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AND
COMMITTEE ON AGRICULTURE
UNITED STATES HOUSE OF REPRESENTATIVES

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Introduction

Good morning Chairman Lucas and Chairman Hastings, as well as other Members of the Agriculture and Natural Resources Committees. My name is Steven Bradbury. I have worked at the Environmental Protection Agency (EPA) in various positions since 1985, serving as the Director of the Mid-Continent Ecology Division in EPA's Office of Research and Development, Director of the pesticide ecological risk assessment division, and as Director of the division responsible for evaluating existing pesticides. I currently serve as the Director of the Office of Pesticide Programs. I am pleased to appear before you today to discuss how EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the steps EPA is taking to protect our nation's threatened and endangered species and their critical habitats under the Endangered Species Act (ESA). I will begin by describing our commitment to protecting the environment and how the principles of science and transparency are integral to EPA's program for regulating pesticides.

EPA's Program for Regulating Pesticides

EPA's Office of Pesticide Programs is charged with administering FIFRA, under which we must ensure that use of a pesticide does not cause "unreasonable adverse effects on the environment." FIFRA

generally requires that, before any pesticide may be sold or distributed in the United States, EPA must license its sale through a process called “registration.” During registration, EPA examines every pesticide product to ensure that it can be used in a manner consistent with the FIFRA standard.

FIFRA also requires EPA to re-evaluate previously registered pesticides against contemporary scientific and safety standards. Under EPA’s registration review program, all registered pesticides are re-evaluated at least every 15 years to ensure that products continue to meet FIFRA’s safety standards and that they are being lawfully marketed in our country. Of course, EPA can at any time take regulatory action to address newly identified risks.

When used properly, pesticides provide significant benefits to society, such as controlling disease-causing organisms, protecting the environment from invasive species, and fostering a safe and abundant food supply. FIFRA’s safety standard requires EPA to weigh these types of benefits against any potential harm to human health and the environment that might result from using a pesticide.

Over the last 30 years, EPA has developed a well-regarded program for evaluating pesticide safety and making regulatory decisions. EPA’s high quality risk assessments consider the best available scientific data from a variety of sources, including from pesticide companies, other governments, or the published literature. EPA regulations require a rigorous battery of tests in order to gain approval for a pesticide, and these data requirements provide consistency across the EPA’s risk assessments. A typical new agricultural pesticide must undergo over 100 different tests to characterize its potential risks. This data set provides, among other things: detailed information on where and how the pesticide will be used; a full battery of human health toxicity studies; data on the fate of the pesticide in the aquatic and terrestrial environments; and a suite of toxicity studies representing broad categories of wildlife and plants – birds, mammals, fish, terrestrial and aquatic plants, algae, insects, and other invertebrates. EPA has a public,

well documented set of procedures that it applies to the use and significance accorded to all data utilized in regulatory decisions. Data generated in response to FIFRA requirements are conducted under, and the results evaluated in accordance with, a series of internationally recognized and harmonized scientifically peer-reviewed study protocols designed to maintain a high standard of scientific quality and reproducibility. Therefore, these data provide a high level of confidence that the observed effects are reliably associated with exposure to the particular pesticide in question.

EPA is committed to consideration of other sources of data as well, including information submitted by the public as part of the regulatory docket of a Federal action under FIFRA, and data identified from the publicly available literature. In making the decision as to whether and how such data are incorporated into an ecological risk assessment EPA reviews the test methods employed and the conditions under which studies were conducted to assure a standard of scientific quality and reproducibility necessary to ensure confidence that the observed effects are reliably the manifestation of exposure to the particular pesticide in question.

EPA uses data and models to conservatively estimate how much pesticide will remain in the environment after use and how those levels compare with levels that could harm humans or the environment. EPA uses public, externally peer-reviewed procedures to analyze data and models to produce its science-based risk assessments that guide our risk management decisions. EPA reaches its conclusions through a scientific, systematic, objective evaluation of relevant information that uses transparent, documented procedures at each step.

EPA has authority to restrict the way a pesticide may be used to ensure that it meets statutory safety standards. Any restrictions on the use of a pesticide identified through registration or registration review as necessary for safe use appear on product labels. Examples of restrictions include reducing application

frequency or rates, prohibiting certain application methods, establishing no-spray buffer zones around sensitive areas and water bodies, limiting use only to trained and certified applicators, or other restrictions. Our regulatory partners, i.e., the state agencies, have the lead for enforcing proper use of pesticides.

If an EPA assessment identifies a risk of concern for a pesticide, pesticide registrants (i.e., manufacturers) will often agree to mitigate the potential risk by making appropriate changes to the way their pesticides may be used. If, however, companies do not voluntarily adopt risk mitigation measures, EPA must pursue administrative procedures to compel the changes. The process, referred to as "cancellation," starts with an independent, external, scientific peer review of the proposed regulatory restrictions by the FIFRA Scientific Advisory Panel, together with review by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS). If requested by a registrant, EPA must then conduct a formal adjudicatory hearing – an administrative trial with witnesses and testimony before an Administrative Law Judge (ALJ). Under FIFRA, registrants may ask the ALJ to refer questions of scientific fact to the National Academies of Science (NAS). Because the cancellation proceeding can be lengthy (often lasting three or more years before EPA reaches a final decision), FIFRA also authorizes EPA to suspend pesticide sale and use when needed to address an "imminent hazard."

Pesticides and Endangered Species

Certain pesticide regulatory actions may also be subject to the requirements of the ESA. The ESA is administered by the U.S. Fish and Wildlife Service (FWS) and the National Oceanic and Atmospheric Administration's (NOAA) Fisheries Service (jointly referred to as the "Services"). The ESA requires all Federal agencies, in consultation with the Services, to ensure that their actions are not likely to

jeopardize species listed as either threatened or endangered ("listed species") or to destroy or adversely modify the critical habitat of listed species.

EPA is committed under FIFRA to protecting endangered and threatened species from adverse effects of pesticides. EPA evaluates extensive toxicity and ecological effects data in order to estimate potential risks to birds, fish, invertebrates, mammals, and plants from the use of the pesticide. Approximately 75 FTE and $2 million in contract dollars are devoted to ecological risk assessments annually.

Because endangered species may need special protections, EPA has developed risk assessment procedures to determine whether a pesticide has the potential to harm individual threatened or endangered animals or plants. EPA provides to the public information about these risk assessment procedures on our website.

EPA has determined in a number of well documented instances that additional restrictions are necessary to address risks to endangered and threatened species and other nontarget species.

- **DDT**. A well known example is the cancelled pesticide DDT, which acted as a reproductive toxicant for certain birds species contributing to their decline, most notably certain raptor species such as Bald Eagles and the Peregrine Falcon. EPA took strong action and cancelled DDT in the U.S. in 1972, and subsequently it was banned for agricultural use worldwide, although limited disease vector control use continues. The EPA's cancellation of DDT and the enactment of the ESA are cited as a major reason for the comeback of Bald Eagle populations.
- **Fenthion**. The use of the avicide fenthion to control pest birds in urban, industrial, and agricultural settings, resulted in secondary poisonings of predatory birds (hawks, owls, falcons) after they consumed poisoned pest birds, such as starlings. The avicide product was cancelled on March 1, 1999.

- **Azinphos methyl**. Use of azinphos methyl poses risks to aquatic ecosystems. EPA has phased out registrations of azinphos methyl products, with the last remaining uses scheduled to end by September 2012.

As part of a thorough ecological risk assessment, EPA makes an "effects determination" regarding whether the use of a pesticide “may affect” or will have “no effect” on a listed species and any designated critical habitat for the species. If EPA determines that the pesticide "may affect" individual organisms in a species, EPA further characterizes whether the use of the pesticide is “likely to adversely affect” or “not likely to adversely affect” the species. Under the current ESA regulations, EPA must consult with the Services regarding any pesticide action that EPA finds may affect listed species or designated critical habitat. EPA can engage the Services in an informal consultation when EPA determines as a result of its risk assessment conclusions that a pesticide’s use "may affect, but is not likely to adversely affect" a listed species. The result of this informal process is typically a letter of concurrence or non-concurrence from the Services, with EPA’s determination.

If EPA determines that a pesticide "may affect and is likely to adversely affect" a listed species, or if a Service does not concur with EPA’s determination that a pesticide’s registered use is "not likely to adversely affect" a species, EPA must engage in formal consultation with the appropriate Service(s). During formal consultation (as described under the Services’ ESA regulations at 50 CFR part 402, Subpart B), EPA provides the Services with its detailed assessment of potential risks and its effects determination. Under the ESA the Services are required to produce a final Biological Opinion within 135 days after initiation of the formal consultation procedure unless the Service and action agency agree to an extension. A Service’s Biological Opinion provides the Service’s view of whether a pesticide’s registration is likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat and, if so, describes Reasonable and Prudent Alternatives (RPA) to avoid jeopardy or

destruction or adverse modification of critical habitat. The Services also exemptany otherwise prohibited take of a species, once an alternative is identified to avoid jeopardizing that species “reasonable and prudent measures” (RPM) to minimize the impact of the take.

As a result of an EPA risk assessment or formal consultation with the Services, EPA may determine that a pesticide’s registration should be altered to ensure use of a pesticide will not likely jeopardize the continued existence of a listed species. In such cases, EPA may require changes to the use conditions specified on the labeling of the product. Often such changes are necessary only in specific geographic areas (rather than nationwide) to ensure protection of the listed species. In those cases, EPA will implement protections through geographically-specific Endangered Species Protection Bulletins, which by reference on the pesticide product’s label become enforceable use limitations for that product within that geographic area. These Endangered Species Protection Bulletins will be developed and provided to pesticide users through a web-based application called “Bulletins Live!” that was developed with the assistance of the U.S. Geological Survey.

ESA Litigation

Litigation has been brought against EPA under the ESA more than a dozen times over the past 10 years challenging the registration of hundreds of EPA registered pesticides on hundreds of listed species because EPA and the Services have not completed consultation. Nearly all of these lawsuits challenged EPA’s failure to consult with the Services on the effects of particular pesticides on listed species. Many of these cases were dismissed, but several resulted in court orders, consent decrees, or settlement agreements that imposed a schedule under which EPA must make effects determinations for numerous pesticides and species, and, as appropriate, to consult with FWS or NOAA.

Several of these cases also resulted in interim injunctive relief during the pendency of those effects determinations and consultations. Typically, the injunctive relief put in place "no-use" buffer zones around waterbodies or other habitat that could contain threatened or endangered species until the Services and EPA completed the ESA consultation process.

These matters are summarized as follows:

- *Californians for Alternatives to Toxics* v. *EPA*, No. COO-3150 (N.D. Cal.). The September 2002 consent decree set forth a schedule for effects determinations (and consultation, as appropriate) regarding the effects of 18 pesticides on 33 listed species in California.
- *Washington Toxics Coalition* v. *EPA*, No. C01-0132 (W.D. Wash). A series of court orders from 2002-2004 required EPA to make effects determinations (and consult, as appropriate) on 54 pesticides on 26 listed salmonid species and imposed interim injunctive relief.
- *Center for Biological Diversity* v. *Johnson*, No. 04-cv-00126 (D.D.C.). The August 2005 settlement agreement set forth a schedule for effects determinations (and consultation, as appropriate) regarding the effects of six pesticides to one listed species, the Barton Springs salamander.
- *Natural Resources Defense Council* v. *EPA*, No. 03-CV-02444 (D. MD). The March 2006 settlement agreement set forth a schedule for determinations (and consultation, as appropriate) regarding the effects of atrazine on approximately 20 listed species.
- *Center for Biological Diversity* v. *Johnson*, No. 02-1580 (N.D. Cal.). Following district court finding on liability, parties agreed to stipulated injunction in October 2006 setting forth schedule for effects determinations (and consultation, as appropriate) regarding the effects of 66 pesticides on the California red-legged frog and providing for interim injunctive relief.

- *Center for Biological Diversity* v. *EPA*, No. C07-02794 (N.D. Cal.) The May 2010 stipulated injunction set forth a schedule for effects determinations (and consultation, as appropriate) regarding the effects of 75 pesticides on 11 species in Northern California and provided for interim injunctive relief that included use limitations.

Pursuant to these settlements and orders, EPA has prepared ESA assessments for various pesticides and species and has transmitted over 170 consultation requests to the Services. Over the last decade, preparation of these ESA assessments has required a very significant level of effort from EPA's pesticide program staff. For example, in 2010 alone, EPA expended nearly $4.5 million in contract funds and staff salary to meet these court ordered or monitored schedules for developing effects determinations for 13 species in California and carrying out work to refine measures recommended by NOAA in two Biological Opinions.

Where EPA determined the use of the pesticide may affect a listed species, EPA requested ESA consultation. To date, EPA has received three Biological Opinions from NOAA completing consultation on the effects of 18 pesticides on threatened and endangered salmonid species in Washington, Idaho, Oregon, and California. Recently EPA received a draft of a fourth Biological Opinion, also addressing listed salmonids in the Northwest, that when final will conclude another six pesticide consultations.

In addition to the litigation noted above, EPA, NOAA, and FWS are currently engaged in three significant cases that potentially could have broad ramifications for the future of the Federal government's ESA compliance efforts on FIFRA pesticide regulatory actions. On January 19 of this year, EPA was sued by the Center for Biological Diversity under the ESA regarding EPA's alleged failure to consult with the Services on the potential effects of more than 300 pesticides and approximately 200 listed species nationwide. The scope of the consultations at issue in this lawsuit, by

itself, is many times larger than those addressed in all of the previous cases combined. The potential implications of this case for EPA Office of Pesticide Program resources and its pesticide Registration Review program generally are considerable. The case is currently stayed so that the parties and others can discuss how a case of this magnitude might proceed.

The other two cases, *Dow AgroSciences* v. *NMFS* (pending in the U.S. District Court for the District of Maryland) and *Northwest Center for Alternatives to Pesticides (NCAP)* v. *EPA* (pending in the Western District of Washington), involve challenges related to the first two of NOAA's recent Biological Opinions on pesticide actions that stem from the consultations on listed salmonids ordered in the *Washington Toxics Coalition* litigation, outlined above. In *Dow AgroSciences,* plaintiffs argue that NOAA's scientific conclusions in the first of those Biological Opinions were arbitrary and capricious, that NOAA failed to rely on the best available data as required by their own regulations, and that NOAA failed to comply with statutory and regulatory procedural requirements in issuing its opinions. Recently the 4th Circuit ruled that this matter is subject to judicial review in U.S. District Court. In the *NCAP* case, several non-governmental organizations assert EPA violations of the ESA for allegedly failing to implement NOAA's first two salmonid Biological Opinions.

Both EPA and the Services are working in close coordination with the Department of Justice in addressing this pending litigation. Obviously, these cases have the potential to have a significant impact on pesticide registration actions generally and the development and implementation of Biological Opinions for the affected pesticides.

Improving the Consultation Process

In EPA's view, a more efficient and effective consultation process should include the following attributes:

- The FIFRA risk assessment process and the development of Biological Opinions would rely on best available information and peer-reviewed scientific procedures and models would be developed to evaluate and estimate the potential effects on listed species resulting from the use of a pesticide and to determine what measures would provide adequate protections;
- The risk assessment, consultation, and risk management processes is transparent and provide meaningful opportunities for public participation so that the public understands the basis for proposed and final actions and can provide information to help improve risk assessments and risk management decisions;
- The risk management process would employ risk mitigation measures that are adequate to protect listed species, and are tailored to specific uses and applicable to specific geographic areas based on species location and biological information to minimize the burdens on pesticide users. Risk mitigation measures necessary for the protection of listed species would be reasonable and clearly communicated to pesticide users; and
- In order to make the best use of agencies' and stakeholders' resources, and to provide protections where and when needed, the risk assessment, consultation, and risk management processes operate in a consistent, efficient, and timely fashion.

Addressing Scientific Issues. As I indicated above, EPA and the Services have been addressing the myriad difficult scientific issues involved in evaluating whether and how pesticides may affect listed species. To this end, in 2009 the three agencies formed a work group of technical experts from EPA's Office of Water and Office of Pesticide Programs and their counterparts from FWS and NOAA. As charged by the senior management in the three agencies, the workgroup has to date, identified and resolved some key issues that arise in no small part due to the different statutory schemes and regulatory frameworks of the various agencies that are not easily reconciled. For example, under FIFRA, EPA is

required to weigh the benefits of use against the risks while under the ESA, Federal agencies are required to ensure that their actions are not likely to jeopardize the continued existence of any listed species.

In March 2011, on behalf of the Departments of Agriculture, Commerce, and Interior, EPA requested that NAS convene a committee of independent experts to review scientific and technical issues that have arisen as a result of our collective responsibilities under the ESA and FIFRA. The recent experience of completing consultations under the ESA for FIFRA related actions affecting Pacific salmon has illustrated a number of scientific issues. The scientific and technical topics on which we seek advice pertain to the approaches utilized by EPA and the Services in assessing the effects of proposed FIFRA actions on endangered species and their habitats. These topics include the identification of best available scientific data and information; consideration of sub-lethal, indirect, and cumulative effects; the effects of chemical mixtures and inert ingredients; the use of models to assist in analyzing the effects of pesticide use; incorporating uncertainties into the evaluations effectively; and the identification of pertinent geospatial information and biological and other datasets that can be employed in the course of these assessments. To provide for the review, EPA and the Services will provide EPA's risk assessments and NOAA's Biological Opinions to the NAS as examples of the different scientific approaches. The issues before the NAS are scientifically complex and of high importance. A concerted, closely coordinated effort to address them openly and actively will assist in the proper execution of the statutory responsibilities under the ESA, FIFRA, and other applicable laws.

The Executive Branch is in the early stages of formulating the specific charge to the NAS panel. Based upon preliminary discussions with the NAS, we believe that the external review could be completed in 18 months, once the panel is convened.

Transparency and Public Participation. The Administration has made transparency a priority to promote accountability and provide information for citizens about what their Government is doing. ESA section 7 consultation is not subject to notice and comment procedures by law. Nonetheless, EPA is, along with using the best available science, enhancing the transparency of our processes and providing meaningful opportunities for public participation are critical for the success of pesticide program.

Accordingly, through our pesticide registration review web site and our endangered species protection web site, EPA has provided the public with access to our assessments and effects determinations, draft biological opinions we have received, our comments on those opinions, and final opinions from the services whether this work was conducted pursuant to litigation or as a matter of course in our registration review program. This input has served to improve our work.

It is through our endangered species web site as well that EPA provides general information about the status of consultations and expected dates for receipt of Draft Biological Opinions; makes available such Drafts; and solicits public input on the recommendations contained in those Draft opinions. EPA then considers such input in our responses to the Services regarding their Draft documents.

As noted above, EPA is focusing its ESA compliance resources primarily on its registration review program. As EPA conducts the statutorily mandated reevaluation of a previously registered pesticide, we will perform an ESA assessment of all uses of the pesticide, and, as necessary, initiate consultation with the Services. Using the registration review program provides an established framework. EPA's Pesticides Program incorporates public participation as an integral part of its existing processes of registration and registration review. The registration review process generally encompasses three opportunities for public comment that may include input and information relative to the ecological risk

assessments and endangered species effects determinations developed as a matter of course, to support registration review. First EPA opens a public docket which contains EPA's plan on how it will proceed with a particular pesticide. As part of this docket, EPA develops and publishes a problem formulation that articulates the scientific work that will be conducted, including any work relative to listed species. The second stage of registration review results in publication of a draft risk assessment that would include EPAs analyses relative to all non-target species including listed species. Subsequently a final risk assessment and proposed registration review decision are published. This decision may contain mitigation EPA believes is necessary to ensure that the risks of continued registration outweigh the benefits – the FIFRA standard for ecological effects, as well as any mitigation EPA proposes is necessary for the specific protection of listed species. Finally, the EPA will publish its final registration review decision. At each of the three steps prior to the final decision, EPA solicits public input. That input is reviewed and analyzed and a response to comment document is developed and issued along with the products in the next phase so that the public may see how their input was considered.

Tailoring risk mitigation measures. Our website also provides a portal to the application called "Bulletins Live!" which is the system developed with the assistance of the US Geological Survey, to provide Endangered Species Protection Bulletins to pesticide users. When changes to a pesticide's use are necessary to protect a listed species, the pesticide label will carry a generic statement that refers the user to our Bulletins Live! web site for information on how to use the pesticide in their geographic area. The generic label statement also will contain a toll free phone number that people can use to request information on use limitations and have an Endangered Species Protection Bulletin mailed to them, in the event they do not have internet access. As noted earlier, these Bulletins set geographically specific pesticide use limitations for the protection of endangered or threatened species and their designated critical habitat where such limitations on use of a pesticide have been determined to be necessary. The

Bulletins contain a map of the selected county, a description of the species being protected, pesticide(s) of concern, pesticide use limitations, and the month for which the Bulletin is valid. EPA and the U.S. Geological Survey are currently developing a more interactive, geo-coded platform to provide this information, which will make it easier to be more geographically specific in terms of where pesticide use may need to be limited in some manner to protect listed species.

While EPA is moving ahead to develop improved tools to communicate geographically specific information, this information will be only as specific and focused as permitted by the species location data and biological information available deemed reliable from the Services. Currently, such information and data are not available in geospatial layers for the more than 1200 listed species across the nation.

Efficiency, Consistency, and Timeliness. ESA consultations and implementation of protections for threatened and endangered species need to be done in a consistent, timely, and predictable manner. Our efficiency will improve significantly once all agencies follow the same durable, accepted scientific methodology for performing ESA assessments, an outcome EPA hopes will be achieved using the recommendations from the National Academies report and with ongoing conversations between EPA, FWS, and NOAA. Measures, such as internal peer review and quality control programs – also will help produce consistent outcomes across different assessors. We need to set and hold ourselves to schedules for conducting assessments, completing consultations, and making decisions about implementation of protection measures. We need to plan and allocate resources to achieve the level of timeliness our external stakeholders expect. And recognizing the enormity of the consultation effort that lies ahead, we need to be as efficient as absolutely possible. Among other things, this will mean using data about species location and biology, that will enable assessors to perform spatially and temporally explicit assessments. EPA is committed to achieving these ends.

Conclusion

EPA's pesticide program is a highly regarded program that makes more than 10,000 regulatory decisions a year, including evaluating approximately 20 new pesticide active ingredients and reevaluating 70 previously approved pesticides annually, as well as reviewing thousands of proposed changes to existing products, among other statutorily mandated decisions. Fulfilling our ESA obligations and meeting our other legal responsibilities will require careful management of our resources, and wise setting of priorities. Conducting ESA assessments for currently registered pesticides and implementing Biological Opinions from the Services will continue to require very significant expenditures of staff and contract resources. We must find ways to make the consultation process more efficient, and streamlining reviews. We should, to the greatest extent possible, strive to avoid duplicating work

I am pleased that the senior leadership of all three agencies recognizes the importance of compliance with the ESA, and the need for fundamental change in how we have operated in the past. Although it will not be easy, by incorporating guidance from the NAS on the critical scientific issues, we can further develop a consultation process that is grounded in the best available science, that is transparent and participatory, and that produces timely and consistent regulatory decisions which fully protect threatened and endangered species without unduly burdening the ability to produce food and fiber products for this country.