

<http://endangered.fws.gov/consultations/s7hndbk/s7hndbk.htm>.

During formal consultation, focus is upon 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. 50 CFR 402.14(h).

At the conclusion of formal consultation, the Services will issue a "biological opinion" that details the effects of the action on the listed species or critical habitat, and 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). A "jeopardy" biological opinion must include reasonable and prudent alternatives, if any are available. Where jeopardy or adverse modification of critical habitat does not exist, the Services must issue an incidental take statement that specifies reasonable and prudent measures necessary to minimize incidental impact. 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 liability. 16 U.S.C. 1536(o).

Service regulations implementing section 7 also authorize the promulgation of counterpart regulations, that establish alternate consultation procedures for a particular Federal agency. 50 CFR 402.04. Authority to promulgate counterpart regulations acknowledges that in certain instances, the section 7 consultation process can benefit from procedures that differ from the traditional consultation process established by the Services. This ANPR contemplates such regulations.

E. EPA's and the Services' Goals for this ANPR

The Services and EPA are seeking ways to better integrate FIFRA pesticide registration and ESA section 7 consultation processes thereby making the section 7 consultation on pesticides more effective and efficient. Additionally, EPA and the Services are seeking to improve public involvement in and understanding of the consultation process on FIFRA actions. In order to meet these goals, the Services and EPA, in consultation with USDA, will propose counterpart regulations governing section 7 consultation for EPA's regulatory actions, as well as any changes to the FIFRA policies and practices, which may be necessary. In addition, EPA and the Services are considering other procedural modifications to the

consultation process for pesticide regulation.

In 1988, Congress addressed the relationship between ESA and EPA's pesticide labeling program. Public Law 100-478, October 7, 1988, amended ESA and 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. Thus, the clear sense of Congress is 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 are working with USDA in this process.

EPA and the Services share the same overall goal—to improve their capacity to provide needed protection for listed species and their critical habitat in an expedited manner that is not unnecessarily burdensome for pesticide users. The Services and EPA believe that procedures and policies that result in better integration of the ESA consultation process with pesticide regulatory programs—both registration and reregistration—should lead to more efficient production of scientifically sound assessments of risks to listed species and critical habitat. That, in turn, should benefit both the listed species and those affected by EPA's pesticide regulatory programs. Improving the process, including shortening the time frames for ESA review of currently registered pesticide products, would enable EPA to more efficiently implement risk mitigation measures to prevent jeopardy to listed species and to avoid adversely modifying critical habitat. Moreover, many of the applications submitted for registration of pesticide products containing new active ingredients involve pesticide formulations that could have less impacts than the currently registered products with which they would compete. Thus, any improvements in the efficiency and effectiveness of the ESA review process could similarly benefit listed species, as well as more broadly provide benefits for human health and the environment. Finally, given the importance of pesticide use for such essential purposes as production of food and fiber and disease prevention, EPA and the Services believe that improved integration of the FIFRA registration/reregistration and section 7(a)(2) consultation processes, under new counterpart regulations, modification to the FIFRA processes, or through other

mechanisms, will be achieved in a way that avoids unnecessary burdens on pesticide users.

In developing a process for conducting future ESA consultations on FIFRA pesticide regulatory actions, the agencies believe it is important to recognize that EPA possesses significant resources and expertise in the field of ecological risk assessment relative to pesticides, while the Services possess the technical and regulatory expertise necessary for consistent administration of ESA. 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 significant 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 must maintain a sizeable 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 its strong scientific data bases and its expertise in the field of ecological risk assessment, EPA's decisions have certain relatively unique characteristics. Pesticide products typically include multiple uses, and can potentially be used in many different parts of the country. Thus, in evaluating a pesticide, EPA considers different locations where the product may be used and whether wildlife or plant species may be affected by such use. This broad scope of review contrasts with actions by Federal agencies that have a narrower geographical scope. In addition, the number of pesticide decisions is also a factor potentially affecting the section 7 consultation process. In a typical year, EPA will make hundreds of decisions regarding pesticide registration, some involving very extensive risk assessments, while others require more limited reviews. For example, in fiscal year 2002, EPA registered 26 new pesticide 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