documentation because we are establishing a security zone.

A draft ''Environmental Analysis Check List'' and a draft ''Categorical Exclusion Determination'' (CED) are available in the docket where indicated under **ADDRESSES.** Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

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 proposes to amend 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. Revise § 165.1183 to read as follows:

§ 165.1183 Security Zones; Cruise Ships, Tank Vessels and High Interest Vessels, San Francisco Bay and Delta ports, California.

(a) *Definitions.* As used in this section—

(1) *Cruise ship* means a passenger vessel, except for a ferry, over 100 feet in length, authorized to carry more than 12 passengers for hire; making voyages lasting more than 24 hours, any part of which is on the high seas; and for which passengers are embarked or disembarked in the San Francisco Bay and Delta ports.

(2) *Tank vessel* means any self-propelled tank ship that is constructed or adapted primarily to carry oil or hazardous material in bulk as cargo or cargo residue in the cargo spaces. The definition of tank ship does not include tank barges.

(3) *High Interest Vessel* or *HIV* means any vessel deemed by the Captain of the Port or higher authority as a vessel requiring protection based upon risk assessment analysis of the vessel and is therefore escorted by a Coast Guard or other law enforcement vessel with an embarked Coast Guard commissioned, warrant, or petty officer.

(b) *Location.* The following areas are security zones:

(1) *Zones for anchored vessels.* All waters, extending from the surface to the sea floor, within 100 yards ahead, astern and extending 100 yards along either side of any cruise ship, tank vessel or HIV that is anchored at a designated anchorage within the San Francisco Bay and Delta port areas shoreward of the line drawn between San Francisco Main Ship Channel buoys 7 and 8 (LLNR 4190 & 4195, positions 37°46.9′ N, 122°35.4′ W and 37°46.5′ N, 122°35.2′ W, respectively);

(2) *Zones for moored or mooring vessels.* The shore area and all waters, extending from the surface to the sea floor, within 100 yards ahead, astern and extending 100 yards along either side of any cruise ship, tank vessel or HIV that is moored, or in the process of mooring, at any berth within the San Francisco Bay and Delta port areas shoreward of the line drawn between San Francisco Main Ship Channel buoys 7 and 8 (LLNR 4190 & 4195, positions 37°46.9′ N, 122°35.4′ W and 37°46.5′ N, 122°35.2′ W, respectively); and

(3) *Zones for vessels underway.* All waters of the San Francisco Bay and Delta port areas, extending from the surface to the sea floor, within 100 yards ahead, astern and extending 100 yards along either side of any cruise ship, tank vessel or HIV that is underway shoreward of the line drawn between San Francisco Main Ship Channel buoys 7 and 8 (LLNR 4190 & 4195, positions 37°46.9′ N, 122° 35.4′ W and 37°46.5′ N, 122°35.2′ W, respectively).

(c) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port, San Francisco Bay, or his designated representative.

(2) Persons desiring to transit the area of the security zone may contact the Captain of the Port at telephone number 415–399–3547 or on VHF–FM channel 16 (156.8 MHz) to seek permission to do so. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or his or her designated representative.

(3) When a cruise ship, tank vessel or HIV approaches within 100 yards of a vessel that is moored, or anchored, the stationary vessel must stay moored or anchored while it remains within the cruise ship, tank vessel or HIV's security zone unless it is either ordered by, or given permission from, the COTP San Francisco Bay to do otherwise.

(d) *Authority.* In addition to 33 U.S.C. 1231, the authority for this section includes 33 U.S.C. 1226.

(e) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the security zone by local law enforcement as necessary.

Dated: October 24, 2003.

Gerald M. Swanson,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco Bay, California.

[FR Doc. 03–28329 Filed 11–10–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 355

[FRL–7585–4]

RIN 2050–AE42

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to delete phosmet from the list of extremely hazardous substances (EHS) under the Emergency Planning and Community Right to Know Act (EPCRA). EPA is proposing this change in response to a petition submitted by the registrant of the pesticide in which they argue that phosmet should be removed from the EHS list because there are no valid data that indicate the chemical meets the listing criteria. Facilities with phosmet on-site would no longer be required to comply with State Emergency Response Commission (SERC) and Local Emergency Planning Committee (LEPC) requirements for the chemical phosmet. In addition, facilities with phosmet would no longer have to file an emergency and hazardous chemical inventory form and Material Safety Data Sheet (MSDS) under EPCRA for phosmet with their SERC, LEPC and local fire department for amounts less than 10,000 pounds.

DATES: *Comments:* Comments must be submitted on or before January 12, 2004.

ADDRESSES: Comments may be submitted electronically, or through hand delivery/courier or by mail. Send an original and two copies of your comments to: SUPERFUND Docket Information Center, Environmental Protection Agency, Mailcode: 5305T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. SFUND–2003–0007. Follow the detailed instructions as provided in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For general information, contact the

Emergency Planning and Community Right-to-Know Hotline at 800–424–9346 or TDD 800–553–7672 (hearing impaired). In the Washington, DC, metropolitan area, call 703–412–9810 or TDD 703–412–3323. For more detailed information on specific aspects of this rulemaking, contact Kathy Franklin, phone 202–564–7987; email: *franklin.kathy@epa.gov*

SUPPLEMENTARY INFORMATION:

I. Does This Notice Apply to Me?

A. Affected Entities: 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 distribute phosmet as a pesticide for commercial use and farms that store, handle and apply phosmet to variety of fruit, nut, and field crops. 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.

II. How Can I Get Copies of This Document and Other Related Information?

Docket. EPA has established an official docket for this action under Docket ID No. SFUND–2003–0007. The official docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The public docket is the collection of materials that is available for public viewing at SUPERFUND Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. This Docket Facility 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. You may copy up to 100 pages from any regulatory document at no cost. Additional copies are $0.15 per page.

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 submit or 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.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility. EPA intends to work toward providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

III. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Electronically. If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''search,'' and then key in Docket ID No. SFUND–2003–0007. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

Comments may be sent by electronic mail (e-mail) to *superfund.docket@epa.gov,* Attention Docket ID No. SFUND–2003–0007. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

You may submit comments on a disk or CD ROM that you mail to the mailing address identified in the following paragraph. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

By Mail. Send an original and two copies of your comments to: SUPERFUND Docket Information Center, U.S. Environmental Protection Agency, Mailcode: 5305T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. SFUND–2003–0007.

By Hand Delivery or Courier. Deliver your comments to: SUPERFUND Docket Information Center (EPA/DC) EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. Attention Docket ID No. SFUND–2003–0007. Such deliveries are only accepted during the Docket's normal hours of operation as identified in the ''How Can I Get Copies of This Document and Other Related Information?'' section.

IV. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be confidential business information (CBI) electronically through EPA's electronic public docket or by e-mail. Send or deliver information identified as CBI only to the following address: SUPERFUND CBI Document Control Officer (5305T), U.S. EPA, 1200 Pennsylvania Avenue, NW., Washington, D.C. 20460, Attention Docket ID No. SFUND–2003–0007. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR, Part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

V. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

I. Introduction and Background

A. Statutory Authority

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

B. Background

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 hazardous substances 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. The facility must also report accidental releases in excess of the Reportable Quantity (RQ) to the LEPC and SERC. Under EPCRA section 311 and 312, some facilities with phosmet on-site in excess of its TPQ are required to submit an emergency and

hazardous chemical inventory form and Material Safety Data Sheet (MSDS) required for phosmet with their SERC, LEPC and local fire department. However, facilities that apply phosmet to crops as a pesticide, do not have to file the inventory form or MSDS 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.

1. Regulatory Background

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.

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.

2. Gowan's Petition to Delist Phosmet

EPA received a petition dated August 8, 1996 from Gowan Company to delete the chemical phosmet from the EHS list under Section 302 of EPCRA. Gowan believes that listing of phosmet was based on an inappropriate toxicity study and argues that phosmet should be removed from the EHS list because there are no valid data that indicate the chemical meets the listing criteria.

Phosmet (O,O-dimethyl-S-phthalimidomethylphosphorodithioate, CAS No. 732–11–6) is a pink to white crystalline solid with chemical formula $C_{11}H_{12}NO_4PS_2$. It is slightly soluble in water and has a relatively low vapor pressure. It is a non-systemic organophosphate insecticide used for agricultural crop protection in fruit, nut and certain field crops. It is also used on trees and ornamental plants. According to EPA's Office of Pesticide Programs (OPP), approximately 1,250,000 pounds active ingredient (a.i.) of phosmet are used annually. Technical grade phosmet contains approximately 94% phosmet. Products containing phosmet can be in the form of dusts, emulsifiable concentrates, soluble concentrates, and wettable powders and can contain varying amounts of the active ingredient phosmet. More information on phosmet can be found in the February 2003 Technical Background Document: Proposed Rule to Delist Phosmet from the EHS List, available in the docket.

II. 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.

The selection criteria were designed as screening tools to identify highly acute toxic chemicals. 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 did not want to miss any acutely toxic chemical of concern.

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, the Agency assumed that humans may be as sensitive as the most sensitive mammalian species tested.

C. 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.

III. Proposed Modification of EHS List

A. Basis of Phosmet Listing

Phosmet was originally listed on the EHS list because a four-hour rat inhalation LC_{50} of 0.054 mg/L, reported in the 1985 RTECS database, met the EHS primary toxicity inhalation criteria of $LC_{50} \leq 0.5$ mg/L. The value in RTECS was cited from a 1982 Russian publication, which was a compilation of toxicity data for many chemicals.

The TPQ for phosmet depends on its physical state. As a solid, phosmet has a TPQ of 10 pounds if it: (1) Is a powder with particle size less than 100 microns, (2) is in molten form, (3) is in solution, or (4) has a National Fire Protection Association (NFPA) reactivity rating of 2, 3, or 4. Otherwise, the TPQ for phosmet is 10,000 pounds.

B. Gowan's Phosmet Petition

Gowan Company of Yuma, Arizona submitted to EPA a petition dated August 8, 1996 requesting that EPA remove phosmet from the EHS list because it does not meet the toxicity criteria. During EPA's review of the petition, Gowan submitted additional toxicity data and other information. EPA also reviewed acute toxicity data for phosmet previously submitted to EPA's Office of Pesticide Programs (OPP) for the registration of phosmet as a pesticide. Gowan argued that the inhalation LC_{50} (rat) value of 0.054 mg/liter/4 hours, as cited in RTECS, is unverifiable because the experimental details, study protocol, and quality control procedures are unavailable. Without these experimental details, Gowan maintained that it is impossible to reconstruct and validate the original experiment. In addition, Gowan asserted that this LC_{50} value is inconsistent with all other available inhalation toxicity data for technical grade (95% purity or higher) phosmet. Gowan also asserted that the phosmet technical grade does not meet the toxicity criteria for listing as an EHS following exposure by the oral or dermal routes, as indicated by a number of experimental studies. Gowan submitted with their petition data from a number of acute inhalation toxicity tests which they believe show that phosmet technical poses a low risk of acute toxicity by inhalation, as indicated by the absence of mortality when test animals were exposed to phosmet vapor or dust. Gowan also claimed that the toxicity studies on phosmet formulations, including wettable powders and liquid formulations, indicate that these phosmet products do not meet the criteria for the EHS list.

Because phosmet is not a high production chemical (less than 2 million pounds annually), EPA focused its efforts on evaluating whether the existing toxicity data meets the primary listing criteria. In addition to the phosmet toxicity data submitted by Gowan and available data from OPP, EPA found data from acute mouse oral toxicity studies identified from a search of toxicity databases and literature. In July 2001, Gowan supplied EPA with data from five acute oral mouse studies and EPA obtained a journal article on an acute mouse oral toxicity study conducted by the National Center for Toxicological Research (NCTR) of the Food and Drug Administration (FDA). More details of the phosmet toxicity studies and their evaluation can be found in the February 2003 Technical Background Document: Proposed Rule to Delist Phosmet from the EHS List available in the public docket.

C. Review of Phosmet Acute Toxicity Data

1. Phosmet Acute Inhalation Toxicity

The four-hour rat inhalation LC_{50} of 0.054 mg/L, reported in 1985 RTECS was cited from a Russian publication (Izmerov *et al.* 1982. Toxicometric Parameters of Industrial Toxic Chemical Under Single Exposure) which contained compiled toxicity values for many chemicals, but no study details. In both the Russian and English translation version of this document, the chemical structure given for phosmet is incorrect, which led Gowan to assert that there was some uncertainty as to whether the chemical being tested was indeed phosmet. EPA was not able to obtain the actual phosmet toxicity study conducted by a Russian researcher L.P. Danilenko, but was able to obtain a translation of a Russian 1969 journal article by Danilenko that discussed the rat inhalation study and the results. Based on the chemical name and chemical synonyms (O,O-dimethyl-phthalimidio-methyl-dithiophosphate or phthalophos) used in (Danilenko 1969), EPA believes the chemical being tested was indeed phosmet. No chemical structure was given in the article.

In Danilenko (1969), the following acute toxicity results were reported for phthalophos, also known as Imidan or phosmet: a four-hour rat inhalation LC_{50} of 54 mg/m^3 (0.054 mg/L); a four-hour rat inhalation LC_{LO} of 31 mg/m^3 (0.031 mg/L); and a four-hour cat inhalation LC_{LO} of 65 mg/m^3 (0.065 mg/L). The tests were performed using an aqueous emulsion of phthalophos (phosmet) on albino rats and cats. The animals were exposed to a liquid aerosol produced by atomization of the preparation with a special sprayer (Boitenko). The concentration of phthalophos (phosmet) in the chamber air was determined by a thin-layer chromatographic method.

However, the Danilenko (1969) article severely lacks 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. The phosmet used in the experiment was manufactured in the Union of Soviet Socialist Republics (USSR) by a research institute using an unknown method. With the number of unanswered key questions regarding the experimental protocol, EPA has determined that the results in this paper are insufficient to provide the basis for the continued listing of phosmet on the EHS list.

EPA evaluated more than 20 other inhalation studies of technical grade phosmet (≥94% phosmet) and other phosmet formulations, such as wettable powders and emulsions. The testing exposure routes included vapor, particulates and aerosols. Only three of these inhalation studies produced any mortality. The LC_{50} data from these three studies were not in the range of the LC_{50} value in the Russian study and did not meet the primary toxicity listing criteria of ≤0.5 mg/L. Of these three studies, results of one study with mortality were not considered appropriate to use because the phosmet formulation contained methylene chloride, a toxic component. Another study conducted in 1994, exposed rats to aerosols from an emulsion containing 27.5% phosmet and 8.4% naphthalenes. The aerosols were respirable-sized having a mass median aerodynamic diameter (MMAD) of 1.5–2.2 microns (μm). This study resulted in a LC_{50} of 1.19 mg/L for male rats and 0.845 mg/L for females. A third study conducted in 1995 reported a LC_{50} of 1.6 mg/L for rats and exposed the animals to a 70% phosmet particulates having a MMAD of 1.61 to 2.38 microns (μm).

Given the uncertainties with the inhalation toxicity data from (Danilenko, 1969) and based on the Agency's review of all the acute inhalation toxicity data for phosmet, EPA believes that there are no inhalation data meeting the primary listing criteria for phosmet of sufficient reliability or quality to support the listing of phosmet as an EHS chemical. As a result, EPA has decided to remove this inhalation value from consideration for the purpose of listing phosmet as an EHS. EPA solicits comments on the validity of the available inhalation toxicity studies to support listing of phosmet as an EHS based on the listing criteria for inhalation toxicity. EPA invites submission of any valid acute inhalation toxicity studies not already made available to EPA. EPA's review of all currently available acute inhalation toxicity studies can be found in the February 2003 Technical Background Document: Proposed Rule to Delist Phosmet from the EHS List available in the public docket.

2. Phosmet Acute Dermal Toxicity

EPA undertook review of existing acute dermal toxicity data for phosmet. EPA could find no dermal toxicity data that met the primary dermal listing criteria of $LD_{50} \leq 50$ mg/kg. The lowest test results for technical phosmet indicated that the dermal LD_{50} is greater than 3160 mg/kg.

3. Phosmet Acute Oral Toxicity

Gowan submitted several acute rat oral studies in 1996, for technical grade phosmet and phosmet powder and emulsion formulations. None of the rat LD_{50} values from these studies met the EHS listing criteria, even when the percentage of inert ingredients in the formulation was taken into account. The lowest reported rat oral LD_{50} for technical grade phosmet (96.1%) is 113 mg/kg, which does not exceed the primary oral listing criteria of 25 mg/kg. The lowest reported rat oral LD_{50} for a phosmet formulation of 70% dust is 147 mg/kg (73.5 mg/kg based on active ingredient). Even when adjusted for the percentage active ingredient, this dose still does not exceed the criteria of 25 mg/kg.

Subsequently, EPA retrieved LD_{50} values from six mouse oral studies on technical grade phosmet from toxicity databases and the literature. Gowan was able to supply five of the mouse studies, which had been conducted by Stauffer Chemical Company. EPA also reviewed oral acute toxicity data available from OPP. Review of the six acute mouse oral studies indicates that mice are more sensitive than rats to phosmet. One mouse study conducted by Stauffer Chemical Company in 1971 reported a phosmet technical LD_{50} of 23.3 mg/kg for mice for technical grade phosmet, percentage unspecified . Another study conducted by researchers at NCTR (Haley *et al.*, 1975) reported LD_{50} results of 23.1 and 24.9 mg/kg for males and female mice, respectively for 99.5% phosmet. Other acute oral studies of technical grade phosmet with mice had LD_{50} results varying from 36.9 to 51 mg/kg. For a phosmet powder formulation, the lowest reported oral LD_{50} was 79.4 mg/kg in mice for 50% phosmet wettable powder. These studies are discussed in more detail in the February 2003 Technical Background Document: Proposed Rule to Delist Phosmet from the EHS List, available in the public docket.

The oral mouse LD_{50} of 23.3 mg/kg for phosmet technical resulted from testing a material called Imidan-EDC. Phosmet is also known by the name ''Imidan.'' Gowan stated that EDC (ethylene dichloride or dichloroethane), was a solvent used in the initial synthesis step of a discontinued process and that the impurity profile is not known. Gowan was not sure whether this product was ever registered for commercial use by Stauffer, who was the previous pesticide registrant with EPA. Gowan never utilized the EDC process and currently uses a benzene process to manufacture technical phosmet, the product currently registered with EPA. According to Gowan, Stauffer also licensed the phosmet-benzene process as a registrant with EPA. The Stauffer researchers determined the mouse oral LD_{50} for Imidan-Benzene to be 43 mg/kg. 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. Gowan believes that the ''Imidan-EDC'' phosmet is an inappropriate test substance. Because of these uncertainties, EPA does not believe the Imidan-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 removed these values from consideration for EHS listing purposes.

4. Phosmet Oral Mouse Study (Haley et al., 1975)

Only one other study (Haley et al., 1975) reported results with an $LD_{50} \leq 25$ mg/kg. This study examined the acute oral toxicity of five organophosphate pesticides (including Imidan or phosmet) in a total of three experiments: a range finding experiment, a pilot experiment, and a main experiment designed to estimate an LD_1 value and extrapolate an $LD_{0.1}$ value. LD_{50} values for phosmet were reported from the pilot study as 25.2 and 23.1 mg/kg for males and females, respectively and from the main study as 23.1 and 24.9 mg/kg for males and females, respectively. The study was conducted by the National Center for Toxicological Research (FDA), Arkansas. After reviewing this information, Gowan made several arguments why the information in the Haley study was insufficient to support the listing of phosmet as an EHS.

Haley *et al.* (1975) conducted two dose response experiments, a pilot study (100 mice) and a main study (660 mice). A linear regression was developed from the pilot results. The LD_{50} and its confidence intervals, and the slope of the regression and its

confidence intervals are provided in the journal article. Using this regression, doses for LD_1, LD_2, LD_4, LD_8, LD_{16}, LD_{32}, and LD_{64} were taken from the regression and used in the main study. The goal of the study was to estimate the LD_1 and extrapolate the $LD_{0.1}$. For the pilot study the actual doses and number of animals killed are not presented. The LD_1, LD_{16}, and LD_{50} results only, by sex, were presented in a table in Haley *et al.* (1975) as predicted doses from the pilot study and calculated doses from the main study. The actual doses in the main study were chosen based on the results from the pilot study. The log of actual doses and percentage of animals killed are presented in a graph for each sex, except the value of the LD_2 for males which gave an aberrant response.

One of Gowan's key criticisms of Haley *et al.* (1975) was that no mortality data was presented from the pilot experiment and complete data from the main experiment is presented only in graphical form. Because the actual doses and animals killed at each dose are not cited, Gowan stated that the LD_{50} results cannot be replicated or confirmed. EPA agrees with Gowan that the lack of tabulated mortality data is a serious flaw in this experiment. EPA attempted to recover the actual mortality data from the National Center for Toxicological Research, but the NCTR was not able to recover it. Gowan also raised other issues regarding Haley *et al.* (1975) which included the variations in main study mortality response, lack of information on the use of control data, and other questions or potential problems with the study methodology or design. The Agency addresses these issues in detail in the technical background document supporting this rulemaking.

5. Phosmet Oral Mouse Study (Gowan 2002)

Because of the uncertainties surrounding verification of results of the Haley study, EPA proposed conducting a new acute oral mouse LD_{50} study using the Up-And-Down Method, as described in the Office of Prevention, Pesticides and Toxic Substances (OPPTS) new Harmonized Test Guideline 870.1100 for Acute Oral Toxicity. This guideline has been adopted by the Federal Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the Organization for Economic Coordination and Development (OECD) and EPA's Science Advisory Panel (SAP). EPA's participation in ICCVAM is part of the Agency's commitment to support testing that reduces the use of animals.

Before EPA initiated the new test, Gowan decided to conduct its own acute toxicity study in mice. Based on its review of the existing toxicity data and the recommended test method, EPA provided Gowan with the recommended test method and comments on Gowan's draft test protocol. EPA recommended that Gowan test at multiple dose levels using the Up and Down Procedure (UDP) for acute oral toxicity. (See Docket for test method and comments provided to Gowan.)

Gowan completed its study of mouse responses to acute oral exposure to phosmet in December 2002. Their study planned to dose 20 female mice at 40 mg/kg, initially, with subsequent doses tested, if warranted. Twenty female mice were administered 40 mg/kg by oral gavage. After 14 days observation, there were no mortalities. Because no mortality occurred at 40 mg/kg, Gowan saw no need to conduct further tests. Thus, Gowan conducted a single dose study rather than an LD_{50} test. Gowan believes the test results confirm that the oral LD_{50} of phosmet exceeds 25 mg/kg listing criterion and that there is no basis for continuing to list phosmet as an Extremely Hazardous Substance.

The study results have been carefully reviewed by a cross-agency ad hoc committee whose consensus was that the Gowan study seemed to confirm the oral mouse LD_{50} results from most of the previous literature studies, which showed LD_{50}s greater than EHS listing criterion of 25 mg/kg. EPA believes that the new test results support the conclusion that the acute oral LD_{50} of phosmet exceeds 25 mg/kg and that phosmet should be removed from the EHS list. The Gowan study appears to be sound and conducted properly according to Good Laboratory Practices, although it is only for a single dose. The large number of mice (20) tested at a much higher concentration than the EHS List criterion supports the probability that the acute oral mouse LD_{50} is greater than 25 mg/kg . In addition, Gowan had done a thorough chemical analysis of the phosmet material that was administered to the animals.

Normally EPA would not accept a single dose study for drawing conclusions about the LD_{50} for a chemical. However, the Agency believes this study can be used in its analysis because of existing data indicating the approximate range of probable LD_{50} values and data showing that phosmet has a steep dose-response curve. Although the new test did not follow new acute oral toxicity testing guidelines, the test results are consistent with the variability of individual animal dose response seen in existing oral mouse LD_{50} studies.

Phosmet is an organophosphate pesticide, with known lethal and toxic human health effects. However, after careful consideration of all of the toxicity data, EPA proposes that phosmet should be delisted from the EHS list for the following reasons: (1) The mouse oral LD_{50} data that meet the criteria from the Haley *et al.* (1975) study have a number of deficiencies that increase the uncertainty around the results, such as lack of tabulated mortality data for either the pilot or the main study, lack of information on treatment of the control data, and considerable variability in the results at the LD_{01}–LD_{08} doses, (2) the Haley LD_{50} results are right at the limit of the oral toxicity listing criteria of 25 mg/kg, and (3) other acute mouse oral studies (including Gowan's December 2002 study conducted using Good Laboratory Practices) indicate the mouse oral LD_{50} exceeds the 25 mg/kg listing criteria. EPA solicits comment on the proposed delisting decision and its rationale, and invites the public to submit or identify relevant peer-reviewed studies or data, of which the Agency may not be aware. EPA invites submission of any valid oral toxicity studies for phosmet that meet the listing criteria which are not already been reviewed by EPA. EPA's review of all currently available acute oral toxicity studies can be found in the February 2003 Technical Background Document: Proposed Rule to Delist Phosmet from the EHS List available in the public docket.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735), 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, which include assessing the costs and benefits anticipated as a result of the proposed regulatory action. 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. 1395.04). 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 email 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 proposed rule will relieve burden for facilities that have phosmet on-site. Therefore, we conclude that this proposed action does not impose any new information collection burden, rather, it would relieve the regulatory burden for those facilities that handled phosmet. 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 are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Comments are requested on the changes included in this proposal. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2823); 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after November 12, 2003, a comment to OMB is best assured of having its full effect if OMB receives it by December 12, 2003. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

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 has fewer than 1000 or 100 employees per firm depending upon the SIC code the firm primarily is classified; (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 today's proposed rule on small entities, I hereby certify that this proposal will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities'' (5 U.S.C. 603 and 604). Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on small entities subject to the rule. This proposed rule would remove requirements for reporting and emergency planning for small entities with phosmet on site. We have therefore concluded that today's proposed rule would relieve regulatory burden for small entities.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

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 analysis, 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 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 is because this proposed rule would 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. In addition, as discussed above, the private sector is not expected to incur costs exceeding $100 million. Therefore, today's proposed rule is not subject to the requirements of Sections 202 and 205 of UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 *FR* 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This proposal 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 proposed 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 proposal.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

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 proposed rule does not have tribal implications, as specified in Executive Order 13175. This proposed rule 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.

EPA specifically solicits additional comment on this proposed rule from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental 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 EPA determines (1) is ''economically significant'' as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has 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 proposal 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 proposed rule present a disproportionate risk to children.

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

This proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This proposed rule reduces regulatory burden. It thus should not adversely affect energy supply, distribution or use.

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 No. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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 4, 2003.

Marianne L. Horinko,

Acting Administrator.

For the reasons set out in the preamble, part 355 of title 40 of the Code of Federal Regulations is proposed to be 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 are amended by removing the entry for CAS No. 732–11–6 for the chemical name Phosmet.

[FR Doc. 03–28308 Filed 11–10–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 22, 24, and 90

[WT Docket Nos. 02–381, 01–14, 03–202; FCC 03–222]

Facilitating the Provision of Spectrum-Based Services to Rural Areas and Promoting Opportunities for Rural Telephone Companies To Provide Spectrum-Based Services; 2000 Biennial Regulatory Review Spectrum Aggregation Limits for Commercial Mobile Radio Services; and Increasing Flexibility To Promote Access to and the Efficient and Intensive Use of Spectrum and the Widespread Deployment of Wireless Services, and To Facilitate Capital Formation

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission examines ways of amending spectrum regulations and policies in order to promote the rapid and efficient deployment of quality spectrum-based services in rural areas.

DATES: Submit comments on or before December 29, 2003. Submit reply comments on or before January 26, 2004.

FOR FURTHER INFORMATION CONTACT: Nicole McGinnis, Wireless Telecommunications Bureau, at (202) 418–0317, or via the Internet at *Nicole.Mcginnis@fcc.gov*. For additional information concerning the information collections contained in this document, contact Judith-B. Herman at (202) 418–0214, or via the Internet at *Judith.B-Herman@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's *Notice of Proposed Rulemaking* (*NPRM*), FCC 03–222, adopted September 10, 2003, and released October 6, 2003. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, 445 12th Street, SW., Washington, DC 20554. The complete text may be purchased from the FCC's copy contractor, Qualex International, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov*. Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365 or at *Brian.Millin@fcc.gov*.

Synopsis of the NPRM

I. Introduction and Overview

1. In this Notice of Proposed Rulemaking (*NPRM*), we continue to examine ways to promote the rapid and efficient deployment of quality spectrum-based services in rural areas. We build upon the record developed in response to our *Notice of Inquiry*, in which we sought comment on how we could modify our policies to further encourage the provision of wireless services in rural areas. *See* Facilitating the Provision of Spectrum-Based Service to Rural Areas and Promoting Opportunities for Rural Telephone Companies to Provide Spectrum-Based Services, WT Docket No. 02–381, *Notice of Inquiry,* 68 FR 723 (January 7, 2003) (*Rural NOI*). We also draw upon the findings and recommendations of the Spectrum Policy Task Force.

2. The Commission's primary mission is the promotion of ''communication by wire and radio so as to make available, so far as possible, to all the people of the United States, without discrimination on the basis of race, color, religion, national origin, or sex, a rapid, efficient, Nation-wide, and world-wide wire and radio communication service.'' Furthermore, for auctionable services, the Commission is required to promote various objectives in designing a system of competitive bidding, including the development and rapid deployment of new technologies, products, and services for the benefit of the public, ''including those residing in rural areas,'' and ''the efficient and intensive use of spectrum.'' Under section 706 of the Communications Act, the Commission is also directed to ''encourage the provision of new technologies and services to the public.'' Consistent with these statutory mandates, the Commission's spectrum policy goals generally have been to facilitate efficient use, competition, and rapid, widespread service consistent with the goals of the Communications Act.

3. On a national scale, the deployment of wireless mobile services has been a huge success, resulting in increased competition and services overall. We believe that a number of measures that the Commission has already adopted have contributed to this successful deployment of wireless service. Recently, the Commission took steps to facilitate spectrum leasing in secondary markets, building upon existing, flexible, market-based policy efforts to encourage more efficient use of spectrum. The Commission did so with the belief that secondary markets would also facilitate investment in rural areas.

4. We recognize the inherent economic challenges of providing telecommunications services in sparsely populated, expansive rural areas. We note that the Federal-State Joint Board has solicited comment on issues relating to the eligibility of wireless carriers to receive universal service support. Further, the Wireless Telecommunications Bureau and the U.S. Department of Agriculture's Rural Utilities Service (RUS) have recently initiated a ''Federal Rural Wireless Outreach Initiative'' that seeks to harmonize the agencies' policies regarding rural wireless deployment and highlight the RUS loan programs available to wireless companies that serve rural communities. At present, programs are available to support the provision of spectrum-based services in rural areas.

5. We believe that rural as well as urban consumers and businesses have benefited from our market-oriented policies that promote facilities-based competition for telecommunications services. The Commission recently found that there is effective competition in the CMRS marketplace as a whole, including in rural areas. The Commission's policy to let market forces determine the number of firms operating in a given geographic area, subject to limits on spectrum availability and aggregation, recognizes this fact, and allows firms to operate at a competitive and efficient scale of operation. The Commission recognizes that, as a result of varying technical and demographic characteristics, the economics of providing service can be significantly different in rural areas as compared to urban areas. Our proposals attempt to acknowledge that market characteristics, especially demographics, will affect the optimal market structure.

6. Furthermore, there may well be a public interest in policies that encourage potential users to become mobile subscribers due to the network externalities that would result. In short, network externalities occur when adding a user to a communications network increases the value of the network for existing users who wish to communicate with that new user. For this reason, it is an especially important Commission goal to facilitate access to service broadly, not just in urban