UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 17, 2002

MEMORANDUM

SUBJECT: PP#0F06121. PC Code 129112. CAS # 141517-21-7. Trifloxystrobin on Barley, Citrus, Corn (Field and Pop), Pecan, Pistachio, Rice, and Stone Fruit. Review of Analytical Methods and Residue Data. EPA Reg #s: 3125-559, 3125-562. DP Barcode: D267787, D272054.

MRID #s: 45080800, 45080806, 45080808, 45080809, 45080810, 45080811, 45126200, 45269400, 45269401, 45269402, 45276400, 45276401.

FROM: Leung Cheng, Chemist
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THROUGH: Stephen Dapson, Branch Senior Scientist
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Stephen C. Dapson
01/18/2002

TO: Cynthia Giles-Parker, Team 22
Fungicide Branch
Registration Division (7505C)

Following is the residue chemistry assessment of a petition for the establishment of permanent tolerances for residues of the fungicide trifloxystrobin (benzeneacetic acid, (E,E)-alpha-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]-, methyl ester], in/on barley, citrus, corn (field and pop), pecan, pistachio, rice and stone fruit. The review was performed by the Oak Ridge National Laboratory under the supervision of RAB3, HED. The data assessment has undergone secondary review within the branch and has been revised to reflect current HED and OPP policy. If any additional input is needed, please advise.

Executive Summary of Residue Chemistry Deficiencies

- Amend Section B/proposed labels.
- Delete use on wheat from the Stratego™ label.
- Revise Section F.
- Submit wheat metabolism studies.
- Submit barley residue data.
- Submit corn residue/bridging data using the appropriate formulation.

cc:RAB3 Reading F, Cheng
RD/I:Team:12/5/2001:SDapson:1/8/2002
7509C:RAB3:LCheng:CM#2:RM810A:12/13/2001:3rab/trifloxystrobin/citrus...rice

PERMANENT TOLERANCE PETITION FOR TRIFLOXYSTROBIN IN/ON:

BARLEY, CITRUS, CORN (FIELD and POP) , PECAN, PISTACHIO, RICE, AND STONE FRUIT

(PP# 0F06121; DP Barcode D267787, D272054)

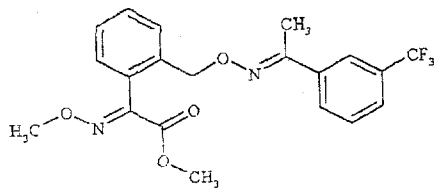
INTRODUCTION

Novartis Crop Protection (Bayer is the new proprietor) has submitted a petition to establish permanent tolerances for residues of the fungicide trifloxystrobin (benzeneacetic acid, (E,E)-alpha-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]-, methyl ester) and the free form of its acid metabolite CGA-321113 ((E,E)-methoxyimino-[2-[1-[3-(trifluoromethyl)phenyl]ethylideneaminooxymethyl]phenyl]acetic acid), in/on the following commodities:

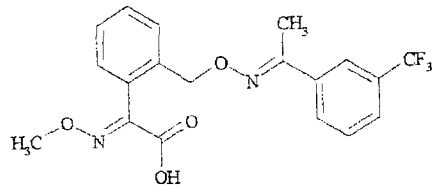
Barley, grain	0.05 ppm
Barley, straw	0.05 ppm
Barley, hay	0.2 ppm
Citrus (crop group 10), fruit	0.3 ppm
Citrus (crop group 10), oil	7.0 ppm
Corn, field, grain	0.05 ppm
Corn, field, forage	0.05 ppm
Corn, field, stover (fodder)	7.0 ppm
Corn, field, aspirated grain fractions	0.1 ppm
Popcorn, grain	0.05 ppm
Popcorn, stover (fodder)	7.0 ppm
Pistachio, nutmeat	0.05 ppm
Rice, grain	3.5 ppm
Rice, straw	7.5 ppm
Stone fruit (crop group 12), fruit	2.0 ppm
Tree Nuts Group (group 14), nutmeat	0.05 ppm
Poultry, fat	0.05 ppm
Poultry, kidney	0.05 ppm
Poultry, liver	0.05 ppm
Poultry, meat	0.05 ppm
Poultry, meat byproducts	0.05 ppm

Trifloxystrobin belongs to a new class of fungicides, the MAEs (β-methoxyacryl esters), which are synthetic analogs of strobilurin A, an antifungal secondary metabolite of the fungus

Strobilurus tenacellus. Trifloxystrobin is intended for use as a broad-spectrum preventative fungicide for control of many plant diseases. It works by interfering with the respiration in plant pathogenic fungi, and it is a potent inhibitor of spore germination and mycelial growth. The structures of trifloxystrobin (CGA-279202) and its acid metabolite (CGA-321113) are shown below.



Trifloxystrobin



CGA-321113

Currently established tolerances for residues of trifloxystrobin and its acid metabolite, CGA-321113 that are listed under 40 CFR 180.555 include bananas (1.0 ppm), cucurbit vegetables (0.50 ppm), grapes (2.0 ppm), raisins (5.0 ppm), peanuts (0.05 ppm), peanut hay (4.0 ppm), pome fruit (0.5 ppm), apple pomace-wet (5.0 ppm), milk (0.02 ppm), meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep (0.05 ppm). HED subsequently recommended (PP#9F5070, D254213, L. Cheng, 4/6/00) permanent tolerances for almonds, nutmeat (0.04 ppm), almonds, hulls (3.0 ppm), hops, dried cones (11.0 ppm), sugar beet, roots (0.1 ppm), sugar beet, tops (4.0 ppm), sugar beet, pulp, dried (0.4 ppm), sugar beet, molasses (0.2 ppm), potato, tubers (0.04 ppm), and time-limited tolerances for fruiting vegetables (0.5 ppm), wheat, grain (0.05 ppm), wheat, hay (0.2 ppm), wheat, straw (5.0 ppm), wheat, bran (0.15 ppm), and aspirated grain fractions (5.0 ppm).

The petitioner additionally requests that the time-limited tolerances for the combined residues of trifloxystrobin and its acid metabolite that were previously established in wheat commodities be changed to permanent tolerances. The registration of two trifloxystrobin formulations (Flint™ and Stratego™ Twin Pak™) for the use on wheat was previously made conditional until a new wheat metabolism study has been accepted. The petitioner has attempted to satisfy the wheat metabolism requirement by submission of two sugar beet metabolism studies.

The proposed tolerance for barley is based on residue data from the submitted corn and rice studies and an earlier submission of wheat residue data, not on barley field trials. Although not specifically identified as such in the submitted materials, CGA-279202 50WG corresponds to the trifloxystrobin water-dispersible granular (WDG or WG) formulation Flint™ (EPA Reg. No. 100-919) and CGA-279202/propiconazole 250EC corresponds to Stratego™ (EPA Reg. No. 100-

966; an EC formulation). The new numbers are 3125-559 for Flint™ and 3125-562 for Stratego™ (e-mail from C. Giles-Parker, 7/20/2001).

CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

1. Previously submitted product chemistry studies satisfy the requirements of 40 CFR 158.155–158.190 for the end-use products (EP) and for the technical grade active ingredient (TGAI). The Registration Division has no objections to the registration of CGA-279202 Technical or the end-use products containing CGA-279202 (Flint™ and Stratego™; the latter also contains propiconazole) (D254920, A. Smith, 4/23/99).

OPPTS GLN 860.1200: Proposed Uses

2a. Flint™: The use directions described on the proposed label are adequate for the use of trifloxystrobin on citrus, pecans, and stone fruits. The proposed use on field corn is not supported by residue data resulting from treatments using the WG formulation, and the use directions for corn do not specify the corn growth stages for the first and second applications, and intervals between the last application and foraging and grazing. For the use on rice, the label must be revised to restrict aquaculture in treated water and use of treated water: Do not apply in rice fields where commercial farming of crayfish will be practiced. Do not drain water from treated rice fields into ponds used for commercial catfish farming, to irrigate other crops, or use of treated water for livestock. The proposed use on barley must be deleted because it is not supported by residue data.

2b. Stratego™: The use directions described on the proposed label are adequate for the use of trifloxystrobin on pecans. The label is not adequate for corn as there are no specification of corn growth stages for the first and second applications, and no intervals between the last application and foraging and grazing; the submitted residue data support a pre-foraging and grazing interval of 30 days. A preharvest interval (PHI) of 35 days should be added to the label for use on rice. The proposed use on barley must be deleted because it is not supported by residue data. RD should verify that the PHIs for pecans and rice, the pre-foraging and grazing intervals for corn, and the rotational crop restrictions on the Stratego™ label are compatible with those specified for the registered use of propiconazole.

In addition, the use of trifloxystrobin on wheat permitted on the Stratego™ label must be deleted since the previous wheat residue data were generated from a WG formulation and no residue data from an EC formulation or wheat bridging residue data have been submitted.

OPPTS GLN 860.1300: Nature of the Residue - Plants

3a. It was stated in an earlier petition (PP#8F4955) that the qualitative nature of the residue in plants is adequately understood for fruits, fruiting vegetables, cucurbit vegetables and peanuts, based on acceptable metabolism studies conducted on apples, cucumbers, peanuts, and a supplementary study on wheat. On the basis of existing metabolism studies, the HED Metabolism Assessment Review Committee (MARC) concluded that both trifloxystrobin and the free form of its acid metabolite CGA-321113 are of concern for both regulatory and risk assessment purposes for plant commodities, and also concluded that additional metabolism studies would be needed to support possible future uses on leafy vegetables, cereals or crops other than fruits, fruiting vegetables, cucurbit vegetables, and peanuts. In the interim, the MARC concluded that trifloxystrobin and the free form of its acid metabolite CGA-321113 are of concern in wheat for both regulatory and risk assessment purposes but that additional metabolism data on wheat are required for a full Section 3 registration. In the previous petition (PP#9F5070), RAB3 concluded that the nature of the residue in almond, hops, fruiting vegetables, tuberous and corm vegetables, and sugar beet is understood, and trifloxystrobin and the free form of its acid metabolite CGA-321113 are of concern for both regulatory and risk assessment purposes in these plant commodities.

3b. In the current petition, Novartis submitted two sugar beet trifloxystrobin metabolism studies. Sugar beets were treated three times with 1x or 5.5x trifloxystrobin, labeled at the [glyoxylphenyl-(U)-^{14}C] or [trifluoromethylphenyl-(U)-^{14}C] position (GP-labeled and TFMP-labeled, respectively). Results for the two radiolabels were comparable. Total residues at all intervals were much greater in the tops than in the roots, and in the soil samples were generally similar to or lower than in the roots. In the tops and roots, the majority of the radiolabel was present as parent compound at all intervals (23.9-96.3% TRR), whereas the most abundant soil metabolite was CGA-321113 (29.3-84.3% TRR). The roots were shown to contain ~ 5.9% of the TRR incorporated into saccharose, 0.4% into cellulose, 2.4% into lignin, and 1.5% into pectin. In addition to the parent CGA-279202 and its two isomers (CGA-331409 and CGA-357262), nine metabolites were identified by TLC and/or HPLC in the sugar beet tops. Seven of the 9 metabolites were also found in the roots and soil. Mass spectrometry confirmed or suggested the identity of most of the compounds. Trifloxystrobin metabolism involves several routes, including cis/trans isomerization, methyl ester cleavage, hydroxylation of the trifluoromethylphenyl ring, glucose conjugation, oxidation of the 2-ethylideneaminooxymethyl group, and cleavage of the methyl ester bond of the parent compound and addition of three hydroxyl groups. Based on these studies, the nature of trifloxystrobin in/on sugar beet is adequately understood, and the major residues include the parent and metabolite CGA-321113. However, the sugar beet metabolism studies do not fulfill the wheat metabolism data requirement because the two crops are too dissimilar.

OPPTS GLN 860.1300: Nature of the Residue - Livestock

4. No livestock data were submitted. The qualitative nature of the residue in livestock is adequately understood based on acceptable studies conducted on goats and laying hens described in PP#8F4955. The MARC has determined that the total toxic residues for livestock, both for regulatory and risk assessment purposes, is trifloxystrobin and the free form of its acid metabolite CGA-321113. Additionally, metabolite L7a (taurine conjugate of trifloxystrobin) in the liver should be included in risk assessment.

OPPTS GLN 860.1340: Analytical Methods - Plants and Livestock

5a. EPA has completed a method validation trial of AG-659A on apples, wet apple pomace, grapes, summer squash, peanut hay, peanuts, cow liver, cow milk and raisins, and concluded that AG-659A is suitable for enforcement of trifloxystrobin and the free form of its acid metabolite (CGA-321113) in plant and livestock commodities (D262400, ACB, BEAD memo, 1/18/2000, P. E. Golden and P. G. Schermerhorn). The limit of quantitation (LOQ) for trifloxystrobin and CGA-321113 is 0.01 ppm each in milk, 0.02 ppm each in plant commodities, ruminant tissues, poultry tissues, and eggs. The enforcement method has been submitted to the Food and Drug Administration for publication in the Pesticides Assessment Manual II (correspondence, L. Cheng, April 13, 2000).

5b. The petitioner used a hybrid of method AG-659A and related method REM 177.04 to determine residues of trifloxystrobin and its metabolite CGA-321113 in/on rice bran. Method REM 177.04 had been previously validated for hops (PP#9F5070); the LOQ was 0.02 ppm each for trifloxystrobin and CGA-321113.

5c. The analytical methods, AG-659A or AG-659A/REM 177.04, are adequate for collecting data for residues of trifloxystrobin and its acid metabolite CGA-321113 in/on all crops associated with this petition.

OPPTS GLN 860.1360: Multiresidue Method

6. The regulable residue was tested in accordance with the Pesticide Analytical Manual, Volume I, Appendix II. Trifloxystrobin gave adequate responses through protocol C, and was completely recovered from fortified apple samples when analyzed through protocols D and E. Acid metabolite CGA-321113 was recoverable through protocol B and residues from apples fortified with CGA-321113 were completely recovered through Section 402 E2/C1 (extraction with methylene chloride). These data were forwarded to FDA.

OPPTS GLN 860.1380: Storage Stability Data

7. Plant commodities: Previously submitted freezer storage stability data showed that residues of trifloxystrobin and its acid metabolite CGA-321113 are stable in cucumbers, grapes, potatoes (tubers), whole wheat plant, wheat grain, and wheat straw for up to 24

months and in apple fruit, apple pomace, grape juice, peanut nutmeat, peanut hay, peanut oil, and potato granules for up to 18.6 months at approximately -20°C. The existing storage stability database for trifloxystrobin and CGA-321113 is adequate to support the crop sample storage intervals presented in this petition: 19 months for citrus, 16.2 months for corn, 8.4 months for pecans, 15.2 months for rice, and 17 months for stone fruit.

8. Livestock commodities: No livestock studies were included in this submission. Previously submitted freezer storage stability data showed that residues of trifloxystrobin and CGA-321113 are stable in beef muscle, beef liver, milk, and eggs stored at approximately -20 °C for at least 12 to 13 months.

OPPTS GLN 860.1500: Crop Field Trials

Barley:

9. No barley field trials were provided. The registrant requested the establishment of a tolerance for trifloxystrobin in barley based on the residue studies for wheat, corn and rice, citing a previous HED memo re azoxystrobin (D254140, G. Herndon, 3/17/99).

Since trifloxystrobin does not meet all the toxicological criteria and chemical properties described for azoxystrobin and there are in-house data indicating differing residue levels in wheat and barley commodities resulting from identical use patterns, RAB3 concludes that barley residue data are required for its use.

Citrus:

10a. The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of trifloxystrobin on citrus. Twenty three field trials (12 on oranges, 6 on grapefruit, and 5 on lemons) were conducted using the WG formulation. Following 4 x 0.15 lb ai/A in either concentrated or dilute sprays and harvested 28-32 days after the last application, residues ranged from 0.04 to 0.23 ppm trifloxystrobin and <0.02 ppm CGA-321113 in oranges (22 samples), <0.02 to 0.22 ppm trifloxystrobin and <0.02 ppm CGA-321113 in lemons (10 samples), and <0.02 to 0.10 ppm trifloxystrobin and <0.02 ppm CGA-321113 in grapefruit (16 samples). The residue data support the proposed tolerance of 0.3 ppm combined residues of trifloxystrobin and CGA-321113 in/on citrus crop group.

10b. Residue decline studies were carried out for the representative crops oranges, grapefruit, and lemons. In general, there was a decline in CGA-279202 concentration with time and no CGA-321113 was detected above 0.02 ppm (the LOQ).

Corn:

11a. The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of trifloxystrobin on corn using the EC formulation. Following 4 x 0.11 lb ai/A applications and a PHI of 30 days, no CGA-279202 was detected at ≥LOQ (0.02 ppm) in any grain sample (23 field corn and 4 popcorn field trials), and only one grain sample had measurable CGA-321113 at 0.027 ppm. No crop residue data reflecting the WG

formulation were submitted. The residue data support the proposed tolerance of 0.05 ppm combined residues of trifloxystrobin and CGA-321113 in/on corn, field and pop, grain resulting from the EC formulation.

11b. For field corn forage, following 2 x 0.11 lb ai/A applications and 29-31day PHIs, residues ranged from <0.02 to 0.12 ppm trifloxystrobin and <0.02 to 0.075 ppm CGA-321113. Combined residue levels were 0.04-0.20 ppm in field corn forage. The residue levels in corn forage (40 samples) exceed the proposed tolerance of 0.05 ppm. RAB3 recommends that the petitioner propose a tolerance of 0.2 ppm combined residues of trifloxystrobin and CGA-321113 in field corn forage, provided that a feeding restriction of 30 days is imposed on the Stratego™ (EC formulation) label before cutting for forage and grazing.

11c. The residues for corn stover (44 samples) following 4 x 0.11 lb ai/A and a 30-day PHI ranged from 0.04 to 5.4 ppm trifloxystrobin and <0.02 to 1.6 ppm for CGA-321113, with a maximum combined level of 7.0 ppm. The data support the proposed tolerance of 7.0 ppm combined residues of trifloxystrobin and CGA-321113 in/on corn stover.

11d. Due to the low residue levels in field corn grain at nearly all sampling times, the decline studies are of minimal value, but there is evidence of decline in both compounds.

11e. The use of trifloxystrobin on field and pop corn proposed on the Flint™ label is not supported by residue data generated with the appropriate formulation or bridging data.

Pecan:

12a. The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of trifloxystrobin on pecan. Five pecan field trials were conducted using either the WG or EC formulation. Following 8 x 0.13 lb ai/A in either dilute or concentrated sprays and harvested 28-30 days after the last application, residues of trifloxystrobin and CGA-321113 were each <0.02 ppm in the nutmeat. The residue data are adequate to support the use on pecan for the EC formulation Stratego™. In combination with the residue data on almond discussed in PP#9F5070 (D254213, L. Cheng, April 6, 2000), the residue data are also adequate to support a tree nut group tolerance at 0.04 ppm for the combined residues of trifloxystrobin and CGA-321113 for the WG formulation Flint™. The petitioner needs to submit a revised Section F reflecting the recommended group tolerance level in/on tree nuts.

12b. The residues found in the pecan decline study were <0.02 ppm each for trifloxystrobin and CGA-321113 at all time intervals, precluding evaluation of potential residue decline.

Pistachio:

13. No residue data for pistachio were submitted. However, the pecan residue data are translatable to pistachio. The proposed tolerance of 0.05 ppm combined residues of

trifloxystrobin and CGA-321113 in/on pistachio is adequate, but should be revised to 0.04 ppm, same tolerance level for pecan. A revised Section F is required.

Rice:

14a. The petitioner has provided residue data reflecting the maximum proposed use pattern of trifloxystrobin with the WG formulation on rice grain. Following 2 x 0.154 lb ai/A applications and harvested 34-40 days after the last application, residues ranged from <0.02 to 3.4 ppm trifloxystrobin and <0.02 to 0.12 ppm CGA-321113 in/on rice grain. The combined residue levels were <0.04 to 3.43 ppm for the WG formulation.

14b. The petitioner has provided residue data reflecting the maximum proposed use pattern of trifloxystrobin with the EC formulation on rice grain. Following 2 x 0.154 lb ai/A applications and harvested 35-40 days after the last application, residues ranged from <0.02 to 0.56 ppm trifloxystrobin and <0.02 to 0.076 ppm CGA-321113 in/on rice grain. The combined residue levels were <0.04 to 0.63 ppm for the EC formulation.

14c. The petitioner has provided residue data reflecting the maximum proposed use pattern of trifloxystrobin with the WG formulation on rice straw. Following 2 x 0.154 lb ai/A applications and harvested 34-40 days after the last application, residues ranged from 0.048 to 6.1 ppm trifloxystrobin and <0.02 to 1.3 ppm CGA-321113 in rice straw. The combined residue levels were <0.068 to 7.3 ppm for the WG formulation.

14d. The petitioner has provided residue data reflecting the maximum proposed use pattern of trifloxystrobin with the EC formulation on rice straw. Following 2 x 0.154 lb ai/A applications and harvested 34-40 days after the last application, residues ranged from 0.20 to 2.6 ppm trifloxystrobin and 0.04 to 1.1 ppm CGA-321113 in rice straw. The combined residue levels were 0.23 to 3.7 ppm for the EC formulation.

14e. Comparison of the results from the side-by-side tests shows that the WG formulation resulted in generally higher combined trifloxystrobin and CGA-321113 residues in grain and straw than the EC formulation. Since the bulk of the residue data were generated using the WG formulation (16 field trials), the submitted residue data are adequate to support the proposed use of the EC formulation. The residue data support the proposed tolerances of 3.5 ppm for combined residues of trifloxystrobin and CGA-321113 in/on rice grain and 7.5 ppm combined residues of trifloxystrobin and CGA-321113 in/on rice straw.

14f. For residue decline in grain, one study showed that levels of trifloxystrobin declined and for the acid metabolite, it showed no definite trend of increase or decrease of residues over time. Another study showed no consistent trend of increase or decrease in levels of trifloxystobin and its acid metabolite over time. For straw, levels of trifloxystrobin declined and levels of the acid metabolite increased over time.

Stone fruit:

15a. The petitioner has provided adequate residue data reflecting the maximum proposed use pattern of trifloxystrobin on stone fruit. For the stone fruit crop group, 27 field trials were conducted on peaches, plums, sweet cherries, and tart cherries. Following 4 x 0.125 lb ai/A applications with the WG formulation and harvested 0-1 day PHI, residues ranged from <0.02 to 0.53 ppm trifloxystrobin and <0.02 ppm CGA-321113 with a combined maximum level of <0.55 ppm in plums (24 samples), <0.02 to 1.9 ppm trifloxystrobin and <0.02 to 0.08 ppm CGA-321113 with a combined maximum level of 1.96 ppm in peaches (32 samples), 0.25 to 0.84 ppm trifloxystrobin and <0.02 to 0.06 ppm CGA-321113 with a combined maximum level of 0.90 ppm in sweet cherries (16 samples), and 0.29 to 0.67 ppm trifloxystrobin and <0.02 to 0.07 ppm CGA-321113 with a combined maximum level of 0.74 ppm in tart cherries (16 samples). The residue data are adequate to support the proposed tolerance of 2.0 ppm for the combined residues of trifloxystrobin and CGA-321113 in/on stone fruits.

15b. One study for each of the 4 stone fruit crops (peaches, plums, sweet cherries, and tart cherries) was a residue decline study. In general, there was a decline in CGA-279202 concentration with time; no CGA-321113 residues were detected above the LOQ of 0.02 ppm.

OPPTS GLN 860.1520: Processed Food/Feed

Citrus:

16. Residues did not concentrate in juice but concentrated in oil (average 118x) and dried pulp (average 3x). Based on the highest average field trial (HAFT) of 0.25 ppm in oranges and average concentration factors, residues in oil and in dried pulp are not expected to exceed 30 ppm in citrus oil and 0.8 ppm in dried pulp. The petitioner needs to propose a tolerance of 30 ppm for combined residues of trifloxystrobin and CGA-321113 in citrus oil and a tolerance of 0.8 ppm for combined residues of trifloxystrobin and CGA-321113 in dried pulp. A revised Section F reflecting these tolerances is required.

Corn:

17a. No concentration was observed for trifloxystrobin in the meal, grits, flour, starch, and dry milled oil; it is not possible to determine a concentration or reduction factor for the acid metabolite (all <0.02 ppm in corn grain before processing and in processed fractions) in these corn fractions. From the 5x study, a concentration of 2.4x was obtained in wet milled oil. Based on the HAFT of 0.026 ppm in corn grain, residues are not expected to exceed 0.1 ppm in corn oil. The petitioner needs to propose a tolerance of 0.1 ppm for combined residues of trifloxystrobin and CGA-321113 in corn oil.

17b. Aspirated grain fractions: From the 5x study, trifloxystrobin concentrated 40x in aspirated grain fractions; it is not possible to determine a meaningful concentration factor for the acid metabolite when the treated corn grain bore <0.02 ppm CGA-321113 before processing. The concentration factor for trifloxystrobin should cover both itself and its acid metabolite since the acid metabolite is only a fraction of the total residue. Based on

the HAFT of 0.026 ppm in corn grain, residues are not expected to exceed 1.2 ppm in aspirated grain fractions. However, since there already exists a time-limited tolerance of 5 ppm in aspirated grain fractions from the use on wheat, the tolerance for aspirated grain fractions should remain at 5 ppm. The petitioner must also change the proposed commodity definition from "Corn, field, aspirated grain fractions" to "Aspirated grain fractions." The Agency does not set tolerances for the aspirated grain fractions of individual crops. A revised Section F is needed.

Rice:

18. Trifloxystrobin and its acid metabolite together did not concentrate in polished rice and showed apparent concentration (average concentration of 1.1x) in rice bran. The mean concentration factor for rice hulls is 2.55x. Based on the HAFT of 3.0 ppm in rice grain, residues in rice hulls are not expected to exceed a tolerance of 8 ppm. The petitioner needs to propose a tolerance of 8 ppm for combined residues of trifloxystrobin and CGA-321113 in rice hulls. A revised Section F reflecting this tolerance is required.

Stone fruit:

19. Residues of trifloxystrobin and its acid metabolite concentrated (1.4x) in dried plums. Based on the HAFT of 0.55 ppm in fresh plums, residues in dried plums are not expected to exceed the proposed crop group tolerance of 2.0 ppm. Therefore, a tolerance in dried plum is not needed.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

20a. In a previously reviewed cattle feeding study, cows were administered up to 20 ppm trifloxystrobin in the diet for 28–30 days. Residues of trifloxystrobin were below the analytical method's LOQs in milk, muscle (round and tenderloin), kidney, and liver at 20 ppm but were detected in omental fat (<0.02–0.05 ppm) and perirenal fat (<0.02–0.06 ppm). Residues of the acid metabolite, CGA-321113, were detected in kidney (<0.02–0.02 ppm) and liver (<0.02–0.09 ppm) at 20 ppm but were below the method LOQs in milk, muscle (round and tenderloin), and fat (omental and perirenal). HED recommended tolerances of 0.02 ppm for the combined residues in milk, 0.05 ppm for the combined residues in meat, fat, and meat byproducts, and that a 0.1 ppm trifloxystrobin equivalent level be used for risk assessment purposes for the liver to account for the significant contribution of metabolite L7a in the liver. The maximum theoretical dietary burdens (MTDBs) including commodities in the present petition (11.5 ppm for beef cattle and 8.33 ppm for dairy cattle) are still below the highest concentration administered in the cattle feeding study. Revised tolerances for ruminant commodities are therefore not needed for the proposed uses. The liver contribution of metabolite L7a, however, increases from 0.05 to 0.11 ppm, resulting in a slightly higher total trifloxystrobin equivalent (L7a + trifloxystrobin + CGA-321113 = 0.16 ppm) to be used for liver for risk assessment.

20b. Feedstuffs potentially utilized in poultry diets associated with the present petition include rice grain, hulls, and bran; barley grain; field corn grain and milled byproducts; and pop corn grain. In a previous poultry feeding study, hens administered trifloxystrobin at up to 15 ppm in the diet had trifloxystrobin and CGA-321113 levels each below the LOQ at all times in eggs and tissues. The MTDB in chickens was calculated as 4.18 ppm based on a diet of 60% rice grain, 25% rice bran, and 15% rice hull. Since the highest feeding level was 3.6x (<10x) the MTDB, tolerances for trifloxystrobin in poultry and eggs at the combined LOQ levels are required. RAB3 recommends that the petitioner propose 0.04 ppm tolerances in/on eggs, fat, meat and meat byproducts of poultry. A revised Section F reflecting these tolerances is needed.

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

21. Confined rotational crop studies were submitted earlier. Data support a 30-day plantback interval (PBI) for crops not listed on the Flint™ label, and a 30-day PBI for celery, cereals, sweet corn, pineapple and sugarcane, and 105-day PBI for all other crops for the Stratego™ label, provided that rotational crop restrictions of the Stratego™ label are compatible with those of the propiconazole labels.

International Harmonization Issues

22. No Codex, Canadian, or Mexican maximum residue levels (MRLs) are established for trifloxystrobin. Harmonization is thus not an issue.

RECOMMENDATIONS

RAB3 cannot recommend for the proposed tolerances for the combined residues of trifloxystrobin and its acid metabolite in/on barley, citrus, corn (field and pop), pecan, pistachio, rice, stone fruit, and poultry and eggs, for reasons given in Conclusions 2 (a,b), 3 (a,b), 9, 11b, 11e, 13, 16, 17a, 17b, 18, and 20b.

However, other than a revised Section F for pistachio, there will be no residue chemistry data requirements that would preclude the establishment of tolerances for the combined residues of trifloxystrobin (benzeneacetic acid, (E,E)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]-, methyl ester) and the free form of its acid metabolite CGA-321113 ((E,E)-methoxyimino-[2-[1-[3-(trifluoromethyl)phenyl]ethylideneaminooxymethyl]-phenyl]acetic acid, in connection with the registration of Flint™ for the use on pistachio, stone fruit, and tree nuts, and Stratego™ for the use on pecan in/on the following commodities at the indicated levels:

Fruit, stone, group	2 ppm
Nut, tree, group	0.04 ppm
Pistachio	0.04 ppm

Provided the petitioner submit a revised Section B/label and revised Section F, and upon submission of adequate wheat metabolism data, there will be no residue chemistry data requirements that would preclude the establishment of tolerances for the combined residues of trifloxystrobin (benzeneacetic acid, (E,E)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]-, methyl ester) and the free form of its acid metabolite CGA-321113 ((E,E)-methoxyimino-[2-[1-[3-(trifluoromethyl)phenyl]ethylideneaminooxymethyl]-phenyl]acetic acid, in connection with the registration of Stratego™ for the use on field and pop corn and of Flint™ and Stratego™ for the use on rice in/on the following commodities at the indicated levels:

Corn, field, grain	0.05 ppm
Corn, field, forage	0.2 ppm
Corn, field, stover	7 ppm
Corn, oil	0.1 ppm
Corn, pop, grain	0.05 ppm
Corn, pop, stover	7 ppm
Rice, grain	3.5 ppm
Rice, hulls	8 ppm
Rice, straw	7.5 ppm

In the interim, RAB3 recommends that the above tolerances for corn and rice commodities be time-limited. Conversion of the time-limited tolerances in/on corn and rice commodities to full Section 3 tolerances may be granted upon submission of adequate wheat metabolism data.

Provided the petitioner submit a revised Section F, there will be no residue chemistry data requirements that would preclude the establishment of tolerances for the combined residues of trifloxystrobin (benzeneacetic acid, (E,E)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-, methyl ester) and the free form of its acid metabolite CGA-321113 ((E,E)-methoxyimino-[2-[1-[3-(trifluoromethyl)phenyl]ethylideneaminooxymethyl]-phenyl]acetic acid, in connection with the registration of Flint™ for the use on citrus in/on the following commodities at the indicated levels:

Citrus, dry pulp	0.8 ppm
Citrus, oil	30 ppm
Fruit, citrus, group	0.3 ppm

Provided the petitioner submit a revised Section F and upon submission of adequate wheat metabolism data, there will be no residue chemistry data requirements that would preclude the establishment of tolerances for the combined residues of trifloxystrobin (benzeneacetic acid, (E,E)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-, methyl ester) and the free form of its acid metabolite CGA-321113 ((E,E)-methoxyimino-[2-[1-[3-(trifluoromethyl)phenyl]ethylideneaminooxymethyl]-

phenyl]acetic acid, in connection with the registration of of Flint™ and Stratego™ in/on the following commodities at the indicated levels:

Eggs	0.04 ppm
Poultry, fat	0.04 ppm
Poultry, meat	0.04 ppm
Poultry, meat byproducts	0.04 ppm

In the interim, RAB3 recommends that the tolerances for poultry and eggs be time-limited. Conversion of the time-limited poultry and eggs tolerances to full Section 3 tolerances may be granted upon submission of adequate wheat metabolism data.

The registration of Stratego™ (EC formulation) for the use on wheat is not supported by wheat residue data generated with the appropriate EC formulation or bridging data. Therefore, the Stratego™ label must be revised to delete the use on wheat.

The request to convert the time-limited tolerances in/on wheat commodities (Flint™ WG formulation) to full Section 3 tolerances is denied due to the lack of adequate wheat metabolism data.

HED will initiate a human health risk assessment for the supported uses.

DETAILED CONSIDERATIONS

OPPTS 830 Series GLNs: Product Properties

Product chemistry data were previously submitted for the 98% trifloxystrobin T/TGAI and for the end-use product CGA-279202 and reviewed in the Registration Division (Alfred Smith, Technical Review Branch, Registration Division, 4/23/99). It was concluded that both the end-use product CGA-279202 and the TGAI meet label requirements of 40CFR156.10 and product chemistry information for 40 CFR 158.155–158.190. The Registration Division has no objections to the registration of CGA-279202 Technical or the end-use products containing CGA-279202 (D254920, A. Smith, 4/23/99).

OPPTS GLN 860.1200: Proposed Uses

For Flint™ (50% active by weight) ground applications should be made in a volume of at least 50 GPA (gallons per acre) for tree crops and 10 GPA for other crops, and aerial applications should be in a volume of at least 10 GPA for tree crops and 5 GPA for other crops. The product must not be applied by chemigation. Treated areas may be replanted immediately following harvest with any crop listed on the Flint™ label, and crops not listed on the Flint™ label can be planted 30 days after the last treatment.

Stratego™ (EC, 1.04 lbs ai/gallon; 3125-562, submitted in June, 2001) may be applied by ground equipment in a volume of at least 10 GPA, and by aerial equipment in a volume of at least 5 GPA. The product must not be applied by chemigation. Treated areas may be replanted immediately following harvest with any crop listed on this label, and celery, cereals, sweet corn, pineapple, and sugarcane may be planted 30 days after the last application. For all other crops, a 105-day plantback interval must be observed.

Barley

For control of rust, leaf blotch, glume blotch, powdery mildew, and tan spot, Flint™ may be applied up to 2 times at 0.11 lb ai/A (0.22 lb ai/A/season) with a PHI (preharvest interval) of 35 days. The label recommends treatment to begin preferably between flag leaf emergence and 50% flowering, but application may be made earlier if needed. The label specifies grazing and foraging intervals of 30 days, and an interval of 45 days before cutting for hay after application of 0.11 lb ai/A. The label prohibits grazing and cutting for forage and hay after 2 applications or a total amount of 0.22 lb ai/A has been applied.

For Stratego™ the proposed use rate is up to 0.08 lb ai/A with a maximum of 2 applications at 14 day retreatment intervals for a total of 0.16 lb ai/A/season; the PHI is 35 days. The fungicide should not be applied after Feekes growth stage 8 (the ligule of the flag leaf emerges). The label specifies grazing and foraging intervals of 30 days, and an interval of 45 days before cutting for hay after application of 0.08 lb ai/A. The label prohibits grazing and cutting for forage and hay after 2 applications, or a total amount of 0.16 lb ai/A has been applied.

Corn (field and pop)

To control rust, leaf blight, leaf spot, gray leaf spot, and eye spot, Flint™ may be applied up to 4 times at 0.11 lb ai/A (or 0.44 lb ai/A/season) 7-10 days apart, with a PHI of 30 days. The label recommends treatment when disease first appears and to continue if conditions are favorable for development of disease. No restrictions have been proposed for grazing or cutting of forage.

For Stratego™ the proposed use rate is up to 0.10 lb ai/A with a maximum of 3 applications at 7-14 day retreatment intervals for a total of 0.30 lb ai/A/season. The product should not be applied after silking or within 30 days of harvest. No restrictions have been proposed for grazing or cutting of forage.

Citrus

For control of alternaria, greasy spot, melanose, and scab, Flint™ may be applied at up to 4 oz product/A (0.125 lb ai/A) with a maximum of 4 applications for a total of 16 oz product/A/season (0.5 lb ai/A/season). The label recommends applications at first flush, petal fall, and after petal fall. The PHI is 30 days.

Pecan

For control of scab and anthracnose, Flint™ may be applied at up to 0.125 lb ai (4 oz product) per acre. Up to 6 applications for a total of 0.75 lb ai/A at 14- to 21-day retreatment intervals are permitted per season. Flint™ is not to be applied after shuck split or within 30 days of harvest.

For Stratego™ the proposed use rate is up to 0.08 lb ai (10 fl oz product) per acre with a maximum of 3 applications at 14-21 day intervals for a total of 0.24 lb ai/A/season. Stratego™ is not to be applied after shuck split or within 30 days of harvest.

Pistachio

For control of blight, Flint™ may be applied at up to 0.125 lb ai per acre. Up to 4 applications for a total of 0.375 lb ai/A at 14-21 day retreatment intervals are permitted per season. The proposed PHI is 60 days.

Rice

For control of rice blast, sheath blight, and sheath spot, Flint™ may be applied at boot, internode elongation or swollen boot stage but before boot splits and head emerges at up to 0.15 lb ai (4.9 oz product) per acre with a maximum of 2 applications (0.31 lb ai/A) per season. The retreatment interval is 14-21 days and the PHI is 35 days. The label does not contain restrictions for the discharge of treated water and aquaculture in treated water.

For Stratego™ the proposed use rate is up to 0.13 lb ai (16 fl oz product) per acre for up to 2 applications at 14-21 day intervals for a total of 0.26 lb ai/A/season. Stratego™ should not be applied once the seed head has emerged, to stubble or ratoon crop rice, or in rice fields where commercial farming of crayfish will be practiced. Do not drain water from treated rice fields into ponds used for commercial catfish farming, or to irrigate other crops. Do not apply in California, and Mississippi, Poinsett, Cross, St. Francis and Lee counties in AR. A PHI has not been specified.

Stone Fruit

For control of cherry leaf spot, powdery mildew, and scab, Flint™ may be applied at up to 4 oz product/A (0.125 lb ai/A). A maximum of 4 applications for a total of 16 oz product/A/season (0.5 lb ai/A/season) is permitted. The label recommends applications begin at petal fall and continue at 7-14 day intervals. The proposed PHI is 1 day.

Stratego™

The Stratego™ label includes wheat among the crops that may be treated. Stratego™ is an EC formulation and the previous wheat residue data were generated using the WG formulation.

Wheat must be deleted from the list of crops that may be treated since there were no wheat residue data generated with the EC formulation or appropriate bridging residue data.

OPPTS GLN 860.1300: Nature of the Residue - Plants

The petitioner submitted two sugar beet metabolism studies (citations below) in this petition. A stem injection experiment was also performed, but was not further described.

> MRID 45269401. Kiffe, M. (2000) Behavior and metabolism of [glyoxyl-phenyl-(U)-^{14}C] CGA-279202 in field grown sugar beets. Crop Metabolism, Novartis Crop Protection Ag, Basel, Switzerland. Study 99MK10, Novartis Number 1267-00, September 21, 2000. Unpublished.
>
> MRID 45269402. Kiffe, M. (2000) Behavior and metabolism of [trifluoromethyl-phenyl-(U)-^{14}C] CGA-279202 in field grown sugar beets. Crop Metabolism, Novartis Crop Protection Ag, Basel, Switzerland. Study 99MK09, Novartis Number 1266-00, September 21, 2000. Unpublished.

Sugar beets (variety *Kassandra*) were treated with trifloxystrobin labeled at either [glyoxyl-phenyl-(U)-^{14}C] or [trifluoromethyl-phenyl-(U)-^{14}C] positions (GP-labeled and TFMP-labeled, respectively). The [^{14}C]trifloxystrobin formulations (9EC125 or A-9604A) were prepared by mixing radiolabeled trifloxystrobin with a blank formulation in tap water. The trifloxystrobin specific activity, radiochemical purity, and application rate are shown in Table 1.

Table 1. Test substances and application rates for sugar beet metabolism studies.

Labeled compound	[glyoxyl-phenyl-(U)-^{14}C] trifloxystrobin (MRID 45269401)	[trifluoromethyl-phenyl-(U)-^{14}C] trifloxystrobin (MRID 45269402)
Proposed use rate (~1X) study (Substudy 1)		
Batch number Specific activity: Application rate (g ai/A) Radiochemical purity:	ILS-234.1 25.54 µCi/mg (56,700 dpm/µg) 57, 53, 51 for 1st, 2nd, 3rd (total=162) 99.4% (1st, 2nd appl.), 97.8 (3rd applic.)	JAK-XVI-86 27.03 µCi/mg (60,000 dpm/µg) 53, 55, 52 for 1st, 2nd, 3rd (total=160) 97.1% (1st, 2nd appl.), 95.8 (3rd applic.)
Exaggerated rate (5.5X) study (Substudy 2)		
Batch number Specific activity: Application rate (g ai/ha) Radiochemical purity:	GAN-XLI-58 13.51 µCi/mg (30,000 dpm/µg) [final] 336, 280, 277 for 1st, 2nd, 3rd (total=892) 98.2% (1st, 2nd appl.), 95.5 (3rd applic.)	JAK-XVI-67 24.32 µCi/mg (54,000 dpm/µg) 280, 281, 311 for 1st, 2nd, 3rd (total=872) 98.7% (1st, 2nd, 3rd applic.)
Unlabeled test substance: Batch number: Purity:	trifloxystrobin AMS 759/3; 99.9%	trifloxystrobin AMS 759/3; 99.9%

For each radiolabel, one plot was treated at 1X and one at the exaggerated rate (5.5X), and one plot served as a control (same control plot used for both labels). The plots were prepared and plants grown using good agricultural practice. The studies were conducted in St. Aubin (FR), Switzerland in spring-summer 1999. Before application, 3 soil samples at 0-30 cm were taken, subdivided into 3 layers (0-10, 10-20, and 20-30 cm), analyzed, and found to have no radioactivity above background levels.

The [^{14}C]trifloxystrobin was applied to the crops three times. The 1X application rate for [glyoxyl-phenyl-(U)-^{14}C] trifloxystrobin was 51-57 g (0.11-0.13 lb) ai/A/application for a total of 162 g (0.36 lb) ai/A/season and for the 5.5X rate was 277-336 g (0.61-0.74 lb) ai/A/application (total=892 g or 2.0 lb ai/A/season), as shown in Table 1. The 1X application rate for [trifluoromethyl-phenyl-(U)-^{14}C] trifloxystrobin was 52-55 g (0.11-0.12 lb) g ai/A/application for a total of 160 g (0.35 lb) ai/A/season and for the 5.5X study was 280-311 g (0.62-0.68 lb) ai/ha/application (total=872 g or 1.9 lb ai/A/season). The applications were made at 3-week intervals starting at growth stage BBCH 39 (crop cover complete and leaves cover 90% of ground); the 2nd and 3rd applications were made at BBCH 39-49 (crop cover complete and beet root has reached harvestable size). Samples were collected 1 hr after the 1st, 2nd, and 3rd applications [3 plants each] and 21 and 45 days after the 3rd application [10-33 plants each] for the 1X and control studies and at 21 and 45 days after the 3rd application for the 5.5X studies [10-14 plants each].

Total radioactive residues (TRR)

The sugar beet samples were separated into roots and tops, each homogenized with liquid nitrogen and aliquots of the homogenized samples (top: ~ 0.05-0.10 g; root ~0.5 g) were combusted and measured for radioactivity. Also, aliquots of the homogenized samples were extracted several times with acetonitrile/water 80:20 v/v. The combined extracts were analyzed by thin layer chromatography (TLC) using pre-coated plates with silica gel 60 F_{254}, 0.25 mm thick using either analytical system II (chloroform: methanol: formic acid: water (75:20:4:2 v/v/v/v); 1-butanol: acetic acid: water (40:10:10 v/v/v)) or analytical system III (toluene: ethyl acetate (9:1 v/v)). Substances were visualized at 254 and/or 366 nm. Non-extractable radioactivity was determined by combustion of extracted samples either directly after the cold extraction or after cold extraction followed by microwave extraction (1-propanol/water 80:20 v/v under argon; 50 minutes at 100-150°C), air-drying, and homogenization in a disk mill.

As shown in Table 2, recoveries for the two radiolabels were similar qualitatively and quantitatively at comparable study intervals. The recovery of applied radiolabel (determined as the sum of the acetonitrile-extractable and non-extractable radioactivity, relative to the total radioactivity determined by combustion for each matrix) was 85.9-119.5% for the GP-labeled samples and was 95.9-116.7% for the TFMP-labeled samples. The vast majority of the radioactivity in the top (>95%) and root (>83%) samples was extractable. For the 1X studies, total residues in tops at the sampling intervals for the GP-labeled trifloxystrobin were 3.204, 2.286, 4.077, 1.396, and 0.727 ppm, and for TFMP-labeled trifloxystrobin were 3.384, 2.280,

4.133, 1.517, and 0.453 ppm. Total residues in the respective root samples were much lower, ranging from 0.010-0.113 ppm for the two radiolabels. For the 5.5X studies, radioactivity levels for the two labels at the sampling intervals ranged from 4.155-10.095 ppm for the tops and 0.342-0.548 ppm for the roots.

Table 2: Recoveries of applied radioactivity (ppm; % TRRs) in sugar beets treated with 1X or 5.5X [glyoxyl-phenyl-(U)-^{14}C] or [trifluoromethyl-phenyl-(U)-^{14}C] trifloxystrobin.

Sampling interval	Crop part	Total residues (ppm)[1]	%Cold/microwave extractable; [% nonextractable]	Residue recovery (%)[2]	Total residues (ppm)[1]	%Cold/microwave extractable; [% nonextractable]	Residue recovery (%)[2]
		glyoxyl-phenyl-(U)-^{14}C			trifluoromethyl-phenyl-(U)-^{14}C		
1X application rate							
1 (1 hr. after 1st applic.)	Tops	3.204	96.5/ 0.1 [0.1]	96.7	3.384	96.9/ NA [4.0]	100.9
	Roots	0.055	106.7/ 0.7 [0.3]	107.7	0.097	102.4/ NA [10.2]	112.5
2 (1 hr. after 2nd applic.)	Tops	2.286	95.2/NA [1.1]	96.2	2.280	98.2/ NA [5.3]	103.5
	Roots	0.033	88.2/ 5.2 [3.0]	96.3	0.010	86.0/ 13.2 [5.2]	104.3
3 (1 hr. after 3nd applic.)	Tops	4.077	99.8/ 0.3 [0.5]	100.6	4.133	95.1/ 1.1 [0.9]	97.1
	Roots	0.063	87.0/ 6.3 [6.9]	100.1	0.051	81.0/ 11.2 [7.9]	100.1
4 (21 d. after 3rd applic.)	Tops	1.396	98.9/ NA [3.9]	102.9	1.517	87.9/ 8.6 [3.7]	100.2
	Roots	0.113	75.6/ 7.5 [12.2]	95.3	0.038	79.1/ 11.4 [11.6]	102.0
5 (45 d. after 3rd applic.)	Tops	0.727	96.9/ NA [4.7]	101.6	0.453	97.0/ 5.3 [2.2]	104.5
	Roots	0.025	84.5/ 9.2 [3.5]	97.2	0.021	99.2/ 6.8 [10.6]	116.7
5.5X application rate							
4 (21 d. after 3rd applic.)	Tops	7.131	98.3/ 0.8 [0.9]	100.0	10.095	96.9/ NA [1.2]	98.1
	Roots	0.342	90.6/ 4.5 [4.9]	100.0	0.548	97.5/ NA [7.0]	104.5
5 (45 d. after 3rd applic.)	Tops	7.757	101.6/ NA [2.4]	104.1	4.155	98.9/ NA [2.7]	101.6
	Roots	0.487	93.9/ 6.7 [6.9]	107.5	0.483	93.0/ 2.8 [3.1]	99.0

NA = not analyzed

[1]ppm in CGA 270202 equivalents. The limit of quantitation (combustion; 1X and 5.5X studies) was 0.017-0.046 ppm for tops, 0.002-0.012 ppm for roots, and 0.001 ppm for soil.

[2]Determined as the sum of the extractable (with 80% acetonitrile) and non-extractable radioactivity, relative to the total radioactivity determined by combustion for each matrix.

Characterization/identification of ^{14}C-residues

TLC analysis of homogenized 80% acetonitrile crude cold/microwave extracts of top and root with analytic system II yielded 33 separate fractions (II_{0a} through II_{25}). Ten of these fractions were identified. A similar pattern of metabolites was seen for the two radiolabels, and for the 1X and 5.5X studies. In the tops and roots of both the 1X and 5.5X studies, the majority of the radiolabel was present as fraction II_{25} (i.e., the parent, 23.9-96.3% TRR). The amount of parent was lower and the number of minor metabolites were higher at days 21 and 45 following the last (3rd) application than at earlier sampling intervals in the 1X studies. Most metabolites in the tops and roots were <5% TRR at all sampling intervals, exceptions being II_{9b}, II_{11} and II_{24} in the tops (5.0-8.2% each) and II_{11}, II_{19a} and II_{24} in the roots (5.0-19.6% each). The distribution of

metabolite fractions identified in sugar beets treated with GP-labeled and TFMP-labeled trifloxystrobin are shown in Tables 3 and 4, respectively.

Table 3. Distribution and characterization of radioactive residues in tops and roots from sugar beets treated with 1X or 5X [glyoxyl-phenyl-(U)-^{14}C] trifloxystrobin.

Fraction	%TRR	ppm	Characterization/identification
Tops - 1 hour after 1st application (TRR = 3.204 ppm)			
ACN:water (1X study)	93.3	2.989	1- and 2-D TLC analysis resolved: Trifloxystrobin 92.5% TRR 2.964 ppm CGA-321113 0.8% TRR 0.026 ppm
[1]Unidentified	3.5	0.11	Not further analyzed
Tops - 1 hour after 2nd application (TRR = 2.286 ppm)			
ACN:water (1X study)	90.0	2.057	1- and 2-D TLC analysis resolved: Trifloxystrobin 85.8% TRR 1.961 ppm Metabolite II_{9b} 1.0% TRR 0.023 ppm Metabolite II_{11} 1.1% TRR 0.025 ppm Metabolite II_{19a} 0.3% TRR 0.007 ppm Metabolite II_{21a} 0.3% TRR 0.007 ppm NOA-414412 0.3% TRR 0.007 ppm NOA-443152 0.3% TRR 0.007 ppm CGA-321113 0.9% TRR 0.021ppm
[1]Unidentified	5.6	0.13	Not further analyzed
Tops - 1 hour after 3rd application (TRR = 4.077 ppm)			
ACN:water (1X study)	94.1	3.836	1- and 2-D TLC analysis resolved: Trifloxystrobin 89.5% TRR 3.649 ppm Metabolite II_{9b} 1.5% TRR 0.061 ppm Metabolite II_{11} 2.2% TRR 0.090 ppm CGA-321113 0.9% TRR 0.037 ppm
[1]Unidentified	6.5	0.27	Not further analyzed
Tops - 21 days after 3rd application			
ACN:water (1X study) **(TRR = 1.396 ppm)** Identified: 78.1% TRR (1.090 ppm) [1]Unidentified: 25.0% TRR (0.35 ppm) 1- and 2-D TLC analysis resolved: Trifloxystrobin 57.0% TRR 0.796 ppm Metabolite II_{9b} 3.4% TRR 0.047 ppm Metabolite II_{10} 1.5% TRR 0.021 ppm Metabolite II_{11} 5.0% TRR 0.070 ppm Metabolite II_{19a} 1.4% TRR 0.020 ppm Metabolite II_{21a} 0.6% TRR 0.008 ppm NOA-414412 1.7% TRR 0.024 ppm NOA-443152 0.4% TRR 0.006 ppm CGA-321113 5.2% TRR 0.073 ppm CGA-373466 1.1% TRR 0.015 ppm			ACN:water (5X study) **(TRR = 7.131 ppm)** Identified: 84.0% TRR (1.090 ppm) [1]Unidentified: 16.4% TRR (0.35 ppm) 1- and 2-D TLC analysis resolved: Trifloxystrobin 78.8% TRR 5.619 ppm Metabolite II_{9b} 1.4% TRR 0.100 ppm Metabolite II_{10} 1.0% TRR 0.071 ppm CGA-321113 2.5% TRR 0.178 ppm CGA-373466 0.3% TRR 0.021 ppm
Tops - 45 days after 3rd application			
ACN:water (1X study) **(TRR = 0.727 ppm)**			ACN:water (5X study) **(TRR = 7.757 ppm)**

Table 3. Distribution and characterization of radioactive residues in tops and roots from sugar beets treated with 1X or 5X [glyoxyl-phenyl-(U)-^{14}C] trifloxystrobin.

Fraction	%TRR	ppm	Characterization/identification
Identified: 52.0% TRR (0.378 ppm) [1]Unidentified: 25.0% TRR (0.35 ppm) 1- and 2-D TLC analysis resolved: Trifloxystrobin 27.5% TRR 0.200 ppm Metabolite II_{9b} 6.2% TRR 0.045 ppm Metabolite II_{10} 1.8% TRR 0.013 ppm Metabolite II_{11} 8.2% TRR 0.060 ppm Metabolite II_{19a} 1.6% TRR 0.012 ppm Metabolite II_{21a} 0.9% TRR 0.007 ppm NOA-414412 1.7% TRR 0.012 ppm NOA-443152 0.4% TRR 0.003 ppm CGA-321113 2.8% TRR 0.020 ppm CGA-373466 0.9% TRR 0.007 ppm			Identified: 87.6% TRR (6.795 ppm) [1]Unidentified: 15.0% TRR (1.164 ppm) 1- and 2-D TLC analysis resolved: Trifloxystrobin 76.6% TRR 5.942 ppm Metabolite II_{9b} 2.3% TRR 0.178 ppm Metabolite II_{10} 0.7% TRR 0.054 ppm Metabolite II_{11} 3.4% TRR 0.264 ppm Metabolite II_{19a} 0.6% TRR 0.047 ppm Metabolite II_{21a} 0.3% TRR 0.023 ppm NOA-414412 1.3% TRR 0.101 ppm NOA-443152 0.2% TRR 0.016 ppm CGA-321113 1.8% TRR 0.140 ppm CGA-373466 0.4% TRR 0.031 ppm
Roots - 1 hour after 1st application (TRR = 0.055 ppm)			
ACN:water (**1X** study)	95.4	0.052	1- and 2-D TLC analysis resolved: Trifloxystrobin 92.3% TRR 0.051 ppm CGA-321113 3.1% TRR 0.002 ppm
[1]Unidentified	4.8	0.003	Not further analyzed
Roots - 1 hour after 2nd application (TRR = 0.033 ppm)			
ACN:water (**1X** study)	74.7	0.025	1- and 2-D TLC analysis resolved: Trifloxystrobin 41.2% TRR 0.014 ppm Metabolite II_{9b} 0.7% TRR <0.001 ppm Metabolite II_{10} 0.7% TRR <0.001 ppm Metabolite II_{11} 0.7% TRR <0.001 ppm Metabolite II_{19a} 19.6% TRR 0.006 ppm Metabolite II_{21a} 2.3% TRR 0.001 ppm NOA-414412 2.3% TRR 0.001 ppm NOA-443152 2.3% TRR 0.001 ppm CGA-321113 4.9% TRR 0.002 ppm
[1]Unidentified	21.9	0.007	Not further analyzed
Roots - 1 hour after 3rd application (TRR = 0.063 ppm)			
ACN:water (**1X** study)	70.0	0.044	1- and 2-D TLC analysis resolved: Trifloxystrobin 41.8% TRR 0.026 ppm Metabolite II_{9b} 4.1% TRR 0.003 ppm Metabolite II_{10} 1.2% TRR 0.001 ppm Metabolite II_{11} 7.2% TRR 0.005 ppm Metabolite II_{19a} 9.2% TRR 0.006 ppm CGA-321113 6.5% TRR 0.004 ppm
[1]Unidentified	30.2	0.010	Not further analyzed
Roots - 21 days after 3rd application Residues are sum of cold and microwave extractable radioactivity.			
ACN:water (**1X** study) **(TRR = 0.113 ppm)** Identified: 51.1% TRR (0.058 ppm) [1]Unidentified: 24.1% TRR (0.024 ppm) [2]Bound/Characterized: 20.6% TRR (0.023 ppm)			ACN:water (**5X** study) **(TRR = ppm)** Identified: 78.1% TRR (1.090 ppm) [1]Unidentified: 25.0% TRR (0.35 ppm)

Table 3. Distribution and characterization of radioactive residues in tops and roots from sugar beets treated with 1X or 5X [glyoxyl-phenyl-(U)-^{14}C] trifloxystrobin.

Fraction	%TRR	ppm	Characterization/identification
1- and 2-D TLC analysis resolved:			1- and 2-D TLC analysis resolved:
Trifloxystrobin	23.9% TRR	0.027 ppm	Trifloxystrobin 57.0% TRR 0.796 ppm
Metabolite II_{9b}	1.7% TRR	0.002 ppm	Metabolite II_{9b} 3.4% TRR 0.047 ppm
Metabolite II_{10}	0.5% TRR	0.001 ppm	Metabolite II_{10} 1.5% TRR 0.021 ppm
Metabolite II_{11}	0.9% TRR	0.001 ppm	Metabolite II_{11} 5.0% TRR 0.070 ppm
Metabolite II_{19a}	9.0% TRR	0.010 ppm	Metabolite II_{19a} 1.4% TRR 0.020 ppm
Metabolite II_{21a}	0.8% TRR	0.001 ppm	Metabolite II_{21a} 0.6% TRR 0.008 ppm
NOA-414412	1.6% TRR	0.002 ppm	NOA-414412 1.7% TRR 0.024 ppm
NOA-443152	0.8% TRR	0.001 ppm	NOA-443152 0.4% TRR 0.006 ppm
CGA-321113	10.8% TRR	0.012 ppm	CGA-321113 5.2% TRR 0.073 ppm
CGA-373466	1.1% TRR	0.001 ppm	CGA-373466 1.1% TRR 0.015 ppm
Roots - 45 days after 3rd application Residues are sum of cold and microwave extractable radioactivity.			
ACN:water (**1X** study) **(TRR = 0.025 ppm)**			ACN:water (**5X** study) **(TRR = ppm)**
Identified: 55.6% TRR (0.014 ppm)			Identified: 78.1% TRR (1.090 ppm)
[1]Unidentified: 52.7% TRR (0.13 ppm)			[1]Unidentified: 25.0% TRR (0.35 ppm)
1- and 2-D TLC analysis resolved:			1- and 2-D TLC analysis resolved:
Trifloxystrobin	33.5% TRR	0.008 ppm	Trifloxystrobin 27.5% TRR 0.796 ppm
Metabolite II_{9b}	0.7% TRR	<0.001 ppm	Metabolite II_{9b} 6.2% TRR 0.045 ppm
Metabolite II_{10}	0.3% TRR	<0.001 ppm	Metabolite II_{10} 1.8% TRR 0.013 ppm
Metabolite II_{11}	0.6% TRR	<0.001 ppm	Metabolite II_{11} 8.2% TRR 0.060 ppm
Metabolite II_{19a}	9.2% TRR	0.002 ppm	Metabolite II_{19a} 1.6% TRR 0.012 ppm
Metabolite II_{21a}	1.1% TRR	<0.001 ppm	Metabolite II_{21a} 0.9% TRR 0.007 ppm
NOA-414412	1.3% TRR	<0.001 ppm	NOA-414412 1.7% TRR 0.012 ppm
NOA-443152	1.0% TRR	<0.001 ppm	NOA-443152 0.4% TRR 0.003 ppm
CGA-321113	7.5% TRR	0.002 ppm	CGA-321113 2.8% TRR 0.020 ppm
CGA-373466	0.4% TRR	<0.001 ppm	CGA-373466 0.9% TRR 0.007 ppm

[1]Unidentified includes resolved, unresolved, and non-extractable residues.
[2]Bound residues consisted of approximately 0.4% cellulose, 2.4% lignin, 1.5% pectin, 5.9% saccharose (%TRR), calculated as the ratio of the specific radioactivity of the respective matrix fraction and of the original root, and multiplying by the percentage of the matrix fraction in root. Characterized residues consisted of 10.4% water-soluble non-saccharides.

Table 4. Distribution and characterization of radioactive residues in tops and roots from sugar beets treated with 1X or 5X [trifluoromethyl-phenyl-(U)-^{14}C] trifloxystrobin.

Fraction	%TRR	ppm	Characterization/identification
Tops - 1 hour after 1st application (TRR = 3.384 ppm)			
ACN:water (**1X** study)	94.9	3.211	1- and 2-D TLC analysis resolved: Trifloxystrobin 94.3% TRR 3.191 ppm CGA-321113 0.6% TRR 0.020 ppm
[1]Unidentified	5.9	0.20	Not further analyzed
Tops - 1 hour after 2nd application (TRR = 2.280 ppm)			
ACN:water (**1X** study)	97.9	2.232	1- and 2-D TLC analysis resolved: Trifloxystrobin 96.3% TRR 2.196 ppm

Table 4. Distribution and characterization of radioactive residues in tops and roots from sugar beets treated with 1X or 5X [trifluoromethyl-phenyl-(U)-^{14}C] trifloxystrobin.

Fraction	%TRR	ppm	Characterization/identification
			Metabolite II_{11} 0.9% TRR 0.021 ppm NOA-414412 0.3% TRR 0.007 ppm CGA-321113 0.4% TRR 0.009 ppm
[1]Unidentified	5.5	0.13	Not further analyzed
Tops - 1 hour after 3rd application (TRR = 4.133 ppm)			
ACN:water (1X study)	89.1	3.683	1- and 2-D TLC analysis resolved: Trifloxystrobin 85.5% TRR 3.534 ppm Metabolite II_{9b} 0.8% TRR 0.033 ppm Metabolite II_{11} 1.3% TRR 0.054 ppm NOA-414412 0.5% TRR 0.021 ppm CGA-321113 1.0% TRR 0.041 ppm
[1]Unidentified	8.2	0.339	Not further analyzed
Tops - 21 days after 3rd application			
ACN:water (**1X** study) **(TRR = 1.517 ppm)** Identified: 81.5% TRR (1.236 ppm) [1]Unidentified: 19.0% TRR (0.288 ppm) 1- and 2-D TLC analysis resolved: Trifloxystrobin 57.0% TRR 1.045 ppm Metabolite II_{9b} 3.4% TRR 0.046 ppm Metabolite II_{10} 1.5% TRR 0.008 ppm Metabolite II_{11} 5.0% TRR 0.058 ppm Metabolite II_{19a} 1.4% TRR 0.009 ppm Metabolite II_{21a} 0.6% TRR 0.006 ppm NOA-414412 1.7% TRR 0.014 ppm NOA-443152 0.4% TRR 0.006 ppm CGA-321113 5.2% TRR 0.041 ppm CGA-373466 1.1% TRR 0.005 ppm			ACN:water (**5X** study) **(TRR = 10.095 ppm)** Identified: 91.0% TRR (9.186 ppm) [1]Unidentified: 7.2% TRR (0.727 ppm) 1- and 2-D TLC analysis resolved: Trifloxystrobin 87.2% TRR 8.803 ppm Metabolite II_{9b} 0.5% TRR 0.050 ppm Metabolite II_{10} 0.4% TRR 0.040 ppm Metabolite II_{11} 1.0% TRR 0.101 ppm Metabolite II_{19a} 0.2% TRR 0.020 ppm Metabolite II_{21a} 0.2% TRR 0.020 ppm NOA-414412 0.2% TRR 0.020 ppm NOA-443152 0.2% TRR 0.020 ppm CGA-321113 1.1% TRR 0.111 ppm
Tops - 45 days after 3rd application			
ACN:water (**1X** study) **(TRR = 0.453 ppm)** Identified: 71.8% TRR (0.325 ppm) [1]Unidentified: 32.9% TRR (0.149 ppm) 1- and 2-D TLC analysis resolved: Trifloxystrobin 49.4% TRR 0.224 ppm Metabolite II_{9b} 4.8% TRR 0.022 ppm Metabolite II_{10} 1.9% TRR 0.009 ppm Metabolite II_{11} 7.5% TRR 0.034 ppm Metabolite II_{19a} 0.7% TRR 0.003 ppm Metabolite II_{21a} 1.2% TRR 0.005 ppm NOA-414412 3.8% TRR 0.017 ppm CGA-321113 2.5% TRR 0.011 ppm			ACN:water (**5X** study) **(TRR = 4.155 ppm)** Identified: 88.0% TRR (3.656 ppm) [1]Unidentified: 13.9% TRR (0.578 ppm) 1- and 2-D TLC analysis resolved: Trifloxystrobin 80.6% TRR 3.349 ppm Metabolite II_{9b} 1.1% TRR 0.046 ppm Metabolite II_{10} 0.4% TRR 0.017 ppm Metabolite II_{11} 2.0% TRR 0.083 ppm Metabolite II_{19a} 0.5% TRR 0.021 ppm Metabolite II_{21a} 0.4% TRR 0.017 ppm NOA-414412 0.8% TRR 0.033 ppm CGA-321113 2.0% TRR 0.083 ppm CGA-373466 0.2% TRR 0.008 ppm
Roots - 1 hour after 1st application (TRR = 0.097 ppm)			
ACN:water (**1X** study)	95.5	0.093	1- and 2-D TLC analysis resolved:

Table 4. Distribution and characterization of radioactive residues in tops and roots from sugar beets treated with 1X or 5X [trifluoromethyl-phenyl-(U)-^{14}C] trifloxystrobin.

Fraction	%TRR	ppm	Characterization/identification
			Trifloxystrobin 92.6% TRR 0.090 ppm CGA-321113 2.9% TRR 0.003 ppm
[1]Unidentified	14.7	0.014	Not further analyzed
Roots - 1 hour after 2nd application (TRR = 0.010 ppm)			
ACN:water (**1X** study)	81.8	0.008	1- and 2-D TLC analysis resolved: Trifloxystrobin 72.8% TRR 0.007 ppm CGA-321113 9.0% TRR 0.001 ppm
[1]Unidentified	22.4	0.002	Not further analyzed
Roots - 1 hour after 3rd application (TRR = 0.051 ppm)			
ACN:water (**1X** study)	55.7	0.028	1- and 2-D TLC analysis resolved: Trifloxystrobin 35.3% TRR 0.018 ppm Metabolite II_{19a} 7.5% TRR 0.004 ppm Metabolite II_{21a} 1.5% TRR 0.001 ppm NOA-414412 4.5% TRR 0.002 ppm NOA-443152 1.5% TRR 0.001 ppm CGA-321113 5.4% TRR 0.003 ppm
[1]Unidentified	44.2	0.023	Not further analyzed

Roots - 21 days after 3rd application Residues are sum of cold and microwave extractable radioactivity.

ACN:water (**1X** study) **(TRR = 0.038 ppm)**

Identified: 75.6% TRR (0.029 ppm)
[1]Unidentified: 25.4% TRR (0.010 ppm)

1- and 2-D TLC analysis resolved:

Trifloxystrobin	51.5% TRR	0.020 ppm
Metabolite II_{9b}	0.7% TRR	<0.001 ppm
Metabolite II_{10}	0.7% TRR	<0.001 ppm
Metabolite II_{11}	1.4% TRR	0.001 ppm
Metabolite II_{19a}	10.0% TRR	0.004 ppm
Metabolite II_{21a}	0.6% TRR	<0.001 ppm
NOA-414412	1.1% TRR	<0.001 ppm
NOA-443152	0.7% TRR	<0.001 ppm
CGA-321113	8.7% TRR	0.003 ppm
CGA-373466	0.2% TRR	<0.001 ppm

ACN:water (**5X** study) **(TRR = 0.548 ppm)**

Identified: 93.2% TRR (0.511 ppm)
[1]Unidentified: 11.3% TRR (0.062 ppm)

1- and 2-D TLC analysis resolved:

Trifloxystrobin	85.2% TRR	0.467 ppm
Metabolite II_{19a}	2.8% TRR	0.015 ppm
CGA-321113	4.9% TRR	0.027 ppm
CGA-373466	0.3% TRR	0.002 ppm

Roots - 45 days after 3rd application Residues are sum of cold and microwave extractable radioactivity.

ACN:water (**1X** study) **(TRR = 0.021 ppm)**

Identified: 76.4% TRR (0.016 ppm)
[1]Unidentified: 43.6% TRR (0.009 ppm)

1- and 2-D TLC analysis resolved:

Trifloxystrobin	42.7% TRR	0.009 ppm
Metabolite II_{9b}	1.0% TRR	<0.001 ppm
Metabolite II_{10}	0.6% TRR	<0.001 ppm
Metabolite II_{11}	1.6% TRR	<0.001 ppm
Metabolite II_{19a}	14.9% TRR	0.003 ppm

ACN:water (**5X** study) **(TRR = 0.483 ppm)**

Identified: 76.0% TRR (0.367 ppm)
[1]Unidentified: 23.1% TRR (0.112 ppm)

1- and 2-D TLC analysis resolved:

Trifloxystrobin	69.9% TRR	0.338 ppm
Metabolite II_{9b}	0.2% TRR	0.001 ppm
Metabolite II_{10}	0.2% TRR	0.001 ppm
Metabolite II_{11}	0.2% TRR	0.001 ppm
Metabolite II_{19a}	2.3% TRR	0.011 ppm

Table 4. Distribution and characterization of radioactive residues in tops and roots from sugar beets treated with 1X or 5X [trifluoromethyl-phenyl-(U)-^{14}C] trifloxystrobin.

Fraction		%TRR	ppm	Characterization/identification		
Metabolite II_{21a}	1.0% TRR	<0.001 ppm		Metabolite II_{21a}	0.1% TRR	<0.001 ppm
NOA-414412	2.3% TRR	0.001 ppm		NOA-414412	0.4% TRR	0.002 ppm
NOA-443152	1.2% TRR	<0.001 ppm		NOA-443152	0.3% TRR	0.001 ppm
CGA-321113	10.8% TRR	0.002 ppm		CGA-321113	2.3% TRR	0.011 ppm
CGA-373466	0.3% TRR	<0.001 ppm		CGA-373466	0.1% TRR	<0.001 ppm

[1]Unidentified includes resolved, unresolved, and non-extractable residues.

Following acetonitrile extraction, radioactive residues in the roots were sequentially extracted from the GP-labeled samples (day 21 after the 3rd application, 1X study) to determine the content of saccharose (aka sucrose, aqueous phase; 61.1% TRR) and of lignin, cellulose, pectin, and water-soluble nonsaccharides (non-extractable fraction; 31.1% TRR). The aqueous phase was acidified, extracted with dichloromethane, ethyl acetate, hydrolyzed in boiling HCl, boiled with phenylhydrazine/acetic acid/water (forming glucose and fructose osazones), and crystallized at 4°C. It was determined that ~5.9% of the TRR in roots was incorporated into saccharose. The non-extractable acetonitrile fraction was boiled in water, alkali, and acid, extracted with dichloromethane, treated with phenylhydrazine/acetic acid/water (to form nonsaccharide osazones), and crystallized. The root samples were determined to contain (as %TRR) 10.4% water-soluble non-saccharides, 0.4% cellulose, 2.4% lignin, and 1.5% pectin.

Identification and isolation of metabolites

Six metabolites, corresponding to fractions II_{10} (glucose conjugate of II_{22}), II_{11} (glucose conjugate of II_{23a}), II_{22} (NOA-414412), II_{23a} (NOA-443152), II_{24} (CGA-321113), and II_{24b} (CGA-373466), as well as the parent (II_{25}) were identified by co-chromatography with standards using either analytical system II or reverse-phase HPLC [analytic system IV: Nucleosil RP18 column, eluent (a) water plus 0.1% phosphoric acid, (b) acetonitrile]. Three additional metabolites were identified or characterized during sequential extraction and isolation of GP-labeled and/or TFMP-labeled day 21 samples: II_{9b} (glucose conjugate of II_{21a}) and II_{21a} (not further elucidated) in the tops and II_{19a} (at least 2 metabolites) in the tops and roots. The time intervals at which these metabolites were found and their levels in the 1X and 5.5X studies using GP- and TFMP- labeled samples are summarized in Tables 5 and 6, respectively. Analysis of TLC fraction II_{25} further with analytic (solvent) system III resolved it into metabolites III_9, III_{12}, and III_{10}, corresponding to CGA-279202 (>75%) and its isomers CGA-331409 and CGA-357262 (latter for GP-labeled samples only).

Table 5: Distribution of metabolite fractions (%TRR) identified in sugar beets treated with [glyoxyl-phenyl-(U)-^{14}C] trifloxystrobin.

Interval	Matrix	Metabolite fraction (%TRR)										Total % identified
		II_{9b}	II_{10}	II_{11}	II_{19a}	II_{21a}	II_{22}	II_{23a}	II_{24}	II_{24b}	II_{25}	
1X Application rate												
1 (1 hr.aft. 1st appl.)	Tops	–	–	–	–	–	–	–	0.8	–	92.5	93.3
	Roots	–	–	–	–	–	–	–	3.1	–	92.3	95.4
2 (1 hr. after 2nd applic.)	Tops	1.0	–	1.1	0.3	0.3	0.3	0.3	0.9	–	85.8	90.0
	Roots	0.7	0.7	0.7	19.6	2.3	2.3	2.3	4.9	–	41.2	74.7
3 (1 hr. after 3rd applic.)	Tops	1.5	–	2.2	–	–	–	–	0.9	–	89.5	94.1
	Roots	4.1	1.2	7.2	9.2	–	–	–	6.5	–	41.8	70.0
4 (21 d. after 3rd applic.)	Tops	3.4	1.5	5.0	1.4	0.6	1.7	0.4	5.2	1.1	57.0	77.3
	Roots	1.7	0.5	0.9	9.0	0.8	1.6	0.8	10.8	1.1	23.9	51.1[1]
5 (45 d. after 3rd applic.)	Tops	6.2	1.8	8.2	1.6	0.9	1.7	0.4	2.8	0.9	27.5	52.0
	Roots	0.7	0.3	0.6	9.2	1.1	1.3	1.0	7.5	0.4	33.5	55.6
5.5X Application rate												
4 (21 d. after 3rd)	Tops	1.4	1.0	–	–	–	–	–	2.5	0.3	78.8	84.0
	Roots	0.3	0.5	–	6.3	0.5	0.9	0.5	8.8	0.5	59.1	77.9
5 (45 d. after 3rd applic.)	Tops	2.3	0.7	3.4	0.6	0.3	1.3	0.2	1.8	0.4	76.6	87.6
	Roots	0.8	0.8	1.5	8.1	1.6	1.7	1.7	5.0	0.4	48.6	70.2

– = not detectable

[1]Total identified/characterized increases to 71.7% if including 20.6% bound radioactivity.

Table 6: Distribution of metabolite fractions identified in sugar beets treated with [trifluoromethyl-phenyl-(U)-^{14}C] trifloxystrobin.

Interval	Matrix	Metabolite fraction (%TRR)										Total % identified
		II_{9b}	II_{10}	II_{11}	II_{19a}	II_{21a}	II_{22}	II_{23a}	II_{24}	II_{24b}	II_{25}	
1X Application rate												
1 (1 hr. after 1st applic.)	Tops	–	–	–	–	–	–	–	0.6	–	94.3	94.9
	Roots	–	–	–	–	–	–	–	2.9	–	92.6	95.5
2 (1 hr. after 2nd applic.)	Tops	–	–	0.9	–	–	0.3	–	0.4	–	96.3	97.9
	Roots	–	–	–	–	–	–	–	9.0	–	72.8	81.8
3 (1 hr. after 3rd applic.)	Tops	0.8	–	1.3	–	–	0.5	–	1.0	–	85.5	89.1
	Roots	–	–	–	7.5	1.5	4.5	1.5	5.4	–	35.3	55.7
4 (21 d. after 3rd applic.)	Tops	3.0	0.5	3.8	0.6	0.4	0.9	0.4	2.7	0.3	68.9	81.5
	Roots	0.7	0.7	1.4	10.0	0.6	1.1	0.7	8.7	0.2	51.5	75.6
5 (45 d. after 3rd applic.)	Tops	4.8	1.9	7.5	0.7	1.2	3.8	–	2.5	–	49.4	71.8
	Roots	1.0	0.6	1.6	14.9	1.0	2.3	1.2	10.8	0.3	42.7	76.4
5.5X Application rate												
4 (21 d. after 3rd)	Tops	0.5	0.4	1.0	0.2	0.2	0.2	0.2	1.1	–	87.2	91.0
	Roots	–	–	–	2.8	–	–	–	4.9	0.3	85.2	93.2
5 (45 d. after 3rd applic.)	Tops	1.1	0.4	2.0	0.5	0.4	0.8	–	2.0	0.2	80.6	88.0
	Roots	0.2	0.2	0.2	2.3	0.1	0.4	0.3	2.3	0.1	69.9	76.0

– = not detectable

The storage stability of plant extracts was evaluated using the 1X study top and root samples from the 21-day PHI. Harvested samples were kept at -18°C prior to extraction (for about 2 months for the GP label and 2 months for the TMP label) and at ≤8°C following extraction until analysis for metabolites (a week later for the GP label and 2 months later for the TMP label). The extracts were analyzed again after ~9 months at ≤8°C. Samples of tops and roots were also re-extracted after 5.5-11 months of frozen storage, and analyzed within 2 weeks. The distribution pattern and quantity of radioactive metabolites was found to be similar after storage for all tested time periods for both radiolabels.

Study summary:

Sugar beets received 3 applications (3-week intervals) of trifloxystrobin radiolabeled at two different positions. The 1X application rate for GP-labeled trifloxystrobin was 0.11-0.13 lb ai/A/application for a total of 0.36 lb ai/A/season and for the 5.5X rate was 0.61-0.74 lb ai/A/application for a total of 2.0 lb ai/A/season. For TFMP-labeled trifloxystrobin, the 1X and

5.5X single application rates were, respectively, 0.11-0.12 lb ai/A (total of 0.35 lb ai/A/season) and 0.62-0.68 lb ai/A (total of 1.9 lb ai/A/season). Samples were collected 1 hr after the 1st, 2nd, and 3rd applications and 21 and 45 days after the 3rd application (intervals 1, 2, 3, 4, and 5, respectively) for the 1X and control studies and at intervals 4 and 5 for the 5.5X studies. The vast majority of the radioactivity in the tops (>95%) and roots (>83%) was extractable. For the 1X studies, total residues in tops for intervals 1-5 for the GP-labeled samples ranged from 0.727-3.204 ppm, and for TFMP-labeled samples ranged from 0.453-4.133 ppm. Total residues in the respective root samples were much lower, ranging from 0.010-0.113 ppm for intervals 1-5 for the two radiolabels. For the 5.5X studies, radioactivity levels for the two labels for intervals 4 and 5 ranged from 4.155-10.095 ppm for the tops and 0.342-0.548 ppm for the roots. Root samples were also determined to contain approximately 5.9% TRR incorporated into saccharose, 10.4% TRR as water-soluble non-saccharides, 0.4% TRR as cellulose, 2.4% TRR as lignin, and 1.5% TRR as pectin.

TLC analysis of top and root samples yielded a similar pattern of metabolites for the two radiolabels at comparable study intervals for the 1X and 5.5X studies. In the tops and roots, the majority of the radiolabel was the parent compound at all intervals (23.9-96.3% TRR). TLC and/or HPLC analysis identified or characterized CGA-279202 and its two isomers (CGA-331409 and CGA-357262) and nine metabolites in sugar beet roots and tops. The metabolites included CGA-321113, CGA-373466, NOA-443152 (II_{23a}) and its glucose conjugate (i.e., metabolite II_{11}), NOA-414412 and its glucose conjugate (i.e., metabolite II_{10}), a structural isomer of NOA-414412 (i.e. II_{21a}) and its glucose conjugate (i.e. metabolite II_{9b}). Metabolite fraction II_{19a} was isolated and postulated to be 2 isomeric dihydroxy (on the TFMP ring) derivatives of II_{23a}. Mass spectrometry confirmed or suggested the identity of most metabolites.

The nature of trifloxystrobin in/on sugar beets is adequately understood. Based on the similar results from the 1x and 5.5x studies using GP-labeled and TFMP-labeled trifloxystrobin, the major residues the parent and its metabolite CGA-321113 (i.e., fraction II_{24}). Metabolite fraction II_{19a}, containing at least of 2 related isomers, was also found in the tops (<5% TRR) and root (6.3-19.6% TRR). The need for inclusion of fraction II_{19a} in the tolerance or risk assessment will be addressed by the HED MARC when it deliberates the metabolism of trifloxystrobin in wheat at a future date.

Proposed metabolic pathway in sugar beets

Trifloxystrobin metabolism involves several routes, including cis/trans isomerization, methyl ester cleavage to form metabolite II_{24} (CGA-321113), followed by cis/trans isomerization to form metabolite II_{24b} (CGA-373466). The trifluoromethyl-phenyl ring can also be hydroxylated to form metabolite II_{22} (NOA-414412) or II_{21a}, which are conjugated to form metabolites II_{10} or II_{9b}, respectively. Oxidation of the 2-ethylideneaminooxymethyl group results in formation of metabolite II_{23a} (NOA-443152), which can be sugar conjugated to form metabolite II_{11}. Metabolite II_{19a} was formed by cleavage of the methyl ester bond of the parent compound and

addition of three hydroxyl groups. In roots, radioactivity is also incorporated into saccharose and bound to cellulose, pectin, and lignin.

The MARC previously concluded that additional metabolism studies would be needed to support possible future uses on leafy vegetables, cereals or crops other than those in the earlier petition (MARC decision memo, F. Ives, 7/13/99). HED previously required additional metabolism data on wheat be submitted for a full Section 3 registration for trifloxystrobin use on cereal grain crops.

OPPTS GLN 860.1300: Nature of the Residue - Livestock

No new studies were submitted with this petition. The HED MARC determined on June 15, 1999 that the qualitative nature of the residue in livestock is adequately understood based on acceptable studies conducted on goats and laying hens (described in PP#8F4955). The Committee determined that the total toxic residues for livestock, both for regulatory and risk assessment purposes, are trifloxystrobin and the free form of its acid metabolite CGA-321113. Additionally, metabolite L7a (taurine, or 2-aminoethanesulfonic acid, conjugate of trifloxystrobin) in liver should be included for risk assessment purposes, assuming equal toxicity as trifloxystrobin (MARC decision memo, F. Ives, 7/13/99).

OPPTS GLN 860.1340: Analytical Methods - Plants

EPA has completed a method validation trial of AG-659A on apples, wet apple pomace, grapes, summer squash, peanut hay, peanuts, cow liver, cow milk, and raisins, and concluded that AG-659A is suitable for enforcement of trifloxystrobin (CGA-279202) and the free form of its acid metabolite (CGA-321113) in plant and livestock commodities (ACB, BEAD memo, 1/18/2000, P. E. Golden and P. G. Schermerhorn). Concurrent method recoveries submitted in this petition support an LOQ of 0.02 ppm for residues of trifloxystrobin and CGA-321113 in citrus, corn, pecan, rice, and stone fruit. Samples of field trials were analyzed for trifloxystrobin and its acid metabolite using AG-659A (all except rice bran which was analyzed by AG-659A/REM 177.04).

A brief description of method AG-659A follows. Homogenized samples are extracted twice with acetonitrile (ACN):water (80:20, v:v); liquid homogenized samples are extracted by shaking, and oils are dissolved directly in ACN:water. Following filtration, the extracts are subjected to three-layer liquid:liquid partitioning with water saturated with sodium chloride, toluene, and hexane. The middle layer is collected, repartitioned with hexane, and evaporated. Residues are reconstituted in 0.085% aqueous phosphoric acid:acetone (95:5, v:v) and cleaned up on a C18 solid-phase extraction column eluted with 0.085% aqueous phosphoric acid:acetone (30:70, v:v). Acetone is removed by evaporation, and the eluate is partitioned into methyl tert-butyl ether: hexane (1:1, v:v). The eluate is evaporated to dryness, and residues are redissolved in 0.1% polyethylene glycol in acetone (v:v) for GC analysis using NPD and a capillary DBWAX column. The method determines the parent CGA-279202 and the acid metabolite CGA-321113 as separate GC peaks. Identification of residues is confirmed by GC/MS and an alternative GC column (DB-

1701 column). The reported LOQ is 0.02 ppm for trifloxystrobin and also 0.02 ppm for its metabolite CGA-321113 in most matrices (PP#8F04955, D254208, F. Ives, 7/22/99).

The method for rice bran is a hybrid of methods AG-659A and REM 177.04. The latter method was previously described and validated for hops (PP#9F5070, D254213, L. Cheng 4/6/00). The method used for bran starts with a smaller subsample of material which is extracted twice with acetonitrile:water (80:20 v/v). The filtered extract is then subjected to 3-layer liquid:liquid partitioning with NaCl-saturated water, toluene, and hexane. The middle layer is collected, repartitioned with hexane, and evaporated. The residue is then dissolved in 0.85% aqueous phosphoric acid:acetone (95:5 v/v). The procedure to this point has followed AG-659A. The reconstituted residue is further refined with solid phase extraction on an oversized C18 packing bed (5 g instead of 1 g) from which it is recovered in 30:70 (v/v) aqueous phosphoric acid:acetone. Following elution from the C18 solid-phase extraction column, the clean-up steps tend to follow method REM 177.04. The extract was made basic by addition of aqueous ammonium hydroxide and partitioned with methyl tert-butyl ether:hexane (5:95, v:v). This separated CGA-279202 into the organic fraction while retaining CGA-321113 in the aqueous fraction. The CGA-279202 organic fraction is loaded onto a solid phase extraction (NH_2) column. The column is washed with hexane and CGA-279202 is eluted with methyl tert-butyl ether. The eluate is evaporated to dryness and the analyte dissolved in 0.1% polyethylene glycol in acetone for analysis. The CGA-321113 basic aqueous fraction is acidified with HCl and the analyte partitioned into methyl tert-butyl ether:hexane (1:1, v:v) which is evaporated to dryness. The sample is dissolved in ethanol:hexane (1:1, v:v) and loaded onto an NH_2 solid phase extraction column. The column is dried, and then washed with acetonitrile:0.085% phosphoric acid in water (9:1, v:v), followed by acetonitrile:2.0% ammonium hydroxide in water (9:1, v:v). CGA-321113 is eluted with acetonitrile:2.0% ammonium hydroxide in water (1:2, v:v), the eluent is acidified, and the analyte is extracted into methyl tert-butyl ether:hexane (1:1, v:v). This fraction is evaporated to dryness and the analyte dissolved in 0.1% polyethylene glycol in acetone for analysis. The CGA-279202 and CGA-321113 final fraction are analyzed separately using the GC determinative step of method AG-659A as described above.

Each analytical set was comprised of a control, at least one recovery sample, and treated samples. The corrected residue results were adjusted upward for procedural recovery where the recovery was less that 100% and residues found in the control sample were subtracted from the recoveries. Control samples were fortified with CGA-279202 and CGA 323111, extracted and analyzed concurrently with field trial samples. Concurrent recovery results for individual crops are summarized below.

Concurrent recoveries for corn commodities were generally in the acceptable range of 70-120%, as shown in Table 7 and 8. Stover had the largest number of recoveries outside 70-120% with 7 of 33 trifloxystrobin and 5 of 33 CGA-321113 values out of range. Grain CGA-321113 values had 5/33 out of range. These results indicate that the method is adequate for data collection in corn matrices. The LOQ was 0.02 ppm.

Table 7. Concurrent recoveries of trifloxystrobin and its acid metabolite CGA-321113 from fortified samples of corn forage, stover, and grain using method AG-659A.

Matrix	Fortification level (ppm)	# of samples		Recovery (%)	
		Trifloxy-strobin	CGA-321113	Trifloxystrobin	CGA-321113
Corn, forage	0.02	2	2	100-108	108-69
	0.10	2	2	82-105	76-88
	0.40	17	17	70-109	67-119
	1.0	3	3	68-74	68-83
	5.0	1	1	56	93
Corn, stover	0.020	1	1	99	70
	0.40	26	26	60-113	63-131
	1.0	3	3	70-88	89-101
	5.0	2	2	82-93	87-111
	25.0	1	1	107	124
Corn, grain	0.020	3	3	82-107	75-116
	0.10	26	26	70-123	65-137
	1.0	3	3	86-107	93-150
	5.0	1	1	98	102

Table 8. Concurrent recoveries of trifloxystrobin and its acid metabolite CGA-321113 from fortified samples of corn processed commodities[1] using method AG-659A.

Matrix	Fortification level (ppm)	# of samples		Recovery (%)	
		Trifloxy-strobin	CGA-321113	Trifloxystrobin	CGA-321113
Whole kernel (BP)	0.020	1	0	115	---
	0.021	0	1	---	87
	0.20	1	0	74	---
	0.21	0	1	---	92
AGF	0.020	1	0	75	---
	0.021	0	1	---	72
	0.20	1	0	73	---
	0.21	0	1	---	81-93
Meal	0.020	1	0	73	---
	0.021	0	1	---	86
	0.20	1	0	81	---
	0.21	0	1	---	96
Large grits	0.020	1	0	74	---
	0.021	0	1	---	93
	0.20	1	0	87	---
	0.21	0	1	---	101

Table 8. Concurrent recoveries of trifloxystrobin and its acid metabolite CGA-321113 from fortified samples of corn processed commodities[1] using method AG-659A.					
Matrix	**Fortification level (ppm)**	**# of samples**		**Recovery (%)**	
		Trifloxy-strobin	**CGA-321113**	**Trifloxystrobin**	**CGA-321113**
Small grits	0.020	1	0	108	---
	0.021	0	1	---	92
	0.20	1	0	80	---
	0.21	0	1	---	83
Flour	0.020	1	0	78	---
	0.021	0	1	---	83
	0.20	1	0	79	---
	0.21	0	1	---	74
Oil, refined	0.020	1	0	89	---
	0.021	0	1	---	89
	0.050	2	0	73-78	---
	0.053	0	2	---	80-89
	0.20	1	0	76	---
	0.21	0	1	---	81
Starch	0.020	1	0	90	---
	0.021	0	2	---	95-106
	0.20	1	0	82	---
	0.21	0	1	---	67

[1]There are slight variations in the recoveries due to correction for moisture calculations which do not significantly affect the results.

Concurrent recovery data from fortified samples (0.02-10.0 ppm) in the submitted rice field trials are given in Table 9. Recoveries of trifloxystrobin and CGA-321113 ranged from 60-125% and 66-138%, respectively, with overall means of 87% and 94%, respectively. Therefore, AG-659A is adequate for collecting data on residues of trifloxystrobin and CGA-321113 in/on rice grain, straw and hulls and AG-659A/REM 177.04 is adequate in/on rice bran.

Table 9. Concurrent recoveries of trifloxystrobin and its acid metabolite CGA-321113 from fortified samples of rice fractions using method AG-659A.				
Substrate	**Trifloxystrobin (CGA-279202)**		**CGA-321113**	
	Fortification (ppm)	**Recovery (%)**	**Fortification (ppm)**	**Recovery (%)**
Straw	0.02	85	0.02	120
	0.10	86, 88, 94, 97, 117	0.10	98, 113, 118, 121, 127
	0.20	97	0.20	106, 114
	0.50	66, 79, 84, 88, 92, 95, 97, 107	0.50	75, 79, 95, 101, 113, 118, 138
	1.0	71, 89, 90, 92	1.0	90, 92, 96, 96
	2.0	75, 79, 91	2.0	68, 79, 97
	5.0	60	5.0	76

Table 9. Concurrent recoveries of trifloxystrobin and its acid metabolite CGA-321113 from fortified samples of rice fractions using method AG-659A.

Substrate	Trifloxystrobin (CGA-279202)		CGA-321113	
	Fortification (ppm)	Recovery (%)	Fortification (ppm)	Recovery (%)
	10.0	87	10.0	93
Grain	0.02	67, 73, 112	0.02	72, 75, 92, 114
	0.05	99	0.05	94, 106, 112
	0.10	66, 71, 74, 81, 84, 85, 93, 94	0.10	66, 86, 91, 99, 100
	0.20	67, 93	0.20	80, 104
	0.50	61, 77, 89, 107	0.50	88, 88, 97, 101
	1.0	74, 80, 100, 125	1.0	80, 85, 102, 103, 136
	2.0	87	2.0	101
	4.0	92	4.0	91
Composite grain (bp)	0.02	117	0.02	102
	0.10	99	0.10	108
Polished rice	0.02	96	0.02	75
	0.10	93	0.10	107
Rice hulls	0.20	67	0.20	77
	2.0	103	2.0	66
Rice bran	0.02	63, 92	0.02	77, 84
	0.05	86, 92	0.05	70, 72
	0.10	82, 86	0.10	67, 67

For citrus, fortification levels ranged from 0.02 ppm to 100 ppm (100 ppm only for orange oil). The overall average recovery for parent CGA-279202 at all fortification levels was 90.9% ± 9.2 %. For the acid metabolite, the overall recovery at all levels for this study was 95.0% ± 8.1%. The summary of concurrent recoveries from citrus fruits is presented in Table 10.

Table 10. Concurrent recoveries of CGA-279202 and CGA-321113 from fortified controls of citrus fruits using method AG-659A.

Test Location (Region)	Substrate	Fortification (ppm)	Percent recovery	
			CGA-279202	CGA-321113
CA (10)	Orange/Fruit	0.02	100	105
		5.0	88.2	98.0
		0.20	102	106
		0.10	98.5	106
		0.10	90.8	98.5
		0.02	117	117
		0.02	117	110
CA (10)	Grapefruit/Fruit	0.10	90.3	90.3
FL (3)	Oranges/Fruit	0.02	98.0	96.5
FL (3)	Oranges/Fruit	0.10	79.5	81.5

Table 10. Concurrent recoveries of CGA-279202 and CGA-321113 from fortified controls of citrus fruits using method AG-659A.

Test Location (Region)	Substrate	Fortification (ppm)	Percent recovery	
			CGA-279202	CGA-321113
FL (3)	Oranges/Fruit	0.10	79.8	90.3
		1.0	71.0	80.8
	Fruit, composite	0.10	80.5	91.3
	Juice	0.10	91.8	101
	Oil	0.02	interference	98.0
	Dried Pulp	0.02	102	81.5
		5.0	82.8	86.8
		5.0	93.6	100
FL (3)	Oranges/Fruit	0.10	81.8	90.5
		0.10	91.8	99.0
		0.10	78.0	80.3
		0.10	96.8	99.0
FL (3)	Grapefruit/fruit	1.0	90.3	93.5
		0.20	89.0	93.0
		0.10	91.0	98.5
		0.10	94.8	97.5
		0.02	85.5	91.5
		0.02	91.5	109
		0.10	80.3	83.5
FL (3)	Lemon/Fruit	0.20	95.0	98.5
TX (10)	Oranges/Fruit	0.10	82.0	83.8
TX (10)	Grapefruit/Fruit	0.20	92.0	94.5
AZ (10)	Oranges/Fruit	0.10	94.5	95.8
AZ (10)	Grapefruit/Fruit	0.10	82.0	96.5
AZ (10)	Lemon/Fruit	0.10	91.5	97.5
FL (3)	Orange/Fruit	0.10	91.0	95.3
		0.20	97.5	99.0
		0.10	94.3	101
		0.10	84.8	88.5
		0.02	92.0	97.5
		0.02	101	103
FL (3)	Grapefruit/Fruit	0.10	84.5	89.8
CA (10)	Lemons/Fruit	0.10	89.8	97.5
CA (10)	Oranges/Fruit	0.10	99.8	101
		1.0	91.5	96.0
	Fruit, composite	0.10	95.0	103
	Juice	0.02	89.5	102
	Oil	0.02	111	91.5
	Oil	100	70.7	72.8
	Dried pulp	0.02	87.5	88.0
CA (10)	Lemons/Fruit	1.0	93.8	103
		0.20	83.0	93.0
		0.10	88.8	90.5
		0.10	90.8	92.8
		0.02	80.5	90.0
		0.02	85.5	94.5
		0.10	94.8	90.0

Recoveries for pecans are presented in Table 11. In the pecan study, fortification levels ranged from 0.020 ppm to 2.0 ppm. The overall average recovery for parent CGA-279202 at all fortification levels was 88% ± 12.6 %. For the acid metabolite, the overall recovery was 90% ± 12.5.

Table 11. Concurrent recoveries of CGA-279202 and CGA-321113 from fortified controls of pecans using method AG-659A.

Test Location (Region)	Substrate	Fortification (ppm)	Percent recovery	
			CGA-279202	CGA-321113
TX (6)	Pecan	1.0	77	94
		0.02	77	74
NM (8)	Pecan	1.0	73	74
GA (2)	Pecan	0.02	100	108
		0.02	107	102
		0.02	90	77
		2.0	77	80
		2.0	86	85
		0.02	91	96
AL (2)	Pecan	1.0	109	105
LA (4)	Pecan	1.0	81	89

In the stone fruit study, fortification levels also ranged from 0.02 to 2.00 ppm. The overall average recovery for parent CGA-279202 at all fortification levels was 88% ± 11.2 %. For the acid metabolite, the overall recovery at all levels for this study was 84% ± 9.7. The recovery results for stone fruits are presented in Table 12.

Table 12. Concurrent recoveries of CGA-279202 and CGA-321113 from fortified controls of stone fruits using method AG-659A.

Test Location (Region)	Substrate	Fortification (ppm)	Percent recovery	
			CGA-279202	CGA-321113
CA (10)	Peach	0.40	91	89
		0.40	114	83
		0.40	87	89
CA (10)	Plum	0.40	92	88
		0.10	78	66
		0.40	84	90
CA (10)	Plum	0.02	87	67
	(whole fruit, fresh)	0.40	93	87
	(dried fruit)	0.40	91	84
CA (10)	Sweet Cherry	0.40	88	84
		1.00	98	102
		0.10	102	81
TX (6)	Peach	0.10	81	79
NC (2)	Peach	0.40	86	91
SC (2)	Peach	0.10	101	70
GA (2)	Peach	0.40	78	74

Table 12. Concurrent recoveries of CGA-279202 and CGA-321113 from fortified controls of stone fruits using method AG-659A.

Test Location (Region)		Substrate	Fortification (ppm)	Percent recovery	
				CGA-279202	CGA-321113
GA	(2)	Peach	0.40	64	73
		(reanalysis)	0.40	50	90
CA	(10)	Peach	0.10	98	87
CA	(10)	Plum	0.50	94	87
CA	(10)	Plum	2.00	84	82
		(whole fruit, fresh)	1.00	81	77
		(dried fruit)	0.20	97	89
CA	(10)	Sweet Cherry	0.10	91	91
OR	(12)	Plum	0.20	96	92
WA	(11)	Sweet Cherry	2.0	83	79
OR	(11)	Sweet Cherry	0.50	96	93
UT	(9)	Tart Cherry	0.02	84	77
WI	(5)	Tart Cherry	0.02	101	93
PA	(1)	Peach	0.10	82	68
MI	(5)	Peach	0.40	88	91
MI	(5)	Plum	0.02	89	110
MI	(5)	Sweet Cherry	0.40	92	89
MI	(5)	Sweet Cherry	0.10	91	85
MI	(5)	Tart Cherry	0.40	63	63
			0.40	85	86
			0.40	87	91
MI	(5)	Tart Cherry	0.40	88	86
NY	(1)	Tart Cherry	0.40	83	84

Analytical methods AG-659A and AG-659A/REM 177.04 are adequate for collecting data on residues of trifloxystrobin and CGA-321113 in/on matrices citrus, corn, pecans, pistachio, rice, and stone fruit. The petitioner needs to assign a code for the hybrid method of AG-659A and REM 177.04, however.

OPPTS GLN 860.1340: Analytical Methods - Livestock

No livestock studies were included in this submission. GC/NPD method AG-659A was proposed for tolerance enforcement purposes for residues of trifloxystrobin and the free form of its acid metabolite CGA-321113 in livestock matrices. Acceptable validation data were presented earlier for numerous livestock matrices including tissues or products from cows, chickens, and goats (PP#8F04955, D254208, F. Ives, 7/22/99). For eggs, 12 of 16 recoveries were in the acceptable range of 70-120%, with those outside the range being 129% for trifloxystrobin and 68, 131, and 136% for CGA-321113. All recoveries were within the acceptable range for poultry tissues, with means and SDs of 79±10% for trifloxystrobin and 87±12% for CGA-321113. There was a control group for every recovery sample tested, and residues in all controls were below the LOQ. EPA has completed a method validation trial of AG-659A on apples, wet apple pomace, grapes,

summer squash, peanut hay, peanuts, cow liver, cow milk and raisins, and concluded that AG-659A is suitable for enforcement of trifloxystrobin (CGA-279202) and the free form of its acid metabolite (CGA-321113) in plant and livestock commodities (ACB, BEAD memo, 1/18/2000, P. E. Golden and P. G. Schermerhorn). Recovery data support LOQ's of 0.01 ppm trifloxystrobin and 0.01 ppm its acid metabolite in milk, and 0.02 ppm each in eggs, ruminant and poultry tissues.

OPPTS GLN 860.1360: Multiresidue Method

The regulated residues were tested in accordance with the Pesticide Analytical Manual, Volume I, Appendix II. Trifloxystrobin gave adequate responses through protocol C, and was completely recovered from fortified apple samples when analyzed through protocols D and E. Acid metabolite CGA-321113 was recoverable through protocol B and residues from apples fortified with CGA-321113 were completely recovered through Section 402 E2/C1 (extraction with methylene chloride). These data were forwarded to FDA.

OPPTS GLN 860.1380: Storage Stability Data -Plants

Two freezer storage stability plant studies for trifloxystrobin were submitted previously (PP#9F5070, D254213, L. Cheng 4/6/00). In one study, trifloxystrobin and its metabolite CGA-321113 were shown to be stable in cucumbers (fruit), grapes (mature berries), potatoes (tubers), and wheat (whole plant, grain, and straw) after 24 months of storage. In the second study, trifloxystrobin and its metabolite CGA-321113 were shown to be stable in apple fruit, apple pomace, grape juice, peanut hay, peanut nutmeat, peanut oil, and potato granules/flakes for up to 18.6 months of freezer storage. These results are adequate to support the frozen storage intervals for trifloxystrobin and CGA-321113 residues in samples of corn matrices and processed fractions ($\leq$16.2 months), rice matrices and processed fractions ($\leq$15.2 months), citrus matrices and processed fractions (19 months), pecans (8.4 months), and stone fruit and processed fractions (17 months).

OPPTS GLN 860.1380: Storage Stability Data - Livestock

No new storage stability data in livestock were included in this submission. In a previously submitted freezer storage stability study, beef muscle and liver, milk, and eggs were fortified with CGA-279202 and/or its metabolite CGA-321113 at 1.0 ppm. Results showed that trifloxystrobin and its metabolite CGA-321113 are stable in livestock matrices for 12.2-13.8 months when stored at approximately -20° C (PP#9F5070, D254213, L. Cheng 4/6/00).

OPPTS GLN 860.1500: Crop Field Trials

The formulations used in the field trials were CGA-279202 50WG (citrus fruit, pecans, rice, and stone fruit) and CGA-279202/propiconazole 250EC combination (corn, pecans, and rice). Although not specifically identified as such in the submitted materials, CGA-279202 50WG corresponds to the trifloxystrobin water dispersible granular formulation Flint™ (EPA Reg. No.

100-919) and CGA-279202/propiconazole 250EC corresponds to Stratego™ Fungicide (EPA Reg. No. 100-966).

Barley

No barley field trials were provided. Bayer requested the establishment of a tolerance for trifloxystrobin in barley based on the residue studies for wheat, corn and rice, citing a previous HED memo re azoxystrobin (D254140, G. Herndon, 3/17/99).

The 3/17/99 HED memo states that "[d]ue to the low toxicity of azoxystrobin (no acute dietary, cancer, or short-, intermediate-, or chronic term dermal or inhalation endpoints were identified), the relatively high chronic RfD (0.18 mg/kg/day), removal of the FQPA factor, its limited systemic nature, its low use rates, its ability to be degraded by sunlight, and the rapid incorporation of azoxystrobin metabolites into the general carbon pool after soil metabolism, RAB2 is willing to agree to this reduced data set FOR AZOXYSTROBIN ONLY....RAB2 concludes that it will be appropriate for IR-4 to request a tolerance of 0.10 ppm on barley grain, 0.20 ppm on barley bran, 4.0 ppm on barley straw, and 15 ppm on barley hay, provided that the use pattern is the same."

Since trifloxystrobin does not meet all the toxicological criteria and chemical properties described for azoxystrobin and there are in-house data indicating differing residue levels in wheat and barley commodities resulting from identical use patterns, RAB3 concludes that barley residue data are required for the proposed use on barley.

Citrus fruits

Novartis Crop Protection submitted data from 23 field trials conducted in 1998 and 1999 on oranges, grapefruit and lemons to support a citrus crop group tolerance. Four of the trials were residue decline studies and two were processing studies. Twenty-three field trials were conducted in 4 states using 5 treatment regimes with CGA-279202 50WG on Crop Group 10 (orange, grapefruit, and lemon). Twelve studies (including 2 processing studies) were conducted on oranges, 5 on lemons, and 6 on grapefruit. The results are reported in:

> MRID 45080808. Eudy, L.W. (2000) CGA-279202 and CGA-245704-Magnitude of the Residues in or on Crop Group 10: Citrus Fruits. Novartis Crop Protection, Inc., Human Safety Department, 40 Swing Road, Post Office Box 8300, Greensboro, NC 2749. Novartis Study No. 47-98, February 8, 2000. Unpublished.

The 23 field trials for the citrus crops were conducted in Arizona (3 trials, Region 10), California (6 trials, Region 10), Florida (12 trials, Region 3) and Texas (2 trials, Region 6). The 5 treatments were (1) the control; (2) 4 foliar applications of the 50WG formulation at 4-day intervals at 70 g or 0.15 lb ai/A for a total of 280 g or 0.62 lb ai/A/season (1.2x proposed rate), using a concentrated spray volume of 50-99 GPA; (3) same as treatment 2, except used a dilute spray

volume of 100-400 GPA; (4) and (5) 3.7x and 6.1x proposed rates, applied to field trials where orange samples were to be used for processing studies. Most of the trials consisted of one control and two treated plots.

The samples were frozen after collection and shipped with dry ice or by freezer truck to Greensboro, NC, where they were stored frozen at -20^0 C. Samples were shipped overnight to the processing facilities at CCRL (Fresno, CA), Engler Food Laboratories (Moses lake, WI) or the National Food Laboratory (Dublin, CA). Citrus fruit samples were quartered and then macerated and homogenized; dried pulp was ground with dry ice; orange juice and oil required no additional maceration. Samples were stored frozen until analysis, most of which was done at CCRL. Analytical method AG-659A was used to determine residues of CGA-279202 and its acid metabolite in citrus. The LOQ was 0.02 ppm for each analyte. Decline studies were carried out for the representative citrus crops orange, grapefruit, and lemon. Data for each decline study were taken a total of 6 times, beginning with day 0 and with final PHIs of 36-39 days.

Results from the analyses of CGA-279202 and its acid metabolite in/on citrus are given in Table 13. Residues from all untreated control samples were below the LOQ of 0.02 ppm for both analytes.

In general, there was a decline in CGA-279202 concentration with time and CGA-321113 was not detected above the LOQ.

Table 13. Residues of CGA-279202 and CGA-321113 in/on citrus fruits treated with 4 x 70 g or 0.15 lb ai/A (1.2x max use rate) in either concentrate spray (50-99GPA) or dilute spray (100-400GPA).

Test Location (Region)	Spray type	PHI (days)	Residues [1] found (ppm)	
			CGA-279202	CGA-321113 [2]
Oranges				
CA (10)	Conc	0	0.41	<0.02
	Conc	0	0.43	<0.02
	Dilute	0	0.30	<0.02
	Dilute	0	0.30	<0.02
	Dilute	8	0.35	<0.02
	Dilute	8	0.36	<0.02
	Dilute	18	0.30	<0.02
	Dilute	18	0.27	<0.02
	Dilute	25	0.22	<0.02
	Dilute	25	0.23	<0.02
	Conc	32	**0.23**	<0.02
	Conc	32	0.20	<0.02
	Dilute	32	0.19	<0.02
	Dilute	32	0.16	<0.02
	Dilute	39	0.21	<0.02
	Dilute	39	0.21	<0.02
FL (3)	Dilute	0	0.16	<0.02
	Dilute	0	0.17	<0.02
	Dilute	9	0.07	<0.02

Table 13. Residues of CGA-279202 and CGA-321113 in/on citrus fruits treated with 4 x 70 g or 0.15 lb ai/A (1.2x max use rate) in either concentrate spray (50-99GPA) or dilute spray (100-400GPA).

Test Location (Region)	Spray type	PHI (days)	Residues[1] found (ppm)	
			CGA-279202	CGA-321113[2]
	Dilute	8	0.06	<0.02
	Dilute	16	0.05	<0.02
	Dilute	15	0.05	<0.02
	Dilute	23	0.05	<0.02
	Dilute	22	0.05	<0.02
	Dilute	30	0.04	<0.02
	Dilute	30	0.05	<0.02
	Dilute	37	0.04	<0.02
	Dilute	36	0.04	<0.02
FL (3)	Conc	30	0.18	<0.02
	Conc	30	0.21	<0.02
FL (3)	Conc	30	0.07	<0.02
	Conc	30	0.11	<0.02
FL (3)	Conc	30	0.10	<0.02
	Conc	30	0.10	<0.02
FL (3)	Dilute	26	0.07	<0.02
	Dilute	26	0.08	<0.02
FL (3)	Conc	30	0.15	<0.02
	Conc	30	0.12	<0.02
FL (3)	Dilute	29	0.08	<0.02
	Dilute	29	0.09	<0.02
TX (6)	Conc	30	0.14	<0.02
	Conc	30	0.15	<0.02
	Dilute	30	0.12	<0.02
	Dilute	30	0.11	<0.02
AZ (10)	Conc	29	0.15	<0.02
	Conc	29	0.17	<0.02
Lemons				
CA (10)	Dilute	0	0.20	<0.02
	Dilute	0	0.16	<0.02
	Dilute	9	0.22	<0.02
	Dilute	9	0.23	<0.02
	Dilute	16	0.19	<0.02
	Dilute	16	0.21	<0.02
	Dilute	23	0.14	<0.02
	Dilute	23	0.20	<0.02
	Dilute	30	0.22	<0.02
	Dilute	30	0.16	<0.02
	Dilute	37	0.15	<0.02
	Dilute	37	0.12	<0.02
FL (3)	Conc	28	<0.02	<0.02
	Conc	28	<0.02	<0.02
	Dilute	28	0.02	<0.02
	Dilute	28	0.02	<0.02
AZ (10)	Dilute	3	0.11	<0.02
	Dilute	3	0.09	<0.02
CA (10)	Conc	30	0.12	<0.02
	Conc	30	0.13	<0.02

Table 13. Residues of CGA-279202 and CGA-321113 in/on citrus fruits treated with 4 x 70 g or 0.15 lb ai/A (1.2x max use rate) in either concentrate spray (50-99GPA) or dilute spray (100-400GPA).

Test Location (Region)	Spray type	PHI (days)	Residues [1] found (ppm)	
			CGA-279202	CGA-321113 [2]
CA (10)	Conc	29	0.06	<0.02
	Conc	29	0.09	<0.02
Grapefruit				
FL (3)	Dilute	0	0.17	<0.02
	Dilute	0	0.20	<0.02
	Dilute	9	0.12	<0.02
	Dilute	9	0.13	<0.02
	Dilute	16	0.07	<0.02
	Dilute	16	0.08	<0.02
	Dilute	22	0.08	<0.02
	Dilute	22	0.08	<0.02
	Dilute	29	0.08	<0.02
	Dilute	29	0.08	<0.02
	Dilute	36	0.07	<0.02
	Dilute	36	0.07	<0.02
CA (10)	Dilute	32	0.10	<0.02
	Dilute	32	0.09	<0.02
FL (3)	Conc	30	0.04	<0.02
	Conc	30	0.04	<0.02
TX (6)	Conc	30	0.06	<0.02
	Conc	30	0.03	<0.02
	Dilute	30	0.05	<0.02
	Dilute	30	0.08	<0.02
AZ (10)	Conc	30	<0.02	<0.02
	Conc	30	<0.02	<0.02
FL (3)	Conc	30	0.03	<0.02
	Conc	30	0.03	<0.02
	Dilute	30	0.03	<0.02
	Dilute	30	0.03	<0.02

[1]Results are not corrected for control values but were corrected for procedural recoveries < 100%.
[2]CGA-321113 residues are converted to CGA-279202 equivalents with this factor (wt./wt. conversion factor = 408/394).

Geographic representation of citrus is adequate for the purposes of this petition. As required under OPPTS 860.1500, a total of 23 field trials (12 on oranges, 5 on lemons, and 6 on grapefruit) were conducted in Region 3 (12 trials), 6 (2 trials), and 10 (9 trials).

Study summary

Twenty three field trials (12 on oranges, 6 on grapefruit, and 5 on lemons) were conducted using the WG formulation. Following 4 x 0.15 lb ai/A in either concentrated or dilute sprays and harvested 28-32 days after the last application, residues ranged from 0.04 to 0.23 ppm trifloxystrobin and <0.02 ppm CGA-321113 in oranges (22 samples), <0.02 to 0.22 ppm trifloxystrobin and <0.02 ppm CGA-321113 in lemons (10 samples), and <0.02 to 0.10 ppm trifloxystrobin and <0.02 ppm CGA-321113 in grapefruit (16 samples). The residue data support

the proposed tolerance of 0.3 ppm combined trifloxystrobin and CGA-321113 in/on citrus crop group.

Residue decline studies were carried out for the representative crops oranges, grapefruit, and lemons. In general, there was a decline in CGA-279202 concentration with time and no CGA-321113 was detected above 0.02 ppm (the LOQ).

Corn (field and pop)

Novartis Crop Protection submitted data from 21 field corn trials and 3 popcorn trials conducted in 1998 and 2 field corn and 1 popcorn trial conducted in 1999 to support a permanent tolerance for the various corn commodities. Trials were conducted in EPA crop regions 1 (NY), 2 (NC), 5 (3 in IA, 2 in IL, 3 in IN, 4 in KS, MI, 2 in MN, MO, 3 in NE, 2 in OH, SD, WI), 6 (TX), and 10 (CA). Trifloxystrobin was applied together with propiconazole in all of these field trials, and this review draws no conclusions regarding propiconazole. The results are reported in:

> MRID 45080809. Vincent, T.P. (2000) Propiconazole and CGA-279202 - Magnitude of the residues in or on field corn and popcorn. Novartis Crop Protection, Inc., Human Safety Department, 410 Swing Road, Post Office Box 18300, Greensboro, NC 27419. Novartis Project Identification No. 751-99, March 13, 2000. Unpublished.
>
> MRID 45080810. Vincent, T.P. (2000) Propiconazole and CGA-279202 - Magnitude of the residues in or on field corn and popcorn. Novartis Crop Protection, Inc., Human Safety Department, 410 Swing Road, Post Office Box 18300, Greensboro, NC 27419. Novartis Project Identification No. 144-98, March 13, 2000. Unpublished.

All studies used the formulation CGA-279202 /propiconazole 250EC as a foliar spray application. Except for the two sites that also had processing studies, which included additional treated plots, all trials included at least one treated and one control plot. One of five different treatment schemes was applied: 001- untreated control; 002 - 2 treatments 50 g each ai/A in a minimum of 20 GPA mix at 30 and 37 days after planting; 003 - 4 treatments 50 g each ai/A in mixes of 5 or >20 GPA at 51, 44, 37, and 30 days prior to harvest; 004 - identified as the 3X rate: 4 treatments 150 g each ai/A in mixes of >20 GPA at 51, 44, 37, and 30 days prior to harvest; 005 - identified as the 5X rate: 4 treatments 250 g each ai/A in mixes of >20 GPA at 51, 44, 37, and 30 days prior to harvest. The per season treatment rates were 0 g ai/A, 100 g ai/A (0.22 lb), 200 g ai/A (0.44 lb), 600 g ai/A (1.32 lb), and 1000 g ai/A (2.2 lb), respectively for treatments 001-005. Treatment 004 was a backup in case the 5X treatment study showed phytotoxicity. The 5X group did not show phytotoxicity and corn from the 3X treatment was not harvested. At two of the sites there were also residue decline trials (Sedgwick, KS, Sioux County, IA, and Freeborn County, MN), and at two of the sites there were also processing trials (Champaign County, IL, and Jefferson County, IA).

The first application was made at the following growth stages: heights between 6 and 30 inches, seedling, 4 to 6 collars, 6 to 8 leaf, V4 to V16, vegetative, early whorl, early dough, and silking. The final application for grain and stover was made at stages described as: 6-9 ft, black layer (with 33-90% dry leaves), early dough, dough on kernel tip, hard dough, late dough, early dent, dent, R2-R5, tip soft and mature. The final application to forage was made at the following stages: 12-53 inches high, preboot, 5-10 collars, V8-V10, 7 leaf, midwhorl, and vegetative. The material was applied as a post foliar spray with broadcast tractor mounted or backpack CO_2 sprayers. The two field corn and one popcorn trials conducted in 1999 were intended to replace/supplement three trials in the 1998 trials but all data is reported here.

Zero-day samples were taken after the spray was allowed to dry. Except for samples to be used for the processing study, all samples were frozen and shipped frozen to Novartis Crop Protection (Greensboro, NC) where sample preparation was performed. After sample preparation, samples were frozen and shipped frozen to the analytical laboratory EPL–BioAnalytical Services, Inc. (Harristown, IL). Separate samples of the different corn RACs were homogenized and analyzed for trifloxystrobin and for its acid metabolite, CGA-321113, using Method AG-659A described above. Sufficient sample chromatograms and calibration information were provided. Apparent residues of trifloxystrobin and CGA-321113 were each less than the LOQ (<0.02 ppm) in untreated corn grain, forage and stover. Samples were stored frozen from the time of sample collection until analysis 3.3-16.2 months later.

The decline studies with grains could not be evaluated because grain residues were not quantifiable at all time points. In both corn forage and stover, there was a pronounced decline in trifloxystrobin levels over time. Corn forage residue levels dropped to <0.020 ppm within 23 days of the last treatment and in corn stover residue levels stabilized by day 30 but did not show any decline to below the detection limit. The results from the corn field trials are summarized in Tables 14, 15, and 16 for the 0.5x, 1x, and 5x studies, respectively.

Table 14. Residues of CGA-279202 and its metabolite CGA-321113 on field corn forage following 2 x 0.11 lb ai/A of CGA-279202+propiconazole 250EC.

Test location: County, state (EPA crop region)	PHI (Days)	Residue levels	
		CGA-279202 (ppm)	CGA-321113[1] (ppm)
Field corn forage			
Champaign, IL (5)	29	<0.02, <0.02	<0.02, <0.02
Burleson, TX (6)	31	<0.02, <0.02	<0.02, <0.02
Sampson, NC (2)	30	0.021, <0.02	<0.02, <0.02
Madera, CA (10)	30	<0.02, <0.02	<0.02, <0.02
Jefferson, IA (5)	51	<0.02, <0.02	<0.02, <0.02
Hamilton, IA (5)	30	<0.02, <0.02	0.023, <0.02
Adair, MO (5)	67	<0.02, <0.02	<0.02, <0.02
Sedgwick, KS (5)	15	<0.02, <0.02	<0.02, <0.02
Clinton, IL (5)	29	<0.02, <0.02	<0.02, <0.02

Table 14. Residues of CGA-279202 and its metabolite CGA-321113 on field corn forage following 2 x 0.11 lb ai/A of CGA-279202+propiconazole 250EC.			
Test location: County, state (EPA crop region)	PHI (Days)	Residue levels	
		CGA-279202 (ppm)	CGA-321113[1] (ppm)
Sioux, IA (5)	0 9 16 23 30 37	8.9, 9.5 0.073, 0.15 0.028, 0.020 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02	0.17, 0.18 0.038, 0.046 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02
Clay, SD (5)	30	<0.02, <0.02	<0.02, <0.02
York, NE (5)	30	<0.02, <0.02	<0.02, <0.02
Polk, NE (5)	30	<0.02, <0.02	<0.02, <0.02
Walworth, WI (5)	30	<0.02, <0.02	<0.02, <0.02
Freeborn, MN (5)	0 9 16 23 30 37	14, 18 0.17, 0.21 <0.020, 0.028 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02	0.059, 0.065 0.080, 0.089 <0.020, 0.027 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02
Steele, MN (5)	30	<0.02, <0.02	<0.02, <0.02
Hamilton, IN (5)	29	<0.02, <0.02	<0.02, <0.02
Hamilton, IN (5)	30	<0.02, <0.02	<0.02, <0.02
Fayette, OH (5)	29	<0.02, <0.02	<0.02, <0.02
Ingham, MI (5)	32 29	<0.02, <0.02 <0.02, <0.02	<0.02, <0.02 <0.02, <0.02
Wayne, NY (1)	30	<0.02, <0.02	<0.02, <0.02
Sedgwick, KS 1999 (5)	31	0.12, 0.039	0.075, <0.02

[1]CGA-321113 residues are converted to CGA-279202 equivalents with this factor (wt./wt. conversion factor = 408/394). Limit of quantitation for both residues = 0.02 ppm

Table 15. Residues of CGA-279202 and its metabolite CGA-321113 on field and pop corn grain and stover following 4 x 0.11 lb ai/A (max proposed use) of CGA-279202+propiconazole 250EC.			
Test location: County, state (EPA crop region)	PHI (Days)	Residue levels[1]	
		CGA-279202 (ppm)	CGA-321113 [2] (ppm)
Grain			
Champaign, IL (5)	29	<0.02, <0.02	<0.02, <0.02
Burleson, TX (6)	28	<0.02, <0.02	<0.02, <0.02
Sampson, NC (2)	34	<0.02, <0.02	<0.02, <0.02
Madera, CA (10)	32	<0.02, <0.02	<0.02, <0.02
Jefferson, IA (5)	29	<0.02, <0.02	0.025, 0.027 **HAFT=0.026**

Table 15. Residues of CGA-279202 and its metabolite CGA-321113 on field and pop corn grain and stover following 4 x 0.11 lb ai/A (max proposed use) of CGA-279202+propiconazole 250EC.				
Test location: County, state (EPA crop region)		PHI (Days)	Residue levels[1]	
			CGA-279202 (ppm)	CGA-321113 [2] (ppm)
Hamilton, IA	(5)	30	<0.02, <0.02	<0.02, <0.02
Adair, MO	(5)	30	<0.02, <0.02	<0.02, <0.02
Sedgwick, KS	(5)	29	<0.02, <0.02	<0.02, <0.02
Sedgwick, KS [P]	(5)	29	<0.02, <0.02	<0.02, <0.02
Clinton, IL	(5)	30	<0.02, <0.02	<0.02, <0.02
Sioux, IA	(5)	9 16 23 30 36	<0.02, <0.02 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02	<0.02, <0.02 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02
Clay, SD	(5)	29	<0.02, <0.02	<0.02, <0.02
York, NE	(5)	30	<0.02, <0.02	<0.02, <0.02
Polk, NE	(5)	30	<0.02, <0.02	<0.02, <0.02
York, NE [P]	(5)	30	<0.02, <0.02	<0.02, <0.02
Walworth, WI	(5)	30	<0.02, <0.02	<0.02, <0.02
Freeborn, MN	(5)	9 16 23 30 37	0.059, 0.023 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02	<0.02, <0.02 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02 <0.02, <0.02
Steele, MN	(5)	30	<0.02, <0.02	<0.02, <0.02
Hamilton, IN	(5)	30	<0.02, <0.02	<0.02, <0.02
Hamilton, IN	(5)	30	<0.02, <0.02	<0.02, <0.02
Hamilton, IN [P]	(5)	30	<0.02, <0.02	<0.02, <0.02
Fayette, OH	(5)	28	<0.02, <0.02	<0.02, <0.02
Ingham, MI	(5)	29	<0.02, <0.02	<0.02, <0.02
Wayne, NY	(1)	30	<0.02, <0.02	<0.02, <0.02
Sedgwick, KS 1999	(5)	29	<0.02, <0.02	<0.02, <0.02
Sedgwick, KS 1999 [P]	(5)	29	<0.02, <0.02	<0.02, <0.02
Fayette, OH 1999	(5)	30	<0.02, <0.02	<0.02, <0.02
Stover				
Champaign, IL	(5)	29	5.4, 3.0	1.6, 1.5
Burleson, TX	(6)	28	0.67, 2.2	0.11, 0.25
Sampson, NC	(2)	34	0.04, 0.04	0.05, 0.04
Madera, CA	(10)	32	0.37, 0.19	0.04, 0.03
Jefferson, IA	(5)	29	0.53, 0.44	0.12, 0.14
Hamilton, IA	(5)	30	1.0, 1.0	0.37, 0.32
Adair, MO	(5)	30	0.35, 0.43	0.13, 0.13
Sedgwick, KS[P]	(5)	29	0.31, 0.37[3]	0.13, 0.14[3]
Clinton, IL	(5)	30	0.71, 0.96	0.43, 0.44

Table 15. Residues of CGA-279202 and its metabolite CGA-321113 on field and pop corn grain and stover following 4 x 0.11 lb ai/A (max proposed use) of CGA-279202+propiconazole 250EC.			
Test location: County, state (EPA crop region)	PHI (Days)	Residue levels[1]	
		CGA-279202 (ppm)	CGA-321113 [2] (ppm)
Sioux, IA (5)	0	4.6, 6.9	0.40, 0.33
	9	2.9, 3.6	0.42, 0.64
	16	0.93, 1.4	0.21, 0.36
	23	1.3, 0.80	0.40, 0.20
	30	0.67, 1.2	0.17, 0.23
	36	0.78, 0.99	0.23, 0.30
Clay, SD (5)	29	3.2, 3.9	0.41, 0.49
York, NE (5)	30	2.9, 2.8	1.0, 1.1
Polk, NE (5)	30	0.64, 0.60	0.16, 0.12
York, NE [P] (5)	30	1.2, 2.7	0.87, 1.7
Walworth, WI (5)	30	2.1, 1.2	0.49, 0.37
Freeborn, MN (5)	0	1.7, 0.86	0.18, 0.28
	9	5.1, 4.1	0.62, 0.59
	16	0.39, 0.68	0.29, 0.33
	23	1.1, 0.52	0.52, 0.26
	30	0.80, 0.88	0.35, 0.36
	37	0.61, 0.63	0.26, 0.27
Steele, MN (5)	30	0.96, 0.86	0.49, 0.37
Hamilton, IN (5)	30	2.6, 3.2	0.25, 0.27
Hamilton, IN (5)	30	2.2, 1.2	0.24, 0.17
Hamilton, IN [P] (5)	30	3.0, 4.0	0.55, 0.42
Fayette, OH (5)	29	0.72, 0.59[3]	0.43, 0.40[3]
Ingham, MI (5)	29	2.0, 1.8	0.76, 0.68
Wayne, NY (1)	30	0.56, 0.58	0.17, 0.11
Sedgwick, KS 1999 (5)	29	0.28, 0.42	0.03, 0.05
Sedgwick, KS 1999 [P] (5)	29	0.20, 0.32	0.020, 0.05
Fayette, OH 1999 (5)	30	1.2, 1.5	0.39, 0.40

[1]Residue levels are not corrected for control values but are corrected for procedural recoveries <100%.

[2] CGA-321113 residues are converted to CGA-279202 equivalents with this factor (wt./wt. conversion factor = 408/394).

[3]Trial received four treatments but at approximately ½ the 0.11 lb ai/A rate. Additional trials were added to compensate. Limit of quantitation for both residues = 0.02 ppm

Table 16. Residues of CGA-279202 and its metabolite CGA-321113 on field corn grain and stover following 4 x 0.55 lb ai/A (5x proposed use) of CGA-279202+propiconazole 250EC.			
Test location: County, state (EPA crop region)	PHI (Days)	Residue levels[1]	
		CGA-279202 (ppm)	CGA-321113 [2] (ppm)
Field corn grain (pp 136-146, MRID 45080810, pg 33, MRID 45080809)			
Champaign, IL (5)	29	<0.02, <0.02	<0.02, <0.02

Table 16. Residues of CGA-279202 and its metabolite CGA-321113 on field corn grain and stover following 4 x 0.55 lb ai/A (5x proposed use) of CGA-279202+propiconazole 250EC.			
Test location: County, state (EPA crop region)	PHI (Days)	Residue levels[1]	
		CGA-279202 (ppm)	CGA-321113 [2] (ppm)
Hamilton, IA (5)	30	0.20, 0.038	0.068, 0.032
Field corn stover (pp 136-146, MRID 45080810, pg 33, MRID 45080809)			
Champaign, IL (5)	29	17, 15	1.3, 1.3
Hamilton, IA (5)	30	13, 18	1.5, 2.1

[1]Residue levels are not corrected for control values but are corrected for procedural recoveries <100%.
[2]CGA-321113 residues are converted to CGA-279202 equivalents with this factor (wt./wt. conversion factor = 408/394).
Limit of quantitation for both residues = 0.02 ppm

Geographic representation of field and pop corn is adequate for the purposes of this petition. As required under OPPTS 860.1500 a total of 23 trials were conducted for field corn in Region 1 (1 trial), 2 (1 trial), 5 (19 trials), 6 (1 trial), and 10 (1 trial). In addition, a total of 4 trials were conducted for pop corn in Region 5.

Study summary

There were no measurable (≥0.020 ppm) trifloxystrobin (CGA-279202) or CGA-321113 residues in any field corn or popcorn grain samples treated at the proposed 1X rate with the nominal 30-day PHI except for two replicates of CGA-321113 representing a single trial which were 0.025 and 0.027 ppm. The maximum combined residues of trifloxystrobin and CGA-321113 in grain was <0.047 ppm.

For field corn forage, following 2 x 0.11 lb ai/A applications and 29-31day PHIs, there were no measurable residues (≥0.020) for trifloxystrobin or for CGA-321113 in the 1998 trials and 0.039-0.12 ppm trifloxystrobin and <0.02-0.075 ppm CGA-321113 in the 1999 trial. Combined residues were <0.04-0.20 ppm in field corn forage.

For field corn and popcorn stover, following 4 x 0.11 lb ai/A, residues of trifloxystrobin were 0.04-5.4 ppm and CGA-321113 were 0.02-1.6 ppm. Combined residues of trifloxystrobin and CGA-321113 were 0.08-7.0 ppm in stover harvested 29-30 days after the last treatment.

All crop field trials were performed using an emulsifiable concentrate which also contains propiconazole, and no field trials were conducted using the WG formulation. Bridging studies were performed on rice and pecans (see below), however, these data are not translatable to corn. As a result, only the EC product is supported by the corn residue data, which are adequate to support the proposed tolerance of 0.05 ppm on field corn and popcorn grain given the maximum combined residue of 0.047 ppm. The proposed tolerance of 0.05 ppm on corn forage is not adequate; RAB3 recommends that the petitioner propose a tolerance of 0.2 ppm in corn forage

provided the label impose a 30 day interval prior to cutting for forage and grazing. The proposed tolerance of 7.0 ppm is adequate for field corn and popcorn stover.

The decline studies provided moderate to strong evidence of a decline in residues over time in/on corn forage and corn stover.

Pecans

Novartis Crop Protection submitted data from 5 field trials conducted in 1998 on pecans to support a tolerance for residues on pecans. One of the trials was a decline study. The results are reported in:

> MRID 45080806. Vincent, Timothy P., (2000) CGA-279202 and CGA-245704-Magnitude Of The Residues In Or On Pecans, Novartis Crop Protection, Inc., 410 Swing Road, Post Office Box 18300, Greensboro, NC 27419. Novartis Study Number 155-98, February 23, 2000. Unpublished.

The pecan field trials were conducted in Texas (Region 1), New Mexico (Region 8), Georgia (Region 2), Alabama (Region 2), and Louisiana (Region 4). Two spray methods were used: a concentrated spray of 50-99 GPA and a dilute spray of 100-400 GPA. These sprays were applied in 8 serial foliar applications at 14-day intervals at a maximum use rate of 57 g ai/A, for a total of 456 g ai/A/season. This is 1.3x the proposed Flint™ label use rate of 6 applications at 57.0 g ai/A for a total of 340 g ai (0.75 lb ai) /A/season. The last application was made about 30 days before harvest of the mature nuts and prior to shuck split. Whole pecans were sampled from all parts of the trees and after collection samples were frozen and shipped to North Carolina where they were stored frozen until analysis. Samples were prepared by grinding the nutmeat after separating it from the shell. The samples were stored frozen until analysis, which was performed in laboratories located in the home states: Coast Ag Research, Inc. (TX), Marathon Ag and Environmental Consulting, Inc. (NM), H and B Ag Research, Inc. (GA), Diamond H Farms (AL), and R & D Research Farm, Inc. (LA). Analytical method AG-659A was used to determine residues of CGA-279202 and its acid metabolite in pecans. The LOQ was 0.02 ppm for each analyte. The decline study used a dilute spray concentration and had PHIs of 0, 8, 15, 22, 29 and 36 days.

Results from the analyses of CGA-279202 and its acid metabolite in/on pecans are given in Table 17. Residues from all untreated control samples were below the LOQ of 0.02 ppm for both analytes.

Table 17. Residues of CGA-279202 and CGA-321113 in/on pecans treated with 8 x 57 g or 0.125 lb ai/A (1.3x max proposed use) in concentrate spray (50-99GPA) or dilute spray (100-400GPA).

Test Location (Region)	Formulation	Spray type	PHI (days)	Residues found (ppm)	
				CGA-279202	CGA-321113
Texas (6)	250EC	Conc	30	<0.02	<0.02
	250EC	Conc	30	<0.02	<0.02

Table 17. Residues of CGA-279202 and CGA-321113 in/on pecans treated with 8 x 57 g or 0.125 lb ai/A (1.3x max proposed use) in concentrate spray (50-99GPA) or dilute spray (100-400GPA).

Test Location (Region)	Formulation	Spray type	PHI (days)	Residues found (ppm)	
				CGA-279202	CGA-321113
	250EC	Dilute	30	<0.02	<0.02
	250EC	Dilute	30	<0.02	<0.02
	50WG	Conc	30	<0.02	<0.02
	50WG	Conc	30	<0.02	<0.02
	50WG	Dilute	30	<0.02	<0.02
	50WG	Dilute	30	<0.02	<0.02
New Mexico (8)	250EC	Conc	28	<0.02	<0.02
	250EC	Conc	28	<0.02	<0.02
	250EC	Dilute	28	<0.02	<0.02
	250EC	Dilute	28	<0.02	<0.02
Georgia (2)	250EC	Dilute	0	<0.02	<0.02
	250EC	Dilute	0	<0.02	<0.02
	50WG	Dilute	0	<0.02	<0.02
	50WG	Dilute	0	<0.02	<0.02
	250EC	Dilute	8	<0.02	<0.02
	250EC	Dilute	8	<0.02	<0.02
	50WG	Dilute	8	<0.02	<0.02
	50WG	Dilute	8	<0.02	<0.02
	250EC	Dilute	15	<0.02	<0.02
	250EC	Dilute	15	<0.02	<0.02
	50WG	Dilute	15	<0.02	<0.02
	50WG	Dilute	15	<0.02	<0.02
	250EC	Dilute	22	<0.02	<0.02
	250EC	Dilute	22	<0.02	<0.02
	50WG	Dilute	22	<0.02	<0.02
	50WG	Dilute	22	<0.02	<0.02
	250EC	Dilute	29	<0.02	<0.02
	250EC	Dilute	29	<0.02	<0.02
	50WG	Dilute	29	<0.02	<0.02
	50WG	Dilute	29	<0.02	<0.02
	250EC	Dilute	36	<0.02	<0.02
	250EC	Dilute	36	<0.02	<0.02
	50WG	Dilute	36	<0.02	<0.02
	50WG	Dilute	36	<0.02	<0.02
Alabama (2)	250EC	Conc	34	<0.02	<0.02
	250EC	Conc	34	<0.02	<0.02
Louisiana (4)	250EC	Conc	30	<0.02	<0.02
	250EC	Conc	30	<0.02	<0.02
	250EC	Dilute	30	<0.02	<0.02
	250EC	Dilute	30	<0.02	<0.02

Geographic representation of pecans is adequate for the purposes of this petition. As required under OPPTS 860.1500, a total of 5 field trials were conducted as recommended in Region 2 (2 trials), 4 (1 trial), 6 (1 trial) and 8 (1 trial).

Study summary

Residues of trifloxystrobin (CGA-279202) and its acid metabolite CGA-321113 in pecan nutmeat were each < 0.02 ppm following 1.3x the maximum proposed rate from either the WG or EC formulation. The residue data, along with the current almond tolerance of 0.04 ppm, support a tree nut crop group tolerance of 0.04 ppm. Therefore, a revised Section F is required revising the proposed tree nut crop group tolerance from 0.05 ppm to 0.04 ppm. The decline study did not demonstrate any conclusive trends in decreasing residues at longer posttreatment intervals because the residues were all below the LOQ.

Rice

Novartis Crop Protection submitted data from 16 rice field trials conducted in 1998 to support a permanent tolerance for trifloxystrobin in/on rice. The results are reported in:

> MRID 45080811. Vincent, T.P. (2000) Propiconazole and CGA-279202 - Magnitude of the residues in or on rice. Human Safety Department, Novartis Crop Protection, Inc., Greensboro, NC. Novartis Project Identification No. 150-98, March 3, 2000. Unpublished.

Sixteen trials were conducted in EPA crop regions 4 (5 in AR, 3 in LA, 2 in MS, 1 in MO), 5 (MO), 6 (2 in TX), and 10 (2 in CA). The distribution and number of trials meet the requirements for crop field trials for rice. Rice was treated with CGA-279202 50WG at 1x, 3x, and 5x the proposed rate (2 x 0.154, 2 x 0.462, 2 x 0.77 lb ai/A) at 49 and 34-40 days before harvest. The 3x rate was a back-up in case the 5x rate induced crop damage; since no damage was present at the 5x rate, harvest of the 3x rate samples was canceled. Two residue decline studies were conducted using the 50WG formulation with PHIs of 14, 21, 27 or 28, 34 or 35, and 42 or 45 days. Rice was also treated with CGA-279202+propiconazole 250EC at the same rate and retreatment interval as the 50WG formulation. All treatments were applied at a minimum of 10 GPA by broadcast spray. One plot was an untreated control. The rice treatment regimes are summarized in Table 18.

Table 18. Application regimes for CGA-279202 and CGA-279202+propiconazole on rice

Treatment #	Chemical	Rate per application	# Applications (interval)
1 (control)	none	n/a	n/a
2	propiconazole 250EC + CGA-279202 250 EC	1x; each at 70 g (0.154 lb) ai/A	2 (49 and 35-40 days before harvest)
3	CGA-279202 50WG	1x; 70 g ai/A	2 (49 and 14, 21, 27 or 28, 34 or 35, 42 or 45 days before harvest)
4	CGA-279202 50WG	3x; 210 g ai/A	2 (49 and 35 days before harvest)
5	CGA-279202 50WG	5x; 350 g ai/A	2 (49 and 35 days before harvest)

After harvest, samples of rice grain and straw were frozen and shipped by freezer truck to Novartis Crop Protection, Greensboro, NC where they were stored frozen (up to 15.2 months) until analysis. Analytical method AG-659A was used to determine residues of CGA-279202 and its acid metabolite CGA-321113 in rice matrices. The LOQ was 0.02 ppm for each analyte.

Results from the analyses of trifloxystrobin and its metabolite CGA-321113 in/on rice straw and grain are given in Table 19. Residues from all untreated control samples were below the LOQ of 0.02 ppm for both analytes with the exception of one grain sample harvested at PHI=34 days during the decline study in MS (0.094 ppm trifloxystrobin; 0.10 ppm CGA-321113).

Table 19. Residues[1] of trifloxystrobin and its acid metabolite following 2 x 0.154 lb ai/A (max proposed use) on rice straw and grain

Test location: County, state (EPA crop region)	Application rate (g ai/A); Formulation	PHI (days)	CGA-279202 (ppm)	CGA-321113 [2] (ppm)
Straw				
Washington, MS (4) (decline study)	2 x 70 or 1x; 50WG	14	0.86; 1.7	0.40; 0.60
		21	0.96; 1.0	0.67; 0.74
		27	0.67; 0.86	0.62; 0.81
		34	0.51; 0.51	0.41; 0.40
		42	0.46; 1.3	0.54; 1.3
Independence, AR (4) (decline study)	2 x 70 or 1x; 50WG	14	1.2; 1.5	0.17; 0.23
		21	0.80; 1.1	0.16; 0.28
		28	0.89; 0.82	0.39; 0.29
		35	0.97; 1.0	0.28; 0.31
		45	0.58; 0.50	0.33; 0.25
Crittenden, AR (4)	2 x 70 or 1x; 250EC	36	**2.6**; 1.7	**1.1**; 0.64
	2 x 70 or 1x; 50WG	36	5.5; **6.1**	**1.3**; 1.2
Jackson, AR (4)	2 x 70 or 1x; 50WG	35	0.64; 0.78	0.16; 0.21
	2 x 350 or 5x; 50WG	35	8.5	1.3
Drew, AR (4)	2 x 70 or 1x; 50WG	35	0.84; 2.0	0.30; 0.12
Arkansas, AR (4)	2 x 70 or 1x; 50WG	34	0.46; 0.57	0.28; 0.26
Pemiscot, MO (4)	2 x 70 or 1x; 50WG	35	2.4; 1.5	0.78; 1.1
Stoddard, MO (5)	2 x 70 or 1x; 250EC	35	0.20; 0.25	0.058; 0.065
	2 x 70 or 1x; 50WG	35	0.12; 0.12	<0.02; 0.02
Wharton, TX (6)	2 x 70 or 1x; 250EC	40	0.37; 0.19	0.083; 0.04
	2 x 70 or 1x; 50WG	40	0.34; 0.44	0.068; 0.10
Colorado, TX (6)	2 x 70 or 1x; 50WG	37	0.048; 0.064	<0.02; <0.02
St. Landry Parish, LA (4)	2 x 70 or 1x; 50WG	35	0.30; 0.42	0.12; 0.17
	2 x 350 or 5x; 50WG	35	5.3	0.84
Jeff Davis Parish, LA (4)	2 x 70 or 1x; 50WG	35	1.1; 1.1	0.37; 0.45
Allen Parish, LA (4)	2 x 70 or 1x; 50WG	35	0.32; 0.54	0.12; 0.19

Table 19. Residues[1] of trifloxystrobin and its acid metabolite following 2 x 0.154 lb ai/A (max proposed use) on rice straw and grain

Test location: County, state (EPA crop region)	Application rate (g ai/A); Formulation	PHI (days)	CGA-279202 (ppm)	CGA-321113 [2] (ppm)
Washington, MS (4)	2 x 70 or 1x; 50WG	35	0.30; 0.50	0.23; 0.32
Merced, CA (10)	2 x 70 or 1x; 50WG	35	4.4; 5.3	0.16; 0.16
Butte, CA (10)	2 x 70 or 1x; 250EC	35	1.7; 2.5	0.46; 0.68
	2 x 70 or 1x; 50WG	35	2.6; 2.5	0.53; 0.62
Grain				
Washington, MS (4) (decline study)	2 x 70 or 1x; 50WG	14	0.16; 0.25	0.10; 0.11
		21	0.15; 0.13	0.059; 0.054; 0.053; 0.034
		27	0.16; 0.20	0.063; 0.070
		34	0.23; 0.25	**0.12**; 0.12
		42	0.19; 0.30	0.093; 0.15
Independence, AR (4) (decline study)	2 x 70 or 1x; 50WG	14	0.18; 0.17	0.033; 0.028
		21	0.056; 0.088	0.021; 0.023
		28	0.036; 0.058	<0.02; <0.02
		35	0.034; 0.036	<0.02; <0.02
		45	0.028; 0.041	0.023; 0.021
Crittenden, AR (4)	2 x 70 or 1x; 250EC	36	0.25; 0.24	0.076; 0.073
	2 x 70 or 1x; 50WG	36	0.34; 0.33	0.065; 0.058
Jackson, AR (4)	2 x 70 or 1x; 50WG	35	0.10; 0.12	0.065; 0.075
	2 x 350 or 5x; 50WG	35	0.63	0.14
Drew, AR (4)	2 x 70 or 1x; 50WG	35	0.11; 0.068	0.054; 0.025
Arkansas, AR (4)	2 x 70 or 1x; 50WG	34	0.11; 0.089	0.10; 0.087
Pemiscot, MO (4)	2 x 70 or 1x; 50WG	35	0.54; 0.68	0.063; 0.074
Stoddard, MO (5)	2 x 70 or 1x; 250EC	35	<0.02; <0.02	<0.02; <0.02
	2 x 70 or 1x; 50WG	35	<0.02; <0.02	<0.02; <0.02
Wharton, TX (6)	2 x 70 or 1x; 250EC	40	<0.02; <0.02	<0.02; <0.02
	2 x 70 or 1x; 50WG	40	<0.02; <0.02	<0.02; <0.02
Colorado, TX (6)	2 x 70 or 1x; 50WG	37	<0.02; <0.02	<0.02; <0.02
St. Landry Parish, LA (4)	2 x 70 or 1x; 50WG	35	<0.02; 0.033	<0.02; 0.035
	2 x 350 or 5x; 50WG	35	0.20	0.15
Jeff Davis Parish, LA (4)	2 x 70 or 1x; 50WG	35	0.039; 0.040	<0.02; <0.02
Allen Parish, LA (4)	2 x 70 or 1x; 50WG	35	<0.02; <0.02	<0.02; <0.02
Washington, MS (4)	2 x 70 or 1x; 50WG	35	0.096; 0.094	0.030; 0.028
Merced, CA (10)	2 x 70 or 1x; 50WG	35	**3.4**; 2.5 HAFT=2.95	0.028; **0.076** HAFT=0.052
Butte, CA (10)	2 x 70 or 1x; 250EC	35	**0.56**; 0.52	0.071; 0.075
	2 x 70 or 1x; 50WG	35	2.4; 2.2	0.10; 0.098

[1]Residue levels are not corrected for control values but are corrected for procedural recoveries <100%.

[2]CGA-321113 residues are converted to CGA-279202 equivalents with this factor (wt./wt. conversion factor = 408/394).
Limit of quantitation for both residues = 0.02 ppm

The geographical distribution and number of trials are adequate to support the proposed use of trifloxystrobin on rice.

Study summary

For rice grain, residues of trifloxystrobin were <0.02-3.4 ppm and CGA-321113 were <0.02-0.12 ppm at 34-35 day PHI from the WG formulation (16 field trials), and were <0.02-0.56 ppm parent and <0.02-0.076 ppm CGA-321113 at 35-36 day PHI from the EC formulation (4 field trials). Combined residues of trifloxystrobin and CGA-321113 were <0.04-3.43 ppm from the WG formulation and were <0.04-0.63 ppm from the EC formulation.

For rice straw, residues of trifloxystrobin were 0.048-6.1 ppm and CGA-321113 were <0.02-1.3 ppm at 36-37 day PHI from the WG formulation, and were 0.20-2.6 ppm parent and were 0.04-1.1 ppm at 36-40 day PHI from the EC formulation. Combined residues of trifloxystrobin and CGA-321113 were <0.068-7.3 ppm from the WG formulation and were 0.23-3.7 ppm from the EC formulation.

Comparison of the results with the two formulations shows that the WG formulation resulted in generally higher combined CGA-279202 and CGA-321113 residues than those from the EC formulation in grain and straw. Since the bulk of the residue data were generated using the WG formulation, the submitted residue data are adequate to support the proposed use of the EC formulation. The residue data support the proposed tolerances of 3.5 ppm for residues of trifloxystrobin in/on rice grain and 7.5 ppm in/on rice straw.

For residue decline in grain, one study showed levels of trifloxystrobin declined and the acid metabolite with no definite trend of increase or decrease; another study showed no consistent trend of increase or decrease in levels of trifloxystobin and its acid metabolite over time. For straw, levels of trifloxystrobin declined and levels of the acid metabolite increased over time.

Stone fruit

Novartis Crop Protection submitted stone fruit (peaches, fresh plums and dry plums, and sweet and tart cherries) field trial data to support the establishment of a tolerance for residues of trifloxystrobin and its acid metabolite in/on the stone fruit crop group at 2.0 ppm. Four of the trials were residue decline studies, one study per crop. The results are reported in:

MRID 45276401. Grunenwald, M. C. (2000) CGA-279202 and CGA-245704-Magnitude Of The Residues In Or On Crop Group 12: Stone Fruits. Novartis Crop Protection, Inc., 410 Swing Road, Post Office Box 18300, Greensboro, NC 27419. Novartis Study Number 149-98, February 9, 2000. Unpublished.

The 27 field trials were conducted in 1999 in 12 states in California (Region 10), Georgia (Region 2), Michigan (Region 5), North Carolina (Region 2), New York (Region 1), Oregon (Region 12), Pennsylvania (Region 1), South Carolina (Region 2), Texas (Region 6), Utah (Region 9), Washington (Region 11), and Wisconsin (Region 5). Four broadcast foliar spray applications were made to stone fruit with the CGA-279202 50WG formulation at the 1x rate of 57 g or 0.126 lb ai/A (total application of 228 g or 0.50 lb ai/A/season) at 7 day intervals. The PHI was 1 day. (Mature plums targeted for processing into prunes were treated at rates of 3x and 5x.) Multiple 1x application rates having differing GPAs were used to demonstrate that varying standard agricultural practices produce comparable residues; 1 trial for each fruit was conducted at 10 GPA to simulate aerial applications. Residue decline studies were conducted in field trials for representative stone fruit: peaches, plums, sweet cherry, and tart cherry with samples collected at PHIs of 0, 1, and 2 days.

After collection, samples were frozen and shipped with dry ice. Samples to be processed into prunes were first shipped to California for processing and then to North Carolina where all samples were stored prior to analysis. Stone fruit were halved, stones and stems removed, and then macerated and homogenized. Samples were stored frozen until analysis which was carried out at a number of sites. Analytical method AG-659A was used to determine residues of CGA-279202 and its acid metabolite in stone fruit. The LOQ was 0.02 ppm for each analyte.

Results from the analyses of CGA-279202 and its acid metabolite in/on stone fruit are given in Table 20. Residues from all untreated control samples were below the LOQ of 0.02 ppm for both analytes, except for 2 peach samples containing 0.72 ppm and 1.0 ppm trifloxystrobin and one peach sample containing 0.04 ppm CGA-321113 acid metabolite.

Table 20. Residues of CGA-279202 and CGA-321113 in/on stone fruits following 4 x 0.126 lb ai/A (1x max proposed use) or 4 x 0.628 lb ai/A (5x max proposed use) of WG formulation.

Test Location (EPA Region)	Rate	PHI (days)	Residue [1] levels (ppm)	
			CGA-279202	CGA-321113
Peaches				
CA (10)	1x	0	0.24	<0.02
	1x	0	0.50	<0.02
	1x	1	<0.02	<0.02
	1x	1	0.21	<0.02
	1x	2	0.20	<0.02
	1x	2	0.19	<0.02
TX (6)	1x	1	1.9	0.06
	1x	1	1.6	0.05
	1x	1	1.7	0.08
	1x	1	1.8	0.08
NC (2)	1x	1	0.28	<0.02
	1x	1	0.32	<0.02
SC (2)	1x	1	0.61	0.05***
	1x	1	0.65	0.05***
	1x	1	0.82	0.06***
	1x	1	0.79	0.06***
GA (2)	1x	1	0.41	<0.02

Table 20. Residues of CGA-279202 and CGA-321113 in/on stone fruits following 4 x 0.126 lb ai/A (1x max proposed use) or 4 x 0.628 lb ai/A (5x max proposed use) of WG formulation.				
Test Location (EPA Region)	Rate	PHI (days)	Residue [1] levels (ppm)	
			CGA-279202	CGA-321113
	1x	1	0.40	<0.02
CA (10)	1x	1	0.06*	<0.02
	1x	1	0.05*	<0.02
	1x	1	0.06**	<0.02
	1x	1	<0.02**	<0.02
CA (10)	1x	1	0.25	<0.02
	1x	1	0.18	<0.02
	1x	1	0.32	<0.02
	1x	1	0.34	<0.02
PA (1)	1x	1	0.82	0.04
	1x	1	0.63	0.04
	1x	1	0.85	0.06
	1x	1	0.89	0.05
MI (5)	1x	1	0.21	<0.02
	1x	1	0.18	<0.02
	1x	1	0.39	<0.02
	1x	1	0.34	<0.02
Plums / prunes				
CA (10)	1x	0	<0.02	<0.02
	1x	0	0.03	<0.02
	1x	1	<0.02	<0.02
	1x	1	0.02	<0.02
	1x	2	0.02	<0.02
	1x	2	0.05	<0.02
CA (10)	1x	1	0.21	<0.02
	1x	1	0.19	<0.02
	1x	1	0.32	<0.02
	1x	1	**0.53**	<0.02
	5x	1	1.4	0.02
	5x	1	1.3	0.02
CA (10)	1x	1	0.15 Whole fruit, fresh	<0.02 Whole fruit, fresh
	5x	1	1.1 Whole fruit, fresh	0.05 Whole fruit, fresh
	1x	1	0.23 Dried prune	0.03 Dried prune
	5x	1	1.4 Dried prune	0.07 Dried prune
CA (10)	1x	1	0.19	<0.02
	1x	1	0.17	<0.02
CA (10)	1x	1	0.09	<0.02
	1x	1	0.08	<0.02
	5x	1	0.25	<0.02
	5x	1	0.28	<0.02
	1x	1	0.07 Whole fruit, fresh	<0.02 Whole fruit, fresh
	5x	1	0.31 Whole fruit, fresh	<0.02 Whole fruit, fresh

Table 20. Residues of CGA-279202 and CGA-321113 in/on stone fruits following 4 x 0.126 lb ai/A (1x max proposed use) or 4 x 0.628 lb ai/A (5x max proposed use) of WG formulation.

Test Location (EPA Region)	Rate	PHI (days)	Residue levels (ppm)	
			CGA-279202	CGA-321113
	1x	1	0.10 Dried prune	<0.02 Dried prune
	5x	1	0.48 Dried prune	<0.02 Dried prune
OR (11)	1x	1	0.06	<0.02
	1x	1	0.04	<0.02
	1x	1	0.06	<0.02
	1x	1	0.04	<0.02
MI (5)	1x	1	0.10	<0.02
	1x	1	0.15	<0.02
	1x	1	0.17	<0.02
	1x	1	0.21	<0.02
Sweet Cherries				
Fresno Co., CA (10)	1x	0	0.45	<0.02
	1x	0	0.63	0.03
	1x	1	0.34	<0.02
	1x	1	0.37	<0.02
	1x	2	0.24	<0.02
	1x	2	0.27	0.02
Stanislaus Co., CA (10)	1x	1	0.56	0.05
	1x	1	0.38	0.04
Yakima Co., WA (11)	1x	1	0.25	0.03
	1x	1	0.26	0.02
Hood R. Co., OR(11)	1x	1	0.25	0.03
	1x	1	0.39	0.03
MI (5)	1x	1	0.33	0.04
	1x	1	0.33	0.05
MI (5)	1x	1	0.63	0.05
	1x	1	0.84	0.06
	1x	1	0.54	0.06
	1x	1	0.63	0.06
Tart Cherries				
UT (9)	1x	1	0.38	0.03
	1x	1	0.30	<0.02
	1x	1	0.53	0.04
	1x	1	0.54	0.04
WI (5)	1x	1	0.55	0.04
	1x	1	0.48	0.04
MI (5)	1x	0	0.67	0.07
	1x	0	0.63	0.06
	1x	1	0.29	0.04
	1x	1	0.53	0.06
	1x	2	0.20	0.03
	1x	2	0.31	0.06
MI (5)	1x	1	0.58	0.04
	1x	1	0.42	0.03
NY (1)	1x	1	0.34	0.04
	1x	1	0.32	0.04

Table 20. Residues of CGA-279202 and CGA-321113 in/on stone fruits following 4 x 0.126 lb ai/A (1x max proposed use) or 4 x 0.628 lb ai/A (5x max proposed use) of WG formulation.				
Test Location (EPA Region)	Rate	PHI (days)	Residue [1] levels (ppm)	
			CGA-279202	CGA-321113
	1x	1	0.66	0.07
	1x	1	0.47	0.05

[1]Results are not corrected for control values but are corrected for procedural recoveries < 100%.
[2]CGA-321113 residues are converted to CGA-279202 equivalents with this factor (wt./wt. conversion factor = 408/394).
*Untreated controls had 0.72 ppm trifloxystrobin.
**Untreated controls had 1.0 ppm trifloxystrobin.
***Untreated controls had 0.04 ppm CGA-321113.

Geographic representation of data for stone fruit is adequate for the purposes of this petition. As required under OPPTS 860.1500, a total of 21 field trials are required for a tolerance on the stone fruit crop group. A total of 21 field trials are required for a tolerance on the stone fruit crop group. A total of 27 field trials were conducted: Region 1 (1 trial), 2 (3 trials), 5 (1 trial), 6 (1 trial) and 10 (3 trials) for peaches; Region 5 (1 trial), 10 (5 trials), and 11 (1 trial) for plums; Region 5 (2 trials), 10 (2 trials) and 11 (2 trials) for sweet cherries, and Region 1 (1 trial), 5 (3 trials), and 9 (1 trial) for tart cherries.

Study summary

For peaches, following 4 x 0.125 lb ai /A/application (1x proposed rate), residues of trifloxystrobin were <0.02-1.9 ppm and residues of CGA-321113 were <0.02-0.08 ppm at a PHI of 1 day; combined residues were <0.04-1.96 ppm.

For plums, following 4 x 0.125 lb ai /A/application (1x proposed rate), residues of trifloxystrobin were <0.02-0.53 ppm and residues of CGA-321113 were <0.02 ppm at a PHI of 1 day; combined residues were <0.55 ppm.

For sweet cherries, following 4 x 0.125 lb ai /A/application (1x proposed rate), residues of trifloxystrobin were 0.25-0.84 ppm and residues of CGA-321113 were <0.02-0.06 ppm at a PHI of 1 day; combined residues were 0.28-0.90 ppm.

For tart cherries, following 4 x 0.125 lb ai /A/application (1x proposed rate), residues of trifloxystrobin were 0.29-0.66 ppm and residues of CGA-321113 were <0.02-0.07 ppm at a PHI of 1 day; combined residues were <0.32-0.73 ppm.

The residue data support the proposed stone fruit crop group tolerance of 2.0 ppm. The residue decline data for stone fruit showed that residues of trifloxystrobin generally decreased with time; residues of CGA-321113 were mostly <0.02 ppm at a 0 day PHI.

OPPTS GLN 860.1520: Processed Food/Feed

Citrus

Two orange processing studies were submitted in conjunction with the field trial studies described above (MRID 45080808). Oranges treated at 1.2x, 3.7x and 6.1x proposed use were processed into juice, oil, and dried pulp.

Valencia oranges from the Seminole County trial (OS-FR-404-98) were sent to Englar Food Laboratories (EFL), Moses Lake, WA for processing to fractions via methods similar to commercial methods. Olinda oranges grown in Tulare County, CA were shipped to National Food Laboratory (NFL), Dublin, CA for processing to fractions similar to commercial methods. Results of the citrus processing studies are summarized in Table 21. Apparent residues in processed fractions were <0.02 ppm each for trifloxystrobin and its acid metabolite.

Table 21. Residues of trifloxystrobin in/on citrus processed fractions from oranges treated with 50 WG.

Fraction	Application rate	CGA-279202 (ppm)	CGA-321113 (ppm)	Combined Residues (ppm)	Concentration Factors
Florida Trial					
Oranges	1.2x 3.7x 6.1x	0.04 0.10 0.35	<0.02 0.02 0.02	0.06 0.12 0.37	
Juice	1.2x 3.7x 6.1x	<0.02 <0.02 <0.02	<0.02 <0.02 <0.02	0.04 0.04 0.04	0.67x 0.33x 0.11x
Dried pulp	1.2x 3.7x 6.1x	0.20 0.54 0.99	0.03 0.07 0.08	0.23 0.61 1.07	3.8x 5.1x 2.9x
Oil	1.2x 3.7x 6.1x	5.6 18.5 66.4	0.68 1.2 1.6	6.28 19.7 68.0	105x 164x 184x
California Trial					
Oranges	1.2x 6.1x	0.06 0.50	<0.02 <0.02	0.08 0.52	
Juice	1.2x 6.1x	<0.02 <0.02	<0.02 <0.02	0.04 0.04	0.5x 0.08x
Dried pulp	1.2x 6.1x	0.15 0.60	<0.02 0.04	0.17 0.64	2.1x 1.2x
Oil	1.2x 6.1x	5.5 30.1	0.57 1.47	6.07 31.6	76x 61x

The submitted citrus processing data are adequate. Residues did not concentrate in juice and concentrated in oil (average 118x) and dried pulp (average 3x). Based on the HAFT of 0.25 ppm

in oranges and average concentration factors, residues in oil (29.5 ppm) and in dried pulp (0.75 ppm) are not expected to exceed 30 ppm in citrus oil and 0.8 ppm in dried pulp. The petitioner needs to raise the proposed tolerance of 7.0 ppm to 30 ppm in citrus oil and propose a tolerance of 0.8 ppm in dried pulp. A revised Section F reflecting these tolerances is required.

Field corn

A processing study was conducted on field corn grown at two locations: Champaign County, IL and Hamilton County, IA, both in EPA Crop Region 5. At both locations multiple plots of different trifloxystrobin treatment levels were grown to prepare samples for processing in the chance that higher levels would show phytotoxicity. Final treatment levels sent for processing were controls, 1x consisting of 4 treatments of 0.11 lb ai/A (50 g ai/A) for a total of 0.44 lb ai/A/season (200 g ai/A/season) or a 5x consisting of four treatments of 0.55 lb ai/A (250 g ai/A) for a total of 2.2 lb ai/A/season (1.0 kg ai/A/season). Mature grain samples were frozen and shipped to the Texas A& M University, Food Protein Center, Bryan, TX for processing into commercial fractions. Processed fractions were then shipped to Novartis Crop Protection, Inc., Greensboro, NC and then onto EPL Bio-Analytical Services, Inc., 395 N. Memorial Parkway, Harristown, IL for analysis.

Mature corn grain was processed according to simulated commercial procedures into meal, grits, flour, corn starch and oil. The petitioner submitted adequate descriptions of the processing procedures and material balance information. In addition, corn grain was also processed according to simulated industrial procedures into aspirated grain fractions.

Analysis of the samples was by AG-659A. The results of the corn processing studies are presented in Table 22.

Table 22. Residues of trifloxystrobin and its acid metabolite CGA-321113 in the processed commodities of corn harvested 30 days following four applications, at 7-10 day intervals, of the CGA-279202/propiconazole 250 EC formulation.

Substrate	Residues, ppm			Concentration Factor for Trifloxystrobin
	Trifloxystrobin	CGA-32113	Total	
Champaign Co., IL - 0.44 lb ai/A/season (1x)				
Whole kernels	<0.02	<0.02	<0.04	
Aspirated grain fractions	0.055	<0.02	<0.057	
Corn meal	<0.02	<0.02	<0.04	
Large grits	<0.02	<0.02	<0.04	
Medium grits	<0.02	<0.02	<0.04	
Small grits	<0.02	<0.02	<0.04	
Corn flour	<0.02	<0.02	<0.04	
Corn starch	<0.02	<0.02	<0.04	

Substrate	Residues, ppm			Concentration Factor for Trifloxystrobin
	Trifloxystrobin	CGA-32113	Total	
Dry milled oil	<0.02	<0.02	<0.04	
Wet milled oil	<0.02	<0.02	<0.04	
Champaign Co., IL - 2.2 lb ai/A/season (5x)				
Whole kernels	<0.02	<0.02	<0.04	
Aspirated grain fractions	0.31	<0.02	<0.33	
Corn meal	<0.02	<0.02	<0.04	
Large grits	<0.02	<0.02	<0.04	
Medium grits	<0.02	<0.02	<0.04	
Small grits	<0.02	<0.02	<0.04	
Corn flour	<0.02	<0.02	<0.04	
Corn starch	<0.02	<0.02	<0.04	
Dry milled oil	<0.02	<0.02	<0.04	
Wet milled oil	0.02	<0.02	<0.04	
Hamilton Co., IA - 0.44 lb ai/A/season (1x)				
Whole kernels	<0.02	<0.02	<0.04	
Aspirated grain fractions	0.026, 0.038	<0.02	0.046, 0.058	
Corn meal	<0.02	<0.02	<0.04	
Large grits	<0.02	<0.02	<0.04	
Medium grits	<0.02	<0.02	<0.04	
Small grits	<0.02	<0.02	<0.04	
Corn flour	<0.02	<0.02	<0.04	
Corn starch	<0.02	<0.02	<0.04	
Dry milled oil	<0.02	<0.02	<0.04	
Wet milled oil	<0.02	<0.02	<0.04	
Hamilton Co., IA - 2.2 lb ai/A/season (5x)				
Whole kernels	0.023	<0.02	<0.043	
Aspirated grain fractions	0.83, 1.02	0.093	0.92, 1.11	36x, 44x
Corn meal	<0.02	<0.02	<0.04	
Large grits	<0.02	<0.02	<0.04	
Medium grits	<0.02	<0.02	<0.04	
Small grits	<0.02	<0.02	<0.04	
Corn flour	<0.02	<0.02	<0.04	
Corn starch	<0.02	<0.02	<0.04	
Dry milled oil	<0.02	<0.02	<0.04	
Wet milled oil	0.055	<0.02	<0.075	2.4x

Study summary

The submitted corn processing data are adequate for the purposes of this petition. It is not possible to derive meaningful concentration or reduction factors when levels of either trifloxystrobin or its acid metabolite or both in the corn grain before processing are <LOQ. Treated corn grain from the Hamilton, IA processing study (5x) was the only sample that contained finite level of trifloxystrobin and <LOQ level of the acid metabolite while all the other grain samples contained <LOQ trifloxystrobin and its acid metabolite. For trifloxystrobin no concentration was observed in meal, grits, flour, starch and dry milled oil, while combined residues were <0.075 ppm in wet milled oil and 0.92-1.1 ppm in aspirated grain fractions from the 5x study.

Based on the 5x study data, residues are not expected to exceed 0.1 ppm in corn oil and 1.2 ppm in aspirated grain fractions. The petitioner needs to propose a tolerance of 0.1 ppm for residues in/on corn oil; however, since there already exists a time-limited tolerance of 5 ppm in aspirated grain fractions from the use on wheat, the tolerance for aspirated grain fractions should remain at 5 ppm.

The petitioner must submit a revised Section F deleting "Corn, field, aspirated grain fractions." The Agency does not set tolerances for the aspirated grain fractions of individual crops.

Rice

Two rice processing studies were submitted in conjunction with the field trial studies described above (MRID 45080811) for the 1x and 5x trifloxystrobin 50WG treatments harvested at a 35-day PHI in Jackson, AR and St. Landry Parish, LA. Large composite grain samples, obtained for processing, were sent directly to the Engineering Biosciences Research Center at the Texas Engineering Experiment Station in Bryan, Texas. After processing, composite sample fractions and processed commodities (polished rice, hulls, and bran) were shipped frozen to Novartis Crop Protection, Greensboro, NC for analysis. Results of the rice processing study are shown in Table 23.

Table 23. Residues of trifloxystrobin in/on rice processed fractions from rice treated with 50 WG.					
Fraction	**Application rate (g ai/A)**	**CGA-279202 (ppm)**	**CGA-321113 (ppm)**	**Combined Residues (ppm)**	**Concentration Factors**
Composite Grain	2 x 70 or 1x	0.055; 0.034	0.038; 0.025	0.093; 0.059	-
	2 x 350 or 5x	0.50; 0.29	0.14; 0.11	0.64; 0.40	-
Polished Rice	2 x 70 or 1x	0.003; 0.006	0.013; 0.012	0.016; 0.018	0.17x; 0.31x
	2 x 350 or 5x	0.014; 0.010	0.047; 0.039	0.061; 0.049	0.10x; 0.12x
Rice Hulls	2 x 70 or 1x	0.14; 0.13	0.036; 0.032	0.18; 0.16	1.9x; 2.7x
	2 x 350 or 5x	1.6; 0.97	0.19; 0.18	1.8; 1.1	2.8x; 2.8x
Rice Bran	2 x 70 or 1x	0.066; 0.049	0.036; 0.037	0.10; 0.086	1.1x; 1.5x
	2 x 350 or 5x	0.38; 0.30	0.11; 0.14	0.49; 0.44	0.77x; 1.1x

The submitted rice processing study is adequate for the purposes of this petition. Combined residues did not concentrate in polished rice and concentrated slightly (average concentration of 1.1x) in rice bran. The mean concentration factor for rice hulls is 2.55x. Based on the highest average field trial (HAFT, 3.0 ppm) in rice grain and a concentration factor of 2.55 (7.65 ppm), residues in rice hulls are not expected to exceed a tolerance of 8 ppm. The petitioner needs to propose a tolerance of 8 ppm for residues in/on rice hulls. A revised Section F reflecting this tolerance is required.

Stone fruits

Two plum processing studies were conducted in conjunction with the field trials described above (MRID 45276401). Plums treated at 1x and 5x proposed use were processed into prunes. Results are summarized in Table 24.

Table 24. Residues of trifloxystrobin in dried plums from fresh plums treated with 50WG.					
Fraction	**Application rate**	**CGA-279202 (ppm)**	**CGA-321113 (ppm)**	**Combined residues (ppm)**	**Concentration Factor**
Fresno County, CA					
Fresh fruit (plums)	1x 5x	0.15 1.1	<0.02 0.05	<0.17 1.15	–
Dried fruit (prunes)	1x 5x	0.23 1.4	0.03 0.07	0.26 1.47	1.5 1.3
Butte County, CA					
Fresh fruit (plums)	1x 5x	0.07 0.31	<0.02 <0.02	<0.09 <0.33	–
Dried fruit (prunes)	1x 5x	0.10 0.48	<0.02 <0.02	<0.12 <0.50	1.3 1.5

The submitted processing data are adequate for the purposes of this petition. Residues concentrated (1.4x) in dried plums. Based on the HAFT (0.55 ppm) in fresh plums and the concentration factor, residues in dried plums (0.77 ppm) are not expected to exceed the proposed crop group tolerance of 2.0 ppm. A tolerance in dried plums is not needed.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

Ruminants

Feedstuffs potentially utilized in beef and dairy cattle diets associated with the present petition include rice grain, straw, hulls, and bran; barley grain and hay; corn (field) grain, forage, stover, aspirated grain fractions, and milled byproducts; popcorn grain and stover; and citrus dried pulp. The maximum theoretical dietary burden (MTDB) using commodities in this and previous petitions is shown below in Table 25.

Table 25. Calculation of the maximum theoretical dietary burden of trifloxystrobin to beef and dairy cattle for commodities associated with this and previous petitions.						
Commodity	**Dry matter (%)**	**Proposed/ Established tolerance (ppm)**	**Beef cattle**		**Dairy cattle**	
			% in diet	**Burden (ppm)**	**% in diet**	**Burden (ppm)**
Field corn, stover	83	7.0	25	2.108	15	1.265
Peanut hay	85	4.0	–	–	35	1.647
Sugar beet tops	23	4.0	20	3.478	10	1.739
Apple pomace, wet	40	5.0	40	5.000	20	2.500
Aspirated grain fractions	85	5.0	15	0.882	20	1.176
Total			100	**11.5**	100	**8.33**

In a previously reviewed cattle feeding study, groups of three cows were dosed with trifloxystrobin at levels equivalent to 2, 6, and 20 ppm for 28-30 days and tissues were analyzed for trifloxystrobin and CGA-321113 (PP#8F04955, D254208, F. Ives, 7/22/99). These dosing levels represented 0.41x, 1.2x, and 4.1x, respectively, the MTDB for dairy cattle (4.86 ppm) and represented 0.32x, 0.97x, and 3.2x, respectively, the MTDB for beef cattle (6.19 ppm) based on feed items of wet apple pomace (5.0 ppm; 40%), peanut hay (4.0 ppm; 25%) and peanut meal (0.05 ppm; 15%). Residues of trifloxystrobin were below the analytical method's LOQs in milk, muscle (round and tenderloin), kidney, and liver at the highest feeding level of 20 ppm. At this same feeding level, residues of trifloxystrobin were detected in omental fat (<0.02–0.05 ppm) and perirenal fat (<0.02–0.06 ppm). Residues of the acid metabolite, CGA-321113, were detected in kidney (<0.02–0.02 ppm) and liver (<0.02–0.09 ppm) at the highest feeding level, but were below the method LOQs in milk, muscle (round and tenderloin), and fat (omental and perirenal). HED recommended tolerances of 0.02 ppm for the combined residues in milk (sum of LOQs of the two analytes) and 0.05 ppm for the combined residues of trifloxystrobin and CGA-321113 in meat and meat byproducts of cattle, including fat. Taking into consideration the significant contribution of metabolite L7a (taurine or 2-aminoethanesulfonic acid conjugate of trifloxystrobin) in the liver, the MARC also recommended that a 0.1 ppm trifloxystrobin equivalent level (0.05 ppm liver tolerance and 0.05 ppm L7a) be used for risk assessment purposes for the liver, based on the livestock metabolism data that a 100 ppm administered dose yielded 0.98 ppm L7a metabolite in the liver.

With the new MTDBs of 11.5 ppm for beef cattle and 8.33 ppm for dairy cattle, still below the 20 ppm dose level (1.7x beef and 2.4x dairy) in the feeding study, it is expected that the established meat and milk tolerances are still adequate to cover the potential transfer of secondary residues resulting from the newly proposed uses. However, for dietary assessment in liver, a value of 0.11 ppm ($11.5 \div 100 \times 0.98$) should be added for the L7a metabolite on top of the tolerance level.

Poultry

Feedstuffs potentially utilized in poultry diets associated with the present petition include rice grain, hulls, and bran; barley grain; field corn grain and milled byproducts; and pop corn grain. The MTDB is shown below in Table 26.

Table 26. Calculation of the maximum theoretical dietary burden of trifloxystrobin to poultry for commodities associated with this petition.

Feed commodity	Proposed tolerance (ppm)	% of Diet	Burden (ppm)
Rice grain	3.5	60	2.10
Rice bran	3.5	25	0.875
Rice hulls	8.0	15	1.20
Total		100	4.18

In a previously reviewed poultry feeding study, groups of 15 hens were administered trifloxystrobin at dietary levels of 0, 1.5, 4.5, and 15 ppm for 28 days (PP#9F5070, D254213, L. Cheng 4/6/00), corresponding to 0, 0.36x, 1.1x, and 3.6x MTDB. Trifloxystrobin and CGA-321113 were both below the LOQ at all times tested for eggs and at the end of the study in chicken skin + attached fat, peritoneal fat, breast + thigh, and liver. Data support the proposed tolerances of 0.05 ppm in eggs, meat, fat, and liver. However, RAB3 recommends that tolerances for residues of trifloxystrobin and its acid metabolite be established at 0.04 ppm (sum of LOQs) in eggs, fat, meat and meat byproducts of poultry. A revised Section F reflecting the specified tolerances is needed.

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

Confined rotational crop studies (PP#8F04955, DP Barcodes: D254208, F. Ives, 7/22/99) and field accumulation studies (PP#9F5070, DP barcodes D254213, L. Cheng, 4/6/00) were submitted previously. Data support a 30-day plantback interval (PBI) for crops not listed on the Flint™ label, and a 30-day PBI for celery, cereals, sweet corn, pineapple and sugarcane, and 105-day PBI for all other crops for the Stratego™ label, provided that rotational crop restrictions of the Stratego™ label are compatible with those of the propiconazole labels.

International Residue

No Codex, Canadian, or Mexican maximum residue levels (MRLs) are established for trifloxystrobin. Harmonization is thus not an issue.

Attachment 1: International Residue Limit Status Sheet
Attachment 2: Structure of trifloxystrobin, its isomers, and its metabolites

Attachment 1.

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name:[Benzeneacetic acid, (E,E)-alpha-(methoxyimino)-2-[[[[1-3-(trifluoromethyl)phenyl] ethylidene]amino]oxy]methyl]-, methyl ester]	Common Name: Trifloxy-strobin	x Proposed tolerance □ Reevaluated tolerance □ Other	Date: November 20, 2001

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: 0F06121 DP Barcode: D267787, D272054 Other Identifier: Chemical 129112
Residue definition (step 8/CXL):N/A	Reviewer/Branch: Leung Cheng/RAB3
	Residue definition: Combined residues of the parent compound and its acid metabolite CGA-321113, [E,E)-Methoxyimino-[2-[1-[3-(trifluoromethyl)phenyl]-ethylideneaminooxymethyl]-phenyl]acetic acid]

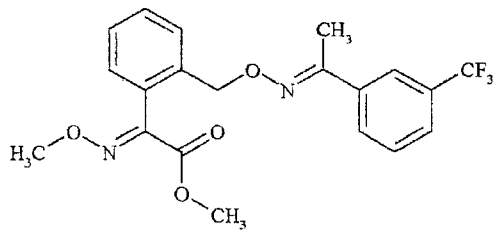
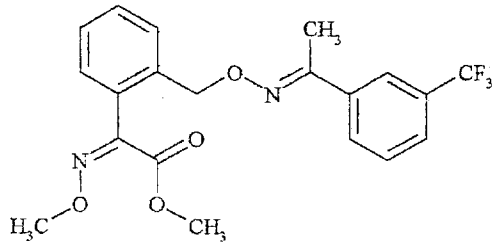
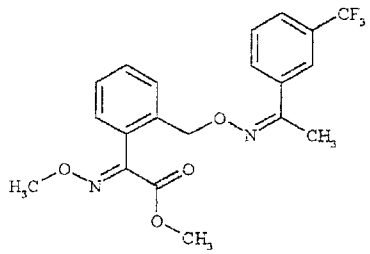
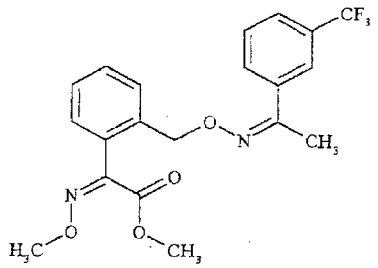
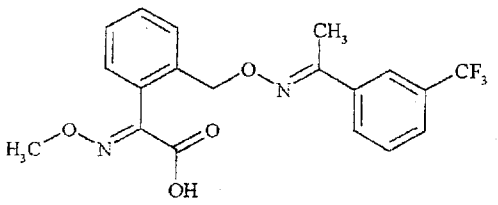
Crop (s)	MRL (mg/kg)	Crop(s)	(ppm)
		Citrus, dry pulp	0.8
		Citrus, oil	30
		Corn, field, grain*	0.05
		Corn, field, forage*	0.2
		Corn, field, stover*	7
		Corn, oil*	0.1
		Corn, pop, grain*	0.05
		Corn, pop, stover*	7
		Eggs*	0.04
		Fruit, citrus, group	0.3
		Fruit, stone, group	2
		Nut, tree, group	0.04
		Pistachio	0.04
		Poultry, fat*	0.04
		Poultry, meat*	0.04
		Poultry, meat byproducts*	0.04
		Rice, grain*	3.5
		Rice, hulls*	8
		Rice, straw*	7.5
		* Time-limited tolerances	

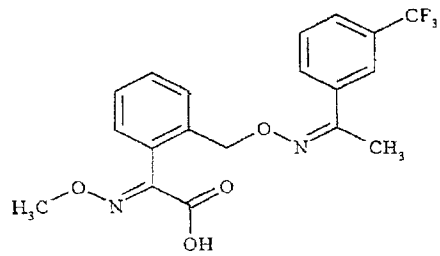
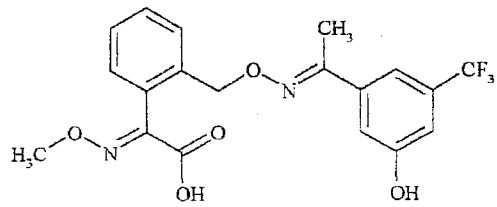
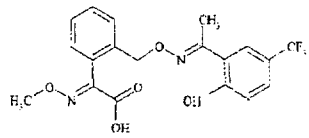
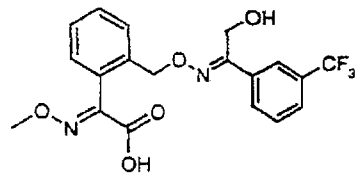
Limits for Canada	Limits for Mexico
X No Limits □ No Limits for the crops requested	X No Limits □ No Limits for the crops requested
Residue definition:	Residue definition:

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

Notes/Special Instructions: S. Funk, 05/30/01.	Rev. 1998

Attachment 2: Structure of trifloxystrobin, its isomers, and its metabolites.

Common Name Chemical Name	Structure
Trifloxystrobin (CGA-279202) **(metabolite fraction II_{25}; III_9)** (E,E)-Methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid methyl ester	
CGA-331409 **(metabolite fraction II_{25}; III_{12})** (E,Z)-Methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid methyl ester	
CGA-357261 **(metabolite fraction II_{25}; III_{11})** (E,Z)-Methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid methyl ester	
CGA-357262 **(metabolite fraction II_{25}; III_{10})** (Z,Z)-Methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid methyl ester	
CGA-321113 **(metabolite fraction II_{24})** (E,E)-Methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid	

Common Name Chemical Name	Structure
CGA-373466 **(metabolite fraction II_{24b})** (Z,E)-Methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid	
NOA-414412 **(metabolite fraction II_{22})** {2-[1-(3-hydroxy-5-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-methoxyimino-acetic acid *(Including sugar conjugate II_{10})*	
NOA-443152 **(metabolite fraction II_{23a})** {2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-methoxyimino-acetic acid *(Including sugar conjugate II_{11})*	
Metabolite fraction II_{21a} {2-[1-(2-hydroxy-5-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-methoxyimino-acetic acid	
Metabolite fraction II_{19a} {2-[1-(2,3-dihydroxy-5-methyl-phenyl)-2-hydroxy-ethylideneaminooxymethyl]-phenyl}-methoxyimino-acetic acid