CHAPTER 1, 2, 3

INTRODUCTION, BACKGROUND AND CONSULTATION HISTORY

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1 INTRODUCTION

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.) establishes a national program for conserving threatened and endangered species of fish, wildlife, plants, and the habitat they depend on. Section 7(a)(2) of the ESA requires Federal agencies to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or adversely modify or destroy their designated critical habitat. Federal agencies must do so in consultation with National Marine Fisheries Service (NMFS) for threatened or endangered species (ESA-listed), or designated critical habitat that may be affected by the action that are under NMFS jurisdiction (50 C.F.R. §402.14(a)). If a Federal action agency determines that an action "may affect, but is not likely to adversely affect" endangered species, threatened species, or designated critical habitat and NMFS concur with that determination for species under NMFS jurisdiction, consultation concludes informally (50 C.F.R. §402.14(b)).

Section 7(b)(3) of the ESA requires that at the conclusion of consultation, NMFS provides an Biological Opinion stating whether the Federal agency's action is likely to jeopardize ESA-listed species or destroy or adversely modify designated critical habitat. If NMFS determines that the action is likely to jeopardize listed species or destroy or adversely modify critical habitat, NMFS provides a reasonable and prudent alternative that allows the action to proceed in compliance with section 7(a)(2) of the ESA. If an incidental take is expected, section 7(b)(4) requires NMFS to provide an incidental take statement that specifies the impact of any incidental taking and includes reasonable and prudent measures to minimize such impacts and terms and conditions to implement the reasonable and prudent measures.

The action agency for this consultation is the Environmental Protection Agency (EPA). The Environmental Protection Agency has requested ESA Section 7(a)(2) consultation from the National Marine Fisheries Service on its registration of the approved uses of pesticide products containing two active ingredients pursuant to the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). The two active ingredients being reviewed are: bromoxynil and prometryn. Both are herbicides used for weed control. This is the ninth biological opinion issued in a series prompted by Settlement Agreements stemming from a 2001 lawsuit (discussed below).

This consultation, biological opinion, and incidental take statement, were completed in accordance with section 7(a)(2) of the statute (16 U.S.C. 1536 (a)(2)), associated implementing regulations (50 C.F.R. §§401-16), and agency policy and guidance was conducted by NMFS Office of Protected Resources Endangered Species Act Interagency Cooperation Division (hereafter referred to as "we"). This biological opinion (Opinion) and incidental take statement were prepared by NMFS Office of Protected Resources Endangered Species Act Interagency Cooperation Division in accordance with section 7(b) of the ESA and implementing regulations at 50 C.F.R. §402.

A complete ESA consultation on EPA's registration of bromoxynil and prometryn would encompass all ESA-listed species and designated critical habitat under NMFS jurisdiction. However, in this instance, as a result of the 2002 order in Washington Toxics Coalition v. EPA on EPA's registration of 37 pesticides, EPA initiated consultation specifically on listed Pacific salmonids under NMFS' jurisdiction and associated designated critical habitat in the states of California, Idaho, Oregon, and Washington. Bromoxynil and prometryn are the penultimate set of pesticides identified in the consultation schedule established in the settlement agreement. This document therefore represents the NMFS Opinion only on the effects of these actions on listed Pacific salmonids under NMFS' jurisdiction in the above-mentioned states, and the Incidental Take Statement only addresses take of those species. A complete record of this consultation is on file at the NMFS Office of Protected Resources in Silver Spring, Maryland.

Updates to the regulations governing interagency consultation (50 CFR part 402) were effective on October 28, 2019 [84 FR 44976]. This consultation was pending at that time, and we are applying the updated regulations to the consultation. As the preamble to the final rule adopting the regulations noted, "[t]his final rule does not lower or raise the bar on section 7 consultations, and it does not alter what is required or analyzed during a consultation. Instead, it improves clarity and consistency, streamlines consultations, and codifies existing practice." We have reviewed the information and analyses relied upon to complete this biological opinion in light of the updated regulations and conclude the Opinion is fully consistent with the updated regulations.

2 BACKGROUND

Pursuant to FIFRA, before a pesticide product may be sold or distributed in the U.S., it must be exempted or registered with a label identifying approved uses by EPA's Office of Pesticide Programs (OPP). Pesticide registration is the process through which EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. Pesticide products (also referred to as "formulated products") may include active ingredients (a.i.s) and other ingredients, such as adjuvants and surfactants. EPA authorization of pesticide uses are categorized as FIFRA Sections 3 (new product registrations), 4 (re-registrations and special review), 18 (emergency use), or 24(c) Special Local Needs (SLN).

Prometryn was first registered in the United States in 1964 as an herbicide for the control of weeds in cotton, celery, pigeon peas, and dill. Bromoxynil was initially registered in 1965 for use as an herbicide in wheat and barley.

In February, 1996 EPA issued a Registration Eligibility Decision (RED) for prometryn in which EPA concluded: "The Agency has determined that all uses of prometryn as currently registered will not cause unreasonable risk to humans or the environment and all uses are eligible for reregistration."

In September, 1998 EPA issued a Registration Eligibility Decision (RED) for bromoxynil in which EPA determined: "The Agency has concluded that no uses, as prescribed in this document, will cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration."

On January 30, 2001, the Washington Toxics Coalition, Northwest Coalition for Alternatives to Pesticides, Pacific Coast Federation of Fishermen's Associations, and Institute for Fisheries Resources filed a lawsuit against EPA in the U.S. District Court for the Western District of Washington (*Wash. Toxics Coalition v. EPA,* Civ. No. C01–132C, 2002 WL 34213031 (W.D.Wash. July 2, 2002), *aff'd*, 413 F.3d 1024 (9th Cir.2005)). This lawsuit alleged that EPA violated section 7(a)(2) of the ESA by failing to consult on the effects to 26 Evolutionarily Significant Units (ESUs) of listed Pacific salmonids of its continuing approval of 54 pesticide active ingredients. On July 2, 2002, the court ruled that EPA had violated ESA section 7(a)(2) and ordered EPA to initiate interagency consultation and make determinations about effects to the salmonids on all 54 active ingredients by December 2004. Pursuant to this Court's order, between August 2002 and December 2004, EPA initiated consultations with NMFS on 37 of those pesticides EPA determined "may affect" listed salmonids; the remaining 17 active ingredients were determined to have "no effect" on listed species or their designated critical habitats.

In December 2002, EPA and the U.S. Fish and Wildlife Service and NMFS began interagency discussions for streamlining EPA's court ordered consultations.

On January 24, 2003, EPA and the Services published an Advance Notice of Proposed Rulemaking seeking public comment on improving the process by which EPA and the Services work together to protect listed species and critical habitat (68 FR 3785).

Between May and December 2003, EPA and the Services reviewed EPA's ecological risk assessment methodology and earlier drafts of EPA's "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency (Overview Document)". EPA and the Services also developed counterpart regulations to streamline the consultation process.

On January 22, 2004, the court in Wash. Toxics Coalition v. EPA, Civ. No. C01–132C entered an injunction vacating EPA's authorization of certain uses of 54 pesticide active ingredients in certain areas and imposing certain other requirements ("Interim Measures"), until issuance by NMFS of a biological opinion or other described termination event. The no-spray buffers in the proposed stipulated injunction extend 300 feet from salmon supporting waters for aerial applications and 60 feet for ground applications for these active ingredients, which include bromoxynil and prometryn.

On January 23, 2004, EPA finalized its Overview Document which specified how EPA would conduct ecological risk assessment on pesticide registrations.

On January 26, 2004, the Services approved EPA's procedures and methods for conducting ecological risk assessments and approved interagency counterpart regulations for EPA's pesticide registration program.

On January 30, 2004, the Services published in the Federal Register (69 FR 4465) proposed joint counterpart regulations for consultation under the ESA for regulatory actions under the Federal Insecticide, Fungicide, and Rodenticide Act.

On August 5, 2004, the Services promulgated final joint counterpart regulations for EPA's ESA-related actions taken pursuant to FIFRA. These regulations and the Alternative Consultation Agreement (ACA) under the regulations allowed EPA to conduct independent analyses of potential impacts of pesticide registration on listed species and their designated critical habitats. The ACA outlined procedures to ensure EPA's risk assessment approach will produce effect determinations that reliably assess the effects of pesticides on listed species and designated critical habitat. Additionally, EPA and the Services agreed to meet annually, or more frequently as may be deemed appropriate. The intention of these meetings was to identify new research and other activities that may improve EPA's current approach for assessing the potential ecological risks posed by use of a pesticide to listed species or designated critical habitat.

On September 23, 2004, the Washington Toxics Coalition and others challenged the counterpart regulations in the U.S. District Court for the Western District of Washington, Civ. No. 04-1998, alleging that the regulations were not authorized by the ESA and that the Services had not complied with the Administrative Procedure Act and the National Environmental Policy Act (NEPA) in promulgating these counterpart regulations.

On August 24, 2006, the court determined the Services did not implement NEPA procedures properly during their promulgation of the joint counterpart regulations for EPA actions under FIFRA. Additionally, the court determined that the "not likely to adversely affect" and emergency consultation provisions of the counterpart regulations waiving Services' review were arbitrary and capricious and contrary to the substantive requirements of ESA section 7(a)(2). The court determined that EPA may write its own biological opinions under the alternative formal consultation procedures, as they required the Services' concurrence with EPA's conclusions. Washington Toxics Coalition, 457 F.Supp. 2d 1158 (W.D.Wash. 2006).

On November 5, 2007, the Northwest Coalition for Alternatives to Pesticides (NCAP) and others filed a legal complaint in the U.S. District Court for the Western District of Washington, Civ. No. 07 1791, against NMFS for its unreasonable delay in completing the section 7 consultations for EPA's registration of the remaining 37 (of the original 54) pesticide active ingredients.

On July 30, 2008, NMFS entered a settlement agreement with NCAP. NCAP had sued NMFS for failing to complete consultation on 37 pesticide active ingredients (17 of the original 54 active ingredients received "no effect" determinations and thus did not require formal consultation) for impacts to listed salmon ESUs. In the settlement agreement NMFS agreed on a schedule for completion of consultation on each active ingredient, with the final consultation due in early 2013. Subsequent settlement agreements (described below) have revised this schedule, with the consultation on the final active ingredient of the 37 now due by December 31, 2020.

On November 18, 2008, NMFS issued the first biological opinion under this schedule for three organophosphates: chlorpyrifos, diazinon, and malathion. This Opinion concluded that EPA's action was likely to jeopardize all but one of the listed salmon ESUs, and likely to adversely modify their designated critical habitat. NMFS included a reasonable and prudent alternative (RPA) that would allow the action to proceed without likely jeopardy and likely adverse modification. The RPA included no-application buffers, as well as other measures.

On April 1, 2009, Dow AgroSciences, LLC, Makhteshim Agan of North America, Inc. and Cheminova Inc., USA, challenged the validity of the OP BiOp under the ESA and the Administrative Procedure Act ("APA"), Dow AgroSciences, LLC v. NMFS, No. 09-cv00824 (D. Md.) ("Dow") (Dkt. No. 1)

On April 20, 2009, NMFS issued the second biological opinion ("Carbamate BiOp") under the NCAP schedule concerning the effects on listed salmonids and their critical habitat of three of the 37 pesticides at issue in Washington Toxics: carbaryl, carbofuran, and methomyl.

On August 31, 2010, NMFS issued its third biological opinion under the NCAP schedule. This third consultation evaluated 12 organophosphate insecticides: azinphos methyl, bensulide, dimethoate, disulfoton, ethoprop, fenamiphos, methamidophos, methidathion, methyl parathion, naled, phorate, and phosmet.

On March 10, 2011, EPA, on behalf of itself and the Departments of the Interior, Commerce and Agriculture, asked the National Academy of Sciences ("NAS") to evaluate the differing risk assessment approaches used by these agencies with regard to pesticides and endangered species. Specifically, the committee was asked to evaluate EPA's and the Services' methods for determining risks to listed species posed by pesticides and to answer questions concerning the identification of the best scientific data, the toxicological effects of pesticides and chemical mixtures, the approaches and assumptions used in various models, the analysis of uncertainty, and the use of geospatial data.

On June 30, 2011, NMFS issued its fourth biological opinion under the NCAP schedule. This fourth consultation evaluated four herbicides: 2,4-D, triclopyr BEE, diuron and linuron; and 2 fungicides: captan and chlorothalonil.

In October 2011, the U.S. District Court for the District of Maryland granted NMFS' cross-motion for summary judgment and denied plaintiff's motion for summary judgment, Dow AgroSciences, LLC v. NMFS, 821 F. Supp. 2d 792 (D. Md. 2011) in regards to DoW AgroSciences' challenge of the 2008 biological opinion for chlorpyrifos, malathion, and diazinon. The dismissed case was subsequently appealed by plaintiffs to the Fourth Circuit (Dow AgroSciences, LLC v. NMFS, 707 F.3d 462 (4th Cir. 2013)).

On May 31, 2012, NMFS issued its fifth biological opinion under the NCAP schedule. This fifth consultation evaluated herbicides: oryzalin, trifluralin, and pendimethalin.

On July 2, 2012, NMFS issued its sixth biological opinion under the NCAP schedule. This sixth consultation evaluated the herbicide thiobencarb.

On February 21, 2013, the U.S. Circuit Court for the Fourth Circuit issued an Opinion which reversed the judgement of the district court (October 2011) and remanded the 2008 OP BiOp (chlorpyrifos, malathion, and diazinon) to NMFS for further explanation on exposure assumptions, reliance on water quality monitoring data, and the technologic and economic feasibility of RPAs.

On April 30, 2013, the NAS issued a report entitled "Assessing Risks to Endangered and Threatened Species from Pesticides". In light of the recommendations in the NAS Report, NMFS, FWS, EPA, and the U.S. Department of Agriculture (USDA) developed a common approach to risk assessment for pesticides. The NAS report contained recommendations on scientific and technical issues related to pesticide consultations under the ESA and FIFRA. Since then, the Agencies have worked to implement the recommendations. Joint efforts to date include: collaborative relationship building between EPA, NMFS, FWS and USDA; clarified roles and responsibilities for the EPA, FWS, NMFS and USDA; agency processes designed to improve stakeholder engagement and transparency during review and consultation processes; multiple joint agency workshops resulting in interim approaches to assessing risks to threatened and endangered species from pesticides; a plan and schedule for applying the interim approaches to a set of pesticide compounds; and multiple workshops and meetings with stakeholders to improve transparency as the pesticide consultation process evolves.

On May 21, 2014, NMFS and NCAP revised the settlement agreement with NMFS to issue a new biological opinion on the organophosphates chlorpyrifos, malathion, and diazinon by December 31, 2017. The agreement noted that NMFS, FWS, and EPA were working to develop a common approach to risk assessment in pesticides consultations that would implement the recommendations of the 2013 National Academies of Sciences report. As part of the settlement NMFS agreed to a December 31, 2019 deadline for the completion of this biological opinion on bromoxynil and prometryn covering the 28 Pacific Salmon (Northwest Coalition for Alternatives to Pesticide (NCAP) v. NMFS, No. 2:07-cv-01791 (W.D. Wash.), Doc. 50, May 21, 2014). On July 26, 2019 the U.S. District Court for the Western District of Washington issued a decision to

amend the 2008 Stipulated Settlement Agreement to read "NMFS shall finalize and publicize a biological opinion concerning the effects of Bromoxynil and Prometryn by October 31, 2021."

On January 7, 2015 NMFS issued its seventh biological opinion under the NCAP schedule. This seventh consultation evaluated the pesticides diflubenzuron, fenbutatin oxide, and propargite.

On December 29, 2017 NMFS, pursuant to the stipulation filed in NCAP v. NMFS, cv-1791-RSL, completed a new nationwide biological opinion for chlorpyrifos, malathion and diazinon.

3 CONSULTATION HISTORY

3.1 Bromoxynil

On November 26, 2004 EPA finalized the biological evaluation for bromoxynil covering 28 listed salmonid species per Washington Toxics Coalition v. EPA, No. C-01-132 (W.D. Wash. July 2, 2002) Court Order. EPA submitted to NMFS a request for initiation on December 1, 2004. The 2004 biological evaluation concluded that bromoxynil will have no effect on four salmonid ESUs/DPSs but may affect 22 ESUs/DPSs (see table 2 for a summary of species-specific conclusions).

Table 1. Summary of Findings for California and Pacific Northwest Salmon and Steelhead ESUs; adapted from EPA's biological evaluation of bromoxynil (Table 49). EPA did not make effect determinations to designated critical habitat.

Species	ESU	Species and Habitat Finding
Steelhead	Southern California	May Affect
Steelhead	South-Central California Coast	May Affect
Steelhead	Central California Coast	May Affect
Steelhead	Central Valley California	May Affect
Steelhead	Northern California	No Effect
Steelhead	Upper Columbia River	May Affect
Steelhead	Snake River Basin	May Affect
Steelhead	Upper Willamette River	May Affect
Steelhead	Lower Columbia River	May Affect
Steelhead	Middle Columbia River	May Affect
Chinook Salmon	Sacramento River winter run	May Affect
Chinook Salmon	Snake River fall run	May Affect

Chinook Salmon	Snake River spring/summer run	May Affect
Chinook Salmon	Central Valley spring run	May Affect
Chinook Salmon	California Coastal	No Effect
Chinook Salmon	Puget Sound	May Affect
Chinook Salmon	Lower Columbia	May Affect
Chinook Salmon	Upper Willamette	May Affect
Chinook Salmon	Upper Columbia	May Affect
Coho Salmon	Central California Coast	No Effect
Coho Salmon	Southern Oregon/Northern California	May Affect
Coho Salmon	Oregon Coast	May Affect
Chum Salmon	Hood Canal summer run	May Affect
Chum Salmon	Columbia River	May Affect
Sockeye Salmon	Ozette Lake	No Effect
Sockeye Salmon	Snake River	May Affect

On June 27, 2011, Bayer CropScience submitted a letter to NMFS which contained: 1) master labels for Bayer Crop Science bromoxynil products; 2) application parameters for each use of bromoxynil; 3) five ecological effects reports (Bruns, 2007; Dorgerloh, 2003; Odin-Feurtet, 1998; Hoberh, 1998; Thomson, 1981); and 4) a bromoxynil Pacific Northwest market profile (GFK-KINET Research).

On June 28, 2011, Albaugh, Inc. submitted a letter to EPA (NMFS cc'd) regarding: "Bromoxynil ESA Consultation with the National Marine Fisheries Service". The letter contained confirmation that Albaugh, Inc. is a technical registrant of bromoxynil and that Albaugh, Inc. wished to be considered as an applicant.

On June 30, 2011, Nufarm, Inc. and Nufarm Limited submitted a letter to EPA (NMFS cc'd) regarding: "Consultation with the National Marine Fisheries Service (NMFS) Regarding the Effects of the Pesticide Bromoxynil". The letter contained confirmation that Nufarm Inc. and Nufarm Limited are registrants of bromoxynil technical and/or formulated products and that both companies wished to be considered as applicants.

On July 15, 2011, Bayer CropScience submitted a letter to NMFS which contained: 1) bromoxynil studies (Bruns, 2007; Hoberg (a), 1998; Hobeg (b), 1998; Repetto, 2011); and 2) a literature search (performed by Exponent) of bromoxynil peer reviewed articles which includes an independent data quality evaluation.

On August 10, 2011, Bayer CropScience submitted a letter to NMFS which contained: 1) Aquatic Ecological Exposure Assessment for Bromoxynil Use in Designated Salmon habitat (Sabbagh, G; Desmarteau, D; 2011) Noted as CBI; and 2) Bromoxynil studies (Fliege, R., 2005; Eyrich, U. and Bogdoll, B., 2009; Prata, F., 2004; Prata, F., 2003; Mackie, J.A.,1999 ; Hatcher, G. and Oddy, A.M., 2000; Greenwood, J. and Lucock, A., 2002) noted as Confidential Business Information.

On September 29, 2011, NMFS hosted a meeting with bromoxynil applicants: Bayer CropScience and Nufarm. At this meeting NMFS provided an overview of the consultation process. The applicants provided a presentation on bromoxynil.

On November 2, 2011, EPA-BEAD finalized the document: "Bromoxynil and its esters (035301, 035302, 035303, 128920) Screening Level Usage Analysis (SLUA)". This information was useful for describing baseline conditions within species habitats.

On January 22, 2013, EPA-EFED finalized the document: "Problem Formulation for the Environment Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments in Support of the Registration Review of Bromoxynil and Bromoxynil Esters."

On April 5, 2018, NMFS requested that EPA update the Description of the Action section of the 2004 bromoxynil Biological Evaluation: "Bromoxynil Analysis of Risks to Endangered and Threatened Salmon and Steelhead; November 26, 2004".

June 28, 2018, EPA responded to NMFS April 5, 2018 request for updated Description of the Action and BE for bromoxynil during an interagency FIFRA/ESA managers meeting by indicating that they did not intend to update the bromoxynil BE. However, they did indicate that they would provide up-to-date labels.

On September 20, 2018, EPA-EFED finalized the document "Draft Ecological Risk Assessment for the Registration Review of Bromoxynil and Bromoxynil Esters".

On November 6, 2018, EPA-BEAD finalized and submitted to NMFS the memorandum: "Bromoxynil (035302 and 128920) National and State Use and Usage Summary."

On December 14, 2018 NMFS transmitted an email to EPA requesting that EPA identify, and provide contact information for all applicants EPA has identified for the prometryn consultation. On December 18, 2018 EPA responded to NMFS' request by providing document: "Bromoxynil.Prometryn.Technical Registrants.docx". In the transmittal email, EPA writes: "attached is the contact information for the applicants that we have identified for the prometryn and bromoxynil consultations".

On March 13, 2019 NMFS provided the draft Description of Action to EPA and designated Applicants (emails from Tony Hawkes to Tracy Perry of EPA, Negela Moaddeb of Bayer,

Nathan Ehresman of NuFarm, and Morris Gaskins of Albaugh). As background, EPA authorizes the use of pesticides through the approval of pesticide product labels which describe how the product can legally be used. EPA provided NMFS electronic copies of all pesticide products that are currently registered and that contain prometryn (email from Wynne Miller of EPA on July 26, 2018). NMFS reviewed each of these labels in detail noting the label requirements. The information obtained from the label review was incorporated into the 3-13-19 draft Description of Action. Reviews of the March 13, 2019 draft were received by NMFS on the following dates: March 21, 2019 – email from Tracy Perry of EPA; March 22, 2019 – email from Negela Moaddeb of Bayer relaying comments from Bayer, Nufarm and Albaugh.

Bayer indicated that a 24(C) registration for field grown roses was no longer registered in California (CA-050012). However, EPA indicated this was still an active registration that should be considered until the product is voluntarily cancelled by Bayer (Tracy Perry email, April 15, 2019). This was communicated to Bayer by NMFS during a phone call on April 18, 2019. Bayer indicated that they would pursue voluntary cancelation. NMFS emailed Bayer guidance on the 24(C) registrations that included instructions for voluntary cancelation (April 15, 2019). Bayer also suggested that there may be further changes to labeling during the registration review process. NMFS requested that EPA and Bayer alert NMFS to any changes in labeling that may occur (email to Tracy Perry April 18, 2019). Modifications were communicated to EPA and Applicants identifying changes to text and explaining rationale for how comments were addressed on the following dates: March 29, 2019 – email to Tracy Perry of EPA; April 2, 2019-email to Negela Moaddeb (Bayer), Nathan Ehresman (Nufarm), and Morris Gaskins (Albaugh).

On March 22, 2019 Bayer provided NMFS with a copy of Bayer's comments on EPA's Draft Ecological Risk Assessment for Registration Review.

On April 18, 2019 NMFS met with Bayer to discuss the bromoxynil ESA consultation. Topics of discussion included: aquatic pesticide exposure modeling, description of the action (i.e. bromoxynil labels), and the ESA Section 7 process in general.

On May 2, 2019 NMFS transmitted to EPA a revised draft Description of the Action dated 4-26-19. Within the transmittal email NMFS instructed: "If we don't receive additional recommendations for changes by the end of the month we will assume EPA agrees that the description of the action is accurate (attached)."

On May 9, 2019 Tracy Perry (EPA) provided to NMFS commitment letters from Nufarm and Albaugh regarding changes to bromoxynil labels. No additional correspondence was received from bromoxynil Applicants regarding the Description of the Action of prometryn. The Description of the Action, including the product labels to be assessed, was subsequently updated and then finalized on May 31, 2019.

On June 14 and June 17, 2019 Bayer sent emails containing 15 bromoxynil ecological toxicity studies per NMFS request. MRID #: 43059605; 43059604; 43059601; 43059602; 41606004; 41606001; 41928302; 40111003; 41928301; 49541402; 49541401; 48540503; 48540504; 2059085; and 0013087.

On June 18, 2019 NMFS met with Bayer to discuss modeling approaches and input parameters for pesticide concentrations in aquatic habitats. Bayer subsequently generated two documents on the topic: 1) a report titled: "Refined Modeling Approach and Water Monitoring Data Analysis for Exposure Assessment of Bromoxynil use in Salmonid Habitat, 25-June-2019"; and 2) a memo submitted to EPA titled: "Bayer's Request for Further Consideration of Adsorption/Desorption Studies with Bromoxynil Esters, June 25, 2019" (MRID: 50891301).

On June 25, 2019 NMFS placed a request with Bayer for an additional four bromoxynil ecological toxicity studies.

On July 30, 2019 Bayer submitted to NMFS a report titled "Summary of the Aquatic Ecotoxicology Database and Relevant Literature Data for Bromoxynil Esters and Phenol for use in an Endangered Species Hazard Characterization, 5-July-2019".

On July 31, 2019 EPA announced the availability of EPA's proposed interim registration review decision and opened a 60-day public comment period on the proposed interim decision for bromoxynil: "Bromoxynil and Bromoxynil Esters, Proposed Interim Registration Review Decision, Case Number 2070, June 2019".

On November 1, 2019 EPA provided NMFS with the "Bromoxynil (PC Codes: 035302 & 128920) National and State Use and Usage Summary" report.

On January 15, 2020 NMFS provided a preliminary draft of the Biological Opinion regarding EPA's registration of pesticides containing bromoxynil and prometryn to EPA and the applicants: Bayer, Syngenta, Albaugh LLC, and Nufarm (the preliminary draft was transmitted to Albaugh LLC and Nufarm on January 16). NMFS requested that EPA and the applicants review the preliminary draft and provide comments by February 14th, later extended (in response to a request by the applicants) to February 28th.

On February 27, 2020 Bayer responded to NMFS request by providing comments on NMFS' preliminary draft of the Biological Opinion regarding EPA's registration of pesticides containing bromoxynil and prometryn.

On November 18, 2020 NMFS sent an additional preliminary draft chapter to EPA and bromoxynil applicants for review. The draft chapter included: reasonable and prudent measures, incidental take statement, terms and conditions, conservation recommendations, and reinitiation notice.

On December 8, 2020 NMFS met with EPA and bromoxynil applicants to discuss the preliminary draft terms and conditions of the RPM. Following the meeting NMFS sent EPA and bromoxynil applicants an updated draft of the RPM chapter for review.

3.2 Prometryn

On November 29, 2002 EPA finalized the biological evaluation for prometryn. EPA submitted to NMFS a request for initiation on the same day, November 29, 2002. The 2002 biological evaluation concluded that prometryn will have "no effect on 17 ESUs but may affect nine ESUs. The may-affect determinations are based on the extent of crop acreage potentially treated in counties within an ESU and possible adverse effects of prometryn on aquatic-plant cover". See table 1 for a summary of species-specific conclusions.

Table 2. Summary conclusions on specific ESUs of listed Pacific salmon and steelhead for prometryn; adapted from EPA's biological evaluation of prometryn (Table 50). EPA did not make effects determinations to designated critical habitat.

Species	ESU	Finding
Steelhead	Southern California	May Affect
Steelhead	South-Central California Coast	May Affect
Steelhead	Central California Coast	No Effect
Steelhead	Central Valley, California	May Affect
Steelhead	Northern California	No Effect
Steelhead	Upper Columbia River	May Affect
Steelhead	Snake River Basin	May Affect
Steelhead	Upper Willamette River	No Effect
Steelhead	Lower Columbia River	No Effect
Steelhead	Middle Columbia River	May Affect
Chinook Salmon	Sacramento River winter-run	No Effect
Chinook Salmon	Snake River fall-run	May Affect
Chinook Salmon	Snake River spring/summer-run	May Affect
Chinook Salmon	Central Valley spring-run	No Effect
Chinook Salmon	California Coastal	No Effect
Chinook Salmon	Puget Sound	No Effect
Chinook Salmon	Lower Columbia	No Effect

Chinook Salmon	Upper Willamette	No Effect
Chinook Salmon	Upper Columbia	May Affect
Coho salmon	Central California	No Effect
Coho salmon	Southern Oregon/Northern California Coasts	No Effect
Coho salmon	Oregon Coast	No Effect
Chum salmon	Hood Canal summer-run	No Effect
Chum salmon	Columbia River	No Effect
Sockeye salmon	Ozette Lake	No Effect
Sockeye salmon	Snake River	No Effect

On February 28, 2011 EPA transmitted an email to NMFS with subject: Prometryn BiOp Labels. Attached in this email were 13 files containing prometryn labels.

On June 30, 2011 Syngenta transmitted two emails to NMFS with subjects: "1 of 2: Syngenta's comments for Prometryn" and "2 of 2: Syngenta's comments for Prometryn". Attached to these emails were two files: 1) Prometryn Salmon Assessment.pdf; and 2) Prometryn Use Restrictions.pdf.

On July 18, 2011 Syngenta submitted a letter to EPA (NMFS cc'd) Subject: Prometryn Information Pertaining to the Evaluation of its Potential Effects on Pacific Salmonids. In this letter Syngenta provided an 11-volume data submission to EPA and NMFS.

On September 28, 2011 NMFS hosted a meeting with EPA, USDA, and Syngenta: "Prometryn – Pre-Biological Opinion Discussion with National Marine Fisheries Service, Syngenta, and USDA". At this meeting NMFS provided an overview of the consultation process. Syngenta representatives gave a presentation that provided an overview of prometryn.

On September 28, 2011 Syngenta transmitted an email to NMFS with subject: "Information Update – Description has changed: Prometryn BiOp Meeting with NMFS and Syngenta". Attached in this email was file: "Syngenta 2_Prometryn Use Restrictions.pdf".

On December 19, 2011 Syngenta transmitted an email to NMFS with subject: "Prometryn – additional information". Attached to this email were two documents: 1) Amendment 1 – Prometryn – Review and Assessment on Pacific Salmonid Species.pdf; and 2) Prometryn – Technical Evaluation of EPA's California Red-Legged Frog Effects Determinations.pdf.

On March 12, 2012 NMFS acknowledged receipt of a CD sent by EPA containing a number of studies relevant to prometryn. NMFS had requested these studies from EPA in an earlier email sent February 17, 2012 with subject: Studies and DERs for prometryn.

On September 10, 2012 EPA-BEAD finalized the "Prometryn (080805) Screening Level Usage Analysis (SLUA) Date: September 10, 2012" document (regulations.gov ID: EPA-HQ-OPP-2013-0032-0004). This information was useful for describing baseline conditions within species habitats.

On December 13, 2012 EPA-BEAD finalized the "BEAD Chemical Profile for Registration Review: Prometryn (080805)" document (regulations.gov ID: EPA-HQ-OPP-2013-0032-0003). The purpose of this document was to convey usage information and a broad overview of the pest management roles to EPA staff for their evaluation of the registration status of prometryn.

On February 1, 2017 EPA-BEAD finalized the "Prometryn (080805) Screening Level Usage Analysis (SLUA)" memorandum (regulations.gov ID: EPA-HQ-OPP-2013-0032-0032). The memo provided an update of the SLUA that was done in 2016. This information was useful for describing baseline conditions within species habitats.

On September 13, 2017, EPA posted the "Preliminary Ecological Risk Assessment in Support of the Registration Review of Prometryn" onto the Prometryn Registration Review Docket (document dated June 9, 2017). (EPA-HQ-OPP-2013-0032).

On April 5, 2018 NMFS requested that EPA update the Description of the Action section of the 2002 prometryn Biological Evaluation: "Prometryn Analysis of Risks to Endangered and Threatened Salmon and Steelhead; November 29, 2002".

June 28, 2018, EPA responded to NMFS' April 5, 2018 request during an interagency FIFRA/ESA managers meeting by indicating that they did not intend to update the prometryn Biological Evaluation. However, they did indicate that they would provide up-to-date labels.

On June 14, 2018 EPA-BEAD finalized the "Prometryn (PC # 080805): Revised Usage and Benefits Information, and Response to Public Comments" document (regulations.gov ID: EPA-HQ-OPP-2013-0032-0055). Information discussed in this memo includes: an overview of the chemical, typical use sites, usage details (i.e. application rates, formulations, methods and handlers), and possible impact of the risk reduction measures that the EPA is considering.

On December 14, 2018 NMFS transmitted an email to EPA requesting that EPA identify, and provide contact information for all applicants EPA has identified for the prometryn consultation. On December 18, 2018 EPA responded to NMFS' request by providing document: "Bromoxynil.Prometryn.Technical Registrants.docx". In the transmittal email, EPA writes:

"attached is the contact information for the applicants that we have identified for the prometryn and bromoxynil consultations".

On January 31, 2019 EPA-BEAD finalized and submitted to NMFS memorandum: "Prometryn (080805) National and State Use and Usage Summary (January 31, 2019)".

On March 13, 2019 the draft Description of Action was provided to EPA and designated Applicants (emails from Tony Hawkes to Tracy Perry of EPA and Cherilyn Moore of Syngenta). As background, EPA authorizes the use of pesticides through the approval of pesticide product labels which describe how the product can legally be used. EPA provided NMFS electronic copies of all pesticide products that are currently registered and that contain prometryn (email from Wynne Miller of EPA on August 28, 2018). NMFS reviewed each of these labels in detail noting the label requirements. The information obtained from the label review was incorporated into the 3-13-19 draft Description of Action. Reviews of the March 13, 2019 draft were received by NMFS on the following dates: March 21, 2019 – email from Tracy Perry of EPA; March 22, 2019- email from Cherilyn Moore of Syngenta.

Syngenta indicated that a multi-active ingredient product (EPA Registration 100-1163) has an active registration but that they intend to phase it out. EPA indicated that this is an active registration and there is no documentation that this product will be phased out (Tracy Perry email March 29, 2019). EPA indicated that this product should still be evaluated despite the fact that it is currently not registered in the state since Syngenta could seek registration with the states at any time (Tracy Perry email April 15, 2017). NMFS conveyed to Syngenta that the product will be evaluated, but that NMFS will note that the product is not currently registered in the Northwest or California (Email to Cherilyn Moore of Syngenta on April 25, 2019). Modifications were communicated to EPA and Applicants identifying changes to text and explaining rationale for how comments were addressed on the following dates: March 29, 2019 – email to Tracy Perry of EPA; April 2, 2019- email to Cherilyn Moore of Syngenta

On May 2, 2019 NMFS transmitted to EPA a revised draft Description of the Action dated 4-26-19. Within the transmittal email NMFS instructed: "If we don't receive additional recommendations for changes by the end of the month we will assume EPA agrees that the description of the action is accurate (attached)." No additional correspondence was received from EPA or Syngenta regarding the Description of the Action of prometryn. The Description of the Action, including the product labels to be assessed, was subsequently finalized on May 31, 2019.

On May 30, 2019 Syngenta provided NMFS with a list of all prometryn studies which have been submitted to EPA since 2002: "Prometryn Studies Submitted 2002 to 2019".

On July 2, 2019 Syngenta sent NMFS copies of six prometryn ecological toxicology studies per NMFS' request: Union Carbide Environmental Services, 1965; Beliles et al., 1965; Humaker,

1985; Hughes and Alexander, 1992a; Hughes and Alexander, 1992b; and Graves et al., 1995). Syngenta flagged all six studies as trade secret, confidential commercial information.

On November 1, 2019 EPA provided NMFS with the "Prometryn (PC Code: 080805) National and State Use and Usage Summary" report.

On January 15, 2020 NMFS provided a preliminary draft of the Biological Opinion regarding EPA's registration of pesticides containing bromoxynil and prometryn to EPA and the applicants: Bayer, Syngenta, Albaugh LLC, and Nufarm (the preliminary draft was transmitted to Albaugh LLC and Nufarm on January 16). NMFS requested that EPA and the applicants review the preliminary draft and provide comments by February 14th, later extended (in response to a request by the applicants) to February 28th.

On February 12, 2020 NMFS held a meeting with Syngenta (at Syngenta's request) to discuss NMFS preliminary draft of the Biological Opinion.

On February 21, 2020 Syngenta provided comments on NMFS' preliminary draft of the Biological Opinion regarding EPA's registration of pesticides containing bromoxynil and prometryn.

On November 18, 2020 NMFS sent an additional preliminary draft chapter to EPA and prometryn applicants for review. The draft chapter included: reasonable and prudent measures, incidental take statement, terms and conditions, conservation recommendations, and reinitiation notice.

On December 9, 2020 NMFS met with EPA and prometryn applicants to discuss the preliminary draft terms and conditions of the RPM. Following the meeting NMFS sent EPA and prometryn applicants an updated draft of the RPM chapter for review.