



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

APR 03 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of a Request for an Extension of Exclusive Use Period for Tetraconazole (DP425426)

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Product Review Panel: January 21, 2015

SUMMARY

When pesticides are registered, the submitter of the original data has 10 years from the date of registration for exclusive use of the data. FIFRA allows for an extension of the period of exclusive use if certain criteria are met. Isagro S.P.A., d/b/a Isagro USA, Inc. submitted a petition to EPA requesting that the exclusive use period be extended for data submitted in support of the tetraconazole registration. A pesticide must meet at least one of the criteria for three minor uses to receive a one-year extension, six minor uses for an extension of two years, and nine minor uses for a maximum of three years extension of exclusive use of the data. BEAD confirms that four minor uses (Amur river grape, hardy kiwifruit, maypop, and Schisandra berry) were supported. Use on gooseberry was evaluated, but BEAD found that it did not meet any biological criteria since there are two other fungicides with the same mode of action available for powdery mildew control.

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides certain data protection rights to submitters of data for their registered pesticides. Section 3(c)(1)(F)(i) states that the original submitter of data has a 10-year exclusive use period from the date of registration for the data submitted in support of the original registration. An extension to the exclusive use period may be allowed if certain criteria are met [section 3(c)(1)(F)(ii)]:

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 [Aug. 3, 1996] 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.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

BACKGROUND

Isagro S.P.A., d/b/a Isagro USA, Inc., a registrant of tetraconazole, submitted a petition to the U.S. Environmental Protection Agency (EPA) for an extension of the exclusive use period for tetraconazole based on minor uses to manage powdery mildew on gooseberry, Amur river grape, hardy kiwifruit, maypop, Schisandra berry, and “cultivars, varieties, and/or hybrids of these.” “Cultivars, varieties, and/or hybrids” are not considered a crop use and so were not eligible for consideration for extension of data use, and therefore, five crops were evaluated for possible qualification for extension of exclusive use of data. The registrant stated that tetraconazole was first registered by the Agency April 14, 2005. BEAD defers the evaluation for Criterion II to the Registration Division, Health Effects Division, and Environmental Fate and Effects Division.

EXTENSION OF EXCLUSIVE USE OF DATA

BEAD concluded that the relevant criterion for the extension of exclusive use of tetraconazole data was Criteria I. Criterion I provides for the extension of exclusive use of data if there are “insufficient efficacious alternative registered pesticides available for the use.” Tetraconazole is the only Group 3 (DMI) fungicide option for growers of Amur river grape, hardy kiwifruit, maypop, Schisandra berry. In general, for optimal disease management different fungicide groups should be alternated to maintain efficacy of modes of action that are relied on to manage important diseases. FRAC has designed a group classification system based on a fungicide’s mode of action (FRAC, 2014). Tetraconazole is classified as a triazole fungicide (FRAC Group 3), which acts as a demethylation inhibitor (DMI) that inhibits sterol biosynthesis in fungi. DMI fungicides are among the most widely used fungicides due to their effectiveness in managing many diseases caused by numerous fungal pathogens. BEAD evaluated the information provided by the registrant for five minor uses of tetraconazole (Amur river grape, hardy kiwifruit, maypop, Schisandra berry, and gooseberry).

Amur river grape, hardy kiwifruit, maypop, and Schisandra berry. Tetraconazole targets powdery mildew on Amur river grape, hardy kiwifruit, maypop, and Schisandra berry. Tetraconazole is the only DMI fungicide registered for these crops. DMI fungicides have been an important group of fungicides used to control powdery mildew of small vine fruit even after azoxystrobin became available in the late 1990s. DMI fungicides provide post-infection activity (systemic) and remain highly effective against susceptible powdery mildew pathogens. As with other newer fungicides, resistance to strobilurin pesticides has become problematic in some locations. Generally, DMI fungicides should be limited to no more than three applications per season.

Three other non-DMI fungicides are registered to manage powdery mildew on these crops—cyprodinil, cyflufenamid and azoxystrobin.

- a. Cyprodinil (FRAC Group 9) is not reliably effective against powdery mildew. The Vanguard label itself states that it provides only suppression (approximately 60% control). Labels that describe efficacy as “suppression” do so because of limited efficacy. For example, cyprodinil was rated as having moderate, but variable efficacy in California grapes (UC, 2013). It was considered not effective for Washington grapes (Grove and Nelson, 2011), and for the mid-Atlantic region (DeMarsay, 2012) cyprodinil was considered only effective against Botrytis, not powdery mildew, on grape. Vanguard use is restricted to three applications per year.
- b. Cyflufenamid (FRAC Group U6) is a new fungicide and is effective against powdery mildew. The Torino label (Gowan, 2014) states that it should be used as a protectant with “very limited curative activity.” It may be applied a maximum of two times per year according to the label. Typically, more than two applications of a fungicide are necessary to manage powdery mildew.
- c. Azoxystrobin (FRAC Group 11) has been the first choice of fungicide for controlling powdery mildew (Grove and Nelson, 2011) and it is highly effective where sensitive pathogen populations occur. It has protectant and locally systemic activity providing some post-infection control. However, there are significant concerns for powdery mildew resistance, which has been observed in several regions in the U.S. For example, in Maryland “resistance has made azoxystrobin...ineffective against powdery...in many mid-Atlantic vineyards” (DeMarsay, 2012). Generally, extension specialists recommend a maximum of two applications per year of Group 11 fungicides rotated with other fungicide chemical groups in order to slow the development of resistance to azoxystrobin.

CONCLUSION

Tetraconazole is the sole Group 3 (DMI) fungicide option for growers of Amur river grape, hardy kiwifruit, maypop, Schisandra berry. Because growers rely on different modes of action for optimal disease management BEAD concludes that tetraconazole meets Criterion I and satisfies the biological criteria established to support the extension of exclusive use of data for these four minor uses.

Tetraconazole, azoxystrobin, and cyflufenamid may each play a role in powdery mildew management in terms of “efficacious alternatives” in an integrated fungicide disease management program. Typically several fungicide applications of fungicides with different modes of action must be made to manage a

heavy infestation of powdery mildew. Common field conditions often require post-infection activity such as provided by tetraconazole. Because of limited efficacy for powdery mildew control, cyprodinil might be used as a rotation member, but likely only under low disease conditions. Use of azoxystrobin requires an integrated rotation program with fungicides having other modes of action. In addition, azoxystrobin has substantial resistance concerns and has been reported to be ineffective at some use sites. Cyflufenamid, while an effective treatment, may only be applied twice per year.

For gooseberry, there are two Group 3 fungicides in addition to tetraconazole that are labeled to manage powdery mildew—propiconazole and myclobutanil. The registrant did not provide comparative efficacy data for these fungicides and BEAD did not find that one DMI fungicide was preferable to another for purposes of powdery mildew control on gooseberry. Because of the availability and apparent efficacy of two other DMI fungicides, BEAD concludes that tetraconazole use on gooseberry does not meet the criteria for extension of exclusive use of data.

REFERENCES

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