

urinary excretion on 3 or more consecutive days to establish that steady-state conditions are achieved.

\* \* \* \* \*

(e) \* \* \*

(3) Other methods based on valid scientific reasons should be used to determine the bioavailability or bioequivalence of a drug product having dose-dependent kinetics (nonlinear system).

\* \* \* \* \*

13. Section 320.29 is amended by revising the section heading and paragraph (a) to read as follows:

**§ 320.29 Analytical methods for an vivo bioavailability or bioequivalence study.**

(a) The analytical method used in an in vivo bioavailability or bioequivalence study to measure the concentration of the active drug ingredient or therapeutic moiety, or its metabolite(s), in body fluids or excretory products, or the method used to measure an acute pharmacological effect shall be demonstrated to be accurate and of sufficient sensitivity to measure, with appropriate precision, the actual concentration of the active drug ingredient or therapeutic moiety, or its metabolite(s), achieved in the body.

\* \* \* \* \*

14. Section 320.30 is amended by revising paragraph (c) to read as follows:

**§ 320.30 Inquiries regarding bioavailability and bioequivalence requirements and review of protocols by the Food and Drug Administration.**

\* \* \* \* \*

(c)(1) General inquiries relating to in vivo bioavailability requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Clinical Pharmacology and Biopharmaceutics (HFD-850), 5600 Fishers Lane, Rockville, MD 20857.

(2) General inquiries relating to bioequivalence requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Bioequivalence (HFD-650), 7500 Standish Pl., Rockville, MD 20855-2773.

**§ 320.31 [Amended]**

15. Section 320.31 *Applicability of requirements regarding an "Investigational New Drug Application* is amended in the introductory text of paragraph (b) by adding after the word "bioavailability" the phrase "or bioequivalence".

Dated: November 5, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98-30880 Filed 11-18-98; 8:45 am]

BILLING CODE 4160-01-F

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[WA 67-7142b; FRL-6188-2]

**Approval and Promulgation of State Implementation Plans: Washington**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

**SUMMARY:** The EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Washington for the purpose of including a variance to a permit issued to the U.S. Army for the operation of three heat recovery incinerators located at Fort Lewis by local air pollution control agency, the Puget Sound Air Pollution Control Agency (PSAPCA). In the Final Rules Section of this **Federal Register**, the EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If the EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

**DATES:** Written comments must be received in writing by December 21, 1998.

**ADDRESSES:** Written comments should be addressed to Montel Livingston, Environmental Protection Specialist (OAQ-107), Office of Air Quality, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Environmental Protection Agency, Region 10, Office of Air Quality, 1200 6th Avenue, Seattle, WA 98101  
The Washington State Department of Ecology, Air Quality Program, 300 Desmond Drive, Lacey, WA 98503

**FOR FURTHER INFORMATION CONTACT:** Mahbulul Islam, Office of Air Quality (OAQ-107), EPA, 1200 6th Avenue, Seattle, WA 98101, (206) 553-6985.

**SUPPLEMENTARY INFORMATION:**

See the information provided in the Direct Final action which is located in the Rules Section of this **Federal Register**.

Dated: November 3, 1998.

**Jane S. Moore,**

*Acting Regional Administrator, Region 10.*

[FR Doc. 98-30848 Filed 11-18-98; 8:45 am]

BILLING CODE 6560-50-P

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 216**

[I.D. 110998A]

**Regulations Governing the Taking and Importing of Marine Mammals; Threatened Fish and Wildlife; Cook Inlet Beluga Whales**

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent to conduct a status review and request for information.

**SUMMARY:** NMFS is initiating a status review of the Cook Inlet beluga whale (*Delphinapterus leucas*) to determine whether designation under the Marine Mammal Protection Act (MMPA) or a change in listing classification under the Endangered Species Act (ESA) is warranted. NMFS intends to undertake the review in conjunction with the Alaska Beluga Whale Committee and the Cook Inlet Marine Mammal Council. The review will give consideration to the current status of Cook Inlet belugas, their distribution, abundance and trends, food habits, biohealth parameters, and reproductive parameters. The effects of the Native subsistence harvest, and the potential effects of other humanly induced impacts, as well as beluga natural mortality will also be examined. To ensure that the review is comprehensive, NMFS is requesting that interested parties submit pertinent information and comments regarding

the status of the Cook Inlet beluga whale.

**DATES:** Comments and information must be received by January 19, 1999.

**ADDRESSES:** Comments and information should be addressed to Chief, Marine Mammal Division (PR2), Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

**FOR FURTHER INFORMATION CONTACT:** Steve Zimmerman, Protected Resources Management Division, Alaska Region, NMFS, (907) 586-7235; Brad Smith/Barbara Mahoney, Protected Resources Management Division, Alaska Region, NMFS, (907) 271-5006; or Margot Bohan, Office of Protected Resources, NMFS (301) 713-2322.

**SUPPLEMENTARY INFORMATION:** Section 4 of the ESA and 50 CFR part 424 contain provisions that allow the Secretary of Commerce (Secretary) to add to or change the species' listing classification on the U.S. List of Endangered and Threatened Wildlife when necessary. MMPA section 115 contains similar provisions regarding determinations on the status of species pursuant to the MMPA. Currently, the Cook Inlet beluga whale is on the candidate species list under the ESA. The candidate species list serves to notify the public that NMFS has concerns regarding the species that may warrant an ESA threatened or endangered listing in the future. Ideally, the candidate list facilitates voluntary conservation efforts prior to a need for listing under the ESA. If the Secretary determines that there is substantial scientific or commercial information to indicate that a change in listing classification may be warranted, a status review is conducted. NMFS intends to undertake a review of the Cook Inlet population of beluga whales in collaboration with the Alaska Beluga Whale Committee and the Cook Inlet Marine Mammal Council.

### Background

Beluga whales are a circumpolar species. They are found in the waters of Canada, Alaska, Russia, Norway and Greenland. In Alaska, five populations are currently recognized and are found seasonally in (1) the Beaufort Sea, (2) the eastern Chukchi Sea, (3) the eastern Bering Sea, (4) Bristol Bay; and (5) Cook Inlet.

The Cook Inlet belugas make up a small, geographically isolated remnant population. In fact, the habitat range used by belugas in Cook Inlet appears to be decreasing. At present, the animals seem to concentrate near river mouths in the northern part of the inlet during much of the year. Limited sightings have occurred elsewhere in the recent past.

Because Cook Inlet belugas are geographically isolated, perturbations that are humanly-induced could have a dramatic effect on the population. The summer concentrations of this beluga population are exposed to the largest industrialized coastal area and to the largest human component in Alaska.

NMFS data indicate that the Cook Inlet population may also be declining in number. There are thought to be approximately 500 beluga whales in Cook Inlet, based on data collected between 1994 and 1998. The index count from the 1998 survey was the lowest reported to date and demonstrates a downward trend that has been ongoing over the last 4 years.

An increasing amount of information has revealed serious threats to this population. With its currently estimated rates of natural mortality and Native harvest, there is concern that the beluga population in Cook Inlet cannot be sustained by annual recruitment. Specifically, there is concern that Native subsistence harvests are exceeding sustainable removal levels. NMFS believes that maintaining a healthy beluga population and ensuring the

long-term sustainability of a beluga whale subsistence harvest in Cook Inlet is in the best interest of all parties concerned. However, if present harvest levels continue to greatly exceed recruitment, the beluga whale population in Cook Inlet could become severely depleted in the foreseeable future. Effective actions must be developed and implemented soon to address such pressing conservation and management issues.

In light of these factors, NMFS is initiating a formal and comprehensive review of the status of the Cook Inlet beluga whale through a cooperative process with the Alaska Beluga Whale Committee and the Cook Inlet Marine Mammal Council. NMFS will obtain the best available information regarding the population's condition and sustainability to determine whether it warrants a depleted designation under the MMPA or a threatened or endangered listing under the ESA, or both.

### Biological Information Solicited

To ensure that the review is comprehensive and is based on the best available data, NMFS is soliciting information and comments from any interested person concerning the status of Cook Inlet beluga whales. It is requested that data, information, and comments be accompanied by (1) supporting documentation, such as maps, logbooks, bibliographic references, personal notes, or reprints of pertinent publications and (2) the name of the person submitting the data, his/her address, and any association, institution, or business that the person represents.

Dated: November 12, 1998.

#### Ann D. Terbush,

*Acting Director, Office of Protected Resources,  
National Marine Fisheries Service.*

[FR Doc. 98-30833 Filed 11-18-98; 8:45 am]

BILLING CODE 3510-22-F