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Sent via Email and USPS Priority Mail, Signature Requested

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Re: Notice of Violations of the Endangered Species Act Regarding Registration of Cuprous Iodide

On behalf of the Center for Biological Diversity, 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 over 900,000 members, with approximately 50,000 members 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 pesticides are one of the foremost threats to the environment, biodiversity and public health, the Center works to prevent and reduce the use of harmful pesticides and to promote sound conservation strategies. The Center commented on EPA’s Proposed Registration of Cuprous Iodide as a New Active Ingredient (Docket #: EPA-HQ-OPP-2013-0433-0004).¹

EPA has violated its ESA Section 7 duties to insure it does not jeopardize the continued existence of listed species or adversely modify or destroy their critical habitat in consultation with the expert fish and wildlife agencies regarding its discretionary decision to register the new active ingredient Cuprous Iodide.² EPA’s failure to insure against jeopardy and adverse modification through consultation with the U.S. Fish and Wildlife Service (“FWS”) and National Marine Fisheries Service (“NMFS”) (collectively “the Services”) is particularly egregious because Cuprous Iodide will present as copper and iodine ions, and EPA knows that copper is “very highly toxic” to freshwater and estuarine/marine fish and invertebrates.³ EPA cannot avoid consultation by pointedly avoiding labeling these risks to listed species as a “may effect”

¹Comment of Center for Biological Diversity, Docket #: EPA-HQ-OPP-2013-0433-0007.

² EPA registered for use the pesticide Cupron Cuprous Iodide Masterbatch, EPA Reg. Number: 84542-9 (enclosed) and the active ingredient Cuprous Iodide, Docket #: EPA-HQ-OPP-2013-0433. EPA issued the label to the registrant, Cupron, Inc., on October 6, 2015; however, EPA has not, to date, published its registration decision to the public docket.

³ *Id.* at 11.

determination.⁴ In particular, copper is a contaminant of concern because of its toxicity to certain sensitive species of algae (phytoplankton) that form the base of the aquatic food web and even small amounts of copper directly damage the sensory capabilities of salmon, making it difficult for them to avoid predators or find their way back to their spawning grounds. The use of Cuprous Iodide as an antimicrobial in products may result in copper released to waterways in virtually every state.

EPA's registration of Cuprous Iodide may affect and is likely to adversely affect federally-listed species. Without consultation and appropriate mitigation, EPA cannot insure that its registration of Cuprous Iodide will not jeopardize federally-listed species or adversely modify their critical habitat. Despite the likely harm to threatened and endangered species, EPA chose to register this pesticide without consultation to determine appropriate mitigation and measures to avoid jeopardizing listed species or adversely modifying critical habitat. EPA's failure to consult is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with Section 7 of the ESA. 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 Cuprous Iodide.

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...."⁵

The ESA vests primary responsibility for administering and enforcing the statute with the Secretaries of Commerce and the Interior. The Secretaries of Commerce and the Interior have delegated this responsibility to the NMFS and the FWS respectively.⁶

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."⁷ 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."⁸ 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."⁹

⁴ Risk Assessment at 3 (excluding concerns for listed aquatic species from the risk conclusions); Proposed Decision at 7 (excluding the exceedence of COCs for listed species from the summary of the assessment of ecological risk).

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

⁶ 50 C.F.R. § 402.01(b).

⁷ 16 U.S.C. § 1531(c)(1).

⁸ 16 U.S.C. § 1532(3).

⁹ 16 U.S.C. § 1536(a)(1).

In order to fulfill the substantive duties 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”¹⁰

Section 7 consultation is required for “any action [that] may affect listed species or critical habitat.”¹¹ 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.”¹²

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.¹³ 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.¹⁴

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.”¹⁵ 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.¹⁶ 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.”¹⁷ “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.”¹⁸ Thus, an action which indirectly (e.g. habitat modification) or directly causes a

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

¹¹ 50 C.F.R. § 402.14.

¹² 50 C.F.R. § 402.02.

¹³ 16 U.S.C. § 1536(b).

¹⁴ 50 C.F.R. § 402.13.

¹⁵ 16 U.S.C. § 1536(d).

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

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

¹⁸ 50 C.F.R. § 17.3.

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.¹⁹ 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.²⁰

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.²¹ FIFRA charges EPA with registering, reviewing, amending, and reregistering chemicals and chemical formulations for use as insecticides, fungicides, and pesticides in the United States.²² Under FIFRA, a pesticide generally may not be sold or used in the United States unless it has an EPA registration for that particular use.²³

EPA may register a pesticide if it makes the following determinations: (1) the labeling complies with FIFRA’s requirements; (2) the composition claims are warranted; (3) the pesticide will perform its intended function; and (4) the pesticide will not cause unreasonable adverse effects on the environment.²⁴ The culmination of the registration process is EPA’s approval of a label for the particular fungicide. FIFRA makes it unlawful to use a pesticide in a manner inconsistent with the label,²⁵ or to make any claims that differ substantially from the label.²⁶ The ESA’s Section 7 requirements apply to EPA’s discretionary registration of pesticides under FIFRA, and its actions in exercising its continuing authority over pesticide regulation.²⁷

FACTUAL BACKGROUND

A. EPA’s Approval of Cuprous Iodide

On October 30, 2013, EPA published a notice in the Federal Register announcing that it had received applications to register pesticide products with new active ingredients, including Cuprous Iodide proposed for use bacteristat and fungistat for indoor non-food use on fibers, carpet, films, plastics, coatings, laminates, adhesives and sealants. (Docket #: EPA-HQ-OPP-

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

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

²¹ See 7 U.S.C. §§ 136-136y.

²² *Id.*

²³ 7 U.S.C. § 136a(a).

²⁴ 7 U.S.C. § 136a(c)(5).

²⁵ *Id.* § 136j(2)(G).

²⁶ *Id.* § 136j(1)(B).

²⁷ *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).

2013-0433).²⁸ On August 27, 2015, EPA posted an announcement to the docket on regulations.gov announcing a proposed registration decision and the opening of a comment period beginning on August 27, 2015 and ending on September 27, 2015.²⁹ Also on August 27, 2015, EPA posted its Proposed Registration Decision for the New Active Ingredient Cuprous Iodide,³⁰ its Human Health and Ecological Risk Assessment for Cuprous Iodide³¹ and its Fact Sheet on the Proposed Registration of a Product containing the New Active Ingredient Cuprous Iodide³² to the docket on regulations.gov.

The Center submitted a detailed comment letter by uploading it to Docket #: EPA-HQ-OPP-2013-0433 on regulations.gov on September 25, 2015 in response to the proposed registration of Cuprous Iodide, 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.³³

On October 6, 2015, EPA issued a label to the registrant, Cupron, Inc., which states that the pesticide Cupron Cuprous Iodide Masterbatch “is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act,” EPA Reg. Number: 84542-9 (enclosed). EPA has not, to date, published its registration decision to the Cuprous Iodide public docket, Docket #: EPA-HQ-OPP-2013-0433, on regulations.gov, nor has EPA responded to the Center’s public comment.

B. Cuprous Iodide May Affect Listed Species

EPA’s own ecological risk assessment demonstrates that Cuprous Iodide may affect listed species. According to EPA, cuprous iodide will present predominantly in the form of copper and iodine ions.³⁴ Copper is “very highly toxic” to freshwater and estuarine/marine fish and invertebrates.³⁵ EPA states that, based on its probabilistic modeling, if the acute Concentration of Concern (“COC”) for any key aquatic receptor group “is exceeded for one day or more, based on results from the high-end scenario . . . , then potential acute risks to such receptors cannot be ruled out.”³⁶ For copper, assuming 84.2% of copper is removed by wastewater treatment, EPA predicted the acute COCs would exceed 2 days for endangered freshwater fish and 72 days for endangered/listed freshwater invertebrates for the high-end scenario.³⁷ This satisfies the low “may affect” threshold for ESA consultation. EPA cannot avoid consultation by pointedly

²⁸ 78 Fed. Reg. 64937 (Oct. 30, 2013).

²⁹ Public Participation for New Active Ingredient Cuprous Iodide, Docket #: EPA-HQ-OPP-2013-0443-0003.

³⁰ Docket #: EPA-HQ-OPP-2013-0443-0004.

³¹ Docket #: EPA-HQ-OPP-2013-0443-0005.

³² Docket #: EPA-HQ-OPP-2013-0443-0006.

³³ Comment submitted by Stephanie M. Parent, Senior Attorney, Docket #: Docket #: EPA-HQ-OPP-2013-0443-0007.

³⁴ Human Health and Risk assessment for Cuprous Iodide (“Risk Assessment) at 8 and 10, Docket #: EPA-HQ-OPP-2013-0433-0005.

³⁵ *Id.* at 11.

³⁶ *Id.* at 14.

³⁷ *Id.* at 13 and 15; Proposed Registration Decision for New Active Ingredient Cuprous Iodide (“Proposed Decision”) at 3, Docket #: EPA-HQ-OPP-2013-0433-0004.

avoiding labeling these risks to listed species as a “may effect” determination.³⁸ Accordingly, EPA has a duty under the ESA to initiate and complete consultation on its proposed registration prior to finalizing it and allowing use of the new active ingredient cuprous iodide.

This information is not new to EPA. When EPA reregistered Copper, it knew that copper is highly toxic to most aquatic species through rapid binding of copper to the gill membranes, which causes damage and interferes with osmoregulatory processes.³⁹ NMFS, one of the agencies with which EPA should have consulted has a wealth of information on the adverse effects of Copper on salmonids.⁴⁰ Finally, in 1998, the United States Geological Survey completed a review of Copper hazards to fish, wildlife and invertebrates.⁴¹ Although dated, the USGS review provides a comprehensive overview of the adverse effects of copper on a significant number of species. This federally-developed information was available to EPA, but EPA ignored it in an attempt to avoid making a “may effect” determination as it is required to do under the ESA.

In addition to EPA’s own findings, publicly available information demonstrates that copper adversely affects many species. It does not appear that EPA considered any of this information in deciding to register Cuprous Iodide. In 2012, a scientific literature review focused on risks to aquatic life from potential increased copper inputs from proposed development, which is similar to the increased copper in waterways as a result of EPA’s approval of the use of Cuprous Iodide.⁴²

With respect to freshwater fish and salmonids, the 2012 scientific literature review found that:

- Copper is acutely toxic (lethal) to freshwater fish in soft water at low concentrations ranging from 10 – 20 part per billion;
- Aquatic habitats are susceptible to copper pollution because they are the ultimate receptor of industrial and urban wastewater, storm water runoff, and atmospheric deposition;
- Copper is one of the most toxic elements to aquatic species, it can accumulate and cause irreversible harm to some species;
- Adverse effects have been demonstrated on various fish “receptors” including gills, olfactory receptors, and lateral line cilia;

³⁸ Risk Assessment at 3 (excluding concerns for listed aquatic species from the risk conclusions); Proposed Decision at 7 (excluding the exceedance of COCs for listed species from the summary of the assessment of ecological risk).

³⁹ EPA Coppers Facts, EPA 738-F-06-014 (June 2008) (enclosed).

⁴⁰ *See, e.g.*, Hecht, S. A., Baldwin, D. H., Mebane, C. A., Hawkes, T., Gross, S. J., & Scholz, N. L. (US Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service) “An overview of sensory effects on juvenile salmonids exposed to dissolved copper: applying a benchmark concentration approach to evaluate sublethal neurobehavioral toxicity.” (2007) (enclosed.)

⁴¹ Eisler, R. Copper hazards to fish, wildlife, and invertebrates: a synoptic review. U.S. Geological Survey, Biological Resources Division, Biological Science Report USGS/BRD/BSR--1998-0002. (1998) (enclosed).

⁴² Woody, Carol Ann, and Sarah Louise O’Neal. “Effects of Copper on Fish and Aquatic Resources.” (2012) (enclosed).

- Because copper impairs key senses such as smell it has potential to impair complex fish behaviors important to survival and reproduction;
- Copper is known to reduce fish resistance to diseases;
- Copper disrupts migration (i.e., fishes avoid copper-contaminated spawning grounds);
- Copper alters swimming;
- Copper causes oxidative damage;
- Copper impairs respiration;
- Copper disrupts osmoregulation structure and pathology of kidneys, liver, gills, and other stem cells;
- Copper impacts mechanoreceptors of lateral line canals;
- Copper impairs functions of olfactory organs and brain;
- Copper is associated with changes in behavior, blood chemistry, enzyme activities, corticosteroid metabolism and gene transcription and expression;
- Copper impairs behaviors such as feeding, predator avoidance, homing, migration and spawning, and therefore, has potential to affect population biodiversity.
- Coho salmon exposed to just 2 ppb increases in Copper for 3 hours at 120 mg/L hardness showed significantly impaired olfactory detection of predator alarm cues and a 50% decline in normal predator avoidance response; impairment in ability to detect and avoid predators can be lethal.⁴³

The 2012 scientific literature review concluded that fish exposed to sublethal or chronic Copper concentrations can potentially suffer the following direct and indirect effects:

- a. Impaired neurological and brain function,
- b. Impaired reproduction,
- c. Impaired predator detection and avoidance,
- d. Impaired ability to find food,

⁴³ *Id.* at 3-12 (citations omitted). Although citations to the numerous scientific studies are omitted herein for purposes of brevity, the Center incorporates all citations by reference to and enclosure of Woody, Carol Ann, and Sarah Louise O'Neal. "Effects of Copper on Fish and Aquatic Resources." (2012). Woody (2012) relied, in part, on a 2009 scientific literature review on the effects of copper on aquatic species: Scannell, P. W. (2009). *Effects of Copper on Aquatic Species: A review of the literature*. ADF & G, Division of Habitat. Scannell (2009) is also enclosed and incorporated herein.

- e. Impaired ability to recognize members of their own species,
- f. Impaired ability to recognize siblings,
- g. Impaired “homing” ability,
- h. Impaired migration behaviors,
- i. Impaired growth,
- j. Depressed immune response.⁴⁴

With respect to other aquatic species, the 2012 scientific literature review concluded that “*numerous studies document adverse effects on freshwater algae, zooplankton, and mussels at levels below Aquatic Water Standards*” for Copper.⁴⁵ In turn, these adverse effects “could result in reduced prey abundance and quality to support fish growth and reproduction,” noting that “Copper is one of the most toxic metals to unicellular algae, which form the base of the salmonid food chain.”⁴⁶ Freshwater mussels and gastropods (snails) are prey for fish. Studies showed growth and survival of freshwater mussels were impaired in relatively hard waters (160-190 mg/L) at Copper concentrations below relevant (Alaska) water quality criteria.⁴⁷

As EPA well knows, Copper is a pollutant of concern in our waterways because of the direct adverse effects to aquatic species and, in part, because of its toxicity to certain sensitive species of algae that form the base of the aquatic food web. Many aquatic species prey on species that are direct or indirect consumers of phytoplankton. At least 669 waters nationwide do not meet water quality standards for copper and are listed as impaired under Section 303(d) of the Clean Water Act.⁴⁸

There are hundreds of freshwater vertebrates, including fish, turtles and salamanders, and freshwater invertebrates, including crayfish, mussels and snails, that may be affected by EPA’s registration of Cuprous Iodide due to off-site transport.⁴⁹ EPA had a duty, prior to registering the use of cuprous iodide, and continues to have a duty, to determine that the use of Cuprous Iodide either is not likely to adversely affect listed species and initiate informal consultation or is likely to adversely affect listed species and initiate formal consultation. 50 C.F.R. § 402.14. EPA has done neither.

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⁴⁴ Woody (2012) at 12 (citations omitted).

⁴⁵ *Id.* at 14 (citation omitted).

⁴⁶ *Id.* (citations omitted).

⁴⁷ *Id.* at 15 (citations omitted).

⁴⁸ http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=706

⁴⁹ See Comment of Center for Biological Diversity at Appendix A, Docket #: EPA-HQ-OPP-2013-0433-0007. This information, along with critical habitat information, should have been readily available to EPA through its Endangered Species Protection Program or through assistance from the U.S. Fish & Wildlife Service or the National Marine Fisheries Service.

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.⁵⁰ EPA’s risk assessment makes clear that the “may affect” threshold is met for multiple listed species nationwide that could be harmed by Cuprous Iodide. Thus, the trigger for consultations has been met, and the Endangered Species Act requires EPA to initiate consultation to ensure that the registration of Cuprous Iodide 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 or threatened species from Cuprous Iodide. As such, EPA’s registration of Cuprous Iodide also violates EPA’s Section 7 duty to avoid jeopardizing the continued existence of any endangered species or threatened species, and to avoid the destruction or adverse modification of critical habitat of listed species.

Simply put, EPA’s own risk assessment and other available information establish that use of Cuprous Iodide may affect listed species or 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 Cuprous Iodide.

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 Cuprous Iodide is a federal action that can cause the take of listed species due to its ability to harm and/or kill listed species. Consequently, in order to achieve safe harbor from ESA take liability in regard to Cuprous Iodide, 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 Cuprous Iodide, 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.

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⁵⁰ 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 EPA. If you have any questions, or would like to discuss this matter, please contact us.

Sincerely,



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enclosures

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