



October 16, 2012

Dr. Steven Bradbury
Office of Pesticides Program
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Docket ID: EPA-HQ-OPP-2012-0442

RE: SCB Comments on the Pesticide Registration Review and Endangered Species Act Consultation Process and Stakeholder Input.

Dear Dr. Bradbury,

The Society for Conservation Biology¹ (SCB) would like to offer the following comments on the U.S. Environmental Protection Agency's (EPA) proposal for *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives*.² Section 7(a)(2) of the Endangered Species Act (ESA) requires the EPA to consult with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively the "Services") prior to registering any pesticide for its use and application in the environment to insure that such pesticide will not jeopardize the existence of any threatened or endangered species, or destroy or adversely modify the species' critical habitat. When the Services determine that an agency action will jeopardize a listed species or adversely modify a species' critical habitat, they must recommend a set of Reasonable and Prudent Alternatives (RPAs) that will avoid the jeopardy/adverse modification prohibition of Section 7(a)(2).

Because most pesticide products are used across vast portions of the United States on a variety of crops at different times of the year, a particular pesticide product could potentially impact dozens of threatened and endangered species. As a result, consultations regarding the use of pesticides in the environment pose significant scientific challenges. This had led to the EPA and Services having substantial difficulty completing such complex Section 7

¹ SCB is an international professional organization whose mission is to advance the science and practice of conserving the Earth's biological diversity, support dissemination of conservation science, and increase the application of science to management and policy. The Society's 5,000 members include resource managers, educators, students, government and private conservation workers in over 140 countries.

² *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternative* (hereafter "EPA PROPOSAL"). The full EPA Proposal is available at regulations.gov under the Docket ID #: EPA-HQ-OPP-2012-0442-0002.



consultations in the past.³ Now, a large backlog of consultations on the registration of over 1200 pesticides exists. This backlog will need to be addressed in the coming years to insure that the potential impacts of pesticides on threatened and endangered species are properly ameliorated.

The success of pesticide consultations in the future should be judged in large part by whether harmful exposures of pesticides on threatened and endangered species are reduced over time. To that end, SCB is encouraged by some of the steps taken by the EPA to make their pesticide risk assessment process more transparent to the public. Pesticide consultations represent a very unusual category of consultations under the ESA, and SCB agrees that the procedures used during these consultations should be modified from the normal approach the EPA and Services use to conduct Section 7 consultations. However, if the EPA and Services are going to deviate from the standard approach to consultations, those modified procedures should ultimately be established through a revised set of counterpart regulations at 50 C.F.R. Subpart D.⁴ In particular, SCB believes that the practice of conducting partial consultations with the Services could help all of the parties identify the highest risk pesticides for detailed analysis, while simultaneously allowing the EPA to move forward with the registrations of pesticides that pose less risk to biodiversity.

Despite the proposed improvements in the EPA's transparency with respect to its ecological risk assessments, SCB is concerned that several long-standing problems with the EPA's risk assessment process still persist, and that as a result, threatened and endangered species will continue to be placed at too great a risk from pesticide exposure in the environment. In particular, SCB has the following three concerns.

First, the EPA has not reconciled its proposed, revised process with some of the long-standing analytical limitations in its 2004 risk assessment process. Pesticides and their "inert" ingredients can, upon entry into the environment, combine in synergistic ways that exacerbate their negative effects. Yet, these cumulative and synergistic effects are not accounted for in the EPA risk assessment process.

Second, the EPA process focuses extensively on acute harm to threatened and endangered species, while discounting the potential impacts that pesticides have on critical habitat of listed species.

Third, and most importantly, the ESA requires that agencies provide the benefit of the doubt to threatened and endangered species during the consultation process where significant scientific uncertainty exists.⁵ Unfortunately, the EPA continues to place too much of the

³ *Washington Toxics Coalition v. EPA*, 413 F.3d 1024 (9th Cir. 2005); *Northwest Coalition for Alternatives to Pesticides v. Lyng*, 844 F.2d 588 (9th Cir. 1988).

⁴ 50 C.F.R Part 402, Subsection D et seq., Counterpart Regulations Governing Actions by the U.S. E.P.A. Under FIFRA.

⁵ See House Conference Report 96-697, 1979 U.S.C.C.A.N. 2576 (emphasis added); *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir.1988).



burden of uncertainty on threatened and endangered species in determining which restrictions on pesticide use is appropriate. The EPA's decision to permit a higher level of risk for listed species than the ESA normally requires can be demonstrated by contrasting the EPA's conclusions from past consultations, in which the agency rarely determined that the use of a pesticide would jeopardize threatened and endangered species, with the subsequent conclusion of the Services regarding those same pesticides, wherein the Services concluded that jeopardy would occur.

While setting the appropriate level of risk may implicate more than the best available science,⁶ it is a policy decision that the EPA should make based on general principles of conservation and evidence-based decision-making.⁷ Accordingly, SCB recommends the following changes and additions to the EPA's draft proposal:

- 1) The EPA and Services should enter into a programmatic consultation on the EPA's 2004 Ecological Risk Assessment Process to address the documented shortcomings in the EPA's current analytical approach.
- 2) The EPA should allow all interested persons an equal opportunity to review draft Biological Opinions and RPAs produced by the Services regarding pesticide registrations at the same time in a transparent manner. The ESA does not permit a pesticide registration applicant an opportunity to review the biological opinion prior to the public.
- 3) The EPA must address adverse modification of critical habitat from pesticide exposure directly, as an independent consideration in its risk assessment process.
- 4) The EPA and the Services should begin the process of revising the existing counterpart regulations on pesticide consultations with the goal of improving the formal consultation process, not avoiding the formal consultation process.
- 5) The EPA should incorporate considerations of each species current conservation status when making policy decisions regarding acceptable risk from pesticide exposure rather than a one-size-fits-all approach to allocating risk.

I. Introduction to the Pesticide Registration Process

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) bars any person in any state from distributing or selling a pesticide product that the EPA has not registered pursuant to FIFRA.⁸ Any person that seeks to use a pesticide and apply it in the environment within the United States must comply with the labeling restrictions on the product. FIFRA

⁶ See National Academy of Science. 1995. *Science and the Endangered Species Act* at 159 ("Even though estimates of risk are grounded in scientific information, those implementing the act often make value judgments when making decisions about listing, jeopardy, etc....Making good use of science, as instructed in the ESA, requires making appropriate connections between the values and objectives being pursued in a decision and the scientific evidence and reasoning used to evaluate alternative ways of meeting those objectives. Science by itself is not sufficient input to policy decisions, apart from the objectives and values it serves.").

⁷ Pullin, A.S. and T.M. Knight. 2009. *Doing More Good than Harm – Building an Evidence-base for Conservation and Environmental Management*. *Biological Conservation* 142:931-934.

⁸ 7 U.S.C. § 136a(a).



establishes the basic review process through which the EPA registers pesticides and sets the labeling restrictions for such pesticide products.⁹ As part of the registration process, the EPA must determine whether the use of the pesticide will cause “unreasonable adverse effects on the environment” following the procedures set under FIFRA.¹⁰ To determine how a pesticide reacts in the environment, the EPA conducts an ecological risk assessment which examines the effects of a pesticide on the soil, surface water, ground water, and on plants and animals, including endangered species. The ecological risk assessment process for threatened and endangered species is set forth in the EPA’s 2004 *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs: Endangered and Threatened Species Effects Determinations*.¹¹ As part of this ecological risk assessment, the EPA must consider the “environmental fate” of the pesticide, in other words what chemical byproducts form after the pesticide is applied in the environment and how those chemical degradates interact in the environment. However, the ecological risk assessment does not consider the cumulative or synergistic effects posed by multiple pesticides on the environment. The current ecological risk assessment procedures were developed without formal input from the Services through the ESA Section 7 formal consultation process.¹²

Today, there are over 1,000 registered pesticides in the United States. FIFRA not only requires that all new pesticides be registered, but also requires that all pesticides initially registered before 1984 be subject to “reregistration review” to determine whether those pesticides also result in unreasonable adverse effects to the environment.¹³ As part of the registration and reregistration process, the EPA is required to conduct Section 7 consultations with the Services for each pesticide registration that may affect threatened or endangered species. Unfortunately, for the overwhelming majority of pesticides, the EPA has failed to enter into consultations with the Services unless forced to do so by court order. As a result, there is a massive backlog of consultations that will need to occur over the next decade to address the impacts of pesticides on endangered and threatened species.

The Endangered Species Act “represent[s] the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.”¹⁴ Section 1 of the Act states that it is the policy of Congress “that *all* Federal departments and agencies shall seek to conserve endangered species and threatened species and *shall* utilize their authorities in furtherance of the purposes of this Act.”¹⁵ As the Supreme Court explained, the “plain intent of Congress in enacting this statute was to halt and reverse the trend toward species extinction, *whatever the cost*.”¹⁶ The Section 7 consultation process analyzes the risks of a

⁹ 7 U.S.C. § 136(a)-(d).

¹⁰ 7 U.S.C. § 136(bb).

¹¹ U.S. Environmental Protection Agency Office of Pesticides Program. 2004. Overview of the Ecological Risk Assessment Process: Endangered and Threatened Species Effects Determinations (hereafter “ECOLOGICAL RISK ASSESSMENT PROCESS”). Available at: <http://www.epa.gov/espp/consultation/ecorisk-overview.pdf>

¹² See *Washington Toxics Coalition v. U.S. Dept. of Interior*, 457 F.Supp.2d 1158 (W.D. Was. 2006).

¹³ 16 U.S.C. § 136a-1.

¹⁴ *Tennessee Valley Authority v. Hill*, 437 U.S. 153, 180 (1978).

¹⁵ 16 U.S.C. § 1531(c)(1).

¹⁶ *Tennessee Valley Authority v. Hill*, 437 U.S. at 184.



potential federal agency action, such as registering a pesticide, on threatened and endangered species. Under Section 7 each federal agency must “insure that actions authorized, funded, or carried out by them do not jeopardize the continued existence” of a threatened or endangered species or “result in the destruction or modification of [critical] habitat of such species....”¹⁷

While the EPA must meet its statutory obligations under FIFRA to determine whether a pesticide will cause “unreasonable adverse effects on the environment,” meeting this obligation does not absolve the EPA of its statutory duties under the ESA to insure that its actions do not jeopardize listed species. Because each pesticide registration represents a discretionary agency action, the EPA must consult with the Services on the impacts of registrations that may affect listed species and/or critical habitat.¹⁸ Meeting these two statutory duties should not place the EPA in a statutory dilemma because FIFRA and the ESA serve complementary goals of protecting the environment. Unfortunately, the EPA has failed to appreciate that the ESA requires a higher standard of precaution against the risk of harm to listed species and habitat than FIFRA requires. As a result, threatened and endangered species have been exposed to harmful level of pesticides in the environment for many years due to the EPA’s failure to implement reasonable and prudent alternatives to mitigate these impacts.

Recent history illustrates that the EPA and Services approach analyzing and the setting of acceptable risk of harm to threatened and endangered species very differently. Beginning in 2000 as the result of a court order, the NMFS and EPA have consulted on the potential impacts of 28 types of pesticides, herbicides, and insecticides, on threatened and endangered salmon and steelhead in the Pacific Northwest. In most of these consultations, the EPA has come to very different conclusions regarding the magnitude of the risk of harm that these pesticides products pose to listed species compared to the NMFS.

To take one example, in 2003 and 2004 the EPA completed its biological evaluation of the potential impacts to salmon and steelhead from three pesticides, oryzalin,¹⁹ pendimethalin,²⁰ and triflurian.²¹ In its evaluation, the EPA concluded that oryzalin would have “no effect” on nine species of salmon and steelhead, and was not likely to adversely affect (NLAA) 17 species of salmon and steelhead.²² For none of listed species, did EPA

¹⁷ 16 U.S.C. § 1536(a)(2).

¹⁸ *Washington Toxics Coalition v. EPA*, 413 F.3d 1024 (9th Cir. 2005); *Northwest Coalition/or Alternatives to Pesticides v. Lyng*, 844 F.2d 588 (9th Cir. 1988). The Supreme Court has clarified in *National Association of Home Builders v. Defenders of Wildlife*, 551 U.S. 644 (2007), that the consultation duty is triggered only by discretionary actions. Since the registration of a pesticide and the restrictions placed on the applicator by the EPA are both discretionary, the consultation requirement applies.

¹⁹ EPA. 2003. *Oryzalin Analysis of Risks to Endangered and Threatened Salmon and Steelhead*. Available at: <http://www.epa.gov/oppfead1/endanger/litstatus/effects/oryzalin-analysis.pdf>

²⁰ EPA. 2004. *Pendimethalin Analysis of Risks to Endangered and Threatened Salmon and Steelhead*. Available at: <http://www.epa.gov/oppfead1/endanger/litstatus/effects/pendimeth/analysis.pdf>

²¹ EPA. 2003. *Triflurian Analysis of Risks to Endangered and Threatened Salmon and Steelhead*. Available at: <http://www.epa.gov/oppfead1/endanger/litstatus/effects/triflur-analy.pdf>

²² In the intervening time between the EPA’s biological evaluations of pesticides for their impacts on salmon and steelhead in 2003 and the time the NMFS completed its biological opinions on those pesticides, the NMFS listed



reach the conclusion that oryzalin “may affect” a threatened or endangered species. It is important to understand what these three effects determinations mean. A “no effect” finding means that the EPA concluded that an action would have not any effect on a listed species or its critical habitat.²³ A “not likely to adversely affect” findings means that EPA concluded that the only effects on listed species deriving from the use of oryzalin would be “discountable, insignificant, or completely beneficial.”²⁴ A “may affect” finding would have been appropriate had the EPA found that oryzalin would have had “any effect on listed species or designated critical habitat.”²⁵ In other words, through its risk assessment process, the EPA concluded that the effects of oryzalin would not appreciably harm any listed species in the Pacific Northwest.

Normally, a “NLAA” and a “may affect” finding triggers informal and formal consultations under the ESA respectively.²⁶ Had the EPA not been compelled by a court order, it would have not have been required to enter formal consultations for the nine species it found that oryzalin would have “no effect.” And for the 17 NLAA species, it could have requested a letter of concurrence from NMFS that formal consultation was not necessary. However, because of the court order, the NMFS entered formal consultations on all 28 species at risk. After its analysis, NMFS concluded that oryzalin would result in jeopardy for 10 listed species, including one species that EPA had concluded oryzalin would have “no effect” upon (California coastal Chinook salmon). NMFS also concluded that oryzalin would adversely modify critical habitat for the 10 listed species that were placed at jeopardy by oryzalin.²⁷

For pendimethalin, the EPA concluded that the pesticide would have “no effect” on 22 listed species, and was not likely to adversely affect 4 listed species. After its own analysis, NMFS concluded that pendimethalin would adversely modify critical habitat and result in jeopardy for 14 listed species, including 10 species for which EPA concluded that pendimethalin would have “no effect.” For trifluralin, a somewhat more toxic pesticide, the EPA concluded that trifluralin would have “no effect” on 11 listed species, was “not likely to adversely affect” four listed species, and “may affect” 11 species. NMFS determined that pendimethalin would adversely modify critical habitat and result in jeopardy for 14 listed species. Interestingly, for the species where NMFS found jeopardy, the EPA’s determination of “may affect” was not determinative of where a jeopardy conclusion was reached. Rather, jeopardy was found for six of the “no effect” species, three “NLAA” species, and six “may

two additional Evolutionarily Significant Units under the Endangered Species Act, the Puget Sound Steelhead and the Lower Columbia River Coho salmon. In SCB’s analysis of the EPA’s effects determinations and the NMFS biological opinions, SCB has not included these two most-recently added species.

²³ USFWS & NMFS. 1998. *Consultation Handbook: Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act* at xvi. Available at:

http://www.fws.gov/endangered/esa-library/pdf/esa_section7_handbook.pdf

²⁴ *Id.* at xv.

²⁵ *Id.* at xvi

²⁶ *Id.* at 3-1, 4-1.

²⁷ NMFS. 2012. Final Biological Opinion: Registration of Pesticides Oryzalin, Pendimethalin, Trifluralin. Available at: http://www.nmfs.noaa.gov/pr/pdfs/consultations/pesticides_batch5opinion.pdf



affect” species. For all three pesticides, the EPA’s risk assessment incorrectly concluded that the pesticide would have “no effect” on at least one listed species where the NMFS concluded that the use of the pesticide would jeopardize the continued existence of that species.

It is worth emphasizing that in situations where an action agency finds “no effect,” there is no legal requirement to even initiate the informal consultation process. Without a court order, each of these pesticides would have been registered without any mitigation measures specifically to address the impacts to listed salmon and steelhead species. For the EPA to arrive at a “no effect” determination repeatedly, while the NMFS reaches a jeopardy conclusion for the same species regarding the same pesticide, is evidence that there is a fundamental dissonance between the EPA and the Services regarding their analytical approach to assessing acceptable risk for threatened and endangered species.

The results from this biological opinion are not atypical. To date, the EPA has completed approximately 676 effects determinations regarding the registration of pesticides in the Pacific Northwest (counting each pesticide product’s effects on a separate listed species as a unique determination). NMFS has completed six biological opinions that have reviewed each of these effects determinations. From these, the NMFS concluded that jeopardy and/or adverse modification of critical habitat to listed salmon and steelhead species would occur for 293 of those pesticide registrations. Of those 293 jeopardy/adverse modification findings, the EPA concluded for 49 of those registrations that the pesticide would have no effect on a listed species and concluded for 40 registrations that the pesticide was not likely to adversely affect a listed species where NMFS found jeopardy/adverse modification of critical habitat.

In other words, over 30 percent of the time, the EPA reached the opposite result than NMFS regarding the effects a pesticide would have on listed salmon and steelhead species. As discussed below in greater detail, this is a very high Type II error rate. And, it is worth emphasizing that the EPA agrees that the FWS and NMFS are the “expert” agencies when it comes to assessing the risks to endangered species.²⁸ While it may be true, as stated in the EPA proposal, that the EPA is “the expert agency on pesticide regulation and the enforceability of labels,”²⁹ this does not logically mean that the EPA is therefore the expert agency on assessing toxicological harm to the environment, and especially to wildlife. While the EPA should be supported in its efforts to improve the procedures and process it uses during the Section 7 consultation process, such improvements can only go so far in addressing the underlying substantive deficiencies in the EPA’s analytical approach to pesticide regulation. Thus, SCB is providing the following recommendation regarding not only procedural improvements to the EPA’s pesticide review process but also substantive changes that the EPA needs to make to its pesticide review process to address the harm that pesticides continue to cause to threatened and endangered species.

²⁸ EPA Proposal at 9

²⁹ *Id.*



II. Increased Public Participation in Pesticide Consultations Should Allow all Interested Persons to Provide Meaningful Input to the EPA. Modified Consultation Procedures Should Ultimately be Codified in Counterpart Regulations.

Under the EPA's proposal for pesticide consultations, the EPA would hold focus groups early in the process to identify data needs regarding the impacts of a pesticide on the environment.³⁰ The EPA would enter into informal consultations with the Services early in the process to make a refined biological evaluation prior to the initiation of any needed formal consultation. According to the EPA, early informal consultations would provide several benefits including:

1) incorporation of more refined species biology and habitat information into EPA effects determinations prior to formal consultation, 2) a further reduction in the number of "may affect" determinations, and 3) fewer resources (for both EPA and the Services) needed to complete any needed consultation because the best available information has been incorporated into EPA's biological evaluation.³¹

For pesticides that the EPA determines "may affect" listed species, the EPA would still enter into formal consultations with the Services. The Services would then develop a Biological Opinion (BO) to determine whether jeopardy and/or adverse modification of critical habitat are likely. Where jeopardy or adverse modification is found, the BO would recommend Reasonable and Prudent Alternatives (RPAs) that would insure the pesticide registration would avoid the likelihood of jeopardizing listed species or adversely modifying its critical habitat. Under the EPA proposal, the Service would convene a meeting with the EPA and the pesticide applicant to identify what additional information – beyond that provided by the EPA in its package initiating consultation – can be provided to develop the draft biological opinion. The Services would prepare a draft biological opinion that would contain the Services' analyses and conclusions regarding whether use of the pesticide is likely to result in jeopardy or adverse modification of critical habitat.

Prior to formally transmitting the draft biological opinion to the EPA, the Service would provide the EPA and the applicant with an opportunity to identify any perceived errors in the description of the proposed action and the effects analysis. Subsequent to any errors being corrected, the Service will provide the EPA with the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The EPA will make this draft Biological Opinion and the proposed RPAs available for public comment. The EPA will organize all of the public comments to aid the Service in their review of the comments and will highlight comments of particular note. Under the proposal, during this public comment period, the EPA and the Services would specifically reach out to growers to engage in what technologically and economically feasible approaches could be implemented that minimize

³⁰ *Id.* at 6-7.

³¹ *Id.* at 6.



the impact on growers and allow them to meet their pest control needs while achieving the necessary protection goals to avoid jeopardy to threatened and/or endangered species.

SCB is encouraged that the EPA's revised pesticide review process includes an opportunity for the Services to convene meetings to address areas where the Services need additional data from the EPA on the effects of pesticides. In the past, there have been problems with the EPA's ability to provide the Services with the data needed to complete a consultation. For example, the FWS was unable to conclude the consultation process on the effects of over 40 pesticides on the California red-legged frog due to lack of information from the EPA.³² The FWS requested that the EPA provide additional data, but no substantive responses have been made to this request to the best of SCB's knowledge. As a result, the FWS never concluded its consultation with the EPA, potentially leaving the California red-legged frog at higher risk of extinction than the ESA allows for.

While convening a meeting with the Services to address data gaps is a good first step, there must be consequences if the EPA remains incapable of providing the necessary information to the Services for them to complete legally mandatory consultations. In situations like these, where the EPA is unable to provide sufficient data, the ESA requires that the benefit of the doubt be given to protecting endangered species during the consultation process. When the EPA fails to provide the Services with the required information to fully analyze the risks of pesticides on listed species, then by definition, the EPA cannot insure against jeopardy. As a result, the biological opinion must reach a jeopardy finding; the consultation process cannot drag on indefinitely. There need to be additional incentives for EPA and the pesticide registrant to provide the Services with the data they need to complete a consultation. That incentive should be a "jeopardy" determination in the absence, or inadequacy of, required data. SCB recommends that the EPA proposal should expressly state that the consequences of failing to provide the needed data means that a pesticide product's registration or use would result in jeopardy to the species.

In addition, SCB has several concerns with the EPA's proposed changes to the procedures regarding pesticide consultations. First, SCB is concerned that the EPA is providing the applicant an opportunity to review and identify "any perceived errors" in the effects analysis of the draft biological opinion prior to the rest of the public's ability to do so. This is particularly troubling because of the applicant's likely bias in what type of errors would be likely to attempt to correct. In general, there are two types of scientific errors: Type I errors, in which an experimental approach incorrectly concludes that there is an effect when one does not exist (false positive), and Type II errors, in which an experiment fails to account for an actual effect (false negative). Presumably, a pesticide applicant would be most concerned with

³² USFWS Letter to EPA re: Informal Consultations on the Effects of Atrazine Re-registration on the Endangered Alabama Sturgeon and Endangered Dwarf Wedge mussel. Docket #: *FWS/AES/DCHRS/032435*. Available at: <http://www.epa.gov/espp/litstatus/effects/atrazine/2008/fws-nonconcur.pdf>; USFWS letter to EPA re: Request for Initiation of Formal Consultations on the Effects of Reregistration of pesticides. Docket #: *FWSI/AES/DCHRS/039744*. Available at: http://www.epa.gov/espp/litstatus/consultationRejection_fws.pdf



addressing Type I errors in which a negative environmental impact is wrongly connected to the use of a particular pesticide. A Type I error during the Services' review under the ESA may result in a pesticide not being registered or being registered with unnecessary pesticide use restrictions.

But a focus on minimizing Type I errors necessarily increases the probability of Type II errors, i.e. concluding that there is no effect from a pesticide when in fact impacts are occurring. SCB is deeply concerned that the EPA is making a policy choice that has the likely consequence of increasing Type II errors with respect to pesticide impact analysis. This is a mistake that EPA has made in the past³³ and is incompatible with the Endangered Species Act requirement to provide the benefit of the doubt to endangered species when uncertainty exists.³⁴ Providing the EPA and the applicant with an opportunity to review the Services' effects analysis with what is likely to be a sole focus on eliminating perceived Type I errors prior to allowing all other parties to review the same analysis does not comport with the basic scientific principle of objective peer review, which rigorously tests scientific conclusions regardless of personal biases.³⁵ The surest way to avoid this dangerously one-sided approach to reviewing the biological opinion is to allow all parties to review all aspects of the draft biological opinion at the same time. Doing so would also meet the larger goal of greater transparency in the EPA and Services' review process.

Second, SCB is concerned that EPA is overstating the scope of the "defined opportunities under the statute and regulations" regarding the rights of the applicant during the development of a biological opinion. The ESA itself does not provide for a Federal agency or an applicant to review a biological opinion prior to the publication of the draft biological opinion. Section 7(b)(3)(A) states that the Services "Promptly after conclusion of consultation...the Secretary shall provide to the Federal agency and the applicant, if any, a written statement setting forth the Secretary's opinion."³⁶ This does not include an early review of the draft biological opinion. And while the ESA's implementing regulations do allow for the distribution of the draft biological opinion to the applicant, they do not provide the applicant with a special opportunity to comment that is denied the public. The regulations state "If requested, the Services shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The applicant may request a copy of the draft biological opinion."³⁷ Nothing in the regulations suggests that the applicant may comment on a pre-decisional draft of the biological opinion, let alone do so when the public does not have that chance. SCB recommends that this provision in the EPA's proposal be modified to meet the legal requirement of the ESA and its implementing regulations, and keep applicant input on an equal footing with the broader public.

³³ *Washington Toxics Coalition v. U.S. Dept. of Interior*, 457 F.Supp.2d at 1186.

³⁴ House Conference Report 96-697, 1979 U.S.C.C.A.N. 2576 (emphasis added).

³⁵ SCB notes that the EPA's own handbook on peer review notes the importance of impartiality in reviewing scientific work. EPA. 2006. Peer Review Handbook, 3rd Edition. Available at:

http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2012.pdf

³⁶ 16 U.S.C. § 1536(b)(3)(A).

³⁷ 50 C.F.R. §402.14(g)(5).



Finally, because pesticide consultations represent an unusual category of consultations, and because the procedures to accomplish such consultations may need to be modified, the Services should consider revising their counterpart regulations to accommodate these changes. The ESA's implementing regulations provide for the development of counterpart regulations specifically to address agency actions where consultations are more complex and harder to complete using the standard procedures.³⁸ The Services have had difficulty in the past with development of counterpart regulations, including for pesticide consultations because the counterpart regulations were designed to limit the consultation process, not to make it more accurate and effective. Thus, in *Wash. Toxics Coalition v. U.S. Dept. of Interior*, the Services counterpart regulations were partially invalidated because Services allowed the EPA to make "unilateral" decisions as to whether a pesticide was not likely to jeopardize threatened and endangered species.³⁹ Based on "extremely strong technical and scientific evidence in the record" the Court determined that the EPA's risk assessment process for pesticides fails to insure against jeopardy of threatened and endangered species, and that there was no reason to justify giving the EPA the authority to make unilateral decisions under the counter-part regulations.

SCB is concerned that one of the EPA's stated goal for this revised process is to reach a "further reduction in the number of 'may affect' determinations" under the ESA. As shown above, the EPA has regularly made "no effect" and "not likely to adversely affect" determinations where the NMFS has found jeopardy in the case of protected salmon and steelhead. Further reducing the number of "may affect" determinations would likely increase the amount of Type II errors that the EPA makes, meaning that more harm to threatened and endangered species would likely go unaddressed. The policy goal for the EPA should be to complete more accurate consultations that adequately protect endangered species. Whether achieving this goal results in more or less "may affect" conclusions should not be determinative of the EPA's policy choices.

To achieve the goal of accurate and effective consultations, the existing consultation counterpart regulations may still be of use. SCB believes that partial consultations should be considered as an alternative path forward for pesticide consultations. Under 50 C.F.R. § 402.47, the Services may make successive effects determinations for consultations that are "unusually complex due to factors such as the geographic area or number of species that may be affected by the action."⁴⁰ SCB believes that these partial consultations may provide an alternative path forward for pesticide consultations, and believes that the Services should consider conducting a set of consultations using this process in a similar fashion to the pilot projects launched by the EPA and the Services last year. Ideally, successive effects determinations could allow for pesticides to be registered in geographic areas where the risks to threatened or endangered species are minimal, while allowing for a more rigorous evaluation where the risks to species are greater. SCB recognizes that consultations on pesticides, especially where the pesticide is used across the nation are very complex. But

³⁸ 50 C.F.R. § 402.04

³⁹ *Wash. Toxics Coalition v. United States*, 457 F. Supp. 2d 1158, 1182 (W.D. Was. 2006)

⁴⁰ 50 C.F.R. § 402.47.



rather than developing procedures that eliminate complexity from the analysis, the Services and the EPA should develop procedures that focus additional analysis where it is needed most. Under this approach, additional agency resources can be allocated both from the EPA and the Services to focus consultations where the risks to threatened and endangered species are greatest. The benefit of a partial consultation would be that the rest of the biological opinion covering areas where impacts are minimal would not be delayed while additional work is done addressing areas where a pesticide's impacts are more substantial.

III. The EPA Should Revise its Ecological Risk Assessment Process in Consultation with the Services to Address the Cumulative Impacts and Synergistic Effects of Pesticides in the Context of the Environmental Baseline.

SCB recommends that the EPA commit to revising its ecological risk assessment process, which was last updated in 2004, and does not incorporate any of the lessons learned from the last ten years of consultations with the Services. Ideally, as a discretionary agency action, this revision to the ecological risk assessment process should occur in conjunction with a programmatic biological opinion with the Services. This would help to address areas where the analytical approaches of the Services and the EPA differ.

The facts illustrate a long history of disagreement in analytical approach for evaluating pesticides. As the Court noted in the *Washington Toxics* case, there are many areas of analytical disagreement between the Services and the EPA regarding pesticides including:

- 1) Consideration of sub-lethal, cumulative, and synergistic effects.
- 2) Consideration of inert ingredients, surfactants, pesticide.
- 3) Consideration of estimates of exposure
- 4) Assumptions regarding predictability of implementation and enforcement
- 5) Assumptions about the use of surrogates in laboratory testing.⁴¹

Unfortunately, the EPA's 2004 risk assessment process was signed off on by upper-level Service personnel despite "the non-equivalence between Service effects determinations and EPA's risk assessments." This arbitrary policy choice might have been avoided had the Services entered into formal consultation with EPA rather than a non-transparent, procedurally questionable approach. As a result, the Court found that the Services failed to insure that the original counterpart regulations were sufficiently precautionary, in that they permitted EPA not to apply more protective safety factors.

SCB is concerned that the revised process that the EPA has put forward fails to address any of the above documented concerns. While it is important to improve the process for consultations on pesticides, process-improvements can only accomplish so much unless the EPA commits to improving some of the substantive defects of its current approach to evaluating pesticides. The EPA's risk assessment framework for determining whether unreasonable adverse effects to the environment will occur is laboratory driven and does not,

⁴¹ *Washington Toxics Coalition v. U.S. Dept. of Interior*, 457 F.Supp.2d at 1184.



in its present form, account for the environmental baseline facing threatened and endangered species. As a hypothetical example, there may be situations where a highly endangered species is placed at risk of jeopardy by a relatively safe (less harmful) pesticide, while a less-endangered species is not placed at risk of jeopardy by a much more toxic pesticide. This may not be intellectually satisfying, but it is certainly possible for this to occur in the real world. The ESA is designed to address the actual risk to each endangered and threatened species based on real-world conditions. An ecological risk assessment process that relies primarily on modeling cannot reliably meet this objective.

The EPA's revised process states that the EPA will reach out to the Services earlier in the process to gather additional information on the listed "species biology and habitat information."⁴² The EPA should provide a detailed explanation as to what it means by "species biology and habitat information." If the species biology data that EPA is requesting are limited to life history characteristics (e.g. age at sexual maturity, number of offspring, juvenile development, etc.) and habitat is limited to maps of where a species is located, such information will not fundamentally alter the EPA's approach to conducting risk assessment. However, if species biology and habitat information *includes the current environmental baseline for that species*, then the EPA may be a significant step closer to being in a position to fundamentally improve the accuracy of its ecological risk assessment process. As defined in the Services' Joint Consultation Handbook, the environmental baseline includes "the past and present impacts of all Federal, State, or private actions and other human activities in an action area, the anticipated impacts of all proposed Federal projects in an action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions that are contemporaneous with the consultation in process." In other words, the baseline accounts for the risk facing a particular species at a particular point in time. If the risk assessment process is tailored to address each listed species' environmental baseline, then the EPA could tailor additional mitigation measures where they are needed most. SCB believes that if the environmental baseline truly informs each pesticide registration, as demonstrated by preventative measures on the pesticide use label to minimize risk to threatened and endangered species, then fewer consultations with the Services might be necessary.

But at the moment, the EPA's ecological risk assessment process does not equate to the survival and recovery framework of the ESA consultation process because the EPA framework is driven by laboratory tests and models of pesticide exposure pathways.⁴³ While the EPA model is impressive in its attempted scope, it does not address real-world concerns such as individual species' particularized sensitivity to pesticides, and the cumulative effects of multiple pesticides in the environment. Pesticides are present in most United States watersheds, according to the most recent assessment of the U.S. Geological Survey. When these mix in the environment, their toxicity and other deleterious effects may be increased

⁴² EPA PROPOSAL at 6.

⁴³ For example, the ecological risk assessment process focuses primarily on the dietary exposure route even when other routes of exposure (inhalation from soil fumigants or dermal exposure for amphibians that respire through their skin) are the most logical pathway of pesticide exposure.



synergistically. But models can only accomplish so much because each species may be affected differently by different pesticide mixtures in the environment. A focus on the pesticide chemical alone cannot determine if jeopardy will result from the addition of one more pesticide into the environment. As the Court noted in *Washington Toxics*, the results of multiple pesticides in the environment “can be antagonistic, additive, or synergistic,” yet the EPA focuses only on the effects of a single chemical in the environment. Similar concerns have been raised regarding the spectrum of indirect effects and sub-lethal effects beyond growth and reproduction that could nevertheless impact a species’ survival, such as olfactory communication or immune system health. Finally, there have been repeated concerns regarding the EPA’s approval of questionable surrogate species to determine a pesticide’s ecological risk. For example, the EPA risk assessment procedures do not require testing on reptiles and amphibians, but instead uses Mallard ducks and Bobwhite Quails (two species of birds) as surrogates for terrestrial-phase amphibians and reptiles, and bluegill sunfish, rainbow trout, and fathead minnows as surrogates for aquatic phase amphibians.⁴⁴ Given the variability in the sensitivity of species to any given pesticide, it is not likely that the EPA’s risk assessment procedures are addressing the most sensitive threatened and endangered species that are at risk of exposure to pesticides in the environment.

SCB acknowledges that these deficiencies do not necessarily represent failure to use the best available science with regard to each type of risk EPA has chosen to consider or discount. Rather, the EPA is making policy choices regarding which types of risk to even consider in a process designed to avoid “unacceptable” environmental harm. However, if everyone agrees that the Fish and Wildlife Service and the National Marine Fisheries Service are the “expert agencies” when it comes to determining whether an action will jeopardize a species or adversely modify its critical habitat, then it is clear that the EPA’s policy decisions have not been consistent with the mandate of the Endangered Species Act. And if the EPA is not the expert agency when it comes to determining the effect of pesticides on threatened and endangered species, than any process designed to result in less consultations is highly questionable from a policy perspective. Accordingly, SCB recommends that the EPA initiate consultations with the Services on revisions to its ecological risk assessment procedures to insure that those procedures do not, in of themselves, jeopardize the existence of any threatened or endangered species by focusing on the deficiencies noted in *Washington Toxics v. U.S. Dept. of Interior*. And in addition, the revised procedures outlined by the EPA for consultations should incorporate the environmental baseline, not just the species biology, as early as possible in the process as possible.

Finally, SCB notes that some of these concerns could also be addressed if the EPA were to implement the conservation recommendations contained in the biological opinions completed by NMFS with respect to listed salmon and steelhead. Section 7(a)(1) of the ESA directs federal agencies to use their authorities to further the purposes of the ESA by carrying out conservation programs for the benefit of endangered and threatened species. Under Section 7(a)(1), conservation recommendations are provided by NMFS and FWS to the action agency to minimize and avoid adverse effects of a proposed action. NMFS has repeatedly

⁴⁴ ECOLOGICAL RISK ASSESSMENT PROCESS at 32.



proposed to the EPA, and for which has repeatedly failed to meet its Section 7(a)(1) duties by ignoring, the following conservation recommendations:

1. Conduct mixture toxicity analysis in screening-level and endangered species biological evaluations;
2. Develop models to estimate pesticide concentrations in off-channel habitats; and
3. Develop models to estimate pesticide concentrations in aquatic habitats associated with non-agricultural applications, particularly in residential and industrial environments.⁴⁵

IV. The EPA Must Address the Adverse Modification of Critical Habitat as Distinct from the Jeopardy Analysis During its Review of Pesticides.

Loss and the degradation of habitat are the primary threat to the vast majority of imperiled species, a fact that the Congress expressly noted when it passed the Endangered Species Act in 1973.⁴⁶ Accordingly, the recovery of threatened and endangered species depends on sufficient habitat being protected and restored to ensure a species' long term viability. Unfortunately, one of the clearest areas where the EPA's current process fails to account for the needs of threatened and endangered species is the failure to address adverse modification of critical habitat as an independent consideration from the jeopardy analysis. As noted above, Section 7(a)(2) of the ESA requires all agencies to consult with the Services in order to insure that their actions will not jeopardize any listed species or destroy or adversely modify a listed species' critical habitat. These two prohibitions are partially redundant because actions that have significant negative impacts on critical habitat will often directly jeopardize the species as well. For example, in the seminal case of *Tennessee Valley Authority v. Hill*, the proposed Tellico dam on Little Tennessee River would have destroyed the critical habitat of the snail darter thereby causing its extinction.⁴⁷ Thus the proposed agency action in that case triggered both jeopardy and the critical habitat prohibitions of the ESA.

However, some agency actions can adversely modify critical habitat without causing jeopardy.⁴⁸ Some federal actions may adversely modify habitat but not cause enough harm to create a likelihood of jeopardy. The jeopardy standard is hard to define quantitatively because it varies with the conservation status of a particular species (i.e. jeopardy is easier to trigger as a species become more and more endangered). Adverse modification of critical habitat should be a relatively straightforward inquiry. "Adverse" means "against," "hostile," or

⁴⁵ See NMFS. 2012. Final Biological Opinion: Registration of Pesticides Oryzalin, Pendimethalin, Trifluralin at 653. Available at: http://www.nmfs.noaa.gov/pr/pdfs/consultations/pesticides_batch5opinion.pdf

⁴⁶ Wilcove, D.S., et al. 1998. *Quantifying threats to imperiled species in the United States: Assessing the relative importance of habitat destruction, alien species, pollution, overexploitation, and disease*. *BioScience* 48(8):607-615.

⁴⁷ *Tennessee Valley Authority v. Hill*, 437 U.S. at 157.

⁴⁸ Owen, D. 2012. *Critical Habitat and the Challenge of Regulating Small Harms*, *Florida Law Review* 64:141-199.



“contrary to,” and “modification” means “change to something.”⁴⁹ Thus, a minor adverse change to critical habitat could trigger the prohibition in Section 7(a)(2) even where jeopardy does not occur. It is also possible that some agency actions will adversely modify critical habitat but will have unknown impacts on a species’ survival. Because the jeopardy standard is basically a question of acceptable risk, there may be instances where that risk cannot be quantified, yet negative impacts to critical habitat will occur. Finally, it is also possible that an action will occur in an area that is designated as critical habitat, but is unoccupied by the species at the time the activity occurs. For example, a pesticide could be applied to the environment at a time of year when a listed species is not present. Listed salmon and steelhead are only present within freshwater portions of their critical habitat at certain times of the year, yet it is possible that a pesticide application could impact critical habitat for that species at any time of year.

The EPA ecological risk assessment process focuses on direct harm to living organisms. To the extent that critical habitat includes biological features (such as plant or animal communities), the EPA risk procedures state that impacts can be evaluated using the indirect effects models for assessing ecological risk. However, where the biological features of critical habitat are not rigorously defined, the EPA’s models can only provide the coarsest of screenings. Thus, the EPA must again make a policy choice as to whether it will provide listed species the benefit of the doubt when it conducts its risk assessment with respect to critical habitat. If the EPA sets a high threshold for acceptable risk, then it can avoid triggering the consultation requirement for adverse modification. If EPA sets a low threshold for acceptable risk, then it will likely need to consult with the Services more on the effects on pesticides in the environment.

It is again worth reviewing the different results in past consultations as they apply to critical habitat. In 2003, the EPA completed an effects determination for the fungicide chlorothanil, in which it concluded that the use of this fungicide would have “no effect” on six species of salmon and steelhead, was “not likely to adversely affect 11 species, and “may affect” nine species.⁵⁰ When NMFS completed its biological opinion for chlorothanil, the use of this fungicide would not jeopardize any of listed species of salmon or steelhead. However, NMFS did conclude that for nine species of salmon and steelhead, chlorothanil would adversely modify those species critical habitat. This determination included seven species for which EPA had made a NLAA determination and two species that it made a “may affect” determination. When chlorothanil enters the waterways in the Pacific Northwest, it degrades water quality and therefore degrades the value of the critical habitat for those species.⁵¹

⁴⁹ *Id.* at 155.

⁵⁰ EPA. 2003. Chlorothanil Analysis of Risks to Endangered and Threatened Salmon and Steelhead. Available at: <http://www.epa.gov/oppfead1/endanger/litstatus/effects/chloroth-analysis.pdf>

⁵¹ NMFS. 2011. Biological Opinion: Registration of Pesticides 2,4-D, Triclopyr BEE, Diuron, Linuron, Captan, and Chlorothanil. Available at: http://www.nmfs.noaa.gov/pr/pdfs/consultations/pesticide_opinion4.pdf



The degradation of critical habitat is just as important as the possibility of jeopardy under the ESA. And in many ways, evaluating potential adverse modification to critical habitat from pesticide contamination should be a more straight-forward analysis for both the EPA and Services to complete. Where adverse modification of critical habitat is anticipated, it may also be relatively straightforward for the EPA and Services to address through mitigation and other pesticide use restrictions. Again, SCB remains concerned that the EPA's stated goal of reducing "may effect" determinations through revisions to its consultation procedures could potentially result in situations where Type II errors occur. This includes the possibility of failing to fully address impacts to critical habitat in its risk assessment process.

V. The EPA Must Provide the Benefit of the Doubt to Threatened and Endangered Species During the Pesticide Registration Process.

At its most basic level, much of the disagreement between the EPA on one side, and the FWS and NMFS on the other, comes down to a fundamental disagreement about how to address the real-world impacts of pesticides on endangered species, and how to allocate risk in light of the many areas of scientific uncertainty involving pesticides. SCB believes that the allocation of risk should be guided first and foremost by the ESA, and its legislative history. In 1979, Congress amended Section 7 of the ESA and established the modern Section 7 process. The Conference Report on the 1979 Endangered Species Act Amendments 12 states the following:

The Amendment [to the ESA] will permit the wildlife agencies to frame their section 7(b) opinions on the best evidence that is available or can be developed during consultation. If the biological opinion is rendered on the basis of inadequate information then the federal agency has a continuing obligation to make a reasonable effort to develop that information. This language continues to give the *benefit of the doubt to the species*, and it would continue to place the burden on the action agency to demonstrate to the consulting agency that its action will not violate section 7(a)(2).⁵²

This language does not mean that, where relevant information cannot be timely developed, the EPA must still guarantee with 100 percent certainty that the registration of a pesticide will not jeopardize or adversely modify the critical habitat of any threatened or endangered species. However, it does mean that where scientific uncertainty exists, the EPA and Services must give the benefit of the doubt to the endangered species and craft protective measures that minimize the risks posed by pesticides to endangered species. As the Supreme Court explained, "the pointed omission of the type of qualifying language...reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies."⁵³

⁵² House Conference Report 96-697, 1979 U.S.C.C.A.N. 2576 (emphasis added).

⁵³ *Tennessee Valley Authority v. Hill*, 437 U.S. at 185.



As discussed above, one of the most effective ways that EPA could afford this first priority to endangered species would be by changing how it allocates risk in its ecological assessment process. Under its current practices, the EPA integrates the results of pesticide exposure and toxicity data to evaluate the likelihood of adverse ecological effects on non-target species and develops a risk quotient (RQ) for each pesticide based on a level of pesticide exposure that would kill 50% of the organisms that were exposed to such levels (LC50). Once the RQ has been established for a particular pesticide, it is compared to EPA's level of concern (LOCs) for different types of organisms. It is critical to note that the EPA has made an express policy choice to use LOC's as the "policy tool" for evaluating direct effects of pesticides.⁵⁴ This decision is *not* a science-based decision, but rather a risk allocation policy choice.

Thus, the EPA has made the choice that the LOC for acute (short term) risks to all non-target organisms must be below 0.5 ($RQ < 0.5$) otherwise additional use restrictions must be imposed on the pesticide. For threatened and endangered species, if the LOC is below 0.05 for any threatened or endangered aquatic animal ($RQ > 0.05$) or below 0.1 ($RQ > 0.1$) for any threatened or endangered mammals or birds, then no additional restrictions are required for such pesticide. The decision to set the LOC for threatened or endangered aquatic animals at 0.05 is a policy choice. SCB cannot and does not have a scientific explanation for why that particular level does or does not represent the best available science because this decision represents a normative policy choice by the EPA. At best, SCB can only state that the decision to set a particular acceptable level of concern does (or does not) comport with the principles of conservation biology. Unfortunately, the EPA's general approach does not align with the basic principles of conservation biology or the ESA's broad goal to provide the benefit of doubt to threatened and endangered species.

To elaborate on this point, the EPA's *entire* ecological risk assessment process fails to distinguish meaningfully between threatened species and endangered species under the ESA. Threatened species are very different than endangered species in the type and magnitude and temporal aspects of the extinction threat they face. In the Pacific Northwest, there are dozens of endangered and threatened salmon and steelhead species. For these salmon and steelhead species, the EPA and NMFS have conducted consultations regarding the impacts of dozens of pesticides. But, the conservation status of these species varies widely. The Oregon Coast Coho population numbers in the hundreds of thousands, while the Snake River sockeye salmon population numbers in the tens to hundreds.⁵⁵ Yet, both of these species would be considered "aquatic endangered species" under the EPA ecological risk assessment procedures. The level of acceptable risk for a species in the hundreds of thousands is very different than the level of risk for a species in the hundreds. Why then should the LOC be the same for both species? Similarly, there is no particular scientific reason why aquatic species should have a lower LOC than terrestrial species if one considered the conservation status of a particular species. Just as there may be two aquatic species with different conservation

⁵⁴ ECOLOGICAL RISK ASSESSMENT PROCESS at 46.

⁵⁵ Northwest Environmental Advocates v. U.S. Environmental Protection Agency, No. 05-cv-01876-AC (D. Or. Feb. 28, 2012).



statuses, there could just as easily be a “threatened” (lower risk) aquatic species that has a very different conservation than a terrestrial species that is endangered. The EPA risk assessment procedure would provide a lower LOC for the aquatic species, even though the terrestrial species may be much more endangered. Finally, there is no reason why the LOC for all threatened and endangered species could simply be set at a very low and uniform level. If the EPA wanted to be truly precautionary in its approach to pesticides, it could just as easily set the LOC for all threatened and endangered species at 0.001. Even more cautiously, the EPA could adopt the approach of the European Union on pesticides and require all pesticide registrants to prove that their products are safe, rather than requiring the EPA (or an interested party) to prove that the product is harmful to listed species.⁵⁶

CONCLUSION

The success of pesticide consultations in the future should be judged by whether harmful exposures of pesticides on threatened and endangered species are reduced over time and whether they result in more robust recovery of listed species. Reducing the number of consultations simply to reduce the number of consultations is not a rational conservation objective. SCB supports the efforts of the EPA to make their ecological risk assessment process more transparent to the public, but believes that EPA must also address the several long-standing, substantive concerns with its existing risk assessment process. Thank you for your consideration of these comments.

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⁵⁶ European Commission Regulation EC 1107/2009 & Directive 91/414/EEC. Available at: http://ec.europa.eu/food/plant/plant_protection_products/legislation/index_en.htm