

Disinfection Byproducts Rule (DBPR) to provide greater protection against risks associated with microbial pathogens and disinfection byproducts in drinking water. The Committee provided consensus recommendations for the LT2ESWTR and Stage 2 DBPR in September 2000, as stated in an Agreement in Principle (65 FR 83015, December 29, 2000). In this meeting, EPA will inform the Committee regarding the status of development of the LT2ESWTR and Stage 2 DBPR.

Dated: November 25, 2002.

**Cynthia C. Dougherty,**

*Director, Office of Ground Water and Drinking Water.*

[FR Doc. 02-30461 Filed 11-29-02; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7414-9]

### Meeting of the National Drinking Water Advisory Council

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with section 10(a)(2) of Public Law 92-423, "The Federal Advisory Committee Act," notice is hereby given of the forthcoming conference call meeting of the National Drinking Water Advisory Council (Council), established under the Safe Drinking Water Act, as amended (42 U.S.C. 300f *et seq.*). The Council will discuss underground injection control with respect to the practice of hydraulic fracturing for coal-bed methane production.

**DATES:** The meeting will be held on December 12, 2002, from 10 a.m. to 1 p.m., Eastern Standard Time.

**ADDRESSES:** Council members will teleconference into Room 2123 of the EPA East building, which is physically located at 1201 Constitution Avenue, NW, Washington, DC. A limited number of additional phone lines may be available for members of the public who are outside of the Washington DC metropolitan commuting area and are unable to attend in person. Any additional teleconferencing lines that are available will be reserved on a first-come, first-serve basis by the Designated Federal Officer.

**FOR FURTHER INFORMATION CONTACT:** Members of the public who would like to attend the meeting, present an oral statement, submit a written statement in advance, or make arrangements to teleconference into the meeting should

contact Brenda Johnson, Designated Federal Officer, National Drinking Water Advisory Council, by December 6, 2002. Ms. Johnson can be reached at (202) 564-3791; by e-mail at [johnson.brendap@epa.gov](mailto:johnson.brendap@epa.gov), or by regular mail at U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water (M/C 4601M), 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

**SUPPLEMENTARY INFORMATION:** The Council encourages the public's input and will allocate a portion of the meeting for this purpose. To ensure adequate time for public involvement, oral statements will be limited to five minutes, and it is preferred that only one person present the statement on behalf of a group or organization. Any person who wishes to file a written statement can do so before or after a Council meeting. Written statements received prior to the meeting will be distributed to all members of the Council before any final discussion or vote is completed. Any statements received after the meeting will become part of the permanent meeting file and will be forwarded to the Council members for their information.

Dated: November 25, 2002.

**Cynthia C. Dougherty,**

*Director, Office of Ground Water and Drinking Water.*

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0311; FRL-7283-7]

### Endangered Species Protection Program Field Implementation

**AGENCY:** Environmental Protection Agency (EPA or Agency).

**ACTION:** Notice of proposed field implementation approach and request for comment.

**SUMMARY:** EPA's Office of Pesticide Programs is describing, and requesting comment on, implementation of its Endangered Species Protection Program (ESPP, or the Program). The goal of the ESPP is to carry out responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in compliance with the Endangered Species Act (ESA), while at the same time not placing unnecessary burden on agriculture and other pesticide users. This Notice describes how EPA proposes to implement its responsibilities under section 7(a)(2) of ESA by completing and upgrading

County Bulletins, amending pesticide labels to reference County Bulletins, and enhancing monitoring programs.

Regulations found at 50 CFR part 402 acknowledge that there may be Federal programs for which revisions to standard regulatory processes could result in more effective and efficient coordination among Federal agencies and thus, more effective and efficient protection of listed species. As such, those regulations (50 CFR part 402) allow Federal agencies to establish alternate procedures, applicable to specific Federal programs, for satisfying the provisions of ESA section 7(a)(2). Those alternate procedures are known as counterpart regulations.

Through a separate Advance Notice of Proposed Rulemaking (ANPR) to be issued on or about the same date as this Notice, EPA, the Department of the Interior (DOI), and the Department of Commerce (DOC) are seeking public input on ways that such counterpart regulations could improve the ESA consultation process with respect to pesticide registrations. Similarly, implementing regulations under FIFRA may be revised to ensure a more effective program.

The docket for this Notice (docket identification number OPP-2002-0311) includes a summary of the current technical review and consultation approaches employed by the Agency, and the standard evaluation procedure used for ecological risk assessments. That information has been subject to public comment in the past, has been used during EPA's Interim Endangered Species Protection Program, and will continue to be used until the Agency, DOI and DOC take comment on these aspects of the Program through the ANPR and modify them as appropriate. **DATES:** Comments, identified by docket ID number OPP-2002-0311, must be received on or before March 3, 2003. **ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of this Notice.

**FOR FURTHER INFORMATION CONTACT:** Mary Powell, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-7384; fax number: (703) 308-3259; e-mail address: [powell.mary@epa.gov](mailto:powell.mary@epa.gov).

**SUPPLEMENTARY INFORMATION:** This Notice is organized into four units. Unit I. provides general information about applicability of this Notice, availability of additional information, and how to

comment on the Notice. Unit II. provides background information, including the Agency's legal authority for taking this action, the Interim ESPP, and EPA's efforts to develop this proposed field implementation approach. Unit III. describes the proposed field implementation of the ESPP, and Unit IV. provides the references cited throughout this Notice.

While the Agency seeks comments on any aspect of this Notice, it also is hoping to obtain input on certain specific aspects. Within the various units of this Notice, EPA has indicated specific issues on which the Agency is particularly interested in obtaining comment. These issues are noted within the appropriate units under a subheading of "Specific Input Requested." Further, the Agency seeks comment on whether any aspect of this field implementation proposal is more appropriately addressed through the counterpart regulations that are the subject of a separate ANPR, to be published by the Agency, DOI, and DOC on or about the same date as this Notice.

## I. General Information

### A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to farmers; pesticide registrants; pesticide users; agricultural trade associations; public interest groups; groups involved in or interested in endangered species protection; and local, State, Tribal, U.S. Territory, and Federal government agencies. Because other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-0311. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the

Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in

EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

### C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number (in this case, number OPP-2002-0311) in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is

EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2002-0311. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID Number OPP-2002-0311. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2002-0311.

3. By hand delivery or courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA., Attention: Docket ID Number OPP-2002-0311. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

#### *D. How Should I Submit CBI To the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or

CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find these suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number (in this case, docket ID number OPP-2002-0311) in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

## **II. Background Information on the Endangered Species Protection Program**

### *A. Authority and Responsibility under FIFRA and ESA*

Since 1970, EPA has had responsibility for regulating the sale, distribution and use of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). EPA has granted registrations, or licenses, to thousands of pesticides containing hundreds of active ingredients and has continuing oversight over such actions. These registrations encompass thousands of different use sites and practices across the United States.

FIFRA as amended (7 U.S.C. 135 *et seq.*) governs the regulation of pesticides in the United States. Under FIFRA, a pesticide product may be sold or distributed in the United States only if it is registered or exempted from registration by EPA. Before a product can be registered unconditionally, it must be shown, among other things, that the pesticide, when used in accordance with widespread and commonly recognized practice, will not generally cause "unreasonable adverse effects on the environment" (section 3(c)(5)). FIFRA defines this standard 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" the pesticide (FIFRA section (2)(bb)(1)). This is known as the FIFRA risk/benefit standard.

Amendments to FIFRA in 1988 required that in addition to the original registration decision, all pesticides first registered before November 1984 be reviewed against more up-to-date data requirements and standards, and decisions made about whether these pesticides should be "reregistered" (FIFRA section 4(a)). FIFRA was amended again in 1996 with enactment of the Food Quality Protection Act. FQPA put into place a new standard for assessing human dietary risk (FIFRA section 2(bb)(2)), but it did not alter the risk benefit-standard of section 2(bb)(1) for assessing ecological risk. It also required that EPA periodically review pesticide registrations (establishing a goal of such review every 15 years) to determine whether such registrations meets the requirements of the Act (FIFRA section 3(g)(1)(A)).

Congress enacted the ESA (16 U.S.C. 1531 *et seq.*) to protect and promote the recovery of animal and plant species that are threatened or in danger of becoming extinct and to ensure that the critical habitat upon which they depend is not destroyed or adversely modified. The ESA institutes certain prohibitions against "taking" threatened or endangered (listed) species.

Section 7(a)(1) of the ESA, 16 U.S.C. 1536(a)(1), requires Federal agencies use their authorities in furtherance of the purposes of the Act, by carrying out programs for the conservation of listed species. Public Law 100-478, October 7, 1988, amended the ESA and states that EPA should fulfill its obligation to conserve listed species, while at the same time considering the needs of agriculture and other pesticide users. Section 7(a)(2) of the ESA, 16 U.S.C. 1536, and the implementing regulations at 50 CFR part 402, further require Federal agencies to ensure that their

actions are not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat. This duty extends to licensing activities such as the registration of pesticides by EPA. In meeting the section 7(a)(2) requirement, EPA must consult with the Services regarding the effects of Agency actions on listed species. In fulfilling this requirement, Federal agencies must use the best scientific and commercial data available. The Secretary of the Interior has delegated the interagency consultation responsibilities to the U.S. Fish and Wildlife Service; the Secretary of Commerce has delegated the interagency consultation responsibilities to the National Oceanic and Atmospheric Administration.

EPA and the Services are currently engaged in a number of separate, but related activities relative to EPA's responsibilities under the ESA. First, under ESA section 7(a)(1), EPA and the Services are engaged in an ongoing Proactive Conservation Review. This review of EPA's ESPP, is intended to clarify for the Federal agencies, EPA's approach to risk assessment, criteria that indicate a listed species may be at risk, and the requirements imposed on EPA by the ESA regulations governing consultation. The review will also identify areas or issues relative to risk assessment, criteria and consultations that may require modification to ensure an effective and efficient process of consultation among EPA and the Services. While this review is conducted under ESA section 7(a)(1), the outcomes of the review will likely be used to help focus discussions on technical and science policy issues that need to be addressed in order to effectively carry out responsibilities under ESA section 7(a)(2).

As noted in the **SUMMARY** section of this Notice, EPA and the Services are also publishing an ANPR, at or about the same time as publication of this Notice. The purpose of the ANPR is to gain public input relative to the consultation, technical, and science policy issues that need to be addressed in order to effectively carry out responsibilities under ESA section 7(a)(2).

As part of the ESPP, this **Federal Register** Notice proposes a field implementation plan for putting in place any protection measures necessary to ensure EPA's compliance with ESA section 7(a)(2). This plan, once final, will be used to put in place protection measures identified through consultations with the Services. EPA may also use this implementation

approach as appropriate, to put measures in place necessary to protect listed species, even in the absence of a Biological Opinion from the Services.

#### *B. EPA's Role*

1. *ESA section 7(a)(1) obligations.* As noted in Unit II.A. above, EPA has responsibilities under both section 7(a)(1) and 7(a)(2) of the ESA. Under section 7(a)(1), EPA uses its authorities to conserve listed species, in consultation with the Services. The Proactive Conservation Review discussed in Unit II.F.2. is being carried out under section 7(a)(1) of ESA. In addition, EPA has carried out a number of other activities intended to conserve listed species including: Hosting a Wb site that contains listed species fact sheets and a county-scale data base of listed species occurrences; maintaining a toll-free telephone number for public inquiries relative to pesticide use and listed species protection; and producing and disseminating educational materials for students. Additionally, EPA has worked with State agencies responsible for pesticide programs, to ensure that pesticide applicators certified by the States, receive information during their certification training, relative to endangered species protection needs.

2. *ESA section 7(a)(2) obligations.* Under section 7(a)(2) of ESA, EPA must ensure that its actions are "not likely to jeopardize the continued existence of any" listed species or "result in the destruction or adverse modification of" their designated critical habitat. In carrying out its responsibilities, EPA's challenge is how to implement FIFRA, a risk/benefit statute, in a way that ensures compliance with the requirements of the ESA mandate to protect listed species and to do so at use sites that are geographically, ecologically, agronomically, and economically diverse and changeable. EPA seeks to carry out these protections for thousands of pesticide products in ways that users can be expected to implement reliably and routinely without unnecessary burden.

The Agency is responsible for reviewing information and data to determine whether a pesticide product may be registered for a particular use. As part of that determination, the Agency assesses whether listed species or their designated critical habitat may be affected by the use of the product. If EPA determines that the action may affect a listed species, the interagency coordination regulations require the Agency to enter into a process with the Services called "consultation" (50 CFR 402.14). The consultation process is designed to ensure that the Agency

action is not likely to jeopardize the continued existence of a listed species or result in destruction or adverse modification of its designated critical habitat (ESA section 7(a)(2)). Following consultation, the Agency is responsible for implementing protections, if necessary, through its available authority. More information on "may affect determinations" and consultations may be found in Unit II.D. EPA must also "confer" with the Services if its actions may jeopardize the continued existence of species proposed for listing or result in destruction or adverse modification of habitat proposed for designation as critical habitat. Consultation is not necessary if EPA determines that a particular action will have "no effect" on listed species or designated critical habitat. (See Unit II.D.1.c. for a discussion of "no effect determinations.")

#### *C. The Roles of FWS and NOAA Fisheries*

DOI's U.S. Fish and Wildlife Service (FWS) administers the ESA for most species. DOC's National Marine Fisheries Service (NOAA Fisheries) administers the ESA for certain listed marine and anadromous species. Both FWS and NOAA Fisheries (jointly, the Services) enter into formal or informal consultation or conference with EPA concerning effects to listed species and species proposed for listing as well as effects on critical habitat. The consultation process is described in Unit II.D.3. below. The Services may determine whether an EPA action is likely to cause jeopardy to the continued existence of a species and if so, the Services may propose reasonable and prudent alternatives to the action to avoid jeopardy. The Services may also issue incidental take statements that authorize takings of listed species incidental to certain Federal actions.

#### *D. Effects Determinations and Consultations*

In the past, EPA has conducted a number of consultations with the Services. The Agency's experience with those has demonstrated that the agencies need to reexamine their programs to improve both the efficiency and effectiveness of consultation. EPA and the Services are currently participating in a joint Proactive Conservation Review (see Unit II.F.2.) to explore potential modifications for better integrating the FIFRA and ESA processes. The Agency, DOI and DOC are seeking public input on the consultation process and EPA's endangered species assessment

processes through a separate ANPR, to be published on or about the same date as this Notice, and intend to address these provisions through counterpart regulations. Similarly, subsequent to the ANPR, certain FIFRA regulatory processes may be reviewed for possible revisions that could make the program more efficient or effective.

While the Agency is not seeking comment on these aspects of its protection efforts through this Notice, it is including a summary of its current process for making effects determinations and consulting with the Services in Unit II.D.2. below, for purposes of providing context to the reader.

1. *Effects determinations.* To the degree possible, endangered species issues are and will be addressed within the Agency's existing processes of registration and reregistration. Concurrently, the Agency will review those pesticides that have been through reregistration and that may affect listed species, or did not undergo ESA review during reregistration.

EPA has no standard data requirements for endangered species effects determinations, beyond those normally required during registration and reregistration. However, in making such effects determinations in the past, the Agency has requested data for specific listed species concerns, and may continue to do so in the future. As the Proactive Conservation Review and ANPR move forward (see Unit II.F.2.), and as EPA begins to meld the process for making these determinations into existing registration and reregistration activities, the Agency may revisit the necessity for identifying data requirements specific to listed species.

The potential of a pesticide to directly affect any particular species is based on two factors: The toxicity of the chemical to the species, and exposure. The latter includes the estimated environmental concentrations (EECs) that would result from labeled use of a pesticide and the potential for actual exposure of the species of concern to those EECs. Direct effects may be in either of two broad categories: Acute effects or chronic effects, including both lethal and sublethal effects. Species may also be affected indirectly through modification of their habitat or through effects on their food supply. EPA relies on a wide range of environmental data to assess the potential effects of pesticides on listed species. These data include toxicological studies, laboratory and field studies of the fate and transport of pesticides, mathematical fate and transport models, and field studies

monitoring pesticide concentrations and adverse effects to non-target organisms.

a. *Acute lethal and sublethal effects.* Acute data are derived from toxicity tests with lethality as the primary endpoint. The standard acute tests submitted for pesticide registration also include analysis of observable sublethal effects. For example, a typical acute test for a fish will include concentrations that cause no mortality and often no observable sublethal effects, as well as concentrations that would cause 100% mortality. Sublethal effects may or may not be observed at concentrations below that which cause 100% mortality. Where sublethal effects are observed, the Agency includes such information in its assessment of whether a pesticide may affect a listed species. The effects at test concentrations can be used to statistically predict the effects likely to occur at various pesticide concentrations; a well-done test can even be extrapolated to concentrations below those tested (or above the test concentrations, if the highest concentration did not produce 100% mortality).

b. *Chronic lethal and sublethal effects.* Potential chronic effects of a pesticide can be evaluated based on several types of tests and conducted on one of several possible species, depending on the listed species of interest. For example, chronic tests for a listed bird could be conducted on the mallard or bobwhite quail, whereas such tests for a listed estuarine species would be conducted on mysid shrimp. Chronic tests primarily evaluate the potential for reproductive effects and effects on the offspring. Other observed sublethal effects are also required to be reported. An abbreviated chronic test is usually the first chronic test conducted and will indicate the likelihood of reproductive or chronic effects at relevant concentrations. If such effects are found, then a full life-cycle test will generally be required. If the nature of the chemical is such that reproductive effects are expected, the abbreviated test may be skipped in favor of the full life-cycle test. These chronic tests are designed to determine a "no observable effect level" (NOEL) and a "lowest observable effect level" (LOEL).

c. *Assessment.* EPA typically evaluates the potential of a pesticide to affect listed species by conducting a screening level assessment and, if necessary, a species-specific assessment. During the screening level assessment process, the Agency generally does not determine whether in fact any specific threatened or endangered species may be affected by the pesticide, but merely whether a concern would exist if a

threatened or endangered species were exposed to the EECs, given the toxicity of the specific pesticide to the species. The screening steps start out very conservative and become more refined with each step. EPA determines that there is "no effect" on listed species if, at any step in the screening level assessment, no Levels of Concern (LOCs) are exceeded. After EPA performs all the available steps in the screening level assessment, a pesticide may still exceed the Agency's LOCs for listed species (see Unit II.D.1.d.). The Agency will then conduct a species-specific assessment to make effects determinations for individual listed species and their designated critical habitat. Units II.D.1.d. through II.D.1.g. provide an example of this process for aquatic species. Similar steps are undertaken for terrestrial species.

d. *Screening level assessment.* EPA begins its screening level assessments by conducting a basic ecological risk assessment that uses available data and generally conservative assumptions to establish the EEC. EPA then uses increasingly specific methods and data and more refined exposure models to refine the EEC of the pesticide. Where available, EPA may also use field monitoring data for a variety of purposes. At each screening step, the more refined EEC is compared to the toxicity of the pesticide active ingredient to determine whether the pesticide exceeds LOCs established for listed aquatic and terrestrial species. EPA's Standard Evaluation Procedure for Ecological Risk Assessment (June, 1986. EPA-540/9-85-001) provides that LOCs are exceeded for acute effects on listed species when the EEC of a pesticide is greater than 1/20th the LC<sub>50</sub> for appropriate aquatic species or 1/10th the LC<sub>50</sub> or LD<sub>50</sub> for appropriate terrestrial species. Thus, under current practices, the LOCs for listed species incorporate an extra level of protection that is not used in the LOCs for other non-target species. (LC<sub>50</sub> is the statistically derived estimate of concentration expected to cause 50% lethality. LD<sub>50</sub> is the statistically derived estimate of oral dose expected to result in 50% lethality.) LOCs are exceeded for chronic and/or reproductive effects when the EEC exceeds the NOEL in appropriate studies.

In the first step of EPA's screening level assessment, the Agency uses a quantitative comparison between the default EEC and the toxicity of the chemical. A default EEC is based on application rates from pesticide labels and on extremely conservative assumptions of movement of the pesticide to water rather than on actual

chemical fate and transport data. Toxicity values for the pesticide are taken from data submitted by pesticide registrants to support their registration request. The application rate is determined from pesticide labels. EPA then compares the toxicity values with the default EEC to determine whether the pesticide exceeds EPA's endangered species LOCs. If no LOCs are exceeded, the pesticide has "no effect" on listed species and the analysis ends. However, if an LOC is exceeded, EPA may proceed to the next screening step to refine its assessment.

In this next step, the Agency refines its ecological risk assessment by running the GENEEC (generic EEC) model with a variety of inputs on application methods and rates, and chemical fate and transport data to calculate the EEC. Running this model provides a more refined EEC for comparison with the toxicity data. Again, if an endangered species' LOC is exceeded at this step, EPA may proceed to the next step to further refine its assessment. If the model described below is not available for the particular use scenario being evaluated, EPA would typically move to a species-specific assessment as described in Unit II.D.1.e. below.

In the next step, the Agency uses a much more sophisticated model the Pesticide Root Zone Model-Exposure Analysis Modeling System (PRZM/EXAMS) to calculate more refined EECs. This model includes more chemical fate and transport data, and it involves selecting a use site (e.g., wheat or apples) scenario and modifying the scenario to reflect the nature of the pesticide use. These scenarios are based upon actual field data on crop location, extent to which the crop is grown, soil characteristics, climate, etc. Use site scenarios exist only for major and a few minor crops, and would need to be developed to run this model for other crops. If an endangered species LOC is exceeded at this step, a species-specific assessment is conducted.

e. *Species-specific assessment.* To conduct a species-specific assessment, EPA takes the basic quantitative information from its screening level assessment developed for all non-target organisms and puts that information in context for individual listed species and their locations. Important ecological parameters such as stream flow rates and soil types, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species are typically considered. Where reliable, published

data are not available, information for such parameters is typically obtained through contacts with knowledgeable experts, including extension agents, crop advisors, resource specialists, and watershed experts. These steps enable the Agency to refine its generic assessment into one specific to individual listed species and their designated critical habitat. If LOCs are exceeded after this analysis, the Agency may work with the registrant to determine whether sufficient protection measures can be incorporated into the registration or reregistration to achieve a no-effect determination. Only if those efforts are unsuccessful will EPA declare a "may affect determination."

f. *Use of field monitoring in assessing risks.* Field monitoring data can supplement modeling and provide a more direct means to assess whether species may be exposed to the pesticide at a level sufficient to cause an effect, if the monitoring program was designed or is appropriate for this purpose. For example, using monitoring data where water samples are obtained one time per quarter year does not necessarily provide information from which exposure levels can be determined, although data can alert EPA to locations where pesticide exposure may be occurring to trigger further assessment or analysis. However, even in cases where appropriately designed monitoring was conducted, EPA would still typically conduct exposure modeling when field monitoring data do not exist for all species locations, and EPA would still typically conduct a species-specific assessment, as described in Unit II.D.1.e. above, to determine whether a particular species may be exposed to the monitored levels of the pesticide.

In summary, EPA typically evaluates the potential of a pesticide to affect listed species by conducting increasingly refined screening level assessments, and, if necessary, a final species-specific assessment.

2. *Consultation procedures.* Service regulations provide for two types of consultations once a "may affect determination" has been made.

a. *Informal consultation.* Informal consultation is an option available to an action agency (in this case EPA) to assist the action agency in determining whether formal consultation is required. During this process, the Services can suggest modifications to an EPA action to avoid the likelihood of adverse effects to a listed species or its designated critical habitat. The informal consultation process is completed with a written concurrence by the Services with EPA's determination that its action

is "not likely to adversely affect" listed species or designated critical habitat. If the Services do not concur with EPA's finding of "not likely to adversely affect," then formal consultation must be initiated.

b. *Formal consultation.* Formal consultation is required if the Agency determines that a pesticide may affect or is likely to adversely affect a listed species or critical habitat. In this case, EPA makes a written request for formal consultation with the Services on a particular Agency action (i.e., a pesticide registered for a specific use).

Basically, a consultation package consists of EPA's assessment of the potential for a listed species or designated critical habitat to be adversely affected by the registration of a particular pesticide. More specifically, the package includes a description of the action under consideration, areas that may be affected, listed species or critical habitats at issue, a description of the manner in which the action may affect any listed species or critical habitat, and an analysis of cumulative effects and any relevant reports. The consultation package must use the best scientific and commercial data available.

In response, the Services develop and provide to EPA a Biological Opinion, which provides the Services' opinion on whether the use of the pesticide in question is "likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat" (50 CFR 402.14(g)).

If a Biological Opinion concludes that an action is likely to jeopardize a listed species or adversely modify its designated critical habitat, then the Biological Opinion will include "reasonable and prudent alternatives," if any, that EPA may undertake to avoid the likelihood of jeopardy to the species or destruction or adverse modification of critical habitat. Reasonable and prudent alternatives (50 CFR 402.02) are actions that:

(1) The consulting agency is capable of implementing under its authority and jurisdiction.

(2) Allow the agency action to be implemented in a manner consistent with its intended purpose.

(3) Are economically and technologically feasible.

(4) Are not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat.

Biological Opinions will frequently include information for use in implementing protections. For those few species that the Services determine are

subject to collection threats, the Services generally will encourage development of alternative protections, such as landowner agreements (see Unit II.E.3.b. for more information on landowner agreements).

Biological Opinions may also include an "incidental take statement." For listed species, to "take" means "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (ESA section 3). Incidental take refers to takings that result from, but are not the purpose of, carrying out an otherwise lawful activity (50 CFR 402.02). Incidental take statements specify, among other things, the amount or extent of any anticipated incidental taking (e.g., the number of individuals) and the "reasonable and prudent measures" needed to minimize the impact of such a taking. The Biological Opinion may contain reasonable and prudent measures to reduce the impact of incidental take, even if no jeopardy to the listed species is found. If the amount or extent of taking specified in the incidental take statement is exceeded, EPA must reinstate formal consultation (50 CFR 402.16(a)). The incidental take statement also conveys to the action agency, any applicant to the agency, and any users of the product an exemption from the take prohibitions of the ESA, provided that the action is implemented in a manner consistent with the reasonable and prudent measures included with the incidental take statement (ESA section 7(o)(2)).

Reinitiation of consultation must occur if new information reveals effects of the action that may affect listed species or critical habitat in a manner or extent not previously considered; if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the Biological Opinion; or if a new species is listed or critical habitat designated that may be affected by the identified action (50 CFR 402.16).

#### *E. Initial Efforts at Program Implementation*

EPA's past efforts to carry out its responsibilities under FIFRA and ESA fall into three areas: Assessment and consultation; implementation of protections; and an interim Program that relies on education, cooperation and public outreach.

1. *Assessment and consultation.* EPA has been consulting with FWS on endangered species issues since 1977, and has used a variety of approaches to these consultations. The various approaches yielded variable results in

terms of efficiency, effectiveness at addressing potential risk to a given species, and equity among pesticide registrants and equity among pesticide users.

a. *"Case-by-case" consultations.* In more than 80 instances, the Agency has assessed the potential effects of a pesticide on all listed species, across all proposed uses of a single pesticide. The benefit to this approach to consultation (one pesticide, all proposed uses) is that it is comprehensive as to the agency action and manageable since it involves a single pesticide. The major drawbacks to this approach resulted from use limitations being proposed for a specific pesticide while competing pesticides that may also pose risks to species had not yet been reviewed.

b. *"Cluster" consultations.* In order to mitigate the potential inequity to competing registrants from the case-by-case approach, the Agency engaged the FWS in several "cluster" consultations. These consultations were based on an assessment of all pesticides registered for use on certain crops. For example, in the "cotton cluster" EPA assessed and consulted as appropriate on any pesticide registered for use on cotton. By approaching assessment and consultation in this manner, the Agency alleviated the potential inequity of case-by-case consultations since competitive products for the same use were assessed at the same time. However, this approach carried with it certain other problems. The consultations resulting from this approach were much larger and more complex. At the request of the FWS, EPA reinstated consultation on portions of these "clusters" to address newly listed species and obtain "incidental take" statements. The resulting reinitiation encompassed certain uses of 112 pesticides that had the potential to affect one or more of 165 different listed species. For both the original consultations and the reinitiation, the statutory time frame provided for the Services to complete a Biological Opinion proved difficult to meet. This approach, while eliminating the inequity among pesticide registrants, created a potential inequity among pesticide users. In these cluster consultations, a pesticide was assessed for one crop, but not for other crops for which it was registered. If the assessed crop was grown adjacent to the unassessed crop, growers of the one crop could face use limitations while growers of the other did not.

c. *"Species-based" consultations.* A third approach to assessment and consultation was intended to ensure that a species was completely addressed at once. This "species-based" approach

was used to request formal consultation for 31 pesticides. Under this approach, the Agency and the Services identified the species most vulnerable to effects from exposure to pesticides; identified all the pesticides to which that species might be exposed; and identified all other species that might be exposed to those uses of these pesticides. The Agency's consultation would encompass any combination of these factors that produced a "may affect determination." Because of the diversity of uses of these pesticides and the large number of species potentially affected, it was necessary to divide the consultation into two parts. FWS has completed part I. EPA asked FWS to suspend work on part II while EPA and the Services undertake the ESA Section 7(a)(1) Proactive Conservation Review to facilitate the overall consultation process (see Unit II.F.2. for more information on the Proactive Conservation Review). The benefits of this approach appear to be that a particular species would be protected from all pesticide exposures with a potential to harm the species, at one time. However, because of the complexity of these assessments, the time necessary to identify protections is protracted significantly.

2. *Implementation of protections.* In the past, EPA has proposed several approaches for implementing an endangered species protection program (53 FR 7716, March 9, 1988; 54 FR 27984, July 3, 1989). Under these previous proposals, product labels would have been amended, where necessary, to instruct users to follow specific use limitations. These limitations would have been described in County Bulletins developed by EPA to protect listed species in their area. Bulletins would contain general information about the ESPP, a map of the county depicting areas in which limitations applied, and a table indicating the particular use limitations for specific pesticides in specific areas of the county. States and Tribes would have had the option to initiate and propose to EPA alternative plans for protecting listed species in their area. If EPA deemed these plans to be feasible, and the Services deemed them protective of the species, EPA would adopt the provisions of the plan as the Federal requirements for that State or Tribe.

Other elements of implementation would have included public participation, to include the opportunity for comment on the maps and County Bulletins and State-initiated plans (Unit III.F.).

Moving forward with a final program implementation scheme did not seem feasible at those earlier points in the history of the program's development. There remained significant issues with potential resulting inequities and resource implications created by the variety of priority setting schemes for assessment and consultation. There also was concern that County Bulletins, enforceable under FIFRA misuse provisions, did not provide sufficient flexibility for pesticide applicators to exercise judgement based on local conditions, to protect listed species in ways that posed the least burden. Consequently, EPA decided, for the interim, to maintain its case-by-case approach to assessment and consultation and to conduct a voluntary ESPP to protect listed species and their habitats. As part of this interim program, EPA has undertaken a number of activities designed to address efficiency, effectiveness and equity issues and to develop an improved ESPP implementation plan.

3. *Interim program.* The interim ESPP relies on education, cooperation and public outreach to achieve its goals. The interim ESPP involves the voluntary participation of States and pesticide users, typically through the use of Interim Pamphlets as described below. Some States also have participated in the program by developing and piloting State-initiated plans to protect listed species within that State. Key components of the interim ESPP include:

a. *Distributing Interim Pamphlets.* These Pamphlets, which are precursors to the County Bulletins, were developed for voluntary use during the Interim ESPP to encourage the protection of listed species. Based largely on Biological Opinions, the Pamphlets include the name of the species of concern, a table of the pesticides that may harm that species, a description of the use limitations necessary to protect the species, and a county-level map showing the geographic areas associated with these use limitations. The type of map and level of detail depends in part on the sensitivity of the listed species to other factors, such as collection. (See Unit III.B. for distribution procedures and more information on County Bulletins.)

b. *Developing State- and Tribe-specific approaches.* Several States have developed alternative approaches to protecting certain listed species during the Interim Program. For example, Minnesota and Wisconsin have succeeded in protecting listed plants by developing landowner agreements with private individuals. These agreements

identify protective measures specific to the geographic area involved in the agreement and are made with FWS and the appropriate State agencies.

California has put a program in place whereby use of particular pesticides requires a State permit, the provisions of which take into account the proximity of use to a listed species. Still others have proceeded under the general direction of the Agency's Interim Program but have developed alternatives to county mapping that better communicate protection measures to their citizens.

#### *F. Development of this Implementation Proposal*

In developing this implementation proposal, EPA considered information and comments from a number of sources. Those sources included public comments submitted in response to past proposals and other information described below.

1. *EPA initiatives.* EPA has been working on the technical aspects of the ESPP. These efforts include collecting additional data on species biology and habitat locations, agricultural crop and other pesticide use locations, and pesticide toxicity and exposure. In certain cases, additional research was conducted that specifically provided data needed to address risks to listed species. Examples include studies on herbicide effects on cacti, and effects of insecticide use on terrestrial snails.

As required by Public Law 100-478, October 7, 1988, EPA completed and submitted a report to Congress titled "Report to Congress on the Endangered Species Protection Program as it Relates to Pesticide Regulatory Activities." The report describes the joint efforts by EPA, USDA, and FWS to determine the effects of pesticide use on listed species. It also summarizes EPA's efforts to communicate use limitations to pesticide users, to determine alternatives to outright prohibitions, to develop and distribute accurate maps of use limitation areas related to listed species, and to improve communications among EPA, USDA, and FWS.

2. *Proactive Conservation Review.* In a joint effort with the Services, the Agency has undertaken a Proactive Conservation Review, authorized under ESA section 7(a)(1). EPA and the Services are analyzing the processes EPA uses to determine whether a pesticide may affect a listed species and to assess generic mitigation measures. The Services and EPA have agreed to explore issues relative to five specific areas: (1) EPA's test methodologies, (2) environmental exposure assessment

processes, (3) risk assessments, (4) conservation measures, and (5) follow-up to EPA action to ensure continuing protection and conservation of listed species. One product of the Proactive Conservation Review will be a handbook setting forth the processes and procedures that will be followed by EPA, NOAA Fisheries and FWS relative to species conservation, pesticide consultations, and protection measures for listed species deemed to be potentially affected by pesticide exposure.

3. *EPA Regional programs.* EPA Regional offices continue to act as liaisons with State lead agencies (SLAs) for pesticide regulatory activities, Tribes and U.S. territories; train State representatives in the ESPP; distribute program materials; contribute to the development of educational and outreach materials; and work closely with States in developing State-initiated plans.

4. *State efforts.* To ensure that the county maps delineating the pesticide use limitation areas are precise and reflect the result of assessments that were based on currently occupied habitat, EPA has continued to work with the States, FWS, and USDA in developing, reviewing and revising the maps. Opportunity also has been provided for their comment on the specific pesticide use limitations for individual species.

State involvement varies, but review usually includes participation by the SLA responsible for pesticide programs at the State level (usually the State Department of Agriculture), State heritage and conservation agencies, the pesticide coordinator for pesticide applicator certification and training, and others. EPA has encouraged the States to include a balanced role for representatives of non-government environmental groups and the pesticide user community as well.

States continue to play an active role in other aspects of the ESPP. Their efforts include developing State-initiated plans, incorporating endangered species modules into pesticide applicator certification and training programs, refining species location information, and providing input on the future directions of the ESPP and ways to achieve program goals more effectively.

5. *National partners' workshops.* As EPA began to revitalize the ESPP, three national workshops were held (in 1997, 1999 and 2001). The purpose of these workshops was to seek input on future directions of the ESPP and on ways to achieve goals more effectively. These workshops resulted in the formulation



of the framework for this final program proposal.

At the heart of each of these workshops was the discussion of a range of practical, nuts-and-bolts solutions for furthering endangered species protection consistent with the ESA. A few dominant themes were apparent throughout: To better protect threatened and endangered species, everyone involved needs to communicate better; to share information, data and resources; and to identify and focus on priorities to make better use of limited resources. While the use of technology to foster endangered species protection is crucial, consideration must also be given to non-technological alternatives and innovative practices (see Unit III.E.3.b. for some examples).

### III. The Endangered Species Protection Program - Field Implementation Proposal

EPA's implementation proposal is based on two goals. The first is to provide appropriate protection to listed species and their habitats from potential harm due to pesticide use. The second is to avoid placing unnecessary burden on pesticide users and agriculture.

The following sections describe the elements of EPA's proposed approach to implementing endangered species protections under existing ESA regulations. These elements include: Scope, approach to reviewing pesticides, completing and upgrading County Bulletins, amending pesticide labels to reference County Bulletins, enhancing monitoring programs, compliance and enforcement, and public participation. Finally, this section describes the role of States and Tribes in the Program, implementation timing, and program maintenance.

#### A. Scope of the ESPP

All pesticide products for which EPA makes a "may affect" determination may be subject to the ESPP.

1. *Indoor products determination.* EPA has determined that pesticide products bearing label directions only for use indoors, and where the applied pesticide remains indoors, will not result in exposure to listed species. Therefore, these products will have "no effect" on listed species and generally would not be subject to the ESPP. Indoor use includes application within transport vehicles and within any structure with enclosed walls and a roof, such as buildings, greenhouses, outbuildings, etc.

This "no effect" determination would not apply to a pesticide that is applied indoors, but could expose outdoor environments (such as pesticides

applied in cooling towers or used as cattle dips). Whether these products result in a "may affect" determination will be assessed on a case-by-case basis. If a "may affect" determination is made for these products, they would be subject to the ESPP.

2. *Public health emergencies.* Under section 18 of FIFRA (40 CFR part 166), a State or Federal public health agency may request that EPA grant an emergency exemption from pesticide registration requirements for a public health emergency if the State or Federal agency can demonstrate that:

a. An emergency, non-routine condition exists that requires the use of a pesticide.

b. Effective registered pesticides or alternative practices are not available or economically or environmentally feasible.

c. The situation will present significant risks to human health.

Public health emergencies, verified by State or Federal public health authorities, include situations in which:

(1) A pest outbreak poses a significant risk to human health or in which the elements for disease outbreak (i.e., virus activity, large population of disease vectors either present or pending, or others) are demonstrated to be in place and prompt action is required to avert an actual disease outbreak, and

(2) An actual disease outbreak is in progress and immediate action is essential to arrest the outbreak.

In the latter case, a crisis exemption under section 18 may be appropriate, which allows a Federal or State agency to authorize the emergency use of a pesticide if its use is critical and enough time is not available for EPA to receive and complete a review of the specific request for a public health exemption. Consultations on emergency actions are conducted in accordance with Service regulations found at 50 CFR 402.05.

Generally, in accordance with the ESA, EPA does not authorize use of a pesticide under section 18 if that pesticide will jeopardize a listed species or adversely modify critical habitat. However, if no practical alternative control measures are available, during a public health emergency, a public health exemption under section 18 may be sought for the use of a pesticide that was found to jeopardize listed species or adversely modify its critical habitat. *Specific Input Requested - Public Health Emergencies*

- Is the above section 18 approach the appropriate mechanism to address potential intersections of public health and listed species protections?

- Should actions relative to public health emergencies require consultation

with the Services, and if so, should it be an emergency consultation?

- What specific alternatives might be appropriate? How do these alternatives allow the appropriate weighing and balancing of public health and listed species protection?

3. *Review of pesticides.* To the degree possible, endangered species issues will be addressed within the Agency's existing review processes of registration and reregistration so that when a registration or reregistration decision is made, it fully addresses issues relative to listed species protection.

Concurrently, the Agency will begin a process to review those pesticides that have been through reregistration review and were found potentially to affect listed species or their critical habitat, or where the potential for effects on listed species or their critical habitat was not considered. This does not limit EPA's ability to make changes in its technical approach nor in its data requirements. EPA and the Services are seeking input relative to the technical and consultation aspects of the program through an ANPR.

EPA attempted several different approaches to prioritizing reviews in the past (see Unit II.E.a. through II.E.c.), each resulting in a different set of issues and each more or less effective in differing ways. EPA's proposed approach of addressing potential effect to listed species on a chemical-by-chemical basis, is not without issues. With any approach, EPA believes the best way to address the issues is to develop a technical and consultation process that allows the Federal Government to make appropriate decisions in a timely manner. By focusing our internal processes to address listed species concerns during registration and reregistration where possible, and by identifying and implementing improvements in the technical aspects of review and in the consultation processes, EPA believes many of the issues resulting from a chemical-by-chemical approach to review will be resolved.

4. *Effect determinations and consultations.* EPA's technical review policies (Unit II.D.) and the Services' technical information and analysis requirements under the ESA section 7 consultation regulations currently form the analytical and procedural bases of EPA's Interim Endangered Species Protection Program. As noted in Unit II.F.2., EPA is engaged in a Proactive Conservation Review with the Services under ESA section 7(a)(1) to analyze, among other things, the processes EPA uses to determine whether a pesticide may affect a listed species. Further, EPA

and the Services will be taking comment through an ANPR on options for counterpart regulations that could amend the existing ESA and FIFRA regulatory regimes in a manner that improves consultations on pesticide actions. Until these efforts are finalized, EPA's current procedures and the Services' existing regulations at 50 CFR part 402 will continue to form the analytical and procedural bases of the ESPP.

#### *B. Completing and Upgrading County Bulletins*

The Interim Pamphlets (Unit II.E.3.) have been the centerpiece of the ESPP. As a top priority, EPA will update existing Pamphlets to reflect all current Biological Opinions, including the identified species of concern, a table of pesticides that may harm those species, and current use limitations to protect listed species. EPA will then convert these Pamphlets to County Bulletins. The Agency will continue to provide access to the Bulletins through its home page on the Internet ([www.epa.gov/espp](http://www.epa.gov/espp)) and improve the distribution network.

The Bulletins will be developed by EPA in cooperation with the Services, USDA, States and Tribes. EPA will generally determine appropriate use limitations and recommendations in the Bulletins by reviewing results of ESA section 7 consultations and any other relevant information that addresses the needs of the listed species. The Bulletins will only be maintained and issued for counties for which protection measures have been deemed necessary. Bulletins will:

1. Identify the species of concern.
2. Name the pesticides that may harm the listed species.
3. Provide a description of the protection measures necessary to protect the species. Where species or habitat descriptions are helpful or necessary to identify use limitations, EPA will also include this information.
4. Contain a county map showing the geographic area associated with the protection measures, depending on the sensitivity of the species to other factors such as collection. Typically, maps will show a shaded area indicating the area where pesticide use should be modified to protect that species. Within shaded areas on the maps, the specific protection measures will be identified for the pesticide and the species being protected.

To ensure precision, EPA has been working with other Federal agencies and the States in revising the maps and the tables of pesticide use. EPA will develop draft maps and tables of

pesticide use limitations and send them to the States, Services, and USDA for review as EPA updates the information for the County Bulletins, or as completion of consultations results in EPA's decision to include additional pesticides or species, or delete currently included pesticides or species. Based on comments from Federal agencies, States and Tribes during the review process, EPA will work with the commenters to resolve any problems and to make any necessary revisions to the Bulletins.

EPA also is working on making the maps easier to use. For example, EPA has been exploring various mapping formats in attempting to convey information to pesticide users most effectively. In some cases, township-range-section designation may be the best way to delineate the habitat of a species, while in other situations, local landmarks such as roads or streams may work more effectively.

The Bulletins also will contain a printing date to indicate the date the Bulletin was issued. As new information becomes available and a Bulletin is revised, EPA will issue a new, revised Bulletin with a new printing date. This Bulletin will supersede the Bulletin previously issued, as identified by the new printing date. EPA will review the County Bulletins as necessary, but generally will not update them more than once annually.

#### *Specific Input Requested - County Bulletins*

County Bulletins will be the main basis for conveying information to pesticide users. The Agency is particularly interested in comment on various aspects of these documents as detailed below. (To facilitate comment, an Interim Pamphlet may be printed from the Web site at [www.epa.gov/espp/usa-map.htm](http://www.epa.gov/espp/usa-map.htm).)

- Are there ways to make the instructions for use easier to understand?
- Is the mapped information depicted in a way that is understandable? For example, is the use of township-range-section designations appropriate?
- Is the use of natural and man-made landmarks appropriate?
- Is it clear what pesticides are subject to what use modifications to protect listed species?
- Are there ways to make the protection measures easier to understand?
- Are the narrative descriptions of habitat or of species as a map supplement helpful?
- How can the Agency make protection areas as specific as possible

without infringing on the privacy of individual landowners, who may be the sole custodians of a species on their property, while still protecting the species and not subjecting the species to potential harm by revealing its specific location?

- How can EPA ensure that growers know they have the most recent Bulletins?
- Is annual updating of the Bulletins the right frequency? If not, how often should EPA update them?
- How can EPA work with States to improve the development of Bulletins?

#### *C. Bulletin Distribution Procedures*

EPA has been developing its distribution plan for Bulletins and other ESPP information. A key factor in developing this plan is to make sources of Bulletins and other information convenient to pesticide users. In addition, different mechanisms may be appropriate for different States and Tribes. As a result, distribution mechanisms could include several or all of the following methods, depending on the State or Tribe:

1. Mechanisms identified by SLAs.
2. Direct mailing to pesticide applicators within an affected county.
3. Pesticide dealers and distributors. Ideally, Bulletins will be available when and where pesticide applicators buy or obtain their pesticides.
4. Cooperative Extension Service, Natural Resources Conservation Service, Agricultural Stabilization and Conservation offices, and USDA county offices in the vicinity of affected counties.
5. The Services' regional and field offices, where appropriate.
6. EPA Headquarters, Regional offices, EPA's toll-free number and Web site.

EPA plans to evaluate these mechanisms continually and to modify any part of the distribution process as the need arises and as more is learned about the effectiveness of the various mechanisms.

#### *Specific Input Requested - Bulletin Distribution*

- Are the mechanisms identified for Bulletin distribution appropriate?
- What other mechanisms would be of value?

#### *D. Amending Pesticide Labels to Reference County Bulletins*

EPA proposes to request label amendments of pesticide products for which protection measures have been identified. This amendment would generally include a statement directing the user to follow the information in the County Bulletin. The label also would include a statement regarding the

potential for effects to listed species. Finally, the label would include information on how the user can obtain the County Bulletin. The County Bulletins, in turn, would contain specific information on species and areas where protection measures were necessary. Such a system would help ensure that pesticide users are aware, before applying pesticides, of both the potential harm to listed species and how they can obtain information necessary to protect listed species.

The Agency has several approaches to requesting label amendments for currently registered pesticides. In Reregistration Eligibility Decisions (REDs), the Agency can make clear its regulatory position on listed species protection and indicate the labeling that would be necessary for products to be considered eligible for reregistration. The Agency also could issue a Pesticide Registration (PR) Notice requesting amendments of pesticide labels for which limitations have been identified to protect listed species or critical habitat. The Agency also could determine that in the absence of the amended label language, the pesticide would no longer meet the risk/benefit standard of FIFRA and would, therefore, be subject to cancellation.

The Agency intends to use the first approach when completion of a listed species and critical habitat assessment and the identification of use limitations coincides with completion of a RED. However, this approach will not work in those instances where these two activities are not coincidental (i.e., the RED is completed ahead of the listed species determinations or vice versa).

To facilitate label changes in these situations, the Agency would first review the existing Interim Pamphlets to determine that the information is current. The Agency then intends to prepare a PR Notice that will generally request registrants of products in those Pamphlets to make label changes relative to listed species. Specific suggested label language would be articulated in the PR Notice. After passage of the time frames that would be articulated in that Notice, products for which revised label statements are requested, and which do not bear that statement, may be considered misbranded under FIFRA section 12(a)(1)(E) and may be subject to a Notice of Intent to Cancel. If necessary, subsequent PR Notices would generally be issued annually to request label changes for additional products. These Notices will also indicate any products that have been removed from the Program.

Because the label statements would not be county-specific or use-site specific, registrants would not need to change their product label once the appropriate changes have been made, if protection measures are extended to new locations or new species need protection. Label changes would be necessary only if the protective measures specified in the Bulletin are rescinded for all uses of the product. As noted in Unit III.H., the Agency intends to take public input on several phases of listed species assessment before implementing new measures.

The Agency proposes the following generic label statement to be adopted for instructing pesticide users about listed species protection:

This product may have effects on federally listed threatened and endangered species or critical habitat in some counties. When using this product, you must follow the measures contained in the County Bulletin for the county in which you are applying the pesticide. To determine whether your County has a Bulletin consult <http://www.epa.gov/espp/usa-map.htm>. Bulletins also may be available from local pesticide dealers, extension offices, or State pesticide agencies.

#### *Specific Input Requested - Labels*

The Agency specifically requests comment on how best to accomplish label changes to protect listed species, where EPA, FWS or NOAA Fisheries has identified use limitations to ensure protection. The Agency also seeks suggestions for specific label language to relay the information articulated in this section.

#### *E. Enforcement*

For pesticide products determined to affect listed species or critical habitat, the Agency is proposing that the product labels carry a statement directing users to follow the appropriate County Bulletin in effect at the time of product application. Another option is that all Bulletins published by an annual date certain will be in effect for 12 months. In either case, pesticide users who fail to follow provisions applicable to their pesticide application, whether that failure results in harm to a listed species or not, would be subject to enforcement under the misuse provisions of FIFRA (section 12(a)(2)(G)).

#### *Specific Input Requested - Enforcement*

In connection with these approaches, EPA seeks public comment on whether:

- Either or both of these approaches provide effective means to implement species protection.
- There are alternative means to ensure appropriate protection of species that may be adversely affected from the use of a pesticide.

#### *F. Enhancing Monitoring Programs*

Evaluating the extent to which the ESPP is protecting and contributing to the conservation of listed species can be accomplished in several ways. Potential options include monitoring to determine the degree to which pesticide users in affected areas are or are not applying pesticides in accordance with the County Bulletins, best management practices associated with landowner agreements, and State-specific approaches.

To determine the feasibility of this type of monitoring, EPA proposes several pilot studies. At least two States would conduct a pilot study with the Agency regarding adherence to information in the Bulletins. States selected for this pilot would be from among those that are currently working on more efficient ways to distribute County Bulletins. EPA also proposes that another State, from among those currently employing landowner agreements in their endangered species protection efforts, pilot a review of the effectiveness of landowner agreements. Finally, the Agency proposes that two additional States assist in piloting a review of the effectiveness of State-specific approaches (Unit II.E.3.b.). Again, the States selected for this pilot would be from among those that have implemented protection programs that vary from EPA's proposal in some significant respect.

Also, it is important that data being collected through acceptable sources be used to the fullest extent possible to maximize efficiencies and minimize costs. EPA proposes to use more effectively the information being obtained by the U.S. Geological Survey to detect pesticides in surface and ground water, information provided to EPA's Office of Water under the Clean Water Act, and State-level ground or surface water monitoring resulting from State pesticide program efforts. EPA will also use the technical data identified during section 7 consultations with the Services. EPA proposes to analyze this information to determine if residues of pesticides are occurring at levels of concern in aquatic environments. Further, EPA proposes to augment these data with targeted terrestrial residue monitoring, possibly to include post-registration monitoring by registrants or others. Locations would be determined with input from the Services and the appropriate State or Tribe, based on proximity of pesticide use sites with species locations. If such pilots result in broader monitoring, this would be conducted as part of the States' or Tribes' ongoing enforcement efforts.

Finally, EPA would continue and improve upon its cooperation with the Services, States, Tribes, and others to review reported incidents in which pesticides have had an impact on listed species and critical habitat. EPA has been working with FWS field offices throughout the country, as well as other Federal and State agencies, to ensure that EPA has the best possible information on incidents. EPA's Environmental Fate and Effects Division maintains an Ecological Incidents Information System. EPA also gathers incident information from registrant reports submitted under FIFRA section 6(a)(2), or those in which pesticide registrants report to the Agency on observed adverse effects.

#### *Specific Input Requested - Enhanced Monitoring*

In particular, the Agency is interested in obtaining public input on the following issues:

- The appropriate role of pesticide registrants and manufacturers in performing environmental monitoring.
- The role incident data could play in protecting listed species and critical habitat.
- Whether there are other ongoing monitoring programs EPA should consider reviewing routinely for information.
- The role the Services should play in monitoring programs.
- Other methods of monitoring that might be appropriate for the agencies to implement.
- How to improve the quality of information on the effects of pesticides on listed species and critical habitat.

#### *G. Role of the States and Tribes*

Because local and State and Tribal circumstances may influence the effectiveness of different approaches to listed species protection, States and Tribes will continue to be integral to the success of the ESPP. Specific roles include review of county maps; review of use limitations to protect species; determining the effectiveness of the program; and, at their discretion, development of alternative approaches for protecting listed species.

1. *Review of county maps.* States and Tribes will be requested to provide input to the Agency on county maps to accomplish several things. First, accuracy of the maps is key to success of relaying information to pesticide users. Therefore, States and Tribes will be requested to provide feedback on draft maps relative to whether they accurately depict landmarks, rivers, roads, etc. Further, State and Tribal input on how best to characterize use limitation areas on the County maps

will be sought. For example, some States believe that their pesticide users would be best served by designating limitation areas based on township-range-section mapping, while other States believe their pesticide users would prefer designations based on natural and man-made landmarks such as rivers, roads and railways.

2. *Review of use limitations to protect species.* States and Tribes also will be requested to provide input to the Agency on any potential use limitations for species protection. The purpose of this review would be for the Agency to ascertain, based on local conditions, whether specific use limitations could be implemented. States and Tribes will also be sources of input on the technological and economic feasibility of implementing any proposed use limitations.

3. *Help determine the effectiveness of the program.* Because States and Tribes are in closer contact with pesticide users than is the Agency, they will be requested to assist the Agency in determining whether the ESPP as implemented is effective in protecting listed species. They also will be requested to assist in determining whether the limitations outlined in County Bulletins are being followed or modified based on local conditions, and whether any generic changes in the County Bulletins would improve the success of this program.

4. *Develop alternative approaches to protect listed species.* States and Tribes may develop and propose alternative plans for protecting listed species in their areas. Such a plan would recommend measures and approaches that EPA could use to protect listed species in that area. If these plans are submitted to EPA for review and approval, EPA will coordinate with the Services and consult, as appropriate, to determine that the provisions of the plan will provide adequate protections for listed species within that State or Tribal land. If EPA approves the plan following any necessary consultation with the Services, EPA would then adopt it and could require, through Bulletins, that users comply with the requirements of the plan. Alternative plans can be developed for all or a portion of the species affected in that State or Tribal land.

An alternative plan may be submitted to EPA at any time. However, once the federally initiated actions are implemented within an area, those requirements will be effective in that area until the alternative plan is approved for implementation.

#### *H. Public Participation*

EPA has encouraged the involvement of Federal agencies, States, Tribes and members of the public throughout the development of the ESPP and will continue to provide opportunities for public participation once the program is final. EPA intends the final ESPP to be as flexible as possible and to modify it as necessary to achieve the goals of protecting listed species and minimizing the impact on pesticide users. Eventually, the ongoing program will meld its components of public participation with existing practices in the registration and reregistration processes.

EPA will always welcome comments from the public on the various aspects of the program. EPA intends periodically to reevaluate the Program, review public comments, and modify the ESPP to continually improve protection of listed species while serving the public interest. Additionally, there are several major phases of a listed species assessment that have opportunity for public input: (1) Prior to a "may affect determination" by EPA, (2) subsequent to such determination but during development of information with which to consult with the Services, and (3) prior to issuance of a Biological Opinion to EPA by the Services. EPA proposes to engage the public in each of these phases as noted below. When any of these phases corresponds with a public participation phase under EPA's ongoing review processes (i.e., reregistration review), that ongoing public process will be used.

1. *Prior to a "may affect determination."* The Agency proposes to notify affected pesticide registrants and provide them an opportunity to update information or provide additional information relative to the determination. Subsequently, the Agency will make public in draft, any determination that a pesticide "may affect" a listed species. The public will have a 30-day opportunity to provide input to that determination.

2. *Subsequent to a "may affect determination."* The Agency will accept information provided for use during consultation with the Services. Information provided subsequent to a "may affect determination" being made will not be considered by the Agency alone but will be shared with the Services for joint consideration during consultation.

3. *Public comment on draft Biological Opinion.* The Agency intends to request that the Services provide draft Biological Opinions to the Agency upon

their development. The Agency will provide opportunity for public input to any reasonable and prudent measures or alternatives recommended by the Services in these draft Biological Opinions. The purpose of this review would be to determine whether the alternatives or measures can be reasonably implemented and whether there are alternative measures that may provide similar protection but result in less impact. The Agency will consider this input in developing its response to the draft Biological Opinions.

#### *Specific Input Requested - Public Participation*

The Agency seeks specific suggestions on how the public could most effectively be informed of the Agency's determinations and consultations. The Agency also seeks other suggestions for enhancing public involvement in the ESPP.

#### *I. Implementation Timing*

Once public comment on this Notice has been considered and a final Notice issued, the Agency intends to begin field implementation of the ESPP. At the same time, EPA recognizes that technical and consultation process issues may change based on input in response to the ANPR the Agency will issue with DOI and DOC on or about the same date as this Notice, or changes to FIFRA implementation regulations. However, the Agency believes the responsible approach is to implement in a timely manner, those aspects of listed species protection that the Agency can, while building modifications and efficiencies into the longer term effort of a sustained approach to protecting listed species.

Within 6 months of reviewing existing Interim Pamphlets for accuracy, the Agency intends to modify them as appropriate and issue them as County Bulletins. While the Bulletins will be widely available, they will be effective upon reference to them on pesticide labels. The Agency also will develop for public comment a PR Notice that will identify time frames in which the Agency anticipates that registrants could modify labels for these products.

Upon issuance of a final Notice of Program Field Implementation, the Agency will begin the process of reviewing, for endangered species implications, those pesticides for which REDs have already been issued but for which specific endangered species assessments were not completed during the RED process.

As pesticides are reviewed and determinations made for listed species, the Agency will begin creating Bulletins or preparing to include these pesticides

in existing Bulletins, as appropriate. EPA will review the County Bulletins as necessary, but generally update them not more than once annually.

#### *Specific Input Requested - Implementation Timing*

How can EPA time the release of County Bulletins to minimize the potential disruption to pesticide users during a growing season?

#### *J. Program Maintenance*

To the degree possible, endangered species issues are and will be addressed within the Agency's existing processes of registration and reregistration. Concurrently, the Agency will review those pesticides that have been through reregistration and were found potentially to affect listed species, or did not undergo ESA review during reregistration. Once all registered pesticides have been re-evaluated, EPA's future obligations to consult under ESA will be fulfilled through an ongoing process of evaluation and referral. If new, valid information becomes available on existing pesticide registrations, or if new species affected by specific pesticides are listed under the ESA, EPA will re-evaluate its determinations and reinitiate consultation when appropriate. EPA anticipates that reinitiation on the basis of new information will occur on an annual or biannual basis, as necessary. EPA will periodically reinitiate consultation, as appropriate, on pesticides already included in the Program to obtain Biological Opinions for newly listed species. It is not the Agency's intent, however, to change product labels and County Bulletins constantly; rather, EPA intends to maintain the ability to act on listed species and critical habitat issues if a new body of data becomes available.

#### **IV. References**

All references are available for public review in the public docket. The references used in this document are:

1. U.S. Environmental Protection Agency. 2002. Process for Assessing Potential Risks to Endangered and Threatened Species and Consultation with the National Marine Fisheries Service and the U.S. Fish and Wildlife Service.
2. U.S. Environmental Protection Agency. 1986. Hazard Evaluation Division Standard Evaluation Procedure, Ecological Risk Assessment.
3. U.S. Environmental Protection Agency. 1991. Report to Congress on the Endangered Species Protection Program as it Relates to Pesticide Regulatory Activities.

#### **List of Subjects**

Environmental protection, Pesticides, Endangered species.

Dated: November 25, 2002.

**James Jones,**

*Acting Director, Office of Pesticide Programs.*

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#### **ENVIRONMENTAL PROTECTION AGENCY**

[FRL-7415-4]

#### **CERCLA Administrative Consent Order Containing Proposed Past Costs Settlement Related to the Butternuts Landfill Superfund Site, Town of Butternuts, Otsego County, NY**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice; request for public comment.

**SUMMARY:** In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, amended ("CERCLA"), 42 U.S.C. 9622(i), notice is hereby given by the U.S. Environmental Protection Agency ("EPA"), Region II, of an administrative consent order ("Order") pursuant to sections 104, 106, 107, and 122 of CERCLA 42 U.S.C. 9604, 9606, 9607, and 9622, addressing, *inter alia*, proposed recovery of past response costs paid by EPA with regard to the Butternuts Landfill Superfund Site ("Site") located in the Town of Butternuts, Otsego County, New York. The Order requires the settling party, Hugo Neu Schnitizer East ("Respondent"), to perform a removal action at the Site and also pay \$40,000 in reimbursement of EPA's past response costs at the Site. The settlement includes a covenant not to sue the Respondent pursuant to sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606, 9607(a), for performance of the removal action and for recovery of EPA's past costs and oversight costs.

For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating only to the portion of the Order which settles EPA's claim for recovery of its past response costs. EPA will consider all such comments received and may modify or withdraw its consent to the past costs settlement if comments received disclose facts or considerations that indicate that the proposed past costs settlement is inappropriate, improper or inadequate. EPA's response