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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 2/10/04

SUBJECT: PP#s 2F6434 and 3F6580 **Human Health Risk Assessment for Boscalid.** Proposal for Tolerances for Residues in/on Soybeans, Pome Fruit, and Hops.

DP Barcode:	D297935		
Chemical#:	128008		
Class:	Fungicide		
Trade Name:	Endura™	EPA Reg#:	7969-197
	Pristine™	EPA Reg#:	7969-199
40 CFR:	§180.589		

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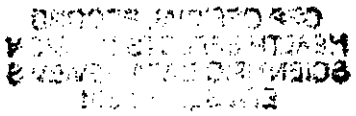

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1.0 EXECUTIVE SUMMARY

General Background

The first human health risk assessment for boscalid (formerly BAS 510 F) was completed on 9/8/2003 by Y. Donovan, *et al.* (D290022). The Health Effects Division (HED) recommended in favor of the establishment of tolerances on a number of plant and animal commodities. These tolerances were published in the Federal Register Environmental Documents (July 30, 2003). Although the registrant had proposed tolerances on pome fruit and hops, the residue data had not been reviewed by HED. Therefore, HED did not recommend in favor of tolerances on these commodities. The residue data have since been reviewed, along with data on soybeans. As a result, this current human health risk assessment addresses these three commodities. There have been no additions to the toxicological database, and no changes in either the toxicological endpoints chosen for hazard evaluation or the FQPA Safety Factor determination. Therefore, reference may be made to the previous risk assessment for information pertaining to the toxicological database as well as much of the information pertaining to the residue chemistry database (i.e., the information which does not pertain specifically to the commodities in this assessment: soybeans, pome fruit, and hops).

Two formulated end-use products contain boscalid. One of these is Endura™ Fungicide (EPA Reg. No. 7969-197), which contains 70% boscalid. The other end-use product is Pristine™ Fungicide (EPA Reg. No. 7969-199), which contains a 2:1 mixture of boscalid and pyraclostrobin as co-active ingredients (25.2%:12.8%). Pristine™ is proposed for use on pome fruit, soybeans, and hops, whereas Endura™ is proposed for use on pome fruit and soybeans only.

The hazard assessment was summarized in the previous risk assessment. As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13-50 years old. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD) for the general population or females 13-50 years old. An acute aggregate risk assessment is not needed. Chronic toxicity was seen in several species of animals. Effects were seen in the thyroid and liver. The chronic NOAEL was 21.8 mg/kg bw/day. The FQPA Safety Factor was reduced to 1x and the uncertainty factor for intraspecies variability and interspecies extrapolation was 100x. As a result, the chronic population adjusted dose was 0.218 mg/kg/day. For the dermal route, the absorption rate was 15% relative to oral. For the inhalation route, the absorption rate was assumed to be 100%. The residential and occupational level of concern (LOC) for all routes is an MOE of 100. The Cancer Assessment Review Committee (CARC) classified boscalid as having "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." The quantification of human cancer risk was therefore not recommended.

Residential Exposure Estimates

A non-occupational dermal post-application exposure/risk assessment for individuals golfing and harvesting fruit at "U-pick" farms and orchards was conducted in the previous occupational and

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residential exposure (ORE) assessment. As no new residential uses are proposed, a residential exposure/risk assessment is not required.

Dietary Exposure Estimates

In target crops, rotational crops, and drinking water, parent boscalid is the only residue of concern for both tolerance expression and risk assessment. In animal commodities, parent boscalid, a hydroxy metabolite, and the glucuronide of the hydroxy metabolite are the residues of concern for tolerance expression and risk assessment.

Method D9908 was used for data collection in the soybean, pome fruit, and hops field trials. This method has been adequately validated for data collection, and the reported limit of quantitation (LOQ) is 0.05 ppm for residues of boscalid in/on plant matrices. Submitted freezer storage stability data support the freezer storage interval (from collection to analysis) of samples in the soybean, pome fruit, and hops field trial and processing studies.

The submitted field trials performed on hops, pome fruit, and soybeans are adequate to support the recommended tolerances. The following tolerances are supported by the field trial data: hops cones, dried (35 ppm), pome fruit (3.0 ppm), apple pomace, wet (10 ppm), soybean vegetable (2.0 ppm), soybean seed (0.1 ppm), soybean hulls (0.2 ppm), soybean aspirated grain fractions (3.0 ppm). The registrant needs to submit a revised Section F in which a tolerance of 2.0 ppm is proposed for soybean vegetable and a tolerance of 3.0 ppm is proposed for soybean aspirated grain fractions. The proposed tolerances of 3.0 for pome fruit, 0.1 ppm for soybean seed, 0.2 ppm for soybean hulls, and 35 ppm for hops are adequate. The revised Section F should specify the correct commodity definition for apple pomace as apple pomace, wet, for hops as hops cones, dried, and for soybean (Immature) as soybean vegetable. The registrant did not propose tolerances for soybean forage and hay. As the boscalid labels have feeding restrictions on forage and hay, it is not necessary to establish tolerances for these commodities.

The apple and soybean processing studies are adequate for the establishment of tolerances on apple and soybean processing commodities. The apple processing study supports a tolerance of 10 ppm for apple pomace. As residues do not concentrate in apple juice, a separate tolerance is not required for juice. The soybean processing study supports the proposed tolerance of 0.2 ppm for soybean hulls. As residues do not concentrate in meal or oil, tolerances are not required for these commodities. There are no data deficiencies that would preclude the establishment of the tolerances for apple or soybean processing commodities. The registrant needs to submit a revised Section F in which a tolerance of 10 ppm is proposed for apple pomace, wet.

Dietary Exposure Analysis

The chronic dietary exposure analysis was performed using two separate models: DEEM-FCID™ and Lifeline™. The analysis was based on tolerance-level residues (in some cases modified by DEEM™ (Version 7.81) default processing factors), and assume 100% crop treated. In both cases, the risk estimates are well below HED's level of concern for the general U.S. population and all population subgroups. The results of the DEEM-FCID™ and Lifeline™ analyses are comparable. The most highly exposed population subgroup from DEEM™ is

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children 1-2 years, which has an exposure estimate of 0.057 mg/kg/day, and utilizes 26% of the cPAD. The most highly exposed population subgroup from Lifeline™ is also children 1-2 years, which has an exposure estimate of 0.053 mg/kg/day, and utilizes 24% of the cPAD.

Drinking Water Exposure Estimates

EFED provided the Tier I estimated drinking water concentrations (EDWCs) for boscalid in surface water and in groundwater for use in the human health risk assessments. EFED used the simulation model FIRST to calculate the surface water EDWCs and used the simulation model SCI-GROW to calculate the groundwater concentration. The turf use represents the highest annual application rate for boscalid. Since the completion of the previous risk assessment for boscalid, the aerobic soil metabolism half lives used as input parameters for the FIRST and SCI-GROW models have been revised. The revised environmental drinking water concentrations from FIRST are 87.53 ppb for acute and 25.77 ppb for chronic. The SCI-GROW estimate for groundwater exposure has changed from 0.57 to 0.63 ppb.

Aggregate Exposure Scenarios and Risk Conclusions

Acute Aggregate Risk

As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute dietary risk to the general population or to the subpopulation females 13-50 years old. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD) for the general population or females 13-50 years old. An acute aggregate risk assessment is not needed.

Short-Term Aggregate Risk

The short-term aggregate risk assessment takes into account average exposure estimates from dietary consumption of boscalid (food and drinking water) and non-occupational uses (golf course). Postapplication exposures from the use on golf courses is considered short-term, and applies to adults and youth. Therefore, a short-term aggregate risk assessment was conducted. Since all endpoints are from the same study, exposures from different routes can be aggregated. The MOE from food and non-occupational uses is 1400, and the calculated short-term DWLOC is 6100 ppb. EFED's surface and ground water EDWCs are considerably lower than the DWLOC. Therefore, short-term aggregate risk does not exceed HED's level of concern. The MOE and DWLOC are also considered representative for youth.

Intermediate-Term Aggregate Risk

As no intermediate-term non-occupational exposures are anticipated, an intermediate-term aggregate risk assessment is not needed.

Chronic Aggregate Risk

The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of boscalid (food and drinking water) and residential uses. As the exposure resulting from contact with turf grass (golf courses) is considered short term rather than chronic, the chronic aggregate assessment includes food and drinking water only. The calculated chronic DWLOCs for chronic exposure to boscalid in drinking water range from 1600 to 7200 ppb. EDWCs generated by EFED are less than HED's calculated chronic DWLOCs. Therefore, the chronic aggregate risk associated with the use of boscalid does not exceed HED's level of concern for the general U.S. population or any of the population subgroups.

Occupational Exposure Estimates

Occupational handler assessments were based primarily on surrogate unit exposures from the PHED, as presented in the PHED Surrogate Exposure Guide (8/98). All MOEs for the handlers were greater than the target of 100 at the baseline level (ranging from 250 to 18,000).

The occupational post-application exposure and risk estimates were calculated by coupling HED DFR defaults (for hops & soybeans) or crop specific DFR values (for pome fruits, 1.3 $\mu g/cm^2$) with activity specific transfer coefficients (Tc) from the HED Science Advisory Council For Exposure Policy Number 3.1. All post-application MOEs were greater than the target MOE of 100 (ranging from 260 to 13,000). The 12 hour REI appearing on the label is appropriate for this chemical.

Recommendations

HED concludes that there is a reasonable certainty that no harm will result to the general U.S. population, including infants and children, from short-term and chronic aggregate exposure to boscalid residues. HED has no objection to the establishment of permanent tolerances for the residues of boscalid in or on the following:

Table 1. HED Recommended Tolerances for Boscalid

Commodity Expression	Tolerance (ppm)
Pome Fruit Crop Group, Group 11	3.0
Apple Pomace, Wet	10
Hops Cones, Dried	35
Soybean, Vegetable	2.0
Soybean Seed	0.1
Soybean Hulls	0.2
Soybean Aspirated Grain Fractions	3.0

Note to Product Manager: The original petition for boscalid established soybean seed and hull tolerances under rotational crops at the same levels as needed for the present action. These rotational crop tolerances should be deleted when the new tolerances are established for direct use on soybeans. In addition, the conditions of registration noted in our previous chemistry chapter (8/15/2003) and risk assessment (9/8/2003) should apply to the present uses if they have not been satisfied.

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

For a discussion of the physical and chemical properties of boscalid see the previous risk assessment (D290022, Y. Donovan, *et al.*, 9/8/2003).

3.0 HAZARD CHARACTERIZATION

As there have been no changes to the hazard characterization since the previous risk assessment, see the HED HIARC Report (TXR No. 0051713, 3/7/2003) or the previous risk assessment (D290022, Y. Donovan, *et al.*, 9/8/2003), for a discussion of this topic.

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered and Proposed Uses

Registered Uses: As stated above, HED recently recommended in favor of the establishment of tolerances on a wide variety of crops and animal commodities (Memo, D290022, Y. Donovan, *et al.*, 9/8/2003). These tolerances were published in the Federal Register Environmental Documents (July 30, 2003). Tolerances on primary crops range from 0.05 ppm on the Tuberous and Corm Vegetable Crop Subgroup (1C) to 30 ppm on peppermint and spearmint tops. Tolerances on rotational crops range from 0.05 ppm on several commodities to 3.5 ppm on flax seed. Animal commodity tolerances range from 0.02 ppm for eggs to 0.35 ppm for the meat byproducts of cattle, goats, horses, and sheep.

Formulations and Proposed Uses: Two formulated end-use products contain boscalid. One of these is Endura™ Fungicide (EPA Reg. No. 7969-197), which contains 70% boscalid. The other end-use product is Pristine™ Fungicide (EPA Reg. No. 7969-199), which contains a 2:1 mixture of boscalid and pyraclostrobin as co-active ingredients (25.2%:12.8%). Pristine™ is proposed for use on pome fruit, soybeans, and hops, whereas Endura™ is proposed for use on pome fruit and soybeans only. Crops are to be treated with a broadcast spray which can be made by either ground or aerial equipment (except for hops which cannot be treated aerially). Soybeans may receive a maximum of two treatments with a seven day retreatment interval. Hops may receive a maximum of three treatments with a ten day retreatment interval. Pome fruit may receive a maximum of four treatments with a seven day retreatment interval. PHIs range from zero days for pome fruit to 21 days for soybean mature seed, forage, and aspirated grain fractions.

Application rates range from 0.29 lb ai/A for pome fruit to 0.48 lb ai/A for soybeans. Maximum seasonal application rates range from 0.96 lb ai/A for soybeans to 1.3 lb ai/A for hops.

4.2 Dietary Exposure/Risk Pathway

4.2.1 Residue Profile

For a discussion of the residue chemistry topics that do not pertain specifically to soybeans, pome fruit, and hops (i.e., metabolism studies, analytical enforcement methods, frozen storage stability studies, etc.) see Memo (D290022, Y. Donovan, *et al.*, 9/8/2003). For a more detailed discussion of these topics, reference may also be made to the MARC Decision Memo (D286786, M. Nelson, 01/09/03) as well as the residue chemistry summary document associated with the previous risk assessment (D286787, M. Nelson, 8/15/03).

Metabolism of Boscalid

In target crops, rotational crops, and drinking water, parent boscalid is the only residue of concern for both tolerance expression and risk assessment. In animal commodities, parent boscalid, a hydroxy metabolite, and the glucuronide of the hydroxy metabolite are the residues of concern for tolerance expression and risk assessment.

Data Collection Method for Plants

Method D9908 was used for data collection in the soybean, pome fruit, and hops field trials. This method determines residues of boscalid in plant matrices. Residues are extracted with an aqueous organic solvent mixture followed by liquid/liquid partitioning and column clean-up. Quantitation is by LC/MS/MS. This method has been adequately validated for data collection, and the reported limit of quantitation (LOQ) is 0.05 ppm for residues of boscalid in/on plant matrices.

Enforcement Methods

Adequate methods are available to enforce tolerances on plants (Method D0008, GC/MS) and animals (Method DFG S19, GC/ECD).

Freezer Storage Stability in Plant Commodities

Submitted freezer storage stability data indicate that residues of boscalid are stable in diverse representative crop matrices (sugar beet root, cabbage, canola seed, pea, peach, and wheat grain, forage, and straw) for at least one year of frozen storage (MRID 45405109). Boscalid residues have also been shown to be stable in peanut oil and meal for up to 45 days (duration of study (MRID 45405122)). These data support the freezer storage interval (from collection-to-analysis) of samples in the soybean, pome fruit, and hops field trial and processing studies.

Magnitude of the Residue Studies

Field trials were conducted to determine the magnitude of boscalid residues in soybeans, pome fruit, and hops. The field trial studies, their results, and HED's conclusions concerning the adequacy of these studies are summarized below.

The submitted field trials performed on hops, pome fruit, and soybeans are adequate to support the recommended tolerances. The hops and soybean field trials were performed according to the use directions. For pome fruit, the total application rate used in field trials was 1.6x that specified on the proposed label. The individual application rate was the specified rate; however, six applications were made as opposed to the four that were proposed. As the actual total application rate was not considerably higher than the proposed total application rate, the field trials are considered to be adequate for tolerance setting purposes. Adequate storage stability studies have been submitted to demonstrate that boscalid residues are stable over the storage periods used in field trials. The analytical method used for data collection has been demonstrated to be adequate for analysis of hops, pome fruit, and soybean commodities. As the parent compound is the only residue of concern in plant commodities, it was the only residue measured in the field trials.

The following tolerances are supported by the field trial data: hops cones, dried (35 ppm), pome fruit (3.0 ppm), apple pomace, wet (10 ppm), soybean vegetable (2.0 ppm), soybean seed (0.1 ppm), soybean hulls (0.2 ppm), soybean aspirated grain fractions (3.0 ppm). The registrant needs to submit a revised Section F in which a tolerance of 2.0 ppm is proposed for soybean vegetable and a tolerance of 3.0 ppm is proposed for soybean aspirated grain fractions. The proposed tolerances of 3.0 for pome fruit, 0.1 ppm for soybean seed, 0.2 ppm for soybean hulls, and 35 ppm for hops are adequate. The revised Section F should specify the correct commodity definition for apple pomace as apple pomace, wet, for hops as hops cones, dried, and for soybean (immature) as soybean vegetable. The registrant did not propose tolerances for soybean forage and hay. As the boscalid labels have feeding restrictions on forage and hay, it is not necessary to establish tolerances for these commodities.

The results of the hops, pome fruit, and soybean field trials are given in Table 2.

Table 2. Summary of Residues from the Crop Field Trials with Boscalid

Crop Matrix	Applic. Rate (lb ai/A)	PHI (days)	Residues (ppm)				
			Mean	Std. Dev.	HAFT	Min.	Max.
Hops (proposed use = 1.32 lb ai/A total application rate, 14-day PHI)							
Hops	1.35 lb ai/A	14	21	11	22	11	31
Pome Fruit (proposed use = 1.16 lb ai/A total application rate, 0-day PHI)							
Apple	1.8 lb ai/A	0	0.76	0.4	1.4	0.17	2.1
Pear	1.8 lb ai/A	0	0.93	0.5	1.6	0.37	2.3
Soybeans (proposed use = 0.96 lb ai/A total application rate, 21-day PHI)							
Soybean Mature Seed	1.0 lb ai/A	21	<0.05	0	<0.05	<0.05	<0.05

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Table 2. Summary of Residues from the Crop Field Trials with Boscalid							
Crop Matrix	Applic. Rate (lb ai/A)	PHI (days)	Residues (ppm)				
			Mean	Std. Dev.	HAFT	Min.	Max.
Soybean Vegetable (Immature Seed)	1.0 lb ai/A	5	0.11	0.3	1.2	<0.05	1.3
Forage	1.0 lb ai/A	14	5.6	3.5	16	0.27	16
Hay	1.0 lb ai/A	21	5.5	4.9	21	0.1	22
Aspirated Grain Fractions	1.0 lb ai/A	21	1.6	-	1.6	0.71	2.4

Magnitude of the Residue in Processed Food/Feed.

Processing studies were conducted on soybeans and apples. The processing factors and HED's conclusions concerning the adequacy of these studies are summarized below.

Table 3. Processing Factors for Apple and Soybean Commodities				
Apple Juice	Apple Wet Pomace	Soybean Hulls	Soybean Meal	Soybean Refined Oil
0.07	5.5	1.8	0.2	0.4

Conclusions. The apple and soybean processing studies were conducted at exaggerated rates. The apple trial was conducted at a 1.8x rate. The soybean trial was conducted at a 2.2x rate (compared to the Pristine label rate) or a 2.6x rate (compared to the Endura label rate). The residue data are supported by the storage stability studies, and the analytical methods are adequate for the analysis of parent boscalid (the only residue of concern in plants). The apple processing study supports a tolerance of 10 ppm for apple pomace. As residues do not concentrate in apple juice, a separate tolerance is not required for juice. The soybean processing study supports the proposed tolerance of 0.2 ppm for soybean hulls. As residues do not concentrate in meal or oil, tolerances are not required for these commodities. There are no data deficiencies that would preclude the establishment of tolerances for the apple or soybean processing commodities. The registrant needs to submit a revised Section F in which a tolerance of 10 ppm is proposed for apple pomace, wet.

International Harmonization

Boscalid is a relatively new fungicide. There are currently no pending or established Codex maximum residue limits (MRLs) for boscalid. There are also no Mexican MRLs. The previous risk assessment was performed as a joint review with PMRA/Canada. The tolerances were harmonized with respect to the residue of concern and tolerance levels.

4.2.2 Chronic Dietary Exposure and Risk

The chronic dietary exposure assessment for boscalid is attached (Attachment 1, D295907, D. Dotson, 2/10/2004).

The chronic dietary exposure analysis was based on tolerance-level residues (in some cases modified by DEEM (Version 7.81) default processing factors), and assume 100% crop treated. Even with these highly conservative assumptions, the risk estimates are well below HED's level of concern. The most highly exposed population subgroup from DEEM™ is children 1-2 years, which has an exposure estimate of 0.057 mg/kg/day, and utilizes 26% of the cPAD. The most highly exposed population subgroup from Lifeline™ is also children 1-2 years, which has an exposure estimate of 0.053 mg/kg/day, and utilizes 24% of the cPAD.

Table 4. Summary of Dietary Exposure and Risk for Boscalid

Population Subgroup	Acute Analysis	DEEM: Chronic Analysis		Lifeline: Chronic Analysis	
		Dietary Exposure (mg/kg/day)	% cPAD	Mean Exposure (mg/kg/day)	% cPAD
General U.S. Population	Not Applicable: No Acute Dietary Endpoint	0.014597	6.7	0.01378	6.3
All Infants (< 1 year old)		0.03509	16	0.03421	16
Children 1-2 years old		**0.056809**	**26**	**0.0525**	**24**
Children 3-5 years old		0.039112	18	0.03983	18
Children 6-12 years old		0.019162	8.8	0.01806	8.3
Youth 13-19 years old		0.01046	4.8	0.00975	4.5
Adults 20-49 years old		0.010351	4.7	0.01094	5
Adults 50+ years old		0.010935	5	0.01121	5.1
Females 13-49 years old		0.010349	4.7	0.01191	5.5

4.2.3 Cancer Dietary

The Cancer Assessment Review Committee (CARC) stated that boscalid exhibited "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." The quantification of human cancer risk is therefore not necessary.

4.3 Water Exposure/Risk Pathway (Attachment 2, EFED memo of 11/10/03, K. Costello, D293435)

EFED provided the Tier I estimated drinking water concentrations (EDWCs) for boscalid in surface water and in groundwater for use in the human health risk assessments. EFED used the

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simulation model FIRST to calculate the surface water EDWCs and used the simulation model SCI-GROW to calculate the groundwater concentration. Because boscalid is a relatively new chemical, monitoring data were not available. The turf use represents the highest annual application rate for boscalid. Since the completion of the previous risk assessment for boscalid, the aerobic soil metabolism half lives used as input parameters for the FIRST and SCI-GROW models have been revised. The revised environmental drinking water concentrations from FIRST are 87.53 for acute and 25.77 ppb for chronic. The SCI-GROW estimate for groundwater exposure has changed from 0.57 to 0.63 ppb.

Table 5. Tier I EDWCs for Drinking Water Risk Assessment Based on Boscalid use on Turf.	
Surface water drinking water sources	acute: 87.5 ppb chronic: 25.8 ppb
Groundwater drinking water sources	0.63 ppb

4.4 Non-Occupational Exposure/Risk Pathway (Attachment 3, HED ORE memo of 2/xx/2004, Shih-Chi Wang, D290072)

Boscalid is not intended for use on residential turfgrass or turfgrass being grown for sale or other commercial use such as sod production. Therefore, a residential exposure/risk assessment was not performed. A short-term non-occupational dermal post-application exposure/risk assessment for individuals golfing and harvesting fruit at "U-pick" farms and orchards was conducted in the previous assessment (D290072; S. Wang, M. Collantes, and G. Bangs, 6/23/03). As no new residential uses are proposed, a new residential exposure/risk assessment is not required.

4.5 Other (Spray Drift, etc.)

Spray drift is always a potential source of exposure to residents living in close proximity to spraying operations. This situation is particularly the case with aerial application. However, to a lesser extent, spray drift resulting from the ground application of boscalid could also be a potential source of exposure. The Agency has been working with the Spray Drift Task Force (a membership of U.S. pesticide registrants), EPA Regional Offices, State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, and is developing a policy on how to apply appropriately the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with pesticide application.

5.0 AGGREGATE RISK ASSESSMENT AND RISK CHARACTERIZATION

Aggregate exposure risk assessments were performed for short-term and chronic scenarios. As HED does not have ground and surface water monitoring data to calculate a quantitative aggregate exposure, drinking water levels of comparison (DWLOCs) were calculated. A DWLOC is a theoretical upper limit on a pesticide's allowable concentration in drinking water after aggregating exposure to that pesticide through food and residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and estimated exposure through food and residential uses. HED uses DWLOCs in the risk assessment process to assess potential concern for exposure associated with pesticides in drinking water. DWLOC values are not regulatory standards for drinking water.

To calculate chronic DWLOCs, the dietary food estimates (from DEEM-FCID™) were subtracted from the chronic PAD value to obtain the maximum water exposure level. DWLOCs were then calculated using the following standard body weights and drinking water consumption figures: 70kg/2L (adult male and US Population), 60 kg/2L (adult female), and 10kg/1L (infant & children). DWLOCs were calculated based on the DEEM-FCID™ exposure estimates rather than the Lifeline exposure estimates. As stated in Section 4.2.2, however, the exposure estimates from the two models are comparable.

5.1 Acute Risk

As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute dietary risk to the general population or to the subpopulation females 13-50 years old. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD) for the general population or females 13-50 years old. An acute aggregate risk assessment is not needed.

5.2 Short-Term Risk

The short-term aggregate risk assessment takes into account average exposure estimates from dietary consumption of boscalid (food and drinking water) and non-occupational uses (golf courses). Postapplication exposures from the proposed use on golf courses is considered short-term, and applies to adults and youth. Therefore, a short-term aggregate risk assessment was conducted. As all endpoints are from the same study, exposures from different routes can be aggregated. Table 6 summarizes the results. The MOE from food and non-occupational uses is 1400, and the calculated short-term DWLOC is 6100 ppb. Compared to EFED's surface and ground water EDWCs, the DWLOC is considerably greater. Therefore, short-term aggregate risk does not exceed HED's level of concern.

The MOE and DWLOC are considered to be representative for youth because youth and adults possess similar body surface area to weight ratios, and because the dietary exposure for youth (13-19 years old) is less than that of the general U.S. population.

Table 6. Short-Term Aggregate Risk and DWLOC Calculations for the General U.S. Population (Inhalation/Oral/Dermal Endpoints and NOAELs the Same)

Population	Short-Term Scenario									
	NOAEL mg/kg/day	Target MOE	Max Exposure[2] mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food and residential)[4]	Max Water Exposure[5] mg/kg/day	Ground Water EDWC[6] (*units*)	Surface Water EDWC[6] (*units*)	Short-Term DWLOC[7] (µg/L)
U.S.	21.8	100	0.218	0.014597	0.0008	1400	0.2026	0.63	25.77	6100

[1]The target MOE for dermal is 100.
[2] Maximum Exposure (mg/kg/day) = NOAEL/Target MOE
[3] Residential Exposure = Dermal exposure from golf course only
[4] Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]
[5] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)
[6] The crop producing the highest level was used.
[7] DWLOC(µg/L) = $\frac{\text{[maximum water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L) x } 10^{-3} \text{ mg/µg]}}$
[8] Adult female body weight was used, which covers adult male risk. The dietary exposure for the U. S. population is higher than that of groups having residential (golf) exposure (i.e., adults, youth 13-19).

5.3 Intermediate-Term Risk

As no intermediate-term non-occupational exposures are anticipated, an intermediate-term aggregate risk assessment is not needed.

5.4 Chronic Risk

The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of boscalid (food and drinking water) and residential uses. As the exposure resulting from contact with turf grass (golf courses) is considered short term, the chronic aggregate assessment includes food and drinking water only. The calculated DWLOCs for chronic exposure to boscalid in drinking water range from 1600 to 7200 ppb. EDWCs generated by EFED are less than HED's calculated chronic DWLOCs (Table 7). Therefore, the chronic aggregate risk associated with the use of boscalid does not exceed HED's level of concern for the general U.S. population or any population subgroups. If the Lifeline™ exposure estimates had been used, the risk estimates for all population subgroups would still be within HED's level of concern.

Table 7. Chronic Aggregate Exposures to Boscalid Residues.

Scenario/ Population Subgroup	cPAD, (mg/kg/day)	Chronic Food Exposure, (mg/kg/day)	Maximum Chronic Water Exposure[1], (mg/kg/day)	Ground Water EDWC[2], (ppb)	Surface Water EDWC[2], (ppb)	Chronic DWLOC[3], (ppb)
General U.S. Population	0.218	0.014597	0.2034	0.63	26	7100
All Infants (< 1 year old)	0.218	0.03509	0.18291	0.63	26	1800
Children 1-2 years old	0.218	0.056809	0.16119	0.63	26	1600

Table 7. Chronic Aggregate Exposures to Boscalid Residues.						
Scenario/ Population Subgroup	cPAD, (mg/kg/day)	Chronic Food Exposure, (mg/kg/day)	Maximum Chronic Water Exposure[1], (mg/kg/day)	Ground Water EDWC[2], (ppb)	Surface Water EDWC[2], (ppb)	Chronic DWLOC[3], (ppb)
Females 13-49 years old	0.218	0.010349	0.20765	0.63	26	6200
Adults 50+ years old	0.218	0.010935	0.20707	0.63	26	7200

1 Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from dietary exposure analysis (mg/kg/day).

2 EECs from EFED studies.

3 Chronic DWLOCs were calculated as follows:

$$\text{Chronic DWLOC}(\mu g/L) = \frac{[\text{maximum chronic water exposure (mg/kg/day)} \times \text{body weight (kg)}]}{[\text{water consumption (L)} \times 10^{-3}\ \text{mg}/\mu g]}$$

5.5 Cancer Risk

The Cancer Assessment Review Committee (CARC) stated that boscalid exhibited "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." The quantification of human cancer risk was not recommended.

6.0 CUMULATIVE RISK

FQPA (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

HED did not perform a cumulative risk assessment as part of this tolerance action for boscalid because HED has not yet initiated a review to determine if there are any other chemical substances that have a mechanism of toxicity common with that of boscalid. For purposes of this tolerance action, EPA has assumed that boscalid does not have a common mechanism of toxicity with other substances.

On this basis, the registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether boscalid shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for boscalid need to be modified or revoked. If

HED identifies other substances that share a common mechanism of toxicity with boscalid, HED will perform aggregate exposure assessments on each chemical, and will begin to conduct a cumulative risk assessment.

HED has recently developed a framework that it proposes to use for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance was issued for public comment on January 16, 2002 (67 FR 2210-2214) and is available from the OPP Website at: http://www.epa.gov/pesticides/trac/science/cumulative_guidance.pdf. In the guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed.

Before undertaking a cumulative risk assessment, HED will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the "*Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity*" (64 FR 5795-5796, February 5, 1999).

7.0 OCCUPATIONAL EXPOSURE AND RISK (Attachment 3, HED ORE memo of 2/xx/2004, Shih-Chi Wang, D290072)

Pesticide handler and workers performing post-application activities will be exposed to boscalid during and after the application of the fungicide. No data on the number of exposure days per year were provided. For this risk assessment, it was assumed that handlers would be exposed for less than 6 months per year. Long-term exposure is not expected. For detailed use rates and use patterns, please see Attachment 3.

7.1 Occupational Handler

There are seven handler scenarios that are expected to result in the highest exposure for the proposed uses of boscalid:

a. Mixing/Loading Water Dispersible Granule for Ground-boom Applications (Scenario 1)
b. Mixing/Loading Water Dispersible Granule for Air Blast Applications (Scenario 2)
c. Mixing/Loading Water Dispersible Granule for Aerial Applications (Scenario 3)
d. Applying Sprays with Ground-boom Equipment (Scenario 4)
e. Applying Sprays with Air Blast Equipment (Scenario 5)
f. Applying Sprays with a Fixed Wing Aircraft (Scenario 6)
g. Flagging during Aerial Applications (Scenario 7)

Pome fruits and soybeans are treated by two end-use products (for pome fruits: Pristine™ at 0.291 lb ai/A and Endura™ at 0.284 lb ai/A; for soybeans: Pristine™ at 0.252 lb ai/A and Endura at 0.481 lb ai/A). Because both products are water dispersible granules (WG), those exposure and risk estimates calculated from the lower application rates will be less than those exposures and risks calculated from the higher application rates. Hence, only those exposures and risks resulting from the higher application rates (i.e. worse cases), were evaluated in this assessment.

Under the worst case scenarios, all MOEs for the handlers were greater than the target MOE of 100 at the baseline level (ranging from 250 to 18,000). The details regarding the exposures/risks for handlers can be found in the 12/18/03 memorandum by S. Wang (D296545, Occupational and Residential Exposure/Risk Assessment for Uses of Boscalid on Pome Fruits, Soybeans, and Hops).

7.2 Postapplication Exposure and Risk Estimates

There is a potential for occupational exposure resulting from the entering of areas previously treated with boscalid. Occupational post-application exposure is expected to be short- and intermediate-term in duration.

The occupational dermal post-application exposure and risk estimates were calculated by coupling HED DFR defaults (for hops & soybeans) or the crop specific DFR value (for pome fruits, 1.3 $\mu g/cm^2$) with activity specific transfer coefficients (Tc) from the HED Science Advisory Council For Exposure Policy Document Number 3.1: Agricultural Transfer Coefficients, August 2000. All post-application exposure estimates were greater than the target MOE of 100. They ranged from 260 to 13,000; and therefore, did not exceed HED's level of concern. The details regarding the post-application exposures/risks can be found in the 12/18/03 memorandum by S. Wang (D296545, Occupational and Residential Exposure/Risk Assessment for Uses of Boscalid on Pome Fruits, Soybeans, and Hops).

Because all post-application MOEs are above the target MOE of 100, the Restricted Entry Interval (REI) may be based on acute toxicity of the active ingredient. The technical material has a Toxicity Category III or IV. Per the Worker Protection Standard (WPS), a 12-hr REI is required. Therefore, the 12 hour REI appearing on the label is appropriate for this chemical.

8.0 DATA NEEDS

8.1 Toxicology

None.

8.2 Residue Chemistry

Submission of a suitably revised Section F.

There were several conditions of registration associated with the granting of the initial tolerances for boscalid (see Memo, D290022, Y. Donovan, *et al.*, 9/8/2003). In the event that these conditions have not been satisfied, they apply to the soybean, pome fruit, and hops registrations as well.

Attachments: 1. HED DEEM Memo, D295907, D. Dotson, 2/10/2004.
2. EFED Memo, D293435, K. Costello, 11/10/2003).
3. HED ORE Memo D290072, S. Wang, 2/xx/2004.

cc without Attachments: D. Dotson, S. Wang, RAB2 Reading File