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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: May 6, 1999

MEMORANDUM

Subject: **PP8E5034**. Request for Permanent Tolerances for **Spinosad** on **Tuberous and Corm Vegetables**. **Human Health Risk Assessment.**
DP Barcode D250164 Submission S549904
PC Code 110003 40 CFR 180.495

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To: Robert Forrest/Sidney Jackson, PM Team 05
MUIERB/RD (7505C)

1.0 EXECUTIVE SUMMARY

The Interregional Research Project Number 4 (IR-4), on behalf of the Agricultural Experimental Stations of Indiana, Ohio, Washington, Wisconsin, Idaho, and Oregon, has submitted a petition for the establishment of permanent tolerances for spinosad in/on commodities of the tuberous and corm vegetables crop subgroup (Subgroup 1-C). Spinosad is an insecticide consisting of two related spinosyn compounds, Factor A and Factor D. The two active ingredients are typically present at an 85:15 (A:D) ratio.

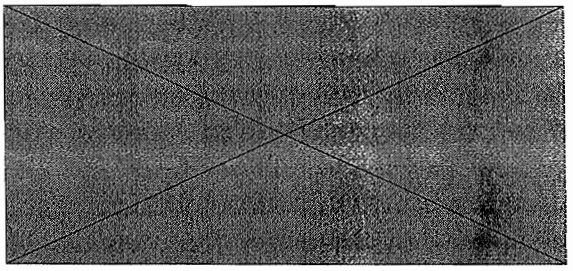
Toxicology studies did not identify acute dietary or short-term, intermediate-term, or chronic dermal or inhalation toxicity endpoints; thus these risk assessments are not required. Similarly, a carcinogenic risk assessment for spinosad is not required. The chronic dietary endpoint for spinosad comes from the chronic toxicity study in dogs (52 weeks) and is based on the occurrence of vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum enzymes such as alanine aminotranferase, and aspartate aminotransferase, and triglyceride levels at 8.46 mg/kg/day (LOAEL). The NOAEL from this study was 2.68 mg/kg/day resulting in an RfD of 0.027 mg/kg/day.

The nature of the residue for spinosad is adequately understood in both plants and animals. For all commodities, the residue of concern is parent spinosad (Factors A and D combined). Adequate enforcement methods for plants and animals have already been accepted by the Agency. The method for plants is adequate for enforcement of tolerances in/on potatoes commodities.

Application rates for spinosad are low. For tuberous and corm vegetables, the application rate ranges from 0.047 to 0.094 lb ai/A, with total seasonal application not to exceed 0.33 lb ai/acre. The pre-harvest interval is 7 days for tuberous and corm vegetables. In field studies on potatoes at 1x and 5x the application rate, residues were below the data-collection method LOD (0.005 ppm) in/on all samples.

In addition to agricultural uses, spinosad is also registered for residential use. While this use may result in non-dietary, oral exposure of children to spinosad, HED has not performed a quantitative risk assessment for this route of exposure because a qualitative analysis indicated that this route is not likely to result in exposure levels above HED's level of concern. HED performed a chronic dietary risk assessment. Highly conservative Tier 1 exposure analysis from the Dietary Exposure Evaluation System (DEEM) estimates that chronic dietary (food only) exposure will occupy 39% of the cPAD for children ages 1-6 years (the highest-exposed population subgroup). Exposure estimates for all adult populations are less than 29% of the cPAD. Based on dietary (food only) exposures HED has back-calculated Drinking Water Levels of Comparison (DWLOCs) for spinosad. The DWLOCs range from 170 ῆg/L to 750 ῆg/L; these values are well above the chronic Tier II estimated environmental concentration of 0.092 ῆg/L. Although exposure to spinosad via drinking water may occur, exposure is not expected to exceed the calculated DWLOCs for any population subgroup. **Thus, aggregated risk from exposure to spinosad is below the Agency's level of concern for adults, infants, and children.**

2.0 PHYSICOCHEMICAL PROPERTIES CHARACTERIZATION



Spinosad is a fermentation product of *Saccharopolyspora spinosa*. The product consists of two related active ingredients: **Spinosyn A** (Factor A; CAS# 131929-60-7) or 2-[(6-deoxy-2,3,4-tri-O-methyl-αϕ-L-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetra hydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetr adecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and **Spinosyn D** (Factor D; CAS# 131929-63-0) or 2-[(6-deoxy-2,3,4-tri-O-methyl-αϕ-L-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetra hydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a, 16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. Typically, the two factors are present at an 85:15 (A:D) ratio.

Both spinosyns are non-volatile, with vapor pressures of 2.4×10-10 and 1.6×10-10 mm Hg for Factors A and D, respectively. Water solubility of spinosad is dependent on both pH and the Factor of interest. Factor A is more soluble than Factor D and both are more soluble at lower pHs, as shown in Table 1, below. Because of its large size (molecular weight = 731 or 745 Daltons for Factors A and D, respectively), spinosad is not readily translocated across biological membranes, making it a non-systemic insecticide. While the parent compounds are rather stable in the absence of sunlight, exposure to light induces fairly rapid photolysis (half-lives on the order of 1 to 16 days). The products of photolysis are quickly broken down and incorporated into the general carbon pool. Thus, after treatment, spinosad will likely remain on treated surfaces where it will be rapidly degraded in the presence of sunlight.

Table 1. Physicochemical Properties of Spinosad Factors A and D.

Property	Spinosyn A	Spinosyn D
Vapor Pressure, mm Hg	2.4×10-10	1.6×10-10
Melting Point, °C	84 - 100	161 - 170
Water Solubility, ppm		
pH 5	290	28.7
pH 7	235	0.332
pH 9	16	0.053

3.0 HAZARD CHARACTERIZATION

Summarized in Table 1 are the toxicological endpoints for spinosad. For a complete hazard characterization, please see HED's previous Human Health Risk Assessment for Spinosad (G. J. Herndon, *et al.*, 4/21/99, DP Barcodes D237013, D242939,

D242941, D243796).

HED's FQPA Safety Factor Committee met on April 26, 1999 and recommended that the 10x Safety Factor to account for enhanced sensitivity of infants and children be reduced to 1x (i.e., removed). This recommendation is based on (1) the completeness of the toxicological database, (2) no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure, and (3) no requirement for a developmental neurotoxicity study.

Table 1. Summary of Toxicological Endpoints for Spinosad (HIARC, 1/22/98)

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY	MOE REQUIRED
Acute Dietary	None	No appropriate endpoint available; risk assessment not required		
Chronic Dietary	NOEL=2.68 UF = 100	systemic toxicity.	Chronic Toxicity -Dog	100
	FQPA SF = 1x	RfD = 0.027 mg/kg/day **cPAD = 0.027 mg/kg/day**		
Short-Term (Dermal)	None	No appropriate endpoint available. No dermal absorption expected based on lack of toxicity at 2000 mg/kg/day as well as molecular structure and size.		
Intermediate-Term (Dermal)	None	No appropriate endpoint available. No dermal absorption expected based on lack of toxicity at 2000 mg/kg/day as well as molecular structure and size.		
Long-Term (Dermal)	None	No appropriate endpoint available; use pattern does not indicate a need for this risk assessment		
Inhalation (Any Time Period)	None	The low toxicity, use pattern and application rate does not indicate a need for risk assessment via this route.		

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

Spinosad is an insecticide of the Naturalyte class of compounds developed by Dow-Elanco. It is highly active against target insect pests, but has low toxicity to mammals and most non-target insects. Spinosad has a novel mode of action. It is believed to act by prolonging activity of the neurotransmitter acetylcholine, but without affecting the activity of acetylcholinesterase (Salgado, V.L., 1997. "The modes of action of spinosad and other insect control products." *Down to Earth*. **52**(1):35-43).

Spinosad is registered for use on a number of agricultural commodities, including

apples, Brassica vegetables, and fruiting vegetables (excluding cucurbits). Additionally, spinosad is registered for pest control in turfgrass and ornamental plants. Registered formulations of spinosad are Success, SpinTor, and Tracer, and Conserve. These formulations vary from 1 to 4 lb ai/gallon and may be broadcast, band, or aerially applied. Application rates range from 0.023 to 0.156 lb ai/A, depending on the target pest and the crop. The maximum seasonal application rate is 0.45 lb ai/A. Application intervals range from 7 to 14 days, with restriction against too many applications per season and/or pest generation, to avoid resistance. Pre-harvest intervals range from 1 to 14 days.

4.2 Dietary Exposure

The residue of concern for spinosad is parent spinosad (as specified in 40 CFR 180.495), which is made up of Spinosyn Factors A and D. Because of the non-systemic nature of spinosad, these residues are primarily found on the surfaces of treated commodities.

Field trials with potatoes at 1x and 5x the proposed use rate showed spinosad to be non-detectable (LOD = 0.005 ppm) in/on samples collected 6-8 days after the final broadcast treatment (memo, M. Doherty, DP Barcode D250164, 3/9/99). HED recommended that the petitioner revise their proposed tolerance to be 0.02 ppm. HED has used this tolerance level in performing the dietary exposure analysis.

4.2.1 Chronic Food Exposure

HED performed a chronic dietary exposure analysis (memo, M. Doherty, DP Barcode D255571, 5/4/99) using the Dietary Exposure Evaluation Model (DEEM). This model incorporates 1989-1992 food consumption data from USDA's Continuing Survey of Food Intake by Individuals and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of spinosad in the commodity supply. The Tier 1 analysis used tolerance-level residues for all commodities with spinosad tolerances, including the pending tolerance for tuberous and corm vegetables, and assumed that all food forms contain spinosad residues at the tolerance level. Additionally, the analysis included LOQ-level residues for all other food forms (i.e., commodities without existing or pending tolerances) to cover a Section 18 request (PP#99DA0009) for the use of spinosad to control Mediterranean fruit fly. Therefore, the chronic dietary (food only) analysis represents a highly conservative estimate of dietary exposure to spinosad. HED has taken this into consideration as part of this human health risk assessment.

Estimates of chronic dietary (food only) exposure to spinosad and associated risk are shown in Table 3. Note that since the FQPA Safety Factor was reduced to 1x, the cPAD and the RfD are equal. Exposure estimates for all population subgroups except those specific to infants and children were similar to that of the general U.S. population (0.0057 mg/kg/day, 21% cPAD), ranging from 0.0046 mg/kg/day (17% cPAD) for males 20+ years to 0.0069 mg/kg/day (26% cPAD) for peoples of

non-Hispanic/non-white/non-black origins. The evenness of the exposure estimates across these subgroups indicates that exposure to spinosad is not heavily affected by ethnic, seasonal, or regional dietary influences.

4.2.2 Water

Monitoring data depicting residue levels of spinosad in drinking water are not available. Therefore, HED cannot perform a quantitative risk assessment for drinking water exposure. Instead, HED had used modeled estimated environmental concentrations (EECs), provided by EFED, and back-calculated drinking water levels of comparison (DWLOCs) to determine whether exposure to spinosad via drinking water is likely to be of concern.

EFED concludes that the available data on spinosad shows that the compound is not mobile or persistent, and therefore has little potential to leach to ground water. Spinosad may however contaminate surface water upon the release of water from flooded fields to the environment. Additionally, HED's Metabolism Assessment Review Committee determined that the spinosyn Factors A and D are not expected to reach groundwater (2/10/98). In order to assess drinking water exposures, EFED used the screening models PRZM and EXAMS to generate surface water EECs associated with application of spinosad to various crops. Modeled scenarios were selected because they are expected to represent roughly the upper 90th percentile for surface water vulnerability, given the chemical's geographic use range. The Tier 2 chronic surface water EEC for spinosad is **0.092 ῆg/L** and is based on application of the insecticide to cole crops (0.13 lb ai/A/application, 0.45 lb ai/A/season). The EEC value is over 1000 times less than the lowest DWLOC (Table 2). **Drinking water is not expected to be a significant source of exposure to spinosad.**

Table 3. Summary of Chronic Dietary Exposure and Risk and Drinking Water Levels of Comparison for Spinosad.

Population Subgroup1	Dietary Exposure, mg/kg/day2	% cPAD3	Max. H2O Exposure, mg/kg/day4	DWLOC, ῆg/L5	EEC, ῆg/L6
U.S. Population (total)	0.005658	21	0.021342	747	0.092
Non-Hisp/non-white/non-black	0.006925	26	0.020075	703	0.092
Children 1-6 yrs	0.010522	39	0.016478	165	0.092
Females 13+ (nursing)	0.006384	24	0.020616	618	0.092

1 The population subgroups shown are the U.S. population, the non-Hispanic/non-white/non-black subpopulation (whose estimated exposure is greater than that of the U.S. population), and the subpopulations within the children and female subgroups with the highest exposure.
2 Tier 1 dietary (food only) estimated exposure to spinosad.
3 % cPAD = Dietary Exposure (mg/kd/day)/(chronic RfD (mg/kg/day) ÷ FQPA Safety Factor).
4 Maximum Water Exposure = cPAD (mg/kg/day) - Dietary Exposure (mg/kg/day).
5 DWLOC = Drinking Water Level of Comparison = Maximum Water Exposure (mg/kg/day) × body weight (70 kg males, 60 kg females, 10 kg children) ÷ water consumption (2 L/day adults, 1 L/day children) × 103 ῀g/mg.
6 EEC = Estimated Environmental Concentration. Values are Tier 2 chronic estimates for surface water.

4.3 Occupational Exposure

As shown in Table 1, the HIARC was not concerned with dermal or inhalation routes of exposure for spinosad; thus, an occupational exposure assessment is not required. For a complete characterization, please see HED's previous Human Health Risk Assessment for Spinosad (G. J. Herndon, *et al.*, 4/21/99, DP Barcodes D237013, D242939, D242941, D243796).

4.4 Residential Exposure

No acute dietary, cancer, or short-, intermediate-, or chronic-term dermal or inhalation endpoints were identified by HIARC. Spinosad is currently registered on turf grass, creating a potential for non-dietary oral exposure to children who ingest grass. To calculate a quantitative dietary risk from a potential ingestion of grass (in the absence of acute-, short-, or intermediate-term oral endpoints), RAB2 would need to default to the chronic dietary endpoint. This scenario would represent a child eating grass for > 6 months continuously. Based on the low application rate for spinosad on turf (0.41 lbs.ai./A.), its non-systemic nature, its short half life (especially in sunlight), and the rapid incorporation of spinosad metabolites into the general carbon pool, RAB2 believes that residues of spinosad on turf grass after application would be low and decrease rapidly over time. RAB2 believes that it is inappropriate to perform a quantitative dietary risk representing a chronic scenario from children eating turf grass. Qualitatively, the risk from children eating turf grass does not exceed HED's level of concern.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

Based on very conservative Tier 1 chronic dietary exposure estimates, and the qualitative estimates of risks associated with exposure to spinosad in drinking water and via turf grass, the aggregate risk from exposure to spinosad is below HED's level of concern. HED has no objection to the establishment of permanent tolerances for spinosad in/on commodities of the tuberous and corm vegetables crop subgroup (1C) at 0.02 ppm.

6.0 DATA NEEDS

HED noted in the review of the residue chemistry data on tuberous and corm vegetables that the registrant is required to submit a new Section F with a requested tolerance of 0.02 ppm. No other data gaps exist with respect to petition 8E5034.

cc: M. Doherty, RAB2 Reading File, PP8E5034

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 5/11/99

SUBJECT: ID# 99DA0009 SECTION 18 EXEMPTION FOR USE OF **SPINOSAD** IN **QUARANTINED AREAS (ALL CROPS/FOODS) TO CONTROL THE FRUIT FLY (FAMILY TEPHRITIDAE)** IN **FLORIDA.**

DP Barcode: D254868
Trade Name: NAF-550 Fruit Fly Bait — Chem#: 110003
Reg#: formulation not reg. — Case#: 291753
Class: Insecticide — 40 CFR: 180.495

TO: Dan Rosenblatt/Robert Forrest, PM Team 5
MUIRB
Registration Division (7505C)

FROM: G. Jeffrey Herndon
RAB2/HED (7509C)

THRU: Michael Doherty
RAB2/HED

THRU: Richard Loranger, Branch Senior Scientist
RAB2/HED (7509C)

INTRODUCTION

The USDA Animal and Plant Health Inspection Service (APHIS) has requested a quarantine exemption for use of spinosad for the eradication of exotic fruit flies in Florida. Spinosad, formulated as NAF-550 Fruit Fly Bait (0.008% ai), is to be applied using ground or aerial equipment in non-urban areas, and only ground equipment in urban areas. For control of the Mediterranean fruit fly, Caribbean fruit fly, Mexican fruit fly and Apple maggot on fruit and

nut trees, vines, vegetables, and ornamentals, apply 12 to 48 fl.oz. of formulation (0.000069 to 0.000276 lb.ai.) per acre when used as a broadcast application or 1 to 3 fl.oz. of formulation per tree when used as a spot spray. The expected retreatment interval will be 5 to 10 days. The total number of applications must include a sufficient amount of time to cover two life cycles beyond the last fly find to ensure that immature life stages such as eggs and larvae develop and are exposed to retreatment. A 5-day retreatment interval would require 10 to 14 applications to span two life cycles in Florida during the summer. A 1 day PHI is specified.

RECOMMENDATION

The human health risk assessment that was recently completed in conjunction with the Section 3 registration of spinosad on tuberous and corm vegetables (memo of M. Doherty dated 5/6/99, concerning PP# 8E5034) took into account the aggregate risks from this proposed Section 18 use of spinosad for medfly control. In that memo, aggregate risks to infants, children, and adults were found to be acceptable. Worker risks should not exceed those calculated from the currently registered Section 3 uses of spinosad, which were found to have acceptable risk. HED has no objection to the issuance of this Section 18 registration for use of spinosad to control medflies in Florida. A time limited tolerance for residues of spinosad Factors A and D (as noted in 40 CFR 180.495) should be established at 0.02 ppm for "all crops" (using similar language to that used for the food handling establishment tolerance for chlorpyriphos - see 40 CFR 185.1000(c)) to cover residues from this proposed Section 18 use.

CONCLUSIONS

Dietary Exposure

No field trial residue data are available from the proposed use of spinosad to control medflies. Based on the ultra-low use rate and photodegradability of spinosad, RAB2 would expect residues to be non-detectable. In order to estimate what residues might be, RAB2 compared the use rates between the medfly and the crop exhibiting the highest residues (the greens subgroup of the Brassica (cole) leafy vegetables). Both use patterns specify a 1-day PHI. The highest residues were found on mustard greens (6.76 ppm) at a 1 day PHI sequential applications of spinosad at 0.089, 0.089, 0.134, and 0.134 lb.ai./A. (0.045 lb.ai./A./season). Based on this data, a tolerance of 10 ppm was established.

Due to its non-systemic nature, its short half-life (especially in sunlight), and the rapid incorporation of spinosad metabolites into the general carbon pool, RAB2 believes that residues will be driven more by the last application than the seasonal rate. RAB2 performed the following calculations:

$$\frac{\text{mustard green residue}}{\text{mustard green use rate}} = \frac{\text{medfly residue}}{\text{medfly use rate}}$$

from a per application standpoint:

6.8 ppm	=	x
0.134 lb.ai./A.		0.000276 lb.ai./A.

x = 0.014 ppm

In the absence of data, RAB2 is recommending an "all crop" tolerance be established for residues of spinosad from the proposed use on medflies. For calculating dietary risk, this involves performing a chronic assessment using a 0.02 ppm tolerance for all commodities in DEEM, other than those already covered by a higher tolerance as a result of use on growing crops. This should be viewed as a conservative risk assessment - the risk assessment assumes that every food form consumed by someone in the U.S. would have residues of spinosad on them, and that the residues would be at tolerance levels. The DEEM run performed in conjunction with the Section 3 registration of spinosad on tuberous and corm vegetables includes the 0.02 ppm "all commodities" tolerance recommended for in this Section 18 request (see memo of M. Doherty dated 5/4/99, concerning PP# 8E5034). The human health risk assessment that was recently completed in conjunction with the Section 3 registration of spinosad on tuberous and corm vegetables (memo of M. Doherty dated 5/6/99, concerning PP# 8E5034) took into account the aggregate risks from this proposed Section 18 use of spinosad for medfly control. In that memo, aggregate risks to infants, children, and adults were found to be acceptable.

Worker Exposure

RAB2 concludes that, when compared to existing Section 3 registrations, this Section 18 use of spinosad will result in:

- much lower use rates (less active ingredient handled per day)
- lower potential for exposure (formulation is ready to use - prediluted)
- lower exposure for post-application workers (the resulting application rate per acre is much lower)

RAB2 concludes that the occupational exposure from this proposed Section 18 use will not exceed (and will likely be considerably less than) the exposure from the current Section 3 uses on growing crops.

cc: RAB2 reading file, G.J. Herndon

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

MAY 20 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Memorandum

Subject: Section 18 Quarantine Exemption for the Use of Spinosad (99-DA-09) and Diazinon (99-DA-01) to Eradicate Exotic, Quarantined, Fruit Fly Species in Florida

From: James J. Jones,
Director, Registration Division,
Office of Pesticide Programs

To: Susan B. Hazen,
Acting Deputy Director for Pesticide Programs,
Office of Pesticide Programs

I. APPLICANT'S REQUEST

Applicant: U.S. Department of Agriculture, Animal and Plant Health Inspection Service

Pesticides: Spinosad (Spinosyn A CAS# 131929-60-7 and Spinosyn D CAS#131929-63-0) and Diazinon (CAS# 333-41-5)

Sites: Quarantined areas within the State of Florida where infestations of exotic fruit flies have been identified

Pests: Exotic (non-indigenous, quarantined) subtropical members of the fruit fly family, Tephritidae, including, but not limited to Mediterranean fruit fly (*Ceratitis capitata*) Melon fruit fly (*Dacus cucurbitae*) Oriental fruit fly (*Bactrocera dorsalis*) West Indian fruit fly (*Anastrepha obliqua*) Mexican fruit fly (*Anastrepha ludens*) Caribbean fruit fly (*Anastrepha suspensa*)

Use Pattern: Spinosad will be applied by air and ground equipment in quarantined areas where active infestations of exotic fruit flies have been identified. Bait spray applications will use 0.10 grams spinosad per acre (0.00025 lbs ai/acre) at between 5-10 day intervals, until eradication is achieved. Outbreaks have historically been discovered near port areas, so programs may be carried out in populated/urban settings.

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Diazinon will be used as a complementary control measure applied as a soil drench treatment around nursery stock and within the drip line of host trees where fruit fly larvae are discovered. Applications of diazinon will be made at the rate of 1.8 ounces of a.i. per 1,000 square feet of soil surface. Soil drench applications will be made in sufficient water to wet the top inch of soil. One application is authorized.

Acreage: Total acreage needed is difficult to estimate. The magnitude and scope of the pesticidal response is related to the discovery and intensity of infestations. The 1997-1998 seasons may be considered a worst-case standard. During 1997, there was a widespread outbreak requiring treatment to approximately 450 square miles. The 1998 season involved four geographically distinct eradication programs totaling just over 100 square miles of treated area.

Use Season: Use is responsive to an infestation. No treatments will be made unless a quarantined fruit fly pest is discovered. High risk season is April through July.

Duration: Quarantine exemption is authorized for three years.

Emergency/Registered Alternatives

The purpose of this quarantine exemption is to assist the USDA/APHIS and the Florida Department of Agriculture and Consumer Services (FDACS) eradicate incipient populations of non-established exotic, quarantined, fruit fly pests. There are numerous fruit fly species that are of concern to quarantine officials. The Mediterranean fruit fly is generally considered the most problematic and destructive fruit fly pest as it is capable of infesting about 250 different varieties of fruits and vegetables. Favorite host material of the Mediterranean fruit fly includes citrus fruits, stone fruits, and tomatoes. Female Mediterranean fruit flies deposit eggs directly into host fruits and vegetables. The developing maggots feed and tunnel through the host commodity causing the fruit to rot and drop from the tree.

USDA/APHIS has the overall responsibility of protecting the United States from invasive and harmful exotic pest and plant species. USDA/APHIS carries out quarantine operations under the authorities of the Organic Act and the Federal Plant Pest Act. These statutes authorize USDA/APHIS to carry out eradication programs against harmful pest and plant species which are new to or not widely prevalent throughout the United States. Species such as the Mediterranean fruit fly, Oriental fruit fly, Mexican fruit fly, and melon fly are not established in the contiguous United States. (Hawaii has an endemic population of the Mediterranean fruit fly and other fruit fly species.) Thus, their discovery triggers an eradication campaign. The discovery of quarantined pests in the United States also carries significant trade implications.

Agricultural commodities cannot be shipped out of an outbreak area where a quarantined species has been discovered. USDA/APHIS oversees trade in agricultural goods and prohibits either inter-state or international trade of agricultural commodities from a quarantined zone.

Florida is the country's second leading producer of fruits and vegetables. USDA/APHIS maintains that the economic consequences of permitting the establishment of the Mediterranean fruit fly in Florida would be catastrophic. An analysis by the applicant estimates that the economic losses associated with the establishment of this pest could total $1.5 billion annually. The trade connected with exported citrus makes up an important portion of the anticipated economic loss as trading partner countries would likely place bans on the receipt of agricultural commodities that are suspect. Trade statistics from 1996 indicate that citrus exports from Florida accounted for more than $510 million. Florida's citrus industry is reported to directly employ 120,000 people connected with production, processing and sales. Other important factors which would contribute to the economic situation should a quarantined fruit fly pest become established in Florida include crop losses, pest control costs, and quarantine compliance costs. In addition, there are expected to be collateral losses to the quality of life due in Florida if such destructive pests become established.

A characteristic of fruit fly infestations is that they can become established and spread quickly. In addition, the trade sanctions which prohibit the movement of produce and other potential host material from infested areas are activated as soon as an outbreak is discovered (i.e. free movement of goods requires affirmation that the area is free of quarantined species). Given these factors, the threshold for action against a quarantined fruit fly pest is very low. An eradication program is likely to be initiated if one pregnant female or two adult exotic fruit flies are discovered. In general, eradication programs are designed to cover two fruit fly life cycles. Fruit fly life cycles are variable across species and are also influenced by temperature. The life cycle for a Mediterranean fruit fly, for example, is between 25-31 days. USDA/APHIS typically declares an outbreak "eradicated" following two life cycles of negative trapping (i.e. no finds) following the last fly find.

USDA/APHIS and FDACS have developed a program for the prevention and detection of exotic fruit flies. The prevention efforts include quarantine agreements with the United States' trading partners where the pest is endemic, public education efforts aimed at international travelers, and border interdiction programs. Sterile Mediterranean fruit flies have also been introduced into high risk areas as an outbreak prevention strategy. The concept underlying the preventive sterile fly release program is that the sterile flies are capable of overwhelming a developing outbreak that is too small to have been detected under the states' fruit fly surveillance and monitoring program.

The exotic insect detection activities involve the placement of insect traps near host material to monitor for the presence of quarantined fruit fly species. Most frequently, traps are baited with a pheromone that is attractive to male fruit flies. A detailed federal protocol has been developed which outlines the recommended procedures for the placement and handling of fruit fly traps. The protocol calls for the placement of 10 traps per square mile in high risk areas. Because of numerous factors that make Florida a good host for exotic fruit fly species, all locations south of the Daytona Beach area are generally considered to be capable of supporting infestations.

If the prevention methods are not successful and an outbreak is discovered, USDA/APHIS and FDACS have used pesticide treatments to eradicate incipient exotic fruit fly populations. No

pesticides are labeled under section 3 for use against these pests in quarantine programs. Further, there are no alternative practices or techniques that are known to reliably eradicate a significant outbreak.

USDA/APHIS maintains that the release of sterile Mediterranean fruit flies is a control technique that is useful for decreasing the size of a developing outbreak or eradicating small background populations. During the 1997 and 1998 eradication programs, USDA/APHIS and FDACS used sterile releases following treatments of baited malathion. However, the applicant maintains that the release of sterile flies is not likely to be capable, alone, of completely eradicating a significant outbreak.

The objective of the sterile release program is to decrease the chances that a wild female fruit fly will mate with a wild male. The sterile release program involves the large-scale rearing of flies which have been irradiated during their development in order to compromise their sex organs. In other respects, these flies are normal as compared to wild flies and will even attempt to mate. However, the eggs that result from the pairing of a wild female and sterile male will not be viable. In this way, the developing population is undercut.

The sterile release technique is thought to be effective only if the sterile flies greatly outnumber wild flies. Sterile flies are typically released at a rate of 500,000 per square mile per week. Another limitation of the sterile release technique is that it is not thought to be effective against all members of the Tephritidae family. This technique has utility against the Mediterranean fruit fly, the Caribbean fruit fly, the melon fruit fly, and the Mexican fruit fly.

USDA/Agricultural Research Service (ARS) and other research organizations are also working on other techniques for controlling exotic fruit flies. USDA/ARS is experimenting with bio-control of fruit fly larvae through the release of parasitic wasps that feed on immature fruit flies. It is envisioned that this technique can be useful in depressing the size of a pest population, but it is not likely to become a key component of an eradication program. Another technique that is being researched for broad use against fruit flies involves design of a strong pheromone attractant in a bait station that is impregnated with an insecticide. This is a desirable design since no pesticides would actually have to be broadcast in the environment. The use of a methyl eugenol bait station to help control the Oriental fruit fly in this manner is already in use. However, at the present time, reliance on parasitic wasps, bait stations, or any other non-pesticidal means to address an infestation of Mediterranean fruit fly is not possible.

II. BACKGROUND

Florida's long growing season, abundant host material, and high-traffic air and shipping ports make the state vulnerable to the introduction of many exotic fruit fly infestations. There are 17 international airports in Florida. Periodic outbreaks of the Mediterranean fruit fly have been discovered in Florida since 1929. California and Florida are the two states in the contiguous United States which have the most difficulty with exotic fruit fly species. Most of Florida's outbreaks have

been discovered in proximity to a port location, particularly the Miami and Tampa Bay areas.

Exotic fruit fly outbreaks are generally attributed to the inadvertent introduction of the pest connected with international travel or the import shipment of a contaminated agricultural commodity. Fruit flies are not capable of flying from a location where they are endemic to the United States. Consequently, their discovery is thought to be connected with human activity.

Florida experienced severe Mediterranean fruit fly problems in 1997 and 1998. In 1997, a wide-ranging outbreak covering about 450 square miles in central and western Florida occurred. This outbreak is thought to have originated in the Tampa area and was largely located in Hillsborough, Polk, and Manatee Counties. During the 1998 season, Florida experienced a total of four geographically distinct outbreaks. The 1998 outbreaks were located in and around Dade County, Lake County, Highlands County, and Manatee County. These outbreaks required treatments to over 100 square miles.

Baited malathion, diazinon, and sterile releases were used against these outbreaks. Malathion has been used by quarantine officials in Florida since 1956. Malathion is applied along with a corn-based attractant by ground or aerial equipment. For recent outbreaks, malathion is applied at a rate of 2.4 ounces per acre. In order to be effective, adult fruit flies must feed on the baited malathion. Overall, malathion has been used against 13 outbreaks in Florida.

Diazinon is used to augment treatments against adult fruit flies. It is applied as a soil drench at 1.8 ounces per 1,000 square feet of soil within the drip line of host trees. The diazinon is watered into the soil to target fruit fly larvae, pupae, and hatched young adult flies that may be emerging from the ground. Limited treatments of diazinon are expected to be needed. In 1998, a total of 0.5 gallons of diazinon was used to treat 184 sites.

As part of its request, USDA/APHIS also requested a quarantine exemption for malathion. USDA/APHIS indicated that malathion would be used to support the program where it would be difficult or impossible to use spinosad. However, EPA is still in the process of considering the request for malathion. Whereas, it is possible at this time to make emergency and safety findings to support the exemption authorizations for both spinosad and diazinon.

This is the first year that spinosad has been requested for this use. The submission is based on several important considerations:

(1) Several recently completed trials comparing the effectiveness of spinosad, malathion, and SureDye (an unregistered product containing a photo active dye) against exotic fruit flies have been performed. These data suggest that spinosad provides comparable or better control of the target pest than malathion or SureDye. Field trials have been performed in Hawaii against wild Mediterranean fruit flies and also in Florida against sterile Mediterranean fruit flies.

(2) In connection with the 1997 and 1998 outbreaks of the Mediterranean fruit fly outbreaks,

the media have focused considerable attention on the quarantine operations. The coverage has frequently been critical. In addition, an active citizen opposition campaign against the use of malathion in the Tampa and Sarasota areas has developed. The groups Citizens Rally Against Malathion (CRAM) and Sarasota/Manatee Citizens Rally Against Malathion (SCRAM) have worked to bring attention to the issues surrounding the involuntary exposure of individual members of the public to pesticide treatments. SCRAM and CRAM brought a lawsuit against the state and federal entities involved in this program in June, 1998. The intent of the lawsuit was to delay or force the cancellation of plans to aerially treat the Bradenton, Florida area with baited malathion. Although the injunction was denied, the group has helped to educate the public about fruit fly pests, encourage citizen participation in prevention activities such as fruit stripping campaigns, and support political measures to address exotic fruit fly prevention.

(3) Assurance from EPA that a safety finding can be made for spinosad. Spinosad is a reduced-risk pesticide that was originally registered in 1997. The active ingredient is a bacterium derived from a fermentation process. The bacterium in the product is dead and it acts as a contact and stomach poison to numerous insect pests. It has low toxicity to mammals and non-target species. Because of its low toxicity, EPA is in a position to establish an "all commodity" tolerance for spinosad use in fruit fly quarantine programs. This will permit USDA/APHIS and FDACS to make treatments against outbreaks in any agricultural setting.

Progress Toward Registration

This is the first time that spinosad has been requested for this use in the fruit fly quarantine program under section 18. Diazinon has been requested in previous fruit fly quarantine programs.

The emergency exemption regulations do not require the Agency to consider the progress toward registration provision when evaluating an emergency exemption that addresses quarantined pests. Nevertheless, Dow-Agro Sciences, the manufacturer of spinosad, has informed EPA that they are interested in obtaining a federal registration for this use. The company has informed EPA that the application is not likely to be submitted before 2001.

EPA is not aware of plans by the registrant to obtain a section 3 registration for this use of diazinon.

III. EPA EVALUATIONS

BIOLOGICAL AND ECONOMIC ANALYSIS REVIEW

The Biological and Economic Analysis Division (BEAD) reviewed this use and concurs that the exotic fruit fly situation in Florida should be considered an "emergency" within the meaning of the section 18 regulations. The purpose of the requested program is to address incipient populations of quarantined fruit fly pests. The section 18 regulations establish that an emergency exemption may be granted in order to address outbreaks of such pests. At 40 Code of Federal Regulations

166.2(b), the section 18 regulations state that, "A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not theretofore known to be widely prevalent or distributed within and throughout the United States..."

BEAD's review also addressed the issue of whether alternative pesticides or agronomic practices might address the problems associated with the introduction of exotic fruit flies. Their conclusion was that in spite of the substantial investment in prevention and detection activities by USDA/APHIS and FDACS, it is not possible to eradicate infestations of these exotic fruit fly species without the availability of an efficacious insecticide. Alternative control measures include sterile fly release, fruit stripping and host elimination. None of these methods are considered to be effective enough to reliably eradicate an outbreak.

No economic analysis is needed in order to support the issuance of these actions. EPA can substantiate the emergency condition on the grounds that the requested program is intended to address quarantined pests (40 CFR 166.2(b)) and no alternative pesticides or practices are available to provide the necessary control of these pests.

RISK ASSESSMENT AND STATUTORY FINDINGS

Spinosad

The Health Effects Division (HED) reviewed this request and has no objection to the issuance of this section 18 exemption. An aggregate risk assessment which considers exposures to spinosad from dietary consumption of treated foods, drinking water, and residential uses of the pesticide was performed. The assessment concluded that risks from this section 18 request as well as all registered uses of spinosad appear to be below the level of concern for adults, infants and children.

The attached time-limited tolerance document establishes an "all commodity" tolerance for spinosad in connection with use of the pesticide under this section 18 quarantine exemption. It will be published in the upcoming weeks. The tolerance is set at the Level of Quantitation (LOQ) of 0.02 parts per million for spinosad for commodities without existing, separate, tolerances under 40 CFR 180.495.

HED performed a conservative exposure assessment of the dietary risks from spinosad. A Tier 1 exposure analysis using the Dietary Exposure Evaluation System (DEEM) with residues at the tolerance level estimates that chronic dietary exposure does not exceed the level of concern for any population subgroup. The highest exposed population subgroup is children ages 1-6 years with exposures at 39% of the chronic Population Adjusted Dose (cPAD). The FQPA Safety Factor Committee has determined that spinosad poses no special risk to the rat or rabbit in utero or through postnatal exposure. Thus, the Safety Factor was removed (1x). Exposure estimates for adults are less than 29% of the cPAD.

Toxicology studies did not identify acute dietary or short-term, intermediate-term, or chronic dermal or inhalation endpoints. So risk assessments for these exposure durations are not necessary. Similarly, a carcinogenic risk assessment for spinosad is not required.

The RfD is based on the results of a chronic dietary exposure study with a NOAEL of 2.68 mg/kg/day and an uncertainty factor of 100. The effect in the chronic dietary study is based on the occurrence of vacuolation in glandular cells and lymphatic tissues, arteritis, and increases in serum enzymes such as alanine aminotransferase, and aspartate aminotransferase, and triglyceride levels.

OPP's Minor Use, Inerts, and Emergency Response Branch (MUIERB) reviewed the confidential statement of formula and label for this unregistered formulation (NAF-550 Fruit Fly Bait) in order to assess whether the inert ingredients in the product are acceptable. Based on verbal communication from the Team Leader of the Inerts Team on April 28, 1999, it appears that the ingredients in the proposed formulation are permissible for use in a pesticide intended for food use.

MUIERB's review did note a problem with the "Ingredient Statement" of the submitted label. The "Ingredient Statement" on the proposed label contains a partial list of the inert ingredients ("Inert Ingredients: includes water, sugars and attractants.....99.992%"). This characterization of the inert ingredients is problematic because EPA labeling policy requires that if any individual inert ingredient is listed (i.e. "water, sugars...."), than each ingredient within the formulation must also be listed. Alternatively, it is also acceptable to not list any individual inert ingredients and have labeling text that simply reads, "Inert Ingredients... 99.992%". This problem was verbally conveyed to the registrant on April 28, 1999.

OCCUPATIONAL EXPOSURE RISK -- HAZARD ASSESSMENT

No toxicity end-points were identified for spinosad for either dermal or inhalation exposure routes. Therefore, an occupational exposure risk assessment is not needed.

Diazinon

HED considered this request and concluded that residues on food will not exceed established tolerance levels. Given the limited use pattern, non-systemic nature of diazinon, and practice of discarding fallen fruit suspected of containing larvae of the quarantined pest, HED does not expect residues on crops. A total of 10 gallons of diazinon was requested by USDA/APHIS. In order to emphasize the limited nature of diazinon use under this quarantine exemption, HED noted that if the entire quantity of diazinon requested is actually used, less than 15 acres will be treated.

With respect to worker exposure and risk, HED concluded that the use will not exceed (and will likely be considerably less than) the exposure from the current section 3 uses on fruit and nut trees. This is based on the following factors: (1) the application is comparable to existing registrations (2) less active ingredient will be handled by workers (3) less dermal and inhalation exposure than current section 3 uses is expected and (4) the use is likely to result in low exposure for

post-application workers.

RISK CHARACTERIZATION MEASURES FOR ECOLOGICAL EFFECTS

Spinosad

The Environmental Fate and Effects Division (EFED) reviewed this request and concluded that no acute or chronic levels of concern are exceeded for terrestrial animals, aquatic animals, or plants. The available data indicate that spinosad is slightly to practically non-toxic to birds; practically non-toxic to small mammals; slightly toxic to freshwater fish and freshwater invertebrates. However, spinosad is very highly toxic to the eastern oyster and honey bee.

Risk quotients (RQs) were calculated for terrestrial and aquatic species based on high-end exposure assumptions from this use. RQs were less than 1 for all species in connection with potential exposures from both ground and aerial applications of spinosad.

Risk Quotients for Spinosad
Medfly Aerial Spray; 10 Applications at 0.00025 lbs ai/A (5 day reapplication interval)
(Terrestrial EEC's Based on Fate Program Maximum Residue*
Aquatic EEC's Based on GENEEC Model)

Surrogate Species[a]	Exposure	Toxicity	Risk Quotient
Bobwhite and Mallard Subacute Dietary $LC50_b$	0.29 ppm	>5156 ppm	<0.1
Bobwhite Reproduction $NOAEC_c$	0.29 ppm	550 ppm	<1
Bluegill Freshwater Fish Acute $LC50_d$	0.005 ppb	5.94 ppm	<0.05
Rainbow Trout Fish Early Life Stage $NOAEC_e$	0.0007 ppb	0.498 ppm	<1
Aquatic Invertebrate (Daphnid) Acute $LC50_f$	0.005 ppb	14 ppm	<0.05
Daphnid Life Cycle $NOAEC_g$	0.0007 ppb	0.0006 ppm	<1
Estuarine (Sheepshead minnow) Acute $LC50_h$	0.005 ppb	7.87 ppm	<0.05
Sheepshead Minnow Early Life Stage $(NOAEC)_i$	0.0007 ppb	1.15	<1
Estuarine (Oyster) $EC50_j$	0.005 ppb	0.3 ppm	<0.05
Mysid Life Cycle $NOAEC_k$	0.0007 ppb	0.0842	<1
Seedling Emergence $EC25_l$	0. 18 lb ai/A	<25% response	<1
Vegetative Vigor $EC25_l$	0. 18 lb ai/A	<25% response	<1
(Nonvascular plant) Freshwater Diatom $EC50_m$	0.005 ppb	0.09 ppm	<1

Footnotes:

* FATE Program parameters used: initial concentration of 0.06 lb ai/A based on maximum Kenaga value on short grass; aerobic soil metabolism half-life of 17.3 days; 10 applications at 0.00025 lb al/A with a 5 day re-application interval.

[a] most sensitive species tested is used as surrogate; birds are considered to be protective of mammals, since mouse acute toxicity data show an LD_{50} value for mice > 5,000 mg/kg (practically non-toxic), which is higher than thatfor birds (LD50

> 1333 for both bobwhite and mallard).
[b] MRIDs 43414530 and 43414531; terrestrial EEC was derived using short-grass Kenaga, with no degradation.
[c] MRIDs 43414532 and 43414533
[d] MRID 43414534
[e] MRID 43414541
[f] MRID 43414537
[g] MRID 43848801
[h] MRID 43414540
[I] MRID 44420601
[j] MRID 43444104
[k] MRID 44420602
[l] terrestrial plants tested for seedling emergence and vegetative vigor include: corn, oats, wheat, onion, carrots, radish, soybean, cucumber, sunflower and tomato; MRID 43848802; Tier I vegetative vigor/emergence study results showed less than a 25% detrimental effect, when compared to the controls, for all species tested at an application rate of 0.18 lb ai/A. Since the proposed maximum application rate is 0.00025 lb ai/a it is presumed that acute high and endangered species levels of concern are not exceeded for terrestrial or semi-aquatic plants
[m] MRID 43414543 and 43414546

Risk Quotients for Spinosad
Medfly Ground Spray; 1 Applications at 0.00025 lbs ai/A
(Aquatic EEC's Based on Urban Runoff Model)

Surrogate Species	Exposure	Toxicity	Risk Quotient
Bluegill Freshwater Fish Acute LC50	0.15 ppb	5.94 ppm	<0.05
Rainbow Trout Fish Early Life Stage NOAEC	0.15 ppb	0.498 ppm	<1
Aquatic Invertebrate (Daphnid) Acute LC50	0.15 ppb	14 ppm	<0.05
Daphnid Life Cycle NOAEC	0.15 ppb	0.0006 ppm	<1
Estuarine (Sheepshead minnow) Acute LC50	0.15 ppb	7.87 ppm	<0.05
Sheepshead Minnow Early Life Stage (NOAEC)	0.15 ppb	1.15	<1
Estuarine (Oyster) EC50	0.15 ppb	0.3 ppm	<0.05
Mysid Life Cycle NOAEC	0.15 ppb	0.0842	<1
(Nonvascular plant) Freshwater Diatom EC50	0.15 ppb	0.09 ppm	<1

Spinosad is highly toxic to honey bees with an acute contact LC-50 value of 0.0029 ug/bee. Spinosad's toxicity to honey bees is greater than that of most organophosphate pesticides, for example, malathion (0.29 ug/bee) and parathion (0.175 ug/bee). In order to mitigate the risks to honey bees from this use, EFED recommends the following language for the product labeling: "Notify beekeepers 24 hours prior to a treatment, providing advice on how they can protect their bees." In addition, because of spinosad's toxicity to molluscs, EFED recommends modifying the "Environmental Hazards" statement on the proposed labeling to read, "This pesticide is highly toxic to aquatic invertebrates." Alternatively, EFED supports modifying this statement so that it reads, "This product is highly toxic to molluscs."

With respect to endangered species, no levels of concern are exceeded by the proposed use pattern.

Diazinon

EFED reviewed this request and concluded that levels of concern, particularly for birds, could be exceeded. Small mammals and aquatic life are also potentially at risk although they are not thought to be as sensitive to diazinon exposure as birds. Diazinon is highly toxic to birds (avian LD-50 levels for mallards are 1.18 mg/kg). There are documented incidents of avian mortality involving diazinon use. Based on the requested use rate in connection with this section 18 of 4.9 pounds a.i./acre, EFED's risk assessment for the chemical suggests that risk quotients may be as high as 74 times the level of concern. (Based on comparing the EEC/LC-50 against a level of concern of 0.5. EEC = range from 1176 ppm to 661.5 ppm and LC-50 = 32 ppm yields a risk quotient of 37 and 21. These risk quotients are 74 and 42 times, respectively, the LOC of 0.5). In order to mitigate risks to avian species, EFED recommended that treated areas should be covered following an application.

EFED has concerns about the impacts of this program on endangered species. It is thought that the program might pose hazards to endangered and threatened birds and small mammals. However, since the treatment area is determined in response to an outbreak, it is impossible for EFED to provide specific comments on the impacts of the section 18 to endangered species. The review acknowledges that the quarantine program contains a provision which will permit the U.S. Fish and Wildlife Service to be consulted prior to the initiation of any eradication campaign so impact against endangered and threatened species can be mitigated.

Diazinon is toxic to aquatic invertebrates and fish. The EFED risk assessment for aquatic species involved an LC-50 of 0.2 microgram/L for aquatic invertebrates (Gammarus fasciatus) and 90 microgram/L for bluegill sunfish. The peak EEC is 26 microgram/L. That yields a risk quotient (EEC/LC-50) of 0.29 for fish and 130 for aquatic invertebrates. Thus, the risk quotient is 0.58 times the LOC of 0.5 for fish and 260 times the LOC for aquatic invertebrates.

RISK CHARACTERIZATION MEASURES FOR ENVIRONMENTAL FATE EFFECTS

Spinosad

EFED believes that the available data on spinosad shows that the compound is not mobile or persistent and, therefore, has little potential to leach to ground water or to be transported to surface waters in high concentrations. Spinosad has been shown to photolyze extremely rapidly in a buffered aqueous solution (half-life of less than one-day). However, since EFED has not evaluated spinosad in this formulation and it is not clear that such rapid photolysis would take place for the material in the formulated bait, EFED used a more conservative soil photolysis value in its

evaluation of this request.

The main route of dissipation for spinosad in soil is biotic degradation. There are two active components of spinosad, spinosad Factor A and spinosad Factor D. Factor A has a half-life that ranges from 9.4 to 17.3 days. Factor D's half-life is 14.5 days. Under anaerobic conditions, the degradation of spinosad is significantly longer for both Factor A (half-life of 161 days) and Factor D (half-life of 250 days).

EFED evaluated data from different soil types that suggests that spinosad Factor A is relatively immobile. Further, spinosad Factor A does not appear to bioaccumulate.

Diazinon

The major route of dissipation for diazinon is through aerobic soil metabolism (half-life of 31 days). EFED considers diazinon to possess moderate aqueous solubility and small adsorption Freundlich coefficients (3.7 - 11.7).

SCI-GROW and PRZM/EXAMS modeling analysis using the highest permitted rates for diazinon indicates that the chemical could reach ground-water and surface water to a significant degree. Monitoring data also suggest that diazinon can be detected in groundwater and surface water. For example, groundwater monitoring data from the National Water Quality Assessment Program showed that diazinon was detected in 109 out of 3,243 samples analyzed. NWQA program data also suggest that diazinon is frequently found in surface water. It was detected in 1,900 out of 5,214 samples. Many of the surface water detections occurred in urban settings.

The table below contains modeling and monitoring information on diazinon levels in ground and surface water:

Estimated and Measured Concentration of Diazinon in Ground and Surface Water		
Source	Groundwater	Surface Water
Modeling	acute and chronic: 0.56 microgram/L	acute: 26 microgram/L chronic: 4.3 microgram/L
Monitoring (not final)	PGWDB: trace - 3.2 microgram/L NAWQA: 0.002 - 0.16 microgram/L	NAWQA: 0.002 - 3.8 microgram/L

In order to protect water resources, OPP/EFED recommends that the diazinon soil drench treatments should be restricted if wells or other potable drinking water sources will be contaminated from the treatment of adjacent trees.

IV. RECOMMENDATION

I recommend the authorization of a section 18 quarantine exemption for the use of spinosad and diazinon against exotic, quarantined fruit fly species in Florida. This recommendation is based on the following:

1. OPP/BEAD believes that emergency conditions exist due to the fact that Florida is vulnerable to infestations of numerous exotic, quarantined fruit fly species. Sterile fruit fly releases, border enforcement, trade arrangements with foreign countries, and public education campaigns are all important prevention strategies that help decrease the likelihood that an infestation of a quarantined fruit fly pest will occur. However, the periodic outbreaks of these pests in Florida suggests that prevention efforts, alone, cannot keep these species out of Florida. The section 18 regulations envision the need to authorize the use of pesticides under an emergency exemption program in order to address incipient outbreaks of quarantined pest species. Without an adequate eradication program, there is a high likelihood that Mediterranean fruit fly and possibly other quarantined pests will become endemic in Florida.

2. HED reviewed this exposure and concluded that occupational risks, dietary risks, aggregate risks, and risk to infants and children are within the limits established under FQPA. HED has no objections to use under these emergency exemptions of diazinon or spinosad.

3. A tolerance in connection with this section 18 use will be established through the publication of a *Federal Register* notice. A tolerance of 0.02 ppm for spinosad will be set on "all agricultural" commodities in connection with use of the pesticide in quarantine programs where a separate tolerance does not already exist. The time-limited tolerance will be set to expire on December 1, 2002. HED's review suggests that no time-limited tolerance is needed in connection with the diazinon soil drench use.

4. EFED has concluded that the use of spinosad under this section 18 is not likely to produce hazard levels for wildlife and non-target species that exceed EPA's level of concern. Spinosad is considered practically non-toxic to birds and small mammals and slightly toxic to freshwater fish and invertebrates. EFED calculated Risk Quotients for terrestrial and aquatic species in connection with exposure to spinosad under this exemption. Risk Quotients were less than 1 for all species.

   Spinosad is considered to be very highly toxic to the eastern oyster and honey bees. EFED recommended mitigation measures in order to diminish the impacts of use under this exemption to these species. With respect to honey bees, the authorization carries a special

notification provision under which bee keepers must be given 24 hours advance notice of any planned treatments. The authorization also strengthens the "Environmental Hazards" section of the proposed labeling. Labels are to carry the following language, "This pesticide is highly toxic to aquatic invertebrates."

5. EFED believes the available data on spinosad suggests that the compound is not mobile or persistent and, therefore, has little potential to leach to ground water or to be transported to surface water in high concentrations. Spinosad has been shown to photolyze rapidly. However, this formulation of spinosad has not been separately evaluated. Spinosad Factor A has a half-life that ranges from 9 - 17 days. Spinosad Factor D's half-life is 14 days. Spinosad does not appear to bioaccumulate.

6. EFED evaluated this request for diazinon and concluded that, in spite of the small volume of pesticide requested, levels of concern, particularly for birds could be exceeded. Small mammals and aquatic life are also potentially at risk. Diazinon is highly toxic to birds (avian LD-50 for mallards is 1.18 mg/kg). EFED's risk assessment suggests that the Risk Quotient may exceed the level of concern for birds by a large margin. In order to mitigate risks to avian species, EFED advised that the immediate treatment area should be covered with a plastic tarp following the soil drench application. EFED also has concerns for endangered and threatened species in connection with diazinon use. Since it is not possible to evaluate impacts against endangered and threatened species without considering an identified treatment area, EFED has no specific comments or recommendations in this area. However, EFED's review noted that prior to initiating treatments, USDA/APHIS will be consulting with the U.S. Fish and Wildlife Service in order to minimize impacts on endangered and threatened species.

   Diazinon is toxic to aquatic invertebrates and fish and Risk Quotients appear to exceed the level of concern. The "Environmental Hazards" statement on the product label carries the following language, "This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in areas near the application site....."

7. Diazinon's half-life is considered to be 31 days. Monitoring data and modeling analysis suggests that diazinon can reach ground-water and surface water to a significant degree. Monitoring data from the National Water Quality Assessment Program showed that diazinon was detected in 109 out of 3,243 samples analyzed. It was also detected in 1,900 out of 5214 surface water samples. Although this use represents a small percentage of the overall

volume of diazinon used in Florida, EFED recommended that treatments should be restricted if wells or other potable drinking water sources will be contaminated from the treatment of adjacent trees. The exemption authorization contains this restriction.

8. This is the first year that this use of spinosad has been requested under a section 18 quarantine exemption. Efforts to obtain a section 3 registration for this use are underway. This is a repeat request for diazinon for this use.

Marcia E. Mulkey

Susan B. Hazen
Acting Deputy Director for Pesticide Programs
Office of Pesticide Programs

5/20/99
Date