

process that leaves the identity of the article intact. See *United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass'n v. United States*, 628 F.Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. See, e.g., Headquarters Ruling ("HQ") 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

For example, in HQ H267177, CBP held that Indian- and Chinese-origin Acyclovir was not substantially transformed in the United States when it was combined with excipients and processed into tablets. In that case, the Indian or Chinese Acyclovir was the only active pharmaceutical ingredient in the final product. Accordingly, we found that the processing performed in the United States did not result in a change in the medicinal use of the finished product. Furthermore, the Acyclovir maintained its chemical and physical characteristics and did not undergo a change in name, character, or use. Consistent with our previous rulings, we held that processing the Acyclovir into dosage form and packaging it for sale in the United States did not constitute a substantial transformation. Accordingly, the country of origin of the final product for purposes of U.S. Government procurement was either China or India, where the active ingredient was produced.

Similarly, in HQ H233356, CBP held that the processing and packaging of imported mefenamic acid into dosage form in the United States did not constitute substantial transformation. Based on previous CBP rulings, we found that the specific U.S. processing—which involved blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product—did not substantially transform the mefenamic acid because its chemical character remained the same. Accordingly, we held that the country of origin of the final product was India, where the mefenamic acid was produced.

In HQ 561975, we also held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the

United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

Here, as in the cases cited above, the processing of bulk imported pharmaceuticals into dosage form will not result in a substantial transformation. In this case, the processing begins with Taiwanese-origin bulk pravastatin sodium and, after this product is combined with inactive ingredients in India, results in pravastatin sodium tablets in individual doses of 10, 20, 40, or 80 milligrams. Because the product is referred to as "pravastatin sodium" both before and after the Indian processing, no change in name occurs in India. Furthermore, no change in character occurs in India because the pravastatin sodium maintains the same chemical and physical properties both before and after the Indian processing. Finally, because the imported, bulk-form pravastatin sodium had a predetermined medicinal use as an antilipimic agent that is used to reduce the risk of myocardial infarction, no change in use occurs after processing in India. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is Taiwan, where the active ingredient was produced.

HOLDING:

The country of origin of the pravastatin sodium tablets for purposes of U.S. Government procurement is Taiwan.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel,
Executive Director,
Regulations & Rulings,
Office of Trade.

[FR Doc. 2017-18205 Filed 8-25-17; 8:45 am]

BILLING CODE 9111-14-P

INTER-AMERICAN FOUNDATION

Sunshine Act Meetings

TIME AND DATE: September 6, 2017, 11:00 a.m.–12:00 p.m.

PLACE: Via tele-conference hosted at Inter-American Foundation, 1331 Pennsylvania Ave. Suite 1200, NW., Washington, DC 20004.

STATUS: Meeting of the Board of Directors, Open to the public.

MATTERS TO BE CONSIDERED: Next steps for updating advisory council membership.

The role of the Board in funding decisions.

FOR DIAL-IN INFORMATION CONTACT: Karen Vargas, Executive Assistant, (202) 524-8869.

CONTACT PERSON FOR MORE INFORMATION: Paul Zimmerman, General Counsel, (202) 683-7118.

Paul Zimmerman,
General Counsel.

[FR Doc. 2017-18263 Filed 8-24-17; 4:15 pm]

BILLING CODE 7025-01-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R8-ES-2017-N084; FF08EVEN00-FXFR1337088SSO0]

Marine Mammal Protection Act; Stock Assessment Report for the Southern Sea Otter in California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; response to comments.

SUMMARY: In accordance with the Marine Mammal Protection Act of 1972, as amended (MMPA), and its implementing regulations, we, the U.S. Fish and Wildlife Service (Service), announce that we have revised our stock assessment report (SAR) for the southern sea otter stock in the State of California, including incorporation of public comments. We now make our final revised SAR available to the public.

ADDRESSES: *Document Availability:* You may obtain a copy of the SAR from our Web site at <https://www.fws.gov/ventura/endangered/species/info/soo.html>. Alternatively, you may contact the Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003; telephone: 805-644-1766.

FOR FURTHER INFORMATION CONTACT: For information on the methods, data, and results of the stock assessment, contact Lilian Carswell by telephone (805-677-3325) or by email (Lilian_Carswell@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 are announcing the availability of the final revised SAR for the southern sea otter (*Enhydra lutris nereis*) stock in the State of California.

Background

Under the MMPA (16 U.S.C. 1361 *et seq.*) and its implementing regulations

in the Code of Federal Regulations (CFR) at 50 CFR part 18, we regulate 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. 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 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. This can be written as:

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

Section 117 of the MMPA 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 Southern Sea Otter in California

The southern sea otter SAR was last revised in 2014. Because the southern sea otter qualifies as a strategic stock

due to its listing as a threatened species under the ESA, the Service reviewed the stock assessment in 2015. The review concluded that the status had not changed, nor could it be more accurately determined. However, upon review in 2016, the Service determined that revision was warranted.

Before releasing our draft SAR for public review and comment, we submitted it for technical review internally and for scientific review by the Pacific Regional Scientific Review Group, which was established under the MMPA (16 U.S.C. 1386(d)). In a December 6, 2016 (81 FR 87951), **Federal Register** notice, we made our draft SAR available for the MMPA-required 90-day public review and comment period. Following the close of the comment period, we revised the SAR based on public comments we received (see Response to Public Comments) and prepared the final revised SAR. Between publication of the draft and final revised SARs, we have not revised the status of the stock itself (the southern sea otter continues to retain its status as a strategic stock). However, we have updated the SAR to include the most recent information available.

Summary of Final Revised Stock Assessment Report for the Southern Sea Otter in California

The following table summarizes some of the information contained in the final revised SAR for southern sea otters in California, which includes the stock’s N_{min} , R_{max} , F_r , PBR, annual estimated human-caused mortality and serious injury, and status:

SUMMARY—FINAL REVISED STOCK ASSESSMENT REPORT FOR THE SOUTHERN SEA OTTER IN CALIFORNIA

Southern sea otter stock	N_{MIN}	R_{MAX}	F_R	PBR	Annual estimated human-caused mortality and serious injury	Stock status
Mainland	3,194	0.06	0.1	9.58	Figures by specific source, where known, are provided in the SAR.	Strategic.
San Nicolas Island	78	0.13	0.1	0.51		
Summary	3,272	10		

Response to Public Comments

We received comments on the draft SAR from the Marine Mammal Commission (Commission), Friends of the Sea Otter, and the Humane Society of the United States. We present substantive issues raised in those comments that are pertinent to the SAR,

edited for brevity, along with our responses below.

Comment 1: Without adequate observer coverage to document the rate at which sea otters are being caught in crab and lobster gear, it is not possible to know if modifications to these traps should be required. Therefore, the Commission recommends that the

Service collaborate with NMFS and the California Department of Fish and Wildlife (CDFW) to (1) establish an observer program with adequate coverage to obtain reliable information on the rate and circumstances under which sea otters are being taken in crab and lobster trap fisheries operating within the range of the southern sea

otter, or (2) implement a precautionary requirement for all trap gear to be modified to reduce the probability of sea otter bycatch to near zero.

Response: We recognize that the probability of bycatch in trap fisheries will rise as the southern sea otter expands its range to the north, increasing overlap with the Dungeness crab fishery, and to the south, increasing overlap with the spiny lobster fishery and finfish trap fishery in southern California. We will continue to work with CDFW and other partners to assess the best means of testing and, if appropriate, implementing precautionary trap modifications in the fisheries that may interact with sea otters. We note that, based on tests that have occurred to date, relatively minor modifications to Dungeness crab traps (reducing the fyke opening from 4 × 9 inches (10.2 × 22.9 cm) to 3 × 9 inches (7.6 × 22.9 cm)) would exclude most independent (post-weaning) sea otters while not impeding the capture of crabs (Hatfield et al. 2011). Comparable modifications have not been identified for spiny lobster traps or the large-fyke finfish traps used in southern California. While observer programs would increase our opportunity to detect bycatch, analyses indicate that high levels of observer effort would be required to avoid false-negative conclusions, even if the rate of bycatch mortality is substantial enough to reduce the population growth rate (Hatfield et al. 2011). We will continue to work with USGS, NMFS, and CDFW to explore options for assessing sea otter bycatch.

Comment 2: Figure 3 in the draft SAR shows an increasing trend in the number of strandings as a proportion of the spring count of sea otters (termed “relative mortality” in the report), from roughly 5 percent in the late 1980s to 12 percent in the past 4 years. The draft SAR attributes this pattern largely to the increase in shark-bite mortality at the peripheries of the southern sea otter’s range. However, this interpretation assumes that search effort and stranding rates have not increased, an assumption that is not addressed in the report. The Service should address all of the factors that could explain the apparent increase in the relative number of strandings.

Response: We have added a discussion of other factors that could explain the increase in the relative number of strandings and the relative frequency of shark-bitten carcasses.

Comment 3: The Service should place greater emphasis on the fact that the “relative mortality” rate is an underestimate of the true mortality rate because a substantial portion of

carcasses likely never strand or are never found, as has been demonstrated in this and other sea otter populations.

Response: We have added text emphasizing that relative mortality is an index of mortality and an underestimate of the true mortality rate.

Comment 4: An effective opportunity for public review and comment cannot occur if the public does not have access to all of the sources of information used to produce a draft stock assessment. The draft SAR contains numerous references to sources of information that are not easily available to the public. The Service should consider implementing a policy regarding the use of different data/information sources that would ensure that those sources have been reviewed and are easily available to the public. The Commission understands that in some cases the best available science has not been reviewed and published. In those cases, if the Service uses such information in an SAR, it should make the information easily available to the public.

Response: We utilize peer-reviewed publications whenever possible. However, when the best available science on a topic of direct importance to the SAR has not yet been reviewed and published, we believe it is preferable to present that information to the public rather than to withhold it. We may cite an informal source when new scientific information becomes available and update the citation in a subsequent revision of the SAR when that information has been reviewed and published. We have updated several such citations in the final SAR. Our notice of availability (81 FR 87951; December 6, 2016) includes contact information, which is made available for the use of anyone wishing to obtain additional information, including any of the sources of information referenced in the SAR.

Comment 5: In accordance with section 117(c)(1)(A) of the MMPA, the Service may review a stock’s status annually and update its stock assessment report only when it considers it appropriate to do so. However, given the rapid changes that are ongoing within the current and historical range of the southern sea otter, the failure of the population to expand its range significantly in the past 20 years, and the sudden shifts in count trajectories in different parts of the range over the last few years, the Commission recommends that the U.S. Fish and Wildlife Service make its stock assessment reviews available yearly to the appropriate Scientific Review Group (SRG) and the Commission, at a minimum, from this point forward.

Response: We typically provide a presentation to the Pacific SRG on the status of the southern sea otter even in years when we determine that a revision of the SAR is not warranted. We will continue to make such presentations and, from this point forward, will provide our reasoning to the Pacific SRG and Commission in years when we determine that a revision of the SAR is not warranted.

Comment 6: “Stock definition and geographic range” must be expanded to include the importance of range expansion in southern sea otter survival and recovery.

Response: We have added text emphasizing the importance of range expansion to recovery of the southern sea otter and referencing Service documents that discuss the subject in greater detail.

Comment 7: “Current population trend” should be revised to include the declining trend in the southern portion of the range due to shark bite mortality.

Response: We have added text that describes the regional declining trends and their relationship to increases in shark bite mortality.

Comment 8: The SAR should identify shark bite mortality as a factor impeding the recovery of the southern sea otter and encourage the close monitoring of this significant trend. The Service should confirm that delisting would not be appropriate even if the delisting threshold of 3,090 animals is met for 3 consecutive years unless the threat posed by shark bites has been addressed.

Response: We will continue to monitor shark-bite mortality through the stranding and necropsy programs led by USGS and CDFW, and we have added text that makes more explicit the relationship between high rates of shark-bite mortality and the lack of range expansion. However, we do not believe that the SAR is the appropriate document in which to discuss threats to the species in comprehensive detail or to make recommendations regarding delisting. We will update our assessment of the status of the southern sea otter in relation to the five threat factors described in section 4(a)(1) of the ESA in the next 5-year review.

Comment 9: “Status of Stock” should be discussed in relation to the five statutory delisting criteria and the recovery plan, in addition to optimum sustainable population (OSP) under the MMPA, noting that OSP has been discussed for the California coast but should also be considered on a range-wide basis, after accounting for the possible need to avoid interbreeding

between northern and southern sea otters.

Response: As noted in our response to Comment 8, we do not believe that the SAR is the appropriate document in which to discuss threats to the species in comprehensive detail. However, we have added text that references our most recent 5-year review (Service 2015). We have also added text clarifying that a formal determination of OSP will be developed with reference to the entire historic range of the subspecies.

Comment 10: “Habitat issues” should be revised to include (1) the spatial structure of southern sea otter habitat and its contribution in preventing recovery of the species and (2) a detailed discussion of the risk posed by oil spills.

Response: We have added text clarifying the relationship between the pace of range expansion, the spatial structure of sea otter habitat, and oil spill risk. However, as noted in our response to Comments 8 and 9, we do not believe that the SAR is the appropriate document in which to discuss threats to the species in comprehensive detail. We address oil spill risk and the effects of the spatial structure of sea otter habitat on population growth in our most recent 5-year review (Service 2015). We will update our assessment of these and other factors in the next 5-year review.

Comment 11: There are recent reports of what appear to be increasing rates of shooting-related incidents. For example, in 2016 alone there were reports of at least three sea otters being shot. In 2015, a California man was sentenced for shooting an air rifle at sea otters. While these incidents are more recent than the time period of the SAR, which is largely through 2014, they do represent the most recent available information and should be considered for inclusion since the Service provided information on some deaths as recently as 2016.

Response: We have added text stating that three sea otters died of gunshot wounds in 2016. However, we do not include these mortalities in the current calculation of mean annual mortality because they occurred outside the 5-year analysis window (2011–2015).

Additional References Cited

Chinn, S.M., M.A. Miller, M.T. Tinker, M.M. Staedler, F.I. Batac, E.M. Dodd, L.A. Henkel. 2016. The high cost of motherhood: end-lactation syndrome in southern sea otters. *Journal of Wildlife Diseases* 52:307–318. doi: 10.7589/2015-06-158.

Lafferty, K.D. M.T. and Tinker. 2014. Sea otters are recolonizing southern California in fits and starts. *Ecosphere* 5:50. <http://dx.doi.org/10.1890/ES13-00394.1>.

Tinker, M.T. 2014. Models and sea otter conservation. Pp. 257–300 in Larson, S., G. VanBlaricom and J. Bodkin, eds., *Sea Otter Conservation*. New York: Elsevier.

Tinker, M.T., and B.B. Hatfield. 2016. California sea otter (*Enhydra lutris nereis*) census results, spring 2016. U.S. Geological Survey Data Series 1018. 10 pp. <http://dx.doi.org/10.3133/ds1018>.

Authority

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

Dated: July 26, 2017.

Gregory Sheehan,

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

[FR Doc. 2017-18169 Filed 8-25-17; 8:45 am]

BILLING CODE 4333-15-P

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have issued the following permits to conduct certain activities with endangered species, marine mammals, or both. We issue these permits under the Endangered Species Act (ESA) and the Marine Mammal Protection Act (MMPA).

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281. To locate the **Federal Register** notice that announced our receipt of the application for each permit listed in this document, go to www.regulations.gov and search on the permit number provided in the tables in **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Joyce Russell, (703) 358–2023 (telephone); (703) 358–2281 (fax); or DMAFR@fws.gov (email).

SUPPLEMENTARY INFORMATION: On the dates below, as authorized by the provisions of the ESA, as amended (16 U.S.C. 1531 *et seq.*), we issued requested permits subject to certain conditions set forth therein. For each permit for an endangered species, we found that (1) the application was filed in good faith, (2) the granted permit would not operate to the disadvantage of the endangered species, and (3) the granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-HQ-IA-2017-0054; FXIA1671090000-156-FF09A30000]

Foreign Endangered Species and Marine Mammals Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

Permit No.	Applicant	Receipt of application Federal Register notice	Permit issuance date
Endangered Species			
50819A	Zoological Society of San Diego/San Diego Zoo Global	82 FR 24381; May 26, 2017	June 30, 2017.
18137C	University of Wisconsin-Madison	82 FR 24381; May 26, 2017	July 3, 2017.
75285A	Michael Ryckamn	82 FR 24381; May 26, 2017	June 29, 2017.
14745C	Cleveland Metroparks Zoo	82 FR 24381; May 26, 2017	July 11, 2017.
06369C	Indiana Purdue University	82 FR 14742, March 22, 2017	July 3, 2017.
Marine Mammals			
80164B	North Slope Borough Department of Wildlife Management ...	81 FR 95628; December 28, 2016	July 3, 2017.