

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SPINOSAD USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	N/A	N/A	Classification: Not likely to be carcinogenic to humans Q1* = N/A Risk Assessment not required.

\*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

## B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.495) for the residues of spinosad, in or on a variety of raw agricultural commodities. Tolerances range from 0.02 ppm (many commodities; limit of quantitation) to 20 ppm (aspirated grain fractions). Risk assessments were conducted by EPA to assess dietary exposures from spinosad in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. An acute dietary exposure risk assessment is not required because the Agency did not identify an acute dietary endpoint that was applicable to females (13+ years) or to the general population, including infants and children.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the U. S. Department of Agriculture (USDA) 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary (food only) analysis represents a moderately refined estimate of dietary exposure to spinosad due to the use of default processing factors, percent crop treated (PCT) estimates for agricultural crops having previously registered uses, and anticipated residues for meat and milk. This Tier 3 DEEM™ analysis shows that dietary (food only) exposure estimates are below the Agency's LOC for all population subgroups. The highest chronic dietary exposure was for children 1–6 years old at 0.018540 mg/kg/day, representing 69% of the cPAD. Exposure for the U.S. population was 0.008127 mg/kg/day, representing 30% of the cPAD.

iii. *Cancer.* Spinosad has been classified by the Agency as a not likely human carcinogen. Therefore, a cancer dietary exposure analysis was not performed.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: Almond 5%; apple 28%; apricot 5%; avocado 5%, bean, snap 9%; broccoli 62%; cabbage 32%; cauliflower 54%; celery 78%; collards

24%; cherry 5%; eggplant 14%; grapefruit 1%; grape, wine 1%; kale 32%; lemon 11%; lettuce, head 59%; Lettuce, other 42%; mustard greens 17%; orange 6%; peach 4%; pepper 45%; pistachio 1%; prune/plum 5%; spinach 32%; pumpkin 1%; squash 1%; sweet corn 1%; tangerine 6%; turnip, greens 6%; tomato, fresh 30%; tomato, processed 2%; watermelon 1%; cotton 3%; dry bean/pea 1%; peanut 1%; potato 1%; wheat, and winter 1%.

The Agency believes that the 3 conditions listed above have been met. With respect to condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant