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Service

Spinosad Bait Spray Applications

Human Health Risk Assessment, March 1999

DRAFT

Human Health Risk Assessment: Spinosad Bait Spray Applications

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Human Health Risk Assessment: Spinosad Insecticide Applications

I. INTRODUCTION

The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) conducts programs to detect and eradicate various species of exotic fruit flies (ie. Mediterranean fruit fly, Mexican fruit fly) that enter the United States. A variety of eradication methods are available for use in urban, suburban, rural, and agricultural areas to prevent exotic fruit flies from becoming established and destroying economically important crops. APHIS is constantly seeking more effective eradication methods that pose lower potential risk to humans and their environment. Laboratory testing results have shown Spinosad to have good efficacy against Mediterranean and Mexican fruit flies. Field studies are planned to further test this insecticide. If these studies show good efficacy and the Environmental Protection Agency approves registration of this insecticide, routine program applications could be anticipated in future eradication efforts.

The methods used to assess the environmental risks associated with program applications of the insecticide are summarized in chapter 2. These methods generally conform to those used by other federal agencies. Information generated by other agencies is used where possible, but certain elements of the risk assessment are unique to USDA and reflect the specific goals of the risk assessment.

Bait spray applications are the method being analyzed for use of Spinosad insecticide. When possible, quantitative risk assessments are performed for each application method and rate where there is apparent potential for human health effects. Qualitative risk assessments are done when adequate data for quantitative calculations are unavailable (primarily with effects from chronic exposure). The risk of human health effects are quantified by estimating possible exposure doses to workers and to the general population and then comparing those doses to exposure levels not known to cause effects in humans or laboratory animals.

II. RISK ASSESSMENT METHODS

The risk assessment procedures used in this document are similar to those recommended by the National Research Council of the National Academy of Sciences in *Risk Assessment in the Federal Government, Managing the Process* (NRC, 1983) which recommends that risk assessments be conducted in four stages: exposure assessment, hazard identification, dose-response assessment, and risk characterization. Risk assessment, as opposed to risk management, is intended to be an objective application of this four-stage process. Risk management is the procedure used to decide which alternatives should be pursued based on the risk assessment results in the context of other factors such as feasibility and socioeconomic effects.

In implementing the guidelines provided by NRC (1983), this risk assessment uses existing government risk assessments and risk assessment methodologies within the constraints of the specific program goals and objectives of USDA. The use of existing risk assessments avoids a duplication of effort, capitalizes on the expertise of other organizations, and makes a more concise document.

II.A. EXPOSURE ASSESSMENTS

II.A.1. Exposure Scenarios. The pesticide exposure scenarios considered in this risk assessment are determined by the application method and the chemical and toxicological properties of the pesticide. Depending on the properties and application method, the risk assessment considers acute, subchronic, or chronic durations of oral, dermal, inhalation or combined exposure to the pesticide by the general population and pesticide workers.

Exposure scenarios are classified into three categories (routine, extreme, and accidental) based upon the plausible range of exposures. Not all categories of scenarios are applicable to all exposure routes. For example, direct consumption of pesticide product from traps would only occur in an accidental scenario, not in routine or extreme scenarios. Routine exposures assume that the recommended application rates for pesticides are followed and that recommended safety precautions are followed. Furthermore, routine exposures are based on the most likely estimates of physiological modeling parameters such as food or water consumption rates and values for skin surface exposure. Extreme exposures assume that recommended procedures and precautions are not followed and use more conservative, but still plausible, modeling parameters that increase the estimate of exposure. Extreme exposures usually consider only acute exposure, because it is not plausible to assume that safety recommendations will be completely disregarded or that individuals will consume extraordinary quantities of contaminated media for prolonged periods of time. Accidental exposure scenarios assume some form of equipment failure or gross human error. Although accidental exposure scenarios are *worst case* scenarios within the context of the risk assessment, they are, intended, nonetheless, to represent realistic rather than catastrophic events. Some accidental exposure scenarios are specific to a program activity, but many are extensions of extreme exposure scenarios. As with extreme exposures, accidental exposure scenarios consider only acute exposure.

Table II-1 summarizes the factor(s) used in determining the typical conditions for acute exposure scenarios by the exposure route. Not all scenarios apply to every program activity. Aerial spraying of pesticide near residential areas involves a relatively high likelihood of general population exposure under diverse conditions. This activity may involve a broad range of exposure scenarios.

Variability within scenarios for exposure media is considered by estimating exposed or absorbed doses for individuals of different age groups (i.e., adults, young children, toddlers, and infants). Children may behave in ways that increase the exposure to applied pesticides (e.g., long periods of outdoor play, pica, or imprudent consumption of contaminated media or materials). In addition, anatomical and physiological factors, such as body surface area, breathing rates, and consumption rates for food and water, are not linearly related to body weight and age (EPA/ECAO, 1989a, 1990; EPA/OHEA, 1988). Consequently, the models used to estimate the exposure dose (e.g., mg pesticide/kg body weight/day) based on chemical concentrations in environmental media (e.g., ppm in air, water, soil, vegetation, or food) generally indicate that children, compared to individuals of different age groups, are exposed to the highest doses of chemicals for a given environmental concentration. Appendix 1 summarizes the anatomical, physiological, and behavioral parameters used most often in this risk assessment.

Many acute exposure scenarios for the general population involve a single route of exposure. Sometimes this is justified by the nature of the exposure scenario. When the relative significance of different routes of exposure is not apparent, the single-route exposure scenarios are used to identify the most important routes and help to determine the most relevant multiple-route-exposure.

Scenarios involving occupational exposure are based on job categories (i.e., pilots, backpack applicators, mixers/loaders, and ground personnel) and include routine, extreme, and accidental exposure scenarios.

An attempt is made to limit the number of scenarios assessed for each program activity because an excessive number of scenarios can obscure rather than clarify the findings of the risk assessment. For example, if the acute exposure scenario for toddlers swimming for 4 hours in a pool within the treatment area suggests a very low degree of potential hazard based upon the regulatory reference value (RRV), then there is no need to calculate exposures of adults swimming for 4 hours in a pool within the treatment area. RRVs for non-carcinogenic effects are exposure values intended to be estimates of exposure levels at or below the level where no adverse effects are expected for a given exposure route and duration.

Table II-1: Factors Defining Acute Exposure Scenarios Involving the General Population

Exposure Route	Media	Factors Defining Exposure Scenarios for:			Applicability
		Routine	*Extreme*	*Accidental*	
Oral	contaminated vegetables	age	amount consumed	NA[1]	aerial or backpack application
	runoff water	age	amount consumed	NA	aerial or backpack application
	groundwater	age	amount consumed	NA	aerial or backpack application
	contaminated soil	age, child and toddler	amount consumed and time after treating	pica behavior	aerial or backpack application
	direct consumption of pesticide	NA	NA	age	traps or bait stations
Dermal	contaminated vegetation and soil	age	duration of exposure	NA	aerial or backpack application
	directly sprayed	age	skin surface exposed	number of exposures	aerial application
Inhalation	outdoor air	age	duration of exposure	time after treating	aerial application
Multiple-Route	swimming pool: oral, dermal, and inhalation	age	duration of exposure	NA	aerial application

	consumption of contaminated groundwater, vegetation, and breathing contaminated air	age	duration of exposure and amount consumed	NA	aerial application

[1]NA = Not applicable

II.A.2. Environmental Fate and Transport. After characterizing the necessary exposure scenarios, a variety of exposure assessment methods are applied to estimate levels of the pesticide in environmental media and exposed or absorbed doses among humans. These methods fall into five categories including the GLEAMS root zone model, groundwater, runoff water, surface water, and soil.

II.A.2.a. GLEAMS Model - GLEAMS is a mathematical model that simulates pesticide transport by examining the pesticide characteristics, the climatic conditions (precipitation and temperature), and the soil characteristics of a field-size area (Davis et al., 1990). The GLEAMS model consists of separate inputs for hydrology, erosion, and pesticide components. These parameters consider land use, soil characteristics, and the slope of the site. The GLEAMS model only applies to pervious or unpaved parts of the treatment area. A 0.25-acre lot size is assumed to represent the typical residential area. The overland flow method is used for determining the mass of pesticides sorbed to sediments and dissolved in water. Rainfall data from the National Climatic Data Center (U.S. Department of Commerce, 1983) for calender years are input into GLEAMS for each site. Solar radiation data are obtained from the GLEAMS model.

II.A.2.b. Runoff Water from Impervious Surfaces - If the GLEAMS analysis indicates that runoff from pervious areas is negligible, then runoff from the impervious areas is the only source of pesticide in the surface waters. A concentration in this runoff is estimated by dividing the mass of the pesticide available per unit area by the rainfall per unit area. This assumes that all of the pesticide available in the impervious area would go into solution in the runoff water. The amount of the pesticide remaining on the impervious surfaces when the storm events occurred is determined by estimating the degradation rate on asphalt. Such estimates, in turn, are usually based on degradation rates of the pesticide from other impervious materials such as teflon (CDFA, 1991). To determine the mass of the pesticide remaining at the time of the storm event, the following equation is used:

$$M_{t1} = M_{t0}\,(e)^{-k(\Delta t)} \qquad (1)$$

where:

M = mass of the pesticide (mg/m^2) at t_1 or t_0

Δt = interval in days

k = degradation rate of the pesticide on asphalt ($days^{-1}$)

Once the remaining mass of the pesticide is determined, the rain volume is estimated. In urban settings, the "first flush" or first 0.5 inches of rainfall are regarded as containing most of the pollutants that accumulate on impervious surfaces, such as parking lots, roads, cars, and rooftops (Schueler, 1987). The concentration of the pesticide in this runoff water is determined using the following equation:

$$C_{RW} = M_{t1}/R \qquad (2)$$

where:

C_{RW} = pesticide concentration in runoff water (mg/L)
t_1 = time of storm event
M = mass of the pesticide at time t_1 (mg/m^2)
R = volume of rain (L/m^2)

II.A.2.c. Groundwater - The GLEAMS model provides estimates of pesticide concentrations in leachate entering groundwater, but does not model the concentration in the groundwater after dilution by the volume of groundwater in the aquifer. Groundwater models are available (EPA/EAG, 1988), but are highly site specific and much more data intensive than root zone models. For this risk assessment, the concentration in groundwater is used as a direct index of exposure. This procedure is highly conservative, and any indication of risk using this approach is appropriately qualified in the risk characterization.

II.A.2.d. Surface Water - In some cases, the concentration of pesticide in a small contained pond is estimated directly from the application rate. This estimate usually is used to support the exposure scenario of a toddler drinking directly from a backyard pond shortly after application of the pesticide. This estimate is made from the equation:

$$CONC = APP_{rate}/(Dpth)(1{,}000\ L/m^3) \qquad (3)$$

where:

CONC = concentration of the pesticide in water (mg/L)
APP_{rate} = application rate of the pesticide (mg/m^2)
Dpth = mixing depth of the water (m)

II.A.3. Dose Estimates

After environmental exposure levels have been estimated, oral, dermal, and inhalation exposure levels are converted to common units of dose (e.g., mg pesticide/kg of body weight/day for oral or dermal). These conversions are made to help identify the major routes of exposure and to facilitate estimating the effects of multiple-route exposure to contaminants. Generally, RRVs for dermal exposure are not available; therefore, the hazards associated with systemic toxic effects after dermal exposure to a compound usually are compared to RRVs for oral exposure (e.g., reference doses (RfDs)). The risk characterization of inhalation exposure is expressed in units comparable to the RRVs (e.g., threshold limit values (TLV) or reference concentrations (RfCs)).

II.A.3.a. Oral -- If the consumed quantity of a toxic agent is known (e.g., as in the accidental ingestion of the pesticide in the trap contents), this quantity is divided by the body weight to convert the intake amount to a dose:

$$D = I/BW \tag{4}$$

where:
- D = dose (mg/kg)
- I = intake (mg)
- BW = body weight (kg)

When material containing a known or estimated concentration of toxic agent is consumed, the intake may be expressed as the product of the concentration and the quantity of contaminated material consumed:

$$I = C(Amt) \tag{5}$$

where:
- C = concentration of toxic agent in material (mg/kg)
- Amt = amount (kg) of material consumed

In scenarios involving the consumption of contaminated water during swimming, consumption estimates, as summarized in appendix 1, are available as volume of water per unit of time. Assuming a water density of unity, water volume is converted to water weight. This intake rate is multiplied by the assumed duration of swimming to obtain the weight of water consumed. This amount is then used in equation 5 to derive the intake of the pesticide.

Pesticide intake from the consumption of contaminated fish can be calculated from the equation:

$$I = C_{H_2O}\ (Amt_{fish})\ BCF \tag{6}$$

where:
- C_{H_2O} = concentration of toxic agent in water (mg/L)
- Amt = amount (kg) of toxic agent in fish
- BCF = bioconcentration factor (L/kg)

The amount calculated from this equation may be used in equation 4 to estimate the consumed dose. Most BCFs reported in the literature attempt to measure the steady state levels of chemicals between the fish and the water. Also, many BCFs are based on whole-body residues. Consequently, for such measurements, the use of equation 6 assumes that the fish was exposed to a constant concentration of the agent in water prior to consumption, that the level in the fish had reached steady-state with the level in the water, that the concentration of the agent in the edible portion of the fish is the same as the concentration in the whole-body, and that any food processing prior to consumption (e.g. cooking) does not substantially affect the residues in the edible portion of the fish. These factors should be addressed whenever equation 6 is used in an exposure assessment.

II.A.3.b. Dermal -- There are various methods for converting dermal exposure to dose units of mg/kg/day (EPA/OHEA, 1992). These methods, briefly discussed in section II.A.3.b.1, are designed to estimate absorbed dose when the critical components of the exposure can be defined by duration, exposed skin area, and concentration of the toxic agent in a defined vehicle. Many exposure scenarios of concern, however, involve human activities that cannot be modeled easily. Methods specific to such exposure assessments are presented in section II.A.3.b.2.

II.A.3.b.1. General Methods. Simple dermal exposure can be expressed as the cumulative dose absorbed per unit area of exposed skin for each exposure event. Event, in this context, refers to one exposure episode that lasts for a specified duration. For organic and inorganic compounds in acqueous solutions, Fick's First Law at steady-state can be used to estimate dermal absorption by the equation:

$$DA = K_p \ (C_w) \ t_{event} \qquad (7)$$

where:

DA = dermal absorption (mg pesticide/cm^2 exposed skin - event)
K_p = permeability coefficient in acqueous solution (cm/hr)
C_w = concentration of chemical in water (mg/cm^3)
t_{event} = duration of the event in hours

Several methods of estimating the permeability coefficient (K_p) of chemicals in acqueous solution have been described (EPA/OHEA, 1992). Most models for estimating permeability have only been validated for specific classes of compounds. Since most organic compounds of concern are lipophilic, many models are not applicable. If an estimate of K_p is not available for an organic compound, K_p may be estimated from the following relationship:

$$\log K_p = -2.72 + 0.71 \log K_{ow} - 0.0061 \ MW \qquad (8)$$

where:

$K_p = 10^{\log K_p}$
K_{ow} = octanol-water partition coefficient of compound
MW = molecular weight

A more conservative approach from the standpoint of potential permeability of hydrophilic compounds is taken by Flynn (1990; as cited in EPA/OHEA, 1992). Compounds of high molecular weight (>150) and log Kow less than 0.5 are assumed to have a log K_p equal to -5. This approach assures that permeability of the compound through the skin will not be underestimated and this approach will be taken in this risk assessment.

For soil, EPA/OHEA (1992) recommends estimating the fraction of agent that is absorbed from soil adhering to the skin:

$$DA = C_{soil} \ (AF) \ ABS_{fract} \qquad (9)$$

where:

C_{soil} = contaminant concentration in soil (mg/mg)
AF = adherence factor of soil to skin (mg/cm^2 -event)
ABS_{fract} = absorption fraction

Once the cumulative absorbed dose (DA) has been estimated, the daily absorbed intake can be calculated as:

$$I = DA\ (N)\ A \tag{10}$$

where:

I = intake of agent (mg/day)
N = number of events/day
A = skin surface (cm^2) in contact with the agent

Equation 9 can be applied to media other than soil for which some estimate of applied dose and general absorption fraction can be made. Combining equations 9 and 10 for this exposure calculation gives the following equation:

$$I = AD\ (ABS_{fract}) \tag{11}$$

where:

AD = applied dose (mg)

As discussed in EPA/OHEA (1992), the use of general absorption fractions (i.e. those that are not time specific) is inconsistent with the physiological and chemical processes of dermal transport. Nonetheless, this approach is useful in cases where K_p is not known and cannot be estimated reliably or when exposure cannot be characterized adequately by concentration, duration, and exposed surface area (section II.A.3.b.2).

II.A.3.b.2. Indirect Dermal Exposure. Many exposures of concern to this risk assessment involve complex activities that may not be modeled adequately by Fick's First Law or other factors that may affect the accuracy of the estimate. Such activities include dermal exposures from aerial sprays, exposure from contaminated surfaces, and occupational exposures during handling or application.

II.A.3.b.2.i. Direct Sprays -- Direct sprays are modeled using Fick's Law, the nominal or estimated deposition rate, and assuming the conservative approach to permeability taken by Flynn (1990; as cited in EPA/OHEA, 1992). None of these approaches directly considers the effect(s) of any of the materials in the formulation on the dermal absorption of the active ingredient. Some of the pesticide formulations of concern to this risk assessment are known to contain materials such as protein baits, lures, and dispersants. Materials like protein baits are likely to make the active ingredient less bioavailable, but also may cause the active ingredient to adhere more strongly to the skin surface. Empirical data are not adequate to permit a quantitative or even qualitative assessment on the net effect that these materials may have on the absorption of the active toxic agent.

II.A.3.b.2.ii. Dermal Uptake from Contaminated Surfaces -- Another common exposure scenario in this risk assessment involves the uptake of a pesticide from contaminated vegetation. In this exposure scenario, the amount of toxic agent absorbed will depend on the amount of agent transferred to the skin surface. Ross et al. (1990) measured the adherence of chlorpyrifos and d-trans allethrin to individuals exercising on a contaminated carpet. Based on this analysis, Fong et al. (1990) proposed a time-dependent transfer coefficient model in which the transfer rate R_t in cm^2/hour is defined as:

$$R_t = R_{Dosimeter}/R_{Surface}\ (t) \qquad (12)$$

where:

R_t = transfer rate in cm^2/hr
$R_{Dosimeter}$ = total residue mass measured on the subject (mg)
$R_{Surface}$ = residue density on the surface (mg/cm^2)
t = time (hours)

In the study by Ross et al. (1990) no substantial differences were noted between the transfer rates for chlorpyrifos (3,160 cm^2/hour) and d-trans allethrin (3,802 cm^2/hour). This study also demonstrated that transfer rates decreased with time over a 12.5-hour post-application period. This pattern was associated with a decrease in the dislodgeable residues. As a consequence, this method can overestimate uptake if nominal application rates rather than dislodgeable residues are used as the index of exposure.

Fong et al. (1990) also suggest that the transfer rate, R_t, is linearly related to the surface area of the individuals involved in the activity so that:

$$R_{t1} = SA_1\ (R_{t2})/SA_2 \qquad (13)$$

where:

R_t = transfer rate
SA = body surface area

Transfer rates of 3,500 and 1,050 cm^2/hour for adults and young children, respectively, are estimated from the data of Ross et al. (1990). The amount of chemical adhering to the skin of an individual who spends a specified amount of time on a contaminated surface can be calculated as:

$$DOSE_{Exp} = R_t\ (DUR)\ R_{Surface} \qquad (14)$$

where:

$DOSE_{Exp}$ = exposed dose adhering to the skin surface (mg)
DUR = duration of activity (hours)

Fong et al. (1990) recommend using the product of $DOSE_{Exp}$ and an estimate of absorption fraction to derive the absorbed dose (see equation 14). This is essentially the approach used by CDHS (1991) to estimate the dermal uptake of malathion from turf. A study by Harris and Solomon (1992) can be used to examine this approach. In this study, a group of five volunteers entered an area 1 hour after it had been treated with a 190 g/L solution of 2,4-D amine at an application rate of 11 $\mu g/cm^2$. The average amount of 2,4-D amine as a dislodgeable residue was measured at 8.5×10^{-4} mg/cm^2. The volunteers, wearing only shorts and short-sleeved shirts, stayed on the plot for 1 hour, exposing as much of their body surface as possible to the treated turf. Based on an analysis of urinary metabolites, the average absorbed dose was 1.83×10^{-3} mg/kg. Applying the method of Fong et al. (1990) to this scenario and using an absorption efficiency of 5.3% for 2,4-D from Feldmann and Maibach (1974), the expected dose level would be 0.02915 mg/kg (1.1×10^{-2} mg/cm^2 x 3,500 cm^2/hour x 1 hour x 0.053 ÷ 70 kg), which overestimates exposure by a factor of 15.92. Using dislodgeable residues, rather than the nominal application rate, the estimated exposure is 2.2×10^{-3} mg/kg, which is almost the same as the observed mean dose rate. Overestimates are to be expected when using nominal application rates (Ross et al., 1990).

One limitation of this analysis may be the use of 2,4-D absorption data for 2,4-D amine. The physical properties of these compounds differ considerably, particularly in respect to water solubility. This affects the estimate of the K_{ow} and the calculation of the K_p The absorption rate for 2,4-D amine is considerably lower than 2,4-D. The quantitative effect that these differences make on measuring absorption efficiencies (as in the 1974 study of Feldman and Maibach) is unclear. Confidence in this method is increased by the agreement between dose levels measured by Harris and Solomon (1992) and the dose estimates based on Ross et al. (1990).

The use of Fick's First Law does not satisfactorily model the results of Harris and Solomon (1992). Using the application concentration of 190 g/L (190 mg/mL), assuming an actual exposed surface area of 3,000 cm^2 (60% of surface area for an adult wearing shorts, a short sleeve shirt, and shoes), and taking the K_p estimate of 0.00011 for 2,4-D amine, the estimated absorbed dose would be 0.9 mg/kg (190 mg/mL x 0.00011 x 1 hour x 3,000 ÷ 70 kg). This overestimates dose by a factor of approximately 500. As discussed in section II.A.3.b.2., this method is best applied to more simple exposure scenarios.

II.A.3.b.2.iii. Dermal Uptake by Job Category -- Various job categories, such as backpack sprayer, are similar among pesticide applications. Studies are available in which absorbed doses were measured among a group of workers applying a pesticide at a given application rate. Estimates of the absorbed dose for different application rates and exposure durations can be determined by the equation:

$$DOSE_{Est} = DOSE_{Meas}\ (DUR_{Est})\ AR_{Est}/DUR_{Meas}\ (AR_{Meas}) \qquad (15)$$

where:

Meas = experimentally measured values
Est = values of chemical for which dose is being estimated
AR = application rate (mg/m^2)

Dermal exposure to the chemical of concern can be estimated from studies involving the job category of concern. Adjustments must be made for differences in exposure duration, application rate and rates of dermal absorption as in the equation:

$$DOSE_{Est} = DOSE_{Meas}\ (DUR_{Est})\ AR_{Est}\ (K_{pEst})/DUR_{Meas}\ (AR_{Meas})\ K_{pMeas} \qquad (16)$$

Although this approach may be preferable to attempts to model complex job activities using Fick's Law, the linear relationships implied in equations 15 and 16 have not been validated. In addition to this inherent uncertainty, there may be a lack of correspondence among job activities. Measured data for specific job activities may not correspond well to the job activities of the agency program. Differences in dermal penetration rates among pesticides are not addressed by the data in studies specific to certain pesticides.

II.A.3.b.2.iv. Dermal Uptake from Accidental Spills -- This risk assessment concerns an accidental exposure. One such exposure involves the worker who accidently spills chemical onto the skin and does not wash for a given period of time. This exposure can be modeled by Fick's First Law. In estimating absorbed dose, the amount spilled is incidental; the important exposure parameters are the concentration of active ingredient in the solution, the nature of the vehicle, and the skin surface over which the material is spilled. The presence or absence of contaminated clothing is also a critical factor. Dermal absorption is likely to be greater if spilled on clothing than on bare skin. The clothing would act as a poultice, retarding evaporation and drainage. The most conservative exposure scenario would be to assume a spill on clothing that was not removed by the individual.

II.A.3.c. Inhalation. The conversion of inhalation exposure to an equivalent oral dose is inappropriate for risk characterization. The risk characterization of inhalation exposure is made relative to RRVs for inhalation exposure (TLVs or RfCs). Guidelines for deriving RfCs are applicable for a limited number of chemical classes (EPA/ECAO, 1990). Threshold limit values are available for some compounds from the ACGIH (1990) and OSHA regulations. When such values are not available, the following equation may be used as a default:

$$I = CONC_{air}\ (BR)\ ABS_{fract}\ (DUR) \tag{17}$$

where:

I = intake (mg)
BR = breathing rate (m^3/hour)
ABS = absorption fraction
DUR = duration (hours)

This is a crude and highly uncertain approximations. As with the absorption efficiency for dermal exposure, the absorption fraction for inhalation exposure does not reflect any meaningful kinetic process. No general default values for the absorption fraction are currently in use.

II.A.4. Site Selection. The broad geographic distribution of program activities requires consideration of those areas where insect infestations are anticipated by APHIS. The potential areas of infestation are based on previous history of introduction and shipping patterns for commodities known to be the sources of pest infestations. The site characteristics within these areas determine the environmental fate and potential exposures in these areas and adjacent locations.

Selecting different locations affects exposure assessment primarily through differences in soil types, terrain, and meteorological conditions, all of which serve as inputs for the GLEAMS model. The availability of USDA soil surveys or comparable is important for accurate assessments. If soil survey data are not available for a selected location, soil survey data on an alternate location, near the location of concern and having similar or comparable soil types, may be selected.

Each selected location may cover a wide geographical area comprised of various soil types and topographical features. Consequently, specific sites within a location are not selected for modeling. Instead, a composite site, with typical soil characteristics and terrain features, is constructed for each location. The composite site is intended to represent the soil types and terrain features most likely to be the subject of program activities.

II.B. TOXICOLOGICAL ASSESSMENTS

Quantitative toxicological assessments involve the derivation of dose levels associated with an acceptable risk level. This dose is referred to as the regulatory reference value (RRV). RRVs for non-carcinogenic effects are exposure values intended to be estimates of exposure levels at or below the level where no adverse effects are expected for a given exposure route and duration. This assumes that non-carcinogenic effects have population thresholds for adverse effects from exposures. RRVs are estimates of exposure levels at or below the threshold level. RRVs are derived by taking an experimental threshold dose for the route of exposure and dividing by an uncertainty factor. The uncertainty factor is intended to account for differences between the experimental exposure and the conditions for which the RRV is being derived. The basis for using specific uncertainty factors is presented in Table II-2.

TABLE II-2: Uncertainty Factors Used to Derive RRVs

Factor	Basis
Interhuman	Use a 10-fold factor when extrapolating from valid experimental results using prolonged exposure to average healthy humans. This factor is intended to account for the variation in sensitivity among humans.
Experimental to human	Use a 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies on human exposure are not available or are inadequate. This factor is intended to account for the uncertainty in extrapolating animal data to humans. If adjustments to the dose metameter are adequate, this factor can be reduced or eliminated.
LOAEL to NOAEL	Generally use a 10-fold factor when deriving an RRV from a LOAEL instead of a NOAEL. This factor is intended to account for the uncertainty in extrapolating from LOAELs to NOAELs.

Subchronic to chronic	Generally use a 10-fold factor when deriving an RRV from less than chronic results on experimental animals or humans. This factor is intended to account for the uncertainty in extrapolating from less than chronic NOAELs to chronic NOAELs.
Incomplete data base	Generally use a 10-fold factor when deriving an RRV from valid results in experimental animals when the data are "incomplete." This factor is intended to account for the inability of any study to address all possible adverse outcomes.
Modifying factor	Use professional judgement to determine an additional uncertainty factor that is >1 and <10 for deriving an RRV. The magnitude of the modifying factor depends upon the professional assessment of the scientific uncertainties of the study and data base not explicitly treated above. The default value is 1.

Threshold limit values (TLVs) usually serve as the basis for inhalation RRVs. TLVs are adopted without modification as inhalation RRVs for occupational exposure. For exposure scenarios involving the general population, inhalation reference concentrations (RfCs) are adopted without modification as inhalation RRVs for chronic exposure. When RfCs are not available, the TLV is modified to account for the duration of daily exposure and sensitive subgroups in the general population. TLVs are designed to protect workers in occupational exposure settings during the work day (ie. 8 hours/day). Inhalation RRVs for the general population must be protective for the full 24-hour day. Consequently, the TLV is reduced by one third (8 hours/24 hours) when applied to the general population. This adjustment is made with the assumption that exposures are equitoxic as long as the product of concentration and duration is constant (e.g., $c_1 \times d_1 = c_2 \times d_2$). This is an expression of Haber's Law (Kennedy, 1989) which is a reasonable approximation over limited ranges of concentration and duration. TLVs do not explicitly consider sensitive subgroups; therefore, the TLV adjusted for continuous exposure is further reduced by a factor of 10, according to U.S. EPA procedure, to account for sensitive subgroups.

This risk assessment derives the RRVs for spinosad for the general population and occupational exposure. The anticipated short half-life in the environment, low exposure levels, and low toxicity provide adequate information to indicate a comparable exposure level of concern, independent of whether that exposure is acute, subchronic, or chronic. Although inhalation exposure is possible, oral and dermal exposure are anticipated to be the major routes of exposure and inhalation has been shown to be less critical in these exposure scenarios (SERA, 1992). This limits the selection of RRVs in this risk assessment to those for oral exposures (using the calculations for converting dermal exposure to the same units).

The RRV selected for spinosad is 0.027 mg/kg/day for the general population and 0.27 mg/kg/day for occupational exposures. These values are based on a chronic feeding study in dogs. This study determined a NOEL to dogs of 2.68 mg/kg/day and a LOEL to dogs of 8.46 mg/kg/day based upon vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum enzymes(EPA, 1998a). The RRV values were determined by applying an uncertainty (safety) factor of 10 to the NOEL to account for inter-species variation for occupational exposures and by applying an uncertainty factor of 100 to the NOEL to account for inter-species and intra-species variation for general population exposures. There is no increased sensitivity of infants or children to spinosad over that of the general population, so it is unnecessary to apply an additional uncertainty factor of 10 for protection of this subgroup of the population.

II.C. RISK CHARACTERIZATION

Risk characterization is the process of comparing the exposure assessment with the toxicological assessment to express the level of concern regarding an exposure scenario or set of scenarios (NRC, 1983). Since there is only one RRV for each chemical insecticide in the formulated material, the total combined oral and dermal exposure to each chemical for a given scenario is compared to the RRV for that chemical. If the total exposure to a chemical in a given scenario exceeds the RRV, then the risk exceeds the acceptable level. If exposure to a chemical in a scenario equals the RRV, then the risk just meets the acceptable level. Since these exposures are at the limit of acceptable exposure, slight deviations from this scenario could pose unacceptable risk. The level of concern are low for exposures from scenarios that are considerably less than the RRV. The agency constantly strives to limit human exposure to acceptable levels and eliminate potential for exposures to levels at or above the RRV.

Description of the potential risk of adverse effects is generally expressed as the hazard quotient (HQ). The equation for calculation of a hazard quotient is:

$$HQ_{rd} = E_{rd}/RRV_{rd} \tag{18}$$

where:

HQ_{rd} = route and duration specific hazard quotient
E_{rd} = exposure by the specific route and duration
RRV_{rd} = RRV for the specific route and duration

The hazard quotient expresses the likelihood of potential adverse effects from given exposures. Hazard quotient values less than 1 are not anticipated to cause any adverse effects. The smaller the hazard quotient, the lower the likelihood of any possible adverse effects. The anticipated adverse effects are generally slight when the hazard quotient is at 1 or slightly higher, but individual reactions may vary due to interindividual variability. Although most people would not be expected to respond adversely to conditions where the hazard quotient is 1, there are individuals within the population who are more sensitive to the chemical exposure and could express adverse reactions from even lower exposures.

III. PROGRAM ACTIVITIES

III.A. SPINOSAD BAIT SPRAY APPLICATIONS

This risk assessment concerns bait spray applications of spinosad only. An overview of this activity is presented in table III-1.

TABLE III-1: Mediterranean Fruit Fly Eradication Program Activities				
Activity	Insecticide(s)	Risk of Public Exposure		
		High	Moderate	Low
Bait spray Application	Spinosad	X		

III.A.1. Spinosad Bait Spray. Both aerial and ground applications of this bait spray are being considered for use in fruit fly programs. Aerial applications are performed with helicopters or fixed-wing aircraft, whereas ground applications involve the use of backpack sprayers for eradication and hydraulic sprayers for crop certification in commercial, host-plant nurseries or orchards. The tentative application rate per acre includes a mixture of 0.008 % spinosad and 28 % sugar and attractants diluted in water. This application rate results in actual deposition of 0.00028 lbs a.i./acre (0.0003 kg a.i./ha or 0.03 mg a.i./m^2) of spinosad.

An aerial spray program may be triggered by the detection of two fruit flies of either sex or by the detection of a mated female. In a typical aerial spray program, bait spray is applied twice to a 9-mi^2 area surrounding the infestation epicenter. The two applications usually are made 7 days apart, and sterile flies are released after the second application. In the past, some infestation areas were larger than 9 mi^2 because of multiple-fly finds in locations nearby. In several eradication programs, certain areas received more than two aerial applications of bait spray due to additional fly finds or poor quality of sterile fruit flies (lack of mating competitiveness with wild flies).

Ground applications of bait spray are applied by backpack or pumpup sprayers to host-plant foliage as 3-ft^2 bait stations containing 6 mL of bait mixture. When applied alone as a method of eradication, the bait stations are placed within the quarantine boundaries at a density of 60 stations/acre.

Bait stations may also be applied using hydraulic rigs at commercial orchards and nurseries, for certification purposes. Before host fruit grown within the quarantine boundaries can be moved, the host tree must receive at least three (California requires four) bait station treatments during the preceding 30 days before fruit is harvested.

Because bait spray applications may occur in populated areas, residents living in the treatment area are the likeliest candidates for human exposure. Individuals of all ages may be exposed to residues of the bait spray mixture as a result of typical application operations. The workers at risk are those who would be involved directly in the treatment program, including the aerial and ground applicators, mixers, loaders, and other ground-based, program personnel.

III.B. LOCATIONS UNDER REVIEW

Seven geographical areas are reviewed in this risk assessment, including Brownsville, Texas; Gulfport, Mississippi; Los Angeles, California; Miami, Florida; Orlando, Florida; Santa Clara County, California; and Chelan County, Washington. The California and Florida locations were selected because of their previous involvement in fruit fly eradication programs. The selection of sites in Washington and Texas was based on an assessment of likely points of infestation from other countries. The Mississippi site was selected as a surrogate for New Orleans, Louisiana. Like the Washington and Texas sites, New Orleans is a likely point of entry for fruit flies from other countries. Adequate soil survey data are not available, however, for New Orleans. For each location, a composite site was constructed based on an analysis of the relevant USDA soil survey and site visits. In addition, rainfall data for 1986-1990 were obtained from the U.S. Weather Service. These data were used as input files for the GLEAMS model and to select rain scenarios for environmental modeling.

Table III-2 summarizes site-specific soil data for each composite site. The general assumptions applied to all sites are summarized in table III-3. General assumptions (e.g. the size and shape of the composite site) were selected as plausible representations of a typical, single-family residence. Some site-specific soil parameters, not specified in the USDA soil surveys, were based on values recommended by Davis et al. (1990) for the soil regarded as typical for each site.

All sites contain several different soils, and judgements had to be made regarding which soils should be considered representative of each area. For Brownsville, a soil survey of Cameron County was used as the source of information (USDA, 1977). The soils regarded as representative of the area are Laredo silty clay loam, Olmito silty clay, and Benito- and Laredo-urban land complexes. The Laredo silty clay loam was determined to be the most representative of the area.

For Gulfport, a soil survey of Harrison County was used as the source of information (USDA, 1975). The most prevalent soils in the area are Eustis loamy sand (0-5% slopes), Latonia loamy sand, Lakeland fine sand, Ocilla loamy sand, and Plummer loamy sand. Of these five soils, Eustis loamy sand and Latonia loamy sand were considered most representative and were combined into a single soil type for the purpose of environmental fate modeling.

TABLE III-2: Site-Specific Hydrology and Erosion Parameters for the GLEAMS Model[a]

Parameter	Site						
	Brownsville	Gulfport	Los Angeles	Miami	Orlando	Santa Clara	Chelan County
Typical Soil	Silty Clay Loam	Loamy Sand	Sandy Loam	Marly Silt Loam	Fine Sand	Loam	Loam
Hydrology Data							
Hydrological Group	B	A	B	B	B/D	B	B
Saturated conductivity	0.15	0.30	0.15	0.15	0.15	0.15	0.20
Evaporation parameter	4.0	3.3	3.5	4.5	3.3	4.5	4.5
SCS curve no.	61	35	61	61	61	61	61
Hydraulic slope	0.01	0.05	0.02	0.01	0.02	0.02	0.08
Soil porosity	0.47	0.40	0.40	0.43	0.42	0.40	0.40
Field capacity	0.36	0.19	0.22	0.32	0.18	0.26	0.26
Wilting point	0.20	0.05	0.08	0.12	0.03	0.11	0.11
Organic matter (%)	1	1	1	1	1	1	1
Erosion Data							
Surface clay	0.35	0.05	0.10	0.20	0.05	0.15	0.20
Surface silt	0.55	0.20	0.10	0.60	0.05	0.20	0.35
Surface sand	0.10	0.75	0.80	0.20	0.90	0.65	0.45
Clay surface	200	20	20	20	20	100	20
Organic matter surface area	1,000	1,000	1,000	1,000	1,000	1,000	1,000
Flow profile slope	0.01	0.05	0.02	0.01	0.02	0.02	0.02
Soil erosion factor	0.402	0.186	0.313	0.189	0.189	0.455	0.398

Contouring factor	0.6	0.5	0.6	0.6	0.6	0.6	0.6

[a]For details regarding values expressed in units of measure, see appendix 2.
NA = Not applicable

TABLE III-3: Standard Modeling Values Used in Exposure Assessments for All Sites

Parameter	Value	Sites
Field length to width ratio	1	All sites assume a 1/4 acre square lot.
Effective rooting depth in inches	12	Constant assumption at all sites.
Number of soil horizons	1	Constant assumption at all sites.
Surface area for organic matter	1,000	Recommendation in Davis et al. (1990) for organic matter on the surface.
Soil loss ratio	0.1	Constant assumption at all sites.
Contouring factor for overland flow profile	0.046	Recommendation in Davis et al. (1990) for good grass.
Winter cover factor	0.5	Recommendation in Davis et al. (1990) for pasture.
Leaf area index	2.8-3.0	Recommendation in Davis et al. (1990) for well kept grass.

For Los Angeles, a soil survey of Orange County, California was used as the source of information (USDA, 1978). The dominant soil types include Hueneme fine sandy loam (drained), Metz loamy sand, and San Emigdio fine sandy loam (moderately fine substratum, 0-2% slopes). The soil properties were combined into a single representative soil type for the environmental fate models.

For Miami, a partial soil survey of Dade County was used as the source of information (USDA, 1992). The soil type most representative of the area is Biscayne marly silt loam. It is a poorly drained soil, with a seasonal high water table within 10 inches of the soil surface from July to October.

For Orlando, a soil survey of Orange County, Florida was used as the source of information (USDA, 1989). This site is dominated by three soils, including Smyrna fine sand, Sanibel muck, and Smyrna-urban land complex. The representative soil type chosen for Orlando was Smyrna fine sand.

For Santa Clara County, a soil survey of eastern Santa Clara County was used as the source of information (USDA, 1974). The three soils regarded as the most common are the Pleasanton loam, Cropley clay, and Arbuckle gravelly loam. Pleasanton loam at 0-2% slopes was selected as the most representative soil for this area.

For Chelan County (Wenatchee, WA), a soil survey of the Chelan area was used as the source of information (USDA, 1975a). Although orchards may occur in several soil series, the traditional and most productive areas in Washington State are on the Burch loams. These were selected as the most representative soil for this area.

Rainfall amount and frequency differ substantially among sites. This risk assessment analyzes 2-year storms occurring 24, 48, and 72 hours after pesticide application. The routine scenario for surface water runoff and groundwater percolation for Miami, Orlando, and Gulfport sites involved a storm occurring 48 hours after pesticide application; for all other sites, the routine scenario involved a storm occurring 72 hours after application. The extreme scenario for surface water runoff and groundwater percolation for all sites involved a storm occurring 24 hours after pesticide application.

IV. CHEMICAL-SPECIFIC DATA

IV.A. QUANTITATIVE ASSESSMENTS

The quantitative dose-response assessments derived in this chapter are summarized in table 4-1. Duration-specific RRVs for general population and occupational exposure are derived whenever data supporting dose/duration/severity relationships are available. RRVs for both the general population and occupational exposure are based on the same experimental observation, the only difference being the use of uncertainty factors. The role of uncertainty factors in estimating risk for exposure is described in chapter 2. Allowance for the uncertainty factor of 10 for occupational exposure is not made for spinosad where data are limited for higher exposures. Allowance is made for differences in resistance of the general population relative to the working population for exposures to spinosad. The special disease conditions or impaired physical states that this factor is intended to account for are not prevalent among the work force. Adapting a fixed factor to account for sensitive subgroups within the work force, however, is without regulatory precedent and cannot be based on empirical data.

TABLE IV-1: Duration-Specific RRVs for Chemical Exposure

Chemical	Exposed Population	Acceptable Cumulative Daily Dermal and Oral Exposure (mg/kg/day)		
		Acute	Subchronic	Chronic
Spinosad	General	0.027	0.027	0.027
	Occupational	0.27	0.27	0.27

Any daily exposure to the general public or program workers that approaches or equals the RRV might be of consequence to sensitive subgroups. Any daily exposure that exceeds the RRV would be of consequence. This issue is discussed further as it pertains to each risk characterization.

Table IV-2 presents selected chemical and physical properties of the program chemicals and 2,4-D, which is used as a surrogate chemical in some of the exposure assessments (chapter V). Spinosad consists of several metabolites or factors that account for the toxic action. In particular, spinosyn factors A and D are of primary concern. The log octanol-water coefficient (log K_{ow}) at pH 7 for spinosyn A is 3.9 and for spinosyn D is 4.4. Although its value may differ slightly from formulations of spinosad, it should have similar chemical properties. Other physical and chemical properties are summarized in appendix 2. Table IV-3 briefly summarizes the output from the GLEAMS modeling by presenting the highest concentrations of spinosad in surface soil and interstitial soil water for a 2-year storm at each of the six potential program sites.

TABLE IV-2: Chemical-Specific Data Used for Toxicological Assessments[a]						
Chemical	Molecular Weight	Log K_{ow}	Log K_p	K_p (cm/hour)	Density (g/cc)	Water Solubility (mg/mL)
spinosyn A	732	3.9	-4.0	0.0001	applied product = 1.09	0.235
spinosyn D	746	4.4	-4.5	0.00003		0.0003
2,4-D[b]	221.04	2.81	-2.07	0.0084	1.57[c]	0.9
2,4-D amine[d]	266.1	0.55	-3.95	0.00011	1.4	750
malathion[b]	330.36	2.36	-3.06	0.00087	1.23	0.13

[a]Data taken from appendix 2, unless otherwise specified
[b]Used as a surrogate chemical in exposure assessments
[c]Humburg et al. (1989)
[d]Used in exposure validation
[e]Determined from algorithms for calculating K_p (Flynn, 1990)
K_{ow} = Octanol-water partition coefficient; K_p = permeability coefficient

TABLE IV-3: Summary of GLEAMS Modeling for Maximum Levels of Spinosad in the Upper 1 cm of Soil (µg/g) and Interstitial Soil Water (µg/L)							
Media	Site						
	Browns-ville	Gulfport	Los Angeles	Miami	Orlando	Santa Clara	Chelan County
Soil	0.0006	0.0005	0.0005	0.0006	0.0006	0.0004	0.0005
Water	0.0370	0.0466	0.0247	0.0247	0.0055	0.0028	0.0316

IV.A.1. Spinosad. Spinosad (Tracer®) is a mixture of compounds (spinosyns) produced naturally by the actinomycete fungus, *Saccharopolyspora spinosa*. Applications of spinosad are registered for use on various crops and has permanent tolerances for some fruits (including citrus), nuts, vegetables, cotton, and meat.

Acute toxicity of spinosad is low by all routes of exposure. Spinosad is of very slight acute oral toxicity to mammals. The acute oral median lethal dose (LD_{50}) to rats is greater than 5,000 milligrams (mg) of spinosad per kilogram (kg) body weight (Dow Agrosciences, 1998; EPA, 1998a). The acute dermal LD_{50} to rats is greater than 2,800 mg/kg. The acute inhalation median lethal concentration (LC_{50}) to rats is greater than 5.18 mg per liter (L). Primary eye irritation tests in rabbits showed slight conjunctival irritation.

Primary dermal irritation studies in rabbits showed slight transient erythema and edema. Spinosad was not found to be a skin sensitizer.

Subchronic and chronic studies of spinosad also indicate low hazard. The systemic NOEL for spinosad from chronic feeding of dogs was determined to be 2.68 mg/kg/day (EPA, 1998a). The LOEL for this study (8.22 mg/kg/day) was based upon vacuolated cells in glands (parathyroid) and lymphatic tissues, arteritis, and increases in serum enzymes. No studies found any evidence of neurotoxicity or neurobehavioral effects. A neuropathology NOEL was determined to be 46 mg/kg/day for male rats and 57 mg/kg/day for female rats. No evidence of carcinogenicity was found in chronic studies of mice and rats. EPA has classified the carcinogenic potential of spinosad as Group E - no evidence of carcinogenicity (EPA, 1998b).

There has been no evidence of mutagenic effects from spinosad (EPA, 1998a). Test have been negative for mouse forward mutations without metabolic activation to 25 μg/ml and with metabolic activation to 50 μg/ml. No increases in chromosomal aberrations in Chinese hamster ovary cells were observed without activation to 35 μg/ml or with activation to 500 μg/ml. No increase in frequency of micronuclei in bone marrow cells of mice were found for 2 day exposures of spinosad up to 2,000 μg/ml. No unscheduled DNA synthesis was observed in adult rat hepatocytes in vitro at concentrations of spinosad as high as 5 μg/ml.

Reproductive and developmental toxicity studies have found that these effects occur only at doses that exceed those which cause other toxic effects to the parent animal. The reproductive NOEL from a 2-generation study of rats was determined to be 10 mg/kg/day with a LOEL of 100 mg/kg/day based upon decreased litter size, decreased pup survival, decreased body weight, increased dystocia, increased vaginal post-partum bleeding, and increased dam mortality (EPA, 1998a).

The primary active ingredients in spinosad are spinosyn factor A and spinosyn factor D. All other substance in the formulated products of spinosad are of lower toxicity. Spinosyns are relatively inert and their metabolism in rats results in either parent compound or N- and O-demethylated glutathione conjugates as excretory products (EPA, 1998a). Studies have found that 95% of the spinosad residues in rats are eliminated within 24 hours.

The RRV selected for spinosad is 0.027 mg/kg/day for the general population and 0.27 mg/kg/day for occupational exposures. These values are based on a chronic feeding study in dogs. This study determined a NOEL to dogs of 2.68 mg/kg/day and a LOEL to dogs of 8.46 mg/kg/day based upon vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum enzymes(EPA, 1998a). The RRV values were determined by applying an uncertainty (safety) factor of 10 to the NOEL to account for inter-species variation for occupational exposures and by applying an uncertainty factor of 100 to the NOEL to account for inter-species and intra-species variation for general population exposures. There is no increased sensitivity of infants or children to spinosad over that of the general population, so it is unnecessary to apply an additional uncertainty factor of 10 for protection of this subgroup of the population.

IV.B. QUALITATIVE ASSESSMENTS

Qualitative data regarding the lures and attractants have been described in the Human Health Risk Assessment APHIS Fruit Fly Programs (SERA, 1992) and in the chemical background statement on attractants (Labat-Anderson, 1992f). These reviews of the lures and attractants cover all information that is known to date and no further description will be presented here.

V. ANALYSIS OF POTENTIAL EXPOSURE

V.A. SPINOSAD BAIT SPRAY APPLICATIONS

Exposure to Spinosad bait spray involves simultaneous exposure to insecticide and bait in the formulation. Since the basic mode of toxic action of both chemicals is considered to be different and the hazards from the bait are minimal, the hazards from individual exposures consider only the level of the exposure to spinosad relative to the RRV(s) for that compound. If exposure is much less than the RRV, then the risk can be considered minimal.

V.A.1. Occupational Exposure.

Spinosad bait sprays are applied by aircraft, backpack sprayers, pumpup sprayers, and hydraulic sprayers. For aircraft applications, exposure scenarios may involve pilots, mixers and loaders, or ground personnel. Ground personnel include kytoon handlers, flaggers, and the quality control crew. Field monitoring data regarding the exposure of any of these groups to spinosad were not located in the available literature. For pilots, mixers and loaders, backpack sprayers, and hydraulic rig operators, data on a surrogate chemical, 2,4-D, are used to estimate exposure. For ground personnel, exposure estimates are made from nominal application rates. The exposure assessments for each of these groups are summarized in table V-1 for spinosad.

TABLE V-1: Summary of Exposure Assessment for Occupational Exposure to Spinosad from Aerial Applications of Bait Spray

Group	Exposure Scenario	Dose (mg/kg/day)	Comment
Pilots	routine	5.11×10^{-7}	Uses pilot data on 2,4-D by Nash et al. (1982), adjusting for differences in dermal absorption.
	extreme	4.68×10^{-6}	
Backpack applicators	routine	1.8×10^{-6}	Uses backpack applicators data on 2,4-D by Lavy et al. (1987), adjusting for differences in dermal absorption.
	extreme	4.5×10^{-6}	
Hydraulic Rig applicators	routine	9.0×10^{-7}	Uses hack-and-squirt exposures with 2,4-D by Lavy et al. (1987), adjusting for differences in dermal absorption.
	extreme	3.4×10^{-6}	
Mixers/loaders	routine	1.1×10^{-6}	Based on exposed dose. Actual risk is lower.
	extreme	7.3×10^{-6}	

Ground personnel[a]	routine	$1.1x10^{-3}$	Exxagerated exposure conditions which encompass accidental exposures
	extreme	$3.0x10^{-3}$	

[a]Includes kytoon handlers, flaggers, and quality control crew.

V.A.1.a. Pilots - Exposure for pilots was estimated using the data from Nash et al. (1982), in which occupational exposure to 2,4-D from aerial spraying was determined by urinalysis. This study indicates that the average dose to which a pilot would be exposed is $7.6x10^{-5}$ mg/kg per pound a.i. of 2,4-D applied. In other words, for every pound of 2,4-D applied, the pilot absorbed a dose of $7.6x10^{-5}$ mg 2,4-D/kg body weight. The upper limit of the 95% confidence interval determined from this study is $2.51x10^{-4}$ mg/kg per pound a.i. of 2,4-D applied. These doses are composites of all routes of exposure to which the pilot is subject during the application process.

For pilots, it is assumed that two aircraft are used, regardless of the size of the spray area. Exposure is based on the amount of pesticide sprayed; therefore, routine exposure assumes that two pilots treat 9 mi^2 (each pilot will spray 4.5 mi^2), and extreme exposure assumes an area of 25 mi^2 (12.5 mi^2 each). The total amount of insecticide applied for the routine scenario is 0.8064 pounds spinosad. The total amount of insecticide applied for the extreme scenario is 2.24 pounds spinosad. [For example, the nominal application for spinosad is 0.00028 pounds/acre, and there are approximately 640 acres in a square mile. Thus, the total amount of the pesticide applied can be calculated as 0.00028 pounds/acre x 640 acre/mi^2 x 4.5 mi^2 = 0.8064 pounds.] For 2,4-D, this would result in a dose of $6.13x10^{-5}$ mg/kg/day [$7.6x10^{-5}$ (mg/kg)/pound x 0.8064 pounds/day]. As indicated in table IV-2, the dermal penetration rate is 1×10^{-4} cm/hour for spinosyn A, is 3×10^{-5} cm/hour for spinosyn D, and the corresponding rate for 2,4-D is 8.4×10^{-3} cm/hour. The dermal penetration rate for spinosad is approximately 7×10^{-5} cm/hour. The ratio of these coefficients, $7 \times 10^{-5} \div 8.4 \times 10^{-3}$ or 0.00833, is used to adjust the dose estimate of $6.13x10^{-5}$ mg/kg/day to a spinosad equivalent of $5.11x10^{-7}$ mg/kg/day. The estimated dose of spinosad, using the upper limit of the dose and application rates (extreme scenario), is $4.68x10^{-6}$ mg/kg/day.

V.A.1.b. Backpack Sprayers - The method of estimating exposure to backpack sprayers is similar to the method for estimating pilot exposure. Lavy et al. (1987) estimated the doses of 2,4-D in backpack sprayers. In this study, each worker applied 117 L of the herbicide mixture over a 7-hour period, which was equivalent to 2.29 pounds 2,4-D a.i. Statistical analysis of these data provided the mean and upper limits of the 95% confidence interval values, used to determine routine and extreme exposure scenarios involving backpack applicators in the fruit fly programs. The mean dose rate was 0.0348 mg/kg per pound a.i. of 2,4-D applied. The upper limit of the 95% confidence interval was 0.0422 mg/kg per pound a.i. of 2,4-D applied.

For the routine exposure scenario, it was assumed that each worker would apply 25 gallons of the mixture (equivalent to 0.0182 pounds a.i. of spinosad); for the extreme exposure scenario, it was assumed that each worker would apply 50 gallons of the mixture (equivalent to 0.0364 pounds a.i. of spinosad). Furthermore, it was assumed that the backpack applicators in the program would wear protective clothing, including disposable coveralls, hats with face shields, boots, and gloves. A study by Nigg et al. (1986) indicates that protective clothing substantially reduces the risk of occupational exposure. These investigators conducted exposure monitoring studies involving applicators and mixers and loaders handling the pesticide, dicofol. Pads were placed inside and outside regular work clothes and Tyvek suits. In addition, exposure was measured for workers wearing or not wearing gloves. The dicofol application rate was 3 pounds a.i./acre using airblast equipment. The applicators decreased their total dermal exposure 38% by wearing the Tyvek suit, 27% by wearing gloves, and 65% by wearing both. Therefore, a clothing penetration factor of 0.35 (i.e. exposure reduced to 35% of that experienced without protective clothing) was used for all applicators in this risk assessment.

Based on the mean exposure rate of 0.0348 mg/kg per pound a.i., an application rate of 0.0182 pounds a.i./day, a clothing penetration factor of 0.35, and the standard adjustment for 2,4-D to spinosad dermal exposure, the daily dose for routine exposure is 1.9×10^{-6} mg/kg/day (0.0348 x 0.0182 x 0.35 x 0.00833). For the extreme exposure scenario, the daily dose, calculated in a similar way, is 4.5×10^{-6} mg/kg/day.

V.A.1.c. Hydraulic Rig Operators - As with the backpack sprayers, no estimates regarding exposure associated with the application of malathion for hydraulic rig operators were located in the available literature. Neither information about the total number of pounds a.i. applied by a rig operator daily nor information about the relationship of application rates to exposed or absorbed doses of rig operators was located. This assessment, therefore, is based on a literature review of program chemicals and an extensive review of available data on pesticide exposure by van Hemmen (1992).

One approach to indirectly estimate exposure is to use the data of Lavy et al., (1987) which involves the hack-and-squirt method of applying 2,4-D. In this study, each of 15 workers applied 1.9 liters of herbicide (0.5 pounds a.i.) over a 5.5 hour period. Statistical analysis of these data provided the mean value and upper limit of the 95% confidence interval. Doses of spinosad bait spray to which hydraulic rig operators are exposed were calculated from this study. The mean dose was estimated as 0.0171 mg/kg per pound a.i. of 2,4-D applied. The upper limit of the 95% confidence interval was estimated as 0.0316 mg/kg per pound a.i. of 2,4-D applied.

Using the same assumptions as those used to estimate exposure for backpack operators and substituting the dose application-rate relationships for the hack-and-squirt operators, dose estimates spinosad in routine and extreme exposure scenarios are 9.0×10^{-7} and 3.4×10^{-6} mg/kg/day, respectively. Confidence in this assessment is rather low because of the lack of data regarding hydraulic rig operators.

V.A.1.d. Mixers and Loaders - The procedure of mixing and loading spinosad bait spray in support of aerial and ground applications is usually accomplished in two steps. First, the concentrated spinosad is mixed with the bait spray at a storage location and transported to the application site. Second, the mixture is loaded into the application equipment. The mixing and loading procedure may be performed by one individual or by two co-workers. This risk assessment is based on the conservative assumption that both steps are performed by one worker. Furthermore, this risk assessment assumes the use of two aircraft, regardless of the area to be treated. If it is assumed that each aircraft is serviced by one mixer and loader, exposure will be based on handling the total number of pounds a.i. applied by each aircraft. Routine exposure scenarios assume that two pilots spray 9 mi^2 (each pilot will spray 4.5 mi^2); extreme exposure scenarios assume an area of 25 mi^2 (12.5 mi^2 each). The total amount of spinosad handled by each mixer and loader will be 1.6128 and 4.48 pounds a.i. for the respective routine and extreme exposure scenarios.

Exposure estimates for mixers and loaders using closed mixing systems were based on a study by Cowell et al. (1987). In this study, four mixers and loaders worked with Lasso EC®, an emulsifiable concentrate formulation of the herbicide, alachlor. Each worker pumped the concentrated herbicide from minibulk tanks (100 gallons each) to saddle tanks, where water was added. The workers then pumped the mixture into tractor tanks for application. All workers processed 80 pounds a.i. and wore clothing that covered their arms, legs, and torsos. They also wore gloves that were impervious to alachlor. Patch tests after the operation revealed alachlor residues on the forehead, face, and the back and front of the neck. Residues did not penetrate the clothing, as demonstrated by a patch under the shirt.

Conservative dose estimates were based on the total deposition of the herbicide on exposed skin surfaces in the Cowell et al. (1987) study. The mean deposition of the four workers in the study was 6.91×10^{-7} mg/kg per pound a.i. applied. The deposition based on the upper limit of the 95% confidence interval was 1.64×10^{-6} mg/kg per pound a.i. applied.

From the mean deposition rate and the 1.6128 pounds/day routine application, the daily exposure dose to spinosad is estimated as approximately 1.1×10^{-6} mg/kg/day (6.91×10^{-7} mg/kg per pound a.i. x 1.6128 pounds/day). The corresponding dose for the extreme exposure scenario for spinosad is 7.3×10^{-6} mg/kg/day. These doses are low enough, relative to the occupational RRV of 0.27 mg/kg/day for spinosad, that any adjustments for absorption efficiency are inconsequential.

V.A.1.e. Ground Personnel - Ground personnel who are potentially at risk of exposure to spinosad from aerial application, include kytoon handlers, flaggers, and the quality control crew. The functions and activities of each of these labor categories suggest differences in exposure levels: kytoon handlers > flaggers > quality control crew. Flaggers and kytoon handlers guide the flight crew to ensure that the correct areas are treated, but flaggers work from inside vehicles equipped with lighting and signal devices.

The quality control crew does not enter the treated site until the application has been completed.

A general assessment will be made for ground personnel. The routine scenario is based on the assumption that an individual is dressed in long pants, long sleeves, and shoes, and has an exposed skin area of 0.2 m^2 (appendix 1). The extreme scenario is based on the assumption that an individual is dressed in shorts, a short-sleeved shirt, and shoes, and has an exposed skin area of 0.52 m^2 (appendix 1). It is also assumed that the individual is outside during spraying and that the exposed body surface is covered with the spray. Finally, it is assumed that individual is exposed constantly to 4.1×10^{-6} mg/m^3 of spinosad (the maximum anticipated workday air concentration based on previous programs (CDFA, 1991)). The exposure by inhalation is inconsequential relative to the dermal exposure.

Using Fick's first law and an 8-hour event period (ie. 6 hours on the job and 2 hours after work before a shower), the DA_{event} is 4.02×10^{-5} mg·cm^2/event (5.76×10^{-5} cm/hour x 0.0872 mg/cm^3 x 8 hours). Given an exposed area of 0.2 m^2 (2,000 cm^2), the absorbed dose is 0.08036 mg (4.02×10^{-5} mg·cm^2/event x 2,000 cm^2) for a 70 kg person or 1.148×10^{-3} mg/kg/day. Since the extreme exposure (2.986×10^{-3} mg/kg/day) of this already extreme exposure scenario is less than the RRV (0.27 mg/kg/day), job-specific scenarios for ground personnel are not discussed further in this document.

V.A.1.f. Accidental Exposure - The absorbed dose described in the scenario for ground personnel in the previous assessment encompasses many reasonable accidental "spill" scenarios. The amount of material spilled on the skin surface matters less than the concentration of the material and the area of the skin over which the material is applied. For example, assume that some severe accident occurs and a worker is completely drenched with the bait spray and waits 2 hours before showering. Assuming a total body surface of 1.94 m^2 or 19,400 cm^2, the DA_{event} is 1×10^{-5} mg·cm^2/event (5.76×10^{-5} cm/hour x 0.0872 mg/mL x 2 hours). The absorbed dose of spinosad is 0.195 mg (1×10^{-5} mg·cm^2/event x 19,400 cm^2) for a 70 kg person or 2.784×10^{-3} mg/kg/day, somewhat less than the extreme exposure scenario outlined above.

V.A.2. General Population Exposure - The nature of bait spray applications suggests several exposure scenarios for different ages and activities of the general population. The exposure scenarios for the general population to spinosad indicate low exposures by most potential routes (Table V-2).

Table V-2: Summary of General Population Exposures to Spinosad from Aerial Applications of Spinosad Bait Spray

Exposure Route	Exposure Scenario	Dose (mg/kg/day)
Soil consumption	routine	1.0×10^{-8}
	extreme	1.5×10^{-8}
	pica behavior	6.0×10^{-7}

Consumption of Contaminated water	runoff water	$1.18x10^{-5}$
	surface water	$4.9x10^{-7}$
Swimming pool exposure	toddler for 4 hours	$2.01x10^{-9}$
Consumption of Contaminated vegetation	routine	$7.66x10^{-7}$
	extreme	$3.96x10^{-6}$
Contact with Contaminated vegetation	routine	$4.3x10^{-7}$
	extreme	$1.0x10^{-6}$

V.A.2.a. Soil Consumption - As indicated in appendix 1, the 10 kg toddler consumes the most soil per unit body weight and will be the age group of concern for this exposure scenario. Output from the GLEAMS model (see table IV-3) indicates that maximum concentrations of spinosad in the upper 1 cm of soil would range from 0.0004 to 0.0006 µg/g for the seven sites under review. The routine and extreme scenario values are derived using the lower and upper ranges of the projected soil levels and the maximum pesticide levels for all sites in the top 1 cm of soil from the GLEAMS model (see table IV-3). The estimated levels of spinosad intake are $1.0x10^{-8}$ mg/kg (0.0000004 mg/g x 0.25 g ÷ 10 kg) and $1.5x10^{-8}$ mg/kg (0.0000006 mg/g x 0.25 g ÷ 10 kg) for routine and extreme exposure scenarios, respectively.

For the accidental exposure scenario, it was assumed that a toddler will ingest 10 g of soil per day (i.e. pica behavior). Assuming a 10 kg body weight and taking the upper limit of the soil levels, the daily dose of spinosad associated with this behavior would be $6.0x10^{-7}$ mg/kg (0.0000006 mg/g x 10 g ÷ 10 kg).

V.A.2.b. Contaminated Water Consumption - Groundwater, surface water, and runoff water are potential sources of exposure to spinosad from bait spray applications.

As indicated in chapter II, groundwater concentrations are based on the concentrations in the interstitial soil water of the bottom soil zone modeled in the GLEAMS analysis. This approach assumes that the groundwater is consumed directly and does not consider the effects of dilution by the aquifer. Based on the GLEAMS results (table IV-3), the maximum concentration of spinosad in the interstitial soil water is $4.66x10^{-5}$ mg/L in Gulfport. This low concentration will not result in a level of concern with any plausible set of exposure assumptions and is not considered further in this risk assessment.

The results of the GLEAMS analysis suggest a low potential for runoff from pervious surfaces. Runoff from impervious surfaces will depend on the amount of spinosad on the surface (mg/m^2) and the amount of water in the runoff. In urban settings, the majority of the pollutants that accumulate on impervious surfaces (e.g., parking lots, roads, cars, and rooftops) are contained in the "first flush" or first 0.5 inches of rainfall (Schueler, 1987).

In the accidental exposure scenario involving runoff water in which an adult hoses down a driveway, immediately after the pesticide application, to remove unwanted residue. Assuming a nominal application rate of 0.103 mg spinosad/m^2 and that 0.25 inches (0.00635 m) of water over the surface of the driveway removes virtually all of the spinosad. The concentration in the water would be 4.72×10^{-4} mg/L [0.03 mg ÷ 1 m x 1 m x 0.00635 m = 4.7244 mg/m^3 or 4.72×10^{-4} mg/L (1 m^3 = 10,000 L)]. Assuming that the 10 kg toddler drank 25% of 1 L of this water (i.e., 25% of the normal daily consumption), the dose would be 1.18×10^{-5} mg/kg/day (4.72×10^{-4} mg/L x 0.25 L ÷ 10 kg).

In another accidental exposure scenario involving surface water, a toddler could drink immediately from a pond after the application of pesticide. Assuming a mixing depth of 6 inches, the concentration of spinosad would be 1.97×10^{-5} mg/L and the dose would be 4.9×10^{-7} mg/kg/day (1.97×10^{-5} mg/L x 0.25 L ÷ 10 kg).

V.A.2.c. Contact with Contaminated Water - Swimming pool scenarios must consider both oral and dermal exposure. An adult is estimated to swallow an average of 50 mL/hour of water while swimming (EPA/OERR, 1989). Assuming that the amount consumed is proportional to body weight, the consumption of swimming pool water for a 10 kg toddler would be 7.1 mL/hour (50 mL/hour x 10 kg ÷ 70 kg). Further assuming that a 10 kg toddler consumes swimming pool water at the rate of 7.1×10^{-3} L/hour and swims for a 4-hour period (appendix 1), the oral dose of spinosad would be 3.1×10^{-11} mg/kg (1.088×10^{-8} mg/L x 7.1×10^{-3} L/hour x 4 hours ÷ 10 kg).

Using Fick's first law, the DA_{event} for spinosad is 2.507×10^{-12} mg/cm^2·event (5.76×10^{-5} cm/hour x 1.088×10^{-8} mg/mL x 4 hours). Assuming that the entire surface area of the toddler is exposed over the 4-hour period (i.e., 0.79 m^2 or 7,900 cm^2), the absorbed amount is 1.98×10^{-8} mg (2.507×10^{-12} mg/cm^2·event x 7,900 cm^2) or 1.98×10^{-9} mg/kg.

The cumulative oral and dermal dose of spinosad to a toddler swimming for 4 hours would be 2.01×10^{-9} mg/kg.

V.A.2.d. Consumption of Contaminated Vegetation - Two scenarios for the consumption of contaminated vegetables were proposed by CDFA (1991) based on the USDA 1977-1978 Food Consumption Survey (USDA, 1982). These scenarios assume a routine consumption rate of 87 g/day and an extreme consumption rate of 231 g/day of home-grown leafy vegetables. Given a residue of spinosad of 0.0012 mg/kg vegetation as the estimated upper limit and the assumption that the vegetation was not washed prior to consumption, the extreme dose for a 70 kg adult would be 3.96×10^{-6} mg/kg/day (0.0012 mg/kg vegetation x 0.231 kg vegetation/day ÷ 70 kg). Given a residue of spinosad of 0.000616 mg/kg vegetation as the estimated mean value and the assumption that the vegetation was not washed prior to consumption, the routine dose for a 70 kg adult would be 7.66×10^{-7} mg/kg/day (0.000616 mg/kg vegetation x 0.087 kg vegetation/day ÷

70 kg).

V.A.2.e. Contact with Contaminated Vegetation - The empirical uptake relationships determined by Fong et al. (1990) as discussed in chapter II, are used to model the uptake of spinosad directly from sprayed vegetation. This scenario is considered accidental because it assumes that the incident occurs immediately after pesticide application. An upper limit of exposure based on a mass deposition of 5.2×10^{-3} mg/cm^2 of malathion was 9.3×10^{-2} mg/kg/day for a highly active adult on the grass surface for 4 hours. This estimate uses the uptake rate of 3,500 cm/hour for malathion reported by Fong et al. (1990) and a dermal absorption coefficient of 9.3% for malathion based on various estimates from published literature (CDFA, 1991). To correct for differences between penetration of malathion and spinosad, the fraction for the permeability coefficient (K_p) of spinosad over that of malathion is used to adjust exposure estimates. The numerical value of this fraction is 0.0066207. The mass deposition of spinosad would be 8.3×10^{-6} mg/cm^2. The estimated absorbed dose of spinosad based on this was calculated as 8.3×10^{-6} mg/cm^2 x 3,500 cm/hour x 4 hours x 9.3×10^{-2} x 0.0066207 (spinosad penetration correction) ÷ 70 kg = 1.0×10^{-6} mg/kg/day. The mass deposition rate for spinosad in the routine scenario would be 3.5×10^{-6} mg/cm^2. The dose for routine contact with contaminated vegetation would be 4.3×10^{-7} mg/kg for spinosad.

VI. HUMAN HEALTH RISK CHARACTERIZATION

Quantitative toxicological assessments involve the derivation of dose levels associated with an acceptable risk level. This dose is referred to as the regulatory reference value (RRV). RRVs for non-carcinogenic effects are exposure values intended to be estimates of exposure levels at or below the level where no adverse effects are expected for a given exposure route and duration. This assumes that non-carcinogenic effects have population thresholds for adverse effects from exposures. RRVs are estimates of exposure levels at or below the threshold level. Further description of RRVs is provided in Chapters II and IV. The RRVs for spinosad are presented in table IV-1.

Description of the potential risk of adverse effects is generally expressed as the hazard quotient (HQ). The hazard quotient is the fraction of the RRV that results from a given exposure scenario. The equation is described in chapter II in the section on risk characterization. The hazard quotient expresses the likelihood of potential adverse effects from given exposures. Hazard quotient values less than 1 are not anticipated to cause any adverse effects. The smaller the hazard quotient, the lower the likelihood of any possible adverse effects. The anticipated adverse effects are generally slight when the hazard quotient is at 1 or slightly higher, but individual reactions may vary due to interindividual variability. Although most people would not be expected to respond adversely to conditions where the hazard quotient is 1, there are individuals within the population who are more sensitive to the chemical exposure and could express adverse reactions from even lower exposures.

VI.A. Spinosad Bait Spray Applications

Potential exposures of humans from program activities are more likely for aerial bait spray applications than other chemical application methods. This is partly a function of the fact that the deposition from aerial applications occurs over large areas where some individuals are likely to move within the treatment areas despite notification of appropriate protection when pesticide applications are anticipated. It is also due to the larger quantities of pesticide used in these applications. As a result of the greater likelihood of human exposures, it is particularly desirable to have low hazard quotients that make allowance for the possible exposure of some individuals who may be more sensitive to the pesticides than the general population. This will help to prevent adverse effects to even those individuals who are more sensitive.

Risks from occupational exposures to insecticides from aerial applications of Spinosad bait spray are presented by the hazard quotients in table VI-1. Risks from general population exposures to insecticides from aerial applications of Spinosad bait spray are presented by the hazard quotients in table VI-2.

Table VI-1: Risk Characterization of Occupational Exposures to Insecticides from Aerial Applications of Spinosad Bait Spray		
Exposure Group	Exposure Scenario	Hazard Quotient
Pilots	routine	1.9×10^{-6}
	extreme	1.7×10^{-5}
Backpack Applicators	routine	6.7×10^{-6}
	extreme	1.7×10^{-5}
Hydraulic Rig Applicators	routine	3.3×10^{-7}
	extreme	1.3×10^{-5}
Mixers/Loaders	routine	4.1×10^{-6}
	extreme	2.7×10^{-5}
Ground Personnel[a]	routine	4.1×10^{-3}
	extreme	1.1×10^{-2}

[a]Includes kytoon handlers, flaggers, and quality control crew.

Table VI-2: Risk Characterization of General Population Exposures to Insecticides from Aerial Applications of Spinosad Bait Spray		
Exposure Route	Exposure Scenario	Hazard Quotient
Soil Consumption	routine	3.6×10^{-7}
	extreme	5.6×10^{-7}
	pica behavior	2.2×10^{-5}
Consumption of Contaminated Water	runoff water	4.4×10^{-4}
	surface water	1.8×10^{-5}
Swimming Pool Exposure	toddler for 4 hours	7.4×10^{-8}
Consumption of Contaminated Vegetation	routine	2.8×10^{-5}
	extreme	1.3×10^{-4}
Contact with Contaminated Vegetation	routine	1.6×10^{-5}
	extreme	3.7×10^{-5}

The risks of adverse effects to program workers and the general population are very slight. The hazard quotients for all scenarios are much less than 1. The highest hazard quotient for occupational exposures ($1.1x10^{-2}$) to spinosad is in the extreme scenario of ground personnel activity. The likelihood of any adverse effects to ground personnel in this extreme scenario is very slight. The risk of adverse effects are negligible for most potential occupational exposures. The highest hazard quotient for general population exposures ($4.4x10^{-4}$) to spinosad is in extreme scenario of a child consuming contaminated runoff water. The hazard quotients for this scenario still exceed a 1,000-fold safety factor, so the potential risks for this scenario are minimal. Other scenarios for the general population have even greater safety factors.

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APPENDICES

Appendix 1. Standard Parameters Used in Exposure Assessments of Humans

Parameter	Group, Modifier	Value	Reference
Body Surface Areas:			
Whole Body	Adult	1.94 m^2	EPA/EAG, 1989
	Child	0.79 m^2	
	Infant	0.253 m^2	
Exposed area while wearing short pants.	Adult	1.2 m^2	
	Child	0.76 m^2	
Exposed area while wearing short pants, short sleeves, and shoes.	Adult	0.52 m^2	
	Child	0.42 m^2	
Exposed area while wearing long pants, long sleeves, and shoes.	Adult	0.2 m^2	
	Child	0.12 m^2	
Lower legs	Adult	0.207 m^2	
Hands, both	Adult	0.084 m^2	
	Child	0.045 m^2	
Body weight:	Adult	70 kg	EPA/ECAO, 1989
	Child	25 kg	EPA/EAG, 1989
	Toddler	10 kg	EPA/ECAO, 1989
	Infant	4 kg	EPA/ECAO, 1989
Breathing rates:	Adult, light heavy	0.8 m^3/hour 4.8 m^3/hour	EPA/EAG, 1989
	Child, light heavy	0.8 m^3/hour 4.2 m^3/hour	
Drinking water consumption:	Adult, routine	2 L	EPA/ECAO, 1989
	Child, routine	1 L	

	Toddler, extreme	0.5 L	Estimate
Soil consumption:	Child, routine	0.05 g	EPA/EAG, 1989
	Child, extreme	1 g	
	Toddler, routine	0.25 g	
	Toddler, extreme	10 g	
Swimming time:	Adult, routine	1 hour	Estimate
	Adult, extreme	2 hours	
	Child, routine	2 hours	
	Child, extreme	4 hours	
Swimming water consumption:	Adult	50 mL/hour	EPA/OERR, 1989

Appendix 2. Chemical and Physical Properties of Spinosad

Note: All physical properties pertain to 20-25°C temperatures unless otherwise noted.

Spinosad

Spinosyn A
CAS # 131929-60-7

Spinosyn D
CAS # 131929-63-0

Density (g/cm^2): 1.09

Henry's constant ($atm\text{-}m^3/mol$) 9.82×10^{-10}
4.87×10^{-7}

Organic Carbon Partition Coefficient (K_{oc}): 708 (Spinosyn A)
(calculated by equation in Briggs, 1990) 1259 (Spinosyn D)

Octanol/Water Partition Coefficient (K_{ow}): 7943 (spinosyn A)

(Log K_{ow} = 3.9 (spinosyn A), 4.4 (spinosyn D))	25118 (spinosyn D)
Plant Washoff fraction:	0.9
Soil Half-life (days):	9.4-17.3 days (spinosyn A) 14.5 days (spinosyn D)
Acqueous Photolysis Half-life (days):	<1 day
Vapor pressure (mm Hg):	2.4×10^{-10} (spinosyn A) 1.6×10^{-10} (spinosyn D)
Water Solubility (mg/L):	235 (spinosyn A) 0.329 (spinosyn D)