

subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which spinosad may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for spinosad in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of spinosad.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison

against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to spinosad they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of spinosad for acute exposures are estimated to be 25 parts per billion (ppb) for surface water and 0.037 ppb for ground water. The EECs for chronic exposures are estimated to be 2.3 ppb for surface water and 0.037 ppb for ground water.

3. *From Non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Spinosad is currently registered for use on residential turf and ornamentals to control a variety of insect pests. The registered residential products for spinosad are Conserve SC Turf and Ornamental (EPA Reg No. 62719-291) and Conserve Fire Ant Bait (EPA Reg No. 62719-304). Conserve Fire Ant Bait is a ready-to-use granular formulation that may be applied by homeowners. For adults, residential exposures may result from dermal and inhalation exposure while applying Conserve Fire Ant Bait and/or from dermal contact with treated turf. However, dermal, post-application exposure is not of concern since no toxicological endpoint was established for dermal exposure. Inhalation exposure is not expected due to the low vapor pressure of spinosad and because the homeowner product is formulated as a granular. Post-application exposure to toddlers was not assessed for the Conserve Fire Ant Bait product since children are not likely to "habit" lawn areas where fire ant mounds are present. Conserve SC is labeled for use on turfgrass and ornamentals by commercial applicators. Since this product will be applied by commercial applicators, homeowner applicator exposure was not assessed. For toddlers, dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. Since dermal post-application exposure is not of concern, only hand-to-mouth, object-to-mouth and incidental ingestion of soil exposures for the turf and ornamental uses were performed. The average aerobic soil metabolism half-life of spinosad (containing factors A and D) is

13–14 days. For the intermediate-term duration, typical lawn maintenance practices, such as mowing and watering, are expected to expedite the dissipation of spinosad on turfgrass. Since residue on turf that is available for transfer after day 30 is expected to be negligible, intermediate-term post-application incidental oral exposures were not assessed. The Agency developed exposure formulas and estimated doses to theoretically assess residential post-application incidental oral exposure scenarios including: (1) Hand-to-mouth, (2) object-to-mouth (turfgrass), and (3) incidental ingestion of soil. The resulting incidental oral ingestion MOEs from residential use of spinosad on turf are as follow:

- MOE for oral hand-to-mouth activities on treated lawns is 800 for short-term (1–30 days).
- MOE for oral object-to-mouth (turfgrass) from treated lawns is 3,300 for short-term.
- MOE for incidental ingestion of soil from treated lawns is 240,000 for short-term.
- Combined incidental oral MOE (hand-to-mouth, object-to-mouth, and soil ingestion) is 640. All MOEs are below EPA's LOC.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether spinosad has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, spinosad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that spinosad has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).