

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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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 fludioxonil they are further discussed in the aggregate risk sections E.

There are no ground or surface water monitoring data available for fludioxonil. Tier I models, FIRST and SCI-GROW, were used to derive the surface water and ground water EECs, respectively. According to the proposed label information, the maximum application rate for fludioxonil is 4 lbs active ingredient (ai)/Acre/year on turf (maximum single application rate of 0.675 lbs ai/Acre). Application to turf provided the high exposure scenario; therefore, the drinking water EECs were derived from the use on turf.

**Ground water.** SCI-GROW provides a ground water screening exposure value for use in determining the potential risk to human health from drinking ground water contaminated with pesticides. The ground water modeling generated a ground water EEC of 0.11 parts per billion (ppb) for fludioxonil.

**Surface water.** The predicted index reservoir concentrations for total residues using FIRST for the proposed use of fludioxonil generated acute and chronic surface water EECs of 132 ppb and 49 ppb, respectively.

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).

Fludioxonil is currently registered for use on the following residential non-dietary sites: Based on the registered labels, fludioxonil can be used as a protectant fungicide for control of

certain diseases of turfgrass and certain foliar, stem and root diseases in ornamentals in residential and commercial landscapes. The risk assessment was conducted using the following residential exposure assumptions: Short- and intermediate-term dermal exposures (adults and toddlers), and short- and intermediate-term incidental ingestion exposures (toddlers).

Fludioxonil is registered for uses on residential lawns and ornamentals; however, it is restricted to professional applicators only. As such, no residential handler (i.e., applicator) exposures are anticipated.

EPA did not select short- or intermediate-term dermal endpoints; subsequently, no residential post-application dermal assessment is included. Additionally, due to the low vapor pressure of fludioxonil, no significant post-application inhalation exposure is anticipated. As a result, there are no significant post-application exposures anticipated from treated landscape ornamentals. Therefore, the residential component of this assessment only includes a post-application assessment for toddler incidental ingestion exposures related to residential lawn applications.

4. **Cumulative exposure to substances with a common mechanism of toxicity.** Section 408(b)(2)(D)(v) of the FFDCA 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 fludioxonil has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fludioxonil and any other substances and fludioxonil 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 fludioxonil 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and

procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

#### *D. Safety Factor for Infants and Children*

1. **In general.** Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. **Prenatal and postnatal sensitivity.** The developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

3. **Conclusion.** There is a complete toxicity data base for fludioxonil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X because:

- The toxicology data base is complete.
- The developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.
- A developmental neurotoxicity study is not required because there was no evidence of neurotoxicity in the current toxicity data base.
- The exposure assessment approach will not underestimate the potential dietary (food and water) and non-dietary exposures for infants and children resulting from the use of fludioxonil.

#### *E. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure