



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 1, 2020

Ian Murphy
Federal Registrations Manager
Bayer CropScience LP
800 N. Lindbergh Blvd.
St. Louis, MO 63167

Subject: Product Name: INDAZIFLAM TECHNICAL
EPA Reg. No. 264-1129
Decision: 553745
Application Date: 7/26/2019
EPA Finding: Extends the exclusive use data protection period by 3 years
from July 26, 2020 to July 26, 2023

Dear Mr. Murphy:

This letter addresses your request that data associated with the original registration of indaziflam receive a three-year extension to the original ten-year exclusive use protection period. The original data protection period started July 26, 2010 and ends July 26, 2020. Though only nine registered minor crops are needed to support the request, the following twelve were cited:

- Citrus Fruit Crop Group 10-10B
 - o Group includes two minor uses: lemon and lime
- Pome Fruit Crop group 11-10
 - o Includes the minor use pear
- Stone Fruit Crop Group 12-12A
 - o Group includes two minor uses: sweet cherry and tart cherry
- Stone Fruit Crop Group 12-12C
 - o Includes the minor use apricot
- Berry and Small Fruit 13-07A
 - o Includes the minor use raspberry
- Berry and Small Fruit 13-07B
 - o Includes the minor use blueberry (highbush)
- Tree Nut 14-12
 - o Includes the minor use pistachio
- Tropical and Subtropical Fruit; Edible Peel Group 23A
 - o Includes the minor use olive

- Coffee
- Hops

EPA is granting the request for an exclusive use extension of three additional years to end July 26, 2023 under EPA Registration No 264-1129. Bayer CropScience 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(c), 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; and
- (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 were submitted in support of the first registration of the new chemical¹. The registration cited was granted on July 26, 2010 and was the first registration for indaziflam. Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B). Data generated by IR-4 are not entitled to

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.

exclusive use protection (see 40 CFR I 52.94(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 Bayer CropScience 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)(1)(F)(ii), and if so, by how many years. FIFRA section 3(c)(1)(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

All twelve crops meet the definition of a minor use as each crop had less than 300,000 acres bearing or harvested. Residue data were sufficient for eleven crops, as only one crop in the Citrus Fruit Crop Group 10-10B is allowed to be cited (lemon or lime). Indaziflam is one of few herbicides classified as a cellulose biosynthesis inhibitor and is the only registered herbicide in the alkylazine group (Group 29 according to the Weed Science Society of America (WSSA)), thus it plays an important role in control of weeds

resistant to other modes of action. The Agency concludes that for the at least nine qualifying use sites (lemon or lime, pear, sweet cherry, apricot, raspberry, pistachio, olive, coffee, and hops), indaziflam satisfies criterion III and will play an important role in herbicide resistance management for specified weeds in these crops. Therefore, nine distinct minor use sites qualify for extension of exclusive use of indaziflam under criterion III, and indaziflam qualifies for the full three-year extension of exclusive use.

The Agency verified there are indaziflam tolerance citations for the minor use crops in 40 CFR 180.653. Additionally, each of the end-use labels contains a resistance management section and WSSA group number code which supports grower awareness and herbicide resistance management efforts.

DETERMINATION

The Agency concludes that the uses listed above are minor uses and were registered within seven years of the original indaziflam registration. These minor uses were found to meet at least one of the four criteria listed above. 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. 264-1129. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration **will expire on July 26, 2023**. A copy of our review is enclosed.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Goodis", written in a cursive style.

Michael Goodis, PE
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Enclosure: Review of Bayer CropScience's Request for an Extension of the Exclusive Use Period for Indaziflam