CENTER for BIOLOGICAL DIVERSITY

March 16, 2015

Sent via Email and Certified Mail Return Receipt Requested
Gina McCarthy, Administrator
United States Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue NW
Mail Code: 1101A
Washington, DC 20460
Mccarthy.gina@epa.gov

Re: Notice of Violations of the Endangered Species Act Regarding Registration of Flupyradifurone

On behalf of the Center for Biological Diversity, the Center for Food Safety, and Defenders of Wildlife, we hereby provide notice, pursuant to Section 11(g) of the Endangered Species Act ("ESA"), 16 U.S.C. §1540(g)(2)(A)(i), that the United States Environmental Protection Agency ("EPA") is in violation of the ESA.

The Center for Biological Diversity ("Center") is a non-profit, public interest corporation with offices in Washington, D.C. and elsewhere in the United States, and approximately 50,000 members in Washington, D.C. and elsewhere in the U.S. The Center and its members are dedicated to protecting diverse native species and habitats through science, policy, education, and law. Recognizing that insecticides are one of the foremost threats to the environment, biodiversity, and public health, the Center works to prevent and reduce the use of harmful insecticides and to promote sound conservation strategies.

EPA has violated the ESA's Section 7 consultation requirement regarding its discretionary decision to register the new active ingredient Flupyradifurone, as well as its discretionary decision to approve three end-use products of Flupyradifurone. EPA's failure to consult with the U.S. Fish and Wildlife Service ("FWS") and National Marine Fisheries Service ("NMFS") (collectively "the Services") is particularly egregious because EPA's own risk assessment found that Flupyradifurone, its products, and its chemical degradates are toxic to several taxonomic groups — potentially impacting hundreds of endangered species.

EPA's registration of Flupyradifurone — and its approval of three products containing Flupyradifurone — will likely jeopardize federally-listed species and adversely modifies the critical habitat of listed species. Despite the likely harm to threatened and endangered species, EPA chose to register this pesticide without consultations to determine appropriate mitigation and measures to avoid jeopardizing listed species. EPA's failure to consult is contrary to its own ecological risk assessment, which concluded that exposure to Flupyradifurone would have acute and chronic impacts on listed birds, mammals, amphibians, reptiles, freshwater invertebrates, and marine invertebrates, and would likely impact the critical habitats of listed species of virtually all taxonomic groups.

In addition, EPA is in violation of Section 9 of the ESA for allowing the "take" of listed species which will result from the use of Flupyradifurone and its end-use products.

LEGAL BACKGROUND

A. The Endangered Species Act

The ESA was enacted, in part, to provide a "means whereby the ecosystems upon which endangered species and threatened species depend may be conserved…[and] a program for the conservation of such endangered species and threatened species…."[1]

The ESA vests primary responsibility for administering and enforcing the statute with the Secretaries of Commerce and Interior. The Secretaries of Commerce and Interior have delegated this responsibility to the NMFS and the FWS respectively.[2]

Section 2(c) of the ESA establishes that it is "the policy of Congress that all Federal departments and agencies shall seek to conserve endangered species and threatened species and shall utilize their authorities in furtherance of the purposes of this Act."[3] The ESA defines "conservation" to mean "the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this Act are no longer necessary."[4] Similarly, Section 7(a)(1) of the ESA directs that the Secretary review "other programs administered by him and utilize such programs in furtherance of the purposes of the Act."[5]

In order to fulfill the substantive purposes of the ESA, federal agencies are required to engage in consultation with FWS (and/or NMFS) to "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the adverse modification of habitat of such species . . . determined . . . to be critical . . . ."[6]

Section 7 consultation is required for "any action [that] may affect listed species or critical habitat."[7] Agency "action" is broadly defined in the ESA's implementing regulations to include "(b) the promulgation of regulations; (c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or (d) actions directly or indirectly causing modifications to the land, water, or air."[8]

[1] 16 U.S.C. §§ 1531-1544; 16 U.S.C. § 1531(b).
[2] 50 C.F.R. § 402.01(b).
[3] 16 U.S.C. § 1531(c)(1).
[4] 16 U.S.C. § 1532(3).
[5] 16 U.S.C. § 1536(a)(1).
[6] 16 U.S.C. § 1536(a)(2) ("Section 7 consultation").
[7] 50 C.F.R. § 402.14.
[8] 50 C.F.R. § 402.02.

At the completion of consultation, FWS or NMFS issues a biological opinion that determines if the agency action is likely to jeopardize the species. If so, the opinion may specify reasonable and prudent alternatives that will avoid jeopardy and allow the agency to proceed with the action.[9] FWS and NMFS may also "suggest modifications" to the action (called reasonable and prudent measures) during the course of consultation to "avoid the likelihood of adverse effects" to the listed species even when not necessary to avoid jeopardy.[10]

Section 7(d) of the ESA provides that once a federal agency initiates consultation on an action under the ESA, the agency, as well as any applicant for a federal permit, "shall not make any irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures which would not violate subsection (a)(2) of this section."[11] The purpose of Section 7(d) is to maintain the environmental status quo pending the completion of consultation. Section 7(d) prohibitions remain in effect throughout the consultation period and until the federal agency has satisfied its obligations under Section 7(a)(2) that the action will not result in jeopardy to the species or adverse modification of its critical habitat.

Section 9 of the ESA prohibits any person, including federal agencies, from taking any endangered or threatened species.[12] The term "take" is defined broadly to include "harass, harm, pursue, hunt, shoot, wound, trap, kill, capture, or collect, or to attempt to engage in any such conduct."[13] "Harm" is further defined as "an act which actually kills or injures wildlife. Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding or sheltering."[14] Thus, an action which indirectly (e.g. habitat modification) or directly causes a decline in the population of an endangered species harms that species. Additionally, any action that precludes the recovery of an endangered species also falls within the meaning of harm.

Federal agencies may be limitedly exempt from the take prohibition through the issuance of an Incidental Take Statement ("ITS") as part of a Biological Opinion.[15] The ITS must identify the expected impacts of the authorized take, the reasonable and prudent measures necessary to minimize those impacts, and the terms and conditions that the agency must comply with to adequately implement those measures.[16]

B. The Federal Insecticide, Fungicide, and Rodenticide Act

Congress enacted the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") to regulate the use of pesticides in the United States.[17] FIFRA charges EPA with registering, reviewing, amending, and reregistering chemicals and chemical formulations for use as insecticides,

[9] 16 U.S.C. § 1536(b).
[10] 50 C.F.R. § 402.13.
[11] 16 U.S.C. § 1536(d).
[12] 16 U.S.C. § 1538(a)(1)(B); 50 C.F.R. § 17.21(c).
[13] 16 U.S.C. § 1532(19); 50 C.F.R § 17.3.
[14] 50 C.F.R. § 17.3.
[15] 16 U.S.C. § 1536(o)(2); 50 C.F.R. § 402.14(i)(5).
[16] 16 U.S.C. § 1536(b)(4); 50 C.F.R. § 402.14(i)(1)(i)-(v).
[17] *See* 7 U.S.C. §§ 136-136y.

fungicides, and pesticides in the United States.[18] Under FIFRA, an insecticide generally may not be sold or used in the United States unless it has an EPA registration for that particular use.[19]

EPA may register an insecticide if it makes the following determinations: (1) the labeling complies with FIFRA's requirements; (2) the composition claims are warranted; (3) the insecticide will perform its intended function; and (4) the insecticide will not cause unreasonable adverse effects on the environment.[20] The culmination of the registration process is EPA's approval of a label for the particular insecticide. FIFRA makes it unlawful to use an insecticide in a manner inconsistent with the label,[21] or to make any claims that differ substantially from the label.[22] The ESA's Section 7 requirements apply to EPA's discretionary registration of insecticides under FIFRA, and its actions in exercising its continuing authority over insecticide regulation.[23]

FACTUAL BACKGROUND

A. Flupyradifurone Overview

Flupyradifurone is a systemic insecticide belonging to the butenolide class of insecticides. Flupyradifurone works by binding with insect nicotinic acetylcholine receptors, which leads to a disorder of the nervous system of the insect and subsequent death.[24]

Flupyradifurone is intended to be used in agricultural applications, and can be applied to a wide variety of crops[25] using variety of applicator methods including foliar spray, soil drench, and systemic seed treatment (soybean only).[26]

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[18] *Id*.
[19] 7 U.S.C. § 136a(a).
[20] 7 U.S.C. § 136a(c)(5).
[21] *Id*. § 136j(2)(G).
[22] *Id*. § 136j(1)(B).
[23] *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) ("We agree with the Eighth Circuit that even though EPA registers pesticides under FIFRA, it must also comply with the ESA when threatened or endangered species are affected."); *Defenders of Wildlife v. Administration*, 882 F.2d 1294 (8th Cir. 1989) (affirming Section 7's application to EPA's registration of pesticides).
[24] EPA. 2014. ENVIRONMENTAL FATE AND ECOLOGICAL RISK ASSESSMENT FOR FOLIAR, SOIL DRENCH, AND SEED TREATMENT USES OF THE NEW INSECTICIDE FLUPYRADIFURONE (BYI 02960) (hereafter "FLUPYRADIFURONE RISK ASSESSMENT"). Office of Pesticide Programs Environmental Fate and Effects Division. Docket #: EPA-HQ-OPP-2013-0226-0015.
[25] Crops include: Bushberry, Except Cranberry (Crop Subgroup 13-07B); Low Growing Berry Except Cranberry (Crop Subgroup 13-07G); Bulb Vegetables (Crop Group 3-07); Cereal Grains Except Rice (Crop Group 15); Citrus Fruits (Crop Group 10-10); Cottonseed (Crop Subgroup 20C); Cucurbit Vegetables (Crop Group 9); Edible Podded Legume Vegetables (Crop Subgroup 6A); Succulent Shelled Pea and Bean (Crop Subgroup 6B); Dried Shelled Pea and Bean (except Soybean); Foliage of Legume Vegetables (except Soybean) (Crop Subgroup 7A); Non-grass Animal Feeds (Alfalfa and Clover only); Forage, Fodder, and Straw of Cereal Grains (Crop Group 16); Fruiting Vegetables (Crop Group 8-10); Hops; Head and Stem Brassica Vegetables (Crop Subgroup 5A); Leafy Brassica Greens (Crop Subgroup 5B); Leafy Vegetables (Except Brassica) (Crop Group 4); Peanuts; Pitaya; Pome Fruits (Crop Group 11-10); Prickly Pear Cactus; Root Vegetables Except Sugar Beet (Crop Subgroup I B); Small Fruit Vine Climbing (Except Fuzzy Kiwifruit) (Crop Subgroup 13-07F); Taro Leaves; Tree nuts (Crop Group 14-12); Turnip Greens; and Tuberous Corm Vegetables (Crop Subgroup I C).
[26] FLUPYRADIFURONE RISK ASSESSMENT at 10.

Flupyradifurone is persistent to very persistent and moderately mobile to mobile depending on soil conditions; it therefore has the potential to reach aquatic environments, including surface and groundwater, for several months or more after application.[27] Flupyradifurone is likely to dissipate from the application point through runoff, erosion, and leaching into groundwater.[28] Given its persistence and ability to reach aquatic environments, there are significant risks for aquatic organisms in both the water column and benthic environments. Both acute and chronic risk to federally threatened and endangered species exceeded Levels of Concern (LOCs) for freshwater and estuarine/marine invertebrates. Because Flupyradifurone is mobile to moderately mobile and persistent in the aquatic environment, there is the potential for both short-term and long-term exposure to aquatic organisms.[29]

Flupyradifurone is highly toxic to honeybees on an acute oral exposure basis, with individual adult bees suffering a 50% mortality rate following ingestion of residues at relatively low exposure levels. Despite this observed high mortality rate, and the determination that "effects of flupyradifurone to non-target terrestrial arthropods is possible *at or below proposed application rates*," EPA did not evaluate risk to other terrestrial invertebrates, including endangered terrestrial invertebrates.[30]

B. EPA's Approval of Flupyradifurone

On May 29, 2013, EPA published a notice in the Federal Register that it had received applications for new pesticide ingredients pursuant to Section 3(c)(4) of FIFRA and announced the opening of five new dockets including a docket for Flupyradifurone (Docket #: EPA-HQ-OPP-2013-0226).[31] On June 5, 2013, EPA published a notice in the Federal Register that it had received applications for residues of pesticide chemicals ("tolerances") for 17 new pesticide tolerances, including Flupyradifurone (see Appendix A).[32]

Rather than providing public notice and comment through the Federal Register, all subsequent decisions and announcements regarding registration of Flupyradifurone were only posted to the docket on Regulations.gov. On September 24, 2014, EPA posted an announcement to the docket for Flupyradifurone announcing a proposed registration decision and the opening of a 30-day comment period.[33] EPA received 32 public comments regarding the proposed registration of Flupyradifurone.

The Center submitted a comment in response to the proposed registration of Flupyradifurone, stating that the EPA has an independent duty to consult with FWS and NMFS under the ESA on the registration of any new active ingredient that may affect protected species, as well as a duty

[27] FLUPYRADIFURONE RISK ASSESSMENT at 6.
[28] *Id.*
[29] *Id*.
[30] *Id*. at 7 (emphasis added).
[31] *Pesticide Products; Registration Applications for New Active Ingredients*, 78 Fed. Reg. 32246-47 (May 29, 2013).
[32] *Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities*, 78 Fed. Reg. 33785-87 (June 5, 2013).
[33] EPA, 2014. PROPOSED REGISTRATION DECISION OF THE NEW ACTIVE INGREDIENT –FLUPYRADIFURONE. (Docket #: EPA-HQ-OPP-2013-0226-0015).

to consult with FWS and NMFS on the approval of any end-use product that may affect protected species.[34] The Center, in its comment, also noted that the ecological risk assessment for Flupyradifurone is under-protective of listed species and should be revisited based on findings of a National Academy of Sciences Report and the interim approaches document.[35]

On January 14, 2015, EPA approved the registration of Flupyradifurone as a new active ingredient (see Appendix B) and two end-use products — the technical formulation "Flupyradifurone TC," and "'Sivanto™ 200 SL."[36] An additional product, "BYI 02960 480 FS" has been proposed, but was not approved by EPA as part of the registration decision. As of February 26, 2015, the technical formulation and its label has been approved and posted to EPA's Pesticide Product Label System. However, the two product labels have not been approved and posted to EPA's online Pesticide Product Label System[37] yet:

Product Name	**Docket ID**	**Date Proposed**	**Active Ingredient %**
BYI 02960 480 FS	EPA-HQ-OPP-2013-0226-0014	9/25/14	Flupyradifurone – 40.68%
Sivanto 200 SL	EPA-HQ-OPP-2013-0226-0013	9/25/14	Flupyradifurone – 17.09%

In response to the Center's comments, EPA acknowledged the need to consult on Flupyradifurone, but stated that it is "focusing most of its resources for assessing impacts to listed species . . . for currently registered pesticides."[38] EPA also stated that it was "working to prioritize its consultation activities with Services and will evaluate the appropriate timing and scope of consultation on Flupyradifurone in connection with those efforts."[39] There is no evidence on the docket for Flupyradifurone or elsewhere on EPA's publically available websites that any such efforts are occurring.

C. Flupyradifurone's Risks to Listed Species

EPA's own ecological risk assessment demonstrates that Flupyradifurone will cause both acute and chronic adverse effects on listed species:

> Acute risk to federally threatened and endangered (listed) species and chronic risk Levels of Concern (LOCs) for freshwater and estuarine/marine invertebrates were exceeded for the majority of proposed uses in this assessment . . . risk estimates exceeded the acute risk to listed birds LOC for all proposed foliar and soil drench uses, as does the proposed seed treatment use . . . .[40]

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[34] Comment submitted by Brett Hartl, Endangered Species Policy Director, Docket ID: EPA-HQ-OPP-2013-0226-0039.
[35] *Id*. at 11.
[36] [36] *See generally*, EPA, 2014. PROPOSED REGISTRATION DECISION OF THE NEW ACTIVE INGREDIENT – FLUPYRADIFURONE. (Docket #: EPA-HQ-OPP-2013-0226-0015).
[37] *See generally*, http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.
[38] *Id*. at 10.
[39] *Id*. at 12.
[40] FLUPYRADIFURONE RISK ASSESSMENT at 6-7.

Additionally, the EPA risk assessment found that Flupyradifurone is highly toxic to honeybees on an acute oral exposure basis, but did not evaluate the risk to *any* endangered terrestrial invertebrates.[41]

While it is clear that aquatic invertebrates, birds, terrestrial-phase amphibians, reptiles, and mammals are at most direct risk from Flupyradifurone, the EPA risk assessment concludes that acute and chronic harm (which includes potential harm to designated critical habitat) will occur for many taxonomic groups that are represented on the list of threatened and endangered species:[42]

Listed Taxon	Direct Effects	Indirect Effects
Terrestrial and semi-aquatic plants – monocots	N/A	Yes
Terrestrial and semi-aquatic plants – dicots	Uncertain	Yes
Birds	Yes (acute and chronic)	Yes
Terrestrial-phase amphibians	Yes (acute and chronic)	Yes
Reptiles	Yes (acute and chronic)	Yes
Mammals	Yes (chronic)	Yes
Aquatic plants	No	Yes
Freshwater fish	No	Yes
Aquatic-phase amphibians	No	Yes
Freshwater invertebrates	Yes (acute and chronic)	Yes
Mollusks	No	Yes
Marine/estuarine fish	No	Yes
Marine/estuarine invertebrates	Yes (acute and chronic)	Yes

Because Flupyradifurone has been approved for agricultural uses across the nation, the list of species that will be adversely affected is potentially quite large.

EPA identified the need for further assessment of buffers in order to protect critical habitat and listed species from adverse effects, but did not conduct any further analysis. The ecological risk assessment concludes that "while any setback buffer between an aquatic water body and the treated field is expected to reduce exposure, methodologies are not available to determine the distance that is needed to eliminate the risk concern from transport runoff."[43] EPA's draft Flupyradifurone Sivanto 200 SL label states that "a level, well-maintained vegetative buffer strip . . . will reduce the potential loading of Flupyradifurone and its degradate . . . from runoff water and sediment."[44] Yet the EPA's approved label restrictions for Flupyradifurone TC and draft

[41] *Id.*
[42] FLUPYRADIFURONE RISK ASSESSMENT at 120.
[43] FLUPYRADIFURONE RISK ASSESSMENT at 6.
[44] 264-RRUR Sivanto 200 SL, Product Label, Docket ID: EPA-HQ-OPP-2013-0226-0013.

label for Flupyradifurone BYI 02960 480 FS do not require vegetative buffer strips or any other types of buffers.[45]

The label for Flupyradifurone Sivanto 200 SL expressly acknowledges the risk to endangered species:

> This product may have effects on endangered species. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the county in which you are applying the product. To obtain Bulletins, no more than six months before using this product, consult http://www.epa.gov/espp/ or call 1-800-447-3813. You must use the Bulletin valid for the month in which you will apply the product.[46]

This generic instruction to pesticide users is a hollow gesture. *Bulletins Live!* only functions if the EPA initiates, and the Services then complete, ESA consultations. EPA cannot absolve its responsibilities to comply with the Endangered Species Act merely by acknowledging the harm to endangered species that exposure to Flupyradifurone will cause.

ESA VIOLATIONS

Consultation under Section 7 of the ESA is required whenever a discretionary agency action "may affect" any listed species or its critical habitat.[47] EPA's risk assessment makes clear that the "may affect" threshold is met for multiple listed species nationwide that could be harmed by Flupyradifurone and its end-use products. Furthermore, EPA's draft label for Flupyradifurone "Sivanto 200 SL" states that "this product may have effects on endangered species."[48] Thus, the trigger for consultations has been met, and the Endangered Species Act requires EPA to initiate consultation to ensure that the registration of Flupyradifurone and its approved products will not jeopardize any listed species or adversely modify critical habitat. EPA's refusal to initiate consultation prior to approving this new pesticide and its associated products violates EPA's Section 7 duty to consult under the ESA.

Moreover, after concluding that the nationwide registration of Flupyradifurone could affect listed species, after concluding that this pesticide is toxic to several taxonomic groups, and after failing to consult with the Services on this registration, EPA has failed to require *any* measures whatsoever to protect not even a single endangered species anywhere in the United States. As such, EPA's registration of Flupyradifurone and its associated end-use products/labels violates EPA's Section 7 duty to avoid jeopardizing the continued existence of any endangered species or

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[45] Flupyradifurone TC, EPA Registration Number 264-1143 (Jan. 15, 2015). *Available at*: http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1; *see also*, 264-RRUR Sivanto 200 SL, Product Label, Docket ID: EPA-HQ-OPP-2013-0226-0013; BYI 02960 480 FS, Product Label, Docket ID: EPA-HQ-OPP-2013-0226-0014.

[46] FLUPYRADIFURONE RISK ASSESSMENT at 6-7; 264-RRUR Sivanto 200 SL, Product Label, Docket ID: EPA-HQ-OPP-2013-0226-0013.

[47] 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a) ("Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required…"); *see Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005); *Defenders of Wildlife v. Administration*, 882 F.2d 1294 (8th Cir. 1989).

[48] 264-RRUR Sivanto 200 SL, Product Label, Docket ID: EPA-HQ-OPP-2013-0226-0013.

threatened species, and to avoid the destruction or adverse modification of critical habitat of listed species.

Simply put, EPA's own risk assessment establishes that use of Flupyradifurone may affect listed species or adversely modify critical habitat nationwide. EPA must satisfy its duty to avoid jeopardizing listed species, or adversely modifying their critical habitat, by initiating the consultation process for its actions in registering Flupyradifurone and its end-use products.

Section 9 of the ESA prohibits any person, including federal agencies, from taking any endangered or threatened species. Federal agencies may be limitedly exempt from the take prohibition through the issuance of an Incidental Take Statement ("ITS") as part of an Biological Opinion issued pursuant to Section 7 of the ESA. As discussed above, registration of Flupyradifurone and its products is a federal action that can cause the take of listed species due to the chemical's ability to harm and/or kill listed species. Consequently, in order to achieve safe harbor from ESA take liability in regard to Flupyradifurone, EPA must have written authorization from FWS and/or NMFS in the form of an ITS. Because EPA has thus far failed to even initiate consultation as to Flupyradifurone, it does not possess an ITS from the wildlife agencies and is therefore in violation of not only Section 7 of the ESA, but also Section 9 of the ESA.

CONCLUSION

If EPA does not act within 60 days to correct the violations described in this letter, we will pursue litigation against EPA. If you have any questions, or would like to discuss this matter, please contact us.

Sincerely,

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APPENDIX A

Posting an FDMS Docket without a Federal Register Notice

MEMORANDUM

SUBJECT: Posting EPA-HQ-OPP-2013-0226 to Regulations.gov for Public Access

TO: Office of Pesticide Programs Docket

FROM: Lois Rossi
Director, Registration Division
Office of Pesticide Programs

This memorandum authorizes the posting of EPA-HQ-OPP-2013-0226 to Regulations.gov for public access.

Background: The Agency received an application from Bayer CropScience to register the new active ingredient flupyradifurone targeting piercing, sucking insects such as aphids and whiteflies in a number of agricultural crops. The purpose of soliciting public comment is to give the public an opportunity to provide questions, concerns, etc. so the Agency may properly address them.

The following documents will be available for a 30-day public comment from September 25, 2014 to October 25, 2014:

- Rury, Kristin; Funk, Steve; Negussie, Meheret; Phang, Whang; Chen, Vincent; Olinger, Christine (2014). "Flupyradifurone: Human Health Risk Assessment for the First Food Use."
- Rury, Kristin; O'Keefe, Barry; Walls, Cassi; LaMay, Alexandra (2014). "Flupyradifurone. Occupational and Residential Exposure Assessment for a New Insecticide Active Ingredient."
- Glaberman, Scott; White, Katrina; Carleton, James N.; Steeger, Thomas; Winfield, Sarah (2014). "Environmental Fate and Ecological Risk Assessment for Foliar, Soil Drench, and Seed Treatment Uses of the New Insecticide Flupyradifurone (BYI 02960)."
- White, Katrina; Carleton, James N.; Winfield, Sarah (2014). "Drinking Water Exposure Assessment for the Section 3 New Chemical Registration for use of Flupyradifurone on a Variety of Agricultural Crops."
- Rossi, Lois (2014). "Proposed Registration Decision of the New Active Ingredient Flupyradifurone."
- Sivanto™ 200SL (draft label)
- BYI 02960 480 FS (draft label)
- Flupyradifurone TC (draft label)

Submit your comments, identified by Docket ID No. EPA-HQ-OPP-2013-0226, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting

comments.

- Mail: EPA-HQ-OPP-2013-0226 Environmental Protection Agency, Mailcode 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460
- Hand Delivery: Environmental Protection Agency Combined Docket, Environmental Protection Agency, 1301 Constitution Ave. NW, WJC West Rm. 3334, Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http://www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at http://www.epa.gov/epahome/dockets.htm.

Should you have any questions regarding this memorandum, please contact Lois Rossi at (703) 305-7090, or via email at RDFRNotices@epa.gov.

APPENDIX B

Registration Decision for the New Active Ingredient Flupyradifurone

Approved by: _____

Jack E. Housenger, Director
Office of Pesticide Programs

Date: 1-14-15

Summary

This document announces that the U.S. Environmental Protection Agency (EPA) has completed its evaluation of the new insecticide flupyradifurone and has concluded that it meets the regulatory standard under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Two products will be registered under Section 3(c)(5) of FIFRA, the technical formulation "Flupyradifurone TC," and an end-use formulation "Sivanto™ 200 SL."

Flupyradifurone is classified as a Reduced Risk pesticide. In comparison to the registered alternatives, flupyradifurone presents a less hazardous ecological and human health profile. The alternatives include neonicontinoids, organophosphates and pyrethroids. Registration of flupyradifurone will provide many growers of very diverse crops across the U.S. with a new pest management tool that presents an effective countermeasure to resistance development.

Background

On October 30, 2012, EPA received an application from Bayer Crop Science for registration of the new insecticide flupyradifurone (CAS Number 951659-40-8), which will be sold under the trade name "Sivanto." The application was also submitted for simultaneous review by the Pest Management Regulatory Agency (PMRA) of Canada and the Australian Pesticides and Veterinary Medicines Authority (APVMA). The EPA, the PMRA and the APVMA combined their resources in terms of scientific and regulatory expertise and conducted a "joint review" of flupyradifurone. Each country led the initial (primary) review of particular elements of the overall data package containing a total of 437 studies; EPA was the primary reviewer of the metabolism studies and North American field trials; PMRA was the lead reviewer of the product chemistry, environmental fate and the ecological toxicity studies. Canada also split the primary review of the mammalian acute toxicity studies with the APVMA. The APVMA was the lead reviewer for the mammalian chronic toxicity studies which in combination with the acute mammalian studies are used to evaluate potential effects on human health. Each country's team of scientists peer-reviewed the primary reviews of their counterparts to reach consensus on the evaluation of the data. While continuing to consult and coordinate, human health and ecological risk assessments were developed by each country individually.

Pesticides can be classified according to their mode of action (MoA) and their structure. One classification scheme is that developed by the Insecticide Resistance Action Committee (IRAC) to assist growers and crop protection professionals in selecting pesticides that can be used in an effective insecticide resistance management strategy. Under the IRAC classification process, flupyradifurone falls within a group of pesticides that inhibit the nicotinic acetylcholine receptor (IRAC Group 4). Similar to other neurotoxic chemicals that inhibit acetylcholine receptors (*e.g.* Group 1), there are multiple sub-groups within each group where chemicals are further sorted by differences in their chemical structure, receptor binding properties, and susceptibility to degradation. For example in Group 1, there are two subgroups, *i.e*, Subgroups 1A (carbamates) and 1B (organophosphates) that have distinctly different properties but both inhibit acetylcholinesterase enzyme activity. Within IRAC Group 4, there are four subgroups of chemicals, *i.e.*, Subgroups 4A (neonicotinoids), 4B (nicotine), 4C (sulfoxaflor) and 4D (butenolides), grouped as agonists of the nicotinic acetylcholine receptor. Flupyradifurone is

classified as a "butenolide" insecticide (IRAC group 4D) and while it targets the nicotinic acetylcholine receptor, it differs from other chemicals within Group 4 in terms of how it binds to the receptor and the extent to which it is metabolized. The differences between flupyradifurone and members of the other three subgroups provide advantages to the new subgroup (butenolides) that are useful in terms of insect resistance management.

Flupyradifurone is intended to be taken up and distributed to various parts of the plant (*i.e.*, the chemical is systemic) to protect against piercing and sucking insects such as aphids, whiteflies, thrips, and psyllids, all of which have become increasingly resistant to other classes of insecticides and are difficult to control. It was proposed to be registered as a liquid formulation applied by foliar application, chemigation and/or soil drench to the following crops:

- Bushberry, Except Cranberry (Crop Subgroup 13-07B);
- Low Growing Berry Except Cranberry (Crop Subgroup 13-07G);
- Bulb Vegetables (Crop Group 3-07);
- Cereal Grains Except Rice (Crop Group 15);
- Citrus Fruits (Crop Group 10-10);
- Cottonseed (Crop Subgroup 20C);
- Cucurbit Vegetables (Crop Group 9);
- Edible Podded Legume Vegetables (Crop Subgroup 6A);
- Succulent Shelled Pea and Bean (Crop Subgroup 6B);
- Dried Shelled Pea and Bean (except Soybean);
- Foliage of Legume Vegetables (except Soybean) (Crop Subgroup 7A);
- Non-grass Animal Feeds (Alfalfa and Clover only);
- Forage, Fodder, and Straw of Cereal Grains (Crop Group 16);
- Fruiting Vegetables (Crop Group 8-10);
- Hops;
- Head and Stem Brassica Vegetables (Crop Subgroup 5A);
- Leafy Brassica Greens (Crop Subgroup 5B);
- Leafy Vegetables (Except Brassica) (Crop Group 4);
- Peanuts;
- Pitaya;
- Pome Fruits (Crop Group 11-10);
- Prickly Pear Cactus; Root Vegetables Except Sugar Beet (Crop Subgroup 1B);
- Small Fruit Vine Climbing (Except Fuzzy Kiwifruit) (Crop Subgroup 13-07F);
- Taro Leaves;
- Tree nuts (Crop Group 14-12);
- Turnip Greens; and Tuberous
- Corm Vegetables (Crop Subgroup 1C).

Flupyradifurone was also proposed for registration as a seed treatment for soybeans. There were no residential use sites proposed.

Evaluation

In evaluating a pesticide registration application, the EPA assesses a wide variety of exposure information (i.e., where and how the pesticide is used) and environmental fate (*i.e.*, how the chemical will move in the environment) and toxicity studies (*i.e.*, effects on humans and other non-target organisms) to determine the likelihood of adverse effects (*i.e.*, risk) from exposures associated with the proposed use of the product. Risk assessments are developed to evaluate the environmental fate of the compound as well as how it might affect a wide range of non-target organisms including humans, terrestrial and aquatic wildlife (plants and animals). On the basis of these assessments, EPA evaluates and approves language for each pesticide label to ensure the directions for use and safety measures are appropriate to mitigate any potential risk. In this way, the pesticide's label helps to communicate essential limitations and mitigations that are necessary for public safety. It is a FIFRA violation to use a pesticide in a way that conflicts with the label.

1. Assessment of Risk to Human Health

EPA requires a wide range of studies in order to assess a pesticide. For flupyradifurone, the database of studies required to support the assessment of risk to human health is complete.

The acute toxicity of flupyradifurone was low for all routes of exposure (oral, dermal, and inhalation). Table 1 summarizes the toxicological endpoints used in the human health risk assessment. The acute endpoint is based on the clinical signs of neurotoxicity in the acute neurotoxicity study in rats. The chronic, short- and intermediate-term endpoint is based on the skeletal muscle myofiber atrophy/degeneration from the 1-year oral toxicity study in dogs.

Table 1.--Summary of Toxicological Doses and Endpoints for flupyradifurone, for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	NOAEL = 35 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = .35 mg/kg/day	**Acute neurotoxicity study – rat** LOAEL = 50 mg/kg/day
Chronic dietary (All populations)	NOAEL= 7.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = .078 mg/kg/day cPAD = .078 mg/kg/day	**1-year oral toxicity study-dog** LOAEL= 28 mg/kg/day
Cancer (Oral, dermal, inhalation)	Flupyradifurone is classified as "not likely to be carcinogenic to humans" based on data showing no treatment related increase in tumor incidence in rat and mouse carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

The evaluation of the chronic toxicity studies indicates that flupyradifurone is not carcinogenic. EPA has not made a common mechanism of toxicity finding for flupyradifurone and any other substances. This means that the available information support the conclusion that flupyradifurone does not have a common mechanism of toxicity with other substances.

Given the low likelihood of adverse effects on humans, more refined estimates of acute and chronic dietary risk were not necessary for flupyradifurone. The assessments incorporated the highest level residues on the commodities and default or empirical processing factors and conservative drinking water estimates of exposure. The dietary assessment also conservatively assumed that 100% of every crop was treated. Neither the acute nor the chronic dietary exposure and risk estimates exceed the Agency's level of concern (LOC).

Risk estimates based on short- and intermediate-term occupational (worker/applicator) exposure to flupyradifurone for both handler (mixing, loading, and application via the dermal and inhalation routes) and post-application activities (via the dermal route) were also below the Agency's LOC.

The "Sivanto™ 200 SL" formulation falls in the lowest acute toxicity categories of III (oral and dermal) and IV (inhalation). Thus, the labeling precautionary signal word is "CAUTION."

2. Assessment of Ecological Risk

The battery of tests required to assess the environmental fate and ecological effects of flupyradifurone is complete.

Flupyradifurone is nonvolatile and does not bioaccumulate. Although it is characterized as being persistent to very persistent (half-lives ranging between 38 to 400 days) and is moderately mobile to mobile, variable half-lives in soil indicate that its persistence and mobility depend on soil types and climatic conditions. The primary route of degradation is through aqueous photolysis (half-life = 2.5 days), and the major routes of dissipation include runoff, erosion, and leaching. Twelve field studies conducted in both North America and Europe indicate that flupyradifurone has biphasic degradation, *i.e.*, a period of rapid loss of roughly 78% of the residues followed by a slow decline of the remaining residues; however, the majority (83%) of the field studies resulted in dissipation half-lives of less than 3 months.

Similar to the human health risk assessment, estimates of risk for non-target plants and animals were generally low, based on conservative screening level exposure values and did not warrant further refinements. The risk assessment for aquatic organisms concluded the following:

- Flupyradifurone is slightly to practically non-toxic to aquatic vertebrates (fish and aquatic-phase amphibians) on an acute exposure basis, and risk estimates were below LOCs for these animals.
- Estimates of chronic risk did not exceed the Agency's LOC for fish and aquatic-phase amphibians.
- There are no risks of concern for aquatic plants.

- Although flupyradifurone is highly toxic to benthic invertebrates and marine crustaceans (mysid shrimp) on an acute exposure basis and acute/chronic risk estimates based on these data do not exceed LOCs, the compound is only slightly toxic to freshwater invertebrates that occupy the water column and to shellfish.

For terrestrial organisms, the risk assessment concluded:

- Only the proposed soybean seed treatment use resulted in chronic risk to birds (and to terrestrial-phase amphibians and reptiles for which birds serve as surrogates).
- Only the risk estimates for foliar uses of flupyradifurone exceeded the chronic risk LOC for terrestrial invertebrates based on laboratory studies; however, field-based studies did not indicate any long-term effects on these organisms.
- There are no risks of concern for terrestrial plants.
- The conservative screening-level risk assessment identified potential risk to mammals based on chronic dietary exposure assuming that the animal is feeding on the treated site continuously and that 100% of their diet contains flupyradifurone residues based on flupyradifurone applications from two or more crop cycles.

EPA is aware of public concerns regarding the potential effects that systemic pesticides may have on honeybees and insect pollinators in general. The Agency is also aware of public concerns regarding the neonicotinoid insecticides (Subgroup 4B) of the IRAC Group 4 insecticides. Although it is not a neonicotinoid, as an insecticide, flupyradifurone is unusual in that laboratory-based studies indicate that the compound is practically non-toxic to adult bees on an acute contact exposure basis. EPA also has data on flupyradifurone which is consistent with the Pollinator Risk Assessment Guidance adopted by EPA and PMRA. (http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance) The guidance has been widely reviewed and EPA is requiring such data for older pesticides in its Registration Review activities. Applying this guidance provided EPA with a robust set of studies assessment factors with which to evaluate potential risks to honey bees. For this evaluation EPA received data on the potential impacts of flupyradifurone on developing bees (larvae, pupae) and data which examined potential adverse effects on honey bee colonies. The registrant for flupyradifurone voluntarily (proactively) conducted such studies to inform this registration decision and submitted them to EPA with the original registration action.

These data underscore how flupyradifurone differs in its acute toxicity from other acetylcholine esterase inhibitors within the IRAC Group 4 as well as those in Group 1. While the acute oral toxicity study indicates that flupyradifurone is highly toxic to individual adult honeybees, longer-term laboratory-based studies of both larval and adult bees show no adverse effects up to the highest dietary concentration tested (*i.e.*, 10,000 micrograms per liter; 10,000 µg/L).

Studies of whole colonies, both under confined semi-field (tunnels) and full-field conditions, examined pollinator-attractive crops, under a conservative exposure scenario. The chemical had been consecutively applied to the site, first as a soil treatment, then as a seed treatment, then again as a foliar treatment at early bloom, and finally again as a foliar treatment at full bloom at the maximum application rate while bees were actively foraging. EPA's review found that flupyradifurone did not result in any adverse effect on overall colony performance or overwintering capacity relative to untreated colonies. Residues measured in pollen and nectar from treated plants indicated that flupyradifurone was typically higher in pollen than in nectar

and that in general, residues declined in pollen and nectar within a two-week window following treatment. Although these field studies indicated a transient increase in adult bee mortality and foraging activity within 24 hours of treatment, the effects were not statistically significant and did not have a measurable impact on the whole colony. In a study where bees were fed a flupyradifurone-spiked sugar solution for six consecutive weeks, there were no adverse effects detected in the treated honeybee colonies relative to untreated colonies. EPA considers the 38 studies used to characterize the potential exposure to and effects of flupyradifurone on bees to be comprehensive and compelling evidence that the compound is not having a pronounced effect on bees even though applications were made during full bloom while bees were actively foraging.

Alternatives

Flupyradifurone is expected to be an alternative insecticide to certain pyrethroids (bifenthrin, *zeta*-cypermethrin), neonicotinoids (thiamethoxam, imidacloprid, acetamiprid), organophosphates (chlorpyrifos, acephate) and avermectins (abamectin). From a human health standpoint, pyrethroids and neonicotinoids generally have somewhat longer re-entry intervals (REIs) for workers than flupyradifurone which has a 4-hour REI. Additionally, some individual chemicals in the pyrethroid and neonicotinoid classes require more personal protective equipment (PPE) for handlers than does flupyradifurone. Organophosphates (OPs) and abamectin are more acutely toxic to humans than flupyradifurone and have varying degrees of REIs and PPE. Some uses involving OP pesticides have been subject to mitigation, owing to risk concerns. Thus, the risk to human health from flupyradifurone compares favorably to these alternatives.

As is typical with most insecticides, flupyradifurone may pose a risk to aquatic invertebrates; however, it is evident that flupyradifurone is less toxic than the majority of the alternatives. For example, comparing the freshwater invertebrate LC_{50} values for *zeta*-cypermethrin (0.0036 µg a.i./L), chlorpyrifos (0.06 µg a.i./L) and abamectin (0.34 µg a.i./L) shows they are much more toxic than flupyradifurone with an LC_{50} of 63.9 µg a.i./L. The estuarine/marine invertebrate LC_{50} value is 0.0035 µg a.i./L for chlorpyrifos, 0.004 µg a.i./L for bifenthrin and 0.02 µg a.i./L for abamectin versus 250 µg a.i./L for flupyradifurone. The cyano-substituted neonicotinoid acetamiprid is three times as toxic as flupyradifurone to freshwater invertebrates, and the nitroguanidine-substituted neonicotinoid thiamethoxam is approximately twice as toxic.

EPA determined that on a comparative hazard basis, flupyradifurone is less toxic to mammals on a chronic exposure basis than most of the leading market alternatives. In a comparison of chronic "no adverse effects level" and "no adverse effects concentration" values, flupyradifurone is much less toxic than abamectin, chlorpyrifos, fenpropathrin, bifenthrin, acephate and *zeta*-cypermethrin.

In terms of risk to birds, the avian LD_{50} value for flupyradifurone is 232 mg a.i./kg body weight showing that it is much less toxic than chlorpyrifos (LD_{50} = 5.62 mg a.i./kg), acetamiprid (5.68 mg a.i./kg), abamectin (85 mg a.i./kg), acephate (109 mg a.i./kg) and imidacloprid (152 mg a.i./kg).

As noted above in section 2 of the Evaluation (Assessment of Ecological Risk), flupyradifurone is classified as practically non-toxic to honeybees on an acute contact exposure basis. Table 2 compares the acute toxicity (96-hr LC_{50}) values of flupyradifurone to the registered alternatives and relative to the alternatives with respect to acute toxicity to honey bees, flupyradifurone is the least toxic.

Table 2. Honeybee acute 96-hr contact LC_{50} values

Chemical	LC_{50} µg a.i./bee
Bifenthrin	0.015
Zeta-cypermethrin	0.023
Thiamethoxam	0.024
Spinetoram	0.024
Chlorpyrifos	0.059
Imidacloprid	0.078
Abamectin	0.54
Acephate	1.2
Acetamiprid	<12.5
Flupyradifurone	**122**
Pyriproxyfen	>100
Spirotetramat	>100

Benefits

Flupyradifurone was submitted to the EPA's Office of Pesticide Programs (OPP) as a Reduced Risk compound for the proposed uses. Based on OPP's Reduced Risk Committee's evaluation, and as noted above in the Alternatives section, the human health and ecological hazard profiles for flupyradifurone are very favorable compared to currently registered alternatives.

Although there are a number of insecticides that interact as either inhibitors or modulators of the acetylcholine esterase enzymes involved in the transmission of nerve impulses and even among those that specifically inhibit the nicotinic acetylcholine esterase (IRAC Group 4), flupyradifurone is in a subgroup of its own (*i.e.*, the butenolides) due to distinct differences in how it interacts with the acetylcholine esterase receptor and how the chemical is metabolized. The differences between flupyradifurone and other chemicals within Group 4 (*e.g.*, neonicotinoids) make the new insecticide an effective means of reducing the likelihood of target pests developing resistance.

Flupyradifurone demonstrates efficacy against a variety of piercing, sucking insects, including species that are challenging to control (*e.g.*, scales, whiteflies), transmit disease (Asian citrus psyllid, Potato psyllid) and/or are known to rapidly develop resistance (whiteflies). It targets specific pests that growers have reported are causing serious damage to crops resulting in significant economic losses. In some locations, the registered alternatives, including neonicotinoids are failing to provide sufficient control for resistant pests. The pests identified by

the commenters include the Blue Alfalfa Aphid, Grape mealybug and vine mealybug, cotton aphid and whiteflies. Currently, there are no registered products that are adequately efficacious against the sugarcane aphid; however, field trials have indicated that flupyradifurone is very effective against this pest. Growers of prickly pear cactus face multiple pest challenges but have few registered products that are effective. Data from the USDA National Institute of Food and Agriculture funded Interregional Research Project Number 4 (IR 4) specialty crop and pest management program has supported the inclusion of this crop on the flupyradifurone label. Thus, registration of flupyradifurone will provide many growers of very diverse crops across the U.S. with a new pest management tool that presents an effective countermeasure to resistance development.

Public Comments

On May 29, 2013, EPA published a Notice of Receipt in the Federal Register of an application for registration of flupyradifurone and announced a public comment period of 30 days. Two comments were received.

The first comment expressed concern that neonicotinoid chemicals and other toxic substances are poisoning the environment, specifically citing concerns over cancer (generally) and concerns regarding pollinator exposure to toxic substances. This comment was not specifically addressing the application to register flupyradifurone but generally directed at the registration of pesticides in general.

In response to this comment, the EPA reiterates that flupyradifurone is not classified as a carcinogen. Also, as an insecticide flupyradifurone is unusual in that it is classified as practically non-toxic to honeybees on an acute contact exposure basis. While the compound is highly toxic to adult worker bees and can result in a transient increase in forager bee mortality, multiple semi-field and full-field studies did not indicate any significant adverse effect on honeybee colony performance and/or overwintering capability. Therefore, relative to many of the available registered alternatives, EPA considers the likelihood of adverse effects (risk) as a result of exposure from the proposed uses of flupyradifurone to be low.

The second comment was from The City of Sacramento Department of Utilities. They expressed concern that registering the chemical flupyradifurone for use on rice will affect drinking water quality in Sacramento. In regard to this second comment, the applicant did not apply for a use on rice.

On June 5, 2013, the EPA published a Notice of Filing in the Federal Register announcing the receipt of the initial filing of the flupyradifurone petition by Bayer Crop Science under the Federal Food, Drug and Cosmetic Act (FFDCA) requesting the establishment of regulations for residues of flupyradifurone on various commodities. This publication also announced a public comment period of 30 days; no comments were received on the FFDCA Notice of Filing.

The EPA announced the proposed decision of the unconditional registration for flupyradifurone on September 25, 2014, and held a public comment period for 30 days, closing October 25, 2014

at 11:59 pm. Twenty-five comments were received during the public comment period, two comments were duplicative; therefore there are twenty-three distinct individual comments posted to the docket. EPA's review and responses are summarized in a separate response to public comments document and is available in the Docket (Docket ID: EPA-HQ-OPP-2013-0226).

Twenty-one comments submitted to the docket supported EPA's proposed decision to register flupyradifurone as a new insecticide active ingredient. There were two comments in opposition of EPA's proposed decision. Supporting comments were submitted by University Research and Extension agents, USDA's IR-4, grower and commodity organization groups representing potatoes, apples, citrus, hops, cotton, wine grapes, alfalfa and growers of hydroponic tomatoes and cucumbers. Individual growers also wrote in support of the registration.

Commenters supporting the registration identified complex pest problems where there are few tools available to combat destructive pests that affect crop production and vector disease. One such pest is the sugarcane aphid which is currently crippling sorghum production in Mississippi, Georgia, and Oklahoma. According to a range of stakeholders, this pest is spreading fast and has moved from sugarcane to sorghum relatively quickly. There are no registered alternatives available that are efficacious against the sugarcane aphid. Sorghum growers have already experienced significant losses and view this pest as the most devastating threat they have ever seen. Emergency exemptions for an unregistered compound (sulfoxaflor) were granted to eight states to combat sugarcane aphid, the only other alternative is high treatment levels of the organophosphate insecticide chlorpyrifos.

The citrus growers are also very eager to use flupyradifurone against the Asian citrus psyllid which transmits citrus greening disease. This disease has severely harmed the Florida citrus industry where fruit yields are significantly impacted. Over time, the citrus greening disease is capable of killing infected trees. It now threatens the California citrus industry. The distinct differences in the activity of flupyradifurone relative to other insecticides is expected to provide an effective countermeasure for growers in these critical situations. It will also fit well into Integrated Pest Management (IPM) programs to provide a rotational tool and alternative to current pest control strategies.

One commenter who opposes to the registration of flupyradifurone focused on potential harm to honey bees and expressed concern for their exposure to flupyradifurone in the water column. The commenter noted that flupyradifurone is very highly toxic to freshwater insects and also indicated that additional applications will cause adverse effects to honey bees. They cited possible risk from the persistence of the degradates. The commenter also was critical of the validity of the semi-field and feeding studies. The other commenter in opposition to the EPA's proposed decision to register flupyradifurone based their concern on EPA not consulting with the U.S. Fish and Wildlife Service and National Marine Fisheries Service under the Endangered Species Act on the registration of a new active ingredient that may affect protected species.

Regulatory Decision

The flupyradifurone database is comprised of 437 studies and is considered to be complete as well as robust. In cooperation with our regulatory partners in Australia and Canada, and

considering the assessed risk to human health and the environment, the Agency concludes that flupyradifurone meets the regulatory standard under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). There are no outstanding data requirements for flupyradifurone. Therefore, the EPA is granting the unconditional registration of flupyradifurone under Section 3(c)(5) of FIFRA.

The PMRA of Canada proposed the registration of flupyradifurone in September, 2014 followed by a 45 day comment period. Their proposal includes both the foliar product and the soybean seed treatment product; final registration and use in Canada is anticipated in early 2015. Authorization of flupyradifurone in Australia is anticipated in early 2015.

In the U.S., two products will be registered, the technical formulation "Flupyradifurone TC," and the end-use formulation "Sivanto™ 200 SL." Sivanto™ 200 SL may be applied as a foliar application, by chemigation, and by soil drench. The maximum annual application rate is 0.365 lb a.i./A/year. All of the proposed uses listed in the beginning of this document (see "Background") will be registered. EPA is still considering its position for the flupyradifurone soybean seed treatment product and is not ready to make a decision at this time on that particular use pattern. However, a use pattern involving foliar application on that crop is being registered now.

EPA is not granting uses that were proposed for the entire Crop Group 18 on a national basis, the non-grass animal feeds (forage fodder, straw and hay) group. Uses of flupyradifurone for non-grass animal feeds will only be granted for clover exclusively in Washington, Oregon, and Idaho, and for alfalfa nationally. An insufficient number of clover trials was submitted to support the tolerance for the entire crop group.

For the food uses, Canadian Maximum Residue Levels (MRLs) and U.S. tolerances are harmonized for primary crop commodities.

Although the risks to non-target organisms and to human health from the use of flupyradifurone are considered to be low, the following mitigation has been added to the label:

- For further protection of workers engaged in a high contact activity, the restricted entry interval for girdling and cane turning activities in grapes is 48 hours.
- For foliar applications, the number of crop cycles per year has been limited to one for all crops except Brassica (Cole) leafy vegetables and leafy vegetables.

The risk assessments supporting this decision can be found in the regulatory docket (Docket ID: EPA-HQ-OPP-2013-0226).