

**CENTER FOR REGULATORY EFFECTIVENESS’ (“CRE”) COMMENTS ON  
EPA’S DRAFT BIOLOGICAL EVALUATIONS (“BES”) FOR  
CHLORPYRIFOS (EPA-HQ-OPP-2008-0850),  
DIAZINON (EPA-HQ-OPP-2008-0351), AND  
MALATHION (EPA-HQ-OPP-2009-0317).  
COMMENTS FILED JUNE 10, 2016, AT [WWW.REGULATIONS.GOV](http://WWW.REGULATIONS.GOV)**

**I. EXECUTIVE SUMMARY**

CRE’s comments address Topic 1: flaws in the environmental models used in the draft BEs.<sup>1</sup>

EPA, NMFS and FWS (“the agencies”) have not produced a public record demonstrating that the regulatory models (“ESA models”) that they used for the BEs are properly validated and meet the required quality standards.<sup>2</sup> These standards include transparency and consistency of model predictions with observed field data.

The agencies should not use any of these models until and unless the agencies have successfully completed the following steps:

1) Demonstrate in a public record that all of the ESA models comply with

A) *Guidance on the Development, Evaluation, and Application of Environmental Models* (EPA 2009) (“CREM Guidance”), at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf);

B) National Academy of Sciences, *Models in Environmental Regulatory Decision Making* (2007) (“NAS Report”), at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#); and

C) The Information Quality Act (“IQA”) Guidelines applicable to EPA, NMFS and FWS.<sup>3</sup>

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<sup>1</sup> See page 4 of <https://www3.epa.gov/pesticides/nas/instructions.pdf> for the agencies’ numbered list of comment topics.

<sup>2</sup> These models are all the models and “tools” included and discussed in “Provisional Models for Endangered Species Pesticide Assessments,” at <https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments>.

<sup>2</sup> These models are all the models and “tools” included and discussed in “Provisional Models for Endangered Species Pesticide Assessments,” at <https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments>.

<sup>3</sup> For IQA Guidelines, see, e.g., <https://www.epa.gov/sites/production/files/2015->

2) This public record should include an external peer review report on compliance of the ESA models with the regulatory requirements listed in items 1A-1C above. NMFS has already done this regarding one of its other regulatory model's compliance with CREM Guidance.<sup>4</sup> We suggest use of EPA's Science Advisory Panels ("SAP") for peer review of the ESA models.

## **II. REQUIREMENTS THAT THE ESA MODELS MUST MEET BEFORE THEY CAN BE USED TO REGULATE**

The agencies have to validate the ESA models before they use them to regulate pesticides or anything else. The models have to be validated in accordance with published 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 ESA models also have comply with other validation procedures and quality standards.

If EPA wants to use models that predict adverse environmental effects from continued use of an already registered pesticide in accordance with its Label, then EPA must support the models' predictions with observed data showing those effects. Otherwise, EPA cannot use those models and their predictions to regulate the pesticide's continued use.

These models requirements stem from the following and other documents.

The National Academy of Sciences has advised EPA that

“It is difficult to imagine that a model is acceptable for a regulatory application without some level of performance evaluation showing that the model matches field observations or at least that its results match the results of another well established model.”<sup>5</sup>

“[A]nother well established model” will also have to have been properly validated.

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[07/documents/epa\\_infoqualityguidelines.pdf](#) (EPA);  
[http://www.cio.noaa.gov/services\\_programs/info\\_quality.html](http://www.cio.noaa.gov/services_programs/info_quality.html) (NOAA/NMFS);  
<https://www.fws.gov/informationquality/topics/FWS%20Information%20Quality%20Guidelines.pdf> (FWS).

<sup>4</sup> Page 1 at [http://www.nmfs.noaa.gov/pr/pdfs/permits/lfa\\_aim\\_review.pdf](http://www.nmfs.noaa.gov/pr/pdfs/permits/lfa_aim_review.pdf) .

<sup>5</sup> National Academy of Sciences, *Models in Environmental Regulatory Decision Making* (2007), page 147, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#) .

The NAS further explained to EPA that “[c]omparing model results with observations is a central component of any effort to evaluate models.”<sup>6</sup> 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.”<sup>7</sup>

The NAS rendered this advice during its peer review of models guidance being developed by EPA’s Council for Regulatory Environmental Modeling (“CREM”).

EPA, NMFS and FWS are implementing an NAS report on how to perform pesticide ESA consultations. The agencies should also implement the NAS report on how to develop, validate and apply the models that they use to perform pesticide ESA consultations.

After NAS review, EPA published final CREM Guidance which 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 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?”<sup>8</sup>

EPA similarly explains in its earlier document *Guidance for Quality Assurance Project Plans for Modeling (EPA 2002)* 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....”<sup>9</sup>

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<sup>6</sup> *Id.*, page 122, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#).

<sup>7</sup> *Id.*, page 114, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#).

<sup>8</sup> Page vii, at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf) (emphasis added).

<sup>9</sup> Page 41, at <https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf>.

The Information Quality Act (“IQA”) provides a mechanism for ensuring compliance with these model requirements. During its review of EPA’s regulatory use of models, the NAS emphasized the IQA ‘s impact on EPA’s selection and use of models:

“Requirements such as those in the Information Quality Act may increase the susceptibility of models to challenges because outside parties may file a correction request for information disseminated by agencies.”

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“It is important that EPA institute best practice standards for the evaluation of regulatory models. Best evaluation practices may be much easier for EPA to implement if its resulting rigorous life-cycle evaluation process is perceived as satisfying regulatory requirements, such as those of the Information Quality Act. However, for an evaluation process to meet the spirit and intent of the Information Quality Act, EPA’s evaluation process must include a mechanism for any person to submit information or corrections to a model. Rather than requiring a response within 60 days, as the Information Quality Act does, the evaluation process would involve consideration of that information and response at the appropriate time in the model evaluation process”

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“In addition, the executive branch has been interested in the quality of information and peer review practices used by federal agencies, including EPA. One set of guidelines developed by OMB is Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (OMB 2001). These guidelines, which were mandated by the Information Quality Act (IQA) (Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515, 114 Stat. 2763 [2000]), called for agencies to issue information-quality guidelines to ensure the quality, objectivity, utility, and integrity of information. Recognizing the critical roles that models have in developing information, EPA has developed its own guidelines for data use to ensure that the models used in regulatory proceedings are objective, transparent, and reproducible (EPA 2002a).”

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“A second, more recent opportunity for external challenge to model use in the regulatory process is through the Information Quality Act (Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515, 114 Stat. 2763 [2000]), which is implemented through OMB’s Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (OMB 2001). Some of challenges under the Information Quality Act result from EPA’s occasional ad hoc approach to developing and using models. This statutory provision allows any interested

person to file ‘requests for correction’ on ‘information’ that is ‘unreliable’ or lacks other qualities, such as objectivity or integrity.”<sup>10</sup>

EPA’s CREM website also identifies IQA Guidelines as applicable to models:

**“Modeling EPA Guidance and Publications developed by other EPA Organizations**

Below is a collection several relevant guidance documents and publications about environmental modeling developed by various organizations throughout EPA...

- [EPA Information Quality Guidelines \(PDF\)](#)(61 pp, 529 K, 10/2002).”<sup>11</sup>

The CREM Guidelines and NAS Report constitute the Gold Standard for developing, validating and using regulatory models. They are not limited to EPA, and they have already been adopted by other agencies like NMFS. Both documents emphasize the critical importance of demonstrating that a regulatory model’s predictions are consistent with reality as defined by observational data.

Consistency with observed field data is a crucial standard in determining whether the ESA models meet the CREM Guidelines, NAS report and IQA Guidelines. There are, however, many other standards that models must meet. These standards are set forth in detail in the CREM Guidance and NAS Report. We do not know whether the ESA models meet these standards because we have been unable to identify a public record that documents their development and validation.

If the agencies want to use the ESA models for any regulatory purpose, then a critical first step is production of a public record documenting their development and validation for each intended regulatory use.

### **III. PEER REVIEW OF THE ESA MODELS**

The BEs and the ESA models are part of a scientific assessment that is a “Highly Influential Scientific Assessment” under the IQA and OMB’s guidelines because their

“dissemination could have a potential impact of more than \$500 million in any one year on either the public or private sector; or that the dissemination is novel,

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<sup>10</sup> Pages 12-13, 68-69, 78-79, and 167, at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#) .

<sup>11</sup> EPA CREM site, <https://www.epa.gov/modeling/modeling-epa-guidance-and-publications-developed-other-epa-organizations> (emphasis and links in the original).

controversial, or precedent-setting; or that it has significant interagency interest.”<sup>12</sup>

Consequently, they must be peer reviewed in accordance with OMB’s Guidelines.<sup>13</sup>

In another regulatory context, NMFS has already commissioned external peer review to determine whether the Acoustic Integration Model (“AIM”) meets the CREM Guidelines, and is 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.*”<sup>14</sup>

In order to comply with peer review requirements, we recommend the agencies use EPA’s SAP process for external peer review of the ESA models, given the SAP’s extensive experience with complex pesticide issues.

#### IV. RECOMMENDED ACTIONS

EPA, NMFS and FWS should not use any of the ESA models until and unless the agencies have successfully completed the following two steps:

1) The agencies have demonstrated in a public record that all the ESA models comply with

A) CREM Guidance at [https://www.epa.gov/sites/production/files/2015-04/documents/cred\\_guidance\\_0309.pdf](https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf);

B) NAS Report at [http://www.nap.edu/download.php?record\\_id=11972#](http://www.nap.edu/download.php?record_id=11972#);

C) IQA Guidelines applicable to EPA, NMFS and FWS;<sup>15</sup> and

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<sup>12</sup> OMB’s “Final Information Quality Bulletin for Peer Review,” page 23, at <https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

<sup>13</sup> *Id.*

<sup>14</sup> Page 1 at [http://www.nmfs.noaa.gov/pr/pdfs/permits/lfa\\_aim\\_review.pdf](http://www.nmfs.noaa.gov/pr/pdfs/permits/lfa_aim_review.pdf) (emphasis added).

<sup>15</sup> For IQA Guidelines, see, e.g., [https://www.epa.gov/sites/production/files/2015-07/documents/epa\\_infoqualityguidelines.pdf](https://www.epa.gov/sites/production/files/2015-07/documents/epa_infoqualityguidelines.pdf) (EPA); [http://www.cio.noaa.gov/services\\_programs/info\\_quality.html](http://www.cio.noaa.gov/services_programs/info_quality.html) (NOAA/NMFS); <https://www.fws.gov/informationquality/topics/FWS%20Information%20Quality>

2) EPA's SAP has issued a favorable peer review report on compliance of ESA models with the regulatory requirements listed in items 1A-1C above.

We thank you for the opportunity to submit these comments, and we look forward to the agencies' responses.

Jim J. Tozzi, PhD  
Member, CRE Board of Advisors  
[www.TheCRE.com](http://www.TheCRE.com)