DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

RIN 1018–AI95

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–AQ69

50 CFR Part 402

Joint Counterpart Endangered Species Act Section 7 Consultation Regulations

AGENCIES: Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Final rule.

SUMMARY: This final rule, developed by the U.S. Department of the Interior, Fish and Wildlife Service (FWS) and the U.S. Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service (NOAA Fisheries) (referred to jointly as ''Services'' and individually as ''Service''), after coordination with the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA), codifies joint counterpart regulations for consultation under section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) (ESA), for regulatory actions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Counterpart regulations, described in general terms in part 402, are intended to provide flexibility in the ways that a federal agency may meet its obligations under the ESA by creating alternative procedures to the section 7 consultation process described in subparts A and B of the same part. These counterpart regulations enhance the efficiency and effectiveness of the section 7 consultation process by increasing interagency cooperation and providing two optional alternatives for completing section 7 consultation for FIFRA regulatory actions. One alternative modifies the process for EPA to conduct informal consultation with the Service for those FIFRA actions that EPA determines are ''not likely to adversely affect'' any federally-protected threatened and endangered species (''listed species'') or critical habitat. The other alternative permits the Service to conduct formal consultation in a manner that more effectively takes advantage of EPA's substantial expertise in evaluating ecological effects of FIFRA regulatory actions on listed species and critical habitats.

DATES: This rule is effective September 7, 2004.

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business hours at the Division of Consultation, Habitat Conservation Planning, Recovery and State Grants, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 420, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Patrick Leonard, Chief, Division of Consultation, Habitat Conservation Planning, Recovery and State Grants, at the above address (Telephone 703/358–2171, Facsimile 703/358–1735) or Jim Lecky, Acting Senior Advisor for Intergovernmental Programs, NOAA Fisheries, 1315 East-West Highway, Silver Spring, MD 20910 (301/713–2239; facsimile 301/713–1940).

SUPPLEMENTARY INFORMATION: Through this final joint rulemaking, the FWS and NOAA adopt additional regulations to enhance the efficiency and effectiveness of the consultation process under section 7 of the ESA and to provide alternatives to the way EPA now consults with the Services under the ESA on regulatory actions under FIFRA involving pesticides. This Notice of Final Rulemaking, developed with assistance from EPA and the USDA, complements the Services' other consultation regulations in 50 CFR part 402. A rule providing an alternative consultation process for a specific Federal agency is called a ''counterpart regulation.'' See 50 CFR 402.04. The purpose of this rule is to improve interagency cooperation for regulatory actions under FIFRA involving pesticides, and provide optional, alternative approaches to consultation on pesticide actions that better integrate the consultation process under section 7 of the ESA with the processes for pesticide regulatory actions taken by EPA under FIFRA. By doing so, the Services expect the administration of the ESA and FIFRA will better protect threatened and endangered species and critical habitat with minimal disruption of the nation's access to products licensed under FIFRA that are necessary for the production of food and fiber and for health and disease protection. Additional supplementary information, including many of the documents mentioned in this Notice, is available on the Internet at *http://endangered.fws.gov/consultations/pesticides*.

1. The Endangered Species Act and Federal Agency Consultations With the Services

Congress enacted the ESA to establish a program for conservation of endangered and threatened species and the ecosystems on which they depend. 16 U.S.C. 1531(b). Section 7 of the ESA, 16 U.S.C. 1536, imposes obligations upon all Federal agencies to protect listed species or designated critical habitat. Section 7(a)(2) of the ESA, 16 U.S.C. 1536(a)(2) directs all Federal agencies, in consultation with and with the assistance of the Secretaries of the Interior and Commerce (delegated to the respective Services), to insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of habitat of such species that has been designated as critical (''critical habitat''). 16 U.S.C. 1536(a)(2). In meeting this requirement, each agency is required to use the ''best scientific and commercial data available.'' 16 U.S.C. 1536(a)(2). The FWS and NOAA Fisheries are jointly responsible for administering the ESA.

The Services adopted joint consultation regulations set forth at 50 CFR part 402 (subparts A and B). These regulatory provisions require action agencies to consult with the Services on any Federal action that ''may affect'' a listed species or critical habitat. Consultation may be concluded ''informally'' if the action agency determines that the Federal action under consideration is ''not likely to adversely affect'' (NLAA) a listed species or critical habitat and the Service gives written concurrence. 50 CFR 402.13(a)(1). Such informal consultation fulfills the action agency's section 7 consultation obligation. 50 CFR 402.14(b)(1). Formal consultation, however, may always be pursued and is required if the action is likely to adversely affect a listed species or critical habitat or if the Service does not concur with an action agency's NLAA determination. During formal consultation, the action agency and Service examine the effects of the proposed action and the Service determines whether the proposed Federal action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat and whether incidental take of listed species is anticipated. 50 CFR 402.14(h), 402.14(i).

Under subparts A and B, the consultation process reviews a variety of

potential ''effects'' on listed species and habitat, including direct, indirect, and cumulative effects. ''Direct effects'' are those effects that will immediately flow from the proposed action. ''Indirect effects'' are those that will be caused by the proposed action, will occur later in time, but are still reasonably certain to occur. Additionally, examination of potential effects must also address ''interrelated'' and ''interdependent'' actions. 50 CFR 402.02. ''Cumulative effects'' are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the area affected by the proposed action. 50 CFR 402.02. For a detailed explanation of these terms, refer to the Consultation Handbook jointly published by FWS and NOAA Fisheries, which further elaborates on the procedures followed by the Services when conducting section 7 consultations. *http://endangered.fws.gov/consultations/s7hndbk/s7hndbk.htm.*

At the conclusion of formal consultation, the Service will issue a biological opinion that details the effects of the action on the listed species or critical habitat, and states whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. If the Service finds an agency action is likely to cause any such effect, the biological opinion must also include reasonable and prudent alternatives, if any are available, that would avoid the effect. Where jeopardy or adverse modification of critical habitat is not likely to occur, but take of listed species is expected, the Service issues an incidental take statement that specifies reasonable and prudent measures and terms and conditions necessary to minimize incidental take. 16 U.S.C. 1536(b)(4). When the terms and conditions of the incidental take statement are followed, all incidental takings that occur are not subject to any prohibition against take that may otherwise apply. 16 U.S.C. 1538(a)(1); 1533(d). Following consultation, the action agency is responsible for implementing protections, if necessary, through its available authority.

Regulations at 50 CFR 402.04 provide that ''the consultation procedures may be superseded for a particular Federal agency by joint counterpart regulations among that agency, the Fish and Wildlife Service, and the National Marine Fisheries Service.'' The Services recognized that in certain instances, the section 7 consultation process can be improved by procedures that differ from the standard consultation process. The purpose of counterpart regulations therefore is to provide an approach that ''allow[s] individual Federal agencies to ''fine tune'' the general consultation framework to reflect their particular program responsibilities and obligations.'' 51 FR 19937 (June 3, 1986). At the same time, the preamble to the 1986 regulations for implementing section 7 of the ESA states that ''such counterpart regulations must retain the overall degree of protection afforded listed species required by the [ESA] and these regulations. Changes in the general consultation process must be designed to enhance its efficiency without elimination of ultimate Federal agency responsibility for compliance with section 7.'' Id. (quoting the preamble justification for the predecessor regulation).

2. FIFRA and Pesticide Regulation

FIFRA is the primary statute under which EPA regulates the use of pesticides in the United States. 7 U.S.C. 136 *et seq.* FIFRA defines a ''pesticide'' as ''* * * any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. * * * FIFRA section 2(u). When a pesticide is sold or distributed, it is generally referred to as a ''pesticide product.'' Pesticides contain both ''active ingredients'' and ''inert ingredients.'' An ''active ingredient'' is ''* * * an ingredient which will prevent, destroy, repel, or mitigate any pest. ''* * * FIFRA section 2(a). Ingredients which are not active are referred to as ''inert ingredients'' or ''other ingredients.'' Under FIFRA, an ''inert ingredient'' is defined as ''an ingredient which is not active.'' FIFRA section 2(m). EPA uses the term, ''formulation,'' to refer to the particular combination of active and inert ingredients in a pesticide product. A pesticide ''use'' refers to the particular combination of circumstances under which a pesticide product may be applied, such as the rate, timing, method, and site of application.

The statutory framework for regulation of new pesticide products. FIFRA generally prohibits the sale or distribution of a pesticide product unless it has first been ''registered'' by EPA. FIFRA section 12(a)(1)(A). EPA issues a license, referred to as a ''registration,'' for each specific pesticide product allowed to be marketed; the registration approves sale of a product with a specific formulation, in a specific type of package, and with specific labeling limiting application to specific uses. Each product is evaluated on a case-by-case basis.

FIFRA requires a person seeking to register a pesticide to demonstrate that the proposed product meets the statutory standard. The proponent of use bears the burden of demonstrating that a pesticide meets this statutory standard. EPA may approve the unconditional registration of a pesticide product only if the agency determines, among other things, that use of the pesticide would not cause ''unreasonable adverse effects on the environment.'' FIFRA section 3(c)(5). The statute defines ''unreasonable adverse effects on the environment'' to include ''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 * * *.'' FIFRA section 2(bb). EPA has a broad duty under FIFRA to avoid unreasonable adverse effects on the environment generally, which includes consideration of effects to all species, whether or not federally protected.

When EPA registers a pesticide, it approves among other things a specific set of labeling for the product which contains directions for and restrictions on use of the product. Labeling includes any written or graphic material attached to the product container, *i.e.*, the label, as well as other material accompanying the product or referenced on the label. FIFRA section 2(p). FIFRA makes it unlawful for any person ''to use any registered pesticide in a manner inconsistent with its labeling.'' FIFRA section 12(a)(2)(G). Thus, directions and restrictions appearing on, or referenced in, a pesticide product label become enforceable Federal requirements subject to penalties for misuse. Under FIFRA, most States have primary responsibility for enforcement against pesticide misuse. See FIFRA section 26.

While most regulatory decisions allowing entry of new pesticide products into the marketplace are made by EPA in its FIFRA section 3 registration program, there are three other programs that can authorize the limited use of new pesticides. Under section 18 of FIFRA, EPA may allow the use of an unregistered pesticide product by a State or Federal agency when necessary to address an emergency situation. Under EPA's regulations, a petition for an exemption must establish that ''emergency conditions—defined as ''an urgent, non-routine situation that requires the use of a pesticide * * *''—exist and that no effective, currently registered pesticide or non-pesticidal pest control method is available. 40 CFR 166.4(d). The emergency exemption regulations provide that EPA will not approve a request unless EPA

determines, among other things, the use of the pesticide product will not cause unreasonable adverse effects on the environment. 40 CFR 166.25(b). In addition, under certain limited circumstances, States may approve a new use of a currently registered pesticide product to meet a ''special local need.'' FIFRA section 24(c). EPA's regulations limit States'' exercise of this authority only to the approval of products that contain active ingredients that are present in a currently approved pesticide product and give EPA broad authority to disapprove products intended for uses that are not closely related to existing uses. See 40 CFR 162.152. States must notify EPA when they exercise this authority and a State's registration shall not be effective for more than 90 days if disapproved by EPA within that period. FIFRA section 24(c)(2). Finally, EPA may issue an experimental use permit under FIFRA section 5 authorizing the limited use of an unregistered pesticide in field experiments to obtain data necessary to support an application for registration. See 40 CFR part 172.

The statutory framework for regulation of existing pesticide products. In addition to a registration program for new pesticide products, EPA conducts a ''reregistration'' program. Reregistration focuses on currently registered pesticides and involves a systematic reexamination of the scientific data to determine whether the pesticides continue to meet contemporary scientific and regulatory standards. See FIFRA section 4. As part of the reregistration process, EPA assesses whether there are adequate data to determine if the statutory standard is met. FIFRA gives EPA authority to require registrants to provide data if EPA ''determines [the] additional data are required to maintain in effect an existing registration of a pesticide.'' FIFRA section 3(c)(2)(B). (Imposition of such additional data requirements is subject to the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501–3520). In the past, EPA has used this authority to require registrants to conduct studies that would provide additional data needed for the evaluation of potential hazards of and exposures to pesticide products. EPA uses such data to assess pesticide risks and to determine whether changes in the terms and conditions of registration would be appropriate. In many cases, EPA's reregistration review has concluded that additional risk mitigation measures were necessary to reduce potential harm to non-target plants and wildlife populations. Many registrants voluntarily have amended their products' registrations to implement these risk mitigation measures. If, however, registrants do not adopt needed risk mitigation, EPA may impose the requirements through cancellation or suspension proceedings, conducted pursuant to FIFRA section 6 and 40 CFR part 164.

EPA may issue a Notice of Intent to Cancel the registration of a pesticide if it appears at any time that the pesticide ''when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment.'' FIFRA section 6(b). The registrant of a pesticide is required to submit to EPA additional factual information regarding unreasonable adverse effects. FIFRA section 6(a)(2); 40 CFR part 159. The decisions whether to approve a pesticide's entry into the marketplace and whether to retain a pesticide on the market are based on the most recent scientific information and the same standard: whether use of pesticide does not cause ''unreasonable adverse effects on the environment.'' FIFRA also contains provisions allowing EPA to ''suspend'' the registration and use of a pesticide, prior to the completion of a cancellation process, if use of the pesticide poses an ''imminent hazard.'' FIFRA section 6(c). FIFRA defines an ''imminent hazard'' as ''a situation which exists when the continued use of a pesticide during the time required for [a] cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened under [the Endangered Species Act].'' FIFRA section 2(1).

EPA's approach to ecological risk assessment. In deciding whether a pesticide product meets the statutory standards for registration or reregistration, EPA considers, among other things, the potential risks to non-target wildlife and plant species posed by use of the pesticide product. A more detailed description of EPA's approach appears in a paper titled: ''Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency'' (''Overview Document'') (January 2004), and in documents referenced in that paper, all of which are part of the administrative record of this final rule. This document describes EPA's risk evaluation process which is based on the current science policy views of EPA's pesticide program, but it is not intended to be legally binding. In any decision under FIFRA, EPA may: (1) Conclude that the general approach to assessing ecological risks of a particular pesticide is inapplicable; or (2) consider factors or types of information other than those described in the Overview Document. If EPA uses a different approach to make an effects determination for a FIFRA action, EPA would provide a detailed explanation of its approach in the record for the action.

EPA's evaluation of such environmental risks follows the principles contained in its Guidelines for Ecological Risk Assessment. (EPA 1998). In 1986, EPA developed detailed guidance for the review and analysis of potential environmental risks from use of pesticide products. See Standard Evaluation Procedures (SEP) for Ecological Risk Assessment (EPA 1986). Since 1986, EPA has made many additions and refinements to the basic approach outlined in the SEP. All of EPA's risk assessment methods have included methodology for an assessment of potential risks to listed species.

EPA's approach to assessing risks of pesticides and framework for making regulatory decisions benefits from the advice of several advisory committees chartered under the Federal Advisory Committee Act (FACA). EPA routinely obtains independent, external, expert scientific peer review of its risk assessment methodologies from the FIFRA Scientific Advisory Panel (SAP). Authorized under FIFRA section 25(d), the SAP is chartered under FACA and consists of seven permanent members appointed by the EPA Administrator and additional ad hoc members who are selected to serve on panels addressing specific scientific issues to which they can contribute their expertise. The SAP provides EPA with recommendations and evaluations of data, models, and methodologies used in EPA's overall risk assessment processes that occur during registration and reregistration. Further information is available at: *http://www.epa.gov/scipoly/sap/.*

EPA also works with stakeholders in the regulated community and environmental and public health advocacy groups through two other FACA-chartered groups: the Pesticide Program Dialogue Committee (PPDC) and the Committee to Advise on Reassessment and Transition (CARAT). For further information see: *http://www.epa.gov/pesticides/ppdc/* and *http://www.epa.gov/pesticides/carat/.* These latter two advisory groups often address ways in which to make regulatory processes more reliable and efficient. All three advisory groups comply with the FACA requirements for

transparency and balanced participation.

EPA requires both new and existing pesticides to be supported by extensive information about the potential ecological risks of the pesticide product. Data requirements appear in EPA regulations at 40 CFR part 158. Laboratory studies conducted to generate data for EPA are subject to Good Laboratory Practice requirements that are designed to ensure that the results are reliable and of high quality. See 40 CFR part 160. EPA's scientists carefully review all data submissions and independently evaluate the potential risks of each pesticide. In situations raising novel or challenging scientific issues, EPA generally seeks outside peer review of its scientific assessments.

EPA requires extensive toxicity and environmental fate data and uses this information, together with field reports of adverse effects on wildlife caused by pesticides and other relevant information, to evaluate the potential hazards to non-target species, including listed species, of a pesticide intended for outdoor use. To assess potential hazard to non-target species, EPA requires a basic set of laboratory toxicity studies on an active ingredient using multiple surrogate species of birds, fish, aquatic invertebrates, non-target insects, and plants. In situations where additional, scientifically valid toxicity data related to effects on wildlife and aquatic organisms are available, EPA will consider them in establishing the toxicity endpoint for risk assessment. EPA conducts risk assessments using the toxicity endpoint from the most sensitive species tested. EPA also requires data from a series of laboratory and field studies of the environmental fate of both the active ingredients in a pesticide product and typical formulations containing the active ingredient. These studies provide data on both the parent active ingredient, as well as its environmental degradates.

EPA combines these data, along with information about how the pesticide product is intended to be used, to develop an estimate of the potential concentrations of residues of the active ingredient and significant environmental degradates in the environment (the Estimated Environmental Concentration or EEC). When estimating EEC, EPA makes conservative assumptions designed not to understate potential exposure in order to avoid the potential for underestimating risk.

When assessing risks to listed species and critical habitat, EPA evaluates data and risks in a tiered fashion. EPA compares its toxicity assessment of an active ingredient with the EEC. As part of a conservative initial risk screening, if this comparison demonstrates that the EEC is well below the amount of active ingredient that would be expected to cause harm to particular species or critical habitats, EPA concludes that the use of pesticide products containing that active ingredient would have ''no effect'' on those listed species or critical habitats. Most of EPA's focus is on the potential risks from exposure to the active ingredient and its significant environmental degradates. EPA also reviews the available information on the other ingredients in pesticide products and on the formulations themselves, to assess the potential for increased risk. If the conservative initial screening assessment indicates that a use of a pesticide may potentially affect a listed species or critical habitat, EPA conducts a more refined assessment looking at species-specific information and information about pesticide use in the area to determine whether, for example, there is spatial and temporal overlap of the pesticide use and species' habitat, such that adverse effects would appear likely.

If the initial comparison and subsequent refined assessments indicate that EPA's best estimate of the EEC for the active ingredient and/or significant environmental degradates could have toxic effects on a listed species or critical habitat, then EPA may require the pesticide applicant or registrant to supply additional laboratory and/or field data in order to refine the risk assessment, seek changes in the allowable use of the pesticide product that are sufficient to mitigate any potential risk, or request initiation of consultation with the Services. Higher tier toxicity data may include studies on the effects of a pesticide on other wildlife species and plants or studies of longer durations of exposure. The Agency may occasionally require higher tier studies to be conducted in the field under simulated or actual use conditions. EPA may also require additional information to improve its estimate of potential exposure. Possible risk mitigation measures include changes in the manner or timing of pesticide applications, the rate or frequency of applications, or geographical restrictions on use.

Between May and December 2003 inter-agency scientific teams from both Services and EPA carefully reviewed EPA's ecological risk assessment methodology, including earlier drafts of the Overview Document and the materials referenced therein. Based on this review, the Services have determined that the approach used by EPA will produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations. The approach used by EPA addresses, where applicable, the informational and analytical requirements set forth at 50 CFR 402.14(c), relies upon the best scientific and commercial data available; and analyzes the best scientific and commercial data available by using sound, scientifically accepted practices for evaluating ecological effects. Additionally, the Services have concluded that the approach used by EPA should produce effects determinations that appropriately identify actions that are not likely to adversely effect listed species, and that are consistent with those that otherwise would be made by the Services. This approach also will produce all information necessary to initiate formal consultation where appropriate. Letter from S. Williams and W. Hogarth to Susan Hazen (January 2004).

3. Public Law 100–478

In 1988, Congress addressed the relationship between ESA and EPA's pesticide labeling program in section 1010 of Public Law 100–478 (October 7, 1988), which required EPA to conduct a study, and to provide Congress with a report of the results, on ways to implement EPA's endangered species pesticide labeling program in a manner that both complies with ESA and allows people to continue production of agricultural food and fiber commodities. This law provided a clear sense that Congress desires that EPA should fulfill its obligation to conserve listed species, while at the same time considering the needs of agriculture and other pesticide users. Accordingly, EPA and the Services have coordinated with USDA in developing these counterpart regulations to ensure that the consultation process is efficient and timely while remaining as protective as the existing regulations.

4. Reasons for a Counterpart Regulation for EPA Pesticide Actions

Rationale for the rule as finalized. In developing a process for conducting future ESA consultations on FIFRA pesticide regulatory actions, the Services and EPA recognized that EPA possesses, expertise and authority in the field of ecological risk assessment relative to pesticides. Under FIFRA, EPA makes decisions to allow new or continued use of a pesticide only after carefully examining extensive data on the potential risks that use of a pesticide

may pose to non-target fish, wildlife, and plant (''wildlife'') species. In addition, EPA's pesticide regulatory program may require companies to conduct studies needed for a risk assessment. As a result, EPA generally has a significant body of scientific information available with which to evaluate the hazards a pesticide may pose to non-target wildlife. Further, to perform its responsibilities under FIFRA, EPA maintains a staff of well-qualified scientists with many years of combined experience in assessing ecological risks. Finally, EPA has performed pioneering work in certain areas of ecological risk assessment, such as the development of exposure models and probabilistic risk assessment techniques.

In addition to EPA's strong scientific data bases and its expertise in the field of ecological risk assessment, EPA's decisions have characteristics that are rarely found in other section 7 consultations. Pesticide products typically are employed for multiple uses, and can potentially be used in many different parts of the country in different times of year. Thus, an ESA consultation on a pesticide registration must consider many different pesticide use patterns and determine whether wildlife species in many different locations throughout the country may be affected by such use. This broad scope of intended use of the product under review contrasts with the narrower geographical scope of most actions by Federal agencies that undergo section 7 consultation.

In addition, the number of annual pesticide decisions made by EPA was also a factor potentially affecting how best to improve the section 7 consultation process. In a typical year, EPA will make hundreds of significant decisions regarding pesticide registration. For example, in fiscal year (FY) 2003, EPA registered 31 new pesticide active ingredients; approved the addition of 334 new uses of previously registered active ingredients on over 1,500 different crops; and completed more than 6,500 more minor registration actions. EPA also completed re-registration assessments on 28 previously registered active ingredients, and processed nearly 500 emergency exemption requests in FY 2003. Numbers of actions in most of these categories have risen each year since FY 2000. The number of requests by EPA to initiate consultation on pesticide actions is expected to increase substantially in future years. The large number of consultations and their complexity is expected to require a significant level of resources, requiring careful use of resources by both EPA and the Services to effectively address issues of high biological priority and high priority to users in the most efficient manner possible. This rule is intended to make the consultation process more efficient because some FIFRA actions could be conducted pursuant to the alternative consultation procedures outlined in this rule.

These factors provided strong reasons for the Services to establish a counterpart rule for EPA FIFRA actions. New, streamlined procedures promise to be more efficient for both EPA and the Services, and potentially more protective of listed species, because they will allow EPA and the Services to focus more resources on those actions most likely to pose risk to listed species. The single greatest opportunity for efficiency in the consultation process is for the Services to take greater advantage of the extensive analysis produced by EPA in its ecological risk assessments of pesticides. Relying more heavily on the EPA's scientific work product, while at the same time assuring EPA's analysis meets the high scientific standards required by the ESA, will reduce the amount of work required from the Services in each consultation and therefore accelerate completion of consultations.

Further, those streamlined procedures are expected to enable EPA to more quickly implement any risk mitigation measures identified as necessary to protect species and critical habitat. Moreover, many of the applications submitted for registration of pesticide products containing new active ingredients involve pesticide formulations that have been developed to have less impact than the currently registered products with which they would compete. Thus, any improvements in the efficiency and effectiveness of the ESA review process that would allow EPA to make decisions more quickly, and therefore allow such new products in the market sooner, should generally benefit listed species, as well as more broadly provide benefits for human health and the environment. Finally, given the importance of maintaining the availability of pesticides for production of food and fiber, disease prevention and other purposes that are essential to the health and well-being of the American people, EPA and the Services believe that improved integration of the FIFRA registration/reregistration and section 7(a)(2) consultation processes under new counterpart regulations will be achieved in a way that avoids unnecessary burdens on pesticide users with no sacrifice to the protection of listed species.

5. The Counterpart Regulations

These counterpart regulations establish new methods of interagency coordination between EPA and the Services and create two new, optional, alternative approaches for EPA to fulfill its obligations to ensure that its actions under FIFRA are not likely to jeopardize the continued existence of listed species or destroy or adversely modify critical habitat. The rule offers an alternative approach when EPA determines that a FIFRA action is not likely to cause adverse effects on listed species or critical habitat, and an alternative approach to formal consultations. EPA could also elect to follow any of the existing procedures for early (§ 402.11), informal (§ 402.13), or formal consultation (§ 402.14) described in subpart B of part 402 for these actions.

A. New Methods of Interagency Cooperation

This counterpart rule establishes three additional methods (§§ 402.42(b), 402.43 and 402.44) of achieving the interagency cooperation that is the fundamental tenet of the section 7 consultation process. First, under § 402.43 EPA could request the Service to provide available information (or references thereto) describing the applicable environmental baseline for each species or habitat that EPA determines may be affected by a FIFRA action, and the Service would provide such information within 30 days of the request. This informational exchange would give EPA early and effective access to the Service's extensive biological database.

Second, under § 402.44 EPA may request the Service to designate a suitably-trained Service Representative (more than one Service employee may jointly serve in this capacity) to participate with EPA in the development of an ''effects determination'' for one or more of those species or habitats. The Service Representative will participate in all relevant discussions with the EPA team (in most cases in person), have access to all documentation and information used to prepare the effects determination (upon acceptance of the same confidentiality limitations applicable to EPA personnel), and have appropriate office and staff support to work effectively as part of the EPA team. The Service Representative will be expected to keep the Service informed at all times as to the progress and scope of the effects determination, and the Service may engage in additional coordination

with EPA as appropriate. In some cases, EPA may decide that it does not require the aid of a designated Service Representative, and may make an effects determination without that form of coordination.

Third, under § 402.42(b), EPA and the Services would establish new procedures for regular and timely exchanges of scientific information to achieve accurate and informed decision-making.

B. Consultation on Actions That Are Not Likely to Adversely Affect Listed Species or Habitats

The section 7 regulations in subpart B require an action agency to complete formal consultation with the Service on any proposed action that may affect a listed species or critical habitat, unless following either a biological assessment or informal consultation with the Service, the action agency makes a determination that the proposed action is not likely to adversely affect any listed species or critical habitat and obtains written concurrence from the Service for the NLAA determination. The alternative process contained in § 402.45 of these counterpart regulations will allow the Service to provide training, oversight, and monitoring to EPA through an alternative consultation agreement that enables EPA to make an NLAA determination for a FIFRA action without formal consultation or written concurrence from the Service. The Services recently adopted a similar approach for certain Federal actions implementing the National Fire Plan. 68 FR 68254 (December 8, 2003).

The new approach to interagency coordination between EPA and the Services is intended to be a flexible, adaptable scheme that will continually evolve and improve over time as scientific knowledge expands. For this reason, although the regulation will require the Service and EPA to have in effect an alternative consultation agreement before EPA can utilize the procedures of § 402.45, the alternative consultation agreement itself is not part of this rule, and the Services have concluded that the alternative consultation agreement will not constitute a rule subject to the notice and comment provisions of the Administrative Procedure Act, 5 U.S.C. 553. As articulated in proposed § 402.45(b), the required content of the alternative consultation agreement includes provisions and procedures to guide the Services and EPA in implementing this subsection. The alternative consultation agreement does not create or mandate standards for effects determinations; nor does it limit EPA's or the Services' discretion in developing and applying scientific methodologies. The alternative consultation agreement will be expected to undergo continuous modification and improvement. EPA and the Service will also be able to mutually agree to depart from the terms of the alternative consultation agreement in a particular case. Further, the alternative consultation agreement will not create any substantive or procedural rights or benefits that could be enforced by third parties against either the Services or EPA.

The Services believe that EPA's expertise in ecological risk assessments of pesticides, together with the safeguards built into the alternative consultation agreement, make case-by-case discussions and written concurrences in EPA's NLAA determinations unnecessary for FIFRA actions. The Services have carefully reviewed EPA's assessment methodologies and believe that when EPA follows its established approach to ecological risk assessment for pesticides EPA will correctly make determinations as to when a pesticide is or is not likely to adversely affect listed species or critical habitat. Requiring the Services to concur on a case by case basis on every NLAA determination made by EPA would unjustifiably divert much of the Services' consultation resources away from projects in greater need of consultation. The counterpart regulations will increase the Services' capability to focus on Federal actions requiring formal consultation by eliminating the requirement to provide written concurrence for actions within the scope of the counterpart regulations. EPA and the Services are committed to implementing this authority in a manner that will be equally as protective of listed species and critical habitat as the current procedures that require written concurrence from the Service.

These counterpart regulations provide an additional tool for accelerating EPA's ESA compliance activities, while providing equal or greater protection of listed species and critical habitat. Under current procedures, EPA already must complete and document a full ESA analysis to reach an NLAA determination. The counterpart regulations permit a FIFRA action to proceed following EPA's NLAA determination without an overlapping review by the Service, where the Service has provided specific training and oversight to achieve comparability between EPA's determination and the outcome of an overlapping review by the Service.

The approach outlined in these counterpart regulations is consistent with subpart B because it leaves the standards for making jeopardy and NLAA determinations unchanged. Further, when EPA operates under these counterpart regulations it will retain full responsibility for compliance with section 7 of the ESA.

Under this rule, EPA will enter into an alternative consultation agreement with either FWS, NOAA Fisheries or both. The alternative consultation agreement will include: (1) A description of the actions that EPA and the Service have taken to document the approach EPA uses to make determinations regarding the effects of its actions on listed species or critical habitat and to evaluate that approach for consistency with the ESA and applicable implementing regulations; (2) a description of the program for developing and maintaining the skills necessary within EPA to make NLAA determinations, including a jointly developed training program based on the needs of EPA; (3) provisions for incorporating new information and newly listed species or critical habitat into EPA's effects analysis on FIFRA actions; (4) processes that EPA and the Service will use to incorporate scientific advances into EPA's effects determinations; (5) a description of a mutually agreed upon program for periodic program evaluations; and (6) provisions for EPA to maintain a list of FIFRA actions for which EPA has made NLAA determinations. By following the procedures in these counterpart regulations, including the establishment of the alternative consultation agreement, EPA will fulfill its ESA section 7 consultation responsibility for actions covered under these regulations.

The purpose of the jointly developed training program between EPA and the Service is to ensure that EPA consistently interprets and applies the provisions of the ESA and the regulations (50 CFR part 402) relevant to these counterpart regulations with the expectation that EPA will reach the same conclusions as the Service. It is expected that the training program will rely upon the ESA Consultation Handbook as much as possible.

The Service will use monitoring and periodic program reviews to evaluate EPA's performance under the alternative consultation agreement at the end of the first year of implementation and then at intervals specified under the alternative consultation agreement. The Service will evaluate whether the implementation of this regulation by EPA continues to be consistent with the best scientific and commercial data

available and the ESA. The result of the periodic program review may be to recommend changes to EPA's implementation of the alternative consultation agreement. The Service will retain discretion for terminating the alternative consultation agreement if the requirements under the counterpart regulations are not met. However, any such suspension, modification, or termination will not affect the legal validity of determinations made prior to the suspension, modification, or termination.

Upon completion of an alternative consultation agreement, EPA and the Service will implement the training program outlined in the alternative consultation agreement. EPA will have full responsibility for the adequacy of its NLAA determinations since there would be no reviewable final agency action by the Service when EPA makes a NLAA determination for a FIFRA action.

The Services and EPA developed a draft of an alternative consultation agreement that addresses the topics identified in proposed § 402.45. This draft alternative consultation agreement is part of the administrative record of this rule, and was made available for the public to read to obtain a better understanding of how the Services anticipate the requirements of § 402.45 would be satisfied.

C. New Optional Formal Consultation Process

The counterpart regulations establish a new formal consultation process (§ 402.46) that will meet all statutory requirements and closely follow the procedural steps specified in the current subpart B process. The new process will combine the central concepts and procedures of the subpart B consultation process with innovations stemming from EPA's expertise in assessing the ecological effects of pesticide products.

The process relies on an effects determination that will be prepared by EPA according to analytical methodologies that the Services have reviewed and endorsed. The effects determination may be prepared, upon EPA's request, with the assistance of a Service Representative. While the contents of an effects determination will depend on the nature of the action, an effects determination submitted under § 402.46 or § 402.47 will contain the information described in § 402.14(c)(1)–(6) and a summary of the information on which the determination is based, detailing how the FIFRA action affects the listed species or critical habitat. EPA could also include three additional sections in an effects determination: (1) A conclusion whether or not the FIFRA action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat and a description of any reasonable and prudent alternatives that may be available; (2) a description of the impact of any anticipated incidental taking of such listed species resulting from the FIFRA action, reasonable and prudent measures considered necessary or appropriate to minimize such impact, and terms and conditions necessary to implement such measures; and (3) a summary of any information or recommendations from an applicant. An effects determination with the required information and the additional discretionary sections would contain the information currently provided by the Service in a biological opinion. All effects determinations will be based on the best scientific and commercial data available.

Once EPA has prepared an effects determination for the species and habitats that may be affected, it may initiate formal consultation on a FIFRA action under this section by delivering to the Service a written request for consultation. The written request will be accompanied by an effects determination as defined in § 402.40(b) and a list or summary of all references and data relied upon in the determination. The Service will be able on request to review any or all of the references and data relied upon in the determination as if it was in the Service's files. The time for conclusion of the consultation under section 7(b)(1) of the Act will run from the date the Service receives the written request from EPA. Any subsequent interchanges between the Service and EPA regarding the information submitted by EPA, including interchanges about the completeness of EPA's effects determination, will occur during consultation, and will not delay the initiation of consultation or extend the time for conclusion of the consultation unless EPA withdraws the request for consultation.

If EPA has prepared the effects determination without a designated Service Representative, the Service retains the discretion to determine within 45 days that additional available information would provide a better information base for the effects determination and may so notify EPA. After such a notification, EPA may revise the effects determination and resubmit it to the Service. The timing and form of EPA's resubmission are within its discretion, but the time limitations in section 7(b)(1) continue to apply. A request for additional information does not represent a finding by the Service that the effects determination was not based on the best scientific and commercial data available. Further, any requested additional information must actually be available to EPA during the specified consultation period. Where a designated Service Representative has participated in the development of the effects determination, the Service will rely upon its representative to identify all desired available information during the preparation of the determination, and this intermediate Service review during consultation is not needed. However, EPA at all times retains its duty to use the best scientific and commercial data available for its effects determinations, and the Services retain their duty to use the best scientific and commercial data available during consultation. Once an effects determination has been resubmitted following an additional information determination, the Service will proceed to conclude the consultation without further requests to EPA for additional information, although the Service may consider additional information at any time during the consultation process. If EPA advises the Service it will not resubmit a revised effects determination to the Service after the Service requests additional information, its initiation of consultation on the effects determination will be deemed withdrawn.

Within the later of 90 days after the Service receives EPA's written request for consultation or 45 days after the Service receives an effects determination resubmitted following an additional information determination by the Service, the Service will take one of three actions: (1) If the Service finds that the effects determination contains all required information and satisfies the requirements of section 7(b)(4) of the Act, and the Service concludes that the FIFRA action that is the subject of the consultation complies with section 7(a)(2) of the Act, the Service will issue a written statement adopting the effects determination; or (2) it may provide EPA a draft written statement modifying the effects determination and as modified adopting the effects determination; or (3) it may provide EPA a draft jeopardy biological opinion along with any reasonable and prudent alternatives if available. Providing these draft documents to EPA is consistent with current agency practice under other consultation procedures in Part 402. The deadlines for Service action are subject to section 7(b)(1) of the Act.

If the Service provides either the draft statement modifying the effects

determination or draft jeopardy opinion, EPA is required to make it available to any applicant upon request. The rule also accommodates EPA's existing discretion to make these draft documents available to the general public for comment within the time periods provided in this rule. The Service will on request meet with EPA and any applicant, each of which may submit written comments to the Service on the draft document within 30 days or a longer period if extended under section 7(b)(1) of the Act. The Service will issue a final biological opinion or final written statement within 45 days after EPA receives the draft opinion or statement from the Service unless the deadline is extended under section 7(b)(1) of the Act. Any such final opinion or statement will be signed by the Service Director, who may not delegate this authority beyond certain designated headquarters officials, and will constitute the opinion of the Secretary and the incidental take statement, reasonable and prudent measures, and terms and conditions under section 7(b) of the Act.

Where consultation on a FIFRA action will be unusually complex due to factors such as the geographic area or number of species that may be affected by the action, a special provision (§ 402.47) allows EPA, after conferring with the Service, to address the effects of the action through successive effects determinations addressing groupings or categories of species or habitats as established by EPA. This provision is needed because for some widely-used pesticides, delaying the initiation of consultation until adequate information is available for every species or habitat that may be affected by the pesticide may result in denying some of the most vulnerable species the benefits of the section 7 consultation process for as much as several years. Further, allowing geographic or other functional groupings of species lets EPA and the Service conduct related biological inquiries together in an efficient, coordinated manner. EPA will use this provision after conferring with the Services, and EPA and the Services intend to collaboratively identify priorities where use of this provision will most effectively address these biological goals. When successive effects determinations are prepared, EPA may initiate consultation based upon each such effects determination using the procedures in § 402.46(a). The procedure in § 402.46(b) and (c) will apply to the consultation. The written statement or opinion provided by the Service under § 402.46(c) will constitute a partial biological opinion as to the species or habitats that are the subject of the consultation. The partial biological opinion would describe the provisions relating to incidental take of such species for inclusion in an incidental take statement at the conclusion of consultation, giving users of pesticide products such as farmers and forest managers, nursery operators, and other pesticide users prompt and reliable guidance for minimizing incidental take of the species. EPA will also retain authority to use such a partial biological opinion, along with other available information, in making a finding under section 7(d) of the Act as to whether the FIFRA action constitutes an irreversible and irretrievable commitment of resources which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative as to those species and habitats. After conclusion of all consultation on the FIFRA action, the previously-issued partial biological opinions will then collectively constitute the opinion of the Secretary and the incidental take statement, reasonable and prudent measures, and terms and conditions under section 7(b) of the Act unless a partial biological opinion were to be modified by the Service using the procedures in § 402.46(c). For pesticide products currently in use, this process will provide prompt guidance for substantial protection for vulnerable species without unduly disrupting longstanding patterns of pesticide use in agriculture, public health vector control or other important pesticide use patterns throughout the country that are vital to the health and welfare of the American people.

The Services emphasize that § 402.47 is not intended as an authorization for EPA to take actions, such as registration of pesticides containing new active ingredients or registration of new uses, without complying with the requirements of section 7(a)(2) of the Act. Rather, for certain complex FIFRA actions the provision strengthens EPA's and the Services' ability to establish the most effective sequence for completing EPA's consultation obligations through a series of focused consultations on specific species or habitats. EPA will not satisfy its procedural obligations under section 7(a)(2) of the ESA until all necessary consultations are completed. Likewise, a Service's issuance of a partial biological opinion following each such focused consultation will not represent the opinion of the Secretary or an incidental take statement under section 7(b) of the ESA until all required consultation is concluded on listed species and habitats.

The Services expect this provision may be used for FIFRA actions in a variety of circumstances. For example, after reviewing an action, EPA might identify differing levels of risk for different species, and might conclude that it would be prudent to seek Service advice on the impacts of concern through formal consultation while EPA continued to analyze the lesser risk concerns. In addition, if EPA needs to update completed consultations on pesticides by addressing impacts on more than one newly listed species, EPA might find it more efficient and effective to consider each species separately, even though a particular pesticide might impact more than one of the newly listed species. Nonetheless, EPA has advised the Services that EPA does not intend to register any new use or active ingredient until completion of consultation under section 7(a)(2) for all species affected by that action. However, like any action agency, EPA retains statutory authority to use appropriate information to make section 7(d) determinations under the ESA. In sum, the Services believe that it is advisable for the consultation process on these and other complex FIFRA actions to have flexibility, so that EPA and the Services can most efficiently and effectively protect listed species and habitats. EPA will only use the provision after conferring with the Service, which should further insure the continued effective and appropriate use of this authority.

This counterpart rule makes clear that the emergency consultation provisions in existing Service regulations are available to EPA for consultation on actions under FIFRA section 18 by providing that EPA could conduct consultation on actions involving requests for emergency exemptions under FIFRA section 18 under section 402.05 or another available consultation procedure. As provided in § 402.05, any required formal consultation on such an action will have to be initiated as soon as practicable after the emergency is under control. For the purposes of the consultation required in § 402.05(b), the definition of formal consultation in § 402.02 will include the procedures in § 402.46 in addition to those in subpart B.

The Services believe that EPA's statutory and regulatory standard for an ''emergency'' under FIFRA section 18 is generally comparable to the intended scope of emergency in § 402.05 and that, therefore, the overwhelming majority of FIFRA emergency exemption actions could properly be considered

emergencies for the purposes of § 402.05. Under EPA regulations, FIFRA section 18 emergency exemptions can only be issued for urgent, non-routine situations where a pesticide is needed to address, for example, significant risks to human health or the environment or significant economic loss. 40 CFR 166.1(a), 166.3(d). Pest problems of these dimensions will generally be encompassed within the provisions of § 402.05(a).

The Services' 1998 Joint Consultation Handbook (page 8–1) contains a passage suggesting that emergency actions under FIFRA may not usually qualify as emergencies ''unless there is a significant unexpected human health risk.'' While a significant unexpected human health risk will permit an emergency consultation under § 402.05, the quoted passage should not be read to mean that the emergency provisions in § 402.05 are available for FIFRA section 18 actions only where an unexpected human health risk is present. Such a narrow reading of the quoted passage is inconsistent with other statements in the Handbook and with past Service practice in comparable circumstances. The plain language of § 402.05 is not so limited, and can be read to encompass the kind of emergency situations that FIFRA section 18 contemplates even if no significant unexpected human health risk is present. The Services believe the use of § 402.05 by EPA for FIFRA section 18 actions under this rule will therefore be consistent with practices currently permitted under subpart B.

The counterpart rule contains other provisions to ensure full compliance with ESA requirements. After a consultation under this subpart has been concluded, EPA shall reinitiate consultation as required by § 402.16 as soon as practicable after a circumstance requiring reinitiation occurs, and may employ the procedures in this subpart or subpart B in any reinitiated consultation. EPA must comply with § 402.15 for all FIFRA actions subject to consultation under this subpart. EPA must prepare a biological assessment for FIFRA actions that constitute ''major construction activities'' to the extent required by § 402.12. The typical regulatory actions EPA takes under FIFRA (*e.g.*, registration, reregistration, section 18 approvals) do not, however, generally constitute ''major construction activities,'' and the Services are not aware of any current FIFRA activities that would meet this definition. This rule allows EPA to employ the conferencing procedures described in § 402.10 for any species proposed for listing or any habitat proposed for designation as critical habitat, and provides that for the purposes of § 402.10(d), the procedures in § 402.46 would be a permissible form of formal consultation.

Summary of Comments Received

On January 30, 2004, the Services proposed the rule that would establish joint counterpart regulations for consultation under section 7 of the ESA to streamline consultation on proposed actions under FIFRA. The comment period was to close on March 30, 2004 but was extended to April 16, 2004. The Services received more than 125,000 comments on the proposed rule from a large variety of entities, including States, agricultural entities, trade associations, industry, conservation groups, coalitions, and private individuals. The overwhelming majority of comments received were part of letter-writing and e-mail campaigns expressing, in a ratio of approximately 1:2, general support for or opposition to the proposal. The Services considered all of the information and recommendations received from all interested parties on the proposed regulations during the public comment period and appreciated the comments received on the proposed rule. The Services received numerous comments on the ACA, the Overview Document and other materials included in the rulemaking record that are neither part of the proposed counterpart regulations nor incorporated by reference into the regulations. Since these documents are not part of the regulations, the Services have only responded to them to the extent that the comments on these documents relate to the proposal to adopt the counterpart regulations.

The following is a summary of the comments received on the proposed counterpart regulations, and the Services' responses.

General Comments

Comment: The proposed rule should be withdrawn and the Services should instead enforce existing consultation rules.

Response: The Services believe that the counterpart regulations will complement the existing section 7 consultation process and therefore are promulgating the final rule.

Comment: The proposed counterpart regulations are an improvement over the current process and will: improve coordination of FIFRA actions and ESA evaluations; increase the speed and efficiency by which steps can be taken to protect species and/or their habitat; and improve the consistency of endangered species assessments for FIFRA-regulated products.

Response: The Services agree with these comments.

Comment: Several elements of the proposed rule were particularly impressive: clarification of the mechanisms by which the Services will get information to EPA on a timely basis; recognition that, in many cases, it is sensible for EPA to proceed with consultations on a phased basis; and confirmation that EPA retains authority to make section 7(d) decisions regarding pesticide impacts.

Response: The Services appreciate these comments.

Comment: The consultation process between the Environmental Protection Agency (EPA) and the Services should be strengthened.

Response: The Services agree that the section 7 consultation process with EPA should be strengthened. The intent of the rule is to enhance the efficiency and effectiveness of the consultation process through increased interagency cooperation.

Comment: There is no need to change the current consultation process system. In fact, there is inadequate justification for doing so. For the public to assess the need for the counterpart regulations, the document should include numbers of how many FIFRA actions resulted in ''no effect'', ''not likely to adversely affect'', and formal consultation, rather than simply how many FIFRA registrations take place. Instead of changing the rules, the Services and EPA should work to improve the existing process, and work with wildlife experts. Moreover, any efficiencies of time that might be gained are unnecessary, because the FIFRA registration process can take years and is compatible with the timeframes in section 7.

Response: The Services do not believe past practices are an indication of the future, and moreover it is difficult to foresee accurately how many FIFRA actions will need to undergo consultation. Nonetheless, the Services, EPA and the Department of Agriculture all agree that the number of consultations on FIFRA actions likely in coming years is so great that the Services could not complete the consultations under the existing processes and meet their other ESA duties in a timely manner with existing resources. The Services do not want to wait until the workload has already become too great before implementing the means to manage the workload more efficiently, and are taking the proactive step of adopting the counterpart regulations at this time. The Services

note that the counterpart regulations do not change the timeframes in section 7.

Comment: The proposed rule will favor the pesticide industry and is therefore not in the public interest.

Response: The Services disagree with this comment. The counterpart regulations will enable EPA and the Services to fully protect endangered species and will enable EPA to provide pesticide users the products they require to meet the needs of the American people.

Comment: Public Law 100–478 did more than express Congressional intent; it also established the goals of EPA's pesticide labeling program, including allowing persons to continue the production of agricultural food and fiber commodities and minimizing the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators.

Response: These counterpart regulations are intended to provide flexibility to EPA under the ESA by creating optional alternative procedures to the existing subpart B consultation process consistent with the goals of Public Law 100–478. These counterpart regulations will enhance the efficiency and effectiveness of the subpart B consultation process by increasing interagency cooperation and providing two optional alternatives for EPA's pesticide registration program. By providing EPA with more flexibility, impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators will be minimized.

Comment: Pesticides are a source of risk to listed species and threaten their survival and recovery. Several commenters noted that pesticides have been found to disrupt the normal functions of immune and endocrine systems of various wildlife species, and even newer pesticides are still highly toxic. Another commenter provided the opposing view that, through EPA's registration process and voluntary withdrawals, the number of available pesticides has been greatly reduced, and the remaining pesticides are more pest-specific and less environmentally hazardous.

Response: The Services agree that some pesticide uses have the potential to affect listed species and critical habitat. These regulations are designed to assist EPA and the Services in evaluating these potential effects.

Comment: Pesticides are necessary in order to manage and control invasive plants, which otherwise degrade critical habitat and endanger susceptible species. Executive Order 13112 on Invasive Species requires all Federal agencies to identify agency action that may contribute to the spread of invasive species and to address the invasive species problem to the extent practical and consistent with their authorities and resources. Use of pesticides has reduced farms' footprints, improved soil conservation, and benefited wildlife.

Response: The Services agree that invasive species can be a threat to listed species, and recognize that use of pesticides can be beneficial, including the possibility of use to control invasive species. This Executive Order, however, does not relieve a federal agency from its obligations under section 7 of the ESA for its actions, including those for the purpose of controlling invasive species.

Comment: Pesticides should be banned in areas inhabited by listed species, except when licensed individuals are controlling invasive species that threaten native wildlife. Another commenter took an opposing position, suggesting that in certain circumstances ''for example, when a crop grows in close proximity to another crop for which pesticide use has been authorized ''a minimum level of pesticide use should be allowed without completing consultation. Yet another commenter suggested that the use of national standards for the protection of listed species frequently do not work due to the variety of special local circumstances.

Response: The Services consider these comments beyond the scope of the counterpart regulations, as we do not have the authority to generally ban the use of pesticides, nor do we have authority to authorize use of a pesticide. The Services note that, through the consultation process, the Services may recommend to EPA a wide range of measures to address identified effects to listed species caused by the use of pesticides, which may be tailored to local conditions.

Comment: Only 1 percent of pesticides reach their targets. There are other methods to promote successful agriculture that do not involve extensive pesticide use. EPA needs to give more than lip service to the identification of non-toxic alternatives.

Response: The Services understand that there are circumstances under which EPA considers non-toxic alternatives under FIFRA; however, the counterpart regulations will apply to EPA's consultation obligation with respect to FIFRA actions and do not address EPA's responsibilities under FIFRA. These counterpart regulations do not limit the ability of EPA to explore alternatives to the action that is subject to consultation.

Comment: The counterpart regulations do not provide the same overall degree of protection for listed species as the existing consultation rules in subpart B. If EPA is not required to obtain a written concurrence from the Services concerning its NLAA determinations, the Services will lose the opportunity to identify data gaps, additional studies, or mitigation measures.

Response: The Services disagree with this comment. The procedures authorized by these counterpart regulations will be as protective of listed species and critical habitat as the process established in subpart B. All consultations under the counterpart regulations will apply the same legal and biological standards as consultations under subpart B. The counterpart regulations merely provide an alternate process for meeting these procedural standards. The Services note that EPA would still have the option of involving the Service Representative to assist with development of effects determinations to identify data gaps, additional studies, or mitigation measures. Most important, through their review of EPA's ecological risk assessment approach, the Services have concluded the EPA's approach should produce effects determinations that appropriately identify actions that are not likely to adversely affect listed species or critical habitat, and with which the Services would likely concur.

Comment: The proposed counterpart regulations organize the consultation process. Such an organized process is favored over the unpredictability of litigation. Another commenter expressed the opposing point of view that reducing the Services' review of pesticide actions could increase litigation against EPA, because EPA would not enjoy the same deference to its risk assessments as the Services would receive, and therefore the FIFRA registrations may actually be delayed.

Response: The Services agree that a carefully structured consultation process is preferable to the unpredictability of litigation. While the Services cannot control litigation decisions made by the public, we do not believe that these counterpart regulations increase EPA's legal vulnerability under the ESA or change judicial review standards, and therefore predicted delays due to litigation would be a matter of speculation.

Comment: A primary purpose of the counterpart regulations must be to alleviate the threat of civil and criminal penalties under the ESA associated with

the pesticide use that has resulted from the lack of a final FIFRA endangered species program. The counterpart regulations must help ensure a timely and efficient pesticide registration process in addition to protection of listed species and their habitats.

Response: The proposed counterpart regulations will improve the effectiveness and efficiency of the consultation process for pesticides, which will result in more expeditious EPA determinations of NLAA and Service determinations regarding the authorization of incidental ''take'' of listed species, including any reasonable and prudent measures that are necessary or appropriate to minimize the impacts of such ''take.'' These regulations will also help ensure that registration and reregistration decisions for which ESA determinations must be made are completed in a timely manner. As a result, the counterpart regulations will improve upon EPA's ability to ensure that pesticide use directions are consistent with the requirements of the ESA and that users properly following pesticide use instructions are not at a theoretical risk of prosecution under the ESA.

Comment: Several commenters suggested that the provisions in § 402.45 for informal consultation on actions that are not likely to adversely affect listed species or critical habitat are not consistent with the legal requirements of the ESA. Commenters suggested that the ESA requires the Services to conduct a formal consultation on any FIFRA action: (1) That may affect a listed species (citing a 1978 congressional report on ESA amendments); or (2) that occurs in an area where a listed species is present even if there is no effect on a listed species; or (3) where EPA makes a no effect determination resulting from mitigation measures adopted by EPA. Another commenter stated the ESA requires the Service to issue a written concurrence for an action agency's not likely to adversely affect determination. A commenter also suggested that the decision in *NRDC* v. *Houston*, 146 F.3d 1118 (9th Cir. 1998) means that the ESA prohibits EPA from making NLAA determinations without consulting with the Services. Another commenter suggested that the counterpart regulations change the threshold for consultation from ''may affect'' to ''likely to adversely affect.''

Response: The Services disagree with these legal conclusions. The Services have concluded that the counterpart regulations do not violate the language or spirit of the ESA. The ESA does not contain an express statutory standard for determining when formal consultation under section 7 is required for a proposed agency action. The 1978 congressional report cited by the commenter in support of a ''may affect'' threshold for formal consultation addressed a draft bill that was not enacted by Congress. The ESA amendments adopted in 1978 do not contain the statutory language discussed in the congressional report. In 1986, the Services issued the subpart B regulations requiring formal consultation for an action that may affect a listed species or critical habitat, but allowing the use of alternative procedures to determine that an action is ''not likely to adversely affect'' (NLAA) listed species or critical habitat and thereby conclude the consultative process.

As stated in the 1986 regulations, § 402.01, ''Section 7(b) of the Act requires the Secretary, after the conclusion of early or formal consultation, to issue a written statement setting forth the Secretary's opinion detailing how the agency action affects listed species or critical habitat.'' However, neither informal consultation nor NLAA concurrence is specified in the ESA, and the ESA does not prescribe requirements directing how the Services should consult with federal agencies on NLAA actions. The Services have exercised their discretion through rulemaking to establish an alternate procedure for actions that are NLAA. The general informal consultation procedure in subpart B, with an individualized concurrence letter from the Services, reflects an exercise of the Services' discretion. Federal agencies and the Services have effectively employed this alternative to formal consultation several hundred thousand times over the past two decades for a myriad of diverse agency actions, and use of this alternative has been upheld in many court decisions. The counterpart regulations rely upon the fundamental structure in the subpart B regulations that created an informal consultative process for actions that are not likely to adversely affect listed species or designated critical habitat, and required formal consultation for other actions to ensure that 7(a)(2) requirements are met.

The counterpart regulations represent an alternative form of informal consultation for NLAA actions subject to § 402.45, creating a new, carefully-structured training, monitoring and oversight relationship between the Services and EPA as an alternative for the individual project-based concurrence system that was created in the subpart B regulatory framework. The counterpart regulations create a system where EPA uses a risk assessment methodology approved by the Services, engages in regular exchanges of scientific information with the Services, and its staff is trained and supervised to perform NLAA determinations just as the Services would in a concurrence letter, with less delay and equal protection for listed species and critical habitat.

The Services believe that through implementation of the ACA, and the provisions of § 402.45 for periodic review, oversight, and termination of the ACA by the Services if necessary, EPA is insuring, in consultation with and with the assistance of the Secretary, that FIFRA actions are not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. For these reasons, the Services believe that the counterpart regulations comply with the ESA.

As reflected in the record of this rulemaking, the Services have concluded that the approach to ecological risk assessment described in EPA's Overview Document is consistent with the ESA, and that this approach will produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations (*See* Letter from S. Williams and W. Hogarth to S. Hazen, January 26, 2004). Accordingly, the Services' opinion, which has taken into account the provisions of section 7(b)(3), is that actions for which EPA makes NLAA determinations are not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. Morevoer, the Services have developed and discusses drafts of the Alternative Consultation Agreement with EPS. The Services and EPA believe that the draft ACA released to the public with the proposed counterpart regulations would, with little substantive alteration, form the basis for a future final ACA. The Services' confidence in the conclusions about the adequacy of EPA's future NLAA determinations is strengthened by the agencies consensus on the need for (and content of) detailed provisions in the ACA that will guide the implementation of § 402.45. Therefore, this alternative form of informal consultation does not require separate written concurrence for individual FIFRA actions. Interagency coordination will continue to occur on NLAA actions through the implementation of the ACA and the ongoing review and monitoring

program. The alternative form of informal consultation described in § 402.45 reflects the exercise of the Services' discretion tailored to the specific circumstances of FIFRA actions.

In any case when EPA determines that a FIFRA action may affect a listed species or critical habitat, EPA is required to follow either the provisions of these counterpart regulations, or the provisions of the existing subpart B regulations. Further, the counterpart regulations continue to require formal consultation, in the manner provided in the regulations, for FIFRA actions that are likely to adversely affect a listed species or critical habitat. Therefore, the counterpart regulations do not change the threshold for consultation, as one commenter believes.

The Services note that the court decision cited by a commenter involved consultation under subpart B where a concurrence letter from the Service is required to conclude informal consultation; the case does not interpret the ESA as creating a statutory duty for an action agency to obtain a concurrence letter from the Service on NLAA actions.

Finally, the Services note that under subpart B, neither informal nor formal consultation is required if a proposed agency action will have no effect on a listed species that is present within the action area, whether or not the ''no effect'' finding results from mitigation measures adopted by the action agency. Under subpart B, the Services do not review an action agency's finding that a proposed action will have no effect on listed species or critical habitat. The counterpart regulations carry forward the same provisions for ''no effect'' actions and are consistent with the requirements of section 7 of the ESA and the subpart B regulations.

Comment: Several commenters questioned the legal validity of § 402.46 and associated provisions on the ground that the section improperly delegates or transfers to EPA the Services' duty to prepare a biological opinion at the conclusion of formal consultation, or limits the Services' ability to reject an effects determination prepared by EPA for use as a biological opinion. Conversely, another commenter suggested that EPA should have the full responsibility for the adequacy of its effects determinations, and there should never be any reviewable agency action by the Services in a formal consultation on a FIFRA action, or at least the Services should have to meet a specified burden of proof to reject an EPA effects determination in a formal consultation.

Response: The counterpart regulations do not delegate or transfer to EPA or otherwise limit the Services' ability to fully perform any legal duty assigned by law to the Services. Section 7 of the ESA requires that formal consultation must conclude with an opinion issued by the Services based on the best scientific and commercial data available. The Services have retained full legal authority to perform this duty. The ESA does not prohibit an action agency from contributing to the biological analysis performed during consultation. The Services are taking advantage of EPA's expertise in ecological risk assessment by allowing EPA to prepare an effects determination that can serve as a biological opinion if approved by the Services. If in the judgment of the Service an effects determination does not contain the information required in a biological opinion, the Service will not consider it for use under §§ 402.46 or 402.47. The Services retain full and complete discretion to accept, modify or reject EPA's effects determinations, and the Services remain fully responsible for every biological opinion issued at the conclusion of formal consultation. While the Services expect EPA's effects determinations to be accurate, there is no requirement that the Services must automatically accept any effects determination, even if there is ''substantial evidence'' (a legal term of art) to support it; the Services must determine the adequacy and accuracy of every effects determination. The Services do not have to meet any specified burden of proof to issue a biological opinion disagreeing with an EPA effects determination. The Services believe requiring them to meet a specified burden of proof to reject an EPA determination is not consistent with their statutory responsibilities and therefore reject that approach. For clarification, the Services wish to note that the counterpart regulations as adopted do not completely follow an earlier approach suggested in the ANPR regarding automatic presumption of validity for EPA findings. For these reasons, under §§ 402.46 and 402.47, the Services' biological opinions constitute agency action by the Services as required by the ESA, although the Services agree that EPA has full responsibility for the adequacy of the effects determinations it prepares for FIFRA actions.

Comment: The provisions for partial consultation violate the ESA because a comprehensive biological opinion must be completed before initiation of the agency action, and this procedural requirement has substantive implications. Moreover, the provision allows EPA to use partial reviews to validate any subsequent determination that an allowed use does not violate the 7(d) restrictions.

Response: As noted previously, the Services emphasize that § 402.47 is not intended as an authorization for EPA to take actions, such as registration of pesticides containing new active ingredients or registration of new uses, without complying with the requirements of section 7(a)(2) of the Act. The provision does not reduce EPA's consultation duties compared to subpart B. Rather, for certain complex FIFRA actions the provision strengthens EPA's and the Services' ability to establish the most effective sequence for completing EPA's consultation obligations through a series of focused consultations on specific species or habitats. EPA will not satisfy its procedural obligations under section 7(a)(2) of the ESA until all necessary consultations are completed. Likewise, the Services' issuance of a partial biological opinion following each such focused consultation will not represent the opinion of the Secretary or operate as an incidental take statement under section 7(b) of the ESA until all required consultation is concluded on listed species and critical habitats. With regard to the possibility that EPA may use such partial biological opinions to validate a subsequent determination to proceed with an action, the Services note that, like any action agency, EPA retains statutory authority to use appropriate information to make section 7(d) determinations under the ESA.

Comment: The provision for successive effects determination provisions in § 402.47 violates section 7(d) of the ESA and is inconsistent with the central purpose of the ESA to preserve ecosystems upon which listed species depend.

Response: The Services disagree with this comment. The provisions of § 402.47 are carefully tailored to fulfill the purposes of the ESA and to comply with section 7(d), which allows the action agency, and not the Services, to determine whether an action can proceed before consultation is concluded.

Comment: The counterpart regulations should be expanded to address actions that would be exempt from any consultation. Not every FIFRA action will require an effects determination; the list of categorical exclusions should be incorporated as part of the ACA or the counterpart regulations.

Response: The Services have not accepted these suggestions. The action agency (here EPA) determines the agency actions on which it wishes to

consult and can make a no effect finding for an action without review by the Services. The ESA does not contain an express provision for categorical exclusions, a term employed under the National Environmental Policy Act. However, action agencies have the opportunity to conduct programmatic or other broad-scale reviews to identify individual actions that do not require any consultation.

Comment: The proposed counterpart regulations improperly transfer the primary duty to avoid jeopardy to listed species from the Services to EPA.

Response: The Services disagree with this comment. Under the ESA, action agencies have the independent legal duty to avoid activities that are likely to jeopardize listed species. The Services assist action agencies in meeting this duty through consultation, and will continue to do so under the new consultation procedures provided in these counterpart regulations.

Comment: The counterpart regulations will lessen EPA's duty or ability to avoid actions that are likely to jeopardize the continued existence of a listed species.

Response: The Services disagree with this comment. EPA's duty and ability to avoid jeopardy are unchanged. In fact, the Services believe EPA may be able to do a better job of avoiding jeopardy under the counterpart regulations because consultations can be completed faster and in greater numbers than may be possible under subpart B procedures.

Comment: EPA has failed to consult with the Services and failed to reinitiate consultation when required. Moreover, EPA has not responded appropriately to notification from the Services that certain pesticides may harm listed species. EPA has never integrated ESA compliance into its reregistration process and decisions. EPA has not fully implemented recommendations in past Biological Opinions, and has no program for protecting species from pesticides.

Response: While the Services are aware of these criticisms of EPA's past record of ESA compliance, the Services intend for these counterpart regulations to enable EPA to comply with the ESA more effectively in the future. These counterpart regulations do not alter EPA's substantive obligations under the ESA in the past or the future. The counterpart regulations recognize EPA's expertise in ecological risk assessment and are carefully tailored to take advantage of that expertise while providing training and meaningful oversight to ensure that EPA makes appropriate determinations. Further, the Services have reviewed EPA's ecological risk assessment process and concluded that it will appropriately integrate consideration of the effects on listed species and critical habitat into its regulatory processes under FIFRA.

Comment: EPA cannot be objective under FIFRA due to conflicting statutory mandates, scientific standards, and safeguards for listed species. Additionally, EPA lacks the legal authority under FIFRA to perform endangered species assessments and anyway, FIFRA legal standards of review are different than those of the ESA. Further, EPA's ties to industry are too close. EPA has displayed little independence, making it incapable of independent assessments.

Response: The Services disagree with this comment. The Services believe EPA is objective in its application of the risk assessment methodologies that have been endorsed by the Services. The Services have a variety of tools available to assure that EPA's effects determinations are objective and scientific and intend to use these tools to achieve that goal as necessary. The Services do not opine on the scope of legal authority of an action agency under the statutes it implements such as FIFRA or other separate legal requirements. EPA must also comply with the ESA, and the Services do not believe there is inherent conflict between the ESA and FIFRA that would prevent EPA from being able to do so.

Comment: It is imperative to develop an organized and scientifically defensible prioritization of previously registered products not yet consulted on. Further, EPA should give highest priority to currently registered pesticides for which EPA is actively preparing Reregistration Eligibility Decisions under FIFRA section 4 and to pesticides seeking new registration under FIFRA section 3. A number of these contain new active ingredients which would pose less environmental and public risks than the pesticide products they would replace, *e.g.*, products to replace the acutely toxic organophosphate insecticides or the fumigant, methyl bromide. A related comment stated that the rule and the ACA should either recognize EPA's existing priority-setting process for decisions concerning new registrations, or allow the agencies to develop a similar process.

Response: These comments are beyond the scope of the proposed rulemaking for the counterpart regulations. However, the Services note that the Services and EPA are discussing prioritization, although action agencies determine when to bring their actions to the Services.

Comment: EPA should be designated the lead regulatory agency in making pesticide product risk assessment and risk management determinations as they relate to the potential impact on endangered species or habitat.

Response: The Services agree that, within the confines of the ESA, EPA has initial responsibility for assessing impacts of pesticides to threatened and endangered species. The intent of the counterpart regulations is for the Services to take greater advantage of EPA's expertise in ecological risk assessment while continuing to exercise all duties required by the ESA.

Comment: Since FIFRA already provides a procedure for public input and comment, it would be duplicative to publish a **Federal Register** notice allowing input by the public in the alternative consultation process.

Response: The commenter has misconstrued the regulation. This regulation does not require such a notice to be published in the **Federal Register**.

Comment: The counterpart regulations should ensure that interagency exchanges and public disclosure of proprietary data and applicant-prepared summaries of data are consistent with section 10 of FIFRA and with EPA's information regulations at 40 CFR 2.209(c) regarding the treatment of confidential business information.

Response: The counerpart regulations do not alter in any respect the Government's obligations under either section 10 of FIFRA or EPA's information regulations regarding the protection of information that either may be, or has been determined to be, confidential business information. EPA regulations at 40 CFR part 2 address in detail the conditions under which such information may be shared by EPA with other government agencies, how such agencies must protect the information, and the circumstances under which such information is subject to public disclosure. Accordingly, the Services do not believe it necessary to revise the proposed rule to address this matter.

Comment: EPA should perform the risk assessment in the course of pesticide registration, in accordance with Service procedures. Should disagreement on the NLAA determination occur, the Services should have to carry the burden to overturn the determination and show that the EPA analysis was incorrect.

Response: The commenter has misconstrued the applicable procedures regarding NLAA determinations. Under these counterpart regulations EPA may make NLAA determinations without

obtaining written concurrence from the Services. The Services will conduct a review of EPA's program for making NLAA determinations in the course of their monitoring and oversight activities, for the purpose of determining whether EPA's program is based on the best scientific and commercial information available and is consistent with ESA and applicable implementing regulations.

Comment: If EPA and the Services are to agree on a risk assessment process that accomplishes both the goals of FIFRA registration and ESA section 7 consultation, then EPA should be able to employ the risk assessment process for both purposes with minimum oversight by the Services.

Response: The Services interpret this comment as an expression of support for the counterpart regulations and believe that, to the extent that the comment urges less oversight, the process and degree of oversight provided under the rule is appropriate.

Comment: Agencies should develop and adopt a specific plan for transitioning currently on-going consultations to the final counterpart regulations.

Response: Although the development of a plan is not required by the regulations, the Services recognize the appropriateness of coordinating with EPA to implement these counterpart regulations for any consultations not yet completed when these regulations take effect.

Comment: The Consultation Handbook should be replaced or rewritten to specifically apply to the counterpart regulations and the ACA.

Response: The Services will review the Consultation Handbook in order to ensure that it is consistent with the regulations.

Comment: The counterpart regulations do not provide enough time for thorough consultation.

Response: The counterpart regulations are consistent with the statutory timelines for consultation in section 7.

Comment: The proposed regulations do not adequately provide remedies for stakeholders in the event that action deadlines are not met during the consultation process.

Response: The Services are committed to meeting all deadlines imposed by the counterpart regulations and decline to provide additional enforcement remedies. However, the Services believe the new procedures will increase the timeliness of the consultation process.

Comment: Clarification is needed in the counterpart regulations as to how the ESA consultation process will affect EPA's ability to meet deadlines for pesticide registration and reregistration in FIFRA as established by the Pesticide Registration Improvement Act (PRIA) of 2003 and the Food Quality Protection Act (FQPA) of 1996.

Response: EPA has an obligation to comply with section 7(a)(2) in connection with certain pesticide regulatory actions it takes under FIFRA. The counterpart regulations do not alter that obligation nor do they alter any of EPA's obligations under FIFRA. The rule is intended, rather, to improve the effectiveness and efficiency of the consultation process. In turn, this should help ensure that EPA can, in a timely manner, make pesticide regulatory decisions for which ESA consultation is required. The counterpart regulations should, therefore, assist EPA in its efforts to meet the deadlines provided in PRIA and the FQPA.

Comment: Decisions on pesticide uses that have no effect or are not likely to adversely affect listed species should not be delayed until decisions have been made on uses that require formal consultation.

Response: Under both the existing regulations and the counterpart regulations, EPA retains the authority to identify the scope of its action, consistent with the definition of ''action'' in § 402.02. Consequently, EPA has the discretion to proceed to make decisions on certain uses determined to have no effect or to be NLAA once these determinations are made.

Comment: EPA's Office of Pesticide Programs (OPP) should work more closely with that agency's Office of Water.

Response: The Services are not in a position to direct the internal operations of EPA's offices.

Comment: The proposal should be expanded to include all appropriate federal agencies and activities, including, at a minimum, the U.S. Army Corps of Engineers and EPA's Offices of Wastewater Management and Wetlands, Oceans, and Watersheds. There is no need to place artificial limits on what activities may be eligible. The joint counterpart regulations should be expanded to include any federal agency that retains or develops in-house expertise on endangered or threatened species.

Response: The purpose of these counterpart regulations is for consultation under section 7 of the ESA for regulatory actions under FIFRA. It is beyond the scope of the counterpart regulations as proposed to include agency actions other than EPA regulatory actions under FIFRA.

Comment: The proposed ''no concurrence'' approach to NLAAs sets a bad precedent for other agencies and should therefore be avoided.

Response: These counterpart regulations are tailored to EPA's existing expertise and knowledge of pesticides regulated under FIFRA. If the Services adopt future counterpart regulations for other federal agencies, those rules would be based on each agency's capabilities and experience.

Comment: Separate consultation rules for FIFRA actions are warranted because such actions are fundamentally different from other federal agency actions subject to ESA section 7.

Response: The Services agree that counterpart regulations for FIFRA actions are warranted. Other federal agencies also consult on large and complex actions, and whether counterpart regulations would be appropriate for other agencies would be considered by the Services on a case-by-case basis.

Comment: It is troubling that EPA is not a cosponsor of these regulations. The final counterpart regulations should include an amendment to § 402.04 so that its first sentence reads as follows (new language italicized): ''The consultation procedures set forth * * * the National Marine Fisheries Service, *or by regulations promulgated by the Services alone in the event the action agency has concurred in that procedure.*'' The Services should also include a letter from the Administrator of EPA (or other appropriate Agency official) expressing the Agency's concurrence in the record of this proceeding.

Response: The proposal did not extend to subpart B, and the Services therefore decline to amend § 402.04 in this final rule. The Services note that EPA supported the development of the counterpart regulations and the Services do not believe the suggestions are legally necessary.

Comment: USDA should have the lead for developing processes that support an approach to determining pesticide exposure mitigation methods. Also, USDA should be included in some official capacity during consultation, to ensure knowledge of actual land management practices.

Response: EPA is the lead action agency; however, the Services have been assured that EPA will continue to collaborate with USDA as well as the Services in developing appropriate and necessary mitigation measures, and obtaining knowledge of land management practices.

Comment: EPA and the Services must coordinate with other offices and

agencies beyond USDA, as appropriate, when dealing with antimicrobials.

Response: The Services will endeavor to coordinate with other offices as appropriate.

EPA's Ecological Risk Assessment Process

A series of general comments stated the Services should not adopt the proposed rule because it is based on EPA's flawed approach to ecological risk assessment and EPA lacks expertise in key areas of ecological risk assessment.

Comment: It is necessary for the sake of consistency to include, either in the counterpart regulations or in the Overview Document, clearly described work flows of the screening-level risk assessment process.

Response: The Services disagree that the counterpart regulations must describe the details of the screening-level risk assessment process. The Services do not believe that a description of the workflow within the Overview Document is necessary to analyze the adequacy of the ecological risk assessment process.

Comment: EPA's approach generally is not adequate for identifying and quantifying the effects of pesticides, because it is not rigorous and not consistent with the current state of scientific knowledge. Because of these shortcomings, EPA will probably mistakenly determine that a pesticide either had no effect or was not likely to adversely affect listed species.

Response: The Services disagree that EPA does not have an adequate ecological risk assessment methodology. After an extensive and intensive review of EPA's approach to assessing the risks of pesticides to listed species and critical habitat, the Services concluded that EPA's approach ''will produce effects determinations that reliably assess the effects of pesticides on * * * listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations.'' See Letter from Steve Williams, Director, FWS, and William Hogarth, Assistant Administrator, NMFS, to Susan B. Hazen, Principal Deputy Assistant Administrator, EPA, dated January 26, 2004 (Letter of January 26, 2004).

More specifically, in the Services' expert judgment, the approach used by EPA is rigorous; it is carefully described in the ''Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency—Endangered and Threatened Species Effects Determinations'' January 23, 2004 (Overview Document) and the 81 support documents cited therein. In addition, EPA's risk assessments for individual chemicals are thoroughly documented, with the result that it is possible to identify the methodology used in each case.

The Services have also concluded that ''the approach used by OPP should produce effects determinations * * * that are consistent with those that otherwise would be made by the Services.'' Letter of January 26, 2004. This conclusion rests on the breadth of types of data that EPA will review and the manner in which EPA will analyze the data. EPA routinely requires a pesticide company to submit a substantial body of data in support of an application for registration. EPA will supplement this required database with information obtained through a systematic search of the open literature on the ecotoxicity of environmental substances. As recounted in detail in the Letter of January 26, 2004, EPA will examine this body of information for all of the types of potential impacts that an agency is required to consider under the ESA. Reliance on these sources of information is consistent with and should fulfill the statutory mandate to ''use the best scientific and commercial information available.''

The Services also disagree that EPA's approach to ecological risk assessment is inconsistent with current science. EPA's pesticide program routinely draws on the latest results from its Office of Research & Development (ORD) and other researchers in the fields of ecotoxicology and environmental fate assessment through participation in national and international professional, scientific conferences and symposia. EPA also works closely with the FIFRA Scientific Advisory Panel (SAP) to obtain expert, independent, external scientific peer review on every aspect of its approach to ecological risk assessment, as well as on specific pesticide assessments. See *http://www.epa.gov/scipoly/sap/* As a consequence of this active exchange of ideas and expertise with scientific leaders, EPA regularly makes changes to improve its methodologies to reflect current science.

Comment: Claims that EPA's risk assessment process is sufficient given the role played by the SAP are misplaced. As demonstrated in recent actions involving atrazine, EPA has demonstrated a willingness to ignore SAP conclusions.

Response: The Services appreciate the value that may be gained by EPA's use of the SAP as an independent peer review. However, the Services' conclusion about the adequacy of EPA's approach to ecological risk assessments is based on our independent review of the approach identified in the Overview Document, of which SAP review is only one part. Ultimately, this conclusion does not rely upon how EPA may have responded to any particular recommendation from the SAP.

Comment: An independent scientific panel with no ties to industry should be convened to review all pesticide registrations and only peer-reviewed data should be used in determinations.

Response: The Services note that although the ESA does not require the use of an outside scientific review panel, it is at EPA's discretion to do so during pesticide registration if it so chooses. The Services also note that limiting information considered to only peer reviewed data is contrary to the statutory requirement of the ESA which requires the use of the ''best scientific and commercial data available.''

Comment: EPA's approach to ecological risk assessment is deficient because it fails to identify up front, even generally, which listed species could potentially be affected by a particular pesticide, and thereby limits the effectiveness of its review by failing to account for species-specific and habitat-specific information in its assumptions, tests, and models. An additional comment suggested the need for more involvement at the field and regional level to capture such information.

Response: Based on the Services' review of the Overview Document, during its initial screen EPA will assess possible toxic effects on all species, including listed species, using the best scientific and commercial data available for this purpose. If EPA determines that any listed or non-listed species may be harmed by a pesticide, EPA will obtain and consider the best available information concerning species-specific and habitat-specific information to determine the extent of those effects on listed species. EPA will do so with the assistance of appropriate field and regional involvement of the Services. The Services believe this is a sound approach to analyze all potential risks to listed species, and disagree that this limits the effectiveness of EPA's review.

Comment: EPA fails to apply the precautionary principle to its regulation of pesticides. EPA assumes no risk to listed species when EPA lacks data. EPA should begin its assessment with the assumption the pesticide will harm listed species and require evidence to the contrary before allowing the chemical's use. Whenever EPA has a data gap, it should require registrants to provide the information necessary to fill that gap.

Response: The Services believe that EPA's ecological risk assessment approach is appropriately cautious in assessing the effects of pesticides to listed species. EPA will use the best scientific and commercial information available to assess risks and will consider all potential risks in light of that information.

More specifically, the assertion that EPA assumes no risk to listed species when EPA lacks data misconstrues EPA's approach in the absence of data. As explained in the Overview Document, EPA has identified a base set of information about a pesticide it considers sufficient to permit an evaluation of the potential risks posed by the pesticide, and has committed to supplement those data with information obtained from the public literature. The types of data required will vary depending on the use pattern of the product and chemical-specific characteristics of the pesticide. EPA requires these data to support the registration of a pesticide, and, unless the data are waived, EPA typically would not approve the use of a pesticide without the required data. If data beyond the base set are considered necessary, EPA will require the applicant to provide those data. The agency will use its best scientific judgments, on a case-by-case basis, and as discussed in detail in the Overview Document, EPA may employ assumptions to account for any uncertainty due to missing data, and many steps within EPA's approach use conservative assumptions.

The ESA does not require Federal agencies to eliminate all forms of uncertainty in assessing impacts to listed species or critical habitat, which would be a practical impossibility. Instead, the ESA requires that decisions be based on the best scientific and commercial data available. The Services agree that such decisions need to be made on a case-by-case basis, using best professional judgment that takes into account all of the available relevant information. The Services have discussed with EPA the need to document in a transparent manner how it addresses data gaps and how it employs assumptions to deal with the resulting uncertainty. The Services are satisfied that EPA's approach to this general subject, as described in the Overview Document, will result in appropriate assessments of the potential risks to listed species and critical habitat.

Comment: EPA's approach to ecological risk assessment is flawed because EPA relies on information supplied by registrants which is therefore biased, and also because EPA does not use the peer-reviewed public literature appropriately. EPA does not have a standard process for locating and obtaining data from the open literature and therefore fails to locate a significant percentage of the available literature. The commenter noted two instances in which EPA had failed either to locate or to use a published study that, the commenter believed, was relevant to the risk assessment for a pesticide.

Response: The Services devoted a considerable amount of attention to the manner in which EPA obtains information on which it bases its effects determination, including data from the open literature (including from both peer-reviewed and non-peer-reviewed sources). EPA is required to base its determinations on the best scientific and commercial data available. Therefore, to the extent that the information supplied by the registrant may be the best scientific and commercial data available, EPA is required to consider the information. As part of the discussions, EPA has committed to conducting literature searches using ECOTOX as part of its ecological risk assessments for pesticides. The ECOTOX database is a comprehensive system, maintained by EPA's ORD, that provides information on chemical effects on ecological species. The publicly available component of ECOTOX is widely used by other Federal, State, tribal and local government agencies (including the Services), international governmental agencies, the regulated community, the wider scientific research community and the public. As discussed in the Overview Document and the Letter of January 26, 2004, EPA's literature search will capture both studies in the publicly available component of ECOTOX and other studies that either have not yet been completely processed and entered into ECOTOX or were considered and rejected as inappropriate for inclusion in the public, web-based component.

Experience to date comparing the results of these broader ECOTOX searches conducted according to the Overview Document with other search strategies suggests that ECOTOX is at least as successful, if not more so, at locating relevant scientific information. Moreover, contrary to the comment, these comparisons indicate that ECOTOX does not fail to identify a significant portion of the relevant literature.

Finally, the Services do not find persuasive the comment stating that EPA did not consider a relevant study from the public literature. Whether or not that is accurate, it does not undermine the Services' conclusion, in the future, that EPA will use an acceptable approach to assessing ecological risks of pesticides. The Services note that EPA has committed to explaining in its risk assessments any decisions not to use a study obtained from the open literature or other source. Thus, if EPA obtains a study published in a scientific journal but decides not to make it part of the risk assessment database, the decision will be fully documented, and both the Services and the public would be able to evaluate the adequacy of EPA's justification. The Services believe this process will ensure that EPA handles studies from the open literature appropriately.

Comment: EPA excludes information generated using methodologies that do not conform exactly to the EPA's overly strict ''Good Laboratory Practices'' (GLP) guidelines.

Response: The comment mischaracterizes EPA's approach to the use of data from the public literature. As stated in the Overview Document, data from the open literature can be used in developing the risk assessment. Since such information is typically not collected using the EPA's GLP guidelines, it is normally considered ''supplemental information,'' meaning that a registrant usually could not satisfy its responsibilities to fulfill EPA's data requirements using such data, but that EPA could and would still use such data as appropriate in the risk assessment.

Comment: EPA relies inappropriately on ''surrogate species'' in its risk assessment. EPA typically has insufficient information about risks because the agency usually lacks testing using important classes of animals—namely amphibians, reptiles, marine mammals, and freshwater mussels—and, despite this limitation, EPA does not include any uncertainty factor to account for the possible variation in sensitivity across species which can be three orders of magnitude.

Response: The Services carefully examined EPA's use of toxicity data from tests with surrogate species. EPA's Overview Document identifies the approximately two dozen different animal and plant species that an applicant or registrant (commonly a pesticide company) is required to study in the standard battery of eco-toxicity tests on a pesticide. The commenters are correct that such species do not include any amphibian, reptilian, or fresh water mussel species. As discussed above, EPA will review the open literature, and it is possible that studies from that source may contain information on the toxicity of a pesticide to additional

species. EPA will use its best scientific judgment to choose the most appropriate surrogate for a listed species from all of the available data. Even with this extensive database, however, risk assessments necessarily must be based on testing with a finite number of species. When a species has not been tested, the data on surrogate species constitutes the best available scientific and commercial information to analyze the toxicological sensitivity of untested species.

Further, EPA has agreed to discuss in its risk assessments the uncertainties associated with use of surrogate species. EPA also committed to work with the Services to develop methods to increase the level of confidence in future assessments.

Finally, although not employed expressly to address uncertainties in relying on surrogate species, the Services note that throughout its risk assessment methodology EPA deliberately uses conservative assumptions that add in a measure of additional protections.

Comment: EPA's approach to ecological risk assessment ignores the potential for pesticides to cause adverse, non-fatal, ''sublethal'' effects on non-target plants and wildlife. In particular, the studies required by EPA are incapable of measuring effects on reproductive systems, immune systems, endocrine systems, and genetic integrity. In addition, one commenter argued that EPA would not consider data showing atrazine caused adverse effects on the sexual development of frogs.

Response: The Services disagree; as explained in EPA's Overview Document, the set of eco-toxicity studies required to support the registration of a pesticide include numerous sublethal endpoints, including the impact of the test substance on reproductive function, as well as endpoints related to body weight, body length, gross pathological effects, and behavioral abnormalities. In addition, EPA has committed to augment its required studies with any information obtained from the open literature, and to use such data on sublethal effects to the extent that sufficient and reliable information establishes a scientifically sound relationship between the effect and the survival or reproductive capacity of an organism. The Services have deemed appropriate the existing sublethal endpoints that are included by OPP in its risk assessment process, and the manner in which they are used for purposes of assessing potential sublethal effects.

In response to the comment concerning EPA's willingness to consider sublethal effects from atrazine, the Services note that, contrary to the comment, EPA has conducted its own review and subsequently has obtained an independent, external peer review of data on atrazine and sexual development of frogs. See SAP meeting on June 17–20, 2003, at *http://www.epa.gov/oscpmont/sap/2003/index.htm*. This series of reviews has led EPA to require the registrants of atrazine to perform additional studies to evaluate these possible effects.

Comment: EPA does not perform a substantial analysis of indirect effects of a pesticide on listed species. EPA had not documented its conclusion that exposure to pesticide concentrations less than ½ the LC50 would not cause effects on non-listed species that could indirectly affect a listed species dependent on that non-listed species. Moreover, EPA incorrectly assumes that where a pesticide has no direct effects on listed species, there is no potential for indirect effects.

Response: Although EPA may not have routinely and fully examined the potential indirect effects of a pesticide on listed species and critical habitat in the past, EPA has committed in its Overview Document to the systematic consideration of such indirect effects. The Services will, on request, provide EPA with information on listed species that will assist EPA in identifying the relevant biological and ecological relationships through which indirect effects might occur.

The commenter also misunderstands the approach to assessing indirect effects. The commenter apparently assumes that the direct-effects screening assessment considers only listed species. A conclusion that no indirect effects on a listed species would occur is based on the fact that indirect effects may only occur when some species—listed or nonlisted—other than the listed species is directly affected. The direct-effects screening assessment considers the full range of plant and animal species. If no species on which a listed species depends is directly affected, then the listed species would not be indirectly affected.

Contrary to the comment, EPA has explained in the Overview Document its approach to the use of different thresholds for listed and non-listed species. The Services are satisfied that the approach EPA intends to use in the future will produce an appropriate assessment of potential indirect effects.

Comment: EPA's approach to assessing impacts to critical habitat is inappropriate, because it assumes that if a pesticide will not have a direct effect on the listed species, then it will not affect the habitat. Moreover, this approach is faulty because it only considers the biological elements of the habitat, and does not take into account the negative impacts of pesticide contamination that would make an area unsuitable.

Response: The commenter misunderstands the approach to assessing risks to critical habitat. EPA uses the same approach to assessing the effects of a pesticide on critical habitat as it uses to assess direct effects on listed species. The difference, however, is that EPA looks at the effects on the principle constituent elements of the critical habitat—those elements of the habitat on which a listed species depends—rather than on the listed species itself. The Services disagree that a pesticide will have negative impacts without affecting any biological element of the habitat. Pesticides do not automatically have an effect simply as a consequence of their presence; rather, the presence of a pesticide in a portion of the habitat constitutes harm to habitat only to the extent it may negatively affect some biological component of that habitat, which is what EPA assesses.

Comment: Cumulative stressors and impacts to endangered and threatened species will no longer be fully addressed.

Response: The ecological risk assessment process as described in the Overview Document commits EPA to consider the environmental baseline when appropriate. As part of the environmental baseline, cumulative stressors and impacts to listed species will be considered.

Comment: EPA does not evaluate the potential effects of exposure either to inert ingredients in pesticide formulations or to substances formed by the environmental degradation of pesticides.

Response: The comments are incorrect. EPA's Overview Document describes the extensive information required to characterize the environmental fate of a pesticide, including the identification of any toxicologically significant degradation products/metabolites. In addition, absent information supporting a different conclusion, EPA assumes that any substance formed by the breakdown of a pesticide is as toxic as its parent compound. Although limited, EPA also receives information from pesticide applicants and registrants about individual inert ingredients in pesticide formulations. The ECOTOX literature search also captures information on mixtures containing pesticide active

ingredients. EPA has committed to review these data as part of its ecological risk assessments. Finally, the Overview Document spells out how EPA will use the data it obtains on the toxicity of pesticide formulations.

The Services recognize that more extensive information is typically available about pesticide active ingredients than inert ingredients, and therefore EPA has a more limited ability to assess the risks posed by these compounds to listed species. In light of these limitations, the Services have concluded that EPA's approach makes appropriate use of the best scientific and commercial information available to evaluate these types of substances.

Comment: Active ingredients are typically formulated with other, sometimes more toxic ''inert'' substances to make pesticide products and such products are then often mixed with adjuvants. EPA's risk assessment process fails to consider the effects of pesticide mixtures on endangered and threatened species. EPA does not assess the potential additive or synergistic effects of exposure to the combination of these substances. Such combinations are important because water monitoring data demonstrate the presence of multiple chemicals in many water samples and that many of the substances appearing in combination share a common mechanism of toxicity.

Response: While there often is very little or no information, EPA has committed to review the open literature for information on whether a pesticide formulation or other chemical mixture will be active in an additive, synergistic or antagonistic manner. If EPA identifies data demonstrating interactive effects, it will use the data in its ecological risk assessments to the extent possible. The Services believe this approach is scientifically appropriate and consistent with the ESA. The Services recognize, however, that this approach still leaves some scientific uncertainty about whether pesticides and other chemicals will interact to produce more serious effects than expected from exposure to individual compounds. There is no scientific consensus on how to address this source of uncertainty. Therefore the Services also think it is appropriate that EPA has committed to the identification of major sources of uncertainty in its risk assessments.

Comment: EPA does not appropriately consider cumulative effects as required under the ESA. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is required to assess cumulative effects for food use pesticides and other substances sharing a common mechanism of toxicity.

Response: EPA's Overview Document contains a commitment to conduct a review of cumulative effects, as defined under the ESA, on those FIFRA actions for which EPA cannot conclude that the action is not likely to adversely affect listed species or critical habitat. Since the nature of any cumulative assessment will depend on the scope of the action being considered, the Services think that EPA has appropriately expressed an intention to evaluate such effects on a case-by-case basis. The Services and EPA intend to work together to ensure that an adequate evaluation of the cumulative effects is performed for an action.

The Services note that the meaning of the term, ''cumulative effects,'' under the ESA is very different from the way that term is used under the FFDCA. Under ESA, cumulative effects refers to the effects on listed species and critical habitat of future State and private activities reasonably certain to occur within the action area of the federal action subject to consultation. Under the FFDCA, EPA must consider the cumulative effects on humans that may result from exposure to the pesticide chemical and other substances sharing a common mechanism of toxicity. Thus, the two meanings are quite distinct, and the FFDCA use of the term should not be applied to assessments under the ESA.

Comment: The ''levels of concern'' (LOCs) used as criteria by EPA to determine whether potential pesticide exposure would pose a risk to a listed species are insufficiently explained and, at least in the case of diazinon, insufficiently protective. In particular, EPA has not justified its use of the 0.1 and 0.05 LOCs for endangered terrestrial and aquatic species, respectively, with acute toxicity values.

Response: As explained in detail in the Overview Document, EPA compares the estimated environmental concentrations expected to result from use of a pesticide with toxicity values observed in required studies and studies from the open literature. If the resulting ratio is less than the LOC, EPA concludes, under the ESA, that the exposure has ''no effect.'' The agency sets different LOCs for different taxa (birds and mammals vs. fish and other organisms), and durations of exposure (short term/acute vs. longer term/chronic).

EPA's Overview Document explains the scientific basis for regarding these LOCs as protective. In the case of the LOC of 0.1 for acute toxicity, this value means that for a pesticide with a typical toxicity profile (slope of the dose-response curve of 4.5) the estimated probability of mortality resulting from exposure to one tenth the value of the median lethal dose (LC50) is approximately 1/300,000. The Overview Document also contains estimates of the probability of mortality for the 0.05 LOC and for other values for the slope of the dose-response curve. The Services are satisfied both with this explanation and with the agency's conclusion that there would be no effect when the ratio of exposure to toxicity is at or below the established LOCs.

Comment: EPA does not estimate pesticide concentrations in surface water.

Response: The Services disagree; as EPA's Overview Document and other public comments make clear, EPA does develop estimates of pesticide concentrations in surface water.

Comment: The models EPA uses to estimate pesticide levels in water are likely to underestimate exposure because EPA uses inappropriately low model inputs.

Response: In the vast majority of cases, the estimates produced from EPA's models equal or exceed the amount of pesticide residue actually present in surface water. While there may be individual model inputs that do not correspond to the highest imaginable value that could be used, EPA's information indicates that the particular combination of central tendency input values and high end input values (many of which are not mentioned by the commenters) produces an estimate of the concentration of a pesticide in water that is likely substantially greater than occurs under real world conditions in most locations where a pesticide is used.

Comment: The input value for pesticide use is not sufficiently conservative because EPA considers only a single pesticide application, when in reality multiple applications may be allowed.

Response: This comment is incorrect; as described in the Overview Document, EPA's model assumes the maximum number of applications specified on the pesticide label.

Comment: EPA assumes homogenous distribution of pesticide residues, and this will understate residues when there is not complete and uniform mixing of residues in the waterbody. In particular, EPA's models do not account for pesticide residues that settle on surface water films of dust or particulate matter, remain in the water, or settle into sediment.

Response: EPA's model accounts for pesticide residue that drifts onto the pond, but it assumes homogenous

mixing of such residue throughout the water body. As described in the Overview Document, there are no scientific models currently capable of reflecting variability in short-term concentrations in different parts of the pond. Thus, the Services regard EPA's approach to reflect the use of the best scientific and commercial information available.

Comment: Listed species may be present in ponds smaller than the 10 hectare value used by EPA.

Response: The comment's description of the pond size used in EPA's model is incorrect. As described in the Overview Document, EPA's model assumes a very small pond (1 hectare surface area and 2 meters deep), receiving runoff from a 10 hectare field.

Comment: EPA assumes that runoff results from a single runoff event, when in reality runoff may occur following multiple runoff events.

Response: This comment is correct with respect to the initial tier model used by EPA, GENEEC. The basic GENEEC model calculates potential runoff following a single rainfall event, using a conservative assumption about total rainfall (6″ in 24 hours). If GENEEC suggests water concentrations that could pose concerns, EPA then employs a more sophisticated model, PRZM/EXAMS, which considers up to 30 years of recorded meteorological data, to place the receiving water body in a landscape receiving multiple rainfall events over the duration of the meteorological record. It is true that the PRZM/EXAMS model considers each rainfall as a single continuous event for each day that the available meteorological data has a record for a precipitation event.

Comment: EPA assumes no contribution from post-application volatilization, when in reality such volatilization may contribute significantly to residues in the receiving waterbody.

Response: The Services disagree with this comment. As the Overview Document states, losses from volatilization post-application in the field are typically taken into account.

Comment: EPA incorrectly assumes spray drift will contribute no more than 1% through ground application and 5% through aerial application, when data demonstrate spray drift accounts for higher loadings in some circumstances. A related comment stated that EPA's existing model estimates drift from aerial applications based on older technologies. EPA and the Services should take into account new technologies and procedures used by aerial applicators.

Response: EPA has committed to examining (and changing if appropriate) its spray drift assumption as part of the risk characterization component of a risk assessment. As described in the Overview Document, the values assumed by EPA tend to overstate exposure in the vast majority of situations, especially when the water body is not immediately adjacent to the treated field, as the model assumes. When appropriate data show the model overestimates drift, for example because new technologies reduce drift, or underestimates drift, EPA will adjust its exposure estimates appropriately.

Comment: EPA's model does not estimate runoff from urban use, and its models do not account for nonagricultural use. Moreover, EPA lacks data on the extent of use of pesticides in urban areas and therefore cannot develop accurate estimates of environmental exposure from such use.

Response: No adequate models currently exist that are specific to estimation of pesticide runoff from urban use, nor that are specific to some nonagricultural uses. Moreover, there is rarely accurate and complete information on the amounts of pesticides used in urban areas. In the absence of such data and models, EPA considers surface water monitoring results in the risk assessment process for urban use pesticides. If such surface water modeling data, when linked to surrounding land use information, suggest that existing modeling efforts may underestimate surface water loads in urban landscapes, the issue would be discussed in the risk characterization section of a risk assessment. This discussion would be accompanied by an analysis of how such data affects the agency's confidence in risk assessment conclusions. The Services think that this approach is consistent with the use of the best scientific and commercial data available to EPA.

Comment: EPA assessments are based on laboratory data and modeling, and EPA often ignores monitoring data or other studies that do not accord with its findings.

Response: The Services disagree. As described in the Overview Document, EPA routinely reviews information from monitoring programs and compares the results with its model estimates of environmental concentrations. Because many factors affect the usefulness of monitoring data, EPA decides on a case-by-case basis whether and how to use such information. Most commonly, EPA uses such data to help characterize the risk assessment by providing information about levels in water that reflect different use conditions and different locations from those modeled. If the monitoring data show higher confirmed detections than estimated by modeling, the higher monitoring values may be used in the risk assessment or the input values to the model may be reevaluated. EPA has committed to document fully the basis for its estimates of aquatic pesticide concentrations. The Services think that this approach is consistent with the use of the best scientific and commercial data available to EPA.

Comment: Some of the background documents regarding EPA's risk assessment process developed by both EPA and the Services for the proposed counterpart regulations are inconsistent with the Information Quality Act (IQA) and EPA's IQA guidelines and quality systems—particularly with regard to EPA's biased use of modeling projections over monitoring data. This commenter noted, however, that the proposed regulatory provisions are statutorily authorized, rational and should be promulgated as soon as possible.

Response: The Services agree, as this commenter noted, that the issues raised regarding the IQA do not suggest the need for modification to the provisions of the proposed rule. This commenter did not suggest that the IQA issues raised reflect upon EPA's ability to ensure that its NLAA determinations are accurate. The Services disagree, however, with this commenter's characterization that EPA's approach is biased against the use of monitoring data. As explained in both the Overview Document and the Services' review of that document, although EPA's experience is that monitoring data are seldom sufficiently robust for risk assessment purposes given the limited range of pesticide use scenarios they represent, EPA's practice is to use monitoring data to estimate exposure when such data are relevant, quantifiable and reliable.

Comment: EPA's ecological risk assessment methodology ignores potentially significant exposures through the dermal and inhalation routes. For example, terrestrial species could inhale pesticide spray or residues that have volatilized. The comments cited data to support the contention that air concentrations of pesticides are significant. Similarly, pesticide sprays could drift off-target and be deposited onto the fur or feathers of non-target organisms.

Response: The Services agree that EPA's approach to ecological risk assessment generally does not quantify the potential dermal and inhalation exposure of non-target wildlife. As EPA

has discussed in its Overview Document, current analysis of terrestrial species focuses exclusively on dietary exposure or expresses exposures as a generalized potentially available biomass of pesticide on a per unit area basis. The Services agree that the dietary exposure analysis is appropriate as a means of estimating dietary exposure. Potential exposure through inhalation or dermal contact currently constitutes an unknown for which the risk assessment provides no available information. EPA has developed proposals to analyze inhalation and dermal exposure for birds in such a way that it may be added to dietary exposure, and thus used in the development of a risk quotient. See *http://www.epa.gov/scipoly/sap/#march.* Similar proposals for other classes of species are expected in the future. EPA reports that it has received one of two SAP peer-review reports on its proposals, and that, when it has received both reports, it will evaluate the peer review suggestions and formulate a plan for implementing the new modeling techniques. The Services encourage the development and implementation of these proposals, following external peer-review by the FIFRA SAP.

The Services conclude that EPA's approach to incorporation of exposure estimates for non-oral routes is consistent with the ESA, in that EPA uses the best scientific and commercial information available. Pending implementation of these proposals, following external peer-review by the FIFRA SAP, the data on dietary exposure remains the best available quantified information provided through existing models.

Comment: EPA may underestimate exposure to the extent that pesticides are applied in ways or amounts other than as allowed on the label.

Response: While the Services recognize that misuse may occur, we believe it is reasonable to assume pesticides are used lawfully unless data demonstrate a widespread and commonly recognized pattern of misuse. In fact, as the Overview Document states, many pesticides are typically applied at lesser rates and frequency than permitted by the label.

Comment: EPA's exposure assessments do not account for movement of pesticides beyond the sites to which they are applied.

Response: As noted in the Overview Document, EPA's exposure assessments do consider off-target movement of pesticides through run-off and drift. These assessments are based on the concentration levels in or immediately adjacent to the site of application, where concentration levels would be highest. The Services agree that the modeling estimates and monitoring information used by EPA represent the best currently available information on exposure, and note that EPA has committed to adjusting these models where appropriate.

Comment: The model used by EPA to estimate drift of pesticides, ''AgDrift,'' is not completely transparent.

Response: EPA has sought independent, external scientific peer review of AgDrift and has held public SAP meetings at which it explained the basic structure of AgDrift. See *http://www.epa.gov/oscpmont/sap/1999/july/boom.pdf* and *http://www.epa.gov/oscpmont/sap/1997/december/spraydrift.htm*. These meetings and EPA's supporting documents provide the public with a comprehensive description of the manner in which the model was constructed and the data on which it is based. As a general matter, EPA and the Services support and strive to achieve fully transparent scientific analyses. To the extent, however, that certain information provided to EPA and the Services is subject to release restrictions under federal law, the Services and EPA must abide by those restrictions. Further, even if such release restrictions apply, the ESA does not authorize the Services or EPA to reject consideration of such information if it otherwise constitutes the best scientific and commercial data available.

Comment: EPA's exposure models have not been validated by monitoring data.

Response: Since the commenter did not identify a specific model, the Services will only address the comment in general terms. The Services have reviewed the appendices accompanying EPA's Overview Document. These appendices describe the extensive reviews undertaken by EPA and external peer review of the models EPA uses to estimate exposure to pesticides. These reviews typically involve, among other things, comparisons of model estimates to data produced by monitoring of compounds in the environment. These comparisons, as well as the extensive external peer review records, support EPA's assertions its models are scientifically sound and are not likely to underestimate potential exposure to pesticides.

Comment: EPA does not have the in-house biological expertise to accurately make ''may affect'' determinations. Another comment pointed out that EPA's Office of Pesticide Programs is the single best federal government entity with the greatest available in-house expertise and resources to apply towards endangered species/pesticide risk assessment and to make appropriate regulatory decisions that adequately protect endangered species from potential adverse effects of pesticides.

Response: The Services note that all federal agencies are required to make ''may affect'' determinations, and are presumed to have the expertise to do so. Furthermore, EPA has a large staff of scientists well-trained in a range of disciplines, who collectively possess the expertise to make accurate assessments of the potential effects of pesticide use on listed species and critical habitat. Finally, in order for EPA to exercise the provisions of § 402.45, the counterpart regulations require that the Services and EPA have in effect an Alternative Consultation Agreement that describes actions which the Services and EPA will take to ensure that personnel have adequate training to carry out their roles.

Comment: EPA has expertise in assessing the fate and transport of pesticides. EPA has expertise in toxicity and ecology but not in evaluation of indirect or sublethal effects. The Services have such expertise.

Response: The Services agree that EPA has expertise in assessing the toxicity and environmental fate and transport of pesticides. The Services also think the agency's expertise extends to the methodology used to assess indirect and sublethal effects, and that EPA has described its approach in its Overview Document.

Comment: EPA does not have expertise in the life cycle, habitat needs, and locations of listed species.

Response: The Services and EPA agree that the Services have greater expertise and knowledge about the biological attributes of listed species and their critical habitat than does EPA. Accordingly, the counterpart regulations contain three additional methods of achieving interagency cooperation that is the fundamental tenet of the section 7 consultation process. Two of these methods deal directly with making the Services' expertise in species biology available to EPA. First, EPA could request the Services to provide available information describing the environmental baseline for each species or habitat that EPA determines may be affected by a FIFRA action. The Services would promptly provide such information. In addition, EPA may request a Service to designate a suitably-trained Service Representative to participate with EPA in development of an effects determination for one or more species or habitats. Third, EPA and the

Services will establish new procedures for regular and timely exchanges of scientific information to achieve accurate and informed decision-making. In light of these methods, the Services conclude that EPA, through the Services, will have ready access to any additional biological information and insights that it would need to complete scientifically sound ecological risk assessments.

Comment: EPA does not have ongoing relationships with local and State wildlife agencies.

Response: EPA has worked with State and local wildlife agencies on a variety of issues, including providing protections for listed species and expects in the future to engage these and other stakeholders more widely in its pesticide regulatory programs. To the extent that EPA thinks that it needs help in developing these relationships, it can collaborate with the Services, either pursuant to the ACA or on a case-by-case basis working with the designated Service Representative.

Comment: Despite assertions to the contrary in the Overview Document, it will not be possible for EPA to perform ''site-specific'' risk assessments for listed species because data on species, habitat and pesticide use do not exist with which to perform such assessments. Moreover, EPA has not conducted adequate site-specific assessments in the past.

Response: EPA has committed in the Overview Document to use a variety of sources to obtain information that would be relevant to a more refined, site-specific assessment. If detailed information is not available, EPA would make the best assessment possible with the best scientific and commercial information available and characterize any uncertainty in its ecological risk assessment.

Comment: EPA has never implemented the approach to ecological risk assessment described in its Overview Document.

Response: Although past risk assessments have not contained every element described in the Overview, the Overview Document reflects the approach to ecological risk assessment that EPA intends to use in the future. In fact, the Overview contains a number of new elements that will strengthen the agency's future evaluations of pesticide impacts on listed species. EPA, however, has routinely been using many of the methodologies described in the Overview Document for a number of years. While some of the methodologies are relatively recent, EPA has experience with all elements of the methodologies described and has begun developing effects determinations using these new methodologies. Further, the rule provides a number of mechanisms the Services can use to ensure that EPA's program for making effects determinations under new subpart D is consistent with the requirements of the ESA.

Comment: Many of EPA's past assessments of ecological risks to listed species and critical habitat were not adequate under the ESA. Commenters cited several specific examples. The Services, in many past reviews of EPA's approach to ecological risk assessment, have disparaged EPA's methodologies and have concluded that they deal inadequately with a range of effects: sublethal effects of pesticide ingredients, indirect effects (alteration of the aquatic community structure), effects of inert ingredients and adjuvants, and additive and synergistic effects resulting from interactions among different chemical substances.

Response: EPA has committed to make effects determinations using the approach to ecological risk assessments reflected in the Overview Document: this approach differs from the approaches EPA has used in the past. The Services believe EPA's approach to ecological risk assessment in the future, as set forth in the Overview Document, addresses the specific concerns in the comment. The Services believe that past determinations are not a relevant measure of EPA's ability to produce adequate effects determinations, and are confident that future effects determinations using the methodologies identified in the Overview Document will fully comport with the ESA. Comments and responses above address the specific concerns identified in these comments.

Comment: EPA's risk assessment process has been demonstrated to be deficient in *NRDC* v. *Whitman* and other litigation.

Response: The Services disagree. First, the litigation cited by the comment has not resulted in any finding that EPA's process for risk assessment is deficient, and second, the risk assessment processes at issue in those lawsuits involved human health, not ecological risks.

Comment: The Government Accounting Office determined that EPA's risk assessment process is biased because it relies on advice of the Science Advisory Boards and it allows people to serve on the SAB who have conflicts of interest.

Response: The Services find this comment irrelevant. The Services' conclusion about the adequacy of EPA's approach to ecological risk assessments rest on the Services' independent review of that approach rather than endorsement of an EPA appointed advisory committee. In addition, none of the Science Advisory Boards reviewed by the GAO dealt with scientific issues involving assessment of the ecological risks of pesticides. In fact, EPA does not rely on the SAB for peer review of scientific issues involving pesticides; a separate federal advisory committee, the FIFRA Scientific Advisory Panel reviews such issues.

Comment: In the Overview Document, voluntary registrant label restrictions should be considered in screening-level risk assessment.

Response: To the extent that this comment requests that EPA include voluntary registrant label restrictions as part of its action, this comment is outside the scope of the counterpart regulations because the Services defer to the action agency to define the scope of the action. The Services note, however, that EPA's standard approach to ecological risk assessment takes into account any mandatory restrictions on the pesticide labeling voluntarily offered by an applicant or registrant and accepted by EPA. EPA then bases the estimates of exposure on these restrictions.

Comment: The proposed counterpart regulations must allow a more ''real world'' assessment of actual risks, as opposed to assuming that all pesticides are generally bad for the environment (which is the current model).

Response: The counterpart regulations do not prescribe use of any particular assumptions in EPA's approach to ecological risk assessment. The statute merely requires that effects determinations be based on the ''best scientific and commercial data available.'' EPA's Overview Document discusses in detail what data EPA uses, how the agency uses these data, and when and how EPA employs assumptions. The Services have determined that EPA's approach is consistent with the statutory mandate to use the best available scientific and commercial information.

Section-by-Section Analysis

Section 402.40—Definitions

Comment: The proposed counterpart regulations change the longstanding definition of ''best scientific and commercial data available'' and ''cumulative impacts'' in a way that is bad for species.

Response: The Services note that ''best scientific and commercial data available'' is not defined in the ESA or part 402 of the regulations and do not

intend to change the way that phrase has been applied in the past. The Services also note that the term ''cumulative impacts'' is not used in the ESA or in the counterpart regulations. The Services use the term ''cumulative effects'' as defined in § 402.02 and specifically reaffirm that definition.

Comment: The requirement for assessing cumulative effects should be waived or at least modified with a disclaimer noting that scientific methods for such assessment are not currently available. Other commenters requested clarification on the definition of ''cumulative effects'' or suggested that the definition was inappropriate.

Response: The term ''cumulative effects'' is defined in § 402.02 of the regulations. These counterpart regulations do not change or waive the existing definition or the requirement to analyze such effects. The Services are aware that the existing scientific tools to assess the combined or additive effects of pesticides are very rudimentary. The ESA requires use of the best ''available'' scientific data, and EPA is not expected to provide more information than is currently available. At the same time, EPA should use what information is available on cumulative effects.

Comment: The agencies should explicitly and broadly define the term ''applicant'' to include any and all registrants of pesticide products (in the context of FIFRA section 2(y)), applicants for registration, as well as multiple persons (because of complex business and legal relationships) involved in a given FIFRA action.

Response: There is a regulatory definition of ''applicant'' at 50 CFR 402.02. The Services will defer to EPA to determine, consistent with this definition, who qualifies as an ''applicant'' when dealing with regulatory actions under FIFRA.

Comment: The requirement that an effects determination contain the information described in § 402.14(c)(1)–(6) should be revised so that unnecessary reprinting of paper is avoided.

Response: The Services note that the effects determination submitted under § 402.46 or 402.47 must contain the information described in § 402.14(c)(1)–(6). However, it is not necessary to print a physical copy of all background information.

Comment: Section 402.40(b)(3) of the counterpart regulations should be revised so that EPA is required to consider any information or recommendations from an applicant, and not just be allowed to consider this information.

Response: Although EPA need not necessarily include all information in an effects determination, it is required to base its determinations on the best scientific and commercial data available. Therefore, to the extent that the information supplied by the applicant may be the best scientific and commercial data available, EPA is required to consider the information.

Comment: Participation of multiple Service Representatives will adversely impact the efficiencies that the proposed counterpart regulations are seeking.

Response: Authorizing the use of multiple Service Representatives is specifically intended to ensure efficiency, for example, by preventing delays if a specific Service Representative is unavailable. The Services will monitor this approach to avoid problems.

Comment: ''Agency action'' should be defined as a specific use of an active ingredient.

Response: The term ''action'' is defined in § 402.02. The Services defer to action agencies to define the action, consistent with this definition.

Section 402.41—Purpose

Comment: The penultimate sentence in § 402.41 should be revised to recognize that in many cases data generated by pesticide registrants and applicants will be the only reliable scientific and commercial data available and that it alone will be enough to support ESA decision-making. Furthermore, the phrase ''best scientific and commercial data available'' needs to be defined to clarify that ''best data'' does not mean ''all data'' and that suspect science should not be used in assessments.

Response: The Services recognize the possibility that the best, and only, data available could come from pesticide registrants and applicants. The ESA requires use of the ''best scientific and commercial data available.'' The Services note that making a determination as to what constitutes ''best scientific and commercial data'' may require a review of data available beyond that generated by pesticide registrants and applicants.

Section 402.42—Scope and Applicability

Comment: Section 402.42(a)(4) properly recognizes the potential value of the procedures that will be established by proposed § 402.47.

Response: The Services agree with this comment.

Comment: Additional detail should be included in the final counterpart regulations on the process to be followed for emergency exemptions.

Response: The Services believe that further definition is not needed in the counterpart regulations. The procedures in § 402.05 have been applied in the past to address a wide range of issues and should be sufficient here.

Comment: Delaying formal consultation is warranted for any type of emergency action. This provision should also apply to the effects determination EPA makes pursuant to ESA section 7(a)(2).

Response: The Services agree that if an action appropriately meets the definition of an ''emergency,'' delay of any required formal consultation is authorized. The Services have historically allowed action agencies to meet their consultation obligations through informal consultation for actions determined to be NLAA. Consistent with this interpretation a determination of NLAA by EPA under § 402.45 would be considered sufficient to meet the requirements of the counterpart regulations.

Comment: The Services should provide a more detailed explanation regarding the application of the proposed counterpart regulations to emergency exemptions issued to States under section 18 of FIFRA and to special local need registrations issued by States under section 24(c) of FIFRA. ESA consultation obligations should not extend to either of these activities, or should be left to independent States.

Response: Section 18 emergency exemptions issued by EPA are actions for the purposes of the ESA. Accordingly, EPA must satisfy the requirements of section 7(a)(2) with regard to those section 18 actions that may affect listed species. Emergency actions under FIFRA section 18 will, in the overwhelming majority of instances, fall within the scope of emergency actions addressed in 50 CFR 402.05, and EPA may, therefore, utilize either the emergency consultation procedures or other available procedures (including the new procedures set forth in §§ 402.45 and .46) to address its consultation obligations in a manner consistent with the need to expeditiously address the emergency.

With regard to section 24(c) registrations, this comment notes that the States, rather than EPA, issue these registrations, and that, therefore, ESA consultation obligations should not extend to section 24(c) registrations. It was not the Services' intention to suggest that State action in issuing section 24(c) registrations should be subject to the ESA consultation requirements. The consultation

obligation under section 7(a)(2) applies only to federal actions and federal agencies. States may, of course, contact the Services independently to discuss the potential effects of their actions on listed species. To the extent, however, that section 24(c) registrations are federal actions within EPA's purview, section 7(a)(2) applies to such registrations in the same manner as it applies to existing FIFRA section 3 registrations.

Comment: ''Reinitiation'' should be more clearly explained in the final counterpart regulations with detailed narrative on when such a procedure would occur.

Response: The counterpart regulations incorporate the existing rules in subpart B for reinitiation of consultation. These rules have been applied by federal agencies for almost two decades with relatively little difficulty, and should function adequately for FIFRA actions without further elaboration.

Comment: Private and State data should be considered a viable alternative to the Services' and EPA's data.

Response: Section 402.42(b) does not exclude any source from providing data. Information from all sources, including industry and States will be considered to satisfy the statutory requirement to use the best scientific and commercial data available.

Section 402.43—Interagency Exchanges of Information

Comment: A month should be eliminated from the assessment process by requiring the Services to provide EPA with both information on the presence of listed species or their critical habitat and information describing the applicable environmental baseline for the species or habitat 30 days after EPA's written request.

Response: The Services disagree with this comment. Baseline information is not always needed and therefore should not be asked for concurrently with presence of listed species or critical habitat data.

Comment: Additional information should be provided to EPA with a species list: specifically, any use of a pesticide in controlling exotics for the benefit of listed species.

Response: Species lists should include all listed species that may be affected positively or negatively.

Comment: The proposed regulations do not indicate how EPA or other affected parties could enforce deadlines for the Services to respond to EPA requests for information. The commenter suggested addressing this by either including language stating that wherever EPA has asked a Service for a response, and the regulations set a time period for providing that response, lack of a Service response can be taken by EPA as concurrence in EPA's position or as evidence that the Service has nothing to add to the decision-making process.

Response: The Services believe that the timelines noted in the counterpart regulations are sufficient enforcement. The Services are committed to meet all of the deadlines and expect to do so.

Section 402.44—Advance Coordination for FIFRA Action

Comment: The proposed language that states the designated Service Representative ''shall normally be available to complete advance coordination with EPA within 60 days' allows for too much leeway. The word ''normally'' should be deleted.

Response: The Services disagree with this comment. The word ''normally'' is included because of potential staffing limitations and availability. The Services believe that 60 days is reasonable.

Comment: A two-week timeframe for the Services to designate a Service Representative followed by a 60-day availability ''hold'' would add four months to the time it would take to implement an effects determination.

Response: The commenter has misconstrued the regulation. The counterpart regulations call for a Service Representative to be designated and provided to EPA within 14 days. The regulations also indicate that advance coordination normally will be completed within 60 days of the date of Service Representative designation. Further, the Services intend that Service Representatives will be available to work with EPA from the time they are designated until the coordination effort is complete.

Comment: EPA should have the option of reconsidering its request should the process of advance coordination become overly burdensome with too many Service Representatives involved in the advance coordination of a given FIFRA action.

Response: The Services note that nothing in the counterpart regulations prevents EPA from withdrawing a request for advance coordination.

Comment: Participation of Service Representatives in the effects determination is unnecessary and will likely delay the process. Another commenter expressed the opposite view, suggesting that the counterpart regulations should require early Service involvement to reduce the amount of work by avoiding unnecessary investigation of species that would not be exposed to or harmed by the pesticide.

Response: The Services believe participation by a Service Representative will lead to a more efficient consultation process, but believe that EPA should have the discretion to determine when to request early Service participation. If early participation by the Service does not prove helpful in a particular case, EPA retains the option of withdrawing its request.

Comment: ''Sufficient detail,'' as used in § 402.44(a), should be defined.

Response: As stated in the counterpart regulations, EPA's description of the planned FIFRA action must be sufficient enough to ''enable the Service to designate a representative with appropriate training and experience.'' The Services believe this text provides a basis for coordination with EPA on the issue.

Comment: Deadlines should be set for EPA to produce an effects determination.

Response: The Services disagree with this comment. It is not within the authority of the Services to tell EPA when effects determinations must be produced.

Section 402.45—Alternative Consultation on FIFRA Actions That Are Not Likely to Adversely Affect Listed Species or Critical Habitat

Comment: The proposal would allow EPA to ignore the environmental baseline when making a NLAA determination for an action. Thus, EPA would not add direct, indirect, and cumulative effects to the baseline as required by 50 CFR 402.14(c)(4) and 402.02.

Response: The commenter misconstrues the obligation of an action agency to consider the environmental baseline under the existing regulations in subpart B. Development of an environmental baseline is only required when the direct or indirect effects of a proposed action, in combination with any effects of interrelated or interdependent actions, are likely to adversely affect any listed species or designated critical habitat. If an action is not likely to adversely affect listed species or critical habitat (an NLAA determination) there would be no change to the environmental baseline and therefore no need to consider it.

Comment: The language in §1A402.45(a) should be changed from ''EPA need not initiate any additional consultation'' to ''need not initiate consultation'.

Response: The Services disagree with this comment. Since § 402.45(a)

describes an alternative form of informal consultation, the suggested phrase would be inaccurate.

Comment: Several elements of the ACA should be incorporated into the counterpart regulations: establishment of a framework for operation of the Coordination, Communication and Implementation Panel, identification of the number of members that will be drawn from the participating agencies and the positions from which those members will be chosen, requirement that all Panel meetings be open to the public, and the entire Guiding Principles section of the ACA. Furthermore, the final counterpart regulations should identify specifically who sits on the Coordination, Communication, and Implementation Panel, their respective roles, and the manner in which they are selected.

Response: The Services agree that these are relevant issues but believe that it is inappropriate to address such issues in a Federal regulation. Because these matters should involve administrative, internal operating procedures affecting only the Services and EPA and because the procedures may change over time, the Services believe these matters are more appropriately addressed through the ACA.

Comment: The Services violated the APA by failing to take comment from the public on the ACA. Because the draft ACA is not final, it offers no assurances that it represents the direction that EPA and the Services intend to go in a final ACA. The agencies are strongly urged to offer a more complete version of the ACA for public review and comment before it is finalized. Commenters expressed concern that the ACA might become a *de facto* regulation of pesticides.

Response: The Services disagree with this comment. A draft version of the ACA was made available to the public during the public comment period of the proposed rule. Further, the proposal provides that the final ACA will be made available to the public. It is important to note that the ACA is not a regulation, but rather, is an agreement intended to describe an interagency process for ensuring and documenting compliance with the terms of the counterpart regulations. As such, it does not establish any standards for compliance with the ESA nor can it serve to regulate pesticides.

Comment: Clarification is needed so that the procedures conducted by the Antimicrobial Division of OPP in its ecological risk assessments are included within the procedures that fulfill the requirements of the proposed 50 CFR 402.45(b)(2)(i).

Response: There is no need to clarify the regulations because the regulations state that the ACA shall describe actions that EPA and the Services have taken to ensure that EPA determinations regarding the effects of its actions under FIFRA, which would include determinations by EPA's Antimicrobial division, are consistent with the ESA and applicable implementing regulations.

Comment: EPA and Service personnel need to be sufficiently trained, including training of Service personnel by EPA in EPA's risk assessment process. Appropriate training and ''certification'' should be better described in the counterpart regulations.

Response: The Services agree that sufficient training is important and note that the counterpart regulations call for the ACA to describe actions that EPA and the Services intend to take to ensure that EPA and Service personnel are adequately trained. The required training must be adequate for EPA and Service personnel to carry out their respective roles but flexibility is necessary to accommodate a variety of roles and evolution of responsibilities. The Services disagree that additional specification of the training should be included within the counterpart regulations themselves.

Comment: EPA should not have to be trained by Service personnel on EPA's risk assessment process. Such a situation would be ''burdensome, bureaucratic and inefficient.''

Response: The Services would not train EPA employees on EPA's risk assessment process. The purpose of the training program is to ensure that EPA consistently interprets and applies the provisions of the ESA and the regulations (50 CFR part 402) relevant to these counterpart regulations with the expectation that EPA will reach the same conclusions as the Services. It is expected that the training program will rely upon the ESA Consultation Handbook as much as possible.

Comment: Criteria should be included in the counterpart regulations or in the ACA for determining which ''new information'' and ''relevant scientific advances'' qualify as best available data. Although new data should include all quality data regardless of the results they support, ''best available data'' are not equivalent to ''all data''.

Response: The Services do not believe that it is appropriate to include language in the counterpart regulations for determining which ''new information'' and ''relevant scientific advances'' qualify as best available data. The reader is referred to the earlier comment regarding § 402.41 in this ''Section-by-Section Analysis'' for a discussion on ''best scientific and commercial data available.''

Comment: An agreement should include procedures for reassessment of a NLAA determination and, as appropriate, reclassification to ''no effect'' or of ''likely to adversely affect'' with reclassification to NLAA or ''no effect.''

Response: The Services do not believe that this is necessary. EPA, as the action agency, retains discretion to revisit its determination.

Comment: The regulation does not define the ''necessary records'' that EPA must retain under § 402.45(b)(2)(vi), leaving undefined the entire basis for oversight and therefore acceptance of EPA's performance.

Response: The counterpart regulations do not instruct EPA and the Services which records EPA must maintain under the ACA, but leave to EPA and the Services discretion to determine which records are necessary to complete program evaluation. The Services expect, however, that the information EPA must already maintain for purposes of the Federal Records Act and judicial review will be sufficient to permit the Services to conduct appropriate periodic evaluations of EPA's process for making effects determinations.

Comment: A requirement that EPA's annual report on NLAA determinations be made public should be incorporated into § 402.45.

Response: The Services note that § 402.45(b)(4) states that ''[t]he alternative consultation agreement and any related oversight or monitoring reports shall be made available to the public to the extent provided by law.''

Comment: The provision in the counterpart regulations allowing deviation from the ACA undermines the value of the procedures and adds uncertainty as to whether listed species will be protected.

Response: The counterpart regulations specify that the parties may depart from the ACA in a particular case to the extent deemed necessary by both the EPA and the Services, ensuring to the satisfaction of the Services that any departure from its terms will be in full compliance with section 7 and the counterpart regulations.

Comment: Greater transparency of EPA's selection of data will reduce the burden of documentation.

Response: EPA and the Services will continue to work collaboratively to ensure transparency of data selection and to minimize documentation burdens.

Comment: The Services' review of implementation of counterpart regulations should be limited to reviewing whether EPA has followed the procedures for risk assessment agreed upon by the agencies. Allowing for review of all NLAA decisions appears to be inconsistent with the proposed counterpart regulations which say that EPA, not the Services, is responsible for the NLAA decisions.

Response: The Services agree that their review of EPA's compliance with the counterpart regulations should focus on implementation of the overall approach and that EPA is responsible for its NLAA determinations. This review, however, will almost certainly involve examination of selected NLAA effects determinations. The focus of this review will be on how EPA is performing under the rule and the ACA and may result in recommendations designed to strengthen EPA's program. While these recommendations may be relevant to assessing the adequacy of particular NLAA determinations, the Services do not intend their oversight efforts to involve a determination-by-determination evaluation of all individual NLAA determinations.

Comment: Allowing any agency to terminate the ACA provides no certainty to applicants, registrants or users that the provisions of the ACA and/or the counterpart regulations will be applicable in the future. The termination provisions should be ''tightened considerably.''

Response: While the Services recognize the concern that § 402.45 may not be available for use in the future, the Services believe meaningful oversight of EPA's activities under this section requires authority to terminate the ACA if, ''EPA fails to comply with the requirements of this subpart, section 7 of the ESA, or the terms of the alternative consultation agreement.'' Since it is difficult to anticipate all possible future circumstances, the Services further believe that these standards provide needed flexibility.

Comment: EPA should be given a period of time to take corrective action before the ACA could be terminated.

Response: The Services do not believe such language is required in the counterpart regulations but note that § 402.45(c) provides for possible corrective action.

Comment: The Services should revise proposed § 402.45(c) so that in the event that the Service Director exercises the authority to terminate an ACA, evaluations already underway in accordance with the existing ACA be allowed to continue. The commenter suggested that this would avoid disruption of schedules and waste of resources that applicants and EPA are likely to have committed.

Response: The Services disagree with making such changes to the counterpart regulations. Any termination of an ACA would legally end EPA's authority to make NLAA determinations concerning evaluations in process without concurrence from the Services. The Services agree that in the event an ACA is terminated some disruption is possible but the Services intend to structure termination of the ACA in a way in which appropriately considers disruptions.

Comment: If the Services terminate the ACA prior NLAAs should not be left in effect.

Response: The Services disagree with this comment. It is possible that the ACA may be terminated for reasons independent of the likely validity of any past NLAA determinations, and therefore requiring all previous NLAA determinations to be revisited would be an inappropriate investment of limited resources, and detract from the ability of the Services and EPA to consult on actions likely to adversely affect listed species. The Services also note that under 402.45, EPA is responsible for the validity of its NLAA determinations and would continue to be responsible for those NLAA determinations if the ACA is later terminated. Information creating uncertainty regarding the basis for an NLAA determination may lead to EPA's reconsideration of the determination, or be the basis for reinitiation of consultation with the Services. Additionally, termination of the ACA may create appropriate grounds for the Services to request reinitiation of consultation on any specific NLAA determination.

Section 402.46—Optional Formal Consultation Procedure for FIFRA Actions

Comment: Section 402.46(a) requires that a written request for consultation be accompanied by an ''effects determination prepared in accordance with § 402.40(b),'' which does not say how the effects determination is to be prepared, just what it should include.

Response: The Services do not intend to prescribe how EPA would prepare effects determinations; consequently, in response to this comment, the Services are changing the language in the final rule from ''prepared in accordance with'' to ''as defined in.''

Comment: The Services should provide EPA with any ''additional information'' at the time of notification under § 402.46(b).

Response: The counterpart regulations provide that the Services' shall describe the additional information in detail and shall identify a means for obtaining that information. The Services intend that EPA be able to obtain the additional information in an efficient manner, and believe it will frequently be more efficient for EPA to obtain it through an identified Website link or by accessing and retrieving selected values from a large database, for example, rather than through the Services. This provision, however, would not preclude a Service from providing the additional information directly, in cases where the Service feels that would be most efficient.

Comment: EPA should be given the ability to dispute the validity and relevance of any additional information sought by the Services and be given the opportunity to continue with the consultation in the absence of the requested additional information.

Response: As stated elsewhere in this preamble, EPA does have this ability. In response to a request for additional information EPA may choose to resubmit the original effects determination with an explanation as to why the requested information was not submitted.

Comment: A deadline for EPA to complete a revised effects determination should be included in the final counterpart regulations.

Response: The Services disagree with this comment and defer to EPA to decide how much time it needs to prepare a revised effects determination.

Comment: EPA should be required to provide biological opinions to applicants, or at least inform applicants of their availability, as soon as the biological opinions are received from the Services. Another commenter stated that the chemical industry should not be given elevated consultation status, while public input is minimized.

Response: Section 402.46(c)(2) of the proposed regulations provides that EPA shall, upon request of an applicant, provide the applicant with any draft biological opinion it receives from the Services. This section tracks the requirements of the existing consultation regulations at § 402.14(g)(5). As with the existing regulations, it leaves to EPA the discretion to develop any additional processes it determines may be appropriate to make draft opinions available to applicants and to the public. In the Services' experience, action agencies have used this provision in the existing regulations to ensure that applicants and the public have the ability to provide input in the

development of final biological opinions. The Services do not believe there is a need, therefore, to create an additional obligation for EPA in this regard.

Comment: State pesticide regulatory agencies should be designated as co-regulators with EPA and should be allowed full participation in the consultation process for species found in their States. These commenters noted that such agencies have primary responsibility for enforcing the misuse provisions of FIFRA as well as unique knowledge of agricultural and other pesticide related activity in their States and should, therefore, be involved in the development of mitigation measures for listed species.

Response: The ESA does not provide the Services with authority to designate States as ''co-regulators.'' While the alternative consultation processes in the counterpart regulations apply only to EPA's effects determinations for FIFRA actions, they do not limit EPA's existing ability to obtain input from State pesticide regulatory agencies to better inform the consultation process. Further, the scope of this rule is limited to the consultation process itself and does not, therefore, address EPA's approach for participation by States and others in the development and implementation of mitigation measures under FIFRA.

Comment: The procedures for applicant involvement during consultation should be formalized with a firm deadline for meeting with applicants and a requirement for written minutes of meetings attended by applicants.

Response: The Services recognize the desirability of meeting promptly with applicants who request a meeting during consultation, but decline to require a fixed deadline for such meetings as it may not be possible to achieve in all cases due to scheduling conflicts and other duties. Likewise, taking formal minutes of every meeting with an applicant would be unduly burdensome; any applicant who attends a meeting with the Service can document the matters discussed at the meeting and submit any written meeting notes to the Service for inclusion in the record.

Comment: The Services' authority to extend deadlines during consultation should be limited because they have overused their authority in the past.

Response: The Services agree that consultations should be completed as quickly as possible, but do not agree fully with this comment. The counterpart rules permit the Services to extend a consultation deadline only as permitted by section 7(b)(1) of the ESA.

Comment: To avoid additional delays, § 402.46(e) should be expanded to make it clear that the specified officials have authority to make decisions based on whatever information has been put before them within the deadlines set forth in the counterpart regulations.

Response: The ESA requires decisions to be based upon the best scientific and commercial data available. The Services believe the counterpart regulations establish procedures that will allow timely decisions based upon the best scientific and commercial data available.

Comment: It is inappropriate that final actions under § 402.46(e) can only be approved by political appointees.

Response: The comment misconstrues the counterpart regulations. Within each of the Services, decisions under § 402.46(e) can be delegated to a senior-level non-political employee.

Section 402.47—Special Consultation Procedures for Complex FIFRA Actions

Comment: Because procedures that are relatively routine in the world of FIFRA regulation are ''unusually complex'' in the context of the Services'' responsibilities, procedures described in proposed § 402.47 are likely to be more commonly invoked than some may expect.

Response: The Services agree that this is a possibility.

Comment: The successive effects determination process should be applied to new registrations in a manner that expedites approval of registrations for individual uses, use patterns, and use rates. Omitting evaluations of new pesticides under the phased approach to consultation will unduly delay issuance of many pending or future reduced-risk products. Another commenter expressed the opposing viewpoint that the counterpart regulations should expressly prohibit the use of this procedure for registration of new pesticides.

Response: The Services do not believe that any changes to the proposed rule are warranted. EPA has advised the Services that EPA does not intend to register any new use or active ingredient until completion of consultation under section 7(a)(2) for all species affected by that action. Thus, there should be no need to use the procedures in § 402.47 for applications seeking to register new active ingredients or new uses of currently registered pesticides. The Services note that EPA and the applicant, of course, retain discretion to define a FIFRA action to relate only to a specific subset of pesticide uses proposed in an application. So long as EPA fulfills its responsibilities under the ESA for all listed species and critical habitat, defining a FIFRA action in this manner could achieve the stated goal of the comment. The Services will work with EPA to expedite consultations on new pesticides to the extent possible.

Comment: EPA and the Services should explore ways to group listed species and/or pesticides in consultations. It might be possible to develop criteria to group listed species either taxonomically or by ecological function. Similarly, active ingredients could be organized into either chemically or toxicologically similar groups and consulted on by group, not individually.

Response: The Services note it is within EPA's discretion to define the action. Batching similar actions together is permitted under subpart B and in fact, the Services encourage batching where appropriate. If EPA wishes, the flexibility provided by § 402.47 may be used to assess affects of pesticides on groups of taxonomically or ecologically similar species.

Comment: Section 402.47 embodies too narrow a reading of the legal effects of a partial biological opinion, which should constitute a final biological opinion for the geographic area that was the subject of the opinion, providing immediate incidental take protection for the completed portions of a phased consultation. Also, effects determinations made by EPA should have incidental take protection.

Response: The Services believe that § 402.47 properly describes the legal effects of a partial biological opinion. Formal consultation on a proposed action is not concluded until all listed species or designated critical habitats that may be adversely affected by the action have been evaluated in a biological opinion. Incidental take protection is provided under section 7(b)(4) at the conclusion of consultation of the proposed action. However, the partial biological opinion would describe the provisions relating to incidental take of such species for inclusion in an incidental take statement at the conclusion of consultation, giving users of pesticide products such as farmers and forest managers, nursery operators, and other pesticide users prompt and reliable guidance for minimizing incidental take of the species. EPA has discretion to determine the geographic limit of any FIFRA action it may propose, and the Services will consult on the action as proposed.

Revisions to the Proposed Rule

In § 402.40(g), we deleted the second sentence which read, ''[t]he Service may designate more than one individual to serve jointly as a Service Representative.'' The change is made to remove redundancy with the first sentence which states that the ''*Service Representative* is the person or persons designated to participate in advance coordination as provided in this subpart.''

In § 402.45(c), we edited the penultimate sentence which read ''[t]he Service Director retains discretion to terminate the alternative consultation agreement . . .'' to read, ''[t]he Service Director retains discretion to terminate or suspend the alternative consultation agreement . . .'' The change is made to clarify the statement and make it consistent with the final sentence of the subsection which begins, ''[t]ermination, suspension, or modification of an alternative consultation . . .''

Language in § 402.46(a) was changed from ''[t]he written request shall be accompanied by an effects determination prepared in accordance with § 402.40(b)'' to ''[t]he written request shall be accompanied by an effects determination as defined in § 402.40(b).'' This change is intended to clarify that the Services do not intend to prescribe how EPA would prepare the effects determinations.

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, this document is a significant rule because of the legal or policy issues it has raised; it was reviewed by the Office of Management and Budget (OMB) in accordance with the four criteria discussed below.

(a) This counterpart regulation will not have an annual economic effect of $100 million or more or adversely affect an economic sector, productivity, jobs, the environment, or other units of government.

(b) This counterpart regulation is not expected to create inconsistencies with other agencies' actions. FWS and NOAA Fisheries are responsible for carrying out the Act.

(c) This counterpart regulation is not expected to significantly affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) OMB has determined that this rule may raise novel legal or policy issues and, as a result, this rule has undergone OMB review.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions), unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Regulatory Flexibility Act requires Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

Pursuant to the Regulatory Flexibility Act, the Secretaries of the Interior and Commerce certify that this regulation will not have a significant economic impact on a substantial number of small entities. The purpose of the rule is to increase the efficiency of the ESA section 7 consultation process for those activities involving pesticide regulation conducted by EPA. The proposed changes are expected to lead to the same protections for listed species as the section 7 consultation regulations at 50 CFR part 402.

Regulations at 50 CFR 402.04 provide that ''the consultation procedures may be superseded for a particular Federal agency by joint counterpart regulations among that agency, the Fish and Wildlife Service, and the National Marine Fisheries Service.'' The preamble to the 1986 regulations for implementing section 7 states that ''such counterpart regulations must retain the overall degree of protection afforded listed species required by the [ESA] and these regulations. Changes in the general consultation process must be designed to enhance its efficiency without elimination of ultimate Federal agency responsibility for compliance with section 7.'' The rule will not have a significant economic impact on a substantial number of small entities for the following reasons.

(1) The rule will modify procedures for formal section 7 consultation and remove the requirement for EPA to conduct informal consultation with and obtain written concurrence from FWS or NOAA Fisheries on those FIFRA actions it determines are NLAA listed species or critical habitat.

(2) The new consultation procedures may affect registrants, who provide EPA with the data used to assess the level of environmental risk. It is estimated that approximately two-thirds of the 1,850 pesticide registrants are small businesses. Because this rule is expected to streamline the consultation process and would therefore potentially accelerate the registration process for new pesticide products and the re-registration process for existing pesticides, these businesses are expected to experience no effect or a small positive effect as a result of this rule.

(3) Agricultural producers, many of which are small businesses, may be indirectly affected by this rule. Because this rule is expected to streamline the consultation process and would therefore potentially accelerate the registration process for new pesticide products pesticides and the re-registration process for existing pesticides, agricultural producers may experience a small indirect benefit from this rule.

Therefore, the Secretaries of the Interior and Commerce certify that this action will not have a significant economic impact on a substantial number of small businesses, organizations, or governments pursuant to the RFA.

Executive Order 13211

On May 18, 2001, the President issued an Executive Order (E.O. 13211) on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Although this rule is a significant action under Executive Order 12866, it is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) These counterpart regulations will not ''significantly or uniquely'' affect small governments. A Small Government Agency Plan is not required. We expect that these counterpart regulations will not result in any significant additional expenditures by entities that develop formalized conservation efforts.

(b) These counterpart regulations will not produce a Federal mandate on State, local, or tribal governments or the

private sector of $100 million or greater in any year; that is, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. These counterpart regulations impose no obligations on State, local, or tribal governments.

Takings

In accordance with Executive Order 12630, these counterpart regulations do not have significant takings implications. These counterpart regulations pertain solely to ESA section 7 consultation coordination procedures, and the procedures have no impact on personal property rights.

Federalism

In accordance with Executive Order 13132, these counterpart regulations do not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior and Commerce regulations under section 7 of the ESA, we coordinated development of these counterpart regulations with appropriate resource agencies throughout the United States.

Civil Justice Reform

In accordance with Executive Order 12988, this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We promulgate these counterpart regulations consistent with section 7 of the ESA.

Paperwork Reduction Act

This rule will not impose any new requirements for collection of information that require approval by the OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This rule will not impose new recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. We may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

National Environmental Policy Act

These counterpart regulations have been developed by FWS and NOAA Fisheries, along with EPA and USDA. The FWS and NOAA Fisheries are considered the lead Federal agencies for the preparation of this proposed rule, pursuant to 40 CFR 1501. We have analyzed these counterpart regulations in accordance with the criteria of the National Environmental Policy Act (NEPA), the Department of the Interior Manual (318 DM 2.2(g) and 6.3(D)), and National Oceanic and Atmospheric Administration (NOAA) Administrative Order 216–6 and have determined, after preparation of an environmental assessment, that the action does not have any significant effects. A Finding Of No Significant Impact has been prepared.

Government-to-Government Relationship With Indian Tribes

In accordance with the Secretarial Order 3206, ''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act'' (June 5, 1997); the President's memorandum of April 29, 1994, ''Government-to-Government Relations with NativeAmerican Tribal Governments'' (59 FR 22951); E.O. 13175; and the Department of the Interior's 512 DM 2, we understand that we must relate to recognized Federal Indian Tribes on a Government-to-Government basis. However, these counterpart regulations do not directly affect Tribal resources since only EPA regulatory actions are subject to the proposed provisions. The intent of these counterpart regulations is to streamline the consultation process; therefore, any indirect effect would be wholly beneficial.

List of Subjects in 50 CFR Part 402

Endangered and threatened species.

Final Regulation Promulgation

■ For the reasons set forth in the preamble, the Services amend part 402, title 50 of the Code of Federal Regulations as follows:

PART 402—[AMENDED]

■ 1. The authority citation for part 402 continues to read as follows:

Authority: 16 U.S.C. 1531 *et seq.*

■ 2. Add a new subpart D to read as follows:

Subpart D—Counterpart Regulations Governing Actions by the U.S. Environmental Protection Agency Under the Federal Insecticide, Fungicide and Rodenticide Act

Sec.

Subpart D—Counterpart Regulations Governing Actions by the U.S. Environmental Protection Agency Under the Federal Insecticide, Fungicide and Rodenticide Act

§ 402.40 Definitions.

The definitions in § 402.02 are applicable to this subpart. In addition, the following definitions are applicable only to this subpart.

(a) *Alternative consultation agreement* is the agreement described in § 402.45.

(b) *Effects determination* is a written determination by the U.S. Environmental Protection Agency (EPA) addressing the effects of a FIFRA action on listed species or critical habitat. The contents of an effects determination will depend on the nature of the action. An effects determination submitted under § 402.46 or § 402.47 shall contain the information described in § 402.14(c)(1)–(6) and a summary of the information on which the determination is based, detailing how the FIFRA action affects the listed species or critical habitat. EPA may consider the following additional sections for inclusion in an effects determination:

(1) A conclusion whether or not the FIFRA action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat and a description of any reasonable and prudent alternatives that may be available;

(2) A description of the impact of any anticipated incidental taking of such listed species resulting from the FIFRA action, reasonable and prudent measures considered necessary or appropriate to minimize such impact, and terms and conditions necessary to implement such measures; and

(3) A summary of any information or recommendations from an applicant. An effects determination shall be based on the best scientific and commercial data available.

(c) *FIFRA action* is an action by EPA to approve, permit or authorize the sale, distribution or use of a pesticide under sections 136–136y of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 *et seq.* (FIFRA). In any consultation under this subpart, EPA shall determine the nature and scope of a FIFRA action.

(d) *Listed species* is a species listed as endangered or threatened under section 4 of the Act.

(e) *Partial biological opinion* is the document provided under § 402.47(a), pending the conclusion of consultation under § 402.47(b), stating the opinion of the Service as to whether or not a FIFRA action is likely to jeopardize the

continued existence of one or more listed species or result in the destruction or adverse modification of one or more critical habitats, and describing the impact of any anticipated incidental taking of such listed species resulting from the FIFRA action, reasonable and prudent measures considered necessary or appropriate to minimize such impact, and terms and conditions necessary to implement such measures.

(f) *Service Director* refers to the Director of the U.S. Fish and Wildlife Service or the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration.

(g) *Service Representative* is the person or persons designated to participate in advance coordination as provided in this subpart.

§ 402.41 Purpose.

The purpose of these counterpart regulations is to enhance the efficiency and effectiveness of the existing consultation process under section 7 of the Endangered Species Act (Act), 16 U.S.C. 1531 *et seq.*, by providing Fish and Wildlife Service and the National Marine Fisheries Service (referred to jointly as ''Services'' and individually as ''Service'') and EPA with additional means to satisfy the requirements of section 7(a)(2) of the Act for certain regulatory actions under FIFRA. These additional means will permit the Services and EPA to more effectively use the scientific and commercial data generated through the FIFRA regulatory process as part of the best scientific and commercial data available to protect listed species and critical habitat. The procedures authorized by these counterpart regulations will be as protective of listed species and critical habitat as the process established in subpart B of this part.

§ 402.42 Scope and applicability.

(a) *Available consultation procedures.* This subpart describes consultation procedures available to EPA to satisfy the obligations of section 7(a)(2) of the Act in addition to those in subpart B of this part for FIFRA actions authorized, funded, or carried out by EPA in which EPA has discretionary Federal involvement or control. EPA retains discretion to initiate early, informal, or formal consultation as described in §§ 402.11, 402.13, and 402.14 for any FIFRA action. The procedures in this subpart may be employed for FIFRA actions as follows:

(1) Interagency exchanges of information under § 402.43 and advance coordination under § 402.44 are available for any FIFRA action.

(2) Alternative consultation under § 402.45 is available for a listed species or critical habitat if EPA determines the FIFRA action is not likely to adversely affect the listed species or critical habitat.

(3) Optional formal consultation under § 402.46 is available for any FIFRA action with respect to any listed species or critical habitat.

(4) The special procedures in § 402.47 are available for consultations on FIFRA actions that will be unusually complex due to factors such as the geographic area or number of species that may be affected by the action.

(5) EPA shall engage in consultation as to all listed species and critical habitat that may be affected by a FIFRA action, and may in its discretion employ more than one of the available consultation procedures for a FIFRA action that may affect more than one listed species or critical habitat.

(6) EPA shall engage in consultation on actions involving requests for emergency exemptions under section 18 of FIFRA that may affect listed species or critical habitat, and may choose to do so under § 402.05 or other provisions of this subpart or subpart B of this part. Any required formal consultation shall be initiated as soon as practicable after the emergency is under control. For the purposes of § 402.05(b) the definition of formal consultation in § 402.02 includes the procedures in § 402.46.

(7) EPA must prepare a biological assessment for a FIFRA action to the extent required by § 402.12.

(8) EPA must comply with § 402.15 for all FIFRA actions.

(9) After a consultation under this subpart has been concluded, EPA shall reinitiate consultation as required by § 402.16 as soon as practicable after a circumstance requiring reinitiation occurs, and may employ the procedures in this subpart or subpart B of this part in any reinitiated consultation.

(b) *Exchanges of scientific information.* As part of any of the additional consultation procedures provided in this subpart, EPA and the Services shall establish mutually-agreeable procedures for regular and timely exchanges of scientific information to achieve accurate and informed decision-making under this subpart and to ensure that the FIFRA process considers the best scientific and commercial data available on listed species and critical habitat in a manner consistent with the requirements of FIFRA and ESA.

§ 402.43 Interagency exchanges of information.

EPA may convey to the Service a written request for a list of any listed species or critical habitat that may be present in any area that may be affected by a FIFRA action. Within 30 days of receipt of such a request the Service shall advise EPA in writing whether, based on the best scientific and commercial data available, any listed species or critical habitat may be present in any such area. EPA may thereafter request the Service to provide available information (or references thereto) describing the applicable environmental baseline for each species or habitat that EPA determines may be affected by a FIFRA action, and the Service shall provide such information within 30 days of the request.

§ 402.44 Advance coordination for FIFRA actions.

(a) *Advance coordination.* EPA may request the Service to designate a Service Representative to work with EPA in the development of an effects determination for one or more listed species or critical habitat. EPA shall make such a request in writing and shall provide sufficient detail as to a FIFRA action planned for consultation to enable the Service to designate a representative with appropriate training and experience who shall normally be available to complete advance coordination with EPA within 60 days of the date of designation. Within 14 days of receiving such a request, the Service shall advise EPA of the designated Service Representative.

(b) *Participation of Service Representative in preparation of effects determination.* The Service Representative designated under paragraph (a) of this section shall participate with EPA staff in the preparation of the effects determination identified under paragraph (a) of this section. EPA shall use its best efforts to include the designated Service Representative in all relevant discussions on the effects determination, to provide the designated Service Representative with access to all documentation used to prepare the effects determination, and to provide the designated Service Representative office and staff support sufficient to allow the Service Representative to participate meaningfully in the preparation of the effects determination. EPA shall consider all information timely identified by the designated Service Representative during the preparation of the effects determination.

§ 402.45 Alternative consultation on FIFRA actions that are not likely to adversely affect listed species or critical habitat.

(a) *Consultation obligations for FIFRA actions that are not likely to adversely affect listed species or critical habitat when alternative consultation agreement is in effect.* If EPA and the Service have entered into an alternative consultation agreement as provided below, EPA may make a determination that a FIFRA action is not likely to adversely affect a listed species or critical habitat without informal consultation or written concurrence from the Director, and upon making such a determination for a listed species or critical habitat, EPA need not initiate any additional consultation on that FIFRA action as to that listed species or critical habitat. As part of any subsequent request for formal consultation on that FIFRA action under this subpart or subpart B of this part, EPA shall include a list of all listed species and critical habitat for which EPA has concluded consultation under this section.

(b) *Procedures for adopting and implementing an alternative consultation agreement.* EPA and the Service may enter into an alternative consultation agreement using the following procedures:

(1) *Initiation.* EPA submits a written notification to the Service Director of its intent to enter into an alternative consultation agreement.

(2) *Required contents of the alternative consultation agreement.* The alternative consultation agreement will, at a minimum, include the following components:

(i) *Adequacy of EPA Determinations under the ESA.* The alternative consultation agreement shall describe actions that EPA and the Service have taken to ensure that EPA's determinations regarding the effects of its actions on listed species or critical habitat are consistent with the ESA and applicable implementing regulations.

(ii) *Training.* The alternative consultation agreement shall describe actions that EPA and the Service intend to take to ensure that EPA and Service personnel are adequately trained to carry out their respective roles under the alternative consultation agreement. The alternative consultation agreement shall provide that all effects determinations made by EPA under this subpart have been reviewed and concurred on by an EPA staff member who holds a current certification as having received appropriate training under the alternative consultation agreement.

(iii) *Incorporation of new information.* The alternative consultation agreement shall describe processes that EPA and the Service intend to use to ensure that new information relevant to EPA's effects determinations is timely and appropriately considered.

(iv) *Incorporation of scientific advances.* The alternative consultation agreement shall describe processes that EPA and the Service intend to use to ensure that the ecological risk assessment methodologies supporting EPA's effects determinations incorporate relevant scientific advances.

(v) *Oversight.* The alternative consultation agreement shall describe the program and associated record keeping procedures that the Service and EPA intend to use to evaluate EPA's processes for making effects determinations consistent with these regulations and the alternative consultation agreement. The alternative consultation agreement shall provide that the Service's oversight will be based on periodic evaluation of EPA's program for making effects determinations under this subpart. Periodic program evaluation will occur at the end of the first year following signature of the alternative consultation agreement and should normally occur at least every five years thereafter.

(vi) *Records.* The alternative consultation agreement shall include a provision for EPA to maintain a list of FIFRA actions for which EPA has made determinations under this section and to provide the list to the Services on request. EPA will also maintain the necessary records to allow the Service to complete program evaluations.

(vii) *Review of Alternative Consultation Agreement.* The alternative consultation agreement shall include provisions for regular review and, as appropriate, modification of the agreement by EPA and the Service, and for departure from its terms in a particular case to the extent deemed necessary by both EPA and the Service.

(3) *Training.* After EPA and the Service enter into the alternative consultation agreement, EPA and the Service will implement the training program outlined in the alternative consultation agreement to the mutual satisfaction of EPA and the Service.

(4) *Public availability.* The alternative consultation agreement and any related oversight or monitoring reports shall be made available to the public to the extent provided by law.

(c) *Oversight of alternative consultation agreement implementation.* Through the program evaluations set forth in the alternative consultation agreement, the Service will determine whether the implementation of this section by EPA is consistent with the best scientific and commercial information available, the ESA, and applicable implementing regulations. The Service Director may use the results of the program evaluations described in the alternative consultation agreement to recommend changes to EPA's implementation of the alternative consultation agreement. The Service Director retains discretion to terminate or suspend the alternative consultation agreement if, in using the procedures in this subpart, EPA fails to comply with the requirements of this subpart, section 7 of the ESA, or the terms of the alternative consultation agreement. Termination, suspension, or modification of an alternative consultation agreement does not affect the validity of any NLAA determinations made previously under the authority of this subpart.

§ 402.46 Optional formal consultation procedure for FIFRA actions.

(a) *Initiation of consultation.* EPA may initiate consultation on a FIFRA action under this section by delivering to the Service a written request for consultation. The written request shall be accompanied by an effects determination as defined in § 402.40(b) and a list or summary of all references and data relied upon in the determination. All such references and data shall be made available to the Service on request and shall constitute part of the Service's administrative record for the consultation. The time for conclusion of the consultation under section 7(b)(1) of the Act is calculated from the date the Service receives the written request from EPA. Any subsequent interchanges regarding EPA's submission, including interchanges about the completeness of the effects determination, shall occur during consultation and do not extend the time for conclusion of the consultation unless EPA withdraws the request for consultation.

(b) *Additional information determination.* For an effects determination prepared without advance coordination under § 402.44, the Service may determine that additional available information would provide a better information base for the effects determination, in which case the Service Director shall notify the EPA Administrator within 45 days of the date the Service receives the effects determination. The notification shall describe such additional information in detail, and shall identify a means for obtaining that information within the time period available for consultation.

EPA shall provide a copy of the Service Director's notification to any applicant. EPA may thereafter revise its effects determination, and may resubmit the revised effects determination to the Service. If EPA advises the Service it will not resubmit a revised effects determination to the Service, its initiation of consultation on the effects determination is deemed withdrawn.

(c) *Service responsibilities.* (1) Within the later of 90 days of the date the Service receives EPA's written request for consultation or 45 days of the date the Service receives an effects determination resubmitted under paragraph (b) of this section, and consistent with section 7(b)(1) of the Act, the Service shall take one of the following actions:

(i) If the Service finds that the effects determination contains the information required by § 402.40(b) and satisfies the requirements of section 7(b)(4) of the Act, and the Service concludes that the FIFRA action that is the subject of the consultation complies with section 7(a)(2) of the Act, the Service will issue a written statement adopting the effects determination; or

(ii) The Service will provide EPA a draft of a written statement modifying the effects determination, which shall meet the requirements of § 402.14(i), and as modified adopting the effects determination, and shall provide a detailed explanation of the scientific and commercial data and rationale supporting any modification it makes; or

(iii) The Service will provide EPA a draft of a biological opinion finding that the FIFRA action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, and describing any reasonable and prudent alternatives if available.

(2) If the Service acts under paragraphs (c)(1)(ii) or (c)(1)(iii) of this section, EPA shall, on request from an applicant, provide the applicant a copy of the draft written statement or draft biological opinion received from the Service. The Service shall at the request of EPA or an applicant discuss with EPA and the applicant the Service's review and evaluation under this section, and the basis for its findings. EPA and any applicant may submit written comments to the Service within 30 days after EPA receives the draft written statement or opinion from the Service unless the Service, EPA and any applicant agree to an extended deadline consistent with section 7(b)(1) of the Act.

(3) The Service will issue a final written statement or final biological opinion within 45 days after EPA receives the draft statement or opinion from the Service unless the deadline is extended under section 7(b)(1) of the Act.

(d) *Opinion of the Secretary.* The written statement or opinion by the Service under paragraphs (c)(1) or (c)(3) of this section shall constitute the opinion of the Secretary and the incidental take statement, reasonable and prudent measures, and terms and conditions under section 7(b) of the Act.

(e) *Delegation of Authority for Service decisions.* Any written statement modifying an effects determination or any biological opinion issued under this section shall be signed by the Service Director and such authority may not be delegated below the level of Assistant Director for Endangered Species (FWS) or Director of Office of Protected Resources (NOAA Fisheries).

§ 402.47 Special consultation procedures for complex FIFRA actions.

(a) *Successive effects determinations.* If EPA determines after conferring with the Service that consultation on a FIFRA action will be unusually complex due to factors such as the geographic area or number of species that may be affected by the action, EPA may address the effects of the action through successive effects determinations under this subpart addressing groupings or categories of species or habitats as established by EPA. EPA may initiate consultation based upon each such effects determination using the procedure in § 402.46(a), and the provisions of § 402.46(b) and (c) shall apply to any such consultation. When consultation is conducted under this section, the written statement or opinion provided by the Service under § 402.46(c) constitutes a partial biological opinion as to the species or habitats that are the subject of the consultation. While not constituting completion of consultation under section 7(a)(2), EPA retains authority to use such a partial biological opinion along with other available information in making a finding under section 7(d) of the Act.

(b) *Opinion of the Secretary.* After conclusion of all consultation on the FIFRA action, the partial biological opinions issued under paragraph (a) of this section shall then collectively constitute the opinion of the Secretary and the incidental take statement, reasonable and prudent measures, and terms and conditions under section 7(b) of the Act except to the extent a partial biological opinion is modified by the Service in accordance with the procedures in § 402.46(c). The Service shall so advise EPA in writing upon issuance of the last partial biological opinion for the consultation.

§ 402.48 Conference on proposed species or proposed critical habitat.

EPA may employ the procedures described in § 402.10 to confer on any species proposed for listing or any habitat proposed for designation as critical habitat. For the purposes of § 402.10(d), the procedures in § 402.46 are a permissible form of formal consultation.

Dated: July 27, 2004.

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[FR Doc. 04–17654 Filed 8–4–04; 8:45 am]

BILLING CODE 4310–55–P