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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 29, 2013

Ruhi Rezaaiyan
Syngenta Crop Protection, Inc.
P.O Box 18300; 410 Swing Road
Greensboro, NC 27519-8300

Subject: **Difenoconazole**
Exclusive use protection request for minor use crop data
100-739; Decision 478400; Difenoconazole Technical; Submission Dated 10/3/06
100-1262; Decision 421935; Inspire; Submission Date 12/18/2009

Dear Ms. Rezaaiyan:

This letter responds to the two requests referenced above for exclusive use protection of minor use crop data. A separate minor crop exclusive use protection request dated 11/14/2008 was found not acceptable because the request was not contained in the application letter for those minor uses as required by FIFRA 3(c)(1)(F)(vi), rather it was requested retrospectively.

You cited FIFRA section 3(c)(1)(F)(vi) 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)(vi) sets forth the criteria for extending the period of exclusive-use protection for minor use data. The minor use period of exclusivity can be extended ten years from data submission providing the data supports minor uses which were actually approved on the label; the data is not publically owned (eg. can't be IR4, public literature, etc); and the 10-year base period of exclusivity on the chemical has ended. The applicable minor use definition for this situation is crops grown on less than 300,000 acres in the US. Data generated by IR-4 is not entitled to exclusive use protection (see 40 CFR 152.94(b).

In the application for new uses dated 10/3/06, exclusive use protection was requested for the following crops: Arracacha; Arrowroot; Artichoke (Chinese and Jerusalem); Burdock; Canna; Cassava (bitter and sweet); Chayote (root); Chufa; Crabapple; Dashen (taro); Eggplant; Ginger; Groundcherry; leren; Loquat; Mayhaw; Pear (and Oriental pear); Pepino; Pepper (Bell); Pepper (all other, excluding Bell—ie. chili, cooking, sweet); Pimiento; Quince; Tanier; Tomatillo; Tumeric; Yam (true); and Yam (bean). Difenoconazole was first registered 8/4/94 so the base exclusive use period expired 8/4/2004 which is before the date of the request. As per the attached review, these crops were found to qualify as minor uses. They were approved on the subject products 1/16/08. The supporting data were found not to be publically owned. Therefore the Agency **GRANTS** your request that data supporting these minor use crops be given exclusive use protection which expires 10/3/16.

In the application for new uses dated 12/18/09, exclusive use protection was requested for the following crops: Apricot; Cherries, Sweet; Cherries, Tart; Nectarine; Peach; Plum; Plumcot; Prune;

Strawberry; Chickpea; and Carrot. Difenoconazole was first registered 8/4/94 so the base exclusive use period expired 8/4/2004, which is before the date of the request. As per the attached review, these crops were also found to qualify as minor uses. They were approved on the subject products 6/22/11. The supporting data were found not to be publically owned. Therefore, the Agency **GRANTS** your request that the data supporting these minor use crops be given exclusive use protection which expires 12/18/19.

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's 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 these minor uses will receive the determined extension of exclusive use protection.

A copy of our review is enclosed. If you have any questions please contact Tony Kish at 703-308-9443 or at kish.tony@epa.gov.

Sincerely,

Lois Rossi

Lois Rossi, Director
Registration Division
Office of Pesticide Programs
Registration Division (7504P)

cc: BEAD review dated 8/8/13

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AUG 0 8 2013

OFFICE OF
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MEMORANDUM

SUBJECT: Minor Use Crop Status for Crops Being Considered in the Request for a New Exclusive Use Period for Protection of Data for Difenoconazole (DP411620)

FROM: Leonard Yourman, Plant Pathologist
Biological Analysis Branch

THRU: Arnet Jones, Chief
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Rosemary Kearns, Chemical Review Manager
Tony Kish, Product Manager, Team 22
Fungicide Branch
Registration Division (7505P)

Product Review Panel: August 7, 2013

SUMMARY
Syngenta has requested a new exclusive use period for protection of data for difenoconazole in support of registrations of several new minor use crops as described in FIFRA § 3(c)(1)(F)(vi). As part of the process, BEAD has evaluated data of the acres of production of the crops listed by the registrant and assessed whether they meet the standard of minor use crops as defined by FIFRA § 2(ll) (FIFRA, 2008). By that definition, BEAD concludes that the crops listed by Syngenta in 2009 (Table 1) and 2006 (Table 2) are grown in the U.S. on fewer than 300,000 acres and are minor use crops.

BACKGROUND
In December, 2009, Syngenta requested that EPA grant a new exclusive use period for protection of data for difenoconazole in support of registrations of new minor use crops (Table 1) for the period of 10 years from the date of submission as described in FIFRA § 3(c)(1)(F)(vi) [FIFRA, 2008]. Previously in October, 2006, Syngenta requested that EPA grant a new exclusive use period for protection of data of several crops (Table 2). Once an exclusive use period has

expired, a registrant may request a new exclusive use period for the data developed to add a minor use to an existing registration that does not have exclusive use protected data.

To establish a new exclusive use period according to FIFRA § 3(c)(1)(F)(vi), the request must be made at the same time that the application for adding the new minor use(s) is submitted. The request must indicate that to the best of the registrant or applicant's knowledge, the exclusive use period has expired and that data submitted to support the minor use(s) are eligible for exclusive use protection. As part of the process, BEAD has evaluated data of the acres of production of the crops listed by the registrant and assessed whether they are grown on fewer than 300,000 acres and, therefore, meet the standard of minor use crops [as defined by FIFRA § 2(ll)] (FIFRA, 2008).

MINOR USE CROPS

As of this writing BEAD concludes that the crops listed by Syngenta in 2009 (see Table 1) and 2006 (see Table 2) are minor use crops grown in the U.S. on fewer than 300,000 acres [as defined by FIFRA § 2(ll)] (FIFRA, 2008). For the 2009 crop list (Table 1), production acres were published in *The Census of Agriculture*, the most current government census of production acres (USDA, 2009). Two of the crops listed were not reported in the census. For chickpeas BEAD consulted a USDA survey—*Crop Production—2012 Summary* (USDA, 2013). BEAD did not find production acres of plumcot, a hybrid of apricot and plum, but BEAD assumed plumcot is grown on fewer than 300,000 acres based on the number of production acres of plum and apricot (109,319 and 13,750 acres, respectively) (Table1). BEAD concludes that the crops listed in Table 1 were produced on fewer than 300,000 acres.

Table 1. Production acres of new uses of difenoconazole listed by the registrant in 2009.

Crop	Total Production Acres[1] (2007)
Apricot	13,750
Cherries, sweet	100,705
Cherries, tart	49,561
Nectarine	31,846
Peach	149,237
Plum & Prune	109,319
Plumcot[2]	Not listed
Strawberry	58,718
Chickpea[3]	207,900
Carrot	90,292

[1] Total production acres reported in the most current Census of Agriculture (USDA, 2009) (except chickpeas and plumcots).

[2] Plumcot is not listed in *The 2007 Census of Agriculture* (USDA, 2009), nor did BEAD find a reliable estimate of plumcot acres. The *Census* lists pluots as grown on 4,332 acres. Plumcot and pluots are different hybrids derived from plum and apricot crosses. BEAD assumes plumcots are grown on fewer than 300,000 acres based on acreage of plums and apricots.

[3] Acreage for total chickpea production (large and small sizes) are based on survey data of 2012 production (USDA, 2013).

For the 2006 crop list, production acres for some of the crops were published in *The Census of Agriculture* (Table 2). Many of the registrant-listed crops appear to have very little, if any, production in the U.S. BEAD assumed that the crops listed by the registrant but not reported by the *Census* were grown on fewer than 300,000 acres and can be considered minor use crops.

Table 2. Production acres of new uses of difenoconazole listed by the registrant in 2006.

Crop	Total Acres[1]
Arracacha	Not listed [in *Census of Agriculture* (USDA, 2009)]
Arrowroot	Not listed
Artichoke (Chinese and Jerusalem)[2]	Not listed
Burdock	Not listed
Canna[3]	Not listed
Cassava (bitter and sweet)	Not listed
Chayote (root)	Not listed
Chufa	Not listed
Crabapple	Not listed
Dasheen (taro)	535 (2007, Hawaii); 592 (2002, harvested U.S.)
Eggplant	6,038 (harvested)
Ginger	185 (2002, harvested)
Groundcherry	Not listed
Leren	Not listed
Loquat	Not listed
Mayhaw	Not listed
Pear (and Oriental pear)[4]	68,216
Pepino	Not listed
Pepper (Bell)	62,363
Pepper (all other, excluding Bell—i.e., chili, cooking, sweet)	37,372
Pimiento	Included as part of "other vegetables" total 47,563 acres
Quince	Not listed
Tanier	Not listed
Tomatillo	Not listed
Tumeric	Not listed
Yam (true)[5]	Not listed
Yam (bean)[6]	Not listed

[1] Total production acres reported in the most current *Census of Agriculture* (USDA, 2009) unless otherwise specified.

[2] Only artichoke (globe) was listed in the Census of Agriculture (USDA, 2009)—grown on 9,687 acres.

[3] Canna is widely used as an ornamental flowering plant in the U.S. In some countries, the rhizomes are used as high-starch food.

[4] Listed for "all pears"

[5] Production of the crop yam (*Dioscorea* spp.) is not listed in the *Census of Agriculture* (USDA, 2009). For comparison, a crop frequently confused with yam, the widely available sweet potato (*Ipomoea batatas*), was grown on 105,284 acres in the U.S. (USDA, 2009).

[6] 'Bean yam' is a name given to several different crops of the *Pachyrhizus* genus, including jicama.

REFERENCES

FIFRA. 2008. FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT [As Amended Through P.L. 110–246, Effective May 22, 2008]
http://www.epa.gov/opprd001/registrationmanual/FIFRA.pdf

USDA. 2009. Census of Agriculture—United States, Summary and State Data, Volume 1, Geographic Area Series. AC-07-A-51. Issued Feb. 2009, Updated Dec. 2009.
http://www.agcensus.usda.gov/Publications/2007/Full_Report/usv1.pdf

USDA. 2013. Crop Production—2012 Summary.
http://usda01.library.cornell.edu/usda/current/CropProdSu/CropProdSu-01-11-2013.pdf