

| Commodity | Parts per million |
|--|-------------------|
| Boysenberry, postharvest | 1.0 |
| Buckwheat, grain, postharvest | 3.0 |
| Cacao bean, roasted bean, postharvest | 1.0 |
| Cattle, fat | 1.0 |
| Cattle, meat | 0.05 |
| Cattle, meat byproducts | 0.05 |
| Cherry, sweet, postharvest | 1.0 |
| Cherry, tart, postharvest | 1.0 |
| Coconut, copra, postharvest | 1.0 |
| Corn, field, grain, postharvest | 3.0 |
| Corn, pop, grain, postharvest | 3.0 |
| Cotton, undelinted seed, postharvest | 1.0 |
| Crabapple, postharvest | 1.0 |
| Currant, postharvest | 1.0 |
| Dewberry, postharvest | 1.0 |
| Fig, postharvest | 1.0 |
| Flax, seed, postharvest | 1.0 |
| Goat, fat | 1.0 |
| Goat, meat | 0.05 |
| Goat, meat byproducts | 0.05 |
| Gooseberry, postharvest | 1.0 |
| Grape, postharvest | 1.0 |
| Guava, postharvest | 1.0 |
| Hog, fat | 1.0 |
| Hog, meat | 0.05 |
| Hog, meat byproducts | 0.05 |
| Horse, fat | 1.0 |
| Horse, meat | 0.05 |
| Horse, meat byproducts | 0.05 |
| Loganberry, postharvest | 1.0 |
| Mango, postharvest | 1.0 |
| Milk, fat (reflecting negligible residues in milk) | 0.05 |
| Muskmelon, postharvest | 1.0 |
| Oat, grain, postharvest | 1.0 |
| Orange, postharvest | 1.0 |
| Pea, dry, seed, postharvest | 1.0 |
| Peach, postharvest | 1.0 |
| Peanut, postharvest | 1.0 |
| Pear, postharvest | 1.0 |
| Pineapple, postharvest | 1.0 |
| Plum, prune, fresh, postharvest | 1.0 |
| Potato, postharvest | 0.05 |
| Raspberry, postharvest | 1.0 |
| Rice, grain, postharvest | 3.0 |
| Rye, grain, postharvest | 3.0 |
| Sheep, fat | 1.0 |
| Sheep, meat | 0.05 |
| Sheep, meat byproducts | 0.05 |
| Sorghum, grain, grain, postharvest | 1.0 |
| Sweet potato, postharvest | 0.05 |
| Tomato, postharvest | 1.0 |
| Walnut, postharvest | 1.0 |
| Wheat, grain, postharvest | 3.0 |

(2) A tolerance of 1.0 ppm is established for residues of the insecticide pyrethrins in or on milled fractions derived from grain, cereal when present as a result of its use in cereal grain mills and in storage areas for milled cereal grain products.

(3) A tolerance of 1.0 ppm is established for residues of the insecticide pyrethrins in or on all food items in food handling establishments where food and food products are held, processed, prepared and/or served. Food must be removed or covered prior to use.

(4) Where tolerances are established on both the raw agricultural commodities and processed foods made there-from, the total residues of pyrethrins in or on the processed food shall not be greater than that permitted by the larger of the two tolerances.

■ 4. Section 180.314 is amended by alphabetically adding the following commodity to the table in paragraph (c) to read as follows

§ 180.314 Triallate; tolerance for residues.

(c) *Tolerances with regional registrations.*

| Commodity | Parts per million |
|---------------|-------------------|
| Wheat, forage | 0.05 |

■ 5. Section 180.339 is amended by alphabetically adding the following commodity to the table in paragraph (a)(1) to read as follows.

§ 180.339 MCPA; tolerances for residues.

(a)(1) *General.*

| Commodity | Parts per million |
|----------------------------|-------------------|
| Grain, aspirated fractions | 3.0 |

■ 6. Section 180.362 is amended by alphabetically adding the following commodity to the table in paragraph (a)(1) to read as follows.

§ 180.362 Hexakis (2-methyl-2-phenylpropyl)distannoxane; tolerances for residues.

(a) * * *
(1) * * *

| Commodity | Parts per million |
|-----------|-------------------|
| Pistachio | 0.5 |

* * * * *
[FR Doc. E8-1535 Filed 1-28-08; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[EPA-HQ-OPPT-2007-0487; FRL-8154-2]

RIN 2070-AB11

Health and Safety Data Reporting; Addition of Certain Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule, issued pursuant to section 8(d) of the Toxic Substances Control Act (TSCA) and its regulations, requires manufacturers (including importers) of consumer products intended for use by children who also manufacture (including import) lead or lead compounds to report certain unpublished health and safety data to EPA. This final rule adds lead and lead compounds to 40 CFR 716.120 because the Interagency Testing Committee (ITC) added the category of lead and lead compounds to the *Priority Testing List* through its 60th ITC Report. The ITC was established under section 4(e) of TSCA to recommend chemicals and chemical mixtures to EPA for priority testing consideration; the ITC periodically amends the TSCA section 4(e) *Priority Testing List* through periodic reports submitted to EPA.

DATES: This final rule is effective on February 28, 2008. For purposes of judicial review, this final rule shall be promulgated at 1 p.m. eastern daylight/standard time on February 12, 2008. (See 40 CFR 23.5.)

A request to withdraw a chemical from this final rule pursuant to 40 CFR 716.105(c) must be received on or before February 12, 2008. (See Unit IV. of the **SUPPLEMENTARY INFORMATION.**)

For dates for reporting requirements, see Unit III.B. of the **SUPPLEMENTARY INFORMATION.**

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2007-0487, by one of the following methods.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC, Attention: Docket ID Number EPA-HQ-OPPT-2007-0487. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. 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 number EPA-HQ-OPPT-2007-0487. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line 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 www.regulations.gov or e-mail. The www.regulations.gov website 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, 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.

Docket: All documents in the docket are listed in the docket index available in www.regulations.gov. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the www.regulations.gov website to view the docket index or access available documents. 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 electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

Data Submissions: Copies of health and safety studies and accompanying cover letters, lists of health and safety studies, requests for extensions of time, and withdrawal requests must be submitted in accordance with the instructions in 40 CFR 716.30, 716.35, 716.60, and 716.105, respectively. Each submission must be identified by docket ID number EPA-HQ-OPPT-2007-0487.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Joe Nash, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8886; fax number: (202) 564-4765; e-mail address: ccd.citb@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may potentially be affected by this action if you manufacture (including import) consumer products intended for use by children and also manufacture (including import) lead or lead compounds. Importers are a subset of manufacturers under TSCA.

Potentially affected entities may include, but are not limited to:

- Manufacturers (including importers) of costume jewelry and novelty manufacturing (NAICS code 339914).

- Manufacturers (including importers) of dolls and stuffed toys (NAICS code 339931).

- Manufacturers (including importers) of games, toys, and children's vehicles (NAICS code 339932).

- Manufacturers (including importers) of fasteners, buttons, needles, and pins (NAICS code 339993).

- Wholesalers of toy and hobby goods, establishments with product line 12812 (NAICS code 42392).

- Discount department stores (NAICS code 452112).

- Warehouse clubs and supercenters (NAICS code 45291).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Do I Submit CBI Information?

Do not submit this information to EPA through www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

II. Background

A. What Action is the Agency Taking?

EPA is amending its model Health and Safety Data Reporting rule under TSCA section 8(d) (TSCA section 8(d) model rule) to require manufacturers (including importers) of consumer products intended for use by children who also manufacture (including import) lead or lead compounds, as listed on the ITC's TSCA section 4(e) *Priority Testing List*, to submit certain unpublished health and safety data to EPA. The import of children's products

that contain lead or lead compounds constitutes the manufacture of lead or lead compounds under TSCA. EPA believes importers of such products are the entities most likely to have the type of health and safety studies EPA is seeking.

Based on information available to the Agency, EPA believes that imported items represent a majority of the value of sales of toys and games (without regard to lead content) in NAICS code 42392. In addition, EPA has reviewed Consumer Product Safety Commission (CPSC) recalls of lead-contaminated children's products. None of the recalls reviewed implicated products that were produced domestically. See CPSC Recalls and Product Safety News at <http://www.cpsc.gov/cpscpub/prerel/prerel.html> (Ref. 1).

Processors are not included in this final rule. As explained in Unit II.B., the ITC listing procedure and the TSCA section 8(d) model rule do not generally result in TSCA section 8(d) model rules that cover processors. Therefore, a domestic company that processes lead in the manufacture of children's products would not be covered, unless that company also manufactures (including imports) lead or lead compounds.

The regulatory text of this document lists examples of chemicals and their CAS numbers in the category of lead and lead compounds. The regulatory text also lists the data reporting requirements imposed by this amendment to the TSCA section 8(d) model rule.

B. What is the Agency's Authority?

Section 8(d) of TSCA allows EPA to "promulgate rules under which the Administrator shall require any person who manufactures, processes or distributes in commerce or who proposes to manufacture, process or distribute in commerce any chemical substance or mixture" to submit lists of certain health and safety studies, as well as copies of such studies (15 U.S.C. 2607(d)). Under TSCA, import is included in the definition of "manufacture" (15 U.S.C. 2602(7)).

The TSCA section 8(d) model rule (15 U.S.C. 2607(d)) is codified at 40 CFR part 716. EPA uses this TSCA section 8(d) model rule to quickly gather current information on chemicals. The TSCA section 8(d) model rule requires past, current, and prospective manufacturers, importers, and (if specified by EPA in a particular rule under TSCA section 8(d)) processors of listed chemicals to submit to EPA copies and lists of unpublished health and safety studies on the listed

chemicals that they manufacture, import, or (if specified by EPA in a particular rule under TSCA section 8(d)) process. These studies provide EPA with useful information and have provided significant support for EPA's decisionmaking under TSCA sections 4, 5, 6, 8, and 9.

The TSCA section 8(d) model rule provides for the addition of TSCA section 4(e) *Priority Testing List* chemicals. Whenever EPA announces the receipt of an ITC report, EPA amends, unless otherwise instructed by the ITC, the TSCA section 8(d) model rule by adding the recommended (or designated) chemicals. In doing so, EPA must provide a 14-day period, which starts 14 days after date of publication of the amendments to the TSCA section 8(d) model rule in the **Federal Register**, for persons to submit information showing why a chemical substance, mixture, or category of chemical substances should be withdrawn from the amendment. The amendment adding these chemicals to the TSCA section 8(d) model rule is effective 30 days after date of publication in the **Federal Register**. If the Administrator withdraws a chemical from the amendment, then no later than 30 days after the date of publication of the amendment in the **Federal Register**, a **Federal Register** document announcing this decision is published.

Explanations of the procedures to follow if a respondent to this rule wishes to assert a claim of confidentiality for a part of a study or certain information contained in a study are provided at 40 CFR 716.55.

C. Related Obligations Under TSCA Section 8

Aside from obligations that will arise under this final rule, persons who manufacture, process, or distribute lead may be subject to other requirements under TSCA section 8. For example, TSCA section 8(e) (15 U.S.C. 2607(e)) requires that:

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

Toxicity data that indicate a substantial risk of injury to health or the environment are the most common kinds of information received by EPA under TSCA section 8(e), but the Agency also often receives information

on exposure, environmental persistence, or other kinds of information that indicate a substantial risk of injury to health or the environment. Of note, given the focus of this TSCA section 8(d) model rule, EPA issued guidance in September 2006 (Ref. 2) that may be relevant to persons who manufacture, process, or distribute lead-containing products intended for use by children. The guidance discusses the circumstances under which reporting under TSCA section 8(e) should be considered for substantial risk information obtained that indicates:

1. Previously unknown and significant human exposure to a chemical known to cause serious health effects (e.g., absorption of a chemical from manufactured products or articles) or

2. The presence of a previously unknown hazardous or toxic constituent in a product, including manufactured articles. Other guidance and information relevant to TSCA section 8(e) reporting are available on the TSCA section 8(e) website at <http://www.epa.gov/oppt/tasca8e/index.htm>.

D. Why is this Action Being Issued as a Final Rule?

EPA is publishing this action as a final rule without prior notice and an opportunity for comment pursuant to the procedures set forth in 40 CFR 716.105(b) and (c). EPA finds that there is "good cause" under the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) to make these amendments without prior notice and comment. EPA believes notice and an opportunity for comment on this action are unnecessary. TSCA directs the ITC to add chemicals to the *Priority Testing List* for which EPA should give priority consideration. EPA also lacks the authority to remove a chemical from the *Priority Testing List* once it has been added by the ITC. As explained earlier in this preamble, pursuant to 40 CFR 716.105(b) and (c), once the ITC adds a chemical to the *Priority Testing List*, EPA in turn is obliged to add that chemical to the list of chemicals subject to the TSCA section 8(d) model rule reporting requirements, unless requested not to do so by the ITC. EPA promulgated this procedure in 1985 after having solicited public comment on the need for and mechanics of this procedure (Ref. 3). Because that rule established the procedure for adding ITC chemicals to the TSCA section 8(d) model rule, it is unnecessary to request comment on the procedure in this action. Finally, 40 CFR 716.105(b) and (c) do provide EPA with the discretion to withdraw a chemical from the TSCA

section 8(d) model rule if a party submits to EPA information showing good cause that a chemical should be removed from the TSCA section 8(d) model rule.

III. Final Rule

A. What Chemicals Are to be Added?

In this document, EPA is adding the category of lead and lead compounds to the TSCA section 8(d) model rule as requested by the ITC in its 60th ITC Report (Ref. 4). This final rule requires manufacturers (including importers) of consumer products intended for use by children who also manufacture (including import) lead or lead compounds to report certain unpublished health and safety data to EPA.

B. What Are the General Reporting Requirements and Deadlines?

The general provisions regarding the submission of copies and lists of studies under EPA's TSCA section 8(d) model rule are located at 40 CFR 716.30 and 716.35, respectively, and additional reporting requirements and exemptions are described elsewhere in 40 CFR part 716. The reporting schedule and reporting period for persons subject to this final rule are described at 40 CFR 716.60 and 716.65. Chemical specific reporting requirements appear at 40 CFR 716.21.

C. What Are the Chemical Specific Reporting Requirements?

Pursuant to 40 CFR 716.20(b)(5), this amendment specifies the types of environmental fate, health, and/or environmental effects studies that must be reported and the chemical grade/purity requirements that must be met or exceeded in individual studies for lead and lead compounds. The amendment requires the submission of all unpublished health and safety studies that:

1. Relate to the lead content of consumer products that are "intended for use by children" as that term is defined at 40 CFR 710.43 (excluding children's metal jewelry, as described by CPSC in its ANPRM) (Ref. 5), or
2. Assess children's exposure to lead from such products (including studies of bioavailability). With regard to grade/purity requirements, studies showing any measurable lead content in such products must be submitted.

The exclusion for children's metal jewelry functions to exempt studies on those products already being directly addressed by CPSC. For more information on CPSC's actions, please see CPSC's Advance Notice of Proposed

Rulemaking (ANPRM) regarding children's jewelry containing lead (Ref. 5).

This final rule does not require reporting of any other health and safety studies.

This amendment also specifies manufacturers subject to these reporting requirements: Manufacturers (including importers) of consumer products intended for use by children who also manufacture (including import) lead or lead compounds.

D. Economic Analysis

The economic analysis for the addition of lead and lead compounds to the TSCA section 8(d) model rule is entitled, *TSCA Section 8(d): Economic Impact Analysis for Adding Lead and Lead Compounds from the 60th Report of the TSCA Interagency Testing Committee to the Health and Safety Data Reporting rule*. November 14, 2007. (Ref. 6).

The number of firms that will be affected by this final rule could not be estimated directly by EPA in the Economic Analysis. In most previous instances, the TSCA section 8(d) analysis has focused on the firms that manufacture the chemicals, as shown in the EPA-maintained Chemical Update System (CUS) database. In this instance, the CUS database does not include those companies that manufacture (including import) consumer products intended for use by children as well as manufacture (including import) lead or lead compounds. Importers are a subset of manufacturers under TSCA.

Reporting requirements are further limited to those studies that relate to the lead content of consumer products (excluding metal toy jewelry) that are intended for use by children or studies that assess children's exposure to lead from such products (including studies of bioavailability).

The U.S. Census Bureau's Economic Census does not separately identify these firms. As a result, it is difficult to estimate the number of firms affected by this rule. The Agency has chosen to estimate the number of affected firms by using census data of the number of firms included in certain NAICS categories, selected with the expectation that these categories include firms which may be engaged in manufacturing or importing children's products. The selected categories and the number of firms in each are:

- NAICS code 339914—Costume jewelry and novelty manufacturing (651 firms).
- NAICS code 339931—Doll and stuffed toy manufacturing (134 firms).

- NAICS code 339932—Game, toy, and children's vehicle manufacturing (733 firms).

- NAICS code 339993—Fastener, button, needle, and pin manufacturing (180 firms).

- NAICS code 42392—Toy and hobby goods and supplies merchant wholesalers (establishments with product line 12812) (1,310 firms).

- NAICS code 452112—Discount department stores (39 firms).

- NAICS code 45291—Warehouse clubs and supercenters (16 firms).

It is expected that some number of firms within those categories will not need to respond, and that some other unknown number of firms not within those categories will be required to respond. This tabulation is meant to be suggestive of the potential number of respondents, given the available information, and cannot be expected to be an accurate point estimate.

The number of studies that might be submitted in response to this final rule is also difficult to estimate. The number of firms involved is likely to be larger than for other chemicals that have been listed under amendments to the TSCA section 8(d) model rule. However, the nature of the studies required to be submitted are restricted to a specific category.

An earlier examination of studies submitted under previous amendments to the TSCA section 8(d) model rule over an 8 year period prior to April 2002 reported an average of 5.66 studies per chemical. An examination of more recent experience with amendments to the TSCA section 8(d) model rule reported an average of 1 study per chemical. Based both on past EPA experience and on the professional judgment of Agency personnel responsible for the TSCA section 8(d) program, EPA estimates an average of 5 studies will be submitted for each of the 12 chemicals listed as examples of chemicals in the lead and lead compounds category, for a total of 60 studies. However, in consideration of the uncertainty of this per chemical estimate and the fact that relevant studies on lead compounds other than the listed 12 example compounds may be reported, the Economic Analysis also estimates the costs in a case where 10 times that number, or 600, studies are submitted (Ref. 6).

Given the assumptions in this unit, the industry reporting costs and burden associated with this rule are estimated in the Economic Analysis (Ref. 6) to be the following:

INDUSTRY REPORTING COSTS (DOLLARS) AND BURDEN (HOURS)

| Collection Activity | (a) Unit Burden Hours | (b) Unit Cost | (c) Number of Firms or Sites Per Activity | (d) = (a) x (c) Total Burden Hours | (e) = (b) x (c) Total Cost |
|-------------------------------------|-----------------------|---------------|---|------------------------------------|----------------------------|
| 1. Review of rule | 2 hours | \$126.66 | 3,063 | 6,126 | \$387,960 |
| 2. Site identification | 3 hours | \$189.99 | 1,317 | 3,951 | \$250,584 |
| 3. Site file search | 3 hours | \$161.34 | 1,361 | 4,083 | \$219,584 |
| 4. Study title lists | 1 hour | \$26.40 | 60 | 60 | \$1,584 |
| 5. Photocopy studies | 0.5 hour | \$13.20 | 60 | 30 | \$792 |
| 6. Robust summaries | 6 hours | \$322.68 | 6 | 36 | \$1,936 |
| 7. CBI review | 1 hour | \$63.33 | 60 | 60 | \$3,800 |
| 8. Post-reporting period submission | 1.5 hours | \$76.53 | 1 | 1.5 | \$77 |
| Total | | | | 14,347 | \$865,949 |

Note: Not all respondents perform all activities.

The sensitivity analysis conducted to estimate the costs if 600 studies are submitted suggests that the burden estimate for this TSCA section 8(d) action is relatively insensitive to the estimate of the number of studies. A ten-fold error in that estimate is calculated to lead to an increase of roughly 1,500 burden hours (or less than 12%), and an increase of about \$74,000 in cost (or less than 10%). The burden and cost estimates are largely determined by the estimate of the number of responding firms, and is relatively insensitive to the estimate of the number of studies.

The estimated annual cost of the TSCA section 8(d) model rule to the Federal Government is approximately the time of one full-time employee, or 2,080 hours. Based on previous TSCA section 8(d) analyses and Agency professional judgment, this particular data collection is expected to represent 25% of 1 year's burden, or the equivalent of approximately 520 hours. That will amount to a cost to Federal Government of \$25,285.

IV. Requesting a Chemical be Withdrawn from the Rule

As specified in 40 CFR 716.105(c), EPA may remove a chemical substance, mixture, or category of chemical substances from this final rule for good cause prior to the effective date of this final rule. Any person who believes that the reporting required by this final rule is not warranted for a chemical substance, mixture, or category of chemical substances listed in this final rule, must submit to EPA detailed reasons for that belief. You must submit your request to EPA on or before February 12, 2008 and in accordance

with the instructions provided in 40 CFR 716.105(c), which are briefly summarized here. In addition, to ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPPT-2007-0487 on your request and submit that request in accordance with the instructions in 40 CFR 716.105(c). If the Administrator withdraws a chemical substance, mixture, or category of chemical substances from the amendment, in accordance with 40 CFR 716.105(c), a **Federal Register** document announcing this decision will be published no later than February 28, 2008.

V. Materials in the Docket

The official docket for this final rule has been established under docket ID number EPA-HQ-OPPT-2007-0487. The official public docket is available for review as specified in **ADDRESSES**. The following is a listing of the documents referenced in this preamble that have been placed in the official docket for this final rule:

1. CPSC. Recalls and Product Safety News. Available on-line at: <http://www.cpsc.gov/cpsc/pub/prerel/prerel.html>.

2. EPA. Toxic Substances Control Act (TSCA) Section 8(e) Notices—Frequent Questions—September 2006—Health and Safety - Questions 25 and 26. Available on-line at: http://www.epa.gov/oppt/tsca8e/pubs/frequentlyaskedquestions_faqs.htm#health2.

3. EPA. Chemical Information Rules; Additional Automatic Reporting; Final Rule. **Federal Register** (50 FR 34809; August 28, 1985).

4. ITC. Sixtieth Report of the ITC. **Federal Register** (72 FR 41414, July 27, 2007) (FRL-8137-6). Available on-line at: <http://www.epa.gov/fedrgstr>.

5. CPSC. Children's Jewelry Containing Lead; Advanced Notice of Proposed Rulemaking; Request for Comments and Information. **Federal Register** (72 FR 920, January 9, 2007).

6. EPA. TSCA Section 8(d): Economic Impact Analysis for Adding Lead and Lead Compounds from the 60th Report of the TSCA Interagency Testing Committee to the Health and Safety Data Reporting rule. November 14, 2007.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted actions under TSCA section 8(d) related to the TSCA section 8(d) model rule from the requirements of Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

The information collection requirements contained in TSCA section 8(d) model rules have already been approved by OMB under the provisions of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and OMB control number 2070-0004 (EPA ICR No. 0575). The collection activities in this final rule are captured by the existing approval and do not require additional review and/or approval by OMB.

EPA estimates that the information collection activities related to health and safety data reporting for the category of lead and lead compounds in this final rule will result in a total

public reporting burden of 14,348 hours, or roughly 4.7 hours per firm. Of that total, an estimated 6,126 hours are estimated to be spent performing an initial review of the final rule. The remaining hours are associated with the actual required reporting activities (Ref. 6). As defined by the PRA and 5 CFR 1320.3(b), "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 which have subsequently changed; 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.

Under PRA, an Agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, including its regulations implementing TSCA section 8(d) at 40 CFR part 716, are listed in the table in 40 CFR part 9 and included on the related collection instrument. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that this final rule will not have a significant adverse economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the Economic Analysis (Ref. 6) for this final rule, and is summarized here.

To estimate the impact of the final rule on a business, EPA used the "sales test," wherein costs for any individual firm are measured as a percent of annual sales. The average cost per company for the final rule is estimated to be \$283. At an average cost for any one firm of \$283, the firm's total sales would have to be less than \$30,000 for this final rule to

have an impact of even 1% of sales. Because of the uncertainty regarding the number and identity of the firms who will be required to respond to this data collection, it is not possible to directly compare the estimated cost to the actual sales volume of those firms. But due to the low level of the impact, it is not expected that this action will have a significant impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. In addition, EPA has determined that this final rule will not significantly or uniquely affect small governments. Accordingly, the final rule is not subject to the requirements of UMRA sections 202, 203, 204, or 205.

E. Executive Orders 13132 and 13175

Based on EPA's experience with past TSCA section 8(d) model rules, State, local, and tribal governments have not been impacted by these rules, and EPA does not have any reasons to believe that any State, local, or tribal government will be impacted by this final rule. As a result, these rules are not subject to the requirements in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) or Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000).

F. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), does not apply to this final rule, because it is not "economically significant" as defined under Executive Order 12866, and does not concern an environmental health or safety risk that may have a disproportionate effect on children. This final rule requires the reporting of health and safety data to EPA by manufacturers (including importers) of certain chemicals requested by the ITC to be added to the TSCA 8(d) model rule in its 60th ITC Report (Ref. 4).

G. Executive Order 13211

This final rule is not subject to Executive Order 13211, entitled *Actions that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not

expected to affect energy supply, distribution, or use.

H. National Technology Transfer and Advancement Act

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Section 12(d) of NTTAA 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.

I. Executive Order 12898

This action does not involve special considerations of environmental justice-related issues pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 716

Environmental protection, Chemicals, Children, Hazardous substances, Health and safety, Lead, Reporting and recordkeeping requirements, Toys.

Dated: January 22, 2008.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

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

PART 716—[AMENDED]

■ 1. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

■ 2. By adding a new paragraph (a)(8) to § 716.21 to read as follows:

§ 716.21 Chemical specific reporting requirements.

(a) * * *

(8)(i) Reporting requirements apply only to manufacturers (including importers) of consumer products

intended for use by children who also manufacture (including import) lead or lead compounds. For the category “lead and lead compounds,” all unpublished health and safety studies that:

(A) Relate to the lead content of consumer products that are “intended for use by children” as that term is defined at 40 CFR 710.43 (excluding children’s metal jewelry), or

(B) Assess children’s exposure to lead from such products (including studies of bioavailability).

(ii) With regard to purity, studies showing any measurable lead content in such products must be submitted.

* * * * *

■ 3. In § 716.120, the table in paragraph (c) is amended by adding in alphabetical order the category “Lead and lead compounds” and its entries to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * * *

(c) * * *

| Category | CAS No. (examples for category) | Special exemptions | Effective date | Sunset date |
|---|---------------------------------|--------------------|-------------------|----------------|
| Lead and lead compounds | * * * | * * | * * | |
| Lead | 7439-92-1 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Acetic acid, lead (2+) salt | 301-04-2 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Carbonic acid, lead (2+) salt (1:1) | 598-63-0 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Lead chloride (PbCl ₂) | 7758-95-4 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Chromic acid (H ₂ CrO ₄), lead (2+) salt (1:1) | 7758-97-6 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Lead oxide (PbO ₂) | 1309-60-0 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Borate (1-), tetrafluoro-, lead (2+) (2:1) | 13814-96-5 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Phosphoric acid, lead (2+) salt (2:3) | 7446-27-7 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Silicic acid, lead salt, basic | 53466-66-3 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Octadecanoic acid, lead salt (1:?) | 7428-48-0 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Sulfuric acid, lead salt (1:?), basic | 63653-42-9 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| Lead sulfide (PbS) | 1314-87-0 | § 716.21(a)(8) | February 28, 2008 | April 28, 2008 |
| | * * * | * * | * * | |

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[FR Doc. E8-1546 Filed 1-28-08; 8:45 am]
BILLING CODE 6560-50-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 080123076-8078-01]

RIN 0648-XF27

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule.

SUMMARY: The Assistant Administrator for Fisheries (AA), NOAA, announces temporary restrictions consistent with the requirements of the Atlantic Large

Whale Take Reduction Plan’s (ALWTRP) implementing regulations. These regulations apply to lobster trap/pot and anchored gillnet fishermen in an area totaling approximately 2,637 nm² (9,045 km²), south of Rockland, Maine, for 15 days. The purpose of this action is to provide protection to an aggregation of northern right whales (right whales).

DATES: Effective beginning at 0001 hours January 31, 2008, through 2400 hours February 14, 2008.

ADDRESSES: Copies of the proposed and final Dynamic Area Management (DAM) rules, Environmental Assessments (EAs), Atlantic Large Whale Take Reduction Team (ALWTRT) meeting summaries, and progress reports on implementation of the ALWTRP may also be obtained by writing Diane Borggaard, NMFS/Northeast Region, One Blackburn Drive, Gloucester, MA 01930.

FOR FURTHER INFORMATION CONTACT: Diane Borggaard, NMFS/Northeast Region, 978-281-9300 x6503; or Kristy Long, NMFS, Office of Protected Resources, 301-713-2322.

SUPPLEMENTARY INFORMATION:

Electronic Access

Several of the background documents for the ALWTRP and the take reduction planning process can be downloaded from the ALWTRP Web site at <http://www.nero.noaa.gov/whaletrp/>.

Background

The ALWTRP was developed pursuant to section 118 of the Marine Mammal Protection Act (MMPA) to reduce the incidental mortality and serious injury of three endangered species of whales (right, fin, and humpback) due to incidental interaction with commercial fishing activities. In addition, the measures identified in the ALWTRP would provide conservation benefits to a fourth species (minke), which are neither listed as endangered nor threatened under the Endangered Species Act (ESA). The ALWTRP, implemented through regulations codified at 50 CFR 229.32, relies on a combination of fishing gear modifications and time/area closures to reduce the risk of whales becoming