

iii. *The GENEEC model uses the 56-day average of pesticide concentrations immediately after an event (application of pesticide).* This short time-period may not adequately characterize a person's average daily exposure over a year, even more so, over a life time of 70 years.

iv. *The GENEEC model assumes that once in every 10 years the EEC will be exceeded.* For the other 9 out of 10 years the level of residue in drinking water is likely to be below the EEC with at least one half of the years falling significantly below by a factor of 5 to 10. Therefore, a person may be exposed to the EEC once in every 10 years or a total of 7 times during a lifetime of 70 years. The Agency believes the potential for such a lifetime exposure is minimal.

v. *Iprodione 3,5-DCA.* As stated in the RED, the DWLOC for 3,5-DCA derived from domestic uses of iprodione was estimated to be 0.55 ppb. The 3,5-DCA EEC in surface water associated with the use of iprodione alone was estimated to be 0.45 ppb. Thus, the iprodione derived 3,5-DCA carcinogenic DWLOC is not exceeded.

vi. *From procymidone 3,5-DCA.* There is no drinking water exposure because procymidone is not registered for use in the United States.

The cumulative, food-only cancer risk associated with 3,5-DCA derived from all three of these imide fungicides is  $6.3 \times 10^{-7}$  when stone fruit and strawberries are excluded from consideration. There is uncertainty in the above risk estimates in that a surrogate  $Q^{1*}$  is being used for 3,5-DCA. However, due to the structural similarities of 3,5-DCA and p-chloroaniline (PCA), EPA believes that for 3,5-DCA, the use of the PCA  $Q^{1*}$  represents an upper-bound estimate.

The 3,5-DCA DWLOC from all three imide fungicides and those currently registered vinclozolin uses which are not being supported after this use season ranges from 0.26 ppb to 1.4 ppb. The estimated concentration of 3,5-DCA in water from applications of iprodione (1998 iprodione RED) is 0.45 ppb and falls within the range of the aggregated DWLOC cited above. The estimated concentration of 3,5-DCA in water from applications of vinclozolin is estimated to range from 0.29 ppb to 2.33 ppb.

As already stated, this range could potentially present a risk of concern based on the model, however, based on how the model estimates residue concentrations for cancer assessment, it is unlikely that a cancer risk of concern is present.

#### F. Safety Determination

1. *U.S. population—i. Acute risk.* The acute dietary (food only) risk does not

exceed the Agency's LOC at the percentiles of exposure up to the 99.8th percentile. Using anticipated residues, PCT data, and PICT data, the population subgroup of concern, females (13+) utilized 83% of the dietary (food only) aPAD at the 99.8th percentile of exposure. For drinking water, the EEC of 5.68 ppb in surface water and the EEC of 0.53 in ground water did not exceed the DWLOC of 30 ppb at the 99.8th percentile of exposure.

ii. *Chronic risk.* Using the exposure assumptions described above, aggregate dietary exposure to the U.S. population will use 4% of the cPAD and exposure to the most highly exposed population subgroup, children (1–6 year old) will use 7% of the cPAD. The chronic DWLOCs for vinclozolin were 41 ppb for the general U.S. population and 35 ppb for the most highly exposed population subgroup, women (13+). The chronic DWLOCs were higher than the chronic EEC of 0.53 ppb in ground water and 0.165 ppb in surface water. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

2. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. All residential exposures are considered to be short- and intermediate-term duration and since the same endpoint applies to both durations of exposures, the dermal and inhalation exposures must be aggregated together with the food and water exposures for each population subgroup of concern, females (13+) and infants and children. 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.

3. *Aggregate cancer risk for U.S. population.* Because the overall anti-androgenic effects are a prerequisite for hyperplasia and tumor formation, and are considered to be protective of the potential carcinogenic outcome of exposure to the anti-androgenic vinclozolin and its metabolites, the overall anti-androgenic aggregate risk which are identical to the chronic aggregate risk. The chronic aggregate risks are presented. The chronic (non-

cancer) aggregate risk was below the Agency's LOC for food and drinking water sources of exposure. Chronic food-source risks were less than or equal to 7% of the cPAD when stone fruit and strawberries are excluded (uses have been canceled). EECs were compared to the chronic DWLOCs. The chronic EEC for residues of vinclozolin per se in ground water (0.53 ppb) was below the chronic DWLOCs for water consumption by adults (41 ppb for the general U.S. population and 35 ppb for females (13+)) and by children (11 ppb).

Cancer risks from vinclozolin derived 3,5-DCA were  $2.6 \times 10^{-7}$  for all crops, excluding strawberries and stone fruits. This risk does not exceed the Agency's LOC. The 3,5-DCA DWLOC from all three imide fungicides (including canola, succulent beans, onions, and raspberries) ranges from 0.26 ppb to 1.4 ppb. It should be noted that vinclozolin is no longer used in onions and raspberries. The 3,5-DCA EEC resulting from iprodione use is 0.45 ppb and falls within the range of the aggregated DWLOC cited above. The 3,5-DCA EEC resulting from vinclozolin use is estimated to range from 0.29 ppb to 2.33 ppb. As already stated, this range could potentially present a risk of concern based on the model, however, based on how the model estimates residue concentrations for cancer assessment, it is unlikely that a cancer risk of concern is present.

4. *Determination of safety.* Based on these risk assessments, there is a reasonable certainty that no harm will result from aggregate exposure to vinclozolin residues.

5. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of vinclozolin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation.

Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children.