



October 10, 2016

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Attention: Steve Schaible (Reduced Risk Program Coordinator)

**Re: Submission of Three Year Exclusive Data Use Extension Petition for
Flupyradifurone**

Flupyradifurone TC (EPA Re. No. 264-1143)

Dear Mr. Schaible,

Bayer is herein submitting a petition for a three-year extension of exclusive use data protection, as provided under FIFRA Section 3(c)(1)(F)(ii) and, additionally, the instructions provided on pages 9 and 10 of the "Questions and Answers – Exclusive Use Data Protection for Minor Use Registration – Revised August 2014" about how to do it for the chemical with reduced risk minor use registration approved by the Agency within certain timeframes, *via* PRIA M007 (new CR No. 188).

A number of registered uses from flupyradifurone have been granted reduced risk designation in the initial submission (10/05/2012, registered on 01/15/2015, reduced risk letter dated on 03/05/2013) and the 2nd submission (09/14/2015, registered on 09/29/2016, reduced risk letter dated on 05/11/2016).

This exclusive data use extension petition document is primarily based on the minor crops (<300,000 acres) within the stone fruit crop grouping 12-12 that had been granted reduced risk designation on 12/1/2015 (reduced risk letter dated 05/11/2016) and was registered on 9/29/2016. As stated on pages 9 and 10 of the "Questions and Answers – Exclusive Use Data Protection for Minor Use Registration – Revised August 2014", the reduced risk determination for a minor use may support a request for extension of the exclusive use period under criteria II if the request is made within 2 months of the registration decision which includes the use(s).

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000



M-567389-01-1

The reduced risk justification documents to support the 12/1/2015 reduced risk decisions are MRID 49619814, 49619815 and 49619816. The reduced risk approval letter is dated 5/11/2016 (Attachment A). Flupyradifurone TC (EPA Reg. No 264-1143) and its end-use product, Sivanto 200 SL (EPA Reg. No. 264-1141), were first registered by the Agency on January 15, 2015. All of the minor crop candidates listed in this exclusive data use extension petition document are registered within 7 years of the commencement of the exclusive use period.

In support of this petition, we are submitting the following:

1. EPA Form 8570-1 dated October 10, 2016
2. PRIA fee payment confirmation: \$ 5,513 (PRIA M007, new CR No. 188)
3. Transmittal document listing exclusive data use extension petition document

Please contact me at 919-549-2634 or at jamin.huang@bayer.com if you have any questions regarding this petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Jamin Huang". The signature is fluid and cursive, with the first name "Jamin" written in a larger, more prominent script than the last name "Huang".

Jamin Huang, Ph.D.
Senior Regulatory Manager

CC: Mark Suarez (PM 07, Invertebrate-Vertebrate Branch 3, RD)

Attachment A



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

OFFICE OF
OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 11 2016

Jamin Huang
Senior Regulatory Manager
Bayer CropScience
2 T.W. Alexander Drive
P.O. Box 12014
Research Triangle Park, NC 27709

Subject: Reduced Risk Decision for Uses of Flupyradifurone on Stone Fruit, Avocado, Pomegranate, Ornamentals, and Greenhouse Vegetables

Dear Mr. Huang,

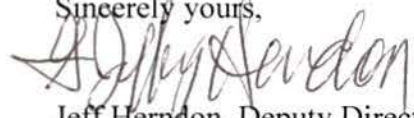
Thank you for your submission requesting reduced risk designation for the use of the insecticide flupyradifurone on the following uses: stone fruit, avocado, pomegranate, ornamentals, and greenhouse vegetables. On December 1, 2015, the Reduced Risk Committee completed its review of this reduced risk rationale and approved flupyradifurone as a "reduced risk" candidate for the requested food uses. Based on the committee's evaluation of the information provided, it appears the mammalian toxicity risk profile for flupyradifurone is favorable compared to those of registered alternatives for these crops. In addition, the chemical should fit in well with integrated pest management and resistance management strategies.

Please note that the reduced risk status of any chemical is an initial assessment. Should information warrant, the Agency may re-evaluate and possibly revoke your submission's reduced risk status. Also, should the Agency determine at any time that the data base for the chemical is unacceptable or incomplete, the Agency may stop the expedited process for the chemical.

Under the Pesticide Registration Improvement Act (PRIA), uses designated as "reduced risk" receive an expedited time frame for review. Meredith Laws is the branch chief in EPA who will now handle all regulatory issues associated with this application. You may contact Meredith at (703) 305-7038.

Thank you for your interest in reduced risk pesticides. If you have any questions regarding the reduced risk pesticide program please feel free to contact Steve Schaible at (703) 308-9362.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Jeff Herndon", written over the typed name.

Jeff Herndon, Deputy Director
Registration Division (7505P)

cc: Meredith Laws