(5) Individuals engaged in the research will have no part in determining the viability of a neonate.

(6) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part.

(c) Nonviable neonates. After delivery, a nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of § 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5). The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§ 46.206 Research involving, after delivery, the placenta, the dead neonate, or neonatal material.

(a) Research involving, after delivery, the placenta; the dead neonate; macerated neonatal material; or cells, tissue, or organs excised from a dead neonate, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of § 46.204 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

(1) That the research in fact satisfies the conditions of § 46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

[FR Doc. 01–16841 Filed 7–5–01; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AH96

Endangered and Threatened Wildlife and Plants; Availability of Draft Environmental Assessment on Proposed Designation of Critical Habitat for the Northern Great Plains Breeding Population of the Piping Plover

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service announce the availability of the draft Environmental Assessment for the proposal to designate critical habitat for the northern Great Plains breeding population of the piping plover (*Charadrius melodus*), under the Endangered Species Act of 1973, as amended. We invite all interested parties to comment on the draft Environmental Assessment and any other aspect of the proposed designation.

DATES: The comment period for the draft Environmental Assessment will close on August 13, 2001. Any comments that are received after the closing date may not be considered in the final decision on this proposal.

ADDRESSES: You may submit written comments and information to Piping Plover Comments, South Dakota Ecological Services Field Office, U.S. Fish and Wildlife Service, 420 South Garfield Avenue, Suite 400, Pierre, South Dakota 57501 or by facsimile to 605–224–9974.

You may hand-deliver written comments to our South Dakota Field Office at the address given above.

You may send comments by electronic mail (e-mail) to FW6_PipingPlover@fws.gov. See the Public Comments Solicited section below for file format and other information on electronic filing.

Copies of the draft Environmental Assessment for the northern Great Plains breeding population of the piping plover are available from the aforementioned address or on the Internet at http://mountain-prairie.fws.gov/pipingplover/ch.

You may view comments and materials received, as well as supporting documentation used in the preparation of this proposed rule, by appointment,

during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Nell McPhillips, Fish and Wildlife Biologist, at the above address or at (605) 224–8693, extension 32.

SUPPLEMENTARY INFORMATION:

Background

We published a proposed rule to designate critical habitat for the northern Great Plains breeding population of the piping plover in the **Federal Register** (66 FR 31760). Section 4(b)(2) of the Endangered Species Act (Act) requires that we designate or revise critical habitat based upon the best scientific and commercial data available and after taking into consideration the economic impacts, and any other relevant impact, of specifying any particular area as critical habitat. 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.

The proposed designation includes 11 areas of prairie alkali wetlands and reservoir lakes in 5 counties in Montana, 18 counties in North Dakota, and 1 county at Lake-of-the-Woods, Minnesota, totaling approximately 196,576.5 acres (ac) [79,553.1 hectares (ha)]. It also includes five areas of portions of four rivers in the States of Montana, North Dakota, South Dakota, and Nebraska, totaling approximately 1,338 miles (mi) [2,152.9 kilometers (km)] of river. If this proposal is made final, section 7 of the Act would prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency.

Public Comments Solicited

We will accept written comments and information during this comment period. If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods (see **ADDRESSES**). If you would like to submit comments by electronic format, please submit them in ASCII file format and avoid the use of special characters and encryption. Please include your name and return e-mail address in your e-mail message. Please note that the e-mail address will be closed out at the termination of the public comment period. If you do not receive confirmation from the system that we have received your message, contact us directly by calling our South Dakota Field Office at (605) 224–8693.

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 above address. Copies of the draft Environmental Assessment are available on the Internet at http://mountain-prairie.fws.gov/pipingplover/ch or by writing to Pete Gober, Field Supervisor (see **ADDRESSES**).

Public Meetings

We have scheduled five informal public meetings at the following addresses on the dates indicated. Public meetings will run from 6–9 p.m., except for Yankton which will run from 5:30–8:30 p.m.

1. Cottonwood Inn Convention Center, U.S. Highway 2E, Glasgow, Montana, July 10, 2000

2. Doublewood Inn, I–94 and Exit 159, Bismarck, North Dakota, July 12, 2001

3. Pierre Chamber of Commerce, Community Room, 800 W. Dakota Avenue, Pierre, South Dakota, July 16, 2001

4. Summit Activities Center, 1801 Summit Street, Yankton, South Dakota, July 17, 2000

5. Central Community College, Main Building, Room 210, 3134 W. Highway 34, Grand Island, Nebraska, July 18, 2001

Author

The primary authors of this notice are the South Dakota Field Office staff (see **ADDRESSES** section).

Authority

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

Dated: June 29, 2001.

John A. Blankenship,

Acting Regional Director, Denver, Colorado.

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