

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 indication of increased susceptibility of rat or rabbits to trifloxystrobin.

3. *Conclusion.* There is a complete toxicity data base for trifloxystrobin 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:

i. There is no indication of increased susceptibility of rat or rabbits to trifloxystrobin. In the developmental and reproduction toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

ii. The Agency determined that a developmental neurotoxicity study in rats is not required.

iii. Although an acute neurotoxicity study is required (the submitted study was unacceptable), the lack of an acute neurotoxicity study does not impact EPA's ability to make an FQPA SF decision.

iv. The acute and chronic dietary food exposure assessments utilize existing and proposed tolerance level residues and 100% crop treated information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.

v. The exposure assessments will not underestimate the potential dietary (food and drinking water) or non-dietary exposures for infants and children from the use of trifloxystrobin.

vi. 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 are not likely to be exceeded.

vii. The residential postapplication assessment is based upon the residential Standard Operating Procedures (SOPs). The assessment is based upon surrogate study data. These data are reliable and are not expected to underestimate risk to adults or children. The residential SOPs are based upon reasonable "worst-case" assumptions and are not expected to underestimate risk.

#### *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 body weights. Default body weights and consumption values as used by the USEPA 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, 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to trifloxystrobin will occupy <1% of the aPAD for females 13–49 years old. An acute dietary endpoint for the general population including infants and children was not identified. In addition, there is potential for acute dietary exposure to trifloxystrobin 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 aPAD for females 13–49 years old, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLOXYSTROBIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–49 years old) .....	2.5	<1	92 turf 48 rice	3.4	75,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to trifloxystrobin from food will utilize 14% of the cPAD for the U.S. population, 54% of the cPAD for children 1–2 years old, 10% of the

cPAD for females 13–49 years old, and 10% of the cPAD for adults 50+ years old. Based on the use pattern, chronic residential exposure to residues of trifloxystrobin is not expected. In addition, there is potential for chronic dietary exposure to trifloxystrobin 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: