

the milk, meat, and meat byproducts of ruminants 40 CFR 180.6(a)(3) as a result of hydramethylnon use on grasses. The Agency has also previously recommended that the grass forage tolerance be increased to 2.0 ppm and the grass hay tolerance be increased to 0.1 ppm. The residue chemistry and toxicological databases support the requested tolerance of 0.05 ppm for hydramethylnon on pineapple. Since there are no detectable hydramethylnon residues in the pineapple feed item, process residues, tolerances for hydramethylnon residues in animal commodities need not be established. Risk assessments were conducted by EPA to assess dietary exposures from hydramethylnon 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. An unrefined, Tier 1 acute dietary exposure assessment was conducted using tolerance-level residues and assuming 100% crop treated (CT) for all registered and proposed commodities. The acute analysis was conducted for females 13–49 years old only as no appropriate single dose endpoint was established for the general U.S. population and infants and children.

The acute dietary exposure estimates are well below the Agency's level of concern (<100% aPAD) at the 95th exposure percentile for females 13–49 years old (<1% of the aPAD).

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996/1998 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 chronic exposure assessments: A Tier 1 (conservative, deterministic assessment using tolerance-level residues, and 100% crop treated (CT) for the proposed commodity; and DEEM-FCID® ver. 1.30, processing factors set to (1) a chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. The chronic dietary exposure estimates are well below the Agency's level of concern (<100% cPAD) for the general U.S. population (<1% of the cPAD) and all population subgroups.

iii. *Cancer.* In a chronic feeding/carcinogenicity study in Charles River CD rats, no compound-related clinical

signs were observed and survival was not affected by treatment. The LOAEL was based on small, soft testes, decreased testicular weights (27%), and testicular atrophy in males; and decreased body weight gain in females (22%). Statistically significant findings of neoplasia were found in the uterus (adenomatous polyps) and adrenals (medullary adenomas), but these were not considered toxicologically significant because they were seen at doses above the MTD.

In an 18 month carcinogenicity feeding study in Charles River CD-1 mice, survival decreased as the dose increased, but not enough to jeopardize the study. The LOAEL was based on testicular degeneration (hypospermia, interstitial cell hyperplasia of Leydig cells, and germinal cell degeneration) in males, and combined lung adenomas and carcinomas in females. Findings of hyperplasia and neoplasia in the lungs of males were not considered toxicologically significant because they were seen at doses above the MTD. Findings in females of statistically significant increases in lung adenomas and combined lung adenomas/carcinomas were, however, considered toxicologically significant.

The Agency's Cancer Peer Review Committee classified hydramethylnon as a Group C-possible human carcinogen, and recommended that, for the purpose of risk characterization, the Reference Dose approach should be used for quantification of human risk. This classification was based upon statistically significant increases in lung adenomas and combined lung adenomas/carcinomas in female mice. Dietary risk concerns due to long-term consumption of hydramethylnon residues are adequately addressed by the chronic exposure analysis using the RfD.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic

evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

A routine chronic dietary exposure analysis for pineapple was based on 100% of pineapple crop treated, and 100% of grasses, forage (pasture and rangeland) treated with hydramethylnon.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA used a conservative, model assessment as outlined in Unit III.C.1.ii. above, using tolerance-level residues and 100% CT for the proposed commodity pineapple, and existing commodities. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which hydramethylnon may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for hydramethylnon in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the use pattern, physical characteristics and environmental fate of hydramethylnon.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1