



## OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

June 12, 2024

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Subject:       Product Name: Bicyclopyrone Technical  
                  EPA Reg. No.: 100-1467  
                  Action Case No.: 00481814  
                  Application Date: June 5, 2023  
                  EPA Finding: Extend the exclusive use data protection period for bicyclopyrone  
                  by 3 years from April 24, 2025 to April 24, 2028

Dear Ms. Foderaro:

This letter addresses Syngenta's request that certain data associated with the original registration of bicyclopyrone receive a three-year extension to the ten-year exclusive use protection period. Bicyclopyrone Technical (EPA Reg. No. 100-1467) was first registered by EPA on April 24, 2015. Without an extension of exclusive use protection, the data protection period would expire on April 24, 2025. Though only nine registered minor crops are needed to support this request, the following sixteen were cited in the request: wormwood, lemongrass, rosemary, banana, plantain, horseradish, broccoli, hops, strawberry, papaya, watermelon, dry bulb onion, green onion, garlic, timothy grass grown for seed, and sweet potato.

After review of this petition, EPA is granting the request for an exclusive use extension of three additional years to end on April 24, 2028, for EPA Registration No. 100-1467.

Syngenta Crop Protection, LLC cited FIFRA section 3(c)(1)(F)(ii) as the authority for EPA to make such a determination. The 1996 Food Quality Protection Act ("FQPA") amendments to FIFRA incorporated this subsection under 3(c)(1)(F). 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 whether there are any exclusive use data associated with a registration. FIFRA section 3(c)(1)(F)(i) and its implementing regulations specifically describe the set of data that are eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 C.F.R. 152.83(a), and the following requirements must be met:

- (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 chemical or new combination (first registration), or an application to amend such registration to add a new use;
- (3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); and
- (4) 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 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 were submitted in support of the first registration of the new chemical<sup>1</sup>. The registration cited was granted on April 24, 2015 and was the first registration for bicycloprrone. 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 exclusive use protection. If the Agency receives a me-too application for this pesticide during the extension period citing Syngenta Crop Protection, LLC 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

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<sup>1</sup> 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.

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)(I)(F)(ii). FIFRA section 3(c)(I)(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 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."

## **SUMMARY OF FINDINGS**

Syngenta Crop Protection, LLC identified sixteen minor crops and submitted information to substantiate that each crop met at least one of the four criteria above. The criteria claimed for each crop are shown in Table 1. Syngenta Crop Protection, LLC claimed criterion I (insufficient efficacious registered alternatives), criterion III (playing a significant part in managing pest resistance), and criterion IV (playing a significant part in integrated pest management) for all of the identified crops.

EPA determined that all sixteen use sites claimed by Syngenta meet the criterion for minor use designation, i.e., less than 300,000 acres bearing or harvested. Fourteen use sites are supported by residue trial data. For plantain and garlic, residue tolerances are based on data from banana and dry bulb onion, respectively, and no separate residue was submitted for these uses. Table 1 summarizes the minor use crops claimed by the registrant, the date those uses were registered, the relevant crop groups, and the exclusive use criteria claimed.

The Agency determined that all sixteen of these minor uses were registered within seven years of the original registration of Bicyclopyrone Technical, EPA Registration No. 100-1467 and are on an active end use product label. Further, EPA verified that there are bicyclopyrone tolerance citations for these sixteen minor uses. EPA also confirmed that the end use product label that includes use on sweet potato and watermelon includes substantive resistance management sections as stated in Pesticide Registration Notice 2017-1 "Guidance for Pesticide Registrants on Pesticide Resistance Management" by identifying the Weed Science Society of America (WSSA) group and by describing a resistance management strategy that includes a limit of two

sequential applications of the product (or an herbicide from the same WSSA group), using tank mixtures when appropriate and other resistance management steps.

**Table 1. Proposed minor crops, registration dates, crop groups, and exclusive use criteria claimed.**

Minor Use Claimed	Date Registered (added to 100-1467) (1)	Crop Group or Subgroup, if registered (on end use label)	Criteria Claimed	Tolerance	Maximum Number of Use Sites Allowed
Wormwood	1/14/2022	Not applicable (2)	I, III, IV	yes	1
Lemongrass	1/14/2022	Not applicable	I, III, IV	Yes	1
Rosemary	1/14/2022	Not applicable	I, III, IV	yes	1
Banana	3/17/2022	Not applicable	I, III, IV	yes	1
Plantain	3/17/2022	Not applicable	I, III, IV	yes (3)	
Horseradish	3/17/2022	Not applicable	I, III, IV	yes	1
Broccoli	3/17/2022	Not applicable	I, III, IV	yes	1
Hops	3/17/2022	Not applicable	I, III, IV	yes	1
Strawberry	3/17/2022	Not applicable	I, III, IV	yes	1
Papaya	3/17/2022	Not applicable	I, III, IV	yes	1
Watermelon	3/17/2022	Not applicable	I, III, IV	yes	1
Onion, dry bulb	3/17/2022	Not applicable	I, III, IV	yes	1
Garlic	3/17/2022	Not applicable	I, III, IV	yes (4)	
Onion, green	3/17/2022	Not applicable	I, III, IV	yes	1
Timothy grass grown for seed	3/17/2022	Not applicable	I, III, IV	yes	1
Sweet potato	3/17/2022	Not applicable	I, III, IV	yes	1

Notes:

(1) Bicyclopyrone (EPA Reg. No. 100-1467) was initially registered on 4/24/2015; the listed minor uses were registered within 7 years of the original registration.

(2) The bicyclopyrone technical label (EPA Reg. No. 100-1467) includes use on the crops as listed in the first column. Many of them are in crop groups or subgroups. The uses are registered on the individual crops, not the crop groups or subgroups.

(3) Based on the table in 40 CFR 180.1(g), a tolerance for residues in or on banana also covers residues in or on plantain, so there is not a separate tolerance for plantain and no residue data on plantain were submitted.

(4) Based on the table in 40 CFR 180.1(g), a tolerance for residues in or on onion, bulb also covers residues in or on several commodities including garlic, so there is not a separate tolerance for garlic and no residue data on garlic were submitted.

EPA reviewed the claimed criteria for wormwood, lemongrass, rosemary, banana, horseradish, broccoli, green onion, watermelon, and sweet potato and determined that at least one of the claimed criteria was met for each of these crops. Specifically, EPA found that for the minor uses wormwood, lemongrass, rosemary, banana, horseradish, broccoli, and green onion, there are insufficient registered alternative herbicides for the claimed target pests in those crops. For watermelon and sweet potato, EPA determined that bicyclopyrone plays or could play a role in resistance management of glyphosate-resistant pigweeds. Because EPA finds that a sufficient number of use sites met criteria I and III to qualify for the maximum three-year extension, EPA

did not assess the remaining use sites and did not assess registrant claims for any sites under criteria IV.

The following is a summary of how each of the nine reviewed crops meets at least one of the criteria and thus counts towards extending the exclusive use period. This summary was based upon the information provided by the registrant and reviewed by EPA. This decision is supported by the document “Review of Extension of Exclusive Use Petition for Bicyclopyrone” dated June 5, 2024. This document contains a more detailed explanation of how each crop meets the standard for extending the exclusive use period.

The Agency determined that seven minor use sites meet criterion I, that there are insufficient efficacious alternative registered pesticides for those use sites. EPA assessed the applicability of criterion I for these crops by confirming the number of active ingredients registered for use on the crop and evaluated the registrant’s claim by examining labels of herbicides registered for use on the crop. The document “Review of Extension of Exclusive Use Petition for Bicyclopyrone” dated June 5, 2024, includes all of the details about the alternatives; the conclusions for the seven minor use sites that qualify as a use site under criterion I are provided below.

#### ***Wormwood***

EPA concludes that wormwood growers have insufficient efficacious alternatives based on crop safety, pest spectrum, and application timing.

#### ***Lemongrass***

EPA concludes that lemongrass growers have insufficient efficacious alternatives based on crop safety and bicyclopyrone’s target weed spectrum.

#### ***Rosemary***

EPA concludes that rosemary growers have insufficient efficacious alternatives based on crop safety, pest spectrum, and lack of registered alternatives for rosemary as a food use.

#### ***Banana***

EPA concludes that banana growers have insufficient efficacious alternatives based on few alternatives for bearing banana, plantback intervals, target pest spectrum, and need for multiple chemicals to replace bicyclopyrone.

#### ***Horseradish***

EPA finds that horseradish growers have insufficient efficacious alternatives based on application timing, pest spectrum and need for multiple chemicals to replace bicyclopyrone.

#### ***Broccoli***

EPA finds that broccoli growers have insufficient efficacious alternatives based on application timing, bicyclopyrone’s target weed spectrum, and lack of registration of alternatives in major broccoli production states.

### ***Green Onion***

EPA finds that green onion growers have insufficient efficacious alternatives based on application timing and need for multiple chemicals to replace bicyclopyrone.

As explained below, EPA also determined that bicyclopyrone plays or will play a significant part in managing pest resistance (meets criterion III) for watermelon and sweet potato.

### ***Watermelon***

As the only HPPD inhibitor (WSSA Group 27 herbicides) registered for use in watermelon, bicyclopyrone provides a unique mode of action for herbicide rotations to manage resistant weeds. The registrant claims that in watermelon, bicyclopyrone can be used before or after crop emergence between crop rows to control Palmer amaranth, redroot pigweed, and common ragweed resistant to glyphosate. Glyphosate-resistant redroot pigweed has been confirmed in the southeast U.S. where watermelon is frequently produced and is considered among the most common and troublesome weeds in cucurbit production. Bicyclopyrone controls pigweed species and is one of several herbicides recommended by extension in Georgia for control of broadleaf and grass weeds between watermelon rows after crop emergence. WSSA Group 2, 3, 10, 15, and 22 herbicides are also recommended by weed scientists for preemergence or postemergence control of broadleaf and grass weeds between rows. However, resistance to Group 2 herbicides in redroot pigweed has also been documented in watermelon-producing states. EPA finds that as a unique mode of action in watermelon, bicyclopyrone could play a role in resistance management of pigweeds in watermelon. Watermelon qualifies as a use site under criterion III.

### ***Sweet Potato***

As the only HPPD inhibitor registered for use in sweet potato, bicyclopyrone provides a unique mode of action for herbicide rotations to manage resistant weeds. The registrant claims that in sweet potato, bicyclopyrone can be used before or after crop emergence between crop rows to control Palmer amaranth, redroot pigweed, and common ragweed resistant to glyphosate. Glyphosate-resistant redroot pigweed has been confirmed in North Carolina. North Carolina is the leading producer of sweet potato in the U.S., followed by Louisiana and California. Bicyclopyrone controls pigweed species and is recommended by extension for pigweed control in sweet potato in Mississippi. In North Carolina, two WSSA Group 14 and two WSSA Group 15 active ingredients are recommended by extension for preemergence control of pigweeds, and a different WSSA Group 14 chemical can provide postemergence control of pigweeds between rows. Fomesafen and S-metolachlor are available under Special Local Needs 24c registration in North Carolina and may not be available in all states where sweet potato is produced. EPA finds that as a unique mode of action in sweet potato, bicyclopyrone could play a role in resistance management of pigweeds in sweet potato. Sweet potato qualifies as a use site under criterion III.

## DETERMINATION

The Agency concludes that Syngenta has provided sufficient evidence to support extension of exclusive use of data under FIFRA Section 3(c)(1)(F)(ii) for at least nine minor use sites required to attain three additional years of data exclusivity under criteria I or III, and these uses were registered within seven years of the original bicyclopyrone registration. The minor use registrations which support this overall finding are wormwood, lemongrass, rosemary, banana, horseradish, broccoli, green onion, watermelon, and sweet potato. Therefore, the Agency **GRANTS** your request for a three-year extension of the original exclusive-use data protection period for data submitted to support EPA Registration No. 100-1467. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(a), submitted in support of this registration **will expire on April 24, 2028**. A copy of our review is enclosed.

Sincerely,

Charles "Billy" Smith, Director  
Registration Division (7505T)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency

Enclosure: Review of Extension of Exclusive Use Petition for Bicyclopyrone