

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the docket control number [PP 9F3804/P646]. All written comments filed in response to these petitions will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays.

A record has been established for this rulemaking under docket number [PP 9F3804/P646] (including comments and data submitted electronically as described below). A public version of this record including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB). Under section 3 (f), the order defines "significant" as those actions likely to lead to a rule: (1) Having an annual effect of the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or

planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements, or establishing or raising food additive regulations do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 20, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is proposed to be amended as follows:

**PART 180—[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.412(a), by amending the table therein by adding and alphabetically inserting the new entries for apricots, cherries (sweet and sour), nectarines, and peaches to read as follows:

**§ 180.412 2-[1-(Ethoxyimino)butyl]-5-[2-(ethiothio)propyl]-3-hydroxy-2-cyclohexene-1-one; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * * *	
Apricots .....	0.2
* * * * *	
Cherries (sweet and sour) .....	0.2
* * * * *	
Nectarines .....	0.2

Commodity	Parts per million
Peaches .....	0.2
* * * * *	
* * * * *	

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**40 CFR Parts 220 and 227**

[FRL-5432-2]

RIN 2040-AC81

**Testing Requirements for Ocean Dumping**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA today is issuing a proposed rule that would clarify certain provisions of the Agency's ocean dumping regulations relating to requirements for bioassay testing. The purpose of today's proposal is to clarify regulatory language that was interpreted by the U.S. Court of Appeals for the Third Circuit in a different manner than EPA intended. Today's proposal would confirm the validity of existing testing practices, and would not change them.

**DATES:** Written comments on this proposed rule will be accepted until April 1, 1996. All comments must be postmarked or delivered by hand to the address below by this date.

**ADDRESSES:** Send written comments on this proposed rule to the Ocean Dumping Proposed Rule Comment Clerk, Water Docket, MC-4101, Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. Commenters should submit any references cited in their comments. Commenters are requested to submit an original and three copies of their written comments and any enclosures. Commenters who want receipt of their comments acknowledged should include a self-addressed, stamped envelope. No facsimile or electronic mail transmissions (faxes or e-mail) will be accepted.

A copy of the supporting documents for this proposed rule are available for review at EPA's Water Docket, Room L-102, 401 M Street, SW, Washington, DC 20460. For access to the docket materials, call 202/260-3027 between 9:00 a.m. and 3:30 p.m., for an appointment.

**FOR FURTHER INFORMATION, CONTACT:** John Lishman, Chief, Marine Pollution

Control Branch, Oceans and Coastal Protection Division (4504F), Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, telephone 202/260-8448.

**SUPPLEMENTARY INFORMATION:**

A. Statutory and Regulatory Background, and Summary of Previous Litigation

The Ocean Dumping Regulations, which govern the evaluation and permitting of material to be ocean dumped, were promulgated by EPA on January 11, 1977, under Title I of the Marine Protection, Research, and Sanctuaries Act of 1972, as amended, 33 U.S.C. 1401 et seq. (hereinafter "the Act" or "the MPRSA"). These regulations are contained in 40 CFR Parts 220-229.

The MPRSA prohibits the transportation of material from the United States for the purpose of ocean dumping without a permit, and prohibits U.S. instrumentalities and U.S. registered or flagged vessels from transporting materials from any location for the purpose of ocean dumping without a permit. The Act also prohibits the unpermitted dumping of material transported from a location outside the United States into the Territorial Sea or the Contiguous Zone, if the dumping affects the Territorial Sea or U.S. territory.

Under Section 102(a) of the Act (33 U.S.C. 1412(a)), EPA has responsibility for issuing permits for the ocean dumping of all materials other than dredged material. Under Section 103(a) of the Act (33 U.S.C. 1413(a)), the Secretary of the Army has responsibility for issuing permits for the ocean dumping of dredged material. This permitting authority has been delegated to the Corps of Engineers ("the Corps"). The Corps applies EPA ocean dumping regulations in making its permit decisions. EPA's role pertaining to the Corps' issuance of dredged material disposal permits is one of review and concurrence. Although the Corps is the permitting authority for dredged material, Section 103 of the Act establishes a substantial role for EPA with regard to the evaluation of the impacts of the ocean disposal of dredged material.

On June 1, 1993, Clean Ocean Action, an organization concerned with issues affecting water quality, as well as other groups ("the plaintiffs"), filed a complaint and a request for injunctive relief in the United States District Court, District of New Jersey, against the Corps, EPA, and the Port Authority of New York and New Jersey ("the Port

Authority"), challenging an ocean dumping permit issued to the Port Authority by the Corps. *Clean Ocean Action v. York*, Civil No. 93-2402 (DRD) (D.N.J.). The permit authorized the Port Authority to perform maintenance dredging from two Port Authority facilities in Newark Bay, and to dispose of the dredged material in the Atlantic Ocean at the New York Bight Dredged Material Disposal Site (also known as the Mud Dump Site).

In a decision dated June 7, 1993, the District Court denied the plaintiffs' request for a preliminary injunction to halt the disposal of the dredged material at the Mud Dump Site. After additional briefing and other proceedings, the District Court issued a formal opinion on June 28, 1994, again denying the requested injunctive relief. In its opinion, the District Court also concluded that the bioassay tests performed on the dredged material met the requirements of the ocean dumping regulations. 861 F. Supp. 1203 (D.N.J. 1994).

On June 12, 1995, the United States Court of Appeals for the Third Circuit affirmed the District Court's denial of a preliminary injunction. *Clean Ocean Action v. York*, 57 F.3d 328 (3d Cir. 1995). The Third Circuit also stated, however, that the District Court had erred in its conclusion that the bioassays performed on the dredged material in issue met the requirements of the ocean dumping regulations.

As a result of the opinion of the Third Circuit, a degree of uncertainty now exists regarding certain of the ocean dumping regulatory testing requirements. Today's proposed rulemaking would clarify those regulatory requirements in a manner that is consistent with existing testing practices.

In particular, the Third Circuit examined the language of 40 CFR 227.6(c). That section currently provides that the potential for significant undesirable effects due to the presence of constituents listed at 40 CFR 227.6(a) "shall be determined by application of results of bioassays on liquid, suspended particulate, and solid phases of wastes according to procedures acceptable to EPA, and for dredged material, acceptable to EPA and the Corps of Engineers." EPA and the Corps had argued, and the District Court had found, that § 227.6(c) reserves discretion in the agencies not to require bioaccumulation bioassay tests in the suspended phase if acceptable procedures for such tests are not available and approved for use. The Third Circuit, however, concluded that § 227.6(c) requires suspended phase

bioaccumulation bioassays even where neither EPA nor the Corps of Engineers has identified acceptable procedures. The Court read that section as reserving discretion in the agencies to determine *how*, but not *whether*, to conduct the tests. 57 F.3d at 332.

As described more fully in Part B of today's preamble, today's proposal would amend §§ 220.2, 227.6, and 227.27 to more clearly reserve discretion regarding when bioassays are to be conducted. This would be done by clarifying that bioassays are not required if there are no Agency-approved procedures, as will be explained in more detail below. (EPA has previously amended §§ 227.6(c)(2) and 227.27(b) of the ocean dumping regulations to clarify specifically that bioaccumulation tests are not required in the suspended phase. See 59 FR 26566 (May 20, 1994) (Interim Final Rule); 59 FR 52650 (October 18, 1994) (Final Rule)).

The Third Circuit opinion also addressed § 227.27(d). That section provides that "appropriate sensitive benthic organisms," which are to be used in solid phase testing under § 227.6(c)(2), means "at least one species each representing filter-feeding, deposit-feeding, and burrowing species chosen from among the most sensitive species accepted by EPA as being reliable test organisms to determine the anticipated impact on the site \* \* \*". There are some marine species that exhibit more than one of the filter-feeding, deposit-feeding, and burrowing characteristics. Current Agency guidance specifies that when bioaccumulation and toxicity testing is performed on the solid phase, two species may be used for each of these two sets of tests, so long as the two species together exhibit all of the three species characteristics. The Third Circuit opinion, however, could be construed to indicate that three different test species should be required for solid phase bioassay tests. See 57 F.3d at 332, 333 n.2. (In the case before the Third Circuit, only one benthic organism was tested for bioaccumulation of dioxin in the solid phase before the District Court required additional testing. 861 F. Supp. at 1210.)

EPA is proposing to amend the definition of the "appropriate sensitive benthic organisms" used in benthic bioassay tests to mean at least two species that together exhibit filter-feeding, deposit-feeding, and burrowing characteristics. Consistent with current Agency guidance, the proposed language would clarify that the use of two such species is sufficient. In addition, today's proposal would amend the definition of "appropriate sensitive

marine organisms," which are to be used in suspended phase tests under § 227.6(c)(3), to mean at least two species that together are representative of the following types of organisms: phytoplankton or zooplankton, crustacean or mollusk, and fish. The proposed language would clarify, consistent with current agency guidance, that the use of two such species is sufficient.

The purpose of today's proposal is to clarify the regulatory language that was interpreted by the Third Circuit in a different manner than EPA intended. The Agency is *not* changing the evaluative procedures that are currently used and set out in program guidance and thus is not changing the level of environmental protection of the ocean dumping program. EPA is allowing for a thirty day period for comment on this proposal. The Agency believes a thirty day comment period is adequate because the proposal would clarify the regulations in a manner consistent with existing practices. The Agency also is working on more comprehensive amendments to the ocean dumping regulations in order to further update them and improve their clarity. The Agency anticipates issuance of a proposal later this year.

## B. Discussion

### (1) *Bioassay provisions*

The mere presence of contaminants or pollutants in material proposed for disposal does not in itself reveal the potential for adverse effects on marine life, or whether pollutants are even present in forms that are bioavailable (Reference 1 and 2). Because of this, exposure of organisms to material proposed for dumping in laboratory tests or other biological effects-based assessments are conducted to determine the potential for adverse biological effects resulting from contaminants that may be present in the material (Reference 3). The determination of both when and how to perform such evaluations often involves complicated scientific and technical judgment. The Agency, as described below, has provided technical guidance to identify acceptable procedures for evaluating the potential biological effects of material proposed for dumping.

In 1977, EPA and the Corps provided national technical guidance on procedures for performing biological evaluations of dredged material in the manual entitled "Ecological Evaluation of Proposed Discharge of Dredged Material into Ocean Waters" ("the Green Book") (Reference 4). EPA provided national technical guidance

for other material in the manual entitled "Bioassay Procedures for the Ocean Disposal Permit Program ("the Blue Book") in 1977 (Reference 5); the Green Book was revised in 1991 (Reference 6). The guidance describes scientifically and technically appropriate testing and evaluations to assess the potential biological effects of material proposed for ocean dumping. Because such guidance has been issued, today's proposal would update the regulations to delete provisions in § 227.6(e) referring to such guidance as being under development and providing interim criteria, as well as similar language from § 227.27(b) and (d).

As previously discussed, the existing regulations provide that bioassays shall be run "in accordance with" approved Agency procedures. This language was intended to reserve Agency technical discretion on when and how to perform such bioassays. However, the Third Circuit opinion has cast some doubt on this issue. To better clarify that the Agency has reserved its discretion in establishing procedures for when and how to perform bioassays, today's proposal would add a new definition of "bioassay" in proposed § 220.2(j) to make clear that references in the regulations to "bioassays" means only those that have been approved for use by EPA, or in the case of dredged material, approved by EPA and the Corps. The intent is to make clear that in the absence of approved procedures, bioassays are not required by the regulations. As a conforming matter, today's proposal would also delete language in existing §§ 227.6(c), (c)(2), (c)(3), and 227.27(a)(2) and (b) referring to bioassay procedures approved by the Agency. The language that is proposed to be deleted becomes redundant or unnecessary in light of the proposed definition of "bioassay."

The proposed definition of bioassay further makes clear that the Agency has reserved its discretion on the evaluative procedures to be used by employing the term "effects-based evaluations." This would be done to avoid any implication that the regulations intend to mandate only the exposure of organisms to materials or contaminants in laboratory tests. While such tests provide one way to evaluate the toxicity and bioaccumulation potential of contaminants from a material proposed for ocean disposal, they are not the only way to make such assessments. Improvements in the sciences of toxicology and risk assessment allow conclusions to be made about the potential environmental impacts of ocean disposal of a material without actually running such laboratory tests in

all cases. As a result, an adequate evaluation of material proposed for ocean dumping does not always require the performance of specific laboratory biological tests for each material or contaminant evaluated. In general, as will be explained below, the following biological effects-based approaches can be used or combined to evaluate material proposed for ocean disposal: (1) Laboratory tests of organisms exposed to the material or results of such tests run on similar material; (2) toxicological and/or risk assessment models; or (3) screening evaluations that use highly protective estimates of exposure and effects assumptions.

As stated above, exposure of organisms to materials or contaminants in laboratory experiments provide one way to measure the potential effects of dumping the material. Results of such tests on similar material may also be adequate for determining the potential effects depending on a number of factors, including, but not limited to, the following: (1) Whether the methods used are consistent with currently approved test procedures; (2) whether organisms tested include those identified in 40 CFR 227.27 (c) and (d), as appropriate; and (3) whether the characteristics of the material tested are sufficiently similar to the material to be dumped so that one can reasonably predict the potential for environmental effects from dumping of the latter material by extrapolating from the results of testing on the former material.

The bioavailability of many contaminants in the environment also can be predicted through the use of toxicological and/or risk assessment models. For example, the equilibrium partitioning model is one approach that can be used to predict the bioavailable fraction of a contaminant in an aquatic sediment (Reference 2). A variation of this model, called the Theoretical Bioaccumulation Potential (TBP) model, has been used to screen dredged material for further bioaccumulation testing (Reference 6). A review of the use of the TBP model in dredged material evaluations indicates that it is highly protective because of the use of conservative assumptions in the model (Reference 7). In the future, incorporation of additional laboratory bioassay and field-generated information into the TBP model will improve its accuracy and reliability. In the meantime, however, its conservatism ensures that using it is an environmentally protective approach (Reference 7).

Finally, conservative assumptions also can be used to predict the "upper bound" of potential environmental

impacts. For example, evaluations can be based on the assumption that 100 percent of a contaminant in a material proposed for ocean disposal will be bioavailable. This approach can be used for screening chemicals that might require further evaluation to determine compliance with water quality criteria by assuming all of the contaminants in the material are dissolved into the water column during dumping. (Reference 6.) The use of TBP, as discussed above, integrates the use of toxicological models with conservative assumptions in determining the bioavailability of contaminants in the material that settles to the bottom after dumping.

The reference to "effects-based evaluations" in proposed § 220.2(j) is intended to make clear that, as provided for in approved Agency procedures, the approaches described above can be used to evaluate the potential environmental effects of material proposed for ocean dumping, either as a screening device in lieu of actual laboratory testing, or in combination with the results of such tests. At the same time, the language is intended to provide flexibility for the future in order to assure that as science and technology improve and other effects-based evaluations are approved for use, they may be used as well.

In addition, the current ocean dumping regulations provide that bioassays are to be conducted "in accordance with" procedures approved by EPA and the Corps. In certain cases, there are no approved laboratory testing protocols available, or as described above, other evaluative tools provide effects-based information comparable to that which might be obtained from running a laboratory bioassay. The Third Circuit opinion, however, could be read as suggesting that even though Agency-approved bioassay test procedures are not specified, the regulation still requires laboratory bioassays to be run. Although the proposed definition of bioassay described above is intended to resolve this point, in order to further remove any possible ambiguity, today's proposal would make a change in regulatory language in § 227.6(c). The proposed change would replace a reference to performing bioassays "in accordance with" approved Agency procedures, to performing bioassays "when bioassay procedures have been approved."

Finally today's proposal would also amend §§ 227.6(c)(2) and (3), 227.27(b), and 227.27(c), which currently provide that bioassays "shall be conducted" using approved organisms and procedures. To avoid any possible ambiguity that this might mandate only

the use of laboratory tests on organisms exposed to the material proposed for dumping, today's proposal would make changes in those sections to clarify that "if" such laboratory testing is conducted it shall use approved organisms and procedures.

In summary, today's proposal is intended to confirm that the Agency has reserved discretion on how to evaluate material proposed for dumping. This has been done, as described above, in three principal ways: (1) by adding a definition of "bioassay" that makes clear that this term means an effects-based evaluation which is to be conducted only if approved procedures exist for such evaluations; (2) by revising language to be clear that the Agency has reserved discretion to identify what, when, and how evaluation processes will be used; and (3) by clarifying that laboratory tests are not required in all cases. These changes make clear that the Agency has reserved its discretion in this complex technical area.

Approved Agency evaluation procedures can be found in the Blue Book, the Green Book, and Regional implementation manuals, or parties seeking to use other procedures may seek their approval from EPA, or in the case of dredged material, from EPA and the Corps. EPA does not intend to require evaluations that have not been approved, or that are not useful in a regulatory context. The determination as to the types of evaluations necessary to assess potential biological effects of material proposed for ocean dumping involves highly complex technical issues, and is impacted by evolving changes in the science and methods underlying such assessments. Today's action by the Agency is intended to preserve EPA's discretion in this complex technical area to ensure that the appropriate and up-to-date evaluations as approved by the Agency are conducted.

#### (2) Number and types of organisms to be tested

The current ocean dumping regulations define "appropriate sensitive marine organisms" and "appropriate sensitive benthic marine organisms" for use in laboratory tests. The type of organisms used can impact on the sensitivity of the tests in determining toxicity, and the existing regulations provide that the organisms to be used represent three categories of organisms. For the liquid and suspended phases the organisms to be used are defined in § 227.27(c) "as at least one species each representative of phytoplankton or zooplankton,

crustacean or mollusk, and fish species chosen from among the most sensitive species documented in the scientific literature or accepted by EPA as being reliable test organisms\* \* \*". For the solid phase, these are defined in § 227.27(d) as "at least one species each representing filter-feeding, deposit-feeding, and burrowing species chosen from among the most sensitive species accepted by EPA as being reliable test organisms\* \* \*".

As discussed above, EPA has described a range of characteristics that the test species need to represent. The Agency believes this approach is protective of the marine environment because different marine organisms are known to exhibit different sensitivities to environmental contaminants (Reference 8). The Agency's approved testing allows the use of two different species that together cover the three species characteristics in 40 CFR 227.27(c) and (d). For example, the marine worm, *Nephtys incisa*, is both a deposit-feeder and burrower (Reference 9), and the amphipod crustacean, *Ampelisca abdita*, is both a filter-feeder and deposit-feeder (Reference 10).

The Third Circuit opinion, however, could be construed to indicate that 40 CFR 227.27(d) requires the use of three different test species for the solid phase. See, 57 F. 3d 328, 333 n. 2. EPA is proposing today to remove any ambiguity about the number and type of organisms specified by §§ 227.27(c) and (d). This would be done by removing the words "one species each," and clarifying that what is meant is at least two species that together are representative of the three categories of organisms. The change makes clear that the use of two species representing the three characteristics specified in the regulations, is acceptable.

#### C. References

1. "Effects-based testing and sediment quality criteria for dredged material", T.D. Wright, R.M. Engler, and J.A. Miller, in *Water Quality Standards for the Twenty-First Century*, EPA-823-R-92-009, December 1992, pp. 207-218.
2. "Technical basis for deriving sediment quality criteria for nonionic organic contaminants for the protection of benthic organisms by using equilibrium partitioning," U.S. Environmental Protection Agency, EPA-822-R-93-011, Washington, DC, September 1993.
3. "The use of bioassays as part of a comprehensive approach to marine pollution assessment," *Mar. Pollut. Bull.* 14:81-84. 1983.
4. "Ecological evaluation of proposed discharge of dredged material into ocean

waters," U.S. Environmental Protection Agency and U.S. Army Corps of Engineers, Second Printing, April 1978.

5. "Bioassay procedures for the ocean disposal permit program," U.S. Environmental Protection Agency, Office of Research and Development, March 1978.

6. "Evaluation of dredged material proposed for ocean disposal—testing manual," U.S. Environmental Protection Agency and U.S. Army Corps of Engineers, April 1991.

7. "TBP revisited: a ten year perspective on a screening test for dredged sediment bioaccumulation potential," V.A. McFarland and P.W. Ferguson, in *Dredging '94 Proceedings of the Second International Conference on Dredging and Dredged Material Placement*, E.C. McNair, Ed., American Society of Civil Engineers, 1994.

8. "Problems associated with selecting the most sensitive species for toxicity testing," J. Cairns, Jr. and B.R. Niederlechner, " *Hydrobiologia* 153: 87–94 (1987).

9. "Guidance manual: bedded sediment bioaccumulation tests," U.S. Environmental Protection Agency, Office of Research and Development, ERL–N Contribution No. N111, September 1989.

10. "Methods for assessing the toxicity of sediment-associated contaminants with estuarine and marine amphipods," U.S. Environmental Protection Agency, EPA/600/R–94/025, June 1994.

#### Compliance With Other Laws and Executive Orders

##### A. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., EPA must prepare a Regulatory Flexibility Analysis for regulations having a significant impact on a substantial number of small entities. The RFA recognizes three kinds of small entities, and defines them as follows:

(1) Small governmental jurisdictions: any government of a district with a population of less than 50,000.

(2) Small business: any business which is independently owned and operated and not dominant in its field, as defined by the Small Business Administration regulations under the Small Business Act.

(3) Small organization: any not for profit enterprise that is independently owned and operated and not dominant in its field.

As discussed below in the discussion of Executive Order 12866, today's proposed rule does not impose economic burdens. Accordingly, EPA has determined that today's proposed rule would not have a significant impact on a substantial number of small

entities, and that a Regulatory Flexibility Analysis therefore is unnecessary.

##### B. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 et seq., is intended to minimize the reporting and record keeping burden on the regulated community, as well as to minimize the cost of Federal information collection and dissemination. In general, the Act requires that information requests and record keeping requirements affecting ten or more non-Federal respondents be approved by the Office of Management and Budget. Since today's proposed rule would not establish or modify any information or record keeping requirements, it is not subject to the requirements of the Paperwork Reduction Act.

##### C. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant," and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to lead to a rule that may:

(1) Have an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations, of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this proposed rule is not a "significant regulatory action" under the terms of Executive Order 12866, and is therefore not subject to OMB review.

##### D. The Unfunded Mandates Reform Act, and Executive Order 12875

Under the Unfunded Mandates Reform Act (UMRA) of 1995, signed into law on March 22, 1995, EPA must prepare a written statement to accompany any rule where the estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, will be \$100 million or more in any year. The UMRA defines a "private sector mandate" for regulatory purposes as one that, among other

things, "would impose an enforceable duty upon the private sector." EPA has determined that today's proposed regulation does not impose any enforceable duties upon the private sector. Therefore, this proposed rulemaking is not a "private sector mandate," and is not subject to the requirements of the UMRA.

Further, EPA has determined that today's action does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This proposed rulemaking should have minimal impact on the regulatory burden imposed on permittees, because the proposed rulemaking merely clarifies ocean dumping testing requirements. Thus, EPA has determined that an unfunded mandates statement is unnecessary.

Executive Order 12875 requires that, to the extent feasible and permitted by law, no Federal agency shall promulgate any regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless funds necessary to pay the direct costs incurred by the State, local, or tribal government in complying with the mandate are provided by the Federal government. EPA has determined that the requirements of Executive Order 12875 do not apply to today's proposed rulemaking, since no mandate is created by this action.

#### List of Subjects

##### 40 CFR Part 220

Environmental protection, Engineer Corps, Water pollution control.

##### 40 CFR Part 227

Environmental impact statements, Water pollution control.

Date: February 23, 1996.

Carol M. Browner,  
Administrator.

For the reasons set out in this preamble, Parts 220 and 227 of Title 40 of the Code of Federal Regulations are proposed to be amended as follows:

#### PART 220—[AMENDED]

1. The authority citation for Part 220 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

2. Section 220.2 is amended by adding paragraph (j) to read as follows:

##### § 220.2 Definitions.

\* \* \* \* \*

(j) *Bioassay* means such effects-based evaluations as may be approved by EPA,

or in the case of dredged material, by EPA and the Corps of Engineers, for use in evaluating whether material has the potential to cause acute, chronic, or other sublethal effects following dumping.

**PART 227—[AMENDED]**

3. The authority citation for 40 CFR Part 227 continues to read as follows: Authority: 33 U.S.C. 1412 and 1418.

4. Section 227.6 is amended: a. In paragraph (a) introductory text by removing the words “(f), (g), and (h)”, and adding, in their place, the words “(e), (f), and (g)”.

b. In paragraph (c) introductory text, by removing from the first sentence the words “according to procedures acceptable to EPA, and for dredged material acceptable to”, and adding, in their place, the words “when bioassay procedures have been approved by EPA, or for dredged material, approved by”;

c. By removing the second and third sentences of paragraph (c)(2) and of paragraph (c)(3) and by adding a new sentence in their place in each paragraph, to read as follows:

**§ 227.6 Constituents prohibited as other than trace contaminants.**

\* \* \* \* \*

(c) \* \* \* (2) \* \* \* If these bioassays involve laboratory testing of organisms, they shall be conducted with appropriate sensitive marine organisms as defined in § 227.27(c), and the procedures used will require exposure of organisms for a sufficient period of time and under appropriate conditions to provide reasonable assurance, based on consideration of the statistical significance of effects at the 95 percent confidence level, that, when the materials are dumped, no significant undesirable effects will occur due to chronic toxicity of the constituents listed in paragraph (a) of this section; and

(3) \* \* \* If these bioassays involve laboratory testing of organisms, they shall be conducted with appropriate sensitive benthic marine organisms, and the procedures used will require exposure of organisms for a sufficient period of time to provide reasonable assurance, based on considerations of statistical significance of effects at the 95 percent confidence level, that, when the materials are dumped, no significant undesirable effects will occur due either to chronic toxicity or to bioaccumulation of the constituents listed in paragraph (a) of this section; and

\* \* \* \* \*

e. By removing paragraph (e) and redesignating paragraphs (f) through (h) as paragraph (e) through (g).

5. Section 227.27 is amended:

a. In paragraph (a)(2), by removing the words “in a bioassay carried out in accordance with approved EPA procedures”;

b. In the first sentence of paragraph (b), by removing the words “using appropriate sensitive marine organisms in the case of the suspended particulate phase, or appropriate sensitive benthic marine organisms in the case of the solid phase”;

c. In paragraph (b), by removing footnote 1 and by revising the last sentence to read as set forth below.

d. By revising paragraphs (c) and (d) to read as follows:

**§ 227.27 Limiting Permissible Concentration (LPC).**

\* \* \* \* \*

(b) \* \* \* If these bioassays involve laboratory testing of organisms, they shall be conducted with appropriate sensitive marine organisms in the case of the suspended particulate phase, or appropriate sensitive benthic marine organisms in the case of the solid phase.

(c) Appropriate sensitive marine organisms means at least two species that together are representative of the following types of organisms: phytoplankton or zooplankton, crustacean or mollusk, and fish. These organisms shall be chosen from among the most sensitive species documented in the scientific literature or accepted by EPA as being reliable test organisms to determine the anticipated impact of the wastes on the ecosystem at the disposal site. If the bioassays involve laboratory testing of these organisms, they shall be run for a minimum of 96 hours under temperature, salinity, and dissolved oxygen conditions representing the extremes of environmental stress at the disposal site, except that phytoplankton or zooplankton may be run for shorter periods of time as appropriate for the organisms tested at the discretion of EPA, or EPA and the Corps of Engineers, as the case may be.

(d) Appropriate sensitive benthic marine organisms means at least two species that together exhibit filter-feeding, deposit-feeding, and burrowing characteristics. These organisms shall be chosen from among the most sensitive species accepted by EPA as being reliable test organisms to determine the anticipated impact on the site.

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**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

RIN 1018-AD62

**Endangered and Threatened Wildlife and Plants; Extension of Comment Period for Proposed Establishment of a Nonessential Experimental Population of California Condors in Northern Arizona**

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

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The U.S. Fish and Wildlife Service (Service) provides notice that the public comment period is extended for the proposal to designate a nonessential experimental population of California condors (*Gymnogyps californianus*) in northern Arizona and southern Utah. This population is proposed to be designated as a nonessential experimental population in accordance with section 10(j) of the Endangered Species Act (Act) of 1973, as amended. The extension of the comment period will allow all interested parties to submit written comments on the proposal.

**DATES:** The current comment period scheduled to close February 29, 1996 is now extended through April 1, 1996.

**ADDRESSES:** Written comments should be sent to the Field Supervisor, U.S. Fish and Wildlife Service, 2321 W. Royal Palm Road, Suite 103, Phoenix, Arizona 85021. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above Service address.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey A. Humphrey, at the above address, 602/640-2720.

**SUPPLEMENTARY INFORMATION:**

**Background**

The Service, in cooperation with the Arizona Game and Fish Department, and the U.S. Bureau of Land Management, proposes to reintroduce California condors (*Gymnogyps californianus*) into northern Arizona. This reintroduction will achieve a primary recovery goal for this endangered species, establishment of a second non-captive population, spatially disjunct from the non-captive population in southern California. Section 10(j) of the Endangered Species Act of 1973 (Act) enables the Service to designate certain populations of