

302.6(b)(1)(iii). A November 8, 2000 final rule (Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Chlorinated Aliphatics Production Wastes; Land Disposal Restriction for Newly Identified Wastes; CERCLA Hazardous Substance Designation and Reportable Quantities; Final Rule) inadvertently removed the maximum observed constituent concentrations for those listed hazardous wastes from the table in that section when it was amended to include the maximum observed constituent concentrations for listed hazardous wastes K174 and K175. (*See* 65 FR 67132.) The maximum observed constituent concentrations were included in the 40 CFR 302.6 regulations to allow generators, transporters, and disposal facilities handling these wastes to calculate reportable quantities (RQs) using the mixture rule<sup>1</sup> developed in connection with the Clean Water Act section 311 regulations. The listed hazardous wastes K169, K170, K171, and K172 and their respective RQs are included in Table 302.4—List of Hazardous Substances

and Reportable Quantities and Appendix A to section 302.4—Sequential CAS Registry Number List of CERCLA Hazardous Substances of Title 40 of the Code of Federal Regulations. However, the aforementioned Table 302.4 and Appendix A do not contain the maximum observed constituent concentrations. Section 302.6 is the only source of these maximum observed constituent concentrations contained in 40 CFR 302—Designation, Reportable Quantities, and Notification.

#### IV. Statutory and Executive Order reviews

For a complete discussion of all of the administrative requirements applicable to this action, see the direct final rule in the Rules and Regulations section of this **Federal Register**.

#### List of Subjects in 40 CFR Part 302

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: February 14, 2012.

**Mathy Stanislaus,**

*Assistant Administrator, Office of Solid Waste and Emergency Response.*

For the reasons set out, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

#### PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

1. The authority citation for part 302 continues to read as follows:

**Authority:** 42 U.S.C. 9602, 9603, and 9604; 33 U.S.C. 1321 and 1361.

2. In § 302.6, paragraph (b)(1)(iii), the table is amended by adding entries K169, K170, K171, and K172 in numerical order to read as follows:

#### § 302.6 Notification requirements.

*	*	*	*	*
(b)	*	*	*	
(1)	*	*	*	
(iii)	*	*	*	

Waste	Constituent	Max ppm
K169 .....	Benzene .....	220.0
K170 .....	Benzene .....	1.2
	Benzo (a) pyrene .....	230.0
	Dibenz (a,h) anthracene .....	49.0
	Benzo (a) anthracene .....	390.0
	Benzo (b) fluoranthene .....	110.0
	Benzo (k) fluoranthene .....	110.0
	3-Methylcholanthrene .....	27.0
	7, 12-Dimethylbenz (a) anthracene .....	1,200.0
K171 .....	Benzene .....	500.0
	Arsenic .....	1,600.0
K172 .....	Benzene .....	100.0
	Arsenic .....	730.0
*	*	*

\* \* \* \* \*

[FR Doc. 2012-4059 Filed 2-21-12; 8:45 am]

**BILLING CODE 6560-50-P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Chapter I

[EPA-HQ-OPPT-2012-0135; FRL-9339-5]

#### Fishing Tackle Containing Lead; Disposition of Petition Filed Pursuant to TSCA Section 21

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

**ACTION:** Petition, reasons for Agency response.

**SUMMARY:** On November 17, 2011, EPA received a petition from the Center for Biological Diversity, the Loon Lake Loon Association, and Project Gulpile (petitioners). The petitioners cited section 21 of the Toxic Substances Control Act (TSCA) and requested EPA to initiate a rulemaking under section 6(a) of TSCA applicable to fishing tackle containing lead (e.g., fishing weights, sinkers, lures, jigs, and/or other fishing tackle), of various sizes and uses that are ingested by wildlife, resulting in lead exposure. After careful consideration, EPA denied the petition by letter dated

discharged in a quantity equal to or greater than its reportable quantity.

<sup>1</sup> 44 FR 50767, Aug. 29, 1979, Final Rulemaking; Water Programs; Determination of Reportable Quantities for Hazardous Substances; and 50 FR 13463, Apr. 4, 1985, Final rule; Notification

Requirements; Reportable Quantity Adjustments. Discharges of mixtures and solutions are subject to these regulations only where a component hazardous substance of the mixture or solution is

February 14, 2012. This notice explains EPA's reasons for the denial.

**FOR FURTHER INFORMATION CONTACT:**

*For technical information contact:* Thomas Groeneveld, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 566-1188; fax number: (202) 566-0470; email address: [groeneveld.thomas@epa.gov](mailto:groeneveld.thomas@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

This action is directed to the public in general. This action may, however, be of interest to you if you manufacture, process, import, or distribute in commerce fishing tackle containing lead. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How can I access information about this petition?*

EPA has established a record for this petition response under docket identification (ID) number EPA-HQ-OPPT-2012-0135. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone

number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

**II. TSCA Section 21**

*A. What is a TSCA section 21 petition?*

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or the expiration of the 90-day period if EPA fails to respond within 90 days.

*B. What criteria apply to a decision on a TSCA section 21 petition?*

Section 21(b)(1) of TSCA requires that the petition "set forth the facts which it is claimed establish that it is necessary" to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B). Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested to evaluate this petition.

**III. Summary of the Petition**

On November 17, 2011, the Center for Biological Diversity, the Loon Lake Loon Association, and Project Gutpile petitioned EPA to "evaluate the unreasonable risk of injury to the environment from fishing tackle containing lead (including fishing weights, sinkers, lures, jigs, and/or other tackle) of various sizes and uses that are

ingested by wildlife resulting in lead exposure" and to "initiate a proceeding for the issuance of a rulemaking under section 6(a) of TSCA to adequately protect against such risks" (Ref. 1, p. 27). The petition expressly states that this petition "asks the EPA to initiate a rulemaking for regulations that adequately protect wildlife against the unreasonable risk of injury from lead fishing tackle \* \* \*. This petition does not request a specific regulatory alternative. It is the obligation of the EPA to determine the least burdensome alternative that adequately addresses the unreasonable risk of injury" (Ref. 1, p. 8). As such, the petition does not actually identify a rule to be issued, amended, or repealed.

This is not the first time EPA has been petitioned to take action with respect to fishing tackle containing lead. On August 3, 2010, the Center for Biological Diversity, American Bird Conservancy, Association of Avian Veterinarians, Project Gutpile, and Public Employees for Environmental Responsibility filed a petition under TSCA section 21 requesting that EPA prohibit under TSCA section 6(a) the manufacture, processing, and distribution in commerce of lead fishing gear (Ref. 2). In particular, the 2010 petitioners requested a nationwide, uniform ban on the manufacture, processing, and distribution in commerce of lead for use in all fishing gear, regardless of size, including sinkers, jigs, and other tackle. EPA denied the petition on November 4, 2010 (Ref. 2). The comments that EPA received from states and a state organization about the 2010 petition highlighted the geographic focus of state controls on lead fishing tackle (Ref. 2). Several state fish and game agencies submitted comments, all supporting denial of the petition (Ref. 2).

Additionally, on October 20, 1992, the Environmental Defense Fund, Federation of Fly Fishers, Trumpeter Swan Society, and North American Loon Fund petitioned EPA under section 21 of TSCA and the Administrative Procedure Act to initiate rulemaking procedures under section 6(a) of TSCA to require that the sale of lead fishing sinkers be accompanied by an appropriate label or notice warning that such products are toxic to wildlife (Ref. 3). EPA granted the petition and, ultimately, in 1994, EPA proposed a rule under section 6(a) of TSCA to prohibit the manufacturing, processing, and distribution in commerce in the United States, of certain smaller size fishing sinkers containing lead and zinc, and mixed with other substances, including those made of brass (59 FR 11122, March 9, 1994). EPA received

comments from many states or state agencies in response to the 1994 proposal; the majority of these comments argued that Federal action was not warranted. That proposal has not been finalized and in 2005 EPA indicated its intent to withdraw the proposal (70 FR 27625, May 16, 2005). Given limited resources and competing priorities, EPA has not yet formally withdrawn the proposal but is currently taking steps to do so.

#### **IV. Disposition of Petition Filed Pursuant to TSCA Section 21**

##### *A. What is EPA's response?*

On February 14, 2012, EPA denied the November 2011 petition. A copy of the Agency's response, which consists of a letter to the petitioners, is available in the docket for this petition. EPA's reasons for denying the petition are provided in Unit IV.B.

##### *B. What are EPA's reason for this denial?*

In denying the petitioners' request, EPA determined that the petitioners did not demonstrate that Federal action is necessary based, in part, on the fact that the petitioners' supporting data indicate that the issue of wildlife exposure to fishing tackle containing lead has a regional or local geographic context coupled with the fact that the states where risk of injury appears to be greatest (based on documented incidences) are largely the states that have taken action to address the risks posed by lead fishing tackle. While several species of waterfowl are included, the most extensive information provided in the petition pertains to the ingestion by loons of fishing tackle containing lead and indicates that common loons are known to ingest lead objects more frequently than other species of water birds sampled across the United States. For loons, most of the documented cases of lead tackle ingestion cited in the petition are for the time period between 1987 and 2002 and are confined to northern states, all of which are located on or near the northern border of the United States. The U.S. Fish and Wildlife Service report cited in the petition also indicates that loon populations are stable or increasing in all of these northern states where lead tackle ingestion by loons has been documented, with the exception of Washington. While such examples suggest harm to wildlife, and waterfowl in particular, they do not, in and of themselves, demonstrate that Federal rulemaking under section 6(a) of TSCA is necessary.

Indeed, as evidenced by the petition, since 2000, a number of states have established regulations that ban or restrict the use of lead tackle. In addition, a number of other states have created state education and/or fishing tackle exchange programs. In light of the emergence and expansion of these programs and other activities over the past decade coupled with a paucity of data on bird mortality attributable to lead tackle ingestion during this same timeframe, the petition does not suffice to establish that a Federal action under section 6(a) of TSCA as requested by the petitioners is necessary to adequately protect wildlife.

Specifically, since 2000, Maine, Massachusetts, New Hampshire, New York, Vermont, and Washington have banned or limited the use of fishing sinkers. Maine, New York, and Vermont have banned the sale of lead fishing sinkers of less than one-half ounce. Two states, Massachusetts and New Hampshire, have expanded the scope of water bodies covered by use prohibitions over time. In Massachusetts, the use of all lead sinkers was initially prohibited in the Quabbin and Wachusett Reservoirs, the loons' primary habitat in the state. The Massachusetts regulations expanded the use prohibitions, effective in 2012, to include additional tackle—lead weights, and lead fishing jigs of less than one ounce—and to encompass all inland waters. In New Hampshire, initial use prohibitions for fishing sinkers and jigs were expanded from lakes and ponds to all waters of the state in 2006. In 2011, Washington State began to regulate fishing tackle containing lead by approving measures to prohibit the use of fishing tackle containing lead at lakes with nesting common loons. EPA also notes that other states (e.g., Minnesota and Wisconsin) have voluntary education or outreach programs, including efforts to discourage the use of fishing tackle containing lead, to raise awareness of lead poisoning in wildlife, and events to exchange fishing tackle containing lead for lead-free alternatives.

Thus, the trend is that states are being responsive to the harms attributed to fishing tackle containing lead by implementing regulatory and voluntary programs.

For example, EPA notes that among the states where the petition cites documented cases of lead tackle ingestion by loons, five of the states regulate the use or sale of fishing tackle containing lead and have been doing so since at least 2006. Further, EPA notes that two states with voluntary programs are among the same states. In other

words, the states where ingestion of fishing tackle containing lead is best linked to loon mortality have responded with regulatory or voluntary programs. In some cases, these programs have expanded over time. The petition does not demonstrate that these state and local efforts are ineffective or have failed to reduce the exposure and risks presented to waterfowl in particular. In light of these state actions, EPA concludes that the petition does not demonstrate that action under TSCA section 6(a) is necessary to adequately protect wildlife.

EPA also notes that when Federal actions have been taken to address the use of lead fishing tackle in federally managed lands and water bodies across the nation, they have been limited to specific, localized National Wildlife Refuges, not the entire National Wildlife Refuge System. For example, use of fishing tackle containing lead is prohibited in several wildlife refuges, including in states with breeding loon populations such as Rachel Carson National Wildlife Refuge in Maine, Seney National Wildlife Refuge in Michigan, and Red Rock Lakes National Wildlife Refuge in Montana.

Moreover, EPA recognizes that state and local natural resource agencies consider geographic context in their resource assessments, and manage these resources based on evaluations of local impacts on fish and wildlife resources and habitats. EPA also is cognizant that these state and local agencies historically have made such evaluations while considering the societal benefits of traditional fishing practices. This perspective is supported by the vast majority of comments received from states and members of the general public on the petition submitted on August 3, 2010 (Ref. 2) and the section 6(a) rule proposed by EPA on March 9, 1994 (59 FR 11122).

In response to the petition submitted on August 3, 2010, EPA received comments from states and a state organization that highlight the geographic focus of state controls on lead fishing tackle. According to the Association of Fish and Wildlife Agencies, "the exposure to certain migratory birds (primarily loons, and to a lesser extent, swans) and related impacts to populations of those birds is localized, and where impacts have been substantiated to be significant, state fish and wildlife agencies have acted to regulate the use of lead sinkers and jigs. In the northeast, five states have enacted restrictions (e.g., ban in certain bodies of water; ban on certain weights and sizes) on the use of lead fishing tackle where studies have identified lead toxicosis as

a contributing factor to declining loon populations. Some states are also offering a fishing tackle exchange program (non-lead for lead products). States have thus demonstrated a responsible exercise of their authority to regulate or restrict lead fishing tackle under circumstances of exposure where it contributes to decline in loon populations" (Ref. 2).

All state agencies that commented on the 2010 petition supported the denial of the petition and provided several reasons why Federal action is unwarranted (Ref. 2). These comments assert that mortality from ingestion of lead fishing tackle is rare and is primarily limited to some areas of the country, that states are already working closely with the U.S. Fish and Wildlife Service on education and exchange programs, and that where there have been impacts on loons and trumpeter swans, states have already taken action. These states contend that, because policy development is biologically, socially, and economically complex, these impacts are best addressed by geographically targeted actions that the states are undertaking. As noted by these commenters, states in the northern part of the country, where the majority of the impacts on loons in particular have been observed, have taken action to limit or ban the use of lead sinkers or have implemented tackle exchange programs.

In addition, comments received on the 2010 petition from Members of Congress, representing two different states (e.g., Arkansas and Wisconsin), also opposed Federal action on lead fishing tackle (Ref. 2). A Representative from Wisconsin opposed a prohibition on lead fishing tackle in favor of voluntary education and outreach programs (Ref 2).

These comments were consistent with the comments EPA received in response to the 1994 proposal. In their comments on the 1994 proposed rule, numerous state fish and wildlife management agencies from across the U.S. commented that they did not believe that the data as a whole (e.g., exposure information, limited incidents of lead toxicity linked to tackle, number of specific species likely to be affected, geographic nature of the issue), support the need for a nationwide ban on fishing tackle containing lead. Many of these states also strongly expressed their opinion that they, as state fish and wildlife agencies, have the best knowledge of the status of bird populations in their states and are therefore best suited to identify if their wildlife resources are impacted, and to determine what the most appropriate

management actions should be, if any. In total, the vast majority of these comments opposed the prohibitions in the 1994 proposed rule.

These comments and the actions taken by states reinforce EPA's conclusion that petitioners have not shown that Federal action under TSCA section 6(a) is necessary to protect wildlife resources at this time.

EPA also recognizes that the market for fishing tackle and equipment continues to change and that the prevalence of non-lead alternatives in the marketplace continues to increase. While fishing tackle containing lead may still constitute the largest percentage of the market, the availability of lead-free alternatives has increased in the last decade (Ref. 2). New non-lead products have entered the market, and the market share of lead sinkers has decreased (Ref. 2). With improvements in technology, changes in consumer preferences, state-level restrictions, and increased market competition, the market for lead fishing sinkers is expected to continue to decrease while the market for substitutes such as limestone, steel, and tungsten fishing sinkers is expected to continue to increase. (Ref. 2). In light of these trends, the petition does not demonstrate that rulemaking is necessary under TSCA section 6(a).

In sum, EPA is not persuaded that the action requested by the petitioners is necessary given the mix of regulatory and education actions states agencies and the Federal Government already are taking to address the impact of lead fishing tackle on local environments. The risk described by the petitioners does appear to be more prevalent in some geographic areas than others, and the trend over the past decade has been for increasing state and localized Federal activity regarding lead in fishing tackle. Therefore, EPA concludes that the petition does not demonstrate that action under TSCA section 6(a) is necessary in light of these state and Federal actions.

Furthermore, for the same reasons stated in this unit, while the petition does provide evidence of exposure and a risk to waterfowl in some areas of the United States, it does not provide a basis for finding that the risk presented is an unreasonable risk. "The finding of unreasonable risk is a judgment under which the decision-maker determines that the risk of health or environmental injury from the chemical substance or mixture outweighs the burden to society of potential regulations" (59 FR 11122, 11138). Again, the risk described by the petitioners appears to be more prevalent in some geographic areas than others,

and the trend over the past decade has been for increasing state and localized Federal activity regarding lead in fishing tackle. Given the mix of regulatory and educational actions state agencies and the Federal Government already are taking to address the impact of lead fishing tackle on local environments, and the other considerations described in Unit IV.B., the petition does not demonstrate that exposure from lead fishing tackle presents an unreasonable risk.

Finally, although EPA proposed to make a finding that lead fishing tackle presented an unreasonable risk in 1994, the Agency did not finalize that rule and indicated its intent to withdraw the proposal in 2005 (70 FR 27625). The Agency's view that the proposal should be withdrawn is buttressed by the emergence and continued expansion of state and local programs in the states that appear to be most affected. Likewise, other data and information (e.g., incidents of lead tackle ingestion and mortality in certain species of waterfowl) that supported that proposal are clearly outdated. To the extent that petitioners rely on that proposal, their reliance is unpersuasive.

For these reasons, EPA denied the petitioners' request.

## V. References

The following is a list of the documents that are specifically referenced in this notice and placed in the docket that was established under docket ID number EPA-HQ-OPPT-2012-0135. For information on accessing the docket, refer to Unit I.B.

1. Center for Biological Diversity, Loon Lake Loon Association, Project Gutpile. Petition to the Environmental Protection Agency to Regulate Lead Fishing Tackle Under the Toxic Substances Control Act; Petition. (November 16, 2011). Available online at: [http://www.epa.gov/oppt/chemtest/pubs/TSCA\\_sinker\\_petition.pdf](http://www.epa.gov/oppt/chemtest/pubs/TSCA_sinker_petition.pdf).
2. U.S. Environmental Protection Agency. Lead Fishing Sinkers and Ammunition Components; Docket. Docket ID: EPA-HQ-OPPT-2010-0681. Available online at: <http://www.regulations.gov/#/docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;pp=10;po=0;D=EPA-HQ-OPPT-2010-0681>.
3. Environmental Defense Fund, Federation of Fly Fishers, the Trumpeter Swan Society, and the North American Loon Fund. Petition to EPA Administrator William K. Reilly pursuant to the Toxic Substances Control Act, and the Administrative Procedure Act; Petition (October 20, 1992).

**List of Subjects**

Environmental protection, Bird, Lead, Lead fishing sinkers, Lead fishing tackle.

Dated: February 14, 2012.

**James Jones,**

*Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2012-4087 Filed 2-21-12; 8:45 am]

**BILLING CODE 6560-50-P**

---

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**National Institutes of Health**
**42 CFR Part 68**

[Docket No. NIH-2008-0003]

**RIN 0905-AA43**

**National Institutes of Health Loan Repayment Programs**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The National Institutes of Health (NIH) proposes to rescind the current regulations governing two of its eight loan repayment programs and issue in their place a new consolidated set of regulations governing all of the NIH Loan Repayment Programs (LRPs). There are currently eight programs, including three for researchers employed by the NIH (Intramural LRPs) and five for non-NIH scientists (Extramural LRPs). The Intramural LRPs include the Loan Repayment Program for Research with Respect to Acquired Immune Deficiency Syndrome (or AIDS Research LRP); Loan Repayment Program for General Research (or General Research LRP), which includes a program for the Accreditation Council for Graduate Medical Education (ACGME) Fellows; and Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds). The Extramural LRPs include the Loan Repayment Program for Contraception and Infertility Research (or Contraception and Infertility Research LRP); Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds); Loan Repayment Program for Clinical Research (or Clinical Research LRP); Loan Repayment Program for Pediatric Research (or Pediatric Research LRP); and Loan Repayment Program for

Health Disparities Research (or Health Disparities Research LRP). This rule complements efforts afforded by EO 13563.

**DATES:** Comments must be received on or before April 23, 2012 in order to ensure that NIH will be able to consider the comments in preparing the final rule.

**ADDRESSES:** Persons and organizations interested in submitting comments, identified by RIN 0925-AA43 and Docket Number NIH-2008-0003, may do so by any of the following methods:

*Electronic Submissions:* You may submit electronic comments in the following way:

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments.

To ensure timelier processing of comments, NIH is no longer accepting comments submitted to the agency by email. The NIH encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal: <http://www.regulations.gov>.

*Written Submissions:* You may submit written comments in the following ways:

- *Fax:* 301-402-0169.
- *Mail:* Attention Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852-7669.
- *Hand delivery/courier (for paper, disk, or CD-ROM submissions):* Attention: Jerry Moore, 6011 Executive Boulevard, Suite 601, Rockville, MD 20852-7669.

*Docket:* For access to the docket to read background documents or comments received, go to the eRulemaking Portal and insert the docket number provided in brackets in the heading on page one of this document into the "Search" box and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20892; by email [MooreJ@mail.nih.gov](mailto:MooreJ@mail.nih.gov); by fax 301-402-0169; or <mailto:MooreJ@mail.nih.gov>; [jm40z@nih.gov](mailto:jm40z@nih.gov) by telephone 301-496-4607 (not a toll-free number) for information about the rulemaking process. For program information contact: the NIH Division of Loan Repayment by email [lrp@nih.gov](mailto:lrp@nih.gov) or telephone 866-849-4047. Information regarding the requirements, application deadline dates, and an online application for the NIH Loan Repayment Programs may be obtained from the NIH

Loan Repayment Program Web site, [www.lrp.nih.gov](http://www.lrp.nih.gov).

**SUPPLEMENTARY INFORMATION:** On November 4, 1988, Congress enacted the Health Omnibus Programs Extension of 1988, Public Law (Pub. L.) 100-607, Title VI of which amended the Public Health Service (PHS) Act by adding section 487A (42 U.S.C. 288-1) entitled Loan Repayment Program for Research with Respect to Acquired Immune Deficiency Syndrome. Subsequently, in the NIH Revitalization Act of 1993 (Pub. L. 103-43), Congress enacted the Loan Repayment Program for Research with Respect to Contraception and Infertility (section 487B; 42 U.S.C. 288-2); the Loan Repayment Program for Research Generally (section 487C; 42 U.S.C. 288-3); and the Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (section 487E; 42 U.S.C. 288-5). The Children's Health Act of 2000 (Pub. L. 106-310), which was enacted on October 17, 2000, added the Pediatric Research Loan Repayment Program (section 487F; <sup>1</sup> 42 U.S.C. 288-6). On November 13, 2000, the Clinical Research Enhancement Act, contained in the Public Health Improvement Act of 2000 (Pub. L. 106-505), enacted the Loan Repayment Program for Clinical Research (section 487F; <sup>2</sup> 42 U.S.C. 288-5a). On November 22, 2000, the Minority Health and Health Disparities Research and Education Act of 2000 (Pub. L. 106-525) enacted the Loan Repayment Program for Health Disparities Research (section 485G, redesignated 464z-5; <sup>3</sup> 42 U.S.C. 285t-2).

Sections 487A, 487B, 487C, 487E, and 487F of the PHS Act authorize the Secretary of Health and Human Services, and section 464z-5 authorizes the Director, National Institute on Minority Health and Health Disparities (NIMHD), to enter into contracts with qualified health professionals under which such professionals agree to conduct research in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$35,000 of the principal and

<sup>1</sup> So in law. There are two sections 487F. Section 1002(b) of Public Law 106-310 (114 Stat. 1129), inserted section 487F above. Subsequently, section 205 of Public Law 106-505 (114 Stat. 2329), which relates to the Loan Repayment Program for Clinical Researchers, inserted a section 487F after section 487E.

<sup>2</sup> So in law. There are two sections 487F. Section 205 of Public Law 106-505 (114 Stat. 2329), inserted section 487F after section 487E. Previously, section 1002(b) of Public Law 106-310 (114 Stat. 1129), which relates to the Pediatric Research Loan Repayment Program, inserted section 487F after section 487E.

<sup>3</sup> Section 485G of the PHS Act, enacted by Public Law 106-525, was redesignated section 464z-5 by P.L. 111-148.