

iii. *Cancer.* The Agency determined that boscalid produced suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential. This cancer classification was based on the following weight of evidence considerations. First, in male Wistar rats, there was a significant trend (but not pairwise comparison) for the combined thyroid adenomas and carcinomas. This trend was driven by the increase in adenomas. Second, in the female rats, there was only a borderline significant trend for thyroid adenomas (there were no carcinomas). Third, the mouse study was negative as were all of the mutagenic tests. Consistent with this weak evidence of carcinogenic effects, the Agency concluded that a dose-response assessment for cancer (either linear low-dose extrapolation or margin of exposure calculation) was not needed.

iv. *Anticipated residue and percent crop treated (PCT) information.* The Agency used tolerance level residues and 100% crop treated for this risk analysis.

2. *Dietary exposure from drinking water.* This is a new chemical and 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 physical characteristics of boscalid.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The 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 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would

ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to boscalid they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of boscalid for chronic exposures are estimated to be 25.6 ug/L for surface water and 0.571 ug/L for ground water. The Agency notes that for surface and groundwater assessments, the application rate for turf was used, which represents the highest seasonal application rate (2.1 lbs. active ingredient/acre/season). The highest single application rate associated with the use of the pesticide on fruiting vegetables, did not result in EEC values higher than those calculated for turf use since the proposed total seasonal application rate for fruiting vegetables is only 1.1 lb. active ingredient/acre/season.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Boscalid is currently being registered for use on the following residential non-dietary sites: The boscalid label with turf use specifies that this product is intended for golf course use only, and not for use on residential turfgrass or turfgrass being grown for sale or other commercial use such as sod production. Although the label does not indicate that the product is applied by licensed or commercial applicators, homeowners will not be applying the product to golf courses. Therefore, a risk assessment for residential handler exposure is not required. The risk assessment was conducted using the following residential exposure assumptions: The Agency uses the term post-application to describe exposures to individuals that occur as a result of being in an

environment that has been previously treated with a pesticide. There are two recreational scenarios associated with boscalid that could lead to exposures for adults and children: (i) Adults and youth golfing and (ii) adults and children picking their own fruit. These exposure durations are anticipated to be short term. Because U-pick is a one-time event (duration <1 day) and the Agency found that the oral studies indicated there were no endpoints appropriate to quantitate acute risk, the U-pick exposure/risk was not evaluated. Therefore, only the golfing scenario was evaluated with respect to non-occupational, non-dietary exposure. The dermal MOEs for adults golfing were 27,000-74,000. Although specific MOEs were not calculated for youths playing golf, the adult MOEs are considered representative since the body surface area to weight ratios for adolescents do not vary significantly from those for adults. The refined assessment is based on reliable data and is unlikely to underestimate exposure/risk.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA 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."

EPA does not have, at this time, available data to determine whether boscalid has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, boscalid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that boscalid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA 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