IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
GREENBELT DIVISION

MAKHTESHIM AGAN OF NORTH AMERICA, INC.
3120 Highwoods Blvd.
Suite 100
Raleigh, NC 27604;

FMC CORPORATION
2929 Walnut Street
Philadelphia, PA 19104; and

DOW AGROSCIENCES LLC
9330 Zionsville Road
Indianapolis, IN 46268

Plaintiffs,

v.

NATIONAL MARINE FISHERIES SERVICE
1315 East-West Highway
Silver Spring, MD 20910
Montgomery County; and

DONNA S. WIETING, as Director of the Office of Protected Resources of the NATIONAL MARINE FISHERIES SERVICE,
1315 East-West Highway
Silver Spring, MD 20910
Montgomery County

Defendants.

Complaint for Declaratory and Other Relief Under the Administrative Procedure Act

Case No. 8:18-cv-961

INTRODUCTION

1. This is an action for declaratory relief and to vacate a biological opinion issued by the National Marine Fisheries Service ("NMFS") on December 29, 2017 (the "2017 Biological Opinion") after formal consultation with the U.S. Environmental Protection Agency ("EPA"). The 2017 Biological Opinion relates to EPA's registrations of pesticides containing the active ingredients chlorpyrifos, diazinon, and malathion ("EPA's Registration Decisions") under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq*.

2. Plaintiffs' claims arise under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-559, 701-706, in conjunction with Defendants' implementation of the Endangered Species Act ("ESA"), 16 U.S.C. §§ 1531-1544, and Defendants' obligations under an order issued by this Court in *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv*., Civ. No. 09-cv-00824 (D. Md. May 30, 2013), Dkt. No. 91 (the "2013 Order"). The 2013 Order vacated a biological opinion related to EPA's Registration Decisions on the same three pesticide ingredients that NMFS had issued on November 18, 2008 (the "2008 Biological Opinion"). That Order also obligated NMFS to develop any successor biological opinions, such as the 2017 Biological Opinion, in a manner consistent with the Fourth Circuit's opinion in *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462 (4th Cir. 2013) (the "2013 Fourth Circuit Opinion"). Plaintiffs seek an order declaring unlawful and setting aside the 2017 Biological Opinion because it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, and was not developed in compliance with the 2013 Order.

3. Defendants' 2017 Biological Opinion found that EPA's Registration Decisions are likely to jeopardize the continued existence of thirty-eight listed Evolutionarily Significant Units ("ESUs" or "species"). It also concluded that EPA's Registration Decisions would likely

result in the destruction or adverse modification of critical habitat for thirty-seven species. To avoid jeopardy, NMFS proposed Reasonable and Prudent Alternatives ("RPAs") and issued an Incidental Take Statement and Reasonable and Prudent Measures ("RPMs").

4. Defendants' procedure for completing the 2017 Biological Opinion did not comply with the ESA, applicable regulations, or the 2013 Order. The Defendants did not adhere to their own regulations for developing biological opinions, as set forth at 50 C.F.R. Part 402. The Defendants did not follow the procedure set forth in a document jointly issued by NMFS and the U.S. Fish and Wildlife Service ("FWS") (NMFS and FWS are jointly referred to below as "the Services"), the U.S. Department of Agriculture ("USDA"), and the EPA titled "Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives" (Docket No. EPA-HQ-OPP-2012-0442) (March 19, 2013) ("Enhancing Stakeholder Input document") or in the Services' published Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act, March 1998 ("Consultation Handbook"). The Defendants failed to comply with the 2013 Order's direction to provide for public involvement in making revisions to the 2008 Biological Opinion to correct the errors in that document.

5. The 2017 Biological Opinion is substantively unlawful. Some of its flaws are the same as those that resulted in the vacatur and remand of the 2008 Biological Opinion in the 2013 Order. The findings in the 2017 Biological Opinion and the RPAs and RPMs therein are contrary to the evidence in the record and legal requirements. The findings, RPAs, and RPMs are not supported by the evidence in several new respects. Among other things, NMFS failed to clearly define the action it was evaluating, improperly relied heavily on information concerning

abandoned or soon-to-be-abandoned historical uses, failed to use the best commercial and scientific information available, failed to provide lawful RPAs and RPMs or a lawful Incidental Take Statement, used newly developed and un-tested models without providing sufficient explanations or information regarding them, and failed to identify or explain the scientific analysis that supported its reasoning for many intermediate and final conclusions.

JURISDICTION AND VENUE

6. Plaintiffs challenge final agency actions as defined by the APA, 5 U.S.C. § 704. The APA requires this Court to hold unlawful and set aside agency action that is arbitrary and capricious or not otherwise in accordance with law. 5 U.S.C. § 706(2)(A). This Court thus has jurisdiction over this action pursuant to the APA, 5 U.S.C. § 706(2). Jurisdiction also exists under 28 U.S.C. § 1331 (federal question); 28 U.S.C. § 2201 (declaratory judgment); and this Court's inherent enforcement authority.

7. Venue is properly vested in this Court pursuant to 28 U.S.C. § 1391(e), because the agency and the federal official responsible for the challenged action reside in this District. In addition, a substantial part of the events giving rise to this claim occurred in this District.

PARTIES

8. Plaintiff Makhteshim Agan of North America, Inc. ("MANA") is a corporation organized under the laws of Delaware and headquartered in Raleigh, North Carolina. MANA supplies agricultural pesticide chemicals. MANA is the U.S. agent for its affiliate ADAMA Makhteshim, Ltd., which holds technical registrations for diazinon and chlorpyrifos and thus is licensed by EPA to sell and distribute pesticides containing diazinon and chlorpyrifos. MANA holds end-use registrations for products that contain diazinon and chlorpyrifos. MANA derives

significant revenue from the sale of those products. MANA's revenues will be adversely impacted by NMFS's jeopardy determinations, RPAs, RPMs, and Incidental Take Statement. MANA actively participated in the administrative proceedings that preceded the release of the 2008 Biological Opinion, including filing comments on a publicly-released draft, providing studies and related materials to NMFS, and participating in meetings with NMFS staff. In addition, although it was not given the opportunity by NMFS to participate in the administrative proceedings that preceded the release of the 2017 Biological Opinion, MANA provided significant comments to EPA on the draft Biological Evaluation for diazinon and chlorpyrifos that the EPA provided to NMFS prior to the preparation of the 2017 Biological Opinion, and to NMFS on the final EPA Biological Evaluation.

9. Plaintiff FMC Corporation ("FMC") is a corporation organized under the laws of Delaware and headquartered in Philadelphia, Pennsylvania. FMC is a supplier of technologies for crop protection, pest control, and vegetation management. In 2015, FMC acquired Cheminova A/S as a wholly-owned subsidiary. The 2015 acquisition included Cheminova A/S's subsidiary Cheminova, Inc. USA, which had been a party to litigation relating to the 2008 Biological Opinion. Cheminova, Inc. USA was dissolved following FMC's acquisition of Cheminova A/S, and all of its pesticide registrations were transferred to FMC. FMC now holds registrations for end-use products that contain malathion that were acquired through the acquisition described above and thus is licensed by EPA to sell and distribute pesticides containing malathion. Cheminova A/S continues to hold a registration for technical malathion that is used to manufacture end-use products containing malathion in the United States. FMC derives significant revenue from the sale of malathion products, which will be adversely impacted by NMFS's jeopardy determination, RPAs, RPMs, and Incidental Take Statement.

With respect to the 2008 Biological Opinioin, Cheminova, Inc. USA actively participated in the administrative proceedings that preceded its release, including providing studies and related materials to NMFS and participating in meetings with NMFS staff. With respect to the 2017 Biological Opinion, neither FMC nor any FMC subsidiaries were given the opportunity to participate in the administrative proceedings that preceded its release. FMC and its subsidiaries nevertheless provided significant comments to EPA on the draft Biological Evaluation for malathion that the EPA submitted to NMFS prior to the preparation of the 2017 Biological Opinion. FMC also provided significant comments to NMFS on the final EPA Biological Evaluation.

10. Plaintiff Dow AgroSciences LLC ("DAS") is a limited liability company organized under the laws of Delaware and headquartered in Indianapolis, Indiana. DAS is a supplier of technologies for crop protection, pest and vegetation management, seeds, traits, and agricultural biotechnology. DAS holds a technical registration for chlorpyrifos and end-use registrations for products that contain chlorpyrifos, and thus is licensed by EPA to sell and distribute pesticides containing chlorpyrifos. DAS derives significant revenue from the sale of chlorpyrifos products. DAS's revenues will be adversely impacted by NMFS's jeopardy determinations, RPAs, RPMs, and Incidental Take Statement. DAS actively participated in the administrative proceedings that preceded the release of the 2008 Biological Opinion, including filing comments on a publicly-released draft, providing studies and related materials to NMFS, and participating in meetings with NMFS staff. In addition, although it was not given the opportunity by NMFS to participate in the administrative proceedings that preceded the release of the 2017 Biological Opinion, DAS provided significant comments to EPA on the draft

Biological Evaluation for chlorpyrifos that the EPA provided to NMFS prior to the preparation of the 2017 Biological Opinion, and to NMFS on the final EPA Biological Evaluation.

11. Defendant NMFS is an agency of the U.S. Department of Commerce that is charged with administering the ESA with respect to marine and anadromous species, including salmonids. NMFS has the responsibility to engage in ESA § 1536 (or "Section 7") consultations with other agencies to evaluate the effects of proposed agency actions on listed species under its jurisdiction.

12. Defendant Donna S. Wieting is the Director of NMFS's Office of Protected Resources ("OPR"). As the Director of OPR, Ms. Wieting is charged with administering the ESA, including consultation with federal agencies whose actions may jeopardize the continued existence of threatened or endangered species or destroy or adversely modify their habitat.

LEGAL FRAMEWORK

13. FIFRA requires that EPA issue a registration for pesticide products before they can be distributed or sold. EPA must grant a registration if the Administrator determines that, among other things, the product will perform its intended function when used in accordance with widespread and common practice and will not generally cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C) and (D). FIFRA defines "unreasonable adverse effects on the environment" to mean certain excessive dietary risks and "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of the pesticide." *Id.* § 136(bb). Among other elements, registration identifies the particular uses to which the product may be put, defines the lawful amounts of the product that may be applied, and specifies application methods. These matters are addressed in the

labeling that accompanies each individual pesticide product. *See* 40 C.F.R. Part 152. Registrations are to be reviewed every fifteen years. 7 U.S.C. § 136a(g)(1).

14. FIFRA was amended in 1988 to systematize EPA's "reregistration" of older chemicals. *See* 7 U.S.C. § 136a-1. The process EPA implemented to carry out this mandate takes many years and involves numerous steps to complete. During reregistration, registrants are required, among other things, to generate scientific data to support reregistration. As part of the process, registrants may seek reregistration of certain uses but may abandon others.

15. EPA documents the results of the reregistration process in active-ingredient-specific Interim Reregistration Eligibility Decisions ("IREDs") and Reregistration Eligibility Decisions ("REDs"). These documents present EPA's updated human health and ecological risk assessments and EPA's conclusions regarding the reregistration eligibility of older products for uses that registrants have decided to support for reregistration. EPA often determines, and documents in the IRED and/or RED, the mitigation steps, beyond those previously required, that are necessary to reduce risk to agricultural workers, wildlife, and the environment for uses supported for reregistration. In the course of preparing an IRED or RED, or thereafter, EPA often holds discussions with the registrants of the pesticide at issue to determine how best to implement these measures. These measures may include the cancellation of certain uses and formulations, a reduction in the amount and frequency of use, employment of new engineering controls, and other protective measures. EPA may then enter into a Memorandum of Understanding with the pesticide registrants to effect product label changes resulting from the change in uses. Using a pesticide in a manner inconsistent with a product label violates FIFRA and may result in enforcement actions. Thus, an IRED or RED itself lists all uses of a pesticide that will be lawful once its requirements have been fully implemented.

16. Section 7 of the ESA provides for an interagency consultation process to assist federal agencies in complying with their duty to avoid jeopardy to listed species or destruction or adverse modification of critical habitat. The formal consultation process for FIFRA actions is mandated only when a federal "action agency" (here EPA) requests that NMFS or FWS, or both, review a proposed action that may affect a listed species or destroy or adversely modify critical habitat. 16 U.S.C. § 1536(a)(2).

17. The Services have promulgated regulations regarding their implementation of Section 7. *See* 50 C.F.R. Part 402. Those regulations include both generally applicable provisions and "counterpart" provisions which may be employed in addressing issues arising under FIFRA. When EPA requests formal consultation for FIFRA actions, it must provide to NMFS and/or FWS the best scientific and commercial data available relating to the proposed action. 50 C.F.R. §§ 402.14(d), 402.40(b)(3). The document in which the EPA provides this information, along with its own analysis of the effects on individual members of listed species, is referred to as a biological evaluation ("BE"). In developing a biological opinion, the Services are also obligated to use "the best scientific and commercial data available." 16 U.S.C. § 1536(a)(2).

18. Both ESA Section 7 and the Services' regulations provide that applicants have rights to participate in the formal consultation process. *See* 16 U.S.C. § 1536(b); 50 C.F.R. §§ 402.14(g), 402.46(c)(2). For example, each Service must discuss with the action agency and each applicant during formal consultation the Service's review and evaluation of the agency action and the basis for any finding in any biological opinion. 50 C.F.R. § 402.14(g). The regulations also expressly provide applicants with the opportunity, upon request, to comment on draft

written statements and draft biological opinions issued by the Services. *Id.* §§ 402.14(g)(5), 402.46(c)(2).

19. In addition to regulations compiled in the Code of Federal Regulations, the Services have published guidance and policy documents on the ESA Section 7 consultation process, including the Consultation Handbook and the Enhancing Stakeholder Input document. These require that NMFS provide action agencies and applicants an opportunity to meet to discuss the information needed for the biological opinion, review draft biological opinions and their contents, such as RPAs, and provide comments through the action agency.

20. The Consultation Handbook and the Enhancing Stakeholder Input document establish procedures and policies that the Services are obligated to follow or, at a minimum, explain why they did not.

21. ESA § 1538 ("Section 9") generally prohibits the taking of a listed species by any person subject to the jurisdiction of the United States, including, but not limited to, federal agencies. 16 U.S.C. § 1538. "Take" is defined to include actions that harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect individual members of the species. 16 U.S.C. § 1532(19). The Services further have defined harm to include "significant habitat modification or degradation which actually kills or injures fish or wildlife by significantly impairing essential behavioral patterns, including breeding, spawning, rearing, migrating, feeding or sheltering." 50 C.F.R. § 222.102. However, a taking is permitted if the Secretary issues an Incidental Take Statement pursuant to ESA Section 7(b)(4) upon completion of formal consultation. 16 U.S.C. § 1536(b)(4).

22. Incidental Take Statements and the RPAs and RPMs that the Service includes in any biological opinion establish how the action agency or applicant can avoid liability under Section 9. *See* 16 U.S.C. § 1536(b)(4)(iv).

23. The APA authorizes courts to review final agency actions and mandates that a court hold unlawful and set aside such actions, findings, and conclusions when they are arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). Biological opinions issued pursuant to Section 7 of the ESA, including the 2017 Biological Opinion, are subject to judicial review under the APA.

FACTS GIVING RISE TO PLAINTIFFS' CAUSE OF ACTION

Background

24. Plaintiffs in this action are FIFRA registrants of the pesticides containing the active ingredients chlorpyrifos, malathion, and/or diazinon.

25. Plaintiffs in this action are "applicants" under Section 7 of the ESA, 16 U.S.C. § 1536, and 50 C.F.R. Part 402.

26. Chlorpyrifos was first registered for use in 1965. Both diazinon and malathion were first registered for use in 1956.

27. The 2017 Biological Opinion described the federal action under consideration as "EPA's registrations of all pesticides containing chlorpyrifos, diazinon and malathion for use as described on product labels." Specific elements of registration approvals of chlorpyrifos, diazinon, and malathion have changed in the years since such products were first registered, in part because reregistration has been substantially completed for chlorpyrifos, diazinon, and

malathion. The approved uses and volumes of each chemical applied for approved purposes have changed, as often have the predominant application methods.

28. The IREDs and REDs for chlorpyrifos, diazinon, and malathion specified many mitigation measures to reduce risk to species. These included, without limitation, changes in allowable application practices and formulations, rate reductions, and reductions in the number of applications. In addition, registrants cancelled some uses.

29. The annual use volume of the products at issue in this case had been substantially reduced by 2017 compared to prior years. Those usage volumes cannot be expected substantially to increase. The 2017 Biological Opinion was required to recognize and consider the implications and impacts of the changes in uses, application methods, and use volumes. Determination of the baseline for analysis of the potential ecological impacts considered in the 2017 Biological Opinion required NMFS to evaluate the implications of the fact that products containing these active ingredients had been used for many previous years in volumes considerably higher than those consistent with current registrations; had been used for a broader range of applications; and had been applied using methods no longer permitted. NMFS was required to evaluate current and potential future impacts against a historic baseline that recognized these facts.

The 2008 Biological Opinion

30. On July 2, 2002, the U.S. District Court for the Western District of Washington ordered EPA to initiate and complete Section 7 consultations and make determinations about the effects on salmonids of fifty-four pesticide active ingredients, including chlorpyrifos, diazinon, and malathion. *Wash. Toxics Coal. v. EPA*, Civ. No. 01-132 (W.D. Wash. July 2, 2002).

31. EPA made Section 7 formal consultation requests to NMFS relating to effects on certain salmonids in California, the Pacific Northwest, and Idaho of the registrations of diazinon on November 29, 2002; relating to chlorpyrifos on April 14, 2003; and relating to malathion on December 1, 2004.

32. In 2007, the Northwest Coalition for Alternatives to Pesticides ("NCAP") and others filed a complaint against NMFS for its alleged unreasonable delay in completing the consultations for the approval of fifty-four pesticide active ingredients subject to the court decision referenced in paragraph 30, including chlorpyrifos, diazinon, and malathion. *NW Coal. for Alternatives to Pesticides, LLC. v. NMFS*, Civ. No. 07-1791 (the "NCAP Litigation") Complaint, Dkt. No. 1 (W.D. Wash., Nov. 5, 2007).

33. On July 30, 2008, NMFS entered into a stipulated settlement agreement with the plaintiffs in the NCAP Litigation. NCAP Litigation, Stipulated Settlement Agreement and Order of Dismissal (Aug. 1, 2008), Dkt. No. 21 (the "2008 NCAP Settlement"). NMFS agreed to a consultation schedule for thirty-seven active ingredients found in pesticides.

34. The 2008 Biological Opinion addressing chlorpyrifos, diazinon, and malathion was the first opinion scheduled to be released in accordance with the 2008 NCAP Settlement. *Id.*, Exhibit 1.

35. On July 31, 2008, NMFS publicly released a draft of the 2008 Biological Opinion that allegedly responded to EPA's consultation requests described in paragraph 31. The draft 2008 Biological Opinion found jeopardy, but it had serious shortcomings.

36. After they became aware of the draft 2008 Biological Opinion, current Plaintiffs Dow Agrosciences LLC and Makhteshim Agan of North America, Inc., along with Cheminova, Inc. USA (the "2008 OP Plaintiffs") insisted on an opportunity to meet with representatives of

NMFS and EPA with regard to it. The 2008 OP Plaintiffs were provided with such opportunities. The 2008 OP Plaintiffs provided NMFS with substantial volumes of additional scientific data and studies and citations to additional pertinent scientific data and studies that were available from EPA or on the internet. The data and studies supported a finding of no jeopardy.

37. NMFS released the final 2008 Biological Opinion on November 18, 2008. It did not address most of information and comments that the 2008 OP Plaintiffs had provided.

38. On April 1, 2009, the 2008 OP Plaintiffs filed a complaint in this District Court challenging the lawfulness of the 2008 Biological Opinion and the RPAs and RPMs it included. In the course of that litigation, decisions were issued both by the District Court and the Fourth Circuit Court of Appeals. As explained more fully in paragraphs 39 and 40 below, on February 21, 2013 the Court of Appeals vacated the 2008 Biological Opinion and remanded the document to this Court to further remand it to NMFS for appropriate action. *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d at 475.

39. In vacating the 2008 Biological Opinion, the Court of Appeals found that NMFS had "relied on a selection of data, tests and standards that did not always appear to be logical, obvious or even rational" and "did not explain [its reliance] with sufficient clarity to enable us to review their reasonableness." *Id.* As examples of these failures, the Court of Appeals specifically noted NMFS's failure to adequately explain: (1) a key assumption in its exposure modeling that all "subyearling" juvenile salmonids in the wild are exposed for 96 hours to a lethal concentration of pesticides; (2) why it had relied on outdated water monitoring data when more recent data was available; and (3) why it had proposed uniform buffer zones in which the

pesticides could not be applied along all water bodies that potentially provided salmonid habitat, regardless of their size, flow rate or other characteristics.

40. The Court of Appeals also stated that in reaching its conclusions, it had "addressed what we consider to be the more obvious flaws, but others are claimed to exist. We have not addressed all of the [2008 OP Plaintiffs'] complaints because on remand, they can be aired and addressed in the renewed agency process. We find it sufficient at this point to vacate the BiOp in its present form and require the Fisheries Service to address not only the flaws we identified but also any additional matters that may be raised on remand." *Id*.

The 2017 Biological Opinion

41. In April, 2013, the National Academies of Sciences' National Research Center released a report entitled "Assessing Risks to Endangered and Threatened Species from Pesticides" ("NRC Report"). NMFS, EPA, FWS, and USDA subsequently agreed to evaluate adoption of the NRC Report's recommendations by completing nationwide biological opinions for five pesticides, including chlorpyrifos, diazinon and malathion, that would evaluate the possible effects of the use of those pesticides on all species and critical habitats. This nationwide biological opinion for chlorpyrifos, diazinon, and malathion was to expand upon and replace the vacated 2008 Biological Opinion, which was limited to salmonid species in California and the Pacific Northwest.

42. The settlement agreement in the NCAP Litigation described in paragraph 33 above was amended several times. On May 21, 2014, NMFS obtained approval from the court supervising the implementation of the settlement agreement to amend it by setting December 31, 2017 as the deadline for release of the nationwide biological opinions described in paragraph 41.

43. In spring and early summer of 2016, EPA made draft BEs pertaining to the registration of chlorpyrifos, diazinon, and malathion available for public comment. EPA indicated that it intended to supply the final versions of the biological evaluations ("BEs") to NMFS as a basis for the 2017 Biological Opinion. Plaintiffs filed substantive comments on the drafts that were highly critical of (among other things) much of the information and analyses included and reflected in the drafts. Similar critical comments were filed by many other entities. EPA published all the comments at www.regulations.gov, in Docket Nos. EPA-HQ-OPP-2008-0351 (diazinon), EPA-HQ-OPP-2009-0317 (malathion), and EPA-HQ-OPP-2008-0850 (chlorpyrifos).

44. On January 17, 2017, EPA transmitted its final BEs on chlorpyrifos, diazinon, and malathion and a request for consultation to NMFS. Among other things, EPA admitted it had not responded to many of the comments that had been filed on the draft BEs concerning, *inter alia*, suggested process improvements and risk evaluation model assumptions. As justification, EPA stated that the comments "were considered but were ultimately not incorporated into the final BEs for chlorpyrifos, diazinon and malathion because they could not feasibly be addressed in time to meet the legal obligation to complete the three BiOps by December, 2017." EPA, Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, January 17, 2016, *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf.

45. On April 13, 2017, counsel for Plaintiffs submitted a letter to Secretary of Commerce Wilbur Ross, with a copy to Mr. Samuel D. Rauch, III, then Acting Assistant Administrator for NMFS and currently Deputy Assistant Administrator for Regulatory Programs, and others, that identified numerous serious deficiencies with the final BEs and provided three

lengthy and detailed technical and scientific reports (one each for chlopyrifos, diazinon, and malathion) explaining why the final BEs were fundamentally flawed and should be set aside (the "BE Letter"). Counsel for Plaintiffs also requested that any biological opinions regarding chlorpyrifos, diazinon, or malathion then being prepared on the basis of the final BEs be set aside.

46. As of the date of this Complaint, Counsel for Plaintiffs have received no response to the BE Letter.

47. On November 9, 2017, NMFS filed a motion with the court supervising the settlement referenced in paragraphs 33 and 42 seeking a two-year extension of the December 31, 2017 deadline for publication of the 2017 Biological Opinion. The motion explained that "significant unforeseen delay and needed interagency coordination has rendered it impossible for NMFS to meet" the 2017 deadline. NCAP Litigation, Motion to Amend (Dkt. 50) at 7. The motion was accompanied by affidavits from NMFS and EPA further explaining why the extension was needed. Among other things, those affidavits explained: (1) that the 2017 Biological Opinion was the first nationwide biological opinion ever drafted and its preparation was proving more complex than NMFS anticipated; (2) that the scope of the 2017 Biological Opinion had introduced many levels of scientific uncertainty; and (3) that there were significant concerns about the methodology EPA had employed in preparing the Biological Evaluations that required further interagency analysis before NMFS could issue the 2017 Biological Opinion. *Id.* at 8-9.

48. The NMFS motion described in paragraph 47 was opposed by the NCAP Litigation Plaintiffs, who filed a cross-motion asking the court to compel NMFS to release "key documents underlying its principal rationale for seeking a two-year extension." The NCAP

Plaintiffs stated that they were "reluctantly amenable to a one to two-month extension of [the December 31, 2017] deadline" to allow the court to consider their cross-motion and NMFS's motion for an extension. NCAP Litigation, Opposition to Motion to Amend and Cross-Motion for Release of Key Documents (Nov. 20, 2017), Dkt. No. 54, at 2-3.

49. On December 29, 2017, prior to any decision on its pending motion, NMFS transmitted the 2017 Biological Opinion to EPA. In a statement subsequently published on NMFS's website, NMFS explained that, because of the deadline, the 2017 Biological Opinion "cannot fully account for the need to coordinate on a different process for developing such opinions or to fully engage the public," and specifically does not address certain "concerns raised by EPA, FWS, and stakeholders regarding a variety of technical and methodological issues[.]" NMFS, Biological Opinion for Pesticides: Chlorpyrifos, Diazinon, and Malathion, *available at* https://www.fisheries.noaa.gov/resource/document/biological-opinion-pesticides-chlorpyrifos-diazinon-and-malathion (last accessed April 4, 2018).

50. The 2017 Biological Opinion repeats all of the errors specifically identified by the Court of Appeals in its 2013 Fourth Circuit Opinion and potentially ignores the Court's specific ruling that the economic feasibility of RPAs must be addressed and the agency's determination explained.

51. At no time after receiving the final BEs from EPA did NMFS discuss with any Plaintiff its review and evaluation of them or other relevant information, the basis for any finding in the 2017 Biological Opinion, or the availability or scope of RPAs.

52. At no time after receiving the BE Letter from Plaintiffs did NMFS respond to Plaintiffs' counsel or discuss with Plaintiffs or Plaintiffs' counsel any of the issues identified in the BE assessment reports contained therein.

53. At no time after receiving the final BEs from EPA did NMFS work with, or use the expertise of, any Plaintiff in identifying RPAs.

54. At no time after receiving the final BEs from EPA did NMFS obtain the written consent from any Plaintiff to the extension of deadlines for preparation and delivery of a biological opinion.

55. At no time after EPA provided the final BEs to NMFS were Plaintiffs provided by EPA or NMFS with an opportunity to comment on a draft of the 2017 Biological Opinion.

56. At no time after receiving the final BEs from EPA did NMFS discuss with any Plaintiff its review and evaluation or the basis for the findings in the 2017 Biological Opinion.

57. At no time after receiving the final BEs from EPA did NMFS convene a meeting with any Plaintiff to identify what additional information beyond that provided by EPA in its package initiating consultation could be provided for consultation and the subsequent drafting of the 2017 Biological Opinion.

58. At no time after receiving the final BEs from EPA did NMFS engage any Plaintiff or, as far as Plaintiff is aware, any other person outside of the U.S. government, to discuss possible label changes needed to avoid jeopardizing the continued existence of listed species and destroying or adversely modifying critical habitat.

59. At no time after receiving the final BEs from EPA did NMFS review with any Plaintiff or agree upon with any Plaintiff the description of the action addressed in the 2017 Biological Opinion.

60. At no time after receiving the final BEs from EPA did NMFS offer any Plaintiff or, as far as Plaintiff is aware, any other person outside of the U.S. government, an opportunity to

provide data and to identify practical considerations that affect the viability of different options for mitigating risks to species.

61. At no time after receiving the final BEs from EPA did NMFS issue a written statement adopting the BEs.

62. At no time after receiving the final BEs from EPA did NMFS issue a written statement modifying the BEs or provide a detailed explanation of the scientific and commercial data and rationale supporting any modification it made.

63. At no time after receiving the final BEs from EPA did NMFS provide EPA with a draft biological opinion.

64. At no time after receiving the final BEs from EPA did NMFS provide Plaintiffs with a written statement described in Paragraph 62 or a draft biological opinion described in Paragraph 63.

65. The 2017 Biological Opinion does not rely upon the best scientific and commercial data available and was not prepared in accordance with the controlling statute, regulations, and procedures.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF: VIOLATION OF THE APA AND THE ESA BY FAILING TO COMPLY WITH DULY-PROMULGATED PROCEDURAL REGULATIONS AND OTHERWISE BINDING PROCEDURES

66. Plaintiffs incorporate by reference all preceding paragraphs.

67. In developing, preparing, finalizing, and transmitting to EPA the 2017 Biological Opinion, NMFS failed to comply with the ESA and applicable regulations regarding applicant

involvement. NMFS's failures violate the Administrative Procedure Act and the ESA because NMFS acted in a manner inconsistent with the ESA and its own regulations.

68. In developing, preparing, finalizing and transmitting to EPA the 2017 Biological Opinion, NMFS failed to comply with its own policies and guidance as set forth in the Consultation Handbook and the Enhancing Stakeholder Input document and discussed in paragraphs 4, 19, and 20.

69. In the 2017 Biological Opinion, NMFS failed to articulate any basis or rationale why it deviated from the ESA, its regulations, or its established and published procedures and guidance.

70. NMFS's failures, described in paragraphs 67 through 69, violate the Administrative Procedure Act and the ESA, and they render the 2017 Biological Opinion arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

SECOND CLAIM FOR RELIEF: PROCEDURAL FAILURE TO COMPLY WITH THE ADMINISTRATIVE PROCEDURE ACT AND WITH THE RULING OF THE COURT OF APPEALS AND DISTRICT COURT TO WHICH NMFS WAS A PARTY

71. Plaintiffs hereby incorporate by reference paragraphs 1-65.

72. This Court's 2013 Order obligated NMFS to prepare successors to the 2008 Biological Opinion in a manner consistent with the 2013 Fourth Circuit Opinion, including the requirement that NMFS (1) "address not only the flaws we identified but also any additional matters that may be raised on remand," and (2) "provide some analysis [of the economic feasibility of the RPAs] it selects." 2013 Fourth Circuit Opinion, 707 F.3d at 475 (internal quotation and citation omitted).

73. The 2017 Biological Opinion is the successor to the 2008 Biological Opinion prepared subject to the 2013 Order and the 2013 Fourth Circuit Opinion.

74. NMFS failed to address the flaws the Fourth Circuit identified in the 2008 Biological Opinion, did not allow the 2008 OP Plaintiffs to raise additional matters in the renewed agency process, and did not address the economic feasibility of RPAs. NMFS also did not create a record addressing whether or how it attempted in the 2017 Biological Opinion to resolve the specific shortcomings that the Fourth Circuit found to be fatal to the 2008 Biological Opinion.

75. NMFS's failure to comply with the 2013 Fourth Circuit Opinion and this Court's 2013 Order on remand violates an order of this Court, the Administrative Procedure Act, and the ESA, and renders the 2017 Biological Opinion arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

THIRD CLAIM FOR RELIEF: VIOLATION OF THE APA AND THE ESA BY NOT USING THE BEST COMMERCIAL AND SCIENTIFIC DATA AVAILABLE

76. Plaintiffs incorporate by reference paragraphs 1-65.

77. In determining that registration of pesticides containing chlorpyrifos, diazinon, and malathion results in jeopardy to certain species and destroys or adversely modifies some critical habitat, NMFS failed to recognize the proper environmental baseline for analysis. NMFS failed to evaluate the action described by EPA and to focus on uses and application methods for chlorpyrifos, diazinon, and malathion now employed or soon to be employed. NMFS improperly relied on information concerning abandoned or soon-to-be-abandoned historical uses and otherwise failed to properly describe the EPA action. Mitigation measures, including improvements in user practices, state and local stewardship programs, and other use changes,

have, and will continue to, dramatically diminish the potential impact of these pesticides on the ESUs and critical habitats NMFS analyzed.

78. In developing the RPAs, RPMs, and Incidental Take Statement, NMFS made the same errors described in paragraph 77.

79. In determining that EPA's Registration Decisions result in jeopardy to certain species and destroy or adversely modify critical habitat, NMFS did not consider the best commercial and scientific data available. Among other failures, the 2017 Biological Opinion continues to rely in its exposure modeling on the unexplained key assumption that all "subyearling" juvenile salmonids in the wild are exposed annually, for 96 continuous hours, to a potentially lethal concentration of pesticides; includes in the RPAs uniform buffer zones in which the pesticides could not be applied, stating that the buffer zones should be imposed along all water bodies that potentially provide or drain to salmonid habitat, regardless of the size, flow rate or other characteristics of each water body, with no satisfactory explanation or justification of any of these determinations; omitted any reference to monitoring data but instead referenced unreliable exposure estimates; improperly assumed, contrary to available data, that populations of fish are uniformly distributed through stream segments and waterways; and ignored readily-available, high-quality spatial information on hydrology.

80. In developing and describing the RPAs, RPMs, and the Incidental Take Statement, NMFS did not rely on the best commercial and scientific data available.

81. The failures set forth in paragraphs 77 through 80 violate ESA Section 7 and NMFS's regulations. These failures constitute a violation of the APA because they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(a)(2).

FOURTH CLAIM FOR RELIEF: VIOLATIONS OF THE APA AND ESA BY FAILING TO PROVIDE LAWFUL RPAS, RPMS, AND AN INCIDENTAL TAKE STATEMENT

82. Plaintiffs incorporate by reference paragraphs 1-65.

83. EPA has the authority to grant a pesticide registration only if the product and its uses will perform their intended function without causing "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C). "Unreasonable adverse effects on the environment" includes taking into account the "economic, social and environmental costs and benefits of the use of the pesticide." 7 U.S.C. §136(bb). This requirement is enforced by the labels that are approved by EPA and that must accompany sale and distribution of pesticide products. Registration of pesticide products and any label amendments under FIFRA must therefore first undergo an economic and environmental cost-benefit analysis. EPA may not impose any restrictions that are inconsistent with this analysis.

84. As to RPAs, RPMs, and the Incidental Take Statement, NMFS failed to conduct, or have conducted by EPA, a cost-benefit analysis described in paragraph 83. NMFS cannot require EPA to impose label revisions for which such analysis should have been performed. Any attempt by EPA to do so would be *ultra vires* and unlawful. NMFS's attempt to impose label revisions as part of the RPAs, RPMs, or Incidental Take Statement that do not meet the FIFRA standard for registration is *ultra vires* and constitutes a violation of the APA because it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(a)(2).

85. NMFS's regulations require that RPAs must be implemented in a manner consistent with the intended purpose of the action, be within the scope of the action agency's legal authority and jurisdiction, and be economically and technologically feasible. 50 C.F.R. §

402.02. NMFS failed to conduct any analysis regarding whether the RPAs were within the scope of EPA's authority. NMFS also failed to conduct any analysis regarding whether the RPAs were in fact economically or technologically feasible. Neither ESA nor any other statute grants NMFS authority to impose on EPA a requirement that the Agency develop and implement a water monitoring program, or to condition an Incidental Take Statement on development and implementation of such a program. NMFS violated the APA because these requirements are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(a)(2).

86. NMFS's regulations state that RPMs, including the terms and conditions that implement them, "cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes." 50 C.F.R. § 402.14(i)(2). The terms and conditions of the RPMs limit the scope of EPA's Registration Decisions and involve more than a minor change to EPA's Registration Decisions, because one of the conditions imposed by NMFS is that EPA develop and implement an extensive and costly monitoring plan for off-channel habitats for listed salmon species. These failures violate the APA because they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(a)(2).

87. The Incidental Take Statement unlawfully incorporates the unlawful RPAs and RPMs. It thus violates the APA because it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(a)(2).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment providing the following relief:

1. Adjudge and declare that NMFS is in violation of the APA and ESA because the 2017 Biological Opinion issued by NMFS relating to EPA's Registration Decisions is arbitrary, capricious, and not in accordance with law and that the RPAs and RPMs are not binding or otherwise effective;

2. Adjudge and declare that NMFS violated the 2013 Order of this Court requiring it to prepare successors to the 2008 Biological Opinion in a manner consistent with the 2013 Fourth Circuit Opinion;

3. Hold unlawful and set aside (*i.e.*, vacate) the 2017 Biological Opinion;

4. Award Plaintiffs their costs of litigation, including reasonable costs, expenses, disbursements, and reasonable attorneys' fees; and

5. Grant Plaintiffs such further and other relief as this Court deems just and proper.

Dated: April 4, 2018

Respectfully submitted,

/s/ David B. Weinberg
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