

calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10 X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of rat or rabbit fetuses following in utero exposure in the developmental studies with fluroxypyr. There is no evidence of increased susceptibility of rats in the reproduction study with fluroxypyr. EPA concluded there are no residual uncertainties for prenatal and/or postnatal exposure.

3. *Conclusion.* There is a complete toxicity data base for fluroxypyr 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 removed and instead, a different additional safety factor of 1X should be used. The FQPA factor is removed because: There is no evidence (quantitative/qualitative) of increased susceptibility following in utero exposure to the acid and the ester of fluroxypyr in rats and rabbits, or following pre and/or postnatal exposure to the acid of fluroxypyr in rats; there are no concerns or residual uncertainties for pre- and/or post-natal toxicity; there is no evidence of neurotoxicity or neuropathology in the available studies; the toxicological database is complete for FQPA assessment; the chronic dietary food exposure assessment utilizes tolerance level residue estimates and assumes 100% CT for all commodities, thus not likely to underestimate exposure/risk;

the dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded; and the residential exposure assessment was conducted using standard assumptions which are based on carefully reviewed data.

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 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 the EPA's Office of Water 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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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.* A quantitative acute risk assessment was not performed. No adverse effect attributable to a single exposure(dose) of fluroxypyr was observed in the oral toxicity studies and no acute risk is expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fluroxypyr from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants, and 1.4% of the cPAD for children (1-2 years old). In addition, there is potential for chronic dietary exposure to fluroxypyr in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit. Based upon the use pattern, chronic (non-dietary) residential exposure to residues of fluroxypyr is not expected.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUROXYPYR

PopulationSubgroup	cPADmg/kg/day	%cPAD(Food)	Surface Water EEC(ppb)	Ground-Water EEC(ppb)	ChronicDWLOC (ppb)
U.S. Population	1	<1	3.3	0.042	35,000
All infants (<1 year old)	1	<1	3.3	0.042	10,000
Children (1-2 years old)	1	1.4	3.3	0.042	9,900

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fluroxypyr is currently registered for use that could result in short-term

residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for fluroxypyr.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food

and residential exposures aggregated result in aggregate MOEs of 31,000 for the U.S. population and 4,500 for children (1-2 years old). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition,