

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline No.	Data requirement	All use patterns	Test substance		Test notes
			MP	EP	
<b>Product Chemistry and Composition</b>					
885.1100 .....	Product identity .....	R	MP	EP	.....
885.1200 .....	Manufacturing process .....	R	TGAI and MP	TGAI and EP	1, 2
885.1250 .....	Deposition of a sample in a nationally recognized culture collection.	R	TGAI	TGAI	3
885.1300 .....	Discussion of formation of unintentional ingredients .....	R	TGAI and MP	TGAI and EP	2
<b>Analysis and Certified Limits</b>					
885.1400 .....	Analysis of samples .....	R	TGAI and MP	TGAI and EP	2, 4
885.1500 .....	Certification of limits .....	R	MP	EP	.....
<b>Physical and Chemical Characteristics</b>					
830.6302 .....	Color .....	R	TGAI	TGAI	.....
830.6303 .....	Physical state .....	R	TGAI	TGAI	.....
830.6304 .....	Odor .....	R	TGAI	TGAI	.....
830.6313 .....	Stability to normal and elevated temperatures, metals and metal ions.	R	TGAI	TGAI	.....
830.6317 .....	Storage stability .....	R	TGAI and MP	TGAI and EP	.....
830.6319 .....	Miscibility .....	R	MP	EP	5
830.6320 .....	Corrosion characteristics .....	R	MP	EP	6
830.7000 .....	pH .....	R	TGAI	TGAI	.....
830.7100 .....	Viscosity .....	R	MP	EP	7
830.7300 .....	Density/relative density/bulk density (specific gravity) .....	R	TGAI	TGAI	.....

(d) \* \* \*

3. Required for each isolate of a microbial pesticide. New isolates must be deposited with an agreement to ensure that the sample will be maintained and will not be discarded for the duration of the associated experimental use permit(s).

\* \* \* \* \*

[FR Doc. 2011-9191 Filed 4-14-11; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 281**

[EPA-R10-UST-2011-0097; FRL-9296-1]

**Oregon: Tentative Approval of State Underground Storage Tank Program: Public Hearing Cancellation**

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

**ACTION:** Proposed rule; cancellation of notice of public hearing.

**SUMMARY:** This document cancels a public hearing on a proposed rulemaking relating to the State of Oregon's application for final approval of its Underground Storage Tank (UST) Program under Subtitle I of the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency did not receive any comments or a request for a public hearing.

**DATES:** The public hearing originally scheduled for April 13, 2011 at 9 a.m. has been cancelled.

**FOR FURTHER INFORMATION CONTACT:** Katherine Griffith, U. S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Suite 900, *Mail Stop:* OCE-082, Seattle, WA 98101, *phone number:* (206) 553-2901, *e-mail:* [griffith.katherine@epa.gov](mailto:griffith.katherine@epa.gov).

**SUPPLEMENTARY INFORMATION:** A notice of proposed rulemaking and a notice of public hearing that appeared in the Federal Register on Wednesday, March 2, 2011 (76 FR 11404) announced that a public hearing was scheduled for April 13, 2011, at 9 a.m. at the United States Environmental Protection Agency, 805 SW. Broadway, Suite 500, Portland, Oregon 97205.

The public comment period for the proposed rulemaking expired on April 1, 2011. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request. As of Monday, April 4, 2011, no one has requested to speak. Therefore, the public hearing scheduled for April 13, 2011, is cancelled.

Dated: April 8, 2011.

**Dennis J. McLerran,**  
*Regional Administrator, Region 10.*

[FR Doc. 2011-9184 Filed 4-14-11; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 355**

[EPA-HQ-SFUND-2010-0586; FRL-9295-6]

RIN 2050-AF08

**Emergency Planning and Notification; Emergency Planning and List of Extremely Hazardous Substances and Threshold Planning Quantities**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to revise the manner by which the regulated community would apply the threshold planning quantities (TPQs) for those extremely hazardous substances (EHSs) that are non-reactive solid chemicals in solution form. Specifically, facilities with a solid EHS in solution would be subject to the Emergency Planning requirements if the amount of the solid chemical on-site, when multiplied by 0.2, equaled or exceeded the lower published TPQ, based on data that shows less potential for the solid chemical in solution to remain airborne in the event of an accidental release. Previously, EPA assumed that 100% of the chemical could become airborne in the event of an accidental release.

**DATES:** Comments must be submitted on or before June 14, 2011.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-SFUND-2010-0586, by one of the following methods:

- <http://www.regulations.gov>: Follow the online instructions for submitting comments.

- *E-mail:* [superfund.docket@epa.gov](mailto:superfund.docket@epa.gov).

- *Fax:* (202) 566-9744.

- *Mail:* Superfund Docket, Environmental Protection Agency, Mail code: [2822T], 1200 Pennsylvania Ave., NW., Washington, DC 20460.

- *Hand Delivery:* EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-SFUND-2010-0586. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>. For additional instructions on submitting comments, go to Section I.B of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically <http://www.regulations.gov> or in hard copy at the Superfund Docket, EPA/DC, EPA West, Room 3334, 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) 566-0276.

**FOR FURTHER INFORMATION CONTACT:** Kathy Franklin, Office of Emergency Management, Mail Code 5104A, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0002; telephone number: (202) 564-7987; fax number: (202) 564-2625; e-mail address: [franklin.kathy@epa.gov](mailto:franklin.kathy@epa.gov). You may also contact the Superfund, TRI, EPCRA, RMP and Oil Information Center at (800) 424-9346 or (703) 412-9810 (in the Washington, DC metropolitan area). The Telecommunications Device for the Deaf (TDD) number is (800) 553-7672 or (703) 412-3323 (in the Washington, DC metropolitan area). You may wish to visit the Office of Emergency Management (OEM) Internet site at [www.epa.gov/emergencies/content/epcra](http://www.epa.gov/emergencies/content/epcra).

**SUPPLEMENTARY INFORMATION:** Here are the contents of today's preamble.

#### I. General Information

- Who is affected by this proposed rule?
- What should I consider as I prepare my comments for EPA?
- What is the statutory authority for this proposed rule?
- What is the background for this proposed rule?

#### II. Summary of This Action

- What is the scope of this proposed rule?
- What is EPA's rationale for proposing the TPQ changes?
- What alternative approaches were considered?
- What are the peer review results?
- What are the economic impacts of the TPQ changes?

#### III. Statutory and Executive Order Reviews

- Executive Order 12866: Regulatory Planning and Review
- Paperwork Reduction Act
- Regulatory Flexibility Act
- Unfunded Mandates Reform Act
- Executive Order 13132: Federalism

- Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
- Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
- Executive Order 13211: Energy Effects
- National Technology Transfer and Advancement Act ("NTAA")
- Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

### I. General Information

#### A. Who is affected by this proposed rule?

Entities that would be affected by this proposed rule are those organizations and facilities subject to section 302 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and its implementing regulations found in 40 CFR part 355, subpart B—Emergency Planning. To determine whether your facility is affected by this action, you should carefully examine the applicability provisions at 40 CFR part 355. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

#### B. What should I consider as I prepare my comments for EPA?

*Tips for Preparing Your Comments.* When submitting comments remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
  - Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
  - Describe any assumptions and provide any technical information and/or data that you used.
  - If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
  - Provide specific examples to illustrate your concerns, and suggest alternatives.
  - Explain your views as clearly as possible.
  - Make sure to submit your comments by the comment period deadline identified.

*C. What is the statutory authority for this proposed rule?*

This proposed rule is being issued under the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), which was enacted as Title III of the Superfund Amendments and Reauthorization Act of 1986 (Pub. L. 99-499), (SARA). The Agency relies on EPCRA section 328 for general rulemaking authority.

*D. What is the background of this proposed rule?*

Title III of SARA (EPCRA) establishes authorities for emergency planning and preparedness, emergency release notification reporting, community right-to-know reporting, and toxic chemical release reporting. It is intended to encourage state and local planning for, and response to releases of, hazardous substances and to provide the public, local governments, fire departments, and other emergency officials with information concerning potential chemical hazards present in their communities. The implementing regulations for emergency planning, emergency release notification and the chemicals subject to these regulations (extremely hazardous substances (EHSs)) are codified in 40 CFR part 355. The implementing regulations for community right-to-know reporting (or hazardous chemical reporting) are codified in 40 CFR part 370.

Subtitle A of EPCRA establishes the framework for local emergency planning. The statute requires that EPA publish a list of EHSs. The EHSs list was established by EPA to identify chemical substances which could cause serious irreversible health effects from accidental releases (52 FR 13378). The Agency was also directed to establish threshold planning quantities (TPQs) for each extremely hazardous substance.

Under EPCRA section 302, a facility which has an EHS in excess of its TPQ on-site must notify the State Emergency Response Commission (SERC) and Local Emergency Planning Committee (LEPC), as well as participate in local emergency planning activities. Under EPCRA section 304, the facility owner or operator must report accidental releases of EHSs and hazardous substances listed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) listed in 40 CFR 302.4 in excess of the reportable quantity (RQ) to the LEPC and SERC. Under EPCRA section 311 and 312, facilities which have a hazardous chemical defined under the Hazard Communication Standards (HCS) of the Occupational

Safety and Health Act (OSHA) at or above 10,000 pounds or an EHS at or above its TPQ or 500 pounds, whichever is lower, are required to submit an Emergency and Hazardous Chemical Inventory form and Material Safety Data Sheet (MSDS) for that chemical to their SERC, LEPC and local fire department.

The purpose of the EHSs list is to focus initial efforts in the development of state and local contingency plans. Inclusion of a chemical on the EHSs 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 and develop a chemical emergency response plan around those risks.

#### 1. Regulatory Background

The list of EHSs and their TPQs are codified in 40 CFR part 355, Appendices A & B. EPA first published the EHSs list and TPQs along with the methodology for determining TPQs as an interim final rule on November 17, 1986 (51 FR 41570). In the final rule of April 22, 1987 (52 FR 13378), EPA made a number of revisions. Among other things, the final rule republished the EHSs list, added four new chemicals and revised the methodology for some TPQs. The final rule also defined TPQs for EHS solids in solution, based on comments on the interim final rule. Details of the methodology used in determining whether to list a substance as an EHS and deriving the TPQs are found in the November 1986 and April 1987 **Federal Register** notices and in the technical support documents in the rulemaking record (“Threshold Planning Quantities Technical Support Document”; “Chemicals That Were Assigned Threshold Planning Quantities Different From the Calculated Index Value”; “Reactive Solids Whose Threshold Planning Quantities Should Be Less than 10,000 Pounds”; “Changes Made to Threshold Planning Quantities Between Proposed Rule and Final Rule”: all dated April 7, 1987, and “Technical Support Document for Determination of Levels of Concern,” November 11, 1986). These documents are found in the docket for this rulemaking.

EPA has since amended the EHSs list and deleted 51 chemicals. Ten chemicals were deleted based on the request of petitioners and the remaining 41 chemicals were deleted as a result of Agency review. The chemicals were deleted because they did not meet the toxicity criteria for the list and/or were

originally listed in error. Petitions requesting deletion of two chemicals, paraquat dichloride (which is discussed below) and isophorone diisocyanate have been denied. Isophorone diisocyanate was not deleted from the EHSs list because its inhalation toxicity met the EHSs listing criteria.

EPA has also changed the TPQs for some of the EHSs. In the April 22, 1987 final rule, EPA reduced the TPQs for 36 substances, while it raised the TPQs for 12 substances based on updated acute toxicity data. Since then, EPA has lowered the TPQ for muscimol because of a typographical error in a prior rulemaking; EPA has raised the TPQ for isophorone diisocyanate because it was mistakenly based on a physical state of reactive solid, when it is actually a liquid; and EPA has denied a petition to raise the TPQs for azinphos methyl and fenamiphos.

After a final rule was published on November 3, 2008 (73 FR 65452) which revised the footnotes to Appendix A and B, EPA found some printing errors in the Appendix A and B tables of the CFR affecting 11 EHS listings. This November 3, 2008 rule did not add, delete or revise any of the EHS names, RQs or TPQs. For the eleven EHSs listings, their RQ and TPQ values are correct, but just appear under the wrong column heading in the table and one EHS chemical name mistakenly appears in CAS No. column. The errors do not appear in the November 3, 2008 FR notice, but only in the 2009 and 2010 versions of the CFR. These errors to the CFR will be corrected in a future effort.

#### 2. Petition for Paraquat Dichloride

Paraquat dichloride was originally listed as paraquat with a CAS No. 1910-42-5 on the final EHSs list. The lower TPQ was set at 10 pounds for paraquat dichloride with a particle size less than 100 microns in diameter, in molten form or as a solid in solution. The higher TPQ was set at 10,000 pounds for a particle size equal to or greater than 100 microns in diameter. ICI Americas submitted a petition in October 1989 that requested the Agency to remove paraquat from the EHSs list or alternatively, revise the TPQ. The TPQ for paraquat was based on an Immediately Dangerous to Life and Health (IDLH) value of 1.5 milligrams per cubic meter (mg/m<sup>3</sup>). The petitioner requested that EPA base the TPQ on the LD<sub>50</sub> or LC<sub>50</sub> test results rather than the IDLH level. LD<sub>50</sub> is the median lethal dose via dermal exposure or ingestion, defined as the dose at which 50 percent of the test animals died during exposure. LC<sub>50</sub> is the median lethal concentration, defined as the concentration level at which 50

percent of the test animals died when exposed by inhalation within the stated study time. ICI Americas also noted that the CAS No. 1910-42-5 represented the chemical paraquat dichloride, not the paraquat cation, which can form many different salts.

On October 12, 1994 (59 FR 51816), EPA denied the petition to delete paraquat or modify the TPQ, but changed the listed chemical name from paraquat to paraquat dichloride. The oral toxicity for paraquat dichloride met the listing criteria based on the paraquat ion only, but did not meet the listing criteria based on total paraquat dichloride weight. Therefore, EPA changed the basis of the listing from an oral LD<sub>50</sub> of 22 milligrams paraquat ion per kg of body weight (mg/kg) to an inhalation LC<sub>50</sub> of 0.00138 milligrams paraquat dichloride per liter of air (mg/L). Because this inhalation toxicity met the EHSs listing criteria, paraquat dichloride was not deleted from the EHSs list. Further explanation of EPA's rationale for denying the petition can be found in the October 12, 1994 final rule (59 FR 51816).

### 3. Zeneca's Request To Reconsider the Paraquat Dichloride Petition

In November 1999, Zeneca (formerly ICI Americas) requested that EPA reconsider either removing paraquat dichloride from the EHSs list or raising its TPQ. Zeneca claimed that the form of the chemical used in inhalation toxicity tests (temporarily atomized powder under laboratory conditions) is not relevant data to use for listing paraquat dichloride. Zeneca believed that it was highly unlikely that inhalable particles or vapors of paraquat dichloride could become airborne during an accidental release. Zeneca did not agree with the rationale EPA used to assign a TPQ of 10 pounds to paraquat dichloride, which is only manufactured, processed and used in solution form. Zeneca claimed that EPA did not explain why a greater potential for airborne dispersion for solids in solution exists as opposed to liquid chemicals.

On October 11, 2000, Syngenta (formerly Zeneca) filed an action in U.S. District Court for the District of Columbia under the Administrative Procedures Act seeking judicial review of EPA's decisions regarding paraquat dichloride. In this complaint, Syngenta requested EPA to either delete paraquat dichloride from the EHSs list or raise its TPQ. On January 23, 2003, EPA filed a Motion for Voluntary Remand in order to reconsider the petition. The court granted EPA's motion and dismissed Syngenta's complaint on January 31,

2003. By order of February 24, 2003, the court denied Syngenta's Motion to Amend Judgment. EPA again reviewed the request to delete paraquat dichloride and/or to raise its TPQ. In a November 21, 2003 letter to the petitioner, EPA reaffirmed its denial to delete paraquat dichloride from the EHSs list. EPA concluded that the acute toxicity of paraquat dichloride meets the criteria for listing it as an EHS chemical. In the same letter to the petitioner, however, EPA agreed to consider a revision to the TPQ for paraquat dichloride in the context of a proposed rule to amend the TPQ for all EHS chemicals handled as solids in solution. This letter is in the docket for today's rulemaking.

## II. Summary of This Action

### A. What is the scope of this proposed rule?

The scope of this proposed rule is to revise the manner by which the regulated community would apply the TPQ for EHS chemicals that are handled as solids in solution. There are 157 EHS chemicals that are non-reactive solids at ambient temperature, which could potentially be affected by this change, if they are handled by facilities in a solution form. The affected chemicals are identified in Appendix C in the "Technical Support Document for Revised TPQ Method for Solids in Solution," which is in the Docket to this rulemaking. These 157 chemicals appear with two TPQs, (the higher TPQ is 10,000 pounds) in Appendix A and B of 40 CFR part 355. However, this change will not apply to the 12 solid EHS chemicals that are reactive solids (noted by footnote "a" in Appendix A and B of 40 CFR part 355). Reactive solids are highly reactive with air or water or are explosive. Because of this, they are more likely than other solids to be dispersed into the air due to the energy or heat created when they react. Other reactive solids form toxic gases when they react with air or water. The explanation for not assigning a 10,000 pound TPQ to each of the reactive solids is discussed in the document, "Reactive Solids Whose Threshold Planning Quantities Should Be Less Than 10,000 Pounds," April 7, 1987, which can be found in the docket to this rulemaking.

Additionally, the proposed methodology of applying TPQs for solids in solution does not affect the reporting requirements for Sections 311 and 312 of EPCRA (40 CFR part 370). Specifically, emergency planning notification under Section 302 helps LEPCs identify those facilities whose accidental releases pose risks to the surrounding community so they can

develop emergency plans that identify the location and number of affected populations, evacuation or shelter-in-place procedures, etc. On the other hand, Sections 311 and 312 require submission of MSDSs and an on-site inventory of hazardous chemicals to help emergency responders assess how to respond to an emergency release or fire. Responders need the amounts, manner of storage and locations of the chemical on-site, not only the amount released off-site. They need information on the chemical and physical properties, hazard ratings, toxicity information and incompatibilities of the chemical, as well as measures needed to contain the spill or fire at the facility. They need to know what type of protective equipment is needed to protect them from exposure, not only airborne, but dermal.

Solid EHSs (except reactive solids) have a 10,000 pound TPQ or a specified lower TPQ for certain forms. For purposes of complying with the emergency planning notification requirements of Section 302 of EPCRA, EPA is proposing that facilities multiply the amount of EHS chemical handled as a solid in solution on-site by 0.2 and then determine if this amount equals or exceeds the established lower TPQ. If the amount of the solid EHS in solution on-site multiplied by 0.2 does not equal or exceed the lower TPQ for that solid EHS, then the facility is not subject to the EPCRA Section 302 emergency planning notification requirements for that substance. This amount includes only the weight of the chemical and not the solvent or other chemicals in solution. The amount of solid in solution may be determined by multiplying the weight percent of the solid in solution in a particular container by the weight of the solution. Solutions include aqueous or organic solutions, slurries, viscous solutions, suspensions, emulsions, and pastes. The revised TPQ methodology for solids in solution is similar to the use of the TPQ for EHS chemicals that are molten solids.<sup>1</sup>

The emergency release notification requirements under EPCRA Section 304 are not affected by this proposal. Section 304 requires facilities to notify the community emergency coordinator for the LEPC of any area likely to be affected by the release and the SERC of any area likely to be affected by the release (defined in 40 CFR 355.42) at or above the reportable quantity (RQ) of

<sup>1</sup> The TPQ for EHSs that are in a molten form on-site is calculated by multiplying the weight of the chemical by 0.3 to determine if the lower TPQ is met or exceeded.

any EHS or CERCLA hazardous substance. The RQ is not the same as the TPQ. TPQs are based on acute mammalian toxicity and potential for airborne dispersion. RQs, on the other hand, are developed using several criteria, including aquatic toxicity, mammalian toxicity, ignitability, reactivity, chronic toxicity, potential carcinogenicity, biodegradation, hydrolysis, and photolysis (50 FR 13468, April 4, 1985).

As an example, a facility has 4,000 pounds of a solution of 37% by weight paraquat dichloride on-site. Therefore, this solution contains 1,480 pounds of paraquat dichloride ( $0.37 \times 4,000$  pounds). The facility would multiply 1,480 pounds by 0.2 which equals 296 pounds. This amount is then compared to the TPQ for paraquat dichloride, which is 10 pounds. Because this amount exceeds the 10 pound TPQ, the facility is required to comply with the emergency notification requirements of Section 302 of EPCRA. As another example, a facility has 10 gallons of a solution of 37% by weight paraquat dichloride on-site. The density of the solution is 9.33 pounds per gallon. Therefore, this solution contains 34.5 pounds of paraquat dichloride ( $10 \text{ gal} \times 9.33 \text{ lb/gal} \times 0.37$ ). The facility would multiply 34.5 pounds by 0.2 which equals 6.9 pounds. This amount is then compared to the TPQ for paraquat dichloride, which is 10 pounds. Because this amount is less than the 10 pound TPQ, the facility is not required to comply with the emergency notification requirements of Section 302 of EPCRA.

Facilities that handle both the powdered and solution forms of a particular solid EHS will have to consider the quantities of each form and the particle size to determine whether they exceed a TPQ. Below are several examples of how to apply the revised TPQ methods in various cases.<sup>2</sup>

*Solid in solution exceed lower TPQ, powder below 10,000 pounds.* A facility has 5,000 pounds of a pure EHS powder form on-site which is less than the 10,000 pound TPQ. However, they have 1,000 gallons of a 35% by weight EHS solid in solution with a density of 9 pounds per gallon. The amount of solids in solution on-site is 3,150 pounds ( $1000 \text{ gallons} \times 9 \text{ pounds per gallon} \times 0.35$ ). Multiplying the 3,150 pounds of solid in solution by 0.2 equates to 630 pounds, which exceeds the lower TPQ of 500 pounds. Thus, the facility must report under Section 302 of EPCRA based on exceeding the lower TPQ for the solid in solution form.

*Solid in solution below lower TPQ, powder exceeds 10,000 pounds.* A facility has 11,000 pounds of a pure EHS solid powder on-site which is more than the 10,000 pound TPQ. They also have 2,000 gallons of a 10% by weight EHS solid in solution with a density of 9 pounds per gallon. The amount of solids in solution on-site is 1,800 pounds ( $2,000 \text{ gallons} \times 9 \text{ pounds per gallon} \times 0.10$ ). Multiplying the 1,800 pounds of solid in solution by 0.2 equates to 360 pounds, which is less than the lower TPQ of 500 pounds. Thus, the facility must report under Section 302 of EPCRA based on exceeding the 10,000 pound TPQ for the solid in powder form.

*Solid in solution below lower TPQ, powder below 10,000 pounds.* A facility has 5,000 pounds of a pure EHS solid powder which is less than the 10,000 pound TPQ. They also have 1,500 gallons of a 15% by weight EHS solid in solution with a density of 9 pounds per gallon. The amount of solids in solution on-site is 2,025 pounds ( $1,500 \text{ gallons} \times 9 \text{ pounds per gallon} \times 0.15$ ). Multiplying the 2,025 pounds of solid in solution by 0.2 equates to 405 pounds, which is less than the lower TPQ of 500 pounds. Thus, the facility is not required to report under Section 302 of EPCRA because it does not exceed the lower 500 pound TPQ for the solid in solution form or the 10,000 pound TPQ for the powder with particle size greater than 100 microns.

*Powdered product less than 100 microns, processed into solution.* If the same amounts of solid EHS were involved as the same scenarios above, except the powder has a particle size of less than 100 microns, then the lower 500 pound TPQ would apply to the powder instead of the 10,000 pounds. If either the amount of powder or solid in solution exceeds the lower TPQ, the facility would be required to report under Section 302 of EPCRA.

EPA is proposing this change based on data in the literature that shows the original assumption of 100% potential airborne release for solids in solution is inappropriate because it appears to overestimate the amount of chemical that would remain airborne after release. Review of the literature for accidental releases of liquid aerosols suggests a new methodology for applying the TPQs for solids in solution is warranted. The data shows that no more than 20% of the release is expected to remain airborne. More detailed discussion can be found in Section II.B.4.a of this preamble and in the technical support document in the docket to this proposed rule.

EPA's revised TPQ methodology for EHS solids in solution and supporting data was peer reviewed and the technical support document was revised based on peer review comments. The results of the peer review and response to peer review comments are found in a separate document, "Peer Review of Technical Support Document for Revised TPQ Method for EHS Solids in Solution," which is available in the docket to this rulemaking. A summary of the peer reviewer's comments and EPA responses to them are presented in Section II.D of this preamble.

*B. What is EPA's rationale for the TPQ changes?*

#### 1. Development of Existing TPQs

The TPQs were initially assigned based on a ranking scheme using a Level of Concern (LOC) based on acute toxicity and the potential for airborne dispersion. The TPQ methodology is described in detail in the "Threshold Planning Quantities Technical Support Document" dated April 7, 1987, which can be found in the docket for this rulemaking. For each chemical, a ranking index was calculated which equaled the LOC divided by an air dispersion factor (V). For gases,  $V = 1$ , while for liquids, V was based on a volatilization model using the molecular weight and boiling point of the chemical.

Solid EHS chemicals with a particle size less than 100 microns in diameter, molten solids, solids in solution, and solids with a National Fire Protection Association (NFPA) reactivity rating of 2, 3, or 4 were assigned a V equal to 1. If the EHS solid does not have a particle size less than 100 microns, is not molten or handled in solution form, and does not have an NFPA reactivity rating of 2, 3, or 4, then the EHS chemical was assigned a TPQ of 10,000 pounds, which corresponds to the highest index value. Solids with an NFPA reactivity rating of 2, 3, or 4 are noted with footnote "b" in the EHSs list.

Between one and 10,000 pounds, chemicals were assigned to the intermediate TPQ categories of 10, 100, 500 or 1,000 pounds based on the order of magnitude ranges of the index values. Also, for solids in molten form, before applying the TPQ, the amount of chemical on-site at any time is multiplied by an adjustment factor of 0.3 to conservatively account for the maximum volatilization of the spilled molten substance that is likely to take place.

<sup>2</sup> For these examples, the EHS is not paraquat dichloride, but an unspecified solid EHS.

## 2. Petitioner's Arguments for Changing Paraquat Dichloride's TPQ

In their complaint, Syngenta did not agree with EPA's rationale to assign a lower TPQ of 10 pounds to paraquat dichloride, which is only manufactured, processed and used in solution form. Syngenta claimed that EPA did not explain why it assumed a greater potential for airborne dispersion for solids in solution as opposed to liquid chemicals. In addition, Syngenta argued that Paraquat Dichloride solution is basically a non-volatile salt dissolved in water, and that the physical and chemical characteristics of many solids like paraquat dichloride limit their capacity to become airborne. Pure paraquat dichloride has a very low vapor pressure and decomposes at about 340° Celsius (C) before it reaches a boiling point. Syngenta further argued that using a liquid volatilization model to set a TPQ for paraquat dichloride is inappropriate.<sup>3</sup> Moreover, Syngenta stated that "the laws of physics preclude the possibility of a release of paraquat dichloride becoming completely airborne. Regardless of the emergency release scenario (extreme temperature, explosion, etc.), the amount to become airborne would not only be less than 100%, it would be virtually zero." Syngenta also stated that although paraquat dichloride can be temporarily atomized under laboratory conditions for testing animals, they do not believe that inhalable particles or vapors of paraquat dichloride can become airborne during an accidental release.

In discussions with EPA, Syngenta also raised the issue of aerosol size as a factor to be considered in developing the TPQ methodology for EHS solids in solution.

## 3. Basis for Existing Solids in Solution TPQs

In the April 7, 1987 "Threshold Planning Quantities Technical Support Document" (page 27), EPA noted that "solids may also be handled in solution and molten form and could potentially follow a liquid release scenario. However, even at molten temperatures, significant amounts of vapor are not likely to be generated." On page 24 of the same technical support document, when discussing liquid releases, EPA assumed that a spill of a liquid could occur as a result of an accidental situation that involves heat (e.g. fire,

exothermic runaway reaction, or reactions with air or water).

More specifically, when a solid chemical is in solution form, the solution can behave like a liquid during an accidental release and be dispersed into the air due to overheating, overpressure or anything that can cause a loss of containment from a vessel or piece of equipment. An accident involving a release of energy could create a liquid aerosol type of release into the air. Such liquid aerosol droplets, if small enough, can be dispersed into the air and remain airborne beyond the facility boundary, resulting in EHS exposure to the surrounding community. Environmental conditions and the properties of the specific chemical will dictate the behavior and dispersion of the chemical after a release or spill has occurred. For example, the solvent can evaporate from solution (especially at higher temperature) and small particulates of solid remaining after evaporation of the solvent can potentially be carried off-site. EPA recognized that the solid EHS (dissolved or suspended in a liquid solution) will not be dispersed into the air based on volatilization of the solid, but because of the energy released from the accident, or by wind.

At the time of the April 1987 rulemaking, EPA did not have sufficient information to determine how much of the solid EHS in solution could be dispersed airborne off-site and conservatively used V=1 for this release scenario. Furthermore, although paraquat dichloride decomposes at a temperature of 340° C (644° Fahrenheit, F), EPA believed that accidents involving aerosol releases of paraquat dichloride solution could potentially occur at temperatures less than 340° C. Boiling solutions containing non-volatile solids result in vaporization of the solvent, but not the solid. However, the turbulence of boiling the solution can entrain liquid aerosol droplets containing the solid into the air.

## 4. Airborne Dispersion of Solids in Solution.

Based on more recent information, EPA has re-evaluated the assumption of 100% airborne releases when setting the TPQ for solids in solution, not just for paraquat dichloride solution, but for all EHS solids in solution, except for the 12 solid EHS chemicals that are reactive solids.

### a. Liquid Aerosol Release Data

EPA reviewed data in the literature on releases of aerosols to evaluate their potential use for revising the application of the TPQs for EHS solids in solution.

EPA was specifically looking for data on how much of a solution containing a dissolved or suspended solid would remain airborne after an accidental release. One problem encountered in reviewing the literature was some studies only involved chemicals that are pure liquids and which have vapor pressures much higher than solid chemicals. That data would likely not represent the release and dispersion of a solid chemical that normally has a very low vapor pressure. However, the U.S. Department of Energy (USDOE) used experimental liquid aerosol release data involving metal salt solutions to estimate the Airborne Release Fraction (ARF) of metal salt solutions for a wide variety of release scenarios. This information was collected in a 1994 report, which is available in the docket to this rulemaking.<sup>4</sup> Many of the USDOE scenarios had very low ARFs; EPA considered the scenarios with higher release potential to best serve the purposes of emergency planning. Also, scenarios which required hypothetical input data to compute the ARF were not used. When median and bounding (maximum) values of ARFs were provided for a scenario, EPA used the maximum ARF in order to be conservative and cover the worst case scenario. EPA summarized the data from those DOE aerosol release scenarios with the highest (ARFs) in the table below. (The ARF values, release scenarios from the USDOE report and other data are discussed in greater detail in the technical support document for this rulemaking, which is available in the docket to this rulemaking.) From this data, EPA determined that a worst case estimate of the ARF for a solution containing non-volatile solids would be 0.2. This particular ARF is based on the scenarios of an aqueous solution or air dried salts under gasoline fire on a metal surface. The airborne fractions from the USDOE report generally contained aerosol sizes less than or equal to 100 microns. Droplets larger than 100 microns in diameter are expected to fall out before they reach a community outside a facility.

Aerosol release scenario	Maximum airborne release fraction (ARF)
Thermal Stress from Boiling .....	0.002

<sup>3</sup> EPA agrees with the petitioner that using the liquid volatilization model to set a TPQ for paraquat dichloride, whether handled as a pure chemical or in solution, is inappropriate. However, the TPQ for paraquat dichloride was not set using the volatilization method.

<sup>4</sup> USDOE. 1994. DOE Handbook, *Airborne Release Fractions/Rates and Respirable Fractions for Nonreactor Nuclear Facilities*. December 1994. US Department of Energy, Washington, DC 20585 DOE-HDBK-3010-94. Volume 1—Analysis of Experimental Data and Volume II—Appendices.

Aerosol release scenario	Maximum airborne release fraction (ARF)
High Pressure Venting Below Liquid Level .....	0.12
Pressure Venting Above the Liquid Level .....	0.002
Superheated Liquid Temp $\geq 50$ °C and $\leq 100$ °C .....	0.1
Superheated Liquid Temp $\leq 50$ °C .....	0.01
Burning Organic Layer Over Aqueous Solution .....	0.1
Aqueous Solution or Dry Salt Under Gasoline Fire on Metal ..	0.2
Aerodynamic Entrainment and Re-Suspension .....	0.1

Using the highest airborne release fraction rather than an average result of the scenarios is consistent with the intent of the emergency planning program to plan for a reasonable worst case scenario. This data is a good surrogate to use to predict the maximum potential aerosol release fraction of EHS solids in solution in the event of an accidental release. Water is probably the most common solvent that would be used with most of the EHS solids, whether they are dissolved, suspended or emulsified in water. Many of the EHS solids are pesticides and pesticides are commonly applied as water solutions or emulsions.

EPA also looked at experimental data collected by the Center for Chemical Process Safety (CCPS) for aerosol releases of water and cyclohexane. CCPS, a directorate of the American Institute of Chemical Engineers (AICHE), was established in 1985 to develop and disseminate technical information for use in the prevention of major chemical process incidents. CCPS develops and publishes guidelines, conducts seminars, symposia, training programs and meetings on chemical process-safety matters; CCPS also cooperates with other organizations, both internationally and domestically, to promote process safety. CCPS's activities are supported by funding and expertise from over 100 entities including, industry, consulting firms and governmental organizations. USEPA is a member of this organization.

In 1989, the CCPS Vapor Cloud Modeling Subcommittee began an "Aerosol Project" to meet some of the research objectives proposed to the U.S. National Vapor Cloud Research Committee, which included developing a superheated liquid release model and developing experimental data to validate the model. The experimental field data was the result of field controlled-release experimentation by CCPS with financial assistance by

special grants from some of the CCPS sponsors and from the USEPA and USDOE. The experimental superheated liquid release data was developed, documented, peer reviewed and, where necessary, corrected. The Vapor Cloud Modeling Subcommittee contracted a review of the fundamental basis for the RELEASE model and to make model improvements to reconcile the cyclohexane, chlorine and methylamine test data. The results of the model development and the experimental field data used was published in 1999 in a CCPS concept book "RELEASE: A Model with Data to Predict Aerosol Rainout in Accidental Releases" by David W. Johnson and John L. Woodward.

EPA did not use the aerosol release fraction from the CCPS data because these liquids did not contain any solid material in solution. Specifically, the reported airborne release fraction for water varied from 0.03 to 0.54 and for cyclohexane varied from 0.36 to 0.94. Cyclohexane with a vapor pressure of 95 millimeters (mm) mercury (Hg) is more volatile than water with its vapor pressure of 24 mm Hg. It is not a good comparison to use aerosol release fractions of volatile liquids to estimate the aerosol release fractions of a solid in solution because solids generally are not very volatile. The water aerosol data might be a close surrogate for estimating a release of an aqueous solution of the solid, but it does not have the important constituent of a dissolved solid, which might influence the amount of aerosol remaining entrained in the air. However, the CCPS data for water supports EPA's belief that assuming a 100% airborne liquid aerosol release is inappropriate because the water aerosol fractions measured in the experiments were less than one. CCPS also had experimental release data for CFC-11 and chlorine (both gases) and methylamine (a highly volatile chemical with a vapor pressure of 300 mm Hg), but EPA did not consider this data for use as a good analogy because of their high volatility and they did not contain any solids.

USDOE was interested in applying the experimental aerosol release data to estimate airborne fractions of liquid aerosol releases that were below respirable size, which they defined as particles of 10 micron Aerodynamic Equivalent Diameter (AED) or less. By USDOE's definition, respirable size particles are those that can be transported through the air and inhaled into the human respiratory system.

For purposes of establishing TPQs, EPA chose a distance of 100 meters (330 feet) to represent the distance from a source inside a chemical facility to the

point where the community might be exposed. This decision was based on data indicating that a particle size greater than 100 microns is not likely to be deposited more than 100 meters from the source ("Threshold Planning Quantities Technical Support Document," USEPA April 7, 1987, Public Docket 300PQ, Document No. 300PQ-2-21). The 100-micron cutoff is also consistent with CERCLA regulations (for reportable quantities) which also uses a 100 micron particle size for powdered materials.

Most of the USDOE experimental aerosol release data had median aerosol diameters of less than 100 microns. This size is consistent with what EPA believes is the size of aerosols to which the community could be exposed. On the other hand, the water and cyclohexane aerosol release data compiled by CCPS had much larger mean aerosol diameter sizes, generally over 100 microns. For the reasons already discussed and because it is likely that aerosol releases with diameters larger than 100 microns will fall out of the air before they reach a community, the water and cyclohexane aerosol release fractions were not used in determining the TPQs for solids in solution.

#### b. Liquid and Solution TPQ Comparison

Pure EHS liquids could also be released accidentally as aerosols via the same catastrophic scenarios (overpressure, superheating). It could be argued that perhaps the TPQ method for solids in solution could also apply to liquids. However, this goes against the ranking used for setting TPQs based on the extent of airborne releases by physical state as being high for gases, less for liquids and even less for solids in solution. Currently, the release scenario used for developing the liquid TPQs considers a spill of the liquid due to a loss of containment. The liquid then escapes into the air by volatilization. An airborne release of solids in solution will require more than a failure of containment to have appreciable airborne dispersion. An energy source, such as overpressure or high temperature would be required to disperse the solution into the air and create aerosol droplets. Not all of the droplets will stay airborne (unlike volatilized vapors) and affect the community, whose exposure depends on droplet size and distance from the facility fence line.

If one assumes that there is an equal potential for airborne releases for gases, liquids, small particulate solids and solids in solution, then the TPQ ranking scheme would change radically and rely

almost entirely on the toxicity of the chemical. However, EPA believes that airborne dispersibility is a critical factor in determining TPQs. Limited state and local resources should be focused on those EHS chemicals that can potentially cause the greatest harm and less on those that might be toxic, but less likely to be released to the air and carried beyond the facility boundary.

As a hypothetical scenario, EPA determined if the current TPQ method for liquids gives more conservative (or at least as conservative) TPQs (lower thresholds) as compared to the proposed TPQ methodology for solids in solution. To do this, EPA estimated the TPQs for liquids by assuming that  $V = 1$ , and then divided it by 0.2 (based on an expected 20% maximum airborne dispersion) to determine the amount of EHS on-site that would trigger emergency planning notification. These amounts or "effective TPQs" were then compared to the current listed TPQs for liquids. For 116 of the 163 EHS liquids, the current TPQs for liquids based on volatilization were equal to or lower than the new effective TPQs based on aerosolization. Most of the other 47 liquids had current TPQs that were about twice the effective TPQ. This comparison with a table of results for the EHS liquids is discussed in the technical support document for this rulemaking. Based on this analysis, EPA believes that using the volatilization model to establish  $V$  for liquid TPQs is still appropriate. The spilled liquid using a boiling point scenario is probably the most prevalent worst-case scenario that is reasonable to use for establishing TPQs for liquids.

Further examination of the 47 liquid chemicals was undertaken to see why these had TPQs greater than the effective TPQs—that is, about twice the effective TPQ. Many of these liquids had effective TPQ values of 5, 50 and 5,000 pounds. However, there are no TPQs of 5, 50 or 5,000 pounds. Rather, the use of order of magnitude index ranges assigned to various TPQ levels resulted in assigned TPQ values of 1, 10, 100, 500, 1,000 and 10,000 pounds. Thus, where the effective TPQs are either 5, 50, or 5,000 pounds, the comparison of a current TPQ versus an effective TPQ may not be valid. More discussion on this can be found in the technical support document.

### *C. What alternative approaches were considered?*

Given the data in the literature available on aerosol releases of solids in solution, EPA considered various alternative approaches. One alternative was using an index ranking method with an assigned  $V$  similar to the

original method of assigning TPQs. Another alternative was to apply the ARF to the existing lower TPQ for solids to develop a new TPQ for solids in solution for each solid EHS. A third alternative was similar to the approach of multiplying the maximum ARF by the amount on-site, except that the ARF would only represent aerosol sizes less than respirable size. Below we discuss these alternatives, as well as the basis for not selecting them.

#### 1. Index Ranking Method With $V$ Less Than 1

This alternative would establish TPQs using a ranking approach based on each chemical's physical state, acute toxicity and, the potential for the chemical to become airborne ( $V$ ). For this alternative,  $V$  would be set to 0.2 for EHS solids in solution.

For the original development of the TPQs, the ranking index was defined as the LOC divided by  $V$ , where  $V$  was set equal to 1 for gases and solids in powder form with a particle size less than 100 microns, molten solids and solids in solution. For liquid EHSs,  $V$  (the potential to become airborne) depended upon the property of volatility (evaporation of liquid into the gas phase). In the development of  $V$  for use in setting TPQs for liquids,  $V$  represented the mass per time evolved to the air per mass of the spill. This is explained in further detail in the April 1987 "Threshold Planning Quantities Technical Support Document" available in the docket.

Most of the values for  $V$  for liquids are approximately 0.1 (see Appendix B in the "Technical Support Document for Revising TPQ Method for Solids in Solution" for this rule). Using a higher  $V$  equal to 0.2 for solids in solution implies that in the event of an accidental release, more of the solution would become airborne than if it were volatilized from a liquid spill. Even if a liquid were accidentally released via aerosol form, the volatility of the liquid chemical will increase the fraction that remains dispersed in the air. Therefore, it would not be a fair representation to have a solid in solution with a  $V$  higher than that used for a volatile liquid. Also, because there are different mechanisms involved in the two types of releases, it may not be comparable to use the 0.2 as a substitute for  $V$  for solids in solution.

#### 2. Existing TPQ and Aerosol Release Fraction

Another alternative is to apply the ARF to the existing lower TPQ for solids to develop a new TPQ. For example, the lower TPQ for paraquat dichloride is 10 pounds. Dividing 10 pounds by 0.2, the

maximum expected aerosol release fraction for a solution would result in a new TPQ of 50 pounds for paraquat dichloride in solution form. For each of the 157 non-reactive solids on the EHSs list, a new TPQ for the solution form of the EHS solid could be determined and listed. However, for each solid non-reactive chemical, there are already two TPQs, one developed based on the ranking index methodology of (Index = Level of Concern/ $V$ ) and one based on the default TPQ of 10,000 pounds for non-molten, non-reactive, non-solution solids with a particle size equal to or greater than 100 microns. Including a third set of TPQs for EHS solids in solution could be confusing to the regulated community. Thus, EPA believes that using the existing lower TPQ for solids and comparing that to the product of the amount on-site multiplied by 0.2 is a better approach, and similar to the approach used for the molten solids form.

#### 3. Using ARF Limited to Smaller Aerosol Sizes

Another approach considered is similar to the proposed approach of multiplying the maximum ARF by the amount on-site, except that the ARF would only represent the fraction of aerosols with particles less than respirable size. Through discussions with the petitioner and EPA's November 2003 response to the petition, EPA has considered whether aerosol size should be used as a factor in developing new TPQs for solids in solution. A consultant for Syngenta believes that EPA should only consider the dispersion of aerosols with particle sizes less than or equal to 4 microns because these smaller aerosols are the size that can enter the lung and because the inhalation toxicity tests used for the basis of the EHSs listing only used very small particles.

This approach would require sufficient data on the aerosol size distribution for each release scenario to develop a new ARF that would include only aerosols of 4 microns and lower. The ARFs currently cited for the scenarios used for the preferred approach include aerosol sizes of 100 microns and lower. For some of the USDOE accident scenarios, it is possible to recalculate the airborne aerosol fractions using the raw experimental data to include only aerosols less than or equal to 4 microns in diameter. This results in smaller airborne release fractions.

EPA does not believe this approach should be used for a number of reasons, including:

- Inhalation toxicity tests are designed to use small particles to ensure that the lung is exposed. However, EPA is not using the inhalation toxicity for risk assessment, but only as a screening tool.

- Although the EHSs listing for paraquat dichloride is based on inhalation toxicity, EPA also has concerns regarding dermal and ingestion exposure via swallowing for the larger aerosols.

- Solvent evaporation from larger aerosols can also create smaller aerosols which can enter the lung.

Each of these is discussed below.

#### a. Aerosol Size in Toxicity Tests

Aerosols may be defined as a suspension of solid or liquid particles in air. Inhalation acute toxicity tests are purposely designed with very small diameter particles in order to ensure that particles are small enough to enter the rodent's lungs and test the toxicity in the lungs. Larger particles may not enter deep areas of the lungs and thus, test results may be misinterpreted if little inhalation toxicity is shown. EPA is not attempting to use the airborne aerosol fraction for purposes of risk assessment, but only as a tool to set screening levels for the amount of chemicals on-site which may potentially cause harm if accidentally released. Also, the size of the aerosols used in an animal laboratory test cannot be assumed to be the same as those that people may be exposed to during an accidental release.

#### b. Particle Size and Exposure

Inhalable size particles enter the respiratory tract, including the head airways and are generally equal to or less than 100 microns. Thoracic size particles (generally equal to or less than 10 microns) travel past the larynx and reach the lung airways and the gas-exchange regions of the lung. Respirable size particles (generally less than or equal to 4 microns) are a subset of thoracic particles that are more likely to reach the gas-exchange region of the lung.<sup>5</sup>

Most particles that enter the upper airways are trapped in mucus that moves to the throat and is swallowed within a few hours. Thus, instead of inhalation exposure deep in the lungs, exposure to larger particles of chemicals may occur through dermal exposure to

mucous membranes or ingestion exposure through swallowing. Emergency planning for EHS chemicals is not limited to inhalation exposure only, although many of the EHS chemical listings are based on studies which meet the EHSs listing criteria for inhalation toxicity. Although airborne exposure is the most likely route of exposure, it is not the only route of exposure. In the event of an accidental release, EPA is concerned about all routes of exposure (inhalation, dermal and ingestion) to the community. Thus, exposure to larger size aerosols (e.g. those above 4 or 10 microns) by any route, such as through the skin or mucous membranes) should not be ignored when setting TPQs.

#### c. Solvent Evaporation From Aerosols

Even after liquid aerosol droplets are released, some of the solvent may evaporate in the air. This would result in even smaller size aerosols or solid EHS particulates in the air to which a community would be exposed. One concern is that droplets of size greater than 100 microns could settle quickly, dry into a smaller particle size and then become airborne again (re-suspension). In the event of an accidental release, the responsible party should clean up chemicals deposited on the facility grounds before additional exposure to the community would take place. The USDOE report did include data on re-suspension of particulates from soil after an aerosol release. However, the amount re-suspended did not add much to the reasonable worst case aerosol release fraction of 0.2. This scenario is explained further in the technical support document for this rule.

#### D. What are the peer review results?

EPA's revised TPQ methodology for EHS solids in solution and supporting data was peer reviewed and the technical support document was revised based on the peer review comments. The description of the peer review process, the results of the peer review and EPA's response to the peer review comments are found in a separate document, "Peer Review of Technical Support Document for Revised TPQ Method for EHS Solids in Solution," which is available in the docket to this rulemaking. Below are the questions posed to the peer reviewers, a summary of the peer reviewers' comments and EPA's responses.

1. Based on your reading and analysis of the information provided, do you find the revised TPQ method to be logical with a sound scientific basis?

Two of the three reviewers agreed that the revised TPQ method was logical with a sound scientific basis using the USDOE experimental aerosol release data. However, one reviewer thought the revised TPQ method may not be based on the most sound science because the LOC is based on Immediately Dangerous to Health and Life values (IDLH) and animal lethality data that he believes may not be appropriate. Nonetheless, this reviewer did think that a cursory review of the effective TPQ list (Appendix B in technical support document) appears to have appropriately listed the ranking of chemicals by potential hazard to the public.

EPA recognizes that use of the IDLH was an imperfect measure for determining the LOC, but believes the approach provides a consistent relative ranking of the EHS. Where animal lethality data were substituted, safety factors were applied to the data to estimate the LOC. Human data were taken into account for some chemicals, such as chemical warfare agents, and adjustments were made to the TPQ initially based on index values. EPA realizes that better data are being developed that could be used for the LOC (such as AEGLs—Acute Exposure Guideline Levels). However, a re-evaluation of the LOC for all EHS chemicals would best be undertaken by a separate rulemaking effort, given the extent and complexity of this issue.

2. Is the writing clear and concise? Has EPA provided the right level of detail? Is the method understandable? Are the results clearly presented?

Two of the three reviewers thought that the revised method was not clear and understandable and suggested improvements. For example, it was recommended that EPA clarify the definition of a solution, as well as include a flowchart of the method or a graph to help describe the approach.

EPA agrees that improvements were needed in order to present the information in a better way for the regulated community to understand and apply, and the revised technical support document addresses those concerns. Thus, additional supporting background information, discussion about the development of TPQs, and examples and calculations of how to apply the TPQs for EHS solids in solution have been added to the technical support document and has been further

<sup>5</sup> USEPA. October 2004. Air Quality Criteria for Particulate Matter. Vol I, Chapter 2 and Volume II, Chapter 6. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Research Triangle Park, NC. EPA/600/P-00/002aF and EPA/600/P-00/002bF

explained in the preamble to the proposed rule. The proposed rule, which was not provided to the peer reviewers, is written more clearly and is less technical than the materials given to the peer reviewers to review.

One reviewer thought that EPA had provided the right amount of detail, and thought the method is understandable, and the text is for the most part readable. However, the reviewer had several clarifications and corrections he thought EPA should make. These clarifications have been made to the technical support document, including improving a description of background on TPQ development, clarifying some terms used in the document, and adding some references and other editorial comments.

This same reviewer thought the argument against the alternative approach of using  $V=0.2$  for developing TPQ for solids in solutions was not that convincing. EPA has revised the discussion of this alternative approach by stating that EPA believes that this approach would result in TPQs that would be too low as compared to TPQs for liquids of similar toxicity because most of the liquids have approximately  $V=0.1$ . EPA believes that liquids have a higher potential for airborne dispersion because of their inherently higher volatility. Also, the mechanism for airborne dispersion for liquids using the spill model is volatilization, whereas solids in solution will be dispersed via aerosolization, so using  $V=0.2$  for solutions may be not comparable.

3. Is the revised method consistent with the overall approach used for setting TPQs for other EHS chemicals?

All three reviewers thought that the revised method was fairly consistent with the approach used for setting other TPQs. However, one reviewer thought that EPA should consider lowering the TPQs for 46 of 163 EHS liquids based on the comparison of using the revised TPQ method versus the current method. EPA believes that using a  $V$  of 0.2 to recalculate the TPQ indexes would result in conservatively low TPQs for solids in solution as compared to liquids of the same toxicity. Given that volatilization requires only the loss of containment of a chemical, whereas aerosolization requires the loss of containment and usually an energy release, EPA believes the higher potential for airborne dispersion should be assigned to liquids as compared to a non-volatile solid in solution. Because there are different mechanisms (volatilization versus aerosolization) involved in the two types of releases, it may not be comparable to use 0.2 as a

substitute for  $V$  for solids in solution. Based on the comments, EPA has revised the discussion in the preamble to the rule and Section VI.A—Use Original Ranking Method to Develop New TPQs of the document, “Technical Support Document for Revised TPQ Method for EHS Solids in Solution.” EPA has also provided a more logical and clearer explanation for TPQs for different forms in Appendix A: Assigning Threshold Planning Quantities (TPQs) for Extremely Hazardous Substances, in the above document.

4. Is the revised method sufficiently protective for fulfilling accident prevention purposes of section 302 of EPCRA?

The reviewers all agreed that the method was sufficiently conservative to fulfill the accident prevention purposes of section 302 of EPCRA.

5. Is the revised method presented in a straightforward and uncomplicated way for the regulated community to understand and apply?

One reviewer thought that the revised method is not particularly straightforward and uncomplicated and that the regulated community will have difficulty understanding and applying it. Another reviewer suggested that examples be provided of how to apply the method when both powdered and solution form of a solid EHS is on-site. One reviewer thought a flow chart might be helpful to summarize the TPQ approach for the full spectrum of chemical forms.

To address these concerns, EPA has provided in the technical support document and the preamble to the proposed rule, a number of examples of how to apply the new TPQ method for solids in solution.

6. Are you aware of any other approaches or significant data/studies that are relevant and should be included or referenced in this document? Please explain

The reviewers were not able to provide any other approaches or data that should be used to revise the TPQ method for solids in solution, although one did provide other recommendations regarding the EHS chemical listing process and the toxicity values used for TPQs. Some of these comments address issues that are outside the scope of the current effort, which focuses only on TPQs for solids in solution.

7. Please Provide Any Other Suggestions You May Have About How To Strengthen the Document

To address other comments and concerns of the reviewers, EPA has clarified that the 12 reactive EHS solids are not subject to the revised TPQ method for solids in solution. EPA has also added several technical references as suggested into the technical support document.

*E. What are the economic impacts of the TPQ changes?*

Currently, facilities, who have an EHS present in an amount equal to or greater than the EHS's TPQ, are required to:

- Notify the SERC and LEPC that the facility is subject to emergency planning notification.
- Notify the SERC and LEPC of a facility representative to participate in the local emergency planning process.
- Notify the LEPC of any relevant facility changes that affect emergency planning.
- Provide the LEPC with the necessary information for developing a local emergency plan, as requested.

For facilities with an EHS that exists as solids in solution, emergency planning notification is required if the amount of solids by weight meets or exceeds the lower published TPQ for that chemical. Solid EHSs have another higher TPQ of 10,000 pounds that applies only if the EHS is not in solution, has a particle size equal to or greater than 100 microns, is not molten and does not have an NFPA reactivity rating of 2, 3, or 4.

The proposed rule would subject facilities with an EHS solid in solution to the emergency planning requirements if the amount of solid chemical on-site, when multiplied by 0.2, equals or exceeds the lower published TPQ. The effect would be to allow facilities to have up to five times larger amounts of EHS solids in solution on-site than before without being subject to the above emergency planning requirements.

Facilities who already had EHS solids in solution on-site above the TPQ and who have already (or should have already) completed emergency planning notification should notify their LEPC if they no longer exceed the TPQ as a result of this rulemaking. Section 303(d)(2) of EPCRA requires facilities to promptly provide to their LEPC any changes relevant to emergency planning. Regulations at 40 CFR 355.21 clarify that relevant changes to emergency planning should be reported within 30 days. EPA expects that this notification will be a minimal burden.

The emergency planning notification requirement is not required annually. Facilities, who are handling an EHS solid in solution for the first time, may benefit from the changes. However, if they have other EHSs on-site which trigger the reporting requirements, they would still have to make the necessary notifications.

EPA believes that the changes proposed by this rule can benefit SERCs and LEPCs to better focus their limited resources on those amounts of EHS chemicals that will potentially cause the greatest harm and to spend fewer resources on those that pose less harm, when released. The EHSs list has a total of 355 chemicals, of which 157 are non-reactive solids. This proposed rule applies only to those 157 non-reactive solids and only when they exist in solution form. While the Agency does not collect information to quantify the number of facilities that may be impacted by this rule, we suspect it will likely be a minimal number of facilities that are impacted since we believe that many of these facilities handle other EHS chemicals that will trigger the emergency planning requirements. However, the Agency solicits comment and data on the number of facilities that may be impacted, and the extent of the impact.

### III. Statutory and Executive Order Reviews

#### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a “significant regulatory action” because it raises novel policy issues arising out of litigation on the listing of paraquat dichloride as an EHS. EPA has decided to modify the manner by which the TPQ is applied for paraquat dichloride, as well as any other EHS that exists as a non-reactive solid in solution. Specifically, facilities with a non-reactive solid EHS in solution would be subject to the Emergency Planning requirements of 40 CFR part 355, subpart B—Emergency Planning only if the amount of non-reactive EHS solids in solution on-site multiplied by 0.2 equals or exceeds the lower published TPQ. Accordingly, EPA submitted this action to the Office of Management and Budget for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

The proposed regulation will not 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.

#### B. Paperwork Reduction Act

This proposed rule does not impose any new information collection burden. Rather, this proposed rule, in effect, raises the amount of chemical on-site required before triggering emergency planning reporting under 40 CFR part 355 for EHS non-reactive solids in solution. Facilities with this form of EHS chemical would have already (or should have already) reported their presence to their SERC and LEPC and identified a Facility Emergency Coordinator and necessary information for development of a local emergency plan to their LEPC. If as a result of this rulemaking, facilities find that they have an EHS solid in solution on-site which no longer equals or exceeds the TPQ, the facility should notify their LEPC. Section 303(d)(2) of EPCRA requires facilities to promptly provide to their LEPC any changes relevant to emergency planning. Regulations at 40 CFR 355.21 clarify that relevant changes to emergency planning should be reported within 30 days. EPA expects that this notification will be a minimal burden. The emergency planning notification requirement is not required annually. There may be a slight burden reduction for facilities who are reporting EHS non-reactive solids in solution for the first time under the Section 302 requirements.

The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations at 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 number 1395.07. 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) 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 proposed rule on small entities, small entity is defined as: (1) A

small business as defined by the Small Business Administration’s (SBA) regulations 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 today’s proposed rule on small entities, I certify that this action 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 rule on small entities.” 5 USC 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 all of the small entities subject to the rule.

This proposed rule changes the manner by which facilities apply the TPQs for those EHSs that are solid chemicals in solution form. Specifically, facilities with a non-reactive solid EHS in solution would be subject to the Emergency Planning requirements of 40 CFR part 355, subpart B—Emergency Planning only if the amount of non-reactive EHS solids in solution on-site, multiplied by 0.2 equals or exceeds the lower published TPQ. We have therefore concluded that today’s proposed rule will relieve regulatory burden for some affected 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

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1532–1538 for state, local, or tribal governments or the private sector. This proposed rule does not impose any new requirements on state, local or tribal governments. Facilities currently with EHS non-reactive solids in solution on-site have already (or should have already) reported these chemicals to their SERC and LEPC and identified a

Facility Emergency Coordinator and the necessary information for developing an emergency plan to their LEPC. We expect that this proposed action will neither increase nor decrease the requirements for SERCs or LEPCs. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This proposed action does not impose any new requirements on state, local or tribal governments.

#### *E. Executive Order 13132: Federalism*

This action 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 would reduce the reporting burden on any facilities that would have an EHS non-reactive solid in solution on-site for the first time and could be subject to the emergency planning requirements for that chemical under 40 CFR part 355, subpart B—Emergency Planning. We also expect that this proposed action will neither increase nor decrease the requirements for SERCs or LEPCs. This rule does not impose any requirements on state or local governments. Thus, Executive Order 13132 does not apply to this action.

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 action from state and local officials.

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

This action does not have tribal implications, as specified in Executive Order 13175, (65 FR 67249, November 9, 2000). This proposed rule would reduce reporting burden on any facilities that would have an EHS non-reactive solid in solution on-site for the first time and could be subject to the emergency planning requirements for that chemical under 40 CFR part 355, subpart B—Emergency Planning. This action also does not impose any new requirements on tribal governments. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866 and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This proposed rule would reduce reporting burden on any facilities that would have an EHS non-reactive solid in solution on-site for the first time and could be subject to the emergency planning requirements for that chemical under 40 CFR part 355, subpart B—Emergency Planning.

#### *H. Executive Order 13211: Energy Effects*

This action is not a “significant energy action” as defined in Executive Order 13211 (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. Rather, this proposed rule would reduce reporting burden on any facilities that would have an EHS non-reactive solid in solution on-site for the first time and could be subject to the emergency planning requirements for that chemical under 40 CFR part 355, subpart B—Emergency Planning.

#### *I. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (“NTTAA”), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or would otherwise be 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. NTTAA directs EPA to provide Congress, through OMB, explanations of when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule does not involve technical standards. Therefore, EPA does not consider the use of any voluntary consensus standards.

#### *J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order (EO) 12898 (59 FR 7629 (February 16, 1994)) establishes

federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. That is, based on new information and data, the Agency believes that amounts of EHS non-reactive solids in solution that would remain airborne from a potential release into the environment from an accident would be lower than previously considered, and thus, would have less impact on the local community. This in turn will allow SERCs and LEPCs to better focus their limited resources on the amounts of EHS chemicals that will potentially cause the greatest harm, including those affecting minority or low-income populations and to spend fewer resources on those that pose less harm, when released.

#### **List of Subjects in 40 CFR Part 355**

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

Dated: April 8, 2011.

**Lisa P. Jackson,**  
*Administrator.*

For the reasons set out in the preamble, title 40, chapter I 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:** Sections 302, 303, 304, 325, 327, 328, and 329 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11002, 11003, 11004, 11045, 11047, 11048, and 11049).

2. Section 355.16 is amended by revising paragraph (b) to read as follows:

**§ 355.16 How do I determine the quantity of extremely hazardous substances present for certain forms of solids?**

\* \* \* \* \*

(b) *Solids in solution.* Multiply the weight percent of non-reactive solids in solution in a particular container by the total weight of solution in the container. Then multiply by 0.2.

\* \* \* \* \*

3. Section 355.61 is amended by adding in alphabetical order the definition of "Solution" to read as follows:

**§ 355.61 How are key words in this part defined?**

\* \* \* \* \*

*Solution* means any aqueous or organic solutions, slurries, viscous solutions, suspensions, emulsions, or pastes.

\* \* \* \* \*

[FR Doc. 2011-9096 Filed 4-14-11; 8:45 am]

BILLING CODE 6560-50-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Part 441**

[CMS-2296-P]

RIN 0938-AP61

**Medicaid Program; Home and Community-Based Services (HCBS) Waivers**

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would revise the regulations implementing Medicaid home and community-based services (HCBS) waivers under section 1915(c) of the Social Security Act by providing States the option to combine the existing three waiver targeting groups as identified in § 441.301. In addition, we are proposing other changes to the HCBS waiver provisions to convey expectations regarding person-centered plans of care, to provide characteristics of settings that are not home and community-based, to clarify the timing of amendments and public input requirements when States propose modifications to HCBS waiver programs and service rates, and to describe the additional strategies available to CMS to ensure State compliance with the statutory provisions of section 1915(c) of the Act.

**DATES:** To be assured consideration, comments must be received at one of

the addresses provided below, no later than 5 p.m. on June 14, 2011.

**ADDRESSES:** In commenting, please refer to file code CMS-2296-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2296-P, P.O. Box 8016, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2296-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or

courier delivery may be delayed and received after the comment period.

**FOR FURTHER INFORMATION CONTACT:** Kathryn Poisal, (410) 786-5940.

**SUPPLEMENTARY INFORMATION:** *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

**I. Background**

Section 1915(c) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to waive certain Medicaid statutory requirements so that a State may offer Home and Community-Based Services (HCBS) to State-specified group(s) of Medicaid beneficiaries who otherwise would require services at an institutional level of care. This provision was added to the Act by the Omnibus Budget and Reconciliation Act of 1981 (Pub. L. 97-35, enacted August 13, 1981) (OBRA '81) (with a number of subsequent amendments). Regulations were published to effectuate this statutory provision, with final regulations issued on July 25, 1994 (59 FR 37719). In the June 22, 2009 **Federal Register** (74 FR 29453), we published the Medicaid Program; Home and Community-Based Services (HCBS) advance notice of proposed rulemaking (ANPRM) that proposed to initiate rulemaking on a number of areas within the section 1915(c) program. We received 313 comments (which can be accessed at <http://www.regulations.gov>) and held teleconferences with stakeholders. The correspondence included comments from States, health care and community support providers and associations, consumer groups, and social workers, and others. In the following sections, we discuss comments relating to questions