**ADDRESSES:** In commenting, please refer to file code CMS–1213–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1213–P, P.O. Box 8012, Baltimore, MD 21244–8012.

Please allow sufficient time for mailed comments to be received timely in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.) Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Janet Samen, (410) 786–4533.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 4 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–9994.

*Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

On November 28, 2003, we issued a proposed rule in the **Federal Register** (68 FR 66920) proposing a prospective payment system for psychiatric hospitals and psychiatric units. The proposed rule would implement section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), which requires the implementation of a per diem prospective payment system for inpatient hospital services of psychiatric hospitals and psychiatric units. The proposed prospective payment system would replace the reasonable cost-based payment system currently in effect. We announced that the public comment period for the proposed rule would close at 5 p.m. on January 27, 2004.

The proposed rule, ''Medicare Program; Prospective Payment System for Inpatient Psychiatric Facilities,'' is unique in that it proposes, for the first time, a completely new payment system for the inpatient hospital services of psychiatric hospitals and psychiatric units of acute care hospitals. Due to the complexity and scope of this proposed rule and because many people have requested additional time to examine the proposed rule so that they may provide meaningful comments on its provisions, we have decided to extend the comment period for an additional 30 days. This document announces the extension of the public comment period to February 26, 2004.

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 23, 2004.

**Dennis G. Smith,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: January 26, 2004.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 04–1945 Filed 1–27–04; 11:10 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**RIN 1018–AI95**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[Docket No: 021223326–4022–02]**

**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:** Proposed rule.

**SUMMARY:** 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), are proposing joint counterpart regulations for consultation under section 7 of the Endangered Species Act of 1973, as amended (ESA) for regulatory actions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Counterpart regulations, described in general terms in the same part, 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 existing section 7 consultation process described in the same part. These counterpart regulations would complement the existing section 7 consultation process described in the same part and 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 process would eliminate the need for EPA to conduct informal consultation and obtain written concurrence from the Service for those FIFRA actions that EPA determines are ''not likely to adversely affect'' any listed species or critical habitat. The other alternative consultation process would permit 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 federally-protected threatened and endangered species (''listed species'') and critical habitats.

**DATES:** Comments on this proposal must be received by March 30, 2004 to be considered in the final decision on this proposal.

**ADDRESSES:** Comments or materials concerning the proposed rule should be sent to the Assistant Director for Endangered Species, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 420, Arlington, Virginia 22203. You may also comment via the Internet to *PesticideESARegulations@fws.gov*. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''Attn: 1018–AI95'' and your name and return address in your Internet message. Comments and materials received in conjunction with this rulemaking will be available for inspection, by appointment, during normal business hours at the above address.

The FWS has agreed to take responsibility for receipt of public comments and will share all comments it receives with NOAA Fisheries, EPA and USDA. All the agencies will work together to compile, analyze, and respond to public comments.

**FOR FURTHER INFORMATION CONTACT:** Gary Frazer, Assistant Director for Endangered Species, at the above address (Telephone 703/358–2171, Facsimile 703/358–1735) or Phil Williams, Chief, Endangered Species Division, NOAA Fisheries, 1315 East-West Highway, Silver Spring, MD 20910 (301/713–1401; facsimile 301/713–0376).

**SUPPLEMENTARY INFORMATION:** The FWS and NOAA Fisheries are proposing for public comment a joint rulemaking to amend existing 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 Proposed Rulemaking (NPR), developed with assistance from EPA and the USDA, would complement the Services' existing 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 proposed 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 concerning this proposed rule 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 whose actions may affect 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. 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 the current consultation regulations, 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. 16

U.S.C. 1536(b)(3)(A). 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 § 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 continued use of the pesticide ''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(l).

*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 Paper'') (January 2004), and in documents referenced in that paper, all of which are part of the administrative record of this NPR. 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 Paper. 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 Paper and the materials referenced therein. Based on this review, the Services have determined that the approach used by EPA designated 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. The Joint Advance Notice of Proposed Rulemaking on Pesticides and Endangered Species**

On January 24, 2003 the Services and EPA published an Advance Notice of Proposed Rulemaking (ANPR) inviting public comment on a variety of ideas for improving the process by which EPA and the Service work together to protect listed species and critical habitat. 68 FR 3785. The ANPR sought public comment on possible approaches to changing the current regulations, policies, and practices of the EPA and Service to better integrate the FIFRA and ESA processes and to improve the efficiency and effectiveness of consultations on pesticide actions. The agencies specifically identified several broad approaches to changing the current process. For example, the ANPR asked for comment on whether it would be possible for EPA to satisfy some or all of its ESA section 7(a)(2) consultation obligations for individual registration actions by completing what could be described as programmatic consultations affecting numerous registration and reregistration actions that share key common characteristics. Under existing Service regulations at 50 CFR part 402, the Service and Federal agencies can engage in consultations that address major national programs. There is potential to use this authority to develop a ''programmatic'' approach to consultation on the pesticide registration program. In addition, even where such programmatic consultations would not be sufficient to complete the consultation process for certain individual actions, the Notice asked for comment on whether they could serve to improve the consultation process on such actions through the standardization of risk assessment methodologies and alternatives for species protections.

The ANPR also requested comment on an approach that would streamline the informal consultation process. For

this approach, which is reflected in the counterpart regulation being proposed today, the ANPR asked for comment on whether there is a need for either further consultation or Service concurrence in those situations where EPA determines that use of a pesticide is ''not likely to adversely affect'' listed species or critical habitat.

The agencies also sought comment on an approach that would focus the review by the Service during consultation. This approach was predicated on the assumption that EPA's practices and policies would be reviewed and, where necessary, revised to ensure that the data and analyses EPA obtains and uses provide the best available information on the effects on listed species. As discussed earlier, EPA has extensive information available with which to assess and mitigate potential risks to listed species and their critical habitat, and EPA has developed considerable expertise in these areas. In view of this expertise, the ANPR therefore asked for comment on whether the Service should rely on EPA's assessment of effects once formal or informal consultation had been initiated on a pesticide regulatory action.

The ANPR also asked for comments on possible changes to the existing framework, while retaining the basic approach of requiring consultation whenever EPA determines that use of a pesticide ''may affect'' protected species. The ANPR covered the following topics:

- Modifying EPA's approach to assessing potential risk to listed species
- Introducing flexibility in the scope of consultations
- The content of consultation packages and definition of the term ''best scientific and commercial data available''
- Establishing timelines for conducting informal and formal consultations on pesticide regulatory actions
- Establishing procedures for consultations on emergency actions under FIFRA
- Clarifying the role of the Service
- Establishing procedures for public participation and clarifying the meaning of the term, ''applicant,'' in the context of consultations between EPA and the Services on pesticide regulatory actions
- Clarifying and improving the roles of States, Tribes, and other entities that might potentially act as non-Federal representatives in consultations between EPA and the Services on pesticide regulatory actions
- Fees
- Process for elevating and resolving disagreements between EPA and the Service

In response to the ANPR, the Services received comments from over 300 groups, organizations, and individuals, about half of which were letters and post cards from different individuals making the same comment. Comments came from a wide range of stakeholder organizations and individuals and presented a diverse array of opinions about what actions the government should take to promote and ensure EPA compliance with the ESA for actions under FIFRA. While most commenters expressed support for the goals of the ESA and many recognized the need to implement the ESA in a manner that was efficient and compatible with FIFRA, there were strongly differing perspectives about what course would best achieve those goals.

In general, environmental advocacy groups raised a number of criticisms about EPA's approach to assessing the risks of pesticides and regulating their use, and argued that historically EPA has had a poor record of compliance with the consultation obligations of the ESA with regard to pesticides. These commenters therefore favored a strong role for the Services and opposed any changes to the existing consultation regulations. In particular, they argued that a rule which either allowed EPA to make NLAA determinations, without consulting with and obtaining the concurrence of the Service, or afforded deference to EPA's assessments, would be contrary to the ESA. Moreover, such a rule would contain insufficient safeguards to assure proper application of the ESA and could be subject to abuse by EPA.

Agricultural pesticide user groups and pesticide manufacturers and trade associations generally stressed the extensive expertise EPA possesses in the assessment of pesticides' ecological risks and the benefits of a more efficient and consistent process. They also argued that the existing consultation regulations were designed primarily for agency actions that involved construction projects or other actions with a relatively limited geographic scope and therefore were inappropriate for the types of regulatory actions taken by EPA under FIFRA. They also questioned whether the Services had the resources and expertise to review FIFRA actions and pointed out that the time required to conduct consultations would delay decisions about the use of socially beneficial pesticides. These commenters therefore expressed support for new consultation procedures that would give EPA greater flexibility to reach conclusions under the ESA about the impact of FIFRA actions on listed species and critical habitat, with reduced or no involvement by the Services.

The Services and EPA have considered all of the comments, and the Services conclude that the goals of the ESA can be fully met using new, more efficient administrative processes that take advantage of EPA's expertise while retaining a strong role for the Services throughout the consultation process to assure that the requirements of the ESA are met. Accordingly, the Services are now proposing a counterpart regulation for consultation on FIFRA actions.

**5. Reasons for a Counterpart Regulation for EPA Pesticide Actions**

*Rationale for the rule as proposed.* In developing a process for conducting future ESA consultations on FIFRA pesticide regulatory actions, the Services and EPA recognized that EPA possesses significant resources, 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 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 or plant 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 is 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, if finalized, may 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 provide strong reasons for the Services to propose establishing 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 would 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 to put these new products in the market sooner could 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 can be achieved in a way that avoids unnecessary burdens on pesticide users with no sacrifice to the protection of listed species.

**6. The Proposed Counterpart Rule**

The proposed counterpart regulations would 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 proposed rule offers a new alternative approach when EPA determines that a FIFRA action is not likely to cause adverse effects on listed species or critical habitat, and a new 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*

The proposed counterpart rule would establish 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 Species or Habitats*

The existing section 7 regulations 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 consultation process contained in section 402.45 of the proposed counterpart regulation 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 or informal 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 proposed regulation would require the Service and EPA to have in effect an alternative consultation agreement before EPA can utilize the procedures of section 402.45, the alternative consultation agreement itself is not part of this rule, and the Services have concluded that the alternative consultation agreement would 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 section 402.45(b), the required content of the alternative consultation agreement include 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 Service's discretion in developing and applying scientific methodologies. The alternative consultation agreement would be expected to undergo continuous modification and improvement. EPA and the Service would 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 would 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed counterpart regulations it will retain full responsibility for compliance with section 7 of the ESA.

Under the proposed rule, EPA would 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 would fulfill its ESA section 7 consultation responsibility for actions covered under these proposed 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 in 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, exclusion, or termination will not affect the legal validity of determinations made prior to the suspension, exclusion, 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 have 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 proposed rule. The public is encouraged to read the draft alternative consultation agreement to obtain a better understanding of how the Services anticipate the requirements of § 402.45 would be satisfied. Such an

understanding may be useful in preparing comments on the proposed rule.

*C. New Optional Formal Consultation Process*

The proposed counterpart regulation establishes a new formal consultation process (§ 402.46) that would meet all statutory requirements and closely follows the procedural steps specified in the current subpart B process. The new process would 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 would 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 would depend on the nature of the action, an effects determination submitted under § 402.46 or § 402.47 would 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 would 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 would be accompanied by an effects determination prepared under § 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 would 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, would occur during consultation, and would 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 would 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 would 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 existing consultation procedures. 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 would be required to make it available to any applicant upon request. The proposed rule would also accommodate EPA's existing discretion to make these draft documents available to the general public for comment within the time periods provided in the draft rule. The Service would 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 would 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 would use this provision after conferring with the Services, and EPA and the Services intend to collaboratively identify priorities where use of this provision would 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) would apply to the consultation. The written statement or opinion provided by the Service under § 402.46(c) would 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 would 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 would 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 would 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. The provision would not reduce EPA's consultation duties compared to Subpart B. Rather, for certain complex FIFRA actions the provision would strengthen 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 would 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 would not represent the opinion of the Secretary or an incidental take statement under section 7(b) of the ESA until consultation is concluded on all listed species and habitats that may be affected by the action.

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 would only use the provision after conferring with the Service, which should further insure the continued effective and appropriate use of this authority.

The proposed counterpart rule would make 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 would 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 would 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 would 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 would 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 the proposed rule would therefore be consistent with practices currently permitted under Subpart B.

The proposed 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 section 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 section 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 section 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. The proposed rule allows EPA to employ the conferencing procedures described in section 402.10 for any species proposed for listing or any habitat proposed for designation as critical habitat, and provides that for the purposes of section 402.10(d), the procedures in section 402.46 would be a permissible form of formal consultation.

**Public Comments Solicited**

We intend that any final action resulting from this proposal be as accurate and effective as possible. We are soliciting comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. Prior to making a final determination on this proposed rule, we will take into consideration all relevant comments and additional information received during the comment period.

If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to the address specified in **ADDRESSES.** You may also hand-deliver comments to the address specified in **ADDRESSES.** You may also comment via the Internet to *PesticideESARegulations@fws.gov*. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''Attn: 1018–AI95'' and your name and return address in your Internet message. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives of officials of organizations or businesses, available for public inspection in their entirety.

**Required Determinations**

**Regulatory Planning and Review**

In accordance with Executive Order 12866, this document is a significant proposed rule because it may raise novel legal or policy issues, and 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 proposed rule will not have a significant economic impact on a substantial number of small entities for the following reasons.

(1) The proposed 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 pesticides 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 proposed rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We propose these counterpart regulations consistent with 50 CFR 402.04 and section 7 of the ESA.

**Paperwork Reduction Act**

This proposed rule would 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 proposed 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, according to 50 CFR 402.04. 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 that an environmental assessment will be prepared prior to finalization of the rule.

**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 Native American 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.

**Proposed Regulation Promulgation**

Accordingly the Services propose to 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. The Service may designate more than one individual to serve jointly as a Service Representative.

### § 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 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 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 prepared in accordance with § 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: January 27, 2004.

**Paul Hoffman,**

*Acting Assistant Secretary for Fish and Wildlife and Parks.*

Dated: January 26, 2004.

**William T. Hogarth,**

*Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration.*

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