

In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

The Secretary has determined that minimal resources are required to implement the requirements in this rule because the organizations involved (e.g., marrow registries and transplant hospitals) currently implement their programs in accordance with the procedures announced in this proposed rule. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The Secretary also has determined that this proposed rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would not have a major effect on the economy or Federal expenditures. We have determined that the proposed rule is not a major rule within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on state, local, and tribal governments or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

The provisions of this rule will not affect the following elements of family well-being: Family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income, or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Section 202 (a) of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any one year by state, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. The current threshold after adjustment for inflation using the Implicit Price Deflator for Gross Domestic Product is about \$141 million. This rule would not meet or exceed that threshold.

This rule is not economically significant under section 3(f) of

Executive Order 12866 and is not being treated as a “significant regulatory action” under section 3(f). Accordingly, the rule has not been reviewed by the Office of Management and Budget.

As stated above, this proposed rule would modify the regulations governing the nation’s Organ Procurement and Transplantation Network (OPTN) and section 301 of NOTA based on legal authority.

#### *Paperwork Reduction Act of 1995*

The amendments proposed in this Rule will not impose any additional data collection requirements beyond those already imposed under the current information collection requirements, which have been approved by the Office of Management and Budget (OMB No. 0915–0310). The currently approved data collection includes worksheets and burden for all marrow transplants.

#### **List of Subjects in 42 CFR Part 121**

Healthcare, Hospitals, Organ transplantation.

Dated: September 19, 2013.

#### **Mary K. Wakefield,**

*Administrator, Health Resources and Services Administration*

Approved: September 25, 2013.

#### **Kathleen Sebelius,**

*Secretary.*

Therefore, under the authority of section 301 of NOTA, as amended, and for the reasons stated in the preamble, the Department proposes to amend 42 CFR part 121 as follows:

### **PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK**

- 1. The authority citation continues to read as follows:

**Authority:** Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b-8 and 1395hh); and section 301 of the National Organ Transplant Act, as amended (42 U.S.C. 274e).

- 2. Section 121.13 is revised to read as follows:

#### **§ 121.13 Definition of human organ under section 301 of the National Organ Transplant Act of 1984, as amended.**

“Human organ,” as covered by section 301 of the National Organ Transplant Act, as amended, means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow and other hematopoietic stem/progenitor cells without regard to the method of their collection, cornea, eye, bone skin, and intestine, including the esophagus, stomach, small and/or large intestine, or

any portion of the gastrointestinal tract.”

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## **DEPARTMENT OF THE INTERIOR**

### **Fish and Wildlife Service**

#### **50 CFR Part 17**

[Docket No. FWS–HQ–ES–2013–0073; FXES11130900000C2–134–FF09E32000]

**RIN 1018–AY00**

### **Endangered and Threatened Wildlife and Plants; Removing the Gray Wolf (*Canis lupus*) From the List of Endangered and Threatened Wildlife and Maintaining Protections for the Mexican Wolf (*Canis lupus baileyi*) by Listing It as Endangered**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; announcement of public hearing.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), recently published a proposal to remove the gray wolf from the List of Endangered and Threatened Wildlife (List) but to maintain endangered status for the Mexican wolf by listing it as a subspecies (*Canis lupus baileyi*). On September 5, 2013, we announced three public hearings on the proposed rule and extended the public comment period to October 28, 2013. We now announce an additional public hearing to be held on October 17, 2013, in Denver, Colorado.

**DATES:** *Written Comments:* The public comment period on the proposal to remove the gray wolf from the List of Endangered and Threatened Wildlife but to maintain endangered status for the Mexican wolf by listing it as a subspecies is open through October 28, 2013. Please note that comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. If you are submitting your comments by hard copy, please mail them by October 28, 2013, to ensure that we receive them in time to give them full consideration.

*Public Hearings:* We will hold a public hearing on October 17, 2013, from 6 p.m. to 8:30 p.m. in Denver, Colorado.

**ADDRESSES:** *Written Comments:* You may submit comments by one of the following methods:

(1) *Electronically*: Go to the Federal eRulemaking Portal: <http://www.regulations.gov>. Search for FWS–HQ–ES–2013–0073, which is the docket number for this rulemaking. Please ensure you have found the correct document before submitting your comments. If your comments will fit in the provided comment box, please use this feature of <http://www.regulations.gov>, as it is most compatible with our comment review procedures. If you attach your comments as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel. Submissions of electronic comments on our Proposed Revision to the Nonessential Experimental Population of the Mexican Wolf, which also published in the **Federal Register** on June 13, 2013, should be submitted to Docket No. FWS–R2–ES–2013–0056 using the method described above.

(2) *By hard copy*: Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–HQ–ES–2013–0073; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

(3) *At the public hearing*: Written comments will be accepted by Service personnel at the public hearing.

We will post all comments that we receive on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

**Public Hearing**: The public hearing will be held at: Paramount Theatre, 1621 Glenarm Place, Denver, Colorado 80202; (303) 405–1245.

**FOR FURTHER INFORMATION CONTACT**: Headquarters Office, Ecological Services; telephone (703) 358–2171. Direct all questions or requests for additional information to: GRAY WOLF QUESTIONS, U.S. Fish and Wildlife Service, Headquarters Office, Ecological Services, 4401 North Fairfax Drive, Room 420, Arlington, VA 22203. Individuals who are hearing-impaired or speech-impaired may call the Federal Relay Service at 1–800–877–8337 for TTY assistance.

#### **SUPPLEMENTARY INFORMATION:**

##### **Public Hearings**

We are holding a public hearing on the date listed in **DATES** at the location listed in **ADDRESSES**. For information on additional public hearings related to this proposed rulemaking action, see our previous notice of public hearings

that published in the **Federal Register** on September 5, 2013, at 78 FR 54614.

We are holding public hearings to provide interested parties the opportunity to present verbal testimony (formal, oral comments) or written comments regarding the June 13, 2013 (78 FR 35664), proposal to remove the gray wolf from the List and maintain protections for the Mexican wolf by listing it as endangered. A public hearing is not, however, an opportunity for dialogue with the Service or its contractors; it is a forum for accepting formal verbal testimony. Anyone wishing to make an oral statement at the public hearings for the record is encouraged to provide a written copy of their statement to us at the hearings. In the event of a large attendance, the time allotted for oral statements may be limited. Speakers can sign up at the hearings if they desire to make an oral statement. Oral and written statements receive equal consideration. There are no limits on the length of written comments submitted to us.

Persons with disabilities needing reasonable accommodations to participate in the public hearings should contact the Headquarters Office (see **FOR FURTHER INFORMATION CONTACT**). Reasonable accommodation requests should be received at least 3 business days prior to the hearing to help ensure availability; at least 2 weeks prior notice is requested for American-sign-language or English-as-a-second-language interpreter needs.

##### **Public Comments**

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments, new information, or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule are hereby solicited. In particular, we are seeking targeted information and comments on our proposed removal of *C. lupus* from the List of Endangered and Threatened Wildlife and addition of *C. l. baileyi* as an endangered subspecies. We also seek comment on the following categories of information.

(1) Biological, commercial trade, or other relevant information concerning our analysis of the current *C. lupus* listed entity and the adequacy of the approach taken in this analysis, with particular respect to our interpretation of the term “population” as it relates to the 1996 Policy Regarding the Recognition of Distinct Vertebrate Population Segments (DPS policy) (61

FR 4722, February 7, 1996) and specifically to gray wolves.

(2) Information concerning the genetics and taxonomy of the eastern wolf, *Canis lycaon*.

(3) Information concerning the status of the gray wolf in the Pacific Northwest United States and the following gray wolf subspecies: *Canis lupus nubilus*, *Canis lupus occidentalis*, and *C. l. baileyi*, including:

(a) Genetics and taxonomy;

(b) New information concerning range, distribution, population size, and population trends;

(c) New biological or other relevant data concerning any threat (or lack thereof) to these subspecies, their habitat, or both; and

(d) New information regarding conservation measures for these populations, their habitat, or both.

As this proposal is intended to replace our May 5, 2011, proposal to remove protections for *C. lupus* in all or portions of 29 eastern contiguous States (76 FR 26086), we ask that any comments previously submitted that may be relevant to the proposal presented in this rule be resubmitted at this time.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination. You may submit your comments and materials by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**. Verbal testimony may also be presented during the public hearings (see **DATES** and **ADDRESSES** sections).

We will post your entire comment—including your personal identifying information—on <http://www.regulations.gov>. If you provide personal identifying information, such as your street address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as some of the supporting documentation we used in preparing this proposed rule, will be available for public inspection on <http://www.regulations.gov> at Docket No. FWS–HQ–ES–2013–0073, or by appointment, during normal business hours at U.S. Fish and Wildlife Service, Headquarters Office, Endangered Species Program, 4401 North Fairfax Drive, Room 420, Arlington, VA 22203.

Our final determination concerning the proposed action will take into

consideration all written comments we receive during all comment periods, comments from peer reviewers, and comments received during the public hearings. The comments will be included in the public record for this rulemaking, and we will fully consider them in the preparation of our final determination.

If you previously submitted comments or information on this

proposed rule, please do not resubmit them. We will incorporate them into the public record as part of this comment period, and will fully consider them in the preparation of our final determination.

#### **Authors**

The primary authors of this notice are the Ecological Services staff of the Headquarters Office, U.S. Fish and Wildlife Service.

#### **Authority**

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 24, 2013.

#### **Rowan W. Gould,**

*Acting Director, U.S. Fish and Wildlife Service.*

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