UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 16, 2015

Tim McPherson
DuPont Crop Protection
Stine-Haskell Research Center
P. O. Box 30
Newark, DE 19714

Subject: **Product Name:** DuPont Cyazypyr Technical
EPA Reg. No.: 352-856, Decision No.: 491028, Application Dated: 3/14/2014, revision, 6/29/2015
EPA Finding: Grants the extension of exclusive-use data protection period for 3 years, ending on January 24, 2027

Dear Mr. McPherson:

This is the Office of Pesticide Programs' response to DuPont Crop Protection (DuPont) petition dated March 14, 2014 requesting to extend the period of exclusive data use for the insecticide cyantraniliprole. The original data protection period started January 24, 2014 and ends January 24, 2024. Cyantraniliprole is a diamide insecticide that affects ryanodine receptors in insect muscle, causing impairment of insect muscle function and paralysis (Group 28) (Insecticide Resistance Action Committee (IRAC), 2014). DuPont submitted a petition to the United States Environmental Protection Agency (EPA) for a three-year extension of the exclusive use period. Since three minor uses must meet one of the criteria for a one-year extension, and the statute limits the extension to a maximum of three years, nine minor uses need to meet at least one of the criteria for a three-year extension. On June 24, 2015 DuPont submitted a revised request listing all 249 minor crops that, in their opinion, qualify to support the exclusive use of cyantraniliprole. In Dupont's latest request, of the 249 listed crops to which cyantraniliprole can be legally applied, cherry (sweet), cherry (tart), tangerines, grapefruit, hazelnut, peach, plum, plumcot, and ginger were evaluated for this review.

DuPont cited Federal Insecticide, Fungicide and Rodenticide Act (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). FIFRA section sets forth the criteria for extending the period of exclusive use protection. The period of exclusivity shall be extended one year for each three qualifying minor uses registered within the first seven years of the commencement of the exclusive use period when the Agency makes certain determinations, discussed in detail below. First, however, a study must

meet the definition of "exclusive use study" as defined in the Code of Federal Regulation Title 40 (40 CFR) section 152.83:

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; 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 qualifies under the definition of exclusive use.

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 you cited, with the product name DuPont Cyazypyr Technical, was initially granted on January 24, 2014 and was the first registration for cyantraniliprole.

Third, the data were not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B).

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

The EPA has determined that the three criteria defining an exclusive use study have been met for data associated with this registration, although, the EPA has not made individual determination on every study associated with the above referenced registration as to exclusive use protection. If the EPA receives a me-too application for this pesticide during the extension period citing DuPont 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.

---

[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 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 the data that pertain solely to the new use.

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 to FIFRA section 3(c)(1)(F)(ii), and if so, by how many years. FIFRA § 3(c)(l)(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 (IPM) program.

Three minor uses must meet one of the criteria for a one-year extension and the statute limits the extension to a maximum of three years. Therefore, in order to grant an extension for three years as requested by DuPont, nine minor uses need to meet at least one of the criteria. As mentioned above DuPont proposed that all 249 minor crops qualify to support the exclusive use of cyantraniliprole.

DuPont submitted information on the role of cyantraniliprole in Criteria II to IV of FIFRA § 3(c)(l)(F)(ii) to support their petition for extension of the exclusive use period.

In support of the Extension for Exclusive Use, DuPont proposed EPA to consider the following:

Criterion II: Cyantraniliprole poses less risks to the environment or human health than its alternatives.

Criterion III: Cyantraniliprole has a unique mode of action and it will play an important role in pest resistance.

Criterion IV: Cyantraniliprole may be used as part of an IPM program.

Analysis of Justification for Exclusive Use Extension

The EPA determined that the minor crops were registered within seven years of the original registration of DuPont Cyazypyr Technical. Cyantraniliprole was first registered on January 24, 2014, which included the 249 crops listed below.

Crop Group Number	Crop Group	Crop(s)
1C	Tuberous and corm vegetables	Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chufa; dasheen (taro); **ginger***; leren; sweet potato; tanier; turmeric; yam bean; yam, true
3-07	Bulb vegetables	Chive, fresh leaves; chive, Chinese, fresh leaves; daylily, bulb; elegans hosta; fritillaria, bulb; fritillaria, leaves; garlic, bulb; garlic, great-headed, bulb; garlic, serpent, bulb; kurrat; lady's leek; leek; leek, wild; lily, bulb; onion, Beltsville bunching; onion, bulb; onion, Chinese, bulb; onion, fresh; onion, green; onion, macrostem; onion, pearl; onion, potato, bulb; onion, tree, tops; onion, Welsh, tops; shallot, bulb; shallot, fresh leaves; cultivars, varieties, and/or hybrids of these
4	Leafy vegetables (except Brassicas)	Amaranth (Chinese spinach); arugula (roquette); cardoon; celery; celery, Chinese; celtuce; chervil; chrysanthemum, edible-leaved; chrysanthemum, garland; corn salad; cress, garden; cress, upland; dandelion; dock (sorrel); endive (escarole); fennel, Florence; lettuce, head and leaf; orach; parsley; purslane, garden; purslane, winter; radicchio (red chicory); rhubarb; spinach; spinach, New Zealand; spinach, vine; Swiss chard
5	Brassica (cole) leafy vegetables	Broccoli; broccoli, Chinese (gai lon); broccoli raab (rapini); Brussels sprouts; cabbage; cabbage, Chinese (bok choy); cabbage, Chinese (napa); cabbage, Chinese mustard(gai choy); cauliflower; cavalo broccolo; collards; kale; kohlrabi; mizuna; mustard greens; mustard spinach; rape greens
8-10	Fruiting vegetables	African eggplant; bush tomato; bell pepper; cocona; currant tomato; eggplant; garden huckleberry; goji berry; groundcherry; martynia; naranjilla; okra; pea eggplant; pepino; nonbell pepper; roselle; scarlet eggplant; sunberry; tomatillo; tree tomato; cultivars, varieties, and/or hybrids of these
9	Cucurbit vegetables	Chayote (fruit); Chinese waxgourd (Chinese preserving melon); citron melon; cucumber; gherkin; gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra); Momordica spp (includes balsam apple, balsam pear, bittermelon, Chinese cucumber); muskmelon (includes cantaloupe); pumpkin; squash, summer; squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); watermelon
10-10	Citrus fruit	Australian desert lime; Australian finger-lime; Australian round lime; Brown River finger lime; calamondin; citron; citrus hybrids; **grapefruit***; Japanese summer grapefruit; kumquat; lemon; lime; Mediterranean mandarin; mount white lime; New Guinea wild lime; pummelo; Russell River lime; satsuma mandarin; sweet lime; tachibana orange; Tahiti lime; tangelo; **tangerine (mandarin)***; tangor; trifoliate orange; uniq fruit; cultivars, varieties, and/or hybrids of these
11-10	Pome fruit	Azarole; crabapple; loquat; mayhaw; medlar; pear; pear, Asian; quince; quince, Chinese; quince, Japanese; tejocote; cultivars, varieties, and/or hybrids of these
12	Stone fruit	Apricot; **cherry, sweet***; **cherry, tart***; nectarine; **peach***; **plum***; plum, Chickasaw; plum, Damson; plum, Japanese; **plumcot***; prune (fresh)
13-07B	Bushberries	Aronia berry; blueberry, highbush; blueberry, lowbush; buffalo currant; Chilean guava; cranberry, highbush; currant, black; currant, red; elderberry; European barberry; gooseberry; honeysuckle, edible; huckleberry; jostaberry; Juneberry (Saskatoon berry); lingonberry; native currant; salal; sea buckthorn; cultivars, varieties, and/or hybrids of these
14-12	Tree nuts	African nut-tree; beechnut; Brazil nut; Brazilian pine; bunya; bur oak; butternut; Cajou nut; candlenut; cashew; chestnut; chinquapin; coconut; coquito nut; dika nut; ginkgo; Guiana chestnut; **hazelnut (filbert)***; heartnut; hickory nut; Japanese horse-chestnut; macadamia nut; mongongo nut; monkey-pot; monkey puzzle nut; Okari nut; Pachira nut; peach palm nut; pequi; Pili nut; pine nut; pistachio; Sapucaia nut; tropical almond; walnut, black; walnut, English; yellowhorn; cultivars, varieties, and/or hybrids of these

20	Oilseeds	Borage; calendula; castor oil plant; Chinese tallowtree; crambe; cuphea; echium; euphorbia; evening primrose; flax seed; gold of pleasure; hare's ear mustard; jojoba; lesquerella; lunaria; meadowfoam; milkweed; mustard seed; niger seed; oil radish; poppy seed; rose hip; safflower; sesame; stokes aster; sweet rocket; tallowwood; tea oil plant; vernonia; cultivars, varieties, and/or hybrids of these

***The nine bolded crops are those that were considered for the extension of exclusive use.**

Information Sources

EPA examined information submitted by the registrant, the United States Department of Agriculture (USDA) Agriculture Census, Mode of Action and resistance management information available from the Resistance Management for Sustainable Agriculture and Improved Public Health organization, and the Pesticide Product Labeling System (PPLS). These additional sources were consulted to confirm or supplement the information submitted by the registrant.

Minor Crop Assessments

EPA focused its review on cherry (sweet), cherry (tart), tangerines, grapefruit, hazelnut, peach, plum, plumcot, and ginger. EPA verified that these crops met the acreage requirement for minor crops (less than 300,000 acres cultivated) under FIFRA section 2(ll)(1) using USDA data.

Summary of Findings

Cyantraniliprole was evaluated by the reduced risk committee and based on the mammalian toxicity and ecotoxicity risk profiles poses less risk compared to registered alternatives for these crops (EPA, 2012). The uses that were granted reduced risk status initially were: Brassica leafy vegetables, bulb vegetables, bushberries, citrus, cotton, cucurbit vegetables, fruiting vegetables, leafy vegetables, oil seeds, pome fruit, stone fruit, tree nuts, tuberous & corm vegetables, fly bait use, turf, ornamentals (greenhouse and nursery), and indoor and outdoor commercial and residential use sites to control public health pests. The nine crops evaluated for the extension of exclusive use fall within these crops groups.

Cyantaniliprole was registered as a reduced risk pesticide on January 24, 2014. Per EPA's policy, the reduced risk status remains valid if the registration is received within 2 years of the reduced risk decision and the request for exclusive use is received within 2 months of the registration decision. As this application was submitted within 2 months of the Agency's reduced risk decision on cyantraniliprole, the alternatives analysis that supported the reduced risk determination remains valid and adequately addresses Criteria II for purposes of the extension of exclusive use request for these minor uses.

As this chemical has been deemed reduced risk, criterion II has been met by the minor uses of cyantraniliprole on cherry (sweet), cherry (tart), peach, plum, plumcot (all included in Stone Fruit crop group 12); tangerines, grapefruit, (both included in Citrus crop group 10-10); hazelnut (included in Tree Nut crop group 14-12); and ginger (included in Tuberous and Corm Vegetable crop group 1C). All nine crops considered for this exclusive use extension are currently uses that are registered on the cyantraniliprole technical label, DuPont Cyazypyr (EPA Reg. No. 352-856).

Hazelnut, tangerine, grapefruit, plum, plumcot, peach, cherry (sweet), and cherry (tart) are included in the end use product label of DuPont Exirel Insect Control (EPA Reg. No. 352-859), and hazelnut and ginger are included in the product label of DuPont Benevia Insect Control (EPA Reg. No. 352-857).

Because Criterion II is met, and only a single criterion must be met to satisfy the exclusive use requirements, analysis of Criterion III or IV is not necessary.

Determination

EPA concludes that cyantraniliprole is an effective, reduced risk tool for control of certain insect pests. Therefore, EPA finds that cyantraniliprole satisfies at least one criteria for an extension of the period of exclusive use for at least nine minor uses: cherry (sweet), cherry (tart), tangerines, grapefruit, hazelnut, peach, plum, plumcot, and ginger.

Therefore, EPA grants your request for a three-year extension of exclusive use data protection for selected data under EPA Registration Number 352-856.

With this three-year extension, exclusive use protection for applicable data, submitted in support of this registration, will expire on January 24, 2027.

Sincerely,

Susan Lewis

Susan Lewis
Director, Registration Division
Office of Pesticide Programs

Enclosure: EPA BEAD Review of a Request for an Extension of the Exclusive Use Period for Cyantraniliprole