Bayer CropScience

Title

Amended Petition for a Three-Year Extension of Exclusive Use Data Protection for Flupyradifurone As Provided For Under FIFRA Section 3(c)(1)(F)(ii)

- Final Report -

Data Requirement

US EPA OCSPP Guideline No. – Not Applicable

Completion Date

December 15, 2017

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Study ID

US0616

Activity ID

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that the information not designated as within the scope of FIFRA, Section 10(d)(1)(A)(B), or (C) in USA and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g) in USA.

However, these data are the property of Bayer CropScience AG and, as such, are considered to be a trade secret and confidential for all purposes other than compliance with FIFRA 10 in USA.

Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality which may exist under any other statute or in any country other than the USA.

In Europe, individual claims of confidentiality of studies submitted should be based on Article 14 based on directive 91/414 and/or on Article 63 based on regulation 1107/2009.

Submitter: Signature Amy J. McCaskill Date: 2017 – 12 - 15

(YYYY-MM-DD)

Typed Name of Submitter: Amy McCaskill

Typed Name of Company Bayer CropScience

The above statement supersedes all other statements of confidentiality that may occur elsewhere in this report.

GOOD LABORATORY PRACTICE STATEMENT

This document is informational, and it does not meet the requirements as defined by 40 CFR 160.3. Since the document does not report a study, no GLP (40 CFR 160 *or* Current OECD Principles of Good Laboratory Practices) statement is required as per PR Notice 2011-3 (VI)(C)(3), p. 11.

Study Director: There is no study director for this document

Sponsor/Submitter: Amy S. McCaskill Date: 2017 – 12 – 15
Signature (YYYY-MM-DD)

Typed Name of Signer: Amy McCaskill

Typed Name of Company: Bayer CropScience

Flupyradifurone – Petition for a Three Year Extension of Exclusive Use Data Protection

Bayer, the sole registrant of the proprietary insecticide, flupyradifurone, is hereby petitioning the Environmental Protection Agency for a three year extension of exclusive use data protection, as provided under FIFRA Section 3(c)(1)(F)(ii). After discussions with the Agency, this amendment to the original petition (MRID 50081901) is to add additional minor crop candidates to support the three year extension.

As with the original petition, Bayer is submitting the additional crop candidates under FIFRA Section 3(c)(1)(F)(ii) and the status of the additional crops as determined by the Agency as reduced risk uses. In support of this amended petition included in this document are the following:

- References to the reduced risk submissions, including the MRID numbers;
- The Agency's reduced risk approval letters; and
- Status to satisfy criterion II, e.g., no change in the human health and ecological toxicity end points since the reduced risk status determination was made; criterion III, playing a significant part in a Resistance Management program; criterion IV, playing a significant part in an Integrated Pest Management program.

A number of flupyradifurone registered uses that are included in the initial submission (10/05/2012, approved on 01/15/2015) and the 2nd submission (09/14/2015, approved on 09/29/2016) have been granted reduced risk designation, see **Attachment 1** (reduced risk approval for the initial submission, dated 03/05/2013) and **Attachment 2** (reduced risk approval for the second submission, dated 05/11/2016).

This exclusive data use extension petition document is based on the minor crops (<300,000 acres) within the stone fruit crop grouping 12-12 and avocado, see Table 1, as well as pomegranate and 4 greenhouse vegetables (cucumber, lettuce, pepper and tomato), see Table 2, that had all been granted reduced risk designation on 12/1/2015 (details in **Attachment 2**) and were registered on 9/29/2016 (in Sivanto 200 SL (EPA Reg. No. 264-1141)) and 12/16/2016 (greenhouse use listed in Altus (EPA Reg. No. 432-1575)) respectively. Table 2 also includes a number of additional minor crop candidates approved by the Agency on 01/15/2015 and their reduced risk status granted on 02/12/2013 (**Attachment 1**).

The submitted reduced risk justification documents to support the 12/1/2015 reduced risk decisions made by the EPA Reduced Risk Committee are MRID 49619814, 49619815 and 49619816. The reduced risk approval letter is dated 5/11/2016 (**Attachment 2**). The justification documents to support the 02/12/2013 reduced risk decisions are MRID 48844242 and 48844243, and the reduced risk approval letter is dated 03/05/2013 (**Attachment 1**). 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 01/15/2015. Altus (EPA Reg. No. 432-1575) was subsequently registered on 12/16/2016.

All of the minor crop candidates listed in this exclusive data use extension petition document were registered within 7 years of the commencement of the exclusive use period.

Table 1: Flupyradifurone Minor Use Crop Candidates (listed in MRID 50081901)

Candidate No.	Crop Common Name	Species	Total Acres 2012	Residue Data to Support	MRID #	Date Registered	Crop Group
1	Sweet Cherries	*Prunus avium*	<105,244[A]	Sweet and sour cherry	49619806	9/29/2016	12-12A
2	Tart Cherries	*Prunus cerasus*	<49,785[B]	Sweet and sour cherry	49619806	9/29/2016	12-12A
3	Peaches	*Prunus persica*	128,480	Peach	49619806	9/29/2016	12-12B
4	Apricot	*Prunus armeniaca*	<12,843[C]	Plum	49619806	9/29/2016	12-12C
5	Nectarines	*Prunus persica*	22,367	Peach	49619806	9/29/2016	12-12B
6	Plums & Prunes	*Prunus domestica*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
7	American Plum	*Prunus americana*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
8	Beach Plum	*Prunus maritima*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
9	Canada Plum	*Prunus nigra*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
10	Cherry Plum	*Prunus cerasifera*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
11	Chickasaw Plum	*Prunus angustifolia*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
12	Damson Plum	*Prunus domestica* ssp. *insititia*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
13	Japanese Plum	*Prunus salicina*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
14	Klamath Plum	*Prunus subcordata*	<88,122[D]	Plum	49619806	9/29/2016	12-12C
15	Plumcot	Interspecific plums (ex. *Prunus salicina* and *Prunus armeniaca*)	3,317	Plum	49619806	9/29/2016	12-12C
16	Capulin	*Prunus salicifolia*	<105,244[A]	Sweet and sour cherry	49619806	9/29/2016	12-12A
17	Black Cherry	*Prunus serotina*	<105,244[A]	Sweet and sour cherry	49619806	9/29/2016	12-12A
18	Nanking Cherry	*Prunus tomentosa*	<49,785[B]	Sweet and sour cherry	49619806	9/29/2016	12-12A
19	Chinese Jujube	*Ziziphus jujuba*	<14,427[E]	Plum	49619806	9/29/2016	12-12C
20	Japanese Apricot	*Prunus mume*	<12,843[C]	Plum	49619806	9/29/2016	12-12C
21	Sloe	*Prunus spinosa*	<14,427[E]	Plum	49619806	9/29/2016	12-12C
22	Avocado	*Persea americana*	73,535	Avocado	49619807	9/29/2016	24B

[A] All acreage of crops/species that comprise the sweet cherry group are aggregated in the 2012 USDA census. Therefore exact acreage for each crop is unknown. However, since total acreage is than the 300,000 acres, all of these crops qualify as minor use crops.
[B] All acreage of crops/species that comprise the tart cherry group are aggregated in the 2012 USDA census. Therefore exact acreage for each crop is unknown. However, since total acreage is than the 300,000 acres, all of these crops qualify as minor use crops.
[C] All acreage of crops/species that comprise the apricot group are aggregated in the 2012 USDA census. Therefore exact acreage for each crop is unknown. However, since total acreage is than the 300,000 acres, all of these crops qualify as minor use crops.
[D] All acreage of crops/species that comprise the plum group are reported under plums and prunes in the 2012 USDA census. Therefore exact acreage for each crop is unknown. However, since total acreage is than the 300,000 acres, all of these crops

qualify as minor use crops.

[E] All acreage of crops/species of Chinese Jujube and Sloe are reported under Other Non-citrus Fruits in the 2012 USDA census. Therefore exact acreage for each crop is unknown. However, since total acreage is than the 300,000 acres, all of these crops qualify as minor use crops.

Acreage Source: 2014 USDA. 2012 Census of Agriculture: United States Summary and State Data. Vol. 1. Geographic Area Series Part 51. AC-12-A-51.

Table 2: Additional Flupyradifurone Minor Use Crop Candidates

Candidate No.	Crop Common Name	Species	Total Acres	Residue Data to Support	MRID #	Date Registered	Crop Group
23	Pomegranate	*Punica granatum*	32,887[D]	Pomegranate	49619808 (IR-4)	9/29/2016	24B
24	Cucumber (GH)	*Cucumis sativus*	≤ 252[E]	Cucumber (GH)	49618602 (IR-4)	12/16/2016	9B
25	Lettuce (GH)	*Lactuca sativa*	≤ 99[E]	Lettuce (GH)	49618603 (PMC)	12/16/2016	4-16A
26	Pepper (GH)	*Capsicum spp.*	≤ 81[E]	Pepper (GH)	49618604 (BCS) 49618605 (IR-4)	12/16/2016	8-10B
27	Tomato (GH)	*Solanum lycopersicum*	≤ 978[E]	Tomato (GH)	49618601 (IR-4)	12/16/2016	8-10A
28	Broccoli	*Brassica oleracea var. italica*	132,300[B]	Broccoli	48843905 48843906	1/15/2015	4-16
29	Cabbage	*Brassica oleracea var.capitata*	59,400[B]	Cabbage	48843905 48843906	1/15/2015	4-16
30	Cauliflower	*Brassica oleracea var. botrytis*	37,300[B]	Cauliflower	48843905 48843906	1/15/2015	5
31	Grapefruit	*Citrus x paradisi*	60,400[A]	Grapefruit	48843913 48843914	1/15/2015	10-10
32	Lemon	*Citrus x limon*	54,300[A]	Lemon	48843913 48843914	1/15/2015	10-10
33	Cucumber	*Cucumis sativus*	124,200[B]	Cucumber	48843912	1/15/2015	9
34	Muskmelon	*Cucumis melo*	55,300[A]	Muskmelon	48843912	1/15/2015	9
35	Squash	*Cucurbita pepo*	37,400[B]	Summer squash	48843912	1/15/2015	9
36	Celery	*Apium graveolens*	29,300[B]	Celery	48843904	1/15/2015	4
37	Lettuce, Head, Leaf, Romaine	*Lactuca sativa*	186,500[B]	Head Lettuce, Leaf Lettuce	48843904	1/15/2015	4
38	Spinach, Fresh and Processed	*Spinacia oleracea*	48,600[B]	Spinach	48843904	1/15/2015	4
39	Pear	*Pyrus spp.*	46,300[B]	Pear	48843916	1/15/2015	11-10
40	Carrot	*Daucus carota subsp. sativus*	84,600[B]	Carrot	48843901	1/15/2015	1
41	Radish	*Raphanus raphanistrum subsp. sativus*	15,800[C]	Radish	48843901	1/15/2015	1

In order to be conservative, when both acres planted and acres harvested are reported separately in the NASS data, acres planted were used.
[A]2017 Nass data. https://www.nass.usda.gov/Statistics_by_Subject/index.php?sector=CROPS
[B]2016 Nass data. https://www.nass.usda.gov/Statistics_by_Subject/index.php?sector=CROPS

[C]2001 Nass data https://www.nass.usda.gov/Statistics_by_Subject/index.php?sector=CROPS
[D]2012 Census of Agriculture, United States Summary and State Data, Volume 1, Part 51. https://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf
[E]2014 Census of Horticultural Specialties. Numbers reported included all acres grown under protection. Greenhouse only acres may be even lower than the numbers reported. https://agcensus.usda.gov/Publications/2012/Online_Resources/Census_of_Horticulture_Specialties/hortic_2_014_014.pdf

Overall, the conditions for all the above listed uses would not be materially changed since the initial reduced risk status was granted, and the determinations are still applicable today as when first made. In particular, there have been no changes in the human health and ecological toxicity end points since the reduced risk status determination was made on 02/12/2013 for the crops in the first submission and 12/01/2015 for the 2nd submission. All of the proposed minor crop candidates listed in Tables 1 and 2 continue to play a significant part in a resistance management program and in an integrated pest management program.

Based on small plot field work, flupyradifurone offers excellent control of aphids on stone fruit crops while preserving beneficial arthropods such as ladybird beetles and predatory mites. Because of this, it will fit well into integrated pest management programs.

Flupyradifurone controls other sucking pests such as San Jose scale which occur on stone fruit. Flupyradifurone is efficacious on this pest and can be used as an alternative mode of action with currently available grower standards and therefore contributes to strong insect resistance management strategies.

In vegetables, such as, cucumber, lettuce, pepper and tomato listed in Table 2, and in crops of subgroup 24B, such as avocado (in Table 1) and pomegranate (in Table 2), flupyradifurone offers excellent control of important pests including aphids and whiteflies. Known to be a soft chemistry towards beneficial insects and pollinators, flupyradifurone is an excellent fit for integrated pest management programs, especially in greenhouses which incorporate biological control. As the only insecticide in IRAC subgroup 4D, flupyradifurone controls both aphids and whiteflies with an alternative mode of action relative to currently available grower standards and therefore contributes to strong insect resistance management strategies.

Additionally, managed and wild bumble bees can contribute to pollination of orchard crops, including stone fruit, http://msue.anr.msu.edu/topic/cherries/horticulture/pollination. Bumble bees are important in commercial pollination of crops such as tomatoes, peppers, cranberries and blueberries where the pollen is more firmly held to the anther and buzz pollination can be more efficient. Bumble bees also contribute to the pollination of pome fruits, cucurbits, berries, alfalfa, seed production (e.g., onion, carrot, Brassica) and oilseeds (e.g., sunflower, safflower). Flupyradifurone also has a favorable bumble bee safety profile, as stated in the referenced risk assessment that "*an acute oral toxicity test was reviewed and demonstrated that technical grade flupyradifurone is no more than moderately toxic to the bumblebee (MRID 49846301, Supplemental) with a 48-hr non-definitive median lethal dose for 50% of the bees tested (LD50) of >8.52 µg a.i./bee".* (DP Barcode: 430349, 430366, 430367; 7/18/2016 EPA Memorandum: Environmental Fate and Ecological Risk Assessment in support of proposed Uses of flupyradifurone on ornamentals, residential, greenhouse, nursery, Stone fruit C12-12, Caneberry 13-07A, taro leaves, turnip greens, abiu, akee apple, avocado, bacury, banana, canistel, cupuacu, etambe, jatoba, kei apple, langstat, lanjut, lucuma, mabolo mango, mangosteen, paho, papaya, pawpaw, pelipisan, pequi, persimmon, plantain, pomegranate, poshte, quandong, sapote, sataw, screw-pine, star apple, tamarind of the indies and wild loquat).

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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RECEIVED
MAR 1 1 2013
BY: AKW

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

Subject: Reduced Risk Decision for Flupyradifurone Food Uses Associated with New Active Ingredient Application

Dear Mr. Huang,

Thank you for your submission requesting reduced risk designation for the use of Bayer Crop Sciences' insecticide new active ingredient, flupyradifurone, on the following uses: citrus, cotton, cucurbit vegetables, fruiting vegetables, and pome fruit. On February 12, 2013, 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, there appears to be a relatively lower risk to honeybees when compared to registered alternatives and the chemical should fit in well with integrated pest management and resistance management strategies. While the reduced risk package provided risk comparison information only for the food uses listed above, using market comparison information the committee expanded the reduced risk designation to also include Brassica leafy vegetables, leafy (non-Brassica) vegetables, root and tuber vegetables, and legume vegetables.

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,

Lois Rossi

Lois Rossi, Director
Registration Division (7505C)

cc: Meredith Laws
Terri Stewart (PMRA)

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

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AND POLLUTION PREVENTION

MAY 1 1 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, Ornamenatals, 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,

Jeff Herndon, Deputy Director
Registration Division (7505P)

cc: Meredith Laws