entry interval of 17 days for pineapples.

Most of the uses for fenamiphos do not result in any significant post-application human exposure since immediately following application the nematicide must be cultivated or irrigated into the soil in order to be effective. The uses that do involve contact with soil following application may result in post-application human exposure (e.g. sod farm turf). With the exception of pineapples, data have not been submitted for uses which may result in significant human exposure following

application. Data should be provided for these uses which may result in workers handling or working with or in the treated soil, (i.e. strawberries, asparagus, ornamental non-flowering plants, ornamental herbaceous plants, sod farm turf, ornamental woody shrubs and vines, and all nursery stock) to determine the appropriate REI which would minimize risk to workers. If further explanation of the use patterns may negate the need for a study, then these data should be submitted to the Agency for evaluation. The waiver previously granted for golf courses is still applicable assuming there is minimal hand contact with the turf, the grass is mechanically cut and the cuttings are mechanically bagged. Entry onto golf courses should be restricted until sprays have dried or dusts have settled.

Restricted Entry Interval (REI):

The acute dermal LD_{50} is 225 mg/kg (male rabbits) and 178.8 mg/kg (female rabbits), placing fenamiphos in Toxicity Category I for the active ingredient. Based on this classification, the criteria as established by Worker Protection Standard (WPS) for Agricultural Pesticides--40 CFR Parts 156 and 170--should be followed. The Agency recommends a 48 hour restricted entry interval (REI) for all sites (unless otherwise noted) within the scope of the WPS (see PR Notice 93-7) as a conservative measure to mitigate risk to workers entering treated areas after application. During the REI, the Agency will allow workers to enter areas treated with fenamiphos only for the few narrow exceptions allowed in the WPS.

There are several sites for which the Agency requests data and /or further clarification of the use patterns which may affect exposure potential. For these sites, the 48 hour REI should be used in the interim, until receipt and evaluation of the requested data.

Data Requirements

Based on the use information and data available, some post-application exposure data are required to support the reregistration of fenamiphos. The data to support guidelines 132-1(b): Soil residue dissipation, 133-3: Dermal exposure and 133-4: Inhalation exposure for the uses that may involve human contact with treated soil include: pre-transplant strawberries and asparagus, ornamental non-flowering plants, ornamental herbaceous plants, sod farm turf, ornamental woody shrubs and vines, and all nursery stock.

Personal Protective Equipment (PPE) Requirements:

PPE selection for mixer/loader/applicators and other handlers will be based on the end-use product. The statements to be

included on the fenamiphos labels are located on the attached Pesticide Worksheets -- Parts One and Two: Reduce PPE When Engineering Controls Used; User Safety Requirements; Application Restrictions; Entry Restrictions; Early Entry PPE; and Notification Statements.

The Agency is requiring PPE for applicators, mixer/loaders and other handlers as well as early entry workers consistent with the PPE level required for pesticides classified as Toxicity Category I for acute dermal toxicity. It should be noted that PR Notices 93-7 and 93-11 indicated that fenamiphos is classified as Toxicity Category II, and that existing data actually indicate that fenamiphos should be classified as a Toxicity Category I pesticide (for acute dermal toxicity).

3. Risk Assessment

a. Dietary

Chronic Dietary Exposure

The chronic analysis used a Reference Dose (RfD) of 0.0001 mg/kg body weight/day, based on a no-observed-effect-level (NOEL) of 0.01 mg/kg bwt/day and an uncertainty factor of 100. The NOEL is based on results of a one-year feeding study in beagle dogs which demonstrated plasma cholinesterase inhibition as an endpoint of effect.

Food uses in this analysis include all published tolerances listed in the Tolerance Index System (TIS) and 40 CFR §180.349 and §185.2950. All published tolerances are being supported in reregistration except soybeans and cocoa beans. New values for anticipated residues (ARs) have been prepared as of 12/20/93. Tolerances exist for feed items such as apple pomace, pineapple bran and raisin waste which result in secondary residues in meat of cattle, goats, horse, poultry, hogs and sheep as well as milk and eggs.

In the tolerance reassessment (Table X; Appendix I) a crop group tolerance for the citrus fruits group at 0.5 ppm and the revocation of established tolerances for grapefruit, lemons, limes, oranges and tangerines of 0.6 ppm is recommended (Codex harmonization - Table D/Citrus fruits group). In the analysis, the raw agricultural commodities (RACs) kumquat, citron and tangelo were added at 0.5 ppm and the other citrus RAC tolerances were unchanged at 0.6 ppm. Revocation of established tolerances on cocoa beans and soybeans has been recommended since there are no registered uses of fenamiphos on these crops. These RACs were left in the analysis since they are still published tolerances.

Tolerances on poultry and eggs are recommended; however, insufficient data are available to determine appropriate

tolerance levels. Interim tolerance levels for estimating of fenamiphos in/on poultry which were used in the dietary analyses have been determined. The tolerance reassessment (Table X) recommends the tolerance for peanuts be increased from 0.02 to 1.0 ppm for reregistration. The dietary analysis reflects the higher proposed value. Finally, a food additive tolerance was proposed by the registrant on pineapple juice at 0.5 ppm. This tolerance has been included in the analysis.

The dietary risk analysis included the following commodities with pending tolerances as if approved, except sugar beets.

Pending Commodity	Tolerance
Cantaloupe	0.05 ppm
Coffee beans	0.2 ppm
potatoes	0.14 ppm
sweet potatoes	0.1 ppm
carrots	0.1 ppm
tomatoes	0.5 ppm
sugar beets	Petition for registration withdrawn
peppers	0.6 ppm

Percent crop treated (PCT) information was used in the chronic dietary analysis. No known usage was indicated for some commodities and was assumed to be 100% crop treated in the analysis. Bananas and pineapple were included in the list of commodities with no known usage. These commodities are often imported and in order to estimate the amount of crop imported the USDA Pesticide Data Program Report of January-June 1992 was used. The chronic dietary analysis assumed that all imports were treated, and thus used 100% and 36% as the percent-crop-treated values for bananas and pineapples, respectively.

The chronic dietary analysis represents an overestimation of exposure and risk in that it considers risk not only from the recommended uses through reregistration, but also for uses that have not been published in the Federal Register (see Table VI). The chronic dietary analysis used tolerance level residues to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. This represents the worst-case scenario. This analysis shows the TMRC for the U.S. population represents 3121% of the RfD and the most exposed subpopulations are non-nursing infants (<1 yr) at 7983% of the RfD and children ages 1-6 at 7725% of the RfD.

The refined analysis incorporated percent crop treated information and residue data in the form of anticipated residues (see Table VI) to calculate the Anticipated Residue Contribution (ARC) for those same population groups. The ARC is considered the more accurate estimate of dietary exposure. These exposure estimates were then compared to the RfD for fenamiphos to get estimates of chronic dietary risk.

The ARC for the U.S. population from the published uses of fenamiphos being recommended through reregistration is 1.0×10^{-5} mg/kg bwt/day, which represents 10% of the RfD. The proposed tolerances being recommended through reregistration contribute 2.0×10^{-6} mg/kg bwt/day, or 2% of the RfD. Pending tolerances for fenamiphos contribute an additional 4.8×10^{-5} mg/kg bwt/day, representing 48% of the RfD. If all new commodities proposed in reregistration and all pending tolerances not yet final were published the resulting ARC would be 5.9×10^{-5} mg/kg bwt/day, representing 59% of the RfD for the general U.S. population. This number could be higher depending upon the eventual tolerance values for poultry and eggs.

The ARC from published uses for the most highly exposed population subgroup, non-nursing infants less than one year of age, is 4.0×10^{-5} mg/kg bwt/day (40% of the RfD). The ARC for new tolerances recommended in reregistration contributes less than 1.0×10^{-6} mg/kg bwt/day (0.2% of the RfD). The ARC for pending tolerances contributes 1.9×10^{-4} mg/kg bwt/day (189% of the RfD). If all new and pending tolerances were published for fenamiphos, the resulting ARC for non-nursing infants less than one would be 2.3×10^{-4} mg/kg bwt/day, representing 229% of the RfD.

Almost all of this increase is due to the pending tolerances on carrots and sweet potatoes. The U.S. population and the population subgroups considered have ARCs for chronic dietary risk below the RfD except nursing and non-nursing infants less than one year of age when all published, pending and new commodities are considered. It appears that chronic dietary risk is minimal for this chemical for published tolerances and of concern for the infants subgroup when the pending tolerances are taken into consideration with the published tolerances.

Table VI. Residue Levels used to Determine Chronic and Acute Dietary Exposure

Commodity	Tolerance, ppm	% Crop Treated	Anticipated Residues[1], ppm	Data Source[2]
Apples	0.25	2	0.005	FT
Apple Juice	--[3]	2	0.004	FT/P
Asparagus	0.02R[4]	NKU[5] (100)	0.005	FT
Bananas and Plantains	0.10	NKU (100)	0.007	FT
Bananas, Dried	--[3]	NKU (100)	--	N/A
Beet - Roots	1.5R	NIM[6] (100)	0.13	FT
Beet - Tops	1.0R	NIM (100)	0.18	FT
Bok Choy	0.5R	11	0.23	FT

Table VI. Residue Levels used to Determine Chronic and Acute Dietary Exposure

Commodity	Tolerance, ppm	% Crop Treated	Anticipated Residues[1], ppm	Data Source[2]
Brussels Sprouts	0.10	1	0.017	FT
Cabbage	0.10	1	0.014	FT
Cherries	0.25	3	0.016	FT
Cherry, juice	--[3]	3	--	N/A
Cocoa Beans[A]	0.02	use cancelled		
Cottonseed Oil[B]	--	1	0.009	FT/P
Cottonseed Meal	--[3]	1	0.005	FT/P
Eggplant	0.1	NKU (100)	0.008	FT
Garlic	0.50	NKU (100)	0.028	FT
Grapes	0.10	14	0.005	FT
Grape Juice (Wine)	--[3]	14	0.005	FT/P
Grapes, Raisins	0.3	14	0.0055	FT/P
Grapefruit	0.60[9]	20	0.011	FT
Grapefruit, Juice	--[3]	20	0.002	FT/P
Kiwifruit	0.1R	14	0.033	FT
Lemons	0.60	32	0.011	FT
Lemons, peel	--	32	0.109	FT
Lemons, juice	--[3]	32	0.002	FT
Limes	0.60	NIM (100)	0.011	FT
Limes, peel	--	NIM (100)	0.109	FT
Limes, juice	--[3]	NIM (100)	0.002	FT/P
Okra	0.30	NKU (100)	0.047	FT
Oranges	0.60	15	0.011	FT
Orange, peel	--	15	0.109	FT
Orange, juice	--[3]	15	0.002	FT/P
Peaches	0.25	1	0.018	FT
Peaches, dried	--[3]	1	--	--

Table VI. Residue Levels used to Determine Chronic and Acute Dietary Exposure

Commodity	Tolerance, ppm	% Crop Treated	Anticipated Residues[1], ppm	Data Source[2]
Peanuts[C]	0.02	2	0.042	FT
Peanut Oil	--[3]	2	0.021	FT/P
Non-Bell Peppers	0.6R	NKU (100)	0.034	FT
Pineapples	0.30	NKU[7] (36)	0.024	FT
Pineapples, dried	--[3]	NKU (36)	--	--
Pineapples, juice	0.5	NKU (36)	0.029	FT/P
Raspberries	0.1	9	0.009	FT
Soybeans[D]	0.05	use cancelled		
Strawberries	0.6	NKU (100)	0.015	FDA
Tangerines	0.6	NIM (100)	0.011	FT
Tangerine, juice	--[3]	NIM (100)	0.002	FT/P
Meat and Meat By-products[7]	0.05	100	0.00012	F
Milk	0.01	100	0.000012	F
Poultry Meat	--[9]	100	0.00011	M
Poultry Liver	--[9]	100	0.00085	M
Poultry Skin	--[9]	100	0.00019	M
Poultry Fat	--[9]	100	0.00013	M
Eggs (whole)	--[9]	100	0.000017	M

1 The anticipated residue values are the best estimates using the residue data available at the time of this document. These values have an inherent uncertainty associated with variations in analytical methods, geographical representation of field trials, seasonal variation of residue levels, etc.
2 Data source Codes: FT = Field Trial data; FT/P = Field Trial/Processing data; FDA = FDA Monitoring data; F = Feeding Study; M = metabolism study.
3 A tolerance has not been established for this processed commodity since residues are reduced upon processing, or the Agency does not typically require residue data for this processed product.
4 R indicates a tolerance with regional registration.
5 The Agency has no information indicating known domestic usage during 1989-1991
6 % crop treated data were not available for this use.
7 A value of 36% crop treated was used in calculation of the anticipated residues for the maximum animal dietary burden.
8 The category includes meat and meat by-products from cattle, goats,

horses, sheep, and hogs. It does not include poultry. This would include meat, fat, organ meats, tallow, fat, etc.
9 No tolerances have been established for poultry products. Submission of poultry feeding studies has been required.
A - Cocoa Beans were included in the Dietary exposure analysis because published tolerances still exist in 40 CFF §180.349. No refinements to PCT or ARs were made.
B - Cottonseed tolerance of 0.05 was used for cottonseed oil and meal tolerances in the dietary analysis.
C - The reassessed tolerance of 0.1 was used as a tolerance level for peanuts in the dietary analysis.
D - Soybeans were included in the Dietary Exposure analysis because published tolerances still exist in 40 CFF §180.349. PCT data available were incorporated (1%).

Acute Dietary Exposure

Cholinesterase inhibition has been identified as an acute dietary concern for fenamiphos having a toxicological endpoint of 0.5 mg/kg bwt/day (NOEL) for maternal toxicity (cholinesterase inhibition) from the rabbit developmental study.

The detailed acute dietary exposure analysis evaluates individual food consumption as reported by respondents in the USDA 77-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis assumes uniform distribution of fenamiphos in the commodity supply. Since the toxicological effect to which high end exposure is being compared in this analysis is cholinesterase inhibition, all standard DRES subgroups are of concern. The analysis includes the U.S. population-48 states and four subgroups: Infants (<1 year), children (1-6 years), females (13+ years) and males (13+ years).

The Margin of Exposure (MOE) is a measure of how closely the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). For cholinesterase inhibition, the Agency is not generally concerned unless the MOE is below 100.

In the analysis, tolerance level residues were used for all commodities except poultry and eggs. High end anticipated residues for poultry and egg tolerance values for other commodities were used to calculate the exposure of the highest exposed individual for the U.S. population in the distribution (0.05 mg/kg bwt/day) and was compared to the NOEL of 0.5 mg/kg bwt/day from the rabbit developmental study to get an MOE of 10. The table below provides the calculated MOEs for all five subgroups.

Table VII. Summary of Acute Dietary Exposures by Population Subgroups

Population Subgroups	High Exposure (mg/kg bwt/day)	Mean Exposure (mg/kg bwt/day)	MOE NOEL/High Exposure	MOE NOEL/Mean Exposure
U.S. pop. -48 states	0.05	.003144	10	159
Infants (< 1 year)	0.075	.007615	7	66
Children (1-6 years)	0.05	.007704	10	65
Females (13+ years)	0.015	.002351	33	213

Males (13+ years)	0.015	.002233	33	224

b. Occupational and Residential

In order to adequately determine the worker risk associated with a chemical, the toxicological end-points of concern must be identified in relation to the duration of these exposures. The toxicological endpoints of significance for occupational exposure are as follows:

1) The toxicological concern associated with short term hazards (one to seven days' exposure) is based on cholinesterase inhibition observed in a developmental study in the form of maternal toxicity at a NOEL of 0.5 mg/kg/day (MRID# 403476-02).

2) The occupational/residential intermediate term exposure (1 week to several months) toxicological endpoint is based on cholinesterase inhibition observed in the 21-day dermal study in rabbits. The maternal toxicity exhibited in the rabbit developmental study, consisting of salivation, ataxia, diarrhea, reduced weight gain, and mortality, is supporting evidence. Both have NOELs of 0.5 mg/kg/day (MRID#s 154497, 403476-02).

3) There are no long-term non-cancer or cancer toxicological endpoints for occupational/residential worker exposure.

The Margins of Exposure (MOE) for workers involved with mixing/loading and applying these chemicals may be estimated by the following equation:

$$MOE = \frac{\text{NOEL (mg/kg/day)}}{\text{Exposure (mg/kg/day)}}$$

A summary of the MOEs for short and intermediate term risk from exposure to fenamiphos (identical values because the NOELs are the same) are as follows:

Table VIII. The Margins of Exposure (MOEs) for Fenamiphos

Exposure Scenario	Daily Dermal Exposure (mg/kg/day)	MOE (dermal)[a]
Mixer/Loader Exposure Levels		
Open Mixing Granulars (I)	0.1	5.0
Open Mixing Emulsifiable Concentrates (EC) (II)	4.0	0.1
Open Mixing for Chemigation (III) [Only ECs]	low pressure 4.5 solid set 0.6	0.1 0.8
Applicator Exposure Levels		
Ground Boom Application (IV)	0.03 - 0.27	16.7 - 3.1
Granular Application (V)	broadcast 6.0 - 29.91 banding 0.0008 - 0.01	<0.01 - 0.02 625 - 167

a The specific MOE for each scenario is provided in Table II. Inhalation exposure is less than 5% and therefore, does not impact on the MOE.

Only the dermal MOEs are provided. Inhalation exposure to workers is generally less than 5% of the total exposure and therefore would not impact on the MOE estimates. As there is a 48 hour REI for post-application, HED is not concerned about exposure for those uses not involving treated soil.

Data Requirements

Product Chemistry and Residue Chemistry

The registrant must submit 61-2: Starting materials and manufacturing process, 61-3: Discussion of formation of impurities, 62-1: Preliminary analysis, 62-2: Certification of ingredient limits, and 62-3: Analytical methods to verify the certified limits for the 85% T (EPA Reg. No. 3125-269); 61-1: Product identity and disclosure of ingredients for the 72.3% FI (EPA Reg. No. 3125-33); and either certify that the suppliers of starting materials and the manufacturing process for the fenamiphos products have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package. These data are considered confirmatory.

Data pertaining to the nitrosamine content of some fenamiphos products are outstanding, but are not expected to be of dietary concern since nitrosamines have not been detected in previously submitted studies for some other products.

Additional confirmatory data must be submitted (see Table B of Product and Residue Chemistry Chapter for specifics) for the following: Animal metabolism (171-4(b)); Residue analytical methods (171-4(c/d)); Storage stability (171-4(e)); Magnitude of the residue in meat, milk, poultry, and eggs - eggs, and the fat, meat, and meat byproducts of poultry (171-4(j)).

In the event the required storage stability data are found to alter the exposure/risk assessment, additional data are reserved pending complete review of the remaining outstanding data (see Table B of Product and Residue Chemistry Chapter for specifics): Magnitude of the residue in meat, milk, poultry, and eggs -Milk and the fat, meat, and the meat byproducts of cattle, goats, hogs, horses, and sheep (171-4(j)).

A food additive tolerance for pineapple juice must be proposed. As there are no registered uses of fenamiphos on soybeans or cocoa beans, the Agency recommends that the established tolerance for soybeans and cocoa beans be revoked.

Occupational and Residential

Based on the use information and data available, post-application exposure data are required to support the reregistration of fenamiphos for the uses that may involve human contact with treated soil. The data to support guidelines 132-1(b): Soil residue dissipation, 133-3: Dermal exposure and 133-4: Inhalation exposure include: pre-transplant strawberries and asparagus, ornamental non-flowering plants, ornamental herbaceous plants, sod farm turf, ornamental woody shrubs and vines, and all

(4B)

nursery stock.

The data are considered confirmatroy because the recommended interim 48-hour REI is expected to offer adequate margins of exposure.

APPENDIX I

Dietary Exposure References

The following table provides the references used to support all of the food uses for the reregistration of fenamiphos.

Table IX. Dietary Exposure References

GLN: Data Requirements	References[1]
171-3: Directions for Use	
171-4 (a): Plant Metabolism	00036831, 00036837, 00038506, 00041025, 00041027, 00041028, 00041030, 00045595, 00045612, 00052504, 00052509, 00052510, 00094349, 00117405, 00119223, 00134943
171-4 (b): Animal Metabolism	00035114, 00036830, 00041206, 00134943, 40997701, 40997702
171-4 (c/d): Residue Analytical Methods	00025103, 00025115, 00052495, 00052526, 00105945, 00112903, 00112904, 00118794, 00119223, 00121865, 00128729, 40303401, 40407701, 40655401, 40655501, 41258101, 41387501, 41548502, 41575601, 41633101, 41642101
171-4 (e): Storage Stability	00036839, 00045605, 00052494, 00056049, 00112903, 00117753, 00118794, 00119223, 00152195, 40303401, 40407701, 40655401, 40655501, 41387501, 41548502
171-4 (k): Magnitude of the Residue in Plants	
Root and Tuber Vegetables Group	
- Beets, garden, roots	40655401
Leaves of Root and Tuber Vegetables Group	
- Beets, garden, tops	40655401
Bulb Vegetables Group	
- Garlic	00103094, 00153468
Brassica Leafy Vegetables Group	

GLN: Data Requirements	References[1]
- Brussels sprouts	00036826, 00036829, 00036843, 00038522, 00052508, 00118790, 41633101
- Cabbage	00036827, 00118790, 00119223, 00152195, 00154528
- Chinese cabbage (bok choy)	41387501
Legume Vegetables (Succulent/Dried) Group	
- Soybeans	00038507, 00038508, 00109257, 00154503, 00154528
Foliage of Legume Vegetables (Succulent/Dried) Group	
- Soybeans, forage and hay	00038507, 00038508, 00109257, 00154503
Fruiting Vegetables Group	
- Eggplant	40655501
- Peppers, non-bell	40303401
Citrus Fruits Group	
- Grapefruit	00038510, 00038511, 00056049, 00101570
- Lemons	00038509, 00038510, 00049668, 00056049, 00101570
- Limes	00038510, 00038511
- Oranges	00036841, 00036842, 00038510, 00038511, 00049668, 00056049, 00098611, 00101570, 00117406, 00134808, 00154528
- Tangerines	00038504
Pome Fruits Group	
- Apples	00029106, 00112904, 00118794
Stone Fruits Group	
- Cherries	00029106, 00112903, 00112904, 00118794

GLN: Data Requirements	References[1]
- Nectarines	
- Peaches	00029106, 00112904, 00118794
Small Fruits and Berries Group	
- Grapes	00028849, 00076988, 00098611, 00105945, 00154528
- Raspberries	00087556
- Strawberries	00158575, 00158576
Miscellaneous Commodities	
- Asparagus	00128729
- Bananas (Plantains)	00025103, 00025112, 00025114, 00075270, 41575601
- Cocoa beans	no MRID[1]
- Cottonseed	00052511, 00055868, 00052518, 00117754, 00118790, 00154528
- Kiwifruits	40407701
- Okra	00106037
- Peanuts	00052501, 00052525, 00078888, 40193501, 41548502
- Pineapples	00079585, 00117406, 00121866, 00134943, 00157805
- Tobacco	41258102, 42674901
171-4(l): Magnitude of the Residue in Processed Food/Feed	
- Apples	00118794
- Cocoa beans	no MRID[1]
- Cottonseed	00118790, 00052511, 41255701
- Grapefruit	00154808
- Grapes	00076988, 00105945, 41194903
- Lemons	00154808

GLN: Data Requirements	References[1]
- Limes	00154808
- Oranges	00154808
- Peanuts	00052501, 00052525, 00078888, 41255702, 41548502
- Pineapples	00134943, 41194904
- Soybeans	
- Tangerines	00154808
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	
- Fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep	00118794, 00119223, 41255706, 41548501
- Milk	
- Eggs, and the fat, meat, and meat byproducts of poultry	
165-1: Rotational Crops (Confined)	
165-2: Rotational Crops (Field)	

1 For additional details concerning the data see the Product and Residue Chemistry Chapters for the Fenamiphos RED document, Branch # 11213 by C. Olinger, dated 1/26/94.

TOLERANCE REASSESSMENT SUMMARY

Tolerances Listed Under 40 CFR §180.349(a):

The tolerances listed in 40 CFR §180.349(a) are for the combined residues of fenamiphos and its cholinesterase-inhibiting metabolites, fenamiphos sulfoxide and fenamiphos sulfone.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.349(a) for the following commodities: apples; bananas; Brussels sprouts; cabbage; cherries; cotton, seed; eggplant; garlic; grapefruit; grapes; lemons; limes; okra; oranges; peaches; peanuts; peanuts, hulls; pineapples; raspberries; strawberries; and tangerines; see Table X for modifications in commodity definitions and Table XI for recommendations for harmonizing U.S. tolerances with Codex MRLs.

A crop group tolerance of 0.5 ppm should be established for the citrus fruits group concomitant with the revocation of the established tolerances for grapefruits, lemons, limes, oranges, and tangerines of 0.6 ppm. The tolerance for peanuts should be

increased to 1.0 ppm.

The established tolerances for cocoa beans and soybeans should be revoked since there are no registered uses of fenamiphos on these crops.

Tolerances have been proposed for the following commodities: broccoli and cauliflower at 0.1 ppm; cantaloupe and coffee beans imported from Mexico at 0.05 and 0.2 ppm, respectively; potatoes at 0.14 ppm; sweet potatoes at 0.1 ppm; carrots at 0.1 ppm; tomatoes at 0.5 ppm and dried tomato pulp at 315 ppm; sugar beets roots at 0.05 ppm, sugar beet tops at 0.1 ppm, and dried sugar beet pulp at 0.1 ppm; and peppers at 0.6 ppm.

Tolerances Listed Under 40 CFR §180.349(b):

The tolerances listed in 40 CFR §180.349(b) are for food items derived from animals (except poultry) and are expressed in terms of the combined residues of fenamiphos and its cholinesterase-inhibiting metabolites fenamiphos sulfoxide, fenamiphos sulfone, des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide, and des-isopropyl fenamiphos sulfone.

The chemical name of one of the metabolites in the 40 CFR tolerance expression is incorrect. The name "ethyl-4-(methylsulfinyl)phenyl phosphoramidate" should be replaced with "ethyl-3-methyl-4-(methylsulfinyl)phenyl phosphoramidate."

Sufficient data are available to assess the adequacy of the established tolerances for milk and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep; see Table X for modifications in commodity definitions. Tolerances for poultry commodities are required but insufficient data are available to recommend appropriate levels. Additional data are required. Total radioactive residue data from poultry metabolism studies will be used at this time to provide a reasonably reliable estimate of residue levels in poultry commodities so the dietary risk from poultry commodities can be estimated.

Tolerances Listed Under 40 CFR §180.349(c):

The tolerances listed in 40 CFR §180.349(c) are with regional registrations, as defined in 180.1(n), for the combined residues of fenamiphos and its cholinesterase-inhibiting metabolites fenamiphos sulfoxide and fenamiphos sulfone.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.349(c) for the following commodities: asparagus; beets, garden, roots; beets, garden, tops; cabbage, Chinese; kiwifruits; and peppers, non-bell; see Table X for modifications in commodity definitions.

Additionally, if the proposed tolerance for peppers is established, then the existing tolerance with regional restriction for non-bell peppers should be revoked.

Tolerances Listed Under 40 CFR §185.2950:

The tolerances listed in 40 CFR §185.2950 are for the combined residues of fenamiphos and its cholinesterase-inhibiting metabolites fenamiphos sulfoxide and fenamiphos sulfone.

Sufficient data are available to ascertain the adequacy of the established food additive tolerances listed in 40 CFR §185.2950 for citrus, oil, refined, and grapes, raisins; see Table X for modifications in commodity definitions.

A food additive tolerance must be proposed for the combined residues of fenamiphos and its sulfoxide and sulfone metabolites in pineapple juice (0.5 ppm).

Tolerances Listed Under 40 CFR §186.2950:

The tolerances listed in 40 CFR §186.3500(a) are for the combined residues of fenamiphos and its sulfoxide and sulfone metabolites.

Sufficient data are available to ascertain the adequacy of the established feed additive tolerances listed in 40 CFR §186.2950 for the following commodities: apples, pomace, dried; citrus, molasses; citrus, pulp, dried; grapes, pomace, wet and dried; pineapples, bran; and grapes, raisin waste; see Table X for modifications in commodity definitions.

Table X. Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR 180.349(a):			
Apples	0.25		
Bananas	0.10		
Brussels sprouts	0.10	0.05	Codex harmonization (see Table D)
Cabbage	0.10		
Cherries	0.25		
Cocoa beans	0.02	Revoke	No registered uses exist.
Cottonseed	0.05		*Cotton, seed*
Eggplant	0.1		
Garlic	0.50		
Grapefruit Lemons Limes Oranges Tangerines	0.60	Revoke and establish at 0.5	Codex harmonization (see Table D)/*Citrus fruits group*
Grapes	0.10		
Okra	0.30		
Peaches	0.25		
Peanuts	0.02	1.0	
Peanuts, hulls	0.40		
Pineapples	0.30		
Raspberries	0.1		
Soybeans	0.05	Revoke	No registered uses exist.
Strawberries	0.6		
Tolerances listed under 40 CFR 180.349(b):			
Cattle, fat	0.05		
Cattle, meat	0.05		
Cattle (mbyp)	0.05		*Cattle, mbyp*
Goats, fat	0.05		
Goats, meat	0.05		
Goats (mbyp)	0.05		*Goats, mbyp*
Hogs, fat	0.05		
Hogs, meat	0.05		
Hogs (mbyp)	0.05		*Hogs, mbyp*
Horses, fat	0.05		
Horses, meat	0.05		
40 CFR 180.349(b) continued:			
Horses (mbyp)	0.05		*Horses, mbyp*
Milk	0.01		
Sheep, fat	0.05		

(continued)

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Sheep, meat	0.05		
Sheep (mbyp)	0.05		*Sheep, mbyp*
Tolerances listed under 40 CFR 180.349(c)			
Asparagus	0.02		
Beets, garden, roots	1.5		
Beets, garden, tops	1.0		
Bok choy	0.5		*Cabbage, Chinese*
Kiwifruit	0.1		*Kiwifruits*
Peppers, non-bell	0.6		
Tolerances listed under 40 CFR 185.2950			
Citrus oil	25.0		*Citrus, oil, refined*
Pineapples, juice	None	0.5	Must be proposed by the registrant
Raisins	0.3		*Grapes, raisins*
Tolerances listed under 40 CFR 186.2950			
Apple pomace (dried)	5.0		*Apples, pomace, dried*
Citrus molasses	2.5		*Citrus, molasses*
Citrus pulp (dried)	2.5		*Citrus, pulp, dried*
Grape pomace	1.0		*Grapes, pomace, wet and dried*
Pineapple bran	10.0	revoke	No longer considered a major feed item
Raisin waste	3.0		*Grapes, raisin waste*

CODEX HARMONIZATION

Several maximum residue limits (MRLs) for fenamiphos have been established by Codex in various commodities. The fenamiphos residues regulated by Codex and the U.S. are equivalent. The Codex MRLs (currently expressed as the sum of fenamiphos, its sulfoxide and sulfone, expressed as fenamiphos) and applicable U.S. tolerances (currently expressed in terms of the combined residues of fenamiphos and its sulfoxide and sulfone metabolites) are listed in Table XI.

Table XI. Codex MRLs and applicable U.S. tolerances. Recommendations for compatibility are based on conclusions following reassessments of U.S. tolerances (see Table X).

Commodity	MRL (mg/kg)[1]	U.S. Tolerance (ppm)	Recommendation
Bananas	0.1	0.10	
Broccoli	0.05[2]	0.1 (proposed)	
Brussels sprouts	0.05[2]	0.10	decrease U.S. tolerance
Cabbages, head	0.05[2]	0.10	
Carrot	0.2		
Cauliflower	0.05[2]	0.1 (proposed)	
Coffee beans	0.1	0.2 (proposed)	decrease proposed U.S. tolerance
Coffee beans, roasted	0.1		
Cotton seed	0.05[2]	0.05	
Grapes	0.1	0.10	
Kiwifruit	0.05[2]	0.1	
Melons, except watermelon	0.05[2]	0.05 (proposed for cantaloupes)	
Oranges, sweet, sour	0.5	0.6	decrease U.S. tolerance for citrus fruits group
Peanut	0.05[2]	0.02[3]	
Pineapple	0.05[2]	0.30	
Potato	0.2		
Soya beans (dry)	0.05[2]	0.05[4]	
Sugar beet	0.05[2]		
Sweet potato	0.1		
Tomato	0.2		

1. All fenamiphos MRLs are final (CXL).

2. At or about the limit of detection.

3. The Agency has recommended for an increase in the U.S tolerance to 1.0 ppm. This tolerance will not be compatible with the Codex MRL.

4. The Agency has recommended for revocation of this tolerance since all of the registered uses have been dropped by the registrant.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

- Compatibility between the U.S. tolerances and Codex MRLs exists for: bananas, cottonseed, and grapes.

- CBTS has recommended for an increase in the level of the U.S. tolerance for peanuts to 1.0 ppm. Compatibility cannot be achieved with the Codex MRL of 0.05 ppm.

- The level of the U.S. tolerances should be decreased to achieve compatibility with the Codex MRLs for Brussels sprouts (from 0.10 to 0.05 ppm) and oranges (from 0.6 for oranges to 0.5 ppm for citrus fruits group). The available residue data support these decreased tolerance levels.

- The U.S. tolerances for the following commodities were based on registered use patterns in the U.S. and cannot be lowered to achieve compatibility with the Codex MRLs: cabbage, kiwifruits, and pineapples.

- A tolerance of 0.05 ppm has been proposed for cantaloupe. This is compatible with the Codex MRL for "melons, except watermelon."

- A tolerance of 0.2 ppm has been proposed for coffee beans. To achieve compatibility with Codex, this proposed tolerance should be decreased to 0.1 ppm, which would be supported by the available data.

- Tolerances of 0.1 ppm have been proposed for broccoli and cauliflower. Since field residue data to support these tolerances remain outstanding, a decision regarding harmonization with Codex MRLs cannot be made at this time.

- No questions of compatibility exist with respect to commodities where: (i) no Codex MRLs have been established but U.S. tolerances exist; and (ii) Codex MRLs have been established but U.S. tolerances do not exist.

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40499803 Talbott, T. (1988) Product Chemistry of Nemacur Concentrate: AD No. 605210: AD No. 301421. Unpublished compilation prepared by Mobay Corp., 22 pp.

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RESIDUE CHEMISTRY

CBTS No.: 733
Subject: EPA Reg. No. 3125-236: Residue Data To Support An Amended Registration for Nemacur 15 Applied to Garlic Grown in the United States. Accession No. 259316, RCB No. 733. From: F. B. Suhre To: H. Jacoby Dated: 5/16/86 MRID(s):00153468

CBTS No.: 720 and 721 Subject: EPA Registration No. 3125-298 and 3125-236: Amended Registration for NEMACUR 3 and NEMACUR 15% G on Pineapples in Hawaii. Accession Number 261774, RCB Numbers 720 and 721. From: F. B. Suhre To: H. Jacoby Dated: 5/19/86 MRID(s): 00157805

CBTS No.: 895 Subject: PP#6E3403 Fenamiphos on Strawberries. Accession Number 262427, RCB No. 895. From: F. B. Suhre To: H. L. Jamerson and Toxicology Branch Dated:6/24/86 MRID(s): 00158575, 00158576

CBTS No.: 1630 Subject: PP#6E3403: Fenamiphos on Strawberries; Amendment of 10-24-86; Revised Labels (Section B) for Nemacur 3 and Nemacur 15G. No Accession Number. RCB Number 1630. From: F.B. Suhre To: H.L. Jamerson and Toxicology Branch Dated: 11/24/86 MRID(s): None

CBTS No.: 2658 Subject: PP#7F3523. Petition Review. Increase the Established 0.4 ppm Tolerance in/or on Peanut Shells to 0.5 ppm. Res. Chem. Br., HED Pet. Rev. Quick Form. From: M. J. Nelson To: L. Rossi Dated: 9/3/87 MRID(s): 40193501

CBTS No.:2842 Subject: PP#7E3559 (RCB #2842) - Fenamiphos on Non-bell Peppers - Evaluation of Analytical Methods and Residue Data (MRID Nos. 40303400 and 40303401) From: N. Dodd To: H. Jamerson and Toxicology Branch Dated: 12/22/87 MRID(s): 40303400 and 40303401

CBTS No.: 3063 Subject: PP#8E3585. Petition Review for Establishment of Tolerance(s). Evaluation of Analytical Method(s) and Residue Data. (Kiwifruit). From: M. J. Nelson To:H. L. Jamerson and Toxicology Branch Dated: 2/17/88 MRID(s): 40407700 and 40407701

CBTS No.: 4030 Subject: PP#8E3651. Fenamiphos (Nemacur®) In or On Table Beets. Evaluation of Analytical Method and Residue Data (MRID #40655400 and 40655401; DEB #4030) From: W.T. Chin To: H. L. Jamerson and Toxicology Branch Dated: 2/28/89 MRID(s): 40655400 and 40655401

CBTS No.: 4032 Subject: PP#8E3650; Fenamiphos on Eggplants - Evaluation of Analytical Methods and Residue Data (MRID #'s. 40655500 and 40655501, RCB#4032) From: F. Toghrol To: H. L. Jamerson and Toxicology Branch Dated: 8/25/88 MRID(s): 40655500 and 40655501

CBTS No.: 5054 Subject: PP#9E3721: Proposal of Tolerances for Fenamiphos (Nemacur®) in or on Coffee Beans and Cantaloupe Imported from Mexico. Evaluation of Analytical Methods and Residue Data (MRID #40971701, 02; DEB#5054) From: W. T. Chin To: S. Lewis and Toxicology Branch Dated: 7/6/89 MRID(s): 40971701 and 40971702

CBRS No.: 5790 Subject: Fenamiphos Registration Standard Follow-up: Response to Residue Chemistry Data Requirements for Processing Studies for Grapes and Pineapples [DEB No. 5790, HED Project No. 9-2139, RD Record No. 251555, MRID Nos. 41194903 and -04] From: D. F. Edwards To: D. Williams Dated: 10/13/89 MRID(s): 41194903 and 41194904

CBRS No.: 5940 Subject: Fenamiphos (aka Nemacur®), Response to Reregistration Guidance Document, Residue Chemistry Data Requirements (MRID Nos. 41255701 through 41255706, 41258101, -02, DEB No. 5940, HED Project No. 0-0067). From: E. T. Haeberer To: D. Williams Dated: 1/22/90 MRID(s): 41255701 through 41255706, 41258101, and 41258102.

CBTS No.: 6396 Subject: PP#0E3845 Fenamiphos on Bok Choy. Evaluation of Analytical Methods and Residue Data. MRID No. 413875-00, 01 DEB No. 6396 From: S. Koepke To: H. Jamerson and

Toxicology Branch Dated: 3/14/90 MRID(s): 41387500 and 41387501

CBRS No.: 6965 Subject: ID#: 3125-236, -283: Fenamiphos [Nemacur]: Amended label use for bananas. [DEB: #6965; MRID: #41575601] From: W. Anthony To: S. Lewis/ S. Jackson Dated: 11/15/90 MRID(s): 41575601

CBTS No.: 6964/7330 Subject: PP#7F3523 - Fenamiphos (Nemacur®) in/on Peanuts, Peanut Hulls, and Peanut Processed Commodities. Review of the September 29, 1989 and July 2, 1990 Amendments. (MRID Nos. 412557-02, and 415485-01 and -02) [DEB Nos. 6964 and 7330] (HED Project Nos. 0-1815 and 1-0235) From: F. D. Griffith To: S. Lewis and Toxicology Branch Dated: 1/29/91 MRID(s): 41255702, 41548501 and 41548502

CBRS No.: 6989 Subject: PP#0F3894. Petition Review for Establishment of Tolerance(s). Evaluation of Analytical Methodology and Residue Data. (Broccoli and Cauliflower). From: F. D. Griffith To: S. Lewis and Toxicology Branch Dated: 10/11/90 MRID(s): None

CBTS No.: 8028 Subject: PP#9E3721: Fenamiphos (Nemacur®) in or on Coffee Beans and Cantaloupe. Amendment of 7/13/89 (no MRID #; CBTS 8028) From: W. T. Chin To: S. Lewis and Toxicology Branch Dated: 6/5/91 MRID(s): None

CBTS Nos.: 8855/8856 Subject: ID #'s 003125-00236/003125-00283. Fenamiphos on Brussels Sprouts. Label Amendment for Nemacur 15G and Nemacur 3EC. CBTS #s' 8855/8856. DP Barcode #'s D170526/D170531. HED # 2-0397. MRID # 41633101. From: J. J. Morales To: C. Giles-Parker Dated: 1/28/92 MRID(s): 41633101

CBTS No.: 8899 Subject: PP#2E4047. Fenamiphos on Peppers. Evaluation of Residue Data and Analytical Methodology. CBTS# 8899. DP Barcode D171113. HED# 2-0444. MRID#'s 420809-00, -01. From: J. Morales To: H. Jamerson and Toxicology Branch Dated: 1/13/92 MRID(s): 42080901

CBTS No.: None Subject: PP#2E4045. Fenamiphos on Non-bell Peppers. Amendment to Review of 12/23/91. From: J. J. Morales To: H. Jamerson and Toxicology Branch Dated: 1/21/92 MRID(s): None

CBTS No.: 9737 Subject: PP#2E4047 - Fenamiphos in/on Peppers. Amendment in Response to Review of 1/13/92. DP Barcode D176833. CBTS# 9737. MRID# none. From: J. J. Morales To: H. Jamerson and Toxicology Branch Dated: 11/30/92 MRID(s): None

CBRS No.: None Subject: The Metabolism Committee Meeting Held on February 23, 1993: Fenamiphos Animal Metabolism From: C. Olinger To: The Metabolism Committee Dated: 3/8/93 MRID(s): None

CBRS No.: 11274 Subject: Reregistration of Fenamiphos: Product

and Residue Chemistry Issues; Chemical No. 100601; Branch No. 11274; DP Barcode No. D187223. From: C. Olinger To: L. Rossi Dated: 3/18/93 MRID(s): None

CBRS No.: 11843 and 11844 Subject: PP's Nos. 6F1693/G5109 and 6F1770: Fenamiphos (Nemacur) in/on Carrots, Sweet Potatoes, Potatoes, Yams, Sugar Beets, and Tomatoes. Amendment of 6F1693/6H5109 dated 4/19/1993. Revised sections B and F. Effect on Estimation of Anticipated Residues for Dietary Exposure Analysis. DP Barcodes D191115 and D191116 From: J. Garbus To: C. Giles-Parker / J. Stone Dated: 8/24/93 MRID(s): 42745100 and 42745101

CBRS No.: None Subject: Reregistration of Fenamiphos: Magnitude of Residue in Meat, Milk, Poultry, and Eggs; Chemical No. 100601; Branch No.: None; DP Barcode No.: None From: C. Olinger To: L. Rossi Dated: 7/27/93 MRID(s): 118794; 119223

CBRS No.: 10995 Subject: Reregistration of Fenamiphos: Anticipated Residue Calculations; Chemical No. 100601; Branch No. 10995; DP Barcode No. D185627. From: C. Olinger To: J. Housenger Dated: 12/20/93 MRID(s): None

CBRS No.: 12875 Subject: Reregistration of Fenamiphos: Storage Stability Issues; Chemical No. 100601; Branch No. 12875; DP Barcode No. D196987; MRID No.: None From: C. Olinger To: L. Rossi Dated: 1/07/94 MRID(s): None

CBRS No.: None Subject: Reregistration of Fenamiphos: Upgrade to Ruminant Metabolism Study; Chemical No. 100601; Branch No.: None; DP Barcode No. D195991 From: C. Olinger To: L. Rossi Dated: 1/13/94 MRID(s):

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1. Bolded references were reviewed in the Update of 2/12/92. Unbolded references were reviewed in the Residue Chemistry Science Chapter of the Reregistration Standard dated 1/2/87. Otherwise, references were reviewed as noted.