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April 13, 2017

David B. Weinberg
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The Honorable Wilbur Ross
Secretary
U.S. Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

Re: "Final" Chlorpyrifos, Diazinon, and Malathion Biological Evaluations Sent by EPA to National Marine Fisheries Service on January 18, 2017

Dear Secretary Ross:

We are writing on behalf of our clients Dow AgroSciences, LLC ("DAS"), Makhteshim Agan of North America, Inc., d/b/a ADAMA ("ADAMA"), and FMC Corporation ("FMC") (together, the "OP Registrants"), to request that you (1) instruct the Acting Assistant Administrator for the National Marine Fisheries Service ("NMFS") to return to the U.S. Environmental Protection Agency ("EPA") three Biological Evaluations ("BEs") that EPA transmitted to NMFS on January 18, 2017; (2) direct that any effort to prepare biological opinions based on them be set aside; and (3) as soon as is reasonably possible (as explained further below), direct legal counsel representing NMFS in *NW Coalition for Alternatives to Pesticides, et al. v. National Marine Fisheries Service*, No. 07-cv-01791 (W.D. Wash.) ("*NCAP v. NMFS*"), to file a motion requesting modification of the existing stipulated settlement agreement to extend the deadline for NMFS to complete nationwide organophosphate ("OP") biological opinions.

Our clients and their affiliates hold EPA registrations for products containing one or more of the OP pesticide active ingredients that are the subject of the BEs (chlorpyrifos, diazinon, and malathion). The BEs are documents from EPA required by the "Interim Approaches" adopted during the Obama Administration in an effort to resolve controversies regarding the relationship between pesticide registration activities under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and activities of EPA and the Departments of Commerce and the Interior under the Endangered Species Act ("ESA").[1]

[1] Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report, *available at* https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

Our clients believe that the Interim Approaches are fundamentally flawed and should be set aside. Drafts of the BEs were released for public review in April, 2016. Substantial comments submitted on those drafts explained the reasons for our clients' view and demonstrated the many flaws in the draft documents.

When EPA sent final versions of the BEs to NMFS, the Agency conceded that it had not responded to most of the comments it had received. This is confirmed in the three reports from expert consultants to our clients that are enclosed with this letter. Those comments also demonstrate that EPA has not even correctly applied in the BEs the processes described as the Interim Approaches.

We will not belabor here the matters addressed in the enclosed reports. But representative examples of the BEs' flaws include the following:

- A major lack of transparency necessary for evaluation and reproduction of results.
- Inclusion of proposed and candidate species that are not afforded protection under ESA.
- Many studies selected by EPA as sources of information on effects and exposure were not evaluated for data quality and relevance. When evaluated, many evaluations did not follow EPA's own study quality criteria. In addition, many scientifically valid, registrant-submitted studies were not evaluated by the Agency, with no explanation. This is not justified and is contrary to EPA's own guidance and the recommendations made by the National Academy of Sciences.
- Effects determinations were made assuming that product may be applied anywhere in the United States, without consideration of distinctions between use patterns, timing of applications, locations of use, and presence of listed species and critical habitats.
- Compounding of conservatism in the assessment of exposure, resulting in unrealistically high and sometimes physically impossible estimates.

- Failure to consider appropriate lines of evidence, as recommended by the National Academy of Sciences, in order to determine the likelihood of an effect occurring.

EPA sought to excuse its failure to properly revise the drafts or otherwise respond to comments by asserting that the revisions were precluded by a legal obligation to complete biological opinions based upon the BEs by December 31, 2017.[2] That position is incorrect. EPA is not bound by any such obligation.

EPA presumably based its assertion on stipulations entered in court cases by NMFS and the U.S. Fish and Wildlife Service ("FWS"). The one of those stipulations to which NMFS was a party did commit NMFS to complete a nationwide OP biological opinion by December 31, 2017. Stipulation and Order to Amend the Stipulated Settlement Agreement Affirmed by this Court on August 1, 2008, *NCAP v. NMFS* (W.D. Wash., May 21, 2014), Dkt. No. 50, at 6.[3] But a party to a settlement agreement may request, by motion, that the court modify the settlement agreement for any "reason that justifies relief." Fed. R. Civ. P. 60. Thus, rather than issue flawed BEs, EPA could have asked NMFS to seek to modify the *NCAP v. NMFS* settlement agreement deadline so EPA could adequately fulfill its own statutory obligations.

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[2] Office of Chemical Safety and Pollution Prevention's Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, at 2 (Jan. 17, 2017), *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf. In failing to "explain or support several assumptions critical to its conclusions," EPA violated the Fourth Circuit Court of Appeals' direction that an agency acting to implement the ESA must explain its analysis "with sufficient clarity" to allow stakeholders to determine whether the analysis is "the product of reasoned decisionmaking." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 464, 475 (4th Cir. 2013). For example, EPA relied on several data sets that it does not dispute are incomplete and/or inaccessible. But it never "cogently explain[ed] why." *Id.* at 473.

[3] The FWS entered into an analogous stipulation in *Center for Biological Diversity v. U.S. Fish and Wildlife Service et al.* *See* Stipulation Amending Original Stipulated Settlement and Order, No. 11-cv-5108 (N.D. Cal. July 28, 2014), Dkt. No. 87 ("Amended Stipulated Settlement"). But that stipulation expressly states that FWS "is not obligated to" complete OP consultations by December 31, 2017, and it provides that if there were to be a delay the parties would meet and confer to discuss appropriate actions and, if necessary, petition the Court to resolve any dispute. Amended Stipulated Settlement at 4-5. We recently have written to Secretary Zinke about the need to address the issues raised by that settlement.

We recently have written to EPA Administrator Pruitt asking that he withdraw from NMFS the three BEs at issue. However, we urge that you not await that action. Instead, our clients respectfully request that you promptly return the BEs to EPA and direct that any effort to prepare biological opinions based on them be set aside. Our clients similarly request that once you, FWS, EPA, and presumably the U.S. Department of Agriculture (which was a party to the development of the "Interim Approaches") have determined how the new Administration is going to address the "Interim Approaches" and, more broadly, the issue of FIFRA-ESA integration, you direct the legal counsel representing NMFS to file a motion to modify the *NCAP v. NMFS* settlement agreement to extend the deadline for nationwide OP biological opinions and take any other appropriate action, and provide EPA with additional time to prepare the BEs.

Thank you for your prompt attention to these requests.

Sincerely,

David B. Weinberg

Counsel to Dow AgroSciences, LLC; Makhteshim Agan of North America, Inc., d/b/a "ADAMA"; and FMC Corporation

Enclosures

cc (without attachments except as noted):

The Honorable Scott Pruitt, Administrator of the United States Environmental Protection Agency
The Honorable Ryan Zinke, Secretary of the United States Department of the Interior
The Honorable Michael Young, Acting Deputy Secretary of the United States Department of Agriculture
The Honorable Jim Kurth, Acting Director of the Fish and Wildlife Service (with attachments)
The Honorable Samuel D. Rauch, III, Acting Assistant Administrator for the National Marine Fisheries Service
The Honorable John Barrasso, Chairman, Senate EPW Committee
The Honorable Tom Carper, Ranking Member, Senate EPW Committee
The Honorable Rob Bishop, Chairman, House Committee on Natural Resources
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The Honorable Pat Roberts, Chairman, Senate Committee on Agriculture, Nutrition and Forestry
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Dr. Sheryl H. Kunickis, Director, Office of Pest Management Policy, United States Department of Agriculture
Mr. Ray Starling, Special Assistant to the President for Agriculture, Trade and Food Assistance (with attachments)
Mr. Richard Keigwin, EPA OPP (with attachments)
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The Honorable Ryan Zinke
Secretary
U.S. Department of the Interior
1849 C Street, NW
Washington, DC 20240

Re: "Final" Chlorpyrifos, Diazinon, and Malathion Biological Evaluations Sent by EPA to Fish and Wildlife Service on January 18, 2017

Dear Secretary Zinke:

We are writing on behalf of our clients Dow AgroSciences, LLC ("DAS"), Makhteshim Agan of North America, Inc., d/b/a ADAMA ("ADAMA"), and FMC Corporation ("FMC") (together, the "OP Registrants"), to request that you (1) instruct the Acting Director of the Fish and Wildlife Service ("FWS") to return to the U.S. Environmental Protection Agency ("EPA") three Biological Evaluations ("BEs") that EPA transmitted to FWS on January 18, 2017; (2) direct that any effort to prepare biological opinions based on them be set aside; and (3) direct legal counsel representing FWS in *Center for Biological Diversity v. U.S. Fish and Wildlife Service et al.*, No. 11-cv-5108 (N.D. Cal.) ("*CBD v. FWS*"), to meet and confer on a timely basis with counsel for the other parties to that case, as required by Paragraph 4(c)(1) of the Stipulation Amending Original Stipulated Settlement and Order approved by the Court on July 28, 2014 (the "Stipulated Settlement"), to discuss further activity in that case. *See* Stipulated Settlement, *CBD v. FWS*, Dkt. No. 87.

Our clients and their affiliates hold EPA registrations for products containing one or more of the organophosphate ("OP") pesticide active ingredients that are the subject of the BEs (chlorpyrifos, diazinon, and malathion). The BEs are documents from EPA required by the "Interim Approaches" adopted during the Obama Administration in an effort to resolve controversies regarding the relationship between pesticide registration activities under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and activities of EPA and the

Departments of the Interior and Commerce under the Endangered Species Act ("ESA").[1]

Our clients believe that the Interim Approaches are fundamentally flawed and should be set aside. Drafts of the BEs were released for public review in April, 2016, and substantial comments submitted on those drafts explained the reasons for our clients' view and demonstrated the many flaws in the draft documents.

When EPA sent final versions of the BEs to FWS, the Agency conceded that it had not responded to most of the comments it had received. This is confirmed in the three reports from expert consultants to our clients that are enclosed with this letter. Those comments also demonstrate that EPA has not even correctly applied in the BEs the processes described as the Interim Approaches.

We will not belabor here the matters addressed in the enclosed reports. But some representative examples of the BEs' flaws include the following:

- A major lack of transparency necessary for evaluation and reproduction of results.
- Inclusion of proposed and candidate species that are not afforded protection under ESA.
- Many studies selected by EPA as sources of information on effects and exposure were not evaluated for data quality and relevance. When evaluated, many evaluations did not follow EPA's own study quality criteria. In addition, many scientifically valid, registrant-submitted studies were not evaluated by the Agency, with no explanation. This is not justified and is contrary to EPA's own guidance and the recommendations made by the National Academy of Sciences.
- Effects determinations were made assuming that product may be applied anywhere in the United States, without consideration of

[1] Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report, *available at* https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

distinctions between use patterns, timing of applications, locations of use, and presence of listed species and critical habitats.

- Compounding of conservatism in the assessment of exposure, resulting in unrealistically high and sometimes physically impossible estimates.

- Failure to consider appropriate lines of evidence, as recommended by the National Academy of Sciences in order to determine the likelihood of an effect occurring.

EPA sought to excuse its failure to properly revise the drafts or otherwise respond to comments by asserting that the revisions were precluded by a legal obligation to complete biological opinions based upon the BEs by December 31, 2017.[2] That position is incorrect. EPA is not bound by any such obligation.

EPA presumably based its assertion on stipulations entered in court cases by FWS and the National Marine Fisheries Service ("NMFS"). The one of those stipulations to which FWS was a party did express an intent to complete a nationwide OP biological opinion by December 31, 2017. *See CBD v. FWS* Stipulated Settlement at 3.[3] But it also expressly stated that FWS "is not obligated to" complete OP consultations by then, and provided that if there were to be a delay

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[2] Office of Chemical Safety and Pollution Prevention's Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, at 2 (Jan. 17, 2017), *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf. In failing to "explain or support several assumptions critical to its conclusions," EPA violated the Fourth Circuit Court of Appeals' direction that an agency acting to implement the ESA must explain its analysis "with sufficient clarity" to allow stakeholders to determine whether the analysis is "the product of reasoned decisionmaking." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 464, 475 (4th Cir. 2013). For example, EPA relied on several data sets that it does not dispute are incomplete and/or inaccessible. But it never "cogently explain[ed] why." *Id.* at 473.

[3] The National Marine Fisheries Service entered into an analogous stipulation in May 2014 in which it agreed to complete an OP biological opinion by December 31, 2017. *See* Stipulation and Order to Amend the Stipulated Settlement Agreement Affirmed by this Court on August 1, 2008, *NW Coalition for Alternatives to Pesticides, et al. v. Nat'l Marine Fisheries Serv.*, No. 07-cv-01791 (W.D. Wash., May 21, 2014), Dkt. No. 50, at 6.

parties would meet and confer to discuss appropriate actions and, if necessary, petition the Court to resolve any dispute. *Id.* at 4-5.

We recently have written to EPA Administrator Pruitt asking that he withdraw from FWS the three BEs at issue. However, we urge that you not await that action. Instead, our clients respectfully request that you promptly return the BEs to EPA and direct that any effort to prepare biological opinions based on them be set aside. Our clients similarly request that once you, NMFS, EPA, and presumably the U.S. Department of Agriculture (which was a party to development of the "Interim Approaches") have determined how the new Administration is going to address the "Interim Approaches" and, more broadly, the issue of FIFRA-ESA integration, you direct the legal counsel representing FWS in *CBD v. FWS* to meet and confer on a timely basis with counsel for the other parties to that case to discuss appropriate further actions.

Thank you for your prompt attention to these requests.

Sincerely,

David B. Weinberg

Counsel to Dow AgroSciences, LLC; Makhteshim Agan of North America, Inc., d/b/a "ADAMA"; and FMC Corporation

Enclosures

cc (without attachments except as noted):

The Honorable Scott Pruitt, Administrator of the United States Environmental Protection Agency
The Honorable Wilbur Ross, Secretary of the United States Department of Commerce
The Honorable Michael Young, Acting Deputy Secretary of the United States Department of Agriculture
The Honorable Jim Kurth, Acting Director of the Fish and Wildlife Service (with attachments)
The Honorable Samuel D. Rauch, III, Acting Assistant Administrator for the National Marine Fisheries Service
The Honorable John Barrasso, Chairman, Senate EPW Committee
The Honorable Tom Carper, Ranking Member, Senate EPW Committee
The Honorable Rob Bishop, Chairman, House Committee on Natural Resources
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The Honorable Pat Roberts, Chairman, Senate Committee on Agriculture, Nutrition and Forestry
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The Honorable Collin Peterson, Ranking Member, House Committee on Agriculture
Dr. Sheryl H. Kunickis, Director, Office of Pest Management Policy, United States Department of Agriculture
Mr. Ray Starling, Special Assistant to the President for Agriculture, Trade and Food Assistance (with attachments)
Mr. Richard Keigwin, EPA OPP (with attachments)
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The Honorable Scott Pruitt
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: "Final" EPA Chlorpyrifos, Diazinon, and Malathion Biological Evaluations Released on January 18, 2017

Dear Mr. Administrator:

We are writing on behalf of our clients Dow AgroSciences, LLC ("DAS"), Makhteshim Agan of North America, Inc., d/b/a ADAMA ("ADAMA"), and FMC Corporation ("FMC") (together, the "OP Registrants"), to request that you withdraw from the Fish and Wildlife Service ("FWS") and National Marine Fisheries Service ("NMFS") (jointly, "the Services") three Biological Evaluations ("BEs") that the Environmental Protection Agency ("EPA") transmitted to them on January 18, 2017.

Our clients and their affiliates hold EPA registrations for products containing one or more of the organophosphate ("OP") pesticide active ingredients that are the subject of the BEs: chlorpyrifos, diazinon, and malathion.

Our clients are unclear about the Administration's intentions related to the ongoing controversy regarding the intersection between pesticide registration activities under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and activities of EPA and the Services under the Endangered Species Act ("ESA"). We would welcome the opportunity to discuss that issue with you. However, our clients' immediate concern is with the fundamental scientific unsoundness of the OP BEs.

The BEs purportedly were prepared in accordance with the "Interim Approaches" to FIFRA-ESA issues adopted by the Obama Administration in November, 2013.[1] Our clients believe that the Interim Approaches are

[1] Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report, *available at* https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

fundamentally flawed and should be set aside. Each client filed substantial comments on drafts of the BEs that were released for public review in April, 2016. Those comments document our clients' views. Yet EPA conceded in its response to these comments that it did not address most of them in the final versions of the BEs.

Reviews of those "final" BEs, enclosed with this letter, confirm this fact. It also demonstrates that the Agency did not correctly apply processes described in the Interim Approaches. Below are what our clients consider some of the most egregious examples of these shortcomings of the BEs:

- A major lack of transparency necessary for evaluation and reproduction of results.
- Inclusion of proposed and candidate species that are not afforded protection under the ESA.
- Many studies selected by EPA as sources of information on effects and exposure were not evaluated for data quality and relevance. When evaluated, many evaluations did not follow EPA's own study quality criteria. In addition, many scientifically valid, registrant-submitted studies were not evaluated by the Agency, with no explanation. This is contrary to EPA's own guidance and the recommendations made by the National Academy of Sciences.
- Effects determinations were made assuming that product may be applied anywhere in the United States, without consideration of distinctions between use patterns, timing of applications, locations of use, and presence of listed species and critical habitats.
- Compounding of conservatism in the assessment of exposure, resulting in unrealistically high and sometimes physically impossible estimates.
- Failure to consider appropriate lines of evidence, as recommended by the National Academy of Sciences, to determine the likelihood of an effect occurring.

EPA's submission of the BEs in their current form is improper in light of both these facts and the many other critical comments EPA has received from the

OP Registrants, farmers, agriculture organizations, public health officials, professional pest control applicators, and others.

Furthermore, in failing to "explain or support several assumptions critical to its conclusions," EPA violated the Fourth Circuit Court of Appeals' direction that an agency acting to implement the ESA must explain its analysis "with sufficient clarity" to allow stakeholders to determine whether the analysis is "the product of reasoned decisionmaking." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 464, 475 (4th Cir. 2013). For example, EPA relied on several data sets that it does not dispute are incomplete and/or inaccessible. But it never "cogently explain[ed] why." *Id.* at 473.

EPA sought to excuse its failure to properly revise the drafts or otherwise respond to comments by asserting that the revisions were precluded by a legal obligation to complete biological opinions based upon the BEs by December 31, 2017.[2] That position is incorrect. EPA is not bound by any such obligation.

EPA presumably based its assertion on stipulations entered in court cases by NMFS and FWS. The one of those stipulations to which NMFS was a party did commit NMFS to complete a nationwide OP biological opinion by December 31, 2017. Stipulation and Order to Amend the Stipulated Settlement Agreement Affirmed by this Court on August 1, 2008, *NW Coalition for Alternatives to Pesticides, et al. v. National Marine Fisheries Service*, No. 07-cv-01791 (W.D. Wash., May 21, 2014) ("*NCAP v. NMFS*"), Dkt. No. 50, at 6. But a party to a settlement agreement may request, by motion, that the court modify the settlement agreement for any "reason that justifies relief." Fed. R. Civ. P. 60. Thus, rather than issue flawed BEs, EPA could have asked NMFS to file a motion to modify the *NCAP v. NMFS* settlement agreement deadline so EPA could adequately fulfill its own statutory obligations.[3] Our clients believe there is significant documentation to support a deadline change.

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[2] Office of Chemical Safety and Pollution Prevention's Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, at 2 (Jan. 17, 2017), *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf.

[3] FWS entered into an analogous stipulation in *Center for Biological Diversity v. U.S. Fish and Wildlife Service et al.* *See* Stipulation Amending Original Stipulated Settlement and Order, No. 11-cv-5108 (N.D. Cal., July 28, 2014), Dkt. No. 87 ("Amended Stipulated Settlement"). But that stipulation expressly states that FWS "is not obligated to" complete OP consultations by December

Finally, EPA compounded its error by taking the position that it would not revisit these BEs even while acknowledging their shortcomings. EPA cannot dodge its ESA statutory obligation to rely on the "best scientific and commercial data available."[4] At this point, EPA should withdraw the BEs from the Services and leave it to NMFS to address the existing settlement agreement deadline.

We recently have written to Secretaries Ross and Zinke asking that they similarly direct NMFS and FWS, respectively, to return the BEs to EPA and halt any work on preparation of biological opinions based on them, but urge that you not await their actions before withdrawing the BEs.

Thank you for your prompt attention to this request.

Sincerely,

David B. Weinberg

Counsel to Dow AgroSciences, LLC; Makhteshim Agan of North America, Inc., d/b/a "ADAMA"; and FMC Corporation

Enclosures

31, 2017, and it provides that if there were to be a delay the parties would meet and confer to discuss appropriate actions and, if necessary, petition the Court to resolve any dispute. Amended Stipulated Settlement at 4-5.

[4] ESA Section 7(a)(2), 16 U.S.C. § 1536(a)(2).

cc (without attachments except as indicated):

The Honorable Ryan Zinke, Secretary of the United States Department of the Interior
The Honorable Wilbur Ross, Secretary of the United States Department of Commerce
The Honorable Michael Young, Acting Deputy Secretary of the United States Department of Agriculture
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