US Environmental Protection Agency
Office of Pesticide Programs

Petition for 3 Year Extension of Exclusive Data Use for Metconazole

December 27, 2013

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Metconazole Fungicide Technical
EPA Reg. No. 72078-1
Extension of the Period of Exclusive Data Use for the Active Ingredient: Metconazole

Mrs. Nicole William
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ATTENTION: Minor Use - Exclusive Use Request

Dear Mrs. William:

Valent U.S.A. Corporation, as the agent for Kureha Corporation, is pleased to submit a petition to extend the period of exclusive data use for the fungicide metconazole. The ten-year exclusivity statute is established under FIFRA Section 3(c) (1) (F) (i). The extension is determined by the number of minor uses added within the first seven years of the exclusive use period to the first registration of the active ingredient, with one additional year of exclusivity granted for every three minor use registrations, up to a maximum of three years. The first registration granted for metconazole is Metconazole Fungicide Technical under the EPA Reg. No. 72078-1 on September 27, 2007. As explained in the attached document, we believe metconazole qualifies for an additional three years of exclusive use data protection.

Granting a three-year extension to the period of exclusive data use for metconazole will change the ten-year period described in FIFRA to thirteen years, extending the exclusive period from September 27, 2017 to September 27,2020. In accordance with FIFRA Section 3(c)(1)(F)(i) this period of exclusive use pertains to all data submitted to support the application for the original registration of the pesticide and to all data submitted to support applications for amendments adding new uses to the registration. The PRIA fee (M007) of $5250 was made in Oct. 2013 by two installments (Agency Tracking ID: 74521043412 and 74521049761). The payment confirmation is in attachments 2 & 3.

Enclosed are four sets of hard copies and CDs of "Petition for 3 Years Extension of Exclusive Data Use for Metconazole as Provided for Under FIFRA Section 3(c) (1) (F) (ii)".

Thank you for your consideration this request if you have any questions, please contact me at 214-784-5536 (sshen@valent.com).

Sincerely,

Sue-Chi Shen
Sr. Regulatory Project Manager
Registration and Regulatory Affairs:

CC: Mrs. Cynthia Giles-Parker, Fungicide Branch, USEPA/OPP/RD
Mrs. Hope Johnson, PM21, USEPA/OPP/RD
Mr. Masaru Mori, Kureha

Petition for 3 Years Extension of Exclusive Data Use for Metconazole as Provided for Under FIFRA Section 3(c) (1) (F) (ii)

Active Ingredient

Metconazole

Authors

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Guideline Reference

None

Completed On

December 26, 2013

Submitted By

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(As the Agent for Kureha Corporation)

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1.0 Introduction

Valent USA, as the agent for Kureha Corporation, hereby petitions EPA to extend by 3 years the period of exclusive data use for Metconazole fungicide by applying the provision of FIFRA Section 3(c) (1) (F) (ii).

FIFRA Section 3(c) (1) (F) (ii) states that:

The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that –

> *(I) there are insufficient efficacious alternative registered pesticides available for the use;*
> *(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;*
> *(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or*
> *(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.*

Metconazole Registrations

Metconazole technical (EPA Reg. No. 72078-1) is currently registered under Kureha Corporation. It was first granted US registration on September 27, 2007. The formulated product that supports the minor use candidates is listed in the table below.

Company	Product name	EPA Reg. No.
Valent USA	Metconazole 50 WDG Fungicide	59639-147

Metconazole technical was registered by U.S. EPA on September 27, 2007. Included in that registration were foliar uses and seed treatment uses.

- Tuberous and corm vegetables (Subgroup 1 C)
- Stone Fruit (Crop Group 12)
- Bushberry (Subgroup 13 B)
- Tree nuts (Crop Group 14)
- Cereal grains (Crop Group 15, except buckwheat , sorghum, millet ,teosinte, rice and wild rice)

- Canola
- Cotton
- Peanut
- Pistachio
- Soybean
- Sugar beet
- Sugarcane

2.0 Metconazole Minor Use Crop Candidates and Residue Data

Residue trials were conducted in crops and the crop group representative crops, including major and minor crops, to support the numerous minor crops on which metconazole is currently registered. Table 1 shows the minor use crop candidates included in this petition for extension of exclusive use of data and the corresponding residue data used to support the registration of these minor crops.

Therefore, residue studies supporting registration are available for 13 minor use crop candidates. In addition, several minor use registrations supported by residue data generated on representative crops for crop group tolerances are given in Table 1. Some uses for metconazole on minor crops were requested by IR-4 with the residue programs conducted by IR-4 or Valent.

All of the minor use crop candidates were registered within the requisite seven year period (prior to September 27, 2014) and added to the metconazole technical fungicide label.

Table 1: Metconazole Minor Use Crop Candidates

Candidate No.	Crop Candidate	<300K Acres[1]	Residue Data to Support	MRID #	Section 18/ IR-4	Date Registered	Crop Group No.	Document Section Number
1	Sweet Potato & Yam	yes	Potato	48143301	IR-4 PR# 09861/09890	11/9/2011	1C	3.0
2	Apricot	yes	Cherry; Peach Plum	46901707 46901708 46901709	IR-4 PR# None[2]	5/6/2008	12	4.0
3	Cherry	yes			IR-4 PR# None[2]	5/6/2008		5.0
4	Nectarine	yes			IR-4 PR# None[2]	5/6/2008		6.0
5	Peach	yes			IR-4 PR# 09297	5/6/2008		9.0
6	Plum	yes				5/6/2008		8.0
7	Prune	yes				5/6/2008		9.0
8	Blueberry, lowbush	yes	Blue-berry, High-bush	48143302	IR-4 PR# 09501	11/9/2011	13-07B	10.0
9	Blueberry highbush	yes			IR-4 PR# 09501	11/9/2011		12.0

Candidate No.	Crop Candidate	<300K Acres[1]	Residue Data to Support	MRID #	Section 18/ IR-4	Date Registered	Crop Group No.	Document Section Number
10	Gooseberry	yes				11/9/2011		12.0
11	Hazelnut	yes	Almond, Pecan	46901710 46901711	None[2] (Data-mining for almonds)	5/6/2008	14	12.0
12	Macadamia Nuts	yes				5/6/2008		13.0
13	Pistachio	yes				5/6/2008		14.0

[1]Based on Residue Chemistry Test Guideline OPPTS 860.1500 Crop Field Trials
[2]Data mining project – no PCR received.

Residue studies supporting registration are available for 13 minor crops, thus qualifying Metconazole for a 3-year extension of data exclusivity (1 year for each of 3 minor crops up to a maximum of 3 years) provided the other criteria listed below are met.

Valent USA believes that the registration of Metconazole on 13 minor crops meets all of the requirements and therefore qualifies for a 3-year extension of data exclusivity (1 year for each of 3 minor crops up to a maximum of 3 years).

Table 2: Summary of the Criteria Met by Each of the Minor Use Crop Candidates

Candidate No	Candidate Crop	Key Fungal Diseases	Criteria I	II	III	IV	Document Section No.
1	Sweet Potato & yam	chlorotic leaf distortion, white rust, Phyllosticta, Septoria leaf spot, Cercospora leaf spot, Alternaria leaf and stem blight	✓		✓		3.0
2	Apricot	brown rot blossom and twig blight, shot hole, powdery mildew, jacket rot	✓		✓		4.0
3	Cherry	brown rot blossom and twig blight, powdery mildew, Botrytis blossom blight and jacket rot	✓	✓	✓		5.0
4	Nectarine	brown rot blossom and twig blight, jacket rot, shot hole, powdery mildew, scab, rust	✓	✓	✓		6.0
5	Peach	brown rot blossom and twig blight, jacket rot, shot hole, powdery mildew, scab, rust	✓	✓	✓		9.0
6	Plum	brown rot blossom and twig blight, ripe fruit rot, powdery mildew, shot hole, scab, rust	✓	✓	✓		10.0
7	Prune	brown rot blossom and twig blight, rust, shot hole	✓	✓	✓		11.0
8	Blueberry, lowbush	mummy berry, anthracnose, Alternaria fruit rot, Botrytis blight, Phomopsis twig blight, Fusicoccum canker, powdery mildew, leaf rust	✓	✓	✓		12.0
9	Blueberry highbush	See blueberry, lowbush	✓	✓	✓		12.0
10	Gooseberry	anthracnose leaf spot, powdery mildew, Septoria leaf spot, Botrytis fruit rot	✓				12.0
11	Hazelnut	Eastern filbert blight	✓				13.0

Candidate No	Candidate Crop	Key Fungal Diseases	Criteria I	II	III	IV	Document Section No.
12	Macadamia Nuts	raceme and blossom blight (*Phytophthora*), raceme blight (*Botrytis*)	✓				13.0
13	Pistachio	Botryosphaeria panicle and shoot blight; Botrytis blossom, shoot and fruit blight; Alternaria late blight; powdery mildew	✓				14.0

Criteria:

(I) There are insufficient efficacious alternative registered pesticides available for the use;
(II) The alternatives to the minor use pesticide pose greater risks to the environment or human health;
(III) The minor use pesticide plays or will play a significant part in managing pest resistance; or
(IV) The minor use pesticide plays or will play a significant part in an integrated pest management program.

Meeting the Criteria for Extension of the Period of Exclusive Data Use

Details of how metconazole meets the exclusivity criteria for various minor uses are described below. Each section gives 1) the acreage for the particular crop(s) and the pest/crop problems; 2) the justification of how metconazole meets the criteria for the particular use; and 3) appropriate references for that section.

3.0 Justification for Metconazole Minor Use on Sweet Potato & Yam

3.1 Acreage, Production and Major Disease Problems.

Sweet potato (*Ipomoea batatas*) is a native American plant which is marketed interchangeably as sweet potato or yam although true yams (*Dioscorea* species) are unrelated. Most sweet potato production is in the southern US with North Carolina being the leading production state with 63,000 acres producing 12.4 million cwt valued at $177.3 million in 2012.[1] Mississippi (24,000 acres producing 3.5 million cwt) and Louisiana (10,000 acres producing 1.9 million cwt) are also major southern production centers and ranked 3 and 4 in the US. Texas, Florida, Arkansas and New Jersey have 1.2 to 6.4 thousand acres. In recent years sweet potato production has increased significantly in California which is now ranked 2nd nationally with 18,000 acres producing 6.2 million cwt. Total US production is 26.4 million cwt on over 130,000 acres valued at more than $500 million.[13,14]

Sweet potatoes are grown from early spring when pre-sprouted seed are bedded to produce transplants which are then grown in the field and harvested in late fall. Roots are cured and stored throughout the year until sold. Because of the extended storage season, the most destructive sweet potato diseases attack the roots post-harvest and these pathogens are also frequently carried over to the field on seed and transplants. Soil fungicides, fumigants and post-harvest treatments are used routinely to control bacterial and fungal diseases during this period.

In the field and in transplant beds, foliar fungal diseases are often major problems which vary in economic impact between production regions and with climatic conditions.[3-8,12] The two most common leaf infecting fungal diseases are chlorotic leaf distortion (CLD), *Fusarium denticulatum*, which can occur throughout the growing season and white rust, *Albugo ipomoeae-panduratae*, which is prevalent in years with frequent rains. Other leaf spot diseases include *Phyllosticta, Septoria* and *Cercospora* leaf spots. *Alternaria* now also represents a significant risk to the North American industry since its identification as a new disease of sweet potato in North Africa (Netherlands Journal of Plant Pathology, 1984). Now named Alternaria leaf and stem blight, *Alternaria* is considered an important disease threat to potato cultivation in tropical and sub-tropical areas.[10]

3.2 Justifications of How Metconazole Meets the Above Criteria:

(I) There are insufficient alternative registered fungicides that are effective and registered for use.

Sweet potato foliar fungal diseases are sporadic in occurrence but when conditions are suitable, the long growing season requires multiple fungicidal treatments. Multi-site, protectant fungicides, commonly used in other minor crops where disease pressure is sporadic are not registered in sweet potato[2] and are not available as alternatives. Single-site fungicides registered on sweet potato are predominantly the strobilurins (Group 11) with azoxystrobin, fluoxastrobin, pyraclostrobin and fenamidone active ingredients available. These Group 11 fungicides provide effective control of *Fusarium, Albugo, Septoria, Cercospora* and *Alternaria* pathogens but since applications must be rotated with another mode of action[20] to manage resistance, other alternatives are needed to provide both control and mode of action rotational partners.[11] Metconazole, Quash, (Group 3) is extremely effective against all these leaf infecting pathogens in many other crops[9].

(III) The minor use pesticide plays or will play a significant part in managing pest resistance

Since metconazole is the only registered product containing a single active ingredient in Group 3, there are no other alternatives that are both effective and allow for resistance management.

3.3 References

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11. Kemble, J. M. ed., 2013. Disease Control for Sweetpotato, Relative Importance of Alternative Management Practices for Disease Control and Relative Importance of Products for Sweetpotato Disease Control, 215-217p. http://www.thegrower.com/south-east-vegetable-guide/

12. Strategic Plan for Pest Management Research and Education in Southern Sweet Potato Production Systems. http://www.ipmcenters.org/pmsp/pmsp_form.cfm

13. USDA, NASS, 2013. Crop Production 2012 Summary, Sweet Potato Area Planted and Harvested. Yield and Production States and United States, 2010-2012.

14. USDA, NASS, 2012. Sweet Potatoes: Production by State 1900-2010.

4.0 Justification for Metconazole Minor Use on Apricot

4.1 Acreage, Production and Major Disease Problems.

US apricot production in 2012 was 69,000 tons valued at $40.8 million, on 12,150 acres. Nearly 90% of apricots are grown in California with 10,800 acres valued at $32.2 million. Other US production states include Washington with approximately 8% and Utah with approximately 1%.[21,22,15]

The primary leaf, twig, blossom and fruit infecting fungal diseases of apricot are brown rot blossom and twig blight, jacket rot, powdery mildew and shot hole disease.[16,17]

Brown rot, blossom and twig blight, *Monilinia laxa* and *Monilinia fructicola*[23] is the most damaging apricot disease that infects and can kill blossoms and associated spurs and leaves. It is most serious in wet conditions requiring 2-3 fungicides for effective control with the most critical spray at red bud to prevent sepal infection.

Ripe fruit rot also caused by *M. fructicola* and *M. laxa* may attack ripe fruit in wet conditions requiring an additional pre-harvest fungicide application.[27] Shot hole disease, *Wilsonomyces carpophilus*, attacks apricots year round, killing buds in winter and spotting leaves and fruit in spring. A dormant fungicide is often applied in winter and several bloom to pre-harvest applications may also be required in spring.[28] Powdery mildew, *Sphaerotheca pannosa* and *Podosphaera tridactyla*, attacks both leaves and fruit in spring and summer requiring fungicide applications from bloom through fruit development.[26] Jacket rot occurs during the jacket stage and causes young fruit to fall from trees. Several pathogens may be involved in jacket rot with *Botrytis cinerea* and *Sclerotinia sclerotiorum* found in addition to *M. laxa* and *M. fructicola*. One to two fungicide applications may be necessary to manage jacket rot effectively.[25]

4.2 Justification to meet Criteria:

(I) There are insufficient alternative registered fungicides that are effective and registered for use

Shot hole disease is a serious threat to apricot production throughout the year (UC Davis, PMG, Apricot, Year Round IPM Program, 2007).[19] and, although many fungicides are registered for disease control on apricots,[18] shot hole efficacy and the need to rotate fungicidal modes of action to avoid resistance, limit grower options severely.[19,20]

Demethylation inhibitors (Group 3) and strobilurins (Group 11) are the key fungicides in managing apricot diseases but resistance to both modes of action has been documented and a strict rotational program limiting strobilurins to a single application per season and DMIs to two successive applications severely reduces available alternatives.[19] These restrictions on the key fungicidal modes of action make resistance management a challenge in apricots where multiple applications may be required since each key disease has specific control requirements: shot hole may require a dormant application in winter and up to 3 fungicides from flowering to fruit development;[28] brown rot requires 2-3 spring applications[23] with an additional application during wet years at fruiting; powdery mildew requires repeated application during fruit set and development;[26]; and jacket rot requires at least 1 application in early fruit set.[25] Fortunately several fungicides are effective on a range of apricot diseases and the number of applications required is reduced by overlapping efficacy. Captan and chlorothalonil provide shot hole control, but they are not effective against powdery mildew and only provide variable control of brown rot. Furthermore, captan cannot be applied for diseases when fruit are present because it causes browning/staining. Thus the multi-site fungicides are primarily used as tank mixes to delay resistance. The strobilurins alone (Group 11) such as Abound and Gem control shot hole disease but are variable for brown rot and do not control jacket rot. Premixes of strobilurins with other single-site fungicides as in Pristine and Luna Sensation (Group 11 with Group 7) provide excellent control of all major diseases but since only single applications in a season for Group 11 fungicides are recommended, an alternative fungicidal mode of action is needed for resistance management. The DMI fungicides (Group 3) alone, such a Bumper, Tilt, Elite, Tebuzol, Indar and Rally, control brown rot but are ineffective against jacket rot and shot hole disease and since more than two successive applications of Group 3 fungicides are not recommended, these materials are not effective as alternatives. Quash, metconazole (Group 3) does provide good to excellent control of all major foliage and fruit diseases of apricot and thus represents the only registered and effective alternative with this efficacy spectrum. Group 3 pre-mixes with other single site modes of action, such as Adamant, Quadris Top and Quilt Xcel (Group 3 + 11), Luna Experience (3 +7) and Inspire Super (3 + 9) do extend the efficacy range of the Group 3 fungicides, but since resistance management requires strict rotation of modes of action, these are not viable alternatives to metconazole.

Thus, based on efficacy and the need to rotate modes of action, there are no effective registered alternatives to metconazole.[19,24]

(III) Metconazole plays a significant role in resistance management.

The need to rotate efficacious fungicides with different modes of action to avoid resistance is a critical need in all stone fruit. In apricot, although there are many registered fungicides,[18] variable efficacy against certain diseases such as jacket rot and shot hole disease, severely limits the availability of effective fungicides that can be used in rotations. Multi-site protectants such as chlorothalonil provide only limited efficacy on brown rot and do not control powdery mildew or jacket rot and thus should be used primarily as tank mix partners to delay resistance. Single-site fungicides are effective but modes of action need to be rotated. Since Group 11 materials are limited to single applications in a season and Group 3 and 7 fungicides are limited to only two consecutive applications, the alternatives available for resistance management are few. Group 11 materials have the broadest efficacy when premixed with other modes of action such as Groups 7, 9 and 3 but since Group 11 premixes are limited to single applications, alternatives are necessary to avoid resistance. Group 3 alternatives are effective against many key diseases but do not control shot hole or jacket rot. Only metconazole (Quash) has sufficiently broad efficacy to control all of the major apricot diseases, including shot hole and jacket rot and thus Quash is a key element in resistance management programs on apricot.[19]

4.3 References

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24. UC Davis Pest Management Guidelines. Apricot, Fungicide Efficacy and Timing, 2012. http://www.ipm.ucdavis.edu/PMG/r5902111.html

25. UC Davis Pest Management Guidelines. Apricot, Jacket Rot, 2007. http://www.ipm.ucdavis.edu/PMG/r5100811.html

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27. UC Davis Pest Management Guidelines. Apricot, Ripe Fruit Rot, 2007. http://www.ipm.ucdavis.edu/PMG/r5100211.html

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5.0 Justification for Metconazole Minor Use on Cherry

5.1 Acreage Production and Major Disease Problems

Two main types of cherries are grown in the US, sweet and tart. 97% of Sweet cherries (87,790 acres, yielding 424,000 tons valued at $777.9 million) are produced in 3 western states: Washington with 34,000 acres, producing 264,000 tons valued at $444.4 million; California with 31,000 acres, producing 92,300 tons valued at $255.1 million and Oregon with 12,500 acres, producing 56,000 tons valued at $55.9 million. Other states with significant sweet cherry production include Michigan, Idaho, Montana, New York and Utah. Tart cherries are primarily grown in Michigan with 75% of production yielding 78,750 tons on 27,300 acres valued at $47.2 million. Other states with significant tart cherry acreage include Utah (3,300 acres), Wisconsin (1,600 acres), Washington (1,600 acres) and New York (1,500 acres).[30,39,32]

Fungal diseases of cherry vary in importance between production areas and local climatic conditions. In drier Washington and Oregon, production areas in the Yakima Valley and Columbia basin, powdery mildew, *Podosphaera clandestina* can reach epidemic proportions rapidly and growers frequently treat before symptoms appear to avoid damaging losses.[33,34] Powdery mildew attacks both foliage and fruit and to prevent leaf infection, growers often spray from shuck (1 week after petal fall) to harvest at 7-14 day intervals. In wetter northern areas brown rot, *Monilinia fructicola* and *M. laxa*, is a serious threat during bloom with treatments applied during flowering to avoid blossom blight and ultimately fruit infection.

In California, cherries are grown primarily in the northern San Joaquin Valley in the Stockton/Lodi area with smaller centers in coastal Santa Clara and the southern San Joaquin Valley. In all California production areas, fungal disease must be controlled to avoid crop loss.[42] Fruit infecting diseases are the most serious with brown rot, blossom and twig blight, *M. fructicola* and *M. laxa* attacking during blossom and fruit development,[45] Botrytis (gray mold) blossom blight, *Botrytis cinerea*, infecting blossoms[44] and ripe fruit rot, *M. fructicola*, *M. laxa* and *B. cinerea*, attacking ripe fruit.[50] Powdery mildew, *P. clandestina*, attacks the foliage causing defoliation but rarely the fruit [49] Management programs require fungicide sprays from bloom to harvest to manage brown rot and Botrytis blossom blight and summer sprays to manage powdery mildew. Post-harvest sprays may also be needed to manage both brown rot and Botrytis blossom blight.[51]

In Michigan and other eastern production centers, brown rot management on tart cherries is critical to avoid serious crop loss[43] with fungicide applications centered on the blossom stage. Cherry leaf spot, *Blumeriella jaapii*, is also a serious threat to production in the eastern US causing severe defoliation and yield loss. To manage these two destructive diseases, repeated fungicide applications at 7-10 day intervals (often 5-7 sprays) are necessary every season from petal fall to harvest, with two postharvest sprays also usually applied.[41,43] As a result of the intensive fungicide programs needed to control brown rot and cherry leaf spot on tart cherries, resistance management is a primary concern to the industry and extensive research is ongoing to develop fungicide alternatives and deployment strategies.[37,38]

5.2 Justification of How Metconazole Meets the Above Criteria:

(I) There are insufficient alternative registered fungicides that are effective and registered for use.

The need for multiple fungicide applications on cherries, which must be applied from blossom to harvest at regular intervals (and often postharvest, as well) to manage defoliation (powdery mildew, cherry leaf spot), blossom blights (brown rot, Botrytis blossom blight), and ripe fruit infection (ripe fruit rot) in all production areas, has placed heavy emphasis on the continuing availability of fungicides with variable modes of action.[34,42,43] Numerous fungicidal products are registered for use on cherries,[31] but the need to rotate fungicidal modes of action to manage resistance[36] and the variable efficacy of the primary fungicide groups against key diseases, severely limits the availability of alternative registered products.[35,43,46] Multi-site fungicides such as chlorothalonil, sulfur, captan and copper have been used extensively in all areas to help manage resistance to single-site fungicides but concerns over phytotoxicity (copper), fruit residues (chlorothalonil), impacts on natural enemies (sulfur) and a general lack of efficacy, have relegated multi-site fungicides to a role as tank mix or rotational partners in managing disease in cherry.[37] This is particularly evident in tart cherries where the combination of biological, environmental, economic and regulatory factors has placed the tart/sour cherry industry in a precarious position regarding disease management.[38]

Single-site fungicides are the foundation of cherry disease control with the Group 3 DMIs and, more recently, the strobilurins (Group 11) providing the greatest efficacy. The strobilurins alone (Gem, Cabrio, Abound) provide moderate to good control of brown rot, Monilinia ripe fruit rot and powdery mildew and excellent control of cherry leaf spot, but are ineffective against Botrytis blossom blight and jacket rot when used alone. Pre-mixes of strobilurins (Group11) with SDHIs (Group 7), such as Pristine and Luna Sensation, broaden the activity spectrum of strobilurins to provide good to excellent control of all cherry fungal diseases, including cherry leaf spot but the need to rotate modes of action in multiple-application programs requires effective alternate fungicides with different modes of action. DMI (Group 3) fungicides used alone in Bumper, Tilt, Indar, Procure, Rally and Rubigan/Vintage, provide good to excellent control of brown rot, Monilinia fruit rot and powdery mildew but are ineffective against both Botrytis blossom/fruit and jacket rot (green fruit rot). Quash (metconazole) and Elite (tebuconazole) are the only Group 3 fungicides that provide excellent control of brown rot of blossoms and fruit, in combination with moderate control of Botrytis fruit and jacket rot fungi. However, only Quash (metconazole) gives reliable control of powdery mildew whereas Elite provides variable control.

Pre-mixes of Group 3 fungicides with single-site, Group 11 fungicides, such as Adament, Quadris Top and Quilt, provide the efficacy against Botrytis fruit rot and jacket rot that is not provided by the Group 3 fungicides alone, with the exception of metconazole.

However, in fungicide programs requiring multiple applications such as those for powdery mildew in the west and cherry leaf spot in the east, where rotations of modes of activity are essential for resistance management, pre-mixes that broaden efficacy do not provide the needed rotations to avoid resistance. This is particularly evident in western production, where only one strobilurin application per season is recommended in California, and in Washington where potential phytotoxicity of strobilurins to apples from drift or sprayer contamination, severely limits Group 11 fungicide use.[35,43,46]

Thus, although multiple fungicidal products are listed for disease control in cherry, variable efficacies against key pathogens, regulatory restrictions and the need to manage resistance through strict rotation of modes of action, severely limit the availability of registered and effective fungicides. Metconazole is the only Group 3 active ingredient with broad efficacy against all of the key cherry diseases and it is thus an essential fungicide which allows growers to manage diseases and rotate modes of action to avoid resistance.

(II) <u>Alternatives to Metconazole Pose a Greater Risk to the Environment and Human Health.</u>

Several protectant fungicides, which are used extensively in tank mixes or as rotational partners (alternatives) with single site fungicides such as Quash to manage resistance in spray programs requiring multiple applications, pose greater risks to the environment and human health. The following examples illustrate these risks:

- Potential risk to honey bees and natural pollinators.
  There is evidence from laboratory studies that captan (M4), applied for cherry diseases such as powdery mildew, brown rot and cherry leaf spot, may pose a significant risk to honey bee larvae. 100% of *Apis mellifera* larvae that were fed on a diet containing captan failed to survive to adulthood.[52] In these studies, larvae fed on diets containing single-site fungicides in Groups 3, 11, 9 and 17 were not toxic and did not differ significantly from controls. In field studies in California almonds, captan was not toxic to adult bees or to subsequent brood development [53] suggesting that field exposure could be reduced to avoid potential toxicity. The University of California recommends choosing fungicides that do not accumulate in pollen or honey bee products (e.g., bee bread, etc.). According to Johnson et al. 2010[54], fungicides that may accumulate to high levels in pollen are chlorothalonil, captan, and iprodione. These reports indicate that there is sufficient doubt surrounding the potential for negative impacts of chlorothalonil, captan and iprodione on pollinators to warrant extreme care in its use, particularly when single site alternatives such as Quash, which are not toxic to bees, are available. The complexity of Colony Collapse Disorder clearly shows that many factors which are not well understood, may interact to affect colony health. Avoiding demonstrated risks, such as those potentially associated with captan, when safe alternatives are available, is a judicious approach to pollinator conservation. The continued inclusion of cautionary statements on potential captan toxicity to bees in the California IPM guidelines[55] reflects this concern. In key production states in the Pacific Northwest, Extension publications[56] specifically state that: "Although fungicides are not thought to be toxic to adult bees, certain fungicides such as captan, iprodione and chlorothalonil affect brood development or affect the micro-organisms that ferment bee bread in the laboratory." These statements reinforce the need for caution in using captan in situations where pollination is critical, when low risk alternatives such as Quash are available.

- Potential risks to human health from captan.
  There is evidence that captan, applied as an agricultural fungicide, can pose significant risks to human health.

  In direct exposure of agricultural workers, captan has been directly associated with increased incidence of Rhinitis, a respiratory ailment, in pesticide applicators[57]. This elevated risk to orchard workers would be avoided if nontoxic, single-site fungicides such as Quash, which are equally effective in disease control, were used.

  In secondary exposure, through drinking water, the State of California, EPA, Office of Environmental Health Hazard Assessment, Safe Drinking Water Safety and Toxic Enforcement Act of 1986 requires the Governor, pursuant to Proposition 65, to revise and publish the list of chemicals known to the State to cause cancer or reproductive toxicity. Captan, which was first listed as a cancer risk in 1990 (CAS No 133-06-2) continues to be listed in 2013 as a cancer-causing chemical[58].

- Impacts of Sulfur on natural enemies of insect and mite pests.
  Sulfur continues to be used at high application rates as a fungicide and an acaricide in fruit production. In 2003, the annual usage rate of sulfur in California was about 34% of the total weight of pesticide active ingredient used in all Agricultural production (8). Although there are no direct impacts of sulfur on human health[59], there is ample evidence in the scientific literature that sulfur is directly toxic to natural enemies, both predators and parasitoids, of arthropod agricultural pests. This toxicity can reduce populations of natural enemies and result in resurgence of pest populations, the antithesis of balanced IPM programs which are the backbone of arthropod pest management promoted in fruit, nut and specialty crops, to reduce insecticide reliance. The potential detrimental impact of sulfur on biological control has resulted in a direct warning to California fruit crop growers to avoid reliance on sulfur as a fungicide in current University of California IPM guidelines[60]. Instances of sulfur toxicity to predators leading to potential mite resurgence have been recorded for grapes in California[61] and the Pacific Northwest[62] and fruit crops in Australia[63]. Impacts of sulfur toxicity on parasitoids have also been recorded with *Trichogramma* (important egg parasitoids of many lepidopteran pests) in Australia[64] and *Anagrus erythronuerae*, an egg parasitoid of the grape leafhopper[65]. The use of single-site fungicides such as Quash, which are applied at extremely low application rates and are not toxic to natural enemies, to enhance biologically balanced IPM programs, represents an important alternative to broad spectrum fungicides such as sulfur[66].

- Potential toxicity of Topsin M to earthworms.
  Topsin M is a single-site (Group 1) fungicide used as an alternative to Quash in cherries to manage cherry leaf spot, brown rot and powdery mildew. However thiophanate-methyl (active ingredient of Topsin M) is toxic to earthworms[67] which are essential components in the decomposition of leaf litter in orchards to improve soil quality and reduce disease inoculum sources. The use of Topsin M as an alternative to Quash, which is not toxic to earthworms, thus increases the risk to the environment.

(III) <u>Metconazole Plays a Significant Role in Resistance Management.</u>

The high disease pressure and risk of catastrophic loss in all cherry production areas, requires multiple-application disease control programs of 5-7 applications to manage powdery mildew, cherry leaf spot and other key diseases.[34,43] Concerns over phytotoxicity (copper), fruit residues (chlorothalonil), impacts on natural enemies (sulfur) and impacts on honeybees (captan) and a general lack of efficacy have reduced multi-site fungicides to a secondary role of rotational and tank mix partners for resistance management in disease management programs. Single-site fungicides now represent the foundation of cherry disease control and in multiple-application programs, the availability of a range of single-site fungicides with differing modes of activity is essential to manage resistance.[36] Group 3 and Group 11 fungicides are the primary single-site materials available for cherry disease control. Group 11 fungicides and pre-mixes are effective but are limited by the need to rotate with other modes of action and the risk of phytotoxicity to apples which is a major concern in the leading cherry production state, Washington. Of the Group 3 fungicides, only metconazole provides effective control of Botrytis fruit rot and jacket rot, in addition to brown rot and powdery mildew. Metconazole is thus a key component of resistance management programs on cherry, allowing growers to manage the major disease threats effectively and rotate with other mode-of-action fungicides to prevent selection of resistance.[47]

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6.0 Justification for Metconazole Minor Use on Nectarine

6.1 Acreage, Production and Major Disease Problems

Nectarines are a simple recessive genetic variation of peaches, *Prunus persica* and major diseases are similar to those attacking peach. All nectarines produced in the US are grown in California in the San Jaoquin and Sacramento Valleys. In 2012, 28,400 acres were grown, producing 229,000 tons valued at $142 million.[71,72,73] Fungal diseases vary seasonally between production regions and tend to be more severe in the northern San Joaquin and Sacramento Valleys where they represent major threats to production.[74]

Brown rot, blossom and twig blight, *Monilinia fructicola* (and occasionally *M. laxa*) is the most widespread and devastating fungal disease attacking twigs, blossoms and fruit[75] requiring at least two fungicide applications during bloom to prevent economic loss. In periods of high humidity, *M. fructicola*, often in combination with *Botrytis cinerea*, causes direct damage to fruit, as ripe fruit rot, which can be economically even more damaging than blossom infection and requires additional pre-harvest fungicidal applications during the last 4 weeks before harvest.[79] Brown rot on blossoms can also be manifested as jacket rot when *Monilinia* spp. *Botrytis cinerea* and/or *Sclerotinia sclerotiorum* attack the calyx. A single fungicide application during bloom that is effective against *B. cinerea* is necessary to prevent infection and shedding of immature fruit.[78]

In the northern San Joaquin and Sacramento Valleys, shot hole disease, *Wilsonomyces carpophilus,* causes significant losses to nectarine attacking buds, leaves and fruit. Damage is most severe in wet years and is accompanied by profuse gumming. Fungicide applications applied to dormant trees and during blossom are required to prevent infection.[68,82]

In more humid production regions in Northern California, powdery mildew, *Sphaerotheca pannosa,* is a major foliage and fruit disease, normally requiring 3 fungicide applications to prevent infection.[68,74, 75] In nectarine orchards adjacent to apple orchards, *Podosphaera leucotricha* may also cause economic damage on nectarine fruit.

Other fungal diseases of more sporadic occurrence which frequently require fungicide application in California nectarines are scab, *Cladosporium carpophilum*, requiring 2-3 applications post bloom[81] and rust, *Tranzschelia discolor*, requiring several spring post-bloom applications.[80]

6.2 Justification of How Metconazole Meets the Above Criteria

(I) There are insufficient alternative registered fungicides that are effective and registered for use

Wilsonomyces carpophilus, which causes shot hole disease of nectarines, is a serious threat to production in the northern San Joaquin and Sacramento Valleys, attacking buds, leaves and fruit[68,74,82] Effective control requires a dormant stage fungicide application at leaf fall to prevent twig infection, followed by additional applications at bloom and pre-harvest to prevent fruit loss.[82] Dormant sprays of multi-site fungicides such as chlorothalonil and ziram are effective, but these need to be followed by single-site, fungicides with differing modes of action from flowering through fruit development to prevent fruit loss and manage resistance. The pre-mix Pristine, (Group 11 and 7) provides excellent shot hole control at bloom and pre-harvest but its use must be rotated with another mode of action group and metconazole, Quash, (Group 3) is the only fungicide that provides good and reliable shot hole control.[83] Other Group 3 fungicides such as Indar, Tilt, Rally and premixes of Group 3 and other modes of action such as Adamant, Inspire Super, Luna Experience, Quadris Top and Quilt Xcel, provide only minimal and often ineffective shot hole control. Additionally, metconazole is the only Group 3 fungicide with activity against *Botrytis cinerea*, a causative agent in both jacket rot and ripe fruit rot of nectarine[84] Rotations during bloom and pre-harvest with metconazole (Group 3) and Pristine (Group 11, 7) are therefore the only alternatives available for shot hole control innectarines grown in northern California production areas, which will also control *Botrytis cinerea*. Metconazole also provides good and reliable control of rust and powdery mildew which can be serious sporadic pests in northern production areas while Group 11 fungicides and pre-mixes containing Group 11 fungicides are limited to single applications due to resistance concerns.[83] Multi-site fungicides such as chlorothalonil, captan and sulfur are used primarily to reduce the selection pressure on strobilurin (Group 11) and DMI-triazole (Group 3) fungicides which are the key elements in disease control. Rotations of Group 3 and Group 11 fungicides provide excellent control of most primary diseases of nectarine, but the continuing availability of metconazole, which is the only Group 3 active ingredient that provides good shot hole control and has activity against *Botrytis,* is essential to enable growers to control the key diseases of apricot and rotate fungicide modes of action effectively. Consequently, metconazole is listed as a recommended fungicide in current control programs for blossom, twig and fruit rot, powdery mildew, rust and jacket rot of nectarine in California.[84]

(II) Alternatives to Metconazole Pose a Greater Risk to the Environment and Human Health.

Recommendations for shot hole disease management call for applications of several multi-site fungicides as alternatives to Quash and Pristine.[82] These fungicides include Bordeaux mixture (M1), chlorothalonil (M5) and Ziram (M3) which are applied during the dormant season at high application rates when orchard maintenance operations such as pruning require extended worker exposure to treated trees. These materials, several of which are under regulatory scrutiny for potential impacts to human health, represent a significantly greater risk to human health than metconazole applications at low rates during bloom which provide equivalent control when workers are not present.

The multi-site fungicide, captan (M4) is widely used in nectarines after bloom to reduce selection pressure on single-site Group 3 and Group 11 fungicides for control of scab, ripe fruit rot and jacket rot. However, captan is highly toxic to honey bee larvae.[77] The use of captan as an alternative for metconazole therefore poses a significant increase in environmental risk to honey bees which are essential to nectarine production and are already facing critical threats from Colony Collapse Disorder.[80,68]

Recommendations for rust and powdery mildew control in California nectarines list multi-site sulfur (M2) including dry sulfur dust formulations as alternatives to single-site fungicides such as metconazole (Group 3).[80] Sulfur applications in orchards at high rates (up to 50 lb/acre) result in significant decreases in air quality and thus pose a greater threat to the environment and human health than single-site fungicides such as metconazole at low rates (2.5-4 oz/acre).

In addition, sulfur is listed as highly toxic to native strains of western predatory mite (*Galendromus occidentalis*) and parasites in California.[77] Predators and parasites are key elements in insect management programs in all stone fruit production areas and using captan as an alternative to single-site fungicides such as metconazole, is therefore likely to interfere with natural control of insect pests and result in greater use of synthetic insecticides, presenting an increased risk to the environment and disrupting IPM programs which are a high priority in California stone fruits.

(III) Metconazole Plays a Significant Role in Resistance Management.

High disease pressure, coupled with a pressing need to manage resistance, make continuing availability of efficacious fungicides with varied modes of action a pressing need for nectarine production in California.[74] DMI (Group 3) and strobilurin fungicides (Group 11) are key elements in managing brown rot and other important nectarine diseases. Resistance to both modes of action has been documented and a strict rotational program which avoids successive applications in the same mode of action group is essential to effectively manage resistance.[84] The most effective resistance management program in California nectarines involves rotations of DMI fungicides (Group 3) with strobilurins (Group 11) during bloom and pre-harvest applied as tank mixes with multi-site fungicides such as chlorothalonil to reduce selection pressure during periods of high pest pressure.[84] The superior efficacy of metconazole (Quash) compared to other Group 3 fungicides for peach diseases, occurring concurrently with brown rot, such as shot hole disease, jacket rot and fruit rot, clearly identifies metconazole as the essential Group 3 fungicide for effective resistance management programs.

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7.0 Justification for Metconazole Minor Use on Peach

7.1 Acreage, Production and Major Disease Problems

The US ranks 2nd in peach production worldwide with 117,630 acres planted in 2012, producing 1.2 million tons valued at $614.6 million.[88,91] In 2011, peaches were commercially produced in 28 states. California produces 72% of US peaches with 56% of the fresh market and 96% of processed peaches. The remainder, primarily fresh market, are grown in the Eastern United States with key epicenters in South Carolina, Georgia, New Jersey and the Upper Midwest.

Disease problems with fungal, bacterial and virus etiology vary in economic importance between production regions and are impacted by local climatic conditions. Fungal diseases represent major threats to production in all regions. High pest pressure from several key pathogens, coupled with an increasing need for effective resistance management, make availability of efficacious fungicides with varied modes of action imperative.[89]

Brown rot, blossom and twig blight, *Monilinia fructicola* (occasionally *M. laxa*) is the most common and devastating fungal disease attacking blossoms, fruit and twigs and causing significant losses in all production areas.[85,90,92] Jacket rot, caused by *Monilinia* spp., *Sclerotinia sclerotiorum* and *Botrytis cinerea* may also be present and require fungicidal control.[93]

In the Northern San Joaquin Valley, shot hole disease, *Wilsonomyces carpophilus* causes significant losses attacking buds, leaves and fruit. Damage is most serious in wet years and is accompanied by profuse gumming. Shot hole control requires fungicide application in dormant orchards and during bloom to prevent infection.[85,97] In the northern San Joaquin and Sacramento valleys, powdery mildew, *Sphaerotheca pannosa* which is favored by cool, moist nights and warm daytime temperatures, is also a key foliage and fruit pest[85,90,96] and normally up to 3 fungicide applications are needed to prevent infection. *Podosphaera leucotricha*, which is derived from inoculum produced in apple trees, may also cause powdery mildew infection in peaches[96] requiring treatment when peaches are grown in proximity to apples. Other fungal diseases which cause sporadic disease and frequently require fungicide applications in California orchards include peach rust, *Tranzschelia discolor* and scab, *Cladosporium carpophilum*.[85,94,95]

In eastern peach production regions, the primary fungal diseases are brown rot, *Monilinia fructicola*, peach scab, *Cladosporium carpophilum*, and powdery mildew, *Sphaerotheca pannosa*. Economic importance varies with production area and climatic conditions, but each of these diseases requires an almost season-long fungicidal program from petal fall until 4 weeks pre-harvest. "*Availability of disease control materials with sufficient range of activity to successfully manage disease in moist, disease-prone, eastern peach production areas*" was identified as a key pest management priority by industry and university specialists in 2005.[89]

7.2 Justification of How Metconazole Meets the Above Criteria

(I) There are insufficient alternative registered fungicides that are effective and registered for use.

Shot hole disease of peaches, *Wilsonomyces carpophilus*, is a serious threat to peach production in the northern San Joaquin and Sacramento valleys of California, attacking buds, leaves and fruit.[85,90] Control may require a dormant stage application at leaf fall to prevent twig infection followed by additional applications at bloom and pre-harvest to prevent fruit infection.[97] Dormant sprays of multi-site fungicides such as chlorothalonil or Ziram are effective, but these need to be followed by single-site fungicides with differing modes of action from bloom to harvest. The pre-mix, Pristine (Group 11 and 7) provides excellent shot hole control but its use should be rotated with another mode of action Group for resistance management.[86] Metconazole, Quash (Group 3), is the only fungicide available that provides good and reliable levels of shot hole control.[99] Other Group 3 fungicides such as Indar, Tilt, Rally and pre-mixes of Group 3 and other modes of action such as Adament, Inspire Super, Luna Experience, Quadris Top and Quilt Xcel, provide minimal and often ineffective shot hole control. Additionally, Quash is the only Group 3 fungicide with activity against *Botrytis cinerea*, a causative agent in both jacket rot and ripe fruit rot.[100] Rotations of Pristine and Quash (metconazole) are therefore, the only alternatives available for shot hole control on peach in Northern California production areas. Of these two fungicides, Quash also provides good and reliable control of peach rust which can be a serious pest in California.[85] Only Group 11, strobilurin fungicides, (where use is limited by resistance concerns) are available as rust control alternatives.[99]

A range of fungicides with differing modes of action are available for control of other major fungal diseases such as brown rot, scab and powdery mildew, which are serious threats in both California and eastern peach production areas.[89,90] Multi-site fungicides such as chlorothalonil and captan are used to minimize selection pressure on strobilurin (Group 11) and DMI-triazole (Group 3) fungicides which are the key components of commonly used fungicide programs on peach. The Group 3 and Group 11 fungicides provide excellent control of brown rot, scab and powdery mildew but resistance to both groups has been detected and the availability of metconazole (which also provides good shot hole control) is essential to enable modes of action to be rotated effectively. Metconazole is therefore listed as a recommended fungicide in current control programs for blossom and twig blight, brown rot, powdery mildew and rust of peach in California.[92,96,94]

(II) Alternatives to metconazole pose a greater risk to the environment and human health.

Some of the multi-site fungicides such as Bordeaux mixture (M1), chlorothalonil (M5) and Ziram (M3) are effective for shot hole management. However, application occurs during the dormant season at high application rates when extensive orchard maintenance operations (e.g., pruning and thinning) are taking place. Alternatively, shot hole control can be achieved with Quash by application at petal fall and pre-harvest when no workers are present and at greatly reduced rates. This practice poses less risk to the orchard workers.

Recommendations for rust and powdery mildew control in California peach orchards list multi-site, sulfur, including dry sulfur dust (Group M2) formulations at high rates (up to 50 lb/A) as key alternatives to single-site fungicides such as Quash (Group 3).[94,96] Sulfur applications in orchards result in significant increases in air quality risk and thus pose a greater risk to the environment than single-site Quash applications at low rates (2.5-4 oz/A). In addition, sulfur is listed as highly toxic to native strains of western predatory mite (*Galendromus occidentalis*) and parasites in California.[98] Predators and parasites are key elements in insect management programs in all stone fruit production areas and using captan as an alternative to single-site fungicides such as Quash is therefore likely to interfere with biological control of insect pests and result in greater use of synthetic insecticides, presenting an increased risk to the environment.

The multi-site fungicide captan is strongly encouraged for pre-harvest green rot and brown rot control in eastern peaches as an alternative to DMIs (Group 3) including metconazole.[89] However, captan is highly toxic to honeybee larvae.[98] Use of captan as a substitute for metconazole therefore represents a significant increase in environmental risk to honeybees and native pollinators, which are essential in peach orchards. Additional stresses to bee populations which are currently also facing critical threats from Colony Collapse Disorder should be avoided.[87]

(III) Metconazole plays a significant role in resistance management.

High disease pressure coupled with a pressing need for resistance management, make continuing availability of efficacious fungicides with varied modes of action a key need for stable and profitable peach production systems in both California and Eastern production regions.[89,90] DMI fungicides (Group 3) and strobilurin fungicides (Group 11) are important components in successful brown rot management. Resistance to both modes of action has been documented and a strict rotational program which avoids successive applications of fungicides with the same mode of action is considered essential to effectively manage resistance.[89] The most effective resistance management programs in both production regions involve the rotation of strobilurin and DMI fungicides during bloom and pre-harvest applied as tank mixes with multi-site fungicides such as chlorothalonil and captan to reduce selection pressure during periods of high disease pressure.[89,100] The superior efficacy of metconazole (Quash) compared to other Group 3 fungicides for peach diseases, which occur concurrently with brown rot such a shot hole disease and jacket rot,[99,100] clearly identify metconazole as the essential Group 3 fungicide for effective resistance management programs.

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8.0 Justification for Metconazole Minor Use on Plum

8.1 Acreage, Production and Major Disease Problems

California is the dominant producer of plums in the US with 141,300 tons valued at $78.4 million on 26,200 acres in 2010.[106] A few other states also produce plums commercially including Oregon, Idaho, Michigan and Washington and together these states raised 12,300 tons valued at $4.3 million.[106,101] There are two major growing regions in California, the San Joaquin Valley where 90% of production is centered and the northern region in the Sacramento valley.[87] In Oregon, plum production is centered in western Oregon and counties in the Willamette Valley.[103]

Brown rot, *Monilinia laxa* and *M. fructicola*, ripe fruit rot, *Monilinia fructicola* and *Rhizopus stolonifer* and powdery mildew, *Sphaerotheca pannosa* and *Podosphaera tridactyla* are the most common and devastating fungal diseases of plums in California.[110-112] Brown rot often does not require treatment in spring in California but several fungicidal applications are needed during the blossom and fruiting stages. Powdery mildew is a sporadic problem in California unless conditions promoting disease are prevalent. Shot hole disease, *Wilsonomyces carpophilus* is observed sporadically in California and control is necessary on susceptible cultivars.[114]

In the Pacific Northwest, brown rot, *M. fructicola* and leaf spot are the most commonly damaging fungal diseases,[103] with leaf spot identified as shot hole disease, *Wilsonomyces carpophilus.*[107] Rust, *Tranzschelia pruni-spinosae*, is also reported in Oregon as a leaf disease causing leaf drop in late summer although control measures are not usually necessary.[107]

In the southeastern United States, brown rot, blossom and fruit blight and scab, *Cladosporium carpophilium*, are the primary fungal diseases.[109]

8.2 Justification of How Metconazole Meets the Above Criteria

(I) There are insufficient alternative registered fungicides that are effective and registered for use.

Multi-site fungicides such as chlorothalonil, captan and sulfur are used on plums to reduce selection pressure on single-site fungicides which must be rotated between modes of action to avoid resistance buildup.[105] DMI-triazole (Group 3) and strobilurin (Group 11) fungicides are the key elements in disease control for blossom brown rot, ripe fruit rot and powdery mildew on plum and the continuing availability of both modes of action groups is essential to enable growers to rotate effectively. In California, 22 Group 3 fungicidal products are registered for brown rot and powdery mildew which would be expected to provide effective control of key pests unless shot hole disease was present.[114] However, in the Pacific Northwest, where shot hole disease is more prevalent,[107] metconazole is the only Group 3 alternative for rotations of modes of action that also provides good and consistent control of shot hole disease.[114] This efficacy is only reported in other stone fruit crops such as peach and nectarine as shot hole disease on plum is not an important concern in California. The importance of metconazole as a rotational alternative to Group 11 fungicides in brown rot and powdery mildew management programs on plums is increased significantly in the Pacific Northwest by the potential for strobilurin-induced phytotoxicity to apples in adjacent orchards. This can result from both drift and/or sprayer contamination,[115,107] and limits the availability and use of strobilurin rotational alternatives in areas where apples are the predominant fruit crop.

(II) Alternatives to metconazole pose a greater risk to the environment and human health.

In the Pacific Northwest metconazole is an important Group 3 fungicide for brown rot, powdery mildew and shot hole disease control. Alternatives to metconazole which are applied in late fall during dormancy and at bloom and post bloom[114] pose greater risks to both human health and the environment in several ways:

- Multi-site protectant fungicides such as Bordeaux and chlorothalonil, which have been implicated in human health concerns, are applied at high rates during dormancy, when orchard maintenance operations such as pruning require extended worker exposure to treated trees and thus pose a greater risk to human health than single-site, targeted sprays after bloom when worker exposure is minimal.

- Captan (M4) applied pre-harvest to reduce selection pressure on single-site fungicides is highly toxic to honeybee larvae.[113] Bees are essential in plum pollination and any additional stress may be detrimental to bee populations which are already facing critical threats from Colony Collapse Disorder.[104]

- Sulfur (M2) applied post bloom at high rates for shot hole disease, brown rot and powdery mildew control may result in significant decreases in air quality in and around orchards. In addition, sulfur is listed as highly toxic to native strains of western predatory mite (*Galendromus occidentalis*) and to parasites in California.[99] Predators and parasitoids are key elements in insect management programs in all plum production areas enabling IPM programs to switch to safer insecticides which reduce risk to human health and the environment. Using high rates of sulfur as alternatives to safer, single-site fungicides would decrease natural control and result in an increase in synthetic insecticide use, to the detriment of existing IPM programs.

- Topsin M (thiophanate-methyl), a benzimidazole, (Group 1) fungicide used as an alternative to metconazole in shot hole disease control in the Pacific Northwest and brown rot control in California is toxic to earthworms which are essential in decomposing leaf litter, a potential site for production of disease inoculum.[107]

(III) Metconazole Plays a Significant Role in Resistance Management

High disease pressure, coupled with a strong need to manage fungicide resistance, make the continued availability of effective fungicides with different modes of action that can be rotated a high priority[105] in all fruit production systems. Demethylation inhibitors (Group 3) and strobilurins (Group 11) are key single-site fungicides in managing brown rot, powdery mildew and shot hole disease in plum. This is particularly evident in the Pacific Northwest where shot hole is a greater concern. The limited effectiveness of Group 3 fungicides other than metconazole in controlling shot hole disease in other stone fruits,[115] make metconazole, which has excellent shot hole efficacy, the preferred Group 3 fungicide on plums. Concerns over potential phytotoxicity from Group 11 fungicides in adjacent apple orchards, which can occur from drift or sprayer contamination (limiting the utility of strobilurins as rotation alternatives), underscore the importance of metconazole in effectively managing fungicide resistance in plums.

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9.0 Justification for Metconazole Minor Use on Prune

9.1 Acreage Production and Major Disease Problems

Prunes are produced on over 56,000 acres. California is the dominant producer of prunes in the US with 55,000 acres in production in 2012 yielding 395,000 tons valued at $156.2 million which represents approximately 60% of world production.[119,118,116,122] Almost all California prunes are a single variety, Improved French Prune (*Prunus domestica*), with primary production centers in the San Joaquin and Sacramento Valleys. Prunes are also grown commercially in the Pacific Northwest with Oregon ranking second with approximately 2% of US production and Washington and Idaho producing smaller but locally significant amounts.

Several diseases may cause problems in prunes with the severity depending on the local weather and climatic conditions. Fungal diseases attack the foliage, twigs, blossom and fruit of prunes, with brown rot, *Monilinia laxa* and *M. fructicola* being the most severe in all production areas. *M. laxa* is the dominant fungus causing blight of blossoms and young fruit while *M. fructicola* is the primary cause of fruit rot.[119] Brown rot management is most effective when fungicides are applied from green bud to bloom. Although post-bloom and early spring applications are sometimes also applied, these have little impact on fruit infection.[130] Rust, *Tranzschelia discolor*, attacks foliage and occasionally fruit in prune orchards and is favored by wet conditions. Infection causes defoliation which can reduce yield significantly.[119,123] In the Pacific Northwest brown rot and rust are also serious threats to prune production, however, leaf spot (reported as shot hole disease), *Wilsonomyces carpophilus*, is also present and this disease influences fungicide selection significantly.[118,123-125]

9.2 Justification of How Metconazole Meets the Above Criteria

(I) There are insufficient alternative registered fungicides that are effective and registered for use.

Single-site fungicides are the key elements for disease control in prunes where fungicide applications for brown rot and rust, which are applied from budding to pre-harvest, provide effective control in most areas without the need for dormant sprays. Group 3 DMI triazoles and Group 11 strobilurins dominate grower choices but must be rotated to reduce resistance buildup.[121] In California there are sufficient materials to do this effectively. In the Pacific Northwest, however, where shot hole disease is a greater threat, most Group 3 fungicides are not effective alternatives since they do not provide adequate shot hole control. Metconazole (Group 3), which has excellent shot hole efficacy on other stone fruit crops[125] is an exception and is thus one of the few rotational alternatives available to growers. The importance of metconazole as a rotational alternative to the Group 11 fungicides in brown rot and rust control programs on prunes in the Pacific Northwest is increased further by the potential for strobilurin-induced phytotoxicity to apples, which can result from spray drift and/or sprayer contamination thus limiting the utility of Group 11 fungicides in rotational programs – an important consideration in the Pacific Northwest where apples are the predominant fruit crop.[125,124,133]

(II) Alternatives to metconazole pose a greater risk to the environment and human health.

In the Pacific Northwest metconazole is an important rotational tool for brown rot, rust and shot hole disease control on prunes. Alternatives to metconazole which are applied in dormancy and at bloom and post- bloom[125] pose greater risks to both human health and the environment in several ways:

- Protectant fungicides such as Bordeaux and chlorothalonil, which have been implicated as potential risks to human health, are applied at high rates during dormancy, when orchard maintenance and pruning require extended worker exposure to treated trees, posing a greater risk to human health than single-site, targeted sprays such as metconazole after bloom when worker exposure is minimal.

- Captan (M4) applied pre-harvest to reduce selection pressure on single-site fungicides such as metconazole is highly toxic to honeybee larvae.[129] Bees are essential in prune pollination and any additional stress may be detrimental to bee populations which are already facing critical threats from Colony Collapse Disorder.[119]

- Sulfur (M2) applied post bloom for shot hole disease, brown rot and rust control can result in significant decreases in air quality in and around orchards and increase risks to human health. In addition, sulfur is listed as highly toxic to native strains of western predatory mites (*Galendromus occidentalis* and parasites in California.[129] Predators and parasitoids are key elements in insect management programs in all prune production areas enabling IPM programs to switch to safer insecticides which reduce risk to human health and the environment. Using high rates of sulfur as alternatives to safer, single-site fungicides such as metconazole would decrease natural control and result in an increase in synthetic insecticide use – to the detriment of established IPM programs.

- Topsin M (thiophanate-methyl), a Group 1 fungicide, which is used as an alternative to metconazole in shot hole disease control in the Pacific Northwest and brown rot control in California, is toxic to earthworms which are essential in the orchard environment for their role in decomposing leaf litter and reducing potential disease inoculum sites.[125]

(III) Metconazole plays a significant role in resistance management.

High disease pressure coupled with a strong need to manage fungicide resistance make the continued availability of effective fungicides with different modes of action that can be rotated, a high priority[121] in all stone fruit production systems. Demethylation inhibitors (Group 3) and strobilurins (Group 11) are key single-site fungicides that are effective in rotations for managing brown rot, shot hole disease and rust in prunes. This is particularly important in the Pacific Northwest where shot hole disease is a greater concern. The limited effectiveness of Group 3 fungicides other than metconazole in controlling shot hole disease in other stone fruits,[125] make metconazole, which has excellent shot hole efficacy, the preferred Group 3 fungicide for rotational programs to manage resistance. Concerns over potential phytotoxicity from Group 11 strobilurins in adjacent apple orchards, which can result from drift and/or sprayer contamination and limit the utility of strobilurins as rotation alternatives, underscore the importance of metconazole (the only Group 3 fungicide with shot hole efficacy) in effectively managing fungicide resistance with rotation in prunes.

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10.0 Justification for Metconazole Minor Use on Low- and Highbush Blueberry

10.1 Acreage, Production and Major Disease Problems

Blueberries are the fruit of various scrubby (low bush) and bushy (high bush) plants in the genus *Vaccinium*. Wild blueberries are found wherever suitable conditions exist with acidic, moist soils which are generally in the northern US from New England to Lake Superior. Cultivated blueberries are hybrids of 2 native species, the high bush, *V. corymbosum* and the low bush, *V. augustifolium*.

Detailed individual production data are not available for low bush and high bush blueberries and thus data is presented for all types. The US is the world's largest producer of blueberries with 564.4 million pounds harvested in 2012 on over 31,000 acres. Nearly 84% of the harvest consists of cultivated blueberries.[142]

The North Central region ranks first in US blueberry production with Michigan producing 93 million pounds (33% of US total) from 18,500 acres valued at $168.1 million in 2007.[145] Other important production states include Oregon (6,100 acres), Washington (5,200 acres), New England (1,400 acres) and Indiana (539 acres). New Jersey, North Carolina, Georgia and Florida also have significant blueberry production. Maine is the leading producer of "wild" low bush blueberries with 91.1 million pounds.[143,145]

Blueberries are very susceptible to infection from a broad range of fungal diseases which cause serious yield losses, even in treated fields.[145] The fungal diseases of blueberry are problems across all production areas of the US, but severity and yield loss can vary with region and climatic conditions. The most serious diseases attack the fruit. Mummy berry, *Monilinia vaccinii-corymbosi*, is the most destructive in all areas, attacking pre-bloom and during bloom causing fruit to shrivel and drop from plants, killing new growth and impacting successive seasonal yields. Losses in Michigan are 75% of fruit and 75% of shoots if untreated. In Oregon/Washington and in the New England states 100% fruit loss can occur in untreated fields. Soil treatments to over-wintering mummy berry stages are not effective and fungicides must be applied from pre-bloom through fruit development to avoid loss.

Fruit rot caused by anthracnose, *Colletotrichum acutatum*, or *C. gloeosporioides* is the most important fungal threat on ripe fruit and is the primary contributor to high microbial loads in processed fruit. Although manifested only on fruit, the fruit rot pathogens must be controlled with fungicides throughout bloom and fruit development. Likewise, Alternaria fruit rot, *Alternaria tenuissima*, a serious fruit pest in all areas, causes ripe fruit to leak after harvest but the pathogen infects during bloom and fruit development and fungicide sprays must be applied during those periods to achieve control. Botrytis blight, *Botrytis cinerea*, also attacks ripe fruit, causing serious losses and also infects during bloom and must be managed with fungicides applied from bloom through fruit development.

A number of serious fungal diseases also attack the blueberry plant and foliage causing losses through twig and stem cankers and/or leaf infection leading to defoliation, all of which can reduce yield. These diseases include: Phomopsis twig blight, *Phomopsis vaccinii*, infecting shoots causing cankers which reduce yield and can infect over an extended period, requiring several fungicide applications; Fusicoccum canker, *Fusicoccum putrefaciens*, infecting young plants which is managed with fungicides applied pre-bloom; and the foliage diseases, powdery mildew, *Microsphaera vaccinii*, and leaf rust, *Naohidemyces vaccinii*, which are sporadic in occurrence but reduce yield by impacting photosynthesis and only require management when infection is widespread.[145-147]

10.2 Justification of How Metconazole Meets the Above Criteria

(I) There are insufficient alternative registered fungicides that are effective and registered for use.

The extremely broad range of fungal diseases which can attack blueberry plants, foliage and fruit can cause serious yield losses in all growing areas and must be managed with multiple fungicide applications applied over extended periods -

from pre-bloom through bloom, fruit development, ripening and foliar disease after harvest. These fungicide programs were historically highly dependent on broad spectrum fungicides such as benomyl (active ingredient in Benlate) thiophanate-methyl (active ingredient in Topsin M), sulfur, captan and chlorothalonil, but in recent years many of these materials have been withdrawn or come under close regulatory scrutiny and the emphasis has now switched to newer, single-site fungicides (PMSP for the North Central Region Blueberry Industry, 2008). Several single-site fungicides are now available with active ingredients exhibiting differing modes of action and multiple pre-mixes and/or tank mix choices are now available to growers.[136]

However, the differing efficacy spectra of each fungicide against the key disease problems on blueberry and the need to rotate modes of action and limit the number of applications of each group to manage resistance, severely limits the actual number of fungicide alternatives available to growers that will provide both effective control of blueberry diseases and reduce resistance development.

The Group 3, DMI fungicides comprise the majority of single-site fungicides registered on blueberry.[136] Of these, propiconazole is the most widely represented active ingredient with 7 products registered (Orbit, Tilt, Bumper, Topaz, Propimax, Shar-shield and Amtide Propiconazole), while metconazole (Quash), fenbuconazole (Indar) and tetraconazole (Mettle) active ingredients each have a single product registration. The most recent fungicide efficacy reports from the Southeast,[13420] New Jersey,[144] Michigan[140,141] and Oregon[137] list the differential efficacy of the Group 3, DMI fungicides. All provide moderate to good or excellent control of mummy berry, Phomopsis twig blight and rust. However, only Quash, metconazole, also provides effective control of anthracnose fruit rot and Alternaria fruit rot, two of the most serious fruit diseases of blueberry. Based on this efficacy distinction, blueberry growers have no fungicide alternatives in the Group 3 mode of action class that are effective on all the key blueberry diseases.

Multiple-site fungicides such as chlorothalonil (M5), captan (M4) and Ziram (M3) provide some control of anthracnose and *Botrytis* but are not effective against the most destructive disease, mummy berry, *Alternaria* or Phomopsis twig blight. Thus, these materials are primarily used as tank mix or rotational partners for resistance management rather than primary fungicidal alternatives control agents.

Single-site fungicides from other mode of action classes such as the strobilurins, Group 11 (Abound) provide effective anthracnose, *Alternaria* and Botrytis fruit rot control, but do not control Phomopsis twig blight and are only moderately effective against mummy berry. Pre-mixes of Group 11 strobilurins with other single-site fungicides such as Pristine (11 + 7) and Quilt (11 + 3) broaden the efficacy spectrum but the need to rotate Group 11 fungicides[138] to avoid resistance limits the effectiveness of these pre-mixes in multiple application fungicide programs. Other single-site mode of action classes such as Elevate (Group 17) and Switch (9 + 12) provide alternatives for resistance management but do not provide efficacy against some of the key blueberry diseases such as mummy berry (Switch) and anthracnose (Elevate).

In conclusion, single-site fungicides now play an increasingly key role in blueberry disease management. Furthermore, the broader efficacy range of metconazole, compared to other Group 3 fungicides and the need to rotate mode of action classes of other single-site fungicides to avoid resistance, clearly demonstrate that there are insufficient registered alternatives to metconazole.

(II) Alternatives to metconazole pose a greater risk to the environment and human health.

Although single-site fungicides now play an increasingly prominent role in blueberry disease management, the lower cost of multi-site fungicides and their important role in resistance management continues to promote the extensive use of multi-site fungicides in blueberry. These alternatives to reduced risk, single-site fungicides such as Quash, metconazole, pose significant increased risks to the environment and human health:

- Captan is a recommended alternative for multiple applications from early bloom through petal fall for Botrytis flower blight in both Oregon[137] and in the Southeastern region.[134] Captan is applied at high rates (up to 5 lb/A per application and 70 lb per crop year) compared to metconazole (2.5 oz/A, with no more than 7.5 oz per crop year) and these sprays are during the period when honeybees are most active and providing pollination which is required for fruit set in blueberry.[145] Captan is highly toxic to honeybee larvae in other pollinated crops[148] and thus represents a significantly increased risk to honeybees and native pollinators in the environment compared to single-site fungicides such as metconazole, which provides good Botrytis management without risk to bees. This risk to pollinators is particularly serious at this time when honeybees are facing critical threats from Colony Collapse Disorder.[139]

(III) Metconazole plays a significant role in resistance management.

The blueberry industry faces an annual threat of serious yield loss from fungal diseases that impact fruit such as mummy berry, Botrytis fruit rot, Alternaria rot and anthracnose fruit rot. These diseases infect developing and ripening fruit over extended time periods and require multiple-application fungicide programs to avoid crop loss. In recent years, these fungicide programs have become increasingly reliant on single-site mode of action fungicides. Of these single-site fungicides, Group 3 fungicides predominate, with the propiconazole active ingredient being available in the most registered products.[136] However, metconazole (Group 3, Quash) is the only effective active ingredient for all the major blueberry fruit diseases and this active ingredient is thus an essential component for fungicide programs which can provide control of the major diseases and effective resistance management in multiple application programs. The most effective fungicide resistance management programs would include metconazole in rotation with other single-site modes of action (Group 11 or 17). Products and pre-mixes with other Group 3 active ingredients should only be used when they target specific disease where they can provide effective control without compromising resistance management. Multi-site fungicides such as chlorothalonil, captan and Ziram would be most effective as tank mix partners and in rotations to reduce selection pressure on single-site fungicides

10.3 References:

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137. DeFrancesco, J., J. Pscheidt and W. Yang, 2013. Pest Management Guide for the Willamette Valley. EM 8538, Oregon State University.

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145. Pest Management Strategic Plan for the North Central Region Blueberry Industry, 2008. http://www.ipmcenters.org/pmsp/pmsp_form.cfm?usdaregion=National%20Site

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147. Ramsdell, D., 1996. Blueberry Diseases in Michigan, Michigan State University, Extension Bulletin E-1731.

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11.0 Justification for Metconazole Minor Use on Gooseberry

11.1 Acreage, Production and Major Disease Problems

Gooseberries of American, *Ribes hirtellum,* and European, *Ribes uva-crispa*, origin were grown commercially in North America until the 1920s with approximately 7,400 acres (gooseberries and currants). Production was centered in the middle Atlantic, upper Midwest and Northeast states with scattered production across the northern half of the country.[149] New York was the leading producer with about 500 acres of gooseberries and currants. North American production was essentially halted in the early 1900s when white pine blister rust was introduced and, when *Ribes* species were implicated as hosts of this serious pine disease, federal and state laws were enacted to prohibit *Ribes* production. These laws were later repealed but some states and counties still prohibit commercial production. No statistical record of gooseberry production is available from recent years, but following the development of resistant varieties, and the demonstration that the link between *Ribes* and white pine blister rust was minimal, gooseberry production has become re-established in states across the US and demand for this specialty crop is increasing.

Several fungal diseases attack gooseberries with infection occurring over extended periods, attacking both foliage and fruit, and resulting in serious yield loss.[157] Anthracnose leaf spot, *Drepanopeziza ribis* attacks both leaves and fruit reducing yield and no resistant varieties are available. Powdery mildew, *Sphaerotheca mors-uvae*, Septoria leaf spot, *Mycosphaerella ribis* and Botrytis fruit rot, *Botrytis cinerea*, are also season-long threats that infect leaves causing defoliation and, if not controlled, causing fruit drop and ripe fruit infection. Due to the extended period of infection and damage, the primary management options include both cultural approaches using resistance and sanitation and chemical controls using and single-site fungicides, predominately Group 3.[159]

11.2 Justification of How Metconazole Meets the Above Criteria

(I) There are insufficient alternative registered fungicides that are effective and registered for use

The fungal diseases attacking gooseberries have extended infection periods which require multiple applications to avoid loss.[157] The registered fungicides available for gooseberry growers are greatly reduced in comparison to other, larger acreage small fruits such as blueberry.[151] Multiple-site fungicides commonly used for disease control and resistance management in small fruit crops such as chlorothalonil, captan and Ziram are not registered and only sulfur is available as a multiple-site rotation partner for single-site fungicides. DMI, Group 3 fungicides are the predominant single-site materials registered on gooseberry. Propiconazole is the most widely available Group 3 active ingredient with 5 registered products (Topaz, Bumper, Propimax, Orbit and Tilt). Metconazole (Quash) and tetraconazole (Mettle) are the only other Group 3 active ingredients registered.

No efficacy data are available specifically for gooseberry but the key diseases, anthracnose leaf spot, powdery mildew, Botrytis fruit rot and Septoria leaf spot, are also present in blueberry and fungicide efficacy tables for blueberry from the Midwest,[155,156] New Jersey,[158] the Southeast[150] and the Pacific Northwest[152] can be used to accurately predict efficacy against the same pathogens on gooseberry. Although 7 Group 3 fungicides are registered on gooseberry, the varying spectra of efficacy of each against the key diseases of gooseberry, and the need to rotate modes of activity to avoid resistance, severely limits fungicide alternatives for gooseberry growers. All Group 3 active ingredients provide good powdery mildew and Septoria leaf spot control, but only metconazole (Quash) also provides good efficacy against anthracnose leaf spot, a primary disease of gooseberry. Quash is also the only Group 3 material that provided effective Botrytis fruit rot control across production areas (Indar, fenbuconazole, is listed as effective on *Botrytis* in blueberries in New Jersey but is not labeled for gooseberries). Single-site fungicides from other mode of action groups such as the strobilurins, Group 11, (only Abound is registered) are effective against *Botrytis* and pre-mixes of activity classes such as Pristine (Group 7+11), Switch (Group 9+12), and Quilt (Group 11+3) broaden the activity spectra of single-site materials but the need to rotate modes of action to avoid resistance[154] limits their availability as alternatives. Metconazole (Quash) is thus the only fungicide that provides efficacy against all key gooseberry diseases while allowing growers to rotate other modes of action to avoid resistance.

11.3 References:

149. Barney, D., 2000. Commercial Production of Currants and Gooseberries in the Inland Northwest and Inter-mountain West of the US: Opportunities and Risks, Hortechnology. 10 (3), 557-561p.

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155. MSU Extension Fruit Management Guide. 2013. Michigan State University , Extension Bulletin, E-154. 2013.

156. Longstroth, M. 2013. Blueberry Bloom Disease Management. http://blueberries.msu.edu/uploads/files/bb_bloom_disease_management_2013.pdf

157. Mid-Atlantic Berry Guide, 2013-14, Chapter 9, Gooseberries and Currants.

158. Oudemans, P., 2013. Commercial Blueberry Pest Control Recommendations for New Jersey, 2013. http://njaes.rutgers.edu/pubs/publication.asp?pid=e265

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12.0 Justification for Metconazole Minor Use on Hazelnut

12.1 Acreage, Production and Major Disease Problems

Oregon grows 99% of the US hazelnut crop with the remainder grown in Washington. In 2012, Oregon produced 34,700 tons of hazelnuts on 29,000 acres located in the Willamette Valley valued at $63.4 million. The US ranks 3rd in world production with 7% of the total crop following Turkey (80%) and the European Union (13%).[162,160]

Eastern filbert blight disease (EFB), *Anisogramma anomala*, is the most damaging and widespread disease of hazelnuts and, if uncontrolled, can cause significant economic loss with most trees eventually killed above the soil line. Fungicides must be used to protect susceptible tissue from bud break in the spring through at least the next 8 weeks, with a minimum of 4 applications.[161,163,164] Other foliar diseases such as powdery mildew infect hazelnuts sporadically but are normally controlled by the EFB control program.

12.2 Justification of How Metconazole Meets the Above Criteria

(I) There are insufficient alternative registered fungicides that are effective and registered for use.

Because of fungicide resistance concerns and resulting label requirements growers must rotate and/or tank mix fungicides with different modes of activity.[154] Four mode of action Groups, 3, 11, M5 and M1 are available for this strategy on hazel nuts.[161,163] Pre-mixes of single-site fungicides are not recommended in Oregon (Olsen, 2013) since only one of the active ingredients in the pre-mix is effective and those active ingredients are available as standalone fungicides. These pre-mixes include Luna Privilege (Group 7 ineffective), Luna Experience (7+3, only Group 3 is effective) and, Pristine (7+11, only Group 11 is effective). The effective, single-site, standalone fungicides in Group 3 are: Propiconazole (Bumper, Propi-Max, Tilt/Orbit); tebuconazole (Tebuzol): and metconazole (Quash). The products containing propiconazole (Bumper, Propi-Max, Tilt/Orbit) result in smaller, thicker, greener leaves and shortened inter-nodes on treated trees[163] and although trees generally grow out of this condition after applications are completed, growers are more likely to choose Group 3 active ingredients metconazole (Quash) or tebuconazole (Tebuzol) as effective alternatives which do not result in physiological tree impacts. The most effective single-site fungicides in Group 11, Gem and Cabrio, (Abound effectiveness rated at only fair – good), together with multi-site chlorothalonil (M5) and copper (M1) formulations, provide good alternatives for mode of action rotations with Group 3, metconazole (Quash) and tebuconazole (Tebuzol). Of these two, Group 3 alternatives, the 25 day PHI for Quash (versus 35 for Tebuzol), the ability to use a silicone based surfactant (recommended for most fungicides in an EFB program) with Quash and the significantly lower product application rates for Quash (3.5 oz/A versus 8.0 oz/A), make metconazole a preferred alternative in EFB programs on hazelnuts.

12.3 Reference:

160. Agricultural Marketing Research Center, 2013, Hazelnuts. http://www.agmrc.org/commodities products/nuts/hazelnuts/

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13.0 Justification for Metconazole Minor Use on Macadamia nuts

13.1 Acreage, Production and Major Disease Problems

Macadamia nuts are grown solely in Hawaii with 95% of production on the island of Hawaii. Hawaii is ranked second in world production to Australia with 15,000 acres producing 22,000 tons valued at $35.2 million in 2012.[167]

Macadamia nuts in Hawaii are relatively free of pests compared to the rest of the world and it is considered a high pest management priority to maintain strict control over the pests that do cause problems and exclude exotic pests that could be introduced.[166,165] Only two fungal diseases attack macadamia trees: raceme and blossom blight, *Phytophthora capsici*, infects during the flowering stage and attacks all flowering stages and developing nuts; and raceme blight, *Botrytis cinerea*, attacks primarily racemes and can destroy flowers. Both fungi are present at low levels in orchards and can quickly reach epidemic proportions during periods of rainfall, cool temperatures and foggy conditions.

13.2 Justification of How Metconazole Meets the Above Criteria:

(I) There are insufficient alternative registered fungicides that are effective and registered for use.

Although fungicide use on macadamia nuts is generally low, the blossom and raceme blights can quickly reach epidemic proportions and effective fungicide alternatives must be available to avert crop loss. Of the multi-site fungicides, only sulfur and copper are registered and neither provides effective control of the fungal blights.

The strobilurin, Group 11, fungicide, azoxystrobin (Abound) and pre-mixes containing Group 11 active ingredients (Pristine, Group 7+11 and Quilt, Group 3+11) are registered and provide effective control of *Phytophthora capsici*, but do not control *Botrytis cinerea*. Group 3 fungicides which are registered on macadamia nuts with the propiconazole active ingredient (Bumper, Tilt, Topaz and Quilt pre-mix) do not control *Phytophthora* or *Botrytis*. Metconazole (Quash) is the only Group 3 fungicide with good efficacy against *Botrytis cinerea* in other cropping systems such as stone fruits and it thus represents a valuable addition to the macadamia fungicide inventory for Botrytis control with no other registered alternatives.

13.3 References:

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166. Pest Management Strategic for Macadamia Nut Production in Hawaii, 2006. http://www.ipmcenters.org/pmsp/pmsp_form.cfm?usdaregion=National%20Site

167. National Agricultural Statistics Service, 2010-2012, Non-citrus Fruits and Nuts.

14.0 Justification for Metconazole Minor Use on Pistachio

14.1 Acreage, Production and Major Disease Problems

Pistachio trees, *Pistacia vera*, were introduced into the US in 1854 and developed rapidly into an important commercial industry after 1976. Ninety-eight percent of US pistachios are grown in California with 444 million pounds from 178,000 acres valued at $879.1 million in 2012.[172,168,176] Other states raising pistachios include Arizona, Nevada, New Mexico, Texas and Utah. The US, with 24% of total production, is the 2nd leading producer of pistachios in the world behind Iran.

Several fungal diseases attack pistachios and can cause serious yield reduction. Botryosphaeria panicle and shoot blight, *Botryosphaeria dothidea* attacks all current season growth and kills buds, shoots and fruit clusters. Although trees are not killed, infected trees are completely unproductive. The disease is especially damaging to the widely planted cultivar "Kerman". Control is difficult, requiring multiple fungicide applications from bloom throughout the growing season.[177,171, 179] Botrytis blossom, shoot and fruit blight, *Botrytis cinerea* also reduces yield in pistachio, infecting trees early and killing shoots and flowers. Control is achieved with early season fungicide application.[175] Alternaria late blight, *Alternaria alternata*, attacks fruit and leaves but primary damage is to leaves which shed early causing debilitating defoliation and yield reduction. Damage is most severe in wet conditions. At least 3 fungicide applications are recommended to obtain control.[174] Powdery mildew, *Oidium* sp., can also be a problem, particularly on Trabonella and Red Aleppo cultivars, causing leaves to yellow and die and fruit to become misshapen but its occurrence is sporadic and control measures are not normally necessary.

14.2 Justification of How Metconazole Meets the Above Criteria

(I) There are insufficient alternative registered fungicides that are effective and registered for use

Two of the most damaging fungal pathogens of pistachio, *Botryosphaeria* and *Alternaria* infect trees over extended periods, requiring multiple applications of fungicides. Botrytis blossom and shoot blight can be equally damaging but 1-2 early season sprays are normally sufficient to obtain control. In multiple fungicide application programs, pistachio growers must balance the need to control all major diseases with the need to manage resistance. Because of these requirements, the differential efficacy spectra of fungicidal active ingredients is critical and the seemingly broad availability of fungicides,[169] is reduced drastically.[171,173]

Multi-site fungicides such as chlorothalonil, copper and sulfur do not provide effective control like primary fungicides and heavy reliance is placed on single-site fungicides.[176]. All available materials provide moderate to good or excellent control of Alternaria late blight and Botryosphaeria panicle and shoot blight, but differential efficacy against Botrytis blossom and shoot blight severely limits fungicidal choices when the need to rotate modes of action to manage resistance[170] is considered. The strobilurins (Group 11) used alone (Abound, Cabrio and Gem) do not control Botrytis blossom and shoot blight. Of the registered Group 3 fungicides only metconazole, Quash, provides good Botrytis control while Bumper/Tilt and Tebuzol control of Botrytis is limited and/or erratic. Combining Group 3 with Group 11 in pre-mix formulations broadens the efficacy spectrum for Adament to pick up Botrytis control (but only moderate and variable control of other diseases) and does not provide any Botrytis control with Quadris Top or Quilt Xcel.

Since the two key modes of action, Group 11 and Group 3, (and pre-mixes of theses), must either be limited in total applications to manage resistance or do not provide effective control of all key diseases, metconazole is an essential component of disease management on pistachio with limited alternatives. Of the remaining single-site fungicidal modes of action available for growers, the only alternatives to metconazole and pre-mixes containing Group 11 (limited to 2 applications/season) or Group 3, which will control all key diseases on pistachio are Group 9 (Scala) or Groups 9 + 12 (Switch), Group 19 (Ph-D) and Group 7 (Fontelis). Given the need to use multiple fungicide applications of different modes of action that will protect pistachio throughout its growth cycle (i.e., dormancy to fruit maturation), metconazole is a critical component of effective disease and resistance management.

14.3 References:

168. Agricultural Marketing Resource Center 2013. http://www.agmrc.org/commodities products/nuts/pistachios/

169. CDMS Label Search, Pistachios, California, 2013. http://www.cdms.net

170. Fungicide Resistance Action Committee 2013. http://www.frac.info

171. Fungicides, Bactericides and Biologicals for Deciduous Tree Fruits, Nut, Strawberry and Vine Crops, 2013. Statewide IPM Program. http://www.ipm.ucdavis.edu/PDF/PMG/fungicideefficacytiming.pdf

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176. UC Davis, Pest Management Guidelines, Pistachio, General Properties of Fungicides Used on Pistachios, 2010. http://www.ipm.ucdavis.edu/PMG/r605900211.html

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178. UC Davis Pest Management Guidelines, Pistachio, Powdery Mildew, 2009. http://www.ipm.ucdavis.edu/PMG/r605100711.html

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15.0 Qualification for Extension of Exclusive Data Use

FIFRA Section 3(c) (1) (F) (ii) allows for the extension of the period of exclusive data use by one additional year for each three minor uses registered within seven years of the initial registration up to a total of three additional years provided that:

(I) there are insufficient efficacious alternative registered pesticides available for the use;
(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;
(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or
(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

Table 1 summarizes the minor crops on which metconazole was registered during the first seven years after initial registration. Table 2 shows and the above text explains how each of the minor crops meets one or more of the above criteria.

(I) *There are insufficient efficacious alternative registered pesticides available for the use.*

There are 13 minor crops that qualify for the extension of metconazole exclusive data use. Despite the number of triazole fungicides already registered, Quash entered crowded disease control markets and established itself as an important part of many disease control programs. This success is due to Quash's high level of activity on a broad range of diseases and low use rates. In particular, metconazole is unique among triazoles for its activity against diseases caused by *Botrytis cinerea* (jacket rot/green fruit rot) and *Wilsonomyces carpophilus* (shot hole).

These diseases are extremely common and devastating to many crops. Extending the spectrum of activity for any Group 3 fungicide to include these diseases is one of the reasons why metconazole is so important to disease control programs.

(II) *The alternatives to the minor use pesticide pose greater risks to the environment or human health.*

Metconazole is highly effective at low doses on a broad spectrum of diseases. Several alternatives to metconazole pose greater risks to the environment, either directly or indirectly. For example, without Quash bloom sprays, applications of other products, at higher rates, are necessary during periods of high worker activity. Consequently, worker exposure is dramatically increased. In other cases, alternatives to metconazole are more toxic to honey bees and earthworms or cause an imbalance in mite predators. Finally, metconazole is highly active at low doses, introducing less fungicide into the environment than other active ingredients.

(III) *The minor use pesticide plays or will play a significant part in managing pest resistance.*

Many uses of metconazole result in better management of fungicide resistance. For example, many fungicides come pre-mixed as two active ingredients. The University of California Guidelines for specialty crops list 12 premix fungicides, 8 of which contain a strobilurin (Group 11). Often, one of the active ingredients is ineffective against the target disease, either due to resistance or inherent inactivity. Use of multiple active ingredients in a premixed product often unintentionally promotes or maintains resistance in the fungal population. Metconazole is sold as a single active ingredient in Quash Fungicide, allowing growers to use it strategically when and where it is needed rather than automatically being applied along with another active ingredient in a premixed product. Furthermore, Group 3 fungicides have been used since the late 1950s without developing pathogen resistance in all but a few pathosystems. Meanwhile, strobilurin fungicides, in use since the 1990s, have far greater resistance problems. Group 3 fungicides continue to be an important part of effective disease and resistance management programs.

16.0 Conclusions

The registration of metconazole on 13 minor crops meets and exceeds the criteria for granting a three-year extension of the exclusive data use period. This qualifies the exclusive use period from September 27, 2017 to September 27; 2020. Metconazole controls many economically important diseases on many minor crops. In addition, it has a broader disease spectrum and lower use rates than other Group 3 fungicides. Alternative protectant fungicides are used at much higher rates and pose risks to the environment, worker safety and beneficial organisms. Quash's single mode of action allows for strategic placement in disease control programs without unnecessarily applying a second active ingredient when not necessary (as in premix products). A broader disease spectrum, low use rates, combined with less impact on worker safety and beneficial insects than its alternatives, makes metconazole an important tool for disease control, resistance management and environmental stewardship.

17.0 Appendix 1

Brand Names of Fungicides with Active Ingredient and FRAC Code

Brand Name	Active Ingredient	Percent A.I.	FRAC Code
Indar	Fenbuconazole	23.5	3
Tilt	Propiconazole	41.8	3
Rally	Myclobutanil	40	3
Gem	Trifloxystrobin	25	11
Cabrio	Pyraclostrobin	20	11
Abound	Azoxystrobin	22.9	11
Adament	Trifloxystrobin Tebuconazole	25 25	11 3
Inspire Super	Difenoconazole Cyprodinil	8.4 24.1	3 9
Luna Experience	Fluopyram Tebuconazole	17.6 17.6	7 3
Quadris Top	Azoxystrobin Difenoconazole	18.2 11.4	11 3
Quilt Xcel	Azoxystrobin Propiconazole	13.5 11.7	11 3
Pristine	Boscalid Pyraclostrobin	25.2 12.8	7 11
Luna Sensation	Trifloxystrobin Fluopyram	21.4 21.4	11 7
Tebuzol	Tebuconazole	38.7/45	3
Elite	Tebuconazole	45	3
Bumper	Propiconazole	41.8	3
Scala	Pyrimethanil	54.6	9
Fontelis	Penthiopyrad	20.4	7
Switch	Cyprodinil Fludioxonil	37.5 25	7 12
Luna Privilege	Fluopyram	41.5	7