ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 712

[OPTS-82004L; BH-FRL 2328-4]

Chemical Information Rules; Preliminary Assessment Information; Manufacturers Reporting; Amendment Adding ITC Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule adds 46 chemicals to the list for which manufacturers must submit Preliminary Assessment Information under section 8(a) of the Toxic Substances Control Act (TSCA). The Interagency Testing Committee (ITC) recommended these chemicals as candidates for testing in its Sixth through Ninth Reports.

EFFECTIVE DATE: This regulation becomes effective on June 20, 1983.

FOR FURTHER INFORMATION CONTACT: For further information on this rule or to obtain copies of the Manufacturer's Report Form: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M Street, SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C. (554-1404), Outside the U.S.A.: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION:
OMB Control Number: 2000-0420

I. Background

EPA issued the Preliminary Assessment Information rule under section 8(a) of the Toxic Substances Control Act. The rule was published in the **Federal Register** of June 22, 1982 (47 FR 26992). The rule required manufacturers of about 250 chemicals to report general production, use, and exposure information using the Preliminary Assessment Information Manufacturer's Report (EPA Form 7710-35). EPA simultaneously proposed and solicited comment on three amendments, including the addition of these 46 chemicals for manufacturer reporting (June 22, 1982; 47 FR 27009).

This amendment to the rule requires manufacturers to submit preliminary assessment information on 46 chemicals. The Sixth through Ninth ITC Reports designated these 46 chemicals (among others) as priority candidates for testing under TSCA section 4. (Other chemicals designated in the Sixth through Ninth ITC Reports were included among those already listed on the Preliminary Assessment Information rule.)

II. Response to Comments

The Agency received five comments on the proposed addition of these 46 chemicals. Two comments requested deleting hexachloroethane (CAS No. 67-72-1), based on EPA's prior decision not to require testing of that chemical under TSCA section 4 (47 FR 18175; April 28, 1982). One comment requested deleting fluoroethene (75-02-5) and tetrafluoroethene (CAS No. 116-14-3), because EPA had already issued an Advance Notice of Proposed Rulemaking published in the **Federal Register** of October 30, 1981 about the testing being considered for fluoroalkenes (46 FR 53704). The comment also said that data collected under this rule would not be available in time to affect testing decisions. Two other comments requested that EPA delete any chemical for which EPA has made a testing decision under TSCA section 4. These commenters considered that there is no current need for preliminary assessment data if EPA has completed its testing decision. The commenters said that future regulatory needs for data are uncertain, and that future needs would be for data current at that future time.

The Agency does not agree with these comments. In most instances, EPA will use preliminary assessment data to be reported under this rule to determine the need for testing the subject chemicals under TSCA section 4. However, the data also have other important uses to EPA. Even where a testing decision has already been made, the reported data will be evaluated to insure that the prior decision was appropriate in the light of the more complete production, exposure and release information provided by the rule.

For example, EPA reported in April 1982, that section 4 testing of hexachloroethane is not warranted at this time, based on its limited exposure and release to the environment. However, if current exposure were to change significantly, this decision may need reconsideration. By placing hexachloroethane under the 8(a) rule, EPA would obtain current information on its production, uses, potential exposure and environmental releases and would be able to determine if exposure to it has changed.

In some cases, the reported data may be needed to assist in allocating testing costs. Test rule analyses currently are based on data collected by contractors, from public literature, or voluntarily submitted by manufacturers. Data from this rule will verify the accuracy of these data. When EPA makes a decision based on voluntary submissions from manufacturers, such as in the case of the fluoroalkenes, data from the Preliminary Assessment Information rule will provide a means of verifying that the voluntary submissions provide a complete picture of the chemical's production, uses, exposure potential, and release. However, if a manufacturer's voluntary submission meets the requirements in § 712.30 (a)(3), he need not submit an additional report.

In addition to section 4 decisions, data obtained under this rule will also be used to assess the need for regulatory controls under other sections of TSCA. In some cases, the data may suggest that review would be appropriate under a different statute, such as the Resource Conservation and Recovery Act of 1976 (Pub. L. 94-580, Oct. 21, 1976). The data will allow comparison among chemicals on the basis of similar information. The comparison will indicate whether priorities are consistent among testing and other regulatory decisions.

III. Who Must Report

Persons subject to the Preliminary Assessment Information rule are specified at 40 CFR 712.20 and 712.25. Additional description may be found in the June 22, 1982, issue of the **Federal Register** (47 FR 26992).

Generally, a manufacturer (or an importer) would submit a Preliminary Assessment Information Manufacturer's Report (EPA form 7710-35) for each of the 46 chemicals he manufactures. If he manufactures a chemical at more than one site, he would submit a form for each site. A manufacturer is exempt from reporting for an individual site if the site production of the listed substance was less than 500 kilograms during the reporting period.

A manufacturer is also exempt from reporting if he qualifies as a small business by meeting the following two criteria during the reporting period: Total annual parent company sales below $30 million, and total production of the listed chemical at the site below 45,000 kilograms. EPA has separately proposed a generic definition of small manufacturers for TSCA section 8 (a) rules (June 23, 1982; 47 FR 27206). If the final generic small manufacturers definition is issued before this rule is final, EPA plans to apply the generic definition to reporting under this rule.

EPA separately proposed that processors report under the limited circumstances when manufacturers cannot provide adequate data (June 22, 1982, 47 FR 27009). When processor reporting requirements are promulgated, processors will be subject to reporting

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on any of these 46 chemicals for which manufacturers' data are inadequate.

IV. Time to Report

This amendment requires manufacturers (and importers) of the 46 chemicals to submit reports by August 17, 1983. This allows 60 days after the effective date of this rule to report.

V. Economic Impact

The cost estimates for a company to comply with the requirements of this proposal are based in part on estimates used in the final Preliminary Assessment Information Rule. One commenter said these estimates were too low. EPA considers its cost estimates to be both accurate and sufficiently current to support the rule. However, the original form filing costs have been increased by 23.3 percent to reflect inflation between development of the original proposal and late 1982.

The cost estimates presented in this analysis were current as of the fourth quarter of 1982. Although actual reporting under this rule will not occur until the latter part of 1983, we have not attempted to adjust the cost estimates to reflect this. The wide variations in the overall rate of price inflation experienced during the recent past prohibit development of accurate cost projections. Additionally, we would not expect actual costs incurred during 1983 to be greatly different from the figures used here.

Costs can be broken down into the following categories:

1. A fixed cost of $590 for a site to become familiar with the regulation and identify the chemicals to report.

2. A variable cost of $520 per report for a site to determine whether information should be claimed as confidential and to complete the form and certification requirements.

We estimate that 39 plant sites will submit 60 reports. This figure excludes plant sites which are exempted by the small business cutoff. Total reporting costs for the 46 chemicals listed in this amendment will approximate $54,200. (For a discussion of the method to estimate reporting costs, see "Economic Impact and Small Business Definition Analysis for the Final TSCA Section 8(a) Preliminary Assessment Information Rule," prepared by ICF, Inc., 1981.)

VI. Public Record

The public record for this rulemaking is a continuation of the record (OPTS-82004) for the Preliminary Assessment Information rule published in the June 22, 1982, issue of the Federal Register (47 FR 26992). All documents, including the index to this public record, are available for inspection in the OPTS Reading Room from 8:00 to 4:00 p.m. on working days (Rm. E-107, 401 M St., SW., Washington, D.C., 20460). This record includes basic information considered by the Agency in developing this rule.

VII. Regulatory Assessment Requirements

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., authorizes the Director of the Office of Management and Budget to review certain information collection requests by Federal agencies. The reporting provisions in this amendment were approved by OMB during the proposal stage (March 1982, under control number 2000-0420), along with two other amendments: automatic reporting on chemicals designated by the Interagency Testing Committee, and reporting requirements for processors of certain chemicals.

This rule requires manufacturers of 46 chemicals to complete the Preliminary Assessment Information Manufacturer's Report (EPA form 7710-35). The information to be submitted will be used by EPA to evaluate risks associated with the chemicals, as well as to determine whether the chemicals should be included in testing rules issued under section 4 of TSCA. In some cases the Agency may require processor follow-up reporting on a chemical when manufacturers' data on customer uses are inadequate.

B. Regulatory Flexibility Act

This amendment is consistent with the objectives of the Regulatory Flexibility Act (Pub. L. 96-354) because it will not have a significant economic impact on a substantial number of small entities. Under this rule, as for previous Preliminary Assessment Information proposed and final rules, manufacturers are "small" and thus exempt from the rule if they meet both of the following criteria:

1. Total annual sales taken together of all sites owned or controlled by the foreign or domestic parent company were below $30 million for the reporting period.

2. Total production of the listed substance for the reporting period was below 45,000 kilograms (100,000 pounds) at the plant site.

EPA consulted with the Small Business Administration, Size Standards Division, in developing this exemption.

C. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this regulation is not major because it does not have an effect of $100 million or more on the economy. It is expected to have a one-time cost of about $54,200. It does not have a significant effect on competition, costs or prices.

This proposed regulation has been submitted to the Office of Management and Budget for review as required by Executive Order 12291.

This proposal lists 46 chemicals for which manufacturers would submit one-page reports. Processors would report only when manufacturers are unable to provide adequate data.

List of Subjects in 40 CFR Part 712

Chemicals, Environmental protection, Reporting and recordkeeping requirements.

(Sec. 8, Pub. L. 94-469, 90 Stat. 2003 (15 U.S.C 2607))

Dated: May 10, 1983.

Lee L. Verstandig,

Acting Administrator.

PART 712—[AMENDED]

Therefore, 40 CFR 712.30 is amended by adding paragraph (f) to read as follows:

§ 712.30 Chemical lists and reporting periods.

* * * * *

(f) A Preliminary Assessment Information Manufacturer's Report must be submitted by August 17, 1983, for each chemical substance listed below.

CAS No.	Chemical Name
67-72-1	Ethane, hexachloro-
75-02-5	Ethene, fluro-
95-70-5	1,4-Benzenediamine, 2-methyl-
95-80-7	1,3-Benzenediamine, 4-methyl-
95-83-0	1,2-Benzenediamine, 4-chloro-
98-56-6	Benzene, 1-chloro-4-(trifluoromethyl)-
108-71-4	1,3-Benzenediamine, 5-methyl-
116-14-3	Ethene, tetrafluoro-
137-09-7	Phenol, 2,4-diamino-dihydrochloride
359-11-5	Ethene, trifluoro-
541-69-5	1,3-Benzenediamine, dihydrochloride
541-70-8	1,3-Benzenediamine, sulfate (1:1)
614-94-8	1,3-Benzenediamine, 4-methoxy-, dihydrochloride
615-28-1	1,2-Benzenediamine, dihydrochloride
615-45-2	1,4-Benzenediamine, 2-methyl-, dihydrochloride
615-46-3	1,4-Benzenediamine, 2-chloro-, dihydrochloride
615-50-9	1,4-Benzenediamine, 2-methyl-, sulfate (1:1)
677-21-4	1-Propene, 3,3,3-trifluoro-
1197-37-1	1,2-Benzenediamine, 4-ethoxy-
1477-55-0	1,3-Benzenedimethanamine

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3663-23-8 Benzenediamine, 4-butyl-
5042-55-7 1,3-Benzenediamine, 5-nitro-
5131-58-8 1,3-Benzenediamine, 4-nitro-
5131-60-2 1,3-Benzenediamine, 4-chloro-
5307-02-8 1,4-Benzenediamine, 2-methoxy-,
5307-14-2 1,4-Benzenediamine, 2-nitro-
6219-67-6 1,3-Benzenediamine, 4-methoxy-, sulfate
6219-71-2 1,4-Benzenediamine, 2-chloro-, sulfate
6219-77-8 1,2-Benzenediamine, 4-nitro-, dihydrochloride
15872-73-8 Phenol, 2,4-diamino-6-methyl-
16245-77-5 1,4-Benzenediamine, sulfate (1:1)
18266-52-9 1,4-Benzenediamine, 2-nitro-, dihydrochloride
20103-09-7 1,4 Benzenediamine, 2,5-dichloro-
25376-45-8 Benzenediamine, ar-methyl-
39156-41-7 1,3-Benzenediamine, 4-methoxy-, sulfate (1:1)
42389-30-0 1,2-Benzenediamine, 5-chloro-3-nitro-
62654-17-5 1,4-Benzenediamine, ethanedioate (1:1)
65879-44-9 Phenol, 2,4-diamino-6-methyl-, hydrochloride
66422-95-5 Ethanol, 2-(2,4-diaminophenoxy)-, dihydrochloride
67801-06-3 1,3-Benzenediamine, 4-ethoxy-, dihydrochloride
68015-98-5 1,3-Benzenediamine, 4-ethoxy-, sulfate (1:1)
68239-80-5 1,3-Benzenediamine, 4-chloro-, sulfate (1:1)
68239-82-7 1,2-Benzenediamine, 4-nitro-, sulfate (1:1)
68239-83-8 1,4-Benzenediamine, 2-nitro-, sulfate (1:1)
68459-98-3 1,2-Benzenediamine, 4-chloro-, sulfate (1:1)
68966-84-7 1,3-Benzenediamine, ar-ethyl-ar-methyl-

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 712

[OPTS-82004K; BH-FRL 2325-5]

Preliminary Assessment Information; Addition of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to add chemicals designated or recommended for testing consideration in the Eleventh Report of the Interagency Testing Committee (ITC) to the Preliminary Assessment Information rule. The rule requires manufacturers of these chemicals to complete the Preliminary Assessment Information Manufacturer's Report (EPA Form 7710-35). EPA will use the information submitted to evaluate risks associated with the chemicals, as well as to determine whether the chemicals should be included in testing rules issued under section 4 of the Toxic Substances Control Act (TSCA).

DATE: Comments must be submitted on or before July 5, 1983.

ADDRESS: Written comments should bear the document control number OPTS-82004K and should be submitted to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St., SW., Washington, D.C. 20460.

All written comments filed under this notice will be available for public inspection in Rm. E-107 at the address given above from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the U.S.A.: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: OMB Control Number: 2000-0420

I. Background

In the **Federal Register** of June 22, 1982 (47 FR 26992), EPA issued the Preliminary Assessment Information Rule under section 8(a) of the Toxic Substances Control Act (TSCA). The rule requires manufacturers of certain chemicals to report general production, use, and exposure information using the Preliminary Assessment Information Manufacturer's Report (EPA Form 7710-35).

The preamble to the rule explained that EPA would amend the list of chemicals subject to the Preliminary Assessment Information Rule when necessary to collect information on additional chemicals. This proposed amendment would add chemicals that ITC's Eleventh Report designated or recommended for EPA's testing consideration.

Under TSCA section 4(e), EPA must respond to ITC designates within 12 months by initiating rulemaking or publishing a notice explaining why such action is not being taken. EPA must also consider chemicals that ITC recommends for testing without statutory designation of a time period for EPA response.

The ITC's Eleventh Report, published in the **Federal Register** of December 3, 1982 (47 FR 54624), designated eleven individual chemicals for testing consideration and EPA response within 12 months. The Eleventh Report also recommended one group of chemicals, carbofuran intermediates, for testing consideration but without stating a given time period for EPA's response. The Report listed three carbofuran intermediates and their CAS numbers: Methallyl 2-nitrophenyl ether (13414-54-5); 7-Nitro-2,2-dimethyl-2,3-dihydrobenzofuran (13414-55-6); and 7-Amino-2,2-dimethyl-2,3-dihydrobenzofuran (68298-46-4). This rule lists these chemicals by their CAS numbers and CAS preferred names: Benzene, 1-[(2-methyl-2-propenyl)oxyl]-2-nitro- (13414-54-5); Benzofuran, 2,3-dihydro-2,2-dimethyl-7-nitro- (13414-55-6); 7-Benzofuranamine, 2,3-dihydro-2,2-dimethyl- (68298-48-4).

In the Eleventh Report, ITC recommended one additional group, trimethylbenzenes, that had been discussed in the ITC Tenth Report. The recommended trimethylbenzenes are: Benzene, 1,3,5-trimethyl- (108-67-8); Benzene, 1,2,3-trimethyl- (526-73-8); and Benzene, trimethyl- (25551-13-7). These chemicals were recommended but not designated for response within 12 months. (Another member of the group, 1,2,4-trimethylbenzene, CAS number 95-63-6, was separately designated in the Tenth ITC Report (May 25, 1982, 47 FR 22585). 1,2,4-Trimethylbenzene was included in the Preliminary Assessment Information Rule published on June 22, 1982 and is not subject to this proposal.)

EPA will use data from this rule to evaluate risks associated with listed chemicals, and to determine whether chemicals should be included in testing rules under TSCA section 4.

II. Who Would Report

Persons subject to the Preliminary Assessment Information rule are specified at 40 CFR 712.20 and 712.25. Additional description may be found in the June 22, 1982 issue of the **Federal Register** (47 FR 26992).

Generally, a manufacturer (or an importer) would submit a Preliminary Assessment Information Manufacturer's Report (EPA form 7710-35) for each of 17 chemicals he manufactures. If he manufactures a chemical at more than one site, he would submit a form for each site. A manufacturer is exempt from reporting for an individual site if the site production of the listed substance was below 500 kilograms during the reporting period.

A manufacturer is also exempt from reporting if he qualifies as a small business by meeting the following two criteria during the reporting period: total annual parent company sales below $30 million, and total production of the listed chemical at the site below 45,000 kilograms. EPA has separately proposed a generic definition of small manufacturers for TSCA section 8(a) rules (June 23, 1982; 47 FR 27206). If the final generic small manufacturers definition is issued before this rule is final, EPA plans to apply the generic definition to reporting under this rule.

EPA separately proposed that processors report under the limited circumstances when manufacturers cannot provide adequate data (June 22, 1982; 47 FR 27009). When processor reporting requirements are promulgated, processors would be subject to reporting on any of the 17 chemicals for which manufacturers' data are found to be inadequate.

III. Time To Report

The length of the reporting period for this amendment is based partly on information supplied in comments on the originally proposed Preliminary Assessment Information rule (February 29, 1980; 45 FR 13646). In those comments, manufacturers discussed how long it would take to perform various activities involved in preparing reports. The length of the reporting period is also based partly on EPA's experience with the timeliness of reports previously submitted under this rule.

The proposed rule published today requires manufacturers of 17 chemicals to submit reports 60 days after the effective date of the rule. EPA estimates that the maximum number of reports any site will have to submit is 5, with most firms submitting one or two reports per site.

IV. Economic Impact

The cost estimates for a company to comply with the requirements of this proposal are based on estimates used in the final Preliminary Assessment Information Rule. However, the original costs have been increased by 23.3 percent to account for the overall rate of price inflation in the period between development of the original proposal and late 1982. The cost estimates in this analysis were current as of the fourth quarter of 1982. Although actual reporting under this rule will not occur until the latter part of 1983, we have not attempted to adjust the cost estimates to reflect this. The wide variations in the overall rate of price inflation experienced during the recent past prohibit development of accurate cost projections. Additionally, we would not expect actual costs incurred during 1983 to be greatly different from the figures used there.

Costs can be broken down into the following categories:

1. A fixed cost of $590 for a site to become familiar with the regulation and identify the chemicals to report.

2. A variable cost of $520 per report for a site to determine whether information should be claimed as confidential and to complete the form and certification requirements.

We estimate that 26 plant sites operated by 23 companies will submit 43 reports under this rule. This figure excludes plant sites which are exempted by the small business cutoff. Total reporting costs for the 17 chemicals listed in this amendment are estimated to be $37,700. (For a discussion of reporting costs, see Economic Impact and Small Business Definition Analysis for the final TSCA Section 8(a) Preliminary Assessment Information Rule, prepared by ICF, Inc., 1981.)

V. Public Record

The public record for this proposed rulemaking is a continuation of the record (OPTS–82004) for the Preliminary Assessment Information rule published in the June 22, 1982, issue of the **Federal Register** (47 FR 26992). All documents, including the index to this public record, are available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m. on working days (Rm. E-107, 401 M Street SW., Washington, D.C. 20460). This record includes basic information considered by the Agency in developing this proposed rule. The Agency will supplement the record with the following types of additional information as it is received.

1. All comments on this proposed amendment.

2. All relevant support documents and studies.

3. Records of all communications between EPA personnel and persons outside the Agency pertaining to the development of this rule. (This does not include inter- or intra-agency memoranda unless specifically noted in the index of the rulemaking record.)

4. Minutes, summaries, or transcripts of any public meetings held to develop this rule.

5. Any factual information considered by the Agency in developing the rule.

EPA will identify the complete rulemaking record on or before the date of promulgation of the regulation, as prescribed by section 19(a)(3) of TSCA, and will accept additional material for inclusion in the record at any time between this notice and that date. The final rule will also permit persons to point out any errors or omissions in the record.

VI. Regulatory Assessment Requirements

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., authorizes the Director of the Office of Management and Budget to review certain information collection requests by Federal agencies. OMB approved the reporting provisions contained in this request and issued OMB control number 2000–0420.

This rule requires manufacturers of 17 chemicals to complete the Preliminary Assessment Information Manufacturer's Report (EPA Form 7710–35). The information to be submitted will be used by EPA to evaluate risks associated with the chemicals, as well as to determine whether the chemicals should be included in testing rules issued under section 4 of TSCA. In some cases the Agency may require processor follow-up reporting on a chemcial when manufacturers' data on customer uses are inadequate.

B. Regulatory Flexibility Act

This amendment, if promulgated, will be consistent with the objectives of the Regulatory Flexibility Act (Pub. L. 96–354) because it will not have a significant economic impact on a substantial number of small entities. Under this proposal, as for previous Preliminary Assessment Information proposed and final rules, manufacturers are "small" and thus exempt from the rule if they meet both of the following criteria:

1. Total annual sales taken together for all sites owned or controlled by the foreign or domestic parent company were below $30 million for the reporting period.

2. Total production of the listed substance for the reporting period was below 45,000 kilograms (100,000 pounds) at the plant site. EPA consulted with the Small Business Administration, Size Standards Division, in developing this exemption.

C. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this regulation is not major because it does not have an effect of $100 million or more on the economy. It is expected to have a one-time cost of about $37,700. It does not have a significant effect on competition, costs or prices.

The reporting provisions in this proposed regulation have been submitted to the Office of Management and Budget as required by Executive Order 12291.

This proposal lists 17 chemicals for which manufacturers would submit one-page reports. Processors would report only when manufacturers are unable to provide adequate data.

List of Subjects in 40 CFR Part 712

Chemicals, Environmental protection, Reporting and recordkeeping requirements.

(Sec. 8, Pub. L. 94–469, 90 Stat. 2003 (15 U.S.C. 2607))

Dated: May 10, 1983.

Lee L. Verstandig,

Acting Administrator.

PART 712—[AMENDED]

Therefore, it is proposed that 40 CFR 712.30 be amended by adding paragraph (g) to read as follows:

§ 712.30 Chemical lists and reporting periods.

* * * * *

(g) A Preliminary Assessment Information Manufacturer's Report must be submitted 90 days after date of publication in the **Federal Register** for each chemical substance listed below:

CAS No. and Chemical name

77–58–7—Stannane, dibutylbis [(1-oxododecyl)oxy]-

108–67–8—Benzene, 1,3,5-trimethyl-

140–66–9—Phenol, 4-(1,1,3,3-tetramethylbutyl)-

526–73–8—Benzene, 1,2,3-trimethyl-

646–06–0—1,3-Dioxolane

1185–81–5—Stannane, dibutylbis (dodecylthio)-

3319–31–1—1,2,4-Benzenetricarboxylic acid, tris-(2-ethylhexyl) ester

6422-86-2—1,4-Benzenedicarboxylic acid, bis-(2-ethylhexyl) ester
13414-54-5—Benzene, 1-[(2-methyl-2-propenyl)oxy]-2-nitro-
13414-55-6—Benzofuran, 2,3-dihydro-2,2-dimethyl-7-nitro-
25168-21-2—2-Butenoic acid, 4,4'-[(dibutylstannylene)bis(oxy)]bis[(4-oxo-, diisooctyl ester, (Z,Z)-
25168-24-5—Acetic acid, 2,2'-[(dibutylstannylene)bis(thio)]bis-, diisooctyl ester
25551-13-7—Benzene, trimethyl-
25852-70-4—Acetic acid, 2,2',2''-[(butylstannylidyne)tris(thio)]tris-, triisooctyl ester
26636-01-1—Acetic acid, 2,2'-[(dimethylstannylene)bis(thio)]bis-, diisooctyl ester
54849-38-6—Acetic acid, 2,2',2''-[(methylstannylidyne)tris](thio)]tris-, triisooctyl ester
68298-46-4—7-Benzofuranamine, 2,3-dihydro-2,2-dimethyl-

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panels of knowledgeable lung disease experts to make case-by-case determinations of asbestos compensation claims. A mechanism also must be developed, he told the subcommittee, to make possible an appeal of the medical decisions handed down by the regional panels.

Weill presented the subcommittee with a proposed set of guidelines for evaluation of compensation claims. These guidelines cover diagnosis and determination of the causes of asbestosis, non-malignant pleural effects, lung cancer, and malignant mesothelioma, and the establishment of criteria for assessing the degree of impairment including performance testing and pulmonary function testing.

Carcinogens

CANCER POLICY CHANGES BEING WEIGHED BY OSHA SAID LIMITED TO RISK ANALYSIS

A draft proposal currently being considered by the Occupational Safety and Health Administration to amend its generic policy for identifying, classifying, and regulating carcinogens reportedly would introduce a risk assessment scheme giving the assistant secretary of labor greater leeway to decide whether to regulate a substance identified as a potential occupational carcinogen.

But in its present form, agency sources told BNA, the draft proposal retains existing criteria for identifying the substances that pose workplace cancer hazards, including exclusionary sections that have drawn criticism from industry associations as being overly rigid in specifying the types of scientific evidence the agency will consider and what weight will be assigned to them.

Furthermore, the agency sources said, the regulation portion of the policy would continue to require reliance on engineering controls as the primary means of hazard control and would maintain the policy's current regulatory assumption that no safe level exists for exposure to a workplace carcinogen. Any mathematical risk assessment models the agency would find acceptable under the policy therefore would not include those that assume a threshold dose, the sources reported.

Several risk assessment models put forth by industry groups rely on threshold assumptions such as those the current OSHA policy rules out and the draft revision reportedly would continue to exclude. For example, in risk assessment hearings held by OSHA on the arsenic standard last summer, a Chemical Manufacturers Association panel, supported by interpretations of existing epidemiologic data, argued that low-level exposure to arsenic posed little or no cancer hazard (Current Report, July 22, 1982, p. 187).

Another controversial risk assessment stance the sources said the OSHA draft would maintain is its choice of a "more worker-protective" conversion factor to be used, in most cases, to correlate animal doses in laboratory experiments with human exposures in the workplace. In choosing a model for interspecies extrapolation, agency staff opted for one that breaks down exposure data into units of body weight and divides cumulative exposures by day, rather than, for example, using units of body surface area and measuring duration by lifetime, the sources said.

"There are other more worker-protective models, but there are many more that are less worker-protective," one source said. "In general, we're coming down on the worker-protective side."

Lists Would Be Replaced

The draft proposal would permanently do away with the present policy's classification scheme in which the agency is required to publish an annual list of candidates for regulation as suspected carcinogens and a semiannual list of those that are found to be of the highest priority (Reference File, 41:7304). The listing provisions, which agency officials began questioning early in the Reagan Administration, were stayed administratively six months ago (Current Report, Jan. 6, p. 611).

Supporting the abolition of the lists would be the reasoning that, with the currently required publication in the *Federal Register* of a regulatory agenda and a regulatory calendar, no additional "special" list should be required for carcinogens. "All our projects involve significant hazards, and we'll treat them all the same way on the regulatory agenda," an agency official said. " How many lists do we need?"

More leeway would be afforded to agency policy officials in the new classification scheme because, as now drafted, the proposed policy would formally incorporate the U.S. Supreme Court's mandate for a finding of significant risk (8 OSHC 1586), a conclusion that depends on policy judgments as well as scientific evidence, the sources said.

The draft now under consideration by the agency — the sources said that staff members were to present it to Assistant Labor Secretary Thorne G. Auchter sometime this month — replaces one that would have proposed wholesale revocation of the policy. The draft revocation proposal was pulled back after it failed to clear internal Labor Department review procedures, leading to the preparation of the new draft proposing only to amend the policy (Current Report, April 28, p. 987).

Butadiene

NEED TO REDUCE 1,000 PPM LIMIT EVALUATED BY AGENCIES; INDUSTRY POSES 100 PPM LEVEL

The Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health are re-valuating the current permissible exposure limit of 1,000 parts per million for 1,3-butadiene, in response to industry data indicating an increase in certain types of tumors in rats exposed to high levels of the substance.

Edward Baier, OSHA director of technical support, told BNA June 13 that his agency has asked for information on the substance from knowledgeable parties, to "see where we should go" on the question of a lower exposure limit. Meanwhile, NIOSH has begun work on a current intelligence bulletin based on available data, according to Richard Lemen, director of the institute's division of criteria documentation and standards development.

A study funded last year by the International Institute of Synthetic Rubber Producers, Inc., concluded that butadiene was a weak oncogen in rats exposed to levels of 1,000 and 8,000 ppm. The findings indicate that butadiene "does not represent a significant occupational hazard" in the synthetic rubber polymer manufacturing industry, according to a letter from M.J. Rhoad, managing director of the rubber producers' group, to the United Rubber Workers of America.

"However," Rhoad added, "considering all information a consensus has been reached [by institute scientists] favoring a limit of 100 ppm (eight hour time-weighted average) as appropriate for workplace control."

Butadiene is used as a component in manufacturing styrene-butadiene rubber products and resins, and as a chemical intermediate. NIOSH estimates that about 70,000 workers are exposed to the substance.

The current 1,3-butadiene exposure level, set in 1971, was based on studies which described the substance as a mild

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irritant exhibiting a low degree of toxicity at even relatively high levels, NIOSH Director J. Donald Millar remarked in a memorandum distributed to OSHA and other regulatory agencies last October. Based on more recent evidence, the American Conference of Governmental Industrial Hygienists this year proposed that the substance be considered a potential human carcinogen on the basis of data from animal studies (Current Report, June 2, p. 3).

Union Favors One PPM

Results of the International Institute of Synthetic Rubber Producers study were submitted last December to the Rubber Workers. The data were sent on to OSHA by Louis Beliczky, the union's director of industrial hygiene, who told BNA June 6 that the union is recommending that the butadiene exposure limit be reduced to one ppm.

Data compiled by the Rubber Workers indicate that exposure levels of less than 100 ppm can be achieved by the rubber industry, according to Beliczky. He cited a survey of 11 plants in which 98.9 percent of the 3,678 samples taken showed butadiene concentrations of less than 100 ppm.

Baier of OSHA said that the agency became aware of the industry data shortly before it received the information from Beliczky. The agency will wait to complete its review of available studies before deciding whether to initiate new rulemaking on the substance, he remarked.

Lemen reported that NIOSH hopes to complete its current intelligence bulletin in three months. The institute has not yet reached a decision on whether the existing exposure limit should be reduced, he said, but added that, in view of information from recent animal studies, the 1,000 ppm level "seems to be a pretty high standard."

Tumor Formation

The study funded by the rubber producers' institute was conducted by Hazleton Laboratories Europe Ltd. Groups of 100 male and 100 female rats were exposed for six hours per day, five days per week, for up to 111 weeks. Additional groups of 10 rats of each sex were exposed for one year to the same concentrations of 1,000 and 8,000 ppm.

Certain types of tumors "were present in larger numbers in the treated animals than in the controls," the study found. Increased numbers of tumors were found in six body sites, but only at three of these sites "could the increases be related to treatment," according to the manufacturers' institute.

Even in these cases, there was no definite relationship between the tumor incidence and butadiene exposure, the institute indicated. Mammary gland tumors appeared earlier in the study in the treated female rats, "suggesting a relation to treatment," the institute remarked. However, it added, "there is some question concerning the interpretation of the number of mammary tumors since they occur with a high and variable frequency in untreated rats of the strain used."

Similarly, higher numbers of thyroid and testis tumors in exposed rodents "appear to be related to treatment," but the highest incidence of testis tumors at the highest dose "was close to the historical control range ... in the same strain and laboratory," the manufacturers' organization remarked.

The study concluded that butadiene acted as a weak oncogen in the exposed rats, rather than a tumorigen. Any direct connection between butadiene exposure and development of tumors in the animals might have been "secondary to a disturbance of [the] physiologic process or a response to a toxic effect," the institute commented.

Possible teratogenic effects from 1,3-butadiene were evaluated in another Hazleton experiment involving exposure of female rats to concentrations of 200, 1,000, and 8,000 ppm. The offspring of the high dose group were found to be smaller than the offspring of the other groups, but the study generally attributed this difference to maternal toxicity, rather than to any teratogenic effects from butadiene.

Litigation

STAY OF LEAD RULE COMPLIANCE PLANS WARRANTED BY CIRCUMSTANCES, OSHA SAYS

The Occupational Safety and Health Administration's decision staying the engineering control compliance provisions of the workplace lead standard for primary and secondary smelters and battery manufacturers "was fully warranted by the record" and was necessary to prevent the "squandering of resources," according to the government.

This response to a petition for review of the assistant labor secretary's order was filed June 1 in *United Steelworkers of America, AFL-CIO v. Thorne G. Auchter* (Nos. 83-1022, 83-1126), in the U.S. Court of Appeals for the District of Columbia Circuit.

Last December, after two earlier deferrals, OSHA stayed the compliance plan requirements under 29 CFR 1910.1025(e)(3)(ii)(B) and (E). Employers in the three lead industries originally were to have completed their plans for instituting engineering controls to reduce lead exposure by June 29, 1982 (Current Report, Dec. 9, 1982, p. 563).

In its first 60-day deferral issued last June in response to industry petitions, the agency said it was allowing the extra time to "spare employers in these industries the expense of developing a detailed schedule for compliance with long-term engineering requirements which are now under agency reconsideration" (Current Report, June 24, 1982, p. 83).

OSHA issued its second deferral in September, maintaining that it needed more time to review comments submitted on its plan to stay the requirements and to prepare a final document (Current Report, Sept. 16, 1982, p. 323).

In challenging the agency's action, the Steelworkers maintained that the stay was procedurally and substantively defective and amounted to a substantial modification of the standard, which should have been subject to a notice and comment procedure (Current Report, March 17, p. 894).

Stay Said Warranted

The stay "was fully warranted by the record," the assistant secretary countered, adding that by December it was believed that the engineering control requirements for the smelters and battery manufacturers "would be altered as a result of new feasibility evidence gathered during the ongoing reconsideration proceedings." Further, it was noted that compliance with certain provisions called for "substantial research and development expenditures as well as extensive contractual obligations for supplies and construction."

"If these companies' engineering control numbers were ultimately to be changed, as then appeared probable, the substantial monies for complying with items B and E would have been wasted. In addition, the requirement that companies enter into contracts for superfluous supplies and services would have resulted in needless dislocation. In the assistant secretary's view, the stay was necessary to prevent such probable squandering of resources," the government maintained.

According to the brief, the assistant secretary is in the process of evaluating the continued need for the stay in light of the data received and the overall review of the standard, and "will take steps regarding the instant stay that are