

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 227

[FRL-5617-6]

RIN 2040-AC81

Testing Requirements for Ocean Dumping

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA today is issuing a final rule clarifying portions of the Agency's ocean dumping regulations regarding the number of species to be used in bioassay testing of the solid phase (that part of the material that would settle rapidly to the bottom after dumping). The purpose of today's rule 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 rule confirms the validity of existing solid phase testing practices under which the use of two species is permissible, provided the two species tested together represent the

three categories of organisms specified in the regulations, and will maintain current safeguards for protection of the marine environment. The proposed rulemaking (February 29, 1996) included proposed changes that would have addressed liquid and suspended particulate phase test species, as well as other aspects of the testing requirements. The Agency has limited the scope of today's final rule to clarify only the number of species to be used in solid phase bioassay tests, in a manner consistent with current testing practices and scientific guidance. The Agency has determined that this final rule will provide protection of our ocean waters, without requiring unnecessary tests.

EFFECTIVE DATE: This final regulation becomes effective on September 30, 1996.

ADDRESSES: A copy of the supporting documents for this rule are available for review at EPA's Water Docket, Room 2616, 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 202/260-1952.

SUPPLEMENTARY INFORMATION:

A. Regulated Entities

Entities potentially regulated by this action are persons or entities seeking permits to dump material into ocean waters under the Marine Protection, Research, and Sanctuaries Act, 33 U.S.C. 1401 et seq. That statute currently bans the ocean dumping of industrial wastes (with the exception of waste from tuna cannery operations in American Samoa or Puerto Rico) and also bans ocean dumping of sewage sludge. As a result, the rule would primarily be of relevance to parties seeking permits from the U.S. Army Corps of Engineers for the ocean dumping of dredged material as well as the U.S. Army Corps of Engineers itself. Potentially regulated categories and entities include:

Category	Examples of potentially regulated entities
Industry	<ul style="list-style-type: none">* Ports seeking dredged material ocean dumping permits.* Marinas seeking dredged material ocean dumping permits.* Shipyards seeking dredged material ocean dumping permits.* Berth owners seeking dredged material ocean dumping permits.* Tuna canneries in American Samoa seeking fish waste ocean dumping permits.
State/local/tribal governments	<ul style="list-style-type: none">* Local governments owning ports or berths seeking dredged material ocean dumping permits.
Federal Government	<ul style="list-style-type: none">* US Army Corps of Engineers.* Federal agencies seeking dredged material ocean dumping permits.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the action. This table lists types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your organization is potentially regulated by this action, you should carefully consider whether your organization is subject to the requirement to obtain an ocean dumping permit in accordance with the Purpose and Scope provisions of Section 220.1 of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION, CONTACT** section.

B. Background

On February 29, 1996, the Agency issued a proposal in the Federal Register to clarify certain provisions of

the Agency's ocean dumping regulations relating to bioassay testing requirements (61 FR 7765) under the Marine Protection, Research, and Sanctuaries Act (33 U.S.C. 1401 et seq.) (hereinafter "the Act" or "the MPRSA"). The original deadline for receipt of comments on the proposed rule was April 1, 1996; however, in response to requests from the public for extension of the comment period, the Agency extended the comment period an additional 30 days, resulting in a final deadline for receipt of comments of May 1, 1996 (61 FR 13794, March 28, 1996).

The purpose of the proposal was to clarify regulatory language that was interpreted by the United States Court of Appeals for the Third Circuit in a different manner than EPA intended. See, *Clean Ocean Action v. York*, 57 F.3d 328 (3d Cir. 1995). That opinion raised a degree of uncertainty about the number of species that had been used in the tests conducted on the solid phase of the material in issue before the court,

and the degree to which the Agency retained flexibility to determine when laboratory bioassay testing is required. The proposed rule addressed both the number of test species to be used under the regulations and issues related to when bioassay testing is required. It was not intended to change the evaluative procedures currently used and set out in program guidance, or the substantive criteria used to evaluate ocean dumping permit applications. The proposal was intended to clarify the regulations in a manner consistent with the Agency's longstanding interpretation of the regulations and existing testing practices. For further information on the statutory and regulatory background of the proposal, the reader is referred to the preamble at 61 FR 7766-7767.

The Agency received a number of comments on the proposed rule, some of which expressed support for the proposal and some of which expressed opposition. A summary of all comments received and the Agency's response is

set out in Section D below. The complete text of all comments received and the Agency's response may be found in "Response to Individual Comments Received on the Proposed Rulemaking on Testing Requirements for Ocean Dumping." This document is included as part of the rulemaking record, and can be inspected at the Agency's Water Docket, the location of which is in the ADDRESSES section above.

C. Description of Final Rule

The Agency has elected to limit the scope of today's final rule to only the issue of the number of species to be used in solid phase tests. Today's rule does not take final action on the parts of the proposal that addressed other testing issues. Although a number of commenters supported proceeding with the entire scope of the proposed rule, as is discussed further below, a number of other commenters were concerned about the potential implications of the other aspects of the proposal. EPA will be investing at least nine months in a process for all affected groups to help the Agency review the ocean disposal testing requirements and ensure that any further revision reflects both sound policy and science.

Accordingly, today's final rule is limited to amending § 227.27(d) of the regulations, which addresses the number of test species to be used in solid phase testing by defining "appropriate sensitive benthic marine organisms" for use in solid phase laboratory bioassay tests. The organisms to be used are defined in existing § 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...." By describing a range of characteristics that the test species must represent for different exposure pathways, the regulations protect the marine environment by considering the different sensitivities to environmental contaminants exhibited by marine organisms with these different characteristics [Reference 1].

The Agency's approved testing procedures provide for the use of no fewer than two different species that together cover the three characteristics specified in 40 CFR 227.27(d). For example, the marine worm, *Nephtys incisa*, is both a deposit-feeder and a burrower [Reference 2], and the amphipod crustacean, *Ampelisca abdita*, is both a filter-feeder and a deposit-feeder [Reference 3]. Because 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), the proposal would have amended 40 CFR 227.27(d) to reflect more clearly EPA's longstanding interpretation of that provision, i.e., that at least two species may be used in solid phase bioassay testing, provided that together they are representative of the three categories of organisms specified in the regulations. The proposal would have done this by removing the words "one species each" from Section 227.27(d) where they modified the three groups of characteristics, and replaced them with "at least two." The proposal would not have changed the requirement that the test species be "chosen from among the most sensitive species" accepted as reliable test organisms.

In addition, although the issue of the number of test species that may be used was addressed by the Third Circuit in the context of the solid phase testing provisions of § 227.27(d), the proposed rule would have made similar changes in 40 CFR 227.27(c) with regard to liquid and suspended particulate phase testing. This was because § 227.27(c) similarly defines "appropriate sensitive marine organisms" to be used in such testing 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 * * *."

As is discussed below, some commenters preferred the use of three species, and expressed concern that allowing the use of multi-characteristic organisms might result in under-estimation of the potential effects of material proposed for disposal. As explained in the discussion of comments below, however, EPA has determined that for the solid phase, the use of two appropriately sensitive species that together are representative of the three categories of organisms specified in the regulations is technically appropriate for use in the ocean dumping regulatory program, and that the regulations should unambiguously allow for such a solid phase testing approach. At the same time, the regulations do not restrict the Corps' and EPA's ability to require testing of more than two species where appropriate.

However, because as described below, the current testing guidance calls for the use of three species for liquid and suspended particulate phase testing, and in light of the concerns expressed over the proposed rule, the Agency has

elected not to include changes to § 227.27(c) as part of today's final rule. That section of the regulations was not specifically at issue before the Third Circuit or addressed in its opinion. The Agency continues to stand by its longstanding interpretation of the existing regulatory language. However, given that the existing practice and guidance for liquid and suspended phase testing currently employ three species testing, that § 227.27(c) was not addressed in the Third Circuit opinion, and the overall concerns expressed by some commenters on the proposed rule, the Agency does not believe it is necessary to include clarifying changes to § 227.27(c) in today's final rule. The remainder of the test species discussion in today's preamble thus focuses on solid phase issues.

While the ocean dumping regulations provide for a comprehensive assessment of the potential environmental impacts of disposal, evaluation of the material to be disposed plays an important role in environmental assessments. The use of laboratory tests forms a major part of the regulatory evaluations of the potential impacts of discharges of material into the aquatic environment [Reference 1]. It is generally recognized that there is no one "white rat" that can predict the potential impact of the disposal of all material on all organisms in all marine ecosystems. This difficulty can be addressed by conducting multiple laboratory tests. However, simply conducting more tests may provide redundant data and may waste resources [Reference 4]. Decisions regarding how many and what kinds of organisms to test are a matter of complex scientific judgment. Experience gained from conducting multiple laboratory tests with a large number of species can be used to determine the relative sensitivity of testing organisms [Reference 5]. In addition, species sensitivity must be understood within the context of the exposure of the organism to the material during the test [Reference 5]. With information about the relative sensitivity of a large number of organisms for different exposures to a material, an optimum suite of testing organisms can be identified. These factors were all thoroughly evaluated by the Agency during the development of the current guidance for testing, and the species recommended for use by that guidance reflects this analysis.

The current recommendations of EPA and the U. S. Army Corps of Engineers for testing organisms are contained in the guidance manual entitled, *Evaluation of Dredged Material Proposed for Ocean Disposal—Testing*

Manual [Reference 6], commonly known as the "Green Book." To assess the potential water column impacts associated with the liquid and suspended particulate phase, the Green Book recommends that toxicity tests be conducted on three appropriately sensitive water column species representing phytoplankton or zooplankton, crustacean or mollusk, and fish [Reference 6]. To assess benthic impacts (impacts to organisms that live on the sea bottom), the Green Book recommends that a 10-day acute toxicity test and a 28-day bioaccumulation test be conducted on the solid phase with at least two "appropriately sensitive marine benthic species" for the type of test conducted (i.e., two acute toxicity organisms for acute toxicity tests and two bioaccumulation organisms for bioaccumulation tests). Thus, current guidance recommends that a total of three species be tested for water column effects, and at least two "appropriate sensitive marine benthic species" be tested for both bioaccumulation and toxicity in the solid phase of the dumped material. Thus, more than two species are tested in the solid phase, and all three species characteristics identified in the regulations are represented in each of the two types of solid phase testing. All three water column species characteristics (phytoplankton or zooplankton, crustacean or mollusk, and fish) and all three solid phase species characteristics (filter-feeding, deposit-feeding, and burrowing) are therefore represented in these tests. The species used are all selected from among the most sensitive and reliable for the type of test in which they are used (acute toxicity or bioaccumulation).

For a particular type of test (e.g., acute toxicity or bioaccumulation tests), the scientific community has generally arrived at a consensus on the most appropriate organisms for testing [References 2, 3, 7, and 8]. For solid phase acute toxicity tests, the amphipods *Ampelisca abdita*, *Eohaustorius estuarius*, *Leptocheirus plumulosus*, and *Rhepoxynius abronius* are documented in the scientific literature as being reliable and sensitive test organisms, and are currently the only organisms subject to an EPA standard method for sediment acute toxicity tests [Reference 3]. Standard methods are desirable because they promote consistency among the different laboratories running the tests. These organisms have been used extensively in the study of aquatic sediment contamination, and have been shown to be good indicators of adverse

ecological effects to benthic communities [References 9–17]. All four of these amphipods share similar sensitivity to contaminants [Reference 3]. However, all four amphipods are not equally appropriate for all sediments; each organism has particular tolerances for sediment grain size, salinity, and other natural characteristics of sediment [Reference 3]. The Agency is not currently aware of reliable infaunal organisms (i.e., organisms living in the sediment and thus in direct contact with sediment contaminants) that are more sensitive than these amphipods for solid phase acute toxicity testing. Nevertheless, the Agency currently recommends that, in addition to the testing of at least one amphipod, at least one additional appropriate sensitive benthic marine organisms (e.g., a mysid shrimp, or a marine polychaete) be tested in the solid phase [Reference 6]. The Green Book has made this recommendation to provide additional assurance that potential interspecies variability is addressed, and also to ensure that the three characteristics listed in Section 227.27(d) are covered. The Agency is not aware of any information to suggest that the regulations need to mandate testing on a third organism to provide adequate information on the potential acute toxicity of organisms exposed to the solid phase of the material.

Where two species are used in acute toxicity testing of the solid phase, two species are used in bioaccumulation testing of the solid phase, and the results of these tests are assessed collectively with other tests and assessments, there is ample information to ensure environmental protection, and the requirements of the Act are fully met. This is particularly true because the number of species used in biological tests is only one of several criteria used to satisfy the ocean dumping regulations before material may be disposed of in marine waters.

The regulations address the protection of marine ecosystems not only through permitting criteria contained in 40 CFR Part 227, but also by selecting disposal sites so as to minimize the effects of disposal activities on the marine environment (See 40 CFR Part 228). The Part 227 criteria include the testing provision being clarified in today's rule, which is used in assessing whether the material is suitable for ocean disposal and will not cause significant undesirable effects on the environment. Direct measurement of the effects of pollution on complex ecosystems is very difficult. While laboratory testing of the potential effects of pollutants on marine organisms does not directly

provide information about ecosystem responses, it can integrate the additive and interactive effects of complex mixtures of chemicals, and examine a variety of endpoints over different exposure periods to predict potential impact at several levels of biological organization for sensitive surrogate species [Reference 9]. Moreover, the species used in testing under the current guidance (e.g., amphipods and polychaetes) play significant roles in the food chain and are ecologically important.

EPA has determined that the variety of appropriately sensitive test organisms used to determine suitability of material proposed for ocean dumping, through water column and solid phase tests that evaluate acute toxicity and potential bioaccumulation, provide sufficient information to determine whether the material proposed for dumping meets the statutory standard of no unreasonable degradation of human health or the marine environment. The final evaluation is a conservative integration of the results from all these tests. In order for a material to be found suitable for dumping, all of the tests performed must indicate that the criteria are met. For instance, if only one of the species used is determined to fail acute toxicity testing, the material is deemed unsuitable for ocean dumping. Given the total testing and site selection process, the use of two appropriately sensitive species for solid phase testing will generally be more than sufficient to protect the environment.

However, given the concern expressed by several commenters, today's final rule is further clarified in two aspects, while still allowing for the use of two species. The first sentence in proposed § 227.27(d) has been revised to delete the phrase "at least two" species, and instead to substitute the phrase "two or more" species. This change is made to make it perfectly clear that the regulations are not intended to limit testing to only two species, and that the Agency retains the authority to require the use of more than two species. In addition, the second sentence of proposed § 227.27(d) is revised from the proposal by adding language to clarify that the species are to be "chosen from among the species that are most sensitive for each type they represent * * *". This change is made in response to concerns expressed by some commenters that some multi-characteristic organisms might not be sensitive for each characteristic they represent. These commenters expressed concern that an organism that was both a filter-feeder and a deposit-feeder might not be among the most sensitive

filter-feeders and among the most sensitive deposit-feeders. As is discussed below, the multi-characteristic organisms identified in the current testing guidance, such as the amphipod, are among the most sensitive and reliable organisms for all the feeding types they are used to represent, and fully comport with this revised provision.

D. Summary of Comments and Agency Response

The comments on the proposed rule generally fell into four broad categories. These categories and the Agency responses are set out below.

(1) *Comment period deadline:* A number of commenters requested additional time to consider the proposal, and submitted requests to extend the public comment period by a certain number of days, or requests that the Agency indefinitely suspend work on the rule. Other commenters took a different view and requested that the Agency not extend the comment period at all, urging the Agency to act expeditiously to complete the rulemaking.

As explained in the preamble to the proposed rule, the Agency originally believed that a 30-day comment period was appropriate because the proposed rulemaking was intended to clarify, not substantively change, the Agency's longstanding interpretation and implementation of the ocean dumping regulations. After carefully considering the comments received prior to the close of the original 30-day comment period, the Agency acted to extend the comment period for an additional 30 days (61 FR 13794). The Agency believes that allowing a 60-day comment period is reasonable and appropriate, since the proposal was intended to clarify the regulations in a manner consistent with the Agency's longstanding interpretation and its current testing manuals. The Agency has further responded to the concern expressed by some commenters regarding the need for additional time by limiting the scope of today's final rule to the number of species to be used in solid phase bioassay testing. The Agency intends to invest at least nine months in a process for all affected groups—industry, labor, and environmental groups—to help the Agency review the ocean disposal testing requirements and ensure that any further revision reflects both sound policy and science. See, letters of July 24, 1996, from EPA Administrator Browner, Transportation Secretary Peña, and Army Secretary West, to Congressmen Frank Pallone, Robert

Menendez, and Robert Torricelli, which are included in the rulemaking record. EPA believes that such an approach, under which issues related to the number of solid phase test species to be used are expeditiously resolved, while remaining issues are included in a review of ocean disposal testing requirements that will involve further discussion among stakeholders, appropriately addresses the range of comments received related to the deadline for public comments. EPA expects that the issues to be addressed in this review, as well as their relative priority, will be identified as part of the definition of this process.

(2) *Effect of proposed rule on environmental protection of the oceans:* A number of commenters expressed concern that the proposed rule would result in a weakening of the existing regulations' protection of the oceans. Other commenters disagreed with this view, agreeing with EPA's position that the proposal was a clarification of the regulations in a manner consistent with Agency practice. Unlike the proposal, today's final rule is limited to the issue of the number of solid phase test species to be used. Thus, those concerns unrelated to the number of species used are not at issue in today's final rule.

To the extent that some commenters raised general concerns about reduced protection of the oceans resulting from the use of two rather than three species in bioassay tests, the Agency notes that the use of two species for solid phase testing does not reflect a change from existing practice, and is fully consistent with the most recent testing manual, the Green Book [Reference 6]. In addition, as is explained elsewhere in this preamble, the Agency has determined that allowing the use of two appropriately sensitive species that together represent the three categories of organisms specified by the regulations, permits a sufficient evaluation of the solid phase of the material proposed for disposal, and is fully protective of the marine environment. Furthermore, under the regulations, the Agency retains the authority to require solid phase testing on more than two species, whenever it believes two species would not provide for an adequate evaluation of the potential impacts to the marine environment. Finally, to the extent these commenters were concerned about the number of species used in liquid or suspended particulate phase testing, as previously discussed, the Agency does in fact include three species for such tests in the national guidance, and today's final rule makes no changes to the relevant regulatory provision.

(3) *Comments unrelated to the number of test species to be used:* A number of specific comments were received on testing issues unrelated to the number of test species, including concerns about the use of models, the use of alternatives to laboratory bioassays, and concerns that the proposal gave the Agency too much discretion with regard to what tests to require. Today's final rule addresses only the number of test species to be used in the solid phase. As stated above, the Agency will be investing at least nine months in a process with affected stakeholders to review the ocean dumping testing requirements. To the extent such issues are raised in that process, EPA will carefully consider those comments.

(4) *Comments on number of species to be used:* One of the comments on the number of species to be used pointed to language in § 102(a) of the Marine Protection, Research, and Sanctuaries Act (MPRSA) addressing the effect of dumping on plankton, shellfish, and wildlife; another comment pointed to similar language addressing the effect of dumping on marine ecosystems. These commenters suggested that the use of two species would be contrary to the specified statutory provisions. The Agency does not agree with this comment. MPRSA § 102(a) does not require that tests be conducted on each of the organisms enumerated, or on marine ecosystems as part of the permitting process, but rather requires that the potential effects of dumping are factors to be considered by EPA in developing the ocean dumping criteria. The Agency has considered the § 102(a) requirements in developing the ocean dumping regulations. For example, 40 CFR § 227.27(a) requires the use of marine water quality criteria in evaluating the suitability of material for dumping. Those criteria were developed after examination of contaminant effects on a wide range of organisms, including fish, shellfish, and plankton [Reference 20]. In addition, testing manuals developed for the ocean dumping regulations identify a range of species for testing, including fish, shellfish, zooplankton, crustaceans and worms [Reference 6]. Finally, the regulations address not only the evaluation of material proposed for disposal as part of the permitting process, but also the selection of ocean disposal sites. The site selection criteria contain provisions protective of marine ecosystems that seek to localize potential impacts, and to avoid locating disposal sites in sensitive areas of the marine

environment. 40 CFR Sections 228.5 and 228.6.

Other commenters questioned whether two species alone were representative of complex marine ecosystems. These commenters did not specifically assert that three species would be fully representative of entire marine ecosystems; however, the commenters appeared to believe that the more species tested, the better the representation of entire marine ecosystems. Depending upon the sensitivity and types of organisms chosen, the Agency agrees with the principle that the greater the diversity of species tested, the more likely they are to be representative of complete ecosystems. The reason so much emphasis is placed on selecting organisms for testing from among the most sensitive, is that in so doing one is assured of protecting the majority of species in the ecosystem. Although the two species may not react to contaminants the same way as all the species in a marine ecosystem, if they are selected from among the most sensitive species they will represent the potential impacts to the marine ecosystem. Furthermore, in implementing a nationwide regulatory program, the Agency also must take into account the difficulty and expense of performing bioassay tests, potential variability in results if non-standardized test species are used, and the large number of tests that may need to be run for large volumes of spatially heterogeneous material, such as dredged material. As explained elsewhere in this preamble, the Agency has determined that for the solid phase, the use of two appropriately sensitive organisms representing three characteristics specified in the regulations normally is sufficient to determine the potential for a dumped material to unreasonably degrade the marine environment, or to endanger human health. Moreover, the regulations do *not* limit the authority to require testing of additional species when warranted.

The Agency's ocean dumping regulations address the protection of marine ecosystems both through permitting criteria contained in 40 CFR Part 227, and site selection criteria contained in 40 CFR Part 228, and not solely through the number of species to be tested. These criteria provide for a thorough assessment of the physical and chemical characteristics of the material, and a thorough evaluation of the suitability of placing that material at a specific location, which is selected after careful assessment of the surrounding environment. In addition, the testing regulations themselves require the

selection of appropriately sensitive and reliable test organisms to predict potential impacts at the disposal site. By requiring that appropriately sensitive organisms are used, the regulations assure that species used in tests will detect potential effects of dumped material on marine life. The organisms recommended for use are identified in the testing manual that implements the regulations [Reference 6]. The organisms recommended are among the most sensitive suitable for use in a regulatory testing program; these organisms include amphipods, shrimp, marine polychaetes, and molluscs. These animals are recognized in the scientific literature as being sensitive predictors of impacts [References 2, 3, 6, and 8]. Using these organisms further protects the ecosystem because these organisms are ecologically important, based on abundance in the environment and their role in the structure of the marine community.

Some commenters supporting the use of three species pointed to EPA's Technical Support Document for Water Quality-based Toxics Control [Reference 21] (hereafter referred to as "the TSD"), which addresses bioassay testing in the Clean Water Act's (CWA) Section 402 point source discharge permitting program. These commenters believe that the TSD called for the use of at least three species in bioassay testing. However, although that manual does generally recommend the use of three species, it also specifically recognizes that the optimum number of species may be fewer, and the relevant CWA regulations (40 CFR § 136.3) do not specify a particular number of species to be used. It also should be noted that the TSD addresses water column bioassays, that the Green Book for the ocean dumping program also recommends the use of three water column species for such tests, and that today's final rule does not address water column testing. Finally, the Agency also notes that for the solid phase of the dumped material, the Green Book recommends use of both a 10-day acute toxicity test and 28-day bioaccumulation test [Reference 6, p. 3–12]. Each of these two tests is conducted with at least two "appropriate sensitive marine benthic species" for the type of test conducted [Reference 6, pp. 11–10 and 12–2]. Thus, more than two species are tested in the solid phase, and all three species characteristics identified in the regulations are represented in each of the two types of solid phase testing.

Other commenters raised concerns that allowing one of the species used to represent two of the three characteristics specified in the regulations might result

in under-estimation of potential effects. These commenters indicated that organisms that are both filter- and deposit-feeders would not represent how organisms that are primarily filter-feeders would respond. The Agency agrees with the commenter that organisms can alter their behavior in response to environmental conditions, including food availability; this point is supported in the literature [Reference 22]. The bioavailability, and ultimately the toxicity, of a contaminant in a sediment may depend upon factors related to how closely an organism is in contact with the sediment, e.g., whether it ingests sediment, or whether it is in contact with the sediment or interstitial water [Reference 18, p. 120]. Behavior that minimizes contact by the organism with the sediment, such as filtering overlying water, will significantly reduce an organism's exposure to contaminants, and will significantly minimize the potential for observing an effect in the organism due to contaminants in the sediment [References 18 and 19]. The Green Book emphasizes that organisms tested in solid phase bioassays should be in intimate contact with the sediment or should ingest sediment [Reference 6, pp. 11–10 and 12–2]. Because an exclusively filter-feeding organism need not be in intimate contact with the sediments, and would have to be fed during the test since there would be nothing to filter (decreasing sediment exposure due to ingestion), the Agency has determined that solid phase testing of such organisms would not yield significant additional results.

The Agency is not aware of, nor do the commenters offer, documentation to explain their belief that true filter-feeders may be more sensitive than species that represent both filter-feeding and deposit-feeding modes. Moreover, based on over twenty years of experience using toxicity tests in the ocean dumping program, the Green Book strongly recommends use of infaunal amphipods as appropriate sensitive benthic marine organisms [Reference 6, p. 11–10]. These organisms represent both filter-feeding and deposit-feeding modes, and are extensively used in the scientific community to study the effects of sediment contamination. They are also among the most sensitive species documented in the scientific literature as being reliable test organisms [References 9–17]. Because of widespread use within the scientific community, a number of standardized protocols have been developed for the amphipod toxicity test [References 3, 7,

8, and 23], and EPA recognizes amphipods as a recommended species for solid phase acute toxicity testing in the Green Book [Reference 6, p. 11–10].

In summary, EPA has determined that the variety of appropriately sensitive test organisms used to determine suitability through water column and solid phase tests that evaluate acute toxicity and potential bioaccumulation provide an adequate basis to determine if a material proposed for dumping will unreasonably degrade the marine environment or endanger human health. The final evaluation is a conservative integration of the results from all these tests. In order for a dredged material to be found suitable for dumping, all of the tests performed must indicate that the criteria are met. For instance, if one of the species used is determined to fail acute toxicity testing, the material is deemed unsuitable for ocean dumping. Given the overall testing and site selection process, the use of two appropriately sensitive species for solid phase testing will generally be more than sufficient to protect the environment.

E. References

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Compliance With Other Laws and Executive Orders

A. 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 affect in a material way the economy, 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.

This rulemaking should have minimal impact on permittees. The rulemaking merely clarifies ocean dumping testing requirements in a manner consistent with current testing practices, under which the use of two solid phase test species is permissible, provided that the two species together represent the three categories of organisms specified in the regulation. It thus has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866, and is therefore not subject to OMB review.

B. Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996

The Regulatory Flexibility Act (RFA) provides that, whenever an agency promulgates a final rule under 5 U.S.C. § 553, an agency must prepare a regulatory flexibility analysis (RFA)

unless the head of the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. §§ 604 & 605. EPA has determined that today's rule will not have a significant economic impact on small entities because the rule does not change current procedures for testing dredged material in order to evaluate its suitability for ocean dumping. The rule merely clarifies these testing requirements in a manner consistent with the Agency's longstanding interpretation of its own regulations. Consequently, EPA's action will not impose any additional economic burden on small entities such as small private dredging operations that seek authorization for the dumping of dredged materials. In fact, to the extent that it relieves small entities of any potential for testing more species than required by Agency practice, the rule reduces any potential economic impact on small private dredgers. For this reason, the Administrator certifies, pursuant to section 605(b) of the Regulatory Flexibility Act, that the rule will not have a significant economic impact on a substantial number of small entities.

C. 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 rule would not establish or modify any information or record-keeping requirements, it is not subject to the requirements of the Paperwork Reduction Act.

D. The Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205

of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or sections 202 and 205 of the UMRA. As is explained elsewhere in this preamble, the rule does not change current procedures for testing dredged material in order to evaluate its suitability for ocean dumping. The rule merely clarifies these testing requirements in a manner consistent with the Agency's longstanding interpretation of its own regulations. Accordingly, it imposes no new enforceable duty on any State, local or tribal governments or the private sector. Even if today's rule did contain a Federal mandate, this rule will not result in annual expenditures of \$100 million or more for State, local, and tribal governments in the aggregate, or the private sector. Thus today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

For the foregoing reasons, EPA also has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus the requirements of Section 203 of UMRA do not apply to today's rule.

E. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule

and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

F. Administrative Procedure Act

The Administrative Procedure Act (APA), 5 U.S.C. 551 et seq., generally requires that substantive rules be published 30 days prior to their effective date except:

"(1) A substantive rule which grants or recognizes an exemption or relieves a restriction; * * *

or (3) as otherwise provided by the agency for good cause found and published with the rule." 5 U.S.C. 553(d).

EPA is issuing today's final rule as immediately effective under the provisions of 5 U.S.C. 553(d). As is explained elsewhere in this preamble, today's final rule is intended to clarify the ocean dumping regulations' testing requirements in a manner consistent with the Agency's longstanding interpretation, existing testing guidance, and current program practice. In the absence of an effective rule clarifying the number of species to be used in ocean dumping testing, Federal projects and permit applicants affected by the Third Circuit opinion in *Clean Ocean Action v. York*, supra, will face uncertainties in developing their future testing plans, and projects for which testing has been completed will remain clouded by the uncertainties stemming from the Third Circuit opinion. Because today's rule is intended to confirm, not alter, the status quo, the Agency believes that there is "good cause" under 5 U.S.C. 553(d)(3) to issue today's rule as immediately effective. Moreover, today's rule confirms that the ocean dumping regulations in fact allow the use of two species, not three, in solid phase bioassay testing. The effect of today's rule is to resolve uncertainties resulting from the opinion of the Third Circuit in a manner that avoids unnecessary testing; thus, the immediate effectiveness of today's rule also is warranted under 5 U.S.C. 553(d)(1).

List of Subjects in 40 CFR Part 227

Environmental impact statements, Environmental protection, Water pollution control.

Dated: September 23, 1996.

Carol M. Browner,
Administrator.

For the reasons set out in this preamble, part 227 of title 40 of the Code of Federal Regulations is amended as follows:

PART 227—[AMENDED]

1. The authority citation for part 227 continues to read as follows:

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

§ 227.27 [Amended]

2. Section 227.27 is amended in paragraph (d) by removing the words “at least one species each representing” and adding, in their place, the words “two or more species that together represent” and by removing the words “species chosen from among the most sensitive species” and adding, in their place, the words “characteristics. These organisms shall be chosen from among the species that are most sensitive for each type they represent, and that are documented in the scientific literature and”.

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