This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00684 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2017–N135; FF01EWFW00–FXES111601M000]

Marine Mammal Protection Act; Stock Assessment Report for the Northern Sea Otter in Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: In accordance with the Marine Mammal Protection Act of 1972, as amended, and its implementing regulations, we, the U.S. Fish and Wildlife Service, have developed a draft revised marine mammal stock assessment report for the northern sea otter stock in the State of Washington. We now make the draft stock assessment report available for public review and comment.

DATES: We will consider comments that are received or postmarked on or before April 17, 2018.

ADDRESSES: If you wish to review the draft revised stock assessment report for the northern sea otter stock in Washington, you may obtain a copy from our website at *http://www.fws.gov/wafwo.* Alternatively, you may contact the Washington Fish and Wildlife Office, 510 Desmond Dr., Suite 102, Lacey, WA 98503 (telephone: 360–753–9440). If you wish to comment on the stock assessment report, you may submit your comments in writing by any one of the following methods:

- *U.S. mail:* State Supervisor, at the above address;
- *Hand delivery:* Washington Fish and Wildlife Office at the above address;
- *Fax:* 360–753–9565; or
- *Email: fw1_waseaottersar@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Deanna Lynch, at the above street address, by telephone (360–753–9545), or by email (*deanna_lynch@fws.gov*). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We announce the availability for review and comment of a draft revised marine mammal stock assessment report (SAR) for the northern sea otter (*Enhydra lutris kenyoni*) stock in the State of Washington.

Background

Under the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and its implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR part 18, the U.S. Fish and Wildlife Service (Service) regulates the taking; import; and, under certain conditions, possession; transportation; purchasing; selling; and offering for sale, purchase, or export, of marine mammals. One of the goals of the MMPA is to ensure that stocks of marine mammals occurring in waters under U.S. jurisdiction do not experience a level of human-caused mortality and serious injury that is likely to cause the stock to be reduced below its *optimum sustainable population* (OSP) level. OSP is defined under the MMPA as ''the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element'' (16 U.S.C. 1362(9)).

To help accomplish the goal of maintaining marine mammal stocks at their OSPs, section 117 of the MMPA requires the Service and the National Marine Fisheries Service (NMFS) to prepare a SAR for each marine mammal stock that occurs in waters under U.S. jurisdiction. A SAR must be based on the best scientific information available; therefore, we prepare it in consultation with established regional scientific review groups established under 117(d) of the MMPA. Each SAR must include:

1. A description of the stock and its geographic range;
2. A minimum population estimate, current and maximum net productivity rate, and current population trend;
3. An estimate of the annual human-caused mortality and serious injury by source and, for a strategic stock, other factors that may be causing a decline or impeding recovery of the stock;
4. A description of commercial fishery interactions;
5. A categorization of the status of the stock; and
6. An estimate of the *potential biological removal* (PBR) level.

The MMPA defines the PBR as ''the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its [OSP]'' (16 U.S.C. 1362(20)). The PBR is the product of the minimum population estimate of the stock (N_{min}); one-half the maximum theoretical or estimated net productivity rate of the stock at a small population size (R_{max}); and a recovery factor (F_r) of between 0.1 and 1.0, which is intended to compensate for uncertainty and unknown estimation errors. This can be written as:

$$PBR = (N_{min})(\tfrac{1}{2} \text{ of the } R_{max})(F_r)$$

Section 117 of the MMPA also requires the Service and NMFS to review the SARs (a) at least annually for stocks that are specified as strategic stocks, (b) at least annually for stocks for which significant new information is available, and (c) at least once every 3 years for all other stocks. If our review of the status of a stock indicates that it has changed or may be more accurately determined, then the SAR must be revised accordingly.

A *strategic stock* is defined in the MMPA as a marine mammal stock ''(A) for which the level of direct human-caused mortality exceeds the [PBR] level; (B) which, based on the best available scientific information, is

declining and is likely to be listed as a threatened species under the Endangered Species Act of 1973, [as amended] (16 U.S.C. 1531 *et seq.*) [the ''ESA''], within the foreseeable future; or (C) which is listed as a threatened species or endangered species under the [ESA], or is designated as depleted under [the MMPA]'' 16 U.S.C. 1362(19).

Stock Assessment Report History for the Northern Sea Otter in Washington

The Washington sea otter SAR was last revised in August 2008. The Washington sea otter is not a strategic stock, thus the Service is required to review the stock assessment at least once every 3 years. The Service reviewed the Washington sea otter SAR in 2011 and concluded that a revision was not warranted because the status of the stock had not changed, nor could it be more accurately determined. However, upon review in 2016, the Service determined that revision was warranted because of changes in population estimates and distribution.

Summary of Draft Revised Stock Assessment Report for the Northern Sea Otter in the State of Washington

The following table summarizes some of the information contained in the draft revised SAR for northern sea otters in Washington State, which includes the stock's N_{min}, R_{max}, F_r, PBR, annual estimated human-caused mortality and serious injury, and status. After consideration of any public comments we receive, the Service will revise and finalize the SAR, as appropriate. We will publish a notice of availability and summary of the final SAR, including responses to submitted comments.

SUMMARY—DRAFT STOCK ASSESSMENT REPORT FOR THE NORTHERN SEA OTTER IN WASHINGTON STATE

Stock	N_{min}	R_{max}	F_r	PBR	Annual estimated human-caused mortality and serious injury	Stock status
Northern Sea Otter (Washington State).	1,806	0.20	0.1	18	Figures by specific source, where known, are provided in the SAR.	Non-Strategic.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

References

In accordance with the MMPA, we include in this notice a list of the information sources and public reports upon which we based the SAR:

Bigg, M.A. and I.B. MacAskie. 1978. Sea otters re-established in British Columbia. J. Mammalogy 59 (4):874–876.

Department Fisheries and Oceans, Canada (DFO). 2015. Trends in the abundance and distribution of sea otters (*Enhydra lutris*) in British Columbia updated with 2013 survey results. DFO Can. Sci. Advis. Sec. Sci. Advis. Rep. 2015/043.

DeMaster, D.P., C. Marzin, and R.J. Jameson. 1996. Estimating the historical abundance of sea otters in California. Endangered Species Update 13(12):79–81.

Estes, J.A. 1990. Growth and equilibrium in sea otter populations. J. Anim. Ecol. 59:358–401.

Hatfield, B.B., J.A. Ames, J.A. Estes, M.T. Tinker, A.B. Johnson, M.M Staelder, and M.D. Harris. 2011. Sea otter mortality in fish and shellfish traps: estimated potential impacts and exploring possible solutions. Endangered Species Research 13:219–229.

Hatfield, B.B. and J.A. Estes. 2000. Preliminary results of an evaluation of the potential threat to sea otters posed by the nearshore finfish trap fishery. Unpublished, 6 pp. + appendices.

Jameson, R.J., K.W. Kenyon, A.M. Johnson, and H.M. Wight. 1982. History and status of translocated sea otter populations in North America. Wildl. Soc. Bull. 10:100–107.

Jameson, R.J., K.W. Kenyon, S.Jeffries and G.R. VanBlaricom. 1986. Status of a translocated sea otter and its habitat in Washington. Murrelet 67:84–87.

Jameson, R.J. 1996. Status reports: West Coast translocation projects, Oregon and Washington. The Otter Raft No. 55, Page 8.

Jameson, R.J., and S. Jeffries. 1999. Results of the 1999 Survey of the Washington Sea Otter

Population. Unpublished Report. 5 pp.

Jeffries, S., D. Lynch, and S. Thomas. 2016. Results of the 2016 Survey of the Reintroduced Sea Otter Population in Washington State. Unpublished Report. 9 pp. Copies may be obtained from the Washington Department of Fish and Wildlife or U.S. Fish and Wildlife Service's Washington Fish and Wildlife Office.

Laidre, K., R.J. Jameson, S.J. Jeffries, and E. Gurarie. 2011. Updated estimates of carrying capacity for sea otters in Washington state. Unpublished final contract report, December 31, 2011, 12 pp. + appendix.

Lance, M.M., S.A. Richardson, and H. Allen. 2004. State of Washington sea otter recovery plan. WDFW, Olympia WA. 91 pp.

Riedman, M.L., and J.A. Estes. 1990. The sea otter (*Enhydra lutris*): behavior, ecology, and natural history. U.S. Fish and Wildlife Service, Washington, DC, Biological Report 90(14). 126 pp.

Scheffer, V.B. 1940. The sea otter on the Washington coast. Pacific Northwest Quarterly, 3:370–388.

Taylor, B.L., M. Scott, J. Heyning, and J. Barlow. 2003. Suggested guidelines for recovery factors for endangered marine mammals. NOAA Technical Memorandum NOAA–TM–NMFS–SWFSC–354, September 2003. 6 pp.

Wilson, D.E., M.A. Bogan, R.L. Brownell, Jr., A.M. Burdin, and M.K. Maminov. 1991. Geographic variation in sea otters, *Enhydra lutris.* J. Mammal. 72(1):22–36.

Authority

The authority for this action is the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*).

Dated: November 30, 2017.

James W. Kurth,

Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2018–00672 Filed 1–16–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[189A2100DD/AAKC001030/A0A501010.999900 253G]

Indian Gaming; Approval of an Amendment to a Tribal-State Class III Gaming Compact in the State of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Puyallup Tribe of the Puyallup Reservation negotiated the Fifth Amendment to the Tribal-State Compact for Class III Gaming between the Puyallup Indian Tribe and the State of Washington governing Class III