



Ms. Tracy Perry
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001
via regulations.gov: EPA-HQ-OPP-2021-0150

Re: Comments on NMFS Draft Salmonid/Steelhead Biological Opinions for metolachlor, 1,3-D (Telone), bromoxynil, and prometryn, EPA-HQ-OPP-2021-0150, comment period ends April 20, 2021

Dear Ms. Perry:

Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CLA represents the interests of its registrant member companies by, among other things, monitoring legislation, federal agency regulations and actions, and litigation that impact the crop protection and pest control industries and participating in such actions when appropriate. CLA's member companies produce, sell, and distribute virtually all the pesticide and biotechnology products used by American farmers.

CLA's comments are presented as a cover letter with two Appendices A and B addressing separate comments to 1,3-D (Telone) and metolachlor (A); and bromoxynil and prometryn (B) for the EPA-HQ-OPP-2021-015 docket.

CLA appreciates the opportunity to comment on the two draft National Marine Fisheries Service's biological opinions on 1,3-D (Telone) and metolachlor, and bromoxynil and prometryn use in Washington, Oregon, Idaho, and California. Should you have any questions or comments, please feel free to contact me at mbasu@croplifeamerica.org or (202) 296-1585.

Sincerely,

A handwritten signature in black ink, appearing to read "Manojit Basu", with a horizontal line underneath.

Manojit Basu
Managing Director, Science Policy
CropLife America

Representing the Crop Protection Industry

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APPENDIX A

CropLife America (CLA) Comments on the Draft Biological Opinion for 1,3-D (also referred to as Telone) and metolachlor

The National Marine Fisheries Service's (NMFS) draft Biological Opinion (BiOp)¹ evaluated the effects of the Environmental Protection Agency's (EPA) registration of the pesticides 1,3-D (Telone)² and metolachlor on 28 Pacific salmonids listed as threatened or endangered under the Endangered Species Act (ESA), along with the designated critical habitats of such salmonids. The draft BiOps find that EPA registered uses of 1,3-D and metolachlor pesticides do not jeopardize the 28 listed salmon and steelhead populations or adversely modify the designated critical habitats of these protected species. In addition to the "no jeopardy" and "no adverse modification" findings, the draft biological opinions also describe reasonable and prudent measures (RPMs) to protect the listed species of salmon and steelhead and their critical habitats.

CLA concurs with the NMFS's conclusions that registered uses of 1,3-D and metolachlor pesticides will not jeopardize 28 listed salmon and steelhead populations or adversely modify the designated critical habitats of these protected species are reasonable and supported by NMFS's analyses and methods used to describe and support its conclusions. Therefore, CLA supports NMFS's conclusion that when implemented the BiOp and associated RPMs will ensure that the proposed uses of bromoxynil and prometryn meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard that registration of 1,3-D and metolachlor pesticides will not cause any unreasonable adverse effects on listed species and their designated critical habitat.³

The NMFS draft 1,3-D and metolachlor BiOp was completed as a final part of a court settlement with the plaintiff Northwest Coalition for Alternatives to Pesticides.⁴ In that settlement, NMFS agreed to complete biological opinions for the 37 active ingredients, with final deadlines specified for the different batches of pesticides. The current BiOPs offered for public review under EPA docket EPA-HQ-OPP-2021-0150 are NMFS's final words on its ESA consultation with EPA consistent with the terms of this settlement.

¹ The Endangered Species Act (ESA) protects species that are at risk of extinction, and also provides for the conservation of the ecosystems on which they depend. The U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Services (NMFS) share responsibility for implementing the ESA.

² Hereafter referred to as 1,3-D.

³ FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

⁴ *See*: Stipulated Settlement, Northwest Coalition for Alternatives to Pesticides v. NMFS, Case 2:07-CV-0179-RSL, August 1, 2008, Western District of Washington, p. 3.



EPA and NMFS have developed their own approaches to evaluating environmental risk, and their approaches differ significantly. According to NMFS⁵, these differences have occurred because of the agencies' different legal mandates, responsibilities, institutional cultures, and expertise. In fact, the current BiOps illustrate and underscore many such differences. The BiOps also underline the importance of the agencies reaching a resolution and consensus regarding their assessment approaches to sustain the FIFRA registration process and more closely match the level of effort with the limited resources available to NMFS and the U.S. Fish and Wildlife Service (FWS).

The current draft BiOp demonstrates that defensible BiOps by NMFS focusing on the ESA-mandated jeopardy and habitat question using the best available scientific and commercial information can be completed successfully with the participation of the registrant and without EPA's overly conservative models⁶ and tools.⁷ This result contrasts sharply with EPA's continuing efforts to develop Biological Evaluations (BEs) using its Revised Method to determine through models and tools whether a registered active ingredient in a pesticide may affect a single individual or habitat without reliable usage information or the participation of the registrant.

In the draft 1,3-D and metolachlor BiOp, NMFS has avoided many of the compounding conservatism problems posed by EPA's recent BEs. For example, NMFS has directly applied the Reasonably Likely to Occur Standard⁸ established by NMFS and FWS (the Services collectively), which EPA should have done in recent BEs.⁹ This difference is important as NMFS has not equated exposure with effect¹⁰ (as the EPA Revised Method does) but provided more reasonable, likely and measurable results concerning endangered salmonid species and designated critical habitat. As described more fully in recent CLA comments, EPA BEs equated exposure with effect (BEs of glyphosate¹¹ and triazine¹²) and failed to clearly apply the NMFS and FWS's Reasonably Likely to Occur Standard in these recent BEs.

NMFS's draft 1,3-D and metolachlor BiOp relied upon a robust Weight of Evidence analysis. CLA maintains that this is critical to Steps 1 and 2 of EPA's work and should be included in its methods and analyses. By not doing so in its BEs, EPA shifted an important risk assessment step to the Services, which has scarce resources. Similarly, NMFS used a broader set of usage

⁵ See: Pesticide Consultations with US Environmental Protection Agency, fisheries.noaa.gov.

⁶ See: Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides, March 12, 2020.

⁷ MAG Tools and other modeling devices in Revised Method...add cite.

⁸ See: 50 C.F.R. § 402.02, Services' Consultation Procedures adopted in 2019.

⁹ See: CLA comments on glyphosate, March 12, 201, EPA-HQ-OPP-2020-0585.

¹⁰ In 2020, the Ninth Circuit Court of Appeals recognized and subsequently affirmed that "exposure is not the same thing as effect" in an adequate ESA analysis of a proposed FIFRA registration of a pesticide upholding the registration of *Enlist Duo*, See: *National Family Farm Coalition et al. v. USEPA*, No. 17-70810 (9th Cir. 2020) at 58.

¹¹ EPA-HQ-OPP-2020-0585, November 20, 2020.

¹² EPA-HQ-OPP-2020-0514, November 20, 2020.



data to prepare the current BiOps than EPA has done recently. NMFS correctly determined that such usage information is adequate and available to support its ecological risk assessment of 28 populations of listed and endangered species and their designated critical habitat. CLA's past comments¹³ on the availability and methods of usage data should be implemented and EPA should reconsider its refusal to use the US Department of Agriculture (USDA) and state data in Steps 1 and 2 of EPA's Revised Method. EPA should utilize broader sets of existing usage data sources available to it and adopt a methodology for acquiring and verifying this data to a subcounty level.¹⁴ By refraining to adopt changes to its Revised Method, EPA shifts part of its risk assessment role to NMFS and FWS.

Finally, there are several lessons to be learnt from the draft 1,3-D and metolachlor BiOp: EPA should make reasonable revisions to EPA's Step 1 and 2 analysis as suggested above along with the adoption of a new Step Zero¹⁵ and place greater emphasis on endangered species conservation and recovery as an integral part of EPA's decision system by linking ecological risk assessments with ESA conservation goals for species and habitat. Past EPA risk assessments have not been designed with conservation or recovery of listed species and restoration of critical habitat as a goal, this should be corrected. Making the changes outlined above will deliver a more workable, legally defensible, and sustainable integration of the requirements FIFRA¹⁶ and with the requirements of the ESA.¹⁷

¹³ *Comments on the Draft Biological Evaluations for Carbaryl and Methomyl EPA-HQ-OPP-2020-0090-0001*; 85 *Fed. Reg.* 15168.

¹⁴ *Comments on the Draft Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides*, August 2019.

¹⁵ *A CropLife America White Paper Report: Thinking about Step Zero*. Step Zero White Paper, 2021.

¹⁶ 7 U.S.C. § 136 *et seq.*

¹⁷ 16 U.S.C. § 1531 *et seq.*



APPENDIX B

CropLife America (CLA) Comments on the Draft Biological Opinion for bromoxynil and prometryn

The National Marine Fisheries Service's (NMFS) draft Biological Opinion (BiOp)¹⁸ evaluated the effects of the Environmental Protection Agency's (EPA) registration of the pesticides bromoxynil and prometryn on 28 Pacific salmonids listed as threatened or endangered under the Endangered Species Act (ESA), along with the designated critical habitats of such salmonids. The BiOps find that EPA registered uses of bromoxynil and prometryn pesticides do not jeopardize the 28 listed salmon and steelhead populations or adversely modify the designated critical habitats of these protected species. In addition to the "no jeopardy" and "no adverse modification" findings, the draft biological opinions also describe reasonable and prudent measures (RPMs) to protect the listed species of salmon and steelhead and their critical habitats.

CLA concurs with the NMFS's conclusions that registered uses of bromoxynil and prometryn pesticides will not jeopardize 28 listed salmon and steelhead populations or adversely modify the designated critical habitats of these protected species are reasonable and supported by NMFS's analyses and methods used to describe and support its conclusions. Therefore, CLA supports NMFS's conclusion that when implemented the bromoxynil and prometryn BiOp and associated RPMs will ensure that the proposed uses of bromoxynil and prometryn meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard that registration of bromoxynil and prometryn pesticides will not cause any unreasonable adverse effects on listed species and their designated critical habitat.¹⁹

The NMFS draft bromoxynil and prometryn BiOp was completed as a final part of a court settlement with plaintiff Northwest Coalition for Alternatives to Pesticides.²⁰ In that settlement, NMFS agreed to complete biological opinions for the 37 active ingredients, with final deadlines specified for the different batches of pesticides. The current BiOPs offered for public review under EPA docket EPA-HQ-OPP-2021-0150 are NMFS's final words on its ESA consultation with EPA consistent with the terms of this settlement.

¹⁸ The Endangered Species Act (ESA) protects species that are at risk of extinction, and also provides for the conservation of the ecosystems on which they depend. The U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Services (NMFS) share responsibility for implementing the ESA.

¹⁹ FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

²⁰ See: Stipulated Settlement, Northwest Coalition for Alternatives to Pesticides v. NMFS, Case 2:07-CV-0179-RSL, August 1, 2008, Western District of Washington, p. 3.



EPA and NMFS have developed their own approaches to evaluating environmental risk, and their approaches differ significantly. According to NMFS²¹, these differences have occurred because of the agencies' different legal mandates, responsibilities, institutional cultures, and expertise. In fact, the draft bromoxynil and prometryn BiOp illustrates and underscores many such differences. The draft bromoxynil and prometryn BiOp also underlines the importance of the agencies reaching a resolution and consensus regarding their assessment approaches to sustain the FIFRA registration process and more closely match the level of effort with the limited resources available to NMFS and the U.S. Fish and Wildlife Service (FWS).

The draft bromoxynil and prometryn BiOp demonstrates that defensible BiOps by NMFS focusing on the ESA-mandated jeopardy and habitat question using the best available scientific and commercial information can be completed successfully with the participation of the registrant and without EPA's overly conservative models²² and tools.²³ This result contrasts sharply with EPA's continuing efforts to develop Biological Evaluations (BEs) using its Revised Method to determine through models and tools whether a registered active ingredient in a pesticide may affect a single individual or habitat without reliable usage information or the participation of the registrant.

In the draft bromoxynil and prometryn BiOp, NMFS has successfully avoided many of the compounding conservatism problems posed by EPA's recent BEs. For example, NMFS has directly applied the Reasonably Likely to Occur Standard²⁴ established by the Services, which EPA should have done in recent BEs.²⁵ This difference is important as NMFS has not equated exposure with effect²⁶ (as the EPA Revised Method often does) but provided more reasonable, likely, and measurable results concerning endangered salmonid species and designated critical habitat. As described more fully in recent CLA comments, EPA BEs equated exposure with effect rather screening registrations of glyphosate²⁷ and triazine²⁸ and failing to clearly apply the NMFS and FWS's Reasonably Likely to Occur Standard.

NMFS's draft bromoxynil and prometryn BiOp relied upon a robust Weight of Evidence analysis. CLA maintains that this is critical to Steps 1 and 2 of EPA's work and should be included in its methods and analyses. By not doing so in its recent BEs, EPA has shifted an important risk assessment step to the Services, which has scarce resources. Similarly, NMFS used a broader

²¹ See: Pesticide Consultations with US Environmental Protection Agency, [fisheries.noaa.gov](https://www.fisheries.noaa.gov).

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²⁷ EPA-HQ-OPP-2020-0585, November 20, 2020.

²⁸ EPA-HQ-OPP-2020-0514, November 20, 2020.



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Finally, there are several lessons from the bromoxynil and prometryn BiOp: EPA should make reasonable revisions to EPA's Step 1 and 2 analysis as suggested above along with the adoption of a new Step Zero³¹ and place greater emphasis on endangered species conservation and recovery as an integral part of EPA's decision system by linking ecological risk assessments with ESA conservation goals for species and habitat. Past EPA risk assessments have not been designed with conservation or recovery of listed species and restoration of critical habitat as a goal, this should be corrected. Making the changes outlined above will deliver a more workable, legally defensible, and sustainable integration of the requirements FIFRA³² and with the requirements of the ESA.³³

²⁹ *Comments on the Draft Biological Evaluations for Carbaryl and Methomyl EPA-HQ-OPP-2020-0090-0001*; 85 *Fed. Reg.* 15168.

³⁰ *Comments on the Draft Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides*, August 2019.

³¹ *A CropLife America White Paper Report: Thinking about Step Zero*. Step Zero White Paper, 2021.

³² 7 U.S.C. § 136 *et seq.*

³³ 16 U.S.C. § 1531 *et seq.*