UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 9, 2018

Dr. Chris Hofelt DABT
Product Registration Manager
BASF Corporation, Agricultural Products
26 Davis Drive, P.O. Box 13528
Research Triangle Park, NC 27709-3528

Subject: EPA Response to BASF Corporation Request for Extension of the Exclusive-Use Data Protection Period for Cyflumetofen
Product Name: Cyflumetofen Technical
EPA Registration Number: 7969-335
Application Dates: May 30, 2017 & August 14, 2017
Decision Number: 530001

Dear Dr. Hofelt:

This document summarizes and announces the U.S. Environmental Protection Agency (EPA) response to BASF Corporation's request of May 30, 2017 that data associated with the original registration of the insecticide cyflumetofen receive a 3-year extension to the original 10-year exclusive-use data protection period.

Background: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides certain data protection rights to data submitters for their registered pesticides. Section 3(c)(l)(F)(i) of FIFRA states that the original data submitter has a 10-year exclusive-use data protection period from the date of registration for the data submitted in support of the original registration. The original 10-year exclusive-use data protection period for cyflumetofen started on May 9, 2014 and will conclude on May 9, 2024. The period of exclusive-use may be extended one year for each three minor uses registered, up to a total of three additional years, if within seven years of the commencement of the exclusive-use data protection 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 pesticide plays or will play a significant part in an integrated pest management (IPM) program.*

The Food Quality Protection Act (FQPA) of 1996 amended FIFRA and added the definition of a minor use. FIFRA section 2(ll) now defines a "minor use" as the use of a pesticide on an animal, on a commercial agricultural crop or site, or the protection of public health where either of the following two

criteria are met *"(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* ***and*** *(A) there are insufficient efficacious alternative registered pesticides available for the use; (B) the alternatives to the pesticide use pose greater risks to the environment or human health; (C) the minor use pesticide plays or will play a significant part in managing pest resistance;* ***or*** *(D) the minor use pesticide plays or will play a significant part in an integrated pest management program."*

In the case of crop groupings, FIFRA section 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.

***Summary of BASF's Submission & Claims*:** Regarding cyflumetofen, this evaluation considers that BASF Corporation (BASF) provided residue data for eight crop trials: oranges, lemons, grapefruit (to support registration for the citrus crops group tolerances; MRID 48849406); apples and pears (to support registration for the pome fruit crop group tolerances; MRID 48542735); almonds and pecans (to support registration for the tree nut crop group tolerances; MRID 48542737); and strawberries (MRID 48542736). Thus, a total of eight crops had residue data submitted. The EPA has 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). In addition to strawberries, BASF listed a total of 36 crops as minor use sites that qualify for Criteria III and IV, all of which are included within the citrus, pome fruit, and tree nut crop groups registered based on the residue data from these major crops. 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 and EPA will consider no more than eight minor crops as support for this extension request.

EPA's assessment verified BASF's claim 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 may 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 species. Therefore, EPA concludes that cyflumetofen plays or will play an important part in managing pesticide resistance. Thus, one of the criteria (I-IV) for an extension of exclusive-use of data has been met by BASF for eight use sites (since eight crops had residue data submitted).

***Support to Qualify for Evaluation Criteria*:** *Requirements for Criterion III*: EPA considers that Criterion III had been met in situations where there was reliable information that the insecticide being evaluated has reasonable utility to delay the development of pest resistance to other insecticides with different MOAs, or where one or more of the target pests have

already developed resistance in the U.S. to alternative insecticides.

***Details of EPA's Evaluation*:** EPA has examined information submitted by BASF, relevant research and extension literature, and descriptions of pesticide MOAs available through the Insecticide Resistance Action Committee (IRAC), a group of industry technical experts. EPA 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 BASF submission.

In addition, the EPA reviewed publicly available information on recent acreage to verify that the eight crops for which residue were submitted are indeed 'minor.' 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 based on the data developed for the major acreage crops (*i.e.*, within the citrus, pome fruit, and tree nut crop groups), there are several minor acreage crops. EPA 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. Therefore, one minor crop could substitute for the major crop from within the crop group on a one-to-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: The EPA's evaluation revealed that there is one other miticidal active ingredient (*i.e.*, cyenopyrafen) in the same MOA group as cyflumetofen. However, EPA has confirmed that only cyflumetofen is currently available to crop growers in the U.S. Therefore, for all crops, including minor crops, cyflumetofen offers a unique MOA to growers who need to implement a resistance-management plan.

Economically important target pests listed on the product label include the two-spotted spider mite, which attacks all the crops considered for this review; the citrus red mite; and the European red mite, 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 BASF. The EPA has confirmed reports of resistance to various classes of miticides in all these mite species. Over the years, various field populations have shown resistance to at least 59 active ingredients; the European red mite to about half as many, and the citrus red mite 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. Since cyflumetofen is a new insecticide in U.S. crops, pests have not yet developed resistance to it in this country. 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.

The Agency has confirmed that the end-use product labels currently listing the referenced minor uses under the tradenames Nealta® Miticide and Sultan® Miticide, with EPA Reg.

Nos. 7969-336 and 7969-337, respectively, contain the resistance-management labeling statements as described by PR Notices 2001-5, both currently under review with the Agency to be updated to contain the resistance-management language described by PR Notice 2017-1. The Agency has verified that these labels are currently being marketed, are being available on EPA's Pesticide Product Lael System (PPLS), and contain these minor uses.

EPA Determination: The EPA has determined that BASF's request to extend the original ten-year exclusive-use protection period for cyflumetofen 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 meets at least one of the FIFRA criteria needed for an extension of the exclusive-use of data. Residue data were submitted for a total of eight crops, which based on a one-for-one substitution equate to eight minor users. While EPA has determined that all crops meet Criterion III, BASF qualifies for an extension supported only by eight minor uses and; therefore, EPA **GRANTS** a two-year extension of the original ten-year exclusive-use data protection for selected data under EPA Reg. No. 7969-335 (Cyflumetofen Technical). Exclusive-use protection for data, which complies with 40 CFR 152.83(c), submitted in support of this registration, **will expire on May 9, 2026.**

A copy of our review supporting BASF's request is enclosed for your use and reference. If you have any questions, please contact Mr. Carmen J. Rodia, Jr. by phone at 703-306-0327 or via e-mail at *Rodia.Carmen@epa.gov* or Mr. Richard J. Gebken by phone at 703-305-6701 or via e-mail at *Gebken.Richard@epa.gov*.

Sincerely,

Michael L. Goodis, P.E.
Director, Registration Division (7505P)
Office of Pesticide Programs

Enclosure: BEAD Review of Request for Extension of the Exclusive-Use Period for Cyflumetofen, dated March 13, 2018