

Based on screening models, FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentrations in Ground Water (SCI-GROW), the estimated environmental concentrations (EECs) of fosetyl-Al for acute exposures are estimated to be 0.0086 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.00003 ppb for surface water and 0.006 ppb for ground water.

### 3. From non-dietary exposure.

Fosetyl-Al is currently registered for use on the following residential non-dietary sites: Lawn, turf, and ornamental plants under the brand names CHIPO® Aliette WDG and Aliette® HG. CHIPO® Aliette WDG is sold to professional applicators only, which includes lawn care operators (LCO). Because all residential uses of CHIPO® Aliette WDG are applied by the LCO, a residential applicator exposure assessment for this product was not performed. Short- and intermediate-term dermal, inhalation, and oral exposures to fosetyl-Al may occur from residential handling/postapplication activities.

For a detailed discussion of fosetyl-Al risk assessment, see Unit III. C. 3. of the final rule on fosetyl-Al tolerances published in the **Federal Register** on August 29, 2002 (67 FR 55339).

### 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 fosetyl-Al 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, fosetyl-Al 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 fosetyl-Al 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).

### 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 fosetyl-Al and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be reduced to 1X. The FQPA factor was reduced 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 by the Agency; and the exposure assessment, which assumes the theoretical maximum residue contribution will not underestimate the potential dietary (food and water) and non-dietary exposures for infants and children resulting from the use of fosetyl-Al.

### 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 drinking water level of concerns (DWLOC) 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 to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is

available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure estimates from dietary consumption of fosetyl-Al (food and drinking water). However, no appropriate endpoint attributable to a single dose (exposure) was identified in oral toxicity studies for fosetyl-Al. Therefore, fosetyl-Al is not expected to pose an acute risk.

2. *Chronic risk.* The chronic aggregate risk assessment takes into account average exposure estimates from food, drinking water, and residential uses. However, based on the use pattern, no chronic residential exposures are expected. Therefore, the chronic aggregate risk assessment will consider exposure from food and drinking water only. Chronic risk estimates resulting from aggregate exposure to fosetyl-Al in food and water are below Agency's LOC.

Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fosetyl-Al from food will utilize 4% of the cPAD for the U.S.