

Dated: September 2, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910 the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemption from the requirement of a tolerance.

* * *

Inert ingredients	Limits	Uses
* * *	*	*
D-glucopyranose, oligomeric, C ₁₀₋₁₆ -alkyl glycosides (CAS Reg. No. 110615-47-9)		Surfactant
* * *	*	*

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■ 3. In § 180.930 the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.930 Inert ingredients applied to animals; exemption from the requirement of a tolerance.

* * *

Inert ingredients	Limits	Uses
* * *	*	*
D-glucopyranose, oligomeric, C ₁₀₋₁₆ -alkyl glycosides (CAS Reg. No. 110615-47-9)		Surfactant
* * *	*	*

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[FR Doc. 05-18241 Filed 9-13-05; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL-7968-3]

National Priorities List for Uncontrolled Hazardous Waste Sites

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response,

Compensation, and Liability Act of 1980 ("CERCLA" or "the Act"), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan ("NCP") include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List ("NPL") constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency ("EPA" or "the Agency") in determining which sites warrant further investigation. These further investigations will allow EPA to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds seven new sites to the General Superfund Section of the NPL.

DATES: The effective date for this amendment to the NCP shall be October 14, 2005.

ADDRESSES: For addresses for the Headquarters and Regional dockets, as well as further details on what these dockets contain, see section II, "Availability of Information to the Public" in the "Supplementary Information" portion of this preamble.

FOR FURTHER INFORMATION CONTACT: Terry Jeng, phone (703) 603-8852, State, Tribal and Site Identification Branch; Assessment and Remediation Division; Office of Superfund Remediation and Technology Innovation (mail code 5204G); U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue NW.; Washington, DC 20460; or the Superfund Hotline, phone (800) 424-9346 or (703) 412-9810 in the Washington, DC, metropolitan area.

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I. Background

A. What Are CERCLA and SARA?

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601-9675 ("CERCLA" or "the Act"), in response to the dangers of uncontrolled releases or threatened releases of hazardous substances, and releases or substantial threats of releases into the environment of any pollutant or contaminant which may present an

imminent or substantial danger to the public health or welfare. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act ("SARA"), Public Law 99-499, 100 Stat. 1613 *et seq.*

B. What Is the NCP?

To implement CERCLA, EPA promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan ("NCP"), 40 CFR part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP sets guidelines and procedures for responding to releases and threatened releases of hazardous substances, or releases or substantial threats of releases into the environment of any pollutant or contaminant which may present an imminent or substantial danger to the public health or welfare. EPA has revised the NCP on several occasions. The most recent comprehensive revision was on March 8, 1990 (55 FR 8666).

As required under section 105(a)(8)(A) of CERCLA, the NCP also includes "criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable, taking into account the potential urgency of such action for the purpose of taking removal action." "Removal" actions are defined broadly and include a wide range of actions taken to study, clean up, prevent or otherwise address releases and threatened releases of hazardous substances, pollutants or contaminants (42 U.S.C. 9601(23)).

C. What Is the National Priorities List (NPL)?

The NPL is a list of national priorities among the known or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The list, which is appendix B of the NCP (40 CFR part 300), was required under section 105(a)(8)(B) of CERCLA, as amended by SARA. Section 105(a)(8)(B) defines the NPL as a list of "releases" and the highest priority "facilities" and requires that the NPL be revised at least annually. The NPL is intended primarily to guide EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is only of limited significance, however, as it does not assign liability to any party or to the owner of any specific property. Neither does placing a site on the NPL

mean that any remedial or removal action necessarily need be taken.

For purposes of listing, the NPL includes two sections, one of sites that are generally evaluated and cleaned up by EPA (the "General Superfund Section"), and one of sites that are owned or operated by other Federal agencies (the "Federal Facilities Section"). With respect to sites in the Federal Facilities Section, these sites are generally being addressed by other Federal agencies. Under Executive Order 12580 (52 FR 2923, January 29, 1987) and CERCLA section 120, each Federal agency is responsible for carrying out most response actions at facilities under its own jurisdiction, custody, or control, although EPA is responsible for preparing a Hazard Ranking System (HRS) score and determining whether the facility is placed on the NPL. EPA's role is less extensive than at other sites.

D. How Are Sites Listed on the NPL?

There are three mechanisms for placing sites on the NPL for possible remedial action (see 40 CFR 300.425(c) of the NCP): (1) A site may be included on the NPL if it scores sufficiently high on the Hazard Ranking System ("HRS"), which EPA promulgated as appendix A of the NCP (40 CFR part 300). The HRS serves as a screening device to evaluate the relative potential of uncontrolled hazardous substances, pollutant or contaminants to pose a threat to human health or the environment. On December 14, 1990 (55 FR 51532), EPA promulgated revisions to the HRS partly in response to CERCLA section 105(c), added by SARA. The revised HRS evaluates four pathways: ground water, surface water, soil exposure, and air. As a matter of Agency policy, those sites that score 28.50 or greater on the HRS are eligible for the NPL; (2) Pursuant to 42 U.S.C 9605(a)(8)(B), each State may designate a single site as its top priority to be listed on the NPL, without any HRS score. This provision of CERCLA requires that, to the extent practicable, the NPL include one facility designated by each State as the greatest danger to public health, welfare, or the environment among known facilities in the State. This mechanism for listing is set out in the NCP at 40 CFR 300.425(c)(2); (3) The third mechanism for listing, included in the NCP at 40 CFR 300.425(c)(3), allows certain sites to be listed without any HRS score, if all of the following conditions are met:

- The Agency for Toxic Substances and Disease Registry (ATSDR) of the U.S. Public Health Service has issued a health advisory that recommends

dissociation of individuals from the release.

- EPA determines that the release poses a significant threat to public health.
- EPA anticipates that it will be more cost-effective to use its remedial authority than to use its removal authority to respond to the release.

EPA promulgated an original NPL of 406 sites on September 8, 1983 (48 FR 40658) and generally has updated it at least annually.

E. What Happens to Sites on the NPL?

A site may undergo remedial action financed by the Trust Fund established under CERCLA (commonly referred to as the "Superfund") only after it is placed on the NPL, as provided in the NCP at 40 CFR 300.425(b)(1). ("Remedial actions" are those "consistent with permanent remedy, taken instead of or in addition to removal actions * * *," 42 U.S.C. 9601(24).) However, under 40 CFR 300.425(b)(2) placing a site on the NPL "does not imply that monies will be expended." EPA may pursue other appropriate authorities to respond to the releases, including enforcement action under CERCLA and other laws.

F. Does the NPL Define the Boundaries of Sites?

The NPL does not describe releases in precise geographical terms; it would be neither feasible nor consistent with the limited purpose of the NPL (to identify releases that are priorities for further evaluation), for it to do so.

Although a CERCLA "facility" is broadly defined to include any area where a hazardous substance release has "come to be located" (CERCLA section 101(9)), the listing process itself is not intended to define or reflect the boundaries of such facilities or releases. Of course, HRS data (if the HRS is used to list a site) upon which the NPL placement was based will, to some extent, describe the release(s) at issue. That is, the NPL site would include all releases evaluated as part of that HRS analysis.

When a site is listed, the approach generally used to describe the relevant release(s) is to delineate a geographical area (usually the area within an installation or plant boundaries) and identify the site by reference to that area. As a legal matter, the site is not coextensive with that area, and the boundaries of the installation or plant are not the "boundaries" of the site. Rather, the site consists of all contaminated areas within the area used to identify the site, as well as any other location to which that contamination

has come to be located, or from which that contamination came.

In other words, while geographic terms are often used to designate the site (e.g., the "Jones Co. plant site") in terms of the property owned by a particular party, the site properly understood is not limited to that property (e.g., it may extend beyond the property due to contaminant migration), and conversely may not occupy the full extent of the property (e.g., where there are uncontaminated parts of the identified property, they may not be, strictly speaking, part of the "site"). The "site" is thus neither equal to nor confined by the boundaries of any specific property that may give the site its name, and the name itself should not be read to imply that this site is coextensive with the entire area within the property boundary of the installation or plant. The precise nature and extent of the site are typically not known at the time of listing. Also, the site name is merely used to help identify the geographic location of the contamination. For example, the name "Jones Co. plant site," does not imply that the Jones company is responsible for the contamination located on the plant site.

EPA regulations provide that the "nature and extent of the problem presented by the release" will be determined by a Remedial Investigation/Feasibility Study (RI/FS) as more information is developed on site contamination (40 CFR 300.5). During the RI/FS process, the release may be found to be larger or smaller than was originally thought, as more is learned about the source(s) and the migration of the contamination. However, this inquiry focuses on an evaluation of the threat posed; the boundaries of the release need not be exactly defined. Moreover, it generally is impossible to discover the full extent of where the contamination "has come to be located" before all necessary studies and remedial work are completed at a site. Indeed, the known boundaries of the contamination can be expected to change over time. Thus, in most cases, it may be impossible to describe the boundaries of a release with absolute certainty.

Further, as noted above, NPL listing does not assign liability to any party or to the owner of any specific property. Thus, if a party does not believe it is liable for releases on discrete parcels of property, supporting information can be submitted to the Agency at any time after a party receives notice it is a potentially responsible party.

For these reasons, the NPL need not be amended as further research reveals

more information about the location of the contamination or release.

G. How Are Sites Removed From the NPL?

EPA may delete sites from the NPL where no further response is appropriate under Superfund, as explained in the NCP at 40 CFR 300.425(e). This section also provides that EPA shall consult with states on proposed deletions and shall consider whether any of the following criteria have been met:

- (i) Responsible parties or other persons have implemented all appropriate response actions required;
- (ii) All appropriate Superfund-financed response has been implemented and no further response action is required; or
- (iii) The remedial investigation has shown the release poses no significant threat to public health or the environment, and taking of remedial measures is not appropriate.

H. May EPA Delete Portions of Sites From the NPL as They Are Cleaned Up?

In November 1995, EPA initiated a new policy to delete portions of NPL sites where cleanup is complete (60 FR 55465, November 1, 1995). Total site cleanup may take many years, while portions of the site may have been cleaned up and available for productive use.

I. What Is the Construction Completion List (CCL)?

EPA also has developed an NPL construction completion list ("CCL") to simplify its system of categorizing sites and to better communicate the successful completion of cleanup activities (58 FR 12142, March 2, 1993). Inclusion of a site on the CCL has no legal significance.

Sites qualify for the CCL when: (1) any necessary physical construction is complete, whether or not final cleanup levels or other requirements have been achieved; (2) EPA has determined that the response action should be limited to measures that do not involve construction (e.g., institutional controls); or (3) the site qualifies for deletion from the NPL. For the most up-to-date information on the CCL, see EPA's Internet site at <http://www.epa.gov/superfund>.

II. Availability of Information to the Public

A. May I Review the Documents Relevant to This Final Rule?

Yes, documents relating to the evaluation and scoring of the sites in this final rule are contained in dockets

located both at EPA Headquarters and in the Regional offices.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "Quick Search," then key in the appropriate docket identification number; SFUND-2005-0006. (Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facilities identified below in section IID.)

B. What Documents Are Available for Review at the Headquarters Docket?

The Headquarters docket for this rule contains, for each site, the HRS score sheets, the Documentation Record describing the information used to compute the score, pertinent information regarding statutory requirements or EPA listing policies that affect the site, and a list of documents referenced in the Documentation Record.

C. What Documents Are Available for Review at the Regional Dockets?

The Regional dockets contain all the information in the Headquarters docket, plus the actual reference documents containing the data principally relied upon by EPA in calculating or evaluating the HRS score for the sites located in their Region. These reference documents are available only in the Regional dockets.

D. How Do I Access the Documents?

You may view the documents, by appointment only, after the publication of this rule. The hours of operation for the Headquarters docket are from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. Please contact the Regional dockets for hours.

Following is the contact information for the EPA Headquarters: Docket Coordinator, Headquarters; U.S. Environmental Protection Agency; CERCLA Docket Office; 1301 Constitution Avenue; EPA West, Room B102, Washington, DC 20004, 202/566-0276.

The contact information for the Regional dockets is as follows: Joan Berggren, Region 1 (CT, ME, MA, NH, RI, VT), U.S. EPA, Superfund Records and Information Center,

Mailcode HSC, One Congress Street, Suite 1100, Boston, MA 02114-2023; 617/918-1417.

Dennis Munhall, Region 2 (NJ, NY, PR, VI), U.S. EPA, 290 Broadway, New York, NY 10007-1866; 212/637-4343.

Dawn Shellenberger (ASRC), Region 3 (DE, DC, MD, PA, VA, WV), U.S. EPA, Library, 1650 Arch Street, Mailcode 3PM52, Philadelphia, PA 19103; 215/814-5364.

John Wright, Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street, SW., 9th floor, Atlanta, GA 30303; 404/562-8123.

Janet Pfundheller, Region 5 (IL, IN, MI, MN, OH, WI), U.S. EPA, Records Center, Superfund Division SRC-7J, Metcalfe Federal Building, 77 West

Jackson Boulevard, Chicago, IL 60604; 312/353-5821.

Brenda Cook, Region 6 (AR, LA, NM, OK, TX), U.S. EPA, 1445 Ross Avenue, Mailcode 6SF-RA, Dallas, TX 75202-2733; 214/665-7436.

Michelle Quick, Region 7 (IA, KS, MO, NE), U.S. EPA, 901 North 5th Street, Kansas City, KS 66101; 913/551-7335.

Gwen Christiansen, Region 8 (CO, MT, ND, SD, UT, WY), U.S. EPA, 999 18th Street, Suite 500, Mailcode 8EPR-B, Denver, CO 80202-2466; 303/312-6463.

Dawn Richmond, Region 9 (AZ, CA, HI, NV, AS, GU), U.S. EPA, 75 Hawthorne Street, San Francisco, CA 94105; 415/972-3097.

Denise Baker, Region 10 (AK, ID, OR, WA), U.S. EPA, 1200 6th Avenue, Mail Stop ECL-115, Seattle, WA 98101; 206/553-4303.

E. How May I Obtain a Current List of NPL Sites?

You may obtain a current list of NPL sites via the Internet at <http://www.epa.gov/superfund/> (look under the Superfund sites category) or by contacting the Superfund Docket (see contact information above).

III. Contents of This Final Rule

A. Additions to the NPL

This final rule adds the following seven sites to the NPL; all to the General Superfund Section:

State	Site name	City/county
CO	Standard Mine	Gunnison National Forest.
GA	Peach Orchard Road PCE Ground Water Plume	Augusta.
NE	Garvey Elevator	Hastings.
NH	Clor-Alkali Facility (Former)	Berlin.
NC	Blue Ridge Plating	Arden.
PA	Jackson Ceramix	Falls Creek.
TX	Sandy Beach Road Ground Water Plume	Azle.

Three of the sites in this final rule received comments supporting listing: Standard Mine, Garvey Elevator and Sandy Beach Road Ground Water Plume (which was proposed as Pelican Bay Ground Water Plume. See Section B, "Site Name Change" below). These sites were all proposed on April 27, 2005 (70 FR 21718) with a 60-day comment period which ended on June 27, 2005. In addition, EPA received one comment for Sandy Beach Road Ground Water Plume expressing concern about the site's impact on their family's health and stating that the temporary filtration system installed by the State of Texas was inadequate. The commenter urged EPA to find a fair and quick resolution to the problem. None of these comments affect the HRS score. All other sites in this rule received no comments.

B. Site Name Change

The Sandy Beach Road Ground Water Plume in Azle, Texas, was proposed to the NPL under a different name. The former name was Pelican Bay Ground Water Plume (see Proposed Rule at 70 FR 21718, April 27, 2005). EPA believes the new name, Sandy Beach Road Ground Water Plume, more accurately identifies the site.

C. What Did EPA Do With the Public Comments It Received?

All seven sites were proposed to the NPL on April 27, 2005 (70 FR 21718). EPA received no substantive comments or only comments supporting the listing of the seven sites and therefore, EPA is placing them on the NPL at this time. The comments supporting the listing of the sites are contained in the Headquarters Docket and are also listed in EPA's electronic public docket and comment system at <http://www.epa.gov/edocket/> using the SFUND-2005-0006 identification number.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

1. What Is Executive Order 12866?

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) the Agency must determine whether a regulatory action is "significant" and therefore subject to Office of Management and Budget (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 entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

2. Is This Final Rule Subject to Executive Order 12866 Review?

No. The listing of sites on the NPL does not impose any obligations on any entities. The listing does not set standards or a regulatory regime and imposes no liability or costs. Any liability under CERCLA exists irrespective of whether a site is listed. It has been determined that this action is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

1. What Is the Paperwork Reduction Act?

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the preamble of the final rules, are listed in 40 CFR part 9.

2. Does the Paperwork Reduction Act Apply to This Final Rule?

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. EPA has determined that the PRA does not apply because this rule does not contain any information collection requirements that require approval of the OMB.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

1. What Is the Regulatory Flexibility Act?

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq., as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996) whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small

entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

2. How Has EPA Complied With the Regulatory Flexibility Act?

This rule listing sites on the NPL does not impose any obligations on any group, including small entities. This rule also does not establish standards or requirements that any small entity must meet, and imposes no direct costs on any small entity. Whether an entity, small or otherwise, is liable for response costs for a release of a hazardous substance depends on whether that entity is liable under CERCLA 107(a). Any such liability exists regardless of whether the site is listed on the NPL through this rulemaking. Thus, this rule does not impose any requirements on any small entities. For the foregoing reasons, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

1. What Is the Unfunded Mandates Reform Act (UMRA)?

Title II of the Unfunded Mandates Reform Act of 1995 (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 by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. Before EPA promulgates a rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least

costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

2. Does UMRA Apply to This Final Rule?

No, EPA has determined that this 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 by the private sector in any one year. This rule will not impose any federal intergovernmental mandate because it imposes no enforceable duty upon State, tribal or local governments. Listing a site on the NPL does not itself impose any costs. Listing does not mean that EPA necessarily will undertake remedial action. Nor does listing require any action by a private party or determine liability for response costs. Costs that arise out of site responses result from site-specific decisions regarding what actions to take, not directly from the act of listing a site on the NPL.

For the same reasons, EPA also has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. In addition, as discussed above, the private sector is not expected to incur costs exceeding \$100 million. EPA has fulfilled the requirement for analysis under the Unfunded Mandates Reform Act.

E. Executive Order 13132: Federalism

1. What Is Executive Order 13132 and Is It Applicable to This Final Rule?

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.”

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

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, the requirements of section 6 of the Executive Order do not apply to this rule.

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

1. What Is Executive Order 13175?

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.”

2. Does Executive Order 13175 Apply to This Final Rule?

This final rule does not have tribal implications. It will 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. Thus, Executive Order 13175 does not apply to this final rule.

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

1. What Is Executive Order 13045?

Executive Order 13045: “Protection of Children from Environmental Health Risks and Safety Risks” (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 may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or 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.

2. Does Executive Order 13045 Apply to This Final Rule?

This rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this section present a disproportionate risk to children.

H. Executive Order 13211

1. What Is Executive Order 13211?

Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355 (May 22, 2001), requires EPA to prepare and submit a Statement of Energy Effects to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, for certain actions identified as “significant energy actions.” Section 4(b) of Executive Order 13211 defines “significant energy actions” as “any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect

on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.”

2. Is This Rule Subject to Executive Order 13211?

This 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 (See discussion of Executive Order 12866 above.)

I. National Technology Transfer and Advancement Act

1. What Is the National Technology Transfer and Advancement Act?

Section 12(d) of the National Technology Transfer and 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.

2. Does the National Technology Transfer and Advancement Act Apply to This Final Rule?

No. This rulemaking does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Possible Changes to the Effective Date of the Rule

1. Has EPA Submitted This Rule to Congress and the General Accounting Office?

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 has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the 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 rule is not a "major rule" as defined by 5 U.S.C. 804(2).

2. Could the Effective Date of This Final Rule Change?

Provisions of the Congressional Review Act (CRA) or section 305 of CERCLA may alter the effective date of this regulation.

Under the CRA, 5 U.S.C. 801(a), before a rule can take effect the federal agency promulgating the rule must submit a report to each House of the Congress and to the Comptroller General. This report must contain a copy of the rule, a concise general statement relating to the rule (including whether it is a major rule), a copy of the cost-benefit analysis of the rule (if any), the agency's actions relevant to provisions of the Regulatory Flexibility Act (affecting small businesses) and the Unfunded Mandates Reform Act of 1995 (describing unfunded federal requirements imposed on state and local governments and the private sector), and any other relevant information or requirements and any relevant Executive Orders.

EPA has submitted a report under the CRA for this rule. The rule will take effect, as provided by law, within 30 days of publication of this document, since it is not a major rule. Section 804(2) defines a major rule as any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) finds has resulted in or is likely to result in: An annual effect on

the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. NPL listing is not a major rule because, as explained above, the listing, itself, imposes no monetary costs on any person. It establishes no enforceable duties, does not establish that EPA necessarily will undertake remedial action, nor does it require any action by any party or determine its liability for site response costs. Costs that arise out of site responses result from site-by-site decisions about what actions to take, not directly from the act of listing itself. Section 801(a)(3) provides for a delay in the effective date of major rules after this report is submitted.

3. What Could Cause a Change in the Effective Date of This Rule?

Under 5 U.S.C. 801(b)(1) a rule shall not take effect, or continue in effect, if Congress enacts (and the President signs) a joint resolution of disapproval, described under section 802.

Another statutory provision that may affect this rule is CERCLA section 305, which provides for a legislative veto of regulations promulgated under CERCLA. Although *INS v. Chadha*, 462 U.S. 919, 103 S. Ct. 2764 (1983) and *Bd. of Regents of the University of Washington v. EPA*, 86 F.3d 1214, 1222

(D.C. Cir. 1996) cast the validity of the legislative veto into question, EPA has transmitted a copy of this regulation to the Secretary of the Senate and the Clerk of the House of Representatives.

If action by Congress under either the CRA or CERCLA section 305 calls the effective date of this regulation into question, EPA will publish a document of clarification in the **Federal Register**.

List of Subjects in 40 CFR Part 300

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

Dated: September 7, 2005.

Barry N. Breen,

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

■ 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by adding the following sites in alphabetical order to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1.—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes ^(a)
CO	Standard Mine	Gunnison National Forest	*
GA	Peach Orchard Road PCE Ground Water Plume	Augusta	*
NC	Blue Ridge Plating	Arden	*
NE	Garvey Elevator	Hastings	*
NH	Chlor-Alkali Facility (Former)	Berlin	*
PA	Jackson Ceramix	Falls Creek	*
TX	Sandy Beach Road Ground Water Plume	Azle	*

TABLE 1.—GENERAL SUPERFUND SECTION—Continued

State	Site name	City/county	Notes ^(a)
*	*	*	*

^(a) A = Based on issuance of health advisory by Agency for Toxic Substance and Disease Registry (if scored, HRS score need not be ≤ 28.50).
C = Sites on Construction Completion list.
S = State top priority (included among the 100 top priority sites regardless of score).
P = Sites with partial deletion(s).

* * * * *

[FR Doc. 05–18235 Filed 9–13–05; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 160

[CMS–0010–IFC]

RIN 0938–AM63

Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings—Extension of Expiration Date

AGENCY: Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: An interim final rule establishing procedures for the imposition, by the Secretary of Health and Human Services, of civil money penalties on entities that violate standards adopted by the Secretary under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was published on April 17, 2003. The interim final rule expires on September 16, 2005. This regulatory action extends the expiration date to March 16, 2006 to avoid the disruption of ongoing enforcement actions while HHS completes with rulemaking to develop a more comprehensive enforcement rule.

DATES: Effective September 14, 2005, the expiration date of 45 CFR part 160, subpart E is extended from September 16, 2005, to March 16, 2006.

FOR FURTHER INFORMATION CONTACT: Carol Conrad, (202) 690–1840.

SUPPLEMENTARY INFORMATION:

I. Background

On April 17, 2003, the Secretary of Health and Human Services published an interim final rule with request for comments. 68 FR 18895. The interim final rule adopted rules of procedure for the imposition by the Department of Health and Human Services (HHS) of civil money penalties on entities that

violate standards and requirements adopted by HHS under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191. These rules are codified at 45 CFR part 160, subpart E (subpart E).

As corrected at 68 FR 22453 (April 28, 2003), subpart E was scheduled to expire on September 16, 2004. On September 15, 2004, HHS published a final rule extending the expiration date for one year, to September 16, 2005. 69 FR 55515. The final rule extended the original expiration date to avoid disruption of ongoing enforcement actions while HHS undertook a rulemaking to propose complete procedural and substantive provisions for the enforcement of the HIPAA rules through the imposition of civil money penalties, which would supersede subpart E.

On April 18, 2005, HHS published a notice of proposed rulemaking proposing this complete set of enforcement provisions. 70 FR 20224. The public comment period on the proposed rules closed on June 17, 2005. HHS is currently considering the public comments received, but will not be able to issue the final rule by September 16, 2005. Thus, in order to preserve the status quo with respect to enforcement during the pendency of the rulemaking, HHS is extending the expiration date of subpart E for an additional six months, to March 16, 2006.

II. Procedural Requirements

A. Determination To Issue Final Rule Extending Expiration Date Without Notice and Comment, To Be Effective in Less Than 30 Days

As noted, HHS has proposed a rule to supersede subpart E. However, this rulemaking will not be completed by September 16, 2005, when the interim final rule that adopted subpart E is scheduled to expire. The resulting hiatus in the procedures for civil money penalty enforcement actions could create confusion for both the public and HHS with respect to enforcement during this period. Thus, HHS hereby extends the expiration date of subpart E to March 16, 2006. This action is being

taken under HHS's authority at 42 U.S.C. 1302(a) and 1320d–6.

Notwithstanding this extension, HHS fully expects to issue the final rule that will result from the pending rulemaking as soon as possible. However, the six-month extension should provide HHS with a period sufficient to avoid another extension, should unexpected circumstances delay the regulatory development process.

The Administrative Procedure Act generally requires agencies to provide advance notice and an opportunity to comment on agency rulemakings. However, there are certain exceptions to this requirement. As the preamble to the April 17, 2003 interim final rule explained, subpart B sets out—

The procedures for provision by the agency of the statutorily required notice and hearing and procedures for issuing administrative subpoenas. Such provisions are exempted from the requirement for notice-and-comment rulemaking under the “rules of agency * * * procedure, or practice” exemption at 5 U.S.C. 553(b)(3)(A).

68 FR 18897. Since this regulatory action does no more than extend the effectiveness of a rule that itself was not required to be issued through notice-and-comment rulemaking, the extension of the rule likewise comes within the exemption of 5 U.S.C. 553(b)(3)(A). Accordingly, we do not request comment on the extension.

We have also determined that good cause exists to waive the requirement of publication 30 days in advance of the rule's effective date under 5 U.S.C. 553(d)(3). Since subpart E is already in effect, no useful purpose would be served in delaying the effective date of this action, as those entities who are subject to subpart E are already on notice of its terms. Making this extension effective on less than 30 days notice accordingly will not impose a burden upon anyone. In addition, to the extent that a delayed effective date occasioned a hiatus in the effectiveness of subpart E, it could cause the confusion that the extension seeks to avoid. Accordingly, we find good cause under 5 U.S.C. 553(d)(3) for not delaying the effective date of this action.