

quarter a manufacturer should refund or credit a covered entity if there is an overcharge.

### Definition of “Knowing and Intentional”

Under section 340B(d)(1)(B)(vi) of the Public Health Service Act, the Secretary is charged with issuing civil monetary penalties for manufacturers who have “knowingly and intentionally” charged a covered entity a price that exceeds the 340B ceiling price. Although the knowing and intentional standard was included in the NPRM issued on June 17, 2015, “knowing and intentional” was not specifically defined. HHS received a number of comments urging HHS to further define these terms. Through this reopening of the NPRM comment period, we are seeking comment on the definition of the knowing and intentional standard for purposes of this civil monetary penalty authority. We believe that, by reopening the comment period as to this issue, all parties will have an opportunity to express their views on this definitional standard prior to finalization of the rule.

HHS is considering whether “knowing and intentional” should be further defined. If the terms are defined, possible definitions could be: (1) Actual knowledge by the manufacturer, its employees, or its agents of the instance of overcharge; (2) willful or purposeful acts by, or on behalf of, the manufacturer that lead to the instance of overcharge; (3) acting consciously and with awareness of the acts leading to the instance of overcharge; and/or (4) acting with a conscious desire or purpose to cause an overcharge or acting in a way practically certain to result in an overcharge. Manufacturers do not need to intend specifically to violate the 340B statute; but rather to have knowingly and intentionally overcharged the 340B covered entity.

HHS understands that this is difficult to demonstrate. As such, HHS is soliciting input on circumstances in which the requisite intent should and should not be inferred. In particular, HHS would like to solicit comment on the concept that manufacturers would not be considered to have the requisite intent in the following circumstances:

- The manufacturer made an inadvertent, unintentional, or unrecognized error in calculating the ceiling price;
- A manufacturer acted on a reasonable interpretation of agency guidance; or
- When a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market

demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers.

HHS welcomes comments regarding other situations where the requisite intent may or may not be demonstrated.

Because of the scope of the proposed rule, and since we have specifically requested the public’s comments on various aspects of the rule, we believe that it is important to allow ample time for the public to consider these approaches to these specific policies in the proposed rule. Therefore, we have decided to reopen the comment period for an additional 30 days. HHS believes that a 30-day period is sufficient and balances the interests of encouraging public participation in the rulemaking process with the desire to not unnecessarily delay key decisions about rulemaking. This document announces the reopening of the comment period to end May 19, 2016.

Dated: April 6, 2016.

**James Macrae,**

*Acting Administrator, Health Resources and Services Administration.*

Approved: April 12, 2016.

**Sylvia M. Burwell,**

*Secretary.*

[FR Doc. 2016–09017 Filed 4–18–16; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 17

[Docket No. FWS–R1–ES–2012–0097; 4500030114]

RIN 1018–AZ74

### Endangered and Threatened Wildlife and Plants; Proposed Rule To Amend the Listing of the Southern Selkirk Mountains Population of Woodland Caribou

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

**ACTION:** Proposed rule; reopening of the comment period.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our May 8, 2014, proposed rule to amend the listing of the southern Selkirk Mountains population of woodland caribou (*Rangifer tarandus caribou*) by defining the Southern Mountain Caribou distinct population segment (DPS) and listing it as threatened. In the May 8, 2014, proposed rule, we also proposed to

reaffirm our November 28, 2012, final designation of critical habitat for the southern Selkirk Mountains population of woodland caribou as critical habitat for the proposed Southern Mountain Caribou DPS. On March 23, 2015, the U.S. District Court of Idaho remanded our November 28, 2012, final critical habitat rule to the Service to correct a procedural error by providing another opportunity for public comment. This reopening of the comment period will provide all interested parties with the opportunity to provide comment on our November 28, 2012, final critical habitat designation, in light of the court’s ruling.

**DATES:** The comment period for the proposed rule published in the **Federal Register** on May 8, 2014 (79 FR 26504), is reopened. We will consider comments received or postmarked on or before May 19, 2016. 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. Any comments that we receive after the closing date may not be considered in the final decision on this action.

**ADDRESSES:**

*Document availability:* You may obtain information and documents associated with the opening of this comment period, a copy of the November 28, 2012, final critical habitat designation (77 FR 71042), as well as information relating to the proposed reaffirmation of critical habitat in the proposed amended listing rule (79 FR 26504, May 8, 2014) and any comments received on that rule at <http://www.regulations.gov> under Docket No. FWS–R1–ES–2012–0097, or by contacting the U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). Information we relied upon for making our November 28, 2012, final critical habitat designation (77 FR 71042) can be found at <http://www.regulations.gov> under Docket No. FWS–R1–ES–2011–0096 and Docket No. FWS–R1–ES–2012–0097, or by contacting the U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

*Comment submission:* You may submit written information by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <http://www.regulations.gov>. In the Search box, enter FWS–R1–ES–2012–0097, which is the docket number for this rulemaking. Then, click the Search button. In the Search panel on the left side of the

screen, under the Document Type heading, click on the box next to "Proposed Rule" to locate this document. You may submit a comment by clicking on "Comment Now!" Please ensure that you have found the correct rulemaking before submitting your comment.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS-R1-ES-2012-0097; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service, MS: BPHC; 5275 Leesburg Pike; Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments received on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us (see the Information Requested section below, for more information).

**FOR FURTHER INFORMATION CONTACT:**

Dennis Mackey, Acting State Supervisor, Idaho Fish and Wildlife Office, 1387 S. Vinnell Way, Room 368, Boise, Idaho (telephone 208-378-5243; facsimile 208-378-5262). If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service at 800-877-8339.

**SUPPLEMENTARY INFORMATION:**

**Background**

On November 30, 2011, we proposed to designate approximately 375,562 acres (ac) (151,985 hectares (ha)) of critical habitat for the southern Selkirk Mountains population of woodland caribou (*Rangifer tarandus caribou*) (76 FR 74018). On November 28, 2012, after considering comments we received from peer reviewers as well as from Federal agencies, State agencies, Tribes, and the general public on the proposed designation, we designated approximately 30,010 ac (12,145 ha) of critical habitat for the southern Selkirk Mountains population of woodland caribou (77 FR 71042).

On May 8, 2014, we proposed to amend the current listing of the southern Selkirk Mountains population of woodland caribou by defining the Southern Mountain Caribou DPS, which includes the currently listed southern Selkirk Mountains population of woodland caribou, as well as populations of mountain caribou in British Columbia (79 FR 26504), and listing the DPS as threatened. In the May 8, 2014, rule, we also proposed to reaffirm the approximately 30,010 ac (12,145 ha) designated as critical habitat on November 28, 2012 (77 FR 71042),

for the southern Selkirk Mountains population of woodland caribou as critical habitat for the proposed Southern Mountain Caribou DPS. As we stated in our May 8, 2014, proposed rule (79 FR 26532), our regulations at 50 CFR 424.12(h) allow us to designate critical habitat only in the United States. Of the 15 populations of mountain caribou that make up the Southern Mountain caribou DPS, the southern Selkirk Mountains woodland caribou population is the only population that moves freely between the coterminous United States and Canada. We determined that critical habitat for the Southern Mountain caribou DPS corresponded exactly to the critical habitat identified for the southern Selkirk Mountains population of woodland caribou in our final rule published on November 28, 2012 (77 FR 71042). Further we determined that the specific area identified in the November 28, 2012, final rule met the definition of critical habitat for the Southern Mountain caribou DPS, and that there are no additional areas that meet the definition of critical habitat.

The May 8, 2014, proposed rule (79 FR 26504) had a 60-day public comment period, ending July 7, 2014. On June 10, 2014, we extended the public comment period an additional 30 days, ending on August 6, 2014, and announced the scheduling of two public hearings, which were held on June 25, 2014, and June 26, 2014 (79 FR 33169). On March 24, 2015, we reopened the public comment period for an additional 30 days, ending on April 23, 2015, to allow the public time to review new information received after the previous public comment period (80 FR 15545).

On March 23, 2015, the U.S. District Court for the District of Idaho ruled in *Center for Biological Diversity v. Kelly*, 93 F. Supp. 3d 1193 (D. Idaho, 2015), that we made a procedural error in not providing for public review and comment on certain aspects of the reasoning that we relied upon in making our November 28, 2012, final designation of critical habitat (77 FR 71042). The reopening of this comment period will provide all interested parties an opportunity to provide comment on the November 28, 2012, final designation of critical habitat, which we proposed to reaffirm in the May 8, 2014, proposed rule as the critical habitat for the Southern Mountain caribou DPS.

The primary factors that we considered in making changes from the November 30, 2011, proposed critical habitat designation (76 FR 74018) to the November 28, 2012, final critical habitat designation (77 FR 71042), which we proposed to reaffirm in the May 8, 2014, proposed rule include:

(1) A revised determination of the geographical area occupied by the southern Selkirk Mountains population of woodland caribou at the time of listing, based on comments we received, including those from peer reviewers, which caused us to reevaluate surveys conducted by Scott and Servheen (1984, 1985).

(2) Census monitoring that documented low numbers of individual caribou observed in the United States during those annual surveys.

(3) Caribou observations within the United States for several years that have consistently been limited to areas close to the United States-Canada border.

(4) Peer review comments received leading to a reanalysis of the appropriate elevational limit of critical habitat (see Kinley and Apps (2007)).

(5) Information and literature reporting the overall decline of the subspecies mountain caribou (*Rangifer tarandus caribou*) across its range, and in particular the decline of woodland caribou populations in the southern extent of their range, including the southern Selkirk Mountains population of woodland caribou.

(6) The applicability as well as the status of the recovery objectives identified in the 1994 Selkirk Mountains Woodland Caribou Recovery Plan (USFWS 1994).

(7) Information on areas currently conserved and managed for the conservation of woodland caribou in the Selkirk Mountains in British Columbia, Canada, as described in The Nature Conservancy (2011) and the 2009 update on the Mountain Caribou Recovery Implementation Plan provided to the Mountain Caribou Progress Board (DeGroot 2012, pers comm.) (see also MCRIP 2009). All documents cited above can be viewed on [www.regulations.gov](http://www.regulations.gov) in the supplemental materials for Docket No. FWS-R1-ES-2012-0097.

**Information Requested**

We intend that any final action will be based on the best scientific data available, and be as accurate and complete as possible. Therefore, we are seeking written comments and information from appropriate Federal and State agencies, the scientific community, and any other interested party during this reopened comment period on our proposed rule that was published in the May 8, 2014, **Federal Register** (79 FR 26504). We are particularly interested in comments and information related to our November 28, 2012, final critical habitat designation, which we have proposed to reaffirm as critical habitat for the Southern

Mountain caribou DPS. This information will be used to finalize the critical habitat designation for the Southern Mountain caribou DPS.

If you submitted comments or information on the proposed reaffirmation of the November 28, 2012, designation of critical habitat in the proposed amended listing rule (79 FR 26504, Docket No. FWS-R1-ES-2012-0097) during the initial comment period from May 8, 2014, to July 6, 2014, the extended comment period (79 FR 33169) from July 6, 2014, to August 6, 2014, or the additional comment period (80 FR 15545) from March 24, 2015, to April 23, 2015, please do not resubmit them. We have incorporated them into the public record as part of this comment period, and we will fully consider them in our final determination.

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, as section 4(b)(2) of the Act directs that critical habitat determinations must be made “on the basis of the best scientific data available.”

You may submit your comments and materials concerning the May 8, 2014, proposed rule (79 FR 26504) by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**. If you submit information via <http://www.regulations.gov>, your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, 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. We will post all hardcopy submissions on <http://www.regulations.gov>. Please include sufficient information with your

comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as some supporting documentation we used in preparing the November 28, 2012, final critical habitat rule, will be available for public inspection on <http://www.regulations.gov> at Docket No. FWS-R1-ES-2012-0097, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

#### Authority

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

Dated: April 5, 2016.

#### Noah Matson,

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

[FR Doc. 2016-08617 Filed 4-18-16; 8:45 am]

**BILLING CODE 4333-15-P**