

**ENVIRONMENTAL PROTECTION  
AGENCY**
**40 CFR Parts 302 and 355**
**[EPA-HQ-SFUND-2007-0469; FRL-8511-4]**
**RIN 2050-AG37**
**CERCLA/EPCRA Administrative  
Reporting Exemption for Air Releases  
of Hazardous Substances From Animal  
Waste**
**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** This notice of proposed rulemaking provides notice of, and requests comments, including any relevant data, on a proposed administrative reporting exemption from particular notification requirements under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, and the Emergency Planning and Community Right-to-Know Act, also known as Title III of the Superfund Amendments and Reauthorization Act. Specifically, the proposed administrative reporting exemption applies to releases of hazardous substances to the air where the source of those hazardous substances is animal waste at farms. Nothing in this proposed rule, however, would change the notification requirements if hazardous substances are released to the air from any other source other than animal waste at farms (*i.e.*, ammonia tanks), as well as releases of any hazardous substances from animal waste to any other environmental media, (*i.e.*, soil, ground water, surface water) when the release of those hazardous substances is at or above its reportable quantity per 24 hours. This administrative reporting exemption is protective of human health and the environment and consistent with the Agency's goal to reduce reporting burden where there would likely be no Federal, state or local emergency response to such release reports. Eliminating such reporting will allow emergency response officials to better focus on releases where the Agency is more likely to take a response action. Finally, in proposing this administrative reporting exemption from the notification requirements under the Comprehensive Environmental Response, Compensation, and Liability Act, section 103(a) and the Emergency Planning and Community Right to Know Act, section 304, EPA is not proposing to limit any of its authorities

under CERCLA sections 104 (response authorities), 106 (abatement actions), 107 (liability), or any other provisions of the Comprehensive Emergency Response, Compensation, and Liability Act or the Emergency Planning and Community Right to Know Act in this rulemaking.

**DATES:** Comments must be received on or before March 27, 2008.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-SFUND-2007-0469, by one of the following methods:

- *www.regulations.gov*: Follow the on-line 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-2007-0469. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](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 [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](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 [www.regulations.gov](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 Unit I.B of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** All documents in the docket are listed in the [www.regulations.gov](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 in [www.regulations.gov](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:** Lynn M. Beasley, Regulation and Policy Development Division, Office of Emergency Management (5104A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-1965; fax number: (202) 564-2625; e-mail address: [Beasley.lynn@epa.gov](mailto:Beasley.lynn@epa.gov).

**SUPPLEMENTARY INFORMATION:** The contents of this preamble are listed in the following outline:

- I. General Information
  - A. Does This Action Apply to Me?
  - B. What Should I Consider As I Prepare My Comments for EPA?
  - C. What Is the Statutory Authority for This Rulemaking?
  - D. Which Hazardous Substances Are We Proposing to Exempt From the Notification Requirements of CERCLA and EPCRA?
- II. Background
- III. Summary of This Action
  - A. What Is the Scope of This Proposed Rule?
  - B. Proposed Definitions
  - C. What Is Not Included Within the Scope of This Proposed Rule?
  - D. What Is EPA's Rationale for This Administrative Reporting Exemption?
  - E. What Are the Economic Impacts of This Administrative Reporting Exemption?
- IV. Statutory and Regulatory Reviews
  - A. Executive Order 12866 (Regulatory Planning and Review)
  - B. Paperwork Reduction Act
  - C. Regulatory Flexibility Act
  - D. Unfunded Mandates Reform Act
  - E. Executive Order 13132 (Federalism)

- F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)
- G. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)
- H. Executive Order 13211 (Energy Effects)
- I. National Technology Transfer and Advancement Act of 1995 (“NTTAA”)
- J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

**I. General Information**

*A. Does This Action Apply to Me?*

Type of entity	Examples of affected entities
Industry .....	NAICS Code 111—Crop Production. NAICS Code 112—Animal Production.
State and/or Local Governments.	State Emergency Response Commissions, and Local Emergency Planning Committees.
Federal Government.	National Response Center.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility is affected by this action, you should carefully examine the criteria in section III.A of this proposed rule and the applicability criteria in §§ 302.6 and 355.40 of title 40 of the Code of Federal Regulations. 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?*

In an effort to implement the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Emergency Planning and Community Right to Know Act (EPCRA) more efficiently, EPA is proposing to establish an administrative reporting exemption from the notification requirements of CERCLA and EPCRA for releases of hazardous substances, such as ammonia and hydrogen sulfide, to the air where the source of the release is animal waste at farms. The Agency believes that a federal response to such notifications is impractical and unlikely. In addition, nothing in this proposal would limit EPA’s authority to take action under its

various authorities under CERCLA sections 104 (response authorities), 106 (abatement actions), 107 (liability), or any of provisions of CERCLA or EPCRA (other than ECPCRA section 304) through this rulemaking.

Therefore, 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 Rulemaking?*

Section 104 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 U.S.C. 9601, *et seq.*, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, gives the Federal government broad authority to respond to releases or threats of releases of hazardous substances from vessels and facilities. The term “hazardous substance” is defined in section 101(14) of CERCLA primarily by reference to other Federal environmental statutes. Section 102 of CERCLA gives the Environmental Protection Agency (EPA) authority to designate additional hazardous substances. Currently there are approximately 760 CERCLA hazardous substances, exclusive of Radionuclides, F-, K-, and Unlisted Characteristic Hazardous Wastes.

CERCLA Section 103(a) calls for immediate notification to the National Response Center (NRC) when the person in charge of a facility has knowledge of a release of a hazardous substance equal to or greater than the reportable quantity (RQ) established by EPA for that substance. In addition to the notification requirements established pursuant to

CERCLA section 103, section 304 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), 42 U.S.C. 11001 *et seq.*, requires the owner or operator of certain facilities to immediately report to State and local authorities releases of CERCLA hazardous substances or any extremely hazardous substances (EHSs) if they exceed their RQ (see 40 CFR 355.40). This proposed rule only applies to CERCLA section 103 notification requirements, including the provisions that allow for continuous release reporting found in paragraph (f)(2) of CERCLA section 103, and EPCRA section 304 notification requirements.

The Agency has previously granted such administrative reporting exemptions (AREs) where the Agency has determined that a federal response to such a release is impracticable or unlikely. For example, on March 19, 1998, the Agency issued a final rule (see 63 FR 13459) that granted exemptions for releases of naturally occurring radionuclides. The rule entitled, Administrative Reporting Exemptions for Certain Radionuclide Releases (“Radionuclide ARE”), granted exemptions for releases of hazardous substances that pose little or no risk or to which a Federal response is infeasible or inappropriate (see 63 FR 13461).

The Agency relies on CERCLA sections 102(a), 103, and 115 (the general rulemaking authority under CERCLA) as authority to issue regulations governing section 103 notification requirements. The Agency relies on EPCRA section 304 as authority to issue regulations governing EPCRA section 304 notification requirements, and EPCRA section 328 for general rulemaking authority.

*D. Which Hazardous Substances Are We Proposing to Exempt From the Notification Requirements of CERCLA and EPCRA?*

EPA proposes to exempt certain releases of hazardous substances to the air from the notification requirements of CERCLA and EPCRA, as implemented in 40 CFR 302.6 and 40 CFR 355.40, respectively. Specifically, we are proposing to exempt those hazardous substance releases which are emitted to the air (typically during digestion, break-down or decomposition) from animal waste at farms. Although ammonia and hydrogen sulfide are the most recognized hazardous substances that are emitted from animal waste, there may also be some amounts of additional hazardous substances released.

Ammonia is a by-product of the break-down of urea and proteins that are

contained in animal waste. Hydrogen sulfide is another by-product of the break-down of animal waste. These hazardous substances can be emitted when animal waste is contained in a lagoon or stored in under-floor manure pits in some animal housing, manure stockpiles, or in the open where animals congregate. Open air or dry manure stockpiles are not generally associated with significant hydrogen sulfide emissions.

Additional hazardous substances may be emitted to the air from animal waste.<sup>1</sup> These hazardous substances would typically be subject to the notification requirements of CERCLA section 103 and EPCRA section 304 once their RQ is met or exceeded. However, this proposed rule will extend the administrative reporting exemption to all hazardous substances emitted to the air from animal waste at farms.

## II. Background

Under CERCLA section 103(a), the person in charge of a vessel or facility from which a CERCLA hazardous substance has been released into the environment in a quantity that equals or exceeds its RQ must immediately notify the NRC of the release. A release is reportable if an RQ or more is released into the environment within a 24-hour period (see 40 CFR 302.6). This reporting requirement serves as a trigger for informing the Federal government of a release so that Federal personnel can evaluate the need for a response in accordance with the National Contingency Plan (NCP) and undertake any necessary response action in a timely fashion.

The NRC is located at the United States Coast Guard (USCG) headquarters and is the national communications center for the receipt of all pollution incidents reporting. The NRC is continuously manned for processing activities related to receipt of the notifications. NCP regulations, 40 CFR 300.125, require that notifications of discharges and releases be made telephonically and state that the NRC will immediately relay telephone notices of discharges (*i.e.*, oil) or releases (*i.e.*, hazardous substances) to

the appropriate predesignated federal on-scene coordinator (OSC). The NRC receives an average of approximately 34,000<sup>2</sup> notifications per year. Of those notifications, averages of approximately 33,700<sup>3</sup> discharge or release notifications are relayed to EPA.

Under EPCRA section 304(a), three release scenarios require notification.

- First, if a release of an extremely hazardous substance occurs from a facility at which a hazardous chemical is produced, used, or stored, and such release requires a notification under section 103(a) of CERCLA, the owner or operator of a facility shall immediately provide notice to the community emergency coordinator for the local emergency planning committees (LEPC) for any area likely to be affected by the release and to the State emergency planning commission (SERC) of any State likely to be affected by the release. (*EPCRA section 304(a)(1)*)

- EPCRA section 304(a) also requires the owner or operator of the facility to immediately provide notice under EPCRA section 304(b) for either of the following two scenarios:

- If the release is an extremely hazardous substance, but not subject to the notifications under section 103(a) of CERCLA. (*EPCRA section 304(a)(2)*)

- If the release is not an extremely hazardous substance and only subject to the notifications under section 103(a) of CERCLA. (*EPCRA section 304(a)(3)*)

EPCRA notification is to be given to the community emergency coordinator for each LEPC for any area likely to be affected by the release, and the SERC of any state likely to be affected by the release. Through this notification, state and local officials can assess whether a response action to the release is appropriate. EPCRA section 304 notification requirements apply only to releases that have the potential for off-site exposure and that are from facilities that produce, use, or store a "hazardous chemical," as defined by regulations promulgated under the Occupational Safety and Health Act of 1970 (OSHA) (29 CFR 1910.1200(c)) and by section 311 of EPCRA.

In establishing the RQs for the various hazardous substances, EPA adjusted the

statutory RQs of CERCLA hazardous substances based on specific scientific and technical criteria that relate to the possibility of harm from the release of a hazardous substance in a reportable quantity. (See 50 FR 13456, April 4, 1985.) The adjusted RQs did not reflect the determination that a release of a substance will be hazardous at the RQ level and not hazardous below that level. EPA did not, at the time, make such a determination because the actual hazard will vary with the unique circumstances of the release. Instead, the RQs reflect the Agency's judgment of which releases should trigger notification to the federal government so that the government may assess to what extent, if any, a federal removal or remedial action may be necessary. (See 50 FR 13465.)

For the purposes of making RQ adjustments under CERCLA, EPA adopted the five RQ levels of 1, 10, 100, 1000, and 5000 pounds originally established pursuant to CWA section 311 (see 40 CFR part 117). The Agency adopted the five-level system primarily because: (1) It has been successfully used pursuant to the CWA, (2) the regulated community was familiar with these five levels, and (3) it provided a relatively high degree of discrimination among the potential hazards posed by different CERCLA hazardous substances.

The methodology used for adjusting RQs begins with an evaluation of the intrinsic physical, chemical, and toxicological properties of each designated hazardous substance. The intrinsic properties examined—called "primary criteria"—are aquatic toxicity, mammalian toxicity (oral, dermal, and inhalation), ignitability, reactivity, and chronic toxicity.<sup>4</sup> In addition, substances that were identified as potential carcinogens were evaluated for their relative activity as potential carcinogens.

The Agency ranks each intrinsic physical, chemical, and toxicological property on a five-tier scale, associating a specific range of values on each scale with a particular RQ value. Thus, each substance receives several tentative RQ values based on its particular properties. For example, ammonia received a tentative RQ of 100 pounds based on its aquatic toxicity levels; however, for the intrinsic property, mammalian toxicity (inhalation), ammonia received a tentative RQ value of 1000 pounds. The lowest of all of the tentative RQs for

<sup>1</sup> *Air Emissions from Animal Feeding Operations: Current Knowledge, Future Needs*. National Research Council of the National Academies, The National Academies Press, Washington, DC (2003), p. 54. Additional hazardous substances may include nitrous oxide (NO) and volatile organic compounds (VOCs). The major constituents of VOC emissions could include organic sulfides, disulfides, C<sub>4</sub> to C<sub>7</sub> aldehydes, trimethylamines, C<sub>4</sub> amines, quinoline (RQ = 5000 pounds), dimethylpyrazine, and C<sub>3</sub> to C<sub>6</sub> organic acids, along with lesser amounts of aromatic compounds and C<sub>4</sub> to C<sub>7</sub> alcohols, ketones, and aliphatic hydrocarbons.

<sup>2</sup> Average number of notifications from years 2000–2006, National Response Center statistics available at, <http://www.nrc.uscg.mil/incident97-02.html>. See Superfund Docket EPA-HQ-SFUND-2007-0469 for a summary table.

<sup>3</sup> Average number of notifications made to EPA from years 2000–2006, National Response Center statistics available at, <http://www.nrc.uscg.mil/epa97-02.html>. The average was calculated from those notifications that went to the EPA Regions 1 through 10, including notifications to the EPA Regions for Continuous Releases. See Superfund Docket EPA-HQ-SFUND-2007-0469 for a summary table.

<sup>4</sup> Chronic toxicity was defined as toxicity resulting from repeated or continuous exposure to either a single release or multiple releases of a hazardous substance.

each hazardous substance becomes the “primary criteria RQ” for that substance. After the primary criteria RQs are assigned, substances are further evaluated for their susceptibility to certain extrinsic degradation processes. These “secondary criteria” are biodegradation, hydrolysis, and photolysis, or “BHP.” If the hazardous substance degrades relatively rapidly to a less harmful compound through one or more of these processes when it is released into the environment, the primary criteria RQ is raised one level. The single RQ assigned to each hazardous substance on the basis of the primary criteria and BHP becomes the adjusted RQ for that substance.

The single RQ approach was adopted to provide a relatively simple reporting system that does not unduly burden either EPA or the regulated community. Since releases into more than one medium often occur, the single RQ approach prevents confusion. Section 102(a) of CERCLA expressly authorizes the Administrator to set a single quantity for each hazardous substance, and the legislative history emphasizes the virtues of simplicity and administrative convenience. (For a more detailed discussion of the methodology that was used to establish the RQs for hazardous substances, see 50 FR 13465, Apr. 4, 1985.)

Owners and operators of farms, like all other facilities, are required to report the release of hazardous substances into the environment<sup>5</sup> in accordance with CERCLA section 103 and EPCRA section 304 when it meets or exceeds the RQ of the hazardous substance. For example, releases into the environment of ammonia or any other hazardous substance, from tanks located on a farm, at or above an RQ are reportable under CERCLA section 103 and EPCRA section 304.

In 2005, EPA received a petition from the National Chicken Council, National Turkey Federation, and U.S. Poultry & Egg Association, seeking an exemption from CERCLA and EPCRA reporting requirements for ammonia emissions from poultry operations. The Agency published a notice in the **Federal Register** on December 27, 2005 (70 FR 76452) that acknowledged receipt of the petition and requested public comment.

<sup>5</sup> Environment means, “(A) the navigable waters, the waters of the contiguous zone, and the ocean waters for which the natural resources are under the exclusive management authority of the United States \* \* \*, and (B) any other surface water, ground water, drinking water supply, land surface or subsurface strata, or ambient air within the United States or under the jurisdiction of the United States.” See CERCLA section 101(8).

The comment period closed on March 27, 2006.

Also, in 2005, EPA offered the owners and operators of animal agricultural operations an opportunity to sign up for an air monitoring study. The purpose of the air monitoring study is to develop emissions estimating methodologies for all animal agricultural operations.<sup>6</sup> Over 2600 animal feeding operations, representing over 14,000 farms, signed up for the study. The monitoring study which began in the spring of 2007 includes 25 representative sites (lagoons or barns) on 21 different farms in 10 states (NC, NY, IA, WI, CA, KY, TX, WA, IN, and OK). The sites will be monitored for two years, allowing the Agency to account for emissions variability by season, and for the effect of any seasonal operational changes (such as pumping out lagoons), that could have an effect on emission levels. At the end of the monitoring study, EPA will use the data along with any other relevant, available data to develop emissions estimating methodologies. The monitoring study results will be publicly available upon completion of the study. In addition, EPA will publish the emissions estimating methodologies based on these results, within 18 months of the study’s conclusion. Thus, such information will be widely available to the public.

### III. Summary of This Action

#### A. What Is the Scope of This Proposed Rule?

The scope of this proposed rule is limited to releases of hazardous substances to the air from animal waste at farms. Specifically, the Agency is proposing an administrative reporting exemption from the CERCLA section 103 and EPCRA section 304 notification requirements as implemented in 40 CFR 302.6 and 302.8 and 40 CFR 355.40, respectively. The scope of this proposed rule is intended to include all hazardous substances that may be emitted to the air from animal waste at farms. (See Section I.D. for further discussion of which hazardous substances we are

<sup>6</sup> The National Academy of Sciences, Board on Agriculture and Natural Resources appointed a 16-person ad hoc committee, the Committee on Air Emissions from Animal Feeding Operations, to evaluate the scientific information needed to address issues raised by EPA regarding CAA regulation of air emissions from animal feeding operations (AFOs) and the U.S. Department of Agriculture aid to farmers in mitigating the effects of air emissions with modified agricultural practices. One of the findings of that Committee was, in part, direct measurements of air emissions at all AFOs are not feasible. Nevertheless, measurements on a statistically representative subset of AFOs are needed.

proposing to include within the administrative reporting exemption.)

#### B. Proposed Definitions

In proposing this rule, the Agency believes it is important to provide clarity with respect to the scope of the proposed reporting exemption. Therefore, the Agency is proposing definitions for *animal waste* and *farm* (to be added to the Code of Federal Regulations) that only pertains to regulations promulgated pursuant to CERCLA section 103 and EPCRA section 304, specifically 40 CFR 302.3 (definitions) and 40 CFR 355.20 (definitions).

*Animal Waste*—means manure (feces, urine, other excrement, and bedding, produced by livestock that has not been composted), digestive emissions, and urea. The definition includes animal waste when mixed or commingled with bedding, compost, feed, soil and other materials typically found with animal waste.

The Agency is not aware of any existing definition for animal waste and thus, seeks comment from the public on the appropriateness, clarity and completeness of this definition.

The Agency also is limiting the proposed reporting exemption to animal waste that is generated on farms, and is proposing a specific definition for *farm* under this proposal. For this proposed exemption only, EPA defines *farm*, by using the definition found in the National Agricultural Statistics Service (NASS) Census of Agriculture, and adopting it. Also, the Agency recognizes that Federal and state research farms utilizing farm animals are subject to the conditions experienced on other farms; therefore, EPA proposes to include Federal and state poultry, swine, dairy and livestock research farms.

*Farm*—means (a.) any place whose operation is agricultural and from which \$1,000 or more of agricultural products were produced and sold, or normally would have been sold, during the census year. Operations receiving \$1,000 or more in Federal government payments are counted as farms, even if they have no sales and otherwise lack the potential to have \$1,000 or more in sales; or, (b.) a Federal or state poultry, swine, dairy or livestock research farm.

EPA seeks comment on the proposed definition for a *farm*, and whether an alternative definition may be more appropriate. In addition, the Agency is aware that animal waste also is generated at other facilities, such as zoos and circuses. Because the focus of this proposal is on animal waste generated or found at farms, we are not proposing to expand the reporting

exemption beyond such facilities. However, the Agency requests comment on whether the reporting exemption should be expanded to other types of facilities that also generate animal waste, and if so, what other types of facilities should be included in the reporting exemption. Any alternative approaches presented must include an appropriate rationale and supporting data in order for the Agency to be able to consider them for final action.

#### *C. What Is Not Included Within the Scope of This Proposed Rule?*

As noted previously, this administrative reporting exemption is limited in scope to those releases of hazardous substances to the air from animal waste at farms. EPA is not proposing to exempt from CERCLA section 103 or EPCRA section 304 notification requirements for releases of hazardous substances from animal waste to any other environmental media or at any other facilities other than farms (i.e., meat processing plants, slaughter houses, tanneries). In addition, EPA is not proposing to exempt from CERCLA section 103 or EPCRA section 304 notification requirements of any release of hazardous substances to the air from any source other than animal waste at farms.

The Agency believes that there could be releases to the air from other sources of hazardous substances at farms where an emergency response to that release may be possible. For example, EPA is not proposing to exempt ammonia releases from ammonia storage tanks at farms. In addition, notification of a release of a hazardous substance, which meets or exceeds its RQ, from animal waste to any environmental media (other than air) is still required under this proposal. Thus, notification that there was a release of a hazardous substance that meets or exceeds the RQ where stored animal waste is released into water (i.e., a lagoon burst) would still be required under this proposal. Such notifications would alert the government to an emergency situation that could pose serious environmental consequences if not immediately addressed. Hence, those releases to the environment would still be reportable at or above their RQ as they are more likely to result in a response action from Federal, state or local governments.

No EPCRA statutory requirements, other than the emergency hazardous substance notification requirements under EPCRA section 304, are included within this proposal. The proposal does not limit the Agency's authority under CERCLA sections 104 (response

authorities), 106 (abatement actions), 107 (liability), or any other provisions of CERCLA and EPCRA to address releases of hazardous substances from animal waste at farms.

#### *D. What Is EPA's Rationale for This Administrative Reporting Exemption?*

EPA's rationale for this administrative reporting exemption is based on the purpose of notifying the NRC, and SERCs and LEPCs when a hazardous substance is released, and then the likelihood that a response to that release would be taken by any government agency.

Upon receipt of a notification from the NRC, EPA determines whether a response is appropriate. See 40 CFR 300.130(c). If it is determined that a response is appropriate, the NCP regulations describe the roles and responsibilities for responding to the release. Thus, the question that EPA considered is whether the Agency would ever take a response action, as a result of such notification, for releases of hazardous substances to the air from animal waste at farms. We believe not and, thus, are proposing to no longer require such reporting. This conclusion is based in part on EPA's experience.<sup>7</sup> Specifically, to date, EPA has not initiated a response to any NRC notifications of ammonia, hydrogen sulfide, or any other hazardous substances released to the air where animal waste at farms is the source of that release. Moreover, we cannot foresee a situation where the Agency would take any future response action as a result of such notification of releases of hazardous substances from animal waste at farms because in all instances the source (animal waste) and nature (to the air over a broad area) are such that on-going releases makes an emergency response unnecessary, impractical and unlikely. Typically, if a response is taken as a result of a release notification, the government may require monitoring or make recommendations to local officials regarding evacuations and shelter-in-place. While this may be an appropriate response to hazardous substances releases from tanks, pipes, vents or in train derailment situations where the emergency may result in acute exposures, the Agency does not believe that this is a necessary or appropriate response to the release of hazardous

substances to the air from animal waste at farms.

Several states have indicated that such response actions are unlikely to be taken as a result of a notification of releases of hazardous substances from animal waste at farms. EPA received 26 comment letters from state and/or local emergency response agencies in its request for public comment on the 2005 petition from the National Chicken Council, National Turkey Federation, and U.S. Poultry & Egg Association ("poultry petition"). All of those commenters supported granting the poultry petition—that is, exempting from CERCLA and EPCRA reporting requirements for ammonia emissions from poultry operations. Generally, those agencies supported the petition because they are aware of the operations in their jurisdictions, were concerned about the resource implications of receiving the notifications (i.e., having to process the notifications), and would not conduct an emergency response as a result of the notifications. Thus, the comments received from state and/or local emergency response agencies is consistent with EPA's view.

Furthermore, the Agency does not need to receive such notifications in order to enforce applicable CWA, CAA, RCRA, and/or other applicable CERCLA and EPCRA regulations at farms. EPA still retains those enforcement authorities to address threats to human health and the environment.

We estimate that the private sector, state and local, and the Federal governments spend approximately three hours per release to prepare and process episodic notifications and 24.5 hours to process continuous release notifications.<sup>8</sup>

Based on these reasons, the Agency believes it is appropriate to propose to eliminate the reporting requirement under CERCLA section 103 and EPCRA section 304 for hazardous substances released to the air at farms where the source of those hazardous substances is animal waste. Nevertheless, the Agency solicits comments on whether there might be a situation where a response would be triggered by such a notification of the release of hazardous substances to the air from animal waste

<sup>7</sup> Notifications must still be made when and if hazardous substances are released to the air at farms from any other source (other than animal waste), as well as releases of any hazardous substances from animal waste to any other environmental media (i.e., soil, groundwater and surface water).

<sup>8</sup> For episodic releases, this estimate was calculated using the burden hours described in the Information Collection Requests 1049.10 and 1395.06 for episodic releases of hazardous substances to the NRC and emergency notifications to SERCs and LEPCs. For continuous releases, this estimate was calculated using the burden hours described in the Information Collection Request 1445.06 for continuous release reporting requirements. Supporting statements for both information collection requests are available in the Superfund Docket, EPA-HQ-SFUND-2007-0469.

at farms, and if so, what an appropriate response would be. Any comments that would support such an action should include an appropriate rationale in order for the Agency to be able to consider it for final action.

#### *E. What Are the Economic Impacts of This Administrative Reporting Exemption?*

This proposed administrative reporting exemption will reduce the costs of complying with CERCLA section 103 and EPCRA section 304 for those farms that release hazardous substances to air from animal waste. Entities that are expected to experience a reduction in burden and cost include both the farms that are no longer required to report those releases, as well as the Federal, state and local governments responsible for receiving the reports. The economic analysis completed for this proposed rule is available in the docket for this rulemaking and is based on the underlying economic analyses that were completed for the regulations that established the notification requirements.<sup>9</sup> We estimate that this proposed rule will reduce burden on farms associated with making notifications under CERCLA section 103 and EPCRA section 304 by approximately 3,432,000 hours over the ten year period beginning in 2009 and associated costs by approximately \$160,173,000 over the same period. We estimate that this proposed rule will also reduce burden on Federal, State and local governments responsible for receiving and processing the notifications under CERCLA section 103 and EPCRA section 304 by approximately 161,000 hours over the ten year period beginning in 2009 and associated costs by approximately \$8,109,000 over the same period. In evaluating the potential burden and cost savings to those farms that would no longer be required to make notifications under CERCLA section 103 and EPCRA section 304 and the government entities that are no longer required to receive and process such notifications, we used the same universe as used in the 2003

<sup>9</sup> The following documents are available in the Superfund Docket, EPA-HQ-SFUND-2007-00469: *Regulatory Impact Analysis of Reportable Quantity Adjustments Under Sections 102 and 103 of the Comprehensive Environmental Response, Compensation, and Liability Act*, Volume 1 (March 1985); *Regulatory Impact Analysis in Support of Rulemaking Under Sections 302, 303, and 304 of Title III of the Superfund Amendments and Reauthorization Act of 1986* (April 1987); and *Economic Analysis in Support of the Continuous Release Reporting Regulation Under Section 103(f)(2) of the Comprehensive Environmental Response, Compensation, and Liability Act* (April 1990).

CAFO Rule (see 68 FR 7176, Feb 12, 2003). We also assumed that over the ten year period (2009–2018) that there would be a declining number of CAFOs; however, some of those operations would increase in size.

#### **IV. Statutory and Regulatory 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.” 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.

Pursuant to the terms of Executive Order 12866, it has been determined that this proposed rule is a “significant regulatory action” because it raises novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this proposed rule to the Office of Management and Budget (OMB) for review and any changes made in response to OMB recommendations have been documented in the docket for this action.

##### *B. Paperwork Reduction Act*

This action does not impose any new information collection burden. Rather, this proposed rule represents a reduction in burden for both industry and the government by administratively exempting the reporting requirement for releases of hazardous substances to the air from animal waste at farms. OMB has previously approved the information collection requirements contained in the existing regulations 40 CFR part 302 and 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 2050–0046, EPA ICR number 1049.10 for 40 CFR 302.6 (Episodic releases of oil and hazardous substances), OMB

control number 2050–0086, EPA ICR number 1445.06 for 40 CFR 302.8 (Continuous release reporting requirements) and OMB control number 2050–0092, EPA ICR number 1395.06 for 40 CFR 355 (Emergency planning and notification). A copy of the OMB approved Information Collection Request (ICR) may be obtained by writing to: Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW., Washington, DC 20460 or by calling (202) 566–1700.

EPA ICR number 1049.10 covers collection requirements for notification of episodic releases of oil and hazardous substances; EPA ICR number 1445.06 covers collection requirements for the continuous release reporting requirements; and EPA ICR number 1395.06 covers collection requirements for the notification requirements for releases of hazardous substances and extremely hazardous substances to both SERCs and LEPCs. Each of these information collections are affected by this proposed rule. However, this proposed rule represents a reduction in the burden for both industry and the government through an administrative reporting exemption from those reporting requirements.

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

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

##### *C. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) 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 this 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 this 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 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 all of the small entities subject to the rule.

This rulemaking will relieve regulatory burden because we propose to eliminate the reporting requirement for releases of hazardous substances to the air from animal waste at farms. We expect the net reporting and recordkeeping burden associated with reporting air releases of hazardous substances from animal waste at farms under CERCLA section 103 and EPCRA section 304 to decrease. This reduction in burden will be realized by small and large businesses. We have therefore concluded that this proposed rule will relieve regulatory burden for all 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*

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for

Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures 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 generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for state, local, or tribal governments or the private sector. That is, the proposal imposes no enforceable duty on any state, local or tribal governments or the private sector; rather, this proposed rule will result in burden reduction in the receipt of notifications of the release to the air of hazardous substances, primarily ammonia and hydrogen sulfide, from animal waste at farms.

Additionally, EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. This proposed rule reduces regulatory burden and the private sector is not expected to incur costs exceeding \$100 million. Thus, the proposal 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 proposed rule does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. There are no state and local government bodies that incur direct compliance costs by this proposed rulemaking. Thus, Executive Order 13132 does not apply to this rule.

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 significantly or uniquely affect the communities of Indian tribal governments, nor would it impose substantial direct compliance costs on them. Thus, Executive Order 13175 does not apply to this rule.

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

The Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically



significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866.

#### *H. Executive Order 13211 (Energy Effects)*

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 will reduce the burden associated with the notification of releases to air of hazardous substances from animal waste at farms.

#### *I. National Technology Transfer and Advancement Act of 1995 (“NTTAA”)*

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 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.

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

Executive Order 12898 (59 FR 7629 (Feb. 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 will 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. As discussed in the Background section of the preamble for this proposed rule, the adjusted RQs do not reflect the determination that a release of a substance will be hazardous at the RQ level and not hazardous below that level. Instead, the RQs reflect the Agency’s judgment of which releases should trigger notification to the federal government so that the government may assess to what extent, if any, a federal removal or remedial action may be necessary. In addition, the requirement to notify the government under CERCLA section 103 and EPCRA section 304 does not require the notifying entity to take any specific action to address the release. Therefore because the notification is not specifically designed to protect human health or the environment and EPA has determined that a response action would be unlikely, EPA does not believe that exempting these releases from CERCLA section 103 and EPCRA section 304 notification requirements will have a disproportionately high and adverse human health or environmental effect on minority or low-income populations.

This proposed rule addresses information collection requirements for CERCLA section 103 and EPCRA section 304. No EPCRA programs, other than the emergency notification program under EPCRA section 304, are included in this proposal and the Agency is not proposing to limit CERCLA sections 104 (response authorities), 106 (abatement actions), 107 (liability), or any other provisions of CERCLA through this proposed rulemaking. The Agency also retains its authority to apply existing statutory provisions in its efforts to prevent minority and or low-income communities from being subject to disproportionately high and adverse impacts and environmental effects. We therefore have determined that this proposal does not have a disproportionately high and adverse human health or environmental effects on minority or low-income populations.

## List of Subjects

### *40 CFR Part 302*

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

### *40 CFR Part 355*

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: December 20, 2007.

**Stephen L. Johnson,**  
*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 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION**

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

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

2. Section 302.3 is amended by adding in alphabetical order the definitions of “Animal waste” and “Farm” to read as follows:

### **§ 302.3 Definitions.**

\* \* \* \* \*

*Animal Waste* means manure (feces, urine, other excrement, and bedding, produced by livestock that has not been composted), digestive emissions, and urea. The definition includes animal waste when mixed or commingled with bedding, compost, feed, soil and other typical materials found with animal waste.

\* \* \* \* \*

*Farm* means:

(1) Any place whose operation is agricultural and from which \$1,000 or more of agricultural products were produced and sold, or normally would have been sold, during the census year. Operations receiving \$1,000 or more in Federal government payments are counted as farms, even if they have no sales and otherwise lack the potential to have \$1,000 or more in sales; or

(2) A Federal or state poultry, swine, dairy or livestock research farm.

\* \* \* \* \*

3. Section 302.6 is amended by adding paragraph (e)(3) to read as follows:



**§ 302.6 Notification requirements.**

\* \* \* \* \*

(e) \* \* \*

(3) Releases to the air of any hazardous substance from animal waste at farms.

\* \* \* \* \*

**PART 355—EMERGENCY PLANNING AND NOTIFICATION**

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

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

5. Section 355.20 is amended by adding in alphabetical order the definitions of “Animal waste” and “Farm” to read as follows:

**§ 355.20 Definitions.**

\* \* \* \* \*

*Animal Waste* as used in § 355.40 only, animal waste means manure (feces, urine, other excrement, and bedding, produced by livestock that has not been composted), digestive emissions, and urea. The definition includes animal waste when mixed or commingled with bedding, compost, feed, soil and other typical materials found with animal waste.

\* \* \* \* \*

*Farm* as used in § 355.40 only, farm means:

(1) Any place whose operation is agricultural and from which \$1,000 or more of agricultural products were produced and sold, or normally would have been sold, during the census year. Operations receiving \$1,000 or more in Federal government payments are counted as farms, even if they have no sales and otherwise lack the potential to have \$1,000 or more in sales; or

(2) A Federal or state poultry, swine, dairy or livestock research farm.

\* \* \* \* \*

6. Section 355.40 is amended by adding paragraph (a)(2)(viii) to read as follows:

**§ 355.40 Emergency release notification.**

(a) \* \* \*

(2) \* \* \*

(viii) Any release to the air of a hazardous substance from animal waste at farms.

\* \* \* \* \*

[FR Doc. E7-25231 Filed 12-27-07; 8:45 am]

**BILLING CODE 6560-50-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare and Medicaid Services****42 CFR Parts 422, 423, and 498****Office of the Inspector General****42 CFR Part 1005****Office of the Secretary****45 CFR Parts 16, 81, 160 and 1303****RIN 0991-AB42****Revisions to Procedures for the Departmental Appeals Board and Other Departmental Hearings**

**AGENCY:** Office of the Secretary, Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** The Department of Health and Human Services (Department) proposes to amend Departmental regulations governing administrative review by the Departmental Appeals Board (DAB) and certain other administrative review regulations to ensure that the final administrative decision of the Department reflects the considered opinion of the Secretary of Health and Human Services (Secretary). Current regulations at 45 CFR Part 16 governing the review of grant disputes do not specifically require the DAB to follow published guidance issued by the Secretary or a Departmental component. The DAB decision is currently the final administrative decision of the Department on such disputes and currently there is no Secretarial review of this final decision. Similarly, the DAB currently provides the final agency review of the imposition of civil monetary penalties (CMPs) for which administrative appeal is available under 45 CFR Part 160, Subpart E, enforcement sanctions under 42 CFR Part 422 and 423, determinations subject to reconsideration and appeal under 42 CFR Part 498 and the imposition by the Inspector General of the Department (I.G.) or the Centers for Medicare and Medicaid Services (CMS) of exclusions, CMPs and assessments subject to appeal under 42 CFR Part 1005. As in 45 CFR Part 16, the decisions of the DAB under these processes are considered the final agency action on matters, though they are not subject to Secretarial review.

This proposed rule would amend DAB regulations to require that the DAB follow published guidance that is not

inconsistent with applicable statutes and regulations and would permit the Secretary an opportunity to review DAB decisions to correct errors in the application of law, or deviations from published guidance, in such disputes. This proposed rule would make technical changes to the regulations at 45 CFR Part 16. This proposed rule would also amend hearing and appeal procedures at 45 CFR Part 160, Subpart E and at 42 CFR Parts 422, 423 and 498 to include a parallel statement regarding the treatment of published guidance. Similarly, this proposed rule would amend the procedures at 45 CFR Part 81 to provide a similar statement regarding the treatment of published guidance by hearing examiners and reviewing authorities. In addition, this proposed rule would amend the hearing and appeal procedures at 45 CFR Part 160, Subpart E and 42 CFR Parts 422, 423, 498 and 1005 to provide a parallel opportunity for Secretarial review of DAB decisions. Finally, this proposed rule would revise the procedures for Head Start grantee appeals by applying the current 60-day time limit for “final decisions” to the Board’s decision.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 28, 2008.

**ADDRESSES:** You may submit comments either by E-mail to [randolph.pate@hhs.gov](mailto:randolph.pate@hhs.gov) or by mail to: Randy Pate, 200 Independence Ave., SW., Room 415F, Washington, DC 20201.

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:** Randy Pate, 202-690-7858.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

HHS was the first federal grantor agency to offer a structured process of administrative dispute resolution for its grantees on a large scale, when, in 1973, it established what was then called the Departmental Grant Appeals Board. The name was changed to the Departmental Appeals Board (DAB) when, as noted below, the jurisdiction was significantly expanded. The name “Departmental Appeals Board” is now used to refer to two entities: (1) the decision-making body consisting of Board Members, appointed by the Secretary, who issue decisions made by panels of three Board Members; and (2) in general, the larger organization, which is located in the Office of the Secretary and which includes not only the Board, but also