



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable Joseph Biden
President of the Senate
Washington, D.C. 20510

Dear Mr. President:

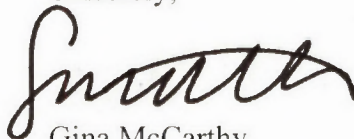
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Should you need additional information or have any questions, please contact me or your staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at kaiser.sven-erik@epa.gov or (202) 566-2753.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Gina McCarthy', written in a cursive style.

Gina McCarthy

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable John Boehner
Speaker of the House of
Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

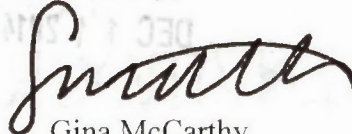
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Sincerely,


Gina McCarthy

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable Debbie Stabenow
Chairwoman
Committee on Agriculture, Nutrition, and Forestry
United States Senate
Washington, D.C. 20510

Dear Madam Chairwoman:

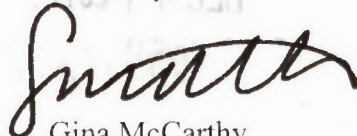
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Sincerely,



Gina McCarthy

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable Thad Cochran
Ranking Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate
Washington, D.C. 20510

Dear Senator Cochran:

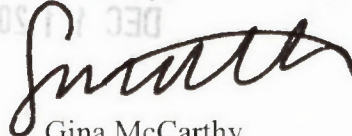
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Sincerely,


Gina McCarthy

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable Frank D. Lucas
Chairman
Committee on Agriculture
United States House of Representatives
Washington, D.C. 20510

Dear Mr. Chairman:

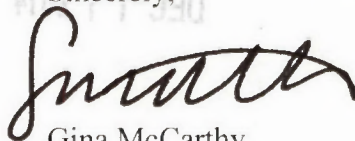
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Gina McCarthy

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable Collin C. Peterson
Ranking Member
Committee on Agriculture
United States House of Representatives
Washington, D.C. 20510

Dear Congressman Peterson:

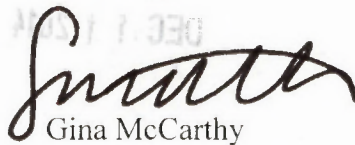
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Sincerely,


Gina McCarthy

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Chairman Boxer:

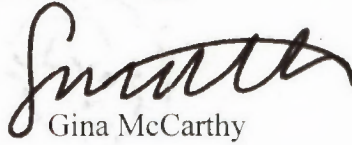
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Gina McCarthy

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable David Vitter
Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

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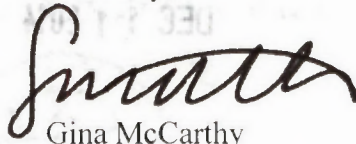
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Gina McCarthy

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable Doc Hastings
Chairman
Committee on Natural Resources
United States House of Representatives
Washington, D.C. 20510

Dear Mr. Chairman:

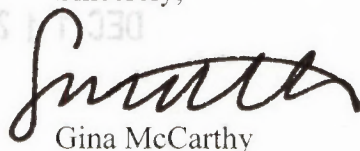
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Sincerely,

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Gina McCarthy

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 11 2014

THE ADMINISTRATOR

The Honorable Peter DeFazio
Ranking Member
Committee on Natural Resources
United States House of Representatives
Washington, D.C. 20510

Dear Congressman DeFazio:

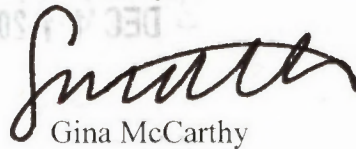
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Gina McCarthy

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Interim Report to Congress
on
Endangered Species Act Implementation in Pesticide Evaluation Programs

U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, National Marine
Fisheries Service, and the U.S. Department of Agriculture

November 2014

Summary of Report

The National Academy of Sciences' report, entitled "Assessing Risks to Endangered and Threatened Species from Pesticides" was released on April 30, 2013. It contained recommendations on scientific and technical issues related to pesticide consultations under the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since then the Environmental Protection Agency (EPA), the National Marine Fisheries Service (NMFS) and the Fish and Wildlife Service (FWS) (i.e., the Services) have worked to implement the recommendations. Joint efforts to date include: collaborative relationship building between EPA, NMFS, FWS, and the Department of Agriculture (USDA); clarified roles and responsibilities for the EPA, the Services, and USDA; agency processes designed to improve stakeholder engagement and transparency during review and consultation processes; two joint agency workshops resulting in interim approaches to assessing risks to ESA-listed species from pesticides; a plan and schedule for applying the interim approaches to a set of pesticide compounds; and multiple workshops and meetings with stakeholders to improve transparency as the pesticide consultation process evolves. As a result of the ongoing collaborative efforts, EPA and the Services are moving forward with developing and applying their interim approach to pesticide consultations, have completed some consultations affording species protections, and developed work products that describe changes to processes intended to streamline consultations and provide ample opportunity for stakeholder engagement as early as possible.

Table of Contents

Purpose of the Report.....	1
Background	1
Legal Authority	2
National Academy of Sciences Study Implementation	4
Meaningful Public Participation and Transparency	12
Anticipating, Minimizing, and Resolving Delays.....	20
Conclusion	23

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Purpose of the Report

This report is intended to provide Congress with a description of the approaches and actions taken by the Environmental Protection Agency (EPA), the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the Department of Agriculture (USDA) (hereafter referred to as the Agencies) to 1) implement the recommendations of National Academy of Sciences' (NAS) National Research Council (NRC) report, entitled, "Assessing Risks to Endangered and Threatened Species from Pesticides" (hereafter referred to as the NRC's study), 2) ensure public participation and transparency during implementation of the recommendations from the NRC's study, and 3) minimize delays in integrating applicable pesticide registration and registration review requirements with species and habitat protections.

Background

On February 7, 2014, President Obama signed into law the Agricultural Act of 2014 (P.L. 113-79). As provided in Section 10013 of Title X – Horticulture, on the Endangered Species Act (ESA) Implementation in Pesticide Evaluation Programs, Congress required this interim report to be delivered 180 days after the Bill was signed into law and a final report in one year. The intent expressed in this provision is to keep the Agencies moving forward as they develop processes that will make it possible for EPA to comply with the ESA in a manner that maximizes resources and minimizes delays of pesticide registration and reregistration decisions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In addition, the provision is intended to encourage meaningful public participation, and reemphasize that all ESA-mandated Reasonable and Prudent Alternatives (RPAs) are technologically and economically feasible, that ESA-mandated Reasonable and Prudent Measures (RPMs) are necessary and appropriate, and that the Agencies have ensured public participation and transparency in the development of RPAs and RPMs.

Legal Authority

EPA regulates the distribution, sale, and use of pesticides under FIFRA. Under Section 3 of FIFRA, subject to limited exceptions, a pesticide must be registered by the EPA prior to its distribution or sale. Before EPA may register a pesticide under FIFRA, the applicant must show, among other things, that using the pesticide according to specifications "will not generally cause unreasonable adverse effects on the environment."¹

If EPA concludes that the pesticide, together with its accompanying labeling and any terms and conditions, will not cause unreasonable adverse effects on the environment, EPA grants the registration and the labeling provisions approved by EPA become the enforceable use directions for the pesticide product. Post-registration, EPA reviews and reevaluates a pesticide every 15 years to determine whether it continues to meet the FIFRA registration standard.² EPA has long stated that it will use the registration review process to address its ESA obligations for pesticide registrations and intends to do so by conducting nationwide scale effects determinations.

Under section 7(a)(2) of the ESA, all federal agencies have responsibility to insure that any action authorized, funded, or carried out by that agency is not likely to jeopardize the continued existence of any federally listed endangered or threatened species (listed species), or result in the destruction or adverse modification of designated critical habitat. Therefore, under ESA, EPA must insure that its activities in administering FIFRA are not likely to jeopardize the continued existence of any federally listed threatened or endangered species or adversely modify designated critical habitat.

¹ FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

² Due to concerns that much of the safety data underlying pesticide registrations becomes outdated and inadequate, FIFRA Section 4 requires that registrations be reviewed every 15 years and requires EPA to reregister all pesticides that were registered before 1984. The goal is to update labeling and use requirements and reduce potential risks associated with older pesticide active ingredients -- those first registered when the standards for government approval were less stringent than they are today. This comprehensive reevaluation of pesticide safety in light of current standards is critical to protecting human health and the environment.

Regulations implementing Section 7 of the ESA require that federal agencies initiate “consultation” with the appropriate Service(s) on certain actions that “may affect” ESA-listed species or designated critical habitat. The appropriate Service depends on the agency’s action, the ESA-listed species potentially affected by that action, and the Service responsible for administering consultations for the listed species potentially affected. The Services conclude a formal consultation by issuing a Biological Opinion that addresses the federal agency action considered during consultation. The appropriate Service determines whether the proposed action assessed in the Biological Opinion is likely to jeopardize the continued existence of any ESA-listed species, or destroy, or adversely modify the designated critical habitat of such species. If the FWS, or NMFS, determines from its assessment that a proposed action is likely to jeopardize the continued existence of the species, or destroy or adversely modify critical habitat, it must provide the federal agency with RPAs to the action, if any exist, that the Service determines will preclude likely jeopardy and destruction or adverse modification of critical habitat. If the relevant Service concludes that take (*i.e.*, harass, harm³, pursue, hunt, shoot, wound, kill, trap, capture, or collect any threatened or endangered species) will not violate ESA section 7(a)(2), the Service provide the federal agency with an incidental take statement (ITS). The ITS identifies the amount or extent of take, RPMs that minimize the impact of take, and implementing terms and conditions. Incidental take that occurs when the agency action is conducted in compliance with the implementing terms and conditions is exempt from statutory or regulatory prohibitions of take that would otherwise apply.

It should be noted that USDA has no formal role in the consultation process. USDA’s role is to provide pesticide use and usage data as well as information on agricultural production practices. The National Agricultural Statistics Service (NASS) is providing assistance with the appropriate use of the Crop Data Layer and other geospatial information related to the location of agricultural crops.

³ Harm is further defined in 50 CFR Part 222

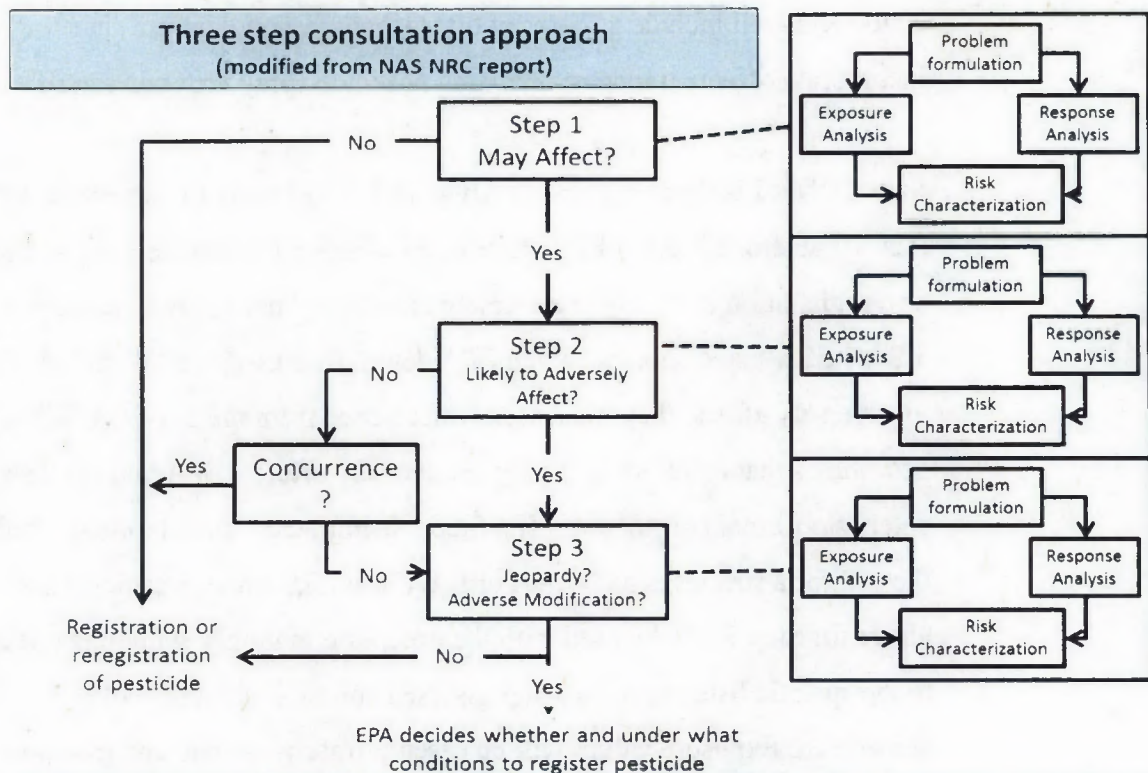
National Academy of Sciences Study Implementation

On March 10, 2011, the Agencies requested that the NRC convene a committee of independent experts. "The committee was asked to evaluate EPA's and the Services' methods for determining risks to ESA-listed species posed by pesticides and to answer questions concerning the identification of the best scientific data, the toxicological effects of pesticides and chemical mixtures, the approaches and assumptions used in various models, the analysis of uncertainty, and the use of geospatial data."⁴ Specifically, the committee was asked to evaluate the protocols used by EPA and the Services to review the best available scientific methods for projecting these effects and consider options for the development of any additional methods that are likely to be helpful, to consider the scientific information available to assess the potential effects of mixtures and inert ingredients, to consider the selection and use of uncertainty factors to account for lack of data and how the choice of those factors affects estimates of uncertainty, and to advise on the use of models to assist in analyzing the effects of pesticide use and on the use of geospatial information and datasets in assessing the risk to endangered and threatened species from pesticides.

On April 30, 2013, the NRC provided their recommendations to the Agencies in the form of a report⁵. Upon receipt of the study report, the Agencies began a joint review and discussion of the recommendations and developed a plan for their implementation. As part of the implementation plan, the Agencies determined which recommendations could be implemented immediately, which recommendations would take longer to implement, and which recommendations required additional interagency discussions. The Agencies are implementing the NRC study's recommended three-step consultation approach, shown below.

⁴ Assessing Risks to Endangered and Threatened Species from Pesticides (National Research Council, 2013; http://www.nap.edu/catalog.php?record_id=18344)

⁵ Ibid.



NOAA FISHERIES



1

- Step 1 ('No Effect/May Affect' determination) - EPA makes the "no effect/may affect" determination independently of the Services at Step 1. If EPA determines that a pesticide's registration, or reregistration, will have "no effect" on ESA-listed species it may move forward with a pesticide's registration, or reregistration, without consulting with the Services. If EPA determines that a pesticide's registration, or reregistration "may affect" ESA-listed species, the pesticide's potential impact on ESA-listed species must be considered under Step 2. The 'No Effect/May Affect' determination will largely be based on the overlap of the action area with the species' ranges and designated critical habitats (i.e., any species or critical habitat that overlaps with the action area will be considered a 'May Affect'). The action area will be defined by identifying pesticide use areas (i.e., the pesticide use footprint) based on currently registered labeled uses (i.e., the Action). In addition, the

action area will include a footprint that extends beyond the use sites to incorporate off-site transport including pesticide spray drift and runoff.

- Step 2 ('Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA)' determination) – EPA determines whether a pesticide's registration, or reregistration is "likely to adversely affect", or "not likely to adversely affect" ESA-listed species. When EPA determines that an effect is "not likely to adversely affect" they must seek concurrence from the Services. When EPA determines that an effect is "likely to adversely affect," EPA and the Services enter into formal consultation, and Step 3 is initiated. To determine whether the call for a species is an NLAA or LAA, a similar process as described above for Step 1 will be used with the exception that only endpoints relevant to the specific listed species being assessed and their habitats will be considered. Exposure values will be based primarily on fate and transport model results that assess the range of labeled uses of the pesticide (rates, methods). For aquatic exposures, PRZM/EXAMS, AgDRIFT and AGDISP will be used to predict exposure in generic habitats, referred to as bins, relevant to groups of listed species with similar habitat preferences. Exposure results for the bin most appropriate for the species being assessed will be used. For terrestrial exposures, TerrPlant, AgDRIFT, AGDISP and T-REX will be used. In this step (i.e., Step 2), a refined version of T-REX that accounts for species-specific characteristics (e.g., body size, diet, etc.), will be used.
- Step 3 ('Jeopardy/No Jeopardy' determination and "Adverse Modification/No Adverse Modification" on effects to designated critical habitat(s) determination) – For all of those species/critical habitat designations found to warrant determinations of LAA, the relevant Service(s) will determine 'jeopardy' or 'no jeopardy' for species and 'adverse modification' or 'no adverse modification' for designated critical habitat. These determinations will be based on a weight-of-the-evidence approach that evaluates species and habitat risk hypotheses and associated lines of evidence. A variety of tools

will be employed to assess the population and species responses including but not limited to population modeling (when appropriate data are available on species and habitat use).

The Agencies are holding a series of internal workshops to develop procedures and methodologies to address NRC study's recommendations that cannot be implemented immediately, but that are considered to be short-term, or long-term goals. The Agencies conducted their first workshop during the week of August 5, 2013, in which interim approaches for estimating risks to listed species from pesticides were developed jointly by the Agency scientists. In keeping with the NRC's study recommendations, the result is a streamlined consultation process that relies on best available data to inform an ecological risk assessment based on robust quantitative and qualitative analyses. The white paper describing the interim approaches entitled, "Interagency Approach for Implementation of the National Academy of Sciences Report" (11/13/2013) is available at the following website: <http://www.epa.gov/oppfead1/endanger/2013/nas.html>

The white paper explains in more detail the procedures and methodologies that will be used in Steps 1, 2, and 3, including how a pesticide's "action area"⁶ will be determined in Step 1 and what constitutes effects thresholds⁷ in Steps 1 and 2. The white paper emphasizes the importance of using quantitative analysis whenever possible and explaining the rationale supporting a qualitative analysis, and states that the ECOTOX toxicology database⁸ supplemented with information from the Services⁹ will generally constitute best available data for toxicity. The white paper explains that as part of

⁶ Action area means all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action (50 CFR § 402.02). (<http://www.fws.gov/endangered/what-we-do/faq.html>)

⁷ Effects thresholds are derived from available, scientifically valid toxicity data. They are designed to be conservative and to represent the risk management goals of the ESA, which are focused on effects to an individual's fitness.

⁸ ECOTOX is a comprehensive database, which provides information on adverse effects of single chemical stressors to ecologically relevant aquatic and terrestrial species. ECOTOX includes more than 40,000 test records covering 5,900 aquatic and terrestrial species and 8,400 chemicals. The primary source of ECOTOX data is the peer-reviewed literature with test results identified through comprehensive searches of the open literature (<http://cfpub.epa.gov/ecotox/>).

⁹ This may include peer-reviewed studies not included in the ECOTOX database and other relevant toxicity studies including those generated by city, county, state, and federal entities.

implementing Steps 1 and 2, predictive models will be used to estimate pesticide concentrations in soil, air, and water and environmental exposures to them, as well as targeted and ambient water quality monitoring. Formulated products with more than one active ingredient, tank mixes, and environmental mixtures will largely be considered qualitatively.

The white paper also identified several follow-up tasks related to the NRC study's recommendations that are considered to be short-term, or long-term goals that will be developed further by the Agencies, specifically:

1. Develop a common approach to weight of evidence (WOE) analyses, using quantitative and qualitative information for making NLAA/LAA (and jeopardy and adverse modifications of critical habitat) decisions.
2. Share information about the FIFRA Endangered Species Task Force (FESTF) database and the U.S. Fish and Wildlife Services' Environmental Conservation Online System (ECOS) and discuss whether/how these tools can be used as part of the interim approach to identify species and define species' ranges and critical habitats. Within ECOS, there are various modules that the agencies are exploring to gather or store species information, including the Information, Planning, and Conservation System (IPaC), the Critical Habitat Portal, and the Threatened and Endangered Species System (TESS). These three modules include various scales of geospatial data for species ranges (e.g., county-level, areas of influence) and critical habitat.
3. Describe "bins" (i.e., type of water body) for aquatic species for use in Steps 2 and 3 for exposure modeling. The water body may vary by depth, width, and flow; it may be static, flowing, estuarine, intertidal, subtidal, or offshore marine.
4. Develop guidance on the construction and use of species sensitivity distributions (SSDs).

5. Discuss proposal for defining agricultural pesticide use areas by aggregation of crop categories in the Cropland Data Layer (CDL) produced by USDA.

The interim approaches, including the follow-up tasks, were presented to the public during a workshop on November 15, 2013. Presentation materials from the stakeholder workshop are available at the following website:

<http://www.epa.gov/oppfead1/endanger/2013/nas.html>

The Agencies have been working continuously since the release of the NRC's study on all of these areas, simultaneously. The expectation is that these additional approaches can be incorporated into the risk assessment process on a "day forward approach". This means that our shared scientific approaches, once fully developed, will be applied to pesticide reviews from that point in time and going forward rather than reworking assessments and decisions already completed.

The Agencies held a second internal workshop during the week of May 5, 2014 to continue development of joint interim approaches for assessing risks to ESA-listed species from pesticides, and to deliberate on the follow-up tasks identified in the white paper. As a result of this workshop, the Agencies have developed a draft annotated outline for EPA's ESA-listed species' risk assessments, or biological evaluations.

Progress towards implementing the NRC study's recommendations considered to be short-term or long-term goals includes:

1. Weight-of-evidence analysis being developed – Developing a common approach to weight-of-evidence analysis that includes an explanation of how all of the information (quantitative and qualitative) was used to draw and support conclusions. Agency scientists have drafted guiding principles that will be further developed in concert with the national-level consultations discussed below. EPA and the Services are working together to develop a

WOE approach that can be used for the species-specific determinations, and are planning on using WOE in Step 2. We have not yet had discussions on using WOE at Step 3.

2. Geospatial data being defined - Identifying sources of geospatial data to map the locations of ESA-listed species, and their designated critical habitat and ranges, and to map crop locations for use in defining a pesticide's action area (Step 1 in the NRC study). The Agencies are pursuing sources of this information considered "best available data" through various sources, including two pesticide industry task forces: Federal Endangered Species Task Force (FESTF) and Generic Endangered Species Task Force (GESTF).
3. The Agencies met with FESTF on November 25, 2013 and again on March 27, 2014. During the November meeting, FESTF representatives provided the Agencies with an overview of their databases and sources of their data. During the March meeting, FESTF representatives provided a more detailed comparison of ESA-listed species' locations from individual sources, and demonstrated an information management system through which species location maps from individual sources could be compiled, contrasted, and compared. FESTF has begun delivery of species range maps that include aggregated available geospatial information (e.g., including critical habitat information from ECOS) to the FWS field offices for use in the development of vetted listed species ranges for the initial pesticide consultations. Once the field offices have completed their review and refinement of the range maps, they will be sent to FWS Headquarters for review prior to delivery to EPA/FESTF as appropriate.
4. The Agencies met with GESTF on January 15, 2014 to discuss their efforts to map crop locations using NASS CDL data. Based on the information and understanding of available data and information on ESA-listed species locations, designated critical habitat and range, and cropping patterns gained from these meetings, the Agencies have drafted an approach for establishing

the action area and determining whether the action may affect ESA-listed species or designated critical habitat, i.e., Step 1 of the NRC's study recommendations. Currently, GESTF is investigating approaches to mapping non-agricultural crops. GESTF expects to share their findings with the EPA by the end of the end of 2014.

5. Exposure modeling being developed - EPA is developing a nationwide pesticide aquatic exposure model that defines the magnitude and extent of pesticide concentrations in water that is spatially explicit and captures seasonal and yearly variations. The outputs of this spatial aquatic model will provide a better definition of the aquatic spatial footprint of pesticide exposures in the action area. EPA just completed a pilot version of the model for the Midwest and is in the process of expanding to the entire country. On March 24, 2014, EPA provided an update on the model at a public workshop. This workshop provided an opportunity for stakeholders to provide technical and scientific feedback on the model. On August 13, 2014, a presentation was made to the American Chemical Society (ACS) meeting.
6. Species Sensitivity Distributions (SSDs) and population modeling being developed - Different methods for deriving species sensitivity distributions have been reviewed and will be applied to the initial consultations that the EPA and Services will conduct in the coming months. The Services and EPA are currently developing population modeling through monthly discussions with academic and government experts. EPA's Office of Research and Development and Office of Pesticide Programs are developing general and species-specific population models. Species sensitivity distributions will be for procedures separate from population modeling.

Based on recent settlement agreements as part of ongoing litigation against EPA and the Services (i.e., Northwest Center for Alternatives to Pesticides (NCAP) v. EPA, NCAP v. NMFS, and Center for Biological Diversity (CBD) v. FWS), the Agencies have agreed to

coordinate completion of nationwide consultations for five pesticides, carbaryl, chlorpyrifos, diazinon, malathion, and methomyl. The dates provided for completion of consultation in those settlements is December 2017 for chlorpyrifos, diazinon, and malathion, and December 2018 for carbaryl and methomyl. The Agencies are beginning to implement the interim approaches for chlorpyrifos, diazinon, and malathion using the annotated outline drafted during the May 2014 workshop.

In addition, three teams of interagency scientists have been formed and are currently working to complete effects determinations (i.e., Steps 1 and 2) for chlorpyrifos, diazinon, and malathion. All three teams have developed SSDs for fish, aquatic invertebrates, and birds and are currently reviewing other toxicity data available in the literature. EPA has developed an analytical approach that identifies and groups data (e.g., endpoints specific to family, species and endpoints) that allows risk assessors to easily access and review relevant toxicity data. Subgroups have been formed to continue to develop methods that may be used by all three chemical teams. These subgroups are focused on problem formulation development, aquatic exposure methodology, and probabilistic methodology. The problem formulation subgroup is identifying critical information that should be included in this portion of the written assessments. The aquatic exposure group is working to develop model assumptions and simulate the diverse aquatic habitats that are necessary for listed species, and the probabilistic subgroup is considering what questions could be addressed with probabilistic methods.

Meaningful Public Participation and Transparency

Existing processes for registration, registration review, and consultation provide multiple opportunities for stakeholder engagement. Although federal law only requires limited public participation in the pesticide registration process, EPA's Pesticide Program began implementing a public participation process for certain registration actions in October 2009. The public participation process for registration actions provides a meaningful

opportunity for the public to comment on major registration decisions at a point in the registration process when comprehensive information and analysis are available. The Agency intends to use the outlined public participation process for the following types of applications: new active ingredients; first food use, first outdoor use; first residential use; and other actions of significant interest.

The current post-registration review process – known as registration review -- was created by section 3(g) of FIFRA and mandates that EPA review pesticides not less often than every 15 years. Under section 3(g)(1)(A)(ii), EPA has established procedures for registration review in its final rule published in the Federal Register (71 FR 45,732, Aug. 9, 2006, as amended at 73 FR 75595, Dec. 12, 2008) and codified at 40 CFR Part 155 Subpart C – Registration Review Procedures. Under the procedures established per 40 CFR part 155 Subpart C, three specific time points have been identified for public notification and comment during registration review: 1) initiation of a pesticide's reevaluation, 2) when a draft risk assessment has been conducted, and 3) for a proposed registration review decision. In addition to the public review and comment periods outlined above, EPA may meet with stakeholders at any time during registration review, either through Agency initiation, or stakeholder request, to discuss an ongoing registration review (40 CFR Part 155.52).

EPA's Endangered Species Protection Program (ESPP) is the EPA program for addressing the requirements of the ESA in connection with EPA's implementation of FIFRA. Announced in a November 2, 2005, Federal Register Notice, the 2005 ESPP document¹⁰ outlines three opportunities for public input and participation during registration review: 1) prior to a "may affect" determination by EPA, 2) when identifying potential mitigation if a risk assessment identifies a listed species concern, and 3) prior to issuance of a Biological Opinion to EPA by the Services. Under the ESPP, EPA will generally engage the public in each of these three stages of its ESA-related work. The first and second opportunity for public review and comment meld with existing

¹⁰ <http://www.gpo.gov/fdsys/pkg/FR-2005-11-02/pdf/05-21838.pdf>

procedures established for registration review. These existing opportunities for public input have been strengthened and enhanced through process improvements jointly developed by the Agencies as described below.

In response to stakeholders' concerns expressed regarding a lack of transparency surrounding pesticides consultations, the Agencies have been seeking input from stakeholders on how to improve opportunities for their engagement in our processes. Specifically, stakeholders expressed the need for increased access to the decision-making process to give states and other stakeholders increased opportunities to provide relevant data for consideration during consultation, and the need for adequate time for public review and comment.

As mentioned above, the interim approaches developed by the Agencies in the summer and fall of 2013 were presented to the public during a workshop on November 15, 2013. On April 22, 2014, at the request of stakeholders, the Agencies held a public workshop to provide a forum for stakeholders to present scientific and technical feedback on the interim approaches. Representatives from the pesticide industry and non-governmental organizations attended the workshop and provided feedback. The scientific and technical presentations are available in the public docket (EPA-HQ-OPP-2014-0233) which can be accessed through www.epa.gov/pesticides/oppfead1/endanger/2013/nas.html. The Agencies are continuing to consider the information provided during the workshop as to how it might improve and facilitate listed species consultations. As described in more detail below in this report, public workshops, such as those held in November 2013, April 2014, and October 2014, further the Agencies' goal of developing a consultation process for pesticide impacts on listed species that is efficient, inclusive, and transparent.

However, the Agencies' efforts to improve transparency for pesticide consultations began earlier. Since 2011, the Agencies have organized and participated in meetings and workshops with stakeholders affected by pesticide consultations. The intention of the outreach efforts was to identify improvements to the registration review and consultation processes that would more fully involve stakeholders. Our intention in organizing and

holding these public meetings has been to obtain as much input as possible from stakeholders affected by ESA-related work and decisions under FIFRA.

A workshop organized with the Minor Crop Farmer Alliance addressing grower concerns was held in Denver, Colorado in May 2011. There was general agreement that information was needed to clarify and confirm product labeling information, identify where crops are grown, and that growers need to be engaged early and often. The meeting minutes and materials provided for and discussed at the workshop can be found at:

<http://www.ffva.com/imispublic/Content/NavigationMenu2/AgResources/Aglinks/Meetingmaterials/default.htm>. Copies of the individual presentations can be found on the following websites: Florida Fruit & Vegetable Association, www.ffva.com; and the California Citrus Quality Council, www.calcitrusquality.org.

Meetings were held in July and September 2011 with the Pesticide Program Dialogue Committee and its subgroup, the Pesticide Registration Improvement Act Process Improvements Workgroup. Members of these fora represent a variety of stakeholders including pesticide registrants, growers, states, and non-governmental organizations. These discussions centered on opportunities for public participation on ESA-related work under registration review and explored the appropriate timing during registration review for initiating consultation with the Services. The meeting minutes can be found at: <http://www.epa.gov/oppfead1/cb/ppdc/pria/index.html#meetings>.

In response to the stakeholder feedback gained in 2011, the Agencies prepared and proposed for public comment the paper entitled, "Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives" (hereafter referred to as the Stakeholder Paper). The Agencies finalized the Stakeholder Paper in March 2013; it can be found at www.regulations.gov in the following docket: EPA-HQ-OPP-2012-0442. The processes described in the Stakeholder Paper supersede similar provisions in the 2005 ESPP document.

The Stakeholder Paper sets the stage for enhanced public engagement and describes changes to the Services' and EPA's review processes intended to enhance opportunities for stakeholders to provide input during review of pesticide registrations and consultations. It begins by emphasizing the value of improved coordination across the Agencies, a key recommendation of the NRC's study. Plans to reach out at the earliest point to pesticide users potentially affected to discuss the technological and economic feasibility of draft RPAs and RPMs intended to avoid jeopardy and adverse modification to critical habitat are included. The proposal describes the process by which stakeholders' comments on RPAs will be received by EPA and provided to the Services, who will then prepare a document to be included in the administrative record of the consultation explaining how comments were considered, and if appropriate, how the final biological opinion was modified to address the comments. The Services will provide the document to EPA, and both the Services and EPA will make the document available to the public upon request. The Agencies believe these changes provide clarity and transparency to Section 7 ESA consultations for pesticides and result in improved ESA pesticide consultations.

The Stakeholder Paper also describes "Focus" meetings, now being held at the start of registration review for pesticide active ingredients. This change brings the affected stakeholders into EPA's review process at the earliest point of a pesticide's registration review cycle. The Stakeholder Paper describes EPA's and the Services' agreement to initiate formal consultations at a later stage in the review process; consulting later in the registration review process allows EPA to develop more refined ecological risk assessments and to engage affected stakeholders in discussions throughout EPA's review process resulting in more focused consultation packages inclusive of any agreed upon mitigation for ESA-listed species. It recognizes USDA's valuable relationships with the agricultural community that provide a critical link between EPA's expertise on pesticides and the Services' expertise on listed species' locations, status and biology. The process changes described in the proposal have the potential to maximize the opportunity to effect changes that provide protections for species and their designated critical habitat,

lessen the impacts on agriculture, and narrow the scope of any necessary ESA consultations. USDA attends Focus meetings regularly, and the Services attend when warranted.

Currently, EPA uses the web application "Bulletins Live!" to set forth geographically-specific pesticide use limitations for the protection of threatened and endangered species and their designated critical habitat. "Bulletins Live!" can be found at <http://www.epa.gov/oppfead1/endanger/bulletins.htm>. EPA is upgrading to "Bulletins Live! Two" (BLT). The upgrades will move away from static county maps to an interactive map such as Bing™, or Google Earth™. BLT will be geo-coded making it possible for users to zoom in and out and focus on their area of interest, conduct searches for products (by name and EPA registration number) in addition to active ingredients, and download data. These upgrades are intended to make the web application setting forth species protections more user friendly for growers likely to be impacted by species protections.

By following the process outlined in the Stakeholder Paper, the following examples show positive outcomes resulting from enhanced stakeholder engagement during 1) consultations resulting from litigation, and 2) registration review.

Litigation Consultations

Rozol - Rozol™ is a rodenticide used to control black-tailed prairie dogs. The consultation was the result of a lawsuit, in which the court-ordered EPA to cancel Rozol's™ registration. EPA and FWS worked collaboratively with stakeholders (registrants) very early during the consultation to identify conservation measures that protect species and their critical habitat. Early mitigation termed "conservation measures" was agreed to prior to the final biological opinion. Incorporation of conservation measures protecting species and their designated critical habitat resulted in a "no jeopardy" conclusion, making RPAs unnecessary. Technologically and economically feasible RPMs were developed collaboratively between FWS, EPA, and the registrant. The consultation was completed efficiently and species protections put in place quickly.

Kaput - Kaput™ is a rodenticide used to control black-tailed prairie dogs which was also the subject of a lawsuit. The Agencies built upon their success from the Rozol™ consultation and applied the same early stakeholder engagement strategy to implement risk mitigation measures that would support a “no jeopardy” conclusion, negating the need for RPA, but achieve species protections through negotiated RPMs.

Thiobencarb - Thiobencarb is one of the pesticides included in the lawsuit related to pesticide impacts on Pacific Northwest salmonids. Early engagement between NMFS, EPA, the California Department of Pesticide Regulation (CDPR), the registrant, and the California Rice Commission allowed EPA and NMFS to develop an implementation plan for thiobencarb use on rice in California. NMFS considered and used existing state programs to mitigate risks to species and protect designated critical habitat. This resulted in a “no jeopardy” conclusion. RPM were based on existing state programs and developed in collaboration with EPA, CDPR, and NMFS. EPA is working with the registrant, state, and impacted growers to implement the RPM via endangered species bulletins. The draft bulletins were made available to affected stakeholders for public comment.

Ongoing pesticide consultations regarding salmonids - Diflubenzuron, propargite, and fenbutatin-oxide are three of the pesticides included in the lawsuit related to pesticide impacts on Pacific Northwest salmonids. EPA and NMFS worked with the registrants to identify pesticide uses that posed the greatest risks to salmonids. Registrants proposed several label modifications to labels to reduce risk to the species. EPA is now working with the registrants to incorporate the agreed upon mitigation measures into pesticide product labels. The final Biological Opinion is scheduled for completion in December 2014.

Registration Review

Starlicide - Starlicide™ is an avicide used mainly on rice, typically in the form of bait. It is currently undergoing registration review; and consultation has not been initiated. It

provides an example of positive outcomes from early stakeholder engagement prior to consultation. In the interest of reducing non-target exposure, EPA met regularly with USDA's Animal and Plant Health Inspection Service (APHIS) and the US Rice Federation to discuss ways to minimize exposure and reduce costly data requirements. The US Rice Federation suggested tilling the soil after the application/bait period would bury leftover bait, making it less accessible to non-targets. This would be a practical mitigation measure that is technologically and economically feasible for the rice use, and may work for some of the other broadcast uses as well. The goal of these outreach efforts is to eliminate or limit the potential for non-target exposures from the rice use and other broadcast uses, subsequently negating the need for the majority of the data requirements for Starlicide™. This modification will be reflected in the consultation EPA initiates with FWS as it works to complete registration review. The Agencies are working towards this kind of successful outcome through collaborative dialogue with stakeholders resulting in technologically and economically feasible mitigation measures, which when implemented have the dual benefits of precluding the need for expensive data requirements, and reducing, or eliminating concerns for listed species.

Gas cartridges - Gas cartridge products are used to control a variety of pests. It is currently undergoing registration review; and informal consultation has been initiated. It provides an example of achieving risk mitigation for some listed species through informal consultation. EPA and APHIS have worked closely together and developed a set of risk mitigation measures that build upon work already completed under previous consultations with FWS. APHIS has agreed to place the risk mitigation measures on their product labels narrowing the scope of consultation. The comment period on EPA's proposed interim decision is now closed. EPA is considering those comments and formulating the interim decision.

Silica - Silica (Diatomaceous Earth) is an insecticide that is currently undergoing registration review. EPA and FWS successfully completed informal consultation on 57 listed species that may be directly or indirectly affected by the use of silica. FWS

concurred with EPA's determination that silica "May affect, but is not likely to adversely affect" these species.

All of the examples described above reflect the benefit of working closely with stakeholders prior to initiation of consultation and sharing the conclusions of past consultations, which allows EPA to build upon work done for existing consultations. These positive outcomes underscore the importance of early engagement with stakeholders, consideration of existing consultations, state programs and state co-regulators, and flexibility.

Registration

EPA recently registered the herbicide, Enlist Duo, containing 2,4-D and glyphosate. The product is for use in controlling weeds in corn and soybeans genetically-engineered to tolerate 2,4-D and glyphosate. EPA scientists used highly conservative and protective assumptions to evaluate ecological risks for the new uses of 2,4-D in Enlist Duo. The assessments confirm that these uses meet safety standards for pesticide registration, and as approved, will be protective of non-target species, including endangered species. To minimize potential exposures of non-target species, use restrictions to minimize drift include 30-foot in-field "no spray" buffer zones around the application areas, no pesticide application when the wind speed is over 15 mph, and only ground applications are permitted. In addition, the approved formulation is less prone to drift than other forms of 2,4-D. EPA's final regulatory decision document is available in EPA docket EPA-HQ-OPP-2014-0195.

Anticipating, Minimizing, and Resolving Delays

In an effort to narrow and further streamline the pending consultations for ESA, EPA is compiling information on existing consultations for the approved use of pesticides on federal lands. By building on existing consultations that have already been completed for certain pesticides, EPA believes that significant efficiencies can be introduced into the nationwide pesticide consultations that will occur during registration review. In addition,

RPAs and RPMs identified in previous biological opinions can serve as the foundation for label clarifications and early risk mitigation since previous consultations have identified such measures as being helpful to endangered species. EPA's intent is to use and build upon those existing consultations between the Services and the other federal agencies. By using the results on consultations already completed by other federal agencies, EPA will reduce duplication of effort and save resources. EPA prepared and sent letters to the Bureau of Land Management, Department of Defense, Forest Service, Tennessee Valley Authority, Bureau of Indian Affairs, National Park Service, FWS, Department of Energy, and the Bureau of Reclamation requesting biological opinions, points of contact, lists of species on federal lands, chemicals approved for use on federal lands, and data. EPA is organizing the responses and information from the federal agencies. Once organized, this information will be reviewed and captured for use in future consultations.

Litigation constrains resources. Agency staff working on litigation-driven, species-specific complaints are diverted from working towards completing national-level consultations. The agencies have worked with litigants to align lawsuits so that the agencies could focus on national level consultations on all ESA-listed species rather than focus on single species, or a small subset of species in smaller geographical areas. The plaintiffs appreciate that the Agencies have limited resources, but have expressed their concern that the Agencies address pesticides that pose the most threat to listed species, first.

In the interest of preventing litigation and addressing plaintiffs concerns, EPA continuously dialogues with potential plaintiffs and employs a 3-pronged strategy that is intended to protect listed species and their designated critical habitat by focusing resources on areas where we can achieve the most protections. First, EPA will undertake the majority of its ESA consultation work through registration review. This allows EPA to focus on chemicals with higher risk, i.e., the "worst first", resulting in the greatest potential benefits for listed species while addressing plaintiff concerns, thus, minimizing potential future litigation. Consistent with the interagency "shared scientific approaches"

and “day forward approach,” we will phase in the interim scientific approaches over time. EPA, FWS, and NMFS will apply the interim measures to initial consultations and, based upon the experience gained with these approaches as well as any new science that may develop, modify procedures as appropriate.

Secondly, EPA intends to complete Overview Document-compliant endangered species assessments for new herbicide tolerant crop uses. An assessment that is Overview Document-compliant follows the procedures and methods described in the Overview Document. Currently, the Overview Document is the basis for all ecological assessments for all chemicals other than chlorpyrifos, diazinon, malathion, carbaryl, and methomyl. EPA will complete these effect determinations as resources allow. To maximize impact within these resources, it is likely that the initial registrations will not be nationwide in scope, and to the extent practical will focus on situations where EPA can make “no-effect” decisions. The Overview Document can be found at the following link: <http://www.epa.gov/oppfead1/endanger/consultation/ecorisk-overview.pdf>. As mentioned above, EPA recently registered the herbicide, Enlist Duo, containing 2,4-D and glyphosate.

Thirdly, EPA will provide information that compares the potential hazards of the new active ingredients to already registered pesticides with similar modes of toxicity and the same use patterns. This will allow stakeholders to compare the relative toxicity of the proposed registration to available alternatives. We believe that older, currently registered chemicals typically have the potential to pose greater risks to ESA-listed species than do the newer, generally safer pesticides being introduced into the marketplace today, and that the comparative hazard information will illustrate this to all stakeholders. This additional hazard information contributes to transparency and promotes good communication with the public, improves relationships and trust with our stakeholders, and maximizes the potential to minimize litigation and prevent delays.

Conclusion

The Agencies have developed a joint, highly robust process to address pesticide consultations under the ESA. We are collaborating on developing interim approaches to apply to national-level risk assessments for pesticides and coordinating our responses on litigation. The scientific procedures and methodologies developed as part of the interim approaches are the best that have ever been developed for ESA-listed species-pesticide consultations. EPA and the Services will continue working towards incorporating the NRC study's recommendations over the coming months to strengthen even further the foundation behind these assessments. EPA and the Services are committed to scientifically sound risk assessments resulting in protections for ESA-listed species that do not unnecessarily hinder agriculture. EPA and the Services are committed to maintaining a robust dialogue with all of our stakeholders to ensure transparency throughout the pesticide consultation process. Regular, meaningful communication and collaboration between the Agencies' management and scientific staff is important to maintaining our current momentum and success.

Positive outcomes from the Agencies' joint efforts include: some early successes on litigation-driven consultations affording species protections for some chemical/species combinations, the Stakeholder Paper, interim approaches to pesticide risk assessments for listed species, interagency workshops, public comment periods on important papers and work products, and meetings open to the public to keep stakeholders informed of our progress as we move forward. In addition, EPA and the Services are working together on negotiations with plaintiffs to address our agency-specific lawsuits. Positive outcomes from this transition include negotiated settlements and extensions on ongoing litigation, allowing EPA and the Services to devote time and resources to implementation of the recommendations provided in the NRC's study and to deliver nationwide assessments for listed species.