

reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the

available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of Acetamid, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-methoxy-1-methylethyl-, (*S*) and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in or on the raw agricultural commodities; grass forage at 10.0 ppm; grass hay at 0.02 ppm; spinach at 0.5 ppm; sugar beet roots at 0.5 ppm; sugar beet molasses at 3.0 ppm; sugar beet tops at 15.0 ppm; sunflower seeds at 0.5 ppm; sunflower meal at 1.0 ppm; and tomato at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

Metolachlor is a chloroacetanilide herbicide that was first registered for use in 1976. Racemic metolachlor consists of 50% each of the *R*-enantiomer (CGA 77101) and the *S*-enantiomer (CGA 77102, or alpha

metolachlor). The *S*-enantiomer is the herbicidally active isomer. *S*-metolachlor is a racemic mixture comprised of 88% *S*-enantiomer and 12% *R*-enantiomer. Toxicity data has been submitted on both metolachlor and *S*-metolachlor. The Agency has determined that *S*-metolachlor has either comparable or decreased toxicity as compared to racemic metolachlor.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by metolachlor are discussed in Table 1a below as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1A.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY FOR METOLACHLOR (PC CODE 108801)

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = 210 milligram/kilogram/day (mg/kg/day) for males LOAEL for males was not established NOAEL = 23.4 mg/kg/day for females LOAEL = 259 mg/kg/day for females based on decreased body weight/body weight gain
870.3150	90-Day oral toxicity in nonrodents	NOAEL = 8.77 mg/kg/day LOAEL = 29.42 mg/kg/day based on decreased body weight gain
870.3200	21-28 day dermal	Systemic NOAEL = 1,000 mg/kg/day Systemic LOAEL was not established dermal irritation NOAEL was not established dermal irritation LOAEL = 10 mg/kg/day based on very slight erythema, dry skin and fissuring (one animal)
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 300 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on an increased incidence of death, clinical signs of toxicity (clonic and/or toxic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive lacrimation) and decreased body weight gain. Developmental NOAEL = 300 mg/kg/day Developmental LOAEL = 1000 mg/kg/day based on slightly decreased number of implantations per dam, decreased number of live fetuses/dam, increased number of resorptions/dam and significant decrease in mean fetal body weight
870.3700	Prenatal developmental in nonrodents	Maternal Toxicity NOAEL = 120 mg/kg/day Maternal Toxicity LOAEL = 360 mg/kg/day based on an increased incidence of clinical observations (persistent anorexia) and decreased body weight gain Developmental Toxicity NOAEL = 360 mg/kg/day Developmental Toxicity LOAEL was not established