

Environmental Assessment

for the

Joint Counterpart Endangered Species Act section 7 Regulation

for

Interagency Consultation on Regulatory Actions Under the

Federal Insecticide, Rodenticide, and Fungicide Act

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I. Need for the Proposed Action

A. Introduction

The U.S. Fish and Wildlife Service (FWS) and the National Oceanic and Atmospheric Administration's National Marine Fisheries Service (NOAA Fisheries)(jointly, Services) are evaluating the environmental effects of establishing counterpart regulations pursuant to section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) (ESA). These counterpart regulations are being proposed in cooperation with the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA). The proposal is intended to implement an efficient process for ESA section 7 consultations on proposed EPA actions permitting the use of a substance pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) (FIFRA). This proposed rule provides optional, alternative approaches to consultation on FIFRA actions that better integrate the consultation process under section 7 of the ESA with the risk assessment processes employed by EPA for regulatory actions taken under FIFRA. The Department of Agriculture is interested in ensuring that safe products are available for the production of food and fiber as well as to promote the welfare of the people of the United States. The Services expect these counterpart regulations will better coordinate the administration of the ESA and FIFRA to ensure threatened and endangered species and critical habitat are protected. The Services also expect that section 7 consultations will be concluded 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.

Need

In a typical year, EPA will make hundreds of decisions regarding product registration under FIFRA. Many of these decisions qualify as Federal actions in the context of section 7 of ESA. Numbers of actions in most of the FIFRA categories have risen since fiscal year (FY) 2000. For example, in FY 2002, EPA registered 26 new active ingredients; approved the addition of 720 new uses of previously registered active ingredients on close to 1,500 different crops; and completed more than 4,700 more minor registration actions. EPA also completed reregistration assessments on 36 previously registered active ingredients, and processed over 500 emergency exemption requests. In FY 2003, EPA registered 31 new 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 reregistration assessments on 28 previously registered active ingredients, and processed nearly 500 emergency exemption requests. The combination of the number and variety of FIFRA regulatory decisions EPA makes each year means that the number of consultations on EPA actions could be far greater than from any other single Federal regulatory program.

Relying on the process the Services usually use pursuant to 50 CFR 402 would require a substantial increase in order to fund a largely duplicative process. More importantly, it would likely result in substantial delays in EPA's ability to process applications for registration and re-registration and compromise EPA's ability to register products and ensure their availability. Failure to register products in a timely manner would prevent newer, less harmful products from replacing existing products, could increase the cost of food and fiber products, and compromise health and safety.

FIFRA requires EPA to ensure that its decisions to register products do not result in unreasonable adverse effects on the environment. EPA conducts ecological risk assessments to determine what risks a product poses and whether changes to the use or proposed use are necessary to protect the environment. As part of the development of the counterpart regulations the Services analyzed EPA's risk assessment process and determined that EPA's process is designed to ensure this it uses the best available data to make their determinations. Because EPA's approach produces data that is consistent with ESA data standards, the data used by EPA can be used to evaluate EPA's actions with respect to the requirements of the ESA. By relying on the assessments already conducted by EPA, the Services will increase their ability to produce biological opinions in a timely manner. In addition, the counterpart regulations allow the Services to participate in EPA's risk assessment process, which will provide the Services insight into the nature of the risks and EPA the benefit of the Services expertise with respect to endangered species improving the outcome of both ESA and FIFRA determinations. Finally, based on the Services review of the EPA process and the understandings regarding oversight to which both agencies have agreed; allowing EPA to use its revised risk assessment process to make NLAA determinations without concurrence from the Services, would also free resources within the Services to focus on the more complicated registration actions that are likely to affect listed species.

II. Alternatives, Including the Proposed Action

A. Alternatives Considered

Proposed Action: Counterpart regulations, as generally described at 50 CFR 402.04, provide an optional alternative to the existing section 7 consultation process described in 50 CFR part 402, subparts A and B. The Counterpart regulations complement the general consultation regulations in part 402 by allowing individual Federal agencies to “fine tune” the general consultant framework to reflect their particular program responsibilities and obligations. Providing an alternative process for completing section 7 consultation for EPA’s actions pursuant to FIFRA will allow the Services to utilize the considerable expertise available at EPA in risk assessment and risk management for purpose of assessing the risk of EPA’s FIFRA actions in the context of the requirements of Section 7 of the ESA. 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 adversely affect a listed species or its critical habitat, and a new alternative approach to formal consultations when EPA determines that a FIFRA action might adversely affect a listed species or its critical habitat. EPA could also elect to follow any of the existing procedures for early (section 402.11), informal (section 402.13), or formal consultation (section 402.14) described in subpart B of part 402 for these actions.

New Methods of Interagency Cooperation: The proposed counterpart rule would establish three additional methods (section 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 section 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 section 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 section 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.

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 not likely to adversely affect (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 a 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).

As articulated in proposed section 402.45(b), 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. It will be implemented via an alternative consultation agreement. The required content of the alternative consultation agreement includes provisions and procedures to guide the Services and EPA in implementing the provisions that will allow EPA to make NLAA determinations without Service concurrence. These provisions and procedures establish mechanisms to ensure continuous modification and improvement in EPA's ability to distinguish actions that are not likely to adversely affect listed species from those that require formal consultation. 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, provided the departure would produce a more reliable assessment of potential effects of a FIFRA action.

Under the proposed rule, EPA would enter into an alternative consultation agreement with either FWS, or 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 NLAA actions covered under these proposed regulations. A draft alternative consultation agreement is available for review at <http://www.nmfs.noaa.gov/pr/laws/pesticides.htm>.

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 would under the provisions of section 402.13. The training program will rely upon the ESA Consultation Handbook to the extent it is applicable.

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 assume full responsibility for the adequacy of its NLAA determinations since EPA would no longer present its NLAA determination for a FIFRA action to the Services for concurrence.

New Optional Formal Consultation Process: The proposed counterpart regulation establishes a new formal consultation process (section 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 products registered under FIFRA.

The process relies on an effects determination that would be prepared by EPA according to analytical methodologies that the Services have reviewed and endorsed (Letter from S. Williams and W. Hogarth to Susan Hazen (January 2004)). 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 section 402.46 or section 402.47 would contain the information described in section 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 section 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 that the Service receives the written request from EPA. Any subsequent communications between the Service and EPA regarding the information submitted by EPA, including communications 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 (section 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 products, delaying the initiation of consultation until adequate information is available for every species or habitat that may be affected by the product 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 section

402.46(a). The procedure in section 402.46(b) and (c) would apply to the consultation. The written statement or opinion provided by the Service under section 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 products such as farmers and forest managers, nursery operators, and other 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 section 402.46(c). For products currently in use, this process would provide prompt guidance, or substantial protection for vulnerable species without unduly disrupting longstanding patterns of use in agriculture, public health vector control or other important use patterns throughout the country that are vital to the health, safety and welfare of the American people.

The Services emphasize that section 402.47 is not intended as an authorization for EPA to take actions, such as registration of products 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 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 product 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 section 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 section 402.05(b), the definition of formal consultation in section 402.02 would include the procedures in section 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 comparable to the intended scope of emergency in section 402.05 and that, therefore, the overwhelming majority of FIFRA emergency exemption actions could properly be considered emergencies for the purposes of section 402.05. Under EPA regulations, FIFRA section 18 emergency exemptions can only be issued for urgent, non-routine situations where a product 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). Problems of these dimensions would generally be encompassed within the provisions of section 402.05(a).

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 the proposed rule or Subpart B in any reinitiated consultation. EPA must comply with section 402.15 for all FIFRA actions subject to consultation under the proposed rule. 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.

No Action: No change in the current consultation procedures would occur. EPA would comply with its obligation to consult with the Services on FIFRA actions using the consultation procedures contained in the existing regulations for interagency cooperation in 50 CFR Part 402. EPA would continue to rely on the process described in “Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency, Endangered and Threatened Species Effects Determinations” (January 2004) to prepare its risk assessments. EPA would use the results of those risk assessments to make effects determinations and where appropriate prepare NLAA determinations for concurrence by the Services (section 402.13) or biological assessment for initiation of formal consultation (section 402.14). The Services would review these biological assessments and any additional information they deemed relevant and determine whether or not the adverse effects anticipated to result from the subject

FIFRA action was likely to jeopardize the continued existence of a listed species. Based on this review, the Services would prepare biological opinions, and where appropriate incidental take statements and Reasonable and Prudent Alternatives.

Pursuant to section 402.14 consultations are concluded within 90 days of initiation and the Services are to render their opinion within 45 days after conclusion of consultation. The Services are challenged to meet these timeframes for complex consultations of national significance and frequently take much longer than the allotted amount of time to issue final biological opinions. Given the complexity of consultations on national FIFRA registrations, additional delays in approval on registration and reregistration actions could be expected.

B. Alternatives considered but eliminated from further review

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 Services work together to protect listed species and critical habitat (68 FR 3785). The alternatives discussed below are drawn from among the ideas identified in the ANPR.

Programmatic consultation: Under existing Service regulations at 50 CFR part 402, the Services 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 product registration or reregistration program. In regulating products under FIFRA, EPA does not develop overall registration and reregistration programs as, for instance, the Forest Service

might develop a forest plan; rather, EPA makes decisions about new and existing product uses on a case-by-case basis, subject to the standards of FIFRA described above. While these decisions are made on a case-by-case basis, in many circumstances these individual registration decisions share common elements. For example, EPA receives hundreds of applications per year for so called “me-too” products that are identical or nearly identical to currently registered products and have identical or nearly identical exposure or toxicological profiles. In addition, some classes of products that are not identical may nonetheless share common exposure or toxicological profiles. Even where products do not share common characteristics, there may be approaches to risk assessment and risk management that are appropriate for identifying and addressing risk concerns to listed species across broad classes of products. Thus, in circumstances where such commonalities exist, it may 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 simultaneously. In addition, even where such programmatic consultations are not sufficient to complete the consultation process for certain individual actions, they may serve to improve the consultation process on such actions through the standardization of risk assessment methodologies and alternatives for species protections. While the Services' current section 7 regulations provide authority for agencies to consult on a group of related actions in this fashion, there may be benefits to using counterpart regulations to establish criteria that would delineate the circumstances under which EPA would be expected to consult with the Services and the circumstances where consultation would not be necessary. Such regulations could identify those practices that EPA would follow to identify and delineate potential adverse effects on listed species and their habitat, as well as the data standards for such evaluations. Such regulations could lead to more efficient use of resources by both the Services and EPA, while at the same

time providing the public with an opportunity to participate more fully in the process of protecting listed species.

While a programmatic approach may provide an opportunity for streamlining, it would still require involvement of the Services in concurrence decisions on projects that are NLAA listed species or critical habitat. This would divert the attention of Service biologists from actions that require formal consultation. Therefore, this alternative does not substantially address the need for improved consultation efficiency. The Services expect the effects of this alternative would be similar to those of the no action alternative. Based on the above discussion, the Services have determined that this alternative does not meet the need of the proposed action, and therefore have eliminated it from further analysis at this time.

Focused review by the Services during consultation: The immediately preceding alternative explores amendments to the circumstances under which informal consultation would be necessary. This alternative considers potential approaches to consultation that would focus review provided by the Services once formal or informal consultation had been initiated. It is predicated on the assumption that in the development of this rulemaking, 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 threatened and endangered 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. Based on this expertise, therefore, in the case of FIFRA regulatory actions, this alternative proposes that the Services would rely on EPA's assessment of effects. When consultation is necessary, an approach would be to provide for a

more focused review of EPA submissions by the Services. This approach would provide for a rebuttable presumption regarding the adequacy of the effects analysis in an EPA request to initiate consultation. There are many potential standards that could be applied to determine whether the effects analysis would be deemed adequate (see section 402.14(c)). The ANPR identified three:

- Whether EPA had considered the most current and best available scientific, commercial, and technical information on listed species and their habitat and that the determinations were not arbitrary and capricious.
- Whether there was clear and convincing information warranting a different conclusion as to the effects of the proposed registration.
- Whether there is substantial evidence to support EPA's effects determinations.

While this alternative has the potential for streamlining, it also would require Service biologists to invest considerable time in concurring with EPA's NLAA determinations. It also describes a potentially confrontational approach to formal consultation where the Service rebuts assertions made by EPA regarding the completeness of the information reviewed and the conclusions presented by EPA based on the information considered. The preferred alternative proposes a collaborative process to ensure EPA's risk assessment methodology identifies the best available scientific information and considers all necessary factors in completing effects determinations to streamline issuance of biological opinions.

Based on the above discussion, the Services have determined that this alternative does not substantially address the need for improved consultation efficiency and does not meet the need

for the proposed action. Therefore, this alternative was eliminated from further analysis at this time.

III. Affected Environment

Under FIFRA EPA has authority to register products for a wide variety of uses, such as agricultural, urban, or forestry uses. Use of a registered product may be authorized at geographic scales ranging from National to local, and either for long-term use or short-term experimentation. For example, in emergency situations products can be authorized in specific geographic areas for limited duration. Because the proposed rule applies broadly to EPA's FIFRA registration program and that program essentially encompasses the entire country, a specific discussion of the affected environment is not possible. Nonetheless, the proposed rule does not propose to change either EPA's obligation under FIFRA to avoid unreasonable adverse effects to the environment or EPA's obligation under the ESA to avoid jeopardizing the continued existence of listed species or adverse modification of critical habitat.

IV. Environmental Consequences

Proposed Action: The proposed action alternative would be a procedural change in conducting ESA section 7 consultations for those FIFRA actions that are not likely to adversely affect listed species or designated critical habitat. It does not propose to change either EPA's obligation under FIFRA to avoid unreasonable adverse effects to the environment or EPA's obligation under the ESA to avoid jeopardizing the continued existence of listed species or adverse

modification of critical habitat. Thus, this alternative would not have any adverse environmental effects.

The Services have carefully reviewed EPA's assessment methodologies and believe that when EPA follows its established approach to ecological risk assessment for products registered under FIFRA, it uses the best available commercial and scientific data and will correctly make determinations as to whether an action is or is not likely to adversely affect listed species or critical habitat. As discussed in the preamble for the section 7 regulations (51 FR 19937), the proposed program must retain the same degree of protection afforded listed species required by the ESA. The standards for analyzing the effect of the proposed FIFRA actions would remain the same. The alternative consultation agreement will describe the standards that EPA will apply in assessing the effects of the action on listed species. Those standards would be consistent with the standards the Services use in concurring with NLAA determinations. The training program will use the section 7 handbook, regulations, and the ESA as the backbone for the program. The EPA will reach the same NLAA determination that the Services would reach; therefore exactly the same outcomes would be expected under the counterpart rule as under the current section 7 process. Therefore, implementing the proposed counterpart regulation will not have any adverse biological effects.

In addition, these proposed counterpart regulations provide a 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 a 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.

EPA's registration program places high priority on registering products that are safer than those currently on the market, those products with public health benefits, and products that are of particular economic importance to producers. For more information on this priority system, please refer to Pesticide Registration Notices 97-2 and 98-7, available online at http://www.epa.gov/PR_Notices. The proposed counterpart regulations should facilitate EPA's ability to address these high priority registration actions by ensuring that the section 7 interagency consultation process does not delay the public's access to new and safer products unnecessarily.

The counterpart regulation will also facilitate completing consultation on currently registered products that have not yet been subjected to section 7 consultations. This will allow EPA and the Services to improve collaboration to ensure that these products meet current scientific and regulatory standards. This process also will ensure that products considered for reregistration are reviewed for consistency with current scientific understanding of their effect on listed species and critical habitat and where appropriate restrictions on use can be applied to reduce risks that are of concern and to ensure the continued use of these products is not likely to jeopardize the continued existence of any listed species or adversely affect its critical habitat.

The Services believe that EPA's expertise in ecological risk assessments, 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. 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.

There may be an increase in administrative costs within EPA given that EPA would assume responsibility for administering this process. However, these would be routine costs associated with implementing a program within the agency. Accordingly, the regulatory procedural changes would only enhance the efficiency of the program without eliminating the ultimate Federal agency responsibility for complying with section 7.

The EPA also would be required to conduct an upfront training program for personnel making the determination, and would need to provide a program that maintains these skills within the agency. The EPA would have to implement procedures for incorporating new listed species and critical habitat into their effects analysis and be more diligent in keeping current on new information regarding species biology. Typically this role has been conducted by the Services.

These administrative expenses would be offset by the benefits of the procedural change. The EPA would not have to expend resources on the informal consultation process or lose time waiting for a concurrence letter from the Services. The time saved ultimately equates to a financial savings in staffing expenses and can ultimately result in faster approval of new less environmentally harmful products which would produce long term biological and economic benefit.

The Services would also likely see a small increase in administrative costs from implementing the alternative consultation agreement. In the short term, the Services would jointly develop a training program that would expend a larger amount of financial resources. However, this up front cost would be balanced by the long-term decrease in time spent analyzing projects that result in concurrence letters. In the long term, the Services would need to monitor how EPA implements the alternative consultation agreement. The monitoring program likely will not be as time consuming as the current process of providing concurrence letters. By removing the need to provide concurrence letters, the Services could devote more time to analyzing and coordinating on projects that do have adverse effects to listed species and critical habitat.

The Services do not anticipate any adverse effects to the environment from implementation of the proposed action.

No Action: Under the no action alternative, EPA would submit its NLAA determinations to the Services for concurrence which would consume Service resources that otherwise could be directed at consultations to ensure FIFRA actions that might adversely affect listed species do not result in jeopardizing the continued existence of those species or adversely modify their

critical habitat. The Services approach to formal consultation under the no action alternative would be reactionary. The Service would respond to biological assessments, where appropriate, prepared pursuant to section 402.12 and requests for formal consultation submitted pursuant to section 402.14. The Services review would not have the benefit of the preconsultation coordination anticipated in the proposed rule and, therefore, would likely undertake analysis that is duplicative of the EPA's analysis. This duplicative analysis is a source of delay that the Services anticipate could be eliminated by the proposed rule.

The "no action" alternative likely will leave EPA more vulnerable to citizen suits under the ESA, since, as noted, EPA and the Services will likely not be able to complete ESA section 7 consultations for FIFRA actions as efficiently and effectively as they could under the proposed counterpart regulation. In turn, such litigation could result not only in court orders compelling consultation for certain products, but might also result in injunctions directed at the use of such products during the pendency of any required consultations. While it is difficult to speculate as to the precise scope and nature of such injunctions in the abstract, it is not clear that measures imposed by the courts would have a more beneficial environmental impact than those developed by the Services and EPA proceeding under the counterpart regulation. Indeed, the Services believe that the federal agencies charged with administration of the ESA are generally in a better position than the courts to establish priorities and develop appropriate measures to protect species and avoid unnecessary economic impacts to society.

VI. Compliance, Consultation and Coordination with Others

The Services worked jointly with EPA, Office of Pesticide Programs and USDA Office of the Secretary and Office of General Counsel to prepare the proposed counterpart regulations. The proposed rule was published in the FR on January 30, 2004 (69 FR 4465). On March 31, 2004 the public comment period was extended to April 16, 2004 (69 FR 16887). The Services received over 70,000 comments on the proposed rule. Most of the comments focused on effects the might occur as a result of actions taken during implementation of FIFRA. However, this rule only allows for a procedural change in the consultation that might occur on those types of projects. The effects of FIFRA actions will still need to be considered; this regulation does not change the effects analysis, or EPA's obligation to ensure the FIFRA actions are not likely to jeopardize the continued existence of any threatened or endangered species or result in the adverse modification of any critical habitat.