

US Environmental Protection Agency Office of Pesticide Programs

Exclusive Use Petition Extension Request for Azoxystrobin

September 1, 2006

Syngenta Crop Protection, Inc. Tel 33 P.O. Box 18300 Greensboro, NC 27419-8300

www.syngenta.com



FEDERAL EXPRESS

September 1, 2006

Office of Pesticide Programs (7504P) U. S. Environmental Protection Agency One Potomac Yard 2777 South Crystal Drive - Room S-4900 Arlington, VA 22202-4501

Attn: Ms. Cynthia Giles-Parker, Chief Fungicides Branch

Subject: Exclusive Use Extension Request Azoxystrobin Heritage[®] Fungicide, EPA Reg. No. 100-1093

Dear Ms. Giles-Parker:

Syngenta Crop Protection, Inc., submits this application under the authority of FIFRA section 3(c)(1)(F)(ii) and requests EPA grant Syngenta Crop Protection, Inc., a 3-year extension of exclusive use for the azoxystrobin data specified within the application. The current azoxystrobin exclusive use period expires February 7, 2007. When EPA grants the requested extension, the new exclusive use period will extend through February 7, 2010.

FIFRA section 3(c)(1)(F)(ii) provides for up to a 3-year extension of the exclusive use period for an active ingredient if certain *qualifying criteria* are met and a sufficient number of registrations for minor uses are obtained within certain timeframes.

For minor uses to be eligible they must first be registered after August 3, 1996. Azoxystrobin was first registered on February 7, 1997, as end-use product, Heritage Fungicide, EPA Reg. No. 100-1093 (formerly 10182-408). Thus, it satisfies the criteria for being first registered after August 3, 1996.

Also, the uses must be approved within a 7-year period following the initial registration and must be marketed for the minor use. Heritage Fungicide has subsequently been registered for and been marketed for use on many minor crops/uses. Syngenta provides specific justification within this application for 13 minor uses that were approved during the 7-year period following initial registration and meet the required criteria. FIFRA section 3(c)(1)(F)(ii) stipulates that a 1-year extension of the exclusive use period will be granted for each 3 minor uses approved up to a total of 3 additional years for all minor uses approved. Thus, azoxystrobin fully meets and even exceeds the



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statutory minimum number of required minor use registrations and, therefore, qualifies for a 3-year exclusive use extension.

Additionally, the statute requires applicants to provide information that allows the Administrator, in consultation with the Secretary of Agriculture to determine that the active ingredient for which the extension is being pursued satisfies at least one of four "qualifying criteria." Syngenta provides evidence within the attached application to document azoxystrobin meets the required criteria for at least 16 minor uses and to support extending the exclusive use period for azoxystrobin data for three years. Azoxystrobin is registered on over 200 minor crops and the 16 supporting minor uses were selected as supporting examples for the Agencys' consideration. Please note that Syngenta has provided a list of the azoxystrobin data eligible for exclusive use extension within the application. Once approval is granted, we request the Agency amend it public records to specifically identify the new exclusive use expiration date of February 7, 2010, for these data.

Syngenta requests that the Agency proceed with the review and evaluation of our application and the granting of the requested extension. Please feel free contact me at (336) 632-2380, if I can be of assistance or answer any questions.

Sincerely Michele A. Schulz

NAFTA Fungicide Team Leader

Attachment Exclusive Use Extension Application

cc: Mr. Tony Kish, EPA Mr. Jim Jones, EPA Dr. Janis McFarland, Syngenta



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LIST OF APPENDICES

Appendix I	Letters from EPA Granting Azoxystrobin Reduced Risk Status
Appendix II	Data Matrix – Heritage Fungicide (Public, Private, and Full Title)
Appendix III	Notice of Pesticide Registration and EPA Stamped Approved Label for Heritage Fungicide
Appendix IV	Notice of Pesticide Registration and EPA Stamped Approved Label for Abound Fungicide
Appendix V	Federal Register – 40 CFR Part 180 References Azoxystrobin: Pesticide Tolerance
Appendix VI	Abound Flowable and Quadris Flowable Final Printed Labeling for Products as Sold Currently

APPLICATION FOR EXTENSION OF EXCLUSIVE USE PERIOD FOR AZOXYSTROBIN EPA REG Nos. 100-1093 AND 100-1098 PREVIOUSLY 10182-408 AND 10182-415

Supporting minor use crops: globe artichoke, asparagus, basil, garden beet leaves, broccoli, cabbage, dillweed, juneberry, lentil, lychee, mango, mint, mustard greens, okra, parsley, and watercress.

I. INTRODUCTION

Syngenta Crop Protection, Inc. submits this application under the authority of FIFRA § 3(c)(1)(F)(ii) and requests EPA grant an extension of the exclusive use period for azoxystrobin data for a period of 3 years. Under FIFRA § 3 (c)(1)(F)(i), a period of 10 years of exclusive use for azoxystrobin data is presently granted Syngenta Crop Protection, Inc., the original submitter of data supporting the initial registration of this active ingredient. Since azoxystrobin was first registered by EPA on February 7, 1997, the 10-year period of exclusive use for azoxystrobin data expires effective February 7, 2007. With this extension, the new exclusive use period will extend through February 7, 2010.

This application provides documentation to show that azoxystrobin satisfies the provisions of FIFRA § 3 (c)(1)(F)(ii) and thereby qualifies for an extension of the exclusive use period. FIFRA permits an extension of the exclusive use period to be granted for data submitted in support of an active ingredient if minor uses are first approved after August 3, 1996 and within a 7-year period following initial registration.

Based upon favorable health, environmental and ecological characteristics the EPA classified azoxystrobin as a Reduced Risk pesticide (Appendix I – Reduced Risk Letters) and accelerated the data evaluation and product approval of this new fungicide active ingredient. Azoxystrobin provides excellent activity against a wide spectrum of diseases and is effective on many diseases that have developed resistance to other classes of fungicides. Thus, it is used in resistance management programs as an alternating product with a different mode of action, compared to those classes of chemistry. The importance of azoxystrobin is also evidenced by the unusually large number and variety of minor uses that have been approved within a short period following initial registration. Azoxystrobin was first registered by EPA on February 7, 1997 and cooperative organizations such as IR-4 have taken an active role in assisting in the development of this important pesticide for a wide number of minor uses.

FIFRA stipulates that at least 3 minor uses must be approved to qualify for a 1 year exclusive use extension of the data up to a maximum of 3 additional years of exclusivity. Syngenta provides supporting documentation in this application for sixteen approved minor uses that support this extension. Thus, azoxystrobin has met the statutory requirements and is a candidate for a three-year extension of exclusive use of data (Appendix II – Data Matrices).

This application provides documentation that will allow the Administrator, in consultation with the Secretary of Agriculture, to determine that the use of azoxystrobin on each claimed minor use satisfies at least one of four stated qualifying criteria.

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II. SUMMARY AND CONCLUSIONS OF APPLICATION

Azoxystrobin is registered on over 200 minor crops (Appendix VI). Sixteen minor crops were selected as examples to support the extension of the exclusive use period for azoxystrobin. These crops include globe artichoke, asparagus, basil, garden beet leaves, broccoli, cabbage, dill, juneberry, lentil, lychee, mango, mint, mustard greens, okra, parsley, and watercress. A discussion of how azoxystrobin satisfies the required criteria is presented in a separate discussion for each minor crop within the application. In summary, the following FIFRA § 3I(1)(F)(ii) qualifying criteria are satisfied for each minor crop claimed within this application:

- Each minor crop meets the statutory definition of being a minor use,
- All claimed minor uses were registered after August 3, 1996,
- All claimed minor uses were approved during the required 7-year window following initial registration of azoxystrobin,
- Syngenta has provided sufficient information to show that at least one of the four qualifying extension criteria has been satisfied. For each minor crop azoxystrobin has superior biological efficacy, significant rate advantages, resistance management partnership and/or IPM uses when compared with potential alternative products and this justifies a position that there are insufficient alternative registered pesticides available for use on
 - each minor crop.

III. STATUTORY FOUNDATION

FIFRA § 3I(1)(F)(ii) permits a one-year extension of the exclusive use period for each 3 minor uses approved after August 3, 1996 and within 7 years of the commencement period of the exclusive use period up to a total of 3 additional years for all minor uses registered by the Administrator.

The registrant or applicant must first demonstrate that each minor use it claims qualifies under the statutory definition of minor use at FIFRA section 2(II). The definition of minor use at FIFRA section 2(II) means the use of a pesticide on an animal, on a commercial agricultural crop or site, or the protection of public health where:

1. the total US acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

2. the EPA Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and

- there are insufficient efficacious alternative pesticides available for the use;
- the alternatives to the pesticide use pose greater risks to the environment or human health;
- the minor use pesticide plays or will play a significant part in managing pest resistance; or

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 2 of 31 the minor use pesticide plays or will play a significant part in an integrated pest management program.

The applicant must provide sufficient information that will allow the Administrator, in consultation with the Secretary of Agriculture, to determine that, in addition to it qualifying as a "minor use", at least one of following four qualifying exclusive use extension criteria is met:

- Qualifying Criteria 1 there are insufficient efficacious alternative registered pesticides available for the use (Biological Efficacy);
- Qualifying Criteria 2 the alternatives to the minor use pesticide use pose greater risks to the environment or human health (Risk);
- Qualifying Criteria 3 the minor use pesticide plays or will play a significant role in managing pest resistance (Pest Resistance); or
- Qualifying Criteria 4 the minor use pesticide plays or will play a significant part in an integrated pest management program (IPM Program).

IV. AZOXYSTROBIN QUALIFIES FOR EXCLUSIVE USE EXTENSION

Minor Uses Were Registered After August 3, 1996

Azoxystrobin received its first EPA registration on February 7, 1997 as an end use product named Heritage Fungicide, EPA Reg. No. 100-1093 (10182-408). (Appendix III – Notice of Product Registration and stamped label for Heritage Fungicide). All minor uses claimed within this application were approved following this initial registration date.

Minor Uses Approved Within Seven Years of First Azoxystrobin Registration

Syngenta markets azoxystrobin for use on many crops to control a wide spectrum of diseases. Following the initial registration of Heritage Fungicide, all minor uses claimed in this application have been approved by EPA at various dates during the required 7-year window and were issued under the Heritage registration. The deadline date that minor uses must be approved to be eligible is **February 7**, 2004 (7 year window date following first registration on February 7, 1997).

To demonstrate that approvals of all of the claimed minor uses were achieved within the required period, Abound Flowable Fungicide, approved by EPA on January 9, 2004 EPA Registration Number 100-1098 (10182-415). This label copy includes directions for use on all of the claimed minor uses referenced in this application. (Appendix IV – A Notice of registration and EPA stamped label).

Syngenta Markets Azoxystrobin for Use on the Claimed Minor Uses

Syngenta markets three branded products containing azoxystrobin that include directions for use on the minor uses claimed within this application. Since Abound Flowable and Quadris Flowable Fungicide products are the most commonly used brands in the agricultural market, discussions will be based on these brands. Heritage Fungicide is sold for use on minor crops in the residential, nursery and specialty markets and has the same excellent broad spectrum efficacy as Abound Flowable and Quadris

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 3 of 31 Flowable.

Product	Brand Name	Minor Use Crops on Label
Heritage Fungicide EPA Reg. No. 100-1093 (10182-408)	Heritage Fungicide	Artichoke, Asparagus, Basil, Garden Beet Leaves, Broccoli, Cabbage, Dill, Juneberry, Lentil, Lychee, Mango, Mint, Mustard Greens, Okra, Parsley and Watercress
Abound Flowable Fungicide EPA Reg. No. 100-1098 (10182-415)	Quadris Flowable Fungicide	Artichoke, Asparagus, Basil, Garden Beet Leaves, Broccoli, Cabbage, Dill, Lentil, Mint, Mustard Greens, Okra, Parsley and Watercress
	Abound Flowable Fungicide	Juneberry, Lychee, Mango,

Claimed Minor Uses Qualify Under FIFRA section 2(II) as a Minor Use

Each minor use supporting this application is an agronomic crop that meets the criteria for being a minor use on the basis that the total acreage for the crop in the United States is less than 300,000 acres as recognized by the Department of Agriculture.

To assure that a claimed crop is a minor use crop and therefore eligible to support an application for exclusive use extension, Syngenta surveyed two recognized public data resources that report crop production in the United States. Our survey of these data sources confirmed the total United States acreage for each crop and it would be classified a "Minor Use Crop" as described within the Food Quality Protection Act at Subtitle A-Minor Use Crop Protection Section 210 (a) (II) (1). The two reference sources surveyed are listed below with their website addresses:

1. National Agricultural Statistics Association 2002 Census of Agriculture report http://www.nass.usda.gov/Census_of_Agriculture/index.asp

2. National Site for the USDA Regional IPM Centers Information System http://www.ipmcenters.org/

The chart below lists the minor uses supporting this application, the respective crop grouping, the MRID number assigned to the residue data supporting the minor use tolerance and reference to at least one Syngenta product that is marketed for use on the crop.

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Minor Use Crop Name on Label	Crop Group Number & Name	First EPA Registration Date	MRID Number For Supporting Minor Use Residue Data
Artichoke, globe	Not in a crop group	10/10/2000	45731301 - artichoke
Asparagus	Not in a crop group	1/9/2004	45544901 - asparagus
Basil	19 – Herbs and Spices	1/9/2004	45736301 - basil
Garden beet leaves	2 – Leaves of Root and Tuber Vegetables	10/10/2000	45640302 - garden beet
Broccoli	5-A Brassica Head and Stem Group	1/9/2004	45730102 – broccoli
Cabbage	5-A Brassica Head and Stem Group	1/9/2004	45730101 – cabbage
Dillweed	19-A Herbs and Spices	1/9/2004	46006901 – dill
Juneberries	Bushberry represents	11/9/2001	45253901 - blueberries
Lentil	Legume Vegetables	4/9/2003	45221607 – dry peas 45221608 – dry beans
Lychee	Tropical fruit	11/9/2001	45205607 - lychee
Mango	Tropical fruit	11/9/2001	45205606 - mango
Mint for fresh or processing into oil (peppermint and spearmint)	Not in a crop group	11/9/2001	45205602 – mint (processed) 45205603 – mint (fresh),
Mustard Greens	5 – Brassica (cole) Leafy Vegetables	11/9/2001	45332501- greens, mustard
Okra	Fruiting Veg supported by tomato/pepper	11/9/2001	45332502 – peppers 44058730 – tomatoes 44058731 – tomatoes 44058735 – tomato (processing)
Parsley	4-A Leafy Vegetables (except Brassica Vegetables)	10/10/2000	46345001 - parsley
Watercress	Not in a crop group	11/9/2001	45205604 - watercress

V. PROCEDURE USED TO IDENTIFY AND EVALUATE ALTERNATIVE ACTIVE INGREDIENTS

The active ingredients products approved for use on the minor crops claimed in this application were identified by searching published tolerances from the 40 CFR §180 and the EPA Pesticide Product Label System (PPLS).

EPA can independently confirm the accuracy of these comparisons referencing the eCFR and PPLS:

http://www.access.gpo.gov/nara/cfr/waisidx_05/40cfr180_05.html http://www.epa.gov/pesticides/pestlabels/.

Utilizing these data and commercial experience Syngenta then screened the active ingredients approved for use on the minor use crops and selected those active ingredients considered to have performance characteristics that were competitive to azoxystrobin.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 5 of 31 There are many fungicides registered for control of plant diseases. In today's competitive market, azoxystrobin provides broad spectrum control of many diseases, and is considered an effective competitor to a large number of active ingredients that are labeled on the same crops.

A product that is labeled to control at least one or more disease organisms controlled by azoxystrobin was considered to have potential to provide similar efficacy and therefore eligible for further evaluation. A product in this group was considered to be a *partial alternative*. The twelve active ingredients in this group of products include chlorothalonil, copper hydroxide, cyprodinil, fludioxonil, mancozeb, maneb, mefenoxam, myclobutanil, propiconazole, pyraclostrobin, trifloxystrobin, triphenyltin. The products containing these active ingredients were then examined to determine registered crops to determine if these products were registered for use on the same minor crops considered for azoxystrobin.

For products that were registered, a listing was made of the labeled diseases per crop and compared to those on the azoxystrobin label. Unless the alternative active ingredient was labeled for all diseases on the azoxystrobin label, it was classified as a *partial alternative*. In some cases, an active ingredient was registered on a crop but did not list any disease on the azoxystrobin label.

Products were classified as *not an alternative* if they failed to be included in the twelve products shown above or if labeling for the products did not claim control of any of the diseases controlled by azoxystrobin. Products classified as *not an alternative* were excluded from further consideration and are not specifically addressed in the narrative discussion in this application.

For each minor use crop Syngenta has developed a narrative discussion of the efficacy offered by the *partial alternatives* and azoxystrobin. This includes a comparison of the list of diseases claimed for azoxystrobin with those for each *partial alternative* to determine whether azoxystrobin has benefits over the alternative products. A table that compares biological efficacy attributes of azoxystrobin and the *partial alternative* active ingredients is provided within the supporting discussion for each minor use crop.

VI. BIOLOGICAL PROFILE FOR AZOXYSTROBIN

Azoxystrobin (CAS No. 131860-33-8) is a member of the strobilurin family of fungicides and is a beta-methoxyacrylate, having broad spectrum activity in all major classes of plant pathogenic fungi on a very broad range of crops. Azoxystrobin has a significant number of characteristics that are found in both the preventative and curative groups of fungicides. There is systemic (xylem only) and translaminar movement within the leaves to provide even distribution within foliage, and it does not accumulate at leaf tips. Foliar applications provide both curative action against some pathogens and preventative action against others and provide antisporulant activity on a wide range of diseases. It is the sum of these properties that make azoxystrobin unique among current fungicides and is best used in early stages of disease development against all pathogens because of its ability to inhibit spore germination. In addition, azoxystrobin provides control of many soilborne diseases when applied early in the growing season. Specific applications for soilborne diseases include seed treatment, in-furrow applications and

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banded applications applied over the row, either shortly after plant emergence or during herbicide applications or cultivation. These applications will provide control of pre- or post-emergence damping off and diseases that infect plants at the soil-plant interface. Azoxystrobin is based on the chemical structure of the naturally - occurring fungicides found in several mushroom species including Oudemansiella mucida and Strobilurus tenacellus. It has a single site mode of action, which is the disruption of electron transport in the cytochrome bc1 complex. The major classes of fungi, including Oomycetes, Ascomycetes, Deuteromycetes, and Basidiomycetes are all susceptible to azoxystrobin - wide spectrum of activity, compared to the other chemical classes of fungicides. A partial listing of fungal foliar and stem diseases on the azoxystrobin labels includes: Albugo, Alternaria, Ascochyta, Aureobasidium, Botryosphaeria, Botrytis, Bremia, Cercospora, Cercosporidium, Cladosporium, Cochilobolus, Collectotrichum, Corynespora, Diaporthe, Didymella, Diplodia, Elsinoe, Entyloma, Erysiphe, Gaeumannomyces, Glomerella, Guignardia, Leptosphaeria, Leveillula, Lophodermium, Microdochium, Monilinia, Mycosphaerella, Myrothecium, Neovossia, Oidiopsis, Passalora, Peronospora, Phaeocrytopus, Phakopsora, Phoma, Phomopsis, Phytophthora, Plasmopara, Podosphaera, Puccinia, Pyrenophora, Pyricularia, Pythium, Ramularia, Rhizoctonia, Sclerotinia, Sclerotium, Seimatosporium, Septoria, Setosphaeria, Sphaerotheca, Stagonospora, Stemphyllium, Tranzschelia, Uncinula, Uromyces, Vaccinium, and Wilsonomyces.

In addition, azoxystrobin is effective on several soil borne diseases including: *Colletotrichum, Helminthosporium, Pythium, Rhizoctonia, and Sclerotium.*

Azoxystrobin is effective on many diseases that have developed resistance to other classes of fungicides, and is thus used in resistance management programs as an alternating product with a different mode of action, compared to those classes of chemistry. Some fungi species have developed resistance to azoxystrobin, and for this reason, specific resistance management programs appear on the respective azoxystrobin labels. For example, the number of consecutive applications and total for annual applications are limited to reduce risk of resistance development. In conjunction with this limitation, there are recommendations to alternate azoxystrobin with fungicides that control the same spectrum but having a different mode of action.

In addition to azoxystrobin, there are many fungicides registered for the crops cited in this document and other crops. From an efficacy standpoint, only a few can be classified as realistic alternatives to azoxystrobin, meaning they have a similar spectrum of diseases controlled. This group of potential alternatives includes: captan, chlorothalonil, copper hydroxide (including other copper products), cyprodinil, ferbam, fludioxonil, iprodione, mancozeb, maneb, mefenoxam, mitram, myclobutanil, PCNB, propiconazole, pyraclostrobin, trifloxystrobin, triphenyltin, and ziram. Other products usually have a narrower control spectrum or other characteristics that make them less attractive from a use, crop tolerance, risk, or efficacy standpoint. These will be mentioned for each minor use crop, but the main comparisons will be with the above products when they are registered on the minor use crops registered.

Resistance Management

Azoxystrobin is an excellent resistance management partner as seen on the label of Heritage Fungicide.

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VII. DISCUSSION OF MINOR USES AND BIOLOGICAL EFFICACY OF AZOXYSTROBIN

A discussion for each claimed minor use crop is presented below. This discussion identifies alternative fungicide active ingredients that are registered on the specific minor use crop and have been classified as a *partial alternative*. The biological efficacy attributes of these *partial alternatives* based on diseases listed on their label are compared with those of azoxystrobin and a conclusion on whether azoxystrobin is superior is presented.

GLOBE ARTICHOKE

Mefenoxam is registered for use on globe artichoke is classified as a *partial alternative* and is compared to azoxystrobin in this discussion.

Globe artichoke qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and this active ingredient classified as a *partial alternative* is presented below:

		Azoxystrobin	Mefenoxam
Foliar / Stem Disease	Scientific Name	Abound Flowable® 100-1098	Ridomil Gold® EC 100-801
Ramularia leaf spot	Ramularia cynarae	x	
Soilborne Diseases			
Root Rot	Pythium spp.		X
Root Rot	Phytophthora spp.		X
Total Diseases		1	2

Criteria 1 – Biological Efficacy Comparison

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies this criteria because there are no efficacious registered alternatives to azoxystrobin for use on globe artichoke to control Ramularia.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 8 of 31 Michele – suggest we delete mefenoxam because it does not qualify as "partial alternative" ie., is not labeled for control of at least one disease that Azoxy claims. Or, if we keep Mefenoxam then we should add pyraclostrobin back to the table and adjust wording below to describe the result.

Azoxystrobin is labeled for control of one disease organism that is not on labeling for products containing the *partial alternative* active ingredient. This foliar/stem disease is ramularia leaf pot (*Ramularia cynarae*) and it is not listed on labeling for the partial alternative active ingredient.

Since azoxystrobin is labeled for control of a disease on globe artichoke and the labels for the *partial alternative* active ingredients does not claim this disease the alternative active ingredients are classified as *unacceptable alternatives*. Azoxystrobin therefore fills an efficacy void of the other registered alternative products for use on globe artichoke.

ASPARAGUS

A total of four fungicide active ingredients are registered for use on asparagus including azoxystrobin, chlorothalonil, mancozeb and myclobutanil. Only one active ingredient is classified as a *partial alternative* and it is compared to azoxystrobin in this discussion. This active ingredient is chlorothalonil.

Asparagus qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and chlorothalonil classified as *partial alternative* is presented below:

		Azoxystrobin	Chlorothalonil
Foliar / Stem Disease	Scientific Name	Abound® 100-1098	Bravo Weather Stik® 50534-188
Purple Spot	Stemphyllium vesicarium (anamorph of Pleospora herbarum) Pleospora herbarum	X @ 0.1-0.25 lbs.ai/A not exceeding <u>1.5</u> lbs.ai/A/season	X @ 1.5-3 lbs.ai/A @ 14- 28 day intervals after harvest <u>not exceeding</u> <u>9.0</u> <u>lbs.ai/A/growing</u> <u>season</u>
Total Disease	S	1	1

Criteria 1 – Biological Efficacy Comparison

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

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Qualifying Criteria - Biological Efficacy, and Risk

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on asparagus and alternative that exits poses greater risks to human health and the environment.

The above table shows that azoxystrobin and chlorothalonil are labeled for the disease stemphyllium purple spot (*Stemphyllium vesicarium* describes the fungus when reproducing asexually) on asparagus. This active ingredient is classified *an unacceptable alternative* because azoxystrobin offers much lower use rates and is a reduced risk partner for chlorothalonil, which poses greater risks to human health and the environment.

BASIL

A total of three active ingredients are registered for use on basil including azoxystrobin, fludioxonil and cyprodinil. Fludioxonil and cyprodinil are not classified as partial alternatives because they do not control any one disease that azoxystrobin controls. Thus, there are no partial alternative products to azoxystrobin.

Azoxystrobin is registered for use on basil and is labeled to control three foliar and stem diseases listed below.

Basil qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria

Criteria 1 - Biological Efficacy Comparison

		Azoxystrobin	Fludioxonil/ cyprodinil
Foliar / Stem Disease	Scientific Name	Abound 100-1098	Switch 100-953
Corynespora blight	Corynespora cassiicola	X	
Dill blight	Cercosporidium punctum	x	-
Phoma blight	Passalora puncta	X	
Total No. Diseases		3	0

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

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Qualifying Criteria - Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on basil.

The table above shows that only azoxystrobin is labeled for control of three diseases including corynespora blight (*Corynespora cassiicola*), dill blight (*Cercosporidium punctum*) and phoma blight (*Passalora puncta*).

Since these diseases are not claimed on other product's labels azoxystrobin has a broader spectrum of biological efficacy than other products and is therefore superior to other registered products for use on basil.

GARDEN BEET LEAVES

A total of four fungicide active ingredients registered for use on garden beet leaves are classified as *partial alternatives* and are compared to azoxystrobin in this discussion. These four products are mefenoxam, pyraclostrobin, trifloxystrobin and copper hydroxide.

Garden beet leaves qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and these four active ingredients classified as *partial alternatives* is presented below:

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Criteria 1 - Biological Efficacy Comparison

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Foliar /		Azoxystrobin	Mefenoxam	Pyraclo strobin	Trifloxy strobin	ternatives Copper Hydroxide
Stem Disease	Species	Quadris 100-1098	Ridomil Gold EC 100-801	Cabrio® 7969-187	Flint® 264-777	Kocide 101 1812-288
Rust	Uromyces betae Uromyces spp.	x			х	
Rust	Puccinia helianthi, Puccinia spp.	х			x	
White rust	Albugo tragopogonis Albugo spp.	x		x		
Cercospora leaf spot	Cercospora betae Cercospora carotae Cercospora pastinaceae Cercospora spp.	x		x	x	x
Alternaria leaf spot	Alternaria alternata Alternaria dauci Alternaria spp.	x		x	x	
Powdery mildew	Erysiphe polygoni Erysiphe spp	x		x	x	
Powdery mildew	Leveillula taurica	x				
Soilborne D	iseases					
Rhizoctonia stem canker	Rhizoctonia solani	x				
Rhizoctonia crown rot	Rhizoctonia solani	x				
Circular spot	Sclerotium rolfsii	x				
Southern blight	Sclerotium rolfsii	x				
Pythium root rot	Pythium aphanidermatum	x				
Pythium	Pythium spp.		X			

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 12 of 31 X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria - Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on garden beet leaves.

Azoxystrobin is labeled for control of six disease organisms that are not on labeling for products containing the four partial alternative active ingredients. One of the organisms is a foliar/stem disease powdery mildew (*Leveillula taurica*). Five of the organisms are soilborne diseases and include rhizoctonia stem canker (*Rhizoctonia solani*), rhizoctonia crown rot (*Rhizoctonia solani*), circular spot (*Sclerotium rolfsii*), southern blight (*Sclerotium rolfsii*) and pythium root rot (*Pythium aphanidematum*).

Since azoxystrobin is labeled for control of diseases on garden beet leaves and labels for products containing alternative active ingredients do not list these diseases the alternative active ingredients are classified as *unacceptable alternatives*. Azoxystrobin has a broader spectrum of biological efficacy than other alternatives and is therefore superior to other registered alternative products for use on garden beet leaves.

Broccoli

A total of six fungicide active ingredients registered for use on broccoli are classified as *partial alternatives* and are compared to azoxystrobin in this discussion.

A comparison of the biological efficacy against certain diseases for azoxystrobin and these four active ingredients classified as *partial alternatives* is presented below:

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Criteria 1 - Biological Efficacy Comparison

Broccoli Diseas	es Controlled By	/ Azoxystrobin Com	Broccoli Diseases Controlled By Azoxystrobin Compared To Registered Partial Alternatives	artial Alternatives			
		Azoxystrobin	Chlorothalonil	Copper Hydroxide	Fludioxonil/ cvprodinil	Maneh	Mafanovom
Foliar / Stem Disease	Scientific Name	Quadris 100-1098	Bravo Weather Stik 50534-188	Kocide 101 1812-288	Switch	Maneb 75DF	Ridomil Gold EC
Alternaria Leaf Spot	Alternaria spp.	X @ 0.25 lbs.ai/A on 7-14 day schedule not exceeding 1.5 lbs.ai/A/season	X @1.125 lbs.ai/A on 7-10 day schedule not exceeding 12 lbs.ai/A/season		×	X @ 1.5 X @ 1.5 Ibs.ai/A on 7- 10 day schedule not to exceed 9.6 bs.ai/A/season	108-001
Black Leaf Spot	Alternaria spp.			X @ 0.38 lbs.ai/A on 7 dav schedule			
Downy Mildew	Peronospora parasítica	X @ 0.25 lbs.ai/A on 7-14 day schedule not exceeding 1.5 lbs.ai/A/season	X @1.125 lbs.ai/A on 7-10 day schedule not exceeding 12 lbs.ai/A/season	X @ 0.38 lbs.ai/A on 7 day schedule		X @ 1.5 lbs.ai/A on 7- 10 day schedule not to exceed 9.6 lbs.ai/A/season	X @ 0.125 lbs.ai/A not exceeding 2 applications ber crop
Total Diseases		2	2	2	-	~	

X - disease is listed on label for products containing the respective active ingredient.

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Qualifying Criteria - Biological Efficacy, Risk

Azoxystrobin satisfies these criteria because there are insufficient efficacious broad spectrum registered alternatives to azoxystrobin for use on broccoli. In addition, chlorothalonil and maneb pose greater risks to human health and the environment than azoxystrobin.

Although chlorothalonil and maneb are also efficacious products for control of alternaria azoxystrobin offers much lower use rates and is a reduced risk partner.

CABBAGE

A total of six *partial alternative* fungicide active ingredients registered for use on cabbage are compared to azoxystrobin in this discussion. These six products are chlorothalonil, copper hydroxide, cyprodinil, fludioxonil, maneb, and mefenoxam.

Cabbage qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and these six active ingredients is presented below:

Cabb	age Diseases	Controlled By	Azoxystrobin C	ompared To	Registere	d Partial alter	natives
		Azoxystrobin	Chlorothalonil	Copper Hydroxide	Maneb	Mefenoxam	Fludioxonil/ cyprodinil
Foliar / Stem Disease	Scientific Name	Quadris 100-1098	Bravo Weather Stik 50534-188	Kocide 101 1812-288	Maneb 75DF 4581- 371	Ridomil Gold EC 100-801	Switch 100-953
Alternaria Leaf Spot Black Leaf Spot	Alternaria spp.	X @ 0.25 lbs.ai/A on 7-14 day schedule	X @1.125 lbs.ai/A on 7- 10 day schedule	X @ 1.0 lbs.ai/A on 7-10 day schedule	X @ 1.5 lbs.ai/A on 7-10 day schedule		x
Downy Mildew	Peronospora parasitica	X @ 0.25 lbs.ai/A on 7-14 day schedule	X @1.125 lbs.ai/A on 7- 10 day schedule	X @ 1.0 lbs.ai/A on 7 day schedule X	X @ 1.5 lbs.ai/A on 7-10 day schedule	X @ 0.125 lbs.ai/A not exceeding 2 applications per crop	
Total Disea	ISES	2	2	2	2	1	

Criteria 1 – Biological Efficacy Comparison

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

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Qualifying Criteria - Biological Efficacy, Risk, Resistance Management

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on cabbage. In the case of chlorothalonil, maneb and copper hydroxide; azoxystrobin poses a lower risk to human health and the environment.

The six active ingredients chlorothalonil, copper hydroxide, maneb, mefenoxam, cyprodinil, and fludioxonil are registered for use on cabbage. Azoxystrobin provides control of foliar/stem diseases including alternaria leaf spot (*Alternaria spp.*) and provides a Reduced Risk alternative and resistance management tool on cabbage.

DILLWEED

A total of three active ingredients are registered for use on dill including azoxystrobin, copper hydroxide and mefenoxam. One fungicide active ingredient registered for use on dill is classified as a potential alternative and is compared to azoxystrobin in this discussion.

Dill qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and the one active ingredient classified as a *partial alternative* is presented below:

		Azoxystrobin	Copper Hydroxide
Foliar / Stem Disease	Scientific Name	Quadris 100-1098	Kocide 101 1812-288
Corynespora blight	Corynespora cassiicola	x	
Dill blight	Cercosporidium punctum	x	
Phoma blight	Passalora puncta	X	Х
Total No. Diseases		3	1

Criteria 1 – Biological Efficacy Comparison

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on dill.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 16 of 31 The active ingredient copper hydroxide is registered for use on dill. Azoxystrobin is labeled for control of corynespora blight (*Corynespora cassiicola*), and dill blight (*Cercosporidium punctum*). The labels for products containing copper hydroxide are not labeled for control of these diseases on dill.

The above table shows that azoxystrobin controls diseases on dill that are not controlled by the other active ingredients. Therefore, these active ingredients are considered unacceptable alternatives because each is not labeled for control of a disease organism for which azoxystrobin is labeled.

Since azoxystrobin is labeled for control of diseases that are not on the alternative's product label it has a broader spectrum of biological efficacy than other alternatives and is therefore superior to other registered alternative products for use on dill.

JUNEBERRY

Juneberry qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. The diseases controlled by azoxystrobin are presented below:

		Azoxystrobin	Cyprodinil/ Fludioxonil
Foliar / Stem Disease	Scientific Name	Abound 100-1098	Switch® 100-953
Botryosphaeria canker	Botryosphaeria spp.	x	
Powdery mildew	Sphaerotheca spp	X	
Septoria blight	Septoria spp.	X	
Mummyberry	Vaccinium spp.	X	X
Alternaria Fruit Rot	Alternaria spp.	X	X
Phomopsis stem canker	Phomopsis vaccinii	X	
Anthracnose fruit rot	Colletotrichum gloeosporoides	x	x
	Total Diseases	7	3

Criteria 1 - Biological Efficacy Comparison

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are shown in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on juneberry.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 17 of 31 There are no partial alternative fungicide active ingredients registered for use on juneberry. The above table shows that only azoxystrobin is labeled for control of four foliar diseases including Botryosphaeria canker (*Botryosphaeria spp.*), Powdery mildew (*Sphaerotheca* spp.), Septoria blight (*Septoria* spp.), and Phomopsis stem canker (*Phomopsis vaccinii*) that are not controlled by the partial alternative active ingredients.

Azoxystrobin is considered superior to other alternative products for use on juneberry because it is the only alternative active ingredient labeled on juneberry for control of the above identified diseases.

Michele we have not reviewed all the regulatory information to substantiate that these are the only ais registered and Gene Hill plans to do this on Monday.

LENTIL

A total of five fungicide active ingredients including azoxystrobin, boscalid, pyraclostrobin, fludioxonil, cyprodinil and mefenoxam are registered for use on lentil. Two of these active ingredients including boscalid & pyraclostrobin are considered partial alternatives to azoxystrobin and they are compared to azoxystrobin in this discussion.

Lentil qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy is presented below:

Lentil Diseases Co	ontrolled By Azox	ystrobin Com	pared To R	egistered Parti	al alternativ	es
		Azoxystrobin	Boscalid	Pyraclostrobin	Fludioxonil /cyprodinit	Mefenoxam
Foliar / Stem Disease	Scientific Name	Quadris 100-1098	Endura 7969- 197	Headline 7969-186	Switch 100-953	Ridomil Gold EC 100-801
Bean Rust	Uromyces appendiculatus	×	x	x		
Anthracnose	Colletotrichum lindemuthianu m	x		x		
Alternaria leaf spot	Alternaria alternata	x		х		
Ascochyta leaf spot	Ascochyta phaseolorum	x	х	х		
Rust	Phakopsora spp.	x		x		
Southern blight	Sclerotium rolfsii	x				
Webb blight	Rhizoctonia solani	x		· .		
Ascochyta blight	Mycosphaerell a pinodes	x		х		

Criteria 1 – Biological Efficacy Comparison

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	ontrolled By Azox	Azoxystrobin	Boscalid	Pyraclostrobin	Fludioxonil /cyprodinil	Mefenoxam
Foliar / Stem Disease	Scientific Name	Quadris 100-1098	Endura 7969- 197	Headline 7969-186	Switch 100-953	Ridomil Gold EC 100-801
Ascochyta leaf and pod spot	Ascochyta spp.	x	x	x		
Alternaria blight Soilborne Diseases	Alternaria spp.	X				
Rhizoctonia root rot	Rhizoctonia solani	x				A - 13)
Total Diseases		11	3	7	0	0

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on lentil.

The above table shows that azoxystrobin is labeled for control of three foliar diseases including Southern blight (*Sclerotium rolfsii*), webb blight (*Rhizoctonia solani*), and alternaria blight (*Alternaria* spp.) and one soil borne disease including rhizoctonia root rot (*Rhizoctonia solani*) on lentil and other alternatives are not labeled for control of these diseases.

Since azoxystrobin is labeled for control of diseases that are not on the alternative products' labels, azoxystrobin has a broader spectrum of biological efficacy than the other alternatives and is therefore superior to the other registered alternative products for use on lentil.

LYCHEE

Three active ingredients including fludioxonil, cyprodinil and copper hydroxide are registered for use on lychee and classified as *partial alternatives* to azoxystrobin.

Lychee qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy for azoxystrobin, copper hydroxide and Switch against certain diseases is presented below:

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Criteria 1 – Biological Efficacy Comparison

Lychee Diseases C	ontrolled By Azo alt	xystrobin Compa ernatives	red To Register	ed Partial
	Scientific	Azoxystrobin	Fludioxonil/ cyprodinil	Copper Hydroxide
Foliar / Stem Diseases	Name	Abound 100-1098	Switch 100-953	Kocide 101 1812-288
Cercospora leaf spot	Cercospora spp.	x		
Anthracnose	Colletotrichum spp.	x	x	x
Powdery Mildew	Erysiphe spp.	x		
Rust	Puccinia spp.	x		
Soilborne Diseases				
Seedling Root Rot, Basal Stem Rot	Rhizoctonia solani	x		
Total No. Diseases		6	1	1

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on lychee.

The above table shows that azoxystrobin is labeled for control of three foliar diseases including cercospora leaf spot (*Cercospora* spp.), powdery mildew (*Erysiphe* spp.) and rust (*Puccinia* spp.) and two soil borne diseases including seedling root rot (*Rhizoctonia* solani) and basal stem rot (*Rhizoctonia* solani) on lychee and copper hydroxide and Switch are not labeled for control of these diseases.

Since azoxystrobin is labeled for control of diseases that are not on the alternative product's label azoxystrobin has a broader spectrum of biological efficacy than the other alternative and is therefore superior to the other registered alternative product for use on lychee.

MANGO

A total of five active ingredients including azoxystrobin, chlorothalonil, fludioxonil, cyprodinil, copper hydroxide and mefenoxam are registered for use on mango. Four of these are classified as partial alternative active ingredients and are compared to azoxystrobin in this discussion.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 20 of 31 Mango qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and these five active ingredients is presented below:

	eases Controlle		obili ooliipuree	Fludioxonil/		leinatives
		Azoxystrobin	Chlorothalonil	cyprodinil	Copper Hydroxide	Mefenoxam
Foliar / Stem Disease	Scientific Name	100-1098	50534-188	Switch 100-953	Kocide 101 1812-288	Ridomil Gold EC100-801
Cercospora leaf spot	Cercospora spp.	x				
Anthracnose	Colletotrichum spp.	x	x	x	x	
Powdery Mildew	Erysiphe spp.	х				
Rust	Puccinia spp.	х				
Soilborne Diseases						
Seedling Root Rot, Basal Stem Rot	Rhizoctonia solani	x				
V diec	Total No. Diseases	6	1	1	1	0

Criteria 1 – Biological Efficacy Comparison

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies Qualifying Criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on mango.

Azoxystrobin provides control of foliar/stem diseases including cercospora leaf spot (*Cercospora* spp.), powdery mildew (*Erysiphe* spp.) and rust (*Puccinia* spp.) and these diseases are not on labeling for chlorothalonil, copper hydroxide and Switch... Also, azoxystrobin is labeled for the soil borne diseases seedling root rot (*Rhizoctonia solani*) and basal stem rot (*Rhizoctonia solani*) and the *alternative products* are not labeled for these two important diseases.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 21 of 31 The above table shows that azoxystrobin is labeled for control of both foliar/stem and soil borne diseases on mango and products containing the other alternative active ingredients are not labeled for control of these diseases. Therefore, these active ingredients are classified as unacceptable alternatives because each is not labeled for control of a disease organism for which azoxystrobin is labeled.

Since azoxystrobin is labeled for control of diseases that are not on the alternative product's label it has a broader spectrum of biological efficacy than other alternatives and is therefore superior to other registered alternative products for use on mango.

MINT (PEPPERMINT AND SPEARMINT)

A total of three fungicide active ingredients registered for use on mint are classified as *partial alternatives* and are compared to azoxystrobin in this discussion. These three products are propiconazole, trifloxystrobin and chlorothalonil.

Mint qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and the three active ingredients classified as *partial alternatives* is presented below:

	•	Azoxystrobin	Propiconazole	Trifloxystrobin	Chlorothalonil
Foliar / Stem Disease	Scientific Name	Quadris 100-1098	Tilt® 100-617	Flint 432-1371	Bravo Weather Stik 50534-188
Powdery Mildew	Erysiphe spp.	X		Х	
Rust Soilborne Diseases	Puccinia menthae	x	x		×
Seedling Root Rot, Basal Stem Rot	Rhizoctonia solani	x			
	Total No. Diseases	4	1	1	1

Criteria 1 - Biological Efficacy Comparison

X – disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy – Are there Sufficient Efficacious Alternatives To Azoxystrobin?

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on mint.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 22 of 31 The three active ingredients including propiconazole, trifloxystrobin and chlorothalonil are registered for use on mint. Azoxystrobin is labeled for control of the foliar/stem disease rust (*Puccinia menthae*) and the two soil borne diseases seedling root rot (*Rhizoctonia solani*) and basal stem rot (*Rhizoctonia solani*). The labels for products containing propiconazole, trifloxystrobin and chlorothalonil are not labeled for soil diseases.

The above table shows that azoxystrobin controls two soil borne diseases on mint that are not on labeling of products containing other registered active ingredients. These active ingredients are considered *unacceptable alternatives* because each is not labeled in mint for control of a disease organism for which azoxystrobin is labeled.

Since azoxystrobin is labeled for control of diseases that are not on the alternative product's label azoxystrobin has a broader spectrum of biological efficacy than other alternatives and is therefore superior to other registered alternative products for use on mint.

MUSTARD GREENS

A total of four fungicide active ingredients registered for use on mustard greens are classified as *partial alternatives* and are compared to azoxystrobin in this discussion.

Mustard greens qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and these active ingredients classified as *partial alternatives* is presented below:

Mustard G	reens Diseas	es Controlled By Partial all	Azoxystrobir ernatives	Compared	To Registered
		Azoxystrobin	Fludioxonil/ cyprodinil	Copper Hydroxide	Maneb
Foliar / Stem Disease	Scientific Name	Quadris 100-1098	Switch 100-953	Kocide 101 1812-288	Maneb 75DF 4581-371
White Rust	Albugo candida	X X @ 0.1-0.25 lbs.ai/A up to 3		X @ 0.38	
Alternaria Leaf Spot Black Spot	Alternaria spp.	times not to exceed 0.75 Ibs.ai/A/season	×	lbs.ai/A on 7 day interval	x
			x		X @ 1.2 lbs.ai/A on 14 day schedule not to exceed
Cercospora Leaf Spot Soilborne Diseases Seedling Root Rot,	Cercospora spp.	х	Suppression only		2.4 Ibs.ai/A/cutting.
Basal Stem Rot	Rhizoctonia solani	x		r8	
	Total Diseases	5		1	2

Criteria 1 - Biological Efficacy Comparison

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on mustard greens.

Azoxystrobin is labeled for the foliar/stem diseases white rust (*Albugo candida*)and soil borne diseases seedling root rot (*Rhizoctonia solani*) and basal stem rot (*Rhizoctonia solani*) and these diseases are not on labeling for products containing fludioxonil, cyprodinil, copper hydroxide or maneb. Also, azoxystrobin is labeled for cercospora leaf spot (*Cercospora* spp.) and this disease is not on labeling for products containing copper hydroxide.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 24 of 31 The above table shows that azoxystrobin controls diseases on mustard greens that are not controlled by the other active ingredients and on this basis these actives are classified as unacceptable alternatives.

Since azoxystrobin is labeled for control of diseases that are not on the alternative's product labels it has a broader spectrum of biological efficacy than other alternatives and is therefore superior to other registered alternative products for use on mustard greens.

OKRA

Azoxystrobin is the only fungicide active ingredient that is registered for use on okra. Thus there are no other active ingredients classified as a potential alternative.

Okra qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. The biological efficacy profile for azoxystrobin is presented below:

	Controlled By Azoxy Registered Partial alter	
Foliar / Stem Disease	Scientific Name	Azoxystrobin Quadris 100-1098
Powdery Mildew	Sphaerotheca spp.	X
Anthracnose	Colletotrichum spp.	X
Soilborne Diseases		
Seedling Root Rot	Rhizoctonia solani	X
Basal Stem Rot	Rhizoctonia solani	X
Total No. Diseases	4	

Criteria 1 – Biological Efficacy Comparison

X – disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on okra.

The above table shows that azoxystrobin is labeled for control of two foliar diseases including powdery mildew (*Sphaerotheca* spp.) and anthracnose (*Colletotrichum* spp.) and two soil borne diseases including seedling root rot (*Rhizoctonia solani*) and basal stem rot (*Rhizoctonia solani*) on okra and no other active ingredients are labeled for control of these diseases on okra.

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 25 of 31 Since azoxystrobin is labeled for control of diseases and no other alternative product's label claims these diseases, then azoxystrobin has a broader spectrum of biological efficacy.

PARSLEY

A total of five fungicide active ingredients registered for use on parsley are classified as potential alternatives and are compared to azoxystrobin in this discussion.

Parsley qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against certain diseases for azoxystrobin and the two active ingredients classified as potential alternatives is presented below:

Criteria 1 – Biological Efficacy Comparison

Parsley Dis	seases Controlle	d By Azoxystr Alternati		To Registere	ed Partial
		Altomat	Aluminum Tris	FI I 11	0
			(O-ethyl	Fludioxonil/	Copper
		Azoxystrobin	phosphonate)	cyprodinil	Hydroxide
Foliar /	0.1	A 11			Kocide
Stem	Scientific	Quadris	Alliette WDG	Switch	101
Disease	Name	100-1098	264-516	100-953	1812-28
Alternaria	Alternaria				
Leaf Spot	sonchi & spp.	X		X	
Cercospora	Cercospora				
leaf spot	spp.	X			
	Microdochium panattonianum Colletotrichum				
Anthracnose	dematium	х			
Septoria leaf	Septoria				
spot	petroselini	х			
	Albugo				
White Rust	occidentalis	х			
Downy	Bremia				
Mildew	lactucae	х	х		
Powdery Mildew	Erysiphe cichoracearum	х			
Webb Blight	Rhizoctonia solani	x			
Soilborne Diseases					
Bottom Rot, Crater rot,		X			
Root rot		X			
	Total No. Diseases	12	1	1	0

Syngenta Crop Protection Application for Extension of Exclusive Use Period Page 26 of 31 X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria – Biological Efficacy

Azoxystrobin satisfies this criteria because there are insufficient efficacious registered alternatives to azoxystrobin for use on parsley.

Azoxystrobin is labeled for control of foliar/stem diseases cercospora leaf spot (*Cercospora* spp.), anthracnose (*Microdochium panattonianum* and *Colletotrichum dematium*), septoria leaf spot (*Septoria petroselini*), white rust (*Albugo occidentalis*), and powdery mildew (*Erysiphe cichoracearum*), webb blight (*Rhizoctonia solani*), and the alternative active ingredients are not labeled for control of these diseases. Azoxystrobin is also labeled for control of soilborne diseases including bottom rot, crater rot and root rot and the alternative products are not labeled for these diseases.

The above table shows that azoxystrobin is labeled for control of diseases on parsley and labels for products containing the five alternative active ingredients do not claim these diseases. Therefore, these active ingredients are considered unacceptable alternatives because each is not labeled for control of a disease organism for which azoxystrobin is labeled.

Since azoxystrobin is labeled for control of diseases that are not on the alternative's product label it has a broader spectrum of biological efficacy than other alternatives and is therefore superior to other registered alternative products for use on parsley.

WATERCRESS

Copper hydroxide and Switch are registered for use on watercress and is classified as a partial alternative to azoxystrobin.

Watercress qualifies as a minor use that supports an extension of the exclusive use period for azoxystrobin based upon azoxystrobin satisfying the biological efficacy qualifying criteria. A comparison of the biological efficacy against one labeled disease is presented below:

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Criteria 1 – Biological Efficacy Comparison

Watercress Disea	ases Controlled By A	Azoxystrobin Co Iternatives	ompared To Re	egistered Partial
		Azoxystrobin	Fludioxonil/ cyprodinil	Copper Hydroxide
Foliar / Stem Disease	Scientific Name	Quadris 100-1098	Switch 100-953	Kocide 101 1812-28
Cercospora leaf spot	Cercospora spp.	X (0.25 Ibs.ai/A and 3 applications per cutting). Do not exceed 1.5 Ibs. Ai per acre per season.	x	X 0.75 lbs/A on a 7-14 day schedule for 4 applications per crop or a total of 3.0 lbs.ai/A/Yr.
	Total No. Diseases	1	1	1

X - disease is listed on label for products containing the respective active ingredient.

The biological efficacy qualities of azoxystrobin are compared with the registered alternatives in the following discussion.

Qualifying Criteria - Biological Efficacy, Risk

Azoxystrobin satisfies this criteria because it has application rate advantages over copper hydroxide and Switch. Azoxystrobin is registered for use to control cercospora leaf spot (*Cercospora* spp.) at a single application rate equal to 1/3 that for copper hydroxide (0.25 lbs. Ai per acre for azoxystrobin and 0.75 lbs. Ai per acre for copper hydroxide). Additionally, azoxystrobin provides environmental advantages over copper hydroxide because it has season maximum application rate one-half that for copper hydroxide (1.5 lbs. Ai per acre per season for azoxystrobin verses 3.0 lbs. Ai per acre per season for copper hydroxide). These significant rate advantages are sufficient to conclude that there are insufficient efficacious registered alternatives to azoxystrobin for use on watercress. Also, azoxystrobin offers a resistance management partner for Switch Fungicide.

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PEST MANAGEMENT STRATEGIC PLANS (PMS PLANS)

In addition to the above specifics, azoxystrobin is recognized as a valuable component of PMS Plans.

The USDA Office of Pest Management Policy (OPMP) is facilitating the production of Pest Management Strategic Plans (PMS Plans) which are developed by growers, commodity associations, land-grant specialists, food processors, crop consultants, and EPA. These plans address pest management needs and priorities for individual commodities.

Each plan focuses on commodity production in a particular state or region. The plans take a pest-by-pest approach to identifying the current management practices (chemical and non-chemical) and those under development. Plans also state the commodity's priorities for research, regulatory activity, and education/training programs needed for transition to alternative pest management practices.

Azoxystrobin is referenced in many of the PMS Plans as a valuable control agent. The following table provides a reference to PMS Plans where azoxystrobin is listed.

Crop	PMSP Plan Name	Internet Address
Mango, Lychee	Tropical Fruit Management Strategic Plan (PMSP), March 31, 2003. Homestead, FL (35 pages)	http://www.ipmcenters.org/pmsp/pdf/FLTropicalfr uit.pdf
Lentils	Pest Management Strategic Plan For Pulse Crops (Chick Peas, Lentils and Dry Beans) in the United States and Canada. Summary of Workshop held on June 26-27, 2002. Saskatoon, Canada	http://www.ipmcenters.org/pmsp/pdf/USCAPulse PMSP.pdf
Mint	Crop Profile for Mint in Wisconsin. January 1999	http://pestdata.ncsu.edu/cropprofiles/docs/wimint. html
Parsley	Crop Profile for Parsley in Ohio. December 1999	http://pestdata.ncsu.edu/cropprofiles/docs/ohpars ley.html

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VIII. REQUEST THREE YEAR EXTENSION OF AZOXYSTROBIN DATA EXCLUSIVE USE PERIOD

The information within this application provides sufficient evidence for the Administrator in consultation with the Secretary of Agriculture to determine that registration of azoxystrobin for use on the minor uses (list crops) satisfy all required qualifying criteria within FIFRA § 3I(1)(F)(ii) to support an extension of the azoxystrobin data exclusive use period. Based upon the information provided in this application Syngenta requests the Agency grant a 3-year extension of the azoxystrobin exclusive use period for (1) all data submitted by Syngenta in support of the initial registration of azoxystrobin on February 7, 1997 and (2) for all azoxystrobin data submitted subsequent to February 7, 1997 in support of federal label expansions. These data are identified within Appendix II).

We respectfully request that the exclusive use period for the data identified within Appendix II be extended for a total period of three years. This extension will revise the present expiration date of February 7, 2007 to February 7, 2010.

IX. REQUEST FOR MEETING

Syngenta will formally request a meeting with the Agency to discuss this application and address any questions the Agency may have associated with its content in the near future.

Ms. Michele Schulz, NAFTA Fungicide Team Lead Syngenta Crop Protection, Inc. Regulatory Affairs 410 Swing Road Greensboro, NC 27419 Telephone (316) 632-2380

Appendices

Appendix I -	Reduced Risk Letters
Appendix II -	Data Matrices
	- Notice of Product Registration and stamped age Fungicide
	- A Notice of registration and EPA stamped label
Appendix V -	40CFR References
Appendix VI - products as s	- Abound and Quadris final printed labels for old currently.

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