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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 11/3/2005

Subject: PP#s 1F6313, 3E6791, 4F6875, and 5E6933: Boscalid, Registrant's Response to Deficiencies Cited in Tolerance Petition 1F6313. Summary of Analytical Chemistry and Residue Data for Rotational Root Crops, Direct Uses on Celery, Spinach, Bananas, Strawberries, Almonds, and Potatoes, and Seed Treatment Uses on Bulb Vegetables, *Brassica* Leafy Vegetables, Legume Vegetables, Peanuts, and Sunflowers.

DP Number:	D322235	Decision No.:	354126
PC Code:	128008	MRID Nos.:	46145101, 46145102, 46160103, 46210606 46351401, 46351402, 46351403, 46351404, 46351405
40 CFR:	180.589		

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Portions of this report were originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B; Durham, NC 27713; submitted 1/14/2005). Those portions have been reviewed by the HED and revised to reflect current OPP policies.

Executive Summary

Boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl), is a fungicide and a member of the carboxamide (anilide) class of compounds. Permanent tolerances have been established in 40 CFR §180.589 for residues of boscalid in/on numerous plant commodities, ranging from 0.05 ppm in/on peanuts and tuberous and corm vegetables (subgroup 1C) to 35 ppm in/on dried hop cones. Separate tolerances have also been established for indirect or inadvertent residues of boscalid in rotational crops, ranging from 0.05 ppm in several commodities to 8.0 ppm in grass forage, fodder, and hay (group 17). Tolerances for the combined residues of boscalid and its glucuronic acid conjugate are also established on animal commodities, ranging from 0.02 ppm in eggs to 0.35 ppm in meat byproducts of cattle, goats, horses, and sheep. Finally, a temporary tolerance of 2.0 ppm has been established in conjunction with a Section 18 request for the use of boscalid on tangerines in California.

This document addresses the registrant's responses to several data deficiencies as well as several requests. In order to resolve data deficiencies, the registrant submitted a tomato storage stability study, a study of storage stability in various other crops, and field rotational crop studies on root and tuber vegetables. The registrant has requested the establishment of a tolerance for imported bananas, an increase in the tolerance for strawberries, decreased PHIs for almonds and potatoes, and seed treatment uses for bulb vegetables, *Brassica* leafy vegetables, legumes, cucurbits, peanuts, and sunflowers. Finally, the Interregional Research Project #4 (IR-4) has proposed tolerances on celery and spinach.

Two currently registered end-use products are proposed for use on crops. One of these is Endura™ Fungicide (EPA Reg. No. 7969-197), which is a water dispersible granule (WDG) that contains 70% boscalid. The other end-use product is Pristine™ Fungicide (EPA Reg. No. 7969-199), which is also a WDG and contains a 2:1 mixture of boscalid and pyraclostrobin as co-active ingredients (25.2%:12.8%). The product proposed for use as a seed treatment is BAS 510 04F Seed Treatment Fungicide. This product is a WDG that contains 70% boscalid by weight and 30% inert ingredients.

The nature of the residue has been adequately delineated in target crops, livestock, and rotational crops. In target crops the parent was the only compound identified in grapes and lettuce (92-98% TRR). Parent was also the predominant compound present in beans. Small amounts of cleavage products were also identified. The Metabolism Assessment Review Committee (MARC) determined that in target crops, the parent only was the residue of concern for risk assessment and tolerance expression. In rotational crop studies performed on radish, head lettuce, and wheat, parent boscalid was the only residue identified in wheat grain. Parent was the major residue identified in lettuce, radish roots, radish tops, and wheat forage. Smaller amounts of the glucoside metabolite were also found (1-21% TRR). Again, the MARC determined that the parent only was the residue of concern for risk assessment and tolerance expression. In goat and hen metabolism studies, the parent, a hydroxy metabolite, and the glucuronide of the hydroxy metabolite were the major residues identified. The MARC concluded that the combined residues of these three compounds are the residues of concern in animal commodities for risk assessment and tolerance expression.

An adequate method is available for enforcement of the current tolerances on plant commodities. BASF Corporation has proposed a GC/MS method, Method D0008, for enforcing tolerances for residues of boscalid in plant commodities. Plant matrix samples are extracted with methanol/water/2N HCl (or hexane/ACN for oil commodities). An aliquot of the extract is partitioned with iso-octane, and the iso-octane phase is cleaned up by solid phase extraction. Residues are separated and detected by GC/MS. The method has not as yet been published in PAM I or II; however, it is available from the Biological and Economic Analysis Division's Analytical Chemistry Branch. In the current crop field trials and the rotational crop field trials, samples were analyzed for boscalid residues using an LC/MS/MS method (BASF Method Number D9908). Method D9908 was validated in conjunction with a previous boscalid petition (D278385, M. Nelson, 8/15/03) and deemed acceptable for data collection.

Pending submission of radiovalidation data, an adequate enforcement method (Method DFG S19) and data collection methods (Methods 471/0 and 476/0) are available for determining residues of boscalid and its glucuronic acid conjugate in eggs, milk, and animal tissues. Revised copies of these methods have been submitted that include the recommended statement on storage of analytical standards in solutions.

With the exception of grape juice, adequate storage stability data are available demonstrating that boscalid is stable under frozen conditions in diverse representative crop matrices for at least 24 months. Samples from the crop field trials, and rotational crop studies were stored frozen for a maximum of 11.3 months. In addition, the complete description of the method (Method 445/0) used in the storage stability study has been submitted.

BASF submitted field trial data for celery and spinach in order to establish a crop group tolerance for the Leafy Vegetables (except *Brassica*) Group. The proposed crop group tolerance is 50 ppm. The available field trial data are adequate and support the proposed use patterns for celery and spinach. The total application rate used in field trials was 1x that specified on the current proposed label. Adequate numbers of field trials were conducted at the maximum proposed use rates, and the appropriate commodities were collected at the proposed preharvest interval (PHI) of 0 days. Samples were analyzed using adequate analytical methods and the sample storage intervals are supported by the available storage stability data. The field trial data indicate that separate tolerances will be required for celery and spinach as maximum boscalid residues substantially exceeded the current tolerance of 11.0 ppm in/on leaf lettuce. The available data indicate that a crop group tolerance for leafy vegetables is not appropriate. The data support separate tolerances of 45 ppm for residues in/on celery and 60 ppm for residues in/on spinach. Maximum residues from the field trials were 19.7 ppm in/on celery and 41.8 ppm in/on spinach. The registrant needs to submit a revised Section F that proposes a tolerance of 45 ppm for celery and 60 ppm for spinach. All tolerance levels recommended in this document were determined by using the Statistically-Based Method for Establishing NAFTA-Harmonized Tolerances.

BASF has requested that the strawberry tolerance be increased from 1.2 ppm to 4.0 ppm. The available field trial data are adequate and will support the request for the increased tolerance on strawberries. The field trials were performed at the 1x application rate and the specified PHI, 0 days. Adequate numbers of field trials were conducted. Three field trials were performed in

addition to the original eight trials. The OPPTS Series 860 Guidelines recommend that at least eight field trials be performed. Samples were analyzed using adequate analytical methods and the sample storage intervals are supported by the available storage stability data. For a 0-day PHI, the available residue data support a 4.5 ppm tolerance for the raw agricultural commodity strawberry. BASF needs to submit a revised Section F that proposes a tolerance of 4.5 ppm for strawberry.

BASF submitted field trial data on almonds in order to support a request for an increase in the almond hull tolerance from 3.0 ppm to 15 ppm. The submitted field trials are adequate to evaluate the registrant's request. The OPPTS Series 860 Guidelines recommend that five field trials be performed in Growing Region 10. The registrant performed five field trials at two different spray dilutions for a total of ten trials. The trials were performed in Region 10. Based on the results of the almond hull analyses, HED recommends in favor of increasing the tolerance from 3.0 ppm to 17 ppm. The proposed PHI for almonds is 25 days, whereas the PHI for all other tree nuts is 14 days. In the five pecan field trials that were originally performed, residues in all samples were below the LOQ of 0.05 ppm. In the almond field trials performed at a 25-day PHI, residues in all samples were also below the limit of quantitation (LOQ) of 0.05 ppm. Although almonds and pecans are the representative commodities of the tree nuts crop group and residues in all nutmeat samples were <0.05 ppm, HED recommends retaining the crop group tolerances for tree nut nutmeat and pistachios at 0.7 ppm. The existing 0.7 ppm tolerances for these commodities are based on the maximum residue in pistachios being 0.64 ppm (see 8/15/2003 M. Nelson summary document, PP#1F6313, D278385). The registrant needs to submit a revised Section F that proposes a tolerance of 17 ppm for almond hulls.

BASF has requested that the Agency establish a tolerance of 0.5 ppm on imported bananas. The submitted field trials are adequate to evaluate the registrant's request. The OPPTS Series 860 Guidelines recommend that for a domestic use, five field trials be performed, one in Growing Region 3 and four in Region 13. The request is for an import tolerance, though, so the field trials were performed in Central and South America. Twelve field trials were performed all together. This number is consistent with the import tolerance guidance published by the Agency in the Federal Register on June 1, 2000. Based on the results of the analyses of the unbagged whole fruit samples, HED recommends in favor of establishing the import tolerance at 0.20 ppm. The registrant needs to submit a revised Section F that proposes a tolerance of 0.20 ppm for banana.

Adequate extensive field rotational crop trials are available on sugar beet, garden beet, and turnips. The representative crops were planted 14 days after soil applications of boscalid (70% WDG) totaling ~1.8 lb ai/A (1x the maximum seasonal rate), and adequate numbers of tests were conducted on each crop in the appropriate regions. The data support reducing the current tolerance for indirect residues on leaves of root and tuber vegetables (Group 2) to 0.1 ppm and establishing a 0.1 ppm tolerance for indirect residues in root vegetables (Subgroup 1A).

The registrant has proposed a label amendment to decrease the tuberous and corm vegetable PHI from 30 days to 10 days. Tuberous and corm vegetables grow underneath the soil surface. The primary means of uptake of residues from foliar applications is by translocation through the leaves. Very often residues increase with an increase in PHI because the residues have more time

for translocation. As a result, HED feels that the two residue decline studies which include samples taken at a 10-day PHI support the request for the decreased PHI.

The registrant has requested the use of boscalid as a seed treatment on *Brassica* leafy vegetables (Crop Group 5), bulb vegetables (Crop Group 3), legume vegetables (Crop Group 6), peanuts, and sunflowers. Tolerances for foliar uses have already been established for all of these commodities. With the exception of peanuts, the tolerances for these commodities are 0.6 ppm or higher. The tolerance for peanuts is 0.05 ppm. As the tolerances for foliar uses are considerably higher than the residues that would result from seed treatment uses (for all of the proposed commodities except peanuts), HED recommends in favor of granting the seed treatment uses for all crops except peanuts. For a seed treatment use on peanuts, the registrant should perform additional field trials in which peanuts have been subjected to both the seed treatment as well as the foliar application. The seed should be treated at the proposed maximum label rate and the foliar applications should be at the maximum label rate. In addition, samples must be taken at the minimum PHI. If residues in the peanut RAC samples exceed the 0.05 ppm tolerance already established for peanuts, the tolerance will likely need to be increased.

Residue Chemistry Deficiencies

No deficiencies were noted in the submitted data that would preclude establishing permanent tolerances for boscalid on celery, spinach, and bananas, and tolerances for indirect residues in root vegetables (Subgroup 1A) and in leaves of root and tuberous crops (Group 2); however, revised Sections F should be submitted that propose tolerances of 45 ppm for celery, 60 ppm for spinach, 4.5 ppm for strawberry, 17 ppm for almond hulls, and 0.20 ppm for banana. In addition, the revised Section F should propose that the existing leafy vegetable tolerance in 40CFR §180.589(d) be revised to "vegetable, leafy, Crop Group 4, except lettuce, celery, and spinach."

The following deficiencies noted in the Agency's earlier review (D278385, M. Nelson, 8/15/03) remain outstanding:

1. Submission of radiovalidation data demonstrating the efficiency of the hydrolysis step in the proposed tolerance enforcement method (DFG S19) for livestock matrices. These radiovalidation data will also be used in support of the data collection method (471/0) for livestock matrices.

2. Submission of radiovalidation data demonstrating the efficiency of the microwave hydrolysis step in Method 476/0, which determines bound residues of boscalid in milk and liver

3. Submission of data demonstrating the frozen storage stability of boscalid residues in processed grape juice (2 months).

4. Submission of the following additional field trials, conducted per their respective proposed use pattern: 3 tests on mustard greens (one each from Regions 2, 3, and 10); 2 tests on cucumber (one each from Regions 2 and 10); and 1 test on sunflower (Region 5).

5. In order to obtain a seed treatment use on peanuts, the registrant should perform additional field trials in which peanuts have been subjected to both the seed treatment as well as the foliar application. The seed should be treated at the proposed maximum label rate and the foliar applications should be at the maximum label rate. In addition, samples must be taken at the minimum PHI. If residues in the peanut RAC samples exceed the 0.05 ppm tolerance already established for peanuts, the tolerance will likely need to be increased.

Background

Boscalid is an anilide fungicide that inhibits mitochondrial respiration, thereby inhibiting spore germination, germ tube elongation, mycelial growth, and sporulation of pathogenic fungi on the leaf surface. Two formulated end-use products are registered for use on a wide variety of crops: Endura™ Fungicide; EPA Reg. No. 7969-197, a water dispersible granule (WDG) containing 70% boscalid, and Pristine™ Fungicide; EPA Reg. No. 7969-199, a WDG that contains a 2:1 mixture of boscalid and pyraclostrobin as co-active ingredients (25.2%:12.8%). The registrant has also proposed a seed treatment product, BASF 510 04F. This product is a WDG that contains 70% boscalid by weight and 30% inert ingredients.

Permanent tolerances [40 CFR §180.589(a)(1)] have been established for residues of boscalid in/on numerous plant commodities, ranging from 0.05 ppm in/on peanuts and tuberous and corm vegetables (subgroup 1C) to 35 ppm in/on dried hops cones. A tolerance of 1.2 ppm has been established for strawberries and a tolerance of 3.0 ppm has been established for almond hulls. Separate tolerances have also been established for indirect or inadvertent residues of boscalid in rotational crops, ranging from 0.05 ppm in several commodities to 8.0 ppm in grass forage, fodder, and hay (group 17) [40 CFR §180.589(d)]. Tolerances for the combined residues of boscalid and its glucuronic acid conjugate are also established on animal commodities, ranging from 0.02 ppm in eggs to 0.35 ppm in meat byproducts of cattle, goats, horses, and sheep [40 CFR §180.589(a)(2)].

The current submissions are the petitioner's responses to deficiencies cited in the original petition (PP#1F06313, D278385, M. Nelson, 8/15/03) pertaining to analytical methods, storage stability data, direct uses on celery and spinach, and residues in/on rotational root crops. IR-4 submitted the field trial studies for celery and spinach. The registrant has also submitted field residue studies for strawberries, almonds, and bananas, as well as a rationale for a decreased PHI on potatoes and other tuberous and corm vegetables. BASF submitted the strawberry and almond studies to support its request for increases in the tolerances on strawberries and almond hulls.

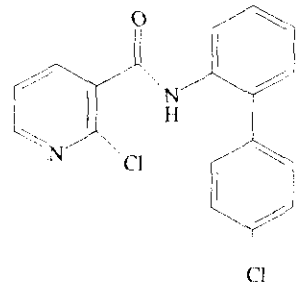
Table 1. Test Compound Nomenclature	
Compound	Boscalid 
Common name	Boscalid
Company experimental name	BAS 510F
IUPAC name	2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
CAS name	3-Pyridinecarboxamide, 2-chloro-N-(4'chloro[1,1'-biphenyl]-2-yl)
CAS #	188425-85-6
End-use products/EP	Endura, Pristine, BAS 510 04F

Table 2. Physicochemical Properties	
Parameter	Value
Melting point/range	142.8-143.8°C
pH	Unspecified
Density	1.38 g/cm^3
Water solubility (20°C)	4.64 mg/L
Solvent solubility (mg/L at 20°C)	Acetone: 16-20 g/100 mL Acetonitrile: 4-5 g/100 mL Methanol: 4-5 g/100 mL Ethyl Acetate: 6.7-8 g/100 mL Dichloromethane: 20-25 g/100 mL Toluene: 2-2.5 g/100 mL 1-Octanol: <1g/100 mL
Vapor pressure at 20°C	7 x 10^{-7} Pa
Vapor pressure at 25°C	2 x 10^{-6} Pa
Dissociation constant (pK_a)	No dissociation in water.
Octanol/water partition coefficient Log(K_{ow})	2.96 (21°C)
UV/visible absorption spectrum	Unspecified

860.1200 Directions for Use

The registrant submitted proposed labels for both Endura and Pristine Fungicides that list the proposed use directions for boscalid on spinach and celery. Strawberries are on the Pristine Label only. The proposed directions for these three crops are summarized in Table 3. With respect to application rates and PHI, the use directions are the same for both Endura and Pristine.

Table 3. Summary of Directions for Use of Boscalid

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Celery and Spinach (Proposed Use)						
Broadcast foliar application Ground or aerial equipment	Endura 70% WDG [7969-197]	0.40	2	0.80	0	
Celery and Spinach (Proposed Use)						
Broadcast foliar application Ground or aerial equipment	Pristine, WDG, 25.2% boscalid, 12.8% pyraclostrobin	0.40	2	0.80	0	
Strawberries (Request for Increased Tolerance)						
Broadcast foliar application Ground or aerial equipment	Pristine, WDG, 25.2% boscalid, 12.8% pyraclostrobin	0.18	5	0.92	0	
Almond (Request for Decreased PHI)						
Broadcast foliar application Ground or aerial equipment	Endura 70% WDG [7969-197]	0.23	4	0.93	25	Do not make more than 2 sequential applications before alternating to a labeled fungicide with a different mode of action
Broadcast foliar application Ground or aerial equipment	Pristine, WDG, 25.2% boscalid, 12.8% pyraclostrobin	0.23	4	0.93	25	
Banana						
Aerial	Cantus Fungicide 50% Boscalid	0.13	4	0.53	0	
Aerial	Banastar Fungicide 50g/L Boscalid	0.13	4	0.53	0	
Seed Treatment						
	BAS 510 04F 70% Boscalid	0.02-0.48 lb ai/100 lb seed	Not Specified	Not Specified	Not Specified	Do not use treated seed for food, feed, or oil purposes

860.1300 Nature of the Residue - Plants

45405021.der (lettuce)
45405022.der (grapes)
45405023.der (beans)
HED MARC Decision Memo D286786 (1/9/2003)

The nature of the residue in plants has been summarized in a previous residue chemistry summary document (PP# 1F06313, D278385, M. Nelson, 8/15/03). The MARC has concluded that the residue of concern in plants for both tolerance expression and risk assessment purposes is the parent compound (Memo D286786, M. Nelson, 1/9/03).

860.1300 Nature of the Residue - Livestock

45405024.der (goats)
45405026.der (poultry)
HED MARC Decision Memo D286786 (1/9/2003)

The nature of the residue in livestock has been summarized in a previous residue chemistry summary document (PP# 1F06313, D278385, M. Nelson, 8/15/03). The MARC has concluded that the residues of concern in livestock for both tolerance expression and risk assessment purposes are the parent, the hydroxy metabolite, and its glucuronide conjugate (Memo, D286786, M. Nelson, 1/9/03).

860.1340 Residue Analytical Methods - Plants

MRID 46351405 (Storage Stability Study Data Collection Method, 445/0)
45405027.der (Data Collection Method, D9908)
45405028.der (Proposed Enforcement Method, D0008)

The data collection method for plants and the tolerance enforcement method have been summarized in a previous residue chemistry summary document (PP# 1F06313, D278385, M. Nelson, 8/15/03). The data collection method for plants, Method D9908 (MRID 45405027) was used for data collection in the celery, spinach, strawberry, almond, and banana field trials and the current rotational crop field trials for root crops.

Method D9908 determines residues of boscalid (and, separately, also pyraclostrobin and its metabolite BF 500-3) in plant matrices. Residues are extracted with an aqueous organic solvent mixture followed by liquid/liquid partitioning and column clean-up. Quantitation of boscalid is by LC/MS/MS, using the positive ionization mode to monitor ion transitions from *m/z* 343 to 307 for boscalid. Quantitation is obtained using an external calibration curve of boscalid standards. The validated LOQ is 0.05 ppm for residues of boscalid in/on plant matrices. Concurrent method recovery data provided in the celery and spinach field trials and the root crop rotational field trials were adequate, indicating that the method is acceptable for data collection.

An additional data collection method (Method 445/0) was used to determine boscalid residues in the storage stability study on plant matrices. This method was reviewed in 45405109.der (12-month interim report) and 46351404.der (24-month final report). Method 455/0 is an LC/MS/MS method that is nearly identical to the previously validated BASF Method D9908. As requested by the Agency (D278385, M. Nelson, 8/15/03), a detailed description of Method 445/0 has been submitted (MRID 46351405); therefore, this deficiency is now resolved.

For Method 445/0, residues are extracted with methanol:water:2 N HCl (70:25:5, v/v/v), concentrated, cleaned up by liquid/liquid partitioning into cyclohexane. Residues are then concentrated and redissolved in methanol:water (80:20, v/v). Residues are analyzed by LC/MS/MS using the positive ionization mode monitoring ion transitions from *m/z* 343 to either 307 or 271. Quantitation is obtained using an external calibration curve of boscalid standards. The validated LOQ is 0.05 ppm for residues of boscalid in/on plant matrices; the LOD was not reported.

The method description report for Method 445/0 contained no validation data for the method; however, concurrent recovery data were provided in conjunction with the storage stability study (46351404.der). Control samples of cabbage, rape seed, pea, peach, sugar beet root, and wheat forage, grain and straw were each fortified with boscalid in duplicate at 0.5 ppm and analyzed according to Method 445/0. Average concurrent recoveries were 87-95% for each matrix, with standard deviations of 7-12%. The overall average recovery across all eight plant matrices was 93% with a standard deviation of 9%.

A separate GC/MS method (Method D0008) is proposed as the enforcement method for residues of boscalid in/on plant matrices (refer to the DER for MRIDs 45405028 and 45405101). The Analytical Chemistry Branch in BEAD concluded that the method is acceptable for enforcement purposes in plants without the need for an EPA validation (D284510, D. Swineford and E. Kolbe, 8/12/03).

860.1340 Residue Analytical Methods - Livestock

45405103.der (Method DFG S19)
45405105.der (Method 746/0)
45405106.der (Method 471/0)
MRID 46351401 (revised Method 471/0)
MRID 46351402 (revised Method 476/0)
MRID 46351403 (revised Method DFG S19)

An enforcement method is available for determining the residues of concern in livestock. Method DFG S19 is based on GC with electron capture detection and was successfully validated by ACB/BEAD (7/17/03 Memo, D. Swineford and E. Kolbe).

In conjunction with the earlier review of PP#1F06313 (D278385, M. Nelson, 8/15/03), the Agency requested that the livestock data collection and tolerance enforcement methods be revised to specify that standard solutions not be stored longer than 60 days before replacement. In response, the petitioner has submitted revised copies of BASF Methods 471/0 and 476/0 and the modified multi-residue method DFG S19 (MRIDs 46351401-46351403) that include the statement on storage of analytical standards in solutions. This deficiency is resolved.

The requirement of radiovalidation data demonstrating the efficiency of the microwave hydrolysis step in Method 476/0 and the enzymatic hydrolysis steps in Methods 471/1 and DFG S19 remain outstanding (D278385, M. Nelson, 8/15/03).

860.1360 Multiresidue Methods

45405107.der

The multiresidue methods (MRMs) have been summarized in a previous residue chemistry summary document (PP# 1F06313, D278385, M. Nelson, 8/15/03). Residues of boscalid and its hydroxy metabolite were not adequately recovered using the MRMs.

860.1380 Storage Stability

46351404.der (Plant Matrices)
46160103.der (Tomato Paste)

The frozen storage stability of boscalid in plants was summarized in a previous residue chemistry summary document (PP# 1F06313, D278385, M. Nelson, 8/15/03). In the interim report (45405109.der), residues of boscalid were stable at -20°C for up to 12 months in sugar beet roots, canola seeds, peas, peaches, and wheat forage, grain, and straw. As a condition of registration, the Agency required the submission of the final 24-month storage stability report on plant matrices, along with data indicating the frozen storage stability of boscalid residues in tomato paste for up to 5 months and in grape juice for up to 2 months.

The final 24-month report of the storage stablity study (46351404.der) has been submitted, along with storage stability data on tomato paste (46160103.der). These studies are summarized below.

46351404.der

This submission is the final report of a 24-month storage stability study. It includes data taken at a storage interval of 18 months. Duplicate stored samples of wheat (forage, grain, and straw), rape seed, sugar beet roots, cabbage, peach, and pea fortified with boscalid (0.5 ppm) were analyzed after 18 and 24 months of frozen storage along with duplicate freshly fortified samples.

The LC/MS/MS method (BASF Method 445/0) used to determine residues of boscalid in/on plant matrices is nearly identical to the previously validated BASF Method D9908 and is adequate for data collection. The LOQ is 0.05 ppm for boscalid residues in/on each plant matrix.

The storage stability data are adequate and indicate that boscalid is stable under frozen (≤ -20° C) conditions in diverse representative crop matrices for at least 24 months. Average corrected recoveries were 76-108% from all frozen plant matrices after 24 months of storage.

46160103.der

In order to generate storage stability data on boscalid residues in tomato paste, paste samples generated and analyzed in conjunction with an earlier tomato processing study (45405126.der, W. Cutchin, 7/2/03) were retained in storage at ≤-20° C for up to 38.4 months. Duplicate stored samples were then reanalyzed after 38.4 months of storage along with a freshly fortified sample.

Residues of boscalid in tomato paste were determined using an LC/MS/MS method (BASF Method Number D9908) which is adequate for data collection. The LOQ is 0.05 ppm for residues of boscalid in tomato paste.

The storage stability data are adequate and indicate that boscalid is relatively stable in frozen (≤-20° C) tomato paste for at least 38 months, declining by ~20% over 3 years. Samples from the tomato processing study (45405126.der, W. Cutchin, 7/2/03) were originally stored frozen for a maximum of 154 days (5 months) prior to the original analysis; therefore, correction of residues for decline during storage is not required.

Conclusions. The storage stability data are adequate and indicate that boscalid is stable under frozen (≤ -20° C) conditions in diverse representative crop matrices for at least 24 months. These data adequately support the crop field trials, processing studies, and rotational crop studies in which samples were stored frozen for a maximum of 12.5 months. In addition, the available data on tomato paste are adequate and support the tomato processing study. However, storage stability data on residues in grape juice remain outstanding.

860.1480 Meat, Milk, Poultry, and Eggs

45405110.der (cattle feeding study)
45643801.der (poultry feeding study)

The results of adequate cattle and poultry feeding studies have been summarized in a previous residue chemistry summary document (PP# 1F06313, D278385, M. Nelson, 8/15/03). Based on these feeding studies and the previously calculated maximum theoretical dietary burdens (MTDB) for cattle (8.74 ppm), swine (1.57 ppm), and poultry (1.85 ppm), tolerances for the combined residues of boscalid and its glucuronide conjugate were established for animal commodities, ranging from 0.02 ppm in eggs to 0.35 ppm in meat byproducts of cattle, goats, horses, and sheep.

A residue chemistry summary document was subsequently prepared for hops, soybeans, and pome fruit (Memo, D290185, D. Dotson, 2/10/2004). The boscalid labels have restrictions that prohibit the feeding of soybean forage and hay to livestock. The MTDBs for beef cattle, dairy cattle, and hogs increased to 15 ppm, 12 ppm, and 2.0 ppm, respectively. There was no change in the poultry MTDB.

The proposed primary uses on spinach and celery and the increased tolerance on strawberries will not affect the potential dietary exposure of livestock to boscalid, as there are no significant feed items associated with these crops. However, the submitted rotational crop field trial data on roots and leaves of root vegetables can affect the dietary burden of ruminants and swine as several of these crops have livestock feed items (e.g. turnip). The available extensive rotational crop field trials discussed below (Section 860.1900) indicate that indirect tolerances for boscalid residues in leaves and roots of root vegetables can be reduced from 1.0 to 0.1 ppm. As no rotational crop commodities were used in the previous calculation of the MTDB for cattle, reducing the tolerance on leaves and roots of rotational root crops does not affect the calculated MTDB for cattle.

The addition of almond hulls to the list of potential livestock feed items results in a slight increase in the MTDB for beef and dairy cattle, however, as shown in Tables 4 and 5, below. Based on the results of the cattle feeding studies, the current tolerances are adequate to cover residues in animal commodities. Therefore, no reassessment of tolerances on cattle, goat, horse, and sheep commodities is required.

Table 4. Theoretical Worst Case Diet for Beef Cattle, Based on Commodities with Proposed and Established Tolerances

Feed Item	Proposed Tolerance Level, ppm	% Dry Matter (DM)	Tolerance ÷ DM Fraction (ppm)	% of Diet	Dietary Burden ppm*
Apple Pomace	10	40	25	40	10.0
Almond Hulls	17	90	18.88	10	1.89
Grass Hay	8.0	88	9.09	50	4.54
Total				100	16.4

*Dietary burden = (tolerance level ÷ dry matter fraction) x (% of diet).

Table 5. Theoretical Worst Case Diet for Dairy Cattle, Based on Commodities with Proposed and Established Tolerances

Feed Item	Proposed Tolerance Level, ppm	% Dry Matter (DM)	Tolerance ÷ DM Fraction (ppm)	% of Diet	Dietary Burden ppm*
Apple Pomace	10	40	25	20	5.0
Almond Hulls	17	90	18.88	10	1.89
Grass Hay	8.0	88	9.09	60	5.45
Carrot Culls	1.0	12	8.33	10	0.83
Total				100	13.2

*Dietary burden = (tolerance level ÷ dry matter fraction) x (% of diet).

The previous calculation of the MTDB for swine included turnip roots (rotational) at 40% of the diet. Recalculation of the MTDB for swine using the lower tolerance for turnip roots results in a MTDB of 1.79 ppm (Table 6). Although the MTDB for swine is reduced by 12% (from 2.03 ppm), this reduction is insufficient to warrant reducing the currently established tolerances on hog fat, meat, and meat byproducts at this time.

Table 6. Calculation of Maximum Dietary Burden of Boscalid Residue for Swine

Feed Item	Current or Recommended Tolerance Level (ppm)	% of Diet	Dietary Burden ppm
Canola meal	3.5	15	0.53
Flax meal	3.5	10	0.35
Soybean AGF	3.0	20	0.60
Carrot culls	1.0	10	0.10

Table 6. Calculation of Maximum Dietary Burden of Boscalid Residue for Swine			
Feed Item	Current or Recommended Tolerance Level (ppm)	% of Diet	Dietary Burden ppm
Trefoil forage	1.0	10	0.10
Sunflower meal	0.6	20	0.09
Turnip Roots	0.1	15	0.015
Total dietary exposure		100	1.79

Based on the available extensive rotational field data on sugar beets, garden beets, and turnips, a lower tolerance should be established for indirect residues in roots and leaves of root crops.

860.1500 Crop Field Trials

46145101.der (spinach field trials)
46145102.der (celery field trials)

In a previous petition (PP# 1F06313, D278385, M. Nelson, 8/15/03), a crop group tolerance was proposed for boscalid residues in/on leafy vegetables (Crop Group 4). However, no data were submitted for celery or spinach which, with head and leaf lettuce, are the representative crops of the leafy vegetable crop group. Therefore, tolerances were only established on leaf and head lettuce. The petitioner has now submitted crop field trial data supporting the direct use of boscalid (70% WDG) on spinach and celery (46145101.der and 46145102.der). The results of the spinach and celery field trials are summarized below.

Celery

Twelve field trials were conducted during 2001, with eight field trials being conducted in the U.S. and four being conducted in Canada. In each test, boscalid (70% WDG) was applied to celery plants using ground equipment as two directed foliar applications at 0.39-0.42 lb ai/A/application, for a total of 0.78-0.82 lb ai/A/season. Applications were made during the vegetative stage when plants were approximately 12-24" tall. The retreatment interval (RTI) was 6-8 days. A single control (0-DAT only) and duplicate treated samples of celery plants were collected from each test at commercial maturity the same day as the last treatment (0-DAT), again at 6-8 DAT, and finally at 13-15 DAT. Samples were stored frozen from collection to analysis for 3.2-9.6 months, an interval supported by available stability data.

Residues of boscalid in/on celery were determined using an LC/MS/MS method (BASF Method Number D9908), which was validated in conjunction with a previous boscalid petition (D278385, M. Nelson, 8/15/03) and deemed acceptable for data collection. The lower limit of method validation (LLMV) was 0.05 ppm, and the calculated LOD and LOQ were 0.02 and 0.06 ppm, respectively.

Residues of boscalid were 1.8-19.7 ppm in/on 24 celery samples harvested immediately after (0-DAT) the last of two foliar applications. Boscalid residues were 0.3-11.0 ppm in/on 24 celery

samples harvested 6-8 DAT and 0.2-9.8 ppm in/on 24 celery samples harvested 13-15 DAT. Average boscalid residues were 8.7 ppm (HAFT = 19.1 ppm) from 0 DAT samples, 3.6 ppm (HAFT = 9.8 ppm) from 7 DAT samples, and 2.3 ppm (HAFT = 9.3 ppm) from 14 DAT samples.

Spinach

In eight spinach field trials conducted during 2001, boscalid (70% WDG) was applied as two directed foliar applications to spinach at commercial maturity, at a RTI of 6-8 days. The application rate was 0.39-0.42 lb ai/A/application using ground equipment, for a total of 0.78-0.82 lb ai/A/season. A single control (0-DAT only) and duplicate treated samples of spinach leaves were collected from each test at commercial maturity the same day as the last treatment (0-DAT) and again at 6-7 DAT and 13-15 DAT. Samples were stored frozen from collection to analysis for 3.2-11.3 months, an interval supported by available stability data.

Residues of boscalid in/on spinach were determined using an LC/MS/MS method (BASF Method Number D9908), which was validated in conjunction with a previous boscalid petition (D278385, M. Nelson, 8/15/03) and deemed acceptable for data collection. The LLMV was 0.05 ppm, and the calculated LOD and LOQ were 0.02 and 0.06 ppm, respectively.

Residues of boscalid were 12.6-41.8 ppm in/on 16 spinach leaf samples harvested immediately after (0-DAT) the last of two foliar applications. Boscalid residues were 4.5-21.3 ppm in/on 16 spinach leaf samples harvested 6-7 DAT and 0.17-17.8 ppm in/on 16 spinach leaf samples harvested 13-15 DAT. Average boscalid residues were 24.9 ppm (HAFT = 39.5 ppm) from 0 DAT samples, 10.4 ppm (HAFT = 21.0 ppm) from 7 DAT samples, and 6.4 ppm (HAFT = 17.1 ppm) from 14 DAT samples. The results of the celery and spinach field trials are summarized in Table 7, below.

Table 7. Summary of Residue Data from the Celery and Spinach Field Trials using a 70% WDG Formulation of Boscalid

Commodity	Total Rate (lb a.i./A)	PHI (days)[1]	Boscalid Residue Levels (ppm)						
			n	Min.	Max.	HAFT[2]	Median (STMdR[3])	Mean (STMR[3])	Std. Dev.
Spinach	0.78-0.82	0	16	12.6	41.8	39.5	24.4	24.9	9.9
		6-7	16	4.49	21.3	21.0	9.0	10.4	6.2
		13-15	16	0.17	17.8	17.1	4.37	6.36	5.93
Celery	0.78-0.83	0	24	1.8	19.7	19.1	8.2	8.7	5.5
		6-8	24	0.3	11.0	9.8	3.4	3.6	2.9
		13-15	24	0.2	9.8	9.3	1.4	2.3	2.6

[1] The proposed PHI for celery and spinach is 0 days.
[2] HAFT = Highest Average Field Trial.
[3] STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.
[4] The Endura™ 70% WDG label rate for lettuce is 0.48 lb ai/A/application and 0.96 lb ai/A/season. The target rate for the celery and spinach field trials was 0.40 lb ai/A/application and 0.80 lb ai/A/season.

Conclusions. The available field trial data are adequate and will support the proposed use patterns of boscalid on celery and spinach. The field trials were performed at the 1x application rate and the specified PHI, 0 days. Adequate numbers of field trials were conducted. Samples were analyzed using adequate analytical methods and the sample storage intervals are supported by the available storage stability data.

The field trial data indicate that separate tolerances will be required for celery and spinach as maximum boscalid residues exceeded the current tolerance of 11.0 ppm in/on leaf lettuce. For a 0-day PHI, the available residue data support a 45 ppm tolerance for celery and a 60 ppm tolerance for spinach. HED determined these tolerances using its Statistically-Based Method for Establishing NAFTA-Harmonized Tolerances. The individual residue values that were used to establish these tolerances are listed in Table 13.

As primary crop tolerances will only be established for lettuce, celery, and spinach, the rotational crop tolerance in 40CFR §180.589(d) will need to be retained for other members of the group. The appropriate wording is "vegetable, leafy, Crop Group 4, except lettuce, celery, and spinach."

Strawberries

In support of the original tolerance request for strawberries, BASF Corporation submitted field trial data on strawberries. Eight trials were conducted in 1999 in US Regions 1 (1 trial; PA), 2 (1 trial; NC), 3 (1 trial; FL), 5 (1 trial; MI), 10 (3 trials; CA), and 12 (1 trial; OR). At each test location, the 70% WG formulation of boscalid was applied as a foliar spray five times at ~0.37 lb ai/A/application, with a 6- to 8-day RTI, for a total rate of 1.81-1.89 lbs ai/A; a spray adjuvant and the ai pyraclostrobin were included in the tank mix. Mature samples were collected at a 0- or 1-day post-treatment interval. In one strawberry field trial, additional samples were collected at 7, 14, 21, and 28 DAT to evaluate residue decline.

At the applied total rate of 1.81-1.89 lbs ai/A, the range of boscalid residues in/on treated mature strawberry samples was 0.16-1.16 ppm. The residue decline data for strawberries indicated that boscalid residues decreased at longer post-treatment intervals with a half life of approximately 15 days and substantial dissipation of residues by approximately 30 days. Residues decreased from about 1 ppm on the day of final application to about 0.15 ppm 28 days later.

In the current submission, the registrant submitted the results of three additional strawberry field trials performed during the 2004-2005 growing season. These additional trials were performed because strawberries have been found to contain over-tolerance residues. The tolerance level is 1.2 ppm. The trials were performed in Growing Region 10: Monterey, Ventura, and Tulare Counties, California. Each trial consisted of an untreated control plot and four treated plots. Two of the treated plots were treated at a 1x application rate and the other two were treated at a 2x application rate. For the 1x treated plots, five broadcast foliar applications were made of a WG formulation containing boscalid (25.2% WG) and pyraclostrobin (12.8% WG) as co-active ingredients. The boscalid application rate was 0.36-0.39 lb ai/A/application and a 6- to 8-day retreatment interval was used. The total application rate was 1.84-1.88 lb ai/A. For the 2x treated plots, five broadcast foliar applications were made with the same formulation as was used

on the 1x treated plots. The boscalid application rate was 0.72-0.76 lb ai/A/application and a 6- to 8-day retreatment interval was used. The total application rate was 3.69-3.74 lb ai/A.

The applications were made to side-by-side plots at each site using either concentrate (30-32 gal/A of water, Treatments 2 and 4) or dilute (148-159 gal/A of water, Treatments 3 and 5) spray volumes. An adjuvant was added to the spray mixture for all applications. Strawberry RAC samples were harvested immediately after the first, second, and last applications (0DAT1, 0DAT2, and 0-day PHI).

Residues of boscalid were quantitated using BASF Method D9908. Acceptable concurrent method recovery data were obtained. The validated LOQ was 0.05 ppm for residues of boscalid. The LOD was 0.005 ppm. The maximum storage intervals of crop samples from harvest to analysis were 34 days (1.1 months). Adequate storage stability data are available to support the storage intervals and conditions used in the field trials.

The results from these trials show that residues of boscalid were 0.86-1.88 ppm (concentrate spray) and 0.96-2.36 ppm (dilute spray) in/on 12 treated strawberry samples harvested 1 day after the last of five spray applications of boscalid totaling 1.84-1.88 lb ai/A/season. After the last of five applications of boscalid totaling 3.69-3.74 lb ai/A/season, residues were 2.14-3.85 ppm (concentrate spray) and 2.02-4.12 ppm (dilute spray) in/on 12 treated strawberry samples harvested at the 0-day PHI. No significant differences in residues of boscalid were observed between the concentrate and dilute spray applications. The results of the initial and current field trials are given in Table 8, below.

Table 8. Summary of Residue Data from the Initial and Current Strawberry Field Trials using a 70% WDG Formulation of Boscalid

Commodity	Total Rate (lb a.i./A)	PHI (days) [1]	Boscalid Residue Levels (ppm)						
			n	Min.	Max.	HAFT [2]	Median (STMdR[3])	Mean (STMR[3])	Std. Dev.
Strawberries	1.8	0-1	26	0.16	2.36	2.04	0.88	1.02	0.61

[1] The proposed PHI for strawberries is 0 days.
[2] HAFT = Highest Average Field Trial.
[3] STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.
[4] The label rate for strawberries is 0.36 lb ai/A/application and 1.81 lb ai/A/season. The target rate for the field trials was 0.36 lb ai/A/application and 1.81 lb ai/A/season.

Conclusions. The available field trial data are adequate and will support the request for an increased tolerance on strawberries. The field trials were performed at the 1x application rate and the specified PHI, 0 days or a PHI of 1 day. With the previously reported half life of 15 days for residues in strawberries, both 0- and 1-day samples may be used to determine the appropriate tolerance level. Adequate numbers of field trials were conducted. Three field trials were performed in addition to the original eight trials. The OPPTS Series 860 Guidelines recommend that at least eight field trials be performed. Samples were analyzed using adequate analytical methods and the sample storage intervals are supported by the available storage stability data. For a 0-day PHI, the available residue data from the eleven total trials support a 4.5 ppm tolerance for the RAC strawberry. HED determined this tolerance using its Statistically-Based

Method for Establishing NAFTA-Harmonized Tolerances. The individual residue values that were used to establish these tolerances are listed in Table 13.

Almonds

The registrant has requested a change in the almond PHI. Currently the Pristine and Endura labels state that for almond "apply no later than 5 weeks after petal fall." The registrant has requested that this statement be removed and that the PHI be set at 25 days. Removing the current statement and setting the PHI at 25 days in effect causes a significant decrease in the PHI. The registrant has also requested an increase in the almond hull tolerance from 3.0 ppm to 15 ppm. In the previous field trials that were performed, residues ranged up to 0.20 ppm in nutmeat and from 0.42 ppm to 2.63 ppm on hulls. Applications were made at a 1x rate and the PHIs ranged from 108 to 148 days.

Field trial data have been generated for boscalid on almonds at the proposed PHI. Five trials were conducted on almonds during the 2003 growing season in NAFTA Growing Region 10 (California). At each test location four broadcast applications of boscalid (70% WG) and pyraclostrobin were made as a tank mix to almonds. As the results of the pyraclostrobin study are not germane to this action, this document addresses the boscalid residues only. Applications were made at 0.22-0.24 lb ai/A/application, with a 6- to 8-day RTI. The total application rates were 0.92-0.93 lb ai/A. The applications were made to side by side plots at each site using either concentrate (56-100 gal/A) or dilute (140-210 gal/A) spray volumes. An adjuvant was added to the spray mixture for all applications. Mature almond RAC samples were harvested at 24-26 days after the last application (DALA). Applications were made at the 1x label rate and samples were taken at the minimum PHI.

The residues of boscalid on almond RAC samples (nutmeat and hulls) were quantitated using a validated LC/MS/MS method, BASF Analytical Method D9908. Acceptable concurrent method validation data for almond commodities were obtained. The validated LOQ was 0.05 ppm for residues of boscalid in/on almond nutmeat and hulls. The LOD was 0.005 ppm. The field residue samples were stored frozen (<-10°C) a maximum of 5 months from harvest to analysis. The available storage stability data indicate that residues of boscalid are stable in/on a variety of frozen plant matrices for at least 18 months.

The results from these trials show that residues of boscalid were below the LOQ of 0.05 ppm in/on all treated nutmeat samples (n = 20) harvested 24-26 days after the last of four concentrated or dilute spray applications of boscalid totaling 0.92-0.93 lb ai/A/season. Boscalid residues were 1.8-11.3 ppm (concentrated spray) and 3.1-13.4 ppm (dilute spray) in/on 20 treated almond hulls samples. No significant differences in the residues were observed in samples taken from trees treated with the concentrated spray as opposed to those treated with the dilute spray. The results of the almond field trials are summarized in Table 9, below.

Table 9. Summary of Residue Data for Almond Field Trials using a 70% WDG Formulation of Boscalid

Commodity	Total Rate (lb a.i./A)	PHI (days)	Boscalid Residue Levels (ppm)						
			n	Min.	Max.	HAFT [1]	Median (STMdR[2])	Mean (STMR[2])	Std. Dev.
Nutmeat (Conc.)	0.92-0.93	24-26	10	<0.05	<0.05	<0.05	<0.05	<0.05	0
Nutmeat (Dilute)	0.92-0.93	24-26	10	<0.05	<0.05	<0.05	<0.05	<0.05	0
Nutmeat (Overall)	0.92-0.93	24-26	20	<0.05	<0.05	<0.05	<0.05	<0.05	0
Hulls (Conc.)	0.92-0.93	24-26	10	1.8	11.3	11.3	3.0	4.6	3.6
Hulls (Dilute)	0.92-0.93	24-26	10	3.1	13.4	11.1	5.4	6.1	3.1
Hulls (Overall)	0.92-0.93	24-26	20	1.8	13.4	11.3	3.9	5.3	3.3

[1] HAFT = Highest Average Field Trial.
[2] STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

Conclusions: The submitted field trials are adequate to evaluate the registrant's request for an increase in the almond hull tolerance. The OPPTS Series 860 Guidelines recommend that five field trials be performed in Growing Region 10. The registrant performed five field trials at two different spray dilutions for a total of ten trials. The trials were performed in Region 10. Based on the results of the almond hull analyses, HED recommends in favor of increasing the tolerance from 3.0 ppm to 17 ppm. HED determined this tolerance using its Statistically-Based Method for Establishing NAFTA-Harmonized Tolerances. The individual residue values that were used to establish these tolerances are listed in Table 13.

The proposed PHI for almonds is 25 days, whereas the PHI for all other tree nuts is 14 days. In the five **pecan** field trials that were originally performed, residues in all samples were below the LOQ of 0.05 ppm. In the almond field trials performed at a 25-day PHI, residues in all samples were also below the LOQ of 0.05 ppm. Although almonds and pecans are the representative commodities of the tree nuts crop group and residues in all nutmeat samples were <0.05 ppm, HED recommends retaining the crop group tolerances for tree nut nutmeat and pistachios at 0.7 ppm. The existing 0.7 ppm tolerances for these commodities are based on the maximum residue in pistachios being 0.64 ppm (see 8/15/2003 M. Nelson summary document, PP#1F6313, D278385). The registrant needs to submit a revised Section F that proposes a tolerance of 17 ppm for almond hulls.

Bananas

Field trial data have been generated for boscalid on bananas. Twelve trials were conducted on banana during the 2003-2004 growing season in Costa Rica (2 trials), Colombia (2 trials), Ecuador (2 trials), Guatemala (1 trial), Honduras (2 trials), Martinique (2 trials), and Mexico (1 trial). At each test location four broadcast foliar applications of boscalid (50% WDG) were made to bananas at 0.125-0.144 lb ai/A per application. The total seasonal application rate ranged from 0.52 to 0.56 lb ai/A. The RTI was 10 to 13 days. Applications were made using ground application equipment, simulating aerial application above the plant canopy, in spray volumes of approximately 3 gal/A of water. An adjuvant (spray oil plus emulsifier) was added to the spray mixture for all applications. Mature banana RAC samples were harvested at 0 DALA.

The residues of boscalid in/on banana samples (unbagged and bagged, whole fruit RAC and pulp) were quantitated using a validated LC/MS/MS method, BASF Analytical Method D9908, the data collection method for plant matrices. Acceptable concurrent method validation data for banana commodities were obtained for boscalid. The validated LOQ was 0.05 ppm for residues of boscalid in/on banana whole fruit and pulp. The LOD was 0.005 ppm.

The field residue samples were stored frozen (<-10°C) a maximum of 4 months from harvest to analysis. The available storage stability data indicate that residues of boscalid are stable in/on a variety of frozen plant matrices for at least 12 months.

In the banana field trials residues of boscalid ranged from <0.05 ppm to 0.18 ppm in/on 12 samples of unbagged whole bananas harvested immediately (0-day PHI) after the last of four applications of boscalid (50% WDG) totaling 0.52-0.56 lb ai/A/season. Boscalid residues were <0.05 ppm in/on all 12 treated bagged whole banana samples. The residues levels of boscalid in treated pulp samples, both bagged and unbagged (n=24), were <0.05 ppm (<LOQ). The results of the banana field trials are summarized in Table 10, below.

Table 10. Summary of Residue Data from Banana Field Trials

Commodity	Total Rate (lb a.i./A)	PHI (days)	Boscalid Residue Levels (ppm)						
			n	Min.	Max.	HAFT [1]	Median (STMdR[2])	Mean (STMR[2])	Std. Dev.
Whole Fruit (bagged)	0.52-0.56	0	12	<0.05	<0.05	<0.05	<0.05	<0.05	0
Whole Fruit (Unbagged)			12	<0.05	0.18	0.18	0.07	0.08	0.04
Whole Fruit (Both)			24	<0.05	0.18	0.18	<0.05	0.07	0.03
Pulp	0.52-0.56	0	24	<0.05	<0.05	<0.05	<0.05	<0.05	0

[1] HAFT = Highest Average Field Trial.
[2] STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

Conclusions: The submitted field trials are adequate to evaluate the registrant's request for the establishment of a tolerance on the RAC banana. The OPPTS Series 860 Guidelines recommend that for a domestic use, five field trials be performed, one in Growing Region 3 and four in Region 13. The request is for an import tolerance, though, so the field trials were performed in Central and South America. Twelve field trials were performed all together. This number is consistent with the import tolerance guidance published by the Agency in the Federal Register on June 1, 2000. Based on the results of the analyses of the unbagged whole fruit samples, HED recommends in favor of establishing the import tolerance at 0.20 ppm. HED determined this tolerance using its Statistically-Based Method for Establishing NAFTA-Harmonized Tolerances. The individual residue values that were used to establish these tolerances are listed in Table 13.

Tuberous and Corm Vegetables: Proposed Decrease in PHI

A tolerance of 0.05 ppm is currently in effect for tuberous and corm vegetables (Crop Subgroup 1C). The registrant performed 16 field trials on potatoes (DER 45405123.der, W. Drew, 7/2/2003). The potatoes were harvested at a PHI of 30 days. Two residue decline studies were performed in which a PHI of 10 days was used. In addition, one of the field trials at the 30-day PHI was performed at a 5x application rate. In all samples including those performed at the 10-day PHI and the one performed at the exaggerated rate, residues were below the LOQ of 0.05 ppm. The registrant has proposed a label amendment to decrease the PHI from 30 days to 10 days. Tuberous and corm vegetables grow underneath the soil surface. The primary means of uptake of residues from foliar applications is by translocation through the leaves. Very often residues increase with an increase in PHI because the residues have more time for translocation. As a result, HED feels that the two residue decline studies support the request for a shorter PHI. HED recommends in favor of the reduction of the PHI from 30 days to 10 days.

Seed Treatment Uses

The registrant has requested the use of boscalid as a seed treatment on *Brassica* leafy vegetables (Crop Group 5), bulb vegetables (Crop Group 3), legume vegetables (Crop Group 6), peanuts, and sunflowers. Tolerances for foliar uses have already been established for all of these commodities. With the exception of peanuts, the tolerances for these commodities are 0.6 ppm or higher. The tolerance for peanuts is 0.05 ppm. As the tolerances for foliar uses are considerably higher than the residues that would result from seed treatment uses (for all of the proposed commodities except peanuts), HED recommends in favor of granting the seed treatment uses for all crops except peanuts. For a seed treatment use on peanuts, the registrant should perform additional field trials in which peanuts have been subjected to both the seed treatment as well as the foliar application. The seed should be treated at the proposed maximum label rate and the foliar applications should be at the maximum label rate. In addition, samples must be taken at the minimum PHI. If residues in the peanut RAC samples exceed the 0.05 ppm tolerance already established for peanuts, the tolerance will likely need to be increased.

860.1520 Processed Food and Feed

As there are no processed food or feed commodities associated with spinach, celery, strawberries, almonds, or bananas, this guideline requirement is not relevant to the current submissions.

860.1650 Submittal of Analytical Reference Standards

The analytical reference standards for boscalid have been submitted to the EPA National Pesticide Standards Repository.

860.1850 Confined Accumulation in Rotational Crops

45405024.der (Rotational crops)

The nature of the residue in rotational crops is adequately understood and was summarized in a previous residue chemistry summary document (PP# 1F06313, D278385, M. Nelson, 8/15/03). The MARC has concluded that the residue of concern in rotated crops for both tolerance expression and risk assessment purposes is the parent compound (D286786, M. Nelson, 1/9/03).

860.1900 Field Accumulation in Rotational Crops

46210606.der (Sugar Beet Garden Beet, and Turnip)

The limited field rotational crop study was summarized in a previous residue chemistry summary document (PP# 1F06313, D278385, M. Nelson, 8/15/03). Because detectable residues of boscalid were observed in radish tops and roots at the longest plant-back interval (PBI) studied (45 days), extensive rotational crop field trials were required to support the establishment of indirect residue tolerances for rotational crop commodities. The petitioner has submitted extensive field rotational crop studies on sugar beets, garden beets, and turnips (46210606.der, summarized below) to support a tolerance for inadvertent residues in root vegetables and leaves of root and tuber vegetables.

Fourteen field rotational crop trials were conducted at field sites in AR, CA, GA, ID, NE, ND (4 tests), OK, SD, TX, VA, and WI between 1997 and 2002 on the representative crops of the leaves of root and tuber vegetables crop group. At each test site, the bare soil was treated three times with boscalid (70% WDG) at 0.70-0.74 lb ai/A for the first application and 0.53-0.56 lb ai/A for the second and third applications, for a total of 1.79-1.86 lb ai/A/season (1x maximum seasonal rate). Applications were made using ground equipment with a RTI of 6-8 days. At each site, rotational crops of sugar beet (7 tests), garden beet (2 tests), or turnips (5 tests) were planted 13-14 days after the last treatment (label specified PBI). A single control and duplicate treated samples of roots and tops from each rotational crop were harvested at intervals reflecting normal agricultural practices. Samples were stored frozen for a maximum of 6 months, an interval that is supported by the available storage stability data.

Samples were analyzed for residues of boscalid using an adequate LC/MS/MS method (BASF Method Number D9908). The LOQ is 0.05 ppm for residues of boscalid in/on all plant matrices; the LOD was not reported. Based on raw data from all treated and control samples, apparent residues could be reliably detected below the 0.05 ppm LOQ, but were reported as <0.05 ppm. Therefore, when calculating average residues, the reviewer used the LOQ value (0.05 ppm) for all residues reported to be <0.05 ppm.

Residues of boscalid were 0.051-0.066 ppm in/on 4 of 14 sugar beet top samples, 0.066 and 0.082 ppm in/on 2 of 10 turnip tops samples, and 0.050 and 0.053 ppm in/on 2 of 10 turnip root samples. Residues were <0.05 ppm (<LOQ) in all remaining RAC samples collected from the rotational sugar beet, garden beet, and turnip matrices. Average residues were 0.05 ppm in/on

sugar beet roots, garden beet tops and roots, and turnip roots, and were 0.052 ppm in/on sugar beet tops and 0.055 ppm in/on turnip tops. The results of the field rotational crop studies are summarized in Table 11, below.

Table 11. Summary of Residue Data on Representative Rotational Crops for the Leaves of Root and Tuber Vegetables Crop Group, Following Treatment of Bare Soil with Boscalid (70% WDG)

Commodity	Total Rate (lb ai/A)	PBI (days)	Boscalid Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT[2]	Median (STMdR[3])	Mean (STMR[4])	Std. Dev.
Sugar beet roots	1.81-1.83	14	14	<0.05	<0.05	<0.05	<0.05	0.050	0
Sugar beet tops		14	14	<0.05	0.066	0.064	0.05	0.052	0.005
Garden beet roots	1.79-1.82	14	4	<0.05	<0.05	<0.05	<0.05	0.050	0
Garden beet tops		14	4	<0.05	<0.05	<0.05	<0.05	0.050	0
Turnip roots	1.80-1.86	13-14	10	<0.05	0.053	0.052	0.05	0.050	0.001
Turnip tops		13-14	10	<0.05	0.082	0.074	0.05	0.055	0.011

[1] The LOQ is 0.05 ppm for each matrix; the LOD was not reported.
[2] HAFT = Highest Average Field Trial.
[3] STMdR = Supervised Trial Median Residue.
[4] STMR = Supervised Trial Mean Residue. In calculating the average, the LOQ was used for samples listed as having residues <LOQ.
NA = not applicable

Conclusions. The field rotational crop data on sugar beet, garden beet, and turnips are adequate. The representative crops were planted 14 days after soil applications totaling the maximum seasonal rate for any rotated crop, and adequate numbers of tests were conducted on each crop in the appropriate regions. These rotational crop data will support reducing the current tolerance for indirect residues on leaves of root and tuber vegetables (group 2) from 1.0 to 0.1 ppm. In addition, the data support a single tolerance at 0.1 ppm for inadvertent residues in root vegetables (subgroup 1A) to replace the current separate tolerances on roots of sugar beet, garden beet, and turnips.

860.1550 Proposed Tolerances

The MARC determined that the residues to be included in the tolerance expression are parent only in primary and rotational crops, and parent plus hydroxy metabolite (free plus bound) in livestock commodities. The additional or revised tolerances being considered under PP#s 1F6313, 3E6791, 4F6875, and 5E6933 are listed in Table 12.

As the proposed use pattern for celery and spinach is different than that for lettuce (0-day PHI vs. 14-day PHI), and maximum residues are higher on celery (19.7 ppm) and spinach (41.8 ppm) than on lettuce (10.4 ppm), a crop group tolerance for leafy vegetables is not appropriate. Separate tolerances should be proposed for celery and spinach at 45 and 60 ppm, respectively. The additional strawberry field trial data, when combined with the original data, support an

increase in the strawberry tolerance. This tolerance should be changed from 1.2 to 4.5 ppm. The additional almond hull data, support an increase in the almond hull tolerance. The tolerance should be changed from 3.0 to 17 ppm. The submitted banana field trial data support the establishment of a tolerance of 0.20 ppm for bananas. HED determined the recommended tolerances for celery, spinach, bananas, strawberries, and almond hulls using its Statistically-Based Method for Establishing NAFTA-Harmonized Tolerances. The individual residue values that were used to establish these tolerances are listed in Table 13.

The available extensive rotational crop field trial data on sugar beets, garden beets and turnips from the 14-day PBI will support reducing the current tolerance for indirect residues on leaves of root and tuber vegetables (Group 2) from 1.0 to 0.1 ppm. In addition, these data will support establishing a tolerance for indirect residues of boscalid in root vegetables (Subgroup 1A) at 0.1 ppm. Once this tolerance is established the separate rotational crop tolerances on roots of sugar beets, garden beets, radishes, and turnips at 1.0 ppm can be deleted.

As far as the leafy vegetables (Crop Group 4) are concerned, primary crop tolerances are only being established on lettuce, celery, and spinach. Tolerances are not being established on the other commodities of the crop group. As a result, the current rotational crop tolerance for leafy vegetables should be maintained.

There are currently no International or Codex MRLs for boscalid. Although the initial U.S. tolerances for boscalid were established in conjunction with a joint review with Canada's PMRA, MRLs have yet to be finalized in Canada. Regulatory Note for Boscalid REG2004-2 (1/30/2004) lists tolerances which have been proposed as part of the Canadian process. The strawberry tolerance in that Note is 1.2 ppm, which agrees with the established U.S. tolerance, but is less than the 4.5 ppm tolerance recommended by HED in the present action. This tolerance is being increased based on the submission of additional residue data to EPA and the use of the NAFTA statistical method that was not available at the time of the joint review. In a similar fashion, HED is recommending revision of rotational crop tolerances for the tops of root and tuber vegetables and for the roots of radishes, turnips, garden beets, and sugar beets. These tolerances are being decreased from 1.0 to 0.1 ppm based on the submission of field rotational crop data. As a result, these tolerances would differ from the proposed Canadian MRLs of 1.0 ppm for the tops and 0.7 ppm for the roots. The HED-recommended tolerances of 45 ppm on celery and 60 ppm on spinach are much higher than the proposed Canadian MRL of 1 ppm on these crops. However, that Canadian level is based on rotational crop residues, while the U.S. is now setting celery and spinach tolerances to cover direct use on these crops. The International Residue Limit Status Sheet is appended to this document as Attachment 1.

Table 12. Tolerance Summary for Boscalid

Commodity	Current Tolerance (ppm)	Recommended Tolerance (ppm)	Comments (correct commodity definition)
40CFR §180.589(a)(1)			
Lettuce, head	6.5	6.5	Permanent tolerances have been established for head and leaf lettuce (D278385, M. Nelson, 8/15/03)
Lettuce, leaf	11.0	11.0	
Celery	None	45	The available data indicate that a crop group tolerance for leafy vegetables is not appropriate. The data support separate tolerances of 45 ppm for residues in/on celery and 60 ppm for residues in/on spinach. Maximum residues from the field trials were 19.7 ppm in/on celery and 41.8 ppm in/on spinach.
Spinach	None	60	
Strawberry	1.2	4.5	Strawberry
Almond Hulls	3.0	17	Almond Hulls
Banana (Imported)	None	0.20	Banana
40CFR §180.589(d)			
Beet, garden, roots	1.0	0.1	Adequate residue data are available to support reducing tolerances on the separate rotational root crops and to establish a single tolerance for inadvertent residues in/on *vegetable, root, subgroup 1A*. In the extensive rotational crop field trials on root crops, maximum residues were 0.053 ppm in/on turnip roots
Radish, roots	1.0		
Turnip, roots	1.0		
Beet, sugar, roots	1.0		
Vegetable, root and tuber, tops, Crop Group 2	1.0	0.1	In the extensive rotational crop trials on sugar beets, garden beets, and turnips, the maximum residues were 0.082 ppm in/on turnip tops.
Vegetable, leafy, Crop Group 4, except lettuce	1.0	1.0	As primary crop tolerances are only being established on lettuce, celery, and spinach, the current rotational crop tolerance for leafy vegetables (group 4) should be maintained. However, the exclusion should be revised to state "except lettuce, celery, and spinach."

Table 13. Boscalid Field Trial Values Used to Establish Recommended Tolerances					
	Strawberries (ppm)	Almond Hulls (ppm)	Celery (ppm)	Spinach (ppm)	Bananas (ppm)
	2.36	13.40	19.7	41.8	0.18
	1.98	12.70	18.4	41.6	0.11
	1.90	11.30	18.3	37.2	0.10
	1.88	11.20	15.6	34.0	0.10
	1.73	10.40	13.4	28.7	0.09
	1.72	7.84	12.6	28.2	0.07
	1.46	7.14	12.5	27.5	0.07
	1.24	6.42	10.7	25.9	5 @ 0.05
	1.20	5.90	9.7	22.8	
	1.17	4.92	9.7	21.9	
	1.16	4.49	8.6	17.9	
	0.96	4.06	8.3	16.3	
	0.90	3.72	8.1	14.7	
	0.86	3.41	7.6	14.3	
	0.83	3.33	6.7	13.0	
	0.66	3.18	6.5	12.6	
	0.63	3.11	5.6		
	0.59	2.84	4.4		
	0.58	2.75	2.7		
	0.54	2.61	2.6		
	0.53	2.52	2.0		
	0.53	1.80	2.0		
	0.39		1.9		
	0.30		1.8		
	0.22				
	0.16				
Recommended Tolerance	4.5	17	45	60	0.20

References

DP Barcodes: D278385, P#1F06313. BAS 510 F (Common Name: Boscalid), New Fungicide Active Ingredient. Residue Chemistry Summary Document, M. Nelson, 8/15/03

cc: D. Dotson

Attachment 1: International Residue Limit Status Sheet

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro [1,1'-biphenyl]-2-yl)	Common Name: Boscalid	☒ Proposed tolerance ☐ Reevaluated tolerance ☐ Other	Date: 8/23/2005

Codex Status (Maximum Residue Limits)	U. S. Tolerances
☒ No Codex proposal step 6 or above ☐ No Codex proposal step 6 or above for the crops requested	Petition Numbers: 3E6791, 4F6875, 5E6933 DP Barcodes: D303314, 311246, 311271, 316092, 316787, 319565
Residue definition (step 8/CXL): Not applicable	Reviewer/Branch: Doug Dotson/RAB2
	Residue definition: Parent boscalid

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Celery	45
		Spinach	60
		Strawberries	4.5
		Bananas	0.20
		Almond Hulls	17
		Root and tuber vegs	0.1
		Tops of roots and tubers	0.1

Limits for Canada	Limits for Mexico
☒ No Limits ☐ No Limits for the crops requested	☒ No Limits ☐ No Limits for the crops requested
Residue definition:	Residue definition:

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions: S. Funk, 08/23/05.

Rev. 1998

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R117770

Chemical: boscalid

PC Code:
128008

HED File Code: 11000 Chemistry Reviews
Memo Date: 11/3/2005
File ID:
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