



September 24, 2018

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Public Comments Processing  
Attn: FWS-HQ-ES-2018-0009  
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Ms. Cathy Tortorici  
U.S. Fish and Wildlife Service  
ESA Interagency Cooperation Division  
Office of Protected Resources  
1315 East-West Highway  
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*Submitted via Regulations.gov*

Re: Comments on the Proposal to Revise the Regulations on Interagency Cooperation Under the Endangered Species Act; Docket ID No. FWS-HQ-ES-2018-0009, 83 Fed. Reg. 35178 (July 25, 2018)

Dear Mr. Aubrey and Ms. Tortorici:

CropLife America (CLA)<sup>1</sup> and RISE (Responsible Industry for a Sound Environment) <sup>®2</sup> respectfully submit these comments on the proposal of the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively, the Services) to amend their regulations on interagency cooperation under Section 7 of the Endangered Species Act (ESA).

CLA, RISE and their members are directly affected by the requirements of Section 7 of the ESA as applied to the registration and registration review decisions of the U.S. Environmental

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<sup>1</sup> Established in 1933, CropLife America represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

<sup>2</sup> RISE is a national not-for-profit trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health.

Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

For decades, CLA and RISE have engaged actively at the intersection of ESA and FIFRA, including through litigation and administrative actions. CLA and RISE are committed to working with other stakeholders to help identify and implement pragmatic improvements to the ESA review process for pesticide registration decisions, with the goal of ensuring that our nation can fulfill its agricultural and pest control needs while meeting the requirements of the ESA. For example, we endorsed the January 2018 Memorandum of Agreement among the Environmental Protection Agency, the Department of the Interior, and the Department of Commerce on Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review (the MoA). And in April 2018, CLA was the lead signatory on a multi-stakeholder letter that identified six administrative improvements to the pesticide consultation process under the MoA.<sup>3</sup>

We commend the Services for proactively offering amendments to the interagency cooperation regulations with the intent to “improve and clarify interagency consultation, and make it more efficient and consistent, without compromising conservation of listed species.” 83 Fed. Reg. at 35179. We emphatically support these goals.

We recognize that the proposed regulatory amendments are not directed specifically at ESA reviews for pesticide registration decisions. However, we believe that several of the proposed amendments would support our goals towards pragmatic improvements to the process. In the interest of continuing to provide constructive feedback to the Services on improvements to the pesticide consultation process, we offer the following comments on the proposed revisions as we envision them being applied in the context of pesticide registration decisions. Although our interests are affected by many aspects of the Services’ proposals on interagency consultations, listing and critical habitat, and the Section 4(d) rule, for brevity our comments here focus on those aspects of the consultation process that most directly affect our interests.

**I. The proposed regulations’ “collaborative” approach to consultations would support the establishment of more efficient consultation processes for pesticide registration decisions.**

The Services propose several amendments to their regulations that would further the goals of clarification and efficiency that we have long advocated for in the context of pesticide consultations. We support these proposals that, in combination, could create more efficient processes for pesticide consultations by taking greater advantage of EPA’s expertise in pesticide regulation and the preparation of the associated ecological risk assessments.

For example, the Services have described the proposed amendments (h)(3) and (h)(4) to the current § 402.14(h) as part of “a collaborative process to facilitate the Federal agency’s development of an initiation package that could be used as all or part of the Service’s biological opinion.” 83 Fed. Reg. at 35188. Proposed § 402.14(h)(4) provides that: “[A] Federal agency

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<sup>3</sup> Letter to Secretaries Perdue, Ross and Zinke and Administrator Pruitt, Re: January 31, 2018 Memorandum of Agreement Implementation (April 10, 2018).

and the Service may agree to follow an optional collaborative process that would further the ability of the Service to adopt the information and analysis provided by the Federal agency during consultation in the development of the Service’s biological opinion to improve efficiency in the consultation process and reduce duplicative efforts.” 83 Fed. Reg. at 35192. The Services describe this as the “adoption” of the Federal agency document and explain that the “end result of the adoption consultation process is expected to be the adoption of the initiation package with any necessary supplementary analyses and incidental take statement to be added by the Service as the Secretary’s biological opinion in fulfillment of section 7(b) of the Act.” *Id.*

This proposal would complement the proposed § 402.14(h)(3), which provides that “the Service may adopt all or part of a Federal agency’s initiation package” in its biological opinion, thus allowing the Services “to utilize portions of these documents in the development of our biological opinion to improve efficiency in the consultation process and reduce duplicative efforts.” *Id.* at 35188.

The increased collaboration with the Federal agency the proposed amendments describe is consistent with our longstanding advocacy for greater coordination between EPA and the Services regarding pesticide consultations. We recommend that the Services utilize this proposed approach to collaborate with EPA to establish more efficient processes for consulting on pesticide registration decisions. In recent years, pesticide biological opinions have included thousands of pages and consumed years of work for the Services and EPA. More efficient consultation processes tailored to pesticide decisions would allow the Services to better manage their overall consultation workload and provide the agricultural and public health sectors with timelier and more predictable outcomes under the ESA. More efficient processes would incorporate several key elements, including taking advantage of the EPA’s greater resources and its unique expertise in ecological risk assessments, as well as those of pesticide registration applicants.

We support these proposed amendments to § 402.14(h) and their application to pesticide consultations. Such application would allow the extensive work EPA undertakes to complete its biological evaluations to be more focused, more efficient and to more readily form the basis of a subsequent biological opinion. In this respect, the proposal is similar to the “optional formal consultation procedure for FIFRA actions” at 50 C.F.R. § 402.46, which allows the Services to finalize their biological opinions based primarily on data, analyses, and write-ups that EPA provides, including draft biological opinions.<sup>4</sup>

The proposed § 402.14(l) “Expedited Consultation” provision would similarly further the purposes of this collaboration with the Federal agency – for our purposes here, the EPA. In their proposal, the Services explain that this proposal would “likely involve proposed actions that would otherwise go through the regular formal consultation process and require an incidental take statement.” A key element of this approach is “the development of a sufficient initiation package (as described in § 402.14(c) of the regulations) that provides all the information needed to allow the Services to prepare a streamlined consultation response with mutually agreed-upon

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<sup>4</sup> This part of the 2004 ESA-FIFRA counterpart regulation was upheld in *Washington Toxics Coalition v. U.S. Fish & Wildlife Serv.*, 457 F. Supp. 2d 1158 (W.D. Wash. 2006).

expedited timeframes.” 83 Fed. Reg. at 35188. The contents of a detailed and comprehensive initiation package—particularly one based on an extensive biological evaluation—should provide a strong foundation for an expedited consultation. We encourage the Services to work with EPA to develop that foundation using the expedited consultation process and optional collaborative consultations. Even if the agencies are unable to adopt this approach today, they could start developing the documentation and policies needed to implement the approach in the near future.

To begin implementing an optional collaborative consultation process for pesticides, the Services should work with EPA to develop guidance and templates that reflect a shared understanding among the three agencies about the contents of pesticide biological evaluations and biological opinions. For example, the agencies could draft a document that summarizes the required contents of each section of a biological opinion, including key science, policy, and legal issues. That document should have a goal of providing EPA with enough guidance for it to draft analyses to provide to the Services for their final biological opinions or for the Services to review responsive materials provided by registration applicants. In particular, guidance on evaluating the potential effects of a FIFRA decision on survival and recovery at the species level (rather than at the individual organism level) would help ensure that EPA’s assessments more closely align with the assessments the Services typically conduct during formal consultation.

Ideally, this process should lead to the Services working with EPA to revisit 50 C.F.R. Part 402, Subpart D and promulgate appropriate provisions to replace those vacated in the *Washington Toxics Coalition v. U.S. Fish & Wildlife Serv.*, 457 F. Supp. 2d 1158 (W.D. Wash. 2006) decision. The work done by EPA and the Services to establish the guidelines suggested above should help to establish the common understanding necessary to successfully implement § 402.46 and reconsider/repromulgate the key elements of former § 402.45. We are not urging a delay in the promulgation of the provisions on which comment is sought here but urge that further attention to 50 C.F.R. Part 402, Subpart D be a high priority as a future improvement.

## **II. Refine the scope of consultations to better reflect the most likely pesticide use scenarios.**

The Services propose to modify the definition of “effects of the action” to state, in pertinent part:

*Effects of the action* are all effects on the listed species or critical habitat that are caused by the proposed action, including the effects of other activities that are caused by the proposed action. An effect or activity is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur.

*Proposed 50 C.F.R. § 402.02.*

First, the proposal would clarify that all activities and effects of a proposed action must occur “but for” the action and must be “reasonably certain” to occur. *Id.* Second, the proposal would eliminate the concepts of indirect effects, direct effects, interrelated actions, and interdependent

actions by consolidating all of those concepts under the broader definition of “effects of the action.” *See* 83 Fed. Reg. at 35183.

We support this broadening of the definition. A major issue with pesticide consultations is how to properly define the scope of the proposed action and its effects. The proposed definition could result in pesticide effects determinations (and, ultimately, biological opinions) that better reflect real-world use scenarios. The proposed definition of “effects of the action” simplifies the definitional task and could help eliminate disputes about the scope of a pesticide action. *See* 83 Fed. Reg. at 35183.

In the context of pesticide registration decisions, any potential effects on listed species or their critical habitat result from the *use* of the registered pesticide, not the registration decision itself. Under the proposal, use of a registered pesticide would be considered an “activity” that is “caused by” the proposed pesticide registration decision – the Federal action – if, and only if, the use meets the but-for and the reasonably certain tests. Importantly, only uses that are reasonably certain to occur would be considered an “activity” in a pesticide consultation. Thus, the Services would presumably not assume maximum allowable label rates, but rather constrain the scope of consulted-on “activities” to reasonably certain use scenarios.

The proposed clarification to “effects of the action” would also address the ambiguities of the current regulation’s phrasing of the distinction between “direct” and “indirect” effects, which has allowed some to argue – incorrectly, we believe – that years of actual use experience with the same or comparable pesticide products now under ESA review can be ignored. The proposed revisions clarify the importance of such use information in providing support for an “activity” that is “reasonably certain” to occur, and properly rely upon years of actual pesticide use experience in addition to the Services’ sound statutory interpretation.

In data-deficient situations, the Services can often make reasonable estimates of use based on actual data from more limited geographic areas or states that are representative of the areas in question. This approach aligns with the Services’ stated policy of “reasonably defin[ing] the reach of the effects analysis and address[ing] concerns about extending the analysis into an unreasonably wide arena.” 83 Fed. Reg. at 35184.

The proposed revisions would also require that the potential *effects* of those pesticide uses (*e.g.*, reduction of prey base) meet both the “but for” and “reasonably certain” standards. More guidance is needed to understand how the Services’ intend to apply the “reasonably certain to occur” standard to effects. The proposal includes an explanation of when “activities” (but not “effects”) are reasonably certain to occur. There is no clear explanation for this distinction, leaving the public with questions about whether the application of this concept to effects is subject to a different standard than that for activities. The Services should clarify this ambiguity.

Also, the proposal does not draw a clear enough distinction between activities and effects, and the value of identifying activities separate from effects. In finalizing the proposed definition of “effects of the action,” the Services should consider including examples in the preamble to the final regulations of how to properly interpret the distinction between a proposed action,

activities, and effects. We urge the Services to clarify these terms and to consider adopting the interpretation set forth above in any future policies or rules specific to pesticide consultations.

### **III. Pursue other opportunities to expedite consultations.**

The Services have identified two other proposals to expedite consultations, both of which could improve the timeliness of pesticide consultations or optimize the use of the Services' limited resources.

#### **a. *Adopt timeframes for informal consultation and consequences for missed deadlines.***

Informal consultation is, essentially, the written concurrence of the Service with the Federal agency's determination that the action is not likely to adversely affect listed species or critical habitat. *See* 50 C.F.R. § 402.13(a). While the Services do not propose specific regulatory amendments to the regulations regarding informal consultation at § 402.13, they do "seek comment on (1) whether a deadline would be helpful in improving the timeliness of review; (2) the appropriate length for a deadline (if not 60 days); and (3) how to appropriately implement a deadline." *Id.* at 35186.

We support the adoption of a realistic and enforceable deadline for informal consultations. Because informal consultations are a well-established part of ESA reviews outside the context of pesticide registration decisions, a 60-day timeline should be appropriate. However, in the context of ESA reviews for pesticide registration decisions, this goal may not be readily achievable in the short term.

As discussed above in support of increased coordination, we encourage the Services to work with EPA to develop guidance and templates that reflect a shared understanding about the contents of pesticide biological evaluations and biological opinions. As those are developed, strict timetables for concurrence may be difficult to achieve. In that interim, it would be appropriate for the Services to set expectations for the duration of specific informal consultations for pesticide actions, in coordination with EPA and the applicant. If those expectations are not met, there should be a process to elevate the consultation to the attention of higher-level managers within EPA and the Services and to appropriate officials within the Departments of the Interior and Commerce. Setting these goals would provide a benchmark to evaluate the performance of the pesticide consultation process over time, with a goal of eventually meeting a predictable fixed period.

#### **b. *Consolidate consultations for joint-jurisdiction species if an applicant prefers to use this approach.***

Although not reflected in any proposed changes to the regulations as part of this announcement, the Services have sought comment "on the merit, authority, and means for the Services to conduct a single consultation, resulting in a single biological opinion, for Federal agency actions affecting species that are under the jurisdiction of both FWS and NMFS." 83 Fed. Reg. at 35179. The value of such a proposal would be in potentially reducing the inefficiencies that

result from the Services' current practice of generally conducting separate consultations, resulting in one biological opinion from FWS and another from NMFS, for federal actions affecting joint jurisdiction species.

In the context of pesticide consultations, the proposal has the potential to vastly reduce the Services' collective workload on certain pesticide consultations by allowing FWS and NMFS biologists to collaborate on a single biological opinion rather than issue two separate opinions, each of which is likely to exceed several hundred pages. Unlike most other consultations, nationwide pesticide consultations could benefit disproportionately from this proposal because many of them are likely to involve both FWS and NMFS species. This is another reason the Services should consider refocusing on the separate set of procedures, rules, or guidelines specific to the unique circumstances of pesticide consultations. As part of this effort, the Services should ensure that they are in internal agreement about their legal, policy, and scientific approaches to pesticide consultations, as we have noticed potential discrepancies between the Services' approaches.

If the Services proceed with a proposal to codify this action through regulation, however, the proposal should allow the applicant the option to pursue this unified consultation approach, rather than be forced to do so. There may be circumstances where combining the two agencies' efforts would result in undue delay or complexity, so it is important that the applicant be allowed to preclude such combinations where that process could result in unnecessary delay of the process.

#### **IV. Increased involvement by pesticide registrants as applicants, and by other stakeholders, could help improve the ESA review of pesticide registration decisions.**

For a variety of reasons, we believe that pesticide registrants have not benefitted from the more direct conversations with the Services that many other Section 7 applicants have enjoyed. We recommend the Services work with EPA to address this imbalance and urge the Services to reaffirm in the regulations themselves the rights of the registrants as applicants, either in the finalization of this regulation, or in an upcoming round of administrative proposals. *See* 83 Fed. Reg. at 35179. The opportunity for involvement by a broader group of stakeholders in pesticide registration decisions, including the user community who would have valuable insight into any reasonable and prudent measures and alternatives, should also be codified.

The Services should codify the role of pesticide registrants as “applicants” in nationwide pesticide consultations and, even more importantly, articulate how the Services will interact with those registrants in a manner that maximizes the opportunities for them to provide data and analyses that help inform the Services’ decisions in informal and formal consultations. For example, registrants and their customers often have unique and valuable information about how, when, and where a pesticide is applied and about toxicological and related characteristics of their products. This information may provide important context about the timing and magnitude of potential effects of the pesticide on listed species. Better communication between the Services and registrants also will streamline development of any reasonable and prudent measures and alternatives and help ensure that those measures and alternatives are technologically and economically feasible to implement.

Relatedly, we urge that the Services consider recognizing the validity and reliability of scientific and technical analyses pertinent to ESA analyses prepared by applicants in support of their FIFRA applications. Here, the Services can take a lesson from EPA, which has developed study guidelines and Good Laboratory Practice procedures that assure good science. The Services should equally be prepared to rely on studies and analyses prepared by applicants that meet established quality standards – such studies will likely be the “best available” studies, which are what the ESA requires as the basis for its decision-making.

Second, we encourage the Services and EPA to develop a joint regulation that codifies the key elements of the 2013 paper finalized by EPA, USDA, and the Services entitled, “Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives.” 78 Fed. Reg. 18585 (March 27, 2013). Importantly, the paper added to the rights of applicants (pesticide registrants) and other important stakeholders, including pesticide users, by committing the Services and EPA to the following, along with other improvements:

- During comment periods on draft biological opinions, the EPA will reach out to potentially affected pesticide users to discuss the technical and economic feasibility of reasonable and prudent alternatives intended to avoid jeopardy to threatened or endangered species.
- EPA will collect and organize comments on draft biological opinions and provide them to the Services. The Services will prepare a document to be included in the administrative record of the consultation explaining how the comments were considered, and as appropriate, how the biological opinion was modified to address the comments.

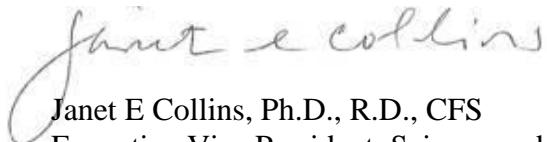
Unfortunately, these and other applicable procedures were not followed in the recent consultations on three organophosphate pesticides purportedly because of court-ordered settlement deadlines that left inadequate time for notice and comment on the draft biological opinions. To help ensure that any future settlement deadlines are consistent with these procedural commitments, the Services and EPA should codify them in regulation.

As stated above, CLA supports the goals and substance of these proposed regulations. Clarity in definitions to better reflect current practice, and to streamline processes, are welcome additions to this process. We believe that the specific suggestions outlined above are consistent with the goals of the proposal and would further support a more effective, efficient process to address ESA review of pesticide registration decisions.

CLA, RISE and their member companies are committed to working with the Services and all interested stakeholders in developing a process for the ESA review of pesticide registration decisions that specifically protects listed species and their habitat, while recognizing the important role that pesticides play in agriculture, and in the protection and enhancement of property, homes and human health. We appreciate the opportunity the proposed revisions of these regulations provides to offer ideas to improve this process and would welcome the opportunity to engage on the ideas contained in this letter.

Should you have any questions about, or wish to have further information on these comments, please contact Janet Collins or Aaron Hobbs using the contact information in their signature lines. Thank you for your consideration of these comments.

Respectfully,



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