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Sent via Email and Certified Mail Return Receipt Requested

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

On behalf of the Center for Biological Diversity and the Center for Food Safety, 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 900,000 members and online activists in the United States, including approximately 50,000 in Washington, D.C. 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 Bicyclopyrone.¹ It has also violated Section 7 regarding its discretionary decision to approve Acuron™ (hereafter “Acuron”) the only end-use product available for sale that includes Bicyclopyrone, without considering the effects of three other already-registered active ingredients that are also constituent ingredients of Acuron, and for which none have undergone Section 7 consultations regarding their effects.² 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 in addition to Bicyclopyrone itself being toxic to several taxonomic groups, the other three active ingredients in Acuron — Atrazine, Mesotrione, and S-Metolachlor — are also toxic pesticides that are almost certainly harming hundreds of threatened and endangered species. Given that this herbicide is to be used on corn in most states, this active ingredient and this pesticide product will almost certainly cause irreparable harm to most listed species in the United States.

¹ Registration Decision of the New Active Ingredient Bicyclopyrone an Herbicide for Use on Corn and Establishment of Tolerances for Corn (field, pop, and sweet) and Imported Sugarcane, Docket #: EPA-HQ-OPP-2014-0355-0077.

² Acuron™ Herbicide Notice of Conditional Registration, EPA Reg. 100-1466, Docket #: EPA-HQ-OPP-2014-0355-0078.

EPA's registration of Bicyclopyrone — and its approval of Acuron — may jeopardize federally-listed species and adversely modify the critical habitat of listed species. Despite the likely harm to threatened and endangered species, EPA chose to register this pesticide without engaging in required consultation to determine appropriate mitigation and measures to avoid jeopardizing listed species. EPA's failure to consult is arbitrary and capricious since its own ecological risk assessment concluded that exposure to Bicyclopyrone would have acute and chronic impacts on listed mammals and plants.³ Furthermore, EPA's decision to limit its analysis to "Bicyclopyrone specifically and not the other compounds" contained in Acuron is arbitrary and capricious, and a violation of the ESA, because the other active ingredient compounds will almost certainly harm listed species.⁴ S-Metolachlor will likely harm listed mammals, birds, freshwater fish, and freshwater invertebrates;⁵ Mesotrione will likely harm listed vascular aquatic plants, estuarine and marine invertebrates;⁶ and Atrazine will likely harm listed plants, birds, mammals, amphibians, reptiles, fish, and freshwater invertebrates.⁷ In short, listed species from virtually *every* taxonomic will be harmed by Acuron.

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 Bicyclopyrone and Acuron.

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..."⁸

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.⁹

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."¹⁰ 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

³ EPA 2015. Environmental Fate and Ecological Risk Assessment for Use of the New Herbicide Bicyclopyrone (NOA449280) Docket #: EPA-HQ-OPP-2014-0355-0015.

⁴ *Id.* at 2.

⁵ EPA 2014. REGISTRATION REVIEW PROBLEM FORMULATION FOR METOLACHLOR AND S-METOLACHLOR.

⁶ EPA 2014. PROBLEM FORMULATION FOR THE ENVIRONMENTAL FATE AND ECOLOGICAL RISK, ENDANGERED SPECIES, AND DRINKING WATER ASSESSMENTS IN SUPPORT OF THE REGISTRATION REVIEW OF MESOTRIONE.

⁷ EPA 2006. Atrazine: FINALIZATION OF INTERIM REREGISTRATION ELIGIBILITY DECISION AND COMPLETION OF TOLERANCE REASSESSMENT AND REREGISTRATION ELIGIBILITY PROCESS.

⁸ 16 U.S.C. §§ 1531-1544; 16 U.S.C. § 1531(b).

⁹ 50 C.F.R. § 402.01(b).

¹⁰ 16 U.S.C. § 1531(c)(1).

necessary.”¹¹ 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.”¹²

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”¹³

Section 7 consultation is required for “any action [that] may affect listed species or critical habitat.”¹⁴ 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.”¹⁵

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.¹⁶ 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.¹⁷

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.”¹⁸ 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.¹⁹ 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.”²⁰ “Harm” is further defined as “an act which actually kills or injures wildlife. Such act may include significant

¹¹ 16 U.S.C. § 1532(3).

¹² 16 U.S.C. § 1536(a)(1).

¹³ 16 U.S.C. § 1536(a)(2) (“Section 7 consultation”).

¹⁴ 50 C.F.R. § 402.14.

¹⁵ 50 C.F.R. § 402.02.

¹⁶ 16 U.S.C. § 1536(b).

¹⁷ 50 C.F.R. § 402.13.

¹⁸ 16 U.S.C. § 1536(d).

¹⁹ 16 U.S.C. § 1538(a)(1)(B); 50 C.F.R. § 17.21(c).

²⁰ 16 U.S.C. § 1532(19); 50 C.F.R. § 17.3.

habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding or sheltering.”²¹ 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 only through the issuance of an Incidental Take Statement (“ITS”) as part of a Biological Opinion.²² 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.²³

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.²⁴ FIFRA charges EPA with registering, reviewing, amending, and reregistering chemicals and chemical formulations for use as insecticides, fungicides, and pesticides in the United States.²⁵ 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.²⁶

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.²⁷ 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,²⁸ or to make any claims that differ substantially from the label.²⁹ 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.³⁰

FACTUAL BACKGROUND

A. Bicyclopyrone Overview

Bicyclopyrone is a selective, systemic herbicide belonging to the hydroxyphenylpyruvate dioxygenase (HPPD) inhibitor class for use on corn. Bicyclopyrone has one technical product, two

²¹ 50 C.F.R. § 17.3.

²² 16 U.S.C. § 1536(o)(2); 50 C.F.R. § 402.14(i)(5).

²³ 16 U.S.C. § 1536(b)(4); 50 C.F.R. § 402.14(i)(1)(i)-(v).

²⁴ See 7 U.S.C. §§ 136-136y.

²⁵ *Id.*

²⁶ 7 U.S.C. § 136a(a).

²⁷ 7 U.S.C. § 136a(c)(5).

²⁸ *Id.* § 136j(2)(G).

²⁹ *Id.* § 136j(1)(B).

³⁰ *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).

manufacturing-use products, and two end-use products (SYN-AI6003 Herbicide and Acuron™ Herbicide). The product Acuron will contain 0.65% Bicyclopyrone, 2.60% Mesotrione, 10.93% Atrazine, and 23.40% S-Metolachlor. According to the registration decision, only Acuron will be marketed to the public. Acuron is intended to be used on corn crops across the country.³¹

Bicyclopyrone is a relatively soluble, nonvolatile compound that is stable to hydrolysis and is expected to be very highly mobile in soil. Bicyclopyrone photodegrades on surface soil, with half-lives ranging from 4 to 13 days. It is stable in anaerobic soil and anaerobic aquatic systems, and only degrades very slowly in aerobic aquatic systems, with half-lives of 393-681 days.³²

Bicyclopyrone may contaminate groundwater via leaching, and may move to surface water bodies via spray drift and runoff. Bicyclopyrone is classified as slightly to practically non-toxic to freshwater and estuarine/marine fish, but is moderately toxic to estuarine/marine invertebrates on an acute exposure basis.³³ Bicyclopyrone exceeded levels of concern for listed dicot plants.³⁴

B. Atrazine, Mesotrione, and S-Metolachlor Overview

Atrazine is one of the most persistent and heavily used pesticides on the market today, with approximately 60-80 million pounds applied each year. Atrazine is highly mobile in the environment, and is now one of the most commonly detected pesticides in drinking water, surface waters, and ground water across the nation. Approximately 75 percent of stream water and about 40 percent of all groundwater samples from agricultural areas tested by the U.S. Geological Survey contained atrazine and its primary degradate, deethylatrazine. And a 2010 analysis of monitoring data by the Natural Resources Defense Council concluded that many surface waters in the Midwestern and Southern United States are significantly contaminated with Atrazine and that many public drinking water systems contained elevated levels of this pesticide. Monitoring data using over 14,000 samples from 139 municipal water systems found that 90 percent had measurable levels of Atrazine. Atrazine has been detected in rainwater, fog, ambient air, arctic ice, and seawater at great distances from urban and agricultural areas.³⁵

EPA's 2003 Interim Reregistration Eligibility Decision for Atrazine states the following with respect to endangered species: "Endangered species LOCs are exceeded for terrestrial plants, birds and small mammals from the agricultural uses of atrazine."³⁶ "Acute risks to endangered freshwater invertebrates and aquatic vascular plants are exceeded for all crop uses except for the typical use rate on corn (1.1 lb ai/A.) Chronic levels of concern for endangered species are exceeded for fish and aquatic invertebrate reproduction for all use rates, except for corn and the typical use rate on sorghum."³⁷

³¹ Acuron™ Herbicide Notice of Conditional Registration EPA Reg. 100-1466, Docket #: EPA-HQ-OPP-2014-0355-0078.

³² EPA 2015. Environmental Fate and Ecological Risk Assessment for Use of the New Herbicide Bicyclopyrone (NOA449280) at 9, Docket #: EPA-HQ-OPP-2014-0355-0015.

³³ *Id.*

³⁴ *Id.* at 10.

³⁵ Chernyak S.M., C.P. Rice and L.L. McConnell. 1996. *Evidence of currently used pesticides in air, ice, fog, seawater and surface microlayer in the Bering Sea and Chukchi Seas*. Marine Pollution Bulletin 32:410-419.

³⁶ EPA 2006. Atrazine: FINALIZATION OF INTERIM REREGISTRATION ELIGIBILITY DECISION AND COMPLETION OF TOLERANCE REASSESSMENT AND REREGISTRATION ELIGIBILITY PROCESS.

³⁷ *Id.*

Atrazine was included in the formal Section 7 consultations with FWS for the rangeland and pastureland reviews in 1984.³⁸ The Biological Opinions for both reviews stated that these uses of atrazine would jeopardize the continued existence of over 60 species of plants associated with rangeland and ten species of plants associated with forests. Atrazine was also included in the sorghum cluster review in 1983, and the Biological Opinion found possible jeopardy to several species of fish plus one insect and one plant species. In addition, Atrazine was one of 109 active ingredients included in the reinitiated Biological Opinion of 1989 from the FWS. In this Opinion, FWS found jeopardy to nine species of freshwater fish, two freshwater crustaceans, four amphibians and twelve species of plants for its uses on field crops, rangeland and forests.³⁹

Atrazine is a highly potent endocrine disruptor and persists in the environment after its use. Extensive scientific research has demonstrated that atrazine causes substantial negative reproductive effects in a variety of taxa when exposure occurs, even at concentrations as low as 0.1 ppb. Scientific research has shown that atrazine inhibits production of testosterone and induces estrogen production in a variety of taxa including amphibians,⁴⁰ fish,⁴¹ reptiles,⁴² and mammals.⁴³ The result of this endocrine disruption includes chemical castration (demasculinization) and feminization, decreased sperm counts, impaired fertility, and a reduction in masculine features. In amphibians, atrazine exposure impairs immune function and increases susceptibility to viral diseases,⁴⁴ bacterial infections,⁴⁵ and macroparasites.⁴⁶ In salmon, atrazine-induced increase in stress hormones in smolt impairs the ability of exposed fish to return to the ocean, leading to high mortality in these commercially and culturally important fish.⁴⁷ All of these types of impacts represent sublethal

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ Hayes, T., et al., *Hermaphroditic, demasculinized frogs after exposure to the herbicide atrazine at low ecologically relevant doses*. Proc. Natl. Acad. Sci. USA, 2002. 99: p. 5476-5480.

⁴¹ Moore, A. and C. Waring, *Mechanistic effects of a triazine pesticide on reproductive endocrine function in mature male Atlantic salmon*. Pesticide Biochem. Physiol., 1998. 62: p. 41-50; Spano, L., et al., *Effects of atrazine on sex steroid dynamics, plasma vitellogenin concentration and gonad development in adult goldfish (Carassius auratus)*. Aquatic Toxicology (Amsterdam), 2004. 66(4): p. 369-379.

⁴² Keller, J. and P. McClellan-Green, *Effects of organochlorine compounds on cytochrome P450 aromatase activity in an immortal sea turtle cell line*. Marine Environmental Research, 2004. 58(2-5): p. 347-351; Crain, D., et al., *Alterations in steroidogenesis in alligators (Alligator mississippiensis) exposed naturally and experimentally to environmental contaminants*. Environ. Health Perspect., 1997. 105: p. 528-533.

⁴³ Babic-Gojmerac, T., Z. Kniewald, and K. J., *Testosterone metabolism in neuroendocrine organs in male rats under atrazine and deethylatrazine influence*. Steroid Biochem., 1989. 33(1): p. 141-146; Šimic, B., et al., *Reversibility of inhibitory effect of atrazine and lindane on 5 -dihydrotestosterone receptor complex formation in rat prostate*. Bull. Environ. Contam. Toxicol., 1991. 46: p. 92-99.

⁴⁴ Forson, D. and A. Storfer, *Effects of atrazine and iridovirus infection on survival and life history traits of the long-toed salamander (Ambystoma macrodactylum)*. Environ. Toxicol. Chem., 2006. 25(1): p. 168-173; Forson, D. and A. Storfer, *Atrazine increases Ranavirus susceptibility in the tiger salamander, Ambystoma tigrinum*. Ecological Applications. Ecol. Appl., 2006. 16(6): p. 2325-2332.

⁴⁵ Hayes, T., et al., *Pesticide mixtures, endocrine disruption, and amphibian declines: Are we underestimating the impact?* Environ. Health Perspect., 2006.

⁴⁶ Gendron, A., et al., *Exposure of leopard frogs to a pesticide mixture affects life history characteristics of the lungworm Rhabdias ranae*. Oecologia, 2003. 135: p. 469-476; Christin, M.-S., et al., *Effects of agricultural pesticides on the immune system of Rana pipiens and on its resistance to parasitic infection*. Environ. Toxicol. Chem., 2003. 22(5): p. 1127-1133.

⁴⁷ Moore, A. and C. Waring, *Mechanistic effects of a triazine pesticide on reproductive endocrine function in mature male Atlantic salmon*. Pesticide Biochem. Physiol., 1998. 62.

effects can result in jeopardy to listed species and therefore must be considered by the EPA and the Services in formal consultations.

Approximately 30-35 million pounds of S-Metolachlor are used in the United States each year. While less toxic than atrazine, S-Metolachlor has likely negative impacts on many endangered species. The *Registration Review Problem Formulation for Metolachlor and S-Metolachlor* states that previous assessments of this active ingredient have identified potential risks to listed mammals, listed birds, listed freshwater fish, and listed freshwater invertebrates.⁴⁸

Mesotrione is used in far less quantity than Atrazine or S-Metolachlor, with approximately 2-3 million pounds being applied in recent years. The ecological risk assessment for Mesotrione states, “there is potential for risk to endangered species,” but is notably sparse in the details of its assessment.⁴⁹ According to EPA, Mesotrione is “slightly to moderately toxic to estuarine/marine invertebrates.”⁵⁰ When put together, these four pesticides are likely to either cause acute or chronic impacts on virtually all taxa:

Potential Impacts (Yes/No) of Acuron Ingredients to ESA-listed Taxonomic Groups				
Listed Taxon	Bicyclopyrone	Atrazine	S-Metolachlor	Mesotrione
Terrestrial plants - monocots	No	Yes	No	No
Terrestrial plants - dicots	Yes	Yes	No	No
Aquatic plants	No	No	No	Yes
Birds	Yes	Yes	Yes	No
Terrestrial-phase amphibians	No	Yes	No	No
Reptiles	No	Yes	No	No
Mammals	Yes	Yes	Yes	No
Freshwater fish	No	Yes	Yes	No
Aquatic-phase amphibians	No	Yes	No	No
Freshwater invertebrates	No	Yes	Yes	No
Marine/estuarine fish	No	Yes	No	No
Marine/estuarine inverts	Yes	Yes	No	Yes

C. EPA’s Approval of Bicyclopyrone and Acuron

On August 13, 2014, EPA published a notice in the federal register announcing that it had received applications to register new pesticides, including Bicyclopyrone (Docket #: EPA–HQ–OPP–2014–0355).⁵¹ No public comments were received. On September 5, 2014, EPA published a notice of filing in the Federal Register requesting the establishment of regulations for pesticide residues of Bicyclopyrone.⁵² On March 13, 2015, EPA posted an announcement to the docket on Regulations.gov announcing a proposed registration decision and the opening of a 30-day

⁴⁸ EPA 2014. REGISTRATION REVIEW PROBLEM FORMULATION FOR METOLACHLOR AND S-METOLACHLOR.

⁴⁹ EPA 2014. PROBLEM FORMULATION FOR THE ENVIRONMENTAL FATE AND ECOLOGICAL RISK, ENDANGERED SPECIES, AND DRINKING WATER ASSESSMENTS IN SUPPORT OF THE REGISTRATION REVIEW OF MESOTRIONE.

⁵⁰ *Id.*

⁵¹ *Receipt of Applications for New Active Ingredients*, 79 Fed. Reg. 47453 (Aug. 13, 2014).

⁵² *Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities*, 79 Fed. Reg. 53009 (Sept. 5, 2014).

comment period. *See* Appendix A. EPA received 41 public comments in support and 5561 public comments in opposition to the proposed registration of Bicyclopyrone.

The Center submitted a detailed comment letter in response to the proposed registration of Bicyclopyrone, 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 to consult with FWS and NMFS on the approval of Acuron.⁵³ The Center's comments noted that EPA had completely failed to assess any synergistic or cumulative impacts of the four-pesticide cocktail in Acuron.⁵⁴ The Center also mailed approximately 4000 pages of supporting literature and approximately 800 GIS maps regarding the registration of Bicyclopyrone on a CD on April 10, 2015, and which was received by EPA on April 14, 2015. Despite this submission, these supporting documents were not uploaded to the docket for Bicyclopyrone.⁵⁵ The Center is resubmitting a copy of this disk with this notice letter.

On April 24, 2015, EPA approved the registration of Bicyclopyrone as a new active ingredient, the end-use product Acuron and several technical products. *See* Appendix B. In response to the Center's comments, EPA acknowledged the need to consult on Bicyclopyrone, but stated that:

The agency is focusing most of its resources for assessing impacts to listed species on the agency's registration review program for currently registered or existing pesticides. EPA believes that, as a general matter, currently registered and existing pesticides may present a greater degree of risk to listed species than most new chemistries coming to market, and that it is therefore environmentally preferable in most circumstances for EPA to assess the impacts of existing pesticides sooner in the process than newer pesticides that are designed to compete with more risky alternatives.⁵⁶

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 Bicyclopyrone in connection with those efforts."⁵⁷ Despite this rationale being entirely illegal — no agency in the federal government may simply ignore its statutory duty to comply with the Endangered Species Act or other laws based on arbitrary resource determinations — and being virtually identical boilerplate to its earlier refusals to consult,⁵⁸ it is utterly nonsensical as a matter of fact. Acuron contains *three* currently registered, existing pesticide active ingredients, all of which are used in far greater quantities within Acuron than Bicyclopyrone. Acuron is only 0.65% Bicyclopyrone. Every gallon of Acuron contains four times as much Mesotrione, seventeen times as much Atrazine, and thirty-five times as much S-Metolachlor as it does Bicyclopyrone. If EPA truly desired to "assess the impacts of existing pesticides sooner in the process" it is hard to imagine a better time to do so than with three

⁵³ Comment submitted by Brett Hartl, Endangered Species Policy Director at Page 8, Docket ID: EPA-HQ-OPP-2014-0355-0057.

⁵⁴ *Id.* at 1, 8, 9.

⁵⁵ USPS Tracking Number: 6505511078725100389798.

⁵⁶ Bicyclopyrone: Response to Public Comments on EPA's "Proposed Registration of the New Active Ingredient Bicyclopyrone." Docket #: EPA-HQ-OPP-2014-0355-0076.

⁵⁷ *Id.* at 12.

⁵⁸ Response to Public Comments on EPA's "Proposed Registration of the New Active Ingredient Flupyradifurone" Docket #: EPA-HQ-OPP-2013-0226-0043.

currently registered pesticides that are used on a massive scale across the United States. Since EPA has never consulted on Atrazine, S-Metolachlor, or Mesotrione, this registration is the right time to do so.

D. Bicyclopyrone Will Harm Listed Species

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

Based on peak estimated environmental concentrations (EECs) and the most sensitive ecotoxicity data across multiple taxa, bicyclopyrone exposure at the maximum proposed application rates may result in risk to federally listed threatened and endangered...species of terrestrial and semi-aquatic dicotyledonous (dicot) plants. Risk estimates also exceed the levels of concern (LOC) for listed and non-listed vascular aquatic plants and the chronic risk LOC for mammals.⁵⁹

There are 769 ESA-listed dicot plants in the United States. Taken together with mammals, Bicyclopyrone alone potentially puts at risk over half of the ESA-listed species in the United States, thus calling into question why EPA claims that Bicyclopyrone should not be prioritized for consultations. Furthermore, according to EPA, Bicyclopyrone is more toxic to mammals and aquatic plants than Atrazine, S-Metolachlor, and Mesotrione; and it is more toxic to terrestrial plants than Atrazine and S-Metolachlor (Mesotrione is the most toxic of the four chemicals to terrestrial plants).⁶⁰ Thus EPA's logic on why it should defer consultations on Bicyclopyrone to focus on chemicals with "a greater degree of risk to listed species" is fatally flawed.

E. Acuron Will Harm Listed Species

Acuron will almost certainly be transported off-site and enter terrestrial and aquatic habitats of listed species. Despite this reality, EPA arbitrarily limited its analysis only to the active ingredient Bicyclopyrone, without considering any cumulative, synergistic, or additive impacts from the other three active ingredients contained in Acuron. In response to comments, EPA only stated the following:

Concerning synergistic effects, the agency does not routinely include a separate evaluation of mixtures of active ingredients. However, there are some data available to the agency regarding synergistic effects and EPA believes it adequately addressed the issue of synergism between bicyclopyrone and atrazine. Although the submitted data and EPA risk assessments tend to focus on individual chemicals, for AcuronTM, a formulation where there are multiple active ingredients, each is subject to an individual risk assessment for a regulatory decision regarding the active ingredient on a particular use site. In the case of AcuronTM, this would be for each active ingredients contained in the formulation (i.e., bicyclopyrone, mesotrione, atrazine,

⁵⁹ EPA 2015. Environmental Fate and Ecological Risk Assessment for Use of the New Herbicide Bicyclopyrone (NOA449280) Docket #: EPA-HQ-OPP-2014-0355-0015.

⁶⁰ Registration Decision of the New Active Ingredient Bicyclopyrone An Herbicide for Use on Corn and Establishment of Tolerances for Corn (field, pop, and sweet) and Imported Sugarcane, Docket #: EPA-HQ-OPP-2014-0355-0077.

and S-metolachlor). If effects data are available for a formulated product for non-target organisms containing more than one active ingredient, they may be used qualitatively or quantitatively in accordance with the agency's Overview Document and the Services' Evaluation Memorandum.⁶¹

This post-hoc justification is notable since EPA did not even mention the words “synergistic” or “cumulative” anywhere in its ecological risk assessment or proposed registration decision. It is also notable because EPA seems to think that it might be absolved of its responsibilities because it “adequately addressed” synergistic effects of Bicyclopyrone and Atrazine. What about the synergistic effects of all four active ingredients? Again, EPA does not devote a single word anywhere in any document on the docket regarding those potentially significant impacts. EPA also did not consider the inert ingredients in Acuron that hold this four chemical mixture together and comprise approximately 62.42% of every gallon of Acuron. Inert ingredients, including surfactants and anti-foaming chemicals within a pesticide end product may also cause negative impact to listed species,⁶² and here again EPA has never consulted with the Services to determine potential impacts to imperiled species protected under the ESA.

Astoundingly, EPA has given the green-light for Acuron to be mixed with additional pesticide products, *including other products containing Atrazine*. According to its label, Acuron can also be mixed with a “burndown herbicide such as Gramoxone®, Touchdown® brands, Roundup® brands, or 2,4-D,”⁶³ a product best known as a key ingredient in Agent Orange. The only things that Acuron cannot be mixed with are organophosphate and carbamate insecticides. But according to the label, this is not based on concern for how these wholly untested chemical cocktails may effect those consuming the corn or the environment more broadly, but rather because, “severe corn injury may occur.” Injuries to listed species do not appear to be a concern when it comes to mixing Acuron with any other pesticide. EPA has the authority and discretion to limit how Acuron is mixed with other pesticides, however it has elected to allow for experimentation of these untested and unknown chemical combinations to occur throughout America's agricultural landscapes..

EPA only claims that if, *after* registration, Acuron is found to be harmful to endangered species due to “evidence from incidents or field observations” then EPA would use its *Bulletins Live! Two* system to “set fourth geographically-specific pesticide use limitations for the protection of threatened and endangered species and their designated critical habitat.”⁶⁴ The entire point of Section 7 of the ESA is to protect endangered species from harm *before* such harm occurs. The Endangered Species Act does not give agencies permission to harm species and then wait until definitive proof of such harms occur in the real world before an agency needs to change its behavior. Moreover, *Bulletins Live! Two* only functions if the EPA initiates, and the Services 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

⁶¹ Bicyclopyrone: Response to Public Comments on EPA's “Proposed Registration of the New Active Ingredient Bicyclopyrone.” Docket #: EPA-HQ-OPP-2014-0355-0076.

⁶² *Washington Toxics Coalition v. U.S. Dept. of Interior*, 457 F. Supp. 2d 1158 (W.D. Wash 2006).

⁶³ Acuron™ Herbicide Notice of Conditional Registration EPA Reg. 100-1466, Docket #: EPA-HQ-OPP-2014-0355-0078

⁶⁴ Bicyclopyrone: Response to Public Comments on EPA's “Proposed Registration of the New Active Ingredient Bicyclopyrone.” Docket #: EPA-HQ-OPP-2014-0355-0076.

Bicyclopyrone will cause and pretending that one day it might do something for species, if there is evidence of harm, down the road.

The reality is that Bicyclopyrone alone in the abstract, and the product Acuron in the real world, will clearly harm hundreds of ESA-listed species. EPA's failure to consult is arbitrary and capricious and a clear violation of the Endangered Species Act.

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.⁶⁵ EPA's risk assessment makes clear that the "may affect" threshold is met for many listed species nationwide that could be harmed by Bicyclopyrone and Acuron. Thus, the trigger for consultations has been met, and the Endangered Species Act requires EPA to initiate consultation to ensure that the registration of Bicyclopyrone 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. EPA has failed to require *any* measures whatsoever to protect even a single endangered species anywhere in the United States. As such, EPA's registration of Bicyclopyrone and Acuron violates EPA's Section 7 mandate that it must avoid jeopardizing the continued existence of any endangered species or threatened species, and avoid the destruction or adverse modification of critical habitat of listed species.

Simply put, EPA's own risk assessment establishes that use of Bicyclopyrone may affect listed species or adversely modify critical habitat. EPA's past ecological risk assessments of Atrazine, S-Metolachlor, and Mesotrione have concluded that those active ingredients may affect listed species and adversely modify critical habitat. 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 Bicyclopyrone and Acuron.

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 a Biological Opinion issued pursuant to Section 7 of the ESA. As discussed above, registration of Bicyclopyrone 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 Bicyclopyrone, 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 Bicyclopyrone or Acuron, it does not possess an ITS from the wildlife agencies and is therefore in violation of Section 9 of the ESA.

⁶⁵ 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).

CONCLUSION

If EPA does not act within 60 days to correct the violations described in this letter, we will pursue litigation against the agency. 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-2014-0355 to Regulations.gov for Public Access

To: Office of Pesticide Programs Docket

FROM: Susan Lewis
Director, Registration Division
Office of Pesticide Programs

Susan Lewis 3/13/2015

This memorandum authorizes the posting of EPA-HQ-OPP-2014-0355 to Regulations.gov for public access.

Background: The Agency received an application from Syngenta Crop Protection to register the new active ingredient bicyclopyrone, for use as an herbicide on corn. 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 3/13/15 to 4/13/15:

1. "Proposed Registration Decision of the New Active Ingredient Bicyclopyrone"
2. "Environmental Fate and Ecological Risk Assessment for Use of the New Herbicide Bicyclopyrone"
3. "Drinking Water Exposure Assessment in Support of the Section 3 New Chemical Registration for the Proposed Use of Bicyclopyrone on Corn"
4. "SYN-A16003 Product" (draft label)
5. "Acuron Product" (draft label)
6. "Bicyclopyrone Wet Paste Manufacturing Use Product" (draft label)
7. "Bicyclopyrone Wet Paste II Manufacturing Use Product" (draft label)
8. "Bicyclopyrone Technical" (draft label)
9. "Bicyclopyrone. Occupational and Residential Exposure Assessment for Proposed Uses on Field Corn, Seed Corn, Silage Corn, Yellow Popcorn and Sweet Corn"

10. "Bicyclopyrone: Human Health Risk Assessment for the Section 3 Registration Action on Corn and the Establishment of Permanent Tolerances for Residues in/on Corn and Imported Sugarcane."

Submit your comments, identified by Docket ID No. EPA-HQ-OPP-2014-0355, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- Mail: EPA-HQ-OPP-2014-0355, 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 Susan Lewis at 703-305-5447, or via email at RDFRNotices@epa.gov.

APPENDIX B



Registration Decision of the New Active Ingredient Bicyclopyrone

**An Herbicide for Use on Corn and Establishment of
Tolerances for Corn (field, pop, and sweet) and Imported
Sugarcane**

Approved by: _____

Jack E. Housenger, Director
Office of Pesticide Programs

Date: _____

4/24/15

Summary

This document announces that the U.S. Environmental Protection Agency (EPA) has completed its evaluation of the new herbicide bicyclopyrone and has concluded that it meets the regulatory standard under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Five products will be registered under Section 3(c)(7)(C) of FIFRA: one technical product, two manufacturing-use products (Bicyclopyrone Wet Paste Manufacturing Use Product and Bicyclopyrone Wet Paste II Manufacturing Use Product), and two end-use products (SYN-A16003 Herbicide and Acuron™ Herbicide). The product Acuron™ will contain 0.65% bicyclopyrone, 2.60% mesotrione, 10.93% atrazine, and 23.40% S-metolachlor. The product SYN-A16003 will contain 18.5% bicyclopyrone. The labels specify that bicyclopyrone is generally to be applied once annually as a pre-emergent application to corn; however, a split application for pre-emergent and early post-emergent is allowed, provided the maximum single and annual application rates are not exceeded. Identical rates and use patterns apply to both end use products.

In accordance with 3(c)(7)(C) of FIFRA the agency has determined that registering bicyclopyrone is in the public interest. Acuron™ can control weeds with a single pre-emergent application that may not require additional post-emergent applications. Acuron™ will be labeled for difficult to control weeds with a lower rate of atrazine, S-metolachlor, and mesotrione; resulting in decreases in the amount of atrazine that will be applied to corn as well as smaller reductions in S-metolachlor and mesotrione. Acuron™'s penetration into the market will result in the reduction of other Syngenta atrazine products, resulting in a reduction of 3.6 million pounds of atrazine per year on acres that would have been treated with those products. The agency is requiring Syngenta to achieve this reduction no later than the 2020 growing season. Labels have language including surface and ground water advisories that stress the potential for runoff management after treatment and statements intended to preclude leaching to groundwater. Language is on the label that is intended to keep the pesticide on the intended treatment area and instructs users of applicator responsibilities and specific techniques to reduce the possibility of spray drift. Aerial application is prohibited and a 25-foot downwind buffer is required to avoid drift to non-target areas. End use labels also contain guidance and information which will slow the development of resistance to the target weeds.

Background

On September 23, 2013, EPA received an application to register products containing the new active ingredient, bicyclopyrone (CAS Number 352010-68-5), an herbicide for use on corn (field, pop, and sweet) from Syngenta Crop Protection. Syngenta also submitted applications for simultaneous review to the Pest Management Regulatory Agency (PMRA) of Canada and the Australian Pesticides and Veterinary Medicines Authority (APVMA). The EPA, PMRA, and APVMA combined scientific and regulatory expertise to conduct a joint review. Each country's team of scientists peer-reviewed the primary reviews of their counterparts. While continuing to consult and coordinate, human health and ecological risk assessments were developed by each country individually.

Bicyclopyrone is an herbicide for use on corn with the establishment of tolerances on corn and imported sugarcane. Bicyclopyrone is to be used on corn for the selective contact and residual control of weeds in field corn, seed corn, silage corn, yellow popcorn, and sweet corn. The maximum single and maximum annual application rates are 0.045 lb ai/acre. One pre-emergent application is allowed, but the labels do allow for split applications (one pre-emergent and one early post-emergent) as long as the maximum single and annual application rates are not exceeded. The minimum retreatment interval (RTI) is 14 days; the pre-harvest interval (PHI), is 45 days.

Acuron™ contains 0.65% bicyclopyrone, 2.60% mesotrione, 10.93% atrazine, and 23.40% S-metolachlor giving the product three different modes of actions (MoA). The product SYN-A16003 contains 16.5% bicyclopyrone and only one MoA. The label for Acuron™ contains information on each of the three different modes of actions. The label for SYN-A16003 contains information on the MoA for bicyclopyrone. Bicyclopyrone and mesotrione are members of the hydroxyphenylpyruvate dioxygenase (HPPD) inhibitor class of herbicides (Herbicide Resistance Action Committee (HRAC) Group 27) and belong to the triketone subclass of chemistry. Bicyclopyrone and mesotrione inhibit the enzyme HPPD and block biosynthesis in plants. Atrazine is a member of the triazine family of herbicides (HRAC Group 5). Atrazine works by inhibiting photosynthesis. S-Metolachlor is a member of the chloroacetamide family of herbicides (HRAC Group 15). S-Metolachlor is a seedling shoot growth inhibitor.

The maximum single and maximum total annual rates for Acuron™ are 3 quarts per acre. When applied at this rate, Acuron™ will apply 0.045 lb ai/acre of bicyclopyrone, 0.18 lb ai/acre of mesotrione, 0.75 lb ai/acre of atrazine, and 1.605 lb ai/acre of S-metolachlor per single application and total per year. The maximum total annual rates on corn, allowed by the agency, for mesotrione is 0.24 lb ai/acre, atrazine is 2.5 lb ai/acre, and S-metolachlor is 3.71 lb ai/acre. The maximum single and maximum total annual rates for Acuron™ are below the maximum use rates allowed by the agency for mesotrione, atrazine, and S-metolachlor.

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 and plants. 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. The pesticide's label helps to communicate essential limitations and mitigations that are necessary for public safety. It is a violation of federal law to use a pesticide in a way that conflicts with the label.

Assessment of Risk to Human Health

EPA requires a wide range of studies in order to assess a pesticide. Both bicyclopyrone (active ingredient specific) and Acuron™ (mixture specific) fall in the lowest acute toxicity category of IV via the eye, oral, dermal, and inhalation routes. The labeling precautionary signal word is “CAUTION” for all products. Atrazine also shows low acute toxicity data. The acute toxicity effects are similar and do not indicate a synergistic effect for atrazine and bicyclopyrone for mammals. The table below summarizes the toxicological endpoints used in the human health risk assessment:

Summary of Toxicological Doses and Endpoints for Bicyclopyrone for Use in Human Health Risk Assessments.				
Exposure/ Scenario	POD	Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population, including Infants and Children)	No endpoint attributable to a single dose and appropriate for the U.S. general population was seen in the bicyclopyrone toxicological database; therefore, an acute dietary point of departure for the general U.S. population was not established.			
Acute Dietary (Females 13- 49 years of age)	LOAEL = 10 mg/kg/day	UF _A = 10X UF _H = 10X FQPA SF /UF _L = 10X	Acute RfD = 0.01 mg/kg/day aPAD = 0.01 mg/kg/day	Prenatal Developmental Study (New Zealand White rabbits) Developmental LOAEL = 10 mg/kg bw based on skeletal variations (the appearance of the 27 th presacral vertebrae).
Chronic Dietary (All Populations)	LOAEL = 0.28 mg/kg/day	UF _A = 10X UF _H = 10X FQPA SF/UF _L = 10X	Chronic RfD = 0.00028 mg/kg/day cPAD = 0.00028 mg/kg/day	Carcinogenicity (rat) LOAEL = 0.28/0.35 mg/kg/day (M/F) based on a dose dependent increase in the incidence of opaque eyes and corneal damage in both sexes compared to controls, an increased incidence of thyroid follicular hyperplasia in males, and an increased incidence of chronic progressive nephropathy in the kidneys of males.
Dermal Short- (1-30 days) and Intermediate- Term (1-6 months)	LOAEL = 10 mg/kg/day DAF = 20.44%	UF _A = 10X UF _H = 10X UF _L = 10X	Occupational LOC for MOE = 1000	Prenatal Developmental Study (New Zealand White rabbits) Developmental LOAEL = 10 mg/kg bw based on skeletal variations (the appearance of the 27 th presacral vertebrae).
Inhalation Short- (1-30 days) and Intermediate- Term (1-6 months)	LOAEL = 10 mg/kg/day	UF _A = 10X UF _H = 10X UF _L = 10X	Occupational LOC for MOE = 1000	Prenatal Developmental Study (New Zealand White rabbits) Developmental LOAEL = 10 mg/kg bw based on skeletal variations (the appearance of the 27 th presacral vertebrae).

Summary of Toxicological Doses and Endpoints for Bicyclopyrone for Use in Human Health Risk Assessments.				
Exposure/Scenario	POD	Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	Classification: "Suggestive evidence of cancer" based on the presence of rare ocular tumors in male rats. Quantification of bicyclopyrone's carcinogenic potential is not required. The Cancer Assessment Review Committee (CARC) recommended using a non-linear approach (<i>i.e.</i> , RfD) that will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to bicyclopyrone.			

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). DAF = dermal absorption factor. RfD = reference dose. MOE = Margin of Exposure. LOC = Level of Concern.

The acute and chronic analyses assumed tolerance-level residues (acute analysis) or average field trial residues (chronic analysis), 100% crop-treated (CT), and modeled drinking water estimates. Since adequate processing studies have been submitted, which indicate that residues do not concentrate in corn or sugarcane commodities, the Dietary Exposure Evaluation Model (DEEM ver. 7.81) default processing factors for these commodities were reduced to 1. The resulting acute [2.9% acute population-adjusted dose (aPAD) for females 13 - 49 years old] and chronic [≤ 91% chronic population-adjusted dose (cPAD); children (1 - 2 years old) were the most highly exposed subgroup] dietary risk estimates are not of concern. The occupational handler exposure and risk estimates indicate that the short- and intermediate-term dermal and inhalation combined margins of exposure (MOEs) are not of concern (*i.e.*, MOE ≥ 1000) with baseline attire (*i.e.*, single layer of clothing, no gloves, and no respirator; all MOEs ≥ 1,700). The occupational post-application dermal exposure and risk estimates are greater than the level of concern of 1000 on the day of application, ranging from 1,800 to 49,000 depending on crop and activity.

Assessment of Ecological Risk

Bicyclopyrone is a relatively soluble, nonvolatile compound that is stable to hydrolysis and is expected to be very highly mobile in soil. Bicyclopyrone photodegrades on surface soil, with half-lives ranging from 4- to 13-days. It is slightly persistent in aerobic soil, metabolizing to multiple organic transformation products and carbon dioxide. It is stable in anaerobic soil and anaerobic aquatic systems, and degrades very slowly in aerobic aquatic systems, with half-lives of 393 - 681 days. Bicyclopyrone photodegrades slowly in water, with half-lives of 11 to 75 days. The new active ingredient is not expected to bioaccumulate in aquatic and terrestrial organisms. Bicyclopyrone may move to groundwater via leaching, and may move to surface water bodies via spray drift and runoff of dissolved or sorbed residues.

Bicyclopyrone is classified as slightly to practically non-toxic to freshwater and estuarine/marine fish (and to aquatic-phase amphibians for which freshwater fish serve as surrogates) as well as to freshwater invertebrates, but is moderately toxic to estuarine/marine invertebrates on an acute

exposure basis. Chronic effects were not observed in either the freshwater fish early life stage toxicity test or the freshwater invertebrate full life cycle test after exposure to bicyclopyrone. No chronic estuarine/marine fish or invertebrate studies were submitted and therefore acute-to-chronic ratios (ACRs) based on freshwater species were used to estimate chronic toxicity endpoints for estuarine/marine animals. Toxicity to aquatic vascular and non-vascular plants was observed upon exposure to bicyclopyrone.

Bicyclopyrone is moderately to practically non-toxic to birds (and to terrestrial-phase amphibians and reptiles for which birds serve as surrogates), mammals, and to young adult honey bees (*Apis mellifera*) on an acute exposure basis.

Risk quotients (RQs) do not exceed the acute or chronic risk levels of concern (LOCs) for both freshwater and estuarine/marine fish and invertebrates or for aquatic-phase amphibians. RQ values were also below LOCs for acute and chronic risk to birds, terrestrial-phase amphibians and reptiles and for acute risk to mammals. However, RQs exceed the LOC for chronic risk to mammals (RQs = 1 - 2.1). Consistent with the MoA of bicyclopyrone as an herbicide, exposure at the maximum labeled application rates may result in risk to terrestrial and semi-aquatic dicotyledenous (dicots) plants (RQs = 1.35 - 11.48). RQ values exceed the LOC for risk to federally listed threatened or endangered (referred to as "listed") dicots for pre-emergent use (RQs = 1.8 - 9.0) as well as for both listed and non-listed aquatic vascular plants.

The following tables provide a comparison of the toxicity of bicyclopyrone relative to alternative compounds for the proposed use on corn. These tables provide a comparison of toxicity data on a chemical-by-chemical basis; the tables are sorted with the most toxic herbicide (based on endpoint values) at the top and the least toxic at the bottom. Only groups of organisms for which LOCs are exceeded for bicyclopyrone are listed.

Vascular Aquatic Plants EC₅₀ and NOAECs

Chemical	EC ₅₀ (mg/L)	NOAEC (mg/L)
Acetochlor	0.0034	0.00012
Topramezone	0.0067	0.001
Bicyclopyrone	0.013	0.003
Mesotrione	0.0177	0.0075
S-metolachlor	0.048	0.0084
Atrazine	0.170	NA
2,4-D	0.2992	NA
Glyphosate	4.9	NA

NA: Not available

Terrestrial Plants NOAECs and EC₂₅

Chemical	EC ₂₅ /IC ₂₅ (lbs ai/A)	NOAEC (lbs ai/A)
Topramezone	0.0001 ²	0.000009 ²
Mesotrione	0.00023 ¹	0.0001 ¹
2,4-D	0.00081 ¹	0.00047 ¹
Bicyclopyrone	0.001 ²	0.0002 ²
Acetochlor	0.0013 ¹	0.0006 ¹
Atrazine	0.003 ¹	0.0025 ¹

S-Metolachlor	0.016 ²	0.0031 ²
Glyphosate	0.16 ²	0.074 ²

¹ Based on seedling emergence study

² Based on the vegetative vigor study

Mammalian Chronic NOAECs and NOAELs

Chemical	NOAEL [#] (mg/kg-bw)	NOAEC [#] (mg/kg-diet)
Topramezone	0.2*	4.0
Bicyclopyrone	2.15	43*
S-Metolachlor	15*	300
2,4-D	16.6	332*
Atrazine	25*	500
Mesotrione	71.4	1428*
Acetochlor	175	3500*
Glyphosate	500	10000

[#] The NOAEL and NOAEC are used to estimate chronic dose-based and dietary-based risk, respectively, to listed mammals.

* Endpoint estimated based on the assumption that 1 mg/kg-bw = 20 mg/kg-diet

Benefits

Bicyclopyrone will initially be marketed as a four-active ingredient herbicide product (Acuron™, also formulated with 2.60% mesotrione, 10.93% atrazine, and 23.40% S-metolachlor). Acuron™ can provide its most effective weed management with a single pre-emergent application that may not require additional post-emergent applications.

Acuron™ will be labeled for difficult to control weeds with a lower rate of atrazine, S-metolachlor, and mesotrione; resulting in decreases in the amount of atrazine that will be applied to corn as well as smaller reductions in S-metolachlor and mesotrione. The agency views these reductions as an environmental benefit. Because of the uncertainty in fully predicting future growers' adoption of Acuron™ and ultimately whether growers will use less than labeled rates over time, as is common with the alternatives, the Agency is requiring submission of annual reporting on herbicide use impacted by the introduction of Acuron™. Syngenta will develop and implement an educational and stewardship program designed to achieve the predicted reductions in herbicide use on corn. Finally, the agency and Syngenta will monitor the use of Acuron™, to ensure that significant reductions in the use of atrazine occur. Additional mitigation measures would be adopted in the event that they do not.

Public Comments

On 8/13/14, EPA published a notice of receipt in the Federal Register of an application for registration of bicyclopyrone and announced a public comment period of 30 days. No comments were received. On 9/5/14, the EPA published a notice of filing in the Federal Register announcing the receipt of the initial filing of the bicyclopyrone petition by Syngenta under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting the establishment of regulations for residues of bicyclopyrone on various commodities. This publication also announced a public comment period of 30 days; seven comments were received on the FFDCA notice of filing. Three of the comments were relevant to bicyclopyrone, the other four comments were relevant to other actions that were batched together with bicyclopyrone in the same Federal Register

document. The commenters noted that pesticides and bicyclopyrone pose a risk to pollinators. The agency has determined that bicyclopyrone is moderately to practically non-toxic to young adult honey bees (*Apis mellifera*) on an acute exposure basis. On 2/11/2015, the EPA published an additional notice of filing in the Federal Register for the import tolerance on sugarcane petition and no relevant comments were received.

The EPA announced the proposed decision of the unconditional registration of bicyclopyrone on 3/13/15, and held a public comment period for 30 days, closing 4/13/15. Forty four submissions were received in response to the public commenting period. Forty one submissions were received from various universities, state corn grower associations, state agri-business associations, state farm bureaus, state food processors associations, IR-4, Syngenta, and the public and were in favor of and supported the registration of bicyclopyrone; noting its benefits of controlling hard to control weeds such as cockle burr, ragweed, etc., helping with herbicide resistance management, its ability to be used as part of a one-pass spray system, and reduction of the use of atrazine, S-metolachlor, and mesotrione. Three submissions were in opposition to the agency's proposed decision to register bicyclopyrone and based their concern on the agency not consulting with the U.S. Fish and Wildlife Service and National Marine Fisheries Service under the Endangered Species Act and not having adequate label and use restrictions to protected listed species. One of the submissions in opposition to registration was a mail campaign submission containing 5,558 letters. 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-2014-0355).

Mitigation and Labeling Requirements

Because of the potential for leaching of bicyclopyrone and its degradates, labels have language including surface and ground water advisories that warn of the potential for runoff after treatment and descriptions of conditions that may be susceptible to leaching to groundwater. In order to mitigate risks, language is on the label that is intended to keep the pesticide on the intended treatment area, thereby reducing the potential for exposure to non-target organisms. For example, the following label language is on the end-use products, SYN-A16003 Herbicide and Acuron™ Herbicide, which instructs users of applicator responsibilities and specific techniques to reduce the possibility of spray drift:

Spray Drift Language

SPRAY DRIFT

Do not apply when weather conditions may cause drift to nontarget areas. Drift may result in injury to adjacent crops and vegetation. To avoid spray drift, DO NOT apply when wind speed is greater than 10 mph or during periods of temperature inversions.

AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR.

The interaction of equipment and weather related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making a decision.

Information on Droplet Size

The most effective way to reduce spray drift potential is to apply large droplets. Use only nozzles producing medium to ultra-course droplets. Do not use nozzles producing fine droplets.

Controlling Droplet Size

Volume – Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

Pressure – Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher rate nozzles instead of increasing pressure.

Number of Nozzles – Use the minimum number of nozzles that provide uniform coverage.

Non-Target Areas

Do not apply this pesticide when this product may drift to non-target areas.

Application Height

Applications must be made at the lowest height above the target area that still provides uniform coverage of the target. Making applications at the lowest yet effective height reduces exposure of droplets to wind.

Wind

Drift potential is lowest when wind speeds are 10 mph or less. However, many factors, including droplet size, pressure, and equipment type determine drift potential at any given wind speed. Note: Local terrain can influence wind patterns.

Leave a 25-foot buffer downwind of the application to avoid drift to non-target areas.

Temperature Inversions

Applications must not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be

identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates, indicates good vertical air mixing.

Environmental Hazards

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

Ground Water Advisory

Bicyclopyrone is known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.

Surface Water Advisory

This product has a high potential for reaching surface water via runoff for several months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of bicyclopyrone from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours.

Aerial Prohibition

Do not apply by air.

Data Requirements

Data from the acute contact and oral toxicity tests with adult honey bees indicate that bicyclopyrone is practically non-toxic to bees on an acute exposure basis. However, at this time, there are no data regarding the potential acute and chronic effects of the compound on honey bee larval development and survival or the potential for chronic effects of adult bees. Therefore, EPA is requiring the submission of this information. This data requirement is explained further below.

Annual Reporting

Acuron™'s introduction will result in reduction in the use of other Syngenta products, resulting in a reduction of 3.6 million pounds of atrazine per year on acres that would have been treated with those products. The agency is requiring Syngenta to achieve this reduction no later than the 2020 growing season.

Syngenta will provide an annual report to EPA no later than March 31 of each year following Acuron™'s first full launch year (the first full launch year currently is anticipated to be 2016 and, if so, the first report would be made in March of 2017). The report will include data on the total application of specific herbicide products to corn grown in the U.S. in the preceding year. In the annual report on the 2018 growing season (provided in March of 2019) Syngenta will demonstrate a 1.6 million pound reduction of atrazine used per year. In the annual report on the 2020 growing season (provided in March of 2021), Syngenta will demonstrate an approximately 3.6 million pound reduction of atrazine used per year. In the event that these reductions are not achieved, mitigation measures will be undertaken to ensure that atrazine uses are reduced.

International Harmonization

There are no established Mexican or Codex maximum residue limits (MRLs) for residues of bicyclopyrone. Bicyclopyrone is the subject of a global data review by the EPA, PMRA, and APVMA. At this time, the residue definitions and the tolerances and MRLs are harmonized among the review partners.

Regulatory Decision

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 bicyclopyrone meets the regulatory standard under FIFRA. Therefore, the EPA is granting a conditional registration of bicyclopyrone under Section 3(c)(7)(C) of FIFRA. The agency initially proposed to register bicyclopyrone as an unconditional registration 3(c)(5). However, due to the data requirements for bicyclopyrone, concerning bees the agency is registering bicyclopyrone as a conditional registration 3(c)(7)(C).

The database submitted to support the assessments of human health risk and environmental fate and ecological risk is adequate to support the use and tolerances. There are no risk estimates of concern for human health. Bicyclopyrone has low potential for acute risk to mammals, birds, freshwater and estuarine/marine fish, freshwater invertebrates, amphibians, reptiles, and adult insects. Bicyclopyrone may pose a risk to non-target terrestrial and aquatic plants, and chronic risk to non-human mammals. Label language as outlined in the "Mitigation and Labeling Requirements" section will reduce the risk to these organisms.

EPA is requiring acute and chronic studies of bicyclopyrone on honey bee larval development and survival and chronic studies of adult bees to support future, more comprehensive pollinator risk assessments for bicyclopyrone. For the proposed use on corn, any exposure to bicyclopyrone transported through the plant into pollen and/or nectar is expected to be much lower than exposure from direct treatment of the crop, which is addressed in the current ecological risk assessment. Additionally, there are no data to suggest that bicyclopyrone's mode of action as a HPPD inhibitor, which results in oxidative stress and chlorophyll loss in plant cells, would have a direct adverse effect on honey bee health. Therefore, this requirement is consistent with the harmonized Guidance for Assessing Pesticide Risks to Bees

(http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf). However, for the use pattern currently proposed, the potential for adverse effects to adult honey bees from direct application is low and there is sufficient information to support a conditional risk-benefit decision.

In accordance with 3(c)(7)(C) of FIFRA the agency has determined that registering bicyclopyrone is in the public interest. Acuron™ can control weeds with a single pre-emergent application that may not require additional post-emergent applications. Acuron™ will be labeled for difficult to control weeds with a lower rate of atrazine, S-metolachlor, and mesotrione; resulting in decreases in the amount of atrazine that will be applied to corn as well as smaller reductions in S-metolachlor and mesotrione. Acuron™'s penetration into the market will result in the reduction of other Syngenta atrazine products, resulting in a reduction of 3.6 million pounds of atrazine per year on acres that would have been treated with those products.

The agency is registering the following five products:

Bicyclopyrone Technical

- 99.3% Bicyclopyrone
- Only for formulation into an herbicide for use in field corn, seed corn, silage corn, sweet corn, and yellow corn.

Bicyclopyrone Wet Paste Manufacturing Use Product

- 94.0% Bicyclopyrone
- Only for formulation into an herbicide for use in field corn, seed corn, silage corn, sweet corn, and yellow corn.

Bicyclopyrone Wet Paste II Manufacturing Use Product

- 89.6% Bicyclopyrone
- Only for formulation into an herbicide for use in field corn, seed corn, silage corn, sweet corn, and yellow corn.

SYN-A16003 Herbicide

- 18.5% Bicyclopyrone
- Only for use as a pre-emergent and post-emergent herbicide for the selective contact and residual control of broadleaf weeds use in field corn, seed corn, silage corn, sweet corn, and yellow corn.

Acuron™ Herbicide

- 0.65% Bicyclopyrone, 2.60% Mesotrione, 10.93% Atrazine, and 23.40% S-Metolachlor
- Only for use as a pre-emergent and post-emergent herbicide for the selective contact and residual control of broadleaf weeds use in field corn, seed corn, silage corn, sweet corn, and yellow corn.

In summary, bicyclopyrone is comparable to the other HPPD inhibitors and as stated above, this new active ingredient meets the regulatory standard under FIFRA. With the terms and

conditions of registration, the agency expects, and will ensure, that the availability of Acuron™ Herbicide results in reductions in the amount of atrazine applied to corn in the U.S. The risk assessments supporting this decision can be found in the regulatory docket (Docket ID: EPA-HQ-OPP-2014-0355).