



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 30, 2018

Dr. Lydia Cox
Director of Regulatory Affairs
Nichino America, Inc.
4550 New Linden Hill Road, Suite, 201
Wilmington, DE 19808

Subject: Response to Request for Extension of the Exclusive-Use Period for Tolfenpyrad Technical
EPA Registration Number: 71711-30
EPA Finding: Extends the Exclusive-Use Data Protection Period by 3 years from July
28, 2020 to July 28, 2023

Dear Dr. Cox:

This is the Office of Pesticide Programs' response to your request of January 9, 2017 that data associated with the original registration of the insecticide tolfenpyrad receive a three-year extension to the original ten-year exclusive-use protection period pursuant to FIFRA section 3(c)(1)(F)(ii). The original data protection period started July 28, 2010 and ends July 28, 2020. Supporting information was submitted for sixteen crops. Because three minor uses are required to meet at least one of the criteria for a one-year extension, to receive the maximum three-year extension of data protection, nine qualifying minor uses are required. Out of the 16 minor crop uses in the petition, the Agency selected leaf lettuce, head lettuce, spinach, celery, orange, lemon, grapefruit, cherry, and plum, for consideration and determined that the use of tolfenpyrad on these crops met the criteria to support the extension of exclusive-use period. Therefore, the Agency is granting the request for an exclusive-use extension of three years to end July 28, 2023, under EPA Registration No. 71711-30.

The 1996 Food Quality Protection Act (FQPA) amended section 3(c)(1)(F) to include 3(c)(1)(F)(ii) which the applicant cites as its authority to make this request. FIFRA section 3(c)(1)(F)(ii) sets forth the criteria for the extending of 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 retain exclusive-use protection. 40 CFR section 152.83 defines the study required as part of the application for exclusive-use protection where 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 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 a study is an exclusive use study only during the 10-year period following the date of 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 were submitted in support of the first registration of the new chemical.¹ The registration of Nichino America, Inc. (Nichino) Tolfenpyrad Technical (71711-30) was granted July 28, 2010, and was the first registration for tolfenpyrad.

Third, the data were not submitted to satisfy 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).

Data generated by IR-4 are not entitled to exclusive-use protection (See 40 CFR 152.94(b)). However, the EPA will count minor uses supported, or generated by IR-4 when determining how many additional years that exclusive use protection may be extended.

Although the EPA has determined that there are exclusive-use-protected data associated with this registration, the EPA has not made individual determinations on every study associated with the above referenced registration as to exclusive-use protection. If the EPA receives a me-too application of this pesticide during the extension period citing Nichino's data, the EPA 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, the 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 of FIFRA section 3(c)(1)(F)(ii), and if so, by how many years.

¹ Data are not protected solely because they pertain to a new chemical, but because they are submitted in support of a particular product registration of a new chemical. Thus data submitted in support of an application of 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 the data that pertain solely to the new use. Thus, for example, if the new use is approved after eight years of first registration, the data supporting that use would gain exclusive use protection for only two years.

FIFRA § 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, and/or
- (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health, and/or
- (III) the minor use pesticide plays or will play a significant part in managing pest resistance, and/or
- (IV) the minor use pesticide plays or will play a significant part in an integrated pest management (IPM) 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.

Analysis of Justification for Exclusive Use Extension

The registrant, Nichino, submitted a petition to the Agency requesting that the exclusive-use period be extended for three years (until July 28, 2023) for data submitted in support of the tolfenpyrad registration. Since three crops must meet the criteria for a one-year extension, at least nine crops must meet at least one of the criteria to receive the maximum three-year extension. Nichino provided information for 16 crops for tolfenpyrad in order to meet the related criteria for a maximum extension of exclusive-use of three years.

The Agency confirmed, based on the USDA Census of Agriculture (USDA 2014) for all 16 submitted crops, the total U.S. acreage for each crop is less than 300,000 acres². Therefore, each of these crops are determined to be minor uses. The Agency also verified there are tolfenpyrad registrations for the following 13 submitted minor use crops (Crop Group(CG)): arugula (CG 4); endive (CG 4); radicchio (CG 4); spinach (CG 4); Swiss chard (CG 4); grapefruit (CG 10-10); kumquat (CG 10-10); lemon (CG 10-10); lime (CG 10-10); tangelo (CG 10-10); tangerine (CG 10-10); cherries (tart)(CG 12-12); cherries (sweet)(CG 12-12), and that these 13 minor uses were each registered within 7 years of the initial registration of July 28, 2010. However, with respect to exclusive use data protection, only nine of these 13 minor uses are qualifying minor uses supported by residue data. As per FIFRA § 3(c)(1)(F)(ii), the Agency will consider one minor

² Crops not listed in the USDA Census of Agriculture are presumed to be cultivated on less than 300,000 acres.

use for each representative crop for which data are provided in the crop grouping. Therefore, the first condition of exclusive use extension has been met for the following nine minor uses: leaf lettuce, head lettuce, spinach, celery, orange, lemon, grapefruit, cherry, and plum.

The Agency has confirmed that the end use product labels currently listing these minor uses (EPA Reg. No. 71711-36) carry the resistance-management labeling statements as described by PR Notice 2001-5 and is 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 the labels for EPA Reg. No. 71711-36 (brand names: Apta, Bexar and Torac) are currently being marketed, are publicly available on the Pesticide Product Label System (PPLS), and contain these minor uses.

Once it was determined that nine qualifying minor uses (i.e., supported by data) were submitted, the Agency applied the statutory criteria to its evaluation of the information submitted by the registrant to determine if at least one criterion has been met for each of these distinct minor uses. The EPA evaluated, under Criterion III, the information submitted by the registrant as well as publicly available information, including descriptions of insecticide Modes of Action (MoA) available through the Insecticide Resistance Action Committee (IRAC), to determine whether tolfenpyrad will play a significant part in managing pest resistance for the submitted crop groups. The Agency considers that Criterion III is met in situations where there is reliable information that the insecticide being evaluated is used 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.

For the leafy vegetables crop group (CG 4) (leaf lettuce, head lettuce, spinach and celery), data and extension experts confirmed that thrips have shown resistance to many alternatives for thrip control. Therefore, the Agency concludes that Criterion III is met for these minor uses based on the development of thrips resistance in the U.S. to some leading alternative active ingredients.

For citrus fruit crop group (CG 10-10) (lemon, orange, and grapefruit), evidence was provided that resistance has developed by citrus thrips to leading alternative pesticides, leaving few alternatives available for control of these pests. The Agency determined, given the extent of reported resistance, that Criterion III is satisfied for these three minor uses, because tolfenpyrad offers a new tool for resistance management of citrus thrips.

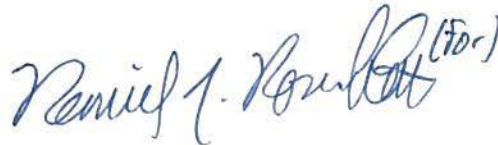
For stone fruit crop group (CG 12-12) (cherry and plum), the Agency considered Nichino's claims that tolfenpyrad is the only IRAC 21A insecticide registered for use on cherries against several pests (including cherry fruit fly, spotted wing drosophila, apple maggot, aphids and plum curculio). Although two other insecticides from IRAC 21A are registered for use on stone fruit, the pests controlled do not overlap with those controlled by tolfenpyrad, namely plum curculio. Therefore, the Agency determined that Criterion III is met for these distinct minor uses because tolfenpyrad will play a significant role in the resistance management of plum curculio, as it is a new mode of action and equally efficacious as industry standards.

In total, the Agency has determined that nine distinct minor uses (leaf lettuce, head lettuce, spinach, celery, lemon, orange, grapefruit, cherry and plum) qualify for extension of exclusive-use as described above.

Determination

EPA concludes that Nichino has satisfied the requirements necessary to extend the period of exclusive-use data. The EPA determined that tolfenpyrad satisfies Criterion III for at least nine minor uses registered within seven years of the original registration. Therefore, the EPA **GRANTS** your request for a three-year extension of exclusive-use data protection for selected data under EPA Registration Number 71711-30. Exclusive-use protection for data, which complies with 40 CFR 152.83(c), submitted in support of this registration, **will expire on July 28, 2023**. A copy of our review is enclosed.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michael L. Goodis" with a circled "For" next to it.

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

Enclosure: Review of Request for an Extension of Exclusive-Use Period for Tolfenpyrad