Center for Regulatory Effectiveness' ("CRE") Comments on Streamlining Regulatory Processes and Reducing Regulatory Burden; National Marine Fisheries Service ("NMFS") and National Ocean Service; 82 FR 31576, 31577 (July 7, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-07-07/pdf/2017-14167.pdf .

CRE's Comments on Endangered Species Act ("ESA") Section 7 Consultations.

Comments Filed August 21, 2017, at www.regulations.gov, Docket No. NOAA– NMFS–2017–0067

I. Executive Summary

These CRE comments address ESA Section 7 consultations among NMFS, the Environmental Protection Agency ("EPA") and the Fish and Wildlife Service ("FWS") (referred to collectively as "the Agencies") during pesticide registration review and registration. [1]

The Agencies have developed and are applying irrational and impracticable new ESA consultation rules for pesticides. These new rules dictate the process by which ESA section 7 consultations must occur, and prescribe the use of several unvalidated computer models. These new rules, which are legally binding, respond in part to a National Academy of Sciences report, but they are in way compelled by that NAS report. These new ESA consultation rules are extremely time consuming and resource intensive. They are unduly burdensome to all involved, including the Agencies. The Agencies do not have the resources to implement the new rules for all the pesticides that are subject to them. The Agencies' inability to implement the new ESA consultation rules will cause wasteful litigation.

The new ESA consultation rules will provide few if any benefits and cause enormous costs. These costs include costs resulting from the prohibition of many pesticides that have been safely manufactured, sold and used for decades. The new ESA consultation rules are economically significant rules and regulatory actions under Executive Orders 12866 and 13563; yet the Agencies have not complied with the requirements of these Executive Orders.

These new ESA Consultation rules violate many other legal requirements, For example, they

- violate the Information Quality Act ("IQA") by requiring use of unvalidated and inaccurate models ("ESA Models");

[1] CRE is filing separate comments that address NMFS' regulation of "Takes" under the Marine Mammal Protection Act ("MMPA").

•violate OMB/OIRA's Final Information Quality Bulletin for Peer Review;

•violate the FIFRA and ESA time limits on consultation; and

•violate Executive Orders 13771 and 13777.

The Agencies should stop using their new ESA consultation rules. Before even considering use of the new rules, the agencies should take those actions necessary to remedy the violations discussed above and below. These actions include by way of example and without limitation

1) sending the new ESA consultation rules and their ESA Models to OMB/OIRA for review before they are used to review, register, or otherwise regulate pesticides;

2) properly validating the ESA Models before they are used to review, register or otherwise regulate pesticides; and

3) submitting the new ESA consulting rules and their ESA Models to peer review in accordance with OMB's Peer Review Bulletin before they are used to review, register, or otherwise regulate pesticides.

The U.S. Department of Agriculture ("USDA") agrees that the Agencies should not use the new ESA consulting rules.[2] The USDA was one of the agencies that requested NAS review of the ESA pesticide consultations process. The USDA also regulates pesticides. The USDA's opposition to the Agencies' new ESA consultation rules should be given particular weight.

II. NMFS' New ESA Section 7 Consultation Rules Violate Executive Orders 12866 and 13563

A) *The Agencies' New ESA Consultation Rules Are Significant Regulatory Actions and Rules Subject to Executive Orders 12866 and 13563*

NMFS, EPA and FWS have developed new ESA Section 7 consultation "processes" for pesticides. The Agencies are applying these new ESA consultation processes "collaboratively" as part of EPA's FIFRA pesticide registration and review program. These new processes are mandatory. They are legally binding on both the Agencies and the pesticide industry. They must and "will be used" during ESA Section 7 pesticide consultations.[3] They are being used now during ESA consultations for

[2] These USDA comments are available at https://www.regulations.gov/document?D=EPA-HQ-OA-2017-0190-32568 .

[3] See, *e.g.,* page 1, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences*

several pesticides.[4]

The new ESA consultation rules are not limited to a single pesticide review or registration. They will be used for all pesticides during each individual pesticide's registration or re-registration by EPA.[5]

These new rules are Agency statements of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy, or to describe the procedure or practice requirements of the Agencies. Consequently, they are "regulatory actions" and a "regulation or rule" subject to Executive Orders 12866 and 13563.[6]

The Agencies have already codified some ESA Section 7 consultation rules.[7] The Agencies have not yet codified their new ESA consultation rules, even though they are using the rules now to review and regulate pesticides, and even though the rules are significant rules and regulatory actions subject to the Executive Order requirements.

The new ESA consultation rules are "significant" rules and regulatory actions subject to Executive Order 12866 and 13563 because they

"a) will have an economic impact greater than $100,000,000;

b) adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; and [are]

c) novel, controversial or precedent-setting or have significant interagency interest." [8]

April 2013 Report, at https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf ; Pages 5-10 and 16, *Interim Report to Congress on Endangered Species Act Implementation in Pesticide Evaluation Programs,* at https://www.epa.gov/sites/production/files/2015-07/documents/esareporttocongress.pdf

[4] *See, e.g., Pesticide Registrations and Endangered Species Act Consultations*, at https://www.fws.gov/endangered/what-we-do/pesticide-consultation.html

[5] See, *e.g.,* https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments; and https://www.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act .

[6] See, *e.g.*, Executive Order 12866, Sections 3(d),(e), at https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf .

[7] 50 CFR Part 402, at https://www.law.cornell.edu/cfr/text/50/part-402 .

[8]Executive Order 12866, Section 3(f), at https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf .

With regard to "controversial" and "significant interagency interest" in item "c" above, the USDA has recommended in written comments against further development and use of the new ESA consultation rules.[9] Moreover, the new rules will preclude compliance with FIFRA and ESA deadlines, thereby fomenting endless litigation.[10]

With regard to the economic impact concerns of items "a" and "b" above, the Agencies are using the new ESA consultation rules to ban three pesticides. These three arbitrarily doomed pesticides are chlorpyrifos, diazinon, and malathion. This ban will have severe economic impacts on manufacturers and farmers well in excess of $100,000,000.

The USDA. filed comments with EPA that described chlorpyrifos "as a critical part of Integrated pest management (IPM) in well over 50 crops grown throughout the United States."[11] The USDA explained that there are no effective alternatives available for several crops. Consequently, banning chorpyrifos will have "immediate and notable impacts on the economic and production stability of many farm crops."[12] The crops for which chlorpyrifos is "critical" have annual production values ranging from $3.4 billion to $13.1 billion.[13]

The USDA also submitted comments to EPA which explained that "[m]alathion is critical to the boll weevil eradication program as it is the key control option available."[14] Banning malathion could cause cotton economic losses well in excess of

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[9] These USDA comments are available at https://www.regulations.gov/document?D=EPA-HQ-OA-2017-0190-32568 .

[10] See page 4 of CropLife comments at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0907, citing 16 U.S.C. 1536(b)(1(8).

[11] USDA Public Comments on EPA's Proposed Chorpyrifos Ban (January 5, 2016), page 10, at http://storage.dow.com.edgesuite.net/dowagro/chlorpyrifos/USDA_Comments_to_EPA_on_CHP.pdf .

[12] *Id.,* at http://storage.dow.com.edgesuite.net/dowagro/chlorpyrifos/USDA_Comments_to_EPA_on_CHP.pdf .

[13] *Id.*, at http://storage.dow.com.edgesuite.net/dowagro/chlorpyrifos/USDA_Comments_to_EPA_on_CHP.pdf .

[14] USDA Public Comments on Malathion (Dec. 21, 2016), page 9, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0115 .

$500,000,000 per year.[15] The USDA comments further explain the substantial losses to several other crops if malathion were banned.[16]

As one last example, the Almond & Hullers Association filed comments with EPA explaining the dire impact on the California almond industry if Diazinon were banned. [17]

B) The Agencies Violated the Requirements of Executive Orders 12866 and 13563

The Agencies violated Executive Orders 12866 and 13563 by not sending the new ESA Pesticide Consultation rules for review by OMB/OIRA.[18] The Agencies' previously sent other ESA consultation rules to OMB/OIRA for review under Executive Order 12866.[19] There is no excuse for the Agencies' failure to comply with the Executive Orders' requirements for the new ESA consultation rules.

The Agencies also violated Executive Order 12866 by not designing the new ESA consultation rules "in the most cost-effective manner to achieve the regulatory objective."[20]

The Agencies also violated Executive Order 12866 by not "assess[ing] both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." [21]

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[15] *Id*., pages 9-11, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0115 .

[16] *Id*., pages 12-23, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0115 .

[17] Almond Hullers & Processors Association Comments on Chlorpyrifos, Diazinon, and Malathion (June 10, 2016), at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0351-0055 .

[18] *E.g.,* Executive Order 12866, Sections 2(b). 6(a)(3), at https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf ; Cost-Benefit and Other Analysis Requirements in the Rulemaking Process (CRS 2014), page 4 at https://fas.org/sgp/crs/misc/R41974.pdf .

[19] See, *e.g.,* Joint Counterpart Endangered Species Act Section 7 Consultation Regulations, 68 FR 33805, 33810 col. 1 (June 5, 2003), at https://www.gpo.gov/fdsys/pkg/FR-2003-06-05/pdf/03-14108.pdf

[20] *E.g.,* Executive Order 12866, Section 1 (b) (5), at https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf ; Cost-Benefit and Other Analysis Requirements in the Rulemaking Process (CRS 2014), page 4 at https://fas.org/sgp/crs/misc/R41974.pdf .

[21] *E.g*., Executive Order 12866, Section 1(b)(6), at https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf ; Cost-Benefit and

The Agencies also violated Executive Order 12866 by not including the new ESA consultation rules on their Unified Regulatory Agenda and Regulatory Plans.[22]

III. The Agencies' New ESA Consultation Rules Require Computer Models that Violate the IQA, Violate the OMB/OIRA Peer Review Bulletin, and Violate Executive Orders 12866, 13563, 13771 and 13777

The Agencies' new ESA consulting rules require the use of and are based on several computer models ("ESA Models"). Like the rest of the new rules, the ESA Models are not limited to a specific pesticide consultation or registration. The Agencies intend to use these ESA Models for all ESA pesticide consultations and registrations.[23] They are an integral and essential part of the Agencies' new ESA consultation rules.

Because the ESA Models are part of the new ESA consultation rules, they violate Executive orders 12866 and 13563 for the reasons discussed above.

The ESA Models also

- violate the Information Quality Act ("IQA");
- violate OMB/OIRA's Final Information Quality Bulletin for Peer Review; and
- violate Executive Orders 13771 and 13777.

A) IQA Violations

The IQA requires that the Agencies validate the ESA Models before they use them to regulate pesticides or for other purposes. Validation is necessary to determine whether the Models are accurate and reliable. Validation has to occur in accordance with published and peer reviewed procedures. The paramount goal of validation is to determine whether the Models' predictions correspond with reality. That must be determined by corroborating the models' predictions with observed data. These validation requirements are well established.[24]

Other Analysis Requirements in the Rulemaking Process (CRS 2014), page 4 at https://fas.org/sgp/crs/misc/R41974.pdf .

[22] *E.g.,* Executive Order 12866, Sections 4(a), (b), at https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf ; Cost-Benefit and Other Analysis Requirements in the Rulemaking Process (CRS 2014), page 4 at https://fas.org/sgp/crs/misc/R41974.pdf .

[23] See https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments .

[24] See, *e.g.*, Page 35, Oct. 26, 2011 Minutes for July 26-28 atrazine SAP, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0399-0080 ; August

The Agencies have never shown this corroboration. Consequently, the ESA Models cannot now be used to regulate; yet the Agencies are using them to assess pesticides during FIFRA and ESA review.

There are many other standards that the ESA Models must meet before they can be used to regulate. The ESA Models and other models used by the Agencies do not meet these other IQA standards for the following and other reasons.

- The final chlorpyrifos Biological Evaluation ("BE") is not transparent. For example, "key cells in the WoE tools used in making species calls [these tools are among the ESA Models] remained hidden and locked. In addition, drift models were unreferenced and unexplained, and methods were not consistently presented, with numerous contradictions found throughout the final document and across prescribed methods…."[25]

- "Inappropriate Use of Aquatic Exposure Models. The models used for the aquatic exposure assessment (PRZM5 and VVWM) were designed to simulate single agricultural fields and small, static water bodies. In the BE for chlorpyrifos, these models were used to simulate landscape and aquatic fate processes in continental-scale watersheds and rivers. Even from a screening-level perspective, this approach was a gross overextension of the models' capabilities. The results obtained from

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11, 2009 Minutes for May 12-14, 2009 SAP, page 17, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0104-0062 ; July 20, 2004 Minutes for March 30-31, 2004 SAP, page 54, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2004-0005-0071 ; National Academy of Sciences, Models in Environmental Regulatory Decision Making (2007), pages 114, 122 and 147, at http://www.nap.edu/download.php?record_id=11972# ; Guidance on the Development, Evaluation, and Application of Environmental Models (EPA 2009) ("CREM Guidance"), page vii, at https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf ; and Guidance for Quality Assurance Project Plans for Modeling (EPA 2002), page 41, at https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf . For the IQA's accuracy requirements, see, *e.g.*, NAS ESA Report, Pages 68-69, at http://www.nap.edu/download.php?record_id=11972#; and EPA IQA Guidelines, page 15, at https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf .

[25] *Response to Dow's Final Biological Evaluation for Clorpyrifos,* Dow Agrosciences, Intrinsik and Stone Environmental (April 11, 2017) ("Dow Response"), page 11, at http://i2.cdn.turner.com/cnn/2017/images/04/20/be.letter.enclosures.--.combined.be.response.documents.pdf

these models and applied to represent environments they were never designed for are not acceptable."[26]

• "Model Quality Assurance. In comments submitted on the draft BE, a number of errors in the WoE tools [among the ESA Models] were identified. Many of these errors were not corrected for the final BE. …EPA has not sought an independent evaluation of the quality and utility of the WoE tools. Though the principal model in the WoE tools (TEDtool) is purportedly derived from existing EPA toolbox applications, considerable changes have been made in the changeover that are noted herein…. The WoE tools [should] be independently reviewed before being used in a regulatory capacity."[27]

On this IQA issue, CRE also incorporates by reference the Dow Response to EPA, Section 4 (Aquatic Exposure Modeling) and Section 5.1 (WoE Tools and Species and Critical Habitat Calls) into CRE's comments.[28]

CRE also incorporates by reference Sections 2 and 3 of the CropLife America comments to EPA of June 10, 2016, into CRE's comments.[29]

These two incorporated comments identify and discuss in detail many quality flaws in the ESA Models. These flaws violate the IQA Guidelines.

The ESA Models' violation of multiple IQA requirements adversely affects implementation of the rules codified at 40 CFR Part 158: "Data Requirements for Pesticides." Part 158 expressly applies to EPA's data requirements for assessing pesticide risks to "endangered species."[30] The Agencies intend to use the ESA Models to meet these data requirements. The National Academy of Sciences (NAS)

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[26] *Id.* page 10, at http://i2.cdn.turner.com/cnn/2017/images/04/20/be.letter.enclosures.--.combined.be.response.documents.pdf

[27] *Id.*, page 9, at http://i2.cdn.turner.com/cnn/2017/images/04/20/be.letter.enclosures.--.combined.be.response.documents.pdf .

[28] These Dow comments are available at http://i2.cdn.turner.com/cnn/2017/images/04/20/be.letter.enclosures.--.combined.be.response.documents.pdf .

[29] These CropLife comments are available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0907 .

[30] 40 CFR § 158.2060 (e)(12), (14), at https://www.law.cornell.edu/cfr/text/40/158.2060 . See also "Data Requirements for Pesticide Registration," at https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration, where EPA explains that the registration data required by Part 158 allow the Agency to determine "whether a pesticide could harm certain nontarget organisms and endangered species…."

deemed the Part 158 rules so important that it included a portion of them as Appendix A to the NAS report on ESA pesticide consultations.[31]

Finally, EPA staff made statements suggesting their belief that the Agencies do not have to corroborate model results with real world data. These statements are based on the EPA staff's claim that they only have to identify one individual of an endangered species that is likely to be adversely affected by a pesticide in order to advance that pesticide to the ESA consultation stage where one of the Services prepares a BiOp for the pesticide.

These EPA staff statements are incorrect because they ultimately depend on unvalidated ESA Models.

For example, EPA's BE determines that Diazinon is likely to adversely affect 1437 different ESA listed species.[32] For Malathion, this number is 1778.[33]

There is no real world evidence showing these adverse effects. EPA and NMFS do not have field data or any other data showing that Diazinon and/or Malathion actually adversely affect individuals from each of these thousands of species. EPA, NMFS, and FWS instead rely on their flawed models to conjure up these adverse effects.

As demonstrated above, consistency with observed field data is a crucial standard in determining whether the ESA Models are validated, meet IQA standards, and can be used to regulate.

The ESA Models do not meet this crucial validation standard. Therefore, they cannot be used to determine adverse effects for one or any number of individuals during ESA pesticide consultations or in any other regulatory context.

B) OMB Peer Review Bulletin Violations

The new ESA consulting rules and their ESA Models are also inconsistent with the requirements of OMB's Peer Review Bulletin. The new rules and their models--and the Biological Evaluations ("BEs") and Biological Opinions ("BiOps") using them--are

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[31] Assessing Risks to Endangered and Threatened Species from Pesticides (NAS April 2013), at https://www.nap.edu/download/18344# ("NAS ESA Report").
[32] Diazinon Executive Summary, at https://www.epa.gov/endangered-species/biological-evaluation-chapters-diazinon-esa-assessment#executive-summary .
[33] Malathion Executive Summary, at https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment .

Highly Influential Scientific Assessments ("HISA").[34] Yet the new rules and their models--and the BEs and BiOps using them--have never been peer reviewed in compliance with OMB's Peer Review Bulletin.

NMFS and FWS have forcefully stated to EPA the Services' belief that peer review is essential for models used in pesticide ESA consultation, and that FIFRA SAP review is the preferred peer review vehicle.[35]

EPA agrees that SAP review is required before EPA can use models to regulate pesticides.[36]

This peer review must be conducted in accordance with the HISA requirements in OMB's Peer Review Bulletin because the new rules and their models, and the BEs and BiOps based on them, are scientific assessments that could have a potential impact of more than $500 million in any year.[37] This economic impact is discussed above in connection with Executive Order 12866 violations.

There are reasons besides economic impact why peer review must be conducted in accordance with the OMB Peer Review Bulletin's requirements for HISA. The new rules and their models, and the BEs and BiOps based on them, are scientific assessments that are "novel, controversial or precedent-setting or [have] significant interagency interest."[38]

With regard to "significant interagency interest," three agencies—EPA, FWS and NMFS—intend to use the new rules and their models to regulate the entire pesticide industry.[39] The USDA is a fourth involved agency, and is critical of the other agencies' work.

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[34] OMB's Final Information Quality Bulletin on Peer Review is available at http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf .

[35] *E.g.*, pages 6, 15-16, 18 and 20, in FWS' and NMFS' Letter to EPA dated January 26, 2004, available at https://training.fws.gov/resources/course-resources/pesticides/Risk%20Assessment/Pestevaluation.pdf.

[36] *E.g.,* Atrazine Final Work Plan, Case Number 0062 (EPA 2013), Pages 4-5, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-0308 .

[37] See EPA Peer Review Handbook (4th Ed.), page 16, at https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf .

[38] EPA Peer Review Handbook (4th Ed.), page 16, at https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf .

[39] See https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments .

With regard to both "significant interagency interest" and "controversial," the new rules and their models are the result of a request by EPA, FWS, NMFS and USDA that the NAS provide guidance to the agencies in hope of resolving heated disputes between them on how to conduct pesticide consultations. [40]

This area is so controversial that EPA maintains a separate litigation website for it.[41] The new rules and their models, and the BEs and BiOps based on them, will be used to ban many pesticides that have been safely used for decades.

The new rules and their models, and the BEs and BiOps based on them, are for the reasons discussed above subject to HISA requirements under the OMB Peer Review Bulletin.

Among other requirements, the OMB Peer Review Bulletin requires that the Agencies inform peer reviewers "of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws."[42] This duty requires that that the Agencies inform peer reviewers of the validation criteria discussed above.

Under OMB's Peer Review Bulletin, this duty also applies to the less stringently reviewed category of Influential Scientific Information ("ISI").[43] EPA's Peer Review Handbook explains that a federal agency's non-HISA scientific or technical work product is subject to the Peer Review Bulletin's ISI requirements if it

> "Will have or does have a clear and substantial impact on important public policies or private sector decisions. Decision Makers should consider the following factors when determining whether a product is likely to be influential:
>
> • Establishes a significant precedent, model or methodology.
>
> • Is likely to have an annual effect on the economy of $100 million or more.

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[40] https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and .
[41] https://www.epa.gov/endangered-species/endangered-species-litigation-and-associated-pesticide-limitations .
[42] OMB Peer Review Bulletin, page 25, at http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf .
[43] OMB Peer Review Bulletin, page 37, at http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf .

• Is likely to adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or state, tribal or local governments or communities.

• Addresses significant controversial issues.

• Focuses on significant emerging issues.

• Has significant cross-Agency/interagency implications.
• Involves a significant investment of Agency resources.

• Considers an innovative approach for a previously defined problem/process/methodology.

• Satisfies a statutory or other legal mandate for peer review."[44]

The new ESA consultation rules and their ESA Models meet all of these criteria. For example, with respect to the new rules and their models, the IQA provides "a statutory or other legal mandate for peer review."

C) FIFRA and ESA Time Limit Violations

CropLife America filed the following comments, which CRE incorporates by reference:

> "THE INTERIM APPROACHES WILL NOT ALLOW THE AGENCIES TO MEET STATUTORY TIMELINES
>
> Both the ESA and FIFRA include specific mandates for timely action. FIFRA requires EPA to review every registered pesticide every fifteen years. Currently, EPA intends to complete ESA assessments and consultations as part of registration review. At the current rate that EPA and the Services are working, as evidenced by the BEs, there is simply no way that EPA can complete registration review within statutory timelines. With regard to the statutory timelines set out in the ESA, these draft BEs make it abundantly clear that EPA and the Services cannot conclude any formal consultation within 150 days from initiation of formal consultation, as is required by the ESA."[45]

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[44] EPA Peer Review Handbook, page 16, at https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf .
[45] Page 4 of CropLife comments at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0907, citing 16 U.S.C. 1536(b)(1(8).

D) Executive Order 13771 and 13777 Violations

The new ESA consultation rules, their ESA Models, and many other aspects of the new rules, violate Executive Orders 13771 and 13777 because, as discussed above and in the incorporated documents, they

> "i) eliminate jobs, or inhibit job creation;
>
> (ii) are outdated, unnecessary, or ineffective;
>
> (iii) impose costs that exceed benefits;
>
> (iv) create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies; [and]
>
> (v) are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) [aka the Information Quality Act/IQA] , or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility…."[46]

IV. Recommended Actions

The Agencies should stop using the new ESA consultation rules.

The Agencies should take those actions necessary to remedy the violations discussed above in these comments. These actions include by way of example and without limitation

1) sending the new ESA consultation rules and their ESA Models to OMB/OIRA for review before they are used to review, register, or otherwise regulate pesticides;

2) properly validating the ESA Models before they are used to review, register, or otherwise regulate pesticides; and

3) submitting the new ESA consulting rules and their ESA Models to peer review in accordance with OMB's Peer Review Bulletin before they are used to review, register, or otherwise regulate pesticides.

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[46] See Executive Order 13777 Sec. 3, at https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda .

We thank you for this opportunity to comment.

Respectfully submitted,

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