



**US Environmental Protection Agency  
Office of Pesticide Programs**

**EPA Response to Petition for Indoxacarb**

**September 10, 2009**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Dr. Richard Carver  
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P.O. Box 30  
Newark, DE 19714-0030

Dear Dr. Carver:

Subject: Request for extension of exclusive use data protection for data submitted for Indoxacarb Technical (EPA Registration No. 352-594)

The Agency **GRANTS** your petition for an exclusive use data protection under EPA Registration No. 352-594 for an additional three (3) years. Exclusive use protection for data submitted in support of this registration which complies with 40 CFR 152.83(c) will expire on October 30, 2013.

This letter is in response to your petition dated October 16, 2007 that data associated with the registration of the active ingredient indoxacarb receive extensions for the exclusive use period. You cited FIFRA section 3(c)(1)(F)(ii) as the authority for the Agency to make such a determination.

The 1996 Food Quality Protection Act (FQPA) amendments to FIFRA incorporated this subsection under 3(c)(1)(F), the section that provides for protection of certain data submitted in support of pesticide registrations. 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 minor uses registered within the first seven years of an original registration whose data retains exclusive use protection, with a maximum of an additional three years of exclusive use protection.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain which data have exclusive use protection. FIFRA section 3(c)(1)(F)(i) and its implementing regulations carefully circumscribe the set of data that are eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 CFR 152.83(c).

Pursuant to 40 CFR 152.83(c), the following requirements must be met for a study to be considered an exclusive use study:

- (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; and
- (2) The study was submitted in support of, or 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);

Provided that, a study is an exclusive use study only during the 10-year period following the date of 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.

Second, the data must have been submitted in support of the first registration of the new chemical.<sup>1</sup> The registration you cited was granted October 30, 2000 and was the first registration for indoxacarb with the product name indoxacarb technical.

Please note, because exclusive use protection is not available for studies that the Agency requires to maintain registration in effect under FIFRA section 3(c)(2)(B) any such data associated with this registration will not receive exclusive use protection under FIFRA section 3(c)(1)(F)(ii).

Now that the Agency has determined that studies associated with this registration are exclusive use studies<sup>2</sup>, we must determine whether you have met the criteria for extending the exclusive use protection period 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:

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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 such 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. See 49 FR 30884, 30889

<sup>2</sup> Because the requestor did not attach a list of data they believe retain exclusive use protection, this response is general in nature. If the Agency receives an application for registering an identical or substantially similar pesticide during the extension period citing the requestor's data, it will then address whether those data have the extension of data protection.

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; or
- (II) the alternatives to the minor use pesticide pose a greater risk to the environment of human health; or
- (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.

The initial registration of indoxacarb occurred on October 30, 2000 and included the following 9 uses that you petitioned the Agency to consider towards extension of the exclusive use period: cabbage; broccoli; tomatoes; peppers; head lettuce; leaf lettuce; apples; pears; sweet corn. The petition also requested consideration of the following 14 uses which were registered on July 16, 2007: mint; southern pea; cranberry; collards; mustard greens; plum; peach; sweet cherry; sour cherry; summer squash; cucumber; cantaloupe; spinach and celery. As required by the statute, the aforementioned uses were all registered within the requisite seven year time period.

After reviewing the currently approved labeling, the Agency has determined that the following 22 uses qualify toward the request for extension of exclusive use data protection: cabbage; broccoli; collards; tomatoes; peppers; head lettuce; leaf lettuce; apples; pears; mint; southern pea; cranberry; mustard greens; plum; peach; sweet cherry; tart (sour) cherry; summer squash; cucumber; cantaloupe; spinach and celery.

The Agency determined that sweet corn does not meet the acreage definition of a minor crop, i.e., the total United States acreage for the crop is less than 300,000 acres. See *The United States Environmental Protection Agency Report on Minor Uses of Pesticides*, found at [http://www.epa.gov/pesticides/minoruse/minor\\_use\\_rpt.pdf](http://www.epa.gov/pesticides/minoruse/minor_use_rpt.pdf). for more information about minor and major crops. A major crop may be counted towards extension of exclusive use protection if

the data generated to support the major crop also support the registration, labeling and marketing of the product on a minor crop(s) in a crop group. In this case, sweet corn is the only commodity in the cereal grains crop grouping which is on the indoxacarb label so it is not eligible to be counted towards an extension of exclusive use data protection. Apples are considered a major crop as they are grown on more than 300,000 acres. However, in this case the generation of apple data supported the registration, labeling and marketing of indoxacarb on the following minor crops in the pome fruits crop group; crab apple, loquat, mayhaw and quince. Therefore the minor uses associated with the apple data are eligible uses for extension. The same is true for tomatoes which are also grown on over 300,000 acres in the United States. Data generated to support the registration of tomatoes also supported the registration, labeling and marketing of indoxacarb on the following minor crops, eggplant, ground cherry, pepino and tomatillo, which are in the fruiting vegetable crop group.

In addition to meeting the minor use requirements, FIFRA section 3(c)(1)(F)(ii) requires that one of the criteria I-IV as stated above be met. DuPont Crop Protection submitted information for criteria I, III and IV. The Agency evaluated the information submitted by DuPont Crop Protection and determined the following:

In support of criterion I, "there are insufficient efficacious alternative registered pesticides available for the use," DuPont Crop Protection indicated that FIFRA section 18 emergency exemptions were granted for use of indoxacarb on cranberries in Massachusetts in 2002 and collards in Georgia in 2003. Section 18s are only granted for pesticide uses with no effective alternatives and in both cases the section 18 requests were renewed prior to the use being registered. The Agency believes that the lack of efficacious alternatives for cranberries and collards still exists. The cranberry and collard uses were registered on July 16, 2007, within the requisite seven year time period. The Agency agrees that this evidence supports criterion I for cranberries and collards.

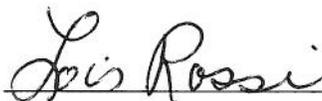
With regard to criterion III, "the minor use pesticide plays or will play a significant part in managing pest resistance," the Agency concluded that indoxacarb has a novel mode of action which makes it a useful tool for pesticide resistance management for 22 of the eligible uses (all uses requested except sweet corn). The uses include cabbage, broccoli, tomatoes, peppers, head lettuce, leaf lettuce, apples, pears, mint, southern pea, cranberry, collards, mustard greens, plum, peach, sweet cherry, sour cherry, summer squash, cucumber, cantaloupe, spinach and celery. The following information submitted by the applicant from the California Department of Pesticide Regulation also supports the claim that the use of indoxacarb meets criteria III for apples, pears, tomatoes, broccoli, cabbage, peas, peppers and lettuce.

Many insects have developed resistance to conventional pesticide chemistries, such as organophosphates, carbamates, and pyrethroids. To combat these pesticide resistant pests new chemistries have been developed with novel modes of action unrelated to previous chemical classes to replace the old chemistries. Indoxacarb is a non-systemic, synthetic organophosphate replacement insecticide that has good field activity against a number of Lepidoptera pests, as well as certain Homoptera and Coleoptera pests.

Indoxacarb, a broad spectrum foliar insecticide, is registered for use on a broad range of crops, which include fruits (apples, pears, and tomatoes), vegetables (bok choy, broccoli, Brussels sprouts, cabbage, cauliflower, Chinese cabbage, corn, eggplant, kohlrabi, peas, peppers, potatoes, and lettuce), soybeans, alfalfa, and cotton. It controls or suppresses many insects, including beet armyworm, cabbage looper, corn earworm, diamondback moth, fall armyworm, imported cabbageworm, southern armyworm, tomato pinworm, and tomato fruitworm.

With regard to criterion IV, that indoxacarb plays or will play a significant part in an integrated pest management program (IPM) for the requested uses, the Agency concluded that indoxacarb plays a significant part in IPM programs for peaches as evidenced by the Experimental Use Permit for indoxacarb which was requested by university tree fruit entomology specialists for their multi-state IPM-based Risk Avoidance and Mitigation Program (RAMP) grant. Indoxacarb was found to be an alternative to organophosphate, carbamate and synthetic pyrethroid insecticides for control of plum curculio and suppression of Oriental fruit moth and a good fit for peach IPM programs in Pennsylvania and California. Indoxacarb use on peaches was subsequently registered on July, 16, 2007, within the requisite seven year time period.

The Agency concluded that 22 of the requested uses meet criterion III including cabbage, broccoli, tomatoes, peppers, head lettuce, leaf lettuce, apples, pears, mint, southern pea, cranberry, collards, mustard greens, plum, peach, sweet cherry, sour cherry, summer squash, cucumber, cantaloupe, spinach and celery. In addition, two uses, collards and cranberries met criterion I and one use, peaches, met criterion IV. Therefore, the Agency **GRANTS** your request for an extension of exclusive use data protection under EPA registration number 352-594 for an additional three (3) years. Exclusive use protection for data submitted in support of this registration which complies with 40 CFR 152.83(c) will expire on October 30, 2013.



Lois Rossi, Director  
Registration Division  
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cc: Meredith Laws  
John Hebert  
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Nicole Williams  
Pat Cimino

## **REFERENCES**

Reduced Risk Insect/Mite Management in Tree Fruit, May 11, 2009. The Pennsylvania Integrated Pest Management Program. Pennsylvania State University.

Pest Management Strategic Plan for Peach Production in California, 2006, Web address: <http://www.ipmcenters.org/pmsp/pdf/CAPEACHPMSP.pdf>