

ENVIRONMENTAL PROTECTION AGENCY
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs

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

Purpose of this Document:

This document is being made available for public review and comment. This document, which was developed jointly by EPA, the U.S. Department of Agriculture (USDA), the National Marine Fisheries Service (NMFS) in the U.S. Department of Commerce and the Fish and Wildlife Service (USFWS) in the U.S. Department of Interior¹, provides guidance to agency staff and managers participating in the associated processes. It does not create or confer legal rights or impose any legally binding requirements on the agencies or any other party. This document is distributed solely for the purpose of providing an opportunity for public comment and should not be construed to represent formal dissemination of any agency determination or policy. As such, the information correction process under the Agency's Information Quality Guidelines does not apply to this document.

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¹ NMFS and USFWS are referred to collectively as the Services.

1 Introduction

This proposal pertains to Federal agency implementation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)² and the Endangered Species Act (ESA)³. This document describes how the agencies will implement the statutes in the context of pesticide registration review decisions.

The process of assessing the potential effects of a pesticide to federally listed threatened or endangered species, determining whether further risk reduction measures (i.e., “reasonable and prudent alternatives” or RPAs) are necessary to ensure no jeopardy to these species, and/or destruction or adverse modification of critical habitat and implementing such measures requires close coordination across multiple federal agencies and impacts a variety of entities including state pesticide regulatory agencies, pesticide users and pesticide companies. The process of ensuring protection of these species is one that will benefit from input by these entities as well as the general public. There are multiple opportunities for soliciting and considering such input at various points in the process as noted below. Because stakeholders, including state governments, universities, and growers/users, have significant amounts of relevant information and are the ultimate implementers of pesticide labels in the field, it is critical that they have a seat at the table during the development of any needed risk reduction measures to ensure that such measures are technologically and economically feasible.

Over the past several years, stakeholder groups have increasingly expressed interest in ESA issues involving pesticide registration. Furthermore, Congressional committees have also stressed the importance of an open and transparent process, ensuring that at multiple stages of the process there are opportunities for broader public participation and that the economic impacts on agriculture are more fully integrated into the process before a final decision is made. This paper provides a proposal for how the Federal agencies could clarify and/or modify their processes to address these concerns and increase the robustness of the overall process. This paper specifically describes changes to EPA’s registration review process which are intended to facilitate ESA pesticide consultations and coordination across these Federal agencies, and calls for a greater role for USDA.

2 EPA’s Registration Review Program

The Food Quality Protection Act (FQPA) of 1996 amended FIFRA to include a mandate that EPA establish a new program⁴, called registration review⁵, so that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, EPA periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can still be used safely. The registration review program challenges EPA to continuously improve its processes, science, and information management while maintaining a collaborative and open process for decision-making. In general, EPA intends to accomplish its work relative to protection of listed species in the course of its registration review program. That work will include, where appropriate, consultation with the Services.

Under EPA’s regulations, the registration review program is a multi-stage process, incorporating opportunities for public comment at critical points in the review process. At the stage where EPA opens

² 7 U.S.C. 136a *et seq.* (<http://www.epa.gov/lawsregs/laws/fifra.html>).

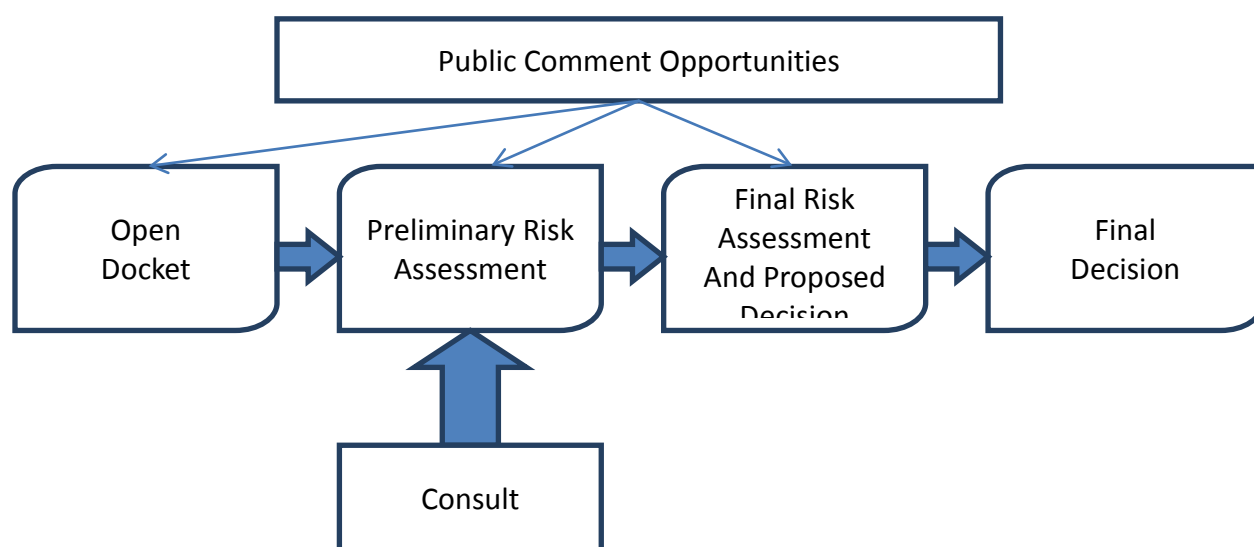
³ 16 U.S.C. §1531 *et seq.* (<http://www.epa.gov/lawsregs/laws/esa.html>).

⁴ FIFRA Section 3(g), 7 U.S.C. 136a(g).

⁵ For more information about EPA’s registration review program, go to http://www.epa.gov/oppsrrd1/registration_review/.

the registration review docket, the Agency issues a preliminary work plan and invites the public to provide feedback on how EPA will scope the review (i.e., problem formulation) and what data will be required as part of this review. Following the completion of that public comment period, EPA reviews the information submitted, develops a response to comments document, and issues a final work plan. After the required data have been submitted and evaluated, EPA develops a preliminary risk assessment and issues that scientific analysis for public comment.⁶ After reviewing public comments, EPA reviews the risk assessment, develops a response to comments document, and proposes risk reduction measures it believes are necessary to address risk concerns and invites the public to provide feedback on its proposed decision. It is only after these multiple stages of public comment that the Agency issues its final registration review decision. Figure 1 provides an overview of the current registration review process.

Figure 1. Original Design of the Registration Review Program



Over the past year, EPA has engaged in significant dialogue with the Services and other stakeholders regarding how to improve the registration review process. At a summary level, most stakeholder groups have recommended that EPA make changes to its process to accomplish several goals: 1) earlier stakeholder involvement in the scoping of the pesticide’s re-evaluation, 2) earlier adoption of risk reduction measures, including incorporation of clarifications and/or new restrictions on product labels, before initiation of any needed consultations with the Services and prior to completion of the registration review, and 3) a more focused consultation process (when and if necessary) that reflects the adoption of such measures.

3 Process Improvement Discussions

In May 2011, the Minor Crop Farmer Alliance convened a workshop in Denver, Colorado, with three primary goals:

⁶ When originally designing the registration review program, EPA intended to initiate consultation with the Services (if needed) at the point in the registration review process where comments were being sought on the preliminary risk assessment. The concept was that while the Agency was soliciting public input on the preliminary assessment, EPA would also engage in consultation with the Services, resulting in a Biological Opinion that could be incorporated into a final risk assessment and proposed registration review decision at the next step in the process.

- Provide grower representatives with an understanding of the processes and analyses leading to the identification of risk and risk reduction options by EPA and by the Services.
- Identify grower-level data that could potentially refine the risk assessment and enhance the risk identification and risk reduction decision processes.
- Initiate discussions on the mechanisms for providing such data.

Several basic themes emerged from these discussions and have served to inform potential improvements to the registration review and consultation processes:

- What are the appropriate points in the registration review process to initiate discussions with both the registrant and the user community to identify, describe and verify crop specific use and usage information?
- What data sources are most complete and relevant to the risk assessment process?
- How will commodity groups know when to engage in the process and how to ensure that information collected and submitted is considered?

Subsequent to the workshop, EPA solicited input from its Federal advisory committee, the Pesticide Program Dialogue Committee (PPDC), regarding potential process changes that would facilitate greater opportunities for public participation and transparency in the registration review process that would have the additional benefit of streamlining any needed Endangered Species Act consultation with the Services.

After considering this public feedback and advice from the PPDC, EPA could implement several changes to the registration review process, further augmenting opportunities for public involvement in the process. These changes are described below.

Earlier involvement of stakeholders in the Registration Review Process

As part of the registration review process, EPA annually publishes a 4-year outlook schedule for when individual pesticides will enter the registration review program. To enhance transparency in the process, EPA could begin including information on the specific timeframe within any fiscal year when the pesticide will begin its review. Having this information available many years in advance would provide early notice for interested stakeholders to provide information to EPA in advance of the pesticide beginning its re-evaluation.

In addition, during FY12, EPA could begin to hold “Focus” meetings during the early stage of registration review. Similar to the “SMART” meetings that were held during reregistration, these “Focus” meetings would provide interested stakeholders with opportunities to: 1) identify the uses that the registrant intends to support for registration review, 2) provide an opportunity to address label clarity issues at an early stage of the review process, and 3) based upon previous assessments, provide for early adoption of risk reduction before the registration review begins.

Purpose #1: From the Agency's experience during the reregistration program, registrants markets and the economic viability of certain pesticide uses change over time. Through the "Focus" meetings, EPA would ask the manufacturers to more explicitly indicate for which uses they intend to continue to seek registration. In essence, this would be an opportunity to begin the process of preliminarily defining the scope of the Federal action that may need to be considered under the Endangered Species Act.

Purpose #2: By working with growers and registrants, any confusion regarding label directions could be addressed at an earlier stage in the process so that a risk assessment that more accurately reflects the intended use of the pesticide can be conducted. Such clarification might include greater specificity on the maximum number and frequency of applications.

Purpose #3: Previous assessments, conducted either to support reregistration decisions or litigation, may have indicated the potential ecological risks. Alternatives may have been developed since those initial evaluations which may indicate that the benefits of the pesticide beginning registration review have changed. There may also be the potential, based upon further field experience with the pesticide, to identify the key efficacious rates critical for crop protection and/or existing conservation practices being employed that could be incorporated into labels as part of "early risk reduction."

It would be EPA's goal to have any early risk reduction incorporated onto product labels before the pesticide reaches the preliminary risk assessment stage.

Consideration of pesticide use and usage data

During the intervening 2-3 years after completion of the final workplan, the registrant is often developing toxicity and exposure data to support the preliminary risk assessment for the pesticide's registration review. As this information is being submitted to the Agency, if needed, EPA would also solicit updated use and usage information from a variety of reliable sources, including USDA and grower organizations, to help frame the ecological risk assessment. These data, such as application methods, application rates, frequency of application, and application timing are critical pieces of information in developing the ecological risk assessment and effects determination. For example, having more complete information on the times of the year when a pesticide is used may enable EPA to more accurately predict the opportunities (or lack thereof) for exposure to listed species.

EPA would incorporate these data as "best available data" in developing its ecological risk assessment and biological evaluation. These data, which may be national and/or local in scope, can also serve to help further refine the label, the uses that will be supported for registration review, and adoption of any additional needed risk reduction, with the possibility of reducing or eliminating the number of "may affect" determinations under the ESA. These data can also be used to describe the situations in which rates higher than "typical" rates are needed and under what conditions, allowing more prescriptive label language to be developed. An ongoing "pilot project" between NMFS, FWS, USDA, and EPA is an example of such an effort to determine how best to incorporate these data into the evaluation process.

EPA has a long history of utilizing these data in making pesticide safety determinations. For example, pesticide usage data collected by USDA's National Agricultural Statistics Service (NASS) have been found to be of exceptional quality and reliability in making food safety determinations (i.e., "reasonable certainty of no harm" determinations) under the FQPA. Congress has directed EPA to use data, such as those developed by NASS when EPA "finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue," provided that the Agency periodically reevaluates the estimate of the anticipated exposure in light of these data.

As a result, these data can be used to help refine the biological evaluation and, perhaps, the pesticide label, taking into account use patterns on a more local or regional basis. Consideration of typical use rates and prescriptive specification on product labels of the conditions under which higher rates may be utilized would further help in clarifying potential ecological exposure scenarios. Utilizing this information, EPA believes that it could develop additional risk reduction (as necessary) to further reduce concerns for listed species, having the direct result of fewer "may affect" determinations, which could potentially preclude or minimize the need for consultation with the Services

Increased use of the informal consultation process

A critical step in developing the biological evaluation is having reliable data on species habitat, range, and behavior. Where necessary, EPA could utilize the informal consultation process to work with the appropriate Service to gather that information for inclusion in a more refined biological evaluation prior to the initiation of any needed formal consultation. Reaching out to the Services for this information at an earlier stage in the process has a number of potential 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. As a result, this assistance would allow EPA to verify any draft conclusions regarding the potential risk to listed species and their habitats and would position EPA to begin discussing potential risk reduction measures with the pesticide registrant. Additionally, this consultation should position the Services well to undertake any formal consultation that may be necessary later in the process since they will previously have been advised of the assessment, supporting data, species potentially at risk etc.

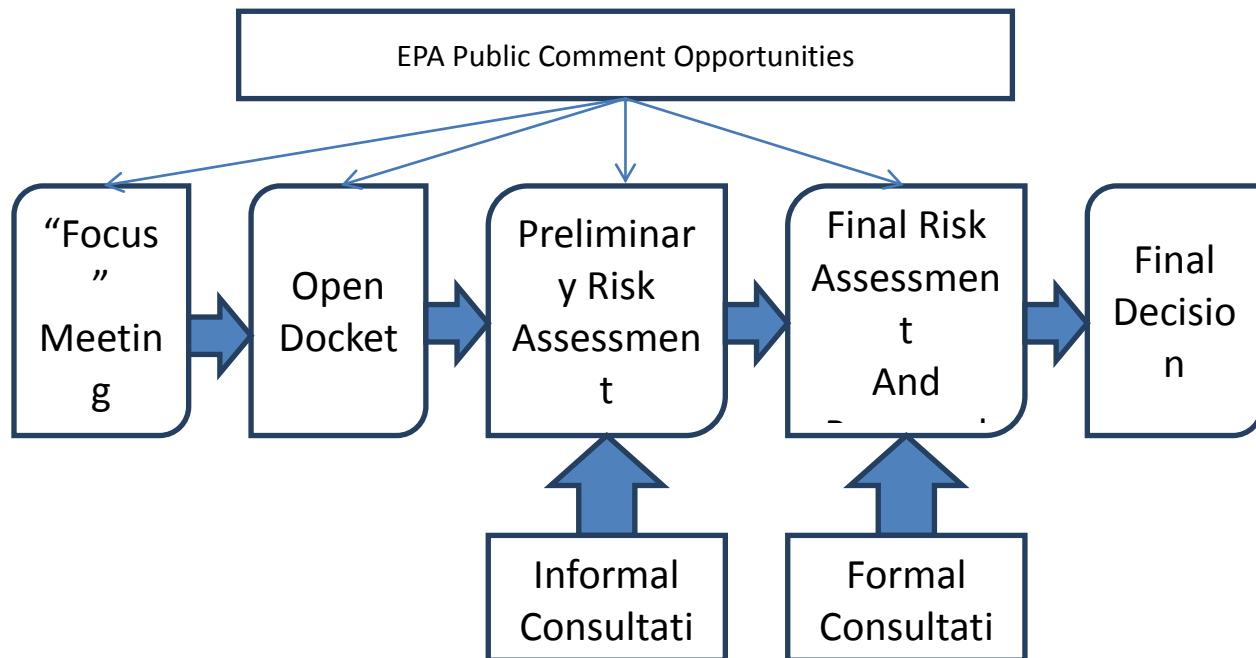
As a result of this feedback, EPA proposes to make two significant changes to its registration review process: 1) hold "Focus" meetings at the start of the registration review for each active ingredient and 2) to initiate any needed formal consultations at a subsequent stage in the review process.

The purpose of the "Focus" meetings will be to multi-fold: 1) to clarify existing label directions, 2) to provide clarification of pesticide usage for the active ingredient, 3) to identify the uses the registrant intends to support for registration review, and 4) to clarify the scope of the re-evaluation effort. EPA believes that these meetings will increase the efficiency of the process and help to better inform the problem formulation and risk assessment phases of the registration review process.

In addition, EPA proposes to change the point in the process where any necessary consultations will be initiated with the Services. Rather than initiate formal consultation during the preliminary risk

assessment stage, EPA envisions that it may instead initiate informal consultation at the preliminary risk assessment stage to help in the identification of species-specific information to further refine the biological evaluation. If necessary, EPA would initiate formal consultation at a later point in the registration review process, perhaps at the proposed decision phase. Figure 2 shows what such a revised registration review process would look like.

Figure 2: Revised Design for the Registration Review Process



One major end result of these process changes is that through public involvement, particularly with growers who are responsible for “on the ground” implementation of labels, risk reduction measures that achieve protection for listed species and designated critical habitat and that are technologically and economically feasible can be achieved, possibly through changes to labels. The involvement of growers will insure that the protection measures are workable.

4 Formal Consultation Process

Under the Services’ ESA regulations⁷, when a Federal agency determines that its proposed action may affect a listed species, the agency is obligated to enter into consultation with the Services to ensure that the action does not result in likely jeopardy to the listed Species.

Where the Services determine that jeopardy and/or adverse modification is likely, they are obligated to work with EPA and the applicant to identify Reasonable and Prudent Alternatives (RPAs), to the extent such measures exist, to insure that the action would avoid the likelihood of jeopardizing listed species or destruction or adverse modification of critical habitat. Service regulations require that such measures be both technologically and economically feasible to the action agency and the applicant. When EPA determines that formal consultation with one or both of the Services is necessary, continued engagement with interested stakeholders is vital. As part of this process, the “applicant,” as defined under the ESA regulations, is identified. The applicant has certain defined opportunities under the

⁷ See 50 CFR part 402.

statute and regulations, including the opportunity to submit information during the consultation and review draft biological opinions obtained through the action agency. The registrant for the pesticides being evaluated is the applicant.

Upon receiving a request for consultation from EPA, the Service would convene a meeting with EPA and the applicant to identify what additional information – beyond that provided by EPA in its package initiating consultation – can be provided to develop the draft biological opinion. During development of a draft biological opinion the Service may discuss with EPA its risk assessment and effects determination to gain a better understanding and they may seek out additional information from other sources. If the Services believe that changes to the pesticide label may be necessary to avoid or reduce the extent of adverse effects to listed species or critical habitat, they would work with EPA, the applicant, and with the consent of the applicant and EPA, product users, to discuss possible label changes needed to avoid jeopardizing the continued existence of any listed species or destroying or adversely modifying critical habitat.

The Services would then prepare a draft biological opinion that would contain the Services' analyses and conclusions regarding whether use of the pesticide is likely to jeopardize the continued existence of a federally-listed species or destroy or adversely modify critical habitat. If the Services determine that jeopardy and/or adverse modification is likely, the draft opinion also would include proposed RPAs to the pesticide registration that will avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. Where the Services anticipate "take" incidental to the proposed action, the draft biological opinion would include proposed measures (Reasonable and Prudent Measures (RPMs)) to minimize the impact of any "take" of listed species.

Once the draft opinion has been developed, the Service would notify EPA and the identified applicants. Prior to formally transmitting the draft biological opinion to EPA, the Service would provide EPA and the applicant with an opportunity to identify any perceived errors in the description of the proposed action and the effects analysis (e.g., use rates, registered uses, scope of the proposed action). Subsequent to any errors being corrected, the Service will provide EPA with the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. EPA will make this draft Biological Opinion available for public comment. All comments will be submitted to EPA, although the applicant may send a copy of its comments directly to the Service. 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. EPA will provide the Services with all of the comments that are submitted in response to the draft Biological Opinion.

It is anticipated that comments would focus on the analyses leading to the conclusions in the opinion, the conclusions themselves, and the reasonableness and practicality of any Reasonable and Prudent Alternatives in the draft biological opinion. This would provide another opportunity for the public to provide invaluable input on the RPAs as well as to provide/suggest/propose alternate risk reduction measures that accomplish the same protection goals that are easier/less costly for the grower/user community to implement.

During this public comment period, EPA and the Services would specifically reach out to growers to engage in what technologically and economically feasible approaches could be implemented that minimize 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. In particular, this process should offer affected stakeholders an opportunity to provide real world data and to identify

practical considerations that affect the viability of different options for mitigating risks to species. EPA will provide a key role by focusing affected entities on the availability of the draft document and timeframes for submission of input.

Upon receipt of the organized public comments from EPA, the Services will prepare a document and include it in the administration record of the consultation that details how such comments were considered and, if appropriate, how the final document was modified to address the comments. The public comments could be on the draft Biological Opinion, Reasonable and Prudent Alternatives, or Incidental Take Statement (including any comments or concerns raised by EPA that were not identified by the public). The Services will include this document in its administrative record and will provide it to EPA. Both the Services and EPA will make the document available to the public upon request.

EPA would generally seek any necessary extensions to the consultation process where it is determine that the statutory timeframes fail to provide adequate time for consideration of information obtained through this process. However, if the extension exceeds more than 60 days (i.e., 150 days from formal initiation), EPA and the Services must seek consent of the applicants. It should be recognized, however, that circumstances beyond the government's control (e.g., litigation deadlines or the refusal of an application to agree to an extension) may force the process described above to be more truncated.

Throughout this process, it is critical that the established expertise of each agency involved in the process is well-recognized: the Services are the expert agencies regarding the species; EPA is the expert agency on pesticide regulation and the enforceability of labels. USDA could lend its expertise on farming/pest management practices and the technological or economic feasibility of adoption of potential risk reduction strategies. Therefore, in developing draft RPAs, the Service should only include risk reduction measures that EPA has the authority to impose and should then defer to EPA to implement these measures utilizing its existing statutory authorities. For example, the Service would identify a level of exposure below which jeopardy would not occur. In response, EPA would implement changes to the registration that it determines would be reasonably likely to ensure that this level of exposure is not exceeded.

5 Conclusion

In summary, the Services, EPA, and USDA intend that these proposed changes will result in greater openness and transparency in the process of developing Biological Opinions for pesticides under the ESA. Consistent with the statutory mandate to use the best available information, the goal of these changes is to improve the respective agencies' understanding, through greater engagement of affected stakeholders, of how pesticides are used, the ways in which they may affect listed species, and how any risks can be effectively mitigated, while preserving the beneficial uses of the pesticides to the extent possible.