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

DOW AGROSCIENCES LLC;
9330 Zionsville Road
Indianapolis, IN 46268

MAKHTESHIM AGAN OF NORTH AMERICA, INC.;
4515 Falls of Neuse Road
Suite 300
Raleigh, NC 27609

CHEMINOVA, INC. USA,
P.O. Box 110566
One Park Drive, Suite 150
Research Triangle Park
Durham, NC 27709

Plaintiffs,

v.

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

JAMES W. BALSIGER, as Acting Assistant Administrator 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

INTRODUCTION

1. This is an action for declaratory relief. Plaintiffs seek judicial review of the biological opinion issued by the National Marine Fisheries Service ("NMFS") on November 18, 2008 ("Biological Opinion") relating to the U.S. Environmental Protection Agency's ("EPA") registrations of pesticides containing the active ingredients chlorpyrifos, diazinon, and malathion ("EPA's Registration Decisions") and the effect of those decisions on protected species of Pacific salmonid species and their habitat. 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.

2. Defendants' Biological Opinion found that EPA's Registration Decisions are likely to jeopardize the continued existence of twenty-seven listed species of Pacific salmonids. NMFS also concluded that EPA's Registration Decisions would likely result in the destruction or adverse modification of critical habitat for twenty-five listed Pacific salmonids with designated critical habitat. To avoid jeopardy, NMFS proposed reasonable and prudent alternatives ("RPAs") and issued an incidental take statement and reasonable and prudent measures ("RPMs") to mitigate alleged impacts.

3. Defendants' findings in the Biological Opinion run contrary to the evidence in the record and legal requirements. 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, and failed to provide lawful RPAs and RPMs or a lawful incidental take statement. NMFS also failed to follow procedures required under the ESA, the APA, its own regulations and guidance, and fundamental principles of administrative law when

developing the Biological Opinion. This suit seeks an order declaring unlawful and setting aside the Biological Opinion because it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to APA, 5 U.S.C. § 706(2), 28 U.S.C. § 1331 (federal question), and 28 U.S.C. § 2201 (declaratory judgment). The APA allows 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). Plaintiffs challenge final agency actions as defined by the APA, 5 U.S.C. § 704.

5. 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

6. 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 thus is licensed by EPA to sell and distribute pesticides containing this active ingredient. DAS derives significant revenue from the sale of chlorpyrifos products. DAS' revenues will be adversely impacted by NMFS' jeopardy determination, RPAs, RPMs, and incidental take statement. DAS has also actively participated in the administrative

proceedings that preceded the release of the Biological Opinion, including filing comments on a publicly-released draft, providing studies and related materials to NMFS, and participating in meetings with NMFS staff.

7. 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 Makhteshim Chemical Works, Ltd., which holds technical registrations for diazinon and chlorpyrifos. MANA itself holds end-use registrations for products manufactured with technical pesticides registered by Makhteshim Chemical Works, Ltd., and thus is licensed by EPA to sell and distribute pesticides containing these active ingredients. MANA is the sole lawful supplier of the active pesticide ingredient diazinon used in the United States, whether the diazinon is contained in MANA's products or those marketed by others. MANA derives significant revenue from the sale of diazinon and chlorpyrifos products. MANA's revenues will be adversely impacted by NMFS' jeopardy determination, RPAs, RPMs, and incidental take statement. MANA actively participated in the administrative proceedings that preceded the release of the Biological Opinion, including filing comments on a publicly-released draft, providing studies and related materials to NMFS, and participating in meetings with NMFS staff.

8. Plaintiff Cheminova, Inc. USA ("Cheminova") is a corporation organized under the laws of Delaware and headquartered in Research Triangle Park, North Carolina. Cheminova is a supplier of technologies for crop protection, pest control, and vegetation management. Cheminova is the U.S. agent for its parent company, Cheminova A/S, which holds technical registrations for malathion and chlorpyrifos. Cheminova itself holds end use registrations for products manufactured with technical

products registered by Cheminova A/S, and thus is licensed by EPA to sell and distribute pesticides containing these active ingredients. Cheminova A/S is the sole lawful supplier of the active pesticide ingredient malathion used in the United States, whether the malathion is contained in Cheminova's products or those marketed by others. Cheminova derives significant revenue from the sale of malathion and chlorpyrifos products, which will be adversely impacted by NMFS' jeopardy determination, RPAs, RPMs, and incidental take statement. Cheminova actively participated in the administrative proceedings that have preceded the release of the Biological Opinion, including providing studies and related materials to NMFS and participating in meetings with NMFS staff.

9. Defendant NMFS is an agency of the U.S. Department of Commerce that is charged with administering the ESA with respect to anadromous species, including salmonids. NMFS has the responsibility to engage in ESA Section 7 consultations with other agencies to evaluate the effects of a proposed agency action on listed species under its jurisdiction.

10. Defendant James W. Balsiger is the Acting Assistant Administrator of NMFS. As Acting Assistant Adminsitrator of NMFS, Balsiger is charged with administering the ESA, including consulation with federal agencies whose actions may jeopardize the continued existance of threatened or endangered species or destroy or adversely modify their habitat.

ESA FRAMEWORK

11. 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 Biological Opinion regarding EPA's Registration Decisions and each of its components, are subject to judicial review under the APA.

12. Section 7 of the ESA mandates 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 begins when a federal "action agency" (here EPA) requests that NMFS or the U.S. Fish and Wildlife Service ("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). The action agency must then provide the best scientific and commercial data available to the Service. *Id*.; 50 C.F.R. § 402.14(d).

13. NMFS, together with FWS, has promulgated regulations regarding its implementation of Section 7. 50 C.F.R. § 402. The Services (NMFS and FWS) also have published various guidance documents on the ESA Section 7 consultation process, including the U.S. Fish & Wildlife Service and National Marine Fisheries Service, Endangered Species Consultation Handbook (1998) ("Consultation Handbook"). Pursuant to those regulations and guidance, once formal consultation is initiated, the responsible Service must review all information provided by EPA, as well as other information, to determine whether the proposed action is likely to jeopardize a listed species or destroy or adversely modify its designated critical habitat. 50 C.F.R. § 402.14(g). The Service must also "give appropriate consideration to any beneficial actions taken by the [EPA] or applicant." 50 C.F.R. § 402.14(g)(8). Plaintiffs are applicants for purposes of this provision. 50 C.F.R. § 402.02.

14. During formal consultation, the Service has an obligation to discuss with the action agency and each applicant the Service's review and evaluation of the agency action and the basis for any

finding in the biological opinion. The applicant has the right to participate in the consultation process. 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14(g). The Services' Consultation Handbook states that "the applicant is entitled to review draft biological opinions obtained through the action agency, and to provide comments through the action agency" prior to public release and that "the Services will discuss the basis of their biological determination with the applicant and seek the applicant's expertise in identifying [RPAs] to the action if likely jeopardy or adverse modification of critical habitat is determined." Consultation Handbook at 2-13.

15. After compliance with required rules and procedures, the Service's consultation conclusions are to be set forth in a biological opinion. The biological opinion must be based upon "the best scientific and commercial data available." *Id*.; 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(d).

16. The Data Quality Act requires federal agencies to adhere to certain policy and procedural guidelines to ensure and maximize "the quality, objectivity, utility, and integrity of information . . . disseminated by federal agencies." Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515. The National Oceanic and Atmospheric Administration ("NOAA"), an agency of the Department of Commerce in which NMFS is subsumed, promulgated Information Quality Guidelines ("IQGs") to comply with the requirements of the Data Quality Act. These guidelines were revised in 2006. The IQGs are applicable to NMFS. Biological opinions must adhere to the IQGs.

17. Section 9 of the ESA 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).

18. As part of a biological opinion the Services may suggest RPAs that can be taken by the action agency and that would likely result in avoiding jeopardy. 16 U.S.C. § 1536(b)(3). RPAs must be (1) implemented in a manner consistent with the intended purpose of the action; (2) consistent with the scope of the action agency's legal authority and jurisdiction; and (3) economically and technologically feasible. 50 C.F.R. § 402.02.

19. If a biological opinion includes RPAs, the Service is required, to the extent possible, to issue as part of the biological opinion an incidental take statement. 16 U.S.C. § 1536(b)(4). The incidental take statement must "specif[y] the impact, *i.e.*, the amount or extent, of such taking on the species." 50 C.F.R. § 402.14(i)(1).

20. The Service may require RPMs as part of an incidental take statement to minimize any impact. 50 C.F.R. § 402.14(i). RPMs, including the terms and conditions that implement them, cannot be used to alter the basic design or scope of any action and may only involve minor changes to the action. 50 C.F.R. § 402.14(i)(2). Further, the Service may not condition an RPM on actions by an action agency that would exceed or be inconsistent with its statutory authority.

FACTS GIVING RISE TO PLAINTIFFS' CAUSE OF ACTION

EPA's Registration of Pesticides

21. FIFRA requires the registration by EPA of pesticide products prior to their distribution and sale. Registration is to be granted when the Administrator of EPA determines that, among other things, the product and its uses will perform their 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(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." 7 U.S.C. §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. 40 C.F.R. Part 152. Registrations are to be reviewed every fifteen years. 7 U.S.C. § 136a(g)(1).

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

23. FIFRA was amended in 1988 to systematize EPA's "reregistration" of older chemicals. 7 U.S.C. § 136a-1. EPA responded to this mandate by implementing a reregistration process for these chemicals that has taken many years and involved numerous steps. Reregistration has been completed for chlorpyrifos and diazinon. It is nearly completed for malathion. During reregistration, registrants were required, among other things, to generate scientific data to support reregistration. As part of the

process, registrants made decisions on what uses to support for registration and made commitments to seek voluntary cancellation of uses they decided not to support for reregistration.

24. 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 reregisration 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, that 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 Memoranda of Understanding with the pesticide registrants to affect 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.

25. Specific elements of registration approvals of chlorpyrifos, diazinon, and malathion have changed in the years since such products were first registered. The approved uses and volumes of each chemical applied for approved purposes have changed, as often have the predominant application methods. The federal action for this Biological Opinion was described by EPA to be the registration of

chlorpyrifos, diazinon, and malathion for uses described on each product's labelling. EPA did not request consultation with NMFS until 2002. Consultation activities were not begun by NMFS until December, 2007. After reregistration was initiated, plaintiffs did not seek to support all of their previously-existing uses. In February, 2002, an IRED was released for chlorpyrifos. In May, 2004, an IRED was released by EPA for diazinon. These IREDs presented all of EPA's reregistration determinations regarding diazinon and chlorpyrifos except those that might be affected by a cumulative risk assessment of all organophosphates. That assessment had not yet been completed. The cumulative risk assessment of the organophosphates was completed in July, 2006. Both the diazinon and chlorpyrifos final REDs were released on July 31, 2006. EPA did not release an interim RED for malathion. The final RED for malathion was released in July, 2006.

26. Each Plantiff participated in the registration and the reregistration processes for the products subject to the case for which it, or an affiliate, holds a registration.

27. The 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 were called upon to implement commitments to voluntarily cancel uses they had decided not to support for reregistration. Cancellation occurs after registrants file requests for voluntary cancellation under FIFRA Section 6(f), 7 U.S.C. § 136d(f). Each of the plaintiffs has filed such requests with regard to one or more of its pesticide registrations. Most of those applications have been acted upon by EPA.

28. The annual use volume of the products at issue in this case had been substantially reduced by 2008 compared to prior years. Under registration requirements in place both before

initiation and prior to the completion of the Biological Opinion, those usage volumes cannot be expected substantially to increase. The 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 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.

Formal Consultation between EPA and NMFS

29. On January 30, 2001, the Washington Toxics Coalition and others filed suit against EPA for failing to consult on the effects to twenty-six Evolutionary Significant Units ("ESUs") of listed Pacific salmonids caused by fifty-four pesticide active ingredients. On July 2, 2002, the Western District of Washington ordered EPA to initiate and complete Section 7 consultations and make determinations about the effects on salmonids by these fifty-four pesticide active ingredients. *Wash. Toxics Coal. v. EPA*, Civ. No. 01-132 (W.D. Wash. July 2, 2002).

30. On November 29, 2002, EPA made a Section 7 formal consultation request to NMFS relating to the registered uses and changes that were being implemented as a result of the pending IRED for diazinon on twenty-six ESUs of Pacific salmonids.

31. On April 14, 2003, EPA made a Section 7 formal consultation request to NMFS relating to the registered uses and changes that were being implemented as a result of the completed IRED for chlorpyrifos on twenty-six ESUs of Pacific salmonids.

32. On January 22, 2004, the Western District of Washington preliminarily enjoined, pending consultation, the application of chlorpyrifos, diazinon, and malathion and other pesticides covered by its July 2, 2002 decision within 20 yards by ground of streams supporting protected salmonids, and the air application of those pesticides within 100 yards of such streams. Additionally, the court imposed several further restrictions on the use of pesticides in specific settings. *Wash. Toxics Coal. v. EPA*, Civ. No. 01-132 (W.D. Wash. January 22, 2004).

33. On December 1, 2004, EPA made an ESA Section 7 formal consultation request to NMFS relating to the registered uses of the active ingredient malathion and its effects on twenty ESUs of Pacific salmonids.

34. NMFS did not promptly respond to any of the consultation requests made by EPA identified in paragraphs 30-31.

35. In 2007, the Northwest Coalition for Alternatives to Pesticides and others filed a complaint against NMFS for its unreasonable delay in completing the consultations for the approval of fifty-four pesticide active ingredients, including diazinon, chlorpyrifos, and malathion. *NW Coal. for Alternatives to Pesticides, LLC. v. NMFS*, Civ. No. 07-1791 (W.D. Wash. 2007). On July 30, 2008, NMFS entered into a stipulated settlement agreement with the plaintiffs in that case. NMFS agreed to a consultation schedule for thirty-seven active ingredients found in pesticides. The Biological Opinion

addressing chlorpyrifos, diazinon, and malathion was the first scheduled opinion to be released in accordance with the stipulated settlement agreement.

The Biological Opinion

36. On July 31, 2008, NMFS publicly released a draft Biological Opinion that allegedly responded to EPA's requests for formal consultation relating to the registrations of chlorpyrifos, diazinon, and malathion. The draft Biological Opinion did not consider any changes to use of chlorpyrifos, diazinon, and malathion as a result of the EPA's IREDs, REDs, or related negotiations with registrants. The draft Biological Opinion found jeopardy.

37. The draft Biological Opinion had other shortcomings. Among others, it failed to consider the mitigation measures developed by EPA in reregistration and stated in the IREDs and REDs. The draft Biological Opinion was not based on the best commercial or scientific data available. The draft Biological Opinion was not based on a correct understanding of EPA's pesticide registration process.

38. NMFS failed to provide Plaintiffs or, upon information and belief, EPA with an opportunity to review a copy of the draft Biological Opinion before it was publicly released. NMFS failed to discuss any aspect of the facts or analysis presented in the draft Biological Opinion with Plaintiffs or, upon information and belief, EPA before it was publicly released. NMFS failed to provide notice to Plaintiffs that the draft Biological Opinion was being released to the public. These actions violated the Services' regulations and guidance setting forth the procedures for including applicants in the consultation process.

39. After they became aware of the draft Biological Opinion, Plaintiffs insisted on an opportunity to meet with representatives of NMFS and EPA with regard to it. Plaintiffs were provided their first opportunity to meet with representatives of NMFS and EPA in response to their requests on August 29, 2008. The meeting was held at EPA's office in Alexandria, Virginia. Representatives of each Plaintiff were allowed to make presentations to NMFS. They did so. Plaintiffs' representatives answered questions from NMFS staff regarding the registration process, the characteristics and use of the pesticides at issue, and related matters.

40. An additional meeting between Plaintiffs, NMFS, and EPA was held at EPA's office in Alexandria, Virginia on October 2, 2008. At that meeting, NMFS explained to Plaintiffs how it formulated the draft Biological Opinion and answered Plaintiffs' questions about the process. In both this meeting and the meeting described in paragraph 39, NMFS personnel displayed little understanding about the EPA registration or reregistration processes. In both meetings, NMFS personnel declined to enter into any meaningful substantive discussions with representatives of Plaintiffs.

41. In response to requests from NMFS, after the August 29, 2008 meeting described in paragraph 39, Plaintiffs provided NMFS with substantial volumes of additional scientific data and studies. Most of this material was physically delivered to NMFS' office in Silver Spring, Maryland. Plaintiffs also provided 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. None of it had been considered by NMFS in preparing the draft Biological Opinion.

42. Plaintiffs met with NMFS and EPA regarding the draft Biological Opinion on October 16, 2008. The meeting was held at NMFS' office in Silver Spring, Maryland. During this meeting,

Plaintiffs provided additional scientific data to NMFS that supported a finding of no jeopardy. Plaintiffs also answered questions from NMFS regarding the EPA registration and reregistration process and the relevant pesticides. NMFS personnel declined to enter into any meaningful substantive discussions with Plaintiffs.

43. Because Plaintiffs provided so much new information, Defendants sought and were granted an extension for the release of the final Biological Opinion by the court before which the settlement described in paragraph 35 had been reached.

44. NMFS released the Biological Opinion on November 18, 2008. Defendants did not respond in the final Biological Opinion to most of Plaintiffs' comments or to the information provided by Plaintiffs. The Biological Opinion ignores much of this information. Defendants have not provided Plaintiffs with any response to their comments and information submission other than the final Biological Opinion itself.

45. NMFS concluded in the November 18, 2008 Biological Opinion that EPA's Registration Decisions are likely to jeopardize the continued existence of twenty-seven listed Pacific salmonids and are likely to destroy or adversely modify critical habitats for twenty-five listed Pacific salmonids with designated critical habitat. NMFS also concluded that EPA's Registration Decisions are not likely to jeopardize Ozette Lake Sockeye salmon. NMFS issued RPAs for the twenty-seven listed Pacific salmonids it found were likely to be jeopardized. NMFS issued RPMs that included a special provision for the Ozette Lake Sockeye salmon. The Biological Opinion requires implementation of the RPAs by EPA within a year of EPA's receipt of the Biological Opinion.

46. For the twenty-seven species that NMFS found would likely be jeopardized, the RPAs require that labels for all pesticide products containing chlorpyrifos, diazinon, and malathion used in California, Idaho, Oregon, and Washington be revised to include five elements. Alternatively, the RPAs allow the label to cross-reference EPA's Endangered Species Protection Program ("ESPP") bulletins that list the required elements. Either making the changes to the labels specified by NMFS or requiring cross-references to ESPP bulletins would require that the current labels be amended. The five elements required to be on the labels or cross-referenced ESPP bulletins are establishment of a buffer of 500 feet from salmonid habitats for ground applications and a buffer of 1,000 feet from salmonid habitats for aerial applications of these pesticide products; prohibition of application when wind speeds equal or exceed 10 mph; retention or establishment of a 20 foot non-crop, vegetative strip on the downhill side adjacent to the application site; prohibition of application when soil moisture is at capacity or a storm event is likely that will produce runoff; and reporting of all incidents of fish mortality in the area of application within four days. The RPAs also would require EPA to develop and implement a monitoring program for off-channel habitats. In describing this RPA element, NMFS specified such details as the number of sites to be sampled, the periods of sampling, and the state-by-state location of sampling sites. NMFS also required EPA to operate this program for the indefinite future and provide annual reports to NMFS that included both summaries of results and all raw data. In establishing these RPAs, NMFS did not undertake or present in the Biological Opinion analyses regarding whether the RPAs were consistent with the intended purpose of EPA's Registration Decisions, within the scope of EPA's legal authority and jurisdiction, or economically and technologically feasible.

47. The Biological Opinion includes an Incidental Take Statement. The Incidental Take Statement states that any fish kill in areas where certain indicators of possible chlorpyrifos, diazinon, or

malathion use are found, of any fish species, would be considered a take to one of the species at issue. The Incidental Take Statement also includes RPMs. These RPMs require EPA to minimize the amount of incidental take from the use of chlorpyrifos, diazinon, and malathion by reducing the risk that those pesticides will reach salmonid habitat; monitor incidental take that may occur; and report monitoring results to NMFS from the previous season.

48. The Biological Opinion includes "terms and conditions" that must be followed by EPA to avoid a taking. These require that EPA develop a monitoring program for off-channel habitats; impose label revisions that require a buffer of 500 feet from Ozette Lake Sockeye habitat for ground applications and a buffer of 1,000 feet from Ozette Lake Sockeye habitat for aerial applications; require on all chlorpyrifos, diazinon, and malathion labels (or alternatively in ESPP bulletins cross-referenced on the labels) instructions for reporting fish kills; and report to NMFS incidents from EPA's incident database that are classified as probable or highly probable.

49. In finding jeopardy and identifying RPAs, RPMs and setting forth an Incidental Take Statement, the final Biological Opinion incorrectly evaluated incident and cumulative effects on salmonids of the registration and use of chlorpyrifos, diazinon and malathion. It also incorrectly evaluated whether those effects are sufficiently likely to occur to jeopardize the survival of salmonids of concern or their habitat. These incorrect evaluations include, but are not limited to, the following:

(a) NMFS ignored a field study, conducted by the University of Alabama for the United States Department of Agriculture, that evaluated aquatic invertebrate and fish effects from repeated malathion applications to cotton near small streams.

(b) NMFS failed to give adequate attention to microcosm and mesocosm studies. The Plaintiffs provided several of these studies to NMFS. Each of these studies involved the construction of an artificial habitat that reflected representative field conditions in accordance with EPA-approved protocols. These habitats then were treated with measured amounts of chlorpyrifos, diazinon, or malathion, and the effects (or lack of effects) of that treatment were evaluated. Performance of these studies cost registrants millions of dollars. These studies are directly relevant to evaluating the effects of chlorpyrifos, diazinon, and malathion on salmonids.

(c) NMFS rejected one mesocosm study that evaluated the effects of malathion on aquatic invertebrates in Europe because of its "high degree of variability." However, the European study included proper statistical tests to account for any variability.

(d) NMFS rejected the use of other microcosm and mesocosm studies because salmonids and salmonid prey species were not included simultaneously. The studies looked at bluegill sunfish. Bluegill sunfish have a very similar survival toxicity profile to the salmonid rainbow trout. Bluegill sunfish are often used in ecological risk assessments as fish surrogates for salmonids. NMFS ignored other important aspects of the studies or made errors in interpreting them.

(e) NMFS overstated the exposure of salmonid prey (food) arising from the use of chlorpyrifos, diazinon, and malathion and the impact of the use of those products.

(f) NMFS misapplied models that had been developed by EPA to project the amount of pesticides applied in accordance with label direction that would reach salmonid habitat.

(g) The Biological Opinion also ignored other reliable data submitted to NMFS by Plaintiffs.

50. In reaching its jeopardy conclusion, NMFS purported to have conducted species level assessments for EPA's Registration Decisions for all ESUs. These assessments were incomplete and inadequate. NMFS provided qualitative descriptions of the possible effects of the proposed action but did not support these conclusions with data. NMFS ignored pertinent data that was in its possession. These data included, but was not limited to, diazinon water monitoring data for the Central Valley Spring-run Chinook salmon. These and other data are necessary to conduct accurate species level assessments.

51. In preparing its Biological Opinion, NMFS relied heavily on modeling estimates. NMFS' modeling was based on inappropriate assumptions. NMFS' analysis assumed no degradation and complete bioavailability. It also assumed that the wind blows from the center of the field to the center of the water body. It included other erroneous elements, mistakes, and assumptions. These erroneous elements, mistakes, and assumptions result in inaccurate and overly conservative conclusions. NMFS rejected risk analysis methods, such as probabilistic risk assessments, the use of which would have overcome many deficiencies in the Biological Opinion.

52. Much of the water monitoring data on which NMFS relied in the Biological Opinion is not current or pertinent to ongoing uses of chlorpyrifos, diazinon, or malathion. NMFS was provided diazinon water monitoring data from 2001 to 2007 for California Central Valley water bodies but NMFS did not use these data in developing the Biological Opinion. In addition, NMFS relied upon malathion monitoring data from large spraying programs (some non-agricultural) such as the Medfly, Boll Weevill,

and mosquito control program. These data are not representative of potential impacts in applying malathion for uses implicating exposure to the endangered salmonid species in question. NMFS relied on other inappropriate water monitoring data.

53. The final Biological Opinion failed to rely on the best scientific and commercial data available in many other respects.

Information Quality Guidelines

54. NOAA IQGs require scientific information to have utility, integrity, and objectivity. Objectivity is defined as information that is "accurate, reliable, and unbiased."

55. The IQGs apply to the preparation by NMFS of biological opinions under Section 7 of the ESA.

56. The IQGs require NMFS to use the best available science and supporting studies and to use data collected by accepted and best available methods. NMFS must identify, among other things, each ecosystem component, the central estimate of risk for the specific ecosystem component, each appropriate upper-bound and/or lower-bound estimate of risk, data gaps, other significant uncertainties, and additional studies known to the agency and not used in the risk analysis.

57. The Biological Opinion does not meet the standards established by the IQGs.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF: VIOLATION OF THE APA

Failure to Consult Regarding the Action Described by EPA

58. Plaintiffs incorporate by reference all preceding paragraphs.

59. In determining that EPA's Registration Decisions result in jeopardy to certain Pacific salmonid species and destroy or adversely modify 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 approved in pertinent IREDs and REDS and now employed or soon to be employed. NMFS improperly relied heavily on information concerning abandoned or soon-to-be-abandoned historical uses and otherwise failed to properly describe the EPA action. Mitigation measures and other use changes have dramatically diminished the potential impact of these pesticides on salmonid species and will continue to do so.

60. In developing the RPAs, RPMs, and Incidental Take Statement, NMFS made the same errors described in paragraph 59. NMFS also sought to impose on EPA requirements for monitoring that exceed NMFS' statutory authority.

61. The failures set forth in paragraphs 59 and 60 violate the APA because NMFS was arbitrary, capricious, and abused its discretion, and otherwise acted not in accordance with law. 5 U.S.C. § 706(a)(2).

SECOND CLAIM FOR RELIEF: VIOLATION OF THE APA , ESA AND INFORMATION QUALITY GUIDELINES

Failure to Use the Best Commercial and Scientific Data Available or Comply with Information Quality Guidelines

62. Plaintiffs incorporate by reference all preceding paragraphs.

63. In determining that EPA's Registration Decisions result in jeopardy to certain Pacific salmonid species and destroy or adversely modify critical habitat, NMFS did not adequately consider the best commercial and scientific data available, including but not limited to the additional scientific data supplied by Plaintiffs.

64. In performing risk assessments as part of the Biological Opinion, NMFS failed to comply with the IQGs by not using the best available science and supporting studies.

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

66. The failures set forth in paragraphs 63 through 65 violate ESA Section 7. 16 U.S.C. § 1536(a)(2). These failures constitute 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).

THIRD CLAIM FOR RELIEF: VIOLATIONS OF THE APA AND ESA

Failure to Provide Lawful RPAs, RPMs, and an Incidental Take Statement

67. Plaintiffs incorporate by reference all previous paragraphs.

68. 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(5)(C) and (D). "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 analysis is enforced by the labels that are approved by EPA 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.

69. 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 68. 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' 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).

70. NMFS' 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 failures are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(a)(2).

71. NMFS' 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 by requiring extensive buffers in relation to Ozette Lake Sockeye salmon habitat. The terms and conditions of the RPMs also 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).

72. 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).

FOURTH CLAIM FOR RELIEF: VIOLATIONS OF THE APA AND ESA

Failure to Adequately Include Applicants in Consultation, Consider or Respond to Comments

73. Plaintiffs incorporate by reference all preceding paragraphs.

74. NMFS did not follow the proper procedures for including Plaintiffs in the consultation process.

75. Before NMFS publicly released the draft Biological Opinion, it failed to discuss the basis of its Biological Opinion with the Plaintiffs, did not provide them with a timely opportunity to comment or submit additional data, and did not seek Plaintiffs' expertise in drafting RPAs. 50 C.F.R. § 402.14(g)(5); 16 U.S.C. § 1536(a)(2); Consultation Handbook at 2-13 (1998). NMFS did not respond to Plaintiffs' comments in the Biological Opinion or in any other adequate document. These and other NMFS actions violated the APA because they were inconsistent with its own regulations and policy and otherwise were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

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

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

4. Grant Plaintiffs such further and other relief as this court deems just and proper.

Respectfully submitted,

/s/ *David E. Markert*
David E. Markert (Bar #17016)
Wiley Rein LLP
1776 K Street, NW
Washington, DC 20006
(202) 719-7496
(202) 719-7049 (fax)
dmarkert@wileyrein.com

David B. Weinberg (*pro hac vice* pending)
Wiley Rein LLP
1776 K Street, NW
Washington, DC 20006

Eric Andreas (*pro hac vice* pending)
Wiley Rein LLP
1776 K Street, NW
Washington, DC 20006

P. Nicholas Peterson (*pro hac vice* pending)
Wiley Rein LLP
1776 K Street, NW
Washington, DC 20006

Attorneys for Plaintiffs DOW AGROSCIENCES LLC and MAKHTESHIM AGAN OF NORTH AMERICA, INC.

/s/ *Deborah B. Baum*
Deborah B. Baum (Bar #05694)
Pillsbury Winthrop Shaw Pittman LLP
2300 N Street, NW
Washington, DC 20037
(202) 663-8000
(202) 663-8007 (fax)
deborah.baum@pillsburylaw.com

David Menotti (*pro hac vice* pending)
Pillsbury Winthrop Shaw Pittman LLP
2300 N Street, NW
Washington, DC 20037

Guy Relford, Esq.
Dow AgroSciences, LLC
9330 Zionsville Road
Indianapolis, IN 46268

Michael Grisham, Esq.
Dow AgroSciences, LLC
9330 Zionsville Road
Indianapolis, IN 46268

Of Counsel for DOW AGROSCIENCES LLC

Mark Hough, Esq.
Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Road
Suite 300
Raleigh, NC 27609

Of Counsel for MAKHTESHIM AGAN OF NORTH AMERICA, INC.

Warren U. Lehrenbaum (admission pending)
Pillsbury Winthrop Shaw Pittman LLP
2300 N Street, NW
Washington, DC 20037

April 1, 2009

Attorneys for Plaintiff CHEMINVOA, INC. USA