

have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the category of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 114

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 114 as follows:

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

1. The authority citation for part 114 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

2. Section 114.12 would be revised to read as follows:

§ 114.12 Expiration date required for a serial.

Unless otherwise provided for in a Standard Requirement or filed Outline of Production, each serial or subserial of biological product prepared in a licensed establishment must be given an expiration date computed from the date of the initiation of the first potency test. A licensed biological product shall be considered worthless under the Virus-Serum-Toxin Act subsequent to the expiration date appearing on the label.

3. Section 114.13 would be revised to read as follows:

§ 114.13 Determination of the expiration dating period of a product.

(a) An expiration dating period shall be assigned to each product. When

tested at any time during the dating period, the potency of the product must not be less than the minimum specified in the filed Outline of Production.

(b) Prior to licensure, a proposed expiration dating period for the product should be determined by assessing the stability of each of its fractions by methods acceptable to Animal and Plant Health Inspection Service. The proposed dating period must be confirmed by testing the serials for potency on multiple occasions throughout the proposed dating period beginning at the date of final formulation specified in the filed Outline of Production. A report of the study should be submitted to Animal and Plant Health Inspection Service for review and filing and the date of approval should be specified in section VI of the filed Outline of Production.

(c) After the product is licensed and its dating period confirmed, the licensee or permittee must submit a plan to monitor the stability of the product and the suitability of its dating period that includes regularly testing serials for potency during and at the end of dating.

(d) Subsequent changes in the dating period for a product may be granted, based on the submission of a study to support a revision of the Outline of Production.

Done in Washington, DC, this 22nd day of April 2005.

W. Ron DeHaven,

Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AT84

Endangered and Threatened Wildlife and Plants; Extension of the Comment Period for Proposed Designation of Critical Habitat for the Arkansas River Basin Population of the Arkansas River Shiner

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; extension of public comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the extension of the public comment period for the proposal to designate critical habitat for the Arkansas River Basin population of the Arkansas River Shiner

(*Notropis girardi*) (October 6, 2004; 69 FR 59859). This action will allow all interested parties an opportunity to comment on the proposed critical habitat designation under the Endangered Species Act of 1973, as amended.

DATES: Comments must be submitted directly to the Service (see **ADDRESSES** section) on or before June 17, 2005. Any comments received after the closing date may not be considered in the final determination on the proposal.

ADDRESSES: If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

1. You may submit written comments and information to the Field Supervisor, Oklahoma Ecological Services Office, U.S. Fish and Wildlife Service, 222 South Houston, Tulsa, Oklahoma 74127–8909.

2. You may hand-deliver written comments and information to our Oklahoma Office, at the above address, or fax your comments to 918–581–7467.

3. You may send your comments by electronic mail (e-mail) to r2arshinerch@fws.gov. For directions on how to submit electronic filing of comments, see the “Public Comments Solicited” section.

All comments and materials received, as well as supporting documentation used in preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Jerry Brabander, Field Supervisor, Oklahoma Office (telephone 918–581–7458; facsimile 918–581–7467).

SUPPLEMENTARY INFORMATION:

Background

On October 6, 2004 (69 FR 59859), we proposed to designate as critical habitat a total of approximately 2,002 kilometers (1,244 miles) of linear distance of rivers, including 91.4 meters (300 feet) of adjacent riparian areas measured laterally from each bank. This distance includes areas that we are proposing to exclude that are discussed below. The areas that we have determined to be essential to the conservation of the Arkansas River Shiner include portions of the Canadian River (often referred to as the South Canadian River) in New Mexico, Texas, and Oklahoma, the Beaver/North Canadian River of Oklahoma, the Cimarron River in Kansas and Oklahoma, and the Arkansas River in Arkansas, Kansas, and Oklahoma.

In developing this proposal, we evaluated those lands determined to be essential to the conservation of the Arkansas River Shiner to ascertain if any specific areas would be appropriate for exclusion from the final critical habitat designation pursuant to section 4(b)(2) of the Act. On the basis of our preliminary evaluation, we believe that the benefits of excluding the Beaver/North Canadian River of Oklahoma and the Arkansas River in Arkansas, Kansas, and Oklahoma, from the final critical habitat for the Arkansas River Shiner outweigh the benefits of their inclusion. The public comment period for the proposed rule was originally scheduled to close on April 30, 2005.

On September 30, 2003, in a complaint brought by the New Mexico Cattle Growers Association and 16 other plaintiffs, the U.S. District Court of New Mexico instructed us to propose critical habitat by September 30, 2004, and publish a final rule by September 30, 2005. The proposed rule was signed on September 30, 2004, and published in the **Federal Register** on October 6, 2004 (69 FR 59859). Additional background information is available in the October 6, 2004, proposed rule.

Critical habitat is defined in section 3 of the Act as the specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features essential to the conservation of the species and that may require special management considerations or protection; and specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. If the proposed rule is made final, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions affecting areas designated as critical habitat must consult with us on the effects of their proposed actions, pursuant to section 7(a)(2) of the Act.

Section 4 of the Act requires that we consider economic and other relevant impacts prior to making a final decision on what areas to designate as critical habitat. We are currently developing a draft economic analysis and draft environmental assessment for the proposal to designate certain areas as critical habitat for the Arkansas River Shiner and will announce their availability at a later date. We may revise the proposal, or its supporting documents, to incorporate or address

new information received during the comment period. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area as critical habitat, provided such exclusion will not result in the extinction of the species.

Pursuant to 50 CFR 424.16(c)(2), we may extend or reopen a comment period upon finding that there is good cause to do so. We are currently developing a draft economic analysis and draft environmental assessment for the proposal and will announce the availability of those documents and solicit data and comments from the public on these draft documents at a later date. We will also announce hearing dates concurrently with the availability of the draft documents. However, it is our intention to leave the public comment period open and uninterrupted until those documents are available for public consideration and comment. We believe that allowing the comment period to close before the full set of supporting draft analytical documents is available could result in hurried and incomplete comments on our proposed rule and could also unnecessarily frustrate respondents. We deem these considerations as sufficient cause to extend the comment period.

We are required by court order to complete the final designation of critical habitat for the Arkansas River Shiner by September 30, 2005. To meet this date, all comments on or proposed revisions to the proposed rule need to be submitted to us during the comment period, as extended by this document (see **DATES**).

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address, which we will honor to the extent allowable by law. If you wish us to withhold your name or address, you must state this request prominently at the beginning of your comments. However, we will not consider anonymous comments. To the extent consistent with applicable law, we will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Comments and materials received, as well as supporting documentation used in preparation of the proposal to designate critical habitat, will be available for public inspection, by appointment, during normal business

hours at the Tulsa Ecological Services Office (see **ADDRESSES** section).

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

Dated: April 21, 2005.

Craig Manson,

Assistant Secretary for Fish and Wildlife and Parks.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AT88

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for the Southwestern Willow Flycatcher

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of availability of draft economic analysis and draft environmental assessment, and notice of public hearings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the draft economic analysis and draft environmental assessment for the proposal to designate critical habitat for southwestern willow flycatcher (*Empidonax traillii extimus*) under the Endangered Species Act of 1973 (Act), as amended. The draft economic analysis considers the potential economic effects of efforts to protect the southwestern willow flycatcher and its habitat, collectively referred to as "flycatcher conservation activities." In the case of habitat conservation, these costs would reflect the costs associated with the commitment of resources to comply with habitat protection measures. The analysis also addresses how potential economic impacts are likely to be distributed and looks retrospectively at costs that have been incurred since the date the species was listed. The draft economic analysis finds that over a 10-year time period costs associated with southwestern willow flycatcher conservation activities are forecast to range from \$29.2 to \$39.5 million per year. Comments previously submitted on the October 12, 2004, proposed rule (69 FR 60706) and the extensions of comment period published December 13, 2004 (69 FR 72161), or March 31, 2005 (70 FR 16474) need not be resubmitted as they have been