

safety factor for the protection of infants and children (i.e., it is derived from the NOAEL of 1.2 mg/kg/day with an MOE of 1,000 – 10x for intraspecies extrapolation; 10x for interspecies variation; and 10x for FQPA). Since this approach (using the cPAD) would be more protective than the proposed POD for cancer risk assessment of 3 mg/kg/day, and includes an additional 10x factor for the protection of infants and children, a separate non-linear risk assessment for cancer is not necessary.

Exposure estimates expressed as a percentage of the anti-androgenic PAD (0.0012 mg/kg/day) were 4% for the general U.S. population and 7% for the most highly exposed population subgroup, children (1–6 years old). In addition, as a point of comparison, the MOE was calculated to be 75,000 for the general U.S. population and 38,000 for children (1–6 years old).

2. *Drinking water.* In general, available monitoring data are of limited use because metabolite concentration measurements were not performed. For both surface water and ground water, the sum of vinclozolin and its principal metabolites, assumed to degrade completely to 3,5-dichloroaniline (herein-after referred to as 3,5-DCA), have been used to assess the cancer risk associated with 3,5-DCA whereas vinclozolin per se has been used for the vinclozolin risk assessments.

In the absence of reliable, available monitoring data, EPA uses models to calculate the estimated environmental concentrations (EECs) of pesticides in ground water and surface water. However, EPA does not use these model estimates to quantify risk. Currently, EPA uses drinking water level of concerns (DWLOCs) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC represents the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and the drinking water consumption patterns and body weights for specific population subgroups. The calculated DWLOC is compared to the model estimate (EEC), and if the model estimates are below the DWLOC, the risks are not considered to be of concern.

For estimating ground water concentrations of vinclozolin and 3,5-DCA, EPA used the Screening Concentration in Ground Water (SCI-GROW) model. Using SCI-GROW, the acute and chronic ground water EEC of

vinclozolin per se is 0.53 parts per billion (ppb), and the acute and chronic ground water EEC of 3,5-DCA is 2.65 ppb.

For estimating surface water concentrations of vinclozolin and 3,5-DCA, EPA used tier II models, Pesticide Root Zone Model (PRZM) 3.12 and Exposure Analysis Modeling System (EXAMS) 2.975. The acute (peak) surface water EEC for vinclozolin is 5.68 ppb and for 3,5-DCA is 26 ppb. The chronic (annual mean) surface water EEC for vinclozolin is 0.165 ppb and for 3,5-DCA is 3.12 ppb.

i. *Acute exposure and risk.* For the population subgroup of concern, females (13+), the DWLOCs for vinclozolin per se at the various percentiles of exposure are as follows: 0 ppb at the 99.9th percentile; 4 ppb at the 99.85th percentile; 30 ppb at the 99.8th percentile; 47 ppb at the 99.75th percentile; 80 ppb at the 99.6th percentile; and 92 at the 99.5th percentile. At all but the very highest percentiles of exposure (99.85th and above), the DWLOC for vinclozolin per se is higher than the EEC of 5.68 ppb in surface water and 0.53 ppb in ground water. Given the level of refinement in the vinclozolin exposure estimate, using the highest percentiles of exposure in estimating risk would unreasonably overstate risk. Therefore, there is reasonable certainty that exposure to vinclozolin per se in drinking water will result in no harm.

ii. *Chronic exposure and risk.* The following chronic DWLOCs were calculated for vinclozolin per se: General U.S. population, 41 ppb; females (13+) 35 ppb; and children (1–6 years old), 11 ppb. The lowest DWLOC of 11 ppb for children 1–6 years old is higher than the EEC of 0.165 ppb in surface water and 0.53 ppb in ground water. Therefore, there is reasonable certainty that exposure to vinclozolin in drinking water will result in no harm.

3. *Non-dietary exposure.* From non-dietary exposure. There are no vinclozolin pesticide products registered for use by homeowners. Therefore, there is no potential for homeowner handler exposure to vinclozolin pesticide products. Vinclozolin can, however, be occupationally used in a manner that may lead to post-application exposures to the general population, in particular, golfers playing on treated golf courses and homeowners and their families coming into contact with or playing on sod which was previously treated on a sod farm. A chemical-specific turf exposure study was used to measure

human exposure as well as residue dissipation over time.

All residential exposures are considered to be short-/intermediate-term duration (i.e., 1 day to 1 week and 1 week to several months, respectively), and the same endpoint applies to both durations of exposure. As the endpoints selected are from oral toxicity studies (NOAEL of 3 mg/kg/day for females (13+)) and NOAEL of 5 mg/kg/day for infants and children, route-to-route exposure was corrected by applying a 25% dermal absorption factor and a 100% default inhalation absorption factor was assumed. A 100% safety factor was used and a 10X FQPA safety factor was added raising the Agency's LOC to 1,000.

Post-application risks to the general population were considered for golfers following treatment of greens, tees, and fairways. Adult golfer exposures, women (13+), were less than the Agency's LOC even on the day of application (MOE = 1,700). Given the magnitude of the MOE for adult women golfers, the Agency does not believe that the risks to child golfers would exceed the Agency LOC either because the skin surface area/body weight ratio of the typical child golfer is similar to that of adults (within 15%). Therefore, the MOE for a child golfer is only slightly less than the MOE for adult golfers.

Since the risk assessment published in the **Federal Register**, of July 18, 2000 (65 FR 44453) establishing the tolerances in canola, BASF has established a 24 day preharvest interval for the harvest of turf for transplant into residential settings. The MOE calculated under this scenario is 1,100 which is below the Agency's LOC.

#### *E. Cumulative Effects*

Cumulative exposure to substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Vinclozolin, procymidone, and iprodione are members of the imide group of the dicarboximide class of fungicides. Each of these three pesticides can metabolize to 3,5-DCA. FQPA requires EPA to estimate cumulative risk from consumption of food and water containing 3,5-DCA derived from vinclozolin, iprodione, and procymidone.

1. *Acute exposure and risk.* EPA has certain evidence that these compounds induce similar toxic effects but has not