

account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk.

A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an

endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure/exposures}$) is calculated. A summary of the toxicological endpoints for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR 4-(DICHLOROACETYL)-1-OXA-4-AZASPIRO[4.5]DECANE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 3 aPAD = acute RfD/FQPA SF SF = 0.033 mg/kg/day	Development toxicity in rabbits LOAEL = 75 mg/kg/day based on decreased body weight gain on day 3 of dosing.
Acute Dietary (General population, including infants and children)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 1 aPAD = acute RfD/FQPA SF SF = 0.1 mg/kg/day	Development toxicity in rabbits Material LOAEL = 75 mg/kg/day based on decreased body weight gain on day 3 of dosing.
Chronic Dietary (All populations)	NOAEL = 2.21 mg/kg/day UF = 300 Chronic RfD = 0.007 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF SF = 0.007 mg/kg/day	Chronic/Carcinogenicity in rats LOAEL = 22.09 mg/kg/day based on histopathological changes in liver and stomach including cystic liver degeneration, periportal hepatocellular vacuolation, and pyloric intestinal metaplasia of the stomach
Short-, intermediate Term Dermal	Dermal (or oral) study NOAEL = 10 mg/kg/day (dermal absorption rate = 25 %)	LOC for MOE = 100 (Residential)	Development toxicity in rabbit LOAEL = 75 mg/kg/day based on decreased body weight gain on day 3 of dosing.
Long-Term Dermal	Oral study NOAEL= 2.21 mg/kg/day (dermal absorption rate = 25 %when appropriate)	LOC for MOE = 100 (Residential)	Chronic/Carcinogenicity in rats LOAEL = 22.09 mg/kg/day was used for deriving the chronic RfD.
Inhalation any time period	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Development toxicity in rabbit LOAEL = 75 mg/kg/day based on decreased body weight gain on day 3 of dosing
Cancer (Oral, dermal, inhalation)	$Q_1^* = 4.85 \times 10^{-2}$ (mg/kg/day). ¹		Likely to be carcinogenic to humans (combined hepatocellular adenoma and /or carcinoma in male mice).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* The tolerances to be established are import tolerances. Thus, the only dietary exposure would be residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, in imported corn commodities. Therefore, risk assessments were conducted by EPA to assess dietary exposures from 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has

indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments:

The acute dietary (food only) assessment is based on Tier 1

assumptions (tolerance level residues, 100% crop treated). For all population subgroups the estimated dietary (food only) risks are less than 1% of the acute population-adjusted dose (PAD). This is well below the Agency's level of concern for the dietary exposure (100% of the PAD).

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing