US Environmental Protection Agency
Office of Pesticide Programs

Exclusive Use Extension Request Response Letter for Metconazole

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

1/20/2015

Sue-Chi Shen
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Subject: Metconazole Fungicide Technical
Exclusive Use Period Extension Request For Data Protection
EPA Reg. No. 72078-1; Decision Number 486438
Establishment of New Three Year Period Through September 28, 2020

Dear Ms. Shen:

This is in response to your request dated December 27, 2013 that data associated with the September 28, 2007 original registration of the active ingredient metconazole, receive a three-year extension for the original ten-year exclusive use protection period from September 28, 2017 to September 28, 2020.

You cited FIFRA section 3(c)(1)(F)(ii) as the authority for the Agency to make such a determination. The 1996 Food Quality Protection Act (FQPA) amendments to FIFRA incorporated this new subsection under 3(c)(1)(F), the section that provides for protection of certain data submitted in support of pesticide registrations. FIFRA section 3(c)(1)(F)(ii) sets forth the criteria for extending the period of exclusive use protection. The period of exclusivity can be extended one year for every three qualifying minor uses registered within the first seven years of an original registration whose data retains exclusive use protection, with a maximum addition of three years to the original ten-year exclusivity period.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain which data have exclusive use protection. FIFRA section 3(c)(1)(F)(i) and its implementing regulations carefully circumscribe the set of data that is eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 CFR §152.83(c).

Pursuant to 40 CFR §152.83(c), the following requirements must be met for a study to be considered an exclusive use study:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;

(2) The study was submitted in support of, or as a condition of approval of; the application resulting in the first registration of a product containing such new

(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); and a study is an exclusive use study only during the 10-year period following the date of the first registration.

The following is our analysis for determining whether the data associated with the registration you have cited contains exclusive use data.

First, the data associated with this registration do pertain to, or have been derived from testing on, a new active ingredient that was first registered after September 30, 1978.

Second, the data must have been submitted in support of the first registration of the new chemical.[1] The registration cited was granted on September 28, 2007, and was the first registration for metconazole with the product name Metconazole Fungicide Technical.

Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B).

Data generated by IR-4 are not entitled to exclusive use protection (see 40 CFR 152.94(b)). However, the Agency will count minor uses supported by IR-4 generated data when determining how many additional years that exclusive use protection may be extended.

Although, EPA has determined that there are exclusive use protected data associated with this registration, the Agency has not made individual determinations on every study associated with the above referenced registration as to the exclusive use protection. If the Agency receives a me-too application for this pesticide during the extension period citing Kureha Corporation data, it will then address which of those data have the extension of protection. Therefore, this response is a general determination that the exclusive use studies associated with this registration will receive the determined extension of exclusive use protection.

After determining that there are exclusive use data associated with this registration, EPA analyzed whether: (1) minor uses have been registered within seven years of the original registration and (2) at least one of the following required criteria were satisfied for extending the exclusive use protection pursuant to FIFRA section 3(c)(l)(F)(ii), states, in pertinent part:

> "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

[1] Data are not protected solely because they pertain to the new chemical, but because they are submitted in support of a particular product registration of a new chemical. Thus, data submitted to support an application for the second (and later) registrations, by whatever applicant, of a product containing the same new chemical acquire no exclusive use protection. Additionally, data submitted in support of subsequent amendments to add new uses to the first registration of a product containing the new chemical gain exclusive use protection, but the protection is limited to data that pertain solely to the new use. Thus, for example, if the new use is approved after eight years of registration, the data supporting that use would gain exclusive use protection for only two years or the remainder of the original 10-year exclusive use period. See 49 FR 30884, 30889.

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."

Kureha Corporation submitted information on 13 minor use crops even though only nine are needed to qualify for the three year extension. The Agency looked at a subset of uses and determined that the following nine minor uses were registered within seven years of the original registration of Metconazole Fungicide Technical:

blueberry, cheery, gooseberry, hazelnut, nectarine, peach, pistachio, plum, and prune.

EPA's assessment concludes that these nine minor uses substantiate the determination that the database for metconazole is eligible for a three year extension. In addition, EPA confirms that the PPLS system includes end use pesticides with these use sites available to the public.

As to the four criteria mentioned above, Kureha Corporation submitted information to support its claims that there are insufficient efficacious alternative registered pesticides and that the metconazole use pesticide plays or will play a significant part in managing pest resistance in each of these minor use crops.

Analysis of Justification for Exclusive Use Extension

Blueberry, highbush

The registrant claims that there are insufficient efficacious alternative registered pesticides to metconazole and that the minor use pesticide plays or will play a significant part in managing pest resistance in blueberry, highbush.

Highbush blueberries are mainly used in commercial plantings in cooler climates and in the southern U.S. (Demchak et al., 2014). Quash, a single active ingredient product of metconazole, and Pristine are rated by industry as the top two fungicides in efficacy against rust (Blueberry

Guide, 2014). Pristine is a pre-mixture or combination product of active ingredients pyraclostrobin and boscalid. Thus in comparison of efficacy among single active ingredient products, metconazole is most effective for control of rust on blueberries. In addition, other fungicides such as fenbuconazole, fluazinam, and propiconazole have a long 30-day pre-harvest interval (PHI) (Valent, 2014). Metconazole has a short 7-day PHI and, therefore, may have a critical role to play as the only effective fungicide available to control some pre-harvest diseases and help protect plants from post-harvest diseases (Berry Guide, 2013). DMI fungicides comprise the majority of single-site fungicides registered on blueberries (CDMS, 2013). Among three DMI fungicides rated for their effectiveness of controlling Anthracnose fruit rot, metconazole is rated as having moderate effectiveness, while the other two are rated as not effective in the Mid-Atlantic region (Berry Guide, 2013). Therefore, criterion I has been met since metconazole may be used 7 days from harvest unlike 30 days for other registered Group 3 fungicides and appears to show greater effectiveness with regard to anthracnose fruit rot than other Group 3 fungicides and rust than all other single active ingredient fungicides.

Cherry

The registrant claims that there are insufficient efficacious alternative registered pesticides to metconazole and that the minor use pesticide plays or will play a significant part in managing pest resistance in cherry.

Multiple efficacious fungicides are needed for rotating modes of action and tank-mixing for season-long disease control in cherry (Adaskaveg et al., 2013; UC IPM, 2013).Pre-mixes of Groups 7 and 11 fungicides broaden the activity spectrum, but the need to rotate modes of action in multiple-application programs requires effective alternate fungicides with different modes of action. In Washington,potential phytotoxicity of strobilurins to apples can result from drift or sprayer contamination, which limits Group 11 fungicides (Vincelli, 2012). Multi-site fungicides are used extensively to help manage resistance but concerns over phytotoxicity (copper), fruit residues (chlorothalonil), impacts on natural enemies (sulfur) and a general lack of efficacy have relegated them to a role as tank mix or rotational partners in management cherry diseases (Valent, 2014). Industry sources suggest that metconazole is one of the top three single active ingredient fungicides with the overall broadest efficacy range against brown rot, *Botrytis cinerea*, Jacket rot, green fruit rot, and powdery mildew (Management Guidelines for Cherry, 2013). The other top two are penthiopyrad (Group 7) and tebuconazole. Thus, the top three efficacious fungicides consist of two modes of action and both are needed in California cherry orchards (UC IPM, 2013).

In addition, Adaskaveg et al. (2013) notes that among DMI fungicides, metconazole and tebuconazole have some activity against *Botrytis cinerea* and also provides a treatment timing table in which DMI fungicides are recommended three times, plus two times to be used tank-mixing with another active ingredient. UC IPM (2013) advises that treatment of brown rot begins at popcorn and repeats every 10 to 14 days through bloom if rains continue. Thus, there is a demand for more efficacious fungicides available for season long cherry disease control.

Criterion I has been met since some factors such as phytotoxicity may limit the availability or growers' choice of registered effective fungicides; metconazole is an effective Group 3 active ingredient among top fungicides with a broad efficacy range against key cherry diseases; and there are insufficient efficacious alternative fungicides available for the use on cherry. In particular, metconazole is needed to have sufficient number of efficacious alternatives fungicides for the management of listed diseases for season long disease control.

Gooseberry

The registrant claims that there are insufficient efficacious alternative registered pesticides available for gooseberry.

Gooseberry production is centered in the middle Atlantic, upper Midwest, and Northeast states (Valent, 2014). Botrytis fruit rot is caused by *Botrytis cinerea* and is a season-long threat that may result in defoliation, fruit drop, and ripe fruit infection. Several DMI fungicides are available but metconazole is the only DMI fungicide recommended to effectively control this disease in the Mid-Atlantic region (Berry Guide, 2013). In addition, the 7-day PHI for metconazole is shorter than some competing products such as Quilt Xcel, a combination product of active ingredients azoxystrobin and propiconazole that has a 30-day PHI (Valent, 2014). Thus, metconazole remains an effective fungicide option to control diseases occurring close to harvest and to help keep leaves on shrubs and prevent post-harvest foliar diseases.

In summary, criterion I has been met since metconazole is the most efficacious DMI fungicide to control Botrytis fruit rot and an effective fungicide option when some other competing fungicides are unavailable for 30 days prior to harvest, and there are insufficient efficacious alternative fungicides available for the use on gooseberries. In particular, the chemical is an efficacious option, with a 7-day PHI, to fill a void in the current program (e.g. unique timing window).

Hazelnut

The registrant claims that there are insufficient efficacious alternative registered pesticides available for hazelnut.

Oregon grows 99% of the U.S. hazelnut crop (Valent, 2014). Eastern Filbert Blight (EFB) is the main disease of hazelnuts and research on control of kernel molds is among critical needs for hazelnut's harvest and post-harvest disease management (Hazelnut PMSP, 2006).

Four modes of FRAC Groups 3, 11, M5, and M1 are available for rotating and/or tank-mixing schemes. Several combination products are registered for EFB control but are not recommended since only one of the active ingredients in the pre-mix is effective (Olsen, 2013). The effective single active ingredient fungicides in Group 3 are propiconazole, tebuconazole, and metconazole. Fungicides must be used during a critical period with a minimum of four applications (Pscheidt et al., 2014) and propiconazole is usually used in the rotation scheme for Group 3. However, with three efficacious propiconazole products available, data reviewed by the Agency shows

metconazole was still used. This could indicate some growers may have limited options due to unavailability of propiconazole products to them or under conditions that favor disease development and warrant shortening spray interval to 10 days or more applications, metconazole may be used for season long disease control. [The products containing propiconazole may result in smaller, thicker, greener leaves and shortened internodes, but trees generally grow out of this condition in two weeks after application (Pscheidt et al., 2014).] These propiconazole products also have a 60-day PHI. Procure has an 18-day PHI but its efficacy rating is only "fair to good" (Pscheidt et al., 2014). In comparison of tebuconazole and metconazole, the 25-day PHI for metconazole (versus 35 for tebuconazole) and the significantly lower application rates (3.5 oz/A versus 8.0 oz/A) with excellent residual make metconazole an option under some situations in EFB programs (Valent, 2014), with an efficacy rating of "good" (OSU, 2014).

The identification of management tools for control of kernel molds is a critical need (DeFrancesco and Clark, 2006). The PHI advantage makes metconazole a candidate in the research for the critical need of the harvest and post-harvest disease management of kernel molds.

In summary, criterion I has been met since metconazole is among top effective and preferred alternatives for some growers with limited options or under certain situations such as long-lasting pest pressure to have sufficient number of efficacious alternatives for season long control. In particular, the PHI that is shorter than competitive fungicides is an advantage for metconazole to fill a void in the current program (e.g. unique timing window).

Nectarine

The registrant claims that there are insufficient efficacious alternative registered pesticides to metconazole and that the minor use pesticide plays or will play a significant part in managing pest resistance in nectarine.

There are four DMI single active ingredient fungicide alternatives registered and evaluated for their efficacy against shot hole in California. Fenbuconazole, propiconazole, and/or tebuconazole are rated as limited, erratic, minimal, and/or often inactive, and only metconazole is rated as good and reliable (Adaskaveg et al., 2013). There is no data reported on the efficacy of metconazole against scab in California. In the Mid-Atlantic region, only metconazole and fenbuconazole are rated as "G" (good) in efficacy against brown rot and scab, and it is advised to select a fungicide with at least a "G" rating among fungicides available (Biggs, 2014). All other three DMI single active ingredient alternatives are rated as poor or not recommended. For the two fungicides rated as "G", metconazole is registered for control of seven diseases, compared to three for fenbuconazole. There is also a FIFRA Section 2(ee) recommendation to use metconazole to control other diseases such as anthracnose in nectarine and other orchard trees in California (CDMS, 2014).

In summary, for California production, criterion I has been met since metconazole is the only registered effective DMI fungicide for shot hole and a top-two DMI fungicide for scab control on nectarines in the Mid-Atlantic region. In addition, the chemical controls a broader range of

diseases than currently registered alternatives such as fenbuconazole with a recommended efficacy rating.

Peach

The registrant claims that there are insufficient efficacious alternative registered pesticides to metconazole and that the minor use pesticide plays or will play a significant part in managing pest resistance in peach.

Criterion I has been met since metconazole is the only registered effective DMI fungicide for shot hole in California and a top-two DMI fungicide for scab control in the Mid-Atlantic region; and the chemical controls a broader range of diseases than currently registered alternatives such as fenbuconazole with a recommended efficacy rating.

Pistachio

The registrant claims that there are insufficient efficacious alternative registered pesticides available for pistachio.

Approximately 98% of pistachio is grown in California (Valent, 2014). Multi-site fungicides such as chlorothalonil, copper, and sulfur do not provide the most effective disease control and heavy reliance is placed on single-site fungicides (Adaskaveg et al., 2013). Alternaria and Botryosphaeria are most damaging fungal pathogens of pistachio infecting trees over extended periods, and multiple applications of fungicides are needed (Crop Profile for Pistachio in California, 1999). Quash (metconazole) is one of two best single active ingredient products against Alternaria late blight, Botrytis blossom & shoot blight, and Botryosphaeria panicle & shoot blight (Adaskaveg et al., 2013). The other is penthiopyrad, a succinate dehydrogenase inhibitor (SDHI). Their efficacy is either excellent and consistent or good and reliable, and metconazole is better than penthiopyrad in efficacy against Botrytis blossom & shoot blight (Adaskaveg et al., 2013). Two other DMI single active ingredient fungicide alternatives are also listed, but their efficacy against Botrytis blossom & shoot blight is rated as limited and/or erratic, and metconazole is the most effective DMI fungicide (Adaskaveg et al., 2013).

Criterion I has been met since there are insufficient efficacious alternative fungicides available, and metconazole is one of two most effective fungicides for control of some important diseases on pistachio and has the best efficacy against one of them, Botrytis blossom & shoot blight.

Plum

The registrant claims that there are insufficient efficacious alternative registered pesticides to metconazole and that the minor use pesticide plays or will play a significant part in managing pest resistance in plum.

DMI fungicides such as metconazole and propiconazole and strobilurin fungicides are key elements in plum disease control, and the continuing availability of both modes of action groups

is essential to enable growers to rotate effectively (UC ANR, 2012). Among three DMI single active ingredient products recommended for control of brown rot blossom blight, metconazole and propiconazole are also registered to control more diseases than fenbuconazole including rust and powdery mildew, and both are needed for season long plum disease control (Olsen et al., 2013). And there are great differences in the activity spectra of different DMI active ingredients (FERA, 2009). Thus in summary, metconazole is needed to have sufficient number of efficacious alternatives for the management of listed diseases for season long disease control.

The importance of DMI fungicides in the Pacific Northwest (PNW) is increased significantly by the potential for strobilurin-induced phytotoxicity to apples in adjacent orchards (Vincelli, 2012). This can result from drift and/or sprayer contamination and, therefore, limits the use of strobilurin rotational alternatives in areas where apples are the predominant fruit crop (Valent, 2014). Multi-site fungicides such as chlorothalonil, captan, copper, and sulfur are important in reducing selection pressure on single-site fungicides. However, their efficacy against plum diseases is rated as moderate and variable, minimal and often ineffective, and/or ineffective, compared to the ratings of excellent and consistent and/or good and reliable for metconazole (UC ANR, 2012).

Shot hole rarely occurs on plums in California and fungicide efficacy data is not available. However, the efficacy of metconazole against shot hole is better than other fungicides in other stone fruit crops such as peach and nectarine (Adaskaveg et al., 2013) and, therefore, metconazole has potential to provide an efficacious alternative in plum disease management in PNW where shot hole is more prevalent (Valent, 2014).

Criterion I has been met since metconazole is one of the most effective DMI fungicides to control plum diseases. In particular, metconazole is needed to have sufficient number of efficacious alternatives for the management of listed diseases for season long disease control. The chemical is a top-two DMI fungicide against brown rot blossom blight with a wider pest spectrum than other DMI fungicides. The chemical is also a suitable candidate in the research, with its efficacy better than other fungicides against shot hole of other stone fruit crops, for plum shot hole management in the future, which is more important in PNW than in California.

Prune

The registrant claims that there are insufficient efficacious alternative registered pesticides to metconazole and that the minor use pesticide plays or will play a significant part in managing pest resistance in prunes. Among three DMI single active ingredient products recommended for control of brown rot blossom blight, metconazole and propiconazole are also registered to control more diseases than fenbuconazole including rust and powdery mildew, and both are needed for season long plum disease control (Adaskaveg et al., 2013). And there are great differences in the activity spectra of different DMI active ingredients (FERA, 2009). Thus in summary, metconazole is needed to have a sufficient number of efficacious alternatives for the management of listed diseases for season long disease control.

Prunes are dried plums. The plum analysis is applicable to the aforementioned prune analysis.

Criterion I has been met since metconazole is one of the most effective DMI fungicides to control prune diseases. In particular, metconazole is needed to have sufficient number of efficacious alternatives for the management of listed diseases for season long disease control. The chemical is a top-two DMI fungicide against brown rot blossom blight with a wider pest spectrum than other DMI fungicides. The chemical is also a suitable candidate in the research, with its efficacy better than other fungicides against shot hole of other stone fruit crops, for prune shot hole management in the future, which is more important in PNW than in California.

Summary of Findings

The Agency concludes that metconazole is an effective and preferred alternative for control of certain diseases on blueberry, cherry, gooseberry, hazelnut, nectarine, peach, pistachio, plum, and prune, and there are insufficient efficacious alternative registered fungicides available for these nine minor uses. Specifically, metconazole's use as an efficacious option: 1) enables growers to have sufficient number of efficacious alternatives fungicides for the management of listed diseases for season long disease control; 2) fills a void in the current program (e.g. unique timing window); and/or 3) controls a broader range of diseases than currently registered alternatives.

Determination

After reviewing your application, the Agency, agrees that for at least nine minor uses, that there are insufficient efficacious alternative registered pesticides to metconazole. Therefore, the Agency **GRANTS** your request for a three (3) year extension of exclusive use data protection for selected data under EPA Registration No. 72078-1. Exclusive use protection for data submitted in support of this registration which complies with 40 CFR §152.83(c) will expire on September 28, 2020.

Sincerely,

Susan Lewis, Director
Registration Division
Office of Pesticide Programs

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