

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 (MOS) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different MOS will be safe for infants and children. MOS 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.* There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with pyraflufen-ethyl. There is no evidence of increased susceptibility of young rats in the reproduction study with pyraflufen-ethyl. EPA concluded there are no residual uncertainties for prenatal and/or postnatal exposure.

3. *Conclusion.* There is a complete toxicity database for pyraflufen-ethyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The field trial data on cotton, while some of which may be limited in geographic representation or lack of early season application, indicate that residues of pyraflufen-ethyl are expected to be finite. 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 of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in

the developmental studies with pyraflufen-ethyl; there is no evidence of increased susceptibility of young rats in the reproduction study with pyraflufen-ethyl; there are no residual uncertainties identified in the exposure databases; the dietary food exposure assessment is expected to be conservative, tolerance-level residues and 100% crop treated information were used; and dietary drinking water exposure is based on conservative modeling estimates.

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 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 bwts. Default bwts and consumption values as used by the United States Environmental Protection Agency 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 bwts 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.* No adverse effect attributable to a single exposure (dose) of pyraflufen-ethyl was observed in the oral toxicity studies, including the developmental toxicity studies in rats and rabbits. Therefore, an acute RfD was not established 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 pyraflufen-ethyl from food will utilize <1% of the cPAD for the U.S. population and <1% of the cPAD for children (1–6 years). Based on the use pattern, chronic residential exposure to residues of pyraflufen-ethyl is not expected. In addition, there is potential for chronic dietary exposure to pyraflufen-ethyl 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 the following Table 3:

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

Population Subgroup ¹	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb) ²	Ground Water EEC (ppb) ²	Chronic DWLOC (ppb) ³
U.S population	0.20	<1	0.28	0.002	7,000
Males (20+ years old)	0.20	<1	0.28	0.002	7,000
Females (13–50 years old)	0.20	<1	0.28	0.002	6,000
Children (1–6 years old)	0.20	<1	0.28	0.002	2,000
Males (13–19 years old)	0.20	<1	0.28	0.002	7,000

¹ Subgroups with the highest food-source dietary exposure were selected for adult males, adult females and children. The following bwts were used (70 kg adult male; 60 kg adult females; 10 kg child).

² The crop producing the highest level was used (potatoes, 0.009 lb active ingredient/acre).

³ Chronic DWLOC (ppb) = [maximum chronic water exposure (mg/kg/day) x bwt (kg)] ÷ [water consumption (L) x 10⁻³ mg/kg]).