U. S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 09/06/2000

SUBJECT: **PP#9F06058: Azoxystrobin.** Evaluation of Residue Chemistry Data to Support Permanent Tolerances for Use of Azoxystrobin on Barley, Bulb Vegetables, Cilantro, Citrus Fruits, Corn, Cotton, Leafy Vegetables (except *Brassica*), Leaves of Root and Tuber Vegetables, Peanuts, Root and Tuber Vegetables, Soybeans, and Wild Rice; Higher Tolerances for the Fat and Meat Byproducts of Cattle, Goats, Horses, and Sheep; and, Apples (Inadvertent Residues).

PC Code: **128810**
DP Barcode: **D260134**
40 CFR: 180.507
Formulation: Heritage Fungicide (10182-408; 50 WDG)
Abound Flowable Fungicide (10182-415; 2.08 lbs ai/gal FlC)
MRID#s: 449152-06 thru 449152-32; 449831-01

TO: J. Bazuin/C. Giles-Parker, PM Team 22
Fungicide Branch
Registration Division (7505C)

FROM: M. J. Nelson, Chemist
Registration Action Branch 2
Health Effects Division (7509C)

mjn

THRU: R. A. Loranger, Senior Scientist
Registration Action Branch 2
Health Effects Division (7509C)

R. Loranger

Zeneca Ag Products has submitted this petition for the establishment of permanent tolerances for the regulable residue of the fungicide azoxystrobin in/on the subject commodities and the Section 3 registration of the cited 50 WDG and 2.08 lbs ai/gal FlC formulations for use on the subject crops.

This data review was conducted by Dynamac Corporation (contractor) under the supervision of RAB2, HED, and has undergone secondary review and revision within RAB2 to ensure it reflects current HED and OPP policy.

This review only addresses residue chemistry issues. Product chemistry data for azoxystrobin technical product were reviewed in conjunction with PP#5F04541 (DP Barcodes D218318 and D218448, J. Garbus, 3/19/96).

Recommendations

Provided the petitioner submits the **requested changes to Section B** (WDG and FlC labels) and the **requested changes to Section F nomenclature and tolerance levels to agree with the listing below,** HED can recommend in favor of the establishment of the following tolerances:

- For combined residues of azoxystrobin (methyl (E)-2-[2-[6-(2-cyanophenoxy)pyrimidin- 4-yloxy]phenyl]-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) in or on the following raw agricultural and processed commodities:

Barley, bran	0.2 ppm
Barley, grain	0.1 ppm
Barley, hay	15.0 ppm
Barley, straw	4.0 ppm
Citrus, dried pulp	**2.0** ppm
Citrus, oil	**4.0** ppm
Coriander, leaves	30.0 ppm
Corn, field, forage	**12.0** ppm
Corn, field, grain	0.05 ppm
Corn, field, refined oil	0.3 ppm
Corn, field, stover	25.0 ppm
Corn, pop, grain	0.05 ppm
Corn, pop, stover	25.0 ppm
Corn, sweet, forage	**12.0** ppm
Corn, sweet (kernels plus cob with husks removed)	0.05 ppm
Corn, sweet, stover	25.0 ppm
Cotton, gin byproducts	**0.02** ppm
Cotton, undelinted seed	**0.02** ppm
Fruit, citrus, group	**1.0** ppm
*Grain, aspirated grain fractions	30.0 ppm
Onion, dry bulb	**1.0** ppm
Onion, green	7.5 ppm
*Peanut	0.2 ppm
*Peanut, refined oil	0.6 ppm
*Peanut, hay	15.0 ppm
Soybean, forage	25.0 ppm
Soybean, hay	55.0 ppm
Soybean, hulls	**1.0** ppm
Soybean, seed	0.5 ppm
Vegetable, leafy, except *Brassica,* group	30.0 ppm

**Vegetable, leaves of root and tuber, group	50.0 ppm
Vegetable, root, subgroup	0.5 ppm
***Vegetable, tuberous and corm, subgroup	**0.03** ppm

Bolding in the above listing reflects changes to the tolerance levels proposed by the petitioner.
* Proposed tolerance is an increase to a currently existing tolerance.
** **Turnip tops (a.k.a. turnip greens) is currently included in this crop group.**
*** Since this subgroup includes potato, the individual listing for potato should be deleted.
NOTE: The proposed separate tolerance for **sugar beet, dried pulp has been deleted** from the listing since it was not warranted, and that for **wild rice has been deleted** from the listing due to no supporting data.]

- An **increase** in the established tolerances for residues of azoxystrobin *per se* in the following animal commodities:

Cattle, fat	0.03 ppm
Cattle, meat byproducts	0.07 ppm
Goat, fat	0.03 ppm
Goat, meat byproducts	0.07 ppm
Horse, fat	0.03 ppm
Horse, meat byproducts	0.07 ppm
Sheep, fat	0.03 ppm
Sheep, meat byproducts	0.07 ppm

[Note: The other currently established animal commodity tolerances, including those for the fat and meat byproducts of **hogs**, do **NOT** require higher tolerances at this time.]

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HED **cannot recommend for** the establishment of the proposed tolerance of 1.5 ppm for the combined residues of azoxystrobin and its Z isomer in/on apple (inadvertent residues), since it is not OPP policy to establish a tolerance for inadvertent residues based upon concerns about the possibility of spray drift or contaminated equipment.

As conditions of registration, the petitioner should provide additional data on storage stability; two additional crop field trials for spinach; and. additional limited field rotational crop studies . The issue of separate field trials or bridging data (side-by-side field trials) on representative crops in support of late season uses of the FlC formulation should also be addressed.

NOTE TO PM: HED's favorable recommendation for the establishment of the proposed tolerances listed above is <u>contingent</u> upon an acceptable human health risk assessment.

Attachment: Azoxystrobin Residue Chemistry Data Review (D260134)

cc with Attachment: PP#9F06058, RAB2 Reading File, M. Nelson

AZOXYSTROBIN
PC Code 128810
(DP Barcode D260134)

PP#9F06058: Evaluation of Residue Chemistry Data to Support Permanent Tolerances for Use of Azoxystrobin on Barley, Bulb Vegetables, Cilantro, Citrus Fruits, Corn, Cotton, Leafy Vegetables (except *Brassica*), Leaves of Root and Tuber Vegetables, Peanuts, Root and Tuber Vegetables, Soybeans, and Wild Rice; Higher Tolerances for the Fat and Meat Byproducts of Cattle, Goats, Horses, and Sheep; and, Apples (Inadvertent Residues)

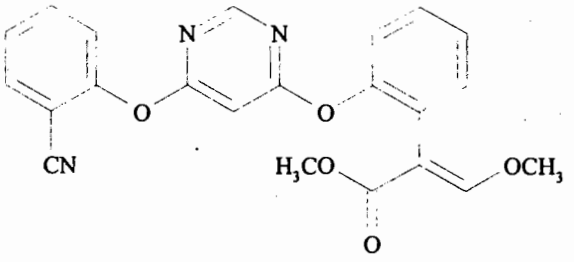
June 2, 2000

Contract No. 68-W-99-053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

AZOXYSTROBIN



PP#9F06058: EVALUATION OF RESIDUE CHEMISTRY DATA TO SUPPORT PERMANENT TOLERANCES FOR USE OF AZOXYSTROBIN ON BARLEY, BULB VEGETABLES, CILANTRO, CITRUS FRUITS, CORN, COTTON, LEAFY VEGETABLES (EXCEPT *BRASSICA*), LEAVES OF ROOT AND TUBER VEGETABLES, PEANUTS, ROOT AND TUBER VEGETABLES, SOYBEANS, AND WILD RICE; HIGHER TOLERANCES FOR THE FAT AND MEAT BYPRODUCTS OF CATTLE, GOATS, HORSES, AND SHEEP; AND, APPLES (INADVERTENT RESIDUES)

(DP BARCODE D260134)

INTRODUCTION

Zeneca Ag Products has submitted a petition proposing the establishment of (or the increase of, as applicable) permanent tolerances for the regulable residue of the fungicide azoxystrobin in/on a number of raw agricultural commodities (RACs), processed commodities, and animal commodities in conjunction with a request for the Section 3 registration of a 50% water dispersible granular formulation (Heritage® Fungicide, EPA Reg. No. 10182-408) and a 2.08 lbs ai/gal flowable concentrate formulation (Abound® Flowable Fungicide, EPA Reg. No. 10182-415).

Specifically, Zeneca is proposing the establishment of permanent tolerances for the combined residues of azoxystrobin (methyl (E)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) in/on the following raw agricultural and processed commodities:

Barley, grain	0.1 ppm
Barley, hay	15.0 ppm
Barley, straw	4.0 ppm
Barley, bran	0.2 ppm

Bulbs [vegetables]	7.5 ppm
Citrus, fruits	3.0 ppm
Citrus, dried pulp	7.0 ppm
Citrus, oil	15.0 ppm
Corn, grain	0.05 ppm
Corn, kernels (sweet)	0.05 ppm
Corn, forage	10.0 ppm
Corn, stover	25.0 ppm
Corn, oil	0.3 ppm
Cotton, seed	0.01 ppm
Cotton, gin by-products	0.01 ppm
Root and Tuber Vegetables	0.5 ppm
Tops of Root and Tuber Vegetables	50 ppm
Sugar beet, dried pulp	0.8 ppm
Leafy Vegetables (excluding *Brassica*)	30.0 ppm
Cilantro	30.0 ppm
Peanuts, nutmeat	0.2 ppm
Peanuts, oil	0.6 ppm
Peanuts, hay	15.0 ppm
Soybean, seed	0.5 ppm
Soybean, forage	25.0 ppm
Soybean, hay	55.0 ppm
Soybean, hulls	1.25 ppm
Wild rice	5.0 ppm

In addition, Zeneca is proposing an increase in the established tolerances for the combined residues of azoxystrobin and its Z isomer in the following animal commodities:

Meat byproducts (cattle, goats, horses and sheep)	0.07 ppm
Fat (cattle, goats, horses, and sheep)	0.03 ppm

Lastly, Zeneca is proposing the establishment of permanent tolerances for the combined indirect or inadvertent residues of azoxystrobin and its Z isomer in/on the following commodity:

Apples	1.5 ppm

Tolerances are currently established for the combined residues of azoxystrobin and the Z isomer in/on various raw and processed food commodities under 40 CFR 180.507(a)(1). Tolerances are established for residues of azoxystrobin *per se* in milk and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep under 40 CFR 180.507(a)(2). Several time-limited tolerances are listed under 40 CFR §180.507(a)(3) and (b).

Associated with this petition are 28 volumes of residue chemistry submissions which are evaluated in this document.

CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

1. Adequate product chemistry data for the azoxystrobin technical product have been previously provided in conjunction with a permanent tolerance petition for residues of azoxystrobin and its Z isomer in/on grapes. No impurities are expected to cause residues of concern.

OPPTS GLN 860.1200: Proposed Uses

2a. The submitted Section B is not adequate; the application rate for leafy vegetables is missing from the 50% WDG specimen label. **The petitioner needs to submit a revised Section B which includes an application rate for leafy vegetables on the 50% WDG product label.**

2b. The petitioner provided specimen labels for a WDG formulation and a FlC formulation proposed for identical uses on a variety of agricultural crops. However, all the field trials submitted in support of this petition reflect the use of the WDG formulation only. The guidelines for conducting field trials (OPPTS GLN 860.1500) state that for pesticides used in late-season foliar applications (as is the case with azoxystrobin proposed uses), separate residue trials or bridging data are needed for different formulations. For the purposes of this petition, conclusions pertaining to the proposed uses will be based on the field trial data for the WDG formulation only. **If the petitioner wishes to maintain use of the FlC formulation, then separate crop field trials or bridging data (side-by-side field trials) on representative crops will be required in support of late season uses.**

OPPTS GLN 860.1300: Nature of the Residue in Plants

3. The petitioner has previously submitted metabolism studies with grapes, peanuts, and wheat in conjunction with earlier petitions (PP#5F4541, D218318 and D218448, 3/19/96, J. Garbus; and PP#6F4762, D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney) which were deemed adequate to support the proposed uses. The HED Metabolism Assessment Review Committee (MARC) has determined that the residues of concern in/on plants are azoxystrobin and its Z isomer (D251683, 12/30/98, W. Wassell).

4a. Cotton: In support of the current petition, Zeneca submitted a cotton metabolism study. Based on this study, the qualitative nature of the residue in cotton is adequately understood. Total radioactive residues were 0.005 ppm in seed, 0.081 ppm in forage, 0.004 ppm in lint, and 0.007 ppm in gin trash following a single at-planting in-furrow application of azoxystrobin at 0.2 oz ai/1,000 feet of row (1x the maximum proposed application rate).

4b. Because of low radioactivity levels, characterization/identification of residues was only conducted in cotton forage. Azoxystrobin was the only compound identified, at 15.0% TRR (0.0128 ppm). The remainder of the radioactivity consisted of unknowns, none of which exceeded 11.4% TRR (0.01 ppm), and unextracted radioactivity (18.3% TRR, 0.006 ppm).

OPPTS GLN 860.1300: Nature of the Residue in Animals

5. The petitioner has previously submitted ruminant and poultry metabolism studies in conjunction with earlier petitions (PP#5F4541, D218318 and D218448, 3/19/96, J. Garbus; and PP#6F4762, D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney) which were deemed adequate to delineate the nature of the residue in animals. The HED MARC has determined that the residue of concern in animals is parent azoxystrobin *per se* (D251683, 12/30/98, W. Wassell).

OPPTS GLN 860.1340: Residue Analytical Method - Plant Commodities

6a. Adequate methodology is available for enforcement of the proposed tolerances. GC/NPD method RAM 243 is adequate for the enforcement of the proposed tolerances in/on apples, barley, bulb vegetables, cilantro, citrus fruits, corn (field, sweet, and pop), root and tuber vegetables, leaves of root and tuber vegetables, leafy vegetables (except Brassica vegetables), peanut hay, wild rice, and non-oily processed commodities. GC/NPD method RAM 260 is adequate for the enforcement of the proposed tolerances in/on cotton, peanut nutmeat, soybeans and oily processed commodities. These methods have undergone method validation by the EPA analytical laboratory (PP#5F4541 and PP#6F4762, 5/29/97, C. Stafford). EPA comments have been incorporated and the revised methods are to be submitted to FDA for inclusion in PAM Volume II.

6b. Based on the submitted concurrent method validation data, the GC/NPD methods used for data collection are adequate.

OPPTS GLN 860.1340: Residue Analytical Methods - Animal Commodities

7. For analysis of animal commodities, the petitioner had previously proposed GC method 255/01 for the enforcement of tolerances for residues of azoxystrobin in animal commodities. This method has been validated by the ACL for the analysis of milk and animal tissues (DP Barcodes D249657 and D249668, 1/25/99, D. Dotson). The BEAD laboratory's written report with an EPA addendum to accompany the method, and the method are to be submitted to FDA for inclusion in PAM Vol. II.

OPPTS GLN 860.1360: Multiresidue Method

8. The petitioner has previously submitted data pertaining to the multiresidue methods testing of azoxystrobin in conjunction with the grape tolerance petition (PP#5F4541; DP Barcodes D218318 and D218448, J. Garbus, 3/19/96). The data indicate that azoxystrobin could not be recovered through application of the multiresidue protocols. These data are to be forwarded to FDA.

OPPTS GLN 860.1380: Storage Stability Data

9a. Plant commodities: In support of the storage intervals and conditions of samples from the field and processing studies, Zeneca referenced previously submitted storage stability studies conducted on various plant commodities. In a study conducted on RACs (DP Barcodes D248887 and D249671, 10/14/98, D. Dotson, M. Doherty, and Y. Donovan), fortified residues of azoxystrobin and the Z isomer were found to be stable for up to two years in/on grapes, wine, apples, peaches, bananas, cucumbers, wheat straw, and rape seed oil. Over the two-year storage period, residues of azoxystrobin and the Z isomer decreased by up to 20% in wheat grain. A similar decrease was observed for residues of azoxystrobin in/on peanuts, pecans, and tomatoes also stored for up to two years. Residues are considered stable for up to 6-8 months in these crops.

9b. A separate study conducted on processed commodities (DP Barcodes D249657 and D249668, 1/25/99, D. Dotson), demonstrated that fortified residues of azoxystrobin and the Z isomer are generally stable for up to one year in/on the processed commodities peanut oil, peanut meal, wheat bran, tomato juice, and tomato paste.

9c. Samples from the submitted field trial and processing studies were stored frozen for up to about 11 months from harvest to analysis. According to OPPTS 860.1380 guidelines, data demonstrating storage stability in five diverse crops can be used to support registration on a wide variety of crops. Adequate storage stability data are available from the representative crops oilseed (rape seed and nuts), non-oily grain (wheat), and fruit or fruiting vegetable (grapes, apples, peaches, and tomatoes), as well as from the processed commodities of these crops. No data are available depicting the storage stability of residues of azoxystrobin and the Z isomer in/on leafy commodities (leafy vegetables and leaves of root and tuber vegetables), root and tuber vegetables, or the processed commodities of root and tubers (i.e., sugar beets). **To support the storage conditions and intervals of crop samples from this petition, as a condition of registration, additional data are required depicting the storage stability of residues of azoxystrobin and the Z isomer in/on a representative leafy vegetable, root and tuber vegetable, and processed commodities of a root and tuber vegetable stored frozen for up to 11 months.** [Note: The results of such a study could *conceivably* require an upward revision of the tolerances on the affected crops.]

OPPTS GLN 860.1500: Crop Field Trials

10a. Root and Tuber Vegetables Group: The available crop field trial data are not adequate to support the proposed crop group tolerance because the potato data (16 trials, all harvested with 13- or 14-day PHIs) do not reflect the PHI (0 days) being proposed on the WDG and FlC labels for the root and tuber vegetables. **To support the proposed crop group tolerance, the requisite number of field trials (12) on potatoes harvested at a 0-day PHI following treatment with azoxystrobin at the maximum proposed seasonal application rate for the root and tuber vegetables would need to be conducted. For alternative options, see Conclusions 10b and 10c.**

10b. The available data will support the establishment of a crop subgroup tolerance for the root vegetables subgroup (Crop Subgroup 1-A). The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on carrots, radishes, and sugar beets, the representative commodities of the root vegetables subgroup. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed "root and tuber vegetables" tolerance level of 0.5 ppm in/on carrots, radishes, and sugar beets following treatment at 1x the maximum proposed seasonal application rate and harvest at 0-day PHI. **For a Crop Subgroup 1-A tolerance, the petitioner should submit a revised Section F to remove the proposed root and tuber vegetables crop group tolerance and to propose a "Vegetable, root, subgroup" tolerance at 0.5 ppm. The petitioner should also submit suitably revised WDG and FlC labels.**

10c. Since potato is the sole representative commodity of the tuberous and corm vegetables subgroup, the available data on potatoes will support the establishment of a crop subgroup tolerance for the tuberous and corm vegetables subgroup (Crop Subgroup 1-C). The use pattern would be the same as for the root vegetables subgroup, except the PHI proposed for the tuberous and corm vegetables subgroup would need to be a minimum of 14 days. The petitioner has previously provided (MRID 44613501; DP Barcodes D248887 and D249671, 10/14/98, D. Dotson, M. Doherty, and Y. Donovan) adequate residue data for potatoes, reflecting a 6 x 0.33 lb ai/A applications use pattern, for a total seasonal application of 2 lbs ai/A, with a 14-day PHI. Those data supported the establishment of a 0.03 ppm tolerance for the combined residues of azoxystrobin and its Z isomer in/on potato, which may now be extended to cover the tuberous and corm vegetables subgroup. **For a Crop Subgroup 1-C tolerance, the petitioner should submit a revised Section F to remove the proposed root and tuber vegetables crop group tolerance and to propose a "Vegetable, tuberous and corm, subgroup" tolerance at 0.03 ppm. The petitioner should also submit suitably revised WDG and FlC labels. Based on the available potato field trial data, the minimum acceptable PHI is 14 days.**

11a. Leaves of Root and Tuber Vegetables Group: The available crop field trial data are adequate to support the proposed leaves of root and tuber vegetables group tolerance. The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on radish tops (in lieu of turnip tops) and sugar beet tops, which can be considered to be representative commodities of the leaves of root and tuber vegetables group. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed crop group tolerance level of 50.0 ppm following treatment at 1x the maximum proposed seasonal application rate. **A revised Section F should be submitted to express the proposed crop group tolerance in terms of "Vegetable, leaves of root and tuber, group" at 50.0 ppm.**

11b. HED has recently concluded that "turnip greens" more appropriately belongs in Crop Group 5, *Brassica* (cole) leafy vegetables (B. Schneider, 2/10/2000). However, we understand its transfer to that crop group is not imminent (conversation with B. Schneider, 8/15/00). Thus, **for now, turnip greens will be covered by the tolerance on the leaves of root and**

tuber vegetables. [Note: If/when transferred, turnip greens may need an individual tolerance listing at 50.0 ppm expressed as "Turnip, tops", depending upon whether there is a *Brassica* leafy vegetables crop group tolerance by that time and whether the use pattern and tolerance level of turnip greens is compatible with it.]

12a. Bulb Vegetables: The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin and its Z isomer on dry bulb onions and green onions. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed "bulbs" [sic] tolerance level of 7.5 ppm, following treatment at 1x the maximum proposed seasonal application rate. However, **because the difference between the highest dry bulb onion residues (0.67 ppm) and the highest green onion residues (6.9 ppm) is greater than 5x, a crop group tolerance for bulb vegetables is not appropriate.**

12b. The petitioner has provided sufficient crop field trial data to support individual tolerances for bulb onions and green onions. **The petitioner should submit a revised Section F to remove the proposed "bulbs" [sic] tolerance and to propose an individual tolerance for "Onion, dry bulb" at 1.0 ppm and "Onion, green" at 7.5 ppm.** We note that even though tolerances are being set specifically on onion, dry bulb and onion, green, because of the definitions and interpretations of 40 CFR 180.1(h), the proposed use will be permitted on all the raw agricultural crops comprising the bulb vegetables crop group; **no revision to the Bulb Vegetables listing on the WDG and FlC labels is required.**

13a. Leafy Vegetables (Except *Brassica* Vegetables) Group: The number and geographic representation of crop field trials are adequate for the representative commodities, celery, head lettuce, and leaf lettuce. For the remaining representative commodity, spinach, both the number and geographic representation of crop field trials are somewhat inadequate. This is especially relevant since the highest residues occurred in spinach. **As a condition of registration, two additional spinach field trials reflecting the maximum proposed seasonal use pattern should be conducted: one in Region 2 and one in Region 9.** [Note: The results of these trials could *conceivably* require an upward adjustment of the crop group tolerance level.]

13b. The petitioner has provided residue data reflecting the maximum proposed use pattern of azoxystrobin on celery, head and leaf lettuce, and spinach, the representative commodities of the leafy vegetables (except *Brassica* vegetables) group. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed "Leafy Vegetables (Excluding *Brassica*)" tolerance level of 30.0 ppm, following treatment at 1x the maximum proposed seasonal application rate. **The petitioner should submit a revised Section F proposing the tolerance of 30.0 ppm in terms of "Vegetable, leafy, except *Brassica*, group".**

14a. Citrus Fruits Group: The petitioner has provided adequate U.S. residue data reflecting the maximum proposed domestic use pattern of azoxystrobin on the representative crops (sweet orange, lemon, and grapefruit) of the citrus fruits group. The results of the U.S. citrus field

trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed 1.0 ppm, following treatment at 1x the maximum proposed seasonal application rate. Residues of azoxystrobin were 0.16-0.41 ppm in/on grapefruit, 0.27-0.74 ppm in/on lemons, and 0.09-0.53 ppm in/on oranges. Residues of the Z isomer were less than the method LOQ (<0.01 ppm) in/on all grapefruit, lemon, and orange samples, except for one lemon sample which had detectable residues of the Z isomer at the method LOQ (0.01 ppm). The proposed tolerance level is 3.0 ppm. **Based on the domestic field trials data only, the petitioner should submit a revised Section F which reduces the proposed tolerance from 3.0 ppm to 1.0 ppm ,and which expresses the tolerance in terms of "Fruit, citrus, group".**

14b. Zeneca also submitted four volumes of grapefruit, lemon, orange, and mandarin field trial data from studies conducted in South Africa. The data reflected various use rates, numbers of applications, and PHIs. Reported residues ranged as high as 2.8 ppm. The petitioner stated that azoxystrobin is intended for use in many countries as well as the U.S., and that azoxystrobin residues in citrus appear to have the potential to be higher in some environments. Therefore, Zeneca included these data in support of both domestic and international uses. The citrus data from South Africa indicate that residues do have the potential to be higher in citrus grown in South Africa. However, **the petitioner did not include any information describing the proposed or registered uses of azoxystrobin on citrus in South Africa, or the proposed or registered uses of azoxystrobin on citrus in any other foreign country.** The Agency is currently developing guidance on the requirements for residue data representing foreign uses when domestic uses are being requested and has recently provided guidance on the data requirements for import tolerances (65 FR 35069, 6/1/2000). This guidance includes import data for oranges and orange juice indicating that South Africa is a minor (<1%) source of imported citrus.

14c. **The submitted data from South Africa are insufficient to support a tolerance which would also include use on imported citrus. If the petitioner wants a citrus fruits tolerance high enough to cover imported citrus, then the petitioner should provide additional information describing the countries in which azoxystrobin is intended for use on citrus to be imported to the U.S. and the intended use patterns in those countries. Because the data from South Africa indicate the potential for higher residues in imported citrus, additional field trial data from countries which represent the major importing regions for citrus (including juice) would also need to be submitted. Those data should reflect the maximum intended use patterns in those countries. At the time such data are submitted, an appropriate tolerance level for citrus fruits (to include use on imported citrus fruits) should also be proposed.**

15. Barley: Zeneca did not submit any barley field trial data to support the establishment of proposed tolerances for residues of azoxystrobin in/on barley grain, hay, and straw. IR-4 had previously requested that the Agency establish tolerances on barley based on the petitioner's wheat data (DP Barcode D254140, 3/17/99, G. Herndon). RAB2 concluded that it would be appropriate to request tolerances of 0.1 ppm on "Barley grain", 15.0 ppm on

"Barley hay", and 4.0 ppm on "Barley straw", provided the use patterns of wheat and barley were the same, which they are.

16. Cilantro (a.k.a. Coriander): Zeneca did not submit any cilantro field trial data to support the establishment of the proposed tolerance for residues of azoxystrobin in/on cilantro at 30.0 ppm. The petitioner included the proposed use pattern for cilantro under the Leafy Vegetables (except *Brassica* Vegetables) section of the specimen labels for the 50% WDG and 2.08 lb ai/gal FlC formulations. Currently, cilantro [coriander, Chinese parsley (leaf)] is a member of the herbs and spices crop group, and specifically the herb subgroup. The Agency has recently proposed that 40 CFR §180.1(h) be modified, allowing a tolerance for parsley, a commodity of the leafy vegetables (except *Brassica*) crop group, to cover residues in cilantro because the two plants have very similar structures (DP Barcode D229372, 1/10/2000, B. Schneider). Since the two RACs are so structurally similar, the use pattern is the same, and a change in the parsley commodity definition is in process, RAB2 is translating the leafy vegetable residue data to cilantro. **The petitioner should submit a revised Section F in which the 30.0 ppm tolerance is proposed in terms of "Coriander, leaves". The petitioner should also submit suitably revised WDG and FlC labels.**

17a. Corn, Field, Pop, and Sweet: Adequate data were submitted from the field corn field trials. Geographic representation is satisfactory. Those field corn data are used to support the proposed tolerances for the combined residues of azoxystrobin and its Z isomer in/on field, pop, and sweet corn commodities. No data were submitted for pop corn or sweet corn commodities.

17b. The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on field corn stover and grain. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance levels of 0.05 ppm for corn grain (field, pop) or 25.0 ppm for corn stover (field, pop, sweet) following treatment at 1x the maximum proposed seasonal application rate.

17c. As allowed by the EPA Residue Chemistry Test Guidelines, OPPTS 860.1000, Table 1, Footnote 27, samples of field corn kernels + cob with husks removed (K +CWHR) were harvested at the milk stage and used as a substitute for sweet corn kernels. The data indicate that the combined residues of azoxystrobin and its Z isomer did not exceed <0.02 ppm (combined LOQs) in any of the field corn (K + CWHR) samples following treatment at 0.75x the maximum proposed seasonal application rate. Extrapolating to 1x the maximum proposed seasonal application rate, the combined residues are not expected to exceed the proposed tolerance of 0.05 ppm for sweet corn (K + CWHR).

17d. The data indicate that the combined residues of azoxystrobin and its Z isomer did not exceed 7.2 ppm in/on field corn forage harvested 6-7 days following the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application. The combined residues of azoxystrobin and its Z isomer were <0.14 to 7.2 ppm in/on 40 samples of field corn forage. The total seasonal application rate was 1.5 lbs ai/A, which is 0.75x the maximum proposed seasonal application rate. Extrapolating to 1x the maximum seasonal

application rate, the combined residues of azoxystrobin and its Z isomer may closely approach the proposed tolerance level of 10.0 ppm in/on corn forage (field, sweet). **A more appropriate proposed tolerance level for corn forage is 12.0 ppm.**

17e. The combined residues of azoxystrobin and its Z isomer in/on aspirated grain fractions from field corn grain treated at 1x the maximum seasonal application rate were 1.9-2.4 ppm; residues concentrated 94-120x. A tolerance of 10.0 ppm is currently established for aspirated grain fractions. Based on the average concentration factor (108x) and the highest average field trial (HAFT) residue for field corn grain (<0.03 ppm), expected residues in aspirated grain fractions are 3.2 ppm, well below the established tolerance. [Note: A higher tolerance is required for aspirated grain fractions, however; see Conclusion 20c.]

17f. **The petitioner should submit a revised Section F proposing individual tolerances for the combined residues of azoxystrobin and its Z isomer in/on field, pop, and sweet corn commodities, expressed as follows:**

Corn, field, grain	**0.05 ppm**
Corn, pop, grain	**0.05 ppm**
Corn, sweet (kernels plus cob with husks removed)	**0.05 ppm**
Corn, field, forage	**12.0 ppm**
Corn, sweet, forage	**12.0 ppm**
Corn, field, stover	**25.0 ppm**
Corn, pop, stover	**25.0 ppm**
Corn, sweet, stover	**25.0 ppm**

18. Cotton: The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on undelinted cottonseed and cotton gin byproducts. The results of the cotton field trials indicate that residues of azoxystrobin and its Z isomer, individually, will not exceed the proposed tolerance level of 0.01 ppm in/on cotton (ginned for undelinted seed and gin byproducts) following treatment at 1x the maximum proposed seasonal application rate. However, **because the method LOQ is 0.01 ppm for each analyte, the proposed tolerance for the combined residues of azoxystrobin and its Z isomer in/on cotton seed and cotton gin byproducts should be increased to 0.02 ppm. The petitioner should submit a revised Section F proposing a tolerance of 0.02 ppm for "Cotton, undelinted seed" and a tolerance of 0.02 ppm for "Cotton, gin byproducts".**

19. Peanut: The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on peanut commodities. The data indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance levels of 0.2 ppm for peanut nutmeats and 15.0 ppm for peanut hay following treatment at 1x the proposed maximum seasonal rate. [Note: Currently, tolerances are established at 0.01 ppm on peanuts and 2.0 ppm on peanut hay.] **The petitioner should submit a revised Section F which increases the established tolerances to 0.2 ppm for "Peanut" and 15.0 ppm for "Peanut, hay".**

20a. Soybean: The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on soybean seed. The results of the soybean field trials indicate that combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance level of 0.5 ppm for "Soybean, seed", following treatment at 1x the maximum proposed seasonal rate.

20b. The results of the soybean field trials also indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance levels of 25.0 ppm in/on "Soybean, forage" and 55.0 ppm in/on "soybean, hay" harvested at a 0-day PHI (hay dried 2-7 days) following a single application at 0.25 lb ai/A. Because the rate used in the forage and hay field trials does not reflect the maximum proposed seasonal application rate of 1.5 lbs ai/A specified for soybeans on the product label, **the petitioner should submit a revised Section B to amend the proposed use pattern for soybean forage and hay. Based on the available data, the product labels for the WDG and FlC formulations should specify only a single application at 0.25 lb ai/A and a 0-day PHI for soybean forage and hay.** [Note: The Agency considers the harvest date for soybean hay to be the date when soybean samples are cut in the field.]

20c. Combined residues of azoxystrobin and its Z isomer in/on aspirated grain fractions from soybeans treated at 1x were 5.5-8.6 ppm; residues concentrated 61-96x. A tolerance of 10 ppm has been established for aspirated grain fractions [40 CFR §180.507(a)(1)]. Based on the average concentration factor (77x) and the HAFT residue for soybeans (0.35 ppm), expected residues in aspirated grain fractions are 27.0 ppm. Therefore, **the petitioner should submit a revised Section F, proposing an increased tolerance to 30.0 ppm for "Grain, Aspirated Grain Fractions".**

21. Wild Rice: Zeneca did not submit any wild rice field trial data to support the establishment of the proposed tolerance for the combined residues of azoxystrobin and its Z isomer at 5.0 ppm. The petitioner indicated that previously reviewed rice data (PP#7F4864; DP Barcode D249657, 1/25/99, D. Dotson) should be translated to wild rice. However, because rice and wild rice are grown in different geographical areas using different cultural practices, the Agency has long considered that translation of rice data to wild rice is not appropriate (memo, L. Kutney, 11/26/85). Thus, **if the petitioner wishes to pursue a tolerance for the combined residues of azoxystrobin and its Z isomer in/on wild rice, field trial data from wild rice field trials treated by the maximum proposed use pattern must be submitted. In the interim, the petitioner should submit a revised Section F which deletes the proposed tolerance for wild rice. The petitioner should also submit suitably revised WDG and FlC labels.**

22. Apple (inadvertent residues): The petitioner is proposing the establishment of a 1.5 ppm tolerance for the combined residues of azoxystrobin and its Z isomer in/on apples, to cover inadvertent residues which might result from spray drift or contaminated equipment. It is not OPP policy to establish an inadvertent residue tolerance based upon concerns about the possibility of spray drift or contaminated equipment. **A revised Section F should be submitted in which the proposed tolerance for apples (inadvertent residues) is deleted.**

23. Residue Decline Trials: No residue decline studies were included with the submitted crop field trial studies (except for the South African citrus trials data). The petitioner had previously provided data from residue decline studies for peaches, peanuts, tomatoes, and wheat. These data indicated that combined residues of azoxystrobin do not appear to significantly change (decline or increase) in commodities harvested at intervals less or greater than the proposed PHIs (DP Barcodes D230634, D230635, D230636, and D230637, L. Kutney, 4/25/97).

OPPTS GLN 860.1520: Processed Food/Feed

24. Barley: Zeneca did not submit any barley processing data to support the establishment of the proposed tolerance for the combined residues of azoxystrobin and its Z metabolite in/on barley bran at 0.2 ppm. In a previous memo (DP Barcode D254140, 3/17/99, G. Herndon), IR-4 had requested that the Agency establish tolerances on barley based on the petitioner's wheat data. RAB2 concluded that it would be appropriate to request a tolerance of 0.2 ppm for "Barley, bran", provided the use patterns for wheat and barley are the same, which they are. No other tolerances for processed barley commodities are warranted.

25a. Citrus: The submitted orange processing study is adequate. Total residues of azoxystrobin and its Z isomer do not concentrate in juice processed from oranges bearing detectable residues.

25b. Total residues of azoxystrobin and its Z isomer may concentrate 1.9-2.3x in dried pulp and 4.4-4.7x in oil processed from oranges bearing detectable residues. The HAFT residue of citrus fruit (grapefruits, lemons, and oranges) treated at 1x the maximum seasonal rate (1.5 lb ai/A/season; 0-day PHI) from the submitted citrus field trials (U.S.) was <0.70 ppm (total residues of azoxystrobin and its Z isomer). Based on the HAFT value and an average concentration factor of 2.1x, the highest expected residues in dried citrus pulp would be 1.5 ppm; based on an average concentration factor of 4.6x, the highest expected residues in citrus oil would be 3.2 ppm. The proposed tolerances for dried citrus pulp (7.0 ppm) and citrus oil (15.0 ppm) are too high, based on domestic citrus field trial data. **The petitioner should submit a revised Section F proposing a tolerance of 2.0 ppm for "Citrus, dried pulp" and a tolerance of 4.0 ppm for "Citrus, oil".**

26a. Field Corn: The submitted field corn processing data are adequate for the purposes of this petition. No concentration of residues of azoxystrobin and the Z isomer was observed in dry milled fractions, corn grits, meal, flour, and refined oil, and the wet milled fraction, corn starch, processed from field corn grain bearing detectable residues.

26b. The processing data indicate that the combined residues of azoxystrobin and its Z isomer concentrated in the wet milled fraction, refined oil, at 5.6 and 5.9x. Based on the HAFT value (<0.03 ppm) and an average concentration factor of 5.8x, the maximum expected combined residue in refined corn oil (0.17 ppm) would not exceed the proposed tolerance of 0.3 ppm. **The petitioner should submit a revised Section F proposing a tolerance of 0.3 ppm expressed in terms of "Corn, field, refined oil".**

27. Cotton: The submitted cotton processing study is adequate. Total residues of azoxystrobin and its Z isomer did not concentrate in cotton meal, hulls, or refined oil processed from undelinted cottonseed treated at 5x the maximum proposed seasonal rate. No tolerances are required for the processed commodities of cotton.

28a. Peanut: The petitioner did not submit any peanut processing data with this petition. Peanut processing data were submitted previously in conjunction with PP#6F4762 (DP Barcodes D230634, D230635, D230636, and D230637, L. Kutney, 4/25/97). The peanut processing data indicated that residues of azoxystrobin and its Z isomer do not concentrate in meal processed from peanuts bearing detectable azoxystrobin residues.

28b. The processing data indicated that residues of azoxystrobin concentrate in refined oil at 3.3x. Residues of the Z isomer were less than the LOQ in both the RAC and processed refined oil samples. Based on the HAFT value (<0.13 ppm, combined residue of 0.12 ppm + <0.01 ppm) for peanut nutmeats and the concentration factor (3.3x), the maximum expected combined residue in refined peanut oil (0.43 ppm) would not exceed the proposed tolerance level of 0.6 ppm. [Note: Currently, a tolerance is established at 0.03 ppm for peanut oil.] **The petitioner should submit a revised Section F which increases the established tolerance to 0.6 ppm and expresses it in terms of "Peanut, refined oil".**

29. Potato: The petitioner did not submit any potato processing data with this petition. Potato processing data were submitted previously in conjunction with PP#8F4995 (DP Barcode D249671, D. Dotson, M. Doherty, and Y. Donovan, 10/14/98). The potato processing data indicated that residues of azoxystrobin and its Z isomer do not concentrate in potato processed commodities. No tolerances for the processed commodities of potatoes are required.

30a. Soybean: The submitted soybean processing study is adequate. Total residues of azoxystrobin and its Z isomer did not concentrate in meal and refined oil processed from soybeans bearing detectable residues.

30b. Total residues of azoxystrobin and its Z isomer concentrated 2.2-2.3x in hulls processed from soybeans with detectable residues. Based on the HAFT value (0.35 ppm, combined residues) for soybean seed treated at 1x the proposed maximum seasonal rate and an average concentration factor of 2.3x, the highest expected residue in hulls would be 0.81 ppm. The petitioner is proposing a tolerance of 1.25 ppm, which is considered too high. **The petitioner should submit a revised Section F proposing a 1.0 ppm tolerance for "Soybean, hulls".**

31a. Sugar beet: The submitted sugar beet processing study is adequate. Combined residues of azoxystrobin and its Z isomer did not concentrate in molasses and refined sugar processed from sugar beet roots bearing detectable residues.

31b. The processing data indicate that the combined residues of azoxystrobin and its Z isomer concentrated 1.6-1.7x in sugar beet, dried pulp. Based on the HAFT value (<0.19 ppm) for sugar beet roots treated at 1x the maximum seasonal rate and an average concentration factor of 1.7x, the maximum expected residue in sugar beet, dried pulp would be 0.32 ppm. Since this value is less than the tolerance proposed (0.5 ppm) for the group containing sugar beet roots, no separate tolerance is warranted for sugar beets, dried pulp. **The petitioner should submit a revised Section F deleting the proposed tolerance of 0.8 ppm for "Beet, sugar, dried pulp".**

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

32a. Zeneca did not submit any feeding study data with this petition. However, a ruminant feeding study was previously submitted and reviewed in conjunction with PP#6F4762 (DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney) and a poultry feeding study was submitted and reviewed with PP#7F4864 and PP#8F4995 (DP Barcodes D249657 and D249668, 1/25/99, D. Dotson).

32b. The feedstuffs associated with the established and pending tolerances were used to calculate a new maximum theoretical daily dietary burden for beef cattle (106 ppm), dairy cattle (74 ppm), swine (10 ppm), and poultry (7 ppm).

32c. Based upon the new maximum daily dietary burdens and the findings of the ruminant feeding study, we conclude that the currently established tolerances for the secondary residues of azoxystrobin in milk (0.006 ppm); meat (0.01 ppm) of cattle, goats, hogs, horses, and sheep; and, the fat (0.01 ppm) and meat byproducts (0.01 ppm) of hogs remain adequate.

32d. We also conclude that secondary residues of azoxystrobin are not likely to exceed the proposed higher tolerances of 0.03 ppm [currently established at 0.01 ppm] for the *fat* of cattle, goats, horses, and sheep or of 0.07 ppm [currently established at 0.01 ppm] for the *meat byproducts* of cattle, goats, horses, and sheep.

32e. The *proposed* tolerances for livestock commodities are expressed in terms of azoxystrobin *and its Z isomer*. The established tolerances for livestock commodities are expressed in terms of azoxystrobin only. The HED MARC has previously concluded (DP Barcode D251683, W. Wassell, 12/30/98) that the residue of concern in livestock is the parent compound only. **The petitioner should submit a revised Section F in which the higher tolerances being proposed for the fat and meat byproducts of cattle, goats, horses, and sheep are expressed in terms of residues of azoxystrobin only.**

32f. Based upon the new maximum daily dietary burden and the findings of the poultry feeding study, we conclude that tolerances for secondary residues of azoxystrobin in eggs and poultry tissues continue to be not required.

OPPTS GLN 860.1850/1900: Confined/Field Accumulation in Rotational Crops

33a. Confined and field rotational crop studies have previously been submitted and reviewed (DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney). The confined rotational crop studies indicate that azoxystrobin is more extensively metabolized in rotational crops than in primary crops. The proposed plantback intervals of 30 days for broadleaf or root crops and 45 days for cereal grains were based on limited field rotational crop studies. These data indicated that, following treatment of the primary crop wheat at 0.8 lb ai/A (0.4x the current maximum proposed seasonal rate), residues of azoxystrobin and its Z isomer were below the LOQ (<0.01 ppm) in/on mustard greens (leafy vegetable), radishes and turnips (root vegetable), and millet hay, straw, and grain (cereal grain) planted ~30 days after treatment (DAT). Residues of azoxystrobin *per se* were 0.02 ppm in/on millet forage at ~30 DAT; however, residues of azoxystrobin and its Z isomer were less than the LOQ in/on millet forage at the 45-day plantback interval.

33b. **Because the previously submitted field rotational crop studies represent only 0.4x the proposed maximum seasonal rate for the annual crops in this petition, as a condition of registration the petitioner will need to conduct additional limited field rotational crop studies at 1x the maximum proposed seasonal rate (2.0 lbs ai/A). When those data are submitted for review, the petitioner should also propose whatever revised plantback intervals for rotational crops may be appropriate.**

International Harmonization Issues

34. No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been proposed or are established for residues of azoxystrobin. Harmonization of international tolerances is thus not currently an issue. An International Residue Limit Status sheet is attached.

RECOMMENDATIONS

Provided the petitioner submits the **requested changes to Section B** (Conclusions 2a, 10b, 10c, 16, 20b, and 21), i.e., the WDG and FlC labels, and submits the **requested changes to Section F** (Conclusions 10b, 10c, 11a, 12b, 13b, 14a, 16, 17f, 18, 19, 20c, 21, 22, 25b, 26b, 28b, 30b, 31b, and 32e) **nomenclature and tolerance levels to agree with the listing below,** HED can recommend in favor of the establishment of the following tolerances:

- For combined residues of azoxystrobin (methyl (E)-2-[2-[6-(2-cyanophenoxy)pyrimidin- 4-yloxy]phenyl]-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) in or on the following raw agricultural and processed commodities:

Barley, bran	0.2 ppm
Barley, grain	0.1 ppm
Barley, hay	15.0 ppm
Barley, straw	4.0 ppm
Citrus, dried pulp	**2.0** ppm
Citrus, oil	**4.0** ppm
Coriander, leaves	30.0 ppm
Corn, field, forage	**12.0** ppm
Corn, field, grain	0.05 ppm
Corn, field, refined oil	0.3 ppm
Corn, field, stover	25.0 ppm
Corn, pop, grain	0.05 ppm
Corn, pop, stover	25.0 ppm
Corn, sweet, forage	**12.0** ppm
Corn, sweet (kernels plus cob with husks removed)	0.05 ppm
Corn, sweet, stover	25.0 ppm
Cotton, gin byproducts	**0.02** ppm
Cotton, undelinted seed	**0.02** ppm
Fruit, citrus, group	**1.0** ppm
*Grain, aspirated grain fractions	30.0 ppm
Onion, dry bulb	**1.0** ppm
Onion, green	7.5 ppm
*Peanut	0.2 ppm
*Peanut, refined oil	0.6 ppm
*Peanut, hay	15.0 ppm
Soybean, forage	25.0 ppm
Soybean, hay	55.0 ppm
Soybean, hulls	**1.0** ppm
Soybean, seed	0.5 ppm
Vegetable, leafy, except *Brassica,* group	30.0 ppm
**Vegetable, leaves of root and tuber, group	50.0 ppm
Vegetable, root, subgroup	0.5 ppm
***Vegetable, tuberous and corm, subgroup	**0.03** ppm

Bolding in the above listing reflects changes to the tolerance levels proposed by the petitioner.
* Proposed tolerance is an increase to a currently existing tolerance.
** **Turnip tops (a.k.a. turnip greens) is currently included in this crop group.**
*** Since this subgroup includes potato, the individual listing for potato should be deleted.
NOTE: The proposed separate tolerance for **sugar beet, dried pulp has been deleted** from the listing since it was not warranted, and that for **wild rice has been deleted** from the listing due to no supporting data.]

- An **increase** in the established tolerances for residues of azoxystrobin *per se* in the following animal commodities:

Cattle, fat	0.03 ppm
Cattle, meat byproducts	0.07 ppm
Goat, fat	0.03 ppm
Goat, meat byproducts	0.07 ppm
Horse, fat	0.03 ppm
Horse, meat byproducts	0.07 ppm
Sheep, fat	0.03 ppm
Sheep, meat byproducts	0.07 ppm

[Note: The other currently established animal commodity tolerances, including those for the fat and meat byproducts of **hogs**, do **NOT** require higher tolerances at this time.]

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HED **cannot recommend for** the establishment of the proposed tolerance of 1.5 ppm for the combined residues of azoxystrobin and its Z isomer in/on apple (inadvertent residues), since it is not OPP policy to establish a tolerance for inadvertent residues based upon concerns about the possibility of spray drift or contaminated equipment.

As conditions of registration, the petitioner should provide additional data on storage stability (9c); two additional crop field trials for spinach (13a); and. additional limited field rotational crop studies (33b). The issue of separate field trials or bridging data (side-by-side field trials) on representative crops in support of late season uses of the FlC formulation should also be addressed (2b).

NOTE TO PM: HED's favorable recommendation for the establishment of the proposed tolerances listed above is <u>contingent</u> upon an acceptable human health risk assessment.

DETAILED CONSIDERATIONS

OPPTS 830 Series GLNs: Product Properties

Product chemistry data for azoxystrobin technical product were reviewed in conjunction with PP#5F4541 (CBTS Nos. 16051 and 16092, DP Barcodes D218318 and D218448, J. Garbus, 3/19/96). It was concluded that the available product chemistry data were adequate to fulfill the requirements for a Section 3 registration/permanent tolerance request. No additional product chemistry data are required for the purposes of this permanent tolerance petition.

OPPTS GLN 860.1200: Proposed Uses

The petitioner provided specimen labels for a 50% water- dispersible granular (WDG) formulation (Product Name = Heritage® Fungicide; EPA Reg. No. 10182-408) and a 2.08 lbs ai/gal flowable concentrate (FlC) formulation (Product Name = Abound® Flowable Fungicide; EPA Reg. No. 10182-415) proposed for use on a variety of agricultural crops. The proposed use patterns for root and tuber vegetables, bulb vegetables, leafy vegetables, citrus fruits, barley, corn (field, sweet, and pop), cotton, peanuts, soybean, and wild rice are described below. The petitioner had previously proposed uses for peanuts, which were evaluated under PP#6F4762 (DP Barcodes D230634, D230635, D230636, and D230637, L. Kutney, 4/25/97), and potatoes, which were evaluated under PP#7F4864 (DP Barcode D248887, 10/14/98, D. Dotson, M. Doherty, and Y. Donovan). The proposed uses for peanuts and potatoes in this petition are less restrictive than those proposed previously.

For both products, ground applications should be made using sufficient volumes for adequate coverage and canopy penetration; and, aerial applications to orchard and non-orchard crops must be made using a minimum spray volume of 10 and 3 gal/A, respectively. Adjuvant may be added to the spray volumes to improve coverage.

Root and Tuber Vegetables [including arracacha, arrowroot, artichoke (Chinese and Jerusalem), beet (garden and sugar), burdock, canna, carrot, cassava, celeriac, chicory, chufa, dasheen (taro), ginger, horseradish, leren, parsley, parsnip, potato, radish, rutabaga salsify, skirret, sweet potato, tanier, tumeric, turnip, and yam]: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to six foliar applications to root and tuber vegetable plants at 0.1-0.33 lb ai/A/application for a maximum seasonal application rate of 2.0 lbs ai/A/season. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than two consecutive applications of the product are made before alternating with other fungicides utilizing a different mode of action. For powdery mildew control, a strict one-to-one alternation program with fungicides utilizing a different mode of action must be maintained. Preventative applications may be made at 5- to 7-day intervals. For all other diseases, applications may begin prior to or in the early stages of disease development and may be made at 7- to 14-day retreatment intervals.

Applications may be made using ground, aerial, or chemigation equipment. Applications may be made on the day of harvest (0-day PHI).

Carrot: For control of early and late blight, the 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to six foliar applications to carrots at 0.15-0.33 lb ai/A/application for a maximum seasonal application rate of 2.0 lbs ai/A/season. For control of soil-borne disease Rhizoctonia root rot, banded or in-furrow applications may be made at the same rate. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than three consecutive applications of the product are made before alternating with other fungicides utilizing a different mode of action. Applications may begin prior to or in the early stages of disease development and may be made at 7- to 14-day retreatment intervals. Applications may be made using ground, aerial, or chemigation equipment. Applications may be made on the day of harvest (0-day PHI). For control of additional diseases, see above section for "Root and Tuber Vegetables."

Potato: For control of early and late blight, black dot, and powdery mildew, the 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to six foliar applications to potatoes at 0.1-0.33 lb ai/A/application for a maximum seasonal application rate of 2.0 lbs ai/A/season. For control of soil-borne diseases, black scurf and silver scurf, banded or in-furrow applications may be made at the same rate. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than one application of the product is made before alternating with other fungicides utilizing a different mode of action. Applications may begin prior to or in the early stages of disease development and may be made at 7- to 14-day retreatment intervals. Applications may be made using ground, aerial, or chemigation equipment. Applications may be made on the day of harvest (0-day PHI). For control of additional diseases, see above section for "Root and Tuber Vegetables."

Previously, the petitioner had proposed up to six applications of the 50% WDG formulation at 0.1-0.25 lb ai/A/application for a maximum seasonal application rate of 1.5 lbs ai/A/year. A 14-day PHI was proposed (PP#7F4864; DP Barcode D248887, 10/14/98, D. Dotson, M. Doherty, and Y. Donovan).

Bulb Vegetables [including garlic, leek, onion (green and bulb), Welch onion, and shallot]: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to six foliar applications to bulb vegetable plants at 0.1-0.20 lb ai/A/application (for foliar diseases, i.e., purple blotch, rust, and white rot) or 0.15-0.25 lb ai/A/application (for downy mildew) for a maximum seasonal application rate of 1.5 lbs ai/A/season. For control of soil-borne disease, i.e., *Rhizoctonia* damping-off, banded or in-furrow applications may be made at the 0.15-0.25 lb ai/A/application rate. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than three consecutive applications of the product are made before alternating with other fungicides utilizing a different mode of action. For downy mildew control, a strict one-to-one alternation program with fungicides utilizing a different mode of action must be maintained. Preventative applications may be made at 5- to 7-day intervals. For all other diseases, applications may begin prior to or in the early stages of disease development and may be made at 7- to 14-day retreatment intervals. Applications may be made using ground, aerial, or chemigation equipment. Applications may be made on the day of harvest (0-day PHI).

Leafy Vegetables (except *Brassica* Vegetables) [including amaranth, arugula, cardoon, celery, celtuce, chervil, chrysanthem, edible cilantro, corn salad, cress, dandelion, dock, endive, fennel, lettuce (head and leaf), orach, parsley, purslane, radicchio, rhubarb, spinach, and Swiss chard]: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to six foliar applications to leafy vegetable plants at 0.1-0.25 lb ai/A/application for a maximum seasonal application rate of 1.5 lbs ai/A/season [the application rate was not included on the 50% WDG label]. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than three consecutive applications of the product are made before alternating with other fungicides utilizing a different mode of action. For downy and powdery mildew control, a strict one-to-one alternation program with fungicides utilizing a different mode of action must be maintained. Preventative applications may be made at 5- to 7-day intervals. For all other diseases, applications may begin prior to or in the early stages of disease development and may be made at 7- to 14-day retreatment intervals. Applications may be made using ground, aerial, or chemigation equipment. Applications may be made on the day of harvest (0-day PHI).

Celery: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to six foliar applications to celery plants at 0.15-0.25 lb ai/A/application for a maximum seasonal application rate of 1.5 lbs ai/A/season. For control of soil-borne diseases, banded or in-furrow applications may be made at the same rate. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than three consecutive applications of the product are made before alternating with other fungicides utilizing a different mode of action. Applications may begin prior to or in the early stages of disease development and may be made at 7- to 14-day retreatment intervals. Applications may be made using ground, aerial, or chemigation equipment. Applications may be made on the day of harvest (0-day PHI).

Citrus Fruits [including calamondin, citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin, orange (sour and sweet), pummelo, and satsuma mandarin]: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to six foliar applications to citrus fruit trees at 0.2-0.25 lb ai/A/application for a maximum seasonal application rate of 1.5 lbs ai/A/season. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than three consecutive applications of the product are made before alternating with other fungicides utilizing a different mode of action. Applications may begin prior to or in the early stages of disease development and may be made at 7- to 21-day retreatment intervals. Applications may be made using ground, aerial, or chemigation equipment. Applications may be made on the day of harvest (0-day PHI).

Barley: The 50% WDG formulation is proposed for up to two foliar applications to barley at 0.1-0.2 lb ai/A/application for a maximum seasonal application of 0.4 lb ai/A/season. Applications should be started in the early stages of disease development on barley at jointing (Feekes 6 or Zadok's 31) up to late head emergence (Feekes 10.5 or Zadok's 59) growth stages. Application before Feekes 6 or Zadok's 31 growth stage or after Feekes 10.5 or Zadok's 59 growth stage is prohibited. The use of a non-phytotoxic crop oil concentrate at 1.0%·(v:v) is recommended to enhance disease control. A 14-day PHI is proposed for barley hay and a 45-day PHI is proposed for barley grain and straw. The harvesting of treated barley for forage is prohibited.

Corn (field, sweet, and pop): The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to eight foliar applications to corn plants at 0.1-0.15 lb ai/A/application (for rust) or 0.15-0.25 lb ai/A/application (for anthracnose leaf blight, gray leaf spot, and northern corn leaf blight) for a maximum seasonal application rate of 2.0 lb ai/A/season. For control of soil-borne disease, i.e., *Rhizoctonia* root and stalk rot, banded and in-furrow applications may be made at the same rate. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than two consecutive applications of the product are made before alternating with other fungicides utilizing a different mode of action. For gray leaf spot, application should start at onset of disease and a second application may be made 14 days later if disease persists. For all other diseases, applications may begin prior to or in the early stages of disease development and may be made at 7- to 14-day retreatment intervals. Applications may be made using ground, aerial, or chemigation equipment. A 7-day PHI is proposed.

Cotton: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for a single soil banded or in-furrow application to cotton plants at 0.1-0.2 oz ai/1,000 feet of row. Banded application should be made prior to infection as a directed spray to the soil. In-furrow application should be made at planting in 5-15 gallons of water.

Peanut: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to two foliar applications to peanut plants at 0.1-0.4 lb ai/A/application for a maximum seasonal application rate of 0.8 lb ai/A/season. Applications should be made 60 and 90 days after planting. For control of soil-borne diseases, banded or in-furrow applications may be made at the same rate. Applications may be made using ground, aerial, or chemigation equipment. A 14-day PHI is proposed.

Previously, the petitioner had proposed up to two foliar applications of the 50% WDG formulation to peanut plants at 0.1-0.4 lb ai/A/application for a maximum seasonal application rate of 0.8 lb ai/A/year. A 50-day PHI was proposed (PP#6F4762; DP Barcodes D230634, D230635, D230636, and D230637, L. Kutney, 4/25/97).

Soybean: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for multiple foliar applications to soybean plants at 0.15-0.25 lb ai/A/application (for aerial blight and frogeye leaf spot) or 0.2-0.25 lb ai/A/application (for anthracnose, alternaria leaf spot, brown spot, cercospora blight and leaf spot, and pod and stem blight) for a maximum seasonal application rate of 1.5 lbs ai/A/season. For control of soil-borne disease, i.e., southern blight, banded or in-furrow applications may be made at the same rate. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than two consecutive applications of the product are made before alternating with other fungicides utilizing a different mode of action. Applications may begin prior to the early stages of disease development using ground, aerial, or chemigation equipment. A 14-day PHI is proposed.

Wild rice: The 50% WDG and 2.08 lbs ai/gal FlC formulations are proposed for up to three foliar applications to wild rice plants (cultivated only) at 0.10-0.30 lb ai/A/application for a maximum seasonal application rate of 0.7 lb ai/A/season. For resistance management, it is proposed that applications be made in an alternating block spray program where no more than two consecutive applications of the product are made before alternating with other fungicides utilizing a different

mode of action. Applications may begin prior to disease development using ground, aerial, or chemigation equipment. Aerial applications should be made in 5-10 gal/A. Applications to rice fields used for aquaculture and crustacea are prohibited. A 14-day interval between the last application and the release of irrigation or flood water is proposed. A 28-day PHI is proposed.

Comments: The submitted Section B is not adequate. Although the petitioner has adequately described the proposed uses on root and tuber vegetables, bulb vegetables, leafy vegetables, citrus fruits, barley, corn (field, sweet, and pop), cotton, soybean, and wild rice, the application rate for leafy vegetables is missing from the 50% WDG specimen label. **The petitioner should submit a revised Section B which includes an application rate for the 50% WDG product label.**

The petitioner provided specimen labels for a WDG formulation and a FlC formulation proposed for identical uses on a variety of agricultural crops. However, all the field trials submitted in support of this petition reflect the use of the WDG formulation only. The guidelines for conducting field trials (OPPTS GLN 860.1500) state that for pesticides used in late season foliar applications (as is the case with azoxystrobin proposed uses), separate residue trials or bridging data are needed for different formulations. In a previous Agency review of a petition for uses on grapes, pecans, peaches, peanuts, bananas, and tomatoes (DP Barcode D236118, 6/23/97, J. Garbus), bridging data or side-by-side comparisons (WDG and FlC formulations) of residue levels in/on peaches and tomatoes were requested. For the purposes of this petition, conclusions pertaining to the proposed uses will be based on the field trial data for the WDG formulation only. **If the petitioner wishes to maintain use of the FlC formulation, then additional bridging data on representative crops will be required in support of late season uses.**

OPPTS GLN 860.1300: Nature of the Residue in Plants

The petitioner has previously submitted metabolism studies with grapes, peanuts, and wheat in conjunction with earlier petitions (PP#5F4541, D218318 and D218448, 3/19/96, J. Garbus; and PP#6F4762, D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney). These studies were deemed adequate to support the proposed uses. The HED Metabolism Assessment Review Committee has determined that the residues of concern in/on plants are azoxystrobin and its Z isomer (D251683, 12/30/98, W. Wassell).

In support of the current petition, Zeneca has submitted data from a study (citation listed below) investigating the metabolism of [^{14}C]azoxystrobin in cotton. The in-life and analytical phases of the study were conducted by Zeneca Agrochemicals (in-life phase in Leland, MS, and analytical phase at Jealott's Hill Research Station, Bracknell, UK).

44915206 Patel, A; Mayes, S; Skidmore, M.; and Hoag, R. (1999) Azoxystrobin Metabolism in Cotton Following and In-Furrow Application. Lab Project Number: 97JH178: RJ2695B. 120 p.

The test substance, [pyrimidinyl-^{14}C]azoxystrobin (specific activity 5008 Bq/µg, radiochemical purity 99.1%) was diluted with unlabeled azoxystrobin and suspension concentrate formulation blank to a specific activity of 2492 Bq/µg. The formulated test substance was applied to cotton at planting as an in-furrow application at 0.2 oz ai per 1,000 feet of row (equivalent to 2.61 lb ai/A based on 40-inch row spacing with 13,068 row feet/A). This application rate is 1x the maximum proposed application rate to cotton. The petitioner stated that because of poor crop emergence, approximately 20% of the cotton seeds were replanted 13 days after application. Immature forage was harvested from the cotton plants 37 days after treatment. Mature cotton seeds were collected by hand 176 days after treatment. Cotton hay was collected by cutting the remainder of the plants above the ground and allowing the plants to dry outdoors for 7 days. Samples were frozen (<-20 C) after collection, shipped via freezer truck to Zeneca (Richmond, CA) and then shipped frozen by air to Zeneca (Bracknell, UK), where samples were stored frozen (≤-15° C) until analysis.

Although the petitioner only conducted this metabolism study with a test substance labeled in the pyrimidinyl ring, we note that in the previously submitted metabolism studies, all but one identified metabolite (2-hydroxybenzonitrile, detected at <2.5% TRR in wheat and peanut commodities) contained the intact pyrimidinyl ring.

Total radioactive residues (TRR)

Forage samples were homogenized in liquid nitrogen. Cotton seed samples were separated into seed and lint. Cotton gin trash was generated by mixing stray lint and seed from hay, boll casings from seeds, leaves from picked cotton and hay, and small twigs from hay. Total radioactive residues (TRR) were determined for most commodities by liquid scintillation counting (LSC) following combustion. The limit of detection (LOD) for LSC determinations of the TRR was reported as <0.001-0.005 ppm. The petitioner additionally determined TRR by summing the radioactivity in extracts and solids following extraction; the petitioner stated that this was the only method used for TRR determinations for samples in which it was hard to obtain a homogeneous sample. The TRR in cotton commodities are presented in Table 1. The petitioner used the summed TRR values for all calculations of percent TRR.

Table 1. Total radioactive residues (TRR) in samples of cotton commodities treated with [pyrimidinyl-^{14}C]azoxystrobin at planting at 0.2 oz ai/1,000 feet of row (1x the maximum proposed application rate).

	TRR, ppm [^{14}C]azoxystrobin equivalents			
	Treated Samples		Untreated Samples	
Commodity	Combustion [a]	Extraction [b]	Combustion	Extraction
Seed	0.005	0.006	0.005	0.004
Forage	0.081	0.085	0.0002	0.0002
Lint	0.004	N/A [c]	0.003	N/A [c]
Gin trash	N/A [c]	0.007	N/A [c]	0.003

[a] TRR determined by combustion of entire sample.
[b] TRR determined by summing radioactivity in extracts and solids remaining following extraction.
[c] Not determined.

Extraction and hydrolysis of residues

Cotton commodity samples were subjected to extraction and/or hydrolysis procedures for residue characterization and identification. During the fractionation procedures, aliquots of extracts, hydrolysates, and nonextractable residues were analyzed for radioactivity by LSC or combustion/LSC. Extracts were concentrated as necessary by rotary evaporation or by evaporation under a stream of nitrogen.

Seed: Crushed seeds were homogenized in hexane and filtered. Because of low radioactivity levels (<0.01 ppm), no further analyses were conducted.

Gin Trash: Gin trash was homogenized in acetonitrile (ACN) and the extract was decanted. Because of low radioactivity levels (<0.01 ppm), no further analyses were conducted.

Forage: Forage was sequentially extracted with ACN (2x), ACN:water (1:1, v:v; 2x), and with water. The extracts were combined, concentrated, and redissolved in ACN:water (64:36, v:v) for TLC analysis, or in ACN:water (60:40, v:v) for further fractionation. A subsample of this extract was evaporated to dryness, partitioned with diethyl ether at pH 6-7, and then partitioned with ethyl acetate (EtOAc) at pH 1-2; each fraction was reserved for TLC analysis. The EtOAc fraction was then subjected to base hydrolysis. The extract was evaporated to dryness, redissolved in 0.1 M sodium hydroxide, and shaken in a water bath at 25° C. Subsamples were removed for analysis after 0 and 20 hours.

Another subsample of the combined ACN:water extract of forage was subjected to base hydrolysis as described above for the EtOAc extract. Subsamples of the hydrolysate were taken after 0, 1, 6, and 24 hours.

The distribution of ^{14}C-activity in the extracts and hydrolysates of cotton commodities is presented in Table 2.

Characterization/identification of residues

Extracts and hydrolysates of forage were analyzed by TLC and HPLC. TLC analyses were used to characterize/identify components in sample extracts. Analyses were conducted on silica gel plates (UV254 for normal phase, KC18F for reverse phase) using the following solvent systems: ACN:water (7:3, v:v); ethyl acetate:ethanol:water:acetic acid (4:2:1:1, v:v:v:v); butanol:water:acetic acid (4:1:1, v:v:v); methanol:0.1 M ammonium formate (60:40, v:v); and chloroform:ACN:water:formicacid (75:25:3:3, v:v:v:v). Metabolites were identified by comparison of retention times and/or co-chromatography with the following reference standards: azoxystrobin, its Z isomer, and compounds 2, 3, 13, 19, 20, 22, 23, 24, 26, 28, 30, 35, 36, and 42 (identified in previously submitted metabolism studies). Radioactivity on TLC plates was detected and quantified using a phosphor-imaging analyzer. Non-labeled standards were visualized using UV light.

HPLC analyses were conducted to confirm the identification of azoxystrobin in forage. Analyses were conducted using an S5ODS2 column and an isocratic mobile phase of ACN:water (7:3, v:v). Radioactivity was detected using a radioisotope detector, and nonlabeled standards were detected by UV.

Table 2. Distribution and characterization radioactive residues in cotton commodities treated at planting (in-furrow) with [pyrimidinyl-^{14}C]azoxystrobin at 0.2 oz ai/1,000 feet of row.

Fraction	% TRR	ppm	Characterization/Identification
Seed (TRR = 0.006 ppm)			
Hexane	14.1	0.001	Not further analyzed (N/A).
Nonextractable	85.9	0.005	N/A.
Gin trash (TRR = 0.007 ppm)			
ACN	2.0	<0.001	N/A.
Nonextractable	98.0	0.007	N/A.
Forage (TRR = 0.085 ppm)			
ACN	54.0	0.046	Subsample (SS) 1: Combined, concentrated, and redissolved in ACN:water (64:36, v:v). SS2: Combined, concentrated, and redissolved in ACN:water (60:40, v:v).
ACN	12.9	0.011	
ACN:water	8.5	0.007	
ACN:water	3.3	0.003	
Water	3.0	0.003	
SS1: Combined ACN:water	75.9	0.065	TLC analysis resolved: Azoxystrobin 15.0% TRR 0.0128 ppm Plus 8 unknowns (each ≤11.4% TRR, <0.01 ppm) and radioactivity at baseline (1.7% TRR, 0.0014 ppm). Concentrated, sequentially partitioned with diethyl ether at pH 6-7 and EtOAc at pH 1-2.
SS1: Aqueous [a]	32.7	0.028	TLC analysis resolved: 7 unknowns (each ≤7.2% TRR, <0.007 ppm).
SS1: Diethyl ether [a]	22.6	0.020	TLC analysis resolved: Azoxystrobin 13.1% TRR 0.0111 ppm Plus 4 unknowns (each ≤1.5% TRR, <0.0014 ppm) and radioactivity at baseline (3.6% TRR, 0.0031 ppm). Identification of azoxystrobin confirmed by HPLC.
SS1: EtOAc [a]	22.3	0.019	TLC analysis resolved: 6 unknowns (each ≤5.3% TRR, <0.005 ppm) and radioactivity at baseline (0.2% TRR, 0.0002 ppm). Subjected to base hydrolysis in 0.1 M sodium hydroxide at 25 C. Subsamples removed after 0 and 20 hours.

(continued; footnotes follow)

Table 2 *(continued)*.

Fraction	% TRR	ppm	Characterization/Identification
SS1: 0-hr hydrolysate	22.3	0.019	TLC analyses were unsuccessful in identifying metabolites.
SS1: 20-hr hydrolysate	22.3	0.019	
SS2: Combined ACN:water	74.0	0.063	Subjected to base hydrolysis in 0.1 M sodium hydroxide at 25 C. Subsamples removed after 0, 1, 6, and 24 hours.
SS2: 0-hr hydrolysate	74.0	0.063	TLC analyses were unsuccessful in identifying metabolites. However, TLC profiles were the same in each subsample, indicating that hydrolysis was instantaneous.
SS2: 1-hr hydrolysate	74.0	0.063	
SS2: 6-hr hydrolysate	74.0	0.063	
SS2: 24-hr hydrolysate	74.0	0.063	
Nonextractable	18.3	0.016	N/A.

[a] Average of two subsamples.

Storage stability

Samples of cotton commodities were stored frozen prior to analysis. The petitioner stated that initial profiling of samples was completed within ~6 months of sample collection; however, further analysis of some forage extracts was completed more than 6 months after sample collection. To demonstrate the stability of the metabolite profile, the petitioner compared the TLC profile of a stored extract with the profile obtained in the original analysis. The profiles were similar, indicating that the metabolite profile did not change significantly during storage. These data are sufficient to support the storage intervals of samples from this study.

Comments:

The qualitative nature of the residue in cotton is adequately understood. Total radioactive residues were 0.005 ppm in seed, 0.081 ppm in forage, 0.004 ppm in lint, and 0.007 ppm in gin trash following a single at-planting in-furrow application of azoxystrobin at 0.2 oz ai/1,000 feet of row (1x the maximum proposed application rate).

Because of low radioactivity levels, characterization/identification of residues was only conducted in forage. Azoxystrobin was the only compound identified, at 15.0% TRR (0.0128 ppm). The remainder of the radioactivity consisted of unknowns, none of which exceeded 11.4% TRR (0.01 ppm), and unextracted radioactivity (18.3% TRR, 0.006 ppm).

OPPTS GLN 860.1300: Nature of the Residue in Animals

The petitioner has previously submitted ruminant and poultry metabolism studies in conjunction with earlier petitions (PP#5F4541, D218318 and D218448, 3/19/96, J. Garbus; and PP#6F4762, D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney) which were deemed adequate to delineate the nature of the residue in animals. The HED Metabolism Assessment Review Committee has determined that the residue of concern in animals is parent azoxystrobin (D251683, 12/30/98, W. Wassell).

OPPTS GLN 860.1340: Residue Analytical Method - Plant Commodities

Enforcement analytical methods - plant commodities

Analytical methodology is available for enforcement of the proposed tolerances. GC/NPD method RAM 243 is adequate for enforcement of the proposed tolerances in/on apples, barley, bulb vegetables, cilantro, citrus fruits, corn (field, sweet, and pop), root and tuber vegetables, leaves of root and tuber vegetables, leafy vegetables (excluding *Brassica* vegetables), peanut hay, wild rice, and non-oily processed commodities. GC/NPD method RAM 260 is adequate for enforcement of the proposed tolerances in/on cotton, peanut nutmeat, soybeans and oily processed commodities. These methods have undergone method validation by the Analytical Chemistry Branch, BEAD (PP#5F4541 and PP#6F4762, 5/29/97, C. Stafford). BEAD comments have been incorporated and the revised methods is to be submitted to FDA for inclusion in the Pesticide Analytical Manual (PAM), Volume II. In the interim, copies may be obtained from PIRIB/IRSB (7502C) and ACB/BEAD (7503W).

Residue data collection methods - plant commodities

Crop commodities from the field trial and processing studies were analyzed by a GC method entitled "*Determination of Azoxystrobin and R230310 in Crops by Gas Chromatography with Nitrogen-Phosphorous Detection*". This method is based on the proposed GC/NPD enforcement method RAM 243. The petitioner submitted descriptions and method validation data (citation listed below) for this GC method. A brief description of the method follows.

> 44915207 Lipton, C. (1998) Azoxystrobin: Determination of Azoxystrobin and R230310 in Crops by Gas Chromatography with Nitrogen-Phosphorus Detection: Lab Project Number: TMR0812B: Unpublished study prepared by Zeneca Ag Products. 28 p.

Briefly, homogenized crop samples were extracted with acetonitrile (ACN):water (90:10, v:v) and filtered under vacuum. The extract was partitioned with dichloromethane, and the dichloromethane phase evaporated to dryness. Residues were then redissolved in ethyl acetate:hexane (20:80, v:v) and purified through a Florisil column. Residues were eluted from the Florisil column with ethyl acetate:hexane (70:30, v:v). Peanut hay samples were not partitioned with dichloromethane; instead, the extract was directly applied to the Florisil column for cleanup. Corn refined oil samples were partitioned with hexane prior to Florisil cleanup to remove additional oils. The Florisil column

eluate was evaporated to dryness, and residues were redissolved in toluene for GC/NPD analysis. The method limit of quantitation was 0.01 ppm for each analyte (azoxystrobin and its Z isomer) in/on all crop matrices, except head lettuce and peanut hay. The reported LOQs for azoxystrobin and its Z isomer were 0.01 and 0.05 ppm, respectively, for head lettuce, and 0.01 and 0.02 ppm, respectively, for peanut hay.

The above method was modified for analysis of citrus oil samples. Orange cold-pressed oil was extracted with hexane and acetonitrile (ACN) in a separatory funnel. The ACN phase was collected, and the remaining hexane phase was extracted with additional ACN. The ACN phases were combined and partitioned again with hexane to remove any remaining oil. The volume was adjusted with water and 5% NaCl solution, and the residues were partitioned with dichloromethane. The dichloromethane phase was decanted through anhydrous sodium sulfate and evaporated to dryness. The dried dichloromethane phase was redissolved in ethyl acetate:hexane and subjected to Florisil column cleanup as for the other matrices. The reported LOQ for azoxystrobin and its Z isomer was 0.01 ppm for each analyte in orange oil.

Spinach samples from the IR-4 field trials were analyzed using a GC/NPD method SOP RAM 243/03 which has been discussed under a previous petition (PP#6F4762; DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney). This method is essentially the same as the GC/NPD method described above except that the residues were redissolved in dichloromethane:hexane (1:1, v:v) and subjected to solid-phase extraction through a silica column, then redissolved in ethyl acetate for GC/NPD analysis. The reported LOQ for azoxystrobin and its Z isomer was 0.02 ppm for each analyte in spinach.

Samples of cotton seed (RAC), cotton processed commodities, and peanut nutmeats were analyzed by a GC method entitled "*Residue Analytical Method for the Analysis of Azoxystrobin and R230310 in Crops of High Lipid Content*". This method is based on the enforcement analytical method RAM 260. The method is essentially the same as that described above except that the dried dichloromethane phase was redissolved in ethyl acetate:methanol or ethyl acetate:toluene (75:25, v:v) for further cleanup by gel permeation chromatography prior to cleanup on a Florisil column. Following gel permeation chromatography, peanut nutmeat residues were applied to an alumina column prior to cleanup on the Florisil column. Residues eluted from the Florisil column were evaporated to dryness and redissolved in acetone or toluene for GC/NPD analysis. The reported LOQ for azoxystrobin and its Z isomer was 0.01 ppm for each analyte in cottonseed, meal, hulls, refined oil and peanut nutmeats.

The petitioner submitted method validation data using fortified samples of almond hulls and nutmeat, cucurbits (cantaloupe, cucumber, and summer squash), and wheat grain, hay, and straw. Method recoveries are presented in Table 3. Sample calculations and representative chromatograms were provided. In addition, the petitioner included concurrent method recovery data. Samples of untreated commodities from the field and processing studies were fortified with azoxystrobin and its Z isomer, and analyzed concurrently with the field trial and processing samples. The concurrent method recoveries are also presented in Table 3.

Table 3. Method validation and concurrent method recoveries of azoxystrobin and its Z isomer from fortified samples of various crop commodities analyzed using the GC/NPD method.

Commodity (MRID)	Fortification Level, ppm	Statistic	Azoxystrobin	Z isomer
Method Validation Data				
Almond, hull and nutmeat (44915207)	0.01-3.0	Average	98%	89%
		Recovery Range	76-119%	70-110%
		CV	19%	20%
		Number	5	5
Cucurbits: cantaloupe, cucumber, and summer squash (44915207)	0.01-0.3	Average	104%	91%
		Recovery Range	94-120%	85-100%
		CV	9%	5%
		Number	8	8
Wheat, grain (44915207)	0.01-0.05	Average	100%	92%
		Recovery Range	81-118%	69-119%
		CV	13%	14%
		Number	14	14
Wheat, hay (44915207)	0.01-10	Average	97%	96%
		Recovery Range	75-116%	82-125%
		CV	14%	16%
		Number	9	9
Wheat, straw (44915207)	0.01-1	Average	107%	96%
		Recovery Range	93-120%	81-115%
		CV	9%	10%
		Number	9	9
Concurrent Method Recovery Data				
Carrot, roots (44915216)	0.01-0.50	Average	97%	84%
		Recovery Range	90-110%	74-89%
		CV	9.4%	8.2%
		Number	4	4
Celery, untrimmed (44915211)	0.01-10	Average	100%	93%
		Recovery Range	86-111%	70-117%
		CV	12.7%	25.2%
		Number	3	3
Corn, field (K+CWHR) (44915215)	0.01, 0.1	Average	104%	91%
		Recovery Range	96-104%; 127%	78-99%
		CV	12.5%	10.8%
		Number	5	5
Corn, field, forage (44915215)	0.01-8.0	Average	94%	78%
		Recovery Range	79-112%	72-82%
		CV	13.6%	5.7%
		Number	5	5

(continued)

Table 3 (*continued*).

Commodity (MRID)	Fortification Level, ppm	Statistic	Azoxystrobin	Z isomer
Corn, field, stover (44915215)	0.01-25	Average	88%	87%
		Recovery Range	71-100%	67%; 81-113%
		CV	12.6%	17.4%
		Number	6	6
Corn, field, grain (44915215)	0.01, 0.1	Average	88%	83%
		Recovery Range	70-104%	71-98%
		CV	13.5%	15.1%
		Number	6	6
Corn, field, aspirated grain fractions (44915215)	1.0, 3.0	Average	103%	98%
		Recovery Range	101-105%	97-99%
		CV	2.7%	1.4%
		Number	2	2
Corn, field, processed: grain, wet milled fractions (starch and refined oil), and dry milled fractions (grits, meal, flour, and refined oil) (44915230)	0.01-1.0	Average	90%	85%
		Recovery Range	74-104%	75-94%
		CV	9%	7%
		Number	12	12
Cotton, undelinted seed (44915214)	0.05-0.2	Average	95%	100%
		Recovery Range	90-104%	92-111%
		CV	5%	5%
		Number	12	12
Cotton, gin byproducts (44915214)	0.05, 0.2	Average	94%	118%
		Recovery Range	90-99%	112-124%
		CV	4%	5%
		Number	4	4
Cotton, processed: seed, meal, hulls, and refined oil (44915231)	0.05, 0.20	Average	95%	99%
		Recovery Range	90-98%	84-112%
		CV	3%	8%
		Number	8	8
Celery, untrimmed stalk (44915211)	0.01-10	Average	100%	93%
		Recovery Range	86-111%	70-117%
		CV	12.7%	25.2%
		Number	3	3
Grapefruit (44915224)	0.01-0.50	Average	89%	95%
		Recovery Range	76-105%	83-110%
		CV	16%	14%
		Number	3	3

(*continued*)

Table 3 (*continued*).

Commodity (MRID)	Fortification Level, ppm	Statistic	Azoxystrobin	Z isomer
Lemons (44915225)	0.01-1.00	Average	93%	91%
		Recovery Range	81-109%	81-108%
		CV	16%	16%
		Number	3	3
Lettuce, head (44915213)	0.01-6.00	Average	102%	95%
		Recovery Range	77-113%	86-117%
		CV	17%	13%
		Number	4	5
Lettuce, leaf (44915212)	0.01-20	Average	94%	95%
		Recovery Range	75-110%	80-105%
		CV	16%	12%
		Number	5	4
Onions, dry bulb (44915210)	0.01-1.0	Average	104%	103%
		Recovery Range	100-108%	95-110%
		CV	3.8%	7.3%
		Number	3	3
Onions, green (44915226)	0.01-8.0	Average	100%	89%
		Recovery Range	84-115%	74-97%
		CV	16%	15%
		Number	3	3
Oranges (44915217)	0.01-0.50	Average	103%	101%
		Recovery Range	83-118%	84-116%
		CV	16%	18%
		Number	4	4
Orange, processed: RAC, dried pulp, oil, and juice (44915228)	0.20-0.50	Average	105%	104%
		Recovery Range	91-113%	89-118%
		CV	9%	12%
		Number	5	5
Peanut, nutmeat (44915221)	0.02, 0.05	Average	105%	105%
		Recovery Range	95-120%	90-116%
		CV	7%	8%
		Number	10	10
Peanut, hay (44915221)	0.2-10.0	Average	100%	103%
		Recovery Range	97-104%	96-111%
		CV	2%	5%
		Number	12	12

(*continued*)

Table 3 (*continued*).

Commodity (MRID)	Fortification Level, ppm	Statistic	Azoxystrobin	Z isomer
Radish, roots (44915223)	0.01-0.50	Average	98%	91%
		Recovery Range	92-106%	78-98%
		CV	7%	12%
		Number	3	3
Radish, tops (44915223)	0.01-40	Average	101%	89%
		Recovery Range	79-116%	83-93%
		CV	19%	6%
		Number	3	3
Soybean, forage (44915209)	0.01-30	Average	95%	98%
		Recovery Range	82-108%	81-117%
		CV	10%	12%
		Number	11	11
Soybean, hay (44915209)	0.01-30	Average	97%	94%
		Recovery Range	79-141%	76-114%
		CV	18%	14%
		Number	10	10
Soybean, seed (44915209)	0.01-0.30	Average	98%	93%
		Recovery Range	81-112%	78-111%
		CV	12%	15%
		Number	9	9
Soybean, aspirated grain fractions (44915209)	0.08, 20	Average	82%	96%
		Recovery Range	68%; 95%	80%, 112%
		CV	23%	23%
		Number	2	2
Soybean, processed: RAC, hulls, meal, and refined oil (44915229)	0.01-2.0	Average	109%	104%
		Recovery Range	104-119%	82-120%
		CV	6%	13%
		Number	7	7
Spinach (44983101)	0.02-30	Average	93%	98%
		Recovery Range	78-109%	83-117%
		CV	9.7%	11.7%
		Number	25	21
Sugar beet, roots (44915208)	0.01-1.0	Average	101%	100%
		Recovery Range	95-107%	92-108%
		CV	5%	7.1%
		Number	5	5

(*continued*)

Table 3 (*continued*).

Commodity (MRID)	Fortification Level, ppm	Statistic	Azoxystrobin	Z isomer
Sugar beet, tops (44915208)	0.01-50	Average	108%	109%
		Recovery Range	97-127%	99-126%
		CV	10.3%	9.3%
		Number	5	5
Sugar beet, roots (processed) (44915232)	0.01, 0.5	Average	99%	96%
		Recovery Range	98, 99%	88, 103%
		CV	1%	11%
		Number	2	2
Sugar beet, molasses (44915232)	0.01, 0.1	Average	97%	92%
		Recovery Range	88, 105%	88, 96%
		CV	12%	6%
		Number	2	2
Sugar beet, dried pulp (44915232)	1	Average	105%	97%
		Recovery Range	105%	97%
		Number	1	1
Sugar beet, refined sugar (44915232)	0.01, 0.1	Average	97%	88%
		Recovery Range	94, 99%	83, 92%
		CV	4%	7%
		Number	2	2

Citrus fruit samples from the field trial studies conducted in South Africa were analyzed using a GC method with thermionic specific detection (TSD) in the nitrogen mode; extraction procedures were similar to those discussed above. Briefly, flesh samples were extracted with ACN:water and/or partitioned with dichloromethane and cleaned up on a silica Bond Elut cartridge. Juice samples were neutralized before partitioning with dichloromethane. Peel samples were extracted with ACN:water (90:10, v:v) and partitioned with dichloromethane. The dichloromethane phase was evaporated to dryness, redissolved in ethyl acetate:methanol (75:25, v:v) for sequential cleanup by gel permeation chromatography and on alumina and Florisil solid-phase extraction cartridges. The reported LOQ of the GC/TSD method was 0.01 ppm for azoxystrobin and its Z isomer in all matrices, except for orange peel (MRID 44915222) and lemon peel (MRID 44915220) samples which had an LOQ of 0.02 ppm for each analyte.

The petitioner submitted (MRID 44915218) an explanation of how whole fruit residues were calculated for the citrus samples from certain South Africa field trials. Residues of azoxystrobin and its Z isomer were determined for citrus fruit flesh and peel samples, and residues for whole fruit were calculated by combining the peel and flesh residues based on their weight ratios. Where residues were less than the method LOQ (<0.01 ppm) in/on flesh samples, a value of "zero" was used in the calculation.

Concurrent method recoveries were reported in conjunction with the South Africa citrus field trials. Citrus samples were fortified with azoxystrobin, its Z isomer, and an internal standard (R216206) which is a positional isomer of azoxystrobin and mimics the recovery of azoxystrobin through the analytical method. The fortified samples were analyzed concurrently with the field trial samples; concurrent method recoveries are reported in Table 4.

Comments:

Based on the submitted concurrent method validation data, the GC/NPD methods are adequate for data collection of residues of azoxystrobin and its Z isomer in/on root and tuber vegetables (carrot, radish, and sugar beet), bulb vegetable (dry bulb and green onions), leafy vegetables, excluding Brassica (celery, head and leaf lettuce, and spinach), citrus fruits (grapefruit, lemons, and oranges), field corn (K+CWHR, forage, stover, and aspirated grain fractions), cotton, peanut (nutmeat and hay), soybean (forage, hay, seed, and aspirated grain fractions), and the processed commodities of citrus fruits, field corn, cotton, sugar beet, and soybeans.

Table 4. Concurrent method recoveries of azoxystrobin and its Z isomer from fortified samples of various crop commodities from the South Africa field trials analyzed using the GC/TSD method.

Commodity (MRID)	Fortification Level, ppm	Statistic	Azoxystrobin	Z isomer
Lemons, flesh (44915220)	0.1, 0.2	Average	102%	108%
		Recovery Range	92-109%	104-110%
		CV	5%	2%
		Number	12	12
Lemons, peel (44915220)	0.5-2.0	Average	99%	101%
		Recovery Range	93-105%	85-110%
		CV	3%	6%
		Number	20	20
Lemons, juice (44915220)	0.05	Average	102%	112%
		Recovery Range	98-106%	108-116%
		CV	3%	3%
		Number	4	4
Grapefruit/Orange, flesh and peel (44915227)	0.05-1.0	Average	97%	116%
		Recovery Range	84-104%	104-124%
		CV	9%	7%
		Number	4	4
Mandarin/Orange, flesh (44915219)	0.02-0.1	Average	103%	112%
		Recovery Range	98-110%	106-119%
		CV	5.3%	5.2%
		Number	4	4
Mandarin/Orange, peel (44915219)	2, 5	Average	98%	108%
		Recovery Range	95-100%	106-110%
		CV	--	--
		Number	2	2
Orange, flesh (44915222)	0.05	Average	94%	106%
		Recovery Range	92-96%	104-108%
		CV	--	--
		Number	2	2
Orange, peel (44915222)	1.0, 2.0	Average	97%	108%
		Recovery Range	94-99%	105-110%
		CV	--	--
		Number	2	2
Orange, juice (44915222)	0.05	Average	99%	110%
		Recovery Range	98-100%	109-111%
		CV	--	--
		Number	2	2

OPPTS GLN 860.1340: Residue Analytical Methods - Animal Commodities

Enforcement method - animal commodities

For analysis of animal commodities, the petitioner had previously proposed GC method 255/01 for the enforcement of tolerances for residues of azoxystrobin in animal commodities. This method has been validated by the ACL for the analysis of milk and animal tissues (DP Barcodes D249657 and D249668, 1/25/99, D. Dotson). The BEAD laboratory's written report with an EPA addendum to accompany the method, and the method, will be submitted to FDA for inclusion in PAM, Vol. II. In the interim, copies are available from PIRIB/IRSD (7502C) and ACB/BEAD (7503W).

OPPTS GLN 860.1360: Multiresidue Method

The petitioner has previously submitted data pertaining to the multiresidue methods testing of azoxystrobin in conjunction with the grape tolerance petition (PP#5F4541; DP Barcodes D218318 and D218448, J. Garbus, 3/19/96). The data indicate that azoxystrobin could not be recovered through application of the multiresidue protocols. The report is to be forwarded to FDA.

OPPTS GLN 860.1380: Storage Stability Data

Storage conditions and intervals

Root and tuber vegetables (carrot, radish, and sugar beet); bulb vegetables (dry bulb and green onions); leafy vegetables, excluding *Brassica* (celery and head and leaf lettuce); citrus fruit (grapefruit, lemons, and oranges); field corn grain and stover samples; and soybean seed samples were collected at normal crop maturity. Field corn (K+CWHR) and forage samples were collected at the milk stage. Immature soybean forage was collected, and a subsample was dried 2-7 days in the field to generate hay. The collected samples were then bagged separately, labeled, and frozen (within 1.5-8 hours) at -15 to -10° C, except in two soybean trials where the seed was wet and required drying for 1-2 days prior to freezing, and for one field corn stover sample which was wet and required drying overnight prior to freezing. All samples were shipped either by ACDS freezer truck, FedEx, or private automobile to the Western Research Center of Zeneca (WRC; Richmond, CA) for analysis. The total storage intervals between harvest and analysis are reported in Table 5.

Bulk soybean grain samples for generation of aspirated grain fractions were transported on dry ice by rental truck to the Food Protein Research and Development Center, Texas A&M University (Bryan, TX). Bulk grain samples were received cold but unfrozen at Texas A&M; these samples were stored frozen (-12° C) at Texas A&M for 26 days until generation of aspirated grain fractions. Cleaned seed and aspirated grain fractions were shipped by FedEx to WRC. Samples were received cold, but unfrozen because of a 2-day delay by FedEx; however, the integrity of the samples was not considered to have been compromised. The total storage intervals between harvest and analysis are reported in Table 5.

Cotton samples from the field trials were bagged, labeled, and frozen within 3 hours of harvest, except in one TX field trial where samples were stored at ambient conditions for <1 day before freezing. Samples were shipped by ACDS freezer truck, FedEx, or hand-delivered on dry ice either directly to the Food Protein Research and Development Center, Texas A&M University for ginning or first to WRC and then to Texas A&M for ginning. Cotton samples were ginned within 2 months of harvest. Undelinted cottonseed and cotton gin byproducts were separately packaged, frozen, and shipped frozen by FedEx to WRC (Richmond, CA). Samples were stored frozen (-18° C) at WRC and were shipped frozen by air freight to Zeneca Agrochemicals, Jealott's Hill Research Station (JHRS; Bracknell, Berkshire, England) for analysis. The total storage intervals between harvest and analysis are reported in Table 5.

Bulk field corn grain samples were collected from the IL trial site, placed in labeled containers, frozen (within 15 minutes of harvest), and shipped by ACDS freezer truck to the University, Food Protein Research and Development Center, Texas A&M for the generation of aspirated grain fractions (AGF) and processed fractions. Processing was completed within 69 days of harvest and samples were frozen. The AGF and processed corn fractions were packed in dry ice and shipped overnight by FedEx to WRC for analysis. The total storage intervals between harvest and analysis are reported in Table 5.

Peanuts and peanut plants were dug 3-10 following the last application and allowed to dry in the field for 4-12 days. The collected samples were then bagged, labeled, and frozen (within 4 hours) at -15° C. All samples were shipped by ACDS freezer truck or by Federal Express on dry ice to WRC. Samples of whole peanuts were separated into hulls and nutmeats using a mechanical peanut sheller prior to transfer to JHRS by air freight for analysis. The total storage intervals of all peanut samples from harvest to analysis are reported in Table 5.

Spinach samples were collected at normal crop maturity, bagged, labeled, and cooled or frozen (within 1 hour) and then maintained at -10 to -33° C. All spinach samples, except the NY trial samples, were shipped directly by ACDS freezer truck or FedEx to the IR-4 Southern Region Laboratory at the University of Florida (Gainesville, FL) for analysis. Samples from the NY field trial were first shipped to the IR-4 Northeast Region Lab (Geneva, NY) and then shipped to IR-4 Southern Region Laboratory. The total storage intervals between harvest and analysis are reported in Table 5.

Cotton samples for processing were bagged, labeled, and frozen within 3 hours of harvest. Samples were shipped on the day of harvest by ACDS freezer truck to the Food Protein Research and Development Center, Texas A&M University for ginning and processing. Samples were stored frozen (-4° C) at Texas A&M prior to processing. Cotton was ginned approximately 77 days after harvest. Undelinted seed was stored frozen (-8° C) for 13 days until processing. Processed samples (hulls, meal, and refined oil) were frozen within 2 hours of processing and were shipped frozen by FedEx to WRC. Samples were stored frozen (-18° C) at WRC and shipped frozen by air freight to JHRS for analysis. The total storage intervals between harvest and analysis are reported in Table 5.

Soybean samples for processing were bagged, labeled, and frozen within 3 hours of harvest. The day after harvest samples were delivered frozen on dry ice by rental truck to the Food Protein Research and Development Center, Texas A&M University for processing. Samples were stored frozen (-4° C) at Texas A&M prior to processing. Soybean (RAC) and processed samples (hulls, meal, and refined oil) were frozen and shipped frozen by FedEx to WRC. The total storage intervals between harvest and analysis are reported in Table 5.

Sugar beet root samples for processing were harvested by hand, placed in labeled containers, and frozen within 3 hours of harvest. Samples were shipped by ACDS freezer truck to Englar Food Laboratories (Moses Lake, WA) for processing. Samples were stored in a cooler (7±3° C) or frozen (-22±8° C) prior to processing. Following processing, the processed samples were packed in dryice and shipped frozen overnight by FedEx to WRC for analysis. The total storage intervals between harvest and analysis are reported in Table 5.

Table 5. Storage intervals of various crop commodities from harvest to analysis.

Crop Commodity	MRID	Storage Interval
Carrot, roots	44915216	1.3-9.3 months
Celery, untrimmed stalks	44915211	2.8-8.5 months
Corn, field (K+CWHR, forage, stover, and grain)	44915215	1.8-11.1 months
Corn, field (grain, cleaned grain, and AGF)	44915215	6.9-8.2 months
Corn, field, grain, wet milled fractions (starch and refined oil) and dry milled fractions (meal, grits, flour, and refined oil)	44915230	8.3-8.7 months
Cotton, undelinted seed and gin byproducts	44915214	5.3-9.3 months
Cotton, undelinted seed, hulls, meal, and refined oil	44915231	7.3-7.5 months
Grapefruit	44915224	2-5.5 months
Lemons	44915225	3.2-6.9 months
Lettuce, head	44915213	1.6-8.8 months
Lettuce, leaf	44915212	1.1-7.4 months
Onion, dry bulb	44915210	5.3-11.2 months
Onion, green	44915226	1.5-4.6 months
Oranges	44915217	2.0-6.2 months
Oranges, dried pulp, and juice	44915228	3.6 months
Oranges, citrus oil	44915228	9.4 months
Peanut, nutmeats and hay	44915221	5.0-6.9 months
Radish, roots and tops	44915223	7.6-8.8 months
Soybean seed and aspirated grain fractions	44915209	4.8-10.6 months
Soybean seed, hulls, meal, and refined oil	44915229	8.3-8.4 months
Spinach	44983101	1.8-11.3 months
Sugar beet, root and tops	44915208	6.0-9.0 months
Sugar beet, roots, molasses, dried pulp, and refined sugar	44915232	4.8-7.2 months

Storage stability data - plant commodities

In support of the storage intervals and conditions of samples from the field and processing studies, Zeneca referenced previously submitted storage stability studies conducted on various plant commodities. In a study conducted on RAC commodities (DP Barcodes D248887 and D249671, 10/14/98, D. Dotson, M. Doherty, and Y. Donovan), fortified residues of azoxystrobin and the Z isomer were found to be stable for up to two years in/on grapes, wine, apples, peaches, bananas, cucumbers, wheat straw, and rape seed oil. Over the two-year storage period, residues of azoxystrobin and the Z isomer decreased by up to 20% in wheat grain. A similar decrease was observed for residues of azoxystrobin in/on peanuts, pecans, and tomatoes also stored for up to two years. Residues are considered stable for up to 6-8 months in these crops.

A separate study conducted on processed commodities (DP Barcodes D249657 and D249668, 1/25/99, D. Dotson), demonstrated that fortified residues of azoxystrobin and the Z isomer are generally stable for up to one year in/on the processed commodities peanut oil, peanut meal, wheat bran, tomato juice, and tomato paste.

Comments:

Samples from the submitted field trial and processing studies were stored frozen for up to ~11 months from harvest to analysis. According to OPPTS 860.1380 guidelines, data demonstrating storage stability in five diverse crops can be used to support registration on a wide variety of crops. Adequate storage stability data are available from the representative crops oilseed (rape seed and nuts), non-oily grain (wheat), and fruit or fruiting vegetable (grapes, apples, peaches, and tomatoes), as well as from the processed commodities of these crops. No data are available depicting the storage stability of residues of azoxystrobin and the Z isomer in/on leafy commodities (leafy vegetables and leaves of root and tuber vegetables), root and tuber vegetables, or the processed commodities of root and tubers (i.e., sugar beets). **To support the storage conditions and intervals of crop samples from this petition, additional data are required depicting the storage stability of residues of azoxystrobin and the Z isomer in/on a representative leafy vegetable, root and tuber vegetable, and the processed commodities of a root and tuber vegetable stored frozen for up to 11 months.**

OPPTS GLN 860.1500: Crop Field Trials

The petitioner provided specimen labels for a water-dispersible granular (WDG) formulation and a flowable concentrate (FlC) formulation proposed for identical uses on a variety of agricultural crops. However, all the field trials submitted in support of this petition reflect the use of the WDG formulation only. The guidelines for conducting field trials (OPPTS GLN 860.1500) state that for pesticides used in late season foliar applications (as is the case with azoxystrobin) separate residue trials or bridging data are needed for different formulations. In a previous Agency review (DP Barcode D236118, 6/23/97, J. Garbus) bridging data or side-by-side comparisons (WDG and FlC formulations) of residue levels in/on peaches and tomatoes were requested. These trials may have been submitted. For the purposes of this petition, conclusions pertaining to the following crops will be based on the field trial data for the WDG formulation only. If the petitioner wishes to maintain use of the FlC formulation, then additional bridging data will be required in support of late season uses.

Root and Tuber Vegetables

Zeneca submitted three volumes of carrot, radish, and sugar beet field trial data to support the establishment of a proposed tolerance for residues of azoxystrobin in/on "Root and Tuber Vegetables" at 0.5 ppm. Data for the leaves of root and tuber vegetables were included in the radish and sugar beet submissions; these data will be discussed in the following section "Leaves of Root and Tuber Vegetables." The citations are listed below.

44915208 Bussey, R.J. and Spillner, C.J. (1999) Azoxystrobin: Residue Levels on Sugar Beets from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-11: Report Number: RR 99-036B. Unpublished study prepared by Zeneca Ag Products. 43 p.

44915216 Aston, J.C. and Bussey, R.J. (1999) Azoxystrobin: Residue Levels on Carrots from Trials Conducted in the United States during 1998: Lab Project Number: AZOX-98-MR-09: Report Number: RR 99-041B. Unpublished study prepared by Zeneca Ag Products. 34 p.

44915223 Bussey, R.J. and Hampton, R. (1999) Azoxystrobin: Residue Levels in Radishes from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-10: Report Number: RR 99-022B. Unpublished study prepared by Zeneca Ag Products. 33 p.

Carrot

Six field trials were conducted during the 1998 growing season in CA(3), FL(1), IL(1), and TX(1). Mature carrots were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.33 lb ai/A/application, made at 6- to 9-day retreatment intervals. The total seasonal application rates were 2.0 lb ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized handheld boom or tractor-mounted broadcast boom sprayer) in 13-20 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume. In one trial (IL), carrots were not of marketable size following six applications because of heavy rain and temperature extremes. Two additional applications of the 80% WDG formulation were made at this site at 0.33 lb ai/A/application, with a 7-day retreatment interval. The total application rate for the IL trial was 2.64 lb ai/A (1.3x the maximum proposed seasonal application rate). A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of carrots were collected by hand from each test site at normal crop maturity. The collected samples were then bagged, labeled, and frozen (within 3 hours) at -15° C. All samples were shipped by ACDS freezer truck or FedEx to WRC (Richmond, CA) for analysis. Total storage intervals from harvest to analysis were 39-284 days (1.3-9.3 months) for carrots.

Samples of carrots were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on six samples of untreated carrots. Residues of azoxystrobin and its Z isomer in/on treated carrot samples are presented in Table 6.

Radish

Five field trials were conducted during the 1998 growing season in CA(1), FL(2), IL(1), and NY(1). Mature radishes were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.33 lb ai/A/application, made at 6- to 8-day retreatment intervals. The total seasonal application rates were 2.0 lb ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized backpack sprayer or tractor-

mounted boom sprayer) in 12-20 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of radishes (roots and tops) were collected by hand from each test site at normal crop maturity. The radish tops were separated from the roots in the field. The collected samples were then bagged separately, labeled, and frozen (within 1.5 hours) at -15° C. All samples were shipped by ACDS freezer truck to WRC for analysis. Total storage intervals from harvest to analysis were 231-267 days (7.6-8.8 months) for radishes.

Samples of radish roots and tops were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Data concerning the radish tops are presented under the following section "Leaves of Root and Tuber Vegetables." Apparent residues of azoxystrobin and the Z isomer were each less than the LOQ in/on a single sample of untreated radish root. Detectable azoxystrobin residues were found in/on four untreated samples of radish root (0.01-0.3 ppm); in these samples, Z isomer residues were less than the LOQ. Residues of azoxystrobin and its Z isomer in/on treated samples of radish roots are presented in Table 6.

Sugar Beet

Nine field trials were conducted during the 1998 growing season in CA(1), CO(1), ID(1), MI(1), MN(3), MT(1), and ND(1). Mature sugar beets were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.33 lb ai/A/application, made at 6- to 9-day retreatment intervals. The total seasonal application rates were 2.0 lb ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (hand-carried or tractor-mounted boom sprayer) in 10-26 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of sugar beets (roots and tops) were collected by hand from each test site at normal crop maturity. The collected samples were then bagged separately, labeled, and frozen (within 4 hours) at -10° C. All samples were shipped by ACDS freezer truck to WRC for analysis. Total storage intervals from harvest to analysis were 183-273 days (6.0-9.0 months) for sugar beets.

Samples of sugar beet roots and tops were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Data concerning the sugar beet tops are presented under the following section "Leaves of Root and Tuber Vegetables." Apparent residues of azoxystrobin and the Z isomer were each less than the LOQ in/on nine samples of untreated sugar beet roots. Detectable azoxystrobin residues were found in/on two untreated samples of sugar beet tops (0.02-0.05 ppm); in these samples, Z isomer residues were less than the LOQ. Residues of azoxystrobin and its Z isomer in/on treated samples of sugar beet roots are presented in Table 6.

Table 6. Residues of azoxystrobin and its Z isomer in/on **root and tuber vegetables (carrot, radish, and sugar beet)** harvested 0 days following six to eight applications of the 80% WDG formulation at 0.33 lb ai/A/application (1-1.3x the maximum proposed seasonal rate).

Test Site (Region)	Total application rate, ai	Residues, ppm		
		Azoxystrobin	Z isomer	Total [a]
Carrot (MRID 44915216)				
Visalia, CA (Region 10)	2.0 lb/A	0.20, 0.26	<0.01, 0.01	<0.21, 0.27
Holtville, CA (Region 10)	2.0 lb/A	0.03, 0.03 [b]	<0.01, <0.01	<0.04, <0.04
Madera, CA (Region 10)	2.0 lb/A	0.28, 0.30	<0.01, <0.01	<0.29, <0.31
Apopka, FL (Region 3)	2.0 lb/A	0.11, 0.14 [b]	<0.01, <0.01	<0.12, <0.15
Champaign, IL [c] (Region 5)	2.64 lb/A	0.16, 0.17	<0.01, <0.01	<0.17, <0.18
Alamo, TX (Region 6)	2.0 lb/A	0.08, 0.13	<0.01, <0.01	<0.09, <0.14
Radish roots (MRID 44915223)				
Visalia, CA (Region 10)	2.0 lb/A	0.09, 0.13	<0.01, <0.01	<0.10, <0.14
Oviedo, FL (Region 3)	2.0 lb/A	0.22, 0.29	<0.01, 0.01	<0.23, 0.30
Belle Glade, FL (Region 3)	2.0 lb/A	0.12, 0.16	<0.01, <0.01	<0.13, <0.17
Champaign, IL (Region 5)	2.0 lb/A	0.38, 0.39 [b]	<0.01, <0.01	<0.39, <0.40
North Rose, NY (Region 1)	2.0 lb/A	0.37, 0.45	<0.01, <0.01	<0.38, <0.46
Sugar beet roots (MRID 44915208)				
Visalia, CA (Region 10)	2.0 lb/A	0.06, 0.1	<0.01, <0.01	<0.07, <0.11
Eaton, CO (Region 8)	2.0 lb/A	0.09, 0.1 [b]	<0.01, <0.01	<0.10, <0.11
Boise, ID (Region 11)	2.0 lb/A	0.03, 0.06	<0.01, <0.01	<0.04, <0.07
Conklin, MI (Region 5)	2.0 lb/A	<0.01, 0.05	<0.01, <0.01	<0.02, <0.06
Fisher, MN (Region 5)	2.0 lb/A	0.04, 0.06	<0.01, <0.01	<0.05, <0.07
Campbell, MN (Region 5)	2.0 lb/A	0.09 [b], 0.26 [b]	<0.01, <0.01	<0.10, <0.27 HAFT=<0.19

(continued; footnotes follow)

Table 6 (*continued*).

Test Site (Region)	Total application rate, ai	Residues, ppm		
		Azoxystrobin	Z isomer	Total [a]
Litchfield, MN (Region 5)	2.0 lb/A	0.06, 0.09	<0.01, <0.01	<0.07, <0.10
Dagmar, MT (Region 7)	2.0 lb/A	0.03, 0.04	<0.01, <0.01	<0.04, <0.05
Havana, ND (Region 5)	2.0 lb/A	0.08, 0.11	<0.01, <0.01	<0.09, <0.12

[a] Total residues were calculated by the study reviewer.
[b] Reported residue is the highest of replicate analyses of a single sample.
[c] Due to heavy rain and temperature extremes, carrots in this trial were not of marketable size following six applications. Two additional applications of the 80% WDG formulation were made at 0.33 lb ai/A/application for a total of eight applications.

Potato

In a previous petition (PP#7F4864; DP Barcode D248887, 10/14/98, D. Dotson, M. Doherty, and Y. Donovan), the petitioner submitted 16 field trial studies on potatoes. In those studies, the 80% WDG formulation was applied six times at 0.33 lb ai/A/ application for a total seasonal rate of 2.0 lbs ai/A (1x the current proposed maximum seasonal rate). Potatoes were harvested 13-14 days following the last application. The frozen storage interval was 52-234 days from harvest-to-analysis. Potato samples were analyzed by Method RAM 243/04. In treated samples, residue levels of azoxystrobin ranged from less than the LOQ (0.01 ppm) to 0.02 ppm; residue levels of the Z isomer were less than the LOQ (0.01 ppm). There was no residue decline or 0-day PHI data.

The petitioner is currently proposing a tolerance and a use pattern with a 0-day PHI for the root and tuber vegetables crop group, but has submitted no additional field trial data for potatoes.

Comments:

The available crop field trial data are not adequate to support the proposed crop group tolerance because no 0-day PHI field trial data were submitted for potatoes. For the establishment of a root and tuber vegetables crop group tolerance, 12 potato field trials will be required and must be conducted in Regions 1 (2 trials), 2 (1 trial), 3 (1 trial), 5 (2 trials), 9 (1 trial), 10 (1 trial), and 11 (4 trials). These additional field trials should be conducted on potatoes harvested at a 0-day PHI following treatment with azoxystrobin at the maximum proposed seasonal application rate.

Alternatively, the available data will support the establishment of a crop subgroup tolerance for the root vegetables subgroup (Crop Subgroup 1-A). The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on carrots, radishes, and sugar beets, the representative commodities of the root vegetables subgroup. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed "root and tuber vegetables" tolerance level of 0.5 ppm in/on carrots, radishes, and sugar beets

harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.33 lb ai/A/application. The total seasonal application rates were 2.0 lb ai/A (1x the maximum proposed seasonal application rate). In one carrot field trial conducted in IL, two additional applications of the 80% WDG formulation were made at 0.33 lb ai/A/application for a total application rate of 2.64 lb ai/A (1.3x the maximum proposed seasonal application rate). Residues of azoxystrobin and its Z isomer from all field trials ranged <0.04-<0.31 ppm in/on carrots, <0.10-<0.46 ppm in/on radishes, and <0.02-<0.27 ppm in/on sugar beet roots treated with the 80% WDG formulation according to the maximum proposed use patterns. **For a Crop Subgroup 1-A tolerance, the petitioner should submit a revised Section F to remove the proposed root and tuber vegetables crop group tolerance and to propose a "Vegetable, root, subgroup" tolerance at 0.5 ppm. The petitioner should also submit suitably revised WDG and FlC labels.**

In addition, the available data on potatoes will support the establishment of a crop subgroup tolerance for the tuberous and corm vegetables subgroup (Crop Subgroup 1-C). Potatoes is the representative commodity of that subgroup. The results of the potato field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed 0.03 ppm in/on tuberous and corm vegetables harvested 13-14 days following the last of six broadcast foliar applications of the 80% WDG formulation at 0.33 lb ai/A/application. The total seasonal application rate was 2.0 lb ai/A (1x the maximum proposed seasonal application rate). [Note: A tolerance of 0.03 ppm, based on this use pattern, is currently established for potatoes.] **For a Crop Subgroup 1-C tolerance, the petitioner should submit a revised Section F to remove the proposed root and tuber vegetables crop group tolerance and to propose a "Vegetable, tuberous and corm, subgroup" tolerance at 0.03 ppm. The petitioner should also submit suitably revised WDG and FlC labels. Based on the available potato field trial data, the minimum acceptable PHI is 14 days.**

Leaves of Root and Tuber Vegetables

Zeneca submitted radish and sugar beet field trial data (citations listed below) to support the establishment of a proposed tolerance for residues of azoxystrobin in/on "Tops of Root and Tuber Vegetables" at 50 ppm. These data were submitted in conjunction with the root and tuber vegetable data; details of the studies, including sample handling, storage intervals, and analytical method, are presented in the previous section "Root and Tuber Vegetables."

44915208 Bussey, R.J. and Spillner, C.J. (1999) Azoxystrobin: Residue Levels on Sugar Beets from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-11: Report Number: RR 99-036B. Unpublished study prepared by Zeneca Ag Products. 43 p.

44915223 Bussey, R.J. and Hampton, R. (1999) Azoxystrobin: Residue Levels in Radishes from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-10: Report Number: RR 99-022B. Unpublished study prepared by Zeneca Ag Products. 33 p.

Radish

Apparent residues of azoxystrobin and the Z isomer were each less than the LOQ in/on four samples of radish tops. Detectable azoxystrobin residues were found in/on one untreated sample of radish tops (0.01 ppm); in this sample, Z isomer residues were less than the LOQ. Residues of azoxystrobin and its Z isomer in/on treated samples of radish tops are presented in Table 7.

Sugar Beet

Apparent residues of azoxystrobin and the Z isomer were each less than the LOQ in/on seven untreated samples of sugar beet tops. Detectable azoxystrobin residues were found in/on two untreated samples of sugar beet tops (0.02-0.05 ppm); in these samples, Z isomer residues were less than the LOQ. Residues of azoxystrobin and its Z isomer in/on treated samples of sugar beet tops are presented in Table 7.

Table 7. Residues of azoxystrobin and its Z isomer in/on **leaves of root and tuber vegetables (radish tops and sugar beet tops)** harvested 0 days following six applications of the 80% WDG formulation at 0.33 lb ai/A/application (1x the maximum proposed seasonal rate).

Test Site (Region)	Total application rate, ai	Residues, ppm		
		Azoxystrobin	Z isomer	Total [a]
Radish, tops (MRID 44915223)				
Visalia, CA (Region 10)	2.0 lb/A	13.4, 14.7	0.15, 0.16 [b]	13.55, 14.86
Oviedo, FL (Region 3)	2.0 lb/A	23.4, 39.3 [b]	1.7, 1.4	25.1, 40.7
Belle Glade, FL (Region 3)	2.0 lb/A	12.7, 12.9	0.45, 0.46	13.15, 13.36
Champaign, IL (Region 5)	2.0 lb/A	9.7, 10.0 [b]	0.21, 0.22	9.91, 10.22
North Rose, NY (Region 1)	2.0 lb/A	23.4, 23.7	0.62, 0.63	24.02, 24.33
Sugar beet, tops (MRID 44915208)				
Visalia, CA (Region 10)	2.0 lb/A	13, 16	0.2, 0.23	13.2, 16.23
Eaton, CO (Region 8)	2.0 lb/A	9.2, 11	0.22, 0.25	9.42, 11.25
Boise, ID (Region 11)	2.0 lb/A	31, 44	0.76, 1.0	31.76, 45
Conklin, MI (Region 5)	2.0 lb/A	7.7, 9.5	0.12, 0.14	7.82, 9.64
Fisher, MN (Region 5)	2.0 lb/A	8.3, 8.7	0.05, 0.06	8.35, 8.76
Campbell, MN (Region 5)	2.0 lb/A	18 [b]; 25	0.48, 0.66	18.48, 25.66
Litchfield, MN (Region 5)	2.0 lb/A	20, 22	0.47, 0.56	20.47, 22.56
Dagmar, MT (Region 7)	2.0 lb/A	4.6, 5.8	0.05, 0.06	4.65, 5.86
Havana, ND (Region 5)	2.0 lb/A	12, 16	0.29, 0.33 [b]	12.29, 16.33

[a] Total residues were calculated by the study reviewer.
[b] Reported residue is the highest of replicate analyses of a single sample.

Geographic representation of data, for the establishment of a tolerance for leaves of root and tuber vegetables group (Crop Group 2), is adequate. The Agency (Table 2 of OPPTS 860.1500) requires a total of 14 trials for the establishment of a crop group tolerance on the leaves of root and tuber vegetables using the representative commodities turnip (5 trials) and sugar/garden beet (9 trials).

Five radish top trials were conducted in Regions 1 (1 trial), 3 (2 trials), 5 (1 trial), and 10 (1 trial). Nine sugar beet top trials were conducted in Regions 5 (5 trials), 7 (1 trial), 8 (1 trial), 10 (1 trial), and 11 (1 trial). For the purposes of this tolerance petition, the Agency will allow the radish top field trials to substitute for the required turnip top field trials.

Comments:

The available crop field trial data are adequate to support the proposed leaves of root and tuber vegetables group tolerance. The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on radish tops (in lieu of turnip tops) and sugar beet tops, which can be considered to be representative commodities of the leaves of root and tuber vegetables group. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed crop group tolerance level of 50.0 ppm following treatment at 1x the maximum proposed seasonal application rate. **A revised Section F should be submitted to express the proposed crop group tolerance in terms of "Vegetable, leaves of root and tuber, group" at 50.0 ppm.**

HED has recently concluded that "turnip greens" more appropriately belongs in Crop Group 5, *Brassica* (cole) leafy vegetables (B. Schneider, 2/10/2000). However, we understand its transfer to that crop group is not imminent (conversation with B. Schneider, 8/15/00). Thus, **for now, turnip greens will be covered by the tolerance on the leaves of root and tuber vegetables.** [Note: If/when transferred, turnip greens may need an individual tolerance listing at 50.0 ppm expressed as "Turnip, tops", depending upon whether there is a *Brassica* leafy vegetables crop group tolerance by that time and whether the use pattern and tolerance level of turnip greens is compatible with it.]

Bulb Vegetables

Zeneca submitted two volumes of dry bulb and green onion field trial data (citations listed below) to support the establishment of a proposed tolerance for residues of azoxystrobin in/on "Bulbs" [sic] at 7.5 ppm.

44915210 Bussey, R.J. and Aston, J.C. (1999) Azoxystrobin: Residue Levels on Dry Bulb Onions from Trials Conducted in the United States during 1997-1998: Lab Project Number: AZOX-98-MR-05: Report Number:-RR 99-042B. Unpublished study prepared by Zeneca Ag Products. 37 p.

44915226 Bussey, R.J. (1999) Azoxystrobin: Residue Levels on Green Onions from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-04: Report Number: RR 98-074B. Unpublished study prepared by Zeneca Ag Products. 31 p.

Dry Bulb Onion

Eight field trials were conducted during the 1997-1998 growing seasons in CA(2), CO(1), IL(1), NY(1), OR(1), TX(1), and WA(1). A second trial was initiated in OR; however, the trial was canceled before the first application because seedlings did not emerge properly. Mature dry bulb onions were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 6- to 8-day retreatment intervals. The total seasonal application rates were 1.5 lb ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized handheld boom or tractor-mounted broadcast boom sprayer) in 11-19 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume.

A single untreated sample and duplicate treated samples of dry bulb onions were collected by hand from each test site at normal crop maturity. The collected samples were then bagged, labeled, and frozen (within 4 hours) at -15° C. All samples were shipped by ACDS freezer truck, FedEx, or private automobile to WRC (Richmond, CA) for analysis. Total storage intervals from harvest to analysis were 162-341 days (5.3-11.2 months) for dry bulb onions.

Samples of dry bulb onions were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on seven samples of untreated dry bulb onions. Detectable azoxystrobin residues were found in one sample of untreated dry bulb onions (0.03 ppm); in this sample, Z isomer residues were less than the LOQ. Residues of azoxystrobin and its Z isomer in/on treated dry bulb onion samples are presented in Table 8.

Green Onion

Three field trials were conducted during the 1998 growing season in AZ(1), CA(1), and TX(1). Mature green onions from the CA and TX trials were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 7-day retreatment intervals. The total seasonal application rate was 1.5 lb ai/A (1x the maximum proposed seasonal application rate). Because onions in the AZ trial grew slowly due to unusually cold wet weather, mature green onions from the AZ trial were harvested on the day of the last of 11 broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 7-day retreatment intervals. The total seasonal application rate was 2.75 lb ai/A (1.8x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized handheld boom or tractor-mounted broadcast boom sprayer) in 10.5-18 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume.

A single untreated sample and duplicate treated samples of green onions were collected by hand from each test site at normal crop maturity. Loosely adhering soil was removed by brushing or shaking, and roots were removed by cutting. The collected samples were then bagged, labeled, and frozen (within 4 hours) at -15° C. All samples were shipped by ACDS freezer truck to WRC for

analysis. Total storage intervals from harvest to analysis were 47-139 days (1.5-4.6 months) for green onions.

Samples of green onions were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on three samples of untreated green onions. Residues of azoxystrobin and its Z isomer in/on treated green onion samples are presented in Table 8.

Table 8. Residues of azoxystrobin and its Z isomer in/on **bulb vegetables (dry bulb and green onions)** harvested 0 days following six or eleven applications of the 80% WDG formulation at 0.25 lb ai/A/application (1-1.8x the maximum proposed seasonal rate).

Test Site (Region)	Total application rate, ai	Residues, ppm		
		Azoxystrobin	Z isomer	Total [a]
Dry bulb onion (MRID 44915210)				
Visalia, CA (Region 10)	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Stockton, CA (Region 10)	1.5 lb/A	0.13, 0.15	<0.01, <0.01	<0.14, <0.16
Eaton, CO (Region 8)	1.5 lb/A	0.28, 0.32 [b]	<0.01, <0.01	<0.29, <0.33
Champaign, IL (Region 5)	1.5 lb/A	0.18, 0.21	<0.01, <0.01	<0.19, <0.22
Alton, NY (Region 1)	1.5 lb/A	0.43, 0.66	<0.01, 0.01	<0.44, 0.67
Hillsboro, OR (Region 12)	1.5 lb/A	0.20, 0.36	<0.01, <0.01	<0.21, <0.37
San Juan, TX (Region 6)	1.5 lb/A	0.38, 0.51	<0.01, <0.01	<0.39, <0.52
Walla Walla, WA (Region 11)	1.5 lb/A	0.06, 0.07	<0.01, <0.01	<0.07, <0.07
Green onions (MRID 44915226)				
Maricopa, AZ [c] (Region 10)	2.75 lb/A	3.1, 3.3	0.30, 0.32	3.40, 3.62
Visalia, CA (Region 10)	1.5 lb/A	1.4, 1.4	0.08, 0.09	1.48, 1.49
Weslaco, TX (Region 6)	1.5 lb/A	4.7, 6.3	0.48, 0.61	5.18, 6.91

[a] Total residues were calculated by the study reviewer.

[b] Reported residue is the highest of replicate analyses of a single sample.

[c] Due to unusually cold, wet weather, following six applications of the test substance the crop was too immature to harvest. Therefore, the spray program was continued and five additional applications were made.

Geographic representation of data for bulb vegetables is adequate for the purposes of this petition. According to Tables 2 and 5 of OPPTS 860.1500, a minimum of 9 trials, (6 for bulb onions and 3 for green onions) are required for the establishment of a crop group tolerance for bulb vegetables. Eight bulb onion field trials were conducted in Regions 1 (1 trial), 5 (1 trial), 6 (1 trial), 8 (1 trial), 10 (2 trials), 11 (1 trial), and 12 (1 trial). Three green onion trials were conducted in Regions 6 (1 trial) and 10 (2 trials). The number of field trials is also adequate to establish individual tolerances for "green onions" and "dry bulb onions." According to Tables 2 and 5 of OPPTS 860.1500, a minimum of 3 trials are required for the establishment of a tolerance for green onions and a minimum of 8 trials are required for the establishment of a tolerance for dry bulb onions.

Comments:

The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin and its Z isomer on dry bulb onions and green onions. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed "bulbs" [sic] tolerance level of 7.5 ppm, following treatment at 1x the maximum proposed seasonal application rate. However, **because the difference between the highest dry bulb onion residues (0.67 ppm) and the highest green onion residues (6.9 ppm) is greater than 5x, a crop group tolerance for bulb vegetables is not appropriate.**

The petitioner has provided sufficient crop field trial data to support individual tolerances for bulb onions and green onions. **The petitioner should submit a revised Section F to remove the proposed "bulbs" [sic] tolerance and to propose an individual tolerance for "Onion, dry bulb" at 1.0 ppm and "Onion, green" at 7.5 ppm.** We note that even though tolerances are being set specifically on onion, dry bulb and onion, green, because of the definitions and interpretations of 40 CFR 180.1(h), the proposed use will be permitted on all the raw agricultural crops comprising the bulb vegetables crop group; **no revision to the Bulb Vegetables listing on the WDG and FlC labels is required.**

Leafy Vegetables (Except *Brassica* Vegetables)

Zeneca submitted three volumes of celery and lettuce (head and leaf) field trial data, and Interregional Research Project No. 4 (IR-4) submitted one volume of spinach field trial data to support the establishment of a proposed tolerance for residues of azoxystrobin in/on "Leafy Vegetables (Excluding Brassica)" at 30 ppm. The citations are listed below.

44915211 Bussey, R.J. and Aston, J.C. (1999) Azoxystrobin: Residue Levels on Celery from Trials Conducted in the United States during 1998: Lab Project Number: AZOX-98-MR-06: Report Number: RR 99-033B. Unpublished study prepared by Zeneca Ag Products. 38 p.

44915212 Bussey, R.J. (1999) Azoxystrobin: Residue Levels on Leaf Lettuce from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-08: Report Number: RR 99-020B. Unpublished study prepared by Zeneca Ag Products. 37 p.

44915213 Bussey, R.J. and Hampton, R. (1999) Azoxystrobin: Residue Levels on Head Lettuce from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-07: Report Number: RR 99-013B. Unpublished study prepared by Zeneca Ag Products. 39 p.

44983101 Thompson, D.C. (1999) Amendment to Azoxystrobin: Magnitude of the Residue on Spinach: Lab Identification Number: 06602.97-FLR11: Study Number: IR-4 PR No. 06602. Unpublished study prepared by IR-4 Project. 192 p.

Celery

Eight field trials were conducted during the 1998 growing season in CA(6), FL(1), and MI(1). Mature untrimmed celery was harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 5- to 9-day retreatment intervals. The total seasonal application rates were 1.5 lb ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized handheld boom or tractor-mounted broadcast boom sprayer) in 15-20 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of untrimmed celery were collected by hand from each test site at normal crop maturity. The collected samples were then bagged, labeled, and frozen (within 8 hours) at -15° C. All samples were shipped by ACDS freezer truck or FedEx to WRC (Richmond, CA) for analysis. Total storage intervals from harvest to analysis were 85-259 days (2.8-8.5 months) for untrimmed celery.

Samples of untrimmed celery were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on five samples of untreated untrimmed celery. Detectable azoxystrobin residues were found in one sample of untreated untrimmed celery (0.01 ppm); in this sample, Z isomer residues were less than the LOQ. Detectable Z isomer residues were found in two samples of untreated untrimmed celery (0.01 and 0.02 ppm); azoxystrobin residues were less than the LOQ in these samples. Residues of azoxystrobin and its Z isomer in/on treated celery samples are presented in Table 9.

Head Lettuce

Eight field trials were conducted during the 1998 growing season in AZ(1), CA(5), FL(1), and NJ(1). Mature head lettuce was harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 5- to 8-day retreatment intervals. The total seasonal application rates were 1.5 lb ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized handheld boom or tractor-mounted broadcast boom sprayer) in 12-20 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of head lettuce were collected by hand from each test site at normal crop maturity. The collected samples were then bagged, labeled, and frozen (within 3 hours) at -15° C. All samples were shipped by ACDS freezer truck or FedEx to WRC for analysis. Total storage intervals from harvest to analysis were 50-267 days (1.6-8.8 months) for head lettuce.

Samples of head lettuce were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQs were 0.01 and 0.05 ppm for each analyte. In trials where the higher LOQ was cited, the petitioner noted that the residues in the treated samples were 3 to >100 times greater than the 0.05 ppm, therefore an LOQ of 0.05 ppm was sufficient. In two trials (CA and NJ) where untreated samples contained non-detectable (<0.05 ppm) residues of the Z isomer, the control samples were reanalyzed for the Z isomer in order to lower the LOQ to 0.01 ppm; the respective treated samples had residues below the 0.05 ppm LOQ, and the lower LOQ was required. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ (0.05 or 0.01 ppm) in/on eight samples of untreated head lettuce. Residues of azoxystrobin and its Z isomer in/on treated head lettuce samples are presented in Table 9.

Leaf Lettuce

Eight field trials were conducted during the 1998 growing season in AZ(2), CA(4), FL(1), and NY(1). Mature leaf lettuce was harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 6- to 8-day retreatment intervals. The total seasonal application rates were 1.5 lb ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized handheld boom, tractor-mounted broadcast boom, or self-propelled small plot sprayer) in 12-18 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of leaf lettuce were collected by hand by cutting the plant above the soil using a clean knife or hand clipper. Decomposed, withered, or diseased leaves were discarded. Leaf lettuce samples were collected at normal crop maturity. The collected samples were then bagged, labeled, and cooled or frozen (within 2 hours) and then maintained at -15° C. All samples were shipped by ACDS freezer truck or FedEx to WRC for analysis. Total storage intervals from harvest to analysis were 33-225 days (1.1-7.4 months) for leaf lettuce.

Samples of leaf lettuce were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ (0.01 ppm) in/on eight samples of untreated leaf lettuce. Residues of azoxystrobin and its Z isomer in/on treated leaf lettuce samples are presented in Table 9.

Spinach

Seven field trials were conducted during the 1997 and 1998 growing seasons in CA(2), NJ(1), NY(1), OR(1), and TX(2). Mature spinach was harvested on the day of and/or 6-7 days following the last of six broadcast foliar applications of the 80% WDG formulation at ~0.25 lb ai/A/application, made at 6- to 9-day retreatment intervals. Spinach in the OR trial received eight applications because the crop matured slowly. The total seasonal application rates for all trials except the OR trial, were 1.4-1.61 lb ai/A (0.9-1x the maximum proposed seasonal application rate). The total seasonal application rate for the OR trial was 2.0 lbs ai/A (1.3x the maximum proposed seasonal application rate). Applications were made using ground equipment (bicycle sprayer, CO_2-backpack sprayer, and tractor-mounted boom sprayer) in 21.95-47.91 gal/A. In five of the seven trials, a crop oil concentrate or other adjuvant was added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

Duplicate untreated samples and treated samples of spinach were collected by hand by cutting the plant above the soil using a clean knife, shears, or scissors. For some trials, the decomposed, withered, or diseased leaves were removed/discarded. Spinach samples were collected at normal crop maturity. The collected samples were then bagged, labeled, and cooled or frozen (within 1 hour) and then maintained at -10 to -33 ° C. All samples, except the NY trial samples, were shipped directly by ACDS freezer truck or FedEx to the IR-4 Southern Region Laboratory at the University of Florida (Gainesville, FL) for analysis. Samples from the NY field trial were first shipped to the IR-4 Northeast Region Lab (Geneva, NY) and then shipped to IR-4 Southern Region Laboratory. Total storage intervals from harvest to analysis were 56-342 days (1.8-11.3 months) for spinach.

Samples of spinach were analyzed for residues of azoxystrobin and its Z isomer using SOP RAM 243/03. This data collection method was discussed in a previous petition (PP#6F4762; DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney) and is essentially the same as the GC/NPD method described under the "Residue Analytical Methods" section. The reported LOQ was 0.02 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on 13 samples of untreated spinach. Residues of azoxystrobin and its Z isomer in/on treated spinach samples are presented in Table 9.

Table 9. Residues of azoxystrobin and its Z isomer in/on **leafy vegetables (celery, head and leaf lettuce, and spinach)** harvested 0 days or 6-7 days following six applications of the 80% WDG formulation at 0.21-0.27 lb ai/A/application (0.9-1x the maximum proposed seasonal rate).

Test Site (Region)	PHI, days	Total application rate, ai	Residues, ppm		
			Azoxystrobin	Z isomer	Total [a]
Celery, untrimmed (MRID 44915211)					
Visalia, CA (Region 10)	0	1.5 lb/A	8.7, 9.4	0.52, 0.54	9.22, 9.94
Irvine, CA (Region 10)	0	1.5 lb/A	3.0 [b], 3.3	0.04, 0.08	3.04, 3.38
San Marcos, CA (Region 10)	0	1.5 lb/A	1.9, 2.6	0.16, 0.21	2.06, 2.81
Camarillo, CA (Region 10)	0	1.5 lb/A	4.3, 4.8	0.13, 0.15	4.43, 4.95
Watsonville, CA (Region 10)	0	1.5 lb/A	5.1, 6.0	0.12, 0.14	5.22, 6.14
Watsonville, CA (Region 10)	0	1.5 lb/A	1.8, 2.5 [b]	0.03, 0.04	1.83, 2.54
Apopka, FL (Region 3)	0	1.5 lb/A	1.9, 2.2	<0.01, <0.01	<1.91, <2.21
Sparta, MI (Region 5)	0	1.5 lb/A	3.1, 4.5	0.05, 0.07	3.15, 4.57
Lettuce, head (MRID 44915213)					
Yuma, AZ (Region 10)	0	1.5 lb/A	3.27, 3.58	0.19, 0.20	3.46, 3.78
Visalia, CA (Region 10)	0	1.5 lb/A	3.19 [b], 3.54	0.34, 0.34	3.53, 3.88
Bard, CA (Region 10)	0	1.5 lb/A	3.62, 3.92	0.18, 0.19	3.80, 4.11
Brawley, CA (Region 10)	0	1.5 lb/A	2.43, 2.50 [b]	<0.01, <0.01	<2.44, <2.51
Watsonville, CA (Region 10)	0	1.5 lb/A	3.90, 5.50	0.03, 0.03	3.93, 5.53
San Marcos, CA (Region 10)	0	1.5 lb/A	3.39, 3.39	0.22, 0.22	3.61, 3.61
Apopka, FL (Region 3)	0	1.5 lb/A	2.03, 2.19 [b]	0.13, 0.16	2.16, 2.35
Baptistown, NJ (Region 2)	0	1.5 lb/A	2.19, 2.79	0.01, 0.01	2.20, 2.80

(continued; footnotes follow)

Test Site (Region)	PHI, days	Total application rate, ai	Residues, ppm		
			Azoxystrobin	Z isomer	Total [a]
Lettuce, leaf (MRID 44915212)					
Yuma, AZ (Region 10)	0	1.5 lb/A	4.3, 4.4	0.21, 0.21	4.51, 4.61
Maricopa, AZ (Region 10)	0	1.5 lb/A	9.7, 10.3	0.29, 0.33	9.99, 10.63
Visalia, CA (Region 10)	0	1.5 lb/A	8.0, 8.3	0.39, 0.36	8.39, 8.66
Watsonville, CA (Region 10)	0	1.5 lb/A	4.2, 5.5	0.09, 0.11	4.29, 5.61
Manteca, CA (Region 10)	0	1.5 lb/A	14.8 [b], 16.0 [b]	0.65 [b], 0.72	15.45, 16.72
San Marcos, CA (Region 10)	0	1.5 lb/A	2.6 [b], 2.8	0.14, 0.15	2.74, 2.95
Oviedo, FL (Region 3)	0	1.5 lb/A	3.4, 3.6 [b]	0.21, 0.21	3.61, 3.81
North Rose, NY (Region 1)	0	1.5 lb/A	5.9, 6.3	0.11, 0.13	6.01, 6.43
Spinach (MRID 44983101)					
Salinas, CA (Region 10)	6	1.49 lb/A	2.01, 2.54	0.113, 0.126	2.123, 2.666
Holtsville, CA (Region 10)	0	1.40 lb/A	12.5, 14.6	0.482, 0.556	12.982, 15.156
	7		9.21, 12.1	0.475, 0.563	9.685, 12.663
Bridgeton, NJ (Region 2)	6	1.48 lb/A	2.25, 3.36	0.142, 0.203	2.392, 3.563
Freeville, NY (Region 1)	0	1.48 lb/A	7.03, 9.46	0.11, 0.16	7.14, 9.62
North Willamette, OR c (Region 12)	0	2.01 lb/A	12.4, 12.6	0.257, 0.228	12.657, 12.828
Weslaco, TX (Region 6)	0	1.61 lb/A	17.9, 19.0	0.491, 0.551	18.391, 19.551
Weslaco, TX (Region 6)	0	1.50 lb/A	19.8, 26.2	0.653, 0.587	20.453, 26.787

[a] Total residues were calculated by the study reviewer.

[b] Reported residue is the highest of replicate analyses of a single sample.

[c] Because the crop matured slowly, this trial received eight applications of the test substance for a total rate of 2.01lb ai/A (1.3x the maximum proposed seasonal rate).

The Agency (Table 2 of OPPTS 860.1500) requires a total of 24 crop field trials for the establishment of a crop group tolerance on leafy vegetables (except *Brassica* vegetables) using the representative commodities celery (6 trials), head lettuce (6 trials), leaf lettuce (6 trials), and spinach (6 trials). A total of 31 trials were conducted on leafy vegetables. Eight celery trials were conducted in Regions 3 (1 trial), 5 (1 trial), and 10 (6 trials). Eight head lettuce trials were conducted in Regions 2 (1 trial), 3 (1 trial), and 10 (6 trials). Eight leaf lettuce trials were conducted in Regions 1 (1 trial), 3 (1 trial), and 10 (6 trials). Five spinach trials (reflecting the proposed 0-day PHI) were conducted in Regions 1 (1 trial), 6 (2 trials), 10 (1 trial), and 12 (1 trial).

Comments:

The number and geographic representation of crop field trials are adequate for the representative commodities, celery, head lettuce, and leaf lettuce. For the remaining representative commodity, spinach, **two additional spinach field trials reflecting the maximum proposed seasonal use pattern should be conducted: one in Region 2 and one in Region 9.** This is especially relevant since the highest residues for the crop group occurred in spinach.

The petitioner has provided residue data reflecting the maximum proposed use pattern of azoxystrobin on celery, head and leaf lettuce, and spinach. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance level of 30 ppm in/on celery, head and leaf lettuce, and spinach harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at ~0.25 lb ai/A/application. The total seasonal application rate was ~1.5 lbs ai/A (~1x the maximum proposed seasonal application rate). One spinach field trial conducted in OR received 8 applications resulting in a total seasonal application rate ~2.0 lbs ai/A (1.3x the maximum proposed seasonal application rate). Residues of azoxystrobin and its Z isomer from all field trials ranged 1.8-9.9 ppm in/on celery, 2.2-5.5 ppm in/on head lettuce, 2.7-16.7 ppm in/on leaf lettuce, and 7.1-26.8 ppm in/on spinach treated with the 80% WDG formulation according to the maximum proposed use patterns. **The petitioner should submit a revised Section F proposing the tolerance of 30.0 ppm in terms of "Vegetable, leafy, except *Brassica*, group".**

Citrus Fruits

Zeneca submitted three volumes of grapefruit, lemon, and orange field trial data to support the establishment of a proposed tolerance for residues of azoxystrobin in/on "Citrus, fruits" at 3.0 ppm. The citations are listed below.

44915217 Bussey, R.J. and Hampton, R. (1999) Azoxystrobin: Residue Levels on Oranges from Trials Conducted in the United States in 1997-1998: Lab Project Number: AZOX-98-MR-03: Report Number: RR 99-012B. Unpublished study prepared by Zeneca Ag Products. 42 p.

44915224 Hampton, R. (1999) Azoxystrobin: Residue Levels on Grapefruit from Trials Conducted in the United States in 1997-1998: Lab Project Number: AZOX-98-MR-01: Report Number: RR 99-011B. Unpublished study prepared by Zeneca Ag Products. 33 p.

44915225 Hampton, R. (1999) Azoxystrobin: Residue Levels on Lemons from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-02: Report Number: RR 99-018B. Unpublished study prepared by Zeneca Ag Products. 31 p.

Grapefruit

Six field trials were conducted during the 1997-1998 growing season in CA(2), FL(3), and TX(1). Mature grapefruits were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 6- to 8-day retreatment intervals. The first application was made approximately 35 days prior to anticipated harvest. The total seasonal application rates were 1.5 lbs ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (portable mist-blower sprayer or tractor-mounted airblast sprayer) in either 53-67 gal/A (low application volume) or 217-242 gal/A (high application volume) with a non-ionic surfactant (0.125%, v:v) added to the spray volume. Two plots at the TX field trial site were treated, one using the low application volume and one using the high application volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of grapefruit were collected by hand from each test site at normal crop maturity. The collected samples were then bagged, labeled, and frozen (within 6 hours) at -15° C. All samples were shipped by ACDS freezer truck to the WRC (Richmond, CA) for analysis. Total storage intervals from harvest to analysis were 61-167 days (~2-5.5 months) for grapefruit.

Samples of grapefruit were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on six samples of untreated grapefruit. Residues of azoxystrobin and its Z isomer in/on treated samples are presented in Table 10.

Lemons

Five field trials were conducted during the 1998 growing season in AZ(1), CA(3), and FL(1). Mature lemons were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 6- to 8-day retreatment intervals. The first application was made 34-37 days prior to anticipated harvest. The total seasonal application rates were 1.5 lbs ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (airblast sprayer) in either 60-68 gal/A (low application volume) or 221-235 gal/A (high application volume) with a non-ionic surfactant (0.125%, v:v) added to the spray volume. Two plots at the FL field trial site were treated, one using the low application volume and one using the high application volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of lemons were collected by hand from each test site at normal crop maturity. The collected samples were then bagged, labeled, and frozen (within 5 hours) at -15° C. All samples were shipped by ACDS freezer truck to the WRC for

analysis. Total storage intervals from harvest to analysis were 98-209 days (~3.2-6.9 months) for lemons.

Samples of lemons were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin were less than the LOQ in/on five samples of untreated lemons. Residues of azoxystrobin and its Z isomer in/on treated samples of lemons are presented in Table 10.

Oranges

Twelve field trials were conducted during the 1997-1998 growing season in CA(3), FL(8), and TX(1). Mature oranges were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 6- to 8-day retreatment intervals. The first application was made 34-35 days prior to anticipated harvest. The total seasonal application rates were 1.5 lbs ai/A (1x the maximum proposed seasonal application rate). Applications were made using ground equipment (air-blast sprayer or mist-blower) in either 53-67 gal/A (low application volume) or 203-248 gal/A (high application volume) with a non-ionic surfactant (0.125%, v:v) added to the spray volume. Two plots at the TX field trial site were treated: one using the low application volume and one using the high application volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated sample and duplicate treated samples of oranges were collected by hand from each test site at normal crop maturity. The collected samples were then bagged, labeled, and frozen (within 6 hours) at -15° C. All samples were shipped by ACDS freezer truck to the WRC (Richmond, CA) for analysis. Total storage intervals from harvest to analysis were 62-189 days (2.0-6.2 months) for oranges, two additional orange samples (one control and one recovery sample) were stored 419 days (~14 months) from harvest to analysis.

Samples of oranges were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin were less than the LOQ in/on twelve samples of untreated orange. Residues of azoxystrobin and its Z isomer in/on treated samples of oranges are presented in Table 10.

Table 10. Residues of azoxystrobin and its Z isomer in/on **citrus fruits (grapefruit, lemons, and oranges)** harvested 0 days following six applications of the 80% WDG formulation at 0.25 lb ai/A/application (1x the maximum proposed seasonal rate).

Test Site (Region)	Total application rate, ai; spray volume [a]	Residues, ppm		
		Azoxystrobin	Z isomer	Total [b]
Grapefruit (MRID 44915224)				
Calipatria, CA (Region 10)	1.5 lb/A; 65 GPA	0.18 [c], 0.21	<0.01, <0.01	<0.19, <0.22
Clovis, CA (Region 10)	1.5 lb/A; 230 GPA	0.17 [c], 0.19	<0.01, <0.01	<0.18, <0.20
LaBelle, FL (Region 3)	1.5 lb/A; 67 GPA	0.16, 0.20	<0.01, <0.01	<0.17, <0.21
Oviedo, FL (Region 3)	1.5 lb/A; 217-229 GPA	0.23, 0.25	<0.01, <0.01	<0.24, <0.26
Mims, FL (Region 3)	1.5 lb/A; 217-229 GPA	0.20, 0.27	<0.01, <0.01	<0.21, <0.28
Raymondville, TX (Region 6)	1.5 lb/A; 53-55 GPA	0.29, 0.29	<0.01, <0.01	<0.30, <0.30
	1.5 lb/A; 230-242 GPA	0.33, 0.41	<0.01, <0.01	<0.34, <0.42
Lemons (MRID 44915225)				
Waddell, AZ (Region 10)	1.5 lb/A; 224-235 GPA	0.42, 0.52	<0.01, <0.01	<0.43, <0.53
Visalia, CA (Region 10)	1.5 lb/A; 60-65 GPA	0.57, 0.65	<0.01, <0.01	<0.58, <0.66
Westmorland, CA (Region 10)	1.5 lb/A; 224-230 GPA	0.27 [c], 0.31	<0.01, <0.01	<0.28, <0.32
Elderwood, CA (Region 10)	1.5 lb/A; 61 GPA	0.54, 0.72 [c]	<0.01, <0.01	<0.55, <0.73
Big Cypress Indian Reservation, FL (Region 3)	1.5 lb/A; 64-68 GPA	0.64, 0.74	<0.01, <0.01	<0.65, <0.75 HAFT = 0.70
	1.5 lb/A; 221-224 GPA	0.41, 0.42	<0.01, 0.01	<0.42, 0.43
Oranges (MRID 44915217)				
Visalia, CA (Region 10)	1.5 lb/A; 60-65 GPA	0.33 [c], 0.37	<0.01, <0.01	<0.34, <0.38
Calipatria, CA (Region 10)	1.5 lb/A; 225 GPA	0.39, 0.41	<0.01, <0.01	<0.40, <0.42
Clovis, CA (Region 10)	1.5 lb/A; 230 GPA	0.25 [c], 0.26	<0.01, <0.01	<0.26, <0.27
Oviedo, FL (Region 3)	1.5 lb/A; 203-216 GPA	0.09, 0.17	<0.01, <0.01	<0.10, <0.18

(continued; footnotes follow)

Test Site (Region)	Total application rate, ai; spray volume [a]	Residues, ppm		
		Azoxystrobin	Z isomer	Total [b]
Oviedo, FL (Region 3)	1.5 lb/A; 224-238 GPA	0.22, 0.23	<0.01, <0.01	<0.23, <0.24
Chuluota, FL (Region 3)	1.5 lb/A; 224-238 GPA	0.25, 0.31	<0.01, <0.01	<0.26, <0.32
Mims, FL (Region 3)	1.5 lb/A; 233-248 GPA	0.25, 0.32	<0.01, <0.01	<0.26, <0.33
Felda, FL (Region 3)	1.5 lb/A; 67 GPA	0.13, 0.30	<0.01, <0.01	<0.14, <0.31
Felda, FL (Region 3)	1.5 lb/A; 67 GPA	0.29, 0.40	<0.01, <0.01	<0.30, <0.41
Alva, FL (Region 3)	1.5 lb/A; 67 GPA	0.13, 0.28	<0.01, <0.01	<0.14, <0.29
Alva, FL (Region 3)	1.5 lb/A; 67 GPA	0.15, 0.38 [c]	<0.01, <0.01	<0.16, <0.39
Raymondville, TX (Region 6)	1.5 lb/A; 53-55 GPA	0.38, 0.50	<0.01, <0.01	<0.39, <0.51
	1.5 lb/A; 230-242 GPA	0.49, 0.53	<0.01, <0.01	<0.50, <0.54

[a] Applications were made as low application volume sprays (53-67 GPA) or high application volume sprays (203-248 GPA).

[b] Total residues were calculated by the study reviewer.

[c] Reported residue is the highest of replicate analyses of a single sample.

Geographic representation of citrus fruit data is adequate for the purposes of this petition. The Agency (Tables 2 and 5 of OPPTS 860.1500) requires a total of 23 trials for the establishment of a crop group tolerance on citrus fruits; 12 trials on oranges, 5 trials on lemons, and 6 trials on grapefruit. Twenty-three citrus field trials were conducted on grapefruit in Regions 3 (3 trials), 6 (1 trial), and 10 (2 trials); on lemons in Regions 3 (1 trial) and 10 (4 trials); and on oranges in Regions 3 (8 trials), 6 (1 trial), and 10 (3 trials). Side-by-side trials conducted with dilute and concentrate spray volumes did not indicate that higher residues were likely to result from either type of application.

Comments:

The petitioner has provided adequate U.S. residue data reflecting the maximum proposed domestic use pattern of azoxystrobin on the representative crops (sweet orange, lemon, and grapefruit) of the citrus fruits group. The results of the U.S. citrus field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed 1.0 ppm in/on grapefruit, lemons, or oranges harvested 0 days following the last of six applications, with 6- to 8-day retreatment intervals, of the 80% WDG formulation at 0.25 lb ai/A/application, for a total application rate of 1.5 lb ai/A (1x the maximum proposed seasonal application rate). Residues of azoxystrobin were 0.16-0.41 ppm in/on

grapefruit, 0.27-0.74 ppm in/on lemons, and 0.09-0.53 ppm in/on oranges. Residues of the Z isomer were less than the method LOQ (<0.01 ppm) in/on all grapefruit, lemon, and orange samples, except for one lemon sample which had detectable residues of the Z isomer at the method LOQ (0.01 ppm). The proposed tolerance level is 3.0 ppm.

Based on domestic field trials data only, the petitioner should submit a revised Section F which reduces the proposed tolerance from 3.0 ppm to 1.0 ppm, and which expresses the tolerance in terms of "Fruit, citrus, group".

Citrus fruit field trials conducted in South Africa

Zeneca also submitted four volumes of grapefruit, lemon, orange, and mandarin field trial data from studies conducted in South Africa. The petitioner stated that azoxystrobin is intended for use in many countries as well as the U.S., and that azoxystrobin residues in citrus appear to have the potential to be higher in some environments. Therefore, Zeneca has included these data in support of both domestic and international uses. The citations are listed below.

44915219 Sapiets, A., Lubbe, G.J.J., and Gibberd, H. (1999) Azoxystrobin: Residue Levels in Citrus from Trials Conducted in South Africa during 1998: Lab Project Number: 98JH016: Report Number: RJ2811B. Unpublished study prepared by Zeneca Agrochemicals. 46 p.

44915220 Sapiets, A. and Mansfield, R.I. (1997) Azoxystrobin: Residue Levels in Lemons from Trials Conducted in South Africa during 1995-96: Lab Project Number: 95JH178: Report Number: RJ2215B. Unpublished study prepared by Zeneca Agrochemicals. 51 p.

44915222 Sapiets, A. and Mansfield, R.I. (1997) Azoxystrobin: Residue Levels in Oranges from Trials Conducted in South Africa during 1995-96: Lab Project Number: 95JH179: Report Number: RJ2216B. Unpublished study prepared by Zeneca Agrochemicals. 40 p.

44915227 Sapiets, A. and Lubbe, G.J.J. (1999) Azoxystrobin: Residue Levels in Citrus from Trials Conducted in South Africa during 1997-1998: Lab Project Number: 97JH289: Report Number: RJ2768B. Unpublished study prepared by Zeneca Agrochemicals. 41 p.

Eight field trials on oranges (4 trials) and mandarins (4 trials) were conducted during the 1998 growing season in South Africa. Mature citrus fruits were harvested on the day of the last of six broadcast foliar applications of a 250 g ai/L (2.08 lbs ai/gal) suspension concentrate formulation at ~300 g ai/ha/application (0.27 lb ai/A/application), made at 6- to 7-day retreatment intervals. The first application was made at 75-77 BBCH growth rate (mandarins) or when 10-70% ripe (oranges). The total seasonal application rates were 1.6 lbs ai/A. Applications were made using ground equipment (orchard sprayer) in 6.0-27.5 L/tree with crop oil (0.5%) added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

Two field trials on oranges were conducted during the 1995-1996 growing season in South Africa. Two separate plots were treated at each trial site. Mature oranges were harvested 94 days following the last of four broadcast foliar applications of a 250 g ai/L suspension concentrate formulation at

~20 g ai/hL/application (0.002 lb ai/gal/ application) or 40 g ai/hL/application (0.004 lb ai/gal/application), made at 16- to 39-day retreatment intervals. The petitioner did not provide a per-hectare or per-acre rate for these field trials. The low and high treatment levels at one site were inadvertently switched; all other treatments were conducted at the proper rate. Applications were made using ground equipment (orchard sprayer) until run-off in 3-22 L/tree with mineral oil (0.5%) added to the spray volume; the water was buffered with Kynobuff at 100 mL/100 L of water. A separate plot at each trial site was left untreated to provide control samples. Separate orange samples were collected from each plot for juicing. Juicing was performed on site on the day of harvest using a domestic juicing machine.

Two field trials on oranges (1 trial) and grapefruit (1 trial) were conducted during the 1997-1998 growing season in South Africa. Two separate plots were treated at each trial site. Mature citrus fruits were harvested 90 days following the last of two broadcast foliar applications of a 250 g ai/L suspension concentrate formulation at ~5 g ai/hL/application (0.0004 lb ai/gal/application) or 7.5 g ai/hL/application (0.001 lb ai/gal/application), made at 40- to 61-day retreatment intervals. The petitioner did not provide a per-hectare or per-acre rate for these field trials. Applications were made using ground equipment (orchard sprayer) until run-off in 13-24 L/tree with mineral oil (0.5%) added to the spray volume; the water was buffered with Curabuff at 1 mL/L of water. A separate plot at each trial site was left untreated to provide control samples.

Two field trials on lemons were conducted during the 1995-1996 growing season in South Africa. Lemons were harvested 0, 7, 14, 21, 28, and 35 days, and at harvest (11 weeks) following the last of six broadcast foliar applications of a 250 g ai/L suspension concentrate formulation at ~20 g ai/hL/application (0.002 lb ai/gal/application) or 40 g ai/hL/application (0.004 lb ai/gal/application), made at 17- to 38-day retreatment intervals. The petitioner did not provide a per-hectare or per-acre rate for these field trials. Applications were made using ground equipment (orchard sprayer) until run-off in 10-19 L/tree with mineral oil (0.5%) added to the spray volume; the water was buffered with Kynobuff at 100 mL/100 L of water. A separate plot at each trial site was left untreated to provide control samples. Separate samples at the two commercial picking intervals (14 and 77 days following treatment) were collected for juicing. Juicing was performed on site on the day of harvest using a domestic juicing machine.

At all test sites, untreated and treated samples were collected by hand, bagged, labeled, and frozen within 5 hours of harvest. When juice samples were taken, these were frozen within 4 hours of harvest. Samples were either transported frozen directly to the Dietary Exposure Section, Jealott's Hill Research Station (Berkshire, England) for analysis, or to the Zeneca Head Office in Johannesburg and then onto Jealott's Hill Research Station. Total storage intervals from harvest to analysis were 52-261 days (1.7-8.6 months).

Samples of citrus fruits were separated into peel and flesh, and homogenized with dry ice. Samples of citrus fruits were analyzed for residues of azoxystrobin and its Z isomer using GC/TSD (nitrogen mode) method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte in all matrices, except lemon and orange peel which had a method LOQ of 0.02 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the respective LOQ in/on four samples each of untreated orange and mandarin flesh; two samples each of untreated orange flesh, peel, and juice; one sample each of untreated orange and grapefruit flesh and peel; fourteen samples of untreated lemon flesh; twelve samples of untreated lemon peel; and four samples of untreated lemon juice. Detectable residues of azoxystrobin were observed in/on the following untreated samples: orange peel (4 samples) at 0.02-0.04 ppm with residues of the Z isomer non-detectable (<0.01 ppm); mandarin peel (4 samples) at 0.01-0.05 ppm with residues of the Z isomer <0.01-0.01 ppm; and lemon peel (2 samples) at 0.02-0.05 ppm with residues of the Z isomer non-detectable (<0.02 ppm). Residues of azoxystrobin and its Z isomer in/on treated samples are presented in Table 11.

Table 11. Residues of azoxystrobin and its Z isomer in/on **citrus fruits (grapefruit, lemons, mandarins, and oranges)** grown in South Africa and harvested following two to six applications of the 250 g ai/L suspension concentrate formulation

South African Town, Region (MRID)	No. of apps. x single app. rate, ai	PHI, days	Matrix	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Grapefruit						
Malelane, Mpumalanga (44915227)	2 x 5 g/hL	90	Flesh	<0.01	<0.01	<0.02
			Peel	0.32	0.03	0.35
			Whole	--	--	0.09
	2 x 7.5 g/hL	90	Flesh	<0.01	<0.01	<0.02
			Peel	0.41	0.04	0.45
			Whole	--	--	0.11
Mandarin						
Marikana, North Providence (44915219)	6 x 0.27 lb/A	0	Flesh	0.15	<0.01	<0.16
			Peel	9.5	0.68	10.18
			Whole [b]	2.6	0.18	2.78
		0	Flesh	0.10	<0.01	<0.11
			Peel	5.7	0.34	6.04
			Whole [b]	2.3	0.13	2.43
		0	Flesh	0.18	<0.01	<0.19
			Peel	7.2	0.45	7.65
			Whole [b]	2.4	0.14	2.54
		0	Flesh	0.11	<0.01	<0.12
			Peel	5.5	0.33	5.83
			Whole [b]	1.7	0.10	1.80
Lemons						
Karino, Mpumalanga (44915220)	6 x 20 g ai/hL	0	Flesh	0.17	0.01	0.18
			Peel	3.2 [c]	0.24	3.44
			Whole	--	--	1.3
		7	Flesh	0.08	0.01	0.09
			Peel	3.0 [c]	0.23	3.23
			Whole	--	--	1.2
		14	Flesh	0.09	<0.01	<0.10
			Peel	3.0 [c]	0.30	3.30
			Juice	0.04	<0.01	<0.05
			Whole	--	--	1.0

(continued; footnotes follow)

Table 11 (*continued*).

South African Town, Region (MRID)	No. of apps. x single app. rate, ai	PHI, days	Matrix	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Lemons (continued)						
Karino, Mpumalanga (44915220)	6 x 20 g ai/hL	21	Flesh	0.19	0.02	0.21
			Peel	2.8	0.27	3.07
			Whole	--	--	1.1
		28	Flesh	0.21 [c]	0.01	0.22
			Peel	2.9	0.30	3.20
			Whole	--	--	0.98
		35	Flesh	0.21	0.01	0.22
			Peel	2.9	0.34	3.24
			Whole	--	--	1.0
		77	Flesh	0.04	0.01	0.05
			Peel	1.4	0.17	1.57
			Juice	0.03	<0.01	<0.04
			Whole	--	--	0.59
Karino, Mpumalanga (44915220)	6 x 40 g ai/hL	0	Flesh	0.66	0.02	0.68
			Peel	5.7 [c]	0.36	6.06
			Whole	--	--	2.4
		7	Flesh	0.14	0.01	0.15
			Peel	5.5 [c]	0.47	5.97
			Whole	--	--	1.9
		14	Flesh	0.36	0.02	0.38
			Peel	5.7	0.58	6.28
			Juice	0.09	<0.01	<0.10
			Whole	--	--	2.0
		21	Flesh	0.52	0.04	0.56
			Peel	5.8	0.67	6.47
			Whole	--	--	2.2
		28	Flesh	0.29	0.02	0.31
			Peel	5.3	0.56	5.86
			Whole	--	--	1.8
		35	Flesh	0.42	0.03	0.45
			Peel	6.2	0.69	6.89
			Whole	--	--	2.2

(continued; footnotes follow)

Table 11 (*continued*).

South African Town, Region (MRID)	No. of apps. x single app. rate, ai	PHI, days	Matrix	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Lemons (continued)						
Karino, Mpumalanga (44915220)	6 x 40 g ai/hL	77	Flesh	0.12	0.01	0.13
			Peel	2.4	0.25	2.65
			Juice	0.11	<0.01	<0.12
			Whole	--	--	1.1
Hazyview, Mpumalanga (44915220)	6 x 20 g ai/hL	0	Flesh	0.26	0.01	0.27
			Peel	4.4	0.40	4.80
			Whole	--	--	1.6
		7	Flesh	0.23	0.01	0.24
			Peel	3.7	0.18	3.88
			Whole	--	--	1.5
		14	Flesh	0.15	0.01	0.16
			Peel	3.4	0.23	3.63
			Juice	0.02	<0.01	<0.03
			Whole	--	--	1.3
		21	Flesh	0.11	0.01	0.12
			Peel	2.7 [c]	0.24	2.94
			Whole	--	--	0.95
		28	Flesh	0.12	<0.01	<0.13
			Peel	3.6 [c]	0.28	3.88
			Whole	--	--	1.1
		35	Flesh	0.09	<0.01	<0.10
			Peel	3.1	0.20	3.30
			Whole	--	--	1.0
		77	Flesh	0.03	0.01	0.04
			Peel	0.84	0.06	0.90
			Juice	0.13	0.01	0.14
			Whole	--	--	0.32
Hazyview, Mpumalanga (44915220)	6 x 40 g ai/hL	0	Flesh	0.41	0.02	0.43
			Peel	6.4	0.26	6.66
			Whole	--	–	2.5

(continued; footnotes follow)

Table 11 (*continued*).

South African Town, Region (MRID)	No. of apps. x single app. rate, ai	PHI, days	Matrix	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Lemons (continued)						
Hazyview, Mpumalanga (44915220)	6 x 40 g ai/hL	7	Flesh	0.39	0.01	0.40
			Peel	5.9	0.24	6.14
			Whole	--	--	2.3
		14	Flesh	0.49	0.02	0.51
			Peel	7.6 [c]	0.48	8.08
			Juice	0.06	<0.01	<0.07
			Whole	--	--	2.7
		21	Flesh	0.35	0.02	0.37
			Peel	4.8	0.28	5.08
			Whole	--	--	1.9
		28	Flesh	0.22	<0.01	<0.23
			Peel	6.1	0.29	6.39
			Whole	--	--	1.9
		35	Flesh	0.25	0.01	0.26
			Peel	5.0	0.30	5.30
			Whole	--	--	1.6
		77	Flesh	0.09	<0.01	<0.10
			Peel	1.5	0.11	1.61
			Juice	0.14	0.01	0.15
			Whole	--	--	0.65
Oranges						
Mataffin, Mpumalanga (44915219)	6 x 0.27 lb/A	0	Flesh	0.10	<0.01	<0.11
			Peel	2.7	0.21	2.91
			Whole [b]	0.86	0.06	0.92
Barberton, Mpumalanga (44915219)	6 x 0.27 lb/A	0	Flesh	0.15	<0.01	<0.16
			Peel	4.5	0.38	4.88
			Whole [b]	1.3	0.10	1.40
Schagen, Mpumalanga (44915219)	6 x 0.27 lb/A	0	Flesh	0.17	<0.01	<0.18
			Peel	4.3	0.32	4.62
			Whole [b]	1.2	0.08	1.28

(continued; footnotes follow)

Table 11 (*continued*).

South African Town, Region (MRID)	No. of apps. x single app. rate, ai	PHI, days	Matrix	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Oranges (continued)						
Nelspruit, Mpumalanga (44915219)	6 x 0.27 lb/A	0	Flesh	0.19	<0.01	<0.20
			Peel	3.2	0.21	3.41
			Whole [b]	0.92	0.05	0.97
Nelspruit, Mpumalanga (44915222)	4 x 20 g/hL	94	Flesh	<0.01	<0.01	<0.02
			Peel	1.6	0.16	1.76
			Juice	<0.01	<0.01	<0.02
			Whole	--	--	0.43
	4 x 40 g/hL	94	Flesh	0.03	<0.01	<0.04
			Peel	2.9	0.30	3.20
			Juice	<0.01	<0.01	<0.02
			Whole	--	--	0.83
Hazyview, Mpumalanga (44915222)	4 x 20 g/hL	94	Flesh	0.02	<0.01	<0.03
			Peel	1.9	0.13	2.03
			Juice	<0.01	<0.01	<0.02
			Whole	--	--	0.57
	4 x 40 g/hL	94	Flesh	0.04	<0.01	<0.05
			Peel	3.1	0.22	3.32
			Juice	<0.01	<0.01	<0.02
			Whole	--	--	0.87
Nelspruit, Mpumalanga (44915227)	2 x 5 g/hL	90	Flesh	<0.01	<0.01	<0.02
			Peel	0.49	0.04	0.53
			Whole	--	--	0.13
	2 x 7.5 g/hL	90	Flesh	<0.01	<0.01	<0.02
			Peel	0.96	0.09	1.05
			Whole	--	--	0.23

[a] Total residues were calculated by the study reviewer, except for whole fruit total residues which were reported by the petitioner.

[b] Whole residues were calculated by the petitioner using weight ratios of the flesh and peel.

[c] Reported residue is the highest of replicate analyses of a single sample.

Study summary:

Combined residues of azoxystrobin and its Z isomer in citrus samples from field trials conducted in South Africa were: (I) 0.09 and 0.11 ppm in/on grapefruits harvested 90 days following the last of two foliar applications of the 250 g ai/L suspension concentrate formulation at 5 g ai/hL/application or 7.5 g ai/hL/application,respectively; (ii) 1.8-2.8 ppm in/on mandarins harvested 0 days following the last of six foliar applications of the 250 g ai/L suspension concentrate formulation at 0.27 lb ai/A/application; (iii) 1.3-1.6, 1.2-1.5, 1.0-1.3, 0.95-1.1, 1.0-1.1, 1.0, and 0.32-0.59 ppm in/on lemons harvested 0, 7, 14, 21, 28, 35, and 77 days, respectively, following the last of six foliar applications of the 250 g ai/L suspension concentrate formulation at 20 g ai/hL/application; (iv) 2.4-2.5, 1.9-2.3, 2.0-2.7, 1.9-2.2, 1.8-1.9, 1.6-2.2, and 0.65-1.1 ppm in/on lemons harvested 0, 7, 14, 21, 28, 35, and 77 days, respectively following the last of six foliar applications of the 250 g ai/L suspension concentrate formulation at 40 g ai/hL/application; (v) 0.9-1.4 ppm in/on oranges harvested 0 days following the last of six foliar applications of the 250 g ai/L suspension concentrate formulation at 0.27 lb ai/A/application; (vi) 0.43-0.57 ppm and 0.83-0.87 ppm in/on oranges harvested 94 days following the last of four foliar applications of the 250 g ai/L suspension concentrate formulation at 20 g ai/hL/application or 40 g ai/hL/application, respectively; and (vii) 0.13 ppm and 0.23 ppm in/on oranges harvested 90 days following the last of two foliar applications of the 250 g ai/L suspension concentrate formulation at 5 g ai/hL/application or 7.5 g ai/hL/ application, respectively. Residues in juice were determined in some of the field trials; in all cases, residues in juice were less than residues in whole fruit.

Comments:

The citrus data from South Africa indicate that residues have the potential to be higher in citrus grown in South Africa. However, the petitioner did not include any information describing the proposed or registered uses of azoxystrobin on citrus in South Africa, or the proposed or registered uses of azoxystrobin on citrus in any other foreign country. The Agency is currently developing guidance on the requirements for residue data representing foreign uses when domestic uses are being requested and has recently provided guidance on the data requirements for import tolerances (65 FR 35069, 6/1/2000). This guidance includes import data for oranges and orange juice indicating that South Africa is a minor (<1%) source of imported citrus.

The submitted data from South Africa are insufficient to support a tolerance which would also include use on imported citrus. If the petitioner wants a citrus fruits tolerance high enough to cover imported citrus, then the petitioner should provide additional information describing the countries in which azoxystrobin is intended for use on citrus to be imported to the U.S. and the intended use patterns in those countries. Because the data from South Africa indicate the potential for higher residues in imported citrus, additional field trial data from countries which represent the major importing regions for citrus (including juice) would also need to be submitted. Those data should reflect the maximum intended use patterns in those countries. At the time such data are submitted, an appropriate tolerance level for citrus fruits (to include use on imported citrus fruits) should also be proposed.

Barley

Zeneca did not submit any barley field trial data to support the establishment of proposed tolerances for residues of azoxystrobin in/on barley grain, hay, and straw at 0.1, 15.0, and 4.0 ppm, respectively. IR-4 had previously requested that the Agency establish tolerances on barley based on the petitioner's wheat data (DP Barcode D254140, 3/17/99, G. Herndon). Due to the similarities in wheat and barley (especially from a residue standpoint), the fact that wheat production and consumption is much higher than barley, and wheat has more processed commodities, RAB2 concurred with the IR-4 proposal. Based on the available wheat field trial data (DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney), RAB2 concluded that it would be appropriate for IR-4 to request tolerances of 0.1 ppm on barley grain, 15.0 ppm on barley hay, and 4.0 ppm on barley straw, provided the use patterns on wheat and barley were the same, which they are.

Cilantro (a.k.a. Coriander)

Zeneca did not submit any cilantro field trial data to support the establishment of the proposed tolerance for residues of azoxystrobin in/on cilantro at 30.0 ppm. The petitioner included the proposed use pattern for cilantro under the Leafy Vegetables (except *Brassica* Vegetables) section of the specimen labels for the 50% WDG and 2.08 lbs ai/gal FlC formulations. Currently, cilantro [coriander, Chinese parsley (leaf)] is a member of the herbs and spices crop group, and specifically the herb subgroup. The Agency has recently proposed that 40 CFR §180.1(h) be modified, allowing a tolerance for parsley, a commodity of the leafy vegetables (except Brassica) crop group, to cover residues in cilantro because the two plants have very similar structures (DP Barcode D229372, 1/10/2000, B. Schneider). Since the two RACs are so structurally similar, the use pattern is the same, and a change in the parsley commodity definition is in process, RAB2 is translating the leafy vegetable residue data to cilantro. **The petitioner should submit a revised Section F in which the 30.0 ppm tolerance is proposed in terms of "Coriander, leaves". The petitioner should also submit suitably revised WDG and FlC labels.**

Field Corn

Zeneca submitted field corn field trial data (citation listed below) to support the establishment of proposed tolerances for residues of azoxystrobin in/on corn grain and corn kernel (sweet) each at 0.05 ppm, corn forage at 10.0 ppm, and corn stover at 25.0 ppm.

> 44915215 Aston, J.C. and Lipton, C. (1999) Azoxystrobin: Residue Levels on Field Corn from Trials Conducted in the United States during 1998: Lab Project Number: AZOX-98-MR-13: Report Number: RR 99-050B. Unpublished study prepared by Zeneca Ag Products. 150 p.

Twenty field trials were conducted during the 1998 growing season in FL(1), IA(3), IL(3), IN(2), MN(2), MO(1), NC(1), NE(2), NY(1), OH(1), TX(1), WA(1), and WI(1). Six trials were planted with corn seed treated with a 250 g ai/L (2.08 lbs ai/gal) soluble concentrate formulation at 43 ppm azoxystrobin (0.26 fl. oz/cwt); the remaining 14 trials were planted with untreated seed. Mature field corn grain and stover were harvested 6-7 days following the last of eight broadcast foliar

applications of the 80% WDG formulation at 0.25 lb ai/A/application, made at 2- to 64-day retreatment intervals. The total seasonal application rates were 2.0 lbs ai/A (1x the maximum proposed seasonal application rate). Samples of field corn forage and kernel plus cob with husks removed (K+CWHR) were harvested 6-7 days following the sixth application (prior to milk stage); total seasonal application rates for corn forage and corn (K+CWHR) were 1.5 lbs ai/A (0.75x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized handheld boom or tractor-mounted broadcast boom sprayer) in 12-20 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume.

In addition, two trials conducted in IA and IL had a second treatment plot used to generate field corn grain for processing. Mature field corn grain was harvested 6 days following the last of eight broadcast foliar applications of the 80% WDG formulation at 1.25 lbs ai/A/application (5x the maximum proposed seasonal application rate). The IA trial was conducted as a back-up trial to provide samples for processing. This trial was canceled after sufficient samples were obtained from the primary trial in IL. Details of the field corn processing study are discussed under the "Processed Food/Feed" section of this review.

A single untreated sample and duplicate treated samples of field corn (K+CWHR) and forage were collected manually at the milk stage from each test site. A single untreated sample and duplicate treated samples of field corn stover and grain were collected at maturity from each test site. Field corn stover samples were harvested manually, while field corn grain samples were harvested either manually or mechanically (combine, thresher, or power sheller). The collected samples were then bagged, labeled, and frozen (within 2.5 hours) at -15° C, with the exception of field corn stover samples from one IA trial site. These samples were damp from a light rain so they were first dried overnight by forced air and frozen 19.2 hours after cutting. All samples were shipped by ACDS freezer truck to WRC (Richmond, CA) for analysis. Total storage intervals of all field corn samples from harvest to analysis were 55-338 days (1.8-11.1 months).

In addition, bulk grain samples were collected from the IL trial site, frozen, and shipped by ACDS freezer truck to the Texas A&M University, Food Protein Research and Development Center (Bryan, TX) for the generation of aspirated grain fractions (AGF). Processing was completed within 61 days of harvest. The AGF collection procedures simulated commercial techniques except that AGF were produced in batches rather than continuously. Briefly, grain was dried in an oven to 10-13% moisture, then circulated through a dust-generating room consisting of a bucket conveyor, drag conveyors, and holding bins for 120 minutes. During this interval, dust and debris (AGF) were collected using a filtration system. A subsample of the clean grain was taken from each sample after the aspiration was complete. The AGF was separated by a sieving process into six fractions based on particle size using >2540-µm, 2030- to 2540-µm, 1180- to 2030-µm, 850- to 1180-µm, and 425- to 850-µm, and <425-µm mesh screens. Samples were frozen within 3 hours of generation. Cleaned grain and AGF samples were shipped frozen to WRC for analysis. Aspirated grain fractions, excluding the >2540-µm fraction, were combined at WRC to represent aspirated grain fractions used in commercial feed production and/or feeding practices. Total storage intervals of field corn samples for generation of AGF from harvest to analysis were 209-249 days (6.9-8.2 months).

Samples of field corn (K+CWHR), forage, stover, grain, and composited AGF were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on 20 samples each of untreated field corn grain and stover and 19 samples each of untreated field corn (K+CWHR) and forage. Detectable azoxystrobin residues were found in one sample of untreated field corn (K+CWHR) at 0.02 ppm and one sample of field corn forage at 0.06 ppm; in these samples, Z isomer residues were less than the LOQ. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on one sample each of untreated field corn grain and field corn cleaned grain. Detectable residues of azoxystrobin and its Z isomer were each found in one sample of untreated field corn AGF at 0.02 ppm. Residues of azoxystrobin and its Z isomer in/on treated corn samples are presented in Table 12 and residues in/on treated aspirated grain fractions are presented in Table 13.

Table 12. Residues of azoxystrobin and its Z isomer in/on **field corn (K+CWHR, forage, stover, and grain)** harvested 6-7 days following six or eight applications of the 80% WDG formulation at 0.25 lb ai/A/application (0.75-1x the maximum proposed seasonal rate).

Test Site (Region)	PHI, days	No. of apps	Total application rate, ai	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Corn, field (K+CWHR)						
North Rose, NY (Region 1)	7	6	1.5 lb/A	<0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Whitaker, NC (Region 2)	6	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Oviedo, FL (Region 3)	7	6	1.5 lb/A	<0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Webster City, IA (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Richland, IA (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Champaign, IL (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Carlyle, IL [b] (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Wyoming, IL [b] (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Noblesville, IN (Region 5)	6	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Sheridan, IN (Region 5)	6	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Holladale, MN [b] (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02

(continued; footnotes follow)

Test Site (Region)	PHI, days	No. of apps	Total application rate, ai	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Campbell, MN (Region 5)	6	6	1.5 lb/A	<0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Leonard, MO [b] (Region 5)	6	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Crofton, NE (Region 5)	6	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
York, NE (Region 5)	6	6	1.5 lb/A	<0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Albia, IA (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
New Holland, OH [b] (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Delavan, WI [b] (Region 5)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
East Bernard, TX (Region 6)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Walla Walla, WA (Region 11)	7	6	1.5 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Corn, field, forage						
North Rose, NY (Region 1)	7	6	1.5 lb/A	0.78, 0.83	0.05, 0.05	0.83, 0.88
Whitaker, NC (Region 2)	6	6	1.5 lb/A	1.2, 1.2	0.08, 0.08	1.28, 1.28
Oviedo, FL (Region 3)	7	6	1.5 lb/A	2.0, 3.6	0.15, 0.26	2.15, 3.86
Webster City, IA (Region 5)	7	6	1.5 lb/A	0.88, 1.1	0.04, 0.05	0.92, 1.15
Richland, IA (Region 5)	7	6	1.5 lb/A	0.66, 0.94	0.03, 0.04	0.69, 0.98
Champaign, IL (Region 5)	7	6	1.5 lb/A	0.95, 1.7	0.07, 0.12	1.02, 1.82
Carlyle, IL [b] (Region 5)	7	6	1.5 lb/A	0.56, 0.58	0.01, 0.02	0.57, 0.60
Wyoming, IL [b] (Region 5)	7	6	1.5 lb/A	0.46, 1.2	0.02, 0.07	0.48, 1.27
Noblesville, IN (Region 5)	6	6	1.5 lb/A	1.6, 2.8	0.09, 0.15	1.69, 2.95
Sheridan, IN (Region 5)	6	6	1.5 lb/A	3.5, 3.8	0.19, 0.22	3.69, 4.02

(continued; footnotes follow)

Test Site (Region)	PHI, days	No. of apps	Total application rate, ai	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Holladale, MN [b] (Region 5)	7	6	1.5 lb/A	0.13, 0.49	<0.01, 0.03	<0.14, 0.52
Campbell, MN (Region 5)	6	6	1.5 lb/A	2.2, 2.8	0.14, 0.18	2.34, 2.98
Leonard, MO [b] (Region 5)	6	6	1.5 lb/A	0.74, 1.5	0.03, 0.08	0.77, 1.58
Crofton, NE (Region 5)	6	6	1.5 lb/A	1.8, 2.4	0.06, 0.09	1.86, 2.49
York, NE (Region 5)	6	6	1.5 lb/A	1.5, 2.8	<0.01, <0.01	<1.51, <2.81
Albia, IA (Region 5)	7	6	1.5 lb/A	0.61, 0.65	<0.01, <0.01	<0.62, <0.66
New Holland, OH [b] (Region 5)	7	6	1.5 lb/A	2.5, 2.7	0.17, 0.19	2.67, 2.89
Delavan, WI [b] (Region 5)	7	6	1.5 lb/A	0.67, 1.1 [c]	0.03, 0.04	0.70, 1.14
East Bernard, TX (Region 6)	7	6	1.5 lb/A	2.8, 2.9	0.06, 0.08	2.86, 2.98
Walla Walla, WA (Region 11)	7	6	1.5 lb/A	1.7, 7.2	<0.01, 0.04 [c]	<1.71, 7.24
Corn, field, stover						
North Rose, NY (Region 1)	6	8	2.0 lb/A	4.8, 9.3	0.14, 0.25	4.94, 9.55
Whitaker, NC (Region 2)	6	8	2.0 lb/A	1.8, 5.2	0.08, 0.27	1.88, 5.47
Oviedo, FL (Region 3)	6	8	2.0 lb/A	7.2, 7.8	0.51, 0.53	7.71, 8.33
Webster City, IA (Region 5)	6	8	2.0 lb/A	1.9, 2.6	0.05, 0.08	1.95, 2.68
Richland, IA (Region 5)	6	8	2.0 lb/A	4.1, 4.4	0.13, 0.14	4.23, 4.54
Champaign, IL (Region 5)	6	8	2.0 lb/A	2.7, 3.2	0.16, 0.15	2.86, 3.35
Carlyle, IL [b] (Region 5)	6	8	2.0 lb/A	6.1, 8.7	0.22, 0.36	6.32, 9.06
Wyoming, IL [b] (Region 5)	7	8	2.0 lb/A	3.0, 4.0	0.10, 0.13	3.10, 4.13
Noblesville, IN (Region 5)	7	8	2.0 lb/A	4.4, 4.7	0.22, 0.23	4.62, 4.93

(continued; footnotes follow)

Test Site (Region)	PHI, days	No. of apps	Total application rate, ai	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Sheridan, IN (Region 5)	6	8	2.0 lb/A	2.4, 2.5	0.08, 0.08	2.48, 2.58
Holladale, MN [b] (Region 5)	7	8	2.0 lb/A	0.95, 1.1	0.02, 0.02	0.97, 1.12
Campbell, MN (Region 5)	7	8	2.0 lb/A	2.5, 2.6	0.11, 0.11	2.61, 2.71
Leonard, MO [b] (Region 5)	6	8	2.0 lb/A	2.9, 3.1	0.14, 0.13	3.04, 3.23
Crofton, NE (Region 5)	6	8	2.0 lb/A	2.6, 2.9	0.06, 0.07	2.66, 2.97
York, NE (Region 5)	7	8	2.0 lb/A	8.4, 16	0.70, 1.0	9.1, 17
Albia, IA (Region 5)	7	8	2.0 lb/A	0.85, 0.88	0.05, 0.04	0.90, 0.92
New Holland, OH [b] (Region 5)	7	8	2.0 lb/A	5.8, 8.7	0.16, 0.30	5.96, 9.0
Delavan, WI [b] (Region 5)	6	8	2.0 lb/A	3.7 [c], 5.3	0.09, 0.11	3.79, 5.41
East Bernard, TX (Region 6)	7	8	2.0 lb/A	20, 21	1.6, 1.8	21.6, 22.8
Walla Walla, WA (Region 11)	7	8	2.0 lb/A	1.8 [c], 3.5	0.03, 0.11	1.83, 3.61
Corn, field, grain						
North Rose, NY (Region 1)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Whitaker, NC (Region 2)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Oviedo, FL (Region 3)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Webster City, IA (Region 5)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Richland, IA (Region 5)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Champaign, IL (Region 5)	6	8	2.0 lb/A	0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Carlyle, IL [b] (Region 5)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Wyoming, IL [b] (Region 5)	7	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02

(continued; footnotes follow)

Test Site (Region)	PHI, days	No. of apps	Total application rate, ai	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Noblesville, IN (Region 5)	7	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Sheridan, IN (Region 5)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Holladale, MN [b] (Region 5)	7	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Campbell, MN (Region 5)	7	8	2.0 lb/A	0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Leonard, MO [b] (Region 5)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Crofton, NE (Region 5)	6	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
York, NE (Region 5)	7	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Albia, IA (Region 5)	7	8	2.0 lb/A	0.01, 0.02	<0.01, <0.01	<0.02, <0.03 HAFT=<0.03
New Holland, OH [b] (Region 5)	7	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Delavan, WI [b] (Region 5)	6	8	2.0 lb/A	<0.01, <0.01 [b]	<0.01, <0.01	<0.02, <0.02
East Bernard, TX (Region 6)	7	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Walla Walla, WA (Region 11)	7	8	2.0 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02

[a] Total residues were calculated by the study reviewer.
[b] Seeds were commercially treated with azoxystrobin prior to planting.
[c] Reported residue is the highest of replicate analyses of a single sample.

Table 13. Residues of azoxystrobin and its Z isomer in/on **field corn grain and aspirated grain fractions** treated with the 80% WDG formulation at 1x the maximum application and seasonal rate.

Field Corn Matrix	Residues, ppm			Concentration Factor [b]
	Azoxystrobin	Z isomer	Total [a]	
Grain prior to aspiration (RAC)	0.01, 0.01, 0.02 [c]	<0.01, <0.01, <0.01	<0.02, <0.02, <0.03	--
Grain (cleaned)	0.01, 0.02, 0.02	<0.01, <0.01, <0.01	<0.02, <0.03, <0.03	--
Aspirated grain fractions	1.8, 2.1, 2.3 [c]	0.07, 0.08, 0.09	1.87, 2.18, 2.39	94x, 109x, 120x

[a] Total residues were calculated by the study reviewer.
[b] Concentration factors were calculated for the total residues using the mean residue value (<0.02 ppm) of corn, field, grain RAC samples prior to aspiration.
[c] Reported residue is the highest of replicate analyses of a single sample.

Comments:

Geographic representation of field corn data is adequate for the purposes of this petition. The Agency (Table 5 of OPPTS 860.1500) requires a total of 20 trials for the establishment of a tolerance on field corn in Regions 1 (1 trial), 2 (1 trial), 5 (17 trials), and 6 (1 trial). Twenty field corn field trials were conducted in Regions 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (15 trials), 6 (1 trial), and 11 (1 trial). Although the petitioner did not conduct the full number of trials (17) in Region 5, no additional field trial data will be required as 15 field trials were conducted in that region. The petitioner indicated that the field corn field trial data should also support a sweet corn registration. According to Table 1 of OPPTS 860.1000, residue data on early sampled field corn will suffice to provide residue data on sweet corn, provided the residue data are generated at the milk stage on K+CWHR and there are adequate numbers of trials and geographic representation from the sweet corn growing regions. The Agency (Table 5 of OPPTS 860.1500) requires a total of 9 trials for the establishment of a tolerance on sweet corn in Regions 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (3 trials), 10 (1 trial), 11 (1 trial), and 12 (1 trial); a reduced number of trials are required as residues were below the LOQ in all sweet corn (K+CWHR) samples. Although there is some variance from this guidance in the geographic location of the field trials provided, since 20 field corn trials are used to support the proposed sweet corn tolerances, we consider that the geographic representation for sweet corn will suffice for purposes of this petition.

The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on field corn grain and stover. The results of the field trials indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance level of 0.05 ppm in/on field corn grain harvested 6 or 7 days following the last of eight broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application. The total seasonal application rate was 2.0 lbs ai/A (1x the maximum proposed seasonal application rate). The combined residues of azoxystrobin and its Z isomer were <0.02 to <0.03 ppm in/on 40 samples of field corn grain.

The data indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance level of 25 ppm in/on field corn stover harvested 6 or 7 days following the last of eight broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application. The total seasonal application rate was 2.0 lbs ai/A (1x the maximum proposed seasonal application rate). The combined residues of azoxystrobin and its Z isomer were 0.90-22.8 ppm in/on 40 samples of field corn stover.

As allowed by the EPA Residue Chemistry Test Guidelines, OPPTS 860.1000, Table 1, Footnote 27, samples of field corn kernels + cob with husks removed (K +CWHR) were harvested at the milk stage and used as a substitute for sweet corn kernels. The data indicate that the combined residues of azoxystrobin and its Z isomer did not exceed <0.02 ppm (combined LOQs) in any of the 40 field corn (K + CWHR) samples harvested 6-7 days following the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application. The total seasonal application rate was 1.5 lbs ai/A, which is 0.75x the maximum proposed seasonal application rate. Extrapolating to 1x the maximum proposed seasonal application rate, the combined residues are not expected to exceed the proposed tolerance of 0.05 ppm for sweet corn (K + CWHR).

The data indicate that the combined residues of azoxystrobin and its Z isomer did not exceed 7.2 ppm in/on field corn forage harvested 6-7 days following the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application. The combined residues of azoxystrobin and its Z isomer were <0.14 to 7.2 ppm in/on 40 samples of field corn forage. The total seasonal application rate was 1.5 lbs ai/A, which is 0.75x the maximum proposed seasonal application rate. Extrapolating to 1x the maximum seasonal application rate, the combined residues of azoxystrobin and its Z isomer may closely approach the proposed tolerance level of 10.0 ppm in/on corn forage (field, sweet). **A more appropriate proposed tolerance level for corn forage is 12.0 ppm.**

The combined residues of azoxystrobin and its Z isomer in/on aspirated grain fractions from field corn grain treated at 1x the maximum seasonal application rate were 1.9-2.4 ppm; residues concentrated 94-120x. A tolerance of 10.0 ppm is currently established for aspirated grain fractions [40 CFR §180.507(a)(1)]. Based on the average concentration factor (108x) and the highest average field trial (HAFT) residue for field corn grain (<0.03 ppm), expected residues in aspirated grain fractions are 3.2 ppm, well below the established tolerance.

Six trials were planted with seeds commercially treated with azoxystrobin at 43 ppm. The use of azoxystrobin-treated seeds did not result in higher residues in any field corn commodity.

The petitioner should submit a revised Section F proposing individual tolerances for the combined residues of azoxystrobin and its Z isomer in/on field, pop, and sweet corn commodities, expressed as follows:

Corn, field, grain ..... 0.05 ppm
Corn, pop, grain ..... 0.05 ppm
Corn, sweet (K+CWHR) ..... 0.05 ppm
Corn, field, forage ..... 12.0 ppm
Corn, sweet, forage ..... 12.0 ppm
Corn, field, stover ..... 25.0 ppm
Corn, pop, stover ..... 25.0 ppm
Corn, sweet, stover ..... 25.0 ppm

Cotton

Zeneca submitted a single volume (citation listed below) to support the establishment of a proposed tolerance for residues of azoxystrobin in/on cotton, seed and gin byproducts each at 0.01 ppm.

44915214 Bussey, R.J., Gill, J.P., and Lister, N. (1998) Azoxystrobin: Residue Levels on Cotton from Trials Conducted in the United States in 1997: Lab Project Number: AZOX-97-MR-01: Report Number: RR 98-055B. Unpublished study prepared by Zeneca Ag Products. 74 p.

Twelve field trials were conducted during the 1997 growing season in AR(1), AZ(1), CA(2), NC(1), NM(1), MS(1), OK(1), TN(1), and TX(3). Mature cotton was harvested 121-186 days following a single banded in-furrow application of the 80% WDG formulation at 0.2 oz ai/1000 ft of row at planting (1x the maximum proposed in-furrow application and seasonal rate). Applications were

made using ground equipment (tractor-mounted in-furrow spray applicator hooked to a planter or CO_2 backpack sprayer) in 3.2-10 gal/A. A separate plot at each trial site was left untreated to provide control samples. In addition, two trials conducted in CA and MS had a second treatment plot used to generate cottonseed for processing. Details of the cottonseed processing study are discussed under the "Processed Food/Feed" section of this review.

A single untreated sample and duplicate treated samples of mature cotton were harvested mechanically (spindle picker or cotton stripper) or by hand from each test site. The collected samples were then bagged, labeled, and frozen within 3 hours of harvest, except in one TX field trial where samples were stored at ambient conditions for <1 day before freezing. Samples were shipped by ACDS freezer truck, FedEx, or hand-delivered on dry ice either directly to the Food Protein Research and Development Center, Texas A&M University (Bryan, TX) for ginning or first to WRC (Richmond, CA) and then to Texas A&M for ginning. Cotton samples were ginned using a simulated industrial ginning process within 2 months of harvest. Briefly, samples with >8% moisture were first dried in a tower dryer at 54-82° C. Burrs, sticks, and other plant parts (gin byproducts) were removed from dry cotton using a Mitchell stick extractor. The remaining lint cotton was saw ginned to remove lint. Undelinted seed and gin byproducts were separately packaged, frozen, and shipped frozen by FedEx to WRC. Samples were stored frozen (-18° C) at WRC and shipped frozen by air freight to Zeneca Agrochemicals, Jealott's Hill Research Station (Bracknell, Berkshire, England) for analysis. Total storage intervals from harvest to analysis were 162-284 days (5.3-9.3 months) for undelinted cotton and gin byproducts.

Samples of undelinted cottonseed and cotton gin byproducts were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on twelve samples of untreated undelinted cottonseed and six samples of untreated cotton gin byproducts. Residues of azoxystrobin and its Z isomer were each less than the method LOQ (<0.01 ppm) in/on all treated samples of undelinted cottonseed (24 samples) and cotton gin byproducts (12 samples).

Geographic representation of cottonseed data is adequate for the purposes of this petition. The Agency (Table 5 of OPPTS 860.1500) requires a total of 9 trials for the establishment of a tolerance on cotton; a reduced number of trials is allowed because residues were below the LOQ in all samples. Twelve cottonseed field trials were conducted in Regions 2 (1 trial), 4 (3 trials), 6 (2 trials), 8 (3 trials), and 10 (3 trials). Geographic representation of data for cotton gin byproducts is also adequate. For the establishment of a tolerance on cotton gin byproducts, the Agency (Table 1 of OPPTS 860.1000) requires that at least three field trials for each type of harvest equipment (e.g., stripper and picker) be conducted, for a total of six field trials. Six trials on cottonseed gin byproducts were conducted in Regions 4 (2 trials), 6 (2 trials), 8 (1 trial), and 10 (1 trial), and three trials were harvested using each type of harvest equipment.

Comments:

The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on undelinted cottonseed and cotton gin byproducts. The results of the cotton field trials indicate that residues of azoxystrobin and its Z isomer, individually, will not exceed the proposed tolerance level of 0.01 ppm in/on cotton (ginned for undelinted seed and gin byproducts) harvested 121-186 days following a single banded in-furrow application of the 80% WDG formulation at 0.2 oz ai/1000 ft. of row at planting (1x the maximum proposed seasonal application rate). However, **because the method LOQ is 0.01 ppm for each analyte, the proposed tolerance for the combined residues of azoxystrobin and its Z isomer in/on cotton seed and cotton gin byproducts should be increased to 0.02 ppm. The petitioner should submit a revised Section F proposing a tolerance of 0.02 ppm for "Cotton, undelinted seed" and a tolerance of 0.02 ppm for "Cotton, gin byproducts".**

Peanut

Peanut field trial data were previously evaluated in conjunction with PP#6F4762 (DP Barcodes D230634, D230635, D230636, and D230637, L. Kutney, 4/25/97); the data reflected a proposed use of up to two foliar applications of the 50% WDG formulation to peanut plants at 0.1-0.4 lb ai/A/application for a maximum seasonal application of 0.8 lb ai/A/year. A 50-day PHI was proposed. In the current petition, the petitioner has proposed the same use pattern for peanuts with a shorter PHI of 14 days. Zeneca submitted peanut field trial data (citation listed below) to support the establishment of proposed tolerances for residues of azoxystrobin in/on peanut nutmeat at 0.2 ppm and peanut hay at 15 ppm.

> 44915221 Bussey, R.J. (1999) Azoxystrobin: Residue Levels on Peanuts from Trials Conducted in the United States in 1997: Lab Project Number: AZOX-97-MR-03: Report Number: RR 98-046B. Unpublished study prepared by Zeneca Ag Products. 71 p.

Twelve field trials were conducted during the 1997 growing season in AL(2), FL(1), GA(2), NC(2), SC(1), TX(3), and VA(1). Mature peanuts and peanut plants were harvested 13 or 14 days following the last of two broadcast foliar applications of the 80% WDG formulation at 0.4 lb ai/A/application (one trial in AL received 0.47 lb ai/A/application), made with 10- to 11-day retreatment intervals. The total seasonal application rates were 0.8-0.94 lb ai/A (1-1.2x the maximum proposed seasonal application rate). Applications were made using ground equipment (CO_2-pressurized handheld boom or tractor-mounted boom sprayers) in 8.9-10 gal/A with a spray adjuvant of crop oil concentrate (1%, v:v) added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

Treated and untreated samples of peanuts and peanut plants were dug 8-10 days following the last application (one trial in TX was dug at 3 days), and plants with peanuts were allowed to dry in the field for 4-12 days. Plants were mechanically threshed, and whole peanuts and hay were collected 13 or 14 days after the last application. Five trials experienced wet weather following digging; at

one site in TX, threshing was prevented until 20 days after the last application because of the damp conditions. The collected samples were then bagged, labeled, and frozen (within 4 hours) at -15° C. All samples were shipped by ACDS freezer truck or by FedEx on dry ice to WRC (Richmond, CA). Samples of whole peanuts were separated into hulls and nutmeats using a mechanical peanut sheller prior to transfer to Jealott's Hill Research Station (Bracknell, UK) by air freight for analysis. Total storage intervals of all peanut samples from harvest to analysis were 151-210 days (5.0-6.9 months).

Samples of peanut nutmeats and hay were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQs for azoxystrobin were 0.01 ppm for peanut nutmeat and hay. The reported LOQs for the Z isomer were 0.01 ppm for peanut nutmeat and 0.02 ppm for peanut hay. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on 12 samples of untreated peanut nutmeat and 7 samples of untreated peanut hay. Detectable azoxystrobin residues were found in 5 samples of untreated peanut hay at 0.01-0.04 ppm; in these samples, Z isomer residues were less than the LOQ. Residues of azoxystrobin and its Z isomer in/on treated samples are presented in Table 14.

We note that the petitioner considered the harvest date to be the date peanut RACs were collected from the field after drying. The Agency considers the harvest date to be the date when samples are dug from the field. Therefore, the study reviewer recalculated post-treatment intervals using the dates peanuts were dug from the field.

Table 14. Residues of azoxystrobin and its Z isomer in/on **peanuts (nutmeats and hay)** harvested 3-10 days following two applications of the 80% WDG formulation at 0.4 lb ai/A/application (1x the maximum proposed seasonal rate).

Test Site (Region)	PTI, [a] days	PHI, [b] days	Total application rate, ai	Residues, ppm		
				Azoxystrobin	Z isomer	Total [c]
Peanut nutmeats						
Notasulga, AL (Region 2)	10	14	0.8 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Huntsboro, AL (Region 2)	9	14	0.94 lb/A [d]	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Chula, GA (Region 2)	8	13	0.8 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Girard, GA (Region 2)	8	14	0.8 lb/A	0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Trap, NC (Region 2)	8	14	0.8 lb/A	0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Whitakers, NC (Region 2)	8	14	0.8 lb/A	0.11, 0.13	<0.01, <0.01	<0.12, <0.14 HAFT = <0.13
Elko, SC (Region 2)	8	13	0.8 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Suffolk, VA (Region 2)	8	14	0.8 lb/A	0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Malone, FL (Region 3)	10	14	0.8 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Brookshire, TX (Region 6)	8	20	0.8 lb/A	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02
Yoakum, TX (Region 6)	10	14	0.8 lb/A	0.05, 0.06	<0.01, <0.01	<0.06, <0.07
Flomot, TX (Region 8)	3	14	0.8 lb/A	<0.01, 0.01	<0.01, <0.01	<0.02, <0.02
Peanut hay						
Notasulga, AL (Region 2)	10	14	0.8 lb/A	2.4, 3.1	0.17, 0.25	2.57, 3.35
Huntsboro, AL (Region 2)	9	14	0.94 lb/A [d]	2.4, 3.0	0.25, 0.30	2.65, 3.30
Chula, GA (Region 2)	8	13	0.8 lb/A	8.1, 13	0.62, 0.99	8.72, 13.99
Girard, GA (Region 2)	8	14	0.8 lb/A	2.7, 3.3	0.16, 0.19	2.86, 3.49
Trap, NC (Region 2)	8	14	0.8 lb/A	6.7, 8.3	0.48, 0.59	7.18, 8.89

(continued; footnotes follow)

Table 14 (*continued*).

Test Site (Region)	PTI, [a] days	PHI, [b] days	Total application rate, ai	Residues, ppm		
				Azoxystrobin	Z isomer	Total [c]
Whitakers, NC (Region 2)	8	14	0.8 lb/A	8.6, 9.3	0.46, 0.52	9.06, 9.82
Elko, SC (Region 2)	8	13	0.8 lb/A	3.7, 4.0	0.21, 0.24	3.91, 4.24
Suffolk, VA (Region 2)	8	14	0.8 lb/A	4.3, 4.3	0.24, 0.25	4.54, 4.55
Malone, FL (Region 3)	10	14	0.8 lb/A	1.4, 1.5	0.15, 0.16	1.55, 1.66
Brookshire, TX (Region 6)	8	20	0.8 lb/A	1.1, 1.2	0.13, 0.14	1.23, 1.34
Yoakum, TX (Region 6)	10	14	0.8 lb/A	4.6, 4.7	0.29, 0.27	4.89, 4.97
Flomot, TX (Region 8)	3	14	0.8 lb/A	8.2, 8.9	0.34, 0.44	8.54, 9.34

[a] Post-treatment interval (PTI) represents the interval between the date of the last application and date peanuts were dug from the field.

[b] Postharvest interval (PHI) represents the interval between the date of the last application and date peanuts were collected from the field after drying.

[c] Total residues were calculated by the study reviewer.

[d] Application rate was 0.47 lb ai/A/application instead of the protocol rate of 0.4 lb ai/A/application.

Geographic representation of peanut data is adequate for the purposes of this petition. The Agency (Table 5 of OPPTS 860.1500) requires a total of 12 trials for the establishment of tolerances for peanut commodities in Regions 2 (8 trials), 3 (1 trial), 6 (2 trials), and 8 (1 trial). The number and location of the available field trials is adequate to support the proposed use on peanuts.

Comments:

The submitted peanut field trial data are adequate. The data indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance level of 0.2 ppm in/on peanut nutmeats [the correct nomenclature is "peanut"] harvested (dug) 3-10 days following the last of two foliar applications of the 80% WDG formulation at 0.4-0.47 lb ai/A/application (0.8-0.94 lb ai/A/season; 1.0-1.2x the proposed maximum seasonal rate). The combined residues of azoxystrobin and its Z isomer were <0.02 to <0.14 ppm in/on 24 samples of peanut nutmeats.

The data indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance level of 15 ppm in/on peanut hay harvested (dug) 3-10 days following the last of two foliar applications of the 80% WDG formulation at 0.4-0.47 lb ai/A/application (0.8-0.94 lb ai/A/season; 1.0-1.2x the proposed maximum seasonal rate). The combined residues of azoxystrobin and its Z isomer were 1.2 to 14.0 ppm in/on 24 samples of peanut hay.

Based on the submitted data, the proposed tolerances for peanut nutmeat (0.2 ppm) and peanut hay (15 ppm) are adequate. [Note: Currently, tolerances are established at 0.01 ppm on peanuts and 2.0 ppm on peanut hay.] **The petitioner should submit a revised Section F which increases the established tolerances to 0.2 ppm for "Peanut" and 15.0 ppm for "Peanut, hay".**

Soybean

Zeneca submitted a single volume (citation listed below) to support the establishment of proposed tolerances for residues of azoxystrobin in/on soybean, seed at 0.5 ppm, forage at 25.0 ppm, and hay at 55.0 ppm.

44915209 Bussey, R.J. and Lipton, C. (1999) Azoxystrobin: Residue Levels on Soybean from Trials Conducted in the United States in 1998: Lab Project Number: AZOX-98-MR-14: Report Number: RR 99-049B. Unpublished study prepared by Zeneca Ag Products. 136 p.

Twenty field trials were conducted during the 1998 growing season in AR(1), GA(1), IL(3), IN(2), IA(2), KS(1), LA(1), MN(2), MO(1), MS(1), NC(1), NE(1), OH(1), and SD(2). Six trials were planted with soybean seed treated with a 250 g ai/L (2.08 lbs ai/gal) soluble concentrate formulation at 43-44 ppm azoxystrobin; the remaining trials were planted with untreated seed. Multiple broadcast foliar applications of the 80% WDG formulation were made to soybeans at each trial site at 0.25 lb ai/A/application (1x the maximum proposed application rate) with 1- to 3-week retreatment intervals. Eighteen trials received six applications for a total application rate of 1.5 lbs ai/A (1x the maximum proposed seasonal rate), one trial (SD) received seven applications (first application at 0.15 lb ai/A because of sprayer malfunction) for a total application rate of 1.65 lbs ai/A (1.1x the maximum proposed seasonal rate), and one trial (KS) received only five applications for a total application rate of 1.25 lbs ai/A (0.8x the maximum proposed seasonal rate) because of rapidly maturing soybeans. The first application was made approximately 71 days prior to anticipated harvest of mature seed. Applications were made using ground equipment (tractor-mounted or CO_2 pressurized hand-held sprayer) in 10-20 gal/A of water with 0.125% nonionic surfactant added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

A single untreated and duplicate treated immature forage samples were cut at the R1-R3 growth stage (beginning bloom to podding) following the first or second application (0-day PHI). Forage samples were frozen within 2 hours of cutting; a separate subsample of forage was dried in the field or on racks for 2-7 days to produce hay. Dried hay was bagged and frozen within 0.5 hour of collection. A single untreated sample and duplicate treated samples of mature soybeans were harvested mechanically or by hand from each test site 10-14 days following the last application. Soybean seed samples were frozen within 2 hours of harvest, except in two trials where the seed was wet and required drying for 1-2 days prior to freezing. Bulk soybean grain samples were harvested from the MS trial for the generation of aspirated grain fractions. All samples were frozen (-15° C) at the field until shipment by ACDS freezer truck or FedEx on dry ice to WRC (Richmond, CA). Bulk grain samples for generation of aspirated grain fractions were transported on dry ice by rental truck to the Food Protein Research and Development Center, Texas A&M University (Bryan, TX).

Bulk grain samples were received cold, but unfrozen at Texas A&M; these samples were stored frozen (-12° C) at Texas A&M for 26 days until generation of aspirated grain fractions. The process simulated terminal grain elevators to remove grain dust, but AGF were produced in batches instead of continuously. Briefly, soybeans (12-13% moisture) were placed in a dust generation room with holding bins, and drag and bucket conveyors. The conveyors were operated for 120 minutes with a filtration system which collected dust and debris generated by cleaning the seed. A subsample of cleaned seed was taken upon completion of the aspiration procedure. The aspirated grain fraction was sieved into six fractions based on particle size (>2540 μm, 2030-2540 μm, 1180-2030 μm, 850-1180 μm, 425-850 μm, and <425 μm). Aspirated grain fractions were then separately frozen. Cleaned seed and aspirated grain fractions were shipped by FedEx to WRC. Samples were received cold, but unfrozen because of a 2-day delay by FedEx; however, the integrity of the samples was not considered to have been compromised. Aspirated grain fractions, excluding the >2540 μm fraction, were combined at WRC to represent aspirated grain fractions used in commercial feed production and/or feeding practices. Total storage intervals from harvest to analysis were 146-323 days (4.8-10.6 months) for all soybean samples.

Samples of soybean forage, hay, seed, and aspirated grain fractions were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on 19 samples of untreated soybean seed, 14 samples of untreated soybean forage, 12 samples of untreated soybean hay, and 1 sample of untreated cleaned soybean seed. Residues of azoxystrobin were detected (0.01-0.06 ppm) in/on one sample each of untreated soybean seed and aspirated grain fractions, five samples of untreated forage, and seven samples of untreated hay; residues of the Z isomer in each of these samples were below the method LOQ (<0.01 ppm). Residues of azoxystrobin and its Z isomer in/on treated soybean samples are presented in Table 15, and residues in/on treated aspirated grain fractions are presented in Table 16.

We note that the petitioner considered the harvest date to be the date soybean hay was collected from the field after drying. The Agency considers the harvest date to be the date when samples are cut in the field. Therefore, the study reviewer recalculated post-treatment intervals using the dates soybean hay was cut in the field.

Table 15. Residues of azoxystrobin and its Z isomer in/on **soybeans** harvested following multiple applications of the 80% WDG formulation at 0.25 lb ai/A/application (1x the maximum proposed application rate).

Test Site (Region)	No. of apps.	Total application rate, ai	PHI, days	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Soybean, forage						
Tillar, AR (Region 4)	1	0.25 lb/A	0	6.8, 18	0.05, 0.14	6.85, 18.14
Chula, GA (Region 2)	1	0.25 lb/A	0	3.4[b], 4.6	0.04, 0.06	3.44, 4.66
Webster City, IA (Region 5)	1	0.25 lb/A	0	9.0, 10	<0.01, <0.01	<9.01, <10.01
Richland, IA (Region 5)	1	0.25 lb/A	0	4.9, 6.8	0.09, 0.11	4.99, 6.91
Champaign, IL (Region 5)	1	0.25 lb/A	0	7.8 [b], 9.4	<0.01, <0.01	<7.81, <9.41
Carlyle, IL [c] (Region 5)	1	0.25 lb/A	0	7.0, 8.3	<0.01, <0.01	<7.01, <8.31
Wyoming, IL [c] (Region 5)	1	0.25 lb/A	0	7.9, 8.5	<0.01, <0.01	<7.91, <8.51
Sheridan, IN (Region 5)	1	0.25 lb/A	0	9.0, 12	0.02, 0.02	9.02, 12.02
Noblesville, IN (Region 5)	1	0.25 lb/A	0	9.2, 9.9[b]	0.02, 0.02	9.22, 9.92
Shawnee, KS [c] (Region 5)	1	0.25 lb/A	0	5.7, 7.4	<0.01, <0.01	<5.71, <7.41
Winsboro, LA (Region 4)	1	0.25 lb/A	0	16 [b], 20	0.24, 0.31	16.24, 20.31
Geneva, MN [c] (Region 5)	1	0.25 lb/A	0	8.9 [b], 9.5	0.02, 0.02	8.92, 9.52
Campbell, MN (Region 5)	1	0.25 lb/A	0	9.0, 12	0.04, 0.05	9.04, 12.05
Clarence, MO (Region 5)	1	0.25 lb/A	0	19, 23	0.01, 0.05	19.01, 23.05
Leland, MS (Region 4)	1	0.25 lb/A	0	5.6, 7.2	0.03, 0.02	5.63, 7.22
Whitakers, NC (Region 2)	1	0.25 lb/A	0	5.6, 7.7	0.05, 0.05	5.65, 7.75
York, NE (Region 5)	1	0.25 lb/A	0	8.7, 11	<0.01, 0.01	<8.71, 11.01
New Holland, OH [c] (Region 5)	1	0.25 lb/A	0	6.8 [b], 7.1	<0.01, <0.01	<6.81, <7.11
Lake Preston, SD [c]	2	0.40 lb/A	0	6.7, 7.6	0.02, 0.01	6.72, 7.61

(continued; footnotes follow)

Test Site (Region)	No. of apps.	Total application rate, ai	PHI, days	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Soybean, hay [d]						
Tillar, AR (Region 4)	1	0.25 lb/A	0/7	50, 51	0.38; 0.14	50.38, 51.14
Chula, GA (Region 2)	1	0.25 lb/A	0/7	6.6, 6.8	0.10, 0.09	6.70, 6.89
Webster City, IA (Region 5)	1	0.25 lb/A	0/3	26, 27	<0.01, <0.01	<26.01, <27.01
Richland, IA (Region 5)	1	0.25 lb/A	0/3	15, 22	0.19, 0.40	15.19, 22.40
Champaign, IL (Region 5)	1	0.25 lb/A	0/6	24, 31	0.29, 0.29	24.29, 31.29
Carlyle, IL [c] (Region 5)	1	0.25 lb/A	0/2	24, 24[b]	0.26, 0.24	24.26, 24.24
Wyoming, IL [c] (Region 5)	1	0.25 lb/A	0/2	21, 27	0.11, 0.20	21.11, 27.20
Sheridan, IN (Region 5)	1	0.25 lb/A	0/4	35, 43	0.30, 0.33	35.30, 43.33
Noblesville, IN (Region 5)	1	0.25 lb/A	0/4	28, 38[b]	0.08, 0.12	28.08, 38.12
Shawnee, KS [c] (Region 5)	1	0.25 lb/A	0/3	8.3, 16	0.06, 0.10	8.36, 16.10
Winsboro, LA (Region 4)	1	0.25 lb/A	0/3	28, 33	0.57, 0.61	28.57, 33.61
Geneva, MN [c] (Region 5)	1	0.25 lb/A	0/5	27, 34	0.64, 0.66	27.64, 34.66
Campbell, MN (Region 5)	1	0.25 lb/A	0/7	50, 53	0.68, 0.74	50.68, 53.74
Clarence, MO (Region 5)	1	0.25 lb/A	0/3	29, 37	0.11, 0.15	29.11, 37.15
Leland, MS (Region 4)	1	0.25 lb/A	0/5	15, 16	0.20, 0.22	15.20, 16.22
Whitakers, NC (Region 2)	1	0.25 lb/A	0/4	19, 22[b]	0.39, 0.44	19.39, 22.44
York, NE (Region 5)	1	0.25 lb/A	0/3	31 [b], 38	0.25, 0.28	31.25, 38.28
New Holland, OH [c] (Region 5)	1	0.25 lb/A	0/4	25, 33	0.11, 0.17	25.11, 33.17
Lake Preston, SD [c] (Region 5)	2	0.40 lb/A	0/3	22, 28	0.07, 0.11	22.07, 28.11

(continued; footnotes follow)

Test Site (Region)	No. of apps.	Total application rate, ai	PHI, days	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Soybean, seed						
Tillar, AR (Region 4)	6	1.5 lb/A	12	0.13, 0.15	0.02, 0.03	0.15, 0.18
Chula, GA (Region 2)	6	1.5 lb/A	14	0.02, 0.05	<0.01, <0.01	<0.03, <0.06
Webster City, IA (Region 5)	6	1.5 lb/A	15	0.01 [b], 0.23	<0.01, <0.01	<0.02, <0.24
Richland, IA (Region 5)	6	1.5 lb/A	14	0.01, 0.02 [b]	<0.01, <0.01	<0.02, <0.03
Champaign, IL (Region 5)	6	1.5 lb/A	16	0.05, 0.09	<0.01, <0.01	<0.06, <0.10
Carlyle, IL [c] (Region 5)	6	1.5 lb/A	13	0.02, 0.02	<0.01, <0.01	<0.03, <0.03
Wyoming, IL [c] (Region 5)	6	1.5 lb/A	12	0.03, 0.03	<0.01, <0.01	<0.04, <0.04
Sheridan, IN (Region 5)	6	1.5 lb/A	12	0.33, 0.33	0.01, 0.02	0.34, 0.35 HAFT = 0.35
Noblesville, IN (Region 5)	6	1.5 lb/A	14	0.04, 0.07[b]	<0.01, <0.01	<0.05, <0.08
Shawnee, KS [c] (Region 5)	5	1.25 lb/A	10	0.02 [b], 0.03 [b]	<0.01, <0.01	<0.03, <0.04
Winsboro, LA (Region 4)	6	1.5 lb/A	13	0.23 [b], 0.24	0.01, 0.01	0.24, 0.25
Geneva, MN [c] (Region 5)	6	1.5 lb/A	13	0.01, 0.02	<0.01, <0.01	<0.02, <0.03
Campbell, MN (Region 5)	6	1.5 lb/A	14	0.04, 0.07	<0.01, <0.01	<0.05, <0.08
Clarence, MO (Region 5)	6	1.5 lb/A	14	0.02, 0.02	<0.01, <0.01	<0.03, <0.03
Leland, MS (Region 4)	6	1.5 lb/A	12	0.06, 0.06	<0.01, 0.01	<0.07, 0.07
Whitakers, NC (Region 2)	6	1.5 lb/A	13	0.17, 0.18	<0.01, <0.01	<0.18, <0.19
York, NE (Region 5)	6	1.5 lb/A	12	0.11, 0.12	<0.01, <0.01	<0.12, <0.13
New Holland, OH [c] (Region 5)	6	1.5 lb/A	14	0.03, 0.06	<0.01, <0.01	<0.04, <0.07
Lake Preston, SD [c] (Region 5)	7	1.65 lb/A	14	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02

(continued; footnotes follow)

Test Site (Region)	No. of apps.	Total application rate, ai	PHI, days	Residues, ppm		
				Azoxystrobin	Z isomer	Total [a]
Britton, SD (Region 5)	6	1.5 lb/A	13	0.01, 0.02[b]	<0.01, <0.01	<0.02, <0.03

[a] Total residues were calculated by the study reviewer.
[b] Reported residue is the highest of replicate analyses of a single sample.
[c] Seeds were commercially treated with azoxystrobin prior to planting.
[d] For soybean hay, the petitioner considered the harvest date to be the date soybean hay was collected from the field after drying; however, the Agency considers the harvest date to be the date when samples are cut in the field. Therefore, the study reviewer presented the postharvest interval (PHI) as the number of days soybean hay was cut following the last application.

Table 16. Residues of azoxystrobin and its Z isomer in/on **soybean seed and aspirated grain fractions** treated with the 80% WDG formulation at 1x the maximum application and seasonal rate.

Matrix	Residues (ppm)			Concentration Factor [b]
	Azoxystrobin	Z isomer	Total [a]	
Soybean seed prior to aspiration (RAC)	0.07, 0.08, 0.09	<0.01, <0.01, <0.01	<0.08, <0.09, <0.10	--
Soybean seed, cleaned	0.08, 0.09, 0.11 [c]	<0.01, <0.01, <0.01	<0.09, <0.10, <0.12	--
Aspirated grain fractions	5.1 [c], 6.2, 8.0	0.36, 0.47, 0.64	5.46, 6.67, 8.64	61x, 74x, 96x

[a] Total residues were calculated by the study reviewer.
[b] Concentration factors were calculated for the total residues using the mean residue value (<0.09 ppm) of soybean, seed RAC samples prior to aspiration.
[c] Reported residue is the highest of replicate analyses of a single sample.

Geographic representation of soybean data is adequate for the purposes of this petition. The Agency (Table 5 of OPPTS 860.1500) requires a total of 20 trials for the establishment of a tolerance on soybeans. Twenty soybean field trials were conducted in Regions 2 (2 trials), 4 (3 trials), and 5 (15 trials). All field trials were conducted at the maximum proposed seasonal rate except for two trials which were conducted at 0.8x and 1.1x the maximum proposed application rate because of either rapidly maturing soybeans (resulting in only five applications) or sprayer malfunction (first application was at 0.1x; six 1x applications were subsequently applied).

Six trials were planted with seeds commercially treated with azoxystrobin at 43-44 ppm. The use of azoxystrobin-treated seeds did not result in higher residues in any soybean commodity.

Comments:

The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of azoxystrobin on soybean commodities. The results of the soybean field trials indicate that combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance level of 0.5 ppm in/on soybean seed harvested 10-16 days following the last of six broadcast foliar applications of the 80% WDG formulation at 0.25 lb ai/A/application with 1- to 3-week retreatment intervals. The total application rate was 1.5 lbs ai/A (1x the maximum proposed seasonal rate), except in one trial which received seven applications (first application at 0.15 lb ai/A because of sprayer malfunction) for a total application rate of 1.65 lbs ai/A (1.1x the maximum proposed seasonal rate) and one trial which received only five applications for a total application rate of 1.25 lbs ai/A (0.8x the maximum proposed seasonal rate) because of rapidly maturing soybeans. The combined residues of azoxystrobin and its Z isomer were <0.02 to 0.35 ppm in/on soybean seed.

The results of the field trials also indicate that the combined residues of azoxystrobin and its Z isomer will not exceed the proposed tolerance levels of 25 ppm in/on soybean forage and 55 ppm in/on soybean hay harvested (0-day PHI; hay dried 2-7 days) following a single application of the 80% WDG formulation at 0.25 lb ai/A/application. The combined residues of azoxystrobin and its Z isomer were 3.4-23.1 ppm in/on immature forage and 6.7-53.7 ppm in/on dried hay. Because the rate used in the forage and hay field trials does not reflect the maximum proposed seasonal application rate of 1.5 lbs ai/A specified for soybeans on the product label, **the petitioner should submit a revised Section B to amend the proposed use pattern for soybean forage and hay. Based on the available data, the product labels for the WDG and FlC formulations should specify only a single application at 0.25 lb ai/A and a 0-day PHI for soybean forage and hay.** [Note: The Agency considers the harvest date for soybean hay to be the date when soybean samples are cut in the field.]

Combined residues of azoxystrobin and its Z isomer in/on aspirated grain fractions from soybeans treated at 1x were 5.5-8.6 ppm; residues concentrated 61-96x. A tolerance of 10 ppm has been established for aspirated grain fractions [40 CFR §180.507(a)(1)]. Based on the average concentration factor (77x) and the HAFT residue for soybeans (0.35 ppm), expected residues in aspirated grain fractions are 27.0 ppm. Therefore, **the petitioner should submit a revised Section F, proposing an increased tolerance to 30.0 ppm for "Grain, Aspirated Grain Fractions".**

Wild Rice

Zeneca did not submit any wild rice field trial data to support the establishment of the proposed tolerance for the combined residues of azoxystrobin and its Z isomer at 5.0 ppm. The petitioner indicated that previously reviewed rice data (PP#7F4864; DP Barcode D249657, 1/25/99, D. Dotson) should be translated to wild rice. However, because rice and wild rice are grown in different geographical areas using different cultural practices, the Agency has long considered that translation of rice data to wild rice is not appropriate (memo, L. Kutney, 11/26/85). Thus, **if the petitioner wishes to pursue a tolerance for the combined residues of azoxystrobin and its Z isomer in/on wild rice, crop field trial data from wild rice field trials treated by the maximum proposed use pattern must be submitted. In the interim, the petitioner should submit a**

revised Section F which deletes the proposed tolerance for wild rice. The petitioner should also submit suitably revised WDG and FlC labels.

Inadvertent Residues on Apples

The petitioner is proposing the establishment of a 1.5 ppm tolerance for the combined residues of azoxystrobin and its Z isomer in/on apples, to cover inadvertent residues which might result from spray drift or contaminated equipment. It is not OPP policy to establish an inadvertent residue tolerance based upon concerns about the possibility of spray drift or contaminated equipment. **A revised Section F should be submitted in which the proposed tolerance for apple (inadvertent residues) is deleted.**

OPPTS GLN 860.1520: Processed Food/Feed

Barley

Zeneca did not submit any barley processing data to support the establishment of the proposed tolerance for residues of azoxystrobin in/on barley bran at 0.2 ppm. In a previous memo (DP Barcode D254140, 3/17/99, G. Herndon), IR-4 had requested that the Agency establish tolerances on barley based on the petitioner's wheat data. Due to the similarities in wheat and barley (especially from a residue standpoint), the fact that wheat production and consumption is much higher than barley, and wheat has more processed commodities, RAB2 concurred with the IR-4 proposal. Based on the available wheat processing data (DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney), RAB2 concluded that it would be appropriate for IR-4 to request a tolerance of 0.2 ppm for barley bran. No other tolerances for processed barley commodities are required.

Citrus fruits

Zeneca has submitted data (citation listed below) depicting the potential for concentration of residues of azoxystrobin and its Z isomer in the processed commodities of oranges.

> 44915228 Bussey, R.J. and Hampton, R. (1999) Azoxystrobin: Processing Study on Oranges from a Trial Conducted in Florida During 1998. Laboratory Project ID: AZOX-98-PR-01; Report Number RR 99-017B. 37 p.

A single field trial was conducted during the 1998 growing season in FL; the same study as described under Magnitude of the Residue for citrus fruits (oranges). Mature oranges were harvested on the day (0-day PHI) of the last of six broadcast foliar applications, with 6- to 8-day retreatment intervals, of the 80% WDG formulation at 0.25 lb ai/A (1x the maximum proposed application rate). The total application rate was 1.5 lbs ai/A (1x the maximum proposed seasonal rate). The first application was made 35 days prior to anticipated harvest. Applications were made using ground equipment (tractor-driven airblast sprayer) in 203-216 gal/A of water with 0.125%

(v:v) of non-ionic surfactant added to the spray volume. A separate plot was left untreated to provide control samples.

Orange samples collected for processing were harvested by hand, placed in labeled containers, and shipped on the day of harvest at ambient conditions to the Citrus Research and Education Center, University of Florida (Lake Alfred, FL) for processing. Samples were refrigerated (5° C) at the University of Florida until processing. Oranges were processed into dried pulp, oil, and juice using simulated commercial processing procedures within 6 days of receipt/harvest. Briefly, oranges were first washed using a commercial-grade fruit cleaner with agitation. Juice was extracted using a commercial in-line juice extractor. The juice stream was passed through a finisher to screen excess pulp from the juice; the fresh juice was collected. The extracted oil/water/peel frit emulsion was passed through a finisher and the peel/frits collected. The remaining oil/water emulsion was further screened, and the emulsion was allowed to separate for at least 5 hours. The concentrated oil emulsion was centrifuged to remove any remaining water. The centrifuged, cold-pressed oil was then sequentially frozen and thawed, filtered, and anhydrous sodium sulfate was added to remove any remaining water. The purified cold-pressed oil was collected. The study report included adequate descriptions of the processing procedures including material balance summaries. The orange RAC and processed dried pulp, cold-pressed oil, and fresh juice were frozen (-23° C) at the processing plant until shipment via ACDS freezer truck to WRC (Richmond, CA). Samples of the RAC and dried pulp were homogenized with dry ice at WRC; oil and juice samples did not required further preparation. All samples were stored frozen (-18±5° C) at WRC until analysis.

Orange RAC and processing samples were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD Method described under the "Residue Analytical Methods" section. The reported method LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each below the method LOQ in/on one sample each of untreated orange (RAC) and processed dried pulp, oil, and juice. Residues of azoxystrobin and its Z isomer in/on the treated processed orange commodities are presented in Table 17; residues of azoxystrobin and its Z isomer were each below the LOQ in treated orange juice samples.

Table 17. Residues of azoxystrobin and its Z isomer in/on **oranges and processed commodities** treated with the 80% WDG formulation at 1x the maximum application and seasonal rate.

Matrix	Residues, ppm			Concentration Factor [b]
	Azoxystrobin	Z isomer	Total [a]	
Orange (RAC)	0.11, 0.12	<0.01, <0.01	<0.12, <0.13	--
Dried pulp	0.23, 0.23	0.02, 0.07	0.25, 0.30	1.9x, 2.3x
Cold-pressed oil	0.55, 0.58	0.02, 0.03	0.57, 0.61	4.4x, 4.7x
Juice	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02	0.2x

[a] Total residues were calculated by the study reviewer.

[b] Concentration factors were calculated for the total residues using the mean residue value (<0.13 ppm) of orange RAC samples.

Study summary:

The submitted orange processing study is adequate. Total residues of azoxystrobin and its Z isomer do not concentrate in juice processed from oranges bearing detectable residues. Total residues of azoxystrobin and its Z isomer may concentrate 1.9-2.3x in dried pulp and 4.4-4.7x in oil processed from oranges bearing detectable residues.

The HAFT residue of citrus fruit (grapefruits, lemons, and oranges) treated at 1x the maximum seasonal rate (1.5 lbs ai/A/season; 0-day PHI) from the submitted citrus field trials (U.S.) was <0.70 ppm (total residues of azoxystrobin and its Z isomer). Based on the HAFT and an average concentration factor of 2.1x, the highest expected residues in dried citrus pulp would be 1.5 ppm; based on an average concentration factor of 4.6x, the highest expected residues in citrus oil would be 3.2 ppm. The proposed tolerances for dried citrus pulp (7.0 ppm) and citrus oil (15.0 ppm) are too high, based on domestic citrus field trial data. **The petitioner should submit a revised Section F proposing a tolerance of 2.0 ppm for "Citrus, dried pulp" and a tolerance of 4.0 ppm for "Citrus, oil".**

Field Corn

Zeneca submitted the following data (citation listed below) from a single test depicting the potential for concentration of residues of azoxystrobin and its Z isomer in the processed commodities of field corn.

> 44915230 Bussey, R.J. and Aston, J.C. (1999) Azoxystrobin: Processing Study on Corn from a Trial Conducted in the United States during 1998: Lab Project Number: AZOX-98-PR-03: Report Number: RR 99-056B. Unpublished study prepared by Zeneca Ag Products. 65 p.

In one trial conducted during the 1998 growing season in IL, field corn grain was harvested 6 days following eight broadcast foliar applications of the 80% WDG formulation at 1.25 lbs ai/A/application, with a 4- to 48-day retreatment interval. The total seasonal application rate was 10 lbs ai/A (5x the maximum proposed seasonal application rate). Applications were made using a tractor-mounted boom sprayer in 12-16 gal/A with a non-ionic surfactant (0.125%, v:v) added to the spray volume. A separate plot was left untreated for controls.

Untreated and treated samples of field corn grain were mechanically harvested using picker equipment. The collected samples were placed in labeled containers, and frozen (within 15 minutes of harvest), and shipped by ACDS freezer truck to the Texas A&M University, Food Protein Research and Development Center (Bryan, TX) for processing.

At the processing facility, treated and untreated field corn grain samples were processed into meal, grits, flour, starch, and refined oil according to simulated small-scale commercial procedures. The **dry-milling procedure** began with the drying and cleaning of the harvested field corn by aspiration and screening. The clean corn was moisture-adjusted to 20-22%, milled, dried at 54-71° C, cooled and put through a shaker screen. Material collected above the screens was aspirated to separate hull + germ material from grits and detached germ. To separate germ from hulls, the hull + germ

material was re-milled and re-aspirated. The grits/detached germ material was gravity-separated into germ and large grits. The germ was oven-dried and frozen for oil extraction. Material which passed through the screen was separated into grits, meal, and flour. The large grits were mechanically sieved through a series of screens. Medium grits were collected from the 0.08-inch screen, small grits were collected from the 0.054-inch screen, coarse meal was collected from the 0.0204-inch screen, meal was collected from the 0.0098-inch screen, and flour was collected from the materials which passed through all screens.

The **wet-milling procedure** began with the drying and cleaning of the harvested field corn by aspiration and screening. The cleaned corn was steeped and heated in water and sulfurous acid, the steepwater was drained, and the wet grain was disc-milled and centrifuged to separate the germ and hulls from cornstock. The germ and hull fractions were dried and aspirated to remove hulls. Starch was collected from the cornstock fraction after screening and centrifugation.

Both the wet- and dry-milled germ fractions were moistened, heated, flaked, and processed in an expeller to produce crude oil and presscake. The crude oil was filtered. The residual oil in the presscake was extracted with hot hexane three times. The hexane/oil fractions were combined and heated to remove hexane. Crude oil fractions were combined, and a portion was combined with NaOH and heated in a refining machine, refrigerated, and the refined oil was decanted. The remaining fraction was soapstock.

The petitioner submitted adequate descriptions and material balance sheets for the processing procedures. The processed samples were packed in dry ice and shipped frozen overnight by FedEx to WRC (Richmond, CA) for analysis. Total storage intervals for samples from the field corn processing study (from harvest to analysis) were 252-265 days (8.3-8.7 months) for field corn grain and its processed fractions.

Samples of field corn grain, its dry milled processed fractions (grits, meal, flour, and refined oil), and its wet-milled processed fractions (starch and refined oil) were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on one sample each of untreated field corn grain, dry milled fractions (grits, meal, flour, and refined oil), and wet milled fractions (starch and refined oil). Residues of azoxystrobin and its Z isomer in/on treated processed corn commodities are presented in Table 18.

Table 18. Residues of azoxystrobin and its Z isomer in the processed commodities of **field corn** harvested 6 days following eight broadcast foliar applications of the 80% WDG formulation at 1.25 lb ai/A/application (10 lb ai/A/season; 5x the maximum proposed seasonal rate).

Field Corn Matrix	Residues, ppm			Concentration Factor [b]
	Azoxystrobin	Z isomer	Total [a]	
Grain (RAC)	0.11, 0.11	<0.01, <0.01	<0.12, <0.12	–
Starch (wet milled)	<0.01, <0.01	<0.01, <0.01	<0.02, <0.02	0.2x, 0.2x
Refined oil (wet milled)	0.65, 0.69	0.02, 0.02	0.67, 0.71	5.6x, 5.9x
Meal (dry milled)	0.06, 0.06	<0.01, <0.01	<0.07, <0.07	0.6x, 0.6x
Grits (dry milled)	0.03, 0.03	<0.01, <0.01	<0.04, <0.04	0.3x, 0.3x
Flour (dry milled)	0.08, 0.08	<0.01, <0.01	<0.09, <0.09	0.8x, 0.8x
Refined oil (dry milled)	0.07, 0.07	<0.01, <0.01	<0.08, <0.08	0.7x, 0.7x

[a] Total residues were calculated by the study reviewer.

[b] Concentration factors were calculated for the total residues using the mean residue value (<0.12 ppm) of the RAC (corn, field, grain) samples.

Comments:

The submitted field corn processing data are adequate for the purposes of this petition. No concentration of residues of azoxystrobin and the Z isomer was observed in dry milled fractions, corn grits, meal, flour, and refined oil, and the wet milled fraction, corn starch, processed from field corn grain bearing detectable residues.

The data indicate that combined residues of azoxystrobin and its Z isomer concentrated in the wet milled fraction, refined oil, at 5.6 and 5.9x. The HAFT residue of corn grain treated at 1x the maximum seasonal rate (2.0 lbs ai/A/season; 7-day PHI) from the submitted field corn studies was <0.03 ppm combined azoxystrobin and Z isomer residues. Based on the HAFT (<0.03 ppm) value and an average concentration factor of 5.8x, the maximum expected combined residue in refined corn oil (0.17 ppm) would not exceed the proposed tolerance of 0.3 ppm. **The petitioner should submit a revised Section F proposing a tolerance of 0.3 ppm expressed in terms of "Corn, field, refined oil".**

Cotton

Zeneca has submitted data (citation listed below) depicting the potential for concentration of residues of azoxystrobin and its Z isomer in the processed commodities of cotton.

44915231 Bussey, R.J., Gill, J.P., and Lister, N. (1998) Azoxystrobin: Processing Study on Cotton from a Trial Conducted in Mississippi During 1997. Laboratory Project ID: AZOX-97-PR-01; Report Number RR 98-058B. 59 p.

Two field trials were conducted during the 1997 growing season in CA(1) and MS(1); however, only the cotton harvested from the MS site was processed. Mature cotton was harvested 173 days following a single banded in-furrow application of the 80% WDG formulation at 1.0 oz ai/1000 ft of row at planting (5x the maximum proposed in-furrow application and seasonal rate). Applications were made using ground equipment (tractor-mounted in-furrow spray applicator hooked to a planter) in 10 gal/A. A separate plot at each trial site was left untreated to provide control samples.

A single untreated and treated sample of mature cotton was harvested mechanically using a spindle picker from the MS plots. The collected samples were then bagged, labeled, and frozen within 3 hours of harvest. Samples were shipped on the day after harvest by ACDS freezer truck to the Food Protein Research and Development Center, Texas A&M University (Bryan, TX) for ginning and processing. Samples were stored frozen (-4° C) at Texas A&M prior to processing. Cotton samples were ginned and processed into undelinted seed, hulls, meal, and refined oil using simulated industrial processes. Cotton was ginned approximately 77 days after harvest. Briefly, burrs, sticks, and other plant parts (gin byproducts) were removed from cotton (received dry; <8% moisture) using a Mitchell stick extractor. The remaining lint cotton was saw ginned to remove lint. Undelinted seed was stored frozen (-8° C) for 13-14 days until processing. Undelinted seed was delinted and cracked to separate hulls from the kernel. The kernel was then dried at 54-71° C, heated to 77-87° C, flaked, and steam expanded at 82-113° C. The expanded kernel was dried again at 54-71° C for 30-40 minutes, and extracted (3x) with hexane at 49-60°C for at total of 60 minutes, yielding meal and crude oil in hexane. Residual hexane was removed from the meal by drying. The hexane solution of crude oil was treated with sodium hydroxide and vacuum stripped, yielding refined oil and soapstock. The study report included adequate descriptions of the processing procedures including material balance summaries. Processed samples (hulls, meal, and refined oil) were frozen within 2 hours of processing and shipped frozen by FedEx to WRC (Richmond, CA). Samples were stored frozen (-18° C) at WRC and shipped frozen by air freight to Zeneca Agrochemicals, Jealott's Hill Research Station (Bracknell, Berkshire, England) for analysis. Total storage intervals from harvest to analysis were 220-226 days (7.2-7.4 months) for undelinted cottonseed, hulls, meal, and refined oil.

All RAC and processing samples were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD Method described under the "Residue Analytical Methods" section with an LOQ of 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each below the method LOQ in/on one sample each of untreated undelinted cottonseed, meal, hulls, and refined oil.

Residues of azoxystrobin and its Z isomer were each less than the method LOQ (0.01 ppm) in/on one sample each of undelinted cottonseed, meal, hulls, and refined oil processed from cotton treated at 5x the maximum proposed seasonal rate.

Comments:

The submitted cotton processing study is adequate. Total residues of azoxystrobin and its Z isomer did not concentrate in cotton meal, hulls, or refined oil processed from undelinted cottonseed treated at 5x the maximum proposed seasonal rate. Residues of azoxystrobin and its Z isomer were each

less than the method LOQ (<0.01 ppm) in/on undelinted cottonseed (RAC), meal, hulls, and refined oil ginned/processed from cotton treated at 5x the proposed maximum seasonal rate. No tolerances are required for the processed commodities of cotton.

Peanut

The petitioner did not submit any peanut processing data with this petition. Peanut processing data were submitted previously in conjunction with PP#6F4762 (DP Barcodes D230634, D230635, D230636, and D230637, L. Kutney, 4/25/97). The peanut processing data indicated that residues of azoxystrobin and its Z isomer do not concentrate in meal processed from peanuts bearing detectable azoxystrobin residues.

The processing data indicated that residues of azoxystrobin concentrate in refined oil at 3.3x. Residues of the Z isomer were less than the LOQ in both the RAC and processed refined oil samples. Based on the HAFT value (<0.13 ppm, combined residue of 0.12 ppm + <0.01 ppm) for peanut nutmeats and the concentration factor (3.3x), the maximum expected combined residue in refined peanut oil (0.43 ppm) would not exceed the proposed tolerance level of 0.6 ppm. [Note: Currently, a tolerance is established at 0.03 ppm for peanut oil.] **The petitioner should submit a revised Section F which increases the established tolerance to 0.6 ppm and expresses it in terms of "Peanut, refined oil".**

Potato

The petitioner did not submit any potato processing data with this petition. Potato processing data were submitted previously in conjunction with PP#8F4995 (DP Barcode D249671, D. Dotson, M. Doherty, and Y. Donovan, 10/14/98). The potato processing data indicated that residues of azoxystrobin and its Z isomer do not concentrate in potato processed commodities. No tolerances for the processed commodities of potatoes are required.

Soybean

Zeneca has submitted data (citation listed below) depicting the potential for concentration of residues of azoxystrobin and its Z isomer in the processed commodities of soybeans.

> 44915229 Bussey, R.J. and Lipton, Ç. (1999) Azoxystrobin: Processing Study on Soybeans from a Trial Conducted in Mississippi During 1998. Laboratory Project ID: AZOX-98-PR-04; Report Number RR 99-051B. 46 p.

Two field trials were conducted during the 1998 growing season in IL(1) and MS(1); however, only the soybeans harvested from the MS site were processed. Mature soybeans were harvested 12 days following six broadcast foliar applications, with 7- to 21-day retreatment intervals, of the 80% WDG formulation at 1.25 lbs ai/A/application (5x the maximum proposed application and seasonal rate). Applications were made using ground equipment (tractor-mounted boom sprayer) in 11-12 gal/A of water with 0.125% non-ionic surfactant added to the spray volume. A separate plot at each trial site was left untreated to provide control samples.

Soybean samples collected for processing were harvested mechanically, placed in labeled containers, and frozen within 2 hours of harvest. The day after harvest samples were delivered frozen on dry ice by rental truck to the Food Protein Research and Development Center, Texas A&M University (Bryan, TX) for processing. Samples arrived unfrozen but cold and were then stored frozen at Texas A&M prior to processing. Soybean samples were processed into hulls, meal, and refined oil using simulated industrial processes. Soybeans were dried at 54-71° C to a moisture content of 7-10%. Whole soybeans were then milled to crack the hull. The hull and kernel were separated by aspiration. The kernels were heated to 71-79° C, flaked, steam expanded at 82-113° C, and dried at 54-71° C. The resulting collets were extracted (3x) with hexane at 49-60° C, dried, and ground to meal. Crude oil in hexane was recovered from the micella by heating to 73-90° C. The hexane solution of crude oil was treated with sodium hydroxide and the phases were allowed to separate, yielding refined oil and soapstock. The study report included adequate descriptions of the processing procedures including material balance summaries. Processed samples (hulls, meal, and refined oil) were frozen and shipped frozen by FedEx to WRC (Richmond, CA). Seed and hull samples were milled with dry ice at WRC to obtain homogenous samples; meal and refined oil samples did not require additional preparation. Samples were stored frozen (-18±5° C) at WRC until analysis. Total storage intervals from harvest to analysis were 252-254 days (8.3-8.4 months) for soybean seed, hulls, meal, and refined oil.

Soybean RAC and processing samples were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD Method described under the "Residue Analytical Methods" section. The reported method LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each below the method LOQ in/on one sample each of untreated soybean (RAC) and processed hulls and meal. Residues of the Z isomer were detected at the method LOQ (0.01 ppm) in/on a single untreated sample of refined oil; residues of azoxystrobin were less than the method LOQ (<0.01 ppm) in that sample. Residues of azoxystrobin and its Z isomer in/on the treated processed soybean commodities are presented in Table 19.

Table 19. Residues of azoxystrobin and its Z isomer in/on **soybeans and processed commodities** treated with the 80% WDG formulation at 5x the maximum application and seasonal rate.

Soybean Matrix	Residues, ppm			Concentration Factor [b]
	Azoxystrobin	Z isomer	Total [a]	
Seed (RAC)	0.44	0.02	0.46	--
Hulls	0.96, 1.0	0.05, 0.05	1.01, 1.05	2.2x, 2.3x
Meal	0.04, 0.04	<0.01, <0.01	<0.05, <0.05	0.1x
Refined oil	0.33, 0.35	<0.01, 0.01	<0.34, 0.36	0.7x, 0.8x

[a] Total residues were calculated by the study reviewer.

[b] Concentration factors were calculated for the total residues using the soybean RAC sample total residues.

Comments:

The submitted soybean processing study is adequate. Total residues of azoxystrobin and its Z isomer did not concentrate in meal and refined oil processed from soybeans bearing detectable residues.

Total residues of azoxystrobin and its Z isomer concentrated 2.2-2.3x in hulls processed from soybeans with detectable residues. The HAFT residue of soybean seed treated at 1x the proposed maximum seasonal rate (1.5 lb ai/A/season; 14-day PHI) from the submitted soybean field trials was 0.35 ppm (total residues of azoxystrobin and its Z isomer). Based on the HAFT (0.35 ppm) value from the soybean field trials and an average concentration factor of 2.3x, the highest expected residues in hulls would be 0.81 ppm. **We recommend the petitioner submit a revised Section F proposing the tolerance at 1.0 ppm for "Soybean, hulls".**

Sugar beet

Zeneca has submitted data (citation listed below) from a single test depicting the potential for concentration of residues of azoxystrobin and its Z isomer in the processed commodities of sugar beets.

> 44915232 Bussey, R. and Spillner, C. (1999) Azoxystrobin: Processing Study on Sugar Beets from a Trial Conducted in Minnesota During 1998: Lab Project Number: AZOX-98-PR-02: Report Number: RR 99-037B. Unpublished study prepared by Zeneca Ag Products. 52 p.

In one trial conducted during the 1998 growing season in MN, sugar beets were harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 1.65 lb ai/A/application, made at 6- to 8-day retreatment intervals. The total seasonal application rates were 9.9 lb ai/A (5x the maximum proposed seasonal application rate). Applications were made using ground equipment (tractor-mounted boom sprayer) in 20 gal/A with a non-ionic surfactant (0.154% for first application, v:v and 0.125% for second through sixth application, v:v) added to the spray volume. A separate plot was left untreated for controls.

Untreated and treated samples of sugar beet roots were harvested by hand. The collected samples were placed in labeled containers, and frozen (within 3 hours of harvest), and shipped by ACDS freezer truck to Englar Food Laboratories (Moses Lake, WA) for processing.

At the processing facility, sugar beet root samples were processed into dried pulp, molasses, and refined sugar using procedures which simulated normal commercial processing conditions. Briefly, the roots were washed in water and sliced into cossettes. The sliced cossettes were placed in a counter-current diffuser with a mixture of fresh water and pulp press water. Sugar from cossettes was extracted into water, and the extract (raw juice) was purified by the addition of lime and carbon dioxide and heated at 80-90° C. Impurities in the extract were precipitated by the addition of a settling aid. The clear liquid was filtered, carbonated with carbon dioxide gas, concentrated, heated at 75-85° C, and was filtered again. The thin juice was concentrated by evaporation to produce thick juice and frozen until further processing. Once thawed, the thick juice was heated at 70-75°

C in a vacuum pan and centrifuged to separate the sugar from the molasses. The sugar was then washed with hot water and dried with hot air to produce refined sugar. The beet pulp left over from the sugar extraction was dried to produce dry pulp.

The petitioner submitted adequate descriptions and material balance sheets for the processing procedures. The processed samples were packed in dry ice and shipped frozen overnight by FedEx to WRC (Richmond, CA) for analysis. Total storage intervals for samples from the sugar beet processing study (from harvest to analysis) were 146-220 days (4.8-7.2 months) for sugar beet roots and its processed fractions.

Samples of sugar beet roots and its processed fractions (dried pulp, molasses, and refined sugar) were analyzed for residues of azoxystrobin and its Z isomer using the GC/NPD method previously described under the "Residue Analytical Methods" section. The reported LOQ was 0.01 ppm for each analyte. Apparent residues of azoxystrobin and its Z isomer were each less than the LOQ in/on one sample each of untreated sugar beet roots, sugar beet dried pulp, molasses, and refined sugar. Residues of azoxystrobin and its Z isomer in/on treated processed sugar beet commodities are presented in Table 20.

Table 20. Residues of azoxystrobin and its Z isomer in the processed commodities of **sugar beet roots** harvested on the day of the last of six broadcast foliar applications of the 80% WDG formulation at 1.65 lb ai/A/application (9.9 lb ai/A/season; 5x the maximum proposed seasonal application rate

Sugar Beet Matrix	Residues, ppm			Concentration Factor [b]
	Azoxystrobin	Z isomer	Total [a]	
Roots (RAC)	0.78, 0.86	0.04, 0.04	0.82, 0.90	–
Dried pulp	1.37, 1.43	0.04, 0.04	1.41, 1.47	1.6x, 1.7x
Molasses	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.02, <0.02, <0.02	>0.02x
Refined sugar	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.02, <0.02, <0.02	>0.02x

[a] Total residues were calculated by the study reviewer.

[b] Concentration factors were calculated for the total residues using the mean residue value (0.86 ppm) of the RAC samples.

Comments:

The submitted sugar beet processing study is adequate. Combined residues of azoxystrobin and its Z isomer did not concentrate in molasses and refined sugar processed from sugar beet roots bearing detectable residues.

The processing data indicate that the combined residues of azoxystrobin and its Z isomer concentrated 1.6-1.7x in sugar beet, dried pulp. The HAFT residue of sugar beet roots treated at 1x the maximum seasonal rate (2.0 lbs ai/A/season; 0-day PHI) from the submitted sugar beet field trial studies was <0.19 ppm combined azoxystrobin and Z isomer residues. Based on the HAFT value (<0.19 ppm) for sugar beet roots treated at 1x the maximum seasonal rate and an average

concentration factor of 1.7x, the maximum expected residue in sugar beet, dried pulp would be 0.32 ppm.

The petitioner is proposing a tolerance of 0.8 ppm for sugar beet, dried pulp and a tolerance of 0.5 ppm for the root and tuber vegetables crop group, which includes sugar beet roots. As discussed under "Root and Tuber Vegetables" in the "Crop Field Trials section" of this review, the submitted field trials data do not support a tolerance for the crop group, but do support a 0.5 ppm tolerance for the root vegetables subgroup, which includes sugar beet roots. Since the maximum expected residue in sugar beet, dried pulp has been calculated above to be 0.32 ppm, which is less than the tolerance proposed (0.5 ppm) for the grouping containing sugar beets roots, no separate tolerance is warranted for this processed commodity. **The petitioner should submit a revised Section F deleting the proposed tolerance of 0.8 ppm for "Beet, sugar, dried pulp".**

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

The petitioner is proposing to increase tolerances for secondary residues of azoxystrobin in the fat and meat byproducts of cattle, goat, horses, and sheep to 0.03 and 0.07 ppm, respectively. Zeneca did not submit animal feeding studies with PP#9F06058. However, a ruminant feeding study was previously submitted and reviewed in conjunction with PP#6F4762 (DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney) and a poultry feeding study was submitted and reviewed with PP#7F4864 and PP#8F4995 (DP Barcodes D249657 and D249668, 1/25/99, D. Dotson).

Magnitude of the Residue: Ruminants

In the ruminant (dairy cattle) feeding study referenced above, the dosing levels were 5, 25, 75, and 250 ppm. A summary of the residues of azoxystrobin in dairy cattle matrices following the oral administration of the test substance over 28-30 consecutive days is presented in Table 21.

Table 21. Summary of Azoxystrobin Residues in Dairy Cattle Matrices Following the Oral Administration of the Test Substance at 5, 25, 75, and 250 ppm over 28-30 Consecutive Days.

Dose Rate in Diet (mg/kg)	Range of Azoxystrobin Residue (ppm)				
	Milk	Muscle	Fat	Kidney	Liver
5	<0.001 - 0.003	<0.01	<0.01	<0.01	<0.01
25	<0.001 - 0.006	<0.01	<0.01	<0.01	<0.01 - 0.01
75	<0.001 - 0.004	<0.01	<0.01 - 0.03	<0.01 - 0.01	0.01 - 0.05
250	0.002 - 0.009	<0.01	0.01 - 0.03	0.01 - 0.02	0.03 - 0.07

Magnitude of the Residue: Poultry

In the poultry feeding study referenced above, the dosing level was 60 ppm. Since no residues of the Z isomer were identified in the poultry metabolism study, egg and tissue samples from the feeding study were analyzed for azoxystrobin residues only. The LOQ of the method (RAM 255) was 0.01 ppm. No quantifiable residues of azoxystrobin were reported in any egg or poultry tissue sample.

Theoretical Maximum Daily Dietary Burden to Livestock

The following commodities are the animal feedstuffs associated with this current petition:

beef and dairy cattle: aspirated grain fractions; barley grain, hay, and straw; carrot culls; dried citrus pulp; field corn grain, forage, stover, and milled byproducts; pop corn grain and stover; sweet corn forage, stover, and cannery waste; cotton undelinted seed, meal, hulls, and gin byproducts; peanut meal and hay; potato culls and process waste; soybean seed, forage, hay, meal, hulls, and silage; sugar beet tops, dried pulp, and molasses; and, turnip roots and tops.

swine: aspirated grain fractions, barley grain, carrot culls, field corn grain and milled byproducts, pop corn grain, cotton meal, peanut meal, potato culls, soybean seed and meal, and turnip roots.

poultry: barley grain, field corn grain, pop corn grain, field corn milled byproducts, cotton meal, peanut meal, and soybean seed, meal, and hulls.

Daily dietary burdens were calculated for beef and dairy cattle, swine, and poultry, taking into consideration the feedstuffs associated with both established and pending tolerances. The results of the calculations of the maximum theoretical daily dietary burdens for livestock are presented in Table 22.

Table 22. Azoxystrobin Maximum Theoretical Daily Dietary Burdens for Livestock

Feed Commodity	Tolerance, ppm	% Dry Matter	% of Diet	Burden (ppm)
Beef cattle				
Rice, grain	5.0	88	20	1.1
Soybean, forage	25.0	35	30	21.4
Turnip, tops	50.0	30	50	83.3
		TOTAL	100	**105.8**
Dairy cattle				
Rice, grain	5.0	88	40	2.3
Soybean, forage	25.0	35	30	21.4
Turnip, tops	50.0	30	30	50.0
		TOTAL	100	**73.7**
Swine				
Rice, grain	5.0	NA	65	3.3
Canola, meal	1.0	NA	15	0.2
Aspirated grain fractions	30.0	NA	20	6.0
		TOTAL	100	**9.5**
Poultry				
Rice, grain	5.0	NA	60	3.0
Rice, bran	5.0	NA	25	1.3
Rice, hulls	20.0	NA	15	3.0
		TOTAL	100	**7.3**

NA = Not applicable to swine and poultry dietary calculations, per OPPTS Test Guidelines, 860.1000, Table 1, Footnote 2.

Comments:

Based on the maximum theoretical daily dietary burden calculated for beef cattle (106 ppm), dairy cattle (74 ppm), swine (10 ppm), and poultry (7 ppm), and taking into account the findings of the ruminant and poultry feeding studies, the following conclusions can be reached:

the currently established tolerances for secondary residues of azoxystrobin in milk (0.006 ppm); meat (0.01 ppm) of cattle, goats, hogs, horses, and sheep; and, the fat (0.01 ppm) and meat byproducts (0.01 ppm) of hogs remain adequate;

a higher tolerance of 0.03 ppm, as proposed by the petitioner, is needed for the fat of cattle, goats, horses, and sheep;

a higher tolerance of 0.07 ppm, as proposed by the petitioner, is needed for the meat byproducts of cattle, goats, horses, and sheep; and,

tolerances continue not to be needed for eggs or poultry tissues.

The *proposed* tolerances for livestock commodities are expressed in terms of azoxystrobin *and its Z isomer*. The established tolerances for livestock commodities are expressed in terms of azoxystrobin only. The HED MARC has previously concluded (DP Barcode D251683, W. Wassell, 12/30/98) that the residue of concern in livestock is the parent compound only. **The petitioner should submit a revised Section F in which the higher tolerances being proposed for the fat and meat byproducts of cattle, goats, horses, and sheep are expressed in terms of residues of azoxystrobin only.**

OPPTS GLN 860.1850/1900: Confined/Field Accumulation in Rotational Crops

Adequate confined rotational crop studies have previously been submitted (DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney). The total radioactive residues, expressed as [^{14}C]azoxystrobin equivalents, accumulated at levels >0.01 ppm in the RACs of lettuce, radishes, and wheat planted in sandy loam soil 30, 200, and 365 days after treatment (DAT) of the soil with [^{14}C]azoxystrobin at 1.8 lb ai/A (~1x the maximum proposed rate for annual crops). Residues were highest in RACs from the 30-DAT interval and declined in the subsequent intervals.

Azoxystrobin was identified in all RACs at the 30-DAT interval. In 30-DAT samples, the Z isomer was only identified in wheat forage and straw. Compound 42 was the major metabolite identified in 30-DAT lettuce and wheat forage and straw. In 30-DAT radish roots, azoxystrobin was the major metabolite and in 30-DAT radish tops, metabolites G_2, N_1, and N_2 were the major metabolites. In 30-DAT wheat grain, ^{14}C-starch was found to account for the largest portion of radioactivity. Several conjugated metabolites (compound 42 and the M, N, and O metabolites) of primary crop metabolites were identified, indicating that azoxystrobin is more extensively metabolized in rotational crops than in primary crops.

The proposed plantback intervals of 30 days for broadleaf or root crops and 45 days for cereal grains were based on limited field rotational crop studies submitted previously (DP Barcodes D230634, D230635, D230636, and D230637, 4/25/97, L. Kutney). These data indicated that, following treatment of the primary crop wheat at 0.8 lb ai/A (0.4x the current maximum proposed seasonal rate), residues of azoxystrobin and its Z isomer were below the LOQ (<0.01 ppm) in/on mustard greens (leafy vegetable), radishes and turnips (root vegetable), and millet hay, straw, and grain (cereal grain) planted ~30 DAT. Residues of azoxystrobin *per se* were 0.02 ppm in/on millet forage at ~30 DAT; however, residues of azoxystrobin and its Z isomer were less than the LOQ in/on millet forage at the 45-day plantback interval.

Because the previously submitted field rotational crop studies represent only 0.4x the proposed maximum seasonal rate for annual crops in this petition, **the petitioner will need to conduct additional limited field rotational crop studies at 1x the maximum proposed seasonal rate (2.0 lbs ai/A).** When these data have been submitted, the appropriate plantback intervals for rotational crops can be determined.

International Harmonization

No Codex, Canadian, or Mexican MRLs have been proposed or are established for residues of azoxystrobin. An International Residue Limit Status sheet is attached.

AGENCY MEMORANDA CITED IN THIS REVIEW

DP Barcodes:	D218318 and D218448
Subject:	PP No. 5F4541: New Chemical: Azoxystrobin (ICIA5504) in/on Grape RACs. Evaluation of Analytical Methods and Residue Data. CBTS Nos. 16051 and 16092
From:	J. Garbus
To:	J. Bazuin/C. Giles-Parker
Dated:	3/19/96
MRID(s):	43678102-43678107, 43678193-43678195, 43678201-43678210, and 43694201-43694206

DP Barcodes:	D230634, D230635, D230636, and D230637
Subject:	PP#6F4762. Azoxystrobin. Permanent Tolerance Petition for Use on Bananas, Peaches, Peanuts, Tomatoes, and Wheat. Evaluation of Analytical Methodology and Residue Data.
From:	L. Kutney
To:	C. Giles-Parker, J. Bazuin, and B. Madden
Dated:	4/25/97
MRID(s):	44058715-44058730, 44058732-44058736, and 44073203-44073205

DP Barcode:	D236118
Subject:	ID 010182-URL: PP Nos. 5F4541, 6F4642, and 6F4762: New Chemical: Azoxystrobin in/on grapes, Pecans, Peaches, Peanuts, Bananas, and Tomatoes. Registration of New End Use Formulation (Flowable/SC) on These Commodities.
From:	J. Garbus
To:	C. Giles-Parker/J. Bazuin
Dated:	6/23/97
MRID(s):	None

DP Barcodes:	D248887 and D249671
Subject:	PP#7F4864. Tolerance Petition for use of Azoxystrobin on Cucurbits. PP#4F4995. Tolerance Petition for use of Azoxystrobin on Bananas, Potatoes, and Stone Fruits. Evaluation of Analytical Methodology and Residue Data.
From:	D. Dotson, M. Doherty, and Y. Donovan
To:	C. Giles-Parker/J. Bazuin
Dated:	10/14/98
MRID(s):	44319305, 44452303, 44595105, 44515109-44595111, 44595114, 44595116, 44613501, and 44613503

DP Barcode: D251683
Subject: Azoxystrobin. Conclusions of the Metabolism Assessment Review committee at Meeting of 11/10/98.
From: W. Wassell
To: G. Kramer
Dated: 12/30/98
MRID(s): None

DP Barcodes: D249657 and D249668
Subject: PP#7F4864. Tolerance Petition for use of Azoxystrobin on Peanut Hay, Pistachios, Rice, Tree Nuts, and Wheat. PP#8F4995. Tolerance Petition for use of Azoxystrobin on Canola. Evaluation of Analytical Methodology and Residue Data.
From: D. Dotson
To: C. Giles-Parker/J. Bazuin
Dated: 1/25/99
MRID(s): 44319303, 44319304, 44319306-44319308, 44452303, 44595104-44595108, 44595113, 44595115, and 44613502

DP Barcode: D254140
Subject: Azoxystrobin on Various commodities. IR-4 Proposal For Reduced Residue Chemistry Data Set.
From: G. Herndon
To: H. Jamerson/R. Forrest
Dated: 3/17/99
MRID(s): None

DP Barcode: D229372
Subject: Short Analysis of the Proposed Commodity Definition 40 CFR 180.1(h) for Parsley
From: B. Schneider
Dated: 1/10/00
MRID(s): None

DP Barcode: None
Subject: Crop Group Proposal: Turnip Greens - Reclassification under 40 CFR 180.41 to Move Turnip Greens from the Leaves of Root and Tuber Vegetable Crop Group 2 to Become a Member of the Brassica Leafy Vegetables Crop Group 5.
From: B. Schneider
Dated: 2/10/00
MRID(s): None

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: methyl (E)-2-(2-(6-(2-cyanophenoxy)-pyrimidin-4-yloxy)-phenyl)-3-methoxyacrylate	Common Name: Azoxystrobin	☐ Proposed tolerance ☐ Reevaluated tolerance ☐ Other	Date: 05/24/00

Codex Status (Maximum Residue Limits)	U. S. Tolerances
X No Codex proposal step 6 or above ☐ No Codex proposal step 6 or above for the crops requested	Petition Number: PP#9F06058 DP Barcode: D260134 Other Identifier:
Residue definition (step 8/CXL): N/A	Reviewer/Branch: K. Luck, Dynamac
	Residue definition: Azoxystrobin and its Z isomer

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Barley, grain	0.1
		Barley, hay	15.0
		Barley, straw	4.0
		Barley, bran	0.2
		Bulbs	7.5
		Citrus, fruits	3.0
		Citrus, dried pulp	7.0
		Citrus, oil	15.0
		Corn, grain	0.05
		Corn, kernel (sweet)	0.05
		Corn, forage	10.0
		Corn, stover	25.0
		Corn, oil	0.3
		Cotton, seed	0.01
		Cotton, gin by-products	0.01

		Root and Tuber Vegetables	0.5
		Tops of Root and Tuber Vegetables	50
		Leafy Vegetables (excluding *Brassica*)	30.0
		Cilantro	30.0
		Peanuts	0.2
		Peanuts, oil	0.6
		Peanuts, hay	15.0
		Soybean, seed	0.5
		Soybean, forage	25.0
		Soybean, hay	55.0
		Soybean, hulls	1.25
		Meat byproducts (cattle, goats, horses and, sheep)	0.07
		Fat (cattle, goats, horses, and sheep)	0.03

Limits for Canada	Limits for Mexico
X No Limits □ No Limits for the crops requested	□ No Limits X No Limits for the crops requested
Residue definition: N/A	Residue definition: Azoxystrobin

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

Notes/Special Instructions:
S. Funk, 05/24/2000