July 23, 2018

Environmental Protection Agency
Office of Pesticide Programs
EPA Docket Center (EPA/DC) (28221T)
1200 Pennsylvania Avenue NW
Washington DC 20460-0001

via Regulations.gov: **EPA-HQ-OPP-2018-0141**

Re: CropLife America Comments to the U.S. Environmental Protection Agency on the "*Biological Opinions for Pesticides Issued Under the Endangered Species Act*;" EPA-HQ-OPP-2018-0141.

Dear Ms. Guilaran:

CropLife America (CLA) appreciates the opportunity to submit these comments, along with the attached materials, in response to the March 23, 2018 request for comments issued by the U.S. Environmental Protection Agency (EPA or the Agency), regarding "Chlorpyrifos, Diazinon, and Malathion; National Marine Fisheries Service Biological Opinion Issued Under the Endangered Species Act," EPA-HQ-OPP-2018-0141, 83 Fed. Reg. 12754 (March 23, 2018) (the BiOp or the NMFS BiOp).

CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners.

CLA and its members have long been actively engaged in improving the process for review under the Endangered Species Act (ESA) for pesticide products, which also are subject to extensive environmental review and registration by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as well as to state review and registration. Due to the complexities associated with both the science and the laws, the ESA review process has been, and continues to be, laborious, difficult and time-consuming. Improvement is needed.

CLA seeks to work with the government and other interested stakeholders, to find reasonable and feasible solution-based approaches that are efficient, continue to ensure safety and regulatory compliance of pesticide products, and improve conservation and potential recovery of endangered species and their habitats. An improved process is needed to make the best use of limited government resources, and to increase transparency and public trust in the risk assessment processes. Creative thinking and new approaches are needed to allow growers and other pesticide users to continue to have access to the tools they need to protect their families, crops, homes and wildlife from pests and diseases.

Background. The NMFS BiOp replaced and expanded upon a 2008 version of a similar document that limited its evaluation of these same three pesticides on salmonids (the 2008 BiOp), on which CLA submitted comments. In 2013, the Court of Appeals for the Fourth Circuit vacated the 2008 BiOp, finding that it "was not the product of reasoned decision-making," but rather "relied on a selection of data, tests, and standards that did not always appear to be logical, obvious, or even rational."[1] Accordingly, the court remanded the 2008 BiOp to NMFS for a "renewed agency process."[2]

Recognizing other flaws in the ESA review process for pesticides, in 2013, EPA adopted a public stakeholder process for ESA consultations—an open and transparent process supported by NMFS, the U.S. Fish and Wildlife Service (FWS or, collectively with NMFS, the Services), EPA, and the U.S. Department of Agriculture (USDA).[3] As explained in the Enhancing Stakeholder Input Report, stakeholder input is critical to the development and evaluation of any measures EPA may implement to address risks to listed species and designated critical habitat.

That same year, EPA, the Services and USDA also issued a white paper containing a summary of joint interim approaches for assessing risks to listed species from pesticides.[4] The NMFS BiOp was developed based on the Interim Approaches, and in its request for these comments, EPA notes: "The methods developed as part of the joint Interim Approaches will continue to be vetted before EPA utilizes these methods broadly to meet its ESA obligations."[5]

Congress repeatedly also has recognized, most recently in the 2014 Farm Bill, that the ESA review process for pesticides must be improved to increase efficiencies, decrease delays, and ensure that action taken in response to the review be feasible in the context of the need for pesticide use. Specifically, the Conference Report on section 10013 stated:

> It is the Managers [*sic*] intent through routine oversight to keep all involved government entities focused on promptly building the "Interim Plan" into a final set of processes and procedures that will maximize the efficient use of limited governmental resources, minimize delays in registrations [*sic*] actions under Section 3 and 33 of FIFRA, make it possible for EPA to comply with the FIFRA requirement that all registrations be reviewed every fifteen years, and ensure meaningful public participation. Additionally, the Managers through this provision reemphasize Congress's intention that all reasonable and prudent alternatives to address ESA concerns are economically and technologically feasible.[6]

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[1] *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.,* 707 F.3d 462, 464, 475 (4th Cir. 2013).
[2] *Id.* at 475.
[3] *See* EPA, Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives at 9 (Mar. 27, 2013) (Enhancing Stakeholder Input Report).
[4] EPA, Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report (Oct. 2015) (Interim Approaches), https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.
[5] 83 Fed. Reg. at 12755.
[6] H.R. Rep. 113-333, at 531 (2014); *see also id.* at 532–33.

Since that time, the work undertaken by EPA, USDA and the Services to develop and implement a more efficient, timely and protective program has not met the goals of Congress and other interested stakeholders. The BiOp was based on national-level endangered species Biological Evaluations (BEs) developed by EPA to assess risks to listed species from registered uses of chlorpyrifos, diazinon, and malathion and EPA released on January 18, 2017.[7] These BEs were completed in accordance with the Interim Approaches Report. CLA, its members and other stakeholders submitted comments critical of the scientific processes, methodologies and outcomes of the BEs, virtually none of which were adopted or considered in the BiOp.

The federal government has continued to recognize the need for improvement of this process ever since NMFS transmitted the BiOp to EPA on December 29, 2017. Only a month later, the EPA Administrator, along with the Secretaries of USDA, Commerce (representing NMFS) and Interior (representing FWS), signed a Memorandum of Agreement on Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review (MOA), charging the four agencies to work to "develop scientific and policy approaches that will increase the accuracy and timeliness of the pesticide consultation process."[8]

The NMFS BiOp. The NMFS BiOp is a prime example of why improvement is needed. In meeting its obligations under the ESA, NMFS must base its BiOp on the "best scientific and commercial data available."[9] As set forth in the attached comments, and in comments submitted by CLA's member companies, including the companies holding the EPA registrations for the BiOp's subject pesticides (the OP Registrants), NMFS has failed to meet its obligations in this regard.

The BiOp rests on multiple overly conservative assumptions layered together to drive its conclusions, relying on the BEs' incorrect exposure estimates and effects determinations. In some instances, it does so in direct violation of the instruction given by the Fourth Circuit in response to the 2008 BiOp.[10] It ignores actual use data and other relevant information, which, in addition to violating the ESA's requirement for the use of "best scientific and commercial data available," also ignores ESA regulations requiring that indirect effects, such as those posed by the use of an EPA-registered pesticide, be "reasonably certain to occur."[11]

These types of inadequacies could have been addressed through greater interaction with the OP Registrants, which should properly be recognized in the ESA review process as "applicants."[12] This lack of the opportunity for their input not only deprives the OP Registrants of important procedural rights, but also deprives the BiOp of the value of their substantive contributions and expert knowledge to help provide the best scientific and commercial data available.

[7] 81 Fed. Reg. 21341 (April 11, 2016) (EPA-HQ-OPP-2016-0167).
[8] https://www.epa.gov/sites/production/files/2018-02/documents/esa-fifra_moa_1.31.18.pdf. at p. 3.
[9] ESA § 7(a)(2), 16 U.S.C. § 1536(a)(2).
[10] *See* 707 F.3d at 470-475.
[11] 50 C.F.R. § 402.02.
[12] 16 U.S.C. § 1536(b); *see* 50 C.F.R. Part 402; Enhancing Stakeholder Input Report.

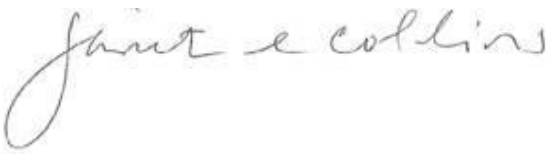
The result of this lack of input by the OP Registrants and other stakeholders is similarly revealed in the inadequacies of the BiOp's reasonable and prudent measures (RPMs) and reasonable and prudent alternatives (RPAs). RPAs must be technically and economically feasible.[13] This type of input could produce meaningful, technological and economically feasible approaches to species protection in agricultural and other settings in which pesticides are used. However, the BiOp did not incorporate that type of meaningful expertise.

The failures of the BiOp to meet the legal requirements laid out here and, in greater detail, by the OP registrants in their own comments, render it arbitrary and capricious under the Administrative Procedure Act. For these reasons, and for the reasons set forth in the attached comments, NMFS should withdraw the BiOp, and, if NMFS does not, EPA should set it aside as fatally flawed. EPA and NMFS should then work together, in coordination with FWS and USDA, as set forth in the MOA, to consider the comments received on the BiOp and its supporting BEs, to improve the processes under which the BEs and the BiOp were developed to reflect the best available science and to meet the requirements of both FIFRA and the ESA.

CLA and its member companies are committed to working with the government and all interested stakeholders in developing a process that specifically protects listed species and their habitat, while recognizing the important role that pesticides play in agriculture, and in the protection and enhancement of property, homes and human health. We would welcome the opportunity to engage on the ideas contained in this letter and participate in the appropriate fora to improve this process.

Should you have any questions or wish to discuss any of these issues further, please contact me directly at (202) 833-4474. Thank you for your consideration of these comments as well as those referenced from CLA member companies and RISE (Responsible Industry for a Sound Environment®).

Respectfully,



Janet E Collins, Ph.D., R.D., CFS
Executive Vice President, Science and Regulatory Affairs

Enclosing "Comments by CropLife America on NMFS Biological Opinions on Chlorpyrifos, Diazinon, and Malathion; Docket identification number EPA–HQ–OPP–2018–0141"

[13] 50 C.F.R. § 402.02.