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[Proposed Rules]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL-7392-2]

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

AGENCY: Environmental Protection Agency.

ACTION: **Proposed** rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing today to modify the designation of the Historic Area Remediation Site (HARS) to establish 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 would

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establish 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. This value would remain in effect until after EPA and the U.S. Army Corps of Engineers (USACE) complete their review of the 2002 HARS human health scientific peer review comments, conduct and respond to the comments on the scientific peer review on the ecological proposal, and revise, as necessary, the process used to evaluate the suitability of 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 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 science review warranted the implementation of this interim change. The September 2000 MOA selected PCBs from the other contaminants because PCBs were specifically mentioned in the HARS designation. This interim change is designed to keep remediation of the HARS current with the latest scientific information concerning PCBs.

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, Judge Jed Rakoff of 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: Comments: Comments must be received by November 7, 2002.

Public Hearings: The public hearing dates are as follows:

1. October 28, 2002, at 7:00 P.M., Monmouth Beach, New Jersey.
2. October 29, 2002, at 2:00 PM., New York, New York.

ADDRESSES: Comments: Comments may be submitted by mail or electronically as follows: 1. By mail: Submit written comments on this notice to: 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) To ensure proper identification of your comments, include in the subject line the name, date and Federal Register citation of this notice.

2. Electronically: Submit your comments electronically to: pabst.douglas@epa.gov Electronic comments must be submitted as an ASCII or WordPerfect file avoiding the use of special characters and any form of encryption. Comments will also be accepted on disks in WordPerfect or ASCII file format sent or delivered to the addresses above. All comments and data in electronic form must be identified by the name, date and Federal Register citation of this notice. No confidential business information should be sent via e-mail.

Public Hearings: The public hearing locations are:

1. Monmouth Beach, New Jersey: Monmouth Beach Municipal Auditorium, 22 Beach Road, Monmouth Beach, New Jersey, 07750.
2. New York City, New York: Room 27D, EPA Region 2, 290 Broadway New York, New York 10007-1866.

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) (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 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:

Category	Examples of potentially affected entities
Industry.....	Ports in NY/NJ Harbor and surrounding areas seeking MPRSA permits for dredged material to be placed at the HARS.

	Marinas in the NY/NJ Harbor and surrounding areas seeking MPRSA permits for dredged material to be placed at the HARS.
	Shipyards in the NY/NJ Harbor and surrounding areas seeking MPRSA permits for dredged material to be placed at the HARS.
	Berth owners in the NY/NJ Harbor and surrounding area seeking MPRSA permits for dredged material to be placed at the HARS.
State/local/tribal governments.....	Local governments owning ports or berths in the NY/NJ Harbor and surrounding area seeking MPRSA permits for dredged material to be placed at the HARS.
Federal.....	US Army Corps of Engineers for its proposed dredging projects in NY/NJ Harbor and surrounding areas to be placed at the HARS. Federal agencies seeking MPRSA permits for dredged material from NY/NJ Harbor and surrounding areas to be placed at the HARS.

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 subject to the requirement to obtain an MPRSA permit in accordance with the Purpose and Scope provisions of 40 CFR 220.1, and you wish to use the site subject to today's proposal. If you have any questions regarding applicability of this action to a particular entity, please consult the person listed in the

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preceding FOR FURTHER INFORMATION CONTACT section.

Other entities potentially affected by today's proposal would include commercial and recreational fishing interests using New York Bight Apex fishing and shellfish 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 proposal on fishery and shellfish resources would be expected to be positive.

II. Background

In 1972, the Congress of the United States enacted the MPRSA 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.

Regulations implementing the MPRSA are set forth at 40 CFR Parts 220 through 229. 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 also 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. EPA's ocean dumping **regulations** provide that EPA's designation of an ocean dumping site is accomplished by promulgation of a site designation in 40 CFR Part 228 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)). Pursuant to that designation, dredged material **proposed** for use at the HARS must be determined to be suitable for use as Remediation Material. Remediation Material is defined as uncontaminated dredged material (i.e., dredged material that meets current Category I standards and will not cause significant undesirable effects including through bioaccumulation).

The designation ensured that material be selected so that 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.

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)). The HARS is being remediated with uncontaminated dredged material (i.e., dredged material that meets current Category I standards and will not cause significant undesirable effects including through bioaccumulation) (hereinafter referred to as "the Material for Remediation" or "Remediation Material").

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 the input from peer review and the public.

EPA is proposing today to modify the HARS designation (40 CFR 228.15(d)(6)) to establish a HARS-specific worm tissue PCB criterion of 113 ppb for dredged material **proposed** for use as Remediation Material, pursuant to 40 CFR 228.10 and 228.11(c). It should be noted that MPRSA site designation does not constitute or imply EPA's approval of actual

placement of 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. Need To Establish a HARS-Specific Tissue PCB Criterion

The need for remediating the HARS is described in detail in the HARS SEIS (EPA 1997a), associated **proposed** (62 FR 26267) and final (62 FR 46142) rulemaking, and the Response to Comments on the **proposed** rule (EPA, 1997b). In summary, the proposal to terminate and de-designate the MDS, and simultaneously redesignate the site and surrounding degraded areas as the HARS, is amply supported by the presence of toxic effects in the HARS (a Category III sediment characteristic), dioxin bioaccumulation exceeding Category I levels in worm tissue collected from the HARS (a Category II sediment characteristic), National Oceanic and Atmospheric Administration (NOAA) ER-L/ER-M exceedances in some HARS sediments, and PCB/TCDD contamination in area lobster stocks. While it is impossible to quantify how much of New York Bight Apex contamination is the direct result of past dredged material disposal, other ocean dumping activities (e.g., former sewage sludge disposal at the 12-Mile Site), or other sources (e.g., via Hudson River plume or atmospheric deposition), the presence of these degraded sediments in the Apex is cause for concern.

Organisms living in or near these degraded surface sediments in near shore 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.

NOAA tissue data from lobsters that were harvested in the New York Bight Apex in 1994 revealed that PCB concentrations in the hepatic tissue (tomalley) of the lobsters were above U.S. Food and Drug Administration consumption guidelines. It must be kept in mind that the lobsters analyzed in the NOAA study were harvested from wild stocks in the Apex, whose populations migrate seasonally through the region, including the HARS. Contamination of these animals cannot be definitively linked to specific areas of dredged

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material disposal, to other past dumping activities, or to other pollution sources. Nor does the study indicate that human consumption of lobster muscle tissue (meat) presents health risks. However, the lobster study data do show that contaminants are being accumulated, and that concern about potential human-health risks is warranted. This contaminant data set complements other evidence of benthic contamination in the New York Bight Apex region.

The evaluative framework used to determine suitability of dredged material for use as Remediation Material at the HARS was developed in 1996 for the MDS and revised in 1998 for the HARS. It is a framework for assessing the potential for human health and ecological effects by comparing bioaccumulation test results to guidance values. These guidance values were derived from researching the best available literature at the time. The 1996 framework continued the use of a PCB guidance value of 400 ppb for worm tissue based on the Matrix approach defined in the 1981 USACE guidance: Final Interpretive Guidance for Bioaccumulation of Petroleum Hydrocarbon, DDT, Cadmium, and Mercury in the New York Bight.

In 1998, EPA began the peer review process specified in the New York/New Jersey Harbor Estuary Program (HEP) Comprehensive Conservation and Management Plan (CCMP). A panel of 11 scientific peer reviewers submitted comments pertaining to the HARS evaluative framework and guidance values. For PCBs and the other matrix values, peer reviewers expressed concerns regarding the relevance of the Matrix approach developed in 1981, and recommended evaluating PCBs and the other matrix values, using human health and ecological risk assessment procedures (USEPA, 2000).

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 the input from peer review and the public.

In addition, the 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 science review warranted the implementation of the 113 ppb value on an interim basis. The September 2000 MOA addressed PCBs and not the other contaminants because PCBs were specifically mentioned in the HARS designation. In addition, experience in evaluating NY/NJ Harbor dredged material indicated that the PCB levels were often significant to the determination. This interim use of the 113 ppb value was intended to keep remediation of the HARS current with the latest scientific information concerning PCBs. The MOA states, "This change [PCBs] reflects current scientific developments and ensures that the agencies' approach remains consistent with the remedial objectives of the HARS designation. Notably, this change will result in improvements in the quality of HARS Remediation Material with respect to numerous parameters other than PCBs, because elevated PCB levels frequently are associated with elevated levels of other chemicals of concern." The 113 ppb HARS-specific PCB value will improve the quality of HARS Remediation Material to reflect current scientific standards, and to provide for the continued management of the HARS to reduce impacts within the PRA to acceptable levels in accordance with 40 CFR 228.11(c), as required in 40 CFR 228.15(6)(A). The 113 ppb figure was understood to be an interim value, since the scientific processes and benchmark measures used to determine whether or not dredged material meets the remediation goals of the HARS were still under review. The review of the guidelines for the HARS has taken longer than anticipated in the MOA and is still underway.

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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, Judge Jed Rakoff of 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 while allowing for the use of 113 ppb value as a binding criteria applicable to dredged materials to be placed at the HARS. The need for establishing a HARS-specific tissue PCB criterion: (1) Reflects EPA Region 2's interpretation and ongoing review of the science associated with responding to the 1998 peer review comments (USEPA, 2000a); (2) is in response to the high degree of public controversy over the question

of suitability of HARS Remediation Material; (3) is appropriate as an interim protective step in light of the remediation goals of the HARS, in particular the specific mention of PCBs in the need for remediating the HARS; (4) represents an interim measure to incorporate recent science (as opposed to 1981 science) as EPA and the USACE develop a new HARS-specific evaluation process by evaluating and responding to the 2002 peer review comments on the human health proposal, conducting the scientific peer review on the ecological proposal, and responding to comments on the ecological proposal; and (5) addresses the court's procedural concerns.

This **proposed** HARS-specific worm tissue PCB value would remain in effect until EPA and the USACE develop a new HARS-specific evaluation process by evaluating and responding to the 2002 peer review comments on the human health proposal, conducting the scientific peer review on the ecological proposal, and responding to comments on the ecological proposal. In total, this effort may take up to 2 years to fully address and implement for all contaminants of concern.

IV. **Proposed** Action

In an effort to continuously incorporate and utilize the best available science to reduce adverse impacts that have occurred within the HARS (see, 40 CFR 228.11), EPA is proposing today to modify the designation of the HARS (40 CFR 228.15(d)(6)) to establish a HARS-specific worm tissue PCB criterion of 113 ppb for dredged material **proposed** for use as Remediation Material. As discussed in detail in Section III, implementation of the HARS-specific tissue PCB criterion of 113 ppb for dredged material **proposed** for use as Remediation Material will provide for continued remediation in accordance with 40 CFR 228.10 and 228.11(c).

V. Derivation of HARS-Specific 113 ppb PCB Criterion

This revision of the worm PCB Matrix value reflects EPA Region 2's interpretation and ongoing review of the science associated with responding to the 1998 peer review comments. This risk-based value was calculated using exposure assumptions chosen to represent specific conditions associated with consuming fish from the HARS. As

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such, we believe it is the best delineation of a level for PCBs at which remediation of the HARS can be assured, based on our current assessment of available knowledge about PCBs, bioaccumulation, and the area of the HARS. The 113 ppb value for PCBs in worm tissue is based on an assessment of human noncancer health hazard risk. It is the lowest of three (cancer, noncancer, and ecological values) PCB risk- or effects-based values derived by EPA Region 2, in consultation with USACE, based in part on the recommendation of 1998 scientific peer reviewers. The general risk assessment basis for this HARS-Specific value is described below; for further details pertaining to the specific derivation of the tissue level used as the HARS-specific value, see USEPA 2000b.

1. Human Health Risk

Uptake of HARS contaminants by marine organisms was assumed to occur through direct exposure to the sediments and/or through uptake from eating contaminated prey. For assessing ecological and human health risks, a simplified description of the food web was used to

describe feeding relationships between species at the HARS. The New York Bight food web used in modeling transfer of contaminants was described by a simplified food chain consisting of three representative levels. These trophic levels were: bottom dwelling organisms, predators, and upper level predators.

For the purpose of evaluating risks to humans, it was assumed that fish consumption is the pathway of concern for humans to be exposed to contaminants in dredged material **proposed** for use as Remediation Material at the HARS, and that the fish consumed would be exposed through trophic transfer of contaminants from invertebrate prey. Because the HARS is located offshore and in open water, and because data shows that suspended and dissolved constituents of dredged material do not persist in the water column following release from the barge, pathways of human exposure other than consumption of seafood (e.g., inhalation, or direct exposure through bathing) were not emphasized in the evaluation process.

To determine whether a tested sediment would result in bioaccumulation that would cause significant undesirable effects with regard to human health, standard human health risk calculations were used to develop tissue values associated with specified levels of protection (cancer risk of 1×10^{-4} , hazard index of 1). The basic risk assessment equations underlying the calculations used to develop the HARS tissues values are as follows:

[GRAPHIC] [TIFF OMITTED] TP08OC02.075

[GRAPHIC] [TIFF OMITTED] TP08OC02.076

Where:

MV--Measured tissue value (mg/kg)
 CPF--Cancer potency factor (Kg-day/mg)
 FIR--Fish Ingestion Rate (g/day)
 CF--Conversion factor (kg/g)
 EF--Exposure frequency (365 days/year)
 ED--Exposure duration (70 years)
 TTF--Trophic transfer factor (unitless)
 BW--Body weight (70 Kg)
 AT--Averaging time (25,550 days)
 BFR--Whole body to fillet ratio (unitless)
 RfD--Reference dose (mg/Kg-day).

Evaluating human risks associated with contaminants in dredged material **proposed** for use at the HARS assumes that recreational anglers represent a reasonably maximally exposed (RME) population for assessing risks to humans. More explicitly stated, EPA Region 2 assumed that there is a subpopulation of anglers that fishes exclusively at the HARS and that all recreationally-caught fish reportedly consumed by this subpopulation of anglers are obtained by angling at the HARS. The assessment assumed that fish are filleted prior to being eaten. In addition, the assessment assumed that the consumed of fish did not use the HARS 100 percent of the time.

The following specific guideline measures and assumptions were applied to all human health risk/effects evaluations to estimate human exposure to HARS contaminants.

Cancer Potency Factor (CPF)/Reference Dose (RD)--Available cancer potency factors (2 per mg/kg-day) and chronic reference doses for oral exposure of PCBs (0.02 [μ]g/kg-day) were obtained from the EPA Integrated Risk Information System (IRIS).
 Seafood consumption (FIR)--A factor of 7.2 grams per day (g/day) was

used as a site-specific estimate of daily fish consumption by high consumers (i.e., New Jersey recreational anglers) in the vicinity of the HARS (USEPA, 2000b).

Exposure Duration (ED): EPA Region 2 assumed a default lifetime exposure of 70 years for its assessment of human health risks (USEPA, 2000b).

Site Use Factor--A factor to express the proportion of time that fish predators may be exposed to contaminated benthic prey residing at the HARS. A factor of 0.777 (i.e., 77.7 percent HARS-area foraging), was derived to estimate site use for a "generic" fish in the diet of the target sub-population (i.e., New Jersey recreational fishers) (USEPA, 2000b).

Whole-body to fillet factor (BFR)--In assessing risks due to PCBs, EPA Region 2/CENAN employ a whole-body to fillet correction factor of 1.35 to estimate the concentration of contaminant in the whole body of the fish that is associated with the concentration in the edible (fillet) portion of the fish (USEPA, 2000b).

Trophic Transfer Factor (TTF)--Trophic transfer of contaminants from benthic prey to fish predators was estimated by applying a discrete factor that expresses the ratio of the residue concentration in predator as a function of the residue concentration in prey. A trophic transfer factor of 3 was applied based on the predictions of a widely applied food web model (Gobas, 1993).

The **regulations** at 40 CFR 227.6 require that there be reasonable assurance that no significant undesirable effects will occur. The **regulations** further provide that such reasonable assurance be based on consideration of statistical significance of effects at the 95 percent confidence

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level. In our current and **proposed** processes, standard statistical tests are in fact used throughout the process of evaluating dredged material for suitability for placement at the HARS. Statistics are used to ensure confidence in the determination whether bioaccumulation measured in test organisms exceeds that in reference organisms. Given the methodology and assumptions used to calculate the value of 113 ppb, we believe that use of the number directly, compared to the arithmetic mean of bioassayed tissues using the material **proposed** to be placed at the HARS, provides the reasonable assurance required by the **regulations**. The additional use of statistical confidence limits, in this situation, does not increase confidence in the determination.

Accordingly, for the purposes of this rule, to promote clarity and to address concerns that have been frequently and vigorously expressed by elected officials and members of the public, the 113 ppb PCB value would be applied directly to the arithmetic mean of the worm bioaccumulation tissue test results, as a pass/fail standard. In light of the unique nature of the HARS as a site with the purpose of remediating the area designated, this approach provides further assurance that no significant undesirable effects will occur, in accordance with 40 CFR 227.6 and will reduce impacts to acceptable levels in accordance with 40 CFR 228.11(c). As such, projects having arithmetic means of PCB worm concentrations above 113 ppb and whose bioaccumulation has been shown with 95% confidence to be statistically significant (as compared to accumulations in reference exposures) would be considered to be unsuitable for placement at the HARS as they would exceed the HARS-specific PCB tissue criterion necessary to achieve the remedial goal of the HARS.

As part of our overall review of the matrix values, including the

ongoing peer review process, we are considering, among other things, whether and how statistical confidence limits should continue to be applied in evaluating bioaccumulation test results. This decision should not be understood as an indication that EPA will not continue to rely on statistical confidence limits in the future, for PCBs as well as for other contaminants of concern, after our ongoing scientific peer review of the HARS TEF is completed.

VI. Supporting Documents

1. 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.

2. 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.

3. USEPA. 2000. 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.

4. USEPA. 2000a. **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.

5. USEPA. 2000b. Memorandum to the File from Douglas Pabst. Subject: Modification of the Matrix Value for PCB in Worm Tissue. September 27, 2000.

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/113rule>.

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 am and 3:30 pm Monday through Friday, excluding legal holidays, for an appointment. The record is also available for viewing at EPA's Region 2 Field 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 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.

VII. 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." It 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. 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 **proposed** rule on small entities, the Agency certifies that this action will not have a significant economic impact on a substantial number of small entities for reasons explained below.

For the purposes of assessing the impacts of today's rule on small entities,

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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. The thresholds used in this analysis are firm level four digit Standard Industrial Classification (SIC) codes. Exhibit 1 presents the SBA size standards used in this analysis.

EPA used current information concerning the potential universe of small entities that could be affected by the rule by obtaining information about all permits issued and any current permit applications. Since the HARS was first designated in 1997, the U.S. Army Corps of Engineers has received 17 permit applications for HARS placement, of which 14 permits were issued (Federal authorizations were not included in this analysis as the USACE is not a small entity), and there are currently 3 permit applications pending. As the HARS is anticipated 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 estimate that this universe of current and pending applications constitute the reasonable universe of entities

affected by the **proposed** rule. Of the 17 permit applications, 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 4, 3 (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, but has not dredged to date. 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.

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

C. Paperwork Reduction Act

This **proposed** 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.

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 **proposed** 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 **proposed** rule to be \$13.5 million. Of this total \$13.5 million would be incurred by the private sector and \$0

would be incurred by State and Local governments. Thus, this **proposed** rule is not subject to the requirements of Sections 202 and 205 of UMRA.

EPA also has determined that this **proposed** rule contains no regulatory requirements that might significantly or uniquely affect small governments. This **proposed** 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 **proposed** 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

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government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes.''

This **proposed** 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 **proposed** 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: Energy Effects

This **proposed** rule is not subject to Executive Order 13211, "Actions Concerning **Regulations** That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and 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 **proposed** 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. Executive Order 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 **proposed** 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. 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 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. 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 establishment of the new PCB matrix value of 113 ppb 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. Consequently, no additional NEPA review is required.

L. 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

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species under its jurisdiction. The action covered by this **proposed** rule is more protective of the marine environment. Accordingly, the conclusions of our earlier consultation with the USFWS for the designation of the HARS is 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) 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 action 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.

M. 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.

N. Plain Language Directive

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

O. 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."

Today's **proposed** rule implements Section 103 of the MPRSA which requires that permits for dredged material are subject to EPA review and concurrence. The **proposed** rule would amend 40 CFR 228.15(d)(6) by establishing a HARS-specific tissue PCB criterion of 113 ppb for dredged material **proposed** for use as Remediation Material.

As the HARS-specific PCB criterion of 113 ppb represents the lower of the non-cancer, cancer, and ecological PCB values, EPA expects that this **proposed** rule would afford additional protection of aquatic organisms at individual, population, community, or ecosystem levels of ecological structures, especially since the previous matrix value was

400 ppb. Therefore, EPA expects today's **proposed** 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: October 1, 2002.

Jane M. Kenny,
Regional Administrator, EPA Region 2.

In consideration of the foregoing, EPA is proposing to amend part 228 of chapter I, title 40 of the Code of federal **Regulations** is amended 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:

Sec. 228.15 Dumping sites designated on a final basis.

* * * * *

(d) * * *

(6) * * *

(v) * * *

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

PCB bioaccumulation worm test results for dredged material approved for use at the HARS as Remediation Material 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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