

## ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL-----]

### **Historic Area Remediation Site (HARS)-Specific Polychlorinated Biphenyl Worm Tissue Criterion**

**AGENCY:** Environmental Protection Agency

**ACTION:** Final rule

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**SUMMARY:** The U.S. Environmental Protection Agency (EPA) today modifies the designation of the Historic Area Remediation Site (hereinafter referred to as HARS) by establishing a HARS-specific worm tissue polychlorinated biphenyl (PCB) criterion of 113 parts per billion (ppb) for use in determining the suitability of proposed dredged material for use as Remediation Material. This amendment to the HARS designation establishes a pass/fail criterion for evaluating PCBs in worm tissue from bioaccumulation tests performed on dredged material proposed for use at the HARS as Remediation Material. The PCB criterion will remain in effect until after EPA and the U.S. Army Corps of Engineers (USACE) complete their review of the 2002 scientific peer review comments on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material for human health effects, conduct and respond to the comments on the future scientific peer review on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material for ecological effects, and revise, as necessary, the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use as Remediation Material at the HARS for all contaminants of concern in accordance with the September 27, 2000 Memorandum of Agreement (MOA) (USEPA, 2000a) between EPA and the USACE.

Among other things, the September 27, 2000 MOA established an interim guidance value of 113 ppb for PCBs in the tissues of bioassayed worms, to be considered when determining whether proposed dredged material from the New York/New Jersey Harbor is acceptable for placement at the HARS. At the time of the MOA, the agencies agreed that, while the peer review was not complete, the implementation of this interim change was warranted based upon existing information. This change is designed to ensure that the remedial goals of the HARS will be met.

Upon signing the MOA, EPA withdrew its concurrence (given prior to the MOA) for the U.S. Gypsum Corporation to place dredged material at the HARS as Remediation Material. U.S. Gypsum brought suit against the USACE and EPA, and in a July 10, 2002 decision, the U.S. District Court, Southern District of New York, held that the announcement of the 113 ppb interim value in the MOA was *de facto* rulemaking that should have been the subject of public notice and comment. This rulemaking is intended to address the court's concerns.

**DATES:** This final regulation is effective on April 16, 2003.

**ADDRESSES:**

1. Electronically. You may obtain electronic copies of this document and various support documents from the EPA home page at the Federal Register <http://www.epa.gov/fedrgstr/>, or on EPA Region 2's homepage at: <http://www.epa.gov/region02/water/dredge>

2. In person. The complete administrative record for this action has been established and includes supporting documentation as well as printed, paper versions of electronic comments. Copies of information in the record are available upon request. The official record of this rulemaking is available for inspection at the EPA Region 2 Library, 16th Floor, 290 Broadway, New York, NY 10007-1866. For access to the docket materials, call Rebecca Garvin at (212) 637-3185 between 9:00 am and 3:30 pm Monday through Friday, excluding legal holidays, for an appointment. The record is also available for viewing at EPA Region 2's Edison NJ Office Library 2890 Woodbridge Avenue, Building 209, MS-245, Edison, New Jersey 08837. For access to the docket materials at this facility, call Ms. Margaret Esser (732) 321-6762 between 9:00 am and 3:30 pm Monday through Friday, excluding legal holidays, for an appointment. The EPA public information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

**FOR FURTHER INFORMATION CONTACT:** Mr. Douglas Pabst, Team Leader, Dredged Material Management Team, U.S. Environmental Protection Agency Region 2, 290 Broadway, New York, NY 10007-1866 (E-mail [pabst.douglas@epa.gov](mailto:pabst.douglas@epa.gov)) (212) 637-3797.

**SUPPLEMENTARY INFORMATION:**

General Information:

**I. Regulated Entities**

Entities potentially affected by this action include those who might have sought or will seek permits or authorizations to place dredged material into ocean waters at the HARS for purpose of remediation, under the Marine Protection, Research, and Sanctuaries Act, 33 U.S.C. 1401 *et seq.* (hereinafter referred to as the MPRSA). The rule would primarily be of relevance to entities in the

New York-New Jersey Harbor and surrounding area seeking permits from the USACE to place Remediation Material at the HARS, as well as the USACE itself. Potentially affected categories and entities seeking to use the HARS include:

<b>Category</b>	<b>Examples of potentially affected entities</b>
<b>Industry.....</b>	<p><b>Ports/facilities in NY/NJ Harbor and surrounding areas seeking MPRSA permits for dredged material to be placed at the HARS.</b></p> <p><b>Marinas in the NY/NJ Harbor and surrounding areas seeking MPRSA permits for dredged material to be placed at the HARS.</b></p> <p><b>Shipyards in the NY/NJ Harbor and surrounding areas seeking MPRSA permits for dredged material to be placed at the HARS.</b></p> <p><b>Berth owners in the NY/NJ Harbor and surrounding areas seeking MPRSA permits for dredged material to be placed at the HARS.</b></p>
<b>State/local/tribal governments.....</b>	<p><b>Local governments owning ports or berths in the NY/NJ Harbor and surrounding areas seeking MPRSA permits for dredged material to be placed at the HARS.</b></p>
<b>Federal Agencies.....</b>	<p><b>US Army Corps of Engineers for its proposed dredging projects in NY/NJ Harbor and surrounding areas to be placed at the HARS.</b></p> <p><b>Other Federal agencies (e.g. U.S. Navy) seeking MPRSA permits for dredged material from NY/NJ Harbor and surrounding areas to be placed at the HARS.</b></p>

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities

likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your organization is affected by this action, you should carefully consider whether your organization is required to obtain a MPRSA permit (See 40 CFR 220.1), and you wish to use the HARS. If you have any questions regarding applicability of this action to a particular entity, please consult the person listed in the preceding “FOR FURTHER INFORMATION CONTACT” section.

Other entities potentially affected by today's final rule would include commercial and recreational fishing interests using New York Bight Apex fishing and shellfishing grounds. However, by establishing a pass/fail interim PCB tissue criterion that is approximately 75 percent lower than the previously established 400 ppb worm tissue guideline for remediation of areas adversely impacted by historic disposal activities (see discussion below), any effects of today's final rule on fishery and shellfish resources would be expected to be positive.

## **II. Background**

On October 8, 2002 EPA proposed modifying the designation of the HARS by establishing a HARS-specific worm tissue PCB criterion of 113 ppb for use in determining the suitability of proposed dredged material for use as Remediation Material. (67 FR 62659).

The MPRSA was enacted in 1972 to address and control the dumping of materials into ocean waters. Title I of MPRSA authorized EPA (and the USACE in the case of dredged material) to regulate dumping in ocean waters. Since the MPRSA was enacted, and through its subsequent

amendments (including the Ocean Dumping Ban Act of 1988, which prohibited ocean dumping of sewage sludge and industrial waste), dumping in the New York Bight has been dramatically reduced.

With few exceptions, the MPRSA prohibits the transportation of material from the United States for the purpose of ocean dumping except as may be authorized by a permit issued under the MPRSA. The MPRSA divides permitting responsibility between EPA and the USACE. Under Section 102 of the MPRSA, EPA has responsibility for issuing permits for all materials other than dredged material (e.g., fish wastes, burial at sea). Under Section 103 of the MPRSA, the Secretary of the Army has the responsibility for issuing permits for the ocean dumping of dredged material. This permitting authority has been delegated to the USACE. Determinations to issue Section 103 MPRSA permits for dredged material are subject to EPA review and concurrence.

Section 102(c) of the MPRSA provides that EPA shall designate recommended times and sites for ocean dumping, and Section 103(b) further provides that the USACE shall use such EPA designated sites to the maximum extent feasible. Regulations implementing these and other provisions of MPRSA are set forth at 40 CFR Parts 220 through 229. 40 CFR Part 228 provides that EPA's designation of an ocean dumping site is accomplished by promulgation of a site designation specifying the site. On October 1, 1986, the Administrator delegated the authority to designate/de-designate ocean dumping sites for dredged material to the Regional Administrator of the Region in which the site is located. In accordance with that authority, EPA Region 2 designated the HARS in September 1997 for placement of dredged material suitable for use as Material for Remediation, 40 CFR 228.15(d)(6); 62 FR 46142 (August 29, 1997). Pursuant to that designation, use of the HARS is restricted to dredged material determined to be suitable for use as Material for Remediation.

Material for Remediation, or Remediation Material, is defined in 40 CFR 228.15 (d)(6)(A) as material “selected so as to ensure it will not cause significant undesirable effects including through bioaccumulation or unacceptable toxicity, in accordance with 40 CFR 227.6.” The HARS was designated for continuing use until EPA determines that the PRA (Primary Remediation Area: a nine square nautical mile area to be remediated) has been sufficiently capped with at least 1 meter of the Material for Remediation. This Remediation Material is, “uncontaminated dredged material (i.e., dredged material that meets current Category I standards and will not cause significant undesirable effects including through bioaccumulation)” (Preamble to HARS designation Final Rule 62 FR 46142). The HARS is being managed to reduce impacts of historical disposal activities at the site to acceptable levels in accordance with 40 CFR 228.11 (c).

On September 27, 2000, EPA and the U.S. Army Corps of Engineers (USACE) entered into a Memorandum of Agreement (MOA) that announced a schedule and a process by which EPA and USACE would review the science and the guidelines used in the evaluation of dredged material proposed for placement as Remediation Material at the HARS. Specifically, the Agencies committed to the shared objective of completing the scientific peer review process initiated by EPA, and responding to input from both the peer review and the public.

EPA is today modifying the HARS designation (40 CFR 228.15(d)(6)) by establishing a HARS-specific worm tissue PCB criterion of 113 ppb for dredged material proposed for use as Material for Remediation, pursuant to 40 CFR 228.10 and 228.11(c). This value will remain in effect until after EPA and the U.S. Army Corps of Engineers (USACE) complete their review of the 2002 scientific peer review comments on the HARS testing evaluation process used for bioaccumulation data

from dredged material proposed for use at the HARS as Remediation Material for human health effects, conduct and respond to the comments on the future scientific peer review on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material for ecological effects, and revise, as necessary, the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use as Remediation Material at the HARS for all contaminants of concern in accordance with the September 27, 2000 MOA between EPA and the USACE. It should be noted that MPRSA site designation does not constitute or imply EPA's approval of the placement of particular material at the site. Before placement of the Material for Remediation at the HARS may commence, the USACE must evaluate permit applications according to EPA's Ocean Dumping Regulations and obtain EPA's concurrence.

### **III. Public Comments**

In the preamble to the proposed rule, EPA requested public comment by November 8, 2002, and held two public hearings (attended by an estimated total of 120 people) as follows:

October 28, 2002, at 7:00 PM: Monmouth Beach Municipal Auditorium, 22 Beach Road, Monmouth Beach, New Jersey, 07750 (16 individuals presented testimony)

October 29, 2002, at 2:00 PM: EPA Region 2 NYC Office, Conference Room 27A, 290 Broadway, NY, NY 10007-1866 (five individuals presented testimony)

In addition to the testimony and comments provided at the hearings, EPA also received 220 sets of written comments on the proposed action.

Dredging and remediation of the HARS has proven to be a controversial and complex issue in recent years. As would be expected in light of such controversy, EPA received both supportive and non-supportive comments. In developing the final rule, EPA reviewed and considered all the written comments as well as those received verbally at the two public hearings. Most of the comments received were e-mails from elected officials, local governments, citizens and environmental/public interest groups that expressed, to varying degrees, support for the 113 ppb HARS-specific worm tissue PCB criterion. Many of these comments requested that the proposed rule be adopted without change. Thus, the 113 ppb HARS-specific PCB worm tissue criterion appears to be acceptable to the majority of those who provided comments. Approximately 40 commenters requested an end to ocean dumping and placement of dredged material at the HARS; for these commenters, the 113 ppb HARS-specific PCB worm tissue criterion appears not to have been sufficiently conservative. Approximately 20 comment letters were critical and non-supportive. Although in the minority based upon number of comments received, they presented the majority of issues raised. These non-supportive comment letters were from the USACE, New York Shipping Association, New York City Economic Development Corporation, private marina owners, ferry operators, dredging applicants, and other business groups. These comment letters requested that EPA not finalize the proposed rule until completion of the human health and ecological scientific peer review process. (That process commenced in 1998, and is expected to be completed in four to five more years.) The non-supportive comments had similar criticism of the proposed rule. Most expressed reservations concerning the scientific basis and economic consequences for the HARS-specific worm tissue PCB criterion of 113 ppb and offered alternative ideas for estimating a HARS-specific PCB worm tissue criterion. Following are summaries of the most significant among these comments:

*Definition of PCBs*

A few comments requested that EPA include a definition of PCBs in the final rule. For purposes of this rule total PCBs are defined in the EPA Region 2/USACE New York District guidance document entitled, *Guidance for Performing Tests on Dredged Material Proposed for Ocean Disposal or the Regional Testing Manual (RTM)* (EPA Region 2/USACE-NYD, 1992). Applicants are instructed to analyze the following 22 PCB congeners: PCB 8, 18, 28, 44, 49, 52, 66, 87, 101, 105, 118, 128, 138, 153, 170, 180, 183, 184, 187, 195, 206, and 209.

The recommended method for estimating total PCB concentrations referenced in the RTM was changed on February 14, 1996 (EPA, 1996). The change was based on a review of various data sets that measured an extended list of PCB congeners (106 or more). The data indicated that total PCB tissue residue could be more reliably estimated by doubling the subtotal of the 22 PCB congeners listed above. The rationale and data sets supporting this change are described in the human health scientific peer review charge for the scientific peer review (EPA, 2001). After doubling the dredging project 28-day worm tissue bioaccumulation results of the 22 PCB congeners to obtain a total PCB tissue residue value for dredged material, the resulting total PCB tissue residue value is adjusted to reflect equilibrium conditions (steady state) by multiplying by 2. The resulting total PCB tissue residue value for dredged material will be compared to the 113 ppb HARS-specific PCB worm tissue criterion, for each dredging project.

*Wait for Completion of the 2002 Scientific Peer Review Prior to Promulgating the 113 ppb HARS-specific PCB worm tissue criterion*

A number of those who commented on the proposed rule suggested that EPA should wait for completion of the scientific peer review prior to promulgating any revision to the old 400 ppb matrix value for PCBs. EPA categorically rejects this view. The 400 ppb worm tissue matrix value, established as guidance in 1981, was based entirely on a non-degradation policy, and was not based on any kind of risk assessment. There is broad scientific consensus that the 400 ppb guidance value is not adequately protective of human health and the environment. Failure to revise the matrix value could result in propagating adverse impacts at the HARS that EPA is endeavoring to remediate.

In contrast, the 113 ppb worm tissue value is a rational, risk-based value, protective of human health and the environment, based upon available scientific information pending completion of the current scientific peer review and evaluation process. There is, moreover, solid evidence that further protective measures are needed. For example, for a number of years, the States of New York and New Jersey have had advisories for “limited consumption” of several species of fish (striped bass and bluefish) and lobster tomalley caught in the waters of the New York/New Jersey Harbor and Bight area, and have, in some cases, prohibited the sale, consumption, and/or harvesting of fish, crustacea, and shellfish due to toxic contamination, especially of PCBs and dioxins.

The HARS designation Supplemental Environmental Impact Statement (SEIS) (USEPA, 1997a), among other documents, contains significant evidence that dredged material disposal has contributed contaminants to the area, and therefore has likely contributed to the present conditions observed in the New York Bight Apex. Organisms living in or near these degraded surface sediments in nearshore waters will be continually exposed to contaminants until the contaminants are buried by natural sedimentation, placement of Remediation Material, or otherwise isolated or removed. Exposed

sediments can directly and indirectly impact benthic and pelagic organisms. Impacts to terrestrial organisms (including human beings) are also possible if the contaminants were to undergo trophic transfer. Those conditions are cause for concern. In particular, contaminant bioaccumulation by infaunal organisms presents the potential for food chain/trophic transfer, potentially posing a risk not only to aquatic animals but also to seafood consumers. For example, elevated levels of PCBs and dioxin/furan compounds were found in the tissues of infaunal species and the hepatopancreas of lobsters collected from the vicinity of the former Mud Dump Site (MDS). The total PCB and 2,3,7,8-TCDD (dioxin) levels in lobster hepatic tissue sampled in the Bight Apex exceeded Food and Drug Administration (FDA) consumption guidance that, in most cases, recommends no consumption, or at least limited consumption, at those levels. (See SEIS Chapter 3.5.1.1.) (USEPA, 1997a).

The 113 ppb criterion appropriately furthers the remediation goals of the HARS. The need for remediating the HARS is extensively documented in the HARS designation rulemaking record, including the *Federal Register* notices (62 FR 26275 and 62 FR 46142), HARS Response to Comments Document (EPA, 1997b) and the HARS SEIS (EPA, 1997a). Bioaccumulation in organisms collected within the HARS was one of the factors leading to the selection of the Remediation Alternative in the HARS SEIS. It is EPA's conclusion that continued use of dredged material that bioaccumulates above 113 ppb in worm tissue would not advance, but would rather hinder, the goals of the HARS remediation and could result in increased tissue levels for organisms living within the site. EPA also concludes that continued ocean placement of dredged material that results in total PCB bioaccumulation above 113 ppb in worm tissue could contribute to human health effects.

EPA strongly disagrees with those comments that suggest that the current peer review process

should be completed before any action is taken to update the old 1981 matrix value of 400 ppb. EPA believes that it is entirely inappropriate to perpetuate an outdated and non-protective criterion simply because scientific consideration of the matter is ongoing. Indeed, science is by definition always ongoing, and in this context scientific developments will continue long after the current peer review of the HARS criteria is completed. Completion of the peer review process will certainly be an important milestone, and EPA anticipates that at that time, the criteria for many contaminants of concern will be revised. It is possible, perhaps even likely, that further revisions of the value for PCBs will also be made at that time. But it is unreasonable to suggest that EPA should not act today, based on the best scientific information available at present, to replace a demonstrably unprotective value with a protective one, simply because better information may be available several years from now.

The scientific peer review process was initiated in 1998, continues today, and more time will be necessary to complete it. EPA believes that the interim PCB criterion is reasonable, based on the currently available scientific information, and is appropriately conservative to provide for the continued management of the HARS to reduce impacts within the Primary Remediation Area (PRA) to acceptable levels in accordance with 40 CFR 228.11(c), as required in 40 CFR 228.15(6)(A). It is important to implement a more appropriately conservative PCB criterion now, rather than to continue using guidelines that could potentially perpetuate benthic conditions that would need further remediation.

It is also important to note that the human health portion of the 2002 scientific peer review has been completed. The consensus opinions of the scientific peer review panel are reported in the June 20, 2002 report entitled *Interim Consensus Report of the HARS Scientific Peer Review. Phase 1: Human Health Evaluation* (USEPA, 2002a). EPA intends to resume Remediation Material

Workgroup (RMW) meetings with the focus on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material, before responding to the peer reviewers' consensus report and finalizing the human health and ecological effects testing evaluation framework (TEF).

One of the central consensus opinions of the 2002 scientific peer review panel is that improvement of estimates of key exposure parameters requires that site-specific studies be conducted to obtain updated or better information. The USACE and EPA have developed several scopes of work for studies to obtain this information. It is clear, however, that many of these necessary studies will require substantial time to complete. The interim PCB tissue criterion would ensure that material that is placed at the HARS attains a level of protection consistent with the current best estimates of exposure and with the remedial intent of the HARS.

The PCB criterion will remain in effect until after EPA and the USACE complete their review of the 2002 scientific peer review comments on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material for human health effects, conduct and respond to the comments on the future scientific peer review on the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use at the HARS as Remediation Material for ecological effects, and revise, as necessary, the HARS testing evaluation process used for bioaccumulation data from dredged material proposed for use as Remediation Material at the HARS for all contaminants of concern in accordance with the September 27, 2000 MOA between EPA and the USACE. When the above steps are completed, any further changes to the HARS testing evaluation process used to evaluate PCBs, or other contaminants

of concern, will be the subject of further rulemaking, as necessary. EPA estimates that it will take four to five years to fully complete this process, including additional rulemaking, as necessary.

*Exposure Assumptions are too Conservative*

A frequent observation made in the negative comments on the proposed rule is that the site-specific exposure assumptions used by EPA in calculating the 113 ppb HARS-specific PCB worm tissue criterion are “overly conservative” or “unrealistic.” EPA rejects this assertion. The 113 ppb HARS-specific PCB worm tissue criterion is designed to be appropriately conservative to protect human health and the marine environment. The value was calculated using a non-cancer Hazard Quotient of 1, the level recommended by EPA Superfund guidance for remediation of sites with hazardous substance contamination; and a cancer risk factor of  $10^{-4}$ , the *minimum* level recommended by EPA Superfund guidance.

Where EPA was conservative in calculating the PCB criterion, this conservative approach was appropriate given the relative paucity of data from which to derive alternative, site-specific exposure figures. However, the conservatism of individual exposure assumptions made in the calculation is balanced by EPA’s use of a less conservative cancer risk level of  $1 \times 10^{-4}$ . Had EPA chosen a more protective cancer risk level of  $1 \times 10^{-5}$  or  $1 \times 10^{-6}$ , as is typical when selecting goals for site remediation, the calculated HARS-specific PCB worm tissue criterion would have been one or two orders of magnitude lower. Thus, EPA believes that the use of what some comments contend is an unrealistically conservative set of exposure assumptions (selected because of the absence of data on which to base arguably more realistic assumptions) is more than offset by EPA’s use of a cancer risk level which is at the very low end of what is considered acceptable under EPA’s other hazardous site

remediation programs. If reliable, site-specific exposure data were available, EPA would use them in its calculations. In finalizing the review of the HARS testing evaluation process, EPA will also evaluate the use of a cancer risk level that is more protective and more consistent with what is typically used in Superfund site remediation. If EPA were to select a more protective cancer risk level, even with different exposure data, the net result might well be a calculated PCB value no higher than, and almost certainly lower than, 113 ppb.

The comments that criticized EPA's conservative exposure assumptions also failed to note the ultimate intent of the proposed rule, which is to further the remediation of the HARS. The need for and intent of such remediation was clearly established in the HARS designation in 1997 (62 FR 46142).

*Implementation of the 113 ppb HARS-specific PCB Worm Tissue Criterion will have Significant Negative Economic Consequences*

Some comments have made dire predictions about economic dislocations if EPA proceeds with the proposed promulgation of the 113 ppb HARS-specific PCB worm tissue criterion. EPA does not believe that this will be a likely outcome. On the contrary, dredging activity, and placement of dredged material at the HARS, has continued apace in the more than two years since the September 2000 MOA, when EPA and USACE first started using the PCB value of 113 ppb. Undoubtedly, some dredgers who would wish to use the HARS will be unable to do so because their material does not satisfy the 113 ppb criterion; and it may cost more for these individual dredgers to dispose of the material elsewhere. However, EPA disagrees that widespread, adverse economic consequences are to be expected from this rulemaking. Specifically, there has been more dredged material placed at the HARS since the 113 ppb PCB value was announced under the September 2000 MOA (approximately

11 million cubic yards, based on scow volume, of maintenance and deepening dredged material), than was placed in previous years (approximately 4 million cubic yards, based on scow volume, of maintenance and deepening) (USACE, 2002). A PCB criterion of 113 ppb would render only approximately 300,000 cubic yards of maintenance dredged material from 3 past projects, since the September 2000 MOA (U.S. Gypsum, Port Imperial, and a portion of Naval Weapons Station Earle), unsuitable for placement at the HARS at an estimated cost of \$14.1 million. A PCB criterion of 113 ppb would render approximately 1.2 million cubic yards (including the 300,000 mentioned earlier) of maintenance dredged material from 8 past projects (including the three discussed above) since the HARS was designated (Buttermilk Channel, Raritan River, Raritan Cutoff, Refined Sugars [now American Sugars], and Castle Astoria) unsuitable for placement at the HARS, which represents an average of 240,000 cubic yards per year (over a 5 year period). EPA estimated a worst case scenario of 1.33 million cubic yards in any given year would be unsuitable for the HARS based upon today's rule, at a cost of \$62.5 million. See response to comment 7-2 in the Response to Comments Document (USEPA, 2003a). Approximately 15 million cubic yards of Remediation Material has been placed at the HARS since it was designated in 1997. No deepening material (below 45 feet Mean Low Water) is expected to be affected by today's rule.

Nevertheless, MPRSA Section 103(b) expressly provides an opportunity for the USACE to select a disposal site meeting the criteria of 40 CFR Part 228, should use of an EPA-designated site prove not to be feasible. Existence of an EPA-designated disposal site thus is not a prerequisite for ocean disposal, nor does it bar use of other sites selected in accordance with Section 103(b).

Further, MPRSA Section 103(b) states that in considering permit applications, the Secretary's

determination as to the need for the dumping is to be “[b]ased upon an evaluation of the potential effect of a permit denial on navigation, economic and industrial development, and foreign and domestic commerce of the United States....” And, in the highly unlikely event that there was to be no economically feasible alternative to ocean disposal, MPRSA Section 103(d) provides the opportunity for the Secretary of the Army to seek a waiver of the environmental criteria. EPA’s rulemaking in no way affects that authority.

#### *Existing Permits/Authorizations Should be “Grandfathered”*

One comment requested that EPA “grandfather” existing dredging projects that have an approved Testing Evaluation Memo (signed by EPA and the USACE), but do not have a USACE permit or authorization. EPA considered this comment and has determined that the 113 ppb HARS-specific PCB worm tissue criterion will be applied to all USACE permit and authorization requests pending as of the effective date of the final rule and all permit and authorization requests filed thereafter.

EPA carefully considered and responded to each comment received. A complete Response to Comments Document has been prepared which contains all the comments received and EPA’s responses to each of these comments. That document is available for viewing at the location specified in the Section titled, “How Can You Get Additional Information or Copies of Support Documents” below.

#### **IV. SUPPORTING DOCUMENTS:**

1. USACE. 1981. Final Interpretive Guidance for Bioaccumulation of Petroleum Hydrocarbon, DDT, Cadmium, and Mercury in the New York Bight. Memorandum from North Atlantic Division Corps of Engineers to G.R. Tobertson, Deputy Director of Civil Works, Dept. of Army.
2. EPA/USACE. 1991. Evaluation of Dredged Material Proposed for Ocean Disposal-Testing Manual. Environmental Protection Agency, Washington, DC, and U.S. Army Corps of Engineers, Washington, DC. EPA-503/8-91/001. February 1991.
3. EPA Region 2/USACE-NYD (New York District). 1992. Guidance for Performing Tests on Dredged Material Proposed for Ocean Disposal. U.S. Army Corps of Engineers New York District and Environmental Protection Agency Region , New York, NY. Draft Release. December 1992.
4. EPA. 1996. Letter dated February 14, 1996 from Mario Del Vicario, U.S. Environmental Protection Agency, region 2, to John Tavolaro, U.S. Army Corps of Engineers New York District. Subject PCB Quantification. February 1996.
5. NY/NJ HEP (New York/New Jersey Harbor Estuary Program). 1996. Comprehensive Conservation and Management Plan for the Harbor Estuary Program, including the Bight Restoration Program. Final Report. March 1996.
6. USEPA. 1997a. Supplement to the Environmental Impact Statement on the New York

- Dredged Material Disposal Site Designation for the Designation of the Historic Area Remediation Site (HARS) in the New York Bight Apex. May 1997.
7. USEPA. 1997b. Response to Comments on the May 13, 1997, Proposed Rule for the Simultaneous De-Designation and Termination of the Mud Dump Site (MDS) and Designation of the Historic Area Remediation Site (HARS). August 1997.
  8. USEPA. 1997c. Biological Assessment for the Closure of the Mud Dump Site and Designation of the Historic Area Remediation Site in the New York Bight Apex. May 1997.
  9. USEPA. 2000a. Memorandum of Agreement: among the Department of the Army, the Environmental Protection Agency, and the U.S. Army Corps of Engineers. *To Strengthen Environmental Protection of the Ocean Environment and to Promote Economic Progress in the Port of New York and New Jersey*. September 27, 2000.
  10. USEPA. 2000b. Proposed Changes to the Bioaccumulation Testing Evaluation Framework and Response to Scientific Peer Reviewers Comments on the Framework for Determining the Suitability of Dredged Material to be Placed at the Historic Area Remediation (HARS). October 19, 2000.
  11. USEPA. 2000c. Memorandum to the File from Douglas Pabst. Subject: Modification of the Matrix Value for PCB in Worm Tissue. September 27, 2000.

12. USEPA. 2001. Scientific Peer Review Package and Charge, Proposed Bioaccumulation Testing Evaluation Framework for Assessing the Suitability of Dredged Material to be Placed at the Historic Area Remediation Site (HARS). USEPA, Region 2. New York, NY. December 21, 2001.
13. USACE. 2002. Email from Stephen Knowles to EPA Region 2. Subject: Ocean Placement Summary Table. December 12, 2002.
14. USEPA. 2002a. Interim Consensus Report of the HARS Specific Peer Review. Phase 1: Human Health Evaluation. July 20, 2002.
15. USEPA. 2002b. Memorandum to the File from Douglas Pabst. Subject: Private Permits Placing Dredged Material at the Historic Area Remediation Site. October 1, 2002.
16. USEPA. 2002c. Memorandum to the File from Douglas Pabst. Subject: Small Businesses Applications to Place Dredged Material at the Historic Area Remediation Site. October 1, 2002.
17. USEPA 2002d. Dun & Bradstreet Reports for Castle Astoria Terminals, American Sugars, Port Imperial Marina, International Matex Tank Chemicals, and New York Waterways. September 20, 2002.
18. USEPA, 2003a. Response to Comments on the October 8, 2002 Proposed Rule for the

Establishment of a Historic Area Remediation Site (HARS)-Specific Polychlorinated Biphenyl Worm Tissue Criterion. March 7, 2003.

19. USEPA 2003b. Memorandum to the File from Douglas Pabst. Subject: Private Permits for Navigational Dredging with Placement of Dredged Material at the Historic Area Remediation Site. March 6, 2003.
20. USEPA 2003c. Email from Robert Hargrove to Douglas Pabst. Subject: Coastal Zone Consistency Review for the Proposed PCB 113 Guideline for the HARS. March 5, 2003.

### **How Can You Get Additional Information or Copies of Support Documents?**

1. Electronically. You may obtain electronic copies of this document and various support documents from the EPA home page at the Federal Register <http://www.epa.gov/fedrgstr/>, or on EPA Region 2's homepage at: <http://www.epa.gov/region02/water/dredge>

2. In person. The complete administrative record for this action has been established and includes supporting documentation as well as printed, paper versions of electronic comments. Copies of information in the record are available upon request. The official record of this rulemaking is available for inspection at the EPA Region 2 Library, 16th Floor, 290 Broadway, New York, NY 10007-1866. For access to the docket materials, call Rebecca Garvin at (212) 637-3185 between 9:00 am and 3:30 pm Monday through Friday, excluding legal holidays, for an appointment. The record is also available for viewing at EPA Region 2's Edison NJ Office Library 2890 Woodbridge Avenue, Building 209,

MS-245, Edison, New Jersey 08837. For access to the docket materials at this facility, call Ms. Margaret Esser (732) 321-6762 between 9:00 am and 3:30 pm Monday through Friday, excluding legal holidays, for an appointment. The EPA public information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

## **V. Statutory and Executive Order Reviews**

### A. Executive Order 12866: Regulatory Planning and Review

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 result in 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 entitlement, 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.”

Today’s action, which establishes a HARS-specific PCB worm tissue criterion of 113 ppb, is not a significant regulatory action under E.O. 12866. In particular, as explained in the Response to Comments Document included in the record for this rule, even if one assumes a worst case scenario of 4 million cubic yards of maintenance dredged material from New York/New Jersey Harbor for one year, the projected worst-case economic impact could be approximately \$62.5 million or as low as \$14.1 million per year depending upon the dredging volume determined to be unsuitable for the HARS (See Response to Comment 7-2 in the Response to Comments Document (USEPA, 2003a)).

Furthermore, the 113 ppb PCB value has been in use since the September 2000 MOA. Since that time there has been only one HARS application where the dredged material was determined unsuitable for the HARS (U.S. Gypsum) on the basis of the 113 ppb PCB value. Two additional HARS applications (Port Imperial Corporation and Naval Weapons Station Earle) would have been rejected under the proposed rule. As such, given that only two businesses (the U.S. Navy is not a maritime business) would have been affected, EPA has seen no material economic impact on maritime businesses in NY/NJ Harbor since the 113-ppb value was announced in the September 2000 MOA (USEPA 2000a). Since the signing of the MOA in September 2000, there has been more dredging and even deepening of NY/NJ Harbor than since the HARS was designated (USACE, 2002). From the time the HARS was designated in 1997 through when the September 2000 MOA was announced, two additional businesses (Castle Astoria and Refined Sugars [now American Sugars]) would have been impacted by today’s rule. A total of four businesses would have been impacted by today’s rule, since the HARS was designated to present. Given that each business represents a different industry, EPA concludes that this rule does not represent a material impact on any one business in New

York/New Jersey Harbor. Therefore, today's rule will not 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. It thus has been determined that this rule is not a "significant regulatory action" under the terms of the Executive Order 12866 and is therefore not subject to OMB review.

#### B. Paperwork Reduction Act

This final rule would not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) because it would not require persons to obtain, maintain, retain, report, or publicly disclose information to or for a Federal agency.

#### C. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

After considering the economic impact of today's final rule on small entities, the Agency certifies that this action will not have a significant economic impact on a substantial number of small entities as explained below.

For the purposes of assessing the impacts of today’s rule on small entities, a small entity is defined as: (1) a small business based on the Small Business Administration’s (SBA) size standards; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. The SBA thresholds define minimum employment, sales revenue, or other factors than may qualify an industry segment as small. Size standards have been established for types of economic activity, or industry, generally under the North American Industry Classification System (NAICS) defined at 13 CFR 121.201. Table 1 lists the SBA size standards and NAICS codes for businesses potentially applicable to today’s rule.

**Table 1. Small Business Size Standards matched to North American Industry Classification System (NAICS). The NAICS codes in this table include modifications made to NAICS by the Office of Management and Budget effective January 1, 2002. Referred to as NAICS 2002. These size standards are based on NAICS 2002. They are effective October 1, 2002**

NAICS codes	NAICS U.S industry title	Size standards in millions of dollars	Size standards in number of employees
221210	Natural Gas Distribution		500

Except	Dredging and Surface Cleanup Activities <sup>1</sup>	\$17.0 <sup>1</sup>	
311312	Cane Sugar Refining		750
311313	Beet Sugar Manufacturing		750
322130	Paperboard Mills		750
324110	Petroleum Refineries <sup>2</sup>		1,500 <sup>2</sup>
327420	Gypsum Product Manufacturing		1,000
336611	Ship Building and Repairing		1,000
336612	Boat Building		500
483111	Deep Sea Freight Transportation		500
4831123	Deep Sea Passenger Transportation		500
483113	Coastal and Great Lakes Freight Transportation		500
483114	Coastal and Great Lakes Passenger Transportation		500
483211	Inland Water Freight Transportation		500
483212	Inland Water Passenger Transportation		500
488310	Port and Harbor Operations	\$21.6	
488320	Marine Cargo Handling	\$21.5	
488330	Navigational Services to Shipping	\$6.0	
493110	General Warehousing and Storage	\$21.5	

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493120	Refrigerated Warehousing and Storage	\$21.5	
493130	Farm Product Warehousing and Storage	\$21.5	
493190	Other Warehousing and Storage	\$21.5	

<sup>1</sup>NAICS code 237990 - Dredging: To be considered small for purposes of Government procurement, a firm must perform at least 40 percent of the volume dredged with its own equipment or equipment owned by another small dredging concern.

<sup>2</sup>NAICS code 324110 - For purposes of Government procurement, the firm may not have more than 1,500 employees or more than 75,000 barrels per day capacity of petroleum-based inputs, including crude oil or bona fide feedstocks. Capacity includes owned or leased facilities as well as facilities under a processing agreement or an arrangement such as an exchange agreement or a throughput. The total product to be delivered under the contract must be at least 90 percent refined by the successful bidder from either crude oil or bona fide feedstocks.

EPA obtained information about all permits issued and any current permit applications in order to assess the potential universe of small entities that could be affected by today's rule. Since the HARS was first designated in 1997, the U. S. Army Corps of Engineers has received 19 private permit application for HARS placement (USEPA, 2003b), of which 15 permits were issued (Federal authorizations were not included in this analysis as the USACE is not a small entity), and there are

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currently 2 active permit applications pending (New York Waterways and Naval Weapons Station Earle Pier 3). The remaining permit applications (New York State Thruway and Department of Army, Op Sail) are no longer active. As the HARS is expected to exist for a limited time, until the PRA has been remediated with at least one meter of Remediation Material, EPA believes it is reasonable to assume that the universe of current and pending applications (based upon over 5 years of application history) constitutes the reasonable universe of entities affected by the today's rule. Of the 19 permit applications, only 4 (Castle Astoria Terminals, Inc., Port Imperial Marina, New York WaterWays, and International Matex Tank Terminals) are small entities, which is not a substantial number of small entities. Of the four, three (Castle Astoria Terminals, Inc., Port Imperial Marina, and New York WaterWays) would have been affected by today's proposal, based upon past permitting information. Castle Astoria Terminals, Inc. has had a permit for HARS placement since 1999, which expired in January 2003, but they never dredged. Port Imperial Marina recently received a permit for HARS placement, but dredges very infrequently. New York WaterWays does not currently have a HARS placement permit, and has not dredged for many years. Further, these small entities are only a very small percentage of their SIC code. This analysis was included in the preamble to the proposed rule (67 FR 62659) and no additional small businesses were identified during the comment period.

In summary, based on past permit information, there would have been only a few small entities affected by the final rule, with low impacts. As such, EPA concludes that the final rule will not have a significant impact on a substantial number of small entities.

Therefore, for the reasons explained above, the Regional Administrator certifies, pursuant to section

605(b) of the RFA, that the final rule will not have a significant economic impact on a substantial number of small entities.

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

Title II of the Unfunded Mandates Reform Act (UMRA), Public Law 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 of 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 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.

EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. EPA estimated total annualized (post-tax) costs of compliance for the final rule to be between \$14.1 million and \$62.5 million (worst case scenario). See response to comment 7-2 in the Response to Comments Document (USEPA, 2003a). Of this total cost, \$14.1 million to \$62.5 million would be incurred by the private sector and none would be incurred by State and Local governments. Thus, this final rule is not subject to the requirements of Sections 202 and 205 of UMRA.

EPA also has determined that this final rule contains no regulatory requirements that might significantly or uniquely affect small governments. This final rule would apply equally to all dredged material to be placed at the HARS, thus there would be no unique effect of the rule on small governments. This rule is not anticipated to result in significant expenditures for small governments based on the universe of permit holders and applicants for the HARS. Thus, the requirements of Section 203 of UMRA also do not apply to this rule.

#### E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in

the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus Executive Order 13132 does not apply to this rule.

#### F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.” “Policies that have Tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian Tribes, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes.”

This final rule does not have Tribal implications. It would not have substantial direct effects on Tribal governments, on the relationship between the Federal government and Indian Tribes, or on the

distribution of power and responsibilities between the Federal government and Indian Tribes, as specified in Executive Order 13175. EPA does not have information indicating that any Tribe would incur costs because of this rule. Thus, Executive Order 13175 does not apply to this rule.

#### G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe might have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health and safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This final rule is not an economically significant rule as defined under Executive Order 12866 and does not concern an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. Therefore, it is not subject to Executive Order 13045.

#### H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This final rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355 (May 22, 1001)) because it is not a significant regulatory action under Executive Order 12866.

#### I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer Advancement Act of 1995 (“NTTAA”), Public Law 104-113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This final rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 requires that, to the greatest extent practicable and permitted by law, each Federal agency must make achieving environmental justice part of its mission. E.O. 12898 provides that each Federal agency must conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that such programs, policies, and activities do not have the effect of excluding persons (including populations) from participation in, denying persons (including populations) the benefits of, or subjecting persons (including populations) to discrimination under such programs, policies, and activities because of their race, color, or national origin.

No action from this final rule will have a disproportionately high and adverse human health and environmental effect on any segment of the population. In addition, this rule does not impose substantial direct compliance costs on those communities. Accordingly, the requirements of Executive Order 12898 do not apply.

#### K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of the rule in the Federal Register. A “major rule” cannot take effect until 60 days after it is published in the Federal Register. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

#### L. National Environmental Policy Act of 1969

Section 102(c) of the National Environmental Policy Act of 1969, Section 4321 et seq., (NEPA) requires Federal agencies to prepare environmental impact statements (EIS) for major Federal actions significantly affecting the quality of the human environment. The object of NEPA is to build into the Agency decision making process careful consideration of all environmental aspects of proposed actions. Although EPA ocean dumping program activities have been determined to be “functionally

equivalent” to NEPA, EPA has voluntarily undertaken to follow NEPA procedures when designating ocean dumping sites. See, 63 FR 58045 (Oct. 29, 1998) .

In August 1982, EPA published a final EIS for the designation of the New York Dredged Material Disposal Site (Mud Dump Site). The EIS assessed the environmental impacts of establishing an ocean disposal site for 100 million cubic yards (mcy) of dredged materials generated within the Port of New York and New Jersey. After completion of the EIS, EPA designated the Mud Dump Site as an Impact Category I disposal site (see, 40 CFR 228.10(c)) with a capacity of 100 mcy (see, 40 CFR 228.15(d)(6)). Approximately 68 mcy of dredged material was disposed of at the Mud Dump Site. In 1997, EPA prepared a Supplemental EIS, for the Designation of the Historic Area Remediation Site (HARS) in the New York Bight Apex (USEPA, 1997a). That document addressed the environmental considerations relevant to the HARS, and identified the Priority Remediation Area (PRA) within the HARS. At the time of the rule designating the HARS, the PCB matrix value for disposal at the site was 400 ppb. The promulgation of the 113 ppb HARS-specific PCB worm tissue criterion is a refinement based on new information since the designation of the HARS, which will have positive impacts on the marine environment. EPA does not consider this refinement as a substantial change in the designation of the HARS, and no additional NEPA review is required.

However, EPA received comments on the proposed rule questioning EPA’s determination that no further NEPA evaluation is required to establish the 113 ppb HARS-specific PCB worm tissue criterion. Specifically, these comments questioned whether EPA was remiss in not evaluating the need for, and impacts associated with the use of, other disposal methods in light of the new PCB criterion. In

point of fact, EPA does not evaluate such issues when designating ocean disposal sites because permission to use an ocean site for the disposal of dredged material can be granted only after a determination has been made that no alternative disposal options exist. Evaluations of alternative disposal options are more properly performed in the review process for individual ocean dumping permit applications. As such, EPA again concludes that no further NEPA documentation is needed to establish a 113 ppb HARS-specific PCB worm tissue criterion.

#### M. The Endangered Species Act

Under Section 7(a)(2) of the Endangered Species Act, 16 U.S.C. 1536(a)(2), federal agencies are required to “insure that any action authorized, funded, or carried on by such agency...is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of habitat of such species...” Under regulations implementing the Endangered Species Act, a federal agency is required to consult with either the U. S. Fish and Wildlife Service or the National Marine Fisheries Service (depending on the species involved) if the agency’s action “may effect” endangered or threatened species or their critical habitat. See, 50 CFR 402.14(a).

EPA initiated its consultation process with the U.S. Fish and Wildlife Service (USFWS) on April 6, 1995 for what was then the Mud Dump Site and surrounding areas. The consultation process was concluded with them on July 28, 1995, with the USFWS’s concurrence that EPA’s action was not likely to adversely affect federally listed species under its jurisdiction. The action covered by this final rule is more protective of the marine environment. Accordingly, the conclusions of our earlier consultation with the USFWS for the designation of the HARS are still valid.

EPA initiated threatened and endangered species consultation with the National Marine Fisheries Service (NMFS) on April 4, 1996. As directed by the NMFS, EPA prepared a Biological Assessment (BA) (USEPA, 1997c) to assess the impacts of the designation of the HARS on the Kemp's ridley and loggerhead sea turtles, and the humpback and fin whales. In May 1997, EPA sent the NMFS a copy of the BA, which concluded that the designation of the HARS is not likely to adversely affect the species in question; NMFS concurred with this conclusion. Since the BA utilized a PCB worm tissue matrix value of 400 ppb and this final rule proposes 113 ppb, any impacts to endangered or threatened species, or their critical habitats resulting from this action will be positive; the conclusion of the earlier consultation with NMFS is still valid.

#### N. Magnuson-Stevens Fishery Conservation and Management Act

The 1996 Sustainable Fisheries Act amendments to the Magnuson-Stevens Fishery Conservation and Management Act (MSFCMA) require the designation of essential fish habitat (EFH) for federally managed species of fish and shellfish. Pursuant to Section 305(b)(2) of the MSFCMA, federal agencies are required to consult with the National Marine Fisheries Service (NMFS) regarding any action they authorize, fund, or undertake that may adversely affect EFH. An adverse effect has been defined by the Act as follows: "Any impact which reduces the quality and/or quantity of EFH. Adverse effects may include direct (e.g., contamination or physical disruption), indirect (e.g., loss of prey, reduction in species' fecundity), site-specific or habitat-wide impacts, including individual, cumulative, or synergistic consequences of actions." EFH became effective after the HARS was designated. However, prior to September 2000 all USACE permits and authorizations were subject to EFH review utilizing a PCB matrix value of 400 ppb and were found acceptable. Since September 2000, all USACE permits and authorizations have been subject to EFH review utilizing a PCB matrix

value of 113 ppb and have been found acceptable. Since this action proposes 113 ppb, any impacts to EFH species, or their critical habitats predicted from this action would be expected to be the same, as such, the consultation requirements of Section 305(b)(2) of the MSFCMA do not apply to this rule.

#### O. Plain Language Directive

Executive Order 12866 requires each agency to write all rules in plain language. EPA has written this final rule in plain language to make this final rule easier to understand.

#### P. Executive Order 13158: Marine Protected Areas

Executive Order 13158 (65 FR 34909, May 31, 2000) requires EPA to “expeditiously propose new science-based regulations, as necessary, to ensure appropriate levels of protection for the marine environment.” EPA may take action to enhance or expand protection of existing marine protected areas and to establish or recommend, as appropriate, new marine protected areas. The purpose of the Executive Order is to protect the significant natural and cultural resources within the marine environment, which means “those areas of coastal and ocean waters, the Great Lakes and their connecting waters, and submerged lands thereunder, over which the United States exercises jurisdiction, consistent with international law.”

The HARS-specific PCB worm tissue criterion of 113 ppb is the non-cancer (hazard quotient of 1), and is the lower of the 282 ppb cancer ( $1 \times 10^{-4}$ ), and 329 ppb ecological PCB values (USEPA, 2000c). EPA expects that this proposed rule would afford additional protection of aquatic organisms at individual, population, community, or ecosystem levels of ecological structures, because the previous matrix value was 400 ppb. Additionally the 113 ppb HARS-specific PCB worm tissue criterion is roughly one-third lower than the 329 ppb PCB value for the protection of ecological health. EPA is

promulgating the 113 ppb HARS-specific PCB worm tissue criterion as it is the lower of the human health (cancer and non-cancer) and ecological protection values. Therefore, EPA expects today's final rule would advance the objective of the Executive Order to protect marine areas.

**List of Subjects in 40 CFR Part 228**

Environmental protection, Water pollution control.

Dated:

Signed:

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Jane M. Kenny  
Regional Administrator  
EPA Region 2

In consideration of the foregoing, EPA is amending part 228 Chapter I of title 40 of the Code of Federal Regulations as follows:

**PART 228- CRITERIA FOR THE MANAGEMENT OF DISPOSAL SITES FOR OCEAN DUMPING**

1. The authority citation for part 228 continues to read as follows:

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

2. Section 228.15 is amended by adding paragraph (d)(6)(v) (E) to read as follows:

**§228.15 Dumping sites designated on a final basis.**

\* \* \* \* \*

(d) \* \* \*

(6) \* \* \*

(v) \* \* \*

(E) HARS-specific Polychlorinated Biphenyl (PCB) Tissue Criterion:

Total PCB bioaccumulation worm test results for dredged material approved for placement at the HARS as Material for Remediation shall not exceed the HARS-specific PCB tissue criterion of 113 ppb. This HARS-specific PCB tissue criterion will be applied to the arithmetic mean concentration reported for the analyses of the worm tissue replicates exposed to the tested sediments, without the use of statistical confidence limits.

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