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

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OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of a Request for an Extension of the Exclusive Use Period for Cyflumetofen (DP# 442357)

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BEAD Product Review Panel Date: February 21, 2018

SUMMARY

When pesticides are registered, the original data submitter has a 10-year period from the date of registration to retain exclusive use of the data. FIFRA allows for an extension of that period of exclusive use if minor uses that meet certain criteria are registered. An extension of one year is provided for every three qualifying minor uses, for a maximum of three years. The registrant, BASF, submitted a petition to the EPA requesting that the exclusive use period be extended for three years for risk assessment data submitted in support of the cyflumetofen registration. Since three crops must meet the criteria for a one-year extension, nine crops need to meet at least one of the criteria to receive the maximum three-year extension.

In this case, the registrant had provided residue data for eight crops in total: oranges, lemons, grapefruit (to support registration for the citrus crops group), apples and pears (to support registration for the pome fruit crop group), almonds and pecans (to support registration for the tree nut crop group), and strawberries. BEAD confirmed that apples, oranges, almonds, and pecans are not minor crops (as defined by FIFRA, which requires minor crops to be grown on

300,000 acres or less). However, several minor crops are included within the crop groups registered on the basis of the residue data from these major crops. BEAD reviewed relevant extension service information on pest management to confirm that major target pests and the role of cyflumetofen are probably similar between the minor crops and the major acreage ones mentioned above. Therefore, a minor crop from within the same crop group may substitute for a major crop with residue data on a one-for-one basis. BEAD's assessment verified the registrant's assertion that cyflumetofen is currently the only miticide in its specific Mode of Action (MOA) grouping (25A) that is currently registered for any crop in the United States, and found that economically important target pests on the label have shown the potential for developing resistance to registered alternatives. Rotation of miticides representing different MOAs is an important component of any effort to delay the evolution or manage the spread of pesticide resistance in any pest species. Therefore, BEAD concludes that cyflumetofen plays or will play an important part in managing pest resistance. Thus, one of the criteria (I-IV) for an extension of exclusive use of data has been met by the cyflumetofen registrant for eight use sites (since eight crops had residue data submitted).

BACKGROUND

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides certain data protection rights to data submitters for their registered pesticides. Section 3(c)(1)(F)(i) states that the original data submitter has a 10-year exclusive use period from the date of registration for the data submitted in support of the original registration. The period of exclusive use may be extended one year for each three minor uses registered, up to a total of 3 additional years, if within 7 years of the commencement of the exclusive use period the registrant demonstrates 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 pesticides plays or will play a significant part in an integrated pest management program*

A minor use is defined in FIFRA Section 2(ll) as the use of a pesticide on an animal, on a commercial agricultural crop or site, or the protection of public health where "*(1) the total U.S. acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture, or (2) the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use.*"

In the case of crop groupings, FIFRA 3(c)(1)(F)(ii) states that "*the registration of a pesticide for a minor use on a crop grouping . . . shall be considered for one minor use for each representative crop for which data are provided.*" That is, the maximum number of eligible distinct minor uses for a crop group is equal to the number of representative crops for which residue data have been submitted. For instance, if residue data were submitted for lemon and

grapefruit as representative crops for citrus, a crop group that contains several minor uses, the data could support multiple minor uses, but a maximum of two uses could support a request for extension of exclusive use. Greenhouse uses are considered separate use sites from field crops in cases where distinct residue data for field-grown crops are submitted to support the registration.

REGISTRANT SUBMISSION AND CHEMICAL BACKGROUND

According to the registrant (BASF), cyflumetofen was first registered by EPA on May 9, 2014 under the tradenames cyflumetofen technical, Nealta® Miticide and Sultan® Miticide, with EPA Registration Numbers 7969-335, 7969-336 and 7969-337, respectively. Cyflumetofen is a pesticide that is labeled only for use as an acaricide (*i.e.*, for control of mites).

Cyflumetofen belongs to the benzoylacetonitrile class of chemistry. It acts by inhibiting electron transport in mitochondrial complex II, thus disrupting metabolism in target mites. The registrant stated that it is currently the only member of its MOA grouping, which is 25A (IRAC 2017) that is registered in the United States.

OVERVIEW OF THE REGISTRANT'S CLAIMS

The registrant stated that residue data were submitted for the following crops: oranges, lemons, and grapefruit, to support the citrus crop group tolerances (MRID 48849406); apples and pears, to support the pome fruit crop group tolerances (MRID 48542735); almonds and pecan to support the tree nut crop group tolerances (MRID 48542737), and strawberries (MRID 48542736). Thus, a total of eight crops had residue data submitted. The registrant also provided a discussion that focused broadly on the efficacy, integrated pest management (IPM) compatibility, and resistance management value of cyflumetofen in all the crop groups for which it is presently registered. The registrant asserted suitability of its request only on the basis of Criteria III and IV. In addition to strawberries, BASF listed a total of 36 crops as minor uses that qualify for Criteria III and IV; these are included within the citrus, pome fruit, and tree nut crop groups.

SUPPORT TO QUALIFY FOR THE CRITERIA EVALUATED BY BEAD

Requirements for Criterion III. BEAD considers that Criterion III had been met in situations where there was reliable information that the insecticide being evaluated has reasonable utility 1) to delay the development of pest resistance to other insecticides with different Modes of Action, or 2) where one or more of the target pests have already developed resistance in the U.S. to alternative insecticides.

Requirements for Criterion IV: IPM is an important strategy for growers to maintain the productivity of crop land while potentially reducing the overall input and environmental impact of pest management tools such as pesticides. Among other things, IPM strategies can help minimize the impact of pesticides on beneficial organisms (such as predators and parasites).

BEAD considers that Criterion IV had been met in situations where there was information that cyflumetofen is useful in managing target pests with low-to-no impact on other aspects of IPM such as the inclusion of non-chemical pest control tactics such as biological control with predatory or parasitic insects and mites.

DETAILS OF BEAD'S EVALUATION

BEAD examined information submitted by the registrant, relevant research and extension literature, descriptions of pesticide Modes of Action (MOA) available through the Insecticide Resistance Action Committee (IRAC), a group of industry technical experts. BEAD then evaluated if cyflumetofen reasonably plays a useful role in either managing pesticide resistance or IPM programs for each of the minor crops included in the registrant's submission.

In addition, BEAD reviewed publicly available information on recent acreage (USDA 2014) to verify that the eight crops for which residue data were submitted are indeed 'minor', as defined by FIFRA (i.e., grown on 300,000 acres or less in the U.S.). The data indicated that almonds, apples, oranges, and pecans are each grown on more than 300,000 acres. The remaining four crops involved were verified as being minor crops. However, within the crop groups that were registered on the basis of the data developed for the major acreage crops (*i.e.*, within the tree nut, citrus, and pome fruit crop groups), there are several minor acreage crops. BEAD consulted pest management and crop production guides from states that have large production of citrus, pome fruit, and tree nuts to verify that many of these minor crops are probably grown in similar regions and face the same mite pests as are the major crops that had registrant data submitted (Beutel 1990, Bell and Wiman 2017, UCIPM 2012, 2017a, b, c, USDA 2017). Therefore, following the policy outlined above (see 'Background' section), one minor crop could substitute for the major crop from within a crop group on a one-for-one basis. Thus (for example) a minor acreage tree nut crop could be considered a replacement for almonds, in the case of cyflumetofen.

Applicability of Criterion III to cyflumetofen

BEAD found that there is one other miticidal active ingredient – cyenopyrafen - in the same MOA group as cyflumetofen (IRAC 2017). However, BEAD also checked the EPA label database (EPA 2017) to confirm that only cyflumetofen is currently available to crop growers in the U.S. Therefore, for all crops that have residue data submitted, cyflumetofen offers a unique MOA to growers who need to implement a resistance management plan.

Economically important target pests listed on the label include (but are not limited to): the two-spotted spider mite (*Tetranychus urticae*), which attacks all the crops that BEAD considered for this review; other spider mites (e.g., the citrus red mite, *Panonychus citrii*, a pest of citrus); and the European red mite, *P. ulmi*, a pest of citrus, pome fruit and tree nuts. The two-spotted spider mite is arguably the most widespread and damaging member of the pests listed by the registrant.

BEAD checked the literature database on insect resistance that is maintained by the Michigan State University and IRAC (MSU 2017), to confirm the existence of resistance in U.S.

populations of the key pests specified above. This confirmed that reports of resistance to various classes of miticides exists in all these mite species. Over the years, various field populations of *T. urticae* have shown resistance to at least 59 active ingredients; *P. ulmi* to about half as many, and *P. citri* to at least eight. While some of these miticides have been phased out or cancelled, several of these are still available in the U.S. and represent MOAs such as carbamates, organophosphates, pyrethroids, and narrower-spectrum chemicals such as abamectin and hexythiazox.

Using insecticides with as many different MOAs as possible against any given pest population is a key resistance management principle that is generally applicable for insect pest control. The goal is to alternate their use either over time (usually called 'rotations') or space (referred to as 'mosaics'); this reduces the likelihood of pest individuals that are resistant to any one MOA surviving and spreading resistance genes to succeeding generations or to populations in other areas. Also, since cyflumetofen is a new insecticide in U.S. crops, pests have not yet developed resistance to it in this country (MSU 2017). This adds to its importance as a resistance management option in crops where some alternatives are older chemistries such as organophosphates and pyrethroids, since insects have had longer exposure to these chemicals.

CONCLUSION

BEAD determined that the registrant's request meets Criterion III (utility as a resistance management tool), since cyflumetofen is the only U.S.-registered member of its MOA group (25A) and should be useful in resistance management plans for economically important target pests. Cyflumetofen therefore meets at least one of the FIFRA criteria (described in the 'regulatory context' section above) needed for an extension of exclusive use of data. Residue data were submitted for a total of eight crops. Therefore, eight sites meet Criterion III to support an extension of exclusive use over the data.

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