

Center for Regulatory Effectiveness' ("CRE") Comments on EPA's Request for Input on Regulations That May Be Appropriate for Repeal, Replacement, or Modification In Accordance with Executive Order 13777, "Enforcing the Regulatory Reform Agenda," 82 FR 17793 (April 13, 2017), at <https://www.gpo.gov/fdsys/pkg/FR-2017-04-13/pdf/2017-07500.pdf>

**Comments Filed at www.regulations.gov,
ID: EPA-HQ-OA-2017-0190-0042.**

**I. In Accordance with Executive Orders 13771 and 13777,
EPA and the Services
Should Repeal, Replace or Modify Their
New Procedures and Practice Requirements for Consulting on
Pesticide Registrations Under FIFRA and the ESA**

The Environmental Protection Agency ("EPA"), the Fish and Wildlife Service ("FWS"), and the National Oceanic and Atmospheric Administration/National Marine Fisheries Service ("NOAA/NMFS") are working together to develop new procedures and practice requirements for consulting on all pesticide registrations under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and the Endangered Species Act ("ESA").¹

These new pesticide ESA consultation procedures and practice requirements will be used for all pesticides during each individual pesticide's registration or re-registration by EPA. These new procedures and requirements 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, these new procedures and practice requirements are subject to Executive Orders 13771 and 13777.

These new ESA pesticide consultation procedures and practice requirements violate the Executive Orders because they will result in the banning of many pesticides that have been safely used for decades. These new procedures and practice requirements are also extremely time and resource intensive, and they are burdensome to all involved, including the agencies. They will provide few if any benefits and cause enormous costs. They are not legally required, and they violate many legal requirements including the Information Quality Act ("IQA").

For example, EPA, NOAA/NMFS and FWS ("the Agencies") are using models during their new ESA pesticide consultations ("ESA Models"). Like the rest of the new

¹ See, e.g., <https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and> .

consultation procedures and practice requirements, the ESA Models are not limited to a specific license or registration. The Agencies intend to use these ESA Models for all ESA pesticide consultations.²

These ESA Models are inconsistent with IQA requirements. The IQA requires that the Agencies demonstrate that the Models are accurate and reliable before they are used. This IQA requirement includes demonstrating that the Models have been properly validated. Proper validation includes showing that the ESA Models' output corresponds with real world observations. The ESA Models have never met this and other IQA requirements. They cannot meet these IQA requirements because they predict ecological harm that does not occur. They generate data that are not accurate, reliable and transparent.

The ESA Models are also inconsistent with the requirements of OMB's Final Information Quality Bulletin on Peer Review ("Peer Review Bulletin"). The ESA Models--and the Biological Evaluations ("BEs") and Biological Opinions ("BiOps") using them--are Highly Influential Scientific Assessments ("HISA").³ Yet the ESA Models--and the BEs and BiOps using them--have never been peer reviewed in compliance with OMB's IQA Peer Review Bulletin.

The ESA Models' inconsistency with multiple IQA requirements adversely affects EPA's 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."⁴ The Agencies intend to use the ESA Models to meet these data requirements. The National Academy of Sciences (NAS) 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.⁵

The ESA Models, and many other aspects of the new pesticide ESA consulting procedures and practice requirements, violate Executive Orders 13771 and 13777 because they

² See <https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments>.

³ 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.

⁴ 40 CFR § 158.2060 (e)(12), (14), at <https://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol24/pdf/CFR-2011-title40-vol24-part158.pdf>. 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...."

⁵ Assessing Risks to Endangered and Threatened Species from Pesticides (NAS April 2013), at <https://www.nap.edu/download/18344#> ("NAS ESA Report").

- “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) [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....”⁶

Consequently, EPA’s Regulatory Reform Task Force should recommend that the EPA Administrator take those actions necessary to ensure that 40 CFR Part 158, and all other relevant rules, do not allow use of the ESA Models, or of any other aspects of the new pesticide ESA consulting procedures and practice requirements that violate the IQA and/or Executive Orders 13771 and 13777.

CRE is also filing copies of these comments with FWS and NOAA/NMFS. The ESA Models, and other aspects of the new ESA pesticide consulting procedures and practice, violate the IQA and Executive Orders 13771 and 13777. Consequently, they adversely affect the Services’ implementation of 50 CFR Part 402: “ESA Section 7 Regulations—Interagency Cooperation.”⁷

The FWS and NOAA/NMFS Regulatory Reform Task Forces should therefore recommend that their agency heads take those actions necessary to ensure that 50 CFR Part 402, and all other relevant rules, do not allow use of the ESA Models, or of any other aspects of the new ESA pesticide consulting procedures and practice requirements that violate the IQA and/or Executive Orders 13771 and 13777.

The new ESA pesticide consulting procedures and practice requirements, including the ESA Models, are themselves 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 an agency.⁸ Consequently, pursuant to Executive Orders 13771 and 13777, the

⁶ See Executive Order 13777 Sec. 3, at <https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda> .

⁷ <http://www.nmfs.noaa.gov/pr/pdfs/laws/sec7regs.pdf> .

⁸ Compare Executive Order 13771 Sec. 4, at <https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and->

EPA, FWS and NOAA/NMFS Regulatory Reform Task Forces should recommend that their agency heads take those actions necessary to ensure that the new consulting procedures and practice requirements do not violate the IQA and/or the Executive Orders.

The U.S. Department of Agriculture (“USDA”) agrees that EPA and the Services should not proceed with the new ESA consulting procedures and practice requirements. USDA representatives made comments to this effect at EPA’s Pesticide Program Dialogue Committee meeting on May 4, 2017, which was devoted to public comments on Executive Order 13777 and pesticides regulation. The USDA was one of the agencies that requested NAS review of the ESA pesticide consultations process. The USDA’s opposition to EPA and the Service’s current implementation of the NAS report should be given particular weight.

**II. The ESA Models Violate the IQA
Because They Are Not Validated:
E.g., They Have Never Been Corroborated with Real World Data**

The IQA requires that the Agencies validate the ESA Models before they use them to regulate pesticides or anything else. Validation is necessary to determine whether the Models are accurate and reliable, and 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. The Agencies have never made this corroboration. Consequently, the ESA Models cannot now be used to regulate; yet the Agencies improperly intend to rely on them to develop the risk assessment data used during a new ESA pesticide consultation process.

The National Academy of Sciences (“NAS”) reviewed the Agencies’ ESA consultation process at the Agencies’ request. The NAS issued a report on this review that emphasizes the importance of IQA compliance. The NAS ESA Report explains that IQA Guidelines require the Agencies to ensure “that the models used in regulatory proceedings are objective, transparent, and reproducible....”⁹ Objectivity includes

[controlling](https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda) with Executive Order 13777 Sec. 2 and 3, at <https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda> .

⁹ NAS ESA Report, Pages 68-69, at http://www.nap.edu/download.php?record_id=11972# .

demonstrating that the ESA Models are accurate and reliable.¹⁰ This demonstration is part of model validation.

Three FIFRA Science Advisory Panels (“SAP”), another NAS report, and two EPA guidance documents emphasize that modeled ecological effects must be compared with field data in order to determine whether the modeled effects are real.¹¹ This comparison is essential to validating the models for regulatory use.

The other NAS report explained to EPA that “[c]omparing model results with observations is a central component of any effort to evaluate models.”¹² Therefore, EPA’s “Elements of Model Evaluation” must include

“Corroboration of model results with observations – Comparison of model results with data collected in the field or laboratory to assess the accuracy and improve the performance of the model.”¹³

The NAS rendered this advice during its peer review of models guidance being developed by EPA’s Council for Regulatory Environmental Modeling (“CREM”). After NAS peer review, EPA published final CREM Guidance that explains:

“Model evaluation is the process for generating information over the life cycle of the project that helps determine whether a model and its analytical results are of sufficient quality to serve as the basis for a decision. Model quality is an attribute that is meaningful only within the context of a specific model application. In simple terms, model evaluation provides information to

¹⁰ *E.g.*, EPA IQA Guidelines, page 15, at <https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf>.

¹¹ *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 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 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 ; 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>.

¹² *Models in Environmental Regulatory Decision Making*, page 122, at <https://www.nap.edu/download/11972#>.

¹³ *Id.*, page 114, at http://www.nap.edu/download.php?record_id=11972#.

help answer the following questions: (a) How have the principles of sound science been addressed during model development? (b) How is the choice of model supported by the quantity and quality of available data? **(c) How closely does the model approximate the real system of interest?** (d) How well does the model perform the specified task while meeting the objectives set by quality assurance project planning.”¹⁴

In EPA’s earlier *Guidance for Quality Assurance Project Plans for Modeling (EPA 2002)*, EPA similarly explains that:

“models are calibrated by comparing the predictions (output) for a given set of assumed conditions to observed data for the same conditions. This comparison allows the modeler to evaluate whether the model and its parameters reasonably represent the environment of interest...”¹⁵

The CREM Guidelines and the NAS Model Report constitute the Gold Standard for developing, validating and using regulatory models. They are not limited to EPA. They have already been adopted by other agencies, including NOAA/NMFS.

NOAA/NMFS commissioned external peer review to determine whether the Acoustic Integration Model (“AIM”) meets CREM Guidelines, and is therefore properly validated and acceptable for regulatory use in determining “takes” under the Marine Mammal Protection Act. The Peer Review Panel’s report explains:

“The three terms of reference [by NMFS] required that the Panel evaluate whether AIM correctly implements the models and data upon which it was based; whether animal movements are adequately simulated; and **whether AIM meets the Council for Regulatory Monitoring (CREM) guidelines for model development and evaluation.**”¹⁶

EPA staff have made statements suggesting their belief that EPA and the Services 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.

¹⁴ CREM Guidance, page vii, at https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf (emphasis added).

¹⁵ Page 41, at <https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf> .

¹⁶ Page 1 at http://www.nmfs.noaa.gov/pr/pdfs/permits/lfa_aim_review.pdf (emphasis added).

EPA's BE determines that Diazinon is likely to adversely affect 1437 different ESA listed species.¹⁷ For Malathion, this number is 1778.¹⁸

There is no real world evidence showing these adverse effects. EPA and the Services 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 listed species. EPA and the Services instead rely on 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 meet the CREM Guidelines, the NAS Model Report, and the IQA Guidelines. This is an IQA standard that applies across the board, including ESA assessments.

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

There are many other standards that the ESA Models must meet before they can be used to regulate. These standards are set forth in detail in the CREM Guidance and NAS Report. 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 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...”¹⁹

- “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

¹⁷ Diazinon Executive Summary, at <https://www.epa.gov/endangered-species/biological-evaluation-chapters-diazinon-esa-assessment#executive-summary>.

¹⁸ Malathion Executive Summary, at <https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment>.

¹⁹ *Response to Dow's Final Biological Evaluation for Chlorpyrifos*, Dow Agrosciences, Intrinsik and Stone Environmental (April 11, 2017) (“Dow Response”), page 11, at http://www.thecre.com/creipd/wp-content/uploads/2017/04/esa_pest_dow_fmc_letter.pdf.

these models and applied to represent environments they were never designed for are not acceptable.”²⁰

- “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.”²¹

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 these CRE comments as if fully set forth herein.

CRE also incorporates by reference Sections 2 and 3 of the CropLife America comments to EPA of June 10, 2016, into these CRE comments as if fully set forth herein.²²

These two incorporated comments identify and discuss in detail many quality flaws in the ESA Models. These flaws violate the IQA Guidelines, and require action under Executive Orders 13771 and 13777.

III. The ESA Models Violate OMB’s Final Information Quality Bulletin for Peer Review Because They Have Not Been Peer Reviewed in Compliance OMB’s Bulletin, Or At All

EPA’s Peer Review Handbook answers the question “Should Environmental Regulatory Models Be Peer Reviewed?” in a manner that requires peer review of the ESA Models:

“In general, the answer is yes. Guidelines for the peer review of environmental regulatory models have been published by the Agency. These can be found on the EPA website under <http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1003E4R.PDF>.”²³

²⁰ *Id.* page 10, at http://www.thecre.com/creipd/wp-content/uploads/2017/04/esa_pest_dow_fmc_letter.pdf.

²¹ *Id.*, page 9, at http://www.thecre.com/creipd/wp-content/uploads/2017/04/esa_pest_dow_fmc_letter.pdf.

²² These CropLife comments are available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0907>.

²³ *Id.* page 52.

EPA's link goes to the Agency's CREM Guidance, which we discussed above. EPA explains that its CREM Guidance

“recommends best practices to help determine when a model, despite its uncertainties, can be appropriately used to inform a decision. Specifically, it recommends that model developers and users: **(a) subject their model to credible, objective peer review**; (b) assess the quality of the data they use; (c) **corroborate their model by evaluating the degree to which it corresponds to the system being modeled**; and (d) perform sensitivity and uncertainty analyses.”²⁴

FWS and NMFS 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.²⁵

EPA agrees that SAP review is required before EPA can use models to regulate pesticides.²⁶

We agree with EPA, NMFS and FWS that the ESA Models should be peer reviewed by FIFRA SAPs before they are used.

This peer review must be conducted in accordance with OMB's Peer Review Bulletin's requirements for Highly Influential Scientific assessments (“HISA”) because the ESA 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.²⁷

For example, the ESA Models will be used to ban the three pesticides that the Agencies are using as guinea pigs for their new ESA consultation process.

These three unfairly and unnecessarily doomed pesticides are chlorpyrifos, diazinon, and malathion.

²⁴ EPA CREM Guidance, page vii (emphasis added), at https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf.

²⁵ *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>.

²⁶ 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>.

²⁷ 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.

The U.S. Department of Agriculture 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.”²⁸ The USDA explained that there are no effective alternatives available for several crops; consequently, banning chlorpyrifos will have “immediate and notable impacts on the economic and production stability of many farm crops.”²⁹ The crops for which chlorpyrifos is “critical” have annual production values ranging from \$3.4 billion to \$13.1 billion.³⁰

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.”³¹ Banning malathion would cause cotton economic losses well in excess of \$500,000,000 per year.³² The USDA comments further explain the substantial losses to several other crops if malathion were banned.³³

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.³⁴

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 ESA Models, and the BEs and BiOps based on them, are scientific assessments that are “novel, controversial or precedent-setting or [have] significant interagency interest.”³⁵

²⁸ USDA Public Comments on EPA’s Proposed Chlorpyrifos Ban (January 5, 2016), page 10, at http://storage.dow.com.edgesuite.net/dowagro/chlorpyrifos/USDA_Comments_to_EPA_on_CHP.pdf .

²⁹ *Id.*, at http://storage.dow.com.edgesuite.net/dowagro/chlorpyrifos/USDA_Comments_to_EPA_on_CHP.pdf .

³⁰ *Id.*, at http://storage.dow.com.edgesuite.net/dowagro/chlorpyrifos/USDA_Comments_to_EPA_on_CHP.pdf .

³¹ USDA Public Comments on Malathion (Dec. 21, 2016), page 9, at

<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0115> .

³² *Id.*, pages 9-11, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0115> .

³³ *Id.*, pages 12-23, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0317-0115> .

³⁴ 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> .

³⁵ 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 .

Three agencies—EPA, FWS and NMFS—are working on the ESA Models and intend to use them to regulate the entire pesticide industry. The USDA is a fourth involved agency, and it is critical of the other agencies’ work.

The ESA Models—and the BEs and BiOps based on them—are intended to be used in all future ESA pesticide consultations.³⁶

The ESA Models—and the BEs and BiOps based on them—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.³⁷

This area is so controversial that EPA maintains a separate litigation website for it.³⁸

The ESA Models—and the BEs and BiOps based on them—will be used to ban many pesticides that have been safely used for decades.

The ESA Models—and the BEs and BiOps based on them—are clearly HISA for purposed of the OMB IQA Peer Review Bulletin.

Among other requirements, the OMB IQA Peer Review Bulletin requires that the Agencies inform peer reviewers “of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws.”³⁹

This duty requires that that the Agencies inform the ESA Models peer reviewers of the validation criteria discussed above in CRE’s comments

Under OMB’s Peer Review Bulletin, this duty also applies to the less stringently reviewed category of Influential Scientific Information (“ISI”).⁴⁰ 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

³⁶ See <https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments> .

³⁷ <https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and> .

³⁸ <https://www.epa.gov/endangered-species/endangered-species-litigation-and-associated-pesticide-limitations> .

³⁹ OMB Peer Review Bulletin, page 25, at http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf .

⁴⁰ OMB Peer Review Bulletin, page 37, at http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf .

“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.
- 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.”⁴¹

The ESA Models meet all of these criteria. For example, the IQA provides “a statutory or other legal mandate for peer review.”

IV. Recommended Actions

Pursuant to Executive Orders 13771 and 13777, EPA’s Regulatory Reform Task Force should recommend that the EPA Administrator take those actions necessary to ensure that 40 CFR Part 158, and all other relevant rules, do not allow use of the ESA Models and/or any other aspects of the new ESA pesticide consulting procedures and practice requirements that violate the IQA and/or Executive Orders 13771 and 13777.

Pursuant to Executive Orders 13771 and 13777, the FWS and NOAA/NMFS Regulatory Reform Task Forces should recommend that their agency heads take

⁴¹ EPA Peer Review Handbook, page 16, at https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

those actions necessary to ensure that 50 CFR Part 402, and all relevant other rules, do not allow use of the ESA Models and/or any other aspects of the new ESA pesticide consulting procedures and practice requirements that violate the IQA and/or Executive Orders 13771 and 13777.

The new ESA pesticide consulting procedures and practice requirements, including the ESA Models, are themselves 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 an agency.⁴² Consequently, pursuant to Executive Orders 13771 and 13777, the EPA, FWS and NOAA/NMFS Regulatory Reform Task Forces should recommend that their agency heads take those actions necessary to ensure that the new consulting procedures and practice requirements do not violate the IQA and/or the Executive Orders.

We thank you for this opportunity to comment.

Respectfully submitted,

Jim J. Tozzi, PhD
Member CRE Board of Advisors
www.TheCRE.com

⁴² Compare Executive Order 13771 Sec. 4, at <https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling> with Executive Order 13777 Sec. 2 and 3, at <https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda>.