ALASKA NATIVE HARBOR SEAL COMMISSION

Dec 12, 2007

Chief, Permits, Conservation and Education Division,
Attn: Permit Regulations ANPR,
Office of Protected Resources, NMFS
1315 East-West Highway, Room 13705
Silver Spring, MD 20910
Via Fax (301-427-2521)

Re: Marine Mammals; advance Notice of Proposed Rulemaking

We are in support of language that would make it OK for ANO's to transfer biological samples from subsistence harvested marine mammals into the scientific research community with no permit requirement for the affected Alaska Natives.

In addition, we support changes to the definition of "authentic native article of handicraft and clothing" in 50 CFR 216.3 by eliminated the date the MMPA became effective (December 21, 1972). In an effort to stay consistent with the regulations that the USFWS has adopted regarding this section, we support this change.

Sincerely,

Monica Riedel

Monica Riedel

800 E. Dimond, Suite 3-625 • Anchorage, Alaska 99515 • (907)345-0555 • Fax (907)345-0566 • Toll Free 1-888-424-5882
Conserving and sustaining the harbor seal for our cultural well-being"

ALLIANCE OF MARINE MAMMAL PARKS AND AQUARIUMS

An international organization dedicated to conservation through public display, education, and research

December 6, 2007

Mr. Michael Payne, Chief
Permits, Conservation and Education Division
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910

VIA E-mail

RE: Docket No. 070809454-7459-01

Dear Mike:

The Alliance of Marine Mammal Parks and Aquariums ("Alliance") is pleased to submit comments on the Advance Notice of Proposed Rulemaking ("ANPR") regarding possible changes to regulations governing the issuance of permits for scientific research and enhancement activities under section 104 of the Marine Mammal Protection Act ("MMPA"), 72 Fed. Reg. 52339 (Sept. 13, 2007).

Background

In 1993, the National Marine Fisheries Service ("NMFS") published a proposed rule that included its suggested revisions to regulations for public display, scientific research, and enhancements permits, 58 Fed. Reg. 53320 (October 15, 1993). Amendments to the MMPA in 1994 made many of these proposals unnecessary. In 1996, NMFS finalized a regulation that updated and consolidated the rules for special exception permits for these activities, 61 Fed. Reg. 21926 (May 10, 1996). In 2001, NMFS proposed to amend the regulations for permits to capture or import marine mammals for purposes of public display, 66 Fed. Reg. 35209 (July 3, 2001). NMFS has indicated to the Alliance that proposed regulations for public display facilities will be written and published after the next reauthorization of the MMPA.

General Comments

As detailed in our comments, the Alliance is concerned that the changes contemplated in this ANPR, aimed at scientific and enhancement activities, will have unintended consequences for the public display community. Although the ANPR states repeatedly that any proposed rulemaking will be limited to permits for scientific research and enhancement activities, many of the changes suggested in the ANPR are to sections of the regulations that also apply to public display. Even where that is not the case, regulatory amendments adopted by the agency with respect to scientific research and

enhancement permits may establish precedents to be followed later with respect to public display. The Alliance believes it is time to separate these activities and bring clarity to regulations for public display facilities. Should the agency agree with this approach, this may require the issuance of a new ANPR, one that clearly indicates that the agency intends to issue distinct regulations for public display facilities.

The Alliance is very supportive of researchers conducting marine mammal studies including those undertaking research with marine mammals in the wild and with animals collected from the wild for research purposes. The Alliance has a Research Committee that promotes responsible scientific study of marine mammals in public display facilities and in the wild. We are a co-sponsor of *Aquatic Mammals*, which is the oldest international scientific, peer-reviewed marine mammal journal. Many of our member marine life parks, aquariums, and zoos fund important field research, which improves the understanding of marine mammal biology, physiology, reproduction, behavior, life history, and ecology. Our members also cooperate with scientists by making animals available for their research and/or making husbandry data gathered at our facilities available – data that are difficult or impossible to obtain in the field.

Much of the research undertaken at Alliance facilities or by Alliance members contributes to the conservation and management of marine mammal populations in the wild. Studies by Alliance members also contribute to the body of knowledge needed to better treat sick, injured, or orphaned stranded marine mammals. (Attached is the Alliance Research Book, summarizing on-going projects.)

With respect to the current scientific research permit regulations, the sad reality is that the existing process for issuing research permits is unreasonably cumbersome and time-consuming. NMFS' effort to streamline and improve the process is timely and welcome. Before proceeding to comment on specific regulatory provisions, we would note that in considering how to streamline the research permitting process NMFS should clarify that no permit is necessary if the research is being conducted with marine mammals currently exhibited in zoological parks and aquariums. There appears to be some confusion about when permitting is required for such research and the ANPR provides the opportunity to clarify this issue. Research with marine mammals in zoological parks and aquariums is under the purview of the Animal and Plant Health Inspection Service ("APHIS") pursuant to their authority over the care and maintenance of marine mammals at public display and other facilities. Additionally, research with these animals is vetted by the Institutional Animal Care and Use Committee ("IACUC") of the research facility initiating the study and/or the facility at which the research will be performed. The MMPA does not authorize or require oversight or permitting by NMFS in these instances.

The following specific comments are organized by the regulatory section to which NMFS is considering changes.

50 C.F.R. § 216.45

The Alliance is heartened the agency is considering modifications to this section to allow a General Authorization ("GA") based on the status of the target stock, rather than based

on the level of harassment. As the ANPR notes, this change would make a GA available for Level A and Level B research on non-strategic stocks of marine mammals. This change will expedite the permit process considerably, which is the goal of all involved.

The Alliance also supports the issuance of a GA for marine mammals defined by the MMPA as strategic. This change, limited to Level B research activities, would require the agency to amend section 104(c)(3)(C) of the MMPA. We would support the agency in its legislative effort to amend the Act.

With respect to strategic stocks, the Alliance understands that permit applications to conduct research with marine mammals listed under the Endangered Species Act ("ESA") must be considered under the stricter rules demanded by the Act. However, a significant number of orphaned, injured, or disabled animals protected under the ESA are given homes in zoological parks or aquariums because these animals cannot survive in the wild. This situation provides scientists a unique opportunity to learn about a species that is not generally on public display and whose population is endangered or threatened.

Under the existing permit process, these animals are treated as if the facility had collected them from the wild for research. Clearly this is not the case. These are beached or stranded animals that we did not collect, which NMFS has determined cannot be released to the wild, and which we are caring for at the request of your agency. The existing regulatory approach which treats these non-releasable stranded and beached animals as if they were intentionally removed from the wild imposes unnecessary burdens on the agency and the public display community. The applicable regulations need to be changed to reflect the special circumstances surrounding these animals. Public display facilities, which often accept the responsibility for caring for stranded animals at NMFS' request, should not be treated as a facility which sought to collect the animals from the wild. The agency should support a regulatory system that corrects this problem and facilitates learning about these species so we can develop information that will contribute to the agency's management of populations in the wild. The permitting process should not be a burden to the agency, researchers, or zoological parks and aquariums that want to conduct important research that will benefit troubled species.

50 C.F.R. § 216.41

The Alliance strongly supports the public display of marine mammals collected for scientific research under a NMFS research permit. Congress approved a public display exception to the MMPA's prohibition on the taking of marine mammals because of the importance of the research and education programs conducted at our facilities. Hence, the Alliance believes the public should be able to view and to learn about animals that have been collected from the wild for research purposes. Introducing people to living, breathing dolphins and other marine mammals is a powerful, proven way to promote wildlife conservation.

In this regard, the agency should be mindful of the report language accompanying two bills amending the MMPA passed by the U.S. House of Representatives in 2004 and 2005. Each report stated:

> The Committee commends the public display community for its role in the conservation and management of marine mammals. Activities sponsored by public display facilities—research, educational programs, and presentations, animal husbandry, breeding, and rescue and rehabilitation—are important aspects to the conservation of marine mammals. The rescue and rehabilitation programs run by these facilities are critical to the survival of stranded animals and for many years participating institutions ran these programs using their own funds. In addition, these facilities play an invaluable role for the general public. These public display facilities are the only place for many Americans to view marine mammals and learn about the conservation needs of these animals. The Committee believes the interactions provided at these facilities generate the general public's good will toward marine mammals and develops their support for conservation and management measures for these and many other ocean creatures.

The current restrictions on the public display of research animals are costly, burdensome, and illogical. According to a 2006 Harris International poll, 94 percent of the public believes that helping species in the wild by studying their biology and physiology in marine life parks, aquariums, and zoos is an essential activity. Ninety three percent of the public believes that research projects that help marine mammals are very important. The public learns about these animals and cares about their conservation in large part because of public display at our facilities. Restricting the learning opportunities provided by viewing these animals is counter to the purposes and intent of the MMPA.

However, the Alliance is very concerned about one part of the suggested new section 216.41(c)(3). Our concern revolves around the suggestion in the ANPR that the public display of non-releasable ESA-listed marine mammals originally obtained under a research permit can occur only if NMFS approves the educational program established by the facility. In 1994, Congress enacted amendments to the MMPA specifically prohibiting NMFS from exercising control over the nature and content of educational programming at public display facilities. To the extent the ANPR proposes to reassert that authority, it is contrary to the language and intent of the MMPA.

50 C.F.R. § 216.37

NMFS is to be commended for attempting to simplify and streamline the rules regarding the transfer of marine mammal parts and products for use by researchers. This administrative process provides the opportunity to infuse some common sense into the regulations. These are parts and specimens, not live animals. The agency should require a simplified, General Authorization and look closely at the rules that now require notifying the Regional Director of any transfer or loan. This appears to be a section that begs for change. The current rules for the use of these parts and specimens for educational purposes are so convoluted as to be unintelligible and unenforceable.

Specifically, the Alliance proposes the establishment of one General Authorization or general permit that would constitute an umbrella under which researchers can, without further permitting, transfer marine mammal parts and products from marine mammals which are (1) already dead or (2) resident in scientific research or public display facilities. This issue arises because the MMPA defines the term "marine mammals" to include parts. Therefore, the MMPA's prohibition on the taking of marine mammals applies to parts. The principal purpose of including parts and products within the definition of marine mammals was to protect species in the wild by insuring there was no illicit traffic of parts and products which would, in turn, generate pressure on wild populations. That purpose and intent is not applicable with respect to the parts and products of animals that are deceased or that are no longer in the wild. Therefore, a General Authorization or permit coupled with appropriate recordkeeping requirements should be sufficient to fulfill the Act's purposes and to achieve the objective of streamlining the permitting process for scientific research.

On the question of streamlining permits related to archiving marine mammal parts for future opportunistic research, the agency should make every effort to improve this process as well. These data have important ramifications for marine mammal health and conservation. The agency may include these parts in the GA suggested above.

While unstated in the ANPR, the Alliance assumes that when the agency suggests adding regulations regarding cell lines and/or gametes, NMFS is referring to those acquired from marine mammals in U.S. waters, or those being imported. NMFS does not have the statutory authority to regulate any use of these specimens within and between zoological parks and aquariums. Nor do we believe that cell line development from stranded or other marine mammals in the wild is a "take" under the MMPA. A new regulation specifying the "requirements and procedures governing the development, use, distribution or transfer, and prohibited sale of cell lines derived from marine mammal tissues" or gametes would be excessive and unwarranted.

50 C.F.R. § 216.33(c)

NMFS is considering publishing a permit application before an environmental assessment or an environmental impact statement is completed. The ANPR implies the agency will not make a decision on how to comply with the National Environmental Policy Act ("NEPA") until after the comment period on the permit application. This suggests the agency is establishing a two-tier comment process that will considerably lengthen the permit process for all MMPA permits. We sincerely hope it is not the agency's intent to establish two sequential comment periods. We are hopeful the agency is suggesting that the NEPA and MMPA processes will proceed concurrently, thereby providing another avenue to improve the permitting process.

50 C.F.R. § 216.33(e)(4)

With respect to species protected under the ESA, NMFS is asking for public comment regarding how to determine if an applicant has applied for a permit in good faith and if the permit will operate to the disadvantage of the protected species. The Alliance is

extremely concerned about these issues because the section NMFS is proposing to amend applies to the issuance of permits to public display facilities. In considering any regulatory changes, the agency should recognize certain facts. First, marine mammal researchers must submit their CVs with a permit application. This provides the agency with the individual's experience and expertise. Second, no responsible researcher would apply for a permit in anything other than "good faith." Third, as to whether the research will be to the "disadvantage" of the species, the permit applicant is currently asked to "Describe the Anticipated Effects of the Proposed Activity." This documentation should be sufficient for any no-detriment finding. Obviously the agency is attempting to solve a particular problem. In doing so, the Alliance does not believe the suggested language would be useful, effective, or constructive.

50 C.F.R. § 216.34

NMFS is seeking comment on whether the regulations set forth in this section should be amended to clarify the proof required to demonstrate the research activity is humane. 50 C.F.R. § 216.34 states: "Humane means the method of taking, import, export, or other activity which involves the least possible degree of pain and suffering practicable to the animal involved." Certainly, as the agency suggests, approval by an Institutional Animal Care and Use Committee should be sufficient. In addition, the American Society of Mammalogists has ethical guidelines addressing this issue and the Society of Marine Mammalogy is finalizing similar guidelines. There is precedent for the agency to require that professional association standards be used and the Alliance recommends that this approach be adopted with respect to any determination regarding humaneness. Should the agency continue in the approach suggested in the ANPR, the agency should be clear that the "humaneness" standard at issue relates solely to the research activity per se in order to avoid any confusion over the use of that term in other sections of the MMPA.

50 C.F.R. § 216.35

The ANPR seeks comments regarding the establishment of minimum qualification standards for scientists applying for research permits. Developing such standards will be extraordinarily difficult as this is a subjective determination and, if carried to extreme, would likely require standards specific to each type of research.

This section of the regulations, which NMFS is considering amending, also applies to public display. If the agency proposes changes to this section, the agency should be clear that the regulations do not apply to professionals at zoological parks and aquariums.

50 C.F.R. § 216.39, 50 C.F.R. § 216.35

In the ANPR, NMFS asks whether the agency should continue its current distinction between major and minor permit amendments and also advocates removal of language in § 216.35(b) that provides for a one-year extension of the original permit. These amendments aid researchers in obtaining permits necessary for the continuation of studies. They provide the agency with flexibility as well. Changing these sections would be a step in the wrong direction advantageous to neither researchers nor the agency,

whose burden to process additional permits would be increased. The Alliance supports preserving the concept of expedited minor amendments. As noted in previous comments, these sections also apply to public display.

50 C.F.R. § 216.40

In the ANPR, the agency is asking for comment on whether a research permit should be suspended, revoked, modified, or denied "for reasons not related to enforcement actions." The ANPR is silent on the reasoning for this recommendation; hence, the Alliance cannot comment. However, the Alliance reminds the agency that this section applies to all permits, including public display, and we are concerned about the legal basis for revoking, etc. a permit if such action is not related to enforcement issues, statutory changes, or changes in the regulations.

General Amendments

Lastly, NMFS is considering a general amendment that would establish specific time periods during which the agency will accept permit applications. While the Alliance supports agency efforts to streamline the permit process, limiting permit applications to specific periods may not be the optimum approach. If the goal of the agency is to review all research proposals involving the same populations or species, in an effort to best manage research with the animals, the agency may need to look for an alternate approach rather than create a new process that is restrictive and does not solve the problem.

Also, field researchers are often limited to seasonal studies. Those studies will likely be jeopardized if permits can be submitted only at specific intervals. We understand the agency must meet NEPA requirements and that processing multiple, similar permits in the same time period would be advantageous to the agency. Recognizing the agency's concerns, the Alliance suggests considering the use of NEPA templates or programmatic EISs as a way to streamline the process and as an alternative to restricting permit applications to specific filing times.

Additional Recommendations

The marine mammal community is a global network of marine life parks, aquariums, and zoos. International membership in the Alliance continues to expand. Animals are moved often for breeding purposes and/or for animal management. These transports do not involve collections from the wild. Therefore, the Alliance recommends that NMFS amend its regulations to clearly establish that permit applications do not require information on stock assessments when the animals have been bred in a zoological park or aquarium or are currently in a facility. In such situations, these are no longer relevant data. The transport of these marine mammals does not have any adverse affect on the original stock or population in the wild. The animals are in facilities and should be provided the best care. This is a time-consuming and arduous requirement that is neither relevant nor meaningful. When the agency addresses public display regulations, we propose that the agency insert language that will preclude stock assessments for animals

currently in zoological parks and aquariums. This language should also be inserted in any proposed regulations for research and enhancement permits.

We appreciate the opportunity to comment on the ANPR. The Alliance recommends that prior to issuing any proposed rulemaking, the agency organize a conference call or meeting with respected marine mammal researchers to discuss the issues raised by NMFS. There may be alternative avenues available to the agency to address concerns raised in the ANPR and there is always benefit from a collective discussion with those who are familiar with the process and supportive of your efforts to streamline it.

Sincerely,

Marilee Menard

Marilee Menard
Executive Director

Subject: Permit Regulations ANPR
From: Susan Millward <susan@awionline.org>
Date: Wed, 12 Dec 2007 19:19:24 -0500
To: NMFS.PR1Comments@noaa.gov

Mike Payne
Chief Permits Division
Office of Protected Resources
NMFS 1315 East-West Highway
Silver Spring, MD 20910

Attn: Permit Regulations ANPR

Dear Mr. Payne,

I submit the following comments on the above-referenced Advance Notice of Proposed Rulemaking (Fed Reg Vol. 72, No. 177, dated September 13, 2007)

1) Section 216.33 - We oppose the proposed change. Compliance with NEPA should be performed prior to the issuance of a permit for public comment. It is important that the public be afforded the opportunity to review the information and processes that NMFS has considered in making its NEPA determination ahead of the public formulating its comments as this information and these processes may have a bearing on the public's comments.

2) Section 216.34 - We support the proposed requirement for proof of IACUC approval pursuant to the Animal Welfare Act.

3) Section 216.35 and Section 216.39 - We support the proposed change provided that the minor amendments are truly minor and do not involve amendments that would in any way place an animal at a greater risk of harassment or harm or put more animals or more species at risk. The public should be allowed to comment on any non-minor amendment which we mean to include amendments to procedures used, additional animals, different sexes and/or ages of animals, additional locations of activity, different time(s) of year of activity, or new species.

4) Section 216.42 - We support the proposed addition to limit the number of personnel on a photography permit as we believe that such permits should not be used as authorizations for eco-tourism.

5) Section 216.45 - We oppose the proposed change. We are concerned that the proposed change would allow for potentially harmful activities to non-ESA listed species or other 'strategic' stock to be authorized under a general authorization without opportunity for public comment.

6) New Section - We support the proposed addition to establish cycles of permit applications.

We appreciate being given the opportunity to comment. Please contact me if you have any questions or require any clarification of my comments.

Sincerely,

Susan Millward
Research Associate
Animal Welfare Institute

ASSOCIATION OF ZOOS & AQUARIUMS

8403 Colesville Road, Suite 710
Silver Spring, MD 20910-3314
301-562-0777 tel 301-562-0888 fax
www.aza.org

December 10, 2007

Mr. Michael Payne, Chief
Permits, Conservation and Education Division
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910

RE: Docket No. 070809454-7459-01

Dear Mike:

On behalf of the 216 accredited institutional members of the Association of Zoos and Aquariums (AZA), I respectfully submit the following comments with regard to the National Marine Fisheries Service's (NMFS) advanced notice of proposed rulemaking (ANPR) regarding possible changes to regulations governing the issuance of permits for scientific research and enhancement activities under section 104 of the Marine Mammal Protection Act ("MMPA"), 72 Fed. Reg. 52339 (Sept. 13, 2007).

AZA institutions draw over 156 million visitors annually and have more than eight million zoo and aquarium members who provide almost $100 million in support. These institutions teach more than 12 million people each year in living classrooms, dedicate millions annually to education, conservation and scientific research programs and support over 1,800 field conservation and research projects in 80 countries.

AZA GENERAL COMMENTS

While AZA applauds the agency's attempt to streamline the cumbersome permitting processes related to marine mammals, we believe that this ANPR will only lead to a more confusing, overly-complicated and exceedingly-slow permit system. Currently, we see that the NMFS MMPA permitting process is gridlocked, with even non-controversial permit renewals requiring over a year to complete. The Permits Division of the Office of Protected Resources is understaffed—constantly facing a myriad of legal challenges. Resources are urgently needed to add staff and to comply with both the Endangered Species Act, MMPA and the National Environmental Policy Act. NMFS' first priority should be swift action to secure the funds necessary to implement its mandate and to find ways to expedite critical permit applications. We do not believe this ANPR addresses those two critical issues.

In addition, AZA is very concerned that while the stated purpose of this ANPR is to address issues focused on marine mammal scientific research and enhancement activities, the ANPR could also significantly impact the public display community. Although the ANPR states repeatedly that any proposed rulemaking will be limited to permits for scientific research and enhancement activities, many of the changes suggested in the ANPR are to sections of the MMPA regulations that also apply to public display. Even where that is not the case, regulatory

procedures that are adopted by the agency with respect to scientific research and enhancement permits may establish precedents to be followed later with respect to public display.

Consequently, AZA urges that this ANPR be withdrawn and that two distinct advanced notices be promulgated which clearly separate research issues from public display issues. AZA recommends that the agency prepare a public display ANPR which discusses: 1) where the information gaps are and what the agency has done to close those gaps and 2) what the recurring problems are, why the agency perceives these as problems (specific incidents) and the potential solutions to those problems (including cost/benefit analyses). Then, respondents could support or oppose these preliminary findings based on their own additional information—scientific or professionally observed. Under this scenario, respondents would have an opportunity to comment on both the perceived regulatory problems and the proposed solutions.

AZA SPECIFIC COMMENTS

Aside from AZA's request for a separate ANPR for the public display of marine mammals, we would like to provide comments on some specific issues raised in the current ANPR.

Research on marine mammals at public display facilities

Knowledge acquired through research with animals in public display facilities, in tandem with field research, is another fundamental contribution to marine mammal conservation. Communicating this knowledge is one of the most effective means of ensuring the health of wild marine mammals in the 21st century. Much of this research simply cannot be accomplished in ocean conditions.

Tens of millions of dollars are being spent on research at and by AZA member facilities that is essential in understanding the anatomy and physiology of marine mammals, in treating sick and injured animals from the wild, and in learning to better manage and assist endangered species. Additionally, many AZA facilities collaborate with marine mammal researchers from colleges, universities, and other scientific institutions that conduct studies important to wild species' conservation and health. Over the years, this body of work has contributed significantly to the present knowledge about marine mammal biology, physiology, reproduction, behavior and conservation. These studies have led to improvements in diagnosing and treating diseases; techniques for anesthesia and surgery; tests for toxic substances and their effects on wild marine mammals; and advancements in diet, vitamin supplementation, and neonatal feeding.

In a couple of instances in this ANPR, it appears that NMFS is trying to establish regulatory protocols for scientific research of marine mammals at public display facilities.

AZA Response: Research at public display facilities is under the purview of the US Department of Agriculture (USDA) pursuant to their authority over the care and maintenance of marine mammals at public display and other facilities. Additionally, research with these animals is vetted by the Institutional Animal Care and Use Committee ("IACUC") of the research facility initiating the study and/or the facility at which the research will be performed. AZA has worked closely with USDA in establishing guidelines for such research and in determining when public display facilities must register as a research facilities. The MMPA does not authorize or require oversight or permitting by NMFS in these instances.

Cell lines and gametes

NMFS is considering adding requirements and procedures governing the development, use distribution or transfer, and prohibited sale of cell lines derived from marine mammal tissues.

AZA Response: It is unclear to AZA why the agency is seeking additional regulatory authorities when the agency cannot complete its current mandated responsibilities in a timely manner. No justification for this additional responsibility is outlined in the ANPR.

The agency also is considering similar regulations pertaining to gametes used by the public display community in assisted reproductive techniques of captive marine mammals.

AZA Response: AZA believes that the same concerns stated above re cell lines are applicable here. In addition, AZA strongly believes that this activity falls under the purview of the USDA and that the MMPA does not authorize or require oversight or permitting by NMFS in these instances.

Environmental Assessments and Environmental Impact Statements

NMFS is proposing publishing a permit application before an environmental assessment or an environmental impact statement is completed. The ANPR implies the agency will not make a decision on how to comply with the National Environmental Policy Act ("NEPA") until after the comment period on the permit application.

AZA Response: AZA is concerned that if this is done sequentially, this will only lengthen the MMPA permit review process.

Thank you for the opportunity to comment on this important proposal. We look forward to working with you and your staff in the future to continue to explore effective and efficient ways for our institutions to work together in the areas of marine mammal protection, education and marine mammal stranding, rescue and rehabilitation.

Regards,

Steven G. Olson
Vice President, Government Affairs

Subject: Permit Regulations ANPR
From: "Boogdanian, Dolores (DCR)" <Dolores.Boogdanian@state.ma.us>
Date: Thu, 13 Dec 2007 16:53:19 -0500
To: NMFS.PR1Comments@noaa.gov

December 13, 2007

Chief, Permits
Conservation and Education Division
Attn: Permit Regulations ANPR
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway, Room 13705
Silver Spring, MD 20910

Dear Sir:

These comments are in connection with proposed changes to the implementing regulations under 50 CFR, Part 216. I have not had the ability to fully study the proposed changes and the queries posed under the ANPR notice, although I appreciate the extent to which NMFS hopes to solicit public input on the issues raised. With time limited, I wish to offer this basic comment regarding any changes to the rules under Part 216, which is that nothing should be changed that would increase the likelihood of a taking of marine mammals, or that would expand the ability of takings for research or display purposes. As other nations continue to take species for alleged research or education purposes – but are more likely for commercial purposes or food – our nation must not follow this destructive and environmentally unjustifiable path. To that end, one particular recommendation would be to modify the definition of "bona fide research" under Section 216.3 to indicate that the research must do more than "likely" add to "basic" scientific knowledge, but would instead add to existing knowledge in a scientifically significant way.

I also would suggest that "large scale drift net" be defined as something less than 2.5 kilometers in size due to the significant impact these drift nets has on the ocean ecology, and the numbers of mammals and other sea creatures snared.

I would also suggest that, in Section 216.22, that officials should be required to limit a taking to those circumstances when there is an imminent threat to public welfare, particularly if the taking will result in mortality.

I wish I could offer more substantive recommendations at this time, but thank you for your consideration of these points.

Dolores Boogdanian
452 Park Drive
Boston, MA 02215

Dave Casper Comments on ANPR

Thank you for the opportunity top comment upon the NMFS permitting process.

Now is a good time for NMFS to examine the issue of research and rehabilitation. There has existed a problem in that stranded animals are either categorized and permitted as animals in rehabilitation, or as research (or public display) animals. Marine mammals that strand are automatically considered to be in rehabilitation until such time that they can be transferred to either a research or public display permit. There has been some ability to conduct research on stranded animals based upon the national stranding permit held by Teri Rowles. Given the changes coming on the impending renewal of the NMFS national stranding protocol some curtailment of these research opportunities may be ahead. This is an issue that should be addressed at this time.

There is a current debate on whether stranded animals should be rehabilitated. The recent review of "Rehabilitation and Release of Marine Mammals in the United States: Risks and Benefits" in Marine Mammal science Vol. 23 No. 4 2007 by Moore et al. is an excellent review of the many issues surrounding the permitting of stranded animals. I would suggest this article as an excellent resource in the current consideration of permitting regulations.

The article correctly states that marine mammal rehabilitation (and by extension, the permitting of marine mammal rehabilitation) is characterized by "polarized attitudes" and "lacks a coherent central set of core values, ethics, or goals."

I wish to couch all of my comments with regard to the collection of scientific information from live stranded marine mammals within the existing legal framework of the MMPA.

The number of marine mammal rehabilitation facilities which conduct bona fide scientific research is very small. It is these facilities which will, over time, generate the scientific information required by regulatory agencies, such as NMFS, to formulate future policies and regulations for marine mammal rehabilitation and hopefully avoid the current "polarized attitudes".

Although the nature of the information collected from live stranded animals must be interpreted in the context of a stranding event (in which some compromise of the animal is inferred), at the same time, the nature of the information that can be collected from live stranded animals, at the present time, cannot be collected from free living marine mammals. As such, research data collected from live stranded animals is an invaluable contribution to the body of knowledge on marine mammals.

Without reiterating the totality of the issue, my comment:

There must be some special permitting status granted rehabilitation facilities that conduct bona fide scientific research, which enables them to 1.) conduct opportunistic research on stranded animals without the delays inherent in the normal path for obtaining a research permit (and/or be dependent upon the national stranding permit held by Teri Rowles), and 2.) have some autonomy in determining the release criteria on a case by case basis depending upon research need.

I would note that the dollar value of a display Tursiops has now far exceeded a point where Tursiops in captivity can be transferred to dedicated research facilities to act as surrogates for live stranded animals in scientific research programs. LML has long argued for the creation of national stranding centers where long term resident stranded animals, and an agenda free from the pressures of public display, can generate the science necessary to resolve many of the important issues surrounding marine mammals.

Submitted via electronic mail and fax

Chief, Permits
Conservation and Education Division
Attn: Permit Regulations ANPR
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway
Room 13705
Silver Spring, MD 20910
Fax: (301) 427-2521
Email: NMFS.Pr1Comments@noaa.gov

Re: Permit Regulations ANPR

Thank you for the opportunity to submit comments on the proposed changes to the regulations and criteria governing the issuance of permits for scientific research and enhancement activities under section 104 of the Marine Mammal Protection Act ("MMPA"). 72 Fed. Reg. 52339 (Sept. 13, 2007). These comments are submitted on behalf of the Center for Biological Diversity, its staff, and members.

The Center for Biological Diversity is a nonprofit environmental organization focused on the conservation of native species and their habitats. The Center's Ocean Program is concerned with the protection of ocean ecosystems and the marine life. The Center has worked extensively toward the conservation of marine mammals and reducing threats to their survival.

Congress enacted the MMPA in 1972 in response to widespread concern that "certain species and population stocks of marine mammals are, or may be, in danger of extinction or depletion as a result of man's activities." 16 U.S.C. § 1361(1). The MMPA is an important mechanism for ensuring the conservation of marine mammals.

Our primary concern is the National Marine Fisheries Service's ("NMFS") proposed change to § 216.45 which could potentially allow a General Authorization for Level A harassment of marine mammals. 72 Fed. Reg. at 52342. Any applications for Level A harassment need specific, noticed review to ensure the conservation of marine mammals. Following is a discussion of this concern as well as other specific comments in response to the Advance Notice of Proposed Rulemaking.

§ 216.41 Permits for Scientific Research and Enhancement:

Efforts to streamline permits for scientific research and enhancement with general permitting requirements should balance the need to facilitate scientific research with thorough environmental review of the impacts of any take authorizations and the need for public participation.

§ 216.45 General Authorization for Level B Harassment for Scientific Research:

We have concerns about the proposed change to the General Authorizations that would focus only on the status of the stock and disregard the level of harassment. The MMPA allows a General Authorization solely for "bona fide scientific research that may result *only in taking by Level B* harassment of a marine mammal." 16 U.S.C. § 1374 (c)(3)(C) (emphasis added). Therefore, NMFS is not authorized by the MMPA to grant a General Authorization for Level A harassment.

The proposed changes violate the MMPA because they would allow a General Authorization for Level A or Level B harassment for non-strategic stocks. Level A harassment means "any act of pursuit, torment, or annoyance which has the potential to injure a marine mammal or marine mammal stock in the wild." 50 C.F.R. § 216.3. This level of harassment could pose a threat to the survival of a marine mammal. Any applications for Level A harassment require scrutiny to ensure the conservation of marine mammals. Prior to issuing a permit for this level of harassment NMFS must allow for an individualized and specific review process, including public notice and opportunity for comment. The purpose of the MMPA is to conserve marine mammals, and such permits should continue to require a thorough and meaningful review prior to issuance.

In regards to the other proposed changes to this section, we support the proposal to clarify that the description of methods in the letter of intent must specify the number of marine mammals, by species or stock, that would be taken, including a justification for such sample sizes. Furthermore, it is acceptable for NMFS to place the authorizations on a review cycle. Such changes to timing should allow reasonable access to scientific research and must ensure compliance with the MMPA, NEPA, and ESA obligations.

Other Comments

§ 216.15 Depleted Species: We agree that this section could be clarified by including an explanation that any species or population stock listed as threatened or endangered under the Endangered Species Act ("ESA") is automatically listed as depleted under the MMPA.

§ 216.33 Permit Application Submission, Review, and Decision Procedures: Any changes proposed to subsection (c) must comply with the National Environmental Policy Act ("NEPA") and its implementing regulations and ensure the appropriate level of environmental documentation and public participation. Efforts to streamline permit procedures must not

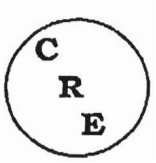
compromise full environmental review that is vital for agency decisionmaking and public information.

Conclusion

When proposing changes to the regulations governing take authorizations under the MMPA for scientific research, NMFS must carefully balance the need to facilitate science in a timely manner with thorough review and the public's right to participate in the process. These comments specifically address changes to the scientific research and enhancement permit regulations, and we look forward to providing additional comments on any future actions concerning implementation of the MMPA.

Sincerely,

/s/ Miyoko Sakashita
Miyoko Sakashita
Staff Attorney
miyoko@biologicaldiversity.org



Center for Regulatory Effectiveness

Suite 500
1601 Connecticut Avenue, N.W.
Washington, D.C. 20009
Tel: (202) 265-2383 Fax: (202) 939-6969
secretary1@mbsdc.com www.TheCRE.com

COMMENTS BY THE CENTER FOR REGULATORY EFFECTIVENESS ("CRE") ON MARINE MAMMALS; ADVANCE NOTICE OF PROPOSED RULEMAKING, DOCKET NO. 070809454-7459-01, 72 FR 58279 (Oct. 15, 2007), SUBMITTED ELECTRONICALLY ON DECEMBER 13, 2007, TO NMFS.Pr1Comments@noaa.gov, AND BY FACSIMILE TO 301-427-2521, ATTN: CHIEF, PERMITS, CONSERVATION AND EDUCATION DIVISION (PERMIT REGULATIONS ANPR)

The National Marine Fisheries Service ("NMFS") published an Advanced Notice of Proposed Rulemaking ("ANPRM") on changes to NMFS' permit regulations under the Marine Mammal Protection Act. These regulations are codified at 50 CFR Part 216. NMFS' ANPRM "invites the public to submit comments on the current regulations, recommended changes to the current regulations that might be considered in a new set of proposed regulations, and any relevant issues pertaining to the permitting process that might be considered as part of future proposed rulemaking." 72 FR 52342-43.

The CRE strongly recommends that NMFS change its MMPA permitting rules by proposing and promulgating incidental harassment authorizations for oil and gas activities in the Gulf of Mexico, as NMFS as already done for Arctic waters, 50 CFR §§ 216.107, 108. Failure to develop these regulations could soon impede oil and gas exploration in the GOM, jeopardizing the national energy supply and security.

Background

The regulations in question are described in NMFS' latest semi-annual regulatory agenda:

> "Abstract: The National Marine Fisheries Service (NMFS) has received an application from the U.S. Minerals Management Service for regulations under section 101(a)(5)(A) of the Marine Mammal Protection Act (MMPA) to authorize the taking of marine mammals incidental to conducting oil and gas exploration activities by U.S. citizens in the Gulf of Mexico. Without this authorization, the taking of marine mammals is prohibited by the MMPA. In order to authorize the taking and issuing of authorizations, NMFS must, through regulations, determine that the proposed activity will have no more than a negligible impact on the affected species and stocks of marine mammals."

72 FR 22370 (April 30, 2007)(RIN: 0648-AQ7).

Center for Regulatory Effectiveness

In the above-quoted *Federal Register* notice, NMFS stated that the regulations would be proposed in August, 2007, with the comment period ending in October, 2007.

As of the date of this letter, the regulations have not yet been proposed. The missed deadlines are not unusual. NMFS has been missing deadlines for these regulations since 2003. 68 FR 30105 (May 27, 2003)(RIN: 0648-AQ7).

These regulations are important. They apply to oil and gas exploration in the GOM. Locating, developing and using the GOM oil and gas resources are necessary for the national prosperity and security.

NMFS has already promulgated incidental harassment regulations for oil and gas activities in Arctic waters. 50 CFR §§ 216.107, 108. These Arctic regulations are part of NMFS Part 216 permit regulations. Incidental harassment permit regulations for the GOM are just as necessary, and should be NMFS' highest priority with respect to MMPA permitting regulation changes.

Recommended Action

We recommend that NMFS change its MMPA permitting regulations by proposing and promulgating reasonable, effective and statutorily authorized incidental harassment regulations for oil and gas activities in the GOM. We recommend that NMFS propose and promulgate these regulations as soon as possible.

Sincerely,

Scott Slaughter
The Center for Regulatory Effectiveness
1601 Connecticut Ave., NW
Ste. 500
Washington, D.C. 20009
202/265-2383

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 216
[Docket No. 070809454–7459–01]
RIN 0648–AV82
Marine Mammals; Advance Notice of Proposed Rulemaking
AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.
ACTION: Advance notice of proposed rulemaking (ANPR); request for comments.

Comments submitted by:
Dr. Randall Davis
Dept. of Marine Biology
Texas A&M University
Galveston, TX 77551
Phone: 281-250-7839
Email: davisr@tamug.edu

and

Dr. William Evans
Managing Editor of the American Midland Naturalist, at University of Notre Dame
Professor Emeritus for Marine Biology, Texas A&M University
Former Assistant Administrator for NOAA Fisheries
Former Undersecretary of Commerce for NOAA
Former Chairman of the Marine Mammal Commission
University of Notre Dame
Notre Dame, Indiana 46556
Phone: 574-631-9923
Email: evans1930@sbcglobal.net

Comments by section:

Section: § 216.23 Native exceptions.

Comment: Any person with a MMP that authorizes the possession of marine mammal parts for bona fide research should be allowed to receive such parts from any Indian, Aleut, or Eskimo who resides on the coast of the North Pacific Ocean or the Arctic Ocean that is taken during subsistence hunting. The Indian, Aleut, or Eskimo should be allowed to receive reasonable compensation for any additional work, transportation or shipping costs associated with conveying the parts to the permittee as necessary for the intended scientific research.

Section: § 216.26 Collection of certain marine mammal parts without prior authorization.

Comment: Section (a) of this paragraph is very clear about the possession of any bones, teeth or ivory of any dead marine mammal which may be collected from a beach or from land within 1⁄4 of a mile of the ocean without prior authorization. This provision should be retained as written even if it is consolidated in another section.

Section: § 216.33(e) Issuance or denial procedures

Comment: If a proposed permit for bona fide research requires preparation of an EA or EIS and cannot be completed within 90 days, then a provisional permit (for two years or the time needed to prepare an EA, EI or other evaluation) should be issued if the research methods have been deemed humane by the applicants Institutional Animal Care and Use Committee (IACUC) and the total number of animals to be taken is less than the Potential Biological Removal (PBR) or if no PBR has been established.

Section: § 216.33(e)(4)

Comment: NMFS should accept that an applicant has applied for a permit ''in good faith'' and that the permit "will not operate to the disadvantage of an endangered or threatened species" if the permit is for bona fide research, has been approved by the applicant's IACUC, and the total number of animals to be taken is less than the Potential Biological Removal (PBR) or if no PBR has been established. Furthermore, if these provisions are met by the applicant, the proposed research should be categorically excluded from the preparation of further environmental documentation.

Section: (e) Issuance or denial procedures

Comment: NMFS should not arbitrarily eliminate items in a permit application without first discussing the matter with the applicant. This recent behavior by NMFS can seriously impede funded research and precludes finding alternatives. A permit proposal for bona fide research is not an arbitrary document but a serious research plan and should not be dissected by OPR without first discussing any concerns with the applicant.

Section: § 216.34 Issuance criteria

Comment: Not later than 90 days after receipt of an application to conduct scientific research under the general authorization, the NMFS should issue a permit to the applicant for bona fide research if the methods have been approved by the applicant's IACUC and the total number of animals to be taken is less than the Potential Biological Removal (PBR) or if no PBR has been established. If NMFS can not issue a permit within 90 days in a manner consistent with the application procedures of the MMPA (Section (d) of US Code. Title 16. Chapter

31. § 1374. Permits), then a provisional permit (for a duration of two years or the time needed to issue the final permit) should be issued within 90 days after receipt of an application if the total number of animals to be taken is less than the PBR or if no PBR has been established. If an EA, EIS or other evaluation is deemed necessary in accordance with the National Environmental Protection Act under 42 U.S.C. 4321 et seq., a provisional permit (for two years or the time needed to prepare an EA, EIS or other evaluation) should be issued within 90 days after receipt of an application if the total number of animals to be taken is less than the PBR or if no PBR has been established.

Section: § 216.35 Permit restrictions

Comment: NMFS wants to change the regulations so that any proposed change resulting in the need for an increased level of take or risk of adverse impact above those authorized in the original permit would no longer be considered under an amendment, and would require a new permit application. The problem lies in the definition of "increased level of take or risk of adverse impact." For example, if a person had a permit to take blood samples for physiological assessment and wanted to conduct an additional test that required an additional 5-10 ml of blood, would this be a minor or major amendment. Or if the person now wanted to add the injection of water labeled with a stable isotope, would this be a major or minor amendment. To most physiologists and veterinarians, these would be minor amendments that did not increase the level of take or risk above what was already approved. However, a permit officer might think otherwise. Objective guidelines need to be formulated with guidance from experienced physiologists, veterinarians and animal care specialists about what constitutes a minor and major amendment to experimental protocols that do not increase the number of species, total number of animals or the location.

NMFS should rely on the applicant's IACUC to objectively evaluate whether they possess qualifications commensurate with their duties and responsibilities to conduct research humanely and professionally. In many cases, NMFS does not have staff with the qualifications that can make this evaluation.

Section: § 216.37 Marine mammal parts

Comment: The language in this section is fine. It should not be made more complicated and should definitely not require more paper work. Attempts to streamline regulations often make the process worse. The same should pertain to cell lines. If a cell line were created legally under a permit, then its conveyance to another lab should be facilitated by minimizing paper work and not impeded with unnecessary regulations. Cell lines, once established, have no effect on marine mammal populations, so NMFS should reduce regulatory control and not increase it. Furthermore, selling a legal cell line, although unlikely, also poses no threat to marine mammal populations and should be encouraged to promote bona fide research. In fact, all regulations promulgated by NMFS

should always be conceived with the idea of promoting science and knowledge along with protecting populations. Unfortunately, some staff at the NMFS Office of Protected Resources have adopted an adversarial, anti-scientific attitude towards research, which is not in the spirit of the MMPA.

Section: § 216.39 Permit amendments

Comment: This goes back to § 216.35 Permit restrictions already mentioned above. Minor amendments must be flexible within the overall context of the existing permit. Amendments that do not result in significant changes to the already permitted protocol (e.g., the addition of an additional physiological test that requires a little additional blood) should be defined as minor amendments. If necessary, allow a veterinarian to distinguish between major and minor changes to the experimental protocol within an existing permit. These decisions should be rational and reasonable within the context of the additional impact on the animal. In addition, changes in the number of animals or their geographical location should be considered minor amendments if the total number of animals is less than the PBR or if no PBR has been established.

Section: § 216.40 Penalties and permit sanctions

Comment: This section is too vague to evaluate, but is frightening in its implications. It appears to implement a policy of arbitrary decisions by NMFS with no recourse on the part of researchers. The Office of Protected Resources already has the reputation of being anti-scientific and sympathetic towards the animal rights community. This appears to be one more step in that direction. This policy, if implemented, needs to be intensely reviewed by the scientific community and should serve the purpose of promoting science, not impeding it.

Section: § 216.41 Permits for scientific

Comment: Streamlining the scientific permit process is disparately needed, but the examples provided would affect relatively few researchers. Here is what is really needed to streamline the process:

Not later than 90 days after receipt of an application to conduct scientific research under the general authorization, the NMFS should issue a permit to the applicant for bona fide research if the methods have been approved by the applicant's IACUC and the total number of animals to be taken is less than the Potential Biological Removal (PBR) or if no PBR has been established. If NMFS can not issue a permit within 90 days in a manner consistent with the application procedures of the MMPA (Section (d) of US Code. Title 16. Chapter 31. § 1374. Permits), then a provisional permit (for a duration of two years or the time needed to issue the final permit) should be issued within 90 days after receipt of an application if the total number of animals to be taken is less than the PBR or if no PBR has been established. If an EA, EIS or other evaluation is

deemed necessary in accordance with the National Environmental Protection Act under 42 U.S.C. 4321 et seq., a provisional permit (for two years or the time needed to prepare an EA, EIS or other evaluation) should be issued within 90 days after receipt of an application if the total number of animals to be taken is less than the PBR or if no PBR has been established.

Section: § 216.45 General Authorization for Level B harassment for scientific research

Comment: Most researchers with valid permits document their projects with digital images or video for teaching and presentation purposes. These activities generally do not increase the level of take. NMFS should facilitate the conduct of this activity. This may mean that a valid research permit automatically comes with permission for documentation for purposes of teaching and public presentation so long as the level of take is not increased. The definition of teaching and presentation should include selling images and video to magazines or video production companies that educate the public about wildlife, so long as the images and videos were taken incidental to bona fide research.

If NMFS is going to institute a cycle for permit applications, it should be quarterly; twice per year is too infrequent and would impede scientific research. However, minor amendments should be accepted at any time.

Friends of the Sea Otter ~ Defenders of Wildlife ~ OPTI/Earth Island Institute

December 13, 2007

SENT VIA FAX AND U.S. MAIL

Mr. Michael Payne
Chief Permits Division
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
Fax: (301) 427-2521

Re: Attn: Permit Regulations ANPR

Dear Mr. Payne:

On September 13, 2007, the National Marine Fisheries Service (NMFS) announced the availability for public comment of the Advance Notice of Proposed Rulemaking (ANPR) for Marine Mammals.

The following comments are submitted by Friends of the Sea Otter (FSO), Defenders of Wildlife (DOW), the Ocean Public Trust Initiative of the Earth Island Institute (OPTI/EII). All of these organizations are committed to the welfare of not only the sea otter but also to otter marine mammals and their environment.

We appreciate the hard work invested in the preparation of the ANPR by all parties involved. We acknowledge the difficulty NMFS has experienced in moving the rules forward to completion. We welcome the opportunity to provide our comments and concerns with the proposed rulemaking at this time, and look forward to continued involvement as the rulemaking moves forward.

As an initial matter, we request clarification that these regulations would not apply to marine mammal species under the jurisdiction of the U.S. Fish and Wildlife Service.

Our primary concern at this stage with the ANPR is that the proposal would greatly increase the scope of activities that NMFS can permit under a general authorization. This means that there will be no opportunity for or possibility of public comment before certain permits are granted. Current regulations only allow a general authorization for research involving a "Level B" harassment. The proposed amendment of the regulations, in section 216.45, would allow research involving "Level A" harassment to be permitted under the general authorization, provided stocks are not listed under the Endangered Species Act (ESA), or otherwise "strategic."

Level A harassment is defined under the Marine Mammal Protection Act (MMPA) as harassment that "has the potential to injure a marine mammal or marine mammal stock in the wild." This change would mean that so long as research does not focus on an ESA listed or otherwise "strategic" stock, it would be allowed and the public would be prevented from seeing what research was proposed until it had already been permitted. This change would require an amendment to the MMPA, which currently allows only Level B harassment to be permitted under a general authorization. The general authorization should continue to be confined solely to Level B harassment, so as to avoid removing the critical component of public review and comment from the permits currently required to conduct any of the broad spectrum of Level A harassments.

Another concern that we have is that the proposal states that NMFS would require new permits for any proposed "major amendments" to an existing permit, but would only grant amendments, rather than going through the new permit process, or any "minor amendments" to an existing permit. (Section 216.35 and 213.39). Under this proposed permitting scheme, the public would not be allowed to comment on minor amendments.

This is a good change, so long as "minor amendments" are carefully defined so as to only pertain to things such as adding personnel, allowing filming and photography of the research, and other truly minor changes that do not amend the species, location, number or demographic of animals, seasons, procedures being performed, allowed manner of taking, or other variables that while slight on paper, might have major impacts on the species itself. The public should be able to comment on these sorts of major changes during a formal process requiring a new permit application and public review.

Our final concern relates to the proposal's compliance with the National Environmental Policy Act (NEPA). NMFS should retain its current requirement that all compliance with NEPA should be done before a permit is put out for public comment. The proposal in section 216.33 is to change this such that NEPA compliance, including

the preparation, review and comment, of an Environmental Assessment or Environmental Impact Statement, is undertaken only after the public has commented. The requirement for public comment prior to NEPA compliance is premature. It is important that the public be able to see what information NMFS has considered and what impacts it expects before commenting, rather than NMFS asking the public to do the literature searches and analysis first before seeing how the agency will weigh the proposal. In addition, the prior public comment requirement of the proposal may undermine the vital public comment opportunities under NEPA, which provide the public the necessary opportunity to review and comment on the agency's science, reasoning, and proposed actions. We strongly support keeping this section's protocol the same.

As NMFS moves forward with the ANPR, we would like to offer support for certain measures that will improve the efficiency and effectiveness of the policy. First, NMFS should establish cycles of permit applications. Currently, permits can be applied for at any time. In the ANPR, NMFS proposes establishing semi-annual dates for submission. This would improve the process by assuring that researchers apply well in advance rather than at the last minute, thereby providing NMFS with advance notice and adequate time for the review of the application. In addition, a scheduled cyclical permit application would allow for a regular schedule of review for outside commenters.

We also support the ANPR's proposal for NMFS to limit the number of personnel involved in a photo ID permit to ensure that permit holders do not use their authorizations for ecotourism.

Finally, we support the proposal for NMFS to require written proof of approval of the proposed research by an Institutional Animal Care and Use Committee (IACUC) before considering the application complete.

Again, we thank you for the opportunity to comment on the ANPR, and look forward to continued involvement in the development of the rules.

Very truly yours,

Friends of the Sea Otter

Defenders of Wildlife

OPTI/Earth Island Institute

Horning Comments on proposed process revision for permit applications under the MMPA and ESA.

Applying GA:
I am in favor of applying GA to level A and B harassments of non-ESA, and level B of ESA listed species, for bona fide research activities.

Photography:
Please consider that photography is an activity that is used in (eco-) tourism, but is also a vital quantitative research tool.
I would recommend that photography be fully exempt from any permitting requirements for all species including ESA listed species, providing no harassment occurs. In other words, if it is possible to collect images without harassing animals, or without the possibility of harassing animals, then no permit should be required, and no GA would even be applicable.
If harassment occurs or may occur, then photography of all species (including ESA listed species) should be covered under the GA for bona fide research.

Requiring IACUC approval:
I am in favor of requiring existing IACUC approval providing this is implemented in a way to simplify and streamline the process. One of the biggest problems with the current process is the extreme level of redundancy / effort duplication between the IACUC and MMPA / ESA processes, combined with the excessive level of detail requested on specific animal procedures within the MMPA/ESA process. In non-legal terminology, I would state that the task of safeguarding humane animal treatment (the welfare of individual animals) should be solely in the hands of the IACUCs, whereas safeguarding the species should be the job of the Office of Protected Resources. For this latter job, the level of detail currently required in MMPA / ESA applications, is excessive and counterproductive.
If IACUC approval becomes a prerequisite, then the Animal Use Protocol (AUP) issued by IACUCs should simply be included in the MMPA / ESA application without requiring duplication of the description of procedures in the MMPA/ESA application. The MMPA / ESA application should then simply consist of primarily the take table listing sample sizes (numbers of animals), and the summary procedures pretty much the way they are listed in current take tables.

It is important to point out that many permits have a duration of 3-5 years. When including processing time and application preparation time, we are talking about a maximum time frame of 6 years. Within 6 years, many procedures change and improve. Being held to procedure descriptions / protocols defined 6 years ago, would prevent process improvement and may end up being less ‘humane’ than possible, and contrary to the three R’s.

It is also important to point out that AUPs require annual re-authorization, and as part of the re-authorization we are required to address possible process improvements (or refinements) and are required to include those where applicable.

Incorporating IACUC / AUP changes into MMPA / ESA permits:
I would recommend to change the MMPA/ESA process such that any changes (e.g. during annual AUP re-authorization) to an AUP issued by an IACUC, are automatically integrated into the MMPA / ESA permit. This may have to be limited to changes that do not affect the risk estimation for the species in question, in terms of species level effects (not the risks to an individual animal).
This might be a way to reduce the potentially negative impact of eliminating major permit amendments.
IACUCs applications and reviews are probably more stringent than MMPA / ESA applications, and are handled by panels that are by and large more specifically qualified to review and assess the appropriateness of animal procedures, than the Office of Protected Resources, or other entities involved in the MMPA process.

Permit Amendments and Risk Assessment:

One of the biggest problems with the current process is related to the overall justification for conducting bona fide research. From a scientific perspective, if a project cannot reach the predicted level of significance or sensitivity, this invalidates the justification of the entire project, including the justification for whichever portion of the project has already occurred. This is best explained by an example:

Initial sample size (or power-) estimation might dictate a sample size of 50 animals, and the permit be issued accordingly. However, results from the first 35 animals sampled allow an updated power analysis, suggesting that a sample size of 60 is needed because of greater than predicted variance. Unless the permit can be amended to 60 animals, the justification for any portion of the project, even the initial 35 animals, is essentially void.

Thus, one could argue that unless the permitted sample size is amended to 60, even the initial permit would retroactively be in violation of one of the basic premises of the MMPA / ESA. In other words, an efficient, quick amendment process would seem to be essential to keep the system in compliance with the original intent of the MMPA / ESA.

If major amendments are to be eliminated, two changes could maintain compliance with the true intent of the MMPA:

1) some kind of automatic sample size adjustment if needed
2) automatic incorporation of any changes to AUPs issued by IACUCs as outline above.

The automatic sample size adjustment could be achieved if there was a built-in e.g. 50% buffer that could be activated if updated power testing can support the need, and this could be published as such in the initial FR notice.

In addition, risk assessments for permitted procedures need to be updated, this is also one the shortcomings in the current process. For example, unintentional mortalities (UM) are permitted per year and cumulative, up to a given number. If none occur, or fewer then permitted, it would seem that permit amendments that increase the risk of mortalities in the remaining years of a permit should be permissible without affecting the overall risk assessment, and such changes – including revised sample sizes – should be possible as minor amendments, or even automatically if properly justified and authorized by IACUCs.

Risk assessment of amendments vs new permits.

Another important consideration is the level of risk associated with e.g. adding a procedure to an existing project by way of a permit amendment, even if there is an increase in risk, vs the additional risk to the species if the procedure has to be carried out as a new project. Often a given procedure carried out as a new project would provide greater risk, as certain activities (e.g. captures, anesthesia) would have to be repeated, which would seem to be contrary to the intent of the MMPA / ESA in minimizing risk to the species. However, allowing major changes only by way of new applications would result in a timeline that might preclude anything but a new project route.

Assessment of causes of mortalities:

In case of unintentional mortalities, unless causes of mortalities can be accurately determined, incurred mortalities need to be seen in relation to natural mortality rates.

If 1000 animals will be worked with by a given project, chances are that over a given time frame a given number of animals will die by natural causes. Unless it can be shown that research caused mortalities, Ums need to be permitted in addition to likely natural mortalities. In this example, if the natural rate for a given specie, sex and age class is 1 in 100, and applicants request to work with 1000 animals and 10 Ums (let's say for a project lasting 1 year), then there is a likely natural mortality of 10 animals within the project, and research related Ums should be permitted up to a total level of 20.

Determination of qualification of project participants:
As with safeguarding welfare and humane treatment of individual animals, the qualification of individuals is best dealt with at the IACUC level, since IACUCs require and offer specific training. This should not be dealt with at all in the MMPA / ESA process.

Dr. Markus Horning, Pinniped Ecology Applied Research Lab
Marine Mammal Institute, Oregon State University
2030 SE Marine Science Drive, Newport, OR 97365, USA
Tel. 541.867.0202 Fax 541.867.0128
markus.horning@oregonstate.edu

THE HUMANE SOCIETY OF THE UNITED STATES

P. Michael Payne, Chief
Permits, Conservation and Education Division
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910

Attn: Permit Regulations ANPR [72 FR 52339]

December 13, 2007

Dear Mr. Payne:

On behalf of the millions of members and constituents of The Humane Society of the United States (The HSUS), the Natural Resources Defense Council (NRDC), WDCS (the Whale and Dolphin Conservation Society), the American Anti-Vivisection Society (AAVS), and the World Society for the Protection of Animals (WSPA), I am writing to provide information and concerns regarding your Advance Notice of Proposed Rulemaking on permit regulations (ANPR). We agree that the regulations can be more effective and clear if streamlined and consolidated, and we support some of the changes proposed by the National Marine Fisheries Service (NMFS or the Agency); however, we have concerns with the nature of some of the proposed revisions. In particular, we are adamantly opposed to the Agency's proposal to permit Level A harassment under the General Authorization. We are opposed to amending the Marine Mammal Protection Act (MMPA) to facilitate changes to regulations governing scientific research. We provide additional comments below under the pertinent sections outlined in the Federal Register notice (FR) of the ANPR.

Subpart A Introduction
216.3 Definitions

We support consolidating and clarifying definitions in this section to remove redundancy and confusion; e.g., there are separate definitions for "article of handicraft" *and* "authentic native articles of handicrafts and clothing." These two terms can probably be combined into one definition that covers all usage of the term "native handicraft" or "authentic native handicraft."

The definition of "humane" should be amended. It states that the "methods of taking, import, export or other activity which involves the least possible degree of pain and suffering practicable to the animal involved." We would like the NMFS to add "stress" to this definition (i.e., "least possible degree of pain, suffering and stress..."). The methodologies and techniques for determining stress levels have been steadily improving and the regulations should reflect these scientific advances.

The definition of pregnant specifies "near term." We would like to remove those words. Pregnant is pregnant (the dictionary definition reads: "having a fetus or fetuses growing in the uterus"). Modern diagnostics make it possible to detect pregnancy in marine mammals at earlier stages than in the past. Every effort should be made to use modern methods of testing for pregnancy to protect mothers and their progeny from stress and harm resulting from research or transfer. That facilities and/or capture operators are not using these available procedures to detect pregnancy is illustrated by a number of recent instances in which pregnant animals have been transferred, only to give birth soon after arrival at the receiving facility, or the incidental/accidental mortality of pregnant females associated with research projects involving the application of satellite tags in survey studies.

Subpart B Prohibitions

216.12 Prohibited importation

We recommend adding to section 216.12(b)(1) a new "i" that would read "Taken in a manner that would otherwise have violated the MMPA," then have the current "i" and "ii" become "ii" and "iii." This is to clarify that the MMPA does not allow the import of animals taken in a manner that, while possibly legal in the exporting country, would not have been legal under the MMPA. The MMPA clearly does not intend, nor has it been generally implemented, to allow the import of marine mammals or their parts taken in a manner that would not be allowed under the MMPA. The regulations should clearly and unambiguously reflect this intention and previous practice. There has been some confusion on this vis-à-vis sovereignty issues, hence our recommendation for the addition of specific language. This recommended addition is not a matter of violating another nation's sovereignty but of maintaining the integrity of U.S. law on land and in waters subject to U.S. jurisdiction.

216.14(c) Marine mammals taken before the MMPA

We support the suggestion to add export to this provision.

216.15 Depleted species

Our groups recommend that the NMFS clarify in the preamble to this section that all Endangered Species Act (ESA)-listed species and stocks (distinct population segments) are automatically considered depleted. Then this section should specifically list all depleted species and stocks that are *non*-ESA listed, such as the eastern spinner dolphin. Specifically listing the Hawaiian monk seal and the bowhead, for example, would not be necessary under this proposed revision. Singling out the monk seal but not including the Steller sea lion, for example, is confusing in the current regulations. The way this section is currently drafted, species and stocks such as the blue whale and the Steller sea lion could arguably be seen as *not* depleted.

Subpart C General Exceptions

216.21 Actions permitted by international treaty, convention, or agreement

We recommend deleting the specific reference to the Fur Seal Act in this section. Other relevant treaties may exist such that this specific reference appears to preclude their consideration.

216.25 Exempted marine mammals and marine mammal products
We agree with the proposal to eliminate this section and incorporate its provisions into the relevant sections in Subpart B. However, any change or consolidation should not include language that would weaken the current strictures on exemptions relating to transferred parts.

Subpart D Special Exceptions
216.33(b)(2)(iii) Applications to export living marine mammals
We recommend that the Agency clarify with specific examples what "comity" might entail; e.g., the relevant foreign agency should provide a written statement specifying that it will afford comity to any permit decision.

216.33 (c) Initial Permit Review
Our groups support retaining the current protocol for initial permit review that requires that the Agency comply with all requirements of the National Environmental Policy Act (NEPA) prior to publishing the permit for public comment. This includes determining whether to conduct an Environmental Assessment (EA) and a Finding of No Significant Impact (FONSI) or, if necessary, a more in-depth Environmental Impact Statement (EIS). We oppose the NMFS proposal to make permits available for public review prior to making these determinations and instead relying on the public to comment on the nature of the environmental review that the Agency should undertake. We believe that the Agency should first make the public aware of its own concerns and its evaluation of impact before asking the public for comment.

While we understand that research permits are, in general, categorically exempt from environmental evaluation if they lack significant environmental impacts, we believe that the public will benefit from seeing how the agency has itself weighed the impacts before it is asked to provide information beyond what the agency itself has reviewed. Asking the public to do an in-depth evaluation of impacts without benefit of the Agency's expertise is an unfair burden on citizens. If, as was the case with the Steller sea lion EA, the public feels that the Agency has erred in its determination, the public can and will point that out, but the public should be allowed to see what the agency itself feels are the likely consequences before being asked to do exhaustive literature searches and extensive review. The Agency should retain its current procedures and not amend them as proposed.

In addition, the proposed permit should not be published for comment until and unless all questions are answered regarding the number and demographic of each species; the timing, geographic area, and nature of the research; and the justification for sample sizes and research objectives and designs are completed. The application should contain the qualifications of all those to be listed under the permit and provide all assurances outlined below under 216.34. The NMFS should make this information available for comment

along with all documents related to NEPA compliance, which should be completed before initial public comment.

216.33(d) Notice of Receipt and Application Review
Similarly, the NMFS should retain its current requirement that it include a NEPA statement in the notice of receipt of an application. This allows the public to see and comment on the level of concern that the Agency itself feels is warranted by the application and assures the public that the requirements of NEPA will be met. The current requirements should be retained.

216.33(e) Issuance or Denial Procedures
We are not opposed to deferring decisions on permits when NEPA requirements result in the Agency exceeding its timetable for processing applications. That said, however, we do not believe that research should be allowed to proceed until a decision can be made, even if a prior permit exists for the activity. Providing a semi-annual application submission schedule (as outlined in "other considerations" below) will likely obviate many of the deadline conflict concerns raised in the FR notice.

216.33(e)(4) Determining "in good faith" and "disadvantage"
Applicants who are under investigation for violations of a prior or existing permit should not be considered to be submitting an application "in good faith." The fact that the agency has been forced to investigate instances of apparent violation of a current (or soon to expire) permit calls into question whether the applicant intends to comply with permit conditions of any additional permit; thus, it raises questions regarding the applicant's "good faith."

The term "disadvantage" must be defined with the precautionary principle in mind. With regard to adverse impacts ("disadvantage"), no evidence of impact should not be confused with evidence of no impact. They are quite different, and the benefit of doubt should go to the species.

216.34 Issuance Criteria
We strongly support requiring that applicants submit written proof that their research has been evaluated and approved by an Institutional Animal Care and Use Committee (IACUC) before the application can be considered complete. Approval of an IACUC does not guarantee that all research facilities follow equivalent standards of humane treatment of animals, but it is a minimal step that all permit applicants should be required to take. In particular, no state or federal research permits should be granted until government agencies comply with the standards of the Animal Welfare Act that clearly pertain to academic and private institutions and individuals.

Even though an IACUC has reviewed and approved a research proposal, approval by an IACUC should not substitute for a proper permit review by the NMFS and the public.

Research has generally been considered bona fide if it is publishable. We are concerned that not all research that can be done and may be published is necessarily bona fide. If

research that will harm or harass marine mammals is not specifically related to a conservation objective, and is largely satisfying an intellectual curiosity about the species, it may not be bona fide even if it is publishable.

When submitting applications, researchers should provide qualifications for all persons listed on the permit to ensure that research is conducted by properly qualified personnel. We also believe that those listed on the permit who will be "under the supervision" of others should be directly supervised by those others. That is, the supervisor should be on site when the research is being conducted. We note that invasive procedures are often granted in permits with the assurance that they will be done under supervision of a veterinarian, yet it is not uncommon that there is no veterinarian on site (e.g., in the case of some of the Steller sea lion research).

216.35 Permit Restrictions

The NMFS proposes to require that applicants apply for new permits if they wish a major amendment to an existing permit, and to grant amendments only for minor changes to a permit. We support this with a caveat. Proposed amendments should only be considered minor if they are merely clarifications or small technical changes such as changes to the number or names of qualified persons under the permit, allowing photography or filming to occur while undertaking permitted research, altering a start date by two weeks or less, and other such changes that are truly minor. Any change to the species, number, sexes or ages of animals to be taken; to the geographic area or timing of the research; the procedures or manner of the taking; or the number of takes requested cumulatively or per animal should be considered major and require submission of a new application with opportunity for the public to comment. It has been a source of some frustration to this commenter that changes that we would consider major (e.g., the procedures being permitted or changes to demographics being sampled) have been granted as minor changes with no opportunity to comment. These sorts of changes should require a new permit application.

216.35(e) Permit Restrictions

Release of captive marine mammals to the wild should also be permitted for welfare or veterinary reasons (in other words, if it is in the best interests of the animal and does not pose a risk to wild populations). There are increasing numbers of situations where captive marine mammals may need release to the wild as a husbandry or management option and this option should not be precluded by the restrictiveness of the current regulatory language. We do not object if this option is bounded by requiring a permit and/or only after consultation with and permission of the Agency, but it should not be precluded by allowing such release only for scientific research or enhancement purposes.

216.36. Permit Conditions

Our groups oppose consolidation of this section with others. Though it may appear redundant, we believe consolidation may result in losing the import of these clear and specific requirements by moving them to another section.

216.37 Marine Mammal Parts

The FR outlines the current requirements for transfer of specimens. It states that "there is no mechanism for facilitating the initial collection of marine mammal parts by institutions for eventual use for research purposes where the bona fide criteria required in section 104(c)(3) cannot be met for each and every part obtained by the institution." The NMFS states that it is considering permitting such activities "when the purpose of the initial receipt of the part may be unknown." This is troubling. It appears to indicate that the Agency would allow "parts" to be collected and/or transferred to another, even if the use to which that specimen would be put is unknown or not "bona fide." Specimens should not be collected until and unless the purpose for collecting them is known. The only exception might be if the specimen can be collected without harm or harassment to the animal (e.g., collecting scat after a rookery has been abandoned for the season, collecting whale scat from the water after the animal dives). Specimen collection involving harassment or invasive methods should only be permitted when there is a clearly defined and bona fide purpose for collecting them.

We strongly support standardized documentation and reporting requirements. The information provided by applicants and recipients should not be discretionary. Quantified and verifiable measures should be mandated.

Our groups support the development of regulations governing the development, use, distribution or transfer, and prohibited sale of cell lines derived from marine mammal tissues. We also support having similar regulations pertaining to gametes used by the public display industry and research community in assisted reproductive techniques of captive marine mammals. There is no reason to treat these marine mammal parts differently from any other marine mammal parts.

216.39 Permit Amendments

As stated above in our comments on 216.35, we agree with the proposal to grant only amendments that would constitute minor technical changes. All changes that would alter the species; the number, sex or ages being sampled; the manner of taking and/or sampling methodology; the location or timing of the research; the sample sizes or other material changes to the research being conducted should require submission of a new application. We support the informational requirements outlined in the FR notice, including allowing discretion for the Office Director to require additional information.

In this section, the Agency also states that if an amendment is proposed by the Office Director, the permit holder will be notified along with an explanation. We feel strongly that changes made by the Office Director, in the absence of a request by the permit holder, should only be for the purpose of imposing additional mitigation or restriction. The Office Director should not permit changes to, or additional, research without a request or in the absence of public comment.

216.40 Penalties and Permit Sanctions

The fact that Congress granted research a categorical exclusion implies that Congress assumed that researchers would operate in the best interest of animals that are in the

public trust. Penalties for violations of permits should be timely and tough. We believe that the NMFS should also have authority to impose "suspension, revocation, modification, and denial of scientific research and enhancement permits for reasons not related to enforcement actions," as outlined in the FR notice. If research poses a risk to animals for any reason, the NMFS should have the right to modify or temporarily or permanently deny the permit.

Further, no additional permits or amendments should be granted to a researcher under investigation, until they are cleared of all charges or have complied with all sanctions. If necessary, the Agency should defer a decision on any permit submitted by a researcher or research team under investigation.

On June 11, 1975 (40 FR 21949), the Agency promulgated a "policy statement" that included language that we believe is germane to permit holders under investigation. We would like the NMFS to consider including this type of language in this section, to wit:

"No permit shall be issued under either Act [MMPA or ESA] to any person who is under investigation or officially charged with a violation until the matter is resolved. Action will be initiated to suspend, in accordance with applicable regulations, a permit of any person under investigation or officially charged with a violation. No permit shall be issued to any person if that person, who is under investigation or officially charged with a violation, is named in the permit application until the matter under investigation or the formal charges against such person have been resolved. If a person, who has been found guilty of a violation (either through administrative or criminal proceedings) or has disposed of a Notice of Violation by a compromise acceptable to the NMFS, should (1) apply for a permit, (2) be working under a permit issued by NMFS, or (3) be included as a participant in activities authorized by a permit or activities set forth in a permit application, the NMFS will consider each such case on its merits, taking into consideration the circumstances surrounding the violation and the severity of the penalty imposed."

216.41 Permits for Scientific Research and Enhancement

We do not support the addition of a section 216.41(c)(3), which would allow the continued maintenance in captivity of animals acquired under an enhancement permit when such enhancement activities have been completed or are not able to be carried out and the animals cannot be returned to the wild. This strikes us as a backdoor for acquiring "novel" exhibit animals via enhancement permits. Indeed, if the activities cannot be carried out, this suggests that there was not a rigorous enough evaluation of those activities in the first place. Presumably the veterinarian of the public display facility in question would be the initial determiner of the non-releasability of the marine mammal – this poses a conflict of interest. If an animal is acquired via a legitimate enhancement permit, the planned enhancement activities are completed or cannot be carried out, and the animal truly cannot be released, then the animal should be held in a research facility or otherwise in a manner that will not allow anyone to profit commercially from its continued maintenance in captivity. Any other outcome poses too great an incentive to

abuse such a provision and/or has the potential to turn a marine mammal into a permanent test subject.

216.42 Photography

We agree that the NMFS should limit the number of personnel that may be included under a permit for photography. Clearly permits should not be misused to promote ecotourism. Similarly, directed photographic research should not be conducted from commercial vessels (e.g., whale watch boats, kayak flotillas, parasail operations) or from craft engaged in commerce at that time. Any photos resulting from such operations should be collected incidentally. Researchers should not be able to use photographic research permits aboard commercial vessels in order to gain the company a competitive advantage over a competitor who does not have a permitted researcher aboard.

Although we do not oppose photography being permitted under the General Authorization, in our experience, it is rare that an applicant simply wishes a permit for photography. Clearly the proposed research protocol with the greatest impact should govern the degree of scrutiny to which a permit application is subjected. Further, it is important that the NMFS closely monitor the number of permits granted for photography for a particular species or geographic locale. Though it may seem a generally benign activity, several permits in a sensitive area (e.g., regular and high use resting, feeding or calving/pupping areas) pose a much greater risk than a single permit. If photography permits are to be granted under the General Authorization, they should not pertain to species listed under the ESA and the Agency must take special care to assure that the need for photography is bona fide and non-duplicative.

216.45 General Authorization for Level B Harassment for Scientific Research

We are adamantly opposed to the proposed change outlined by the NMFS that would make the General Authorization (GA) available for research involving Level A harassment of marine mammals who are not members of a strategic stock. Permitting research based on the status of the stock rather than the nature of the methodology is antithetical to the essence of the MMPA, which is precautionary in nature. Unlike the ESA, the MMPA exists to prevent stocks from becoming imperiled rather than to try to recover already imperiled stocks from extinction. This proposed change to the permit regulations ignores the fact that stocks may be proposed for listing but not yet listed (e.g., polar bears), stocks often have conservation concerns and serious data gaps (e.g., killer whales), and there are stocks where certain types of impacts are known to be harmful even if the stocks are not strategic (e.g., beaked whales and acoustic impacts). This change would preclude public comment while permitting virtually any sort of research that could be envisioned, so long as the target of the research is not listed under the ESA or otherwise designated a strategic stock. This change goes against Congress' (and science's) recognition that marine mammals require special attention from managers because of their aquatic habitat and natural history, which makes them difficult to study and often prevents researchers from noting population declines or other negative impacts until they are well along.

The NMFS has not always informed the public of research permits that have been granted under the GA. In fact the public is *rarely* informed of the issuance of GA permits. But even if the NMFS publishes a timely listing of GA permits, it would not be until after research was permitted that the public might see what had been allowed, by which time it is too late to disagree with the agency's decision short of litigating it. For that reason, GA permits should be reserved for only the most benign of circumstances.

We also wish to note that making this change would clearly require amendment of the MMPA's section 104(c)(3)(C), which confines GA permits to Level B harassment. We oppose this.

In this same section, we agree that, even if no change is made to the General Authorization to allow for Level A harassment, the Agency should require letters of intent to clearly specify the number of marine mammals by species or stock along with a well-grounded basis for requesting that sample size. In the past, permit applicants and holders have requested sample sizes with little or weak justification (e.g., in the case of many of the Steller sea lion research permits). The NMFS has an obligation to insure that sample sizes are robust but not excessive and that the sample size is able to adequately test the hypothesis being investigated.

Other Considerations

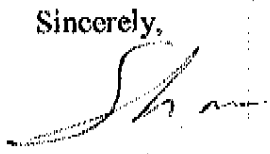
The NMFS has proposed establishing a permitting cycle, such that permits would be submitted semi-annually (twice a year) or quarterly. We strongly support this proposal. Semi-annual permit cycles would allow the NMFS to plan for receipt of applications and have adequate review time. It would prevent the long-standing problem of applicants waiting until the last minute to submit comments and then complaining that the review is extending into their research season. Proper planning will insure both a well-constructed research proposal and adequate review time. Establishing a semi-annual permit cycle would go far to ensuring both.

Conclusion

The HSUS, NRDC, WDCS, AAVS, and WSPA agree that amendments to the current permitting system are warranted. Establishing a semi-annual permit cycle promises to provide clear planning guidelines for researchers and to allow the Agency to better synchronize the deadlines of various Acts. The NMFS should maintain its current NEPA compliance schedule (i.e., publishing NEPA compliance documents prior to asking for public comment) rather than changing it to ask the public to determine the degree of environmental review necessary. We are adamantly opposed to allowing Level A harassment to be permitted under the General Authorization. Any changes to the permitting system should provide for the greatest possible transparency and should be "user friendly" for the public.

Thank you for considering our comments on this Advance Notice of Proposed Rulemaking.

Sincerely,



Sharon B. Young
Marine Issues Field Director
Wildlife and Habitat Protection

Cc: Tim Ragen, Executive Director, Marine Mammal Commission

Post-it® Fax Note 7671	Date 12/13/07	# of pages ▶ 3
To Chief, Permits	From Pamela Yochem	
Co./Dept. NMFS OPR	Co. HSWRI	
Phone # Re: Permit Regs ANPR	Phone # 619-226-3870	
Fax # 301-427-2521	Fax # 619-226-3944	

HUBBS-SEAWORLD RESEARCH INSTITUTE

CELEBRATING FOUR decades of Scientific Excellence

13 December 2007

Samuel D.Rauch III
Deputy Assistant Administrator for Regulatory Programs
National Marine Fisheries Service
National Oceanic and Atmospheric Administration
U.S. Department of Commerce
1315 East-West Highway
Silver Spring, MD 20910

Re: Marine Mammals: Advance Notice of Proposed Rulemaking

Dear Sir,

Scientists at Hubbs-SeaWorld Research Institute have held marine mammal research permits from the National Marine Fisheries Service (NMFS) for over 30 years. Much of the permitted research has been conducted in collaboration with NMFS scientists and other federal and state biologists, and has included studies critical to the conservation and management of protected species, including endangered species such as the Hawaiian monk seal. Results from these studies have been communicated to scientists and resource managers via peer-reviewed publications and presentations at scientific conferences and workshops, and to the general public via our education and outreach initiatives.

We have become increasingly alarmed at the progressive obstruction by the NMFS Office of Protected Resources (OPR) in processing applications for scientific research permits during the past decade. Consequently, we have joined repeatedly with colleagues from other research institutions - during conferences such as the Biennial Conference on the Biology of Marine Mammals and in conversations with NMFS OPR personnel - to request that NMFS re-align its implementation of the Marine Mammal Protection Act to be consistent with the language, construction, and intent of the statute. Rather than implementing the statute as directed by Congress, the NMFS OPR has instead delayed and prevented critical research through its obfuscation and focus on issues that are beyond the authority that Congress has narrow construed to it. This mission drift has resulted in NMFS progressively requesting additional information from applicants that is not required by the Marine Mammal Protection Act, after applicants have provided legally adequate and sufficient information to have affirmative decisions made. Even scientists working within the NMFS agency have been harassed and delayed in the conduct of agency-mandated research. When applicants do capitulate and provide answers to unjustified questions and demands, this is no guarantee of timely processing - rather, applicants are often flooded with follow-up requests for the same information or with additional off-issue questions. Applicants may be sent a list of apparently boiler-plate questions, including questions not applicable to the species they are working with or the procedures they are requesting authorization for. When permits are finally issued, they may contain conditions that effectively prevent applicants from conducting the

2595 Ingraham Street ▮ San Diego, CA 92109 ▮ T: 619.226.3870 ▮ F: 619.226.3944
6295 Sea Harbor Drive ▮ Orlando, FL 32821 ▮ T: 407.370.1650 ▮

contemplated research. In some cases these appear to be residual boilerplate conditions of other unrelated permits, as they are not applicable to the species, activities, or research conditions.

We welcome the NMFS Permit Division's stated objective of improving the efficiency and effectiveness of the permit process. However, the Marine Mammals: Advance Notice of Proposed Rulemaking (MM:ANPR) published in the Federal Register on September 13, 2007, is not an auspicious beginning. The review process so far appears to have been conducted by many of the same individuals who are responsible for the current paralysis in permitting. Questionable rulemaking is not the solution to this crisis. We request that NMFS convene (and fund) a meeting of current and recent Marine Mammal Permit holders and seek their input in revising and streamlining the permit application process so that it meets the extant Congressional mandate articulated in the Marine Mammal Protection Act (MMPA). Further, the NMFS OPR office must be staffed with personnel who are objective and who have at least *de minimus* competence and understanding of the MMPA, of field and laboratory research and of marine mammal biology.

Congress has clearly articulated in the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361 *et seq.*) and in subsequent amendments the procedures for applying for, processing and issuing permits to conduct scientific research. The criteria and standards that permit applicants must satisfy and the obligations of the NMFS OPR to applicants and the public are clear and unequivocal. The NMFS OPR has confused and obstructed the permitting process and the MM-ANPR is another example of this. Virtually all of the elements described in the MM-ANPR as portending to "streamline and clarify general permitting requirements and requirements for scientific research..." are unnecessary and further exacerbate the problem that NMFS OPR has created. The NMFS OPR should simply avoid mission drift and implement the MMPA as it has been instructed to by Congress.

The structure of the MM-ANPR demonstrates the fundamental inadequacy of the NMFS OPR. The MM-ANPR presents a series of questions to the general public asking for instruction in how to implement the MMPA, apparently acknowledging that NMFS OPR is dysfunctional and confused about how it must act. This must be corrected before any formal rulemaking can be legitimate or effective.

A few of our specific concerns relative to the MM:ANPR are listed below:

- MMPA sections intended for public display permits are applied to research permits and *vice versa* – this is an issue with current implementation of the MMPA and is perpetuated in the MM-ANPR;
- Actions proposed to streamline the process would actually add additional delays or barriers, e.g., 1) removing one of the few existing timetables that ensures some kind of response from the agency – the requirement that NMFS issue or deny permits within 30 days of the close of the public comment, 2) eliminating a permit amendment option, 3) eliminating a permit extension option. The MMPA and

extant relevant formal rules already define timetables that applicants and the NMFS OPR must comply with. The failure of NMFS OPR to comply with these time requirements can be no justification for arbitrarily changing the requirements.

- The MM-ANPR requests public comment on off-topic issues such as 1) definitions of 'good faith', 2) minimum qualifications for applicants (we note that no such minimum qualifications exist for NMFS personnel reviewing and processing permit applications!), 3) how to prove that an activity is humane.
- The NOAA Administrative Order No. 216.6 has been misapplied by NMFS OPR staff unqualified to evaluate whether or not NEPA may apply to permit applications or to make relevant decisions about permit applications under review - this failure is evident in the language of the MM-ANPR. It has created substantial delay in application processing and harm to research programs (including NMFS' own agency-mandated research programs) and livelihoods.
- Definitions of terms such as "humane" are clearly stated in the MMPA and the criteria to judge them are straightforward. The NMFS OPR practice of disregarding statutory definitions and substituting its own novel and arbitrary definitions is not appropriate. For example, Congress has not authorized NMFS OPR to demand that an applicant provide proof of approval from an Institutional Animal Care and Use Committee (regulated by the U.S. Department of Agriculture) prior to processing and issuance of an application for a scientific research permit. Indeed, requiring this would bar those who do not have nor need an Institutional Animal Care and Use Committee from applying for a scientific research permit and would be inconsistent with the declared intent and purpose of the MMPA and with U.S. Constitutional guarantees.

These are only a few of our concerns, presented as a means to demonstrate that the MM:ANPR in its current form is deeply flawed. We request that NMFS convene (and fund) a meeting of current and recent permit holders to address needed changes in the way NMFS is currently processing permits and implementing Federal law.

Sincerely,

Pamela K. Yochem, MS, DVM
Executive Vice-President

cc: Director, OPR
Chief, Permits Division, OPR
D. Kent

INSTITUTE for MARINE MAMMAL STUDIES

P.O. Box 207
Gulfport, MS 39502
(228) 896-9182
Fax (228) 896-9183
www.imms.org

December 12, 2007

Michael Payne, Chief
Permits, Conservation and Education Division
Office of Protected Resources
National Marine Fisheries Service
1350 East-West Highway
Silver Spring, MD 20910

Subject: Comments on ANPR for scientific research permits

Dear Mr. Payne:

The Institute for Marine Mammal Studies ("IMMS") is pleased to submit comments on the Advance Notice of Proposed Rulemaking ("ANPR") published by the National Marine Fisheries Service ("NMFS") regarding possible changes to regulations governing the issuance of permits for scientific research and enhancement activities under the Marine Mammal Protection Act ("MMPA"). 72 Fed. Reg. 52339 (Sept. 13, 2007).

IMMS supports the concept of streamlining the existing cumbersome permit process. However, IMMS is concerned about several aspects of the regulations NMFS may be considering. At the outset, IMMS notes that the ANPR is styled as affecting only scientific research and enhancement permits, yet many of the regulatory sections proposed for amendment also apply to public display activities. Even where that is not the case, any regulations proposed by the Agency may have precedential effect. Therefore, if NMFS proceeds with proposed regulations, IMMS suggests that NMFS specifically exclude public display activities from the reach of that proposal.

IMMS believes that the contemplated revision to 50 C.F.R. 216.33(c) pursuant to which NMFS would delay a determination on the proper National Environmental Policy Act ("NEPA") compliance until after receiving comments on the permit application will unnecessarily delay and complicate the permit review process. Separating NEPA compliance from the initial permit review may result in two public comment periods, thereby further lengthening the permit review process. The NEPA process should be concurrent with permit review and not seriatim. Furthermore, many scientific research and enhancement proposals are categorically excluded, or given minimal environmental assessment review, under NEPA because of their minimal environmental impact. If the Agency conducts a two-tier review process, it will effectively be abandoning that procedure to the detriment of the overall permitting process.

With respect to 50 C.F.R 216.33(e)(4), NMFS is asking if it should establish standards regarding whether the permit was applied for "in good faith" and whether the permit "will operate to the disadvantage" of the species. Not only are such actions unnecessary, but it is not clear why NMFS would wish to enter into the quagmire of setting specific standards. At the outset, it is hard to imagine that a reputable scientist would apply for a permit in bad faith or for improper purposes. Similarly, although it is possible to construct a theoretical scenario where research on individual animals in the wild could so impact the species in general as to operate to the disadvantage of the entire species, this does not seem to be likely. It should also be noted that the possibility of such a scenario is nonexistent with respect to animals no longer in the wild. Research on animals already removed from the wild cannot be to the disadvantage of animals in the wild since the research does not involve, or affect, the wild populations. Thus, if NMFS continues down the pathway discussed in the ANPR, NMFS should draw a distinction between activities occurring in the wild and activities occurring with animals that are no longer in the wild.

Similarly, NMFS is considering establishing standards regarding what constitutes humane research and regarding the qualifications which individual researchers must have to conduct the research. Given the large amount of research which could conceivably be undertaken, one is hard pressed to imagine how NMFS, for each and every existing and expected research procedure and plan, will establish minimum qualifications for researchers and then determine "humaneness" standards. NMFS should evaluate individual proposals on their merits rather than seeking to set uniform standards.

In 50 C.F.R. 216.37, NMFS is considering new regulations for the transfer of marine mammal parts, including cells and animal tissues. NMFS' concern appears, in large part, to be whether the marine mammal parts have come from legally taken animals. In that regard, NMFS should be able to assume that tissues, etc. taken from animals resident at scientific or public display facilities are taken from legally held animals.

With respect to NMFS' authority generally, it should be noted that the impact of research on animals held at research and public display facilities, including activities related to reproduction, are reviewed and regulated by APHIS pursuant to its authority under the Animal Welfare Act. In fact, in the 1994 amendments to the MMPA Congress made clear that it is APHIS, not NMFS, that has jurisdiction over the care and maintenance of animals. To the extent the ANPR is proposing to insert NMFS into that process, such a proposal violates the statute and Congressional intent. Additionally, regulating research activities and procedures would stifle innovation and technology.

IMMS is also concerned about the concept of amending 50 C.F.R. 216.40 to allow the suspension, revocation, and modification of scientific research and enhancement permits for reasons unrelated to enforcement actions. There should be no basis for revoking a validly issued permit other than enforcement. If the permittee is operating within the terms of the permit, it is unclear why NMFS would revoke that permit.

The ANPR indicates NMFS is also considering changes to 50 C.F.R. 216.41 to allow the public display of certain animals held pursuant to a research or enhancement permit when such animals cannot be returned to the wild. It is appropriate, particularly with respect to stranded animals, to allow the public display of such animals if it is determined that the animal cannot be released to the wild. Once a marine mammal is deemed un-releasable, its care and maintenance is and should be governed by APHIS regulations and standards. However, the ANPR indicates NMFS will insist that an appropriate educational program is approved by NMFS before the animal can be displayed. In the 1994 amendments to MMPA, Congress made it clear that NMFS is not to be involved in determining the adequacy and structure of educational programs. To the extent that the ANPR proposes to do so, it is inconsistent with the statute and with Congressional intent.

Finally, the ANPR indicates NMFS is considering special limitations on educational filming or photography such that these activities cannot occur without prior written approval from NMFS. Again, one can imagine a scenario in which photographers are harassing animals in the wild, but it is hard to imagine why photographing an animal engaged in its normal activities at a scientific research or other facility should require prior written approval by NMFS. Furthermore, such additional authorization should not be required for those who already possess a Level B Harassment permit.

Although IMMS supports an effort to streamline the existing process for considering scientific research and enhancement permits, IMMS is concerned that NMFS may be falling into the trap of attempting to over regulate activities. Indeed, it was the presentation of a proposed rule of well over 200 pages in 1993 that led to the 1994 amendments to the Marine Mammal Protection Act in which Congress found that NMFS had gone too far. Hopefully, that will not be the case here. As NMFS considers revisions to the scientific research and enhancement permit regulations, IMMS looks forward to working with the Agency to achieve the desired result of improving these processes without simultaneously adding unnecessary and inappropriate requirements.

Sincerely;

Moby A. Solangi, Ph.D.
President

Subject: Fwd: Permit Regulations ANPR
From: NMFS.PR1Comments@noaa.gov
Date: Tue, 18 Sep 2007 11:41:40 -0400
To: Amy.Sloan@noaa.gov

Subject: Permit Regulations ANPR
From: Franklin Lane <flane@tucsonaquarium.com>
Date: Mon, 17 Sep 2007 14:03:49 -0700
To: NMFS.PR1Comments@noaa.gov

I've tried twice to wade through the current law and the proposed changes...Best of luck with this!

So in general...

In an effort to "get legal' I recently shipped ($3,000 postage) the majority of our marine mammal and threatened reptile bio-facts to NOAA's Long Beach office. I was able to legally permit only about 10-12 items and these have enabled us to barely continue with our outreach programs. Most of our collection came from members (conservationists, scuba divers etc) but unfortunately had no paper trail. My plea is to modify the law so educational institutions can permit these types of donations easier. These bio-facts (and therefore the original animal) would serve a much more productive purpose educating our community then collecting dust in a NOAA warehouse.

Thank you

Franklin Lane
Director of Education
Sonoran Sea Aquarium
2021 N. Kinney Rd.
Tucson, Arizona 85754
(520) 908-1600
(520) 578-8020 (fax)
Flane@tucsonaquarium.com
www.tucsonaquarium.com

Permit Regulations ANPR.eml	**Content-Type:** message/rfc822 **Content-Encoding:** 7bit

MARINE MAMMAL COMMISSION
4340 EAST-WEST HIGHWAY, ROOM 905
BETHESDA, MD 20814-4447

17 December 2007

Mr. P. Michael Payne
Chief, Permits Division
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910

Dear Mr. Payne:

The Marine Mammal Commission, in consultation with its Committee of Scientific Advisors on Marine Mammals, has reviewed the Service's 13 September 2007 advance notice of proposed rulemaking (72 FR 52339) seeking public comment on revisions to the Service's implementing regulations at 50 CFR Part 216 governing the issuance of permits for scientific research and enhancement activities involving marine mammals.

Research is our primary means of gathering information about marine mammals and the ecosystems of which they are a part. It is, therefore, essential to our conservation efforts. If implemented effectively, the permitting process should promote research in support of the conservation and management objectives of the Marine Mammal Protection Act, the Endangered Species Act, and related legislation. More specifically, the permitting process provides a mechanism to identify and consider the costs and benefits of research, which should help focus research questions and improve research methods. The process should ensure that research efforts are not unnecessarily duplicative, thereby promoting more effective use of limited research resources. The process should help to ensure research methods are the best available to maximize scientifically valid results. It also should ensure that those methods are as humane as possible. The process also provides a check to ensure that the effects of proposed research, by itself or in combination with other human effects, are not so significant that they (a) place the affected species at excessive risk or, (b) compromise the scientific validity of the results. Finally, the process provides an opportunity for public participation by reviewing and commenting on proposed research.

It is also true, however, that the permitting process imposes costs on those planning to do research. For that reason, the Commission believes that it is incumbent upon the Services and all those involved to make the permitting process not only as effective as possible, but also as efficient as possible. In part, that can be done by avoiding unnecessary research constraints or requirements. A careful examination of the regulations is a good place to start and our recommendations and comments below are aimed at assisting the Service with such an effort. It is also possible and perhaps even likely that further, larger changes may be required to optimize the permitting process. After the rulemaking currently underway, it behooves us all to step back and consider whether further changes are needed to ensure the process is functioning smoothly, equitably, and in a manner that accomplishes permitting objectives with the least burden on the researchers. For example, the difference in processes used by the National Marine Fisheries Service and the Fish and Wildlife Service will not be addressed by the proposed rulemaking, but should be given further consideration. The Commission would be pleased to participate in this larger review process, or even lead it, if necessary.

For the matter presently at hand, the following are the Commission's comments on possible regulatory changes being considered by the Service.

§ 216. Regulations Governing the Taking and Importing of Marine Mammals

The Marine Mammal Commission recommends that the Service propose revisions to this section to incorporate the prohibition on exporting marine mammals, added by the 1994 amendment to the Marine Mammal Protection Act (MMPA). Doing so would bring this section into conformity with the prohibited activities specified in section 102(a) of the Act.

§ 216.3. Definitions

The key determination applicable to scientific research permits is whether the proposed taking is required to further a "bona fide scientific purpose." This term is already defined, both in section 3(22) of the Act and in section 216.3 of the regulations. The existing regulatory definition includes two clarifications not included in the statutory definition. First, it specifies that such research must be carried out by "qualified personnel." Second, it specifies that collecting and maintaining marine mammal parts in a "properly curated, professionally accredited scientific collection" constitutes a bona fide scientific purpose by virtue of contributing to the basic knowledge of marine mammal biology or ecology.

Despite these definitions, determining whether an applicant has satisfactorily demonstrated that proposed research meets the bona fide requirements has proven to be somewhat difficult in practice. However, revising the definition is not the appropriate way to fix the problem. Rather, we suggest that the Service propose changes to the section concerning issuance criteria to explain more clearly how this definition will be applied. Among other things, this would allow the Service to describe who it regards as qualified personnel.

The Service also should describe criteria for institutions that meet the qualifications for maintaining a "properly curated, professionally accredited scientific collection," perhaps by adding a definition of that term. In addition, the Service should consider revising its regulations to clarify that researchers seeking to obtain or use specimens maintained in such a collection will need to obtain separate authorization to transport and possess them.

The other term that the Service should consider defining is "enhancing the survival or recovery of a species," which is the second type of permit being covered by the ANPR. Considerable confusion exists about the term "enhancement" because it is used differently under the permit provisions of the MMPA and those of the Endangered Species Act (ESA). In part, this is because only enhancement permits and permits for scientific research are available under the ESA and enhancement permits have become, by necessity, a catch-all provision. Enhancement under the ESA has been interpreted broadly and such permits have been used to authorize a variety of activities, including captive breeding programs, public display, rescue and rehabilitation, and even trophy hunts of listed species.

In contrast, the enhancement permit provision of the MMPA was added in the late 1980s, when the Act already had provisions pertaining to public display, rescue and rehabilitation of stranded marine mammals, and hunting (under the generally applicable waiver provisions). As such, the MMPA provision was crafted much more narrowly than the ESA provision, aimed almost exclusively at management actions designed to enhance the status of depleted marine mammal stocks in the wild. Up until that time, such activities were largely experimental and they had been authorized under scientific research permits. However, the value of some of these activities, such the monk seal head-start program, was becoming clear, and continuing these proven conservation strategies as scientific research activities was no longer considered appropriate.

Because of the difference in the origin and scope of the enhancement permit provisions under the MMPA and the ESA, the Service's regulations should seek to clarify how this term is used under the MMPA. Additional guidance in crafting an appropriate definition can be found in the legislative history of the 1988 amendments and in the enclosed letter from the Commission to the Fish and Wildlife Service commenting on an enhancement permit application seeking authorization of as variety of activities under the two statutes. Among other things, the Service might want to clarify whether enhancement permits are available for all marine mammal species, or only for those facing conservation challenges—i.e., stocks that are listed as threatened or endangered, designated as depleted, or declining and which may become depleted if remedial actions are not taken.

§ 216.14 (Subpart B). Marine Mammals Taken before the MMPA

The Marine Mammal Commission sees no reason to amend this section to specify that exports of pre-MMPA marine mammals and marine mammal parts are allowed. Section 102(e) of the MMPA and section 216.14(a) of the regulations already make it clear that none of the prohibitions apply to marine mammals taken before the effective date of the Act. Moreover, anyone trying to export a pre-Act marine mammal or marine mammal part will either need to demonstrate that the mammal or part was taken before the Act's effective date, or should already have done so to avoid running afoul of the possession prohibition.

§ 216.15. Depleted Species

Section 3(1)(C) of the MMPA establishes that all marine mammals listed under the ESA are automatically considered depleted. To the extent that the Service believes that regulatory clarification is needed, section 216.15 does not seem to be the right place to accomplish this. This provision is merely a list of those marine mammals that have been designated as depleted (although some have subsequently been listed under the ESA). The Service could provide a catch-all provision in this section to provide the necessary clarification. For example, the Service could add a new subsection (a)[bis] reading, "All marine mammals included in the list of endangered or threatened wildlife published under 50 C.F.R. 17.36. Alternatively, for consistency with the definition of "marine mammal" under section 216.3 (i.e., only species under NMFS jurisdiction), the recommended provision could refer to "...those species listed under sections 224.101(b) and 223.102 of the

Service's regulations. Another alternative would be to add a regulatory definition of "depleted" under section 216.3 to accomplish the clarification the Service is considering.

§s 216.16 and 216.17. Prohibitions under the General Authorization and General Prohibitions

The Commission questions the placement of section 216.16 with the general prohibitions provision. Either it should be moved to Subpart D or parallel provisions applicable to scientific research and other types of permits should be appended and moved to Subpart B. Although the regulations include penalties and permit sanctions under section 216.40, the level of specificity is inconsistent with respect to violations of general authorizations versus permits. For example, it is not clear why it is explicitly prohibited to provide false information in a letter of intent for a general authorization, but not in a permit application. Similarly, there is no specific provision prohibiting a person from violating the terms or conditions of a permit, although there is for a general authorization. These inconsistencies should be rectified.

Subpart C. General Exceptions

The Marine Mammal Commission recommends that the Service amend its regulations to accommodate transfers of marine mammal parts from Alaska Natives to holders of scientific research permits without requiring multiple permits, provided that the parts were legally taken for subsistence purposes in accordance with section 101(b) of the MMPA. The Commission believes that this is best accomplished in the permit regulations, rather than in section 216.23. Perhaps the cleanest way to authorize transfers from Alaska Native subsistence hunters to researchers is to have the researcher seeking such specimens identify that source in the application and obtain samples without specifying the individual hunter(s) from whom specimens would be obtained. The applicant would, however, need to specify the type (species, part, size of sample, etc.) and number of samples being sought in the application. If the permit is issued, such samples then could be obtained from hunters without further authorization. The Commission recognizes potential problems with this approach, but believes that they can be overcome. Samples should be obtained either from parts that are not used for subsistence or the creation of handicrafts, or they should be so small that they would not have an appreciable impact on subsistence/handicraft use. If a hunter is to target specific individuals or certain sex/age classes, or is to be compensated for taking animals, then the hunter should be included as an agent under the permit.

The Service also might consider amending its regulations to allow certain transfers of and tests on marine mammals at the initiative of hunters' groups or Alaska Native organizations, provided that the tests are related to the underlying subsistence use. For example, the Service could re-define the term "subsistence" in section 216.3 to include health screening and testing for contaminants from marine mammals to be used for food such that the taking, transfer, and testing would all be covered by section 101(b). A conforming change to section 216.23 authorizing the transfer also would be needed.

§ 216.25. Exempted Marine Mammals and Marine Mammal Parts

Historically, the Services' marine mammal regulations have been organized to track the corresponding statutory provisions. Just as section 102 originally contained all of the Act's prohibitions, so did Subpart B of the regulations. The exceptions to these prohibitions set forth in the various sections of the Act followed in Subparts C & D. As the Act has evolved and been amended, this arrangement has not been maintained. Some of the prohibitions are now found elsewhere in the regulations (e.g., those related to tuna labeling are contained in Subpart H). Likewise, exceptions to the taking prohibition are found elsewhere in the regulations (e.g., Subpart I et seq.) and even in different parts of the regulations (e.g., Part 229). At the same time, regulations promulgated jointly under the Fur Seal Act of 1966 and the MMPA, but pertaining only to the taking and uses of northern fur seals and the administration of the Pribilof Islands under the Fur Seal Act have been moved and inserted in the middle of Part 216. In short, the organization of the Services' regulations is fraught with inconsistencies in organization. It could use a general overhaul. Such a reorganization and re-writing of the regulations is well beyond the scope of the current ANPR, which we understand to be targeted only at permits for scientific research and species enhancement. Although we suggest that the Service retain their immediate focus on permit-related regulations, the Service may wish to consider a more general reorganization at a later date.

Clearly, various strategies can be used to organize the regulations. On the one hand, certain narrowly drawn prohibitions (e.g., those pertaining to supplying false information in applications) might be usefully placed along with the exception to which they apply. On the other hand, separating all of the prohibitions, exceptions, etc., in separate subparts may be easier for some users of the regulations to follow. The Commission does not have a preference for how the Service organizes the regulations, so long as parallel provisions are treated consistently. For example, the organization of the provisions related to general authorizations should be arranged similarly to those for scientific research permits. For permit-related matters, we encourage the Service to correct the existing organizational inconsistencies as part of the anticipated rulemaking.

§ 216.31. Definitions

The Commission does not recommend any specific changes to this section. We believe, however, that absent a compelling reason, all of the regulatory definitions, even those applicable only to permit issues, should be included in a single section, i.e., § 216.3. Currently, § 216.31 merely clarifies the relationship between the definitions used under the MMPA and those applicable under the ESA. This seems to be all that is needed here. We believe, however, that the Service should provide additional guidance, not necessarily in the regulations, by identifying inconsistencies in definitions used to implement the MMPA and ESA, and noting which the Service considers to be the "more restrictive."

216.32. Scope

The Commission believes that the coverage of this current provision is appropriate. However, the Service may wish to rewrite subsection (b) to read "...and parts from marine mammals listed as threatened or endangered under the ESA" to clarify that it is species, rather than parts, that are the subject of listings.

§ 216.33. Permit application submission, review, and decision procedures
§ 216.33(c). Initial review

Potential conflicts between the requirements of the MMPA permitting provisions and those applicable under the National Environmental Policy Act (NEPA) are not easy to resolve, particularly those related to timing requirements of the two Acts. In *Jones* v. *Gordon* (792F.2d 821; Ninth Circuit 1986), the Ninth Circuit Court of Appeals provided guidance on how the timeline for taking action on permit applications under section 104(d) of the MMPA is to be reconciled with the requirements for preparing NEPA documents when the generally applicable categorical exclusion does not apply. The existing regulatory provision is consistent with that guidance; the proposed changes are not. Thus, the Marine Mammal Commission recommends that the Service review the ruling in that case and propose only changes to its regulations that are consistent with it. The guidance from the ruling is that the seemingly conflicting timing requirements of the two statutes are best reconciled by delaying publication of the notice of availability of the application until an environmental assessment or environmental impact statement has been prepared. Otherwise, the Service risks running afoul of the explicit timing requirements set forth in the MMPA. The Commission believes that the more informal decision-making process being sought by the Service can be accomplished by making a draft of the application available during any scooping and opportunity for public comment under NEPA.

§ 216.33(d). Notice of receipt and application review

As with the proposed changes to subsection (c), the Commission believes that some of the proposed changes are inconsistent with the ruling in *Jones* v. *Gordon*. As such, we recommend that the Service reconsider changing the sequence for publishing the notice of receipt and preparing any necessary NEPA documents. The Commission agrees that the Service should publish a summary of its basis for an initial determination that a permitting action is categorically excluded along with the notice of receipt. The Marine Mammal Commission recommends, however, that the regulations also discuss how it intends to proceed under both the MMPA and NEPA if comments on the notice convince the Service that preparation of an environmental assessment or environmental impact statement is appropriate (e.g., will further consideration of the application be suspended pending preparation of a NEPA document? Will the applicant be asked to withdraw the application pending such preparation? Will the application be denied, requiring re-submittal of the application, etc.?) The Service also might want to pursue amendments to section 104(d) of the MMPA, giving greater flexibility in how the MMPA and NEPA review processes are coordinated.

§ 216.33(e). Issuance or Denial Procedures

Here, too, we believe that the envisioned changes to reconcile the timeline for taking action under the MMPA and NEPA are inconsistent with judicial guidance. Although not an element in *Jones* v. *Gordon*, using similar logic, it is unlikely that a reviewing court would uphold a reconciliation of the MMPA permitting requirements and the ESA consultation requirements that allowed for extending the time to take final action that exceeded the timeframe specified in section 104(d). The Marine Mammal Commission recommends that the Service consider alternatives that are consistent with the statutory timing requirements. To the extent that deferring a decision is necessary, the Commission believes that this should be done only with an applicant's consent and only when an alternative timeframe for completing action on the permit has been identified.

The Commission also questions the value of publishing a notice in the *Federal Register* announcing the deferral of action on a particular permit application. Preparation and publication of such announcements involve staff time and expenses that might better be directed toward the timely processing of applications.

§ 216.33(e)(4). ESA-Listed Species

The Commission believes that applicants seeking to conduct research on endangered or threatened marine mammals apply for such permits in good faith. We are not convinced that this is a problem meriting additional guidance in the regulations. Nevertheless, the Service needs sufficient flexibility to deny permits to those seeking to use a permit to conduct other activities, such as ecotourism or commercial photography, for which a taking authorization may not otherwise be available. If an application is determined to meet the requirements for constituting bona fide research under the MMPA, or meets the requirements for an MMPA enhancement permit, we believe it should be considered to have been applied for in good faith.

Identifying the proposed activities that will operate to the disadvantage of a listed species is more difficult due, in part, to uncertainty regarding what constitutes a disadvantage. For that reason, the Marine Mammal Commission recommends that the National Marine Fisheries Service seek to define the term "disadvantage" in its regulations. This could be done in terms of predicted impacts to the decline or recovery of the species. For example, any effects expected to delay the species' recovery to non-endangered or non-threatened status by X% would be considered to be to the disadvantage of the species.

The term "disadvantage" also applies to actions taken under section 103(a) of the MMPA. Thus, the Service may want to use this opportunity to develop a definition of the term that would be generally applicable under both statutes. Because section 103(a) is generally limited to marine mammal stocks that are not depleted (e.g., within their optimum sustainable population range), such a definition would have to consider not only delay in recovery time (for depleted marine mammals and ESA-listed stocks) but also the level of decline that would be acceptable for stocks already at OSP.

§ 216.34. Issuance Criteria

In many ways, this is the most important section of the Service's permit regulations and, as such, the criteria should be as clear as possible. We believe that the regulations and permit application instructions should provide additional guidance as to how the Service determines whether information submitted by an applicant indicates that "the [proposed] taking is required to further a bona fide scientific purpose." The guidance should be based on objective criteria such that the applicants and others interested in permitting actions know what to expect from decision-makers. To identify potential problems of this nature, the Service may wish to review comments from the Commission and others on applications where consistency with the bona fide requirement was questioned.

An application can meet the bona fide research requirement under three separate criteria, and these should be addressed separately in the regulations. Nonetheless, they share certain common elements. For example, to meet any of the statutory standards for bona fide scientific research, the research results must somehow be disseminated to the appropriate audience. This may be accomplished by publication in a scientific journal or a number of other mechanisms that inform those who assemble and utilize the basic knowledge of marine mammal biology or ecology or who are responsible for marine mammal conservation programs. It may therefore be appropriate in making a decision as to whether to issue a scientific research permit to look at the applicant's plans for publishing or otherwise disseminating the research results and applicant's record of disseminating results through publication or other mechanisms as appropriate as indicators of how likely it is that the information will be made available to the scientific community and/or to resource managers. It must be recognized, however, that some research (e.g., long-term ecological research) requires years of data collection before it is suitable for analysis and publication, other research is conducted by young scientists who are just establishing their publication record, and still other research may be published by scientists or persons whose main interest is outside of marine mammal science. All of these sources may provide highly valuable insights into marine mammal biology, ecology, and conservation, and they should not be precluded from doing so for lack of a publication record.

To assess the potential utility of proposed research, the Service may wish to consider several questions. Is the applicant seeking to resolve novel questions, test new hypotheses, or resolve or confirm disputed results of previous studies? Are the proposed techniques and sample sizes sufficient to yield useful and meaningful results? How likely is it that the research will be or can be carried out as proposed; that is, is the proposal overly ambitious? Are the research techniques proven or experimental? Is the potential contribution to scientific knowledge commensurate with the potential impact on the marine mammal population? These questions must be considered with caution, as the topics being studied, the questions being answered, and the animals and their environment all can have a strong influence on the nature of the research that can be conducted. Good science, by its very nature, often requires that scientists work at the so-called "cutting edge" of our knowledge, which may mean that proposed research often may fall outside the realm of what is

considered standard. Furthermore, the greatest gains in research often are likely to come from research that has a greater uncertainty as to the outcome.

As proposed by the Service in its *Federal Register* notice, the section of the regulations pertaining to issuance of permits for enhancement also should address the requirement that the method of proposed taking be humane (e.g., involves the least possible degree of pain and suffering practicable). The Commission believes that it is appropriate for the Service to require applicants to submit the findings from Institutional Animal Care and Use Committees (IACUCs) when such a review is required under the Animal Welfare Act. Although the Commission does not believe that it would be appropriate for the Service to defer to an IACUC when making a determination of humaneness, the IACUC's findings provide an important starting point for reviewing questions related to humaneness.

§ 216.35. Permit Restrictions

Much of the discussion in the ANPR involves amending permits, which is more appropriately addressed under § 216.39. Consistent with our comments on that section (below), the Commission believes that one-year extensions should be available under a permit amendment where judged appropriate by the Service.

The Commission does not see a need for regulations specifying minimum standards for qualifications of applicants and those conducting activities under a permit. The situations encountered when reviewing permit applications are varied, and we do not see how the qualifications of those participating in authorized activities can be reduced to generally applicable criteria. Some activities, such as administering drugs or anesthetizing animals, may require veterinary training but, in some instances, might be accomplished safely by an experienced marine mammal scientist who is simply consulting with a veterinarian. At the other extreme, some research tasks (e.g., conducting observations) may be appropriately carried out by interested members of the public with a modicum of training and sufficient supervision. We do not believe that much is to be gained by trying to distill the necessary levels of training, education, and experience to perform various research tasks into regulatory language rather than conducting such reviews on a case-by-case basis.

§ 216.36. Permit Conditions

Section 216.35 sets forth conditions that are generally applicable to all permits, whereas section 216.36 largely identifies those conditions or specifications that will vary from permit to permit. The Commission sees some overlap between the types of restrictions set forth in these sections, and the Service may wish to consolidate them or at least rename them to distinguish them more clearly.

§ 216.37. Marine Mammal Parts

The Commission sees a certain logic to the existing regulations concerning marine mammal parts and believes that consolidating sections 216.22, 216.26, and 216.37 might create unnecessary confusion. Section 216.22, for example, flows from section 109(h) of the MMPA, whereas section 216.37 implements the permit provisions of section 104. The underlying statutory requirements differ, so it makes sense for the regulations to differ as well. Section 216.36, which is largely regulatory and pertains to collection of specific types of parts with no prior authorization, probably warrants a separate section.

What constitutes a marine mammal part should be clarified. For instance, the regulatory definition under section 216.3 provides no guidance as to whether items produced by marine mammals (e.g., scats and spews or ambergris) are considered to be marine mammal parts subject to the Act's prohibitions. Although at first consideration the answer may seem obvious, the Service should be careful to consider the consequences with regard to items that may be considered valuable in illicit trade (e.g., ambergris).

The Commission believes separate requirements should be retained for using and transferring parts from marine mammals listed under the ESA. The permitting requirements under the two statutes are different, CITES requirements may differ (ESA-listed species are more likely to be placed on Appendix I), and a scientific research permit may be the only alternative for obtaining parts from ESA-listed species, as opposed to other marine mammal species. Because research permits may be used to obtain parts not otherwise available, heightened scrutiny is warranted.

With regard to authorizing the collection, receipt, import, export, and archiving of marine mammal parts for further research, the Commission has recommended that the Service stipulate that the parts be used for a bona fide scientific purpose, although it may not be possible at the outset to articulate precisely how the parts might eventually be used. Likewise, the Commission has recommended that the Service also require that each part to be imported has been taken in accordance with the laws of the country of origin and not in violation of the MMPA. The Marine Mammal Commission recommends that this guidance be reflected in the Service's regulations. The Marine Mammal Commission also recommends that, as a further safeguard, the Service allow marine mammal parts maintained in an authorized collection to be transferred only to those persons covered by the original permit or who possess a separate permit authorizing the possession and use of the parts. Doing so will ensure that subsequent recipients have demonstrated that their activities constitute bona fide research.

With regard to the development, use, and transfer of cell lines and gametes, the Marine Mammal Commission recommends that the National Marine Fisheries Service propose regulations to allow such activities when they meet the requirements for obtaining a scientific research or enhancement permit, but that possible abuses be prevented by prohibiting commercial use of such products. The Service may want to prohibit sales but allow permit holders to recoup their expenses in developing cell lines or collecting gametes.

§ 216.38. Reporting

Some permit-holders may not be satisfying the requirements set forth in this section on a timely basis. If that is the case, then the Service should consider adding possible consequences for failing to file complete and timely reports, including not re-issuing a research permit.

§ 216.39. Permit Amendments

The Commission does not fully understand the Service's proposal to eliminate the opportunity for permit-holders to seek or the Service to consider major amendments to permits. Although many of the procedures for authorizing a major amendment (e.g., public notice and an opportunity for comment) are the same as for issuing a permit, the Commission questions whether an entirely new application need be submitted. Requiring a new application for each major amendment will increase the paperwork burden of both the permit-holder/applicant and the Service, without much substantive gain. Absent a compelling reason for eliminating major amendments, the Marine Mammal Commission recommends that the National Marine Fisheries Service reconsider its proposal.

The Commission believes that the distinction between major versus minor amendments is necessary. The issue at stake is when public review of a proposed change is warranted. Minor amendments should include only those types of changes that are so minor that potentially adverse public comments are highly unlikely or for activities that are so similar to what was previously authorized under the permit that the opportunity for public review and comment can be considered as having already been provided. The Service should continue to consider other activities that have not been subjected to public review (e.g. new procedures, additional species, and increased numbers) to be major amendments.

§ 216.40. Penalties and Permit Sanctions

The Commission agrees that it would be desirable to provide the Service with latitude to modify permits for reasons not related to enforcement actions. It is not clear, however, that this can be accomplished consistent with the existing statutory directive. In this regard, section 104(e)(1) sets forth only three instances when a permit may be modified, suspended, or revoked. Of these, only clause (B), which requires a violation of the terms and conditions of the permit, applies to scientific research and enhancement permits. In this case, the Service may wish to consider a statutory change as a precursor to regulatory changes.

§ 216.41. Permits for Scientific Research and Enhancement

The Commission believes the organization of this section could be improved and recommends that the Service consider several amendments. First, it is not clear why scientific research and enhancement permits are lumped into a single section of the regulations. Authority for these two types of permits is derived from different provisions of the MMPA (section 104(c)(3) and

104(c)(4)) and they are subject to different criteria and requirements. Just as public display permits and photographic permits are placed in separate sections, it would make sense to separate scientific research permits and enhancement permits in the regulations.

Second, the Commission believes that it would make more sense to link scientific research permits with the regulations pertaining to the general authorization for scientific research (section 216.45) than with enhancement permits. This could be done either by considering these two types of authorizations in the same section of the regulations or in sequential sections.

Third, some of the existing headings of the regulations could be a source of confusion to applicants and the public. For instance, section 216.34 is entitled "issuance criteria," but contains only criteria generally applicable to all permit types. The regulations specific to scientific research permits and enhancement permits set forth more specific issuance criteria. Depending on whether and how the regulations are ultimately restructured and amended, previous comments from the Commission on issuance criteria might be more applicable to this section. At a minimum, the general provisions should explain that more specific criteria are set forth under the sections addressing specific permit types. Similar cross-references may be needed in other sections to link the general provisions with those under the sections concerning specific permit types.

The Service indicates that it is considering proposing changes to the provisions of section 216.41(c)(1)(vi), but it is not clear what those changes would be. The *Federal Register* notice suggests that the Service is considering adding requirements concerning the public display of marine mammals maintained in captivity for purposes of scientific research (e.g., allowing such displays only when necessary to achieve the research objectives and only when authorized by the Office of the Director). However, these requirements already exist under section 216.41(c)(1)(vi)(A). It is not clear whether the Service is considering revising the regulations to eliminate these requirements. If so, the Commission believes that the current restrictions are appropriate, with the possible exception of allowing incidental public display when it will not have any adverse effects on the research being conducted, even if such display is not "necessary" for achieving the research objective.

The Commission believes that the Service should be very cautious in considering new regulations involving the long-term maintenance and public display of marine mammals obtained under scientific research and enhancements permits once the authorized activities have been completed. There are two countervailing concerns here. The first is that animals may be taken from the wild population for the immediate purpose of research and the long-term purpose of display. This may disadvantage the wild population if it is sufficiently small that the removal affects population productivity. The second is that animals brought into captivity only for the purpose of research but then returned into the wild may pose a new risk to the wild population if they carry diseases from the captive setting to the wild. In all cases, we believe that the primary concern should be the protection of the wild population.

Currently, public display permits may not be issued for depleted marine mammals. The proposal being contemplated by the Service would provide a way around this prohibition that could

be subject to abuse and, again, certain safeguards are needed. For example, applicants should be required to indicate at the outset whether permanent maintenance in captivity is contemplated and, if not, what steps might be taken to facilitate eventual release of the animals back into the wild, and how the applicant will ensure that the release poses no significant risk to the wild population. If permanent maintenance is anticipated, the Service should consider not authorizing the placement of the animals in captivity in the first place if the proposed research or enhancement activities are not essential to the conservation of the affected species or place the species at heightened risk.

§ 216.42. Photography

The Commission agrees that the Service should promulgate regulations to implement the provisions of MMPA section 104(c)(6), which pertain to permits authorizing the taking of marine mammals for the purposes of educational or commercial photography. We also agree that those regulations should include provisions that limit the potential for ecotourism being conducted under such permits. We are concerned, however, with the suggestion that such permits might be issued using procedures akin to those applicable to the general authorization. Under section 104(c)(6), photography permits, although limited to taking by Level B harassment, are full-fledged permits subject to public notice and comment requirements of the Act.

§ 216.44. Applicability/Transition

The Service should consider deleting this section because all permits issued before or shortly after the referenced date (10 June 1996) have expired.

§ 216.45. General Authorization

As noted above, we believe that it would make sense to group the regulations pertaining to the general authorization with those concerning scientific research permits. Among other things, this may eliminate the need to repeat some of the regulatory provisions, such as the conditions set forth in section 216.41(c)(1)(vii), which the Service is considering making applicable to general authorization.

We do not agree with the Service's suggestion that the general authorization be expanded to cover research that involves taking by Level A harassment. First, as indicated in the *Federal Register* notice, this would require a statutory change. Regulatory rulemaking cannot be used to amend the Act. Second, we have substantive concerns about the proposed expansion of the general authorization. In essence, this authorization provides a shortcut around some of the procedures applicable to research permits, including the opportunity for prior public notice and opportunity for public comment. Those that crafted the MMPA recognized the value of public participation in decisions involving the authorization of taking of marine mammals. Only in limited situations, such as the general authorization (which currently applies only to relatively benign activities), have exceptions been made. The Commission does not believe that allowing taking by Level A

harassment, which includes the potential for injury of marine mammals and marine mammal stocks, should be authorized without public involvement and opportunity to comment.

Our concern about expanding the scope of the general authorization is heightened by proposals made by the Administration and others to amend the definition of the term "harassment" under the MMPA. Care needs to be taken such that possible amendments to that definition and proposed changes to the scope of the general authorization are considered in tandem. It would be inappropriate to broaden the general authorization to include Level A harassment and at the same time limit what constitutes Level A harassment to takings that have significant effects.

As an alternative, the Marine Mammal Commission recommends that the National Marine Fisheries Service consider seeking amendments to the MMPA and/or ESA that would streamline the process for authorizing the taking of marine mammals listed as threatened or endangered by Level B harassment for scientific purposes. This would make the general authorization applicable to a broader suite of species but would keep it focused on the types of activities that are not of major concern (e.g., photo-identification, population surveys, etc.).

Other Considerations

The Service indicates that it is contemplating adding provisions to the regulations that would limit opportunities for submitting applications to certain times of the year (e.g. quarterly or semi-annually). Our first impression is that such a proposal could impose hardships on some applicants and would no doubt be less convenient for applicants than the current system. Has the Service done any sort of analysis to demonstrate that the alternatives being considered actually are likely to result in smoother processing and timelier agency action? Absent such analysis, it is difficult for the Commission to take a more definitive position on these proposals. It seems that these alternatives have the potential to swamp the Permit Office with a number of applications at certain, albeit predictable, times that will require the same types of back-and-forth with applicants to obtain missing pieces of information and/or clarifications of what is being proposed. Furthermore, different types of research may be appropriate at different times of year, and any limits on applications would complicate preparations for researchers, particularly those whose activities might not coincide with the majority of studies. What might be more useful is making it clearer to applicants what information is required, and why, so that there is a greater likelihood that applications are considered complete at the outset.

Combining analysis under National Environmental Policy Act (NEPA) and section 7 consultations under the ESA may facilitate the processing of permit applications and should be considered as long as measures are taken to ensure that the new procedures do not undermine the intent of either Act. It is our understanding that complying with the requirements of these statutes is often a significant source of delay in taking action on an application. In some respects, the analysis required under the Service's permit regulations and those under these other statutes are overlapping. For instance, the issuance criteria under section 216.34 require the proposed activities be not likely, by themselves or in combination with other activities, to have a significant adverse impact on the

affected species or stocks. For scientific research and enhancement activities, section 216.41(b)(4) requires the Service to find that the proposed activities "will not likely have significant adverse effects on any other components of the marine ecosystem ...." Any activity that satisfies these requirements arguably would qualify for a finding of no significant impact under NEPA, and a no jeopardy finding under section 7 of the ESA. As such, we do not understand why separate, sequential analysis under the three Acts, as is currently the case, should be required. The Marine Mammal Commission therefore recommends that the National Marine Fisheries Service consider ways of revising the regulations to eliminate the need for separate and somewhat duplicative reviews.

Finally, and in some respects most importantly, the larger community involved in permitting issues has still not resolved the concern about cumulative effects of human activities, including research. Although research generally is intended to provide information that should promote more effective conservation efforts, by its very nature it sometimes imposes an added effect on the target species or its habitat. We believe that addressing the cumulative effects issue will require quantitative approaches supported by extensive monitoring and data collection. Although we do not believe that the marine mammal science community is prepared to describe the needed studies to understand such effects, moving in that direction is essential if we are to achieve our conservation goals. In the face of such uncertainty, we believe it is necessary to raise the level of precaution in authorizing studies that may have effects that add to or interact with the effects of other human activities, including other research. We do not see a mechanism for addressing this concern in regulations at this point, but we do wish to emphasize the need to move forward on this topic. The Commission is planning to sponsor an initial workshop on this topic in 2008, and we will contact you as our planning develops.

As noted at the beginning of this letter, we appreciate the fact that you are evaluating the permit regulations to improve the permitting process. We hope that the above comments and recommendations are helpful. If we can be of further assistance in this process, please don't hesitate to contact me.

Sincerely,

Timothy J. Ragen, Ph.D.
Executive Director

Enclosure

MARINE MAMMAL COMMISSION
4340 EAST-WEST HIGHWAY, ROOM 905
BETHESDA, MD 20814

13 August 2001

Mr. Charlie R. Chandler
Chief, Branch of Permits
Division of Management Authority
U.S. Fish and Wildlife Service
4401 N. Fairfax Drive
Arlington, VA 22203

Re: Permit Application No. PRT- 032027 (Monterey Bay Aquarium)

Dear Mr. Chandler:

The Marine Mammal Commission, in consultation with its Committee of Scientific Advisors on Marine Mammals, has reviewed the above-referenced permit application with regard to the goals, policies, and requirements of the Marine Mammal Protection Act. The Marine Mammal Commission apologizes for the length of time it has taken to provide its recommendation on this application. As we discussed with you and your staff, the application raises a number of novel and precedent setting issues that warrant a comprehensive review and thorough consideration.

The applicant is requesting authorization to take southern sea otters for purposes of enhancement and scientific research associated with rehabilitation and post-release monitoring activities (*e.g.*, rescue, release, relocation, *etc.*). A major purpose of the requested permit is to clarify the scope and authority for the southern sea otter rehabilitation programs at the Monterey Bay Aquarium in order to streamline the authorization process for the Aquarium's activities involving southern sea otters.

In general, the Commission believes that the activities for which authorization is being sought are worthwhile and, to the extent consistent with the applicable statutory criteria, should be authorized. Nevertheless, we are concerned that at least some of the proposed activities have not been sufficiently described to enable the Service to make the required findings (*e.g.*, that proposed research is *bona fide*) or appropriately fit within the scope of the permit being sought. In this regard, the Commission has three primary concerns with the applicant's proposals.

First, the applicant is calling for a broad reading of the Marine Mammal Protection Act's enhancement provision that we do not think accurately reflects the intention of its drafters. While the Endangered Species Act's enhancement permit provision has been broadly applied to authorize a host of activities that provide educational opportunities to the public, that provide funding for conservation efforts, or that somehow enhance the affected population in a general sense, the Marine Mammal Protection Act enhancement provision was much more narrowly prescribed. This was, at least in part, in response to a perception by some that the Endangered

Species Act provision had been too broadly interpreted. It also reflected the fact that, unlike the Endangered Species Act, the Marine Mammal Protection Act contained alternative provisions under which public display and rescue and rehabilitation efforts could be authorized. As a party to the negotiations that led to adoption of the Marine Mammal Protection Act enhancement permit authority in 1988, the Commission believes that this provision should be narrowly construed as its drafters intended. As such, the Commission disagrees with the applicant's thesis, set forth in section 13.a. of the application, that "southern sea otter rehabilitation [by itself] is a legitimate enhancement activity." We also disagree with the applicant's assertion, also included in section 13.a., that both the Marine Mammal Protection Act and the Endangered Species Act affords the Service "broad latitude to issue a[n enhancement] permit" in this instance.

The Commission therefore recommends that, subject to resolution of the specific concerns noted below, an enhancement permit be issued for the proposed activities under the Endangered Species Act. As for the Marine Mammal Protection Act, the Commission recommends that rescue and rehabilitation efforts continue to be authorized under section 109(h) of the Act. With the possible exception of the proposal to bank genetic material for possible restocking of the population in the event of an environmental catastrophe and a captive breeding program directed at augmenting the wild population, we believe that the other "enhancement" activities identified in the application can be, and should be, authorized under section 109(h) and/or a scientific research permit. The Commission notes that the Service's response to this application will set a precedent for how future enhancement applications are addressed. We therefore are particularly concerned that any authorization issued under section 104(c)(4) not include any activities that only generally would promote the survival or recovery of the southern sea otter, such as the development of education and outreach programs.

Second, some of the proposed research activities are described too generally for the Commission or other reviewers to assess whether they meet the Marine Mammal Protection Act criteria for issuance of a scientific research permit. For example, the proposal for long-term monitoring attached to the application, in project objective 4, indicates that the applicant intends to study "site selection criteria," but does not provide an experimental design for such a study or even identify what variables will be measured. Further, such a study seems to run counter to the applicant's stated preference for releasing rehabilitated otters at the sites where they were originally collected. Similarly, the proposals to study "sea otter habitat selection and travel strategies" and to "evaluate rehabilitation and release methods based on survival and behavioral data" require further description. In neither case is it clear what precisely will be done, what will be measured, or what sample sizes are anticipated. Additionally, certain activities do not appear to fit within the scope of permits that could be issued under either the Marine Mammal Protection Act or Endangered Species Act.

Third, in several instances, the applicant seeks broad discretion as to how certain activities would be conducted. For example, the applicant requests authorization to recapture any released otters on an "as needed" basis, at the discretion of the permit holder. No estimate of the average or maximum number of captures per animal is provided. In this regard, we call your

attention to the discussion on page 13 of the Service's 19 July 2000 biological opinion on the containment program for the southern sea otter (1-8-99-FW-81). That discussion recounts the difficulties associated with capturing, handling, and holding sea otters under the translocation program and notes that "the stress of being captured, held in captivity, and...undergoing surgery to implant tracking devices resulted in a mortality rate that was higher than anticipated." Although the applicant has been successful in capturing, restraining, and anesthetizing sea otters and is not anticipating any mortalities from the requested activities, it should be recognized that each capture or surgical procedure is likely to be stressful and has the potential to adversely affect the health of, or even kill, the animal involved. This being the case, we do not believe that it would be appropriate for the Service to defer completely to the applicant's judgment as to when, where, how, and perhaps most importantly, how frequently otters would be captured and sampled or otherwise handled.

Similarly, in the context of the proposed scientific research under item 12.a. of the application, the Commission believes that it would be ill-advised for the Service to grant the broad authority sought by the applicant permitting it to recapture any otter rehabilitated and released by the facility "at the discretion of SORAC program staff to monitor health, to facilitate long-term tracking, and to otherwise promote survival and successful integration [of released otters] into the wild population." While these are laudable goals, it would be inappropriate for the Service to defer so completely to an applicant as to the specifics of a research program.

There are other places in the application where the applicant also seeks unprecedented latitude in conducting the proposed activities. For example, the applicant indicates that excess or unused samples would be archived and "would be made available to other researchers at the discretion of the permit holder upon demonstration of compelling scientific need." Although the applicant can play a valuable role in collecting, archiving, and distributing samples, the Commission notes that it is the Service that is responsible for issuing the necessary permits or authorizations that determine which researchers are given access to surplus samples. Further, although the applicant identifies four anesthetic protocols it intends to use, it requests that the use of "better, safer pharmaceutical agents should not be abridged or restricted under the permit." Again, we agree with the underlying objective of the applicant, but believe that any material changes in the protocol for the administration of anesthetics or other drugs should be subject to approval by the Service pursuant to a permit amendment.

Specific Comments

The application states in section 7.b. of the application that "...this proposed permit would acknowledge that the rehabilitation and release of live-stranded southern sea otters constitutes an enhancement activity under the ESA and the MMPA, and that increased monitoring of post-release survival of rehabilitated and released southern sea otters represents a legitimate scientific research endeavor." As noted above, it is the Commission's view that rehabilitation/release activities alone do not meet the statutory criteria for enhancement under the Marine Mammal Protection Act, but, rather, should be authorized under section 109(h) of the Act. Also, as noted

above, we are unable to comment specifically on some of the proposed research projects without additional information sufficient to indicate that these studies constitute *bona fide* research as defined in the Marine Mammal Protection Act.

As noted in section 13.a. of the application, the Monterey Bay Aquarium has not been provided official, written authorization under section 109(h) to carry out rehabilitation activities, including abdominal transmitter implants, and has been conducting such activities based solely on verbal authorizations from the Service. It is unclear why the Service has not provided the necessary written authorization, and the Commission recommends that, if it has not already done so, it do so promptly. As a related matter, the permittee is requesting authority for coordinating and authorizing "a live-stranding network to improve the response capability to southern sea otter strandings." While the Commission appreciates the applicant's desire to improve the effectiveness of the stranding network, it believes that responsibility for stranding network coordination more appropriately rests with the Service. In this regard, the Commission recommends that the Service and the applicant work together to develop a protocol for streamlined response capability. Likewise, transfer between facilities of animals determined to be unreleasable should be done only with the concurrence of the Service.

In light of these concerns, the Commission recommends that the Service: (1) defer final action on the permit application pending receipt and review, in consultation with the Commission, of supplemental information that addresses the issues discussed above and provides a discussion of the study design for each of the proposed research projects sufficient to satisfy the requirements of 50 C.F.R. § 18.31(a)(4), including criteria for recapturing previously released animals and establishment of limits on the maximum number of recaptures per animal, protocols for post-release tracking and monitoring, development of new or refined tag implantation techniques, evaluation of rehabilitation and release methods, and a description of methods to be used to avoid mortalities; and (2) upon determining that the supplemental information is adequate to satisfy the issuance criteria set forth in the Act, grant approval of the requested activities, subject to the following conditions:

(1) that authorization to continue the described research in the second and subsequent years be contingent upon submission and approval of a report on the preceding year's activities and the specific research proposed for the forthcoming year.

(2) that, inasmuch as the applicant is requesting to conduct scientific research activities on the subject animals, the Service, in consultation with the Animal and Plant Health Inspection Service, ensure that the applicant's facility is registered pursuant to § 2.30 of the Animal and Plant Health Inspection Service's regulations governing the humane handling, care, treatment, and transportation of marine mammals, and that the proposed research has been reviewed by the applicant's Institutional Animal Care and Use Committee in accordance with § 2.31 of the regulations;

(3) that surgical implantations of radio tags not be performed on evidently pregnant females or animals weighting less than 20 pounds;

(4) that, although mortalities are not anticipated, the risk of mortalities be recognized by authorizing a low level of such takings (*e.g.*, one or two per year). Further, in the event that the authorized number of mortalities occurs in a given year as a result of the authorized activities, the permittee be required to immediately suspend its research activities pending review and authorization to proceed. Whenever possible, necropsies should be performed to determine the cause of any mortalities occurring during the course of the authorized research activities;

(5) that prior to a decision to euthanize any animals under the permit the applicant consult with and obtain the approval of the Service;

(6) that the Service, in consultation with the Animal and Plant Health Inspection Service is satisfied that the applicant's plans and facilities for transporting the requested animals are adequate to provide for their health and well-being. In this regard, the application states that "[d]epending upon the nature and duration of a transport, various contingencies will be developed to ensure that animal health and comfort is maintained." Contingency protocols should be provided to the Animal and Plant Health Inspection Service for review, prior to their implementation by the Aquarium; and

(7) that the Service be satisfied that appropriate steps will be taken to ensure that the incidental public display of stranded otters undergoing rehabilitation will in no way interfere with rehabilitation activities.

Please contact me if you have any questions concerning this recommendation.

Sincerely,

Rob Mattlin

Robert H. Mattlin, Ph.D.
Executive Director

MYSTIC AQUARIUM
INSTITUTE FOR EXPLORATION

December 11th 2007

Chief, Permits, Conservation and Education Division
F/PR1/ Office of Protected Resources/ NMFS
1315 East-West Highway Room 13705
Silver Spring, MD 20910

Attn: Permit Regulations ANPR

This letter contains comments from Mystic Aquarium and Institute for Exploration (MAIFE) related to the Marine Mammals; Advanced Notice of Proposed Rule Making. MAIFE's concerns center primarily on the issues of marine mammal parts, captive animal research as well as permit cycles, amendments and extensions.

50 C.F.R. § 216.35

Currently changes to the number, location and species taken, imported or exported constitute a major amendment. The proposed rules call for no longer allowing any major amendments to permits and instead require that a new permit application be submitted. First we suggest changing the definition of a minor amendment to: "any change in parts number, location, species or any change in captive animal research where there is no take or effect to wild populations." This should include transferring, importing and exporting ESA-listed captive animals that are in permanent captivity. We suggest simplifying this procedure to require that the facility the animal is being transferred to or from can show that the animals were collected in a humane manner, that the facility has passed APHIS or other required inspections, and that any research required under the permit the animal is held under is continued. We would like to see a transfer policy similar to the 15 day notification required for moving non-listed marine mammals. If this is done then the number of major amendments being submitted should substantially decrease. Perhaps with this scenario eliminating major amendments would be acceptable.

50 C.F.R. § 216.35(b)

With respect to permit extensions the proposed rules suggest doing away with the current one year permit extension. We strongly feel that the move should be in the opposite direction. Please consider a 5 year extension to permits in which the major thrust of the permit remains unchanged (and all reporting requirements are current), especially those permits that have no impact on wild populations (parts and captive animal work only). This would greatly reduce both the applicant and permit office workload.

55 Coogan Boulevard Mystic, Connecticut 06355 • Tel: (860) 572.5955 Fax: (860) 572.5969 • www.mysticaquarium.org

50 C.F.R. § 216.41

For most institutions it is necessary to maintain research animals on public display due to limited space. Current rules allow for display of animals held under Research and Enhancement Permits only when necessary to meet research objectives or if authorized by the Office Director. The proposed rule would allow for long term captive maintenance and public display of ESA listed species originally obtained under a Research and Enhancement Permit and we feel that this an excellent idea. We agree that requiring an appropriate education program and that making the animals available to research (within the means of the institution) is a must, however we do not feel that NMFS should have jurisdiction over an institutions educational programming.

General Amendments

In terms of permit cycles, we believe that quarterly would be acceptable, but that a 6 month cycle is not often enough. If the move is made to permit cycles to simplify the processing and allow for group processing of permits, we would like to see some "guarantee" of timing approval and implementation of the permits. For example- a permit submitted at the start of one cycle would be approved by the end of the following cycle.

Thank you for the opportunity to make comments and suggestions on the proposed rule changes. We appreciate the hard work that the permits office does and are grateful have enjoyed working closely to Amy Sloan and Jennifer Skidmore for all their time, help and support with our permits applications.

Sincerely,

Lisa Mazzaro, Ph.D.
Assistant Director of Research and Animal Care
Mystic Aquarium
55 Coogan Blvd.
Mystic, CT 06355
860-572-5955 x 109
fax: 860-572-5972
email: Lmazzaro@mysticaquarium.org

UNIVERSITY OF HAWAI'I AT MĀNOA

Hawai'i Institute of Marine Biology

Michael Payne
Chief, Permits,
Conservation and Educations Division,
Attn: Permit Regulations ANPR,
Office of Protected Resources,
NMFS
1315 East-West Highway
Room 13705,
Silver Spring,
MD 20910

Dear Dr. Payne,

Thank you for this opportunity to comment on your proposed rule changes to permits and applications under the marine mammal protection act. I find it particularly interesting that you plan to actually attempt to revise the Act again. I generally find the permit process to be increasingly difficult. I am a little disappointed because I did not see anything in this list that attempted to streamline and make the process simpler and easier for scientists. I see things that make it more difficult and complicated. I have been working in the field since the original law was passed and agree that it was successful in stopping the useless slaughter of dolphins in tuna nets. For those of us that conduct research with captive born animals in laboratories, it has taken on a totally duplicative and redundant role with the Animal Welfare act and the Institutional Animal Care and Utilization Committees. Our science must not be duplicative, but the bureaucracies that control us continue to duplicate and become more complex. Please find my direct comments on particular sections below.

Re: 216.34

Many animal care committees check to see whether special permits are in place. Our own at the University of Hawaii has a place to check to see whether a marine mammal permit is required and will not grant protocol approval without an approved marine mammal permit. If NMFS now requires protocol approval prior to granting a permit, a catch-22 situation will be set up. Actually the marine mammal permit and the protocol approval for research with captive animals are redundant and duplicative. Both presumably are assuring that the animals are treated well and the research is reasonable and non-duplicative. The original intent of the marine mammal protection act was to assure that wild populations were protected and animals were not unduly taken. It would seem reasonable to me to no longer require marine mammal permits for captive marine

Coconut Island, P. O. Box 1346, Kāne'ohe, Hawai'i 96744-1346
Telephone: (808) 236-7401, Facsimile: (808) 236-7443

mammal research at bona fide research institutions that have established animal care committees. It seems that you could reduce your workload and reduce the burden on researchers by recognizing this duplicity of effort.

Re: 216.41

It seems very reasonable to me to allow the public display of animals that have been rehabilitated following stranding no matter what the ESA-listing status of those animals may be. Public display facilities have contributed greatly to the rehabilitation of a large number of stranded animals. Formerly stranded animals provide the opportunity for continued knowledge to be gained about their species. It is far better for an unusual species to be rehabilitated and placed on public display than to be euthanized on the beach. All animals should not have to be returned to the wild, it is reasonable to keep formerly stranded animals in captive research or public display facilities.

Re: 216.39

It seems that one more exception could be added to allow the Office Director to grant amendments. If a PI has a small research operation, with approved IACUC breeding protocols, and the number of animals at his facility increases due to animal births, it seems reasonable that the Office Director should be able to amend the permit to increase the number of animals without need for further review or public comment.

Re: 216.42

Restrictions on photography by the marine mammal protection act regulations seems to me to hedge on freedom of speech and expression. I have visitors to my research facility and I urge them to take all of the photos that they would like. Given the public is necessarily restricted from interacting with marine mammals, it bothers me to place any restrictions on photography.

Other Considerations:

I think placing "permit applications and amendments on a cycle" is an inherently bad idea. While some may think it would make the office more efficient, the world does not work that way. All research and permits are on a cycle now. Each of them has a start and end date. That does not make things easy. My last 'simple' permit took 2.5 years to renew. Setting up an artificial annual cycle will not change the demands on the NMFS permits office, it will just throw one more difficulty into a system that is already nearly impossible from a scientists point of view.

Once again, thank you for listening to my opinions. I appreciate this opportunity to express my thoughts.

Sincerely,

Paul E. Nachtigall
Director, Marine Mammal Research Program

National Oceanic and Atmospheric Administration
National Marine Sanctuary Program comments on the
Advance Notice of Proposed Rulemaking for Marine Mammal Protection Act Permits
(Docket # 070809454-7459-01)

December 12, 2007

The NOAA National Marine Sanctuary Program (NMSP) welcomes this opportunity to comment on National Marine Fisheries Service (NMFS) Advance Notice of Proposed Rulemaking (ANPR) regarding proposed changes to implementing regulations and criteria governing the issuance of permits for scientific research and enhancement activities under section 104 of the Marine Mammal Protection Act (MMPA). The NMSP has a long history of successfully working with NMFS and MMPA permittees to protect marine mammals both within and near national marine sanctuaries.

The NMSP supports NMFS's efforts to make issuance of MMPA permits as efficient, streamlined, and effective as possible, and offers several specific comments based on that experience related to coordination of activities that require consultation and/or permit under both the MMPA and National Marine Sanctuaries Act (NMSA). In general, the comments center on the need to coordinate MMPA permit actions with the NMSP in cases where sanctuary resources will be affected or a sanctuary permit or consultation is required.

Coordinating MMPA permits and NMSA section 304(d) consultations

Section 304(d) of the NMSA (16 U.S.C. § 1434(d)) requires federal agencies to consult with the Secretary of Commerce, through NOAA, regarding any action or proposed action, including private activities authorized by licenses, leases, or permits, that is likely to destroy, cause the loss of, or injure any sanctuary resource (for the Stellwagen Bank NMS, the threshold is "may affect" sanctuary resources). If the NMSP finds that the proposed action is likely to destroy, cause the loss of, or injure sanctuary resources, the NMSA requires the NMSP to develop and recommend reasonable and prudent alternatives for the federal agency to implement to protect sanctuary resources.

Activities proposed by federal agencies to be conducted within and/or adjacent to sanctuaries that impact marine mammals, therefore, might trigger the need for both a MMPA permit and NMSA consultation. In these cases, both NMFS and the NMSP may propose various mitigations or recommendations to protect marine mammals. While NMSA and MMPA differ in their mandates and thresholds, increased coordination with NMSP when developing mitigations and recommendations in cases where both statutes apply would benefit both the NMSP and NMFS.

For example, under the NMSA, NMSP recommendations to mitigate or avoid impacts to sanctuary resources are due 45 days after receipt of the "sanctuary resource statement" (which describes the proposed activities and the potential impacts to sanctuary resources). In the ANPR, NMFS proposes deferring MMPA permitting decisions until after the conclusion of ESA section 7 consultation (a 135-day process). This would mean that

final determination of permitted take levels under the MMPA (and imposition of any associated mitigation or monitoring requirements) would probably not take place until well after NMSA recommendations have been submitted to the action agency. Again, although the NMSA and MMPA differ in their requirements, it is desirable (both for the applicant and NOAA) that mitigations and other recommendations made by NOAA meet the mandates of both statutes, to the extent this is possible. Thus, in cases in which both statutes apply, the NMSP recommends NMFS consider a process that results in the 45-day NMSA consultation period being coincident with consideration of the MMPA permit. Although we understand the further difficulty of coordinating when species are listed under the ESA, deferring the MMPA decision to late in the process (and probably well after other consultations are complete) would not facilitate the development of a single, coordinated set of agency mitigation and monitoring requirements that meet the requirements of both the MMPA and NMSA. The NMSP believes that this is best achieved if the processes are run concurrently, to the extent possible.

Coordinating MMPA and NMSP permits

The ANPR also solicited comments on MMPA scientific permits. Our comments on these permits relate to NMFS's proposal in the ANPR to consider including "non-strategic" level A or B take and "strategic" level B take under General Authorizations (GAs). The proposal is for these applications to be accepted on a quarterly or biannual schedule, allowing 90 days for processing each application. The NMSP understands the advantages of such "batch processing" of applications. However, as before, any such proposal should take into account the need to coordinate agency response to the proposed action, especially mitigation and monitoring requirements, with other permits or approvals that might be required for that activity.

For example, batch processing of GA applications may make coordination with NMSP permits more difficult. NMSP regulations generally exempt the need for a sanctuary permit for marine mammal disturbance if an applicant has obtained the appropriate authorization under the MMPA. However, when an applicant proposes conducting an activity within a sanctuary that would otherwise violate other sanctuary prohibitions (for example, placing gear on the seabed or operating a vessel in a certain location), a separate NMSP permit would still be required. NMSP permits are generally processed within 30 days of receipt of a complete application and are not presently subject to a schedule or regular processing intervals. Therefore, in these cases, in considering changes to its scientific permit processing, NMFS should ensure its procedures include sufficient opportunity to coordinate with the NMSP on such details as mitigation and monitoring requirements, coordinated communication with applicants, etc. This is probably best assured when permitting is proceeding on or near the same timeline; however, there are other ways this could be achieved. NMSP would welcome further dialogue on how this coordination might best be accomplished while still accomplishing NMFS's objectives.

Definitions and Permitting Requirements

Finally, this ANPR requested comment regarding the possible need for additional clarification of MMPA definitions and permitting requirements. We offer a suggestion regarding clarifying post-issuance requirements on the applicant. For activities requiring

concurrent processing under the NMSA and the MMPA, action agencies and applicants have demonstrated confusion regarding how to facilitate adaptive management in the light of findings made under these two statutes. For example, it often appears unclear to applicants what they must include in regular reports to various offices within NOAA to allow evaluation by the agency regarding ongoing compliance with mitigation and monitoring requirements and/or the status of current take relative to total allowed take under their MMPA permit. Therefore, NMFS might consider including in its regulations clear statements regarding what an applicant must do after receiving an MMPA permit, specifically: the types of data that must be provided on an ongoing basis to allow NOAA to evaluate the status of their permit; how to count the number of animals that have been "taken" under Level A and Level B; and what the process is if permitted take levels are exceeded. Such clarifications in situations involving coincident oversight of mitigation and monitoring activities by multiple NOAA branches would lead to a better understanding (both within NOAA and between NOAA and the MMPA permittees) regarding the specific requirements of the permit and the permittee's state of compliance at any given time.

1201 New York Avenue, NW • 4th Floor • Washington, DC 20005
P. 202.232.3900 • F. 202.462.8754 • www.OceanLeadership.org

CONSORTIUM FOR
Ocean Leadership

December 13, 2007

VIA E-mail

Mr. Michael Payne, Chief
Permits, Conservation and Education Division
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910

RE: Docket No. 070809454-7459-01

Dear Mr. Payne:

On behalf of the 95 member institutions of the Consortium for Ocean Leadership (Ocean Leadership), appreciates the opportunity to comment on the Advance Notice of Proposed Rulemaking ("ANPR") regarding possible changes to regulations governing the issuance of permits for scientific research and enhancement activities under section 104 of the Marine Mammal Protection Act ("MMPA"), 72 Fed. Reg. 52339 (Sept. 13, 2007). Ocean Leadership applauds the National Marine Fisheries Service (NMFS) for taking this much needed action to revise its permitting regulations. However, Ocean Leadership is deeply concerned that many of the proposed actions in the ANPR will increase the burden for an already overburdened research community and greatly encumber their ability to secure scientific research permits.

The research community provides information that improves our understanding of marine mammal biology, physiology, reproduction, behavior, life history, and ecology – information that is critical to NMFS conservation and management of these species. Yet, this community bears a greater regulatory burden than most commercial fisheries and other activities that provide no benefit to marine mammals and routinely injure or kill them. Ocean Leadership believes that in changing its regulations, NMFS should strive to allocate regulatory effort to those activities that provide the least benefit and highest risk to marine mammals. Any such review would reduce regulation of research in order to increase resources for more harmful activities. Ocean Leadership's major concerns are the cost, time, and regulatory expertise needed for a marine mammal researcher to obtain a permit to conduct research on marine mammals. Likewise the cost, time, and practicality issues (e.g. case-by-case permitting) may not be appropriate for repetitive activities that do not change significantly over time. In general, the permitting process is opaque, has no predictable timeline, is confusing, and it lacks clear guidance as to when compliance with other statutes such as the National Environmental Policy Act (NEPA) or the Endangered

Species Act (ESA) may require researchers to submit additional documentation.

We believe the scientific permitting process is gridlocked, with even non-controversial permit renewals requiring eighteen to twenty-four months to complete. The Permits Division of the Office of Protected Resources is understaffed for both the current and planned permitting processes. Additional resources are urgently needed to comply with both the ESA and NEPA. NMFS Permit Division first priority should be swift action to streamline its permitting process and secure the funds necessary to implement its mandate. Ocean Leadership is deeply concerned that the changes suggested in the ANPR will achieve the opposite effect and will further complicate and slow down an already cumbersome, time-consuming and confusing scientific research permit process.

GENERAL RECOMMENDATIONS

The ocean science and marine mammal research communities are urgently in need of timely, predictable, and cost-effective permitting or authorization processes under the MMPA. Ocean Leadership makes the following recommendations to meet that goal.

- NMFS should work with applicants to reduce the cost and time of preparing the required NEPA and permit application documentation. Because cost and time are most often limiting factors for researchers, NMFS should work to reduce these factors by providing standard background documents, application information, and references available online through its website. Standard biological information such as species descriptions, abundance estimates, geographic area information could be posted on the web and accessible to applicants to incorporate into their application by reference. Reduction in paperwork of including boilerplate assessments of the status of affected stocks, which is something NMFS is already mandated to provide, would reduce the cost and time of applying for a permit, while making more obvious the critical points specific to each permit.

- NMFS should implement programmatic permitting for activities that affect marine mammals, wherever possible. More resource intensive case-by-case permitting should be reserved for unique activities or where circumstances indicate a greater likelihood of harm to marine mammals. Alternatively, NMFS should, when appropriate, look for mechanisms to process and issue collectively, NEPA and permit application documentations that are either similar by species, region, or activity. There may be situations such as Steller sea lion research in Alaska or North Atlantic right whale research in the Northeast where a number of research activities on a particular marine mammal species should be analyzed together and authorizations should be coordinated. Processing similar research activities may streamline the process, but it also carries the risk that a legal challenge on one portion of the permit may stop research associated with other projects under the permit. Furthermore, activities that take place in different oceans and on different species do not lend themselves to this approach so it may not be practical in many cases. Those cases for which this approach may be practical should be identified and discussed in the proposed rule.

SECTION BY SECTION ANALYSIS

Below are Ocean Leadership's specific comments on the ANPR, organized by the regulatory section to which NMFS is considering changes.

50 C.F.R. § 216.3 Definitions

The current regulations include a definition for "bona fide scientific research". The term is currently defined as:

> (1) ...scientific research on marine mammals conducted by qualified personnel, the results of which:
>
> (i) Likely would be accepted for publication in a refereed scientific journal;
>
> (ii) Are likely to contribute to the basic knowledge of marine mammal biology or ecology. (Note: This includes, for example, marine mammal parts in a properly curated, professionally accredited scientific collection); or
>
> (iii) Are likely to identify, evaluate, or resolve conservation problems.
>
> (2) Research that is not on marine mammals, but that may incidentally take marine mammals, is not included in this definition (see sections 101(a)(3)(A), 101(a)(5)(A), and 101(a)(5)(D) of the MMPA, and sections 7(b)(4) and 10(a)(1)(B) of the ESA).

Ocean Leadership believes that all scientific research should be included in this definition whether it is on or incidentally takes marine mammals. We understand that such a proposal would require a change to the MMPA, but we agree with the National Academy of Sciences 1994 report on "Low-frequency Sound and Marine Mammals" and firmly advocate that all research should be regulated under the same provisions.

Likewise the definitions define Intrusive research as

> "a procedure conducted for bona fide scientific research involving: A break in or cutting of the skin or equivalent, insertion of an instrument or material into an orifice, introduction of a substance or object into the animal's immediate environment that is likely either to be ingested or to contact and directly affect animal tissues (i.e., chemical substances), or a stimulus directed at animals that may involve a risk to health or welfare or that may have an impact on normal function or behavior (i.e., audio broadcasts directed at animals that may affect behavior). For captive animals, this definition does not include:
>
> (1) A procedure conducted by the professional staff of the holding facility or an attending veterinarian for purposes of animal husbandry, care, maintenance, or treatment, or a routine medical procedure that, in the reasonable judgment of the attending veterinarian, would not constitute a risk to the health or welfare of the captive animal; or
>
> (2) A procedure involving either the introduction of a substance or object (i.e., as described in this definition) or a stimulus directed at animals that, in the reasonable judgment of the attending veterinarian, would not involve a risk to the health or welfare of the captive animal.

Ocean Leadership questions why this definition is necessary. Is intrusive research any less important than other forms of research, or more suspect? If there is a reason to define intrusive or invasive actions, it is to identify actions that pose a direct risk of injury. Ocean Leadership rejects the notion that producing a stimulus that may affect behavior belongs in the same category. All research where the animals may sense the research activity pose the same risk of affecting behavior. Why add level B effects to a definition whose only rationale should be to highlight activities that pose higher risk e.g. level A vs level B takes. This definition makes worse the situation where uncontrolled effects of research such as vessel noise are given a free pass compared to carefully controlled exposure of similar stimuli. Should not regulations have the opposite bias if it has to have any bias? Ocean Leadership sees little need for this definition, and recommends that it be deleted.

Perhaps the most problematic definition is that for harassment which is currently defined as:

> *Level A Harassment* means any act of pursuit, torment, or annoyance which has the potential to injure a marine mammal or marine mammal stock in the wild.

> *Level B Harassment* means any act of pursuit, torment, or annoyance which has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering but which does not have the potential to injure a marine mammal or marine mammal stock in the wild.

The Ocean Commission Report recommended that "Congress should amend Marine Mammal Protection Act to revise the definition of harassment to cover only activities that meaningfully disrupt behaviors that are significant to the survival and reproduction of marine mammals." Likewise the National Research Council reports expressed concern that the current scientific research regulatory system discourages research that would benefit conservation of marine mammals and their ecosystems and suggested:

- Redefine the definition of Level B harassment as "meaningful disruption of biologically *significant activities.*" *(2000)*
- Incorporate "population status into regulations on harassment" (2000, 1994)

In regard to scientific research activities, recommendations to focus permitting requirements on biologically significant behaviors require that biological significance be carefully defined. The NRC "Committee on Characterizing Biologically Significant Marine Mammal Behavior" recognized that additional scientific research is needed to define biological significance. Nevertheless, clearly defining this standard provides the foundation upon which consideration of alternative regulatory regimes could be undertaken. Ocean Leadership recommends that NMFS convene a group of marine mammal scientists, policy-makers, and Hill staff to develop a definition of harassment that is scientifically based, readily interpreted by the agency, and easily enforced.

50 C.F.R. § 216.14 Marine Mammals Taken Before the MMPA

In the ANPR, NMFS asks whether this section should include provisions to authorize export in addition to import. Ocean Leadership supports authorizing both the import and export pre-Act marine mammals or their products or parts.

50 C.F.R. § 216.15 Depleted species

In order to parallel the definition of "depleted" in the MMPA, Ocean Leadership recommends that NMFS clarify that any species or population stock listed as endangered or threatened under the ESA is automatically listed as depleted under the MMPA.

50 C.F.R. § 216.25 Exempted Marine Mammals and Marine Mammal Products

Ocean Leadership recommends that § 216.25 be removed and the appropriate provisions included in **§§** 216.14 and 216.12.

50 C.F.R. § 216.26 Collection of Certain Marine Mammal Parts without Prior Authorization

NMFS must look for ways to streamline the collection of marine mammal parts from dead stranded marine mammals. Perhaps there should be a general authorization for the collection of marine mammal parts from all stranded/salvaged marine mammals, including those listed as depleted, threatened, or endangered. Once a stranded animal is salvaged under the appropriate authorizations, there should be virtually no permitting requirements or only a general authorization that allows researchers to transfer, import, or export marine mammal parts for scientific research or sample analysis. Streamlining transfer of samples, as long as those

sample transfers are well-documented, and perhaps simply reported to NMFS, will ensure that critical data analyses can be undertaken as expeditiously as possible. A simple reporting system would be valuable. It is important to note the Import/Export would still require CITES permits.

50 C.F.R. § 216.32 Scope

Ocean Leadership believes that the provisions of Subpart D to the permitting regulations should not apply to marine mammals or marine mammal parts born in captivity after December 20, 1972; recommends deleting that phrase in the scope section. The original purpose of the MMPA was to stop the killing and taking of dolphins caught in tuna nets by fishermen primarily in the Eastern Tropical Pacific. It focus was on protecting marine mammals in the wild. The way the act is currently written it goes far beyond protecting the species of wild populations of animals and Ocean Leadership questions the value of its use in controlling laboratory studies. Animals in laboratories are protected by the Animal Welfare Act (AWA). In these situations, all scientific research is reviewed by the Animal Care and Use Committees (IACUC) and inspection are conducted by the Animal Plant Health and Inspection Service (APHIS). The requirement for continuing permits by NMFS for animals born in captivity and used in laboratory studies totally duplicates the better control established by the IACUCs and APHIS. Each experiment in a laboratory must have a protocol approved by the IACUC prior to beginning the experiment. All are evaluated by scientific peers and qualified lay people before they are allowed to be conducted. They are reviewed annually (not once every 5 years) and the facilities inspected every six months by the IACUC in addition to the annual APHIS inspections. All of this is required under the Animal Welfare Act. Ocean Leadership recommends that the MMPA be changed an enforced in a way that it was originally intended. Originally when a marine mammal was taken, it was a one time permit--a permit was granted before an animal was taken from the wild. An animal that is born in a research laboratory is not taken from a wild population and therefore no permit should be required. Once the animal is in the laboratory, jurisdiction for enforcement should be naturally passed over to the Animal Welfare Act and dictated by the IACUCs. To keep NMFS involved in deciding questions like "what research is intrusive" makes no sense when laboratory research is not NMFS's area of expertise. To place binding rules into law restricts necessary research. It makes much more sense to have research peers within an IACUC evaluate the research and examine it in research categories dictated under the AWA. This simple change would free up necessary resources of NMFS and takes one step toward allowing necessary research to continue. More and more laboratories for conducting necessary marine mammal research are closing. Animals are nearly impossible to obtain, when animals are available the price is staggering, and the bureaucracy is enormous. This one small step would signal that the government is committed to solving some of the issues regarding developing a basic scientific understanding of marine mammals. Science needs assistance to continue, it does not need increasingly difficult duplicative restrictions.

50 C.F.R. § 216.33(c) Initial Review

NMFS is considering publishing a permit application for public review and comment prior to the completion of an environmental assessment (EA) or an environmental impact statement (EIS). The ANPR suggests that NMFS will use the public comments when determining whether the activity requires an EA or EIS in accordance with NEPA. For all intents and purposes NMFS is *establishing a two-part comment process—one comment period for the permit and another for* the NEPA document--that will significantly lengthen the permit process for all MMPA scientific research permits. Ocean Leadership believes that NMFS is considering adopting this process so that it might gauge the level of controversy, the likelihood of litigation, and whether the public

deems that an EA or EIS is required. NMFS own regulations require that the agency determine whether a proposed permit is categorically excluded from the need to prepare further environmental documentation, or to prepare an EA with a finding of no significant impact (FONSI) or an EIS—not abrogate that decision until it tests the political or public winds of controversy—and for that reason and the increased delay in permit processing Ocean Leadership opposes this change.

NMFS needs to provide funding agencies and researchers with clear guidelines to use in determining whether or not a particular research activity requires NEPA documentation or a permit under the MMPA. NEPA requires that funding (action) agencies have in place a process to determine whether the actions that they propose might have significant environmental impacts. For actions that appear to have the potential for significant impact, the first step in this process normally involves the preparation of an EA to objectively analyze the possible environmental effects of the proposed action. Key issues are determining when it is necessary to prepare an EA and, in turn, when a permit is required. Ocean Leadership recommends that NMFS provide clear guidelines that can be used to determine what research actions require preparation of an EA and what actions require permitting. Ocean Leadership also recommends that the funding (action) agencies review their internal NEPA processes to ensure that they are adequate to fulfill NEPA requirements in a timely and cost-effective way and that they are designed to minimize the burden that needs to be borne by the individual researcher. NMFS should be careful to apply the same criteria for NEPA processes for research as for other activities.

Ocean Leadership recommends that NMFS Permits Division, FWS and other federal agencies should work toward developing programmatic EAs or EISs related to marine mammal research. The development of an EIS or EA can be costly (between $400,000 to over a $1 million per EIS) and consumes considerable staff resources. NMFS has identified several situations that would favor programmatic EIS's (e.g. right whale research and acoustic criteria), that are in development. Having such programmatic NEPA documents in place can reduce the delay associated with the development of documents for each permit, can provide greater NEPA compliance, which has been a trigger for litigation, and can enhance cumulative impact analysis for those research or incidental take activities. The risk is that, should the programmatic EIS be delayed in process or be contested in court, all research activities under that programmatic EIS could be delayed, challenged or enjoined. Moreover, even though a programmatic EIS may lack all the specifics regarding every activity covering several years of research, supplemental NEPA documents could be developed containing appropriate project specific species analysis. For instance, NSF cannot predict more than 1 – 2 years out which proposals for research requiring a seismic survey research ship will be funded. The resulting projects are often independent, unrelated to each other, and undertaken throughout the oceans of the world. The programmatic EIS can, however, effectively address the specifics of the ship, the equipment and instrumentation utilized for seismic surveys, intensity and spatial characteristics of sound production, and general aspects of mitigation strategies while a supplement NEPA document can address each project-specific species analysis. If NMFS, FWS, and other federal agencies are to produce programmatic EIS documents over the long-term with some regularity, Congress must provide additional funds so these agencies can produce the documents. Finally, other agencies should be encouraged to work with NMFS to assess the information requirements needed to develop these documents and the most effective means to produce them.

50 C.F.R. § 216.33(d) Notice of receipt and application review

Again, Ocean Leadership opposes the approach where NMFS determines the appropriate level of NEPA documentation for the scientific research activity, after consideration of the public

comments received, information presented in the application, and the best available information. NMFS proposes publishing its final NEPA determination on an application in the **Federal Register** prior to or concurrent with notice of permit issuance or denial pursuant to § 216.33(e). This approach will only result in further delays as NEPA requires a comment period for both EA and EIS.

50 C.F.R. § 216.33(e)(4)

With respect to species protected under the ESA, NMFS is seeking input on how to determine if an applicant has applied for a permit "in good faith" and if the permit will operate to the disadvantage of such threatened and endangered species. Since researchers are required to submit their CVs with a permit application, NMFS has ample evidence of the individual's experience, expertise, previous research, and publication record. For repeat applications from a Principle Investigator (PI), NMFS can also compare the goals of the permit, annual reports, and the publication record of the PI. If NMFS has specific evidence of misuse of permits, it should make this available. If not, it should work on mechanisms to make it easier for young investigators with less of a track record to obtain their first permit.

Regarding whether the research will "disadvantage" a threatened or endangered species, the permit applicant is required to "Describe the Anticipated Effects of the Proposed Activity." This documentation should be sufficient for NMFS to make this determination. From NMFS' query in the ANPR, it is difficult define what the problem is or to ascertain how this language or interpretation of this language has caused delays in the issuance of any scientific research permits. It appears that the application requirements already contain ample documentation that can be used to make these determinations. If NMFS is planning to propose additional requirements, it must do so only after making a compelling case that the existing requirements are insufficient to allow them to meet the regulatory mandate or another problem exists for which it is trying to find a solution.

50 C.F.R. § 216.34 Issuance Criteria

NMFS is considering requiring proof of Institutional Animal Care and Use Committee approval to demonstrate the research activity is humane. The National Research Council (1994) recommended that NMFS "Consider transferring some aspects of the regulatory process to less centralized authorities patterned after the IACUCs that regulate animal care and safety in academic and industrial settings." In addition, the American Society of Mammalogists has ethical guidelines addressing this issue and the Society of Marine Mammalogists is finalizing similar guidelines. Therefore there is ample support and precedence for using the guidelines from professional societies or other review boards. Ocean Leadership supports the use of the approval of an IACUC as proof that the proposed activity is humane.

Regarding consolidating paragraphs under this section, Ocean Leadership recommends that paragraphs 5 and 6 be consolidated and that paragraph 3 be deleted since it is already stated in the previous section.

50 C.F.R. § 216.35 Permit Restrictions

The ANPR seeks comments regarding the establishment of additional regulations to specify minimum qualification standards for scientists applying for research permits. Ocean Leadership opposes such regulations. As stated earlier, researchers are required to submit their CVs with a permit application; this CV should provide NMFS with ample evidence of the individual's

experience, expertise, previous research, and publication record. Developing such standards, requiring further documentation to meet such standards and subjectively judging researchers against these standards only serves to increase the regulatory burden on a group that is disproportionately targeted—it does little to achieve and real conservation benefit for protected species.

NMFS is proposing to allow only minor amendments and to remove the part in § 216.35(b) that provides for a 1 year extension of the original permit. Ocean Leadership strongly opposes both actions. With regard to amendments (§§ 216.35 and 216.39), amendments to research permits, including major amendments, are often necessary to secure the permit in a timely manner to allow the research to continue. They are a form of streamlining that already exists in the permitting process, and they provide NMFS with the flexibility to modify a permit that proposes the same research process but perhaps now includes different species, a new location, or increased numbers of animals. Instead NMFS proposes requiring these changes be made not by amendment, but by a separate application for a permit, significantly increasing the number of permit applications on an already overburdened permit staff. NMFS should be seeking ways to improve this process to create even greater flexibility rather than doing away with major amendments. Second, if NMFS eliminates the distinction between major and minor permit amendments, it likely means all amendments will be treated as major amendments, effectively requiring that the applicant go through the permit process as if it is a new permit application.

Finally, Ocean Leadership strongly opposes deleting the regulation that allows for a 1 year extension of the original permit. The agency has repeatedly used this provision to provide researchers with an extension of their existing permit while they wait for the agency to finalize and issue their new permit. If this provision is removed, it will result in the loss of valuable research as once the permit expires researchers can no longer conduct their research until a new permit is received. Unless NMFS can guarantee that it will meet its statutory obligations and issue permits in a timely manner following a mandated timeline, removing this provision will only serve to put researchers in a position where they out of compliance with the law at the same time losing critical information on marine mammals that the agency needs to meet its statutory mandates. Ocean Leadership recommends an automatic extension of permits if a researcher has applied within the appropriate deadline and NMFS cannot issue the next permit before the previous one expires. Because processing permits can take more than one year, this automatic extension process should be flexible, and cross multiple years if required.

50 C.F.R. § 216.37 Marine Mammal Parts

Ocean Leadership commends NMFS for attempting to simplify and streamline the rules regarding the transfer of marine mammal parts and products for use by researchers. Ocean Leadership believes that NMFS should clarify and consolidate this section with other sections (§§ 216.22 and 216.26) involving the transfer of parts legally taken, such that the same provisions would apply to the subsequent transfer of any marine mammal part that was already legally taken under the MMPA and/or ESA. Additionally, Ocean Leadership does not support different requirements for the transfer of parts legally taken from an ESA-listed versus a non ESA-listed marine mammal. The transfer, import, and export of part should be covered under a general authorization that facilitates these activities—especially in the case of parts salvaged from subsistence takes and bycaught or stranded animals. Once a marine mammal is taken either by permit or through some other activity (dead stranded or bycaught) the transfer, import, or export of the parts have no bearing on the conservation status of that species or stock. In fact, scientific research on or analysis of that tissue or part will only benefit the species by providing important information about its health, natural history, physiology or biology.

Ocean Leadership recommends that the requirements to receive an authorization and documentation requirements for a transfer, import, or export should be greatly reduced and simplified, and instead some type of general authorization be put in place. The reporting requirements seem overly burdensome for marine mammal parts, the transfer of which have no conservation consequence. If a person has a general authorization, NMFS should remove all provisions in the regulations that require notification to the Regional Director of any transfer or loan or simplify the reporting requirement so that compliance with the requirement is simple, quick, and easy.

NMFS is considering developing regulatory language to streamline and govern the issuance of research permits involving collection, receipt, import, export, and archiving marine mammal parts for future opportunistic research. Banking tissues for retrospective analysis or analysis at a later date is vital to furthering our understanding of marine mammal health and is specifically provided for under Title IV of the MMPA and as such should satisfy the bona fide scientific purpose requirement. Ocean Leadership strongly supports establishing or merely including under a general authorization, provisions for facilitating the initial collection of marine mammal parts by institutions for eventual use for research purposes. Again, if NMFS develops standardized documentation and reporting requirements for permits involving marine mammal parts to demonstrate that the parts are taken legally and in a humane manner and that all requirements for applicable domestic and foreign laws have been met regarding importation and exportation, the documentation should be clear, simple, and extremely easy to use. NMFS should establish a website for real time notification under a general authorization.

Finally NMFS is considering developing regulations governing the development, use, distribution, or transfer and prohibited sale of cell lines derived from marine mammal tissue and/or gametes. Ocean Leadership strongly opposes these regulations and asserts that NMFS does not have the statutory authority to regulate cell lines or DNA sequences that are developed from marine mammal parts. The development, use, distribution, transfer, or sale of a cell line of DNA sequences derived from a marine mammal part do not constitute a regulated "take." Such action is a poor use of resources and is not consistent with the purposes and policies of the MMPA and only serves to limit scientific research.

50 C.F.R. § 216.40 Penalties and Permit Sanctions

In the ANPR, the NMFS is seeking comment on whether a research permit should be suspended, revoked, modified, or denied "for reasons not related to enforcement actions." The ANPR is silent on the reasoning for this recommendation and any further specifications, making it difficult for Ocean Leadership to provide comments. Ocean Leadership is concerned about the legal basis for revoking, etc. a permit if such action is not related to enforcement issue. Ocean Leadership therefore requests NMFS to clarify the new reasons it envisions for revoking a permit.

50 C.F.R. § 216.41 Permits for Scientific Research and Enhancement

NMFS is considering changing the requirements for public display of marine mammals held under a scientific research permit in § 216.41(c)(1)(vi)(A) such that marine mammals may be on display if necessary to address the research objectives or if authorized by the Office Director, in addition to the existing requirements in § 216.41(c)(1)(vi)(B) and (C).

NMFS is also considering adding a new section, § 216.41(c)(3), to authorize via an enhancement permit the long-term captive maintenance and incidental public display of ESA-

listed species originally obtained under a research or enhancement permit when such activities have been completed or are not able to be carried out and the animals cannot be returned to the wild. Such permits would require that an appropriate educational program is established and approved by Office Director and that the animals are made available for research or enhancement activities at the request of the Office Director. Ocean Leadership provided extensive comments regarding marine mammals housed in captive facilities above. In short, this is an issue for the AWA, not the MMPA. NMFS should work out the details as well as a memorandum of understanding with APHIS to allow APHIS to assume jurisdiction of this situation. In addition, if an animal is to be returned to the wild, NMFS should adhere to its release criteria that have been developed under Title IV of the MMPA.

50 C.F.R § 216.42 Photography

NMFS is considering proposing regulations similar to those for the General Authorization (§ 216.45) and it is also considering limiting the number of personnel that may be involved in order to eliminate potential problems with permit holders using such authorization for ecotourism, since the MMPA does not provide exemptions for harassment of marine mammals via ecotourism permits. NMFS should consider carefully these changes. Blocking the ability of researchers to use whale watch or other eco-tourism vessels for photo id will hinder important research with no benefit to animals. Indeed this regulation could drive researchers to pay for another vessel for ID, increasing cost of research to humans and animals.

50 C.F.R. § 216.45 General Authorization

Ocean Leadership supports NMFS proposed modification to the General Authorization ("GA") that it be based on the status of the target stock, rather than on the level of harassment. NMFS is proposing to make a GA available for Level A and Level B research on non-strategic stocks of marine mammals. Ocean Leadership strongly supports this change as it will expedite the permit process considerably for researchers.
In addition, NMFS proposes making a GA available for stocks defined as strategic under the MMPA, but only for Level B research activities. Ocean Leadership strongly supports this change and understands that a number of paragraphs throughout this section would have to change as a result of this recommendation and that this change would require a similar change in section 104(c)(3)(C) of the MMPA.

NMFS proposes to modify this section to clarify that the description of methods in the letter of intent must specify the number of marine mammals, by species or stock that would be taken, including a justification for such sample sizes. Ocean Leadership does not oppose this modification but cautions NMFS against requiring so much information that the application burden for a GA becomes equivalent to a research permit.

NMFS is proposing to revise the terms and conditions of the GA regulations to clarify that any activity conducted incidental to the research, such as commercial or educational filming or photography, would require prior written approval from NMFS, and such activities would be subject to the same conditions as those specified at § 16.41(c)(1)(vii) for scientific research and enhancement permits, i.e., the conduct of such incidental activities must not involve any taking of marine mammals beyond what is necessary to conduct the research. Again, this seems like a heavy-handed approach, requiring written approval for commercial and educational photography is unnecessary and could merely be authorized as part of the GA. Education and research are linked, creating greater awareness and understanding by the public of these species will only serve to promote conservation and support increased funding for research.

Other Amendments
Lastly, NMFS is considering adding new regulations that would place the permit application and amendment process on a cycle. One option would be to accept permit applications and amendment requests quarterly (i.e., during any one of four three-month cycles per year). Applicants would have firmly established deadlines (made known through FR notification, mailings, and web site) to assist them in planning the submission of their application relative to the proposed start of their research. Another option would be to accept applications and amendments only twice a year, during one of two six-month cycles, establish specific time periods during which the agency will accept permit applications.

Ocean Leadership believes that Congress, Funding Agencies, NMFS and Researchers should work to achieve better linkages between timing of the permit process (e.g. from time of submission to issuance), securing funding for the research, and scheduling of the ships and other resources required for the research to avoid situations where the research is funded and ship time is scheduled but the permit has not been secured. It may be difficult to begin the permitting process, prior to securing funding for the research and likewise difficult to secure funding without a permit. This situation is particularly true for controversial research. The primary problem, however, is not that NMFS has not imposed deadlines on researchers, rather it is that NMFS is not itself required to process permit applications following a mandated timeline. Ocean Leadership is not convinced that changing the permitting system so that permits are submitted according to a particular deadline, may help. Rather, permits must be issued within a certain deadline after submission. That way researchers and their funders could plan their submissions to ensure that there is enough time for the permit to be processed within the mandated deadline. Today there is no such assurance of timely processing.

If NMFS can demonstrate that placing the permit process on a cycle would: (1) meet its NEPA requirements; (2) reduce that processing time because ESA consultations could be batched; and (3) similar permits could be processed together, and (4) guarantee processing of permits within 90-120 days, then Ocean Leadership would support the quarterly submission cycle and would like to explore this idea further with NMFS.

CONCLUSION
The current restrictions on scientific research animals are costly and burdensome and the permitting process needs revamping and streamlining. While we applaud NMFS for taking this step we are concerned that some of the proposal will only result in additional delays and bureaucracy—falling far short of the goal to streamline and improve the process. We appreciate the opportunity to comment on the ANPR. Ocean Leadership recommends that prior to issuing any proposed rulemaking, the agency organize a meeting with respected marine mammal researchers to discuss the proposals in this ANPR. We believe that by doing so, NMFS will benefit from a collective discussion with those who are familiar with the process and supportive of your efforts to streamline it.

Sincerely,

Nina M. Young
Deputy Director for Policy and Government Relations

Subject: Permit Regulations ANPR
From: "irubinstein@juno.com" <irubinstein@juno.com>
Date: Tue, 11 Dec 2007 11:09:35 +0000 (GMT)
To: NMFS.PR1Comments@noaa.gov

Below are my comments for changes to 50 CRF Part 216, I would prefer my name and email address not be published in the public comments section, publishing my comments if fine.

216.35 Permit Restrictions

a). Major vs. minor amendments: I do believe that the major vs. minor amendment process as it stands now should be reviewed, but I do not think you should do away with the major vs. minor amendment. Sometimes a change in sample collection or type of sample is considered a major amendment, I believe a review of what is considered major and minor is warranted. I do not think it is right to make the whole process cease and have to be started over again if you need to make a major amendment to your existing permit. You should still be able to continue your project and just have the piece that needs to change be reviewed. The time period for a new permit is a lengthy process and could cause a significant impact in funding and data collection.

b). One year extension: I do not feel that you should eliminate the one year extension. This allows for some extra data collection without additional take and does not cause very much extra paperwork or time on the part of NMFS, it can also be very helpful to a researcher who needs to get a little bit more data to make their project more sound.

216.39

There seems to be some confusion with what is listed here regarding location, species and numbers where no take is involved....in section 216.35 it says that in cases where location, species and numbers where not take is involved it would be considered a minor amendments. In section 216.39 some of the points are confusing...it states that a minor amendment would not be warranted if 1 i)an increase in the number of species is effected, which is not what it said in 216.35 also 1 iii) a change in location at take, again not what it says in 216.35 The wording of both sections is confusing...

216.41 Permit Deadlines - I think it is a good idea to have established time lines for submitting new permits. Quarterly submissions would be the best way to handle this giving all researchers a realistic time line for submission and not delaying projects too long. Accepting applications only twice a year is very restrictive and would cause issues with funding and animal availability. It will also be helpful to have NMFS on a time line for reviewing and getting back to people. As far a amendments go, I do not feel that the researcher who already has a permit in hand should have to wait the same amount of time as someone does for the new permit cycle. Amendments should be reviewed at any time, with new submission being accepted quarterly.

Thank you for your time, please do not hesitate to contact me with any question.

Belinda Rubinstein

Save the Manatee® Club

December 12, 2007

Chief, Permits, Conservation and Education Division
Attn: Permit Regulations ANPR
Office of Protected Resources, NMFS
1315 East-West Highway, Room 13705
Silver Spring, MD 20910

Re: Permit Regulations ANPR

Dear Chief:

Save the Manatee Club has reviewed the Marine Mammal Protection Act Advanced Notice of Proposed Rulemaking. We appreciate the effort being undertaken to reorganize and/or consolidate the permitting regulation §§ 216 and would like to offer our comments on the proposed changes and clarifications.

The question is posed: "Should we clarify that any species or population stock listed as endangered or threatened under the ESA is automatically listed as depleted under the MMPA?" The intent of this clarification is unclear. For example, as currently written, the Florida Manatee is not listed in § 216.15. As an endangered species, would making this clarification specifically add the Florida Manatee to the list of depleted species in the MMPA?

We do not support the proposed changes in § 216.33 which suggests that NEPA compliance (including an EA or EIS) would be undertaken only after the public has commented on a permit application. NMFS should retain its current protocol of requiring that all compliance with NEPA be done before a permit application is released for public comment. Compliance with NEPA is foundational, and to proceed to permitting prior to determining compliance could be a waste of effort and resources if a project is found to be not in compliance. Further, completing the NEPA review prior to permitting enables the public to view the information NMFS considered and the impacts NMFS expects prior to commenting on the permitting application. Altering this protocol would result in less information available to the public, thus undermining and discouraging their input during the permit application review phase.

We support the proposed changes for § 216.34 which suggests that NMFS require written proof of Institutional Animal Care and Use Committee approval of the proposed activity.

We support the change in § 216.35 that any proposed change resulting in the need for an increased level of take or risk of adverse impact above those authorized in the original permit be no longer considered under an amendment, and would require a new permit application. Public comments should be solicited and considered for any major changes that would require a new permit application.

NMFS proposes to require new permits for any proposed "major amendments" to an existing permit and would grant amendments for "minor amendments" (§ 216.35 and § 216.39). As the public is not allowed to comment on minor amendments, this change is permissible so long as minor amendments only pertain to such things as adding personnel or other truly minor changes that do not amend the species, location, number or demographic of animals, seasons, procedures being performed, manner of taking, etc.

Some of the suggested changes being considered in § 216.41 are unclear. One change being considered is the requirements for public display of marine mammals held under a scientific research permit. It is unclear if this means that mammals caught for scientific research may also be put on display or if this means that marine mammals can be displayed ONLY if that is part of the approved and reviewed research.

We support limiting the number of personnel that may be involved in photography (§ 216.42) in order to eliminate potential problems with permit holders using such authorization for ecotourism, which oftentimes results in harassment of marine mammals.

SAVE THE MANATEE® CLUB, 500 N. MAITLAND AVENUE, MAITLAND, FL 32751
PHONE: (407) 539-0990 FAX: (407) 539-0871
WWW.SAVETHEMANATEE.ORG

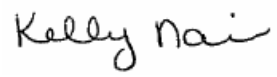
The proposal suggested under § 216.45 could greatly increase the scope of activities that can be permitted under a General Authorization (GA). This means that there is no possibility of public comment prior to the permit being granted. This amendment would also allow research involving Level A harassment to be permitted under the GA, provided stocks are not ESA listed, depleted, or "strategic". GAs should not be allowed for Level A harassment of MMPA species, which, by definition, has the potential to injure a marine mammal or marine mammal stock in the wild.

For GAs issued, we support the suggested change in § 216.45 that any activity conducted incidental to the research authorized, such as commercial or education filming or photography, require prior written approval from NMFS. Such incidental activities must not involve any additional taking of marine mammals.

New sections regarding permit cycles would be a good addition. Permit cycles would improve the process and assure that applicants apply well in advance, thereby providing NMFS with advance notice and adequate time for review. This also allows a regular schedule of review for public comments.

Thank you for taking these comments into consideration.

Sincerely,



Kelly Novic
Staff Biologist

COMMENTS OF SEA WORLD, INC. *ET AL.*,

IN RESPONSE TO THE ADVANCED NOTICE OF PROPOSED RULE AND REQUEST FOR COMMENTS ISSUED BY THE NATIONAL MARINE FISHERIES SERVICE TO CHANGE THE REGULATIONS APPLICABLE TO ISSUING PERMITS FOR SCIENTIFIC RESEARCH AND ENHANCEMENT ACTIVITIES PURSUANT TO THE MARINE MAMMAL PROTECTION ACT

Sea World, Inc., Sea World of Texas, Inc., and Sea World of Florida, Inc. and Busch Entertainment Corporation for themselves and on behalf of all of their respective theme parks maintaining marine mammals ("SeaWorld"),[1] hereby comment on the Advanced Notice of Proposed Rulemaking ("Notice") published by the National Marine Fisheries Service of the United States Department of Commerce ("NMFS"), 72 Fed. Reg. 52339 (September 13, 2007), regarding possible changes to the regulations governing, among other things, the issuance of scientific research and enhancement permits under the Marine Mammal Protection Act.

INTRODUCTION

Commenting on the Notice in a specific and informed manner is difficult for Sea World due to the breadth of, and yet imprecision in, what NMFS actually proposes. The Notice discusses specific changes the agency is considering and also seeks input on any portion of the permitting regulations that could or should be changed. Many of the regulation changes NMFS proposes, however, are bereft of specifics and do not describe with particularity how any changes to the current procedures would be implemented. As a result, SeaWorld requests that NMFS issue a more specific and detailed advanced notice of proposed rulemaking to ensure that interested parties are able to meaningfully participate in the process as the law requires.

---

[1] These entities operate the following parks maintaining marine mammals: Sea World of California, Sea World of Florida, Sea World of Texas, Discovery Cove, and Busch Gardens – Tampa Bay. For convenience purposes, herein we refer to Sea World, Inc., Sea World of Texas, Inc., Sea World of Florida, and Busch Entertainment Corporation collectively as "Sea World."

Sea World likewise is concerned about the potential for conflicting or unclear regulations. In 2001, NMFS published proposed rules to regulate the issuance of public display permits for marine mammals. 66 Fed. Reg. 35209 (July 3, 2001). While NMFS has issued no final notice with respect to those proposed regulations, neither has the agency withdrawn them and the current advanced notice of proposed rulemaking raises numerous potential discrepancies between the two proceedings. For example, back in 2001, NMFS made the determination to address public display permit separately from other permits and, accordingly, drafted regulations addressing only public display permits. *Id.* Now, however, NMFS is proposing to rewrite numerous general permitting regulations that cover both public display and scientific research/ enhancement permits. Because public display permits are fundamentally different from, and involve different issues and considerations than, scientific research and enhancement permits, the agency should separate them and draft proposed regulations for each.[2]

Furthermore, many of the regulation changes discussed in the Notice encompass activities for which NMFS simply lacks the authority to regulate. For example, numerous of the proposed changes attempt to regulate aspects of animal care statutorily within the jurisdiction of the Animal and Plant Health Inspection Service ("APHIS"). In 1994, Congress enacted, and the President signed into law, amendments to the Marine Mammal Protection Act ("MMPA"), Pub. L. 103-238, 16 U.S.C. § 1361 *et seq.* (the "1994 Amendments"). The 1994 Amendments unequivocally established that NMFS has no role in the care, maintenance and general oversight of marine mammals once they leave the wild and enter into the United States. Instead, issues regarding the humane handling, care, treatment, and transportation of marine mammals are left

[2] While SeaWorld had objections to the specific regulations proposed, it supported and still supports separate regulations for public display permits and scientific research and enhancement permits, as NMFS appropriately determined in 2001.

under the exclusive domain of APHIS pursuant to its jurisdiction and responsibilities under the Animal Welfare Act ("AWA"), 7 U.S.C. § 2131, *et seq.* This was made clear in the 1994 amendments and legislative history in order to address the exact same problem that is arising here: attempts by NMFS to over-reach and improperly extend its jurisdiction and authority. *See generally* 141 CONG. REC. H 1852 (1994) (statements by Representative Thomas J. Manton); 141 CONG. REC. H 1604 (1994) (statements by Representative Randy Cunningham); 141 CONG. REC. S 3302 (1994) (statements by Senator Exon); 141 CONG. REC. H 1604 (statements by Representative Gilman). Consequently, any activities by public display facilities in dealing with breeding, as an example, are beyond the scope of regulation by NMFS.

NMFS not only is impermissibly extending its authority with respect to those matters under the jurisdiction of APHIS, but also is reaching beyond the MMPA in order to regulate activities that involve neither an import nor a take. NMFS appears to be operating under the misconception that it regulates all aspects of marine mammals in the United States and that once an animal comes under its jurisdiction for a take or import, it remains under its jurisdiction indefinitely and without regard to the activity involved. However, there simply is no statutory support for this overarching approach. Despite the lack of authority, this misconception permeates a number of the proposals discussed in the Notice, such as discussions relating to the export of marine mammals as to which the MMPA does not require a permit and allows only limited involvement of NMFS

Accordingly, SeaWorld requests that NMFS revisit the Notice and re-issue a proposal that is more specific in the changes proposed and that eliminates proposed and existing regulations that are outside the scope of NMFS' jurisdiction.

DISCUSSION OF SPECIFIC PROPOSALS

Regulation of Exports

At various points in the Notice, NMFS discusses the regulation of exports, as though exports require permits under the MMPA. For example, the Notice states that "NMFS seeks recommendations for developing regulatory language to streamline and govern the issuance of research permits involving collection, receipt, import, export, and archiving marine mammal parts for future opportunistic research." 72 Fed. Reg. at 52341. NMFS is well aware and must remain mindful, however, that the MMPA in fact does *not* require export permits. Once a permit is issued for a "take" or import and the marine mammal is lawfully possessed, no further agency input by means of authorization (consistent with the MMPA) should be necessary except to the extent that the marine mammal is listed on the Appendixes to the Convention on International Trade in Endangered Species ("CITES") in which case CITES permits and authorizations may be necessary, or the marine mammal is an endangered species in which case an Endangered Species Act ("ESA") permit is required.

Accordingly, SeaWorld strongly objects to any language in the proposal and in the current regulations regarding the export of marine mammals when neither an ESA nor CITES permit is required.

Section 216.33

NMFS seeks comments on how to determine whether an applicant has applied for a permit "in good faith" . 72 Fed. Reg. 52340. SeaWorld notes that there are existing federal laws, including criminal laws, that govern the submission of information to the government. There simply is no need for NMFS to require any special or particularized showing by an applicant that an application was applied for in "good faith."

Section 216.34

NMFS must clarify that its suggestion that Section 216.34 should require proof of an Institutional Animal Care and Use Committee ("IACUC") approval in determining what is a "humane" activity is limited only to permit applications submitted by research facilities. That is because the AWA requirement for the establishment of IACUC's is limited to research, but not public display, facilities.

Section 216.35

SeaWorld adamantly opposes the regulation by NMFS of the qualifications of permit applicants. Permit applications should stand or fall on the totality of their merits. NMFS certainly should take into account the backgrounds of applicants but should not be in the business of judging the competence of scientists. Nor should NMFS be establishing minimum criteria below which an applicant's request for a permit would automatically be denied.

Section 216.37

The Notice states that "NMFS is also considering adding to this section [216.37] requirements and procedures governing the development, use, distribution or transfer, and prohibited sale of cell lines derived from marine mammal tissues. We are also considering similar regulations pertaining to gametes used by the public display industry and research community in assisted reproductive techniques of captive marine mammals." 72 Fed. Reg. at 52341 (emphasis added).

NMFS lacks authority to regulate public display facilities in connection with the cell lines and gametes, or their use, transfer and exchange, relating to reproductive techniques. Reproductive techniques fall under the rubric of maintenance and care of marine mammals,

which, in turn, is regulated by APHIS. As is clear under the 1994 amendments to the MMPA and as NMFS publicly conceded in 2001, *see* 66 Fed. Reg at 35211, NMFS does not have the authority to specify the methods of care of marine mammals and marine mammal parts held for public display purposes.[3] Accordingly, SeaWorld objects to any attempt to regulate the transfer, use, development, distribution or sale of gametes and cell lines not being imported or taken from the wild.

Section 216.39

SeaWorld is opposed to the changes proposed in connection with "major" and "minor" amendments. NMFS offers no persuasive rationale for any change and none are warranted, especially since what NMFS proposes – requiring re-submission and reevaluation of applications in many instances where amendments are warranted – will only burden the process and delay the legitimate and efficient issuance of permits.

Section 216.45

There are two primary issues of concern that SeaWorld wishes to address with respect to the proposed changes to Section 216.45. The first relates to the proposal to "clarify" that any activity conducted incidental to the research, such as commercial or educational filming or photography, would require prior written approval from NMFS and that such activities would be subject to the same conditions as those in Sec. 216.41(c)(1)(vii) for scientific research and enhancement permits. There is no apparent authority for requiring that photography and filming be permitted activities absent an instance where such photography and filming in itself would rise to the level of a "take" of a regulated marine mammal. Further, there is no legitimate

---

[3] We also note that on its website NMFS states that "Marine mammal parts . . . do not include urine or feces [but] do include parts derived from tissues, such as cell lines and DNA." *See* http://www.nmfs.noaa.gov/pr/permits/mmpa_permits.htm. We fail to understand how NMFS makes this distinction.

purpose under the MMPA for such requirements. As a result, SeaWorld objects to adding this language and adding another layer of unnecessary and unauthorized regulation to the permitting process.

The second issue that SeaWorld wishes to address with respect to Section 216.45 is the proposal to add new regulatory sections that place the permit application and amendment process on a cycle. Such a cycle would require applicants to have firm quarterly or bi-annually established deadlines by which they would have to submit their applications for a scientific research permit and prior to which any submitted applications would not be reviewed. While SeaWorld fully supports any attempts to streamline or expedite the application process, SeaWorld does not believe that this proposal, in practice, will do so. In fact, SeaWorld believes that it will likely result in the opposite effect and serve to delay the process and prevent beneficial research from ever occurring.

The need and opportunities to conduct scientific research most often can not be planned or anticipated. Imposing submission dates will undoubtedly and substantially delay the review and issuance of scientific research permits, leading to lost opportunities to conduct the research at all, as it will require researchers to wait to submit applications.

Accordingly, SeaWorld objects to any regulations restricting the times that research permit applications can be submitted to and reviewed by NMFS.

ADDITIONAL GENERAL COMMENTS

SeaWorld takes the opportunity afforded by NMFS to comment more generally on the permitting regulations as follows.

1. As noted in the Introduction, NMFS respectfully would be best advised to restructure the regulations by separating the application processes for public display and

scientific research/enhancement permits. The regulations as they currently exist blur the distinctions between these very different types of permits, which leads to unnecessary confusion for applicants and inefficiencies in the respective processes. These problems can and should be rectified by NMFS issuing independent sets of regulations.

2. Section 216.33(b) dealing with "Applications to export living marine mammals" should be eliminated consistent with the fact that the MMPA does not require permits or "applications" for exports. Even more specifically, the alleged "comity" requirement found in sub-section (b)(1)(iii) of Section 216.33 is ultra vires to the MMPA and must especially be targeted for deletion. That is because, among other reasons, NMFS can not dictate policy to foreign governments and has no extra-territorial jurisdiction under the MMPA to enforce any "comity" requirement. *See generally United States v. Mitchell*, 553 F.2d 996 (5th Cir. 1977). As NMFS itself recognized in the 2001 proposed rulemaking proceeding: "NMFS has no jurisdiction over the animals once they are exported . . .." 66 Fed. Reg. at 35213.[4]

3. During an import permit application proceeding last year, SeaWorld was subjected to several comments by activist groups. These comments warrant clarification by NMFS by amending the regulations, as follows:

(a) The activist groups sought to require SeaWorld and/or the agency to research and apply scientific data and information regarding "stock" of species in foreign waters/territories when reviewing a permit application for the import of *captive bred* animals. NMFS should amend its regulations to clarify that: (1) no such information needs to be gathered or analyzed in general because the agency has no jurisdiction over species in foreign

[4] SeaWorld addressed the "comity' issue comprehensively in its comments to NMFS on the 2001 proposed rulemaking and incorporates them herein by reference.

waters/territories and is ill-equipped to make findings about such stock or species, and (2) especially when the import request is for *captive bred* marine mammals, information on wild or foreign stock certainly is irrelevant to a determination whether the import should be allowed.

(b) In light of erroneous comments by activists, NMFS should incorporate by an amendment to the regulations the holding in *Animal Protection Institute of America v. Mosbacher*, 799 F. Supp. 173 (D.D.C. 1992) to the effect that the import of captive bred marine mammals or marine mammals otherwise already in captivity, and their removal from an inventory in a foreign facility, categorically will yield a finding by NMFS that the import/removal will have no adverse effect on the stock or species in the wild, and will not result in takings beyond those authorized by the permit. *See generally* Sections 216.34(a)(4) (requiring an agency finding that the proposed activity will have no significant adverse effect on the species or stock) and 216.34(a)(7) (requiring an agency finding that the proposed import or export will not result in additional unauthorized takings).

(c) NMFS also should clarify – contrary to additional arguments raised by activists – that in reviewing an import application the agency need not make any findings regarding "indirect" effects on marine mammals in the wild. A proposed regulation published in the Federal Register by NMFS in 1993 that would have had NMFS consider "indirect" effects[5] was effectively rejected when the regulations were finalized several years later and no such requirement was included.

(d) NMFS should also promulgate a regulation that clearly establishes that a take that was "humane" pursuant to the laws of the foreign country which sanctioned the take is

---

[5] *See* 58 Fed. Reg. at 53343. (emphasis added).

sufficient proof/evidence that the take was consistent with the humane take requirements for purposes of import under the MMPA. Acceptable proof to that effect should be CITES or other permits issued by the foreign government.

(e) Finally, NMFS should firmly establish by an appropriate amendment in Section 216.3 (i.e., the definitions section) that captive born marine mammals are not "marine mammal parts" as activists mistakenly have claimed.

Respectfully submitted by,

Sea World, Inc., Sea World of Texas, Inc., and Sea World of Florida, Inc. and Busch Entertainment Corporation for themselves and on behalf of all of their respective theme parks maintaining marine mammals

Dated: November 13, 2007

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 216
[Docket No. 070809454–7459–01]
RIN 0648–AV82
Marine Mammals; Advance Notice of Proposed Rulemaking
AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.
ACTION: Advance notice of proposed rulemaking (ANPR); request for comments.

Comments submitted by:
Jan Straley
Assistant Professor of Biology
University of Alaska Southeast
1332 Seward Ave.
Sitka, Alaska 99835 USA

Part 216, Regulations Governing the Taking and Importing of Marine Mammals

Subpart C - General Exceptions

Several regulatory changes are being considered by NMFS in this subpart and include, but are not limited to, the following:

Sec. 216.23 Native exceptions: Does NMFS need to clarify sections regarding transfer of marine mammal parts? Do we need to include provisions for authorizing transfers of marine mammal parts for research purposes? If so, be explicit on how this should occur and whether this should be combined with transfers of other marine mammal parts legally taken, or kept under this section.

Comment: Any person with a MMP that authorizes the possession of marine mammal parts for bona fide research should be allowed to receive such parts from any Indian, Aleut, or Eskimo who resides on the coast of the North Pacific Ocean or the Arctic Ocean that is taken during subsistence hunting. The Indian, Aleut, or Eskimo should be allowed to receive reasonable

compensation for any additional work, transportation or shipping costs associated with conveying the parts to the permittee as necessary for the intended scientific research.

Sec. 216.25 Exempted marine mammals and marine mammal products: Should this section be consolidated with other sections (e.g., incorporate this Sec. 216.25 into Sec. Sec. 216.14 and 216.12; remove Sec. 216.25)? Do we then reserve this section (or use another section) for a consolidated parts transfer section (for parts taken legally under Sec. Sec. 216.22, 216.26, and 216.37) if possible? Subpart C is a substantial component of part 216. Therefore, any comments or recommendations regarding whether the language in other sections in subpart C require further consideration or clarification would be appreciated.

Comment: This provision should be retained as written even if it is consolidated in another section.

Subpart D - Special Exceptions

Sec. 216.31 Definitions: Are there any definitions relevant to marine mammal permitting procedures that need to be added?

Sec. 216.32 Scope: Does the scope of this subpart need to be modified or clarified in any manner?

Sec. 216.33 Permit application submission, review, and decision procedures: Generally, NMFS is considering reorganizing and/or consolidating permitting regulation Sec. Sec. 216.33 (Permit application, submission, review, and decision procedures), 216.34 (Issuance criteria), 216.35 (Permit restrictions), 216.36 (Permit conditions), and 216.41 (Permits for scientific research and enhancement) where possible. We have included some specific recommendations; however any recommendations where regulations need consolidation or simplification in the following sections, and how this might be achieved, would be considered.

Sec. 216.33 (c) Initial review: NMFS regulations currently require

the agency to determine that a proposed permit is categorically excluded from the need to prepare further environmental documentation, or to prepare an environmental assessment (EA) with a finding of no significant impact (FONSI) or a final environmental impact statement (EIS), during initial review of the application and prior to making it available for public comment and review pursuant to Sec. 216.33(d). This sequence precludes public input on the application that may influence NMFS' determination regarding whether the activity requires an EA or EIS. Therefore, NMFS is considering a revision to this section, and the corresponding language at 216.33(d) such that NEPA documentation is not required at the time an application is made available for public review and comment. NMFS Administrative Order 216-6 stipulates that issuance of scientific research, enhancement, photography, and public display permits pursuant to the MMPA and issuance of research permits pursuant to the ESA are, in general, categorically excluded from the need to prepare further environmental documentation because, as a class, they do not have significant environmental impacts. With this recommended change NMFS would continue to evaluate the potential environmental impacts of permits, but could conduct this assessment after the close of the comment period on the application, when comments from the public and other agencies could be considered in that assessment.

Sec. 216.33(d) Notice of receipt and application review: Consistent with the proposed changes to Sec. 216.33(c) regarding NEPA, NMFS proposes to revise the requirements for including a NEPA statement in the notice of receipt of an application. Where NMFS believes a permit would be categorically excluded from the need to prepare further environmental documentation, the notice will so state. If that determination is based on information in an existing EA/FONSI or Final EIS, that document will be referenced in the notice and made available simultaneously with the application. When no previous NEPA documentation relevant to the proposed activity is available, the notice will solicit public input on the appropriate level of NEPA documentation concurrent with review of the application. After the

close of the comment period on the application, NMFS would determine the appropriate level of NEPA documentation for the activity, in consideration of comments received, information presented in the application, and the best available information. NMFS' final NEPA determination on a specific application would be published in the Federal Register prior to or concurrent with notice of permit issuance or denial pursuant to Sec. 216.33(e).

Sec. 216.33(e) Issuance or denial procedures: Consistent with MMPA section 104(d), the current regulations state that ``within 30 days of the close of the public comment period the Office Director will issue or deny a special exception permit." NMFS is considering revising this section to reconcile the ESA section 7 and NEPA compliance timelines with statutory requirements for when permit decisions must be made relative to the close of the comment period. For example, when NMFS determines, subsequent to the public comment period on an application, that issuance of a proposed permit requires preparation of an EA or EIS, processing of the application cannot be completed within 30 days of the close of the comment period. Under the current regulations, NMFS would have to deny the permit because the appropriate NEPA documentation could not be completed in time to support a decision to issue. Rather than deny such permits, NMFS proposes to defer a decision on the application until the appropriate NEPA documentation is completed. Similarly, when formal consultation is required under section 7 of the ESA, which allows 135 days or more for consultation and completion of a Biological Opinion, processing of the application cannot be completed within 30 days of the close of the comment period. Rather than deny such permits, NMFS proposes to defer a decision on the application until the section 7 consultation is completed. In both cases NMFS would publish a notice in the FR within 30 days of the close of the comment period announcing that a decision on the specific application has been deferred pending completion of the appropriate NEPA and ESA section 7 analyses.

Comment: I support these changes. In addition, if a proposed permit for bona fide research requires preparation of an EA or EIS and cannot be completed within 90 days, then a provisional permit (for two years or the time needed to prepare an EA, EI or other evaluation) should be issued if the research methods have been deemed humane by the applicant and there is no concern that there is an impact to the species. In particular, this should occur if the applicant has had previous permits for the same or similar proposed activities.

Sec. 216.33(e)(4): For permits involving marine mammals listed as endangered or threatened under the ESA, NMFS is required to determine whether the permit is consistent with the requirements of section 10(d) of the ESA. NMFS would appreciate comments on how to determine whether an applicant has applied for a permit ``in good faith'' and whether the permit``will operate to the disadvantage of such endangered or threatened species."

Comment: This section should be eliminated because it is taken under consideration through other processes.

Sec. 216.34 Issuance criteria: NMFS would appreciate any recommendations on whether or how this section should be clarified or consolidated with other sections. In support of the applicant's demonstration that the proposed activity is humane, NMFS is considering requiring proof of Institutional Animal Care and Use Committee approval of the proposed activity where such approval would be required pursuant to the Animal Welfare Act. Any comments on this would be appreciated.

Comment: I support that the applicant demonstrate that the proposed activity is humane, this could be with an IACUC or other means. As proposed, this requirement would be a double standard. It would place a requirement on one group of applicants who happen to be affiliated with IACUC institutions and not a requirement for those without.

Sec. 216.35 Permit restrictions: One consideration by NMFS is to provide for only minor amendments to original permits (see Sec. 216.39), not major vs. minor as currently exists, which would require modifying language in this section. Any proposed change resulting in the need for an increased level of take or risk of adverse impact above those authorized in the original permit would no longer be considered

under an amendment, and would require a new permit application. Since the current regulatory process for reviewing and issuing major amendments requires a public comment and review period, the time it takes to issue a major amendment is consistent with the time it takes to process a new application. Amendments would be issued that only covered those activities that are currently consistent with a minor amendment. One exception to this would be that proposed changes in location, species, and numbers where no take is involved (e.g., import of parts or specimens legally acquired by a foreign institution) would be a minor amendment. Similarly, NMFS is considering removing the part in Sec. 216.35(b) that provides for a 1 year extension of the original permit. If this change were implemented neither the life of the original permit nor any subsequent amendment would exceed five years from the effective date of the permit. NMFS would appreciate any comments on this recommendation.

The regulations require individuals conducting permitted activities to possess qualifications commensurate with their duties and responsibilities, or be under the direct supervision of a person with such qualifications. NMFS is seeking input on whether it should promulgate regulations specifying minimum standards for such qualifications or specific criteria by which applicants' qualifications and those of other personnel listed in the application could be evaluated.

Comment: Do not consolidate major and minor amendments. Do not remove option to request a one year extension to the original permit. NMFS should not decide minimum standards or criteria to evaluate if an individual possesses qualifications to commensurate with their duties and responsibilities.

Sec. 216.37 Marine mammal parts: This section of the regulations is the subject of much confusion in interpretation and implementation. This section is similar to the transfer requirements in Sec. 216.22. NMFS is interested in clarifying and consolidating this section with other sections (Sec. Sec. 216.22 and 216.26) involving the transfer of parts legally taken, such that the same provisions would apply to the

subsequent transfer of any marine mammal part that was already legally taken under the MMPA and/or ESA. Should there be different requirements for the transfer of parts legally taken from an ESA-listed versus a non ESA-listed marine mammal? Does there need to be any clarification on how to apply or receive authorization for a transfer, and for determining who can be authorized to receive marine mammal parts and what documentation is required? Are the reporting requirements adequate and necessary, and should they be modified in any way? Does the language in Sec. 216.37(d) regarding export and re-import need to be clarified, and if so, how?

NMFS seeks recommendations for developing regulatory language to streamline and govern the issuance of research permits involving collection, receipt, import, export, and archiving marine mammal parts for future opportunistic research. Currently marine mammal parts taken or obtained under permit may be transferred to another person pursuant to this section of the regulations, but there is no mechanism for facilitating the initial collection of marine mammal parts by institutions for eventual use for research purposes where the bona fide criteria required in section 104(c)(3) of the MMPA cannot be met for each and every part obtained by the institution. We are considering establishing guidelines in this section for determining when such activities would satisfy the bona fide scientific purpose requirement when the purpose of the initial receipt of the part may be unknown. We are also considering establishing standardized documentation and reporting requirements for permits involving marine mammal parts to demonstrate that the parts are taken legally and in a humane manner and that all requirements for applicable domestic and foreign laws have been met regarding importation and exportation.

NMFS is also considering adding to this section requirements and procedures governing the development, use, distribution or transfer, and prohibited sale of cell lines derived from marine mammal tissues. We are also considering similar regulations pertaining to gametes used by the public display industry and research community in assisted reproductive techniques of captive marine mammals. Any recommendations

or comments on these topics would be appreciated.

Comment: NMFS needs to make this section easier and clearer. Don't make it more complicated and do not require more paperwork or another permit process. Do not require that the researchers at a laboratory where the analyses (e.g. involving tissue) are to be conducted be required to become co-investigators on the applicants permit. Continue to allow transfer of marine mammal parts (of any type) be transferred easily between institutions in the United States.

Sec. 216.39 Permit amendments: One consideration already mentioned (in Sec. 216.35) is to provide for only one amendment type, not major vs. minor. This would require consolidating this section considerably. Under this change the language in this section would be consistent with the following:

(a) General. Special exception permits may be amended by the Office Director. Amendments may be made to permits in response to, or independent of, a request from the permit holder. Amendments must be consistent with the Acts and comply with the applicable provisions of this subpart. Special exception permits may be amended by the Office Director without need for further public review or comment.

(1) An amendment means any change to the permit specific conditions under Sec. 216.36(a) provided that the amendment does not result in any of the following:

(i) An increase in the number and species of marine mammals that are authorized to be taken, imported, exported, or otherwise affected;

(ii) A change in the manner in which these marine mammals may be taken, imported, exported, or otherwise affected, where such change would result in an increased level of take or risk of adverse impact; and

(iii) A change in the location(s) in which the marine mammals may be taken, from which they may be imported, and to which they may be exported, as applicable.

(2) A request involving changes to the location, species, and number of marine mammal parts or specimens received, imported, or exported, where no take is involved, would qualify as an amendment.

(b) Amendment requests and proposals.

(1) Requests by a permit holder for an amendment must be submitted in writing and include the following:

(i) The purpose and nature of the amendment;

(ii) Information, not previously submitted as part of the permit application or subsequent reports, necessary to determine whether the amendment satisfies all issuance criteria set forth at Sec. 216.34, and, as appropriate, Sec. 216.41, Sec. 216.42, and Sec. 216.43.

(iii) Any additional information required by the Office Director for purposes of reviewing the proposed amendment.

(2) If an amendment is proposed by the Office Director, the permit holder will be notified of the proposed amendment, together with an explanation.

(c) Review of proposed amendments.

(i) After reviewing all appropriate information, the Office Director will provide the permit holder with written notice of the decision on a proposed or requested amendment, together with an explanation for the decision.

(ii) An amendment will be effective upon a final decision by the Office Director.

Comment: Do not consolidate major and minor amendments. Keep minor amendments as currently regulated. Think simplicity. Minor amendments do not alter the nature of the authorized research.

Sec. 216.40 Penalties and permit sanctions: NMFS is considering specifying criteria and procedures for the suspension, revocation, modification, and denial of scientific research or enhancement permits, in addition to, but consistent with, the provisions of subpart D of 15 CFR part 904. For example, NMFS is considering promulgating specific regulations for suspension, revocation, modification, and denial of scientific research and enhancement permits for reasons not related to enforcement actions.

Comment: This is frightening from a researcher's perspective. The current NMFS regulations are sufficient. OPR should not be in the position of determining a penalty for a permit violation. OPR should be thinking about how scientific research

can benefit the understanding of marine mammals in U.S. waters and should be helping researchers acquire the necessary permits to achieve this goal, not deciding which penalty will occur if some aspect of a permit is violated.

Sec. 216.42 Photography [Reserved]: NMFS may propose regulations similar to those for the General Authorization (Sec. 216.45). We are also considering limiting the number of personnel that may be involved in order to eliminate potential problems with permit holders using such authorization for ecotourism, since the MMPA does not provide exemptions for harassment of marine mammals via ecotourism permits. Any specific recommendations as to what these regulations should or should not include would be considered.

Comment: It is unclear what problems exist (and why will limiting personnel help?) with permit holders and ecotourism. There should be a provision in ALL permits for photo-identification of any species so this can occur on ecotourism vessels (similar to what is, or was, allowed in the Gulf of Maine). Researchers should be allowed to take photographs on ecotourism vessels. This would reduce the impact to the animal by only having one vessel in the area (rather than an ecotourism vessel and a researcher vessel) near a marine mammal AND further the scientific knowledge about the species by collaborating with industry (and educating the public).

Sec. 216.45 General Authorization for Level B harassment for scientific research: NMFS is considering modifications to this section that would make General Authorizations (GAs) available based on the status of the target stock, rather than strictly based on the level of harassment. The recommended change would make a GA available for all Level A and Level B research on all non-strategic stocks of MMPA species. A GA would also be available for stocks defined as strategic under the MMPA, but only for Level B research activities. Under this suggested change a GA would not be appropriate for Level A research on ESA listed species, or depleted and strategic stocks under the MMPA. A number of paragraphs throughout this section would have to change as a result of this recommendation. This change, prior to implementation, would require a similar change in section 104(c)(3)(C) of the MMPA.

Regardless of whether changes are made to allow the GA to apply to level A harassment, NMFS proposes to modify this section to clarify

that the description of methods in the letter of intent must specify the number of marine mammals, by species or stock, that would be taken, including a justification for such sample sizes.

Comment: Change the MMPA to the proposed action.

NMFS is also considering revising the terms and conditions of the GA regulations to clarify that any activity conducted incidental to the research, such as commercial or educational filming or photography, would require prior written approval from NMFS, and such activities would be subject to the same conditions as those specified at Sec. 216.41(c)(1)(vii) for scientific research and enhancement permits, i.e., the conduct of such incidental activities must not involve any taking of marine mammals beyond what is necessary to conduct the research.

Comment: This makes sense. Filming should not drive the research.

Other considerations: NMFS is also considering adding new sections to the regulations. One such consideration would place the permit application and amendment process on a cycle. One option would be to accept permit applications and amendment requests quarterly (i.e., during any one of four three-month cycles per year). Applicants would have firmly established deadlines (made known through FR notification, mailings, and web site) to assist them in planning the submission of their application relative to the proposed start of their research. Another option would be to accept applications and amendments only twice a year, during one of two six-month cycles

One possible disadvantage for applicants under either alternative is that if a submission deadline were missed an applicant would have to wait three (option 1) to six (option 2) additional months for their permit. Applicants are used to requesting amendments at any time. They too would be affected by this modification and a request for an amendment could only happen once a permit cycle. However, a permit

cycle ultimately makes receipt of permits predictable and helps researchers plan the submission of their applications with respect to proposed initiation of their work.

For applications to conduct research on non-ESA listed species, NMFS would aim for an average processing time of 90 days such that processing an application submitted by the deadline for one cycle could be completed by the end of the next cycle (three months later). Another advantage to this is that the average processing time of applications involving ESA-listed marine mammal species would likely be reduced because we would be able to conduct batched consultations and analyses under the ESA and NEPA. In cases where programmatic NEPA documents and corresponding ESA section 7 consultations have been completed, an average processing time of 90 to 120 days could be possible for those research activities covered by the documents.

Comment: I am happy to see considerations for making the application process easier; however, I do not think cycles will solve the problem. Each permit application is different and requires different timelines for resolving issues. I do not see this occurring on a timeline suitable for all applications. I fear that a cycle will prolong the process for some/many applications. I suggest offering provisional permits is a better solution.

United States Department of the Interior

FISH AND WILDLIFE SERVICE
Washington, D.C. 20240

DEC 12 20

In Reply Refer To:
FWS/AIA/DMA

Chief, Permits, Conservation and Education Division
Office of Protected Resources,
National Marine Fisheries Service
1315 East-West Highway, Room 13705
Silver Spring, Maryland 20910.

Attn: Permit Regulations ANPR

Dear Mr. Payne:

Thank you for the opportunity to review the Advance Notice of Proposed Rulemaking (ANPR), request for comments. The Service would welcome the opportunity to work with your staff during the development of these regulations. Our staff coordinates closely with NMFS permit staff, not only for the issuance of joint permits for scientific research, but to address inconsistencies in policies between the two agencies that cause confusion for applicants and permittees. Therefore, we suggest that further consideration should be given to the development of joint regulations for facilitating the implementation of the MMPA and ESA. The staff in the Division of Management Authority have specific comments regarding the ANPR. The DMA will be contacting the Office of Protected Resources to schedule a meeting to discuss these comments and to explore the possibility of developing joint regulations.

Sincerely,

Robert R. Gabel, Chief
Division of Management Authority

Subject: Permit Regulations ANPR
From: John Wise <john.wise@maine.edu>
Date: Wed, 12 Dec 2007 15:16:37 -0500
To: NMFS.PR1Comments@noaa.gov
CC: Sloan_Amy <Amy.Sloan@noaa.gov>

Over the past several years the Wise Laboratory of Environmental and Genetic Toxicology has pioneered the development of marine mammal cell lines. We have created approximately 320 cell lines from 12 organs of 31 different marine mammal species. We have made these cell lines as tools for the community, however, in the process of doing so we have identified several aspects of NMFS regulation that hinder the free exchange of research materials among scientists. In particular, we offer the following 5 points for consideration concerning marine mammal cell lines. For the purposes of this discussion, we have used the following definitions:

> Primary cell lines are cultures of dispersed cells that have not been altered to extend their lifespan and thus have a finite lifespan. They are inclusive of the initial cells that grew out of the tissue.
>
> Immortalized cell lines are cultures of cells that have been altered to extend their lifespan.

1. Determination of when a marine mammal cell line ceases to be a marine mammal part.

Under the current regulations cells isolated/derived from marine mammals are regulated as marine mammal parts. The current regulations are silent on defining when a cell line either primary or immortalized, ceases to be a marine mammal part. This silence creates a fair amount of confusion amongst researchers as they seek to work with the cell lines.

We are aware of the definitions surrounding DNA as a marine mammal part. Specifically, that the original DNA is considered a marine mammal part, but that polymerase chain reaction (PCR) products of that DNA are not. It is tempting to suggest that a similar definition could be applied to cell lines such as once a cell line is immortalized it ceases to be a marine mammal part. Upon reflection, however, we feel that such a definition does not work well for cell lines. The complicating factor as we see it is that there can be significant commercial value in immortalized cell lines and comparatively less in primary cell lines. Developing an immortalized cell line requires primary cells and therefore, if immortalized cell lines prove commercially valuable there will be increased demand to obtain whale parts (primary cells) for this commercialization effort to produce more and different types of immortalized cell lines. Thus, we suggest that both primary and immortalized cell lines should be listed specifically as marine mammal parts.

We do think that the definition should stop there and that products derived from immortalized cell lines should not be considered marine mammal parts. For example, if one developed a marine sensor that included an immortalized cell line as part of that sensor, the sensor would not be considered a marine mammal part despite the involvement of the immortalized cell line. This scenario only creates a demand for the immortalized cell line, which can be grown in mass culture. It would not likely create a demand for more primary cell lines or tissue as no two immortalized cell lines are exactly alike and thus it would be difficult to recreate the same cell line. Thus, the cell line, itself, would not be commercializable, but application of it could be. We suggest, therefore, that immortalized cell lines cease to be considered a marine mammal part once they are modified further.

2. Adjustments to the current permitting/reporting structure and responsibility.

The current regulations require that researchers hold a NMFS permit or be listed as a co-investigator on the permit of another researcher to use cell lines though they do not explicitly state so. This practice forces the responsibility and the liability for cell line use onto the laboratory that generated the cell lines. This practice is contradictory to human cell line research where cell lines for research are distributed freely and without permitting requirements. Thus, there is confusion amongst researchers who wish to use cell lines without any contact with the tissues or animals and those moving into marine mammal research from human health.

The permitting process is very cumbersome for a laboratory that just wants to work with cells. It also forces permitted users to have to explain that NMFS regulates cell lines even though it is not specified in the regulations and requires that the investigator assume an unfair amount of liability if they do share the cell line by

adding the new user as a co-investigator to the permit.

To better assist in the understanding and use of cell lines, we propose the following changes to the current permitting regulations:

a. Define in the permit rules that cell lines are considered marine mammal parts including both primary cell lines and immortalized cell lines.

b. Require the normal permitting process for laboratories that seek to create cell lines whether primary or immortalized cell lines. This step will ensure that NMFS can track those individuals making cell lines as well as ensuring annual reporting on those efforts.

c. Create a new registry process instead of a permitting process for researchers who want to use cell cultures but not create new cell lines. For example, researchers who want to screen for viruses, conduct toxicology testing, or investigate genetic status. This registry would be at NMFS and allow NMFS to track all users of cell lines without the long delay of the permitting process. These researchers should be required to provide an annual report to NMFS describing their efforts and would need to include a statement that they will not sell, commercialize or distribute the cell lines, nor will they attempt to create new cell lines. Of course, if they wanted to develop cell lines they would be free to obtain a full permit.

This registry would allow registered researchers to obtain cell lines from permitted producers of cell lines. Permitted researchers would report a list of registered users who obtained cells from them in their annual report to NMFS. This registry would allow for easier and better sharing of cell lines and keep the responsibility for the cell lines between NMFS and the registered user and remove the permitted user from the middle.

3. Adjustments to the current import/export rules to allow for faster receipt of tissue.

Current import/export rules require a CITES permit to ship the small pieces of tissue. Developing cell lines requires access to fresh tissue as fast as possible. The current need for a CITES permit to import cell lines interferes with the ability to develop some of these specialized cell types.

We suggest that tissue for the purposes of developing cell lines be exempt from CITES to allow for more rapid transport. This exemption would greatly increase the cell types available and the development of new lines that may be very informative about marine mammal health.

The challenge of course is that some may try to circumvent CITES by claiming that their tissue is for cell lines when it isn't. To reduce or prevent these situations, we suggest the following changes to the permitting process:

a. Require that to be CITES exempt for cell lines, the NMFS permit must explicitly indicate that the investigator is permitted to develop cell lines.

b. Require that for a NMFS permit for developing cell lines that the investigator have demonstrated experience developing cell lines to prevent it being listed as an activity that cannot be done.

c. Limit the size of a piece of tissue that can be imported/exported for cell line development to a piece about the size of a quarter.

These changes would limit the cell line activity to teams with track records in developing cell lines and allow for exemption from CITES.

4. Adjustments to the current rules for use of cell lines by investigators outside the United States.

The current rules do not require investigators outside the United States to have or obtain a permit, but they do require permitted U.S. investigators to be responsible for them under their own NMFS permit. This requirement is an unreasonable burden on the U.S. researcher as the NMFS permit has no authority in other countries. We suggest that a solution to this situation is to have foreign investigators join the cell line registry described above. This requirement would make them aware of US law and regulations and place the responsibility for them back onto NMFS, the permitting agency instead of with the investigator.

5. Clarification on Cost Recovery.

The process of developing cell lines is expensive and there is little grant support to do it. It is our understanding that cost recovery is allowed, but the current regulations are silent with respect to what are allowable costs for recovery. We suggest that the new regulations should address this explicitly and describe allowable cost. Such cost might include storage fees (e.g. liquid nitrogen), shipping and handling fees, supply costs for the reagents used to make the cell lines and labor costs used to process the tissue.

John Pierce Wise, Sr., Ph.D.
Director, Maine Center for Toxicology and Environmental Health
Professor of Toxicology and Molecular Epidemiology,
Department of Applied Medical Sciences
University of Southern Maine
96 Falmouth St.
PO Box 9300
Portland, ME 04104-9300

Phone (207) 228-8050
FAX (207) 228-8518
Email John.Wise@usm.maine.edu
www.usm.maine.edu/toxicology

Fedex address:
178 Science Building
96 Falmouth St.
Portland, ME 04103