



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 1, 2015

Ruhi Rezaaiyan
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PO Box 18300
Greensboro, NC 27419

**Subject: Product Name: Difenoconazole Technical
EPA Reg Number 100-739; Decision 486677; Application Dated 10/29/2014
EPA Finding: Establish New 10-Year Period of Exclusive Use for Field Trial Data
on Bushberry subgroup 13-07B (MRID 49227602) until 10/29/2024**

Dear Ms. Rezaaiyan:

This letter responds to the request referenced above for exclusive use protection of minor use crop data. Your request was made at the same time the application for adding the minor uses was submitted. Therefore, the application timing complies with FIFRA 3(c)(1)(F)(vi).

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 providing a 10-year period of exclusive-use protection for minor use data when the exclusive use period has expired. The data pertaining solely to the new minor uses can be given a 10-year exclusive use period from the date these data were submitted providing the data supports minor uses which were actually approved on the label; the data is not publically owned (eg. can't be IR-4, public literature, etc.); and the 10-year base period of exclusivity on the chemical has ended. Furthermore, the study must relate solely to a minor use. A minor use is defined as crops grown on less than 300,000 acres in the US. Data generated by IR-4 are not entitled to exclusive use protection (see 40 CFR 152.94(b)).

In the application dated 10/29/2014, exclusive use data protection was requested for the following members of the dried shelled pea and bean subgroup 6C: Dried Shelled- kidney bean, lima bean (dry), navy bean, tepary bean, adzuki bean, blackeyed pea, catjang, cowpea, Crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, broad bean (dry), guar, lablab bean, field pea, and pigeon pea.

In that same application, data protection was also requested for bushberry subgroup 13-07B members: 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; and sea buckthorn.

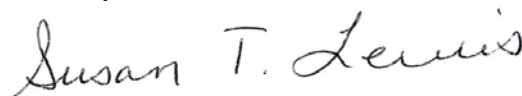
DETERMINATION

The Agency has determined that not all crops in the dried shelled pea and bean subgroup 6C are minor uses. Some of the crops in this group, which were approved 5/6/2015 on difenoconazole labels, are grown on more than 300,000 acres annually (eg., pinto, and lentil), and are therefore considered major use crops. The submitted pea/bean study with MRID 49227601 contains data supporting both minor and major uses. Therefore, your request for protection of data associated with these commodities does not satisfy the exclusive use criteria¹. The Agency concludes that Syngenta's request that exclusive use data protection be applied to MRID 49227601 and include any and all members of the dried shelled pea and bean subgroup 6C subgroup is **DENIED**.

Your request for protection of data associated with commodities in the bushberry crop subgroup 13-07B does qualify for exclusive use protection. All members of this group are considered minor uses and were approved on certain difenoconazole labels 5/6/2015. These data were found to pertain solely to new minor uses, the data was found to support minor uses which were actually approved on the label, the data is not publically owned (eg., can't be IR-4, public literature, etc), and the 10-year base period of exclusivity on difenoconazole ended as of 8/3/1994. The Agency **GRANTS** your request that exclusive use data protection for difenoconazole apply to MRID 49227602 and to all current members of the bushberry crop subgroup 13-07B. This exclusive use data protection period is applicable from 10/29/2014 to 10/29/2024.

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,



Susan Lewis, Director
Registration Division (7505P)
Office of Pesticide Programs

Enclosure: Minor Use Crop Status for Legume Crop Group 6C and Bush Berry Crop Group 13-07B Being Considered in the Request for a New Exclusive Use Period for Protection of Data for Difenoconazole (DP # 421037)

¹*Exclusive use period for certain minor use data.* A study submitted by an applicant or registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use under paragraph (b)(1) of this section is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all the following conditions are met: (1) The study relates solely to a minor use of a pesticide. (2) The applicant or registrant at the time the new use is requested has notified the Administrator that any exclusive use period for the pesticide has expired and that the study is eligible for exclusive use treatment. (3) Less than 10 years have passed since the study was submitted to EPA. (4) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B)(5) The minor use supported by the data has not been voluntarily canceled nor have such data been used to support a non-minor use. See Federal Register 79, 6825