responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that Order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T07–108 to read as follows:

§ 165.T07–108 Savannah River, Savannah, GA.

(a) *Location:* The Coast Guard is establishing a temporary safety zone encompassing all waters of the Savannah River from the Talmadge Bridge (32°05′19″ N 081°05′58″ W) to the east end of the Marriott hotel (32°04′52″ N 081°05′18″ W).

(b) *Regulations.* In accordance with the general regulations in § 165.23 of this part, anchoring, mooring or transiting in this zone is prohibited, except as provided for herein, or unless authorized by the Coast Guard Captain of the Port Savannah, GA or his representative. Any concerned traffic can contact the representative of the Captain of the Port on board the U.S. Coast Guard vessel, which will be on scene throughout the event. Traffic needing permission to pass through this safety zone can contact the representative for the COTP on VHF–FM channel 16 or via phone at (912) 652–4181.

(c) *Dates:* This rule is effective from 4:45 p.m. on November 26, 2004 to 9:30 p.m. on November 26, 2004.

Dated: November 10, 2004.

M.D. Drieu,

Captain, U. S. Coast Guard, Captain of the Port Savannah.

[FR Doc. 04–26097 Filed 11–24–04; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 355

[SFUND–2003–0007; FRL–7842–1]

RIN 2050–AE42

Emergency Planning and Community Right-to-Know Act; Extremely Hazardous Substances List; Deletion of Phosmet

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On November 12, 2003, the Environmental Protection Agency proposed to delete phosmet from the list of extremely hazardous substances (EHS) issued under the Emergency Planning and Community Right-to-Know Act (EPCRA). Today, EPA is taking final action to delete phosmet from the EHS list. Facilities with phosmet on-site will no longer be required to comply with emergency planning and emergency release notification requirements. In addition, facilities handling phosmet will no longer have to file an emergency and hazardous chemical inventory form and Material Safety Data Sheet (MSDS) for phosmet with their State Emergency Response Commission (SERC), Local Emergency Planning Committee (LEPC), and local fire department, for amounts less than 10,000 pounds.

DATES: This rule is effective December 27, 2004.

ADDRESSES: EPA has established a docket for this action under Docket ID No. SFUND–2003–0007. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Superfund Docket is (202) 566–0270.

FOR FURTHER INFORMATION CONTACT: For general information, contact the Emergency Planning and Community Right-to-Know Hotline at (800) 424–9346; in the Washington, DC metropolitan area, contact (703) 412–9810. The Telecommunications Device for the Deaf (TDD) Hotline number is (800) 535–7672. You may also access general information online at the Hotline Internet site, *http://www.epa.gov/epaoswer/hotline/.* For questions on the contents of this document, contact Kathy Franklin, Office of Emergency Management (formerly Chemical Emergency Prevention and Preparedness Office), Office of Solid Waste and Emergency Response, (5104A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Telephone (202)564–7987; Fax (202) 564–8444 e-mail: *franklin.kathy@epa.gov*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me? Entities that would be affected by this section are those organizations and facilities subject to 40 CFR part 355—Emergency Planning and Emergency Release Notification Requirements and 40 CFR part 370—Hazardous Chemical Reporting. To determine whether your facility is affected by this action, you should carefully examine the applicability provisions at 40 CFR part 355 and 40 CFR part 370. Entities potentially affected by this action are facilities that produce phosmet formulations, distribute phosmet as a pesticide for commercial use, and farms that store, handle and apply phosmet. If you have any questions regarding the applicability of this action to a particular entity, consult the person(s) listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr.* 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 public docket, and access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number: SFUND–2003–0007.

The information in this final rule is organized as follows:

I. Background

A. Statutory Authority

This final rule is issued under sections 302 and 328 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA).

B. Extremely Hazardous Substances Under EPCRA

On October 17, 1986, the President signed into law the Superfund Amendments and Reauthorization Act of 1986 (SARA), Pub. L. 99–499 (1986). Title III of SARA established a program designed to require state and local planning and preparedness for spills or releases of certain hazardous materials and to provide the public and local governments with information concerning potential chemical hazards in their communities. This program is codified as the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), 42 U.S.C. 11001–11050.

Subtitle A of EPCRA establishes the framework for local emergency planning. The statute requires that EPA publish a list of ''extremely hazardous substances'' (EHSs). The EHS list was established by EPA to identify chemical substances which could cause serious irreversible health effects from accidental releases (51 *FR* 13378). EPA had previously published this list as the list of acutely toxic chemicals in November 1985, in Appendix A of the Chemical Emergency Preparedness Program Interim Guidance (CEPP Guidance). The Agency was also directed to establish ''threshold planning quantities'' (TPQs) for each extremely hazardous substance.

Under EPCRA section 302, a facility which has on-site an EHS in excess of its TPQ must notify the State Emergency Response Commission (SERC) and Local Emergency Planning Committee (LEPC) as well as participate in local emergency planning activities. Under section 304 of EPCRA, the facility must also report accidental releases in excess of the Reportable Quantity (RQ) to the National Response Center, the LEPC and SERC. However, releases from the application of a registered pesticide are exempted from the EPCRA section 304 emergency release notification according to 40 CFR 355.40(a)(2)(iv).

As provided under 40 CFR 370.20, EHSs are subject to EPCRA section 311 and 312 reporting requirements. Facilities with an EHS present on-site in excess of 500 pounds or its TPQ, whichever is lower, are required to submit an emergency and hazardous chemical inventory form and Material Safety Data Sheet (MSDS) to their SERC, LEPC and local fire department. Facilities must also submit chemical inventory forms and MSDS for other hazardous chemicals present on-site in quantities of 10,000 pounds or more. However, under sections 311 and 312 of EPCRA, facilities that apply chemicals to crops as a pesticide, do not have to file the inventory form or MSDS for those chemicals, because chemicals that are used at facilities in routine agricultural operations are not included as hazardous chemicals subject to the reporting requirements.

The purpose of the extremely hazardous substance list is to focus initial efforts in the development of state and local contingency plans. Inclusion of a chemical on the EHS list does not mean state or local communities should ban or otherwise restrict use of a listed chemical. Rather, such identification indicates a need for the community to undertake a program to investigate and evaluate the potential for accidental exposure associated with the production, storage or handling of the chemical at a particular site.

The list of extremely hazardous substances and their threshold planning quantities are codified in 40 CFR part 355, appendices A & B. EPA first published the EHS list and TPQs along with the methodology for determining threshold planning quantities as an interim final rule on November 17, 1986 (51 *FR* 41573–41579 and 41580). In the final rule, EPA made a number of revisions to the interim final rule (52 *FR* 13387, April 22, 1987). Among other things, the final rule republished the EHS list, with the addition of four new chemicals and revised the methodology for determining some TPQs. Details of the methodology used to determine whether to list a substance as an extremely hazardous substance and for deriving the threshold planning quantities are found in the November 1986 and April 1987 **Federal Register** notices and in technical support documents in the rulemaking records. These records are found in Superfund Docket No. 300PQ. *See* Section III of this notice for the criteria used for determining whether a substance qualifies as an extremely hazardous substance.

EPA has since received a number of petitions to amend the EHS list. To date, 46 chemicals have been delisted from the EHS list in previous rulemakings because they did not meet the toxicity criteria for the list and were originally listed under section 302 in error.

II. Basis for Final Rule

On November 12, 2003 (68 FR 64041), EPA proposed to delete the chemical phosmet from the EHS list under Section 302 of EPCRA, in response to a petition from Gowan Company. Gowan believed that the listing of phosmet was based on an invalid toxicity study and argued that phosmet should be removed from the EHS list because there were no valid data to indicate that the chemical meets the listing criteria.

Phosmet was originally listed on the EHS list because a four-hour rat inhalation LC_{50}, reported in the 1985 Registry of Toxic Effect of Chemical Substances (RTECS) database, met the EHS primary toxicity inhalation criteria of $LC_{50} \leq 0.5$ mg/L. *See* Section III of this notice for discussion of the EHS listing criteria. The secondary toxicity criteria for EHSs did not apply to phosmet because it does not have a high production volume. Approximately 1,125,000 pounds of phosmet as an active ingredient (a.i.) in pesticide formulations are used annually. The LC_{50} result of 0.054 mg/L was from in a 1969 Russian study, unavailable to EPA. However, a translation of a 1969 Russian journal article about the study

was available for review. The phosmet used in the experiment was manufactured in a Russian research institute using an unknown method. The journal article severely lacked key details of the experimental methods, such as the purity of phosmet, extent of animal body exposure, possibility of other routes of exposure, specific emulsion components and their toxicity. With the number of unanswered key questions regarding the experimental protocol, EPA agrees that the Russian study results were not a sufficient basis for keeping phosmet on the EHS list.

However, before EPA took any regulatory action, a comprehensive review was undertaken of available acute toxicity studies by inhalation, dermal and oral routes; this review found no other inhalation or dermal study results for phosmet that met the EHS primary listing criteria of inhalation $LC_{50} \leq 0.5$ mg/L or dermal LD_{50} of ≤50 mg/kg. A review of acute oral toxicity studies indicated that mice were more sensitive than rats to phosmet. The lowest reported rat oral LD_{50} for technical grade phosmet (96.1%) is 113 mg/kg, which did not meet the primary oral listing criteria of ≤ 25 mg/kg. Technical grade phosmet is generally 94% or higher phosmet content. Reported acute oral toxicity LD_{50}s of technical grade phosmet in mice varied from of 23.1 to 51 mg/kg, based on eight studies.

Stauffer Chemical Company in 1971 reported an oral LD_{50} of 23.3 mg/kg for mice for technical grade phosmet, purity unspecified. The phosmet used in the study was manufactured by a different synthesis method (using ethylene chloride (EDC) as solvent) than used by the current and previous pesticide registrants (Gowan and Stauffer) and thus the phosmet tested may not be representative of the phosmet used in commerce. The greater toxicity observed for technical phosmet synthesized via the EDC route presumably may have been due to impurities resulting from the starting material, incomplete synthesis, degradation or other syntheses method-specific factors. Because of these uncertainties, EPA does not believe the phosmet-EDC results are representative for the phosmet manufactured and registered with EPA by either Stauffer Chemical (former pesticide registrant) or Gowan Company (current pesticide registrant). Therefore, EPA did not consider these values in its review of phosmet for EHS listing purposes.

Another study conducted by researchers at the National Center for Toxicological Research (NCTR) reported oral LD_{50} results of 23.1 and 24.9 mg/kg for male and female mice, respectively, using 99.5% phosmet. The results from this study were presented in a journal article (Haley *et al.*, 1975), but the actual study data could not be found. Because the actual doses and number of animals killed at each dose are not cited, the LD_{50} results could not be replicated or confirmed. Other concerns regarding the Haley study included the variations in mortality response, lack of information on the use of control data, and other questions or potential problems with the study methodology and design. The Agency discussed these issues in detail in the technical background document supporting this rulemaking.

Because of the uncertainties surrounding result verification and the design details of the Haley study, EPA proposed conducting a new acute oral mouse LD_{50} study. Gowan then offered to conduct a new study in acute oral toxicity in mice, which they completed in December 2002. In Gowan's study, twenty female mice were administered 40 mg/kg of 98% pure phosmet, by oral gavage. No mortalities occurred. Because the tested dose produced no deaths in the twenty mice, testing at lower doses was considered unnecessary. EPA believes the Gowan study confirms the oral mouse LD_{50} results from the majority of the previous reported studies, which show LD_{50}s greater than the EHS listing criterion of ≤ 25 mg/kg. Therefore, EPA believes that phosmet does not meet the acute oral toxicity listing criterion and it should be removed from the EHS list. Because phosmet does not have a high production volume (about 1.25 million pounds are applied annually), only the primary listing criteria (discussed below) were used to evaluate whether phosmet should be retained on the EHS list.

III. The EHS Listing Criteria

As previously described, in November 1985, EPA published a list of substances in appendix A of the ''Chemical Emergency Preparedness Program Interim Guidance.'' Under section 302(a) of EPCRA, Congress required EPA to adopt that same list as the EHS list. Appendix A defines the list of chemicals as those ''for which an acute toxicity measure has a value meeting the criteria stated in Chapter 6'' of the November 1985 Interim Guidance. The listing criteria discussed in Chapter 6 are the same criteria referenced and discussed in EPA's interim final and final rules establishing the EHS list. Those criteria contain two sets of numerical acute toxicity measures. For purposes of clarification in today's rulemaking, EPA will refer to the two sets of numerical acute toxicity criteria as the primary listing criteria and the secondary listing criteria. In developing these criteria, the Agency presumed that humans may be as sensitive as the most sensitive mammalian species tested.

A. Primary Listing Criteria

The primary acute toxicity criteria are, based on data from mammalian testing:

Inhalation $LC_{50} \leq 0.5$ milligrams per liter of air (mg/L) (for exposure time ≤ 8 hours), or
Dermal $LD_{50} \leq 50$ milligrams per kilogram of body weight (mg/kg), or
Oral—$LD_{50} \leq 25$ milligrams per kilogram of body weight (mg/kg)

LC_{50} is the median lethal concentration, defined as the concentration level at which 50 percent of the test animals died when exposed by inhalation for a specified time period.

LD_{50} is the median lethal dose, defined as the dose at which 50 percent of the test animals died during exposure.

B. Secondary Listing Criteria

EPA included on the EHS list other chemicals that did not meet the primary acute toxicity criteria. These were added based on the secondary acute toxicity criteria below as well as the following factors: large volume production and known risk, as indicated by the fact that some of the chemicals have caused death and injury in accidents.

The secondary acute toxicity criteria are, based on data from mammalian testing:

Inhalation— $LC_{50} \leq 2$ mg/L for exposure time of ≤ 8 hours, or
Dermal—$LD_{50} \leq 400$ mg/kg or
Oral—$LD_{50} \leq 200$ mg/kg

The chemical with the lowest production volume that was included as an EHS based on the secondary criteria and high production volume, had an annual production volume of 30 million pounds. In addition to high production chemicals meeting these criteria, several other chemicals slightly less toxic than the secondary criteria, were listed because of their recognized toxicity as a chemical of concern or known hazard; for example several of them have caused death or injury in accidents.

C. Development of Listing Criteria

The selection criteria were designed as screening tools to identify chemicals with high acute toxicity. The specific values chosen are recognized by the scientific community as indicating a high potential for acute toxicity, and

chemicals meeting the toxicity criteria are considered potentially hazardous. Even with the amount of animal data that are available, some chemicals have no standard acute toxicity test data.

In choosing chemicals for the EHS list, EPA matched the criteria against all mammalian test data for all chemicals. A chemical was identified as acutely toxic according to these criteria if mammalian acute toxicity data for any one of the three routes of administration was equal to or less than the numerical criteria specified for that route. The Agency used LC_{LO} or LD_{LO} data for a chemical in cases where median lethal concentration or dose (LC_{50} or LD_{50}) were not available. The lethal concentration low (LC_{LO}) and the lethal dose low (LD_{LO}) are the lowest concentration in air or the lowest dose in milligrams of chemical per kilogram of body weight, respectively, at which any test animals died. These values may be more variable than those provided from median lethality tests, but for the purposes of screening large numbers of chemicals, it was deemed necessary to provide a second level screening tool in preference to missing potentially toxic chemicals because they were not adequately tested. For inhalation data, the Agency chose to use LC_{50} and LC_{LO} values with exposure periods up to eight hours or even with no reported exposure period. EPA recognized that this was a conservative approach, but wanted to ensure that acutely toxic chemicals of concern were identified.

For purposes of this assessment, the Agency also used lethality data from the most sensitive mammalian species and not only those from rats because it was not possible to predict which species is the appropriate surrogate for humans for a given chemical. In addition, because populations are heterogeneous and individuals are expected to vary considerably in their sensitivity to chemical substances for this assessment, the Agency assumed that humans may be as sensitive as the most sensitive mammalian species tested.

D. Toxicity Data Sources

When the initial list was developed, the Agency used acute toxicity data from the Registry of Toxic Effects of Chemical Substances (RTECS), maintained by the National Institute of Occupational Safety and Health (NIOSH). The RTECS data was compared with the EHS listing toxicity criteria (both primary and secondary). The RTECS data base was used as the principal source of toxicity data for identifying acutely toxic chemicals because it represents the most comprehensive repository of acute toxicity information available with basic toxicity information and other data on more than 79,000 chemicals. Although RTECS is not formally peer-reviewed, data from RTECS is widely accepted and used as a toxicity data source by industry and regulatory agencies alike. The data presented are from scientific literature which has been edited by the scientific community before publication.

IV. Response to Comments on the November 12, 2003 Proposed Rule

EPA received eight comments during the comment period.[1] Four were from growers or agricultural trade associations, one was from a horticultural agent, one was from a certified professional agronomist, one was from an pesticide/fertilizer retailer and one was from the petitioner seeking delisting of phosmet. All commenters supported the removal of phosmet from the EHS list. Most commenters stated that phosmet has been an essential pest control tool. Some commented that EPA used good science to eliminate unnecessary regulation and would provide regulatory relief. Additionally, several of these commenters stated that the delisting would allow public and private resources to be focused on more critical issues.

Gowan Company, the petitioner requesting the removal of phosmet from the EHS list and the one of the pesticide registrants, had already submitted many toxicity studies and other information to EPA before the proposal was published. Their comments on the proposed rule noted that in addition to no valid data being available that indicate phosmet meets the listing criteria, a robust set of valid data is available that unequivocally shows that phosmet does not meet any of the toxicity (or other) listing criteria. Gowan also believes that the proposed rulemaking will appropriately rectify the mischaracterization of risk.

EPA agrees that there are many acute toxicity studies available for phosmet with results that do not meet the listing criteria. The **Federal Register** notice for the proposed rule focused more on those studies that, at first, appeared to meet the listing criteria. As EPA explained in the notice for the proposal, other acute toxicity studies indicate that phosmet does not meet the listing criteria. These studies are summarized and discussed in the technical background document; and available for review in the public docket. EPA did take into consideration the many results of these other acute oral toxicity studies when making its decision to delist phosmet.

EPA also reviewed the 17 technical references and reports submitted by the Working Group on Community Right-to-Know, in July 2002. These references primarily contained information on phosmet's acute and chronic toxicity, human health effects and risks. EPA carefully reviewed the submitted information and saw no new data or studies on acute toxicity that had not already been reviewed and considered in the decision. The EHS listing criteria is based on specific LC_{50} or LD_{50} acute toxicity testing results in mammals and does not rely on chronic, long-term health effects.

V. Regulatory Impacts of This Rule

As a result of this final rule, phosmet will no longer be an EHS listed under section 302 of EPCRA. As a result, facilities that have phosmet on-site will no longer be required to (1) notify their SERCs and LEPCs that they are subject to the emergency planning provisions of EPCRA section 302 for the chemical phosmet; (2) provide to their LEPC a facility emergency coordinator (unless other listed EHS chemicals are present at the facility) and information about phosmet for developing and implementing the emergency plan; and (3) notify SERCs and LEPCs of accidental releases of phosmet under the requirements of EPCRA Section 304. Releases from application of a pesticide were already exempted from Section 304 reporting. LEPCs would no longer be required to include phosmet as part of a local emergency plan for responding to a chemical emergency at a facility.

Phosmet is still a ''hazardous chemical'' under Section 311 and 312 requirements, except when it is used in routine agricultural operations, such as a pesticide applied on crops. According to 29 CFR 1900.1200(c), phosmet is considered a ''toxic'' health hazard because it has an oral rat acute toxicity LD_{50} of less than 200 mg/kg. Facilities that process or distribute phosmet, such as phosmet product manufacturers and agricultural chemical distributors would still be subject to EPCRA section 311 and 312 reporting requirements for phosmet if they have phosmet present in amounts equal to or greater than 10,000 pounds, as provided in 40 CFR 370.20(b)(4).

[1] In addition, the Agency also received toxicity information on phosmet from the Working Group of Community Right-To-Know in July 2002, which requested that these documents be placed in the official docket if the Agency proposed to change phosmet's listing as an Extremely Hazardous Substance under EPCRA.

VI. 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 this regulatory action is ''significant'' and therefore subject to formal review by the Office of Management and Budget (OMB) and to 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.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations 40 CFR part 355 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2050–0092, (EPA ICR No. 1395.05). Copies of the ICR document(s) may be obtained from Susan Auby, by mail at U.S. Environmental Protection Agency, Collection Strategies Division (Mail Code 2822), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, by e-mail at *auby.susan@epa.gov*, or by calling 202–566–1672. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr*. Include the ICR and/or OMB number in any correspondence.

This action does not impose any new information collection burden. This rule will relieve burden for facilities that have phosmet on-site. 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

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

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that is defined by the Small Business Administration by category of business using North America Industrial Classification System (NAICS) and codified at 13 CFR 121.201; (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.

After considering the economic impacts of the final rule on small entities, we have concluded that this action will not have a significant economic impact on a substantial number of small entities. This action would remove requirements for reporting and emergency planning for small entities with phosmet on site, and thus relieves regulatory burden.

D. Unfunded Mandates Reform Act

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 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 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 to have meaningful and timely input in the development of EPA regulatory proposals, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not include a Federal mandate that may result in expenditures of $100 million or more for State, local, or tribal governments, in the aggregate, or the private sector in any one year. This rule will provide regulatory burden relief and does not impose any additional costs to any State, local, or tribal governments.

EPA also has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. The rule will provide burden relief to regulated entities.

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.''

Under 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 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. This rule does not impose any new requirements on States or other levels of government. Instead, it relieves LEPCs of the responsibility of developing and maintaining emergency plans for facilities that handle and store phosmet. SERCs and LEPCs will no longer be notified of releases of phosmet under the requirements of EPCRA Section 304. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

Because this rule deletes phosmet from the list of EHS chemicals, it relieves some burden on local governments for preparing emergency response plans because fewer facilities will be subject to reporting requirements. This action does not prevent any State government from enforcing more stringent standards for this chemical.

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 9, 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.''

This final rule does not have tribal implications, as specified in Executive Order 13175. It does not impose any new requirements on tribal officials. Instead it relieves them of the responsibility of developing emergency plans for facilities that handle and store phosmet. EPA does not believe that tribes have any significant number of facilities that handle, store or use phosmet. Phosmet formulations are handled and stored by farm chemical distributors and used mostly on fruit and nut crops. Today's rule does not significantly or uniquely affect the communities of Indian tribal governments, nor would it impose substantial direct compliance costs on them. Thus, Executive Order 13175 does not apply to this rule.

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

The Executive Order 13045, entitled ''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.

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

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

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 defined under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995

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. This final rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). The rule will be effective December 27, 2004.

List of Subjects in 40 CFR Part 355

Environmental protection, Air pollution control, Chemicals, Chemical accident prevention, Chemical emergency preparedness, Community emergency response plan, Community right-to-know, Extremely hazardous substances, Hazardous substances, Reportable quantity, Reporting and recordkeeping requirements, Superfund, Threshold planning quantity.

Dated: November 18, 2004.

Michael O. Leavitt,

Administrator.

■ For the reasons set out in the preamble, part 355 of title 40 of the Code of Federal Regulations is amended as follows:

PART 355—EMERGENCY PLANNING AND NOTIFICATION

■ 1. The authority citation for part 355 continues to read as follows:

Authority: 42 U.S.C. 11002, 11004, and 11048.

Appendices A and B—[Amended]

■ 2. Appendices A and B to part 355 are amended by removing the entry for CAS No. 732–11–6 for the Chemical Name Phosmet.

[FR Doc. 04–26162 Filed 11–24–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2175–F]

RIN 0938–AM20

Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule finalizes 10-year recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program. Manufacturers must retain records for 10 years from the date the manufacturer reports data to us for a rebate period.

This final rule also finalizes the requirement that manufacturers must retain records beyond the 10-year period if the records are known by the manufacturer to be the subject of an audit or a government investigation.

Furthermore, this final rule responds to public comments on the January 6, 2004 interim final rule with comment period and the proposed rule pertaining to the 10-year recordkeeping requirements, respectively.

DATES: This rule is effective January 1, 2005.

FOR FURTHER INFORMATION CONTACT: Kim Howell, (410) 786–6762.

SUPPLEMENTARY INFORMATION:

I. Background

In order for a pharmaceutical manufacturer's products to be eligible for Medicaid reimbursement under section 1903(a) of the Social Security Act (the Act), the manufacturer must sign an agreement with us on behalf of the Secretary of Health and Human Services to participate in the Medicaid drug rebate program. Among the terms to which the manufacturer must agree is the requirement to retain pricing data to support the calculation of average manufacturer price and best price as defined in section 1927 of the Act. Absent a regulatory or statutory requirement, it has been our position that manufacturers must retain these records indefinitely.

On September 19, 1995, we published a proposed rule (60 FR 48442) in the **Federal Register** that proposed numerous provisions related to the Medicaid drug rebate program. As relevant to this rule, we proposed a new 3-year recordkeeping requirement for drug manufacturers under the Medicaid drug rebate program and proposed a 3-year time limitation during which manufacturers must recalculate and report data to us on the average manufacturer price and best price. On August 29, 2003, we published a final rule with comment period (68 FR 51912) in the **Federal Register** that finalized both provisions. On September 26, 2003, we issued a correction notice (68 FR 55527) in the **Federal Register** to change the effective date of the August 29, 2003 rule from October 1, 2003 to January 1, 2004.

II. Provisions of the Proposed Regulations and Interim Final Rule

On January 6, 2004, we published an interim final rule with comment period that removed the 3-year recordkeeping requirement issued in the August 29, 2003 final rule with comment period, and replaced it with 10-year recordkeeping requirements on a temporary basis for manufacturers participating in the Medicaid drug rebate program, and solicited comments on the 10-year requirement.

Under the 10-year recordkeeping requirement, we required that manufacturers retain records for 10 years from the date the manufacturer reports data to us for a rebate period. We also required that manufacturers retain records beyond the 10-year period if the records are the subject of an audit or a government investigation of which the manufacturer is aware and if the audit findings or investigation related to the average manufacturer price and best price have not been resolved. The provisions of the January 6, 2004 interim final rule related to record retention are scheduled to sunset on December 31, 2004.

In addition, the January 6, 2004 interim final rule with comment period responded to public comments on the August 29, 2003 final rule with comment period that pertain to the 3-year recordkeeping requirement at § 447.534(h). The 3-year recordkeeping requirement for drug manufacturers participating in the Medicaid drug rebate program has caused a significant amount of concern from commenters with regard to the False Claims Act (FCA) and other possible fraud and abuse violations.

Also, on January 6, 2004, we published a proposed rule (69 FR 565) that would remove the 3-year recordkeeping requirement and replace it with 10-year recordkeeping requirement on a permanent basis. We also proposed that manufacturers must retain records beyond the 10-year period if the manufacturers are aware that the records are the subject of an audit or a government investigation and if the audit findings or investigation related to the manufacturer's average manufacturer price and best price have not been resolved. This final rule finalizes both the interim final rule and the proposed rule that we published on January 6, 2004.

III. Analysis of and Response to Public Comments on the January 6, 2004 Interim Final With Comment Period and Proposed Rule

We received 3 timely comments in response to the January 6, 2004 interim final rule with comment period and proposed rule. We received comments from an attorney who represents the pharmaceutical industry, a coalition comprised of national advocacy groups, and a non-profit organization. These comments and our responses are summarized below.

Comment: One commenter urged us to promulgate the 10-year requirement as a final rule, effective before the expiration of the current 10-year requirement on December 31, 2004.

Response: We agree; therefore, we are issuing this final rule to permanently establish the 10-year recordkeeping requirements for manufacturers.

Comment: One commenter expressed the opinion that the January 6, 2004 interim final rule and proposed rule should be modified to change the record retention requirements back to 3 years. A manufacturer would still have the discretion to retain records for as long as it wanted, but would not be subject to a mandatory requirement in excess of the 3-year period. The government would not be restricted by these rules from pursuing claims under the False Claims Act (FCA) or applicable health care laws against a manufacturer for fraud, abuse, or knowingly submitting false data to the government. Changing the record retention requirement back to 3 years would reconcile the current conflict between the 10-year record retention requirement and the 3-year price recalculation reporting requirement. The commenter further stated that the interim final rule and the proposed rule should be finalized to clearly state that the 3-year time