

yards of the P/V HORIZON, while the P/V HORIZON is in the Captain of the Port Hampton Roads zone, must operate only at the minimum speed necessary to navigate safely.

(2) The operator of any vessel in the immediate vicinity of this security zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on board a vessel displaying a U.S. Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on board a vessel displaying a U.S. Coast Guard Ensign.

(iii) Operate at the minimum safe speed within a 500-yard radius of P/V HORIZON.

(e) The COTP will enforce these zones and may enlist the aid and cooperation of any Federal, state, county, or municipal law enforcement agency to assist in the enforcement of the regulation.

(f) *Effective dates.* This rule is effective from April 24 through June 4, 2004.

Dated: April 24, 2004.

Steven M. Hanewich,

Commander, U.S. Coast Guard, Acting Captain of the Port, Hampton Roads.

[FR Doc. 04-10113 Filed 5-3-04; 8:45 am]

BILLING CODE 4910-15-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 716

[OPPT-2003-0028; FRL-7322-8]

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and its regulations, requires manufacturers (including importers) of the following 15 chemicals to report certain unpublished health and safety data to EPA: 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro-; imidazo[4,5-d]imidazole-2,5(1H,3H)-dione, tetrahydro-; stannane, dimethylbis[(1-oxoneodecyl)oxy]-; benzene, 1,3,5-tribromo-2-(2-propenyloxy)-; 1-triazene, 1,3-diphenyl-; benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-; and 9 indium compounds. The Interagency Testing

Committee (ITC), established under section 4(e) of TSCA to recommend chemicals and chemical mixtures to EPA for priority testing consideration, amends the TSCA section 4(e) *Priority Testing List* through periodic reports submitted to EPA. The ITC added the 15 chemicals in this rule to the *Priority Testing List*.

In addition, in order to display the approval of the information collection requirements contained in this final rule as required by the Paperwork Reduction Act (PRA), EPA is amending the table of PRA approval numbers that appear in 40 CFR part 9.

DATES: This final rule is effective on June 3, 2004. For purposes of judicial review, this rule shall be promulgated at 1 p.m. eastern daylight/standard time on May 18, 2004. (See 40 CFR 23.5)

A request to withdraw a chemical from this rule pursuant to 40 CFR 716.105(c) must be received on or before May 18, 2004. (See Unit IV. of the **SUPPLEMENTARY INFORMATION.**)

Reporting Requirements

The reporting described in Unit III.B. is required by August 2, 2004. Any person who manufactures or imports or who proposes to manufacture or import the listed substance from June 3, 2004 to August 2, 2004 must inform (by submitting a list) EPA of any studies initiated during the period from June 3, 2004 to August 2, 2004 within 30 days of their initiation, but in no case later than August 30, 2004. In addition, if any such person has submitted lists of studies that were ongoing or initiated during the period from June 3, 2004 to August 2, 2004 to EPA, such person must submit a copy of each study within 30 days after its completion, regardless of the study's completion date. See 40 CFR 716.60 and 716.65.

ADDRESSES: Submit your withdrawal request, identified by docket ID number OPPT-2003-0028, by one of the following methods:

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

- *Agency Website:* <http://www.epa.gov/edocket/>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

- *E-mail:* oppt.ncic@epa.gov.

- *Fax:* (202) 566-0282.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460-0001, Attention: 8(d) Auto-ITC.

- *Hand delivery/courier:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC, Attention: 8(d) Auto-ITC. 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 OPPT-2003-0028. 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.epa.gov/edocket/>, 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 EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are "anonymous access" systems, 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 EDOCKET or 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 EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL-7181-7).

Docket: All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material,

is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the OPPT Docket, EPA Docket Center (EPA/DC), EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744, and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566-0280.

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: John Harris, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8156; 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 be potentially affected by this action if you manufacture (defined by statute to include import) any of the chemical substances that are listed in § 716.120(a) and (d) of the regulatory text of this document. Entities potentially affected by this action may include, but are not limited to:

- Chemical manufacturers (including importers), (NAICS 325, 324110), e.g., persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.

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 Can I Access Electronic Copies of this Document and Other Related Information?

In addition to EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 9 and part 716 is available on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

C. How Do I Submit CBI Information?

Do not submit this information to EPA through EDOCKET, 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 issuing a final TSCA section 8(d) Health and Safety Data Reporting rule which will require manufacturers (including importers) of 15 chemicals on the ITC's TSCA section 4(e) *Priority Testing List* to submit certain unpublished health and safety data to EPA. The regulatory text of this document lists the 15 chemicals that are being added to the Health and Safety Data Reporting rule as a result of this document. It also lists the data reporting requirements imposed by this amendment to the rule.

B. What is the Agency's Authority?

EPA promulgated the model Health and Safety Data Reporting rule under section 8(d) of TSCA (15 U.S.C. 2607(d)), and it 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 notice or 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 notice or 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 to the list of chemicals subject to the rule (see Table of Chemicals, 40 CFR 716.120). Whenever EPA announces the receipt of an ITC Report, EPA may, at the same time, amend the TSCA section 8(d) model rule by adding the recommended (or designated) chemicals. In doing so, EPA must provide a 14-day period (measured from the date of publication of the **Federal Register** document announcing the rule) 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 Health and Safety Data Reporting rule is effective June 3, 2004. If the Administrator withdraws a chemical from the amendment, a **Federal Register** document announcing this decision is to be published no later than on June 3, 2004.

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

EPA is taking this action pursuant to TSCA section 8(d) and 40 CFR 716.105(b) and (c), which authorize this action to amend the TSCA 8 (d) Health and Safety Data Reporting rule.

III. Final Rule

A. What Chemicals are to be Added?

In this document, EPA is adding 15 chemicals to the TSCA section 8(d) Health and Safety Data Reporting rule. This document addresses the request of the TSCA ITC in its 43rd Report (Ref. 1) by adding 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro- (CAS No. 16691-43-3, 3-amino-5-mercapto-1,2,4-triazole in the 43rd ITC Report) and imidazo[4,5-d]imidazole-2,5(1H,3H)-dione, tetrahydro- (CAS No. 496-46-8) (glycoluril in the 43rd ITC Report) to the TSCA section 8(d) Health and Safety Data Reporting rule. It addresses the request of the ITC in its 50th Report (Ref. 2) by adding stannane, dimethylbis[(1-oxoneodecyl)oxy]- (CAS No. 68928-76-7); benzene, 1,3,5-tribromo-2-(2-propenyloxy)- (CAS No. 3278-89-5); and 1-triazene, 1,3-diphenyl- (CAS No. 136-35-6) to the Health and Safety Data Reporting rule. It also addresses

the request of the ITC in its 51st Report (Ref. 3) by adding benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-(CAS No. 29091-20-1; added to the TSCA 4(e) *Priority Testing List* as 3-chlorotrifluralin in the 48th ITC

Report (Ref. 4) to the Health and Safety Data Reporting rule. Finally, it addresses the request of the ITC in its 47th Report (Ref. 5) as modified in the 51st ITC Report (Ref. 3) by adding 9 indium compounds listed in Table 1 to

the Health and Safety Data Reporting rule. (The CAS No. for indium tin oxide was incorrectly cited in the 51st ITC Report as 17906-11-9. The correct CAS No. as given in the 47th ITC Report is 50926-11-9 (Ref. 6)).

TABLE 1.—INDIUM COMPOUNDS

CAS No.	9 th Collective Index Name	Name in 47 th ITC Report
1312-43-2	Indium oxide (In ₂ O ₃)	Indium (III) oxide
7440-74-6	Indium	Indium
10025-82-8	Indium chloride (InCl ₃)	Indium (III) chloride
13464-82-9	Sulfuric acid, indium(3+) salt (3:2)	Indium (III) sulfate
20661-21-6	Indium hydroxide (In(OH) ₃)	Indium (III) hydroxide
22398-80-7	Indium phosphide (InP)	Indium (I) phosphide
25114-58-3	Acetic acid, indium(3+) salt	Indium (III) acetate
50926-11-9	Indium tin oxide	Indium tin oxide
66027-93-8	Sulfamic acid, indium(3+) salt	Indium (III) sulfamate

B. What are the Reporting Requirements?

Listed in this unit are the reporting requirements for the 15 chemicals added by this amendment to the TSCA section 8(d) model rule. (The specific types of health and safety studies that must be reported for each of the 15 chemicals added to the Health and Safety Data Reporting rule as a result of this document can be found in Unit III.C.)

1. Persons who, in the 10 years preceding the date a substance is listed, either have proposed to manufacture or import or have manufactured or imported the listed substance must submit to EPA, during the 60-day reporting period specified in § 716.65 and according to the reporting schedule set forth at § 716.60, a copy of each specified type of health and safety study which is in their possession at the time the substance is listed.

2. Persons who, at the time the substance is listed, propose to manufacture or import; or are manufacturing or importing the listed substance must submit to EPA during the 60-day reporting period specified in § 716.65 and according to the reporting schedule set forth at § 716.60:

i. A copy of each specified type of health and safety study which is in their possession at the time the substance is listed.

ii. A list of the specified type of health and safety studies known to them but not in their possession at the time the substance is listed.

iii. A list of the specified type of health and safety studies that are ongoing at the time the substance is listed and are being conducted by or for them.

iv. A list of each specified type of health and safety study that is initiated after the date the substance is listed and is conducted by or for them.

v. A copy of each specified type of health and safety study that was previously listed as ongoing or subsequently initiated (i.e., listed in accordance with reporting requirements in Unit III.B.2.iii. and 2.iv., respectively) and is now complete—regardless of completion date.

3. Persons who, after the time the substance is listed, propose to manufacture or import the listed substance must submit to EPA during the reporting period specified in § 716.65 and according to the reporting schedule set forth at § 716.60:

i. A copy of each specified type of health and safety study which is in their possession at the time they propose to manufacture or import the listed substance.

ii. A list of each specified type of health and safety studies known to them but not in their possession at the time they propose to manufacture or import the listed substance.

iii. A list of the specified type of health and safety studies that are ongoing at the time they propose to manufacture or import the listed substance, and are being conducted by or for them.

iv. A list of each specified type of health and safety study that is initiated after the time they propose to manufacture or import the listed substance, and is conducted by or for them.

v. A copy of each specified type of health and safety study that was previously listed as ongoing or subsequently initiated (i.e., listed in accordance with reporting requirements in Unit III.B.3.iii. and 3.iv., respectively) and is now complete—regardless of the completion date.

The reporting described in Unit III.B. is required by August 2, 2004. Any person who manufactures or imports or who proposes to manufacture or import the listed substance from June 3, 2004 to August 2, 2004 must inform (by submitting a list) EPA of any studies initiated during the period from June 3, 2004 to August 2, 2004 within 30 days of their initiation, but in no case later than August 30, 2004. In addition, if any such person has submitted lists of studies that were ongoing or initiated during the period from June 3, 2004 to August 2, 2004 to EPA, such person must submit a copy of each study within 30 days after its completion, regardless of the study's completion date. See 40 CFR 716.60 and 716.65.

Detailed guidance for reporting unpublished health and safety data is provided at 40 CFR part 716. Also found there are explanations of the reporting exemptions.

C. What Types of Studies Must be Submitted?

Pursuant to § 716.20(b)(5) and § 716.50, 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 the 15 chemicals added to the Health and Safety Data Reporting rule as a result of this document are as follows:

For 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro- and imidazo[4,5-d]imidazole-2,5-(1H,3H)-dione, tetrahydro-, all unpublished environmental effects studies and health effects studies on pharmacokinetics, genotoxicity, subchronic toxicity, immunotoxicity, carcinogenicity, reproductive effects, and developmental toxicity where the purity of 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro-orimidazo[4,5-d]imidazole-2,5-(1H,3H)-dione, tetrahydro- is greater than or equal to 90% of the test substance by weight must be submitted. All other studies are exempt at this time from reporting.

For benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on biodegradation, and health effects studies on pharmacokinetics, subchronic toxicity, mutagenicity, reproductive effects, developmental toxicity, and carcinogenicity where the purity of benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)- is greater than or equal to 90% of the test substance by weight must be submitted. All other studies are exempt at this time from reporting.

For stannane, dimethylbis[(1-oxoneodecyl)oxy]-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on hydrolysis and biodegradation and health effects studies on pharmacokinetics, subchronic toxicity, mutagenicity, neurotoxicity, reproductive effects, developmental toxicity, and carcinogenicity where the purity of stannane, dimethylbis[(1-oxoneodecyl)oxy]- is greater than or equal to 90% of the test substance by weight must be submitted. All other studies are exempt at this time from reporting.

For benzene, 1,3,5-tribromo-2-(2-propenyloxy)-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on biodegradation and health

effects studies on pharmacokinetics, subchronic toxicity, neurotoxicity, reproductive effects, developmental toxicity, and carcinogenicity where the purity of benzene, 1,3,5-tribromo-2-(2-propenyloxy)- is greater than or equal to 90% of the test substance by weight must be submitted. All other studies are exempt at this time from reporting.

For 1-triazene, 1,3-diphenyl-, all unpublished health effects studies on pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity where the purity of 1-triazene, 1,3-diphenyl- is greater than or equal to 90% of the test substance by weight must be submitted. All other studies are exempt at this time from reporting.

For the 9 chemicals in the indium compound category, all unpublished health effects studies on pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity where the purity of the indium compound is greater than or equal to 90% of the test substance by weight must be submitted. All other studies are exempt at this time from reporting.

D. Economic Analysis

Only 5 of the 15 compounds in this document were located in EPA's Chemical Update System (CUS) utilizing the supplied CAS numbers, yielding 6 companies producing these chemicals at 6 sites. Because the threshold for reporting to CUS under the Inventory Update Rule is 10,000 pounds, and because there is no requirement that inorganic chemicals be reported to CUS (the majority of the indium compounds are inorganic), EPA assumed that one manufacturer exists per chemical to account for the possibility that there may be manufacturers producing these chemicals that are subject to this rule but that were not captured by CUS (Ref. 7).

EPA estimates of the total costs and burdens to industry and the Federal Government, i.e., EPA, for establishing TSCA section 8(d) reporting requirements for the 15 chemicals (Ref. 7) are as follows:

Industry Reporting Costs (dollars)

- a. Initial review of rule: \$1,705
- b. Site ID and file searches:
 1. Site identification: \$2,557
 2. Site file searches: \$3,120
- c. Copying on-hand studies: \$1,086
- d. Listing studies ongoing and possessed elsewhere: \$383
- e. Review studies for CBI: \$4,528
- f. Newly initiated studies: \$124
- g. Submission of studies completed after initial reporting period: \$54

Grand totals = \$13,557

Industry Reporting Burden (Hours)

- a. Initial review: 32
- b. Reporting: 268

Total reporting burden hours = 300
EPA Costs (dollars) and Burden (hours)

It is estimated that the annual cost to EPA will be 0.26 Full Time Equivalents (FTEs) or 541 hours annually. At an estimated \$91,874 per FTE, the total of 0.26 FTEs will cost EPA \$23,887.

As indicated in § 716.20(b)(5), this final rule specifies the specific types of 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. In order to provide a single location for these chemical or chemical category specific reporting requirements, EPA is establishing a new § 716.21. The chemicals will continue to be listed in § 716.120, with a reference to the specific reporting requirement described in § 716.21.

IV. Requesting a Chemical be Withdrawn from the Rule

As specified in § 716.105(c), EPA may, in its discretion, remove a chemical substance, mixture, or category of chemical substances from this rule for good cause prior to the effective date of this rule. Any person who believes that the reporting required by this rule is not warranted for a chemical listed in this rule, must submit to EPA detailed reasons for that belief. You must submit your request to EPA on or before May 18, 2004 and in accordance with the instructions provided in § 716.105(c), which are briefly summarized here. In addition, to ensure proper receipt by EPA, you must identify docket ID number OPPT-2003-0028. 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 on June 3, 2004.

V. Materials in the Docket

The official docket for this rule has been established under docket ID number OPPT-2003-0028. 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 rule:

1. ITC. 2000. Forty-Third Report of the ITC. **Federal Register** (65 FR 65234, October 31, 2000) (FRL-6049-5). Available on-line at: <http://www.epa.gov/fedrgstr/>.

2. ITC. 2002. Fiftieth Report of the ITC. **Federal Register** (67 FR 49530, July 30, 2002) (FRL-7183-7). Available on-line at: <http://www.epa.gov/fedrgstr/>.

3. ITC. 2003. Fifty-first Report of the ITC. **Federal Register** (68 FR 8976, February 26, 2003) (FRL-7285-7). Available on-line at: <http://www.epa.gov/fedrgstr/>.

4. ITC. 2001. Forty-Eighth Report of the ITC. **Federal Register** (66 FR 51276, October 5, 2001) (FRL-6786-7). Available on-line at: <http://www.epa.gov/fedrgstr/>.

5. ITC. 2001. Forty-Seventh Report of the ITC. **Federal Register** (66 FR 17767, April 3, 2001) (FRL-6763-6). Available on-line at: <http://www.epa.gov/fedrgstr/>.

6. EPA. 2003. Letter from John Walker to Charles M. Auer correcting the CAS No. for indium tin oxide in the 51st ITC Report. April 17, 2003.

7. EPA. 2003. TSCA Section 8(d): Economic Impact Analysis For Adding 15 Chemicals from the 43rd, 47th, 50th, and 51st Report of the TSCA Interagency Testing Committee to the Health and Safety Data Reporting Rule. August 5, 2003.

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 Health and Safety Data Reporting 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) Health and Safety Data Reporting rules have already been approved by OMB under the provisions of 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 all chemicals in this final rule will result in an annual public reporting burden of 20 hours per chemical, for a total of 300 hours for the 15 chemicals (Ref. 7). 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 are listed in 40 CFR part 9 and included on the related collection instrument. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this final rule. 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. This ICR was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), to amend this table without further notice and comment.

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 for this rule (Ref. 7), and is briefly summarized here.

For this final rule, EPA has analyzed the potential small business impacts using the size standards established under the default definition of "small business" established under section 601(3) of RFA, which basically uses the definition used in section 3 of the Small Business Act, 15 U.S.C. 632, under which the SBA establishes small business size standards for each industry sector. (13 CFR 121.201). The SBA size standards, which are primarily

intended to determine whether a business entity is eligible for government programs and preferences reserved for small businesses (13 CFR 121.101), "seek to ensure that a concern that meets a specific size standard is not dominant in its field of operation." (13 CFR 121.102(b)). See section 632(a)(1) of the Small Business Act.

For the chemical manufacturers potentially impacted by this rule, an ultimate corporate parent with 1,000 or fewer employees is considered a small business. Of the 6 companies identified in CUS as manufacturers of the chemicals covered by this rule (see the economic analysis for this rule (Ref. 7) as summarized in Unit III.D.), none meet the SBA definition of small business. Given these results, EPA concludes that there is not a significant adverse economic impact on these small entities as a result of this final rule.

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 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 rule will not significantly or uniquely affect small governments. Accordingly, the rule is not subject to the requirements of UMRA sections 202, 203, 204, or 205.

E. Executive Order 13132 and 13175

Based on EPA's experience with past TSCA section 8(d) 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 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 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 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 Health and Safety Data Reporting rule in its 43rd Report (Ref. 1), 47th Report (Ref. 5), 50th Report (Ref. 2), and 51st Report (Ref. 3).

G. Executive Order 13211

This 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).

J. 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, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 716

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

Dated: April 22, 2004.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

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

PART 9—[AMENDED]

■ 1. By amending part 9 as follows:

■ a. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

■ b. In § 9.1, the table is amended by revising the entries under the undesignated center heading "Health and Safety Data Reporting" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

40 CFR citation	OMB control No.
Health and Safety Data Reporting	
Part 716	2070-0004

PART 716—[AMENDED]

■ 2. By amending part 716 as follows:

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

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

■ b. By adding a new § 716.21 to subpart A to read as follows:

§ 716.21 Chemical specific reporting requirements.

(a) Health and safety studies reportable under part 716 for the

following chemical substances, mixtures, or categories of chemical substances, as listed in § 716.120, must be submitted or listed only as specified in this section:

(1) For 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro- and imidazo[4,5-d]imidazole-2,5-(1H,3H)-dione, tetrahydro-, all unpublished environmental effects studies and health effects studies on pharmacokinetics, genotoxicity, subchronic toxicity, immunotoxicity, carcinogenicity, reproductive effects, and developmental toxicity where the purity of 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro- or imidazo[4,5-d]imidazole-2,5-(1H,3H)-dione, tetrahydro- is greater than or equal to 90% of the test substance by weight must be submitted.

(2) For benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on biodegradation, and health effects studies on pharmacokinetics, subchronic toxicity, mutagenicity, reproductive effects, and developmental toxicity, and carcinogenicity where the purity of benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)- is greater than or equal to 90% of the test substance by weight must be submitted.

(3) For stannane, dimethylbis[(1-oxoneodecyl)oxy]-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on hydrolysis and biodegradation and health effects studies on pharmacokinetics, subchronic toxicity, mutagenicity, neurotoxicity, reproductive effects, and developmental toxicity, and carcinogenicity where the purity of stannane, dimethylbis[(1-oxoneodecyl)oxy]- is greater than or equal to 90% of the test substance by weight must be submitted.

(4) For benzene, 1,3,5-tribromo-2-(2-propenyloxy)-, all unpublished environmental effects studies including bioconcentration, environmental fate studies on biodegradation and health effects studies on pharmacokinetics, subchronic toxicity, neurotoxicity, reproductive effects, and developmental toxicity, and carcinogenicity where the purity of benzene, 1,3,5-tribromo-2-(2-propenyloxy)- is greater than or equal to 90% of the test substance by weight must be submitted.

(5) For 1-triazene, 1,3-diphenyl-, all unpublished health effects studies on pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity where the purity of 1-triazene,

1,3-diphenyl- is greater than or equal to 90% of the test substance by weight must be submitted.

(6) For the 9 chemicals in the indium compound category, all unpublished health effects studies on pharmacokinetics, genotoxicity, subchronic and chronic toxicity, reproductive effects, and developmental toxicity where the purity of the indium

compound is greater than or equal to 90% of the test substance by weight must be submitted.

(b) [Reserved]

■ c. In § 716.120, the table in paragraph (a) is amended by adding the chemicals: 3H-1,2,4-triazole-3-thione, 5-amino-1,2-dihydro-; imidazo[4,5-d]imidazole-2,5(1H,3H)-dione, tetrahydro-; benzenamine, 3-chloro-2,6-dinitro-N,N-

dipropyl-4-(trifluoromethyl)-; stannane, dimethylbis[(1-oxoneodecyl)oxy]-; benzene, 1,3,5-tribromo-2-(2-propenyloxy)-; and 1-triazene, 1,3-diphenyl- listed in ascending CAS number order to read as follows:

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

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

CAS No.	Substance	Specific exemptions	Effective date	Sunset date
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
136-35-6	1-Triazene, 1,3-diphenyl-	§ 716.21(a)(5)	June 3, 2004.	August 2, 2004.
496-46-8	Imidazo[4,5-d]imidazole-2,5(1H,3H)-dione, tetrahydro-	§ 716.21(a)(1)	June 3, 2004.	August 2, 2004.
3278-89-5	Benzene, 1,3,5-tribromo-2-(2-propenyloxy)-.	§ 716.21(a)(4)	June 3, 2004.	August 2, 2004.
16691-43-3	3H-1,2,4-Triazole-3-thione, 5-amino-1,2-dihydro-.	§ 716.21(a)(1)	June 3, 2004.	August 2, 2004.
29091-20-1	Benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-.	§ 716.21(a)(2)	June 3, 2004.	August 2, 2004.
68928-76-7	Stannane, dimethylbis[(1-oxoneodecyl)oxy]-.	§ 716.21(a)(3)	June 3, 2004.	August 2, 2004.
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

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■ d. In § 716.120, the table in paragraph (d) is amended by adding in alphabetical order the category "Indium Compounds"

containing 9 chemicals in alphabetical order to read as follows:

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

* * * * *
(d) * * * *

Category	CAS No.	Special Exemptions	Effective Date	Sunset Date
Indium Compounds:	* * * * *	* * * * *	* * * * *	* * * * *
Acetic acid, indium(3+) salt	25114-58-3	§ 716.21(a)(6)	June 3, 2004.	August 2, 2004
Indium	7440-74-6	§ 716.21(a)(6)	June 3, 2004.	August 2, 2004.
Indium chloride (InCl3)	10025-82-8	§ 716.21(a)(6)	June 3, 2004.	August 2, 2004.
Indium hydroxide (In(OH)3)	20661-21-6	§ 716.21(a)(6)	June 3, 2004.	August 2, 2004.
Indium oxide (In2O3)	1312-43-2	§ 716.21(a)(6)	June 3, 2004.	August 2, 2004.
Indium phosphide (InP)	22398-80-7	§ 716.21(a)(6)	June 3, 2004	August 2, 2004.
Indium tin oxide	50926-11-9	§ 716.21(a)(6)	June 3, 2004	August 2, 2004
Sulfamic acid, indium(3+) salt	66027-93-8	§ 716.21(a)(6)	June 3, 2004	August 2, 2004
Sulfuric acid, indium(3+) salt (3:2)	13464-82-9	§ 716.21(a)(6)	June 3, 2004	August 2, 2004.
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

[FR Doc. 04-9875 Filed 5-3-04; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 040209049-4117-02; I.D. 012204B]

RIN 0648-AR83

Pacific Halibut Fisheries; Catch Sharing Plan

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

ACTION: Final rule; annual management measures and sport fishing regulations for Area 2A Pacific halibut fisheries, and final rule; changes to the Catch Sharing Plan.

SUMMARY: The Assistant Administrator for Fisheries, NOAA (AA), on behalf of the International Pacific Halibut Commission (IPHC), publishes annual management measures promulgated as regulations by the IPHC and accepted by the Secretary of State governing the Pacific halibut fishery. The AA also announces modifications to the Catch Sharing Plan (CSP) for Area 2A and implementing regulations for 2004. These actions are intended to enhance the conservation of Pacific halibut and further the goals and objectives of the Pacific Fishery Management Council (Pacific Council).

DATES: The rule is effective May 1 2004, except for amendments to § 300.63, which are effective June 3, 2004

ADDRESSES: Copies of the CSP and background documents for this action are available at NMFS Northwest Region, 7600 Sand Point Way NE, Seattle, WA 98115-0070. The CSP is also available on the Northwest Region home page at www.nwr.noaa.gov/1sustfsh/halibut01.htm.

FOR FURTHER INFORMATION CONTACT: Jamie Goen or Yvonne deReynier, 206-526-6150.

SUPPLEMENTARY INFORMATION:

Electronic Access

This final rule also is accessible via the Internet at the Office of the Federal Register's website at www.gpoaccess.gov/fr/index.html.

Background

The IPHC manages Pacific halibut in waters off Alaska, British Columbia, and

the U.S. West Coast. On January 20-23, 2004, the IPHC held its annual meeting in Juneau, AK, and recommended its bilateral regulations for 2004. The Secretary of State of the United States has accepted the 2004 IPHC regulations under section 4 of the Northern Pacific Halibut Act (Halibut Act, 16 U.S.C. 773-773k). For U.S. waters, NMFS works with the North Pacific and Pacific Fishery Management Councils to set area-specific fishery management measures. IPHC refers to waters off the U.S. West Coast as "Area 2A."

On February 23, 2004, NMFS published a proposed rule to implement 2004 revisions to the Area 2A CSP for Pacific halibut (69 FR 8162). A complete description of the Pacific Council recommended changes to the CSP and management measures were published in the proposed rule for this action. NMFS requested comment on the proposed rule through March 9, 2004. On February 27, 2004, NMFS published a final rule (69 FR 9231) to implement the IPHC's recommendations, to announce IPHC's approval of the Area 2A CSP, and to announce fishery regulations for U.S. waters off Alaska and fishery regulations for treaty commercial and ceremonial and subsistence fisheries and some regulations for non-treaty commercial fisheries for U.S. waters off the West Coast. None of the Pacific Council's proposed 2004 revisions to the CSP addressed either the treaty fisheries or the non-treaty commercial fisheries.

This final rule implements the Area 2A Pacific halibut CSP for 2004 and the Area 2A management measures for 2004. These management measures are effective until superceded by the 2005 management measures that NMFS will publish in the **Federal Register**. The proposed rule for this action also included a minor revision to the Federal halibut regulations at 50 CFR 300.63, which authorizes vessels with IPHC licenses that are operating in the primary sablefish longline fishery north of Pt. Chehalis to land halibut taken incidentally in that fishery. With this final rule, Federal regulations will state that, in addition to the prohibition on possessing and landing halibut south of Pt. Chehalis, no halibut taken in this fishery may be purchased south of Pt. Chehalis.

Comments and Responses

During the comment period on the proposed rule for implementing the Area 2A CSP, NMFS received two letters and one e-mail of comment. The letters are addressed below in the section on the CSP for Area 2A.

The email generally objected to most of the proposals for changes to the CSP, referred to halibut as an overfished species under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), and suggested shortening fishing seasons, cutting fishing quotas and establishing marine sanctuaries. Pacific halibut is an abundant, healthy stock and is not overfished. The IPHC establishes overall catch limits for halibut. NMFS regulations are intended to give fisheries access to the Area 2A total allowable catch (TAC) and to the various subquotas for sport, commercial, and ceremonial and subsistence fisheries in Area 2A. Where halibut fishing activities may affect overfished groundfish stocks, halibut fishing is restricted to protect those stocks. For example, sport and commercial fisheries off the U.S. West Coast are prohibited within fishery-specific Groundfish Conservation Areas (GCAs) implemented by this action.

Marine sanctuaries are created under the National Marine Sanctuaries Act (16 U.S.C. 1431-1445). This action is taken under the authority of the Northern Pacific Halibut Act, which does not authorize the establishment of marine sanctuaries. This action does, however, establish closed areas requirements for the sport and commercial halibut fisheries to reduce harvest of overfished rockfish. Sport fishing for halibut off the Washington coast is prohibited within the Yelloweye Rockfish Conservation Area (YRCA), implemented herein at Section 24(4)(b)(ii)(C). Commercial fishing for halibut off the U.S. West Coast and sport fishing for halibut off the Oregon coast are prohibited within the non-trawl and recreational (sport) Rockfish Conservation Areas, respectively, implemented herein at Section 27.

Catch Sharing Plan for Area 2

The Pacific Council's Area 2A CSP allocates the halibut catch limit for Area 2A among treaty Indian, non-treaty commercial, and non-treaty sport fisheries in and off Washington, Oregon, and California. Those allocations were described in the proposed rule for this action (69 FR 8162, February 23, 2004). For 2004, the Pacific Council recommended changes to the CSP to modify the Pacific halibut fisheries in Area 2A in 2004 and beyond pursuant to recommendations from the Washington Department of Fish and Wildlife (WDFW) and the Oregon Department of Fish and Wildlife (ODFW). These changes to the CSP will: provide more flexibility for Washington inseason sport fishery management;