**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 766**

**[OPTS-83002; FRL-2916-4]**

## Polyhalogenated Dibenzo-p-Dioxins/ Dibenzofurans; Testing and Reporting Requirements

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

**ACTION:** Proposed Rule.

**SUMMARY:** This document proposes, under section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603, to require manufacturers and importers of 14 commercial organic chemicals to test for the presence of certain chlorinated and brominated dibenzo-p-dioxins (dioxins) and dibenzofurans (furans). In addition, this testing will be required for 20 other commercial organic chemicals not currently manufactured or imported commercially in the United States if their manufacture or importation should resume.

EPA also proposes, under section 8(a) of TSCA, to require manufacturers and importers of the 14 commercially produced chemicals to submit existing test data on contamination of these chemicals with dioxins or furans and to require similar information on the 20 other chemicals should commercial manufacture or importation resume. EPA also proposes to require under section 8(d) that all chemical manufacturers submit health and safety studies on any dibenzo-p-dioxins and/or dibenzofurans.

If the testing proposed under this rule, or other valid existing test data, shows that these commercial chemicals contain dioxins at concentrations at or above 0.1 parts per billion (ppb) per congener and/ or furans at or above 1.0 ppb per congener, EPA proposes to require, with respect to the chemicals the submission of: (1) Production, process, use, exposure, and disposal data under section 8(a) of TSCA; (2) unpublished health and safety studies under section 8(d) of TSCA; and (3) records of allegations of significant adverse reactions both to the chemicals and to the dioxins/furans under section 8(c) of TSCA.

This rule also proposes, under section 8(a) of TSCA, to require the submission of production, process, use, exposure, and disposal data by manufacturers of chemical products made from any of 12 precursor chemicals to determine whether there is further need for dioxin and furan testing of the chemical products made from these precursor chemicals.

**DATES:** The public is asked to submit written comments on or before February 18, 1986. If persons request time for oral comment by February 3, 1986, EPA will hold a public meeting on March 4, 1986, on this rule in Washington, DC. For further information on arranging to speak at the meeting, contact the TSCA Assistance Office.

**ADDRESS:** Since some comments are expected to contain confidential business information, all comments should be sent in triplicate to: Document Control Officer (TS-793), Office of Pesticides and Toxin Substances, Environmental Protection Agency, 401 M St. SW, Rm. E-201, Washington, DC 20460.

Comments should include the docket number OPTS-83002. Non-CBI comments received on this Notice will be available for reviewing and copying from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays, in Rm. E-107, at the above address.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460. Toll free: (800-424-9065); In Washington, DC: (554-1404), Outside the USA: (Operator-202-554-1404).

**SUPPLEMENTARY INFORMATION:**

### I. Background

EPA has long recognized the potential public health and environmental significance of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). 2,3,7,8-TCDD has been described as one of the most toxic substances known to man. It exhibits delayed biological response in many species and is lethal at exceptionally low doses to aquatic organisms, birds, and mammals. It has been shown to be carcinogenic, teratogenic, fetotoxic, and acnegenic. In addition, 2,3,7,8-TCDD has been shown to adversely affect the immune response in mammals. EPA also recongizes the potential health significance of a variety of tetra- through hepta- halogenated dibenzp-p-dioxins and dibenzofurans (HDDs and HDFs) that are structurally related to 2,3,7,8-TCDD in that they are chlorinated or brominated, at the 2,3,7 and 8 positions on the molocular structure (Reference 4). These dioxins and furans, as well as 2,3,7,8-TCDD, are the subjects of this rulemaking. Hereafter, unless otherwise stated, this notice will refer to tetra- through hepa- chlorinated and brominated dioxins and furans substituted at the 2,3,7 and 8 positions as a group by using, interchangeably, the terms "2,3,7,8-substituted dioxins and furans," "2,3,7,8-substituted chlorinated and brominated dioxins and furans," and "2,3,7,8-substituted HDDs/ HDFs."

The 2,3,7,8-substituted chlorinated dioxins and furans have been measured in a number of commercial chemicals (Ref. 37). EPA has reason to believe that they also appear in a number of other commercial chemicals. Further, because of the extreme toxicity of 2,3,7,8-TCDD and the toxicological similarity to 2,3,7,8-TCDD of the other 2,3,7,8-substituted chlorinated and brominated dioxins and furans, there is evidence that even at very low levels all the 2,3,7,8-substituted chlorinated and brominated dioxins and furans may be hazardous to health and the environment.

EPA has long been concerned about polychlorinated dioxins (PCDDs) and furans (PCDFs) as shown by the number of EPA activities completed, underway, or planned for the analysis of both the toxicity of and potential for human and environmental exposures to these chemicals. EPA's National Dioxin Strategy (Ref. 29), issued in December 1983, offers a comprehensive overview of EPA's past, present, and planned activities in this area. EPA's past regulatory efforts on dioxins and furans focused on a number of products and processes that could generate chlorinated dioxins and furans or could otherwise lead to human or environmental exposure to these substances. The activities of concern have been 2,4,5-trichlorophenol production and use (a notice of intent to cancel registrations of pesticides containing 2,4,5-trichlorophenol was published in the **Federal Register** of October 18, 1983 (48 FR 48434)); pentachlorophenol use (a notice of intent to cancel registrations for pesticides containing pentachlorophenol was published in the **Federal Register** of July 13, 1984 (49 FR 28666)); fires involving polychlorinated biphenyls (a final rule was published in the **Federal Register** of July 17, 1985 (50 FR 29170) placing additional conditions and restrictions on the use of PCB transformers, including a phaseout requirement); and the cleanup of PCDD disposal sites (several sites in southeastern Missouri are being cleaned up, and work is under way to clean up several sites where 2,4,5-T was manufactured and disposed). The Agency also completed action to list as hazardous wastes certain wastes that could contain trace amounts of PCDDs and PCDFs. The listing was published in the **Federal Register** of January 14, 1985

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(50 FR 1978). The rule includes specific requirements for disposal of these wastes, including incineration at a Destruction Removal Efficiency of 99.9999 percent.

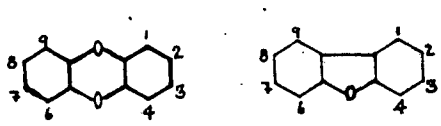
On October 22, 1984, the Environmental Defense Fund and the National Wildlife Federation filed a citizen's petition under section 21 of TSCA, 15 U.S.C. 2620. The petition (Ref. 8) requested that EPA commence certain regulatory actions related to HDDs and HDFs and initiate related investigations and research.

More specifically, the petitioners asked EPA to use its authority under TSCA to analyze aggregate hazards posed by multimedia release of specific 2,3,7,8-substituted congeners of dioxins and furans and to take action under TSCA to commence an integrated, multi-media effort to reduce the risks from the release of these chemicals.

Although the petitioners acknowledged that EPA in its Dioxin Strategy (Ref. 29) has recognized the need for a multi-media approach in cleaning up contamination, they believe that EPA has not taken sufficient action to prevent future contamination from the continued generation of HDDs and HDFs as contaminants during the manufacture of other chemicals and materials. The petitioners requested that EPA take a number of specific regulatory and information-gathering steps under TSCA to regulate generically, as a class of chemicals, the specified congeners; i.e., the 2,3,7,8-HDDs/HDFs.

EPA decided that, in general, it would deny the request to regulate the dioxins and furans under a multi-media TSCA approach for two reasons: (1) The Agency was already proceeding extensively to gather data and initiate regulation under other, more appropriate statutes, and (2) EPA did not have the data necessary to make a finding of unreasonable risk under section 6 of TSCA. EPA did decide, however, to grant part of the petition and initiated this rulemaking under sections 4 and 8 of TSCA to gather additional information on: (1) The presence of 2,3,7,8-substituted congeners of chlorinated and brominated dioxins and furans as contaminants in commercial chemicals; (2) the levels of contamination; (3) the amount of 2,3,7,8-substituted HDDs and HDFs produced, considering the production volume of the contaminated chemicals; (4) the reaction conditions and parameters which produced the 2,3,7,8-substituted HDDs/HDFs; (5) the end uses of the contaminated chemicals; (6) the routes of human and environnmental exposure to the contamined chemicals; (7) the number of people potentially exposed to the contaminated chemicals; (8) significant adverse reactions following exposures to the chemicals or the contaminants; and (9) unpublished health and safety studies on the chemicals or the contaminants. Once these data are submitted, EPA will review them and decide whether additional regulatory action is needed under section 6 of TSCA to limit or control the further manufacture, processing, distribution in commerce, and/or use of chemicals contaminated with 2,3,7,8-substituted chlorinated or brominated dioxins and furans.

The specific congeners referred to in this rule as 2,3,7,8-substituted congeners of chlorinated or brominated dioxins and furans are the 15 2,3,7,8-substituted tetra-, penta-, hexa-, and heptachlorodibenzo-p-dioxins and dibenzofurans, and the 15 2,3,7,8-substituted tetra-, penta-, hexa-, and heptabromodibenzo-p-dioxins and dibenzofurans; i.e., those substituted at the 2,3,7, and 8 positions in the molecules diagrammed below:



## II. Summary of Proposed Rule

### A. Testing Requirements Under Section 4

Under section 4 of TSCA, explained below in Unit IV, EPA may require the contaminant testing of chemicals in order to develop data relevant to assessing the chemicals' risks to health and the environment. EPA has determined that it is appropriate for manufacturers of the 14 chemicals listed below to test these chemicals for contamination with 2,3,7,8-substituted HDDs/HDFs. The additional 20 chemicals not now in commercial production will be tested if commercial production begins or resumes.

The chemicals proposed for testing are listed below along with their Chemical Abstract Services (CAS) registry number, where available:

| CAS No. | Chemical name |
|---|---|
| 79-94-7 | Tetrabromobisphenol-A. |
| 94-75-7 | 2,4-Dichlorophenoxy acetic acid. |
| 94-82-6 | 2,4-Dichlorophenoxybutyric acid. |
| 118-75-2 | 2,3,5,6-Tetrachloro-2,6-cyclohexadiene-1,4-dione. |
| 118-79-6 | 2,4,6-Tribromophenol. |
| 120-83-2 | 2,4-Dichlorophenol. |
| 1163-19-5 | Decabromodiphenyloxide. |
| 4162-45-2 | Tetrabromobisphenol-A-bisethoxylate. |
| 21850-44-2 | Tetrabromobisphenol-A-bis-2,3-dibromopropylether. |
| 25327-89-3 | Allyl ether of tetrabromobisphenol-A. |
| 32534-81-9 | Pentabromodiphenyloxide. |
| 32536-52-0 | Octabromodiphenyloxide. |
| 37853-59-1 | 1,2-Bis(tribromophenoxy)-ethane. |
| | Tetrabromobisphenol-A diacrylate. |

The following additional chemicals will be tested if their commercial manufacture or importation resumes:

| CAS No. | Chemical name |
|---|---|
| 79-95-8 | Tetrachlorobisphenol-A. |
| 87-10-5 | 3,4,5-Tribromosalicylanilide. |
| 87-65-0 | 2,6-Dichlorophenol. |
| 95-77-2 | 3,4-Dichlorophenol. |
| 95-95-4 | 2,4,5-Trichlorophenol. |
| 99-28-5 | 2,6-Dibromo-4-nitrophenol. |
| 120-36-5 | 2[2,4-(Dichlorophenoxy)]-propionic acid. |
| 320-72-9 | 3,5-Dichlorosalicyclic acid. |
| 488-47-1 | Tetrabromocatechol. |
| 576-24-9 | 2,3-Dichlorophenol. |
| 583-78-8 | 2,5-Dichlorophenol. |
| 609-71-9 | Pentabromophenol. |
| 615-58-7 | 2,4-Dibromophenol. |
| 933-75-5 | 2,3,6-Trichlorophenol. |
| 1940-42-7 | 4-Bromo-2,5-dichlorophenol. |
| 2577-72-2 | 3,5-Dibromosalicylanilide. |
| 3772-94-9 | Pentachlorophenyl laurate. |
| 37853-61-5 | Bismethylether of tetrabromobisphenol-A. |
| | Alkylamine tetrachlorophenate. |
| | Tetrabromobisphenol-B. |

The list of chemicals to be tested does not include those chemicals which meet all the criteria for listing, but which EPA believes have use only as pesticides. TSCA excludes pesticides from the definition of "chemical substances" and generally excludes pesticides from TSCA jurisdiction (TSCA section 3(2)). These chemicals are listed here, and the Agency solicits comments on whether they have uses other than as pesticides. Should other uses be found, these chemicals will be subject to the testing and reporting requirements under this rule.

| Cas No. | Chemical name |
|---|---|
| 70-30-4 | 2,2'-Methylenebis(3,4,6-trichlorophenol). |
| 87-86-5 | Pentachlorophenol and salts. |
| 88-06-2 | 2,4,6-Trichlorophenol. |
| 93-72-1 | 2,4,5-Trichlorophenoxypropanoic acid, esters and salts. |
| 93-76-5 | 2,4,5-Tirchlorophenoxyacetic acid, esters and salts. |
| 136-25-4 | 2,2-Dichloropropanoic acid, 2-(2,4,5-trichlorophenoxy)-ethyl esters. |
| 136-78-7 | 2-(2,4-Dichlorophenoxyethyl sulfate), sodium salts. |
| 299-84-3 | Phosphorothioic acid, 0,0-dimethyl 0-(2,4,5-trichlorophenyl) ester. |
| 1689-84-5 | 3,5-Dibromo-4-hydroxybenzonitrile. |
| 2300-66-5 | 3,6-Dichloro-o-anisic acid, dimethylamine salt. |
| 2463-84-5 | o-(2-chloro-4-nitrophenyl)o,o-dimethyl-phosphorothioate. |
| 3380-34-5 | 5-Chloro-2-(2,4-dichlorophenoxy) phenol. |

| Cas No. | Chemical name |
|---|---|
| 25167-83-3 | 2,3,4,6-Tetrachlorophenol. |
| 41198-08-7 | o-(4-Bromo-2-chlorophenyl)o-ethyl s-propyl phosphorothioate. |
| | (2,4-Dichlorophenoxy) acetic acid, esters and salts. |
| | 2,4,-Dichlorophenoxybutyric acid, esters and salts. |
| | 2-[2,4-(Dichlorophenoxyl] propionic acid, esters and salts. |
| | Chlorthiophos. |

EPA is proposing that manufacturers required to test under this rule submit for Agency review, within 6 months of the date of promulgation of the final rule (or 6 months after manufacture or importation resumes for those chemicals not in commercial production), chemical matrix-specific test protocols sensitive enough to quantitate to the 0.1 ppb level for the 2,3,7,8-HDDs and the 1.0 ppb level for the 2,3,7,8-HDFs. EPA proposes that these levels of quantitation (LOQ) be achieved through the use of high-resolution gas chromatography (HR GC) with high resolution mass spectral detection (HR MS), unless another method can be demonstrated to reach the target LOQs.

EPA will review the protocols and offer recommendations where necessary to ensure that the methods are capable of accurately and precisely measuring dioxins and dibenzofurans at the targeted levels. During this review process EPA will take into account the possibility that interferences may not allow quantitation to the levels specified and, in those cases where reasonable efforts have been made to reach the target LOQ, the Agency may agree to an analytical protocol which results in a higher LOQ.

To facilitate the development of extraction, cleanup and analysis procedures in these protocols, EPA will provide a guidance document titled, "Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products" (Ref. 20).

Within 1 year of the completion of EPA review of the protocols, test results must be submitted to EPA.

**B. Reporting Requirements Under Section 8**

Under section 8(a) of TSCA, EPA may require chemical manufacturers and processors to maintain such records and submit such reports as the Agency may reasonably require. EPA has determined that certain chemical manufacturers must submit information to assist the Agency in evaluating the risk from commercial chemicals potentially contaminated with 2,3,7,8-substituted HDDs/HDFs, subject to testing in the section 4 rule. The data required to be submitted under section 8 will be used to complete a comprehensive overview of uses, exposures, risks, and benefits of chemicals containing or potentially containing the 2,3,7,8-substituted HDDs/HDFs in order to assess the need for and nature of future regulatory control measures.

Under section 8(a) of TSCA, EPA is proposing that manufacturers of chemicals listed for testing submit, 90 days after promulgation of the final rule, any available test data, with necessary protocols, which show the results of any testing of their chemicals for concentrations of 2,3,7,8-substituted HDDs/HDFs. EPA will review the data and may exempt the manufacturer from any further testing under section 4 of TSCA.

Also under section 8(a) of TSCA, EPA is proposing to require manufacturers (except small manufacturers) of chemicals using any of the precusor chemicals listed below as feedstocks or intermediates to submit data on production volume, manufacturing process, reaction conditions, exposure, use and disposal for the manufactured chemicals. Precusor chemicals are not themselves contaminated, but can, during further processing and under certain reaction conditions, lead to formation of dioxins and furans in other chemicals. EPA is not aware of the circumstances under which these chemicals are used and the reaction conditions to which they are subject during manufacture of other chemicals. Should EPA learn from its data gathering process that reaction conditions favorable to dioxin and furan formation exist, EPA will review production, use, exposure and disposal data to determine whether a significant risk may exist and whether chemical products should be proposed for testing.

EPA also seeks comment on whether manufacturers of chemicals made from precursor chemicals should also be required to submit existing test data showing that the chemicals have been tested for the presence and levels of 2,3,7,8-HDDs/HDFs.

Precursor Chemicals

| Cas No. | Chemical name |
|---|---|
| 87-84-3 | Pentabromocyclohexane. |
| 89-64-5 | 4-Chloro-2-nitrophenol. |
| 92-04-6 | 2-Chloro-4-phenylphenol. |
| 94-74-6 | 4-Chloro-o-toloxy acetic acid. |
| 94-81-5 | 4-(2-Methly-4-chlorophenoxy) butryic acid. |
| 95-56-7 | o-Bromophenol. |
| 95-88-5 | 4-Chlororesorcinol. |
| 95-57-8 | o-Chlorophenol. |
| 97-50-7 | 5-Chloro-2,4-dimethoxyaniline. |
| 99-30-9 | 2,6-Dichloro-4-nitroaniline. |
| 615-67-8 | Chlorohydroquinone. |
| 827-94-1 | 2,6-Dibromo-4-nitroaniline. |

Also under section 8(a) of TSCA, EPA is proposing to require all manufacturers of chemicals tested and found to contain 2,3,7,8-substituted HDDs/HDFs at or above the LOQs to submit to EPA further information on the chemicals, including production volumes, process data, reaction conditions, exposure, use and disposal. This information will be submitted within 90 days after submission of test results showing contamination levels at or above the LOQs.

In addition, for those chemicals tested and found to contain 2,3,7,8-substituted HDDs/HDFs at or above the LOQs, EPA is proposing to require manufacturers to submit records of alleged adverse reactions to the tested chemicals under section 8(c) of TSCA and health and safety data on the tested chemicals under section 8(d) of TSCA. These data must be submitted within 90 days of submission of a test report showing contamination at or above the LOQs.

Also required under section 8 (c) and (d) are allegations of significant adverse reactions to any dibenzo-p-dioxin and any dibenzofuran, and health and safety studies on any dibenzo-p-dioxin and dibenzofuran. Manufacturers of any chemical listed in this rule for testing are required to submit allegations of significant adverse reactions to any dibenzo-p-dioxin and any dibenzofuran within 90 days after promulgation of the final rule. Any chemical manufacturer possessing health and safety studies on any dibenzo-p-dioxin and any dibenzofuran is required to submit such studies within 90 days after promulgation of the final rule.

EPA will require additional process data under section 8(a) of TSCA if the test results on a given chemical are not clear. Publication of a notice in the **Federal Register** may take place and list chemicals for which some manufacturers have shown no contamination and some manufacturers have shown contamination above the LOQs. This notice would request all manufacturers who have not reported process data under section 8(a) of TSCA to do so.

III. Organization of this Proposal

The remainder of this Notice is organized according to the findings EPA must make under section 4 of TSCA and the factors the Agency must take into consideration before it may issue rules under section 8 of TSCA.

Section 4 of TSCA authorizes EPA to require, by rule, that chemical manufacturers or processors conduct tests to develop data relevant to the determination that the chemicals do or

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do not present an unreasonable risk of injury to health or the environment. EPA must make a number of findings before it may issue a section 4 rule. Under section 4(a)(1)(A), EPA must find that a chemical may present an unreasonable risk of injury to health or the environment, that there are insufficient data and experience upon which the effects of activities involving the chemical can reasonably be determined or predicted, and that testing of the chemical is necessary to develop such data. Section 4(a)(1)(B) provides that, as an alternative to the unreasonable risk finding described in section 4(a)(1)(A), EPA may find that a chemical will be produced in substantial quantities and that it either enters or may reasonably be expected to enter the environment in substantial quantities or that there may be significant or substantial human exposure to the chemical.

Section 4(b) of TSCA requires EPA to deal with a number of issues before promulgating a testing rule. Section 4(b)(1) sets forth three additional issues to be included in a test rule. First, EPA must identify the chemical substances for which testing is required under the rule. Second, EPA is to include "standards for the development of test data." Such standards are defined in section 3(12) as a description of:

(1) The information relating to characteristics of the chemical for which data are being developed, and

(2) Any analysis that is to be performed on such data. Section 3(12) provides further that "to the extent necessary to assure that the data are reliable and adequate," test standards may include a prescription of:

(1) The manner in which data are to be developed,

(2) The specification of any test protocol or methodology,

(3) Any other requirement necessary to assure reliable and adequate data.

Third, section 4(b) requires EPA to specify the period within which persons required to conduct tests shall submit data to EPA. In determining the standards for development of test data and the period for submission of data, EPA's considerations shall include the relative costs of the various test protocols and methodologies that may be required and the reasonably forseeable availability of facilities and personnel needed to perform the testing required.

Section 4(b)(3)(B) sets forth the criteria for determining who should test. Persons who manufacture or intend to manufacture chemicals must test if EPA finds there are insufficient data upon which the effects of chemical manufacture can reasonably be determined or predicted; persons who process or intend to process chemicals must test if EPA makes such findings with respect to chemical processing; persons who manufacture or process must test if EPA makes such findings with respect to chemical distribution in commerce, use, or disposal. Section 4(b)(3) provides that two or more persons required to test may designate a party to conduct testing on their behalf. This provision, however, is not expected to be used for this rule.

Section 4(c) provides for exemptions from testing to avoid submission of duplicative data from different persons and provides for reimbursement of those who actually submitted the data. As explained further in unit IV.B.6, EPA does not expect these provisions to be used in this rulemaking.

Under section 8 of TSCA, EPA must determine the reasonableness of the information-gathering requirements based on the Agency's data needs and the costs of the regulation.

Accordingly, unit IV discusses most of the findings and considerations under section 4 of TSCA; unit V discusses costs of testing; and unit VI discusses the availability of testing facilities and personnel to perform the proposed testing. Unit VII discusses section 8 determinations. In addition, unit VIII discusses compliance and enforcement, unit IX describes the rulemaking record, and unit X lists references used by EPA in preparing this notice. Other regulatory requirements are discussed in unit XI.

## IV. Findings and Considerations

### A. Findings Under Section 4(a)

EPA has made three findings under section 4(a)(1)(A) of TSCA with respect to the 34 chemicals listed in unit II above. (These chemicals are also listed in § 766.20 of the proposed rule.) First, EPA finds that the chemicals may present an unreasonable risk of injury to health or the environment because they may be significantly contaminated with 2,3,7,8-substituted HDDs/HDFs, which may be highly toxic even at trace levels. Further, the cost of testing for the presence of these contaminants at the levels proposed by EPA is reasonable given the highly toxic nature of these dioxins/furans. Second, there are insufficient data upon which the effects of these chemicals on health or the environment can reasonably be determined because currently EPA has little, if any, data on the levels of dioxin or furan contamination or whether there is any dioxin or furan contamination. Third, EPA finds that analytical testing is necessary to develop data on contaminant levels because such testing is the only way to determine conclusively whether and at what levels dibenzo-p-dioxins and dibenzofurans are present.

#### *1. Unreasonable Risk*

EPA has concluded that 2,3,7,8-substituted HDDs/HDFs may be toxic at very low levels, that they may be present in certain chemicals, that their presence in these chemicals may present an unreasonable risk to humans and the environment, and that it is feasible in certain situations to alter process conditions to minimized their formation. In order to protect against the risk from HDDs and HDFs in a reasonable manner, it is necessary to first know where they are formed and at what levels. If the levels present unreasonable risk to health and the environment, EPA may take regulatory action to reduce them. If the levels do not present unreasonable risks to health or the environment, unnecessary regulation will be avoided and chemicals will be "cleared" from list of potentially contaminated products. Furthermore, as discussed in unit V, the costs of testing these chemicals at the levels proposed by EPA are reasonable given, the toxicity of 2,3,7,8-HDDs/HDFs.

a. Toxicity of 2,3,7,8-HDDs/HDFs

In evaluating the toxicity of the 2,3,7,8-substituted HDDs/HDFs, EPA considered strong evidence on the toxicity of 2,3,7,8-TCDD, i.e., data showing that a number of other 2,3,7,8-substituted chlorinated dioxins and dibenzofurans are qualitatively similar to 2,3,7,8-TCDD in their toxic action and other information indicating structural and chemical/biological activity similarities among all the 2,3,7,8-substituted chlorinated, as well as brominated, dioxins and dibenzofurans. EPA has concluded that for purposes of this rule it is prudent public health policy to assume that exposure to the other 2,3,7,8-substituted HDDs/HDFs would pose risks qualitatively similar to those posed by 2,3,7,8-TCDD. The reasons for this decision are discussed below.

The extreme toxicity of 2,3,7,8-TCDD is discussed in detail in EPA's February 1984 Ambient Water Quality Criteria (AWQC) document (Ref. 30) and in a number of other documents EPA has prepared for purposes of regulation. These include the Office of Research and Development's (ORD) Health Assessment Document (HAD) for 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD, 1,2,3,6,7,8-HxCDD, and 1,2,3,6,7,8,9-HpCDD (Ref. 31), the Office of Solid Waste (OSW),

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Health and Environmental Effects Profile (HEEP) for tetra-, penta-, and hexachlorodibenzo-p-dioxins (and the same congeners of dibenzofurans) (Ref. 32), a HEEP document for the brominated dioxins and another for the brominated dibenzofurans (Ref. 33), the Drinking Water Criteria Document (DWCD) prepared for the Office of Drinking Water (ODW) on 2,3,7,8-TCDD (Ref. 34), and a draft (HAD) document being prepared on the chlorine substituted dibenzofuran congeners of concern to EDF/NWF. Of particular note is the relative carcinogenic potency of 2,3,7,8-TCDD, which EPA's Cancer Assessment Group (CAG) estimated as the most potent of 55 suspect human carcinogens (Ref. 31). CAG ranks 2,3,7,8-TCDD as a 2–A carcinogen, which means that the chemical causes cancer in labortory animals and, therefore, may present a risk of cancer to humans. There is also suggestive epidemiological evidence that links 2,3,7,8-TCDD to the occurence of cancer, particularly soft tissue sarcoma, in humans. Cohort studies conducted in Sweden have associated soft tissue sarcomas with occupational exposure to phenoxy acid herbicides, some of which are contaiminated with 2,3,7,8-TCDD (Ref. 31). Although subsequent studies and discussion in the U.S. and elsewhere have added to the relevant information, the concern remains unresolved at this time (Refs. 6,10,13,14). Additional studies are in process which should clarify this issue (Ref. 11, 24 and 25).

Available data on 1,2,3,7,8-pentachlorodibenzo-p-dioxin (1,2,3,7,8-PeCDD), 1,2,3,4,7,8-hexachlorodibenzo-p-dioxin (1,2,3,4,7,8-HxCDD), 1,2,3,6,7,8-hexachlorodibenzo-p-dioxin (1,2,3,6,7,8-HxCDD), and 1,2,3,7,8,9-hexachlorodibenzo-p-dioxin (1,2,3,7,8,9-HxCDD), and 2,3,7,8-tetrachlorodibenzofuran (2,3,7,8-TCDF compared with the much more extensive data on 2,3,7,8-TCDD show that these other HDDs/HDFs are qualitatively similar in their toxic action to 2,3,7,8-TCDD. (See Refs. 5, 11, 12, 16, 24, 25, and 26.) These data suggest that the dioxins and dibenzofurans substituted at the 2,3,7 and 8 positions are relatively toxic congeners. Results are summarized below.

All animal species studies show very low median lethal doses in acute toxicity testing for all the 2,3,7,8-substituted chlorinated dioxins that have been tested. This is illustrated in mice, where 2,3,7,8-TCDD has an $LD_{50}$ value of 0.88 micromole (umol) per kg and 1,2,3,7,8-PeCDD, 1,2,3,4,7,8-HxCDD, 2,3,6,7,8,-HxCDD and 1,2,3,7,8,9-HxCDD have $LD_{50}$ values of 0.94, 2.11, 3.19, and 3.67 umol/kg, respectively. For 2,3,7,8-TCDF, the acute oral $LD_{50}$ in the guinea pig is reported to be 5 $\mu$g/kg/bw (as compared with the acute oral $LD_{50}$ for 2,3,7,8-TCDD in this species, which is 0.6 $\mu$g/kg/bw). Subchronic testing of 2,3,7,8-TCDF in rhesus macaques indiced that this compound is extraordinarily toxic. Based on EPA's review of this study, the no observed effect level (NOEL) for 2,3,7,8-TCDF is expected to be below 5.0 ppb. (Ref. 32). The author of this study concluded that continued daily oral intake of small amounts of 2,3,7,8-TCDF gave monkeys a disease which is clincially and morphologically similar to acute or chronic ingestion of 2,3,7,8-TCDD. For most of the observed biological effects, the potency of the two compounds is within an order of magnitude of each other, with 2,3,7,8-TCDF being slightly less toxic than 2,3,7,8-TCDD (Ref. 3). Some scientists have estimated that in laboratory animals, 2,3,7,8-TCDF is 2 to 33 percent less toxic than 2,3,7,8-TCDD, depending upon the particular effect studied. Further, the toxicity of 2,3,7,8-TCDF in rhesus macaques has been estimated to be about 20 times that of 3,4,4,5-tetrachlorobiphenyl, and 1,000 times more toxic than PCB Aroclor 1248, two of the suspected human carcinogens evaluated by CAG (Refs. 31 and 32).

Other chemical and biological indicators show strong similarities among many of the 2,3,7,8-substituted chlorinated dioxins and dibenzofurans. These similarities, discussed below, correlate with toxicity, persistence, and biodegradation—all factors that indicate these chemicals will cause similar effects on health and the environment.

All the 2,3,7,8-substituted HDDs/HDFs are structurally similar, with two benzene rings chlorinated or brominated at the 2,3,7 and 8 positions, joined by one oxygen bridge in the dibenzofuran molecule and two oxygen bridges in the dibenzo-p-dioxin molecule. This structural similarity between 2,3,7,8-TCDD/TCDF and the other 2,3,7,8-substituted HDDs and HDFs indicates a strong likelihood of very similar biological activity, with corresponding potential for toxic effect. These predicted similarities in biological activity and potential toxic effect are supported by data from studies discussed below.

Tests on the 2,3,7,8,-substituted chlorinated dioxins and dibenzofurans show that these compounds have similar ability to induce enzyme activity, a characteristic closely correlated with the degree of toxicity of a compound (Ref. 3). Comparison of *in vitro* studies shows that the 2,3,7,8-substituted chlorinated dioxins and dibenzofurans have similar ability to induce aryl hydrocarbon hydroxylase (AHH) in rat hepatoma cells at very low levels (Refs. 2 and 23) and have similar affinity to bind to the isolated hepatic aromatic hydrocarbon (Ah) cystolic receptor in certain species (Ref. 22).

The cellular biochemical mechanisms leading to the toxic response resulting from exposure to HDDs/HDFs are not known in complete detail. However, over the last few years experimental data have accumulated which suggest that an important role is played by this Ah receptor protein. This receptor binds halogenated polycyclic aromatic molecules, including HDDs and HDFs. In animals, the binding of 2,3,7,8-TCDD-related compounds to this receptor has been correlated with the expression of several systemic toxic effects, including sensitivity to acute toxic effects ($LD_{50}$ values), thymic involution, chloracnegenic response, and the induction of several enzymes systems, some of which have been linked to carcinogenic pathways (References 2 and 21).

All of the 2,3,7,8-chlorinated dioxins and dibenzofurans, tested show a high likelihood of persisting in the human body and the environment should exposure occur. All are lipophilic, have high octanol/water partition coefficients in the same range (between $10^5$ and $10^7$), are highly persistent under normal environmental conditions (particularly when adsorbed to soil or other substrates) and are generally degraded every little by microbes, and have extensive half-lives in the environment (in excess of 10 years for 2,3,7,8-TCDD (Ref. 32)).

Since bromine as a substituent is more toxicologically active than chlorine (Ref. 33), EPA believes it is prudent to assume that 2,3,7,8-substitued bromodibenzo-p-dioxins and bromodibenzofurans are as toxic as the corresponding chlorinated compounds for purposes of this testing regulation.

EPA has decided that the other halogenated dioxins and dibenzofurans (iodinated and fluorinated) are sufficiently different from the chlorinated and brominated compounds that it would be too highly speculative to include them in this proposed rule.

b. Estimates of Potential Exposure to HDDs/HDFs.

Toxicity and exposure are the two basic components of risk. In the previous unit, EPA summarized available information on the toxicity of 2,3,7,8-HDDs/HDFs and concluded that

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these materials are very toxic at low levels.

In order to estimate the potential for human exposure to 2,3,7,8-HDDs/HDFs which may be found in commercial products, EPA selected three levels of theoretical exposure encountered using three exposure categories. Using the CAG multistage linearized model discussed above, EPA calculated theoretical risks associated with Lifetime Average Daily Dose (LADD) values for each exposure level within each category, and explains below the calculation of risk estimates for the occupational and consumer use categories, which are the categories where significant risks are more likely to be encountered. In order to estimate the potential risks posed by exposures to 2,3,7,8-HDDs/HDFs in commercial products, EPA has assumed the LADDs represent exposures to 2,3,7,8-TCDD.

The Agency concludes that it is reasonable to expect that if these compounds are formed during the manufacturing of commercial chemicals, then exposures to them may arise because of the activities associated with the manufacturing, processing, distribution, use or disposal of the chemicals.

c. Risk Estimates for Persons Exposed to HDDs/HDFs.

EPA has estimated the level of risk associated with human exposures to a household cleaner which contains a chemical theoretically contaminated with 2,3,7,8-TCDD at both the 1.0 ppm and 0.1 ppb level, and for occupational dermal exposures encountered during organic chemical synthesis based on the physicochemical characteristics of 2,4-dichlorophenol (density, etc.) at these same levels. The levels were chosen to represent a range bounded by the approximate average concentration of dioxins reported in chemicals and products (Ref. 37) and the level specified in the Environmental Defense Fund/National Wildlife Foundation petition for total dioxins (Ref. 8). For purposes of this assessment, EPA has assumed that the dioxin present in the feedstock chemical is exclusively 2,3,7,8-TCDD.

*1. Risk Estimates for Household Cleaner Exposures*

EPA has calculated the LADD for a household cleaner used at full strength on a sponge or rag, and theorizes that the contaminated constituent of the cleanser passes through the sponge or rag, contacting the palm and fingers of one hand resulting in dermal exposure to HDDs/HDFs. The exposure model assumes that the cleaner contains 4.5 percent by volume of the contaminated chemical, i.e., every liter of the cleaner contains 45 ml. of the contaminated chemical.

The surface area exposed is calculated at 200 $cm^2$, consisting of one-fifth of the outstretched palm and fingers of one hand. The rate of skin adhesion is calculated at $1.5\times10^{-3}$ $ml/cm^2$, which expresses a measurement of the thickness of the film of water in which the cleaner is dispersed, which remains on the hand after one partial wipe of the cleaning rag or sponge. Absorption of the dispersed cleanser film is assumed to be 100 percent.

The frequency of exposure (number of events per year) is estimated at 52, assuming one use of the cleaner per week, at 52 weeks per year. The average adult body weight is assumed to be 70 kg, and the average life span is assumed to be 70 years.

The LADD is calculated by multiplying the 70-year assumed life span by the annual exposure ($\mu g/yr$), divided by the product of the number of days per average life span (25,550) and the assumed average adult body weight, 70 kg.

At 1.0 ppm, the LADD is estimated at $2.7\times10^{-5}$ $\mu g/kg/day$. Using the CAG risk assessment model for 2,3,7,8-TCDD [$Ql^*(slope)=1.6\times10^5$ $(ng/kg/day)^{-1}$], this LADD would correspond to an upper limit risk level of $4\times10^{-3}$. At 0.1 ppb, the LADD is estimated to be $2.7\times10^{-9}$. Using the CAG risk assessment for 2,3,7,8-TCDD, this LADD corresponds to $4\times10^{-7}$ upper limit risk level.

Thus, dioxin contamination of 0.1 ppb to 1.0 ppm in a chemical which is ultimately used to formulate a household cleaner could present upper limit oncogenic risks in the range of $4.0\times10^{-7}$ to $4\times10^{-3}$, depending on the level of contamination.

*2. Risk Estimates for Occupational Dermal Exposure*

EPA has calculated the LADD for occupational dermal exposures encountered during organic chemical synthesis on the basis of exposure to a chemical with the physicochemical properties of 2,4,-dichlorophenol. The surface area (S) exposed is assumed to be the entire surface area of both hands, estimated at $8.7\times10^{-2}$ $cm^2$. The thickness of the liquid film (T) left on the hands after exposure is calculated at $1.8\times10^{-3}$ cm, which is calculated as the average film thickness of five representative solutions. The frequency (F) of exposure occurrence (events per year) is estimated at 250, the average number of work days per year. Density of the liquid (D), based on the density of 2,4,-dichlorophenol, is estimated at 1.3 $g/cm^3$. The daily exposure (DX) are calculated in $\mu g/kg/day$ at the two levels of contamination (C, in $\mu g/g$) as follows:

$$\frac{S \times T \times D \times C}{\text{70 kg body weight}}$$

Annual exposures (AX) are calculated in $\mu g/kg/yr$ as follows:

$S \times T \times D \times C \times F$

The calculation of the LADD values for the two levels of contamination are explained above under the household cleaner risk estimate calculation.

At the 1.0 ppm level the LADD value is calculated at $2.11\times10^{-2}$ $\mu g/kg/day$. Using the CAG risk assessment model for 2,3,7,8-TCDD [$Q_1^*=1.6\times10^{-5}$ $(ng/kg/day)^{-1}$], this LADD corresponds to an upper limit level of oncogenic risk which EPA projects very close to unity (a theoretical 1 in 1 occurrence, with probability too close for the CAG risk assessment model to calculate). At 0.1 ppb, the calculated LADD value of $2.11\times10^{-6}$ corresponds to a $3\times10^{-4}$ upper limit risk estimate or oncogenic risk. Thus, EPA's model indicates that exposures to chemicals contaminated with HDDs/HDFs (assumed to be as potent as 2,3,7,8-TCDD) during the synthesis of organic chemicals could result in a range of upper limit oncogenic risks from $3\times10^{-4}$ to near unity.

A detailed description of the assumptions outlined above and the calculations performed for event exposure, annual exposure, and LADD values is contained in Reference 37.

As the discussion above indicates, chemical analysis for 2,3,7,8-substituted dioxin congeners at the tenth of a part per billion (ppb) level per congener is necessary to determine exposure levels that may present an unreasonable risk of harm to human health or the environment.

d. Case Study of the Feasibility of Minimizing Dioxin/Furan Contamination During Manufacture

Evidence that the amount of 2,3,7,8-TCDD formed during product chemical reactions can be reduced was presented during the cancellation hearings for the herbicide 2,4,5-T (Ref. 7). During those hearings, Dow Chemical Co. presented testimony describing modifications to production processes which reduced the 2,3,7,8-TCDD content in 2,4,5-T to a level of 0.01 ppm or lower. In 1976, Dow began efforts to remove 2,3,7,8-TCDD in final products, and investigated the possibility of altering reaction process

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conditions to reduce 2,3,7,8-TCDD formation, thereby lowering the content formed during the actual production process.

DOW initially experimented with activated charcoal bed absorption, which allowed a 50 percent reduction in the levels of 2,3,7,8-TCDD in 2,4,5-T reaction product. Additional efforts included eliminating delays and reducing the duration of the reaction process, precise temperature control during the production process, and modification of the alkalinity (pH) of the process. These additional modifications of the reaction process allowed an additional 50 percent reduction (approximate) in the 2,3,7,8-TCDD content of the product.

As evidenced by this example, the reduction of dioxin contamination in commercial products through the manipulation of the reaction chemistry and conditions of process stream is a very real option. The economic feasibility of the process is also viable; Dow stated that should the production of 2,4,5-T be resumed, a level of 0.01 ppm 2,3,7,8-TCDD or below could be met as a process specification in manufacturing the product. This example demonstrates that dioxin contamination can be reduced through direct manipulation of the process chemistry and reaction conditions at a cost consistent with market price requirements.

e. Determination of Unreasonable Risk

EPA has considered the toxicity of 2,3,7,8-HDDs/HDFs, their structure-activity relationship, and the potential for exposure to them if present as contaminants in commercial chemical products. The example outlined in section (d) above illustrates the practicality of reducing or eliminating the amount of 2,3,7,8-TCDD contamination through manipulation of the production process. The cost of testing in this proposed rule is expected to remain under 3 million dollars, generated primarily by the synthesis and manufacture of analytical standards, development of cleanup, extraction, and test methodologies, and analysis of sample series. In balancing the cost of the testing proposed in this rule with potential risks which may result from exposures to 2,3,7,9-HUDDs/HDFs, EPA finds that the cost involved in generating data enabling a reasonable and accurate determination of risk is not excessive. The discussion of risk estimates above illustrates the necessity for levels of quantitation at the 0.1/1.0 ppb level. Although the testing costs are not inexpensive, these levels of quantitation are necessary for each congener of 2,3,7,8-HDDs/HDFs because these levels of exposure may be encountered in actual situations and may present a risk of concern. Even if the levels of quantitation were less sensitive, the incremental decrease in cost experienced in achieving these levels would not significantly decrease the overall costs of the proposed rule. (See Unit V.)

EPA is considering setting different levels of quantitation for each HDD/HDF based on the relative toxicities of the HDDs/HDFs expected to be present in the chemical (Ref. 3). The Agency requests comments on the utility of this method for use in the final rule.

These levels do not, however, constitute an "action level" under section 6 of TSCA, nor under any other statute. Under TSCA that level is dependent upon the Agency first making a determination that the reduction of risk to health or the environment outweighs the cost of society of such reduction. An action level under section 6 would be determined by many factors, including incremental risk reductions to exposed groups by alternative limits on dioxin and dibenzofuran concentrations in commercial chemicals, and the cost of reducing risks at each alternative level. For this purpose EPA must review data on toxicity, exposure, cost, availability of substitutes, and availability of technology. Using this process, it is likely that the "action level" for each chemical subject to a regulation under section 6 will be somewhat different.

*2. Insufficiency of Data and Experience*

With the exception of extensive data on 2,3,7,8-TCDD and some data on several related congeners as discussed in the preceding unit on toxicity, EPA has little or no data upon which to base a determination of toxicity or exposure for the chemicals listed for testing. These determinations are basic to a finding of unreasonable risk. Therefore, EPA is proposing that such data be developed, and that such testing be required in order to provide this data.

*3. Necessity for Testing*

EPA has determined that testing is necessary to generate data on which to base toxicity and exposure, because such data is fundamental to the assessment of risk, and because the analytical data generated by required testing in this proposed rule is currently not available in any accessible or usable form for purposes of assessing these potential risks.

**B. Findings Under Section 4(b)**

*1. Identification of Substances to be Tested*

EPA chose the chemicals for testing based on two broad criteria. Some chemicals have actually been tested in the past and found to contain 2,3,7,8-substituted HDDs/HDFs. The others are chemicals which EPA has good reason to believe are contaminated based on structural similarities with the chemicals actually tested and process conditions considered to aid the formation of dioxins and dibenzofurans. Thus, these listed chemicals contain carbon and utilize chlorine and/or bromine in their manufacture and are manufactured under circumstances that include high temperature or pressure and the presence of alkaline conditions.

Contamination of the listed chemicals is expected to occur during manufacture. Thus, the focus of the testing is on detecting contamination at the beginning of the manufacturing chain to allow EPA to draw conclusions about the degree of contamination during further processing of the chemical.

a. Chemicals to be Tested

The 34 chemicals to be tested are listed under unit II.A of this preamble and § 766.20 of this rule. The 14 chemicals in current commercial production will be immediately affected by promulagtion of this rule. The 20 chemicals not currently in commercial production will be affected should commercial production begin or resume.

b. Test Substance

EPA is proposing that manufacturers test chemicals which are listed in this proposed rule in all grades normally marketed in active commerce. This definition is purposely broad, in order to include as many forms and grades as are routinely found in the marketplace, but eliminates the requirement for testing of specialty chemicals prepared only on special order or in extremely small quantities on a custom basis, e.g., research quantities of analytical purity.

*2. Standards for the Development of Test Data*

This term is defined under section 3(12) of TSCA and refers to the prescription of the information for which test data are to be developed and any analysis to be performed on such data. It also includes the manner in which the data are to be developed, the specification of any test protocol or methodology, and any other requirements needed to provide assurance of the reliability and

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adequacy of the data. These standards should be differentiated from analytical standards.

a. General Analytical Method Consideration

The analytical procedures specified in this proposed rule for the quantitative measurement of 2,3,7,8-HDDs/HDFs in commercial products include: (1) the quantitative extraction or partitioning of the analytes from the commercial product; (2) separation of the 2,3,7,8-HDDs/HDFs from interferences present in the extract; and (3) separation and quantitation of 2,3,7,8-substituted tetra-, hepta-, penta- and hexa-DD/DF congeners, using high-resolution gas chromatography and high-resolution mass spectrometry.

The most significant difference in the analysis of 2,3,7,8-HDDs/HDFs in commercial products in comparison with environmental and biological samples will be the extraction and cleanup procedures. The physical and chemical properties of environmental and biological matrices are typically different enough from the properties of the analytes to allow relative ease of separation. In contrast, the commercial products, in most cases, may be structurally similar to the analytes, complicating the separation and necessitating the complete removal of the matrix to avoid interferences in the final determination.

b. Detection Method

The extreme toxicity of certain 2,3,7,8-HDD/HDF congeners at very low levels of exposure necessitates analytical methods with very high sensitivity and specificity. EPA is specifying the use of high-resolution gas chromatography with high-resolution mass spectrometry (HRGC/HRMS) as the chemical analysis method of choice for this proposed rule.

HRGC is one of the most effective ways of separating the product chemical from 2,3,7,8-HDDs/HDFs and other similar impurities or byproducts which are present in solution following extraction and cleanup of the product chemical. It may be possible to use liquid chromatography to separate HDDs and HDFs from the product, byproducts, and other impurities in a product extract. EPA requests comment and further information on the application of these and other separation techniques to the analysis of halogenated chemical products for HDDs and HDFs.

HRGC optimizes separation of all components of an extract into a form that is most amenable to mass spectrometric detection. The analysis of trace amounts of 2,3,7,8-HDDs/HDFs, even when separated by HRGC, requires special selective detectors to identify and measure them. EPA is specifying high resolution mass spectrometry (HRMS) as the method of identification and measurement of 2,3,7,8-HDDs/HDFs in the extract separated by HRGC as outlined above.

EPA considered two other potentially useful detectors, electron, capture (EC) and low resolution mass spectrometry (LRMS), but believes that these methods are not sufficiently sensitive or specific to confirm unequivocally the presence of other similar compounds which are present in larger amounts or the same amounts as the 2,3,7,8-HDDs/HDFs. Triple quadrupole mass spectrometry (MS/MS) was also considered but EPA believes it has not been demonstrated to be sufficiently reproducible for most applications in this proposed rule.

HRMS provides more precise mass determination than is available using LRMS. Mass determination with relevant mass intensity ratio comparisons provides confirmation of the identity of chemicals separated by HRGC.

Even though EC may be as sensitive, or more sensitive than HRMS, the detection is based on the capacity of a chemical compound to capture electrons. This electron capture capacity cannot satisfactorily distinguish between the very broad class of halogenated hydrocarbon compounds (which include 2,3,7,8-HDDs/HDFs) and many other broad classes of compounds which are detected by EC. Non-2,3,7,8-HDD/HDF compounds which are impurities or byproducts present in the product chemical extract separated by HRGC are very likely to be detected by EC. EC does not have sufficient selectivity to distinguish between: (1) chlorinated/brominated compounds and other halogenated compounds; or (2) 2,3,7,8-HDDs and HDFs and other halogenated aromatic compounds. The selectivity to distinguish among these halogenated compound classes is essential to resolve the confounding of the analysis by the expected presence in the product extract of chemicals in all of these halogenated compound classes. Even more importantly, this proposed rule requires the still greater selectivity *within* these large halogenated compound classes, namely differences in levels of chlorination/bromination within 2,3,7,8-HDDs and distinction between 2,3,7,8-HDDs/HDFs.

Major advances in analytical capabilities for the HDFs during the last 2 years include the development and extensive use of chemical ionization (CI) and the use of CI in a triple-quadrupole mode. Detection limits in the range of parts per trillion (ppt) have been obtained using these techniques. EPA considers either of these two techniques as having potential for the analysis of HDDs and HDFs in commercial products, but these methods are not yet validated or standardized for use at the levels EPA is specifying in this proposed rule. For these reasons, EPA chose HRGC/HRMS as the analytical method in this proposed rule. EPA seeks comments on the adequacy of the analytical methods outlined above, in terms of achieving reliable data at the levels of detection specified in this proposed rule.

c. Method Sensitivity

A chief concern in using any analytical method is the ability to achieve the desired level of detection. The detection limits reported for various HDDs and HDFs in phenoxyalkanoic herbicides range from 5 to 500 ppb. A detection limit of 0.05 ppb can be achieved for specific congeners of TCDD and TCDF assuming a conservative instrument sensitivity (quadrupole MS) and a 1 μl aliquot from a 200 μl final extract of a 1 gram sample. By increasing initial sample size, decreasing final extract volume, or employing a more sensitive MS (magnetic sector double-focusing) instrument, this detection limit might be lowered to 0.01 ppb or 1.0 part per trillion (ppt). These detection limits are determined largely by the sensitivity of the instrument, and sample interferences may sequentially increase the detection limit attainable for a given matrix. EPA is proposing a detection limit of 0.1 ppb for 2,3,7,8-HDDs and 1.0 ppb for 2,3,7,8-HDFs. Using data reported at these limits of detection, the potential risks associated with exposure to 2,3,7,8-HDDs/HDFs in commercial products may be calculated (See Unit IV.A.l.c for a detailed discussion of risk assessment calculated for 2,3,7,8-HDDs/HDFs at the ppb level of exposure). EPA seeks comments on the appropriateness and feasibility of this proposed analytical detection limit.

d. Quality Assurance/Quality Control (QA/QC) Procedures

The first QA/QC procedure is the requirement of a Quality Assurance Plan (QAP). The QAP should include the following: history and disposition of samples, sampling and sample collection procedures, and extraction and instrumental analysis procedures. The QAP documents how the laboratory intends to demonstrate its capability to produce data which meet data quality requirements.

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An accurate trace or history of the life of a sample to be chemically analyzed for 2,3,7,8-HDDs/HDFs must be assembled and should contain information beginning with a description of the system, scheme, or survey design for sample collection. A written record, called a chain-of-custody form, shall follow the sample. Necessary contents of the record are written general descriptions of what happens to the sample, schedules and timetables, disposition, handling, and who has custody. Following final chemical analysis, the last entry in this record should be the disposition of the sample. Any further use (particularly for another activity), movement, or examination of the sample should be added to the history.

Details of the sampling or sample collection procedure are the second section of the QAP. Since the history describes handling, disposition, schedules, and general descriptions of what happens in sampling, the requirement here is a detailed description of sampling and sample collection. Reasons for using a specific or general sample selection process and reasons for not using others must be included here. Estimates of how well the selected samples represent the material to be characterized are an essential part of QA. The greater the variability of composition of a material, the more frequently sampling is required for estimation and quantification purposes. In determining or estimating errors generated in sample collection, control samples or blanks, and 2,3,7,8-HDDs/HDFs (native compounds or, preferably, isotopically labelled compounds) reinforced controls or analytical standards, must be sent to the collection site(s) and returned with the samples for identical handling and treatment. Duplicate samples, which are collected, documented, and handled the same as other samples, are necessary for recovery, precision, and accuracy determinations.

The third section of the QAP is a description of the extraction and chemical analysis or screening test procedures. To determine both extraction, efficiency and measurement efficiency, it is necessary to use analytical standards of isotopically labelled 2,3,7,8-HDD/HDF mixtures or individual isotopically labelled 2,3,7,8-HDD/HDF compounds in control samples. Once capabilities have been established, the operator must determine precision and accuracy and use those determinations to designate acceptable bounds for analytical performance. The operator must keep control chart records to assure that the instrument readings of analytical standards fall within the range of acceptable performance. The operator must establish and describe the quantitative range of an instrument and analytical procedure. Specific requirements are as follows:

For chemical analysis, procedures must be demonstrated to be capable of reproducibly and repeatedly to quantitate 2,3,7,8-HDDs at 0.1 ppb resolvable peak, and 2,3,7,8-HDFs at 1.0 ppb per resolvable peak. Quality control check sample analysis begins the determination of system capabilities. Sets of samples shall be constructed such that no less than one sample set shall be analyzed in a single workday shift. A single set shall contain at the minimum: Calibration standards, method blanks, product samples, and another set of calibration standards, in that order. The calibration standard should contain each 2,3,7,8-substituted congener at concentrations capable of reinforcing a product sample to a product concentration of 0.1 ppb for 2,3,7,8-HDDs and 1.0 ppb for 2,3,7,8-HDFs. A method blank is a sample which has no product but is generated by treating an empty sample container with all of the same steps used in the cleanup, extraction, and chemical analysis of a product sample. A set not meeting the performance criteria below or not having a method blank with nondetected levels of native HDDs/HDFs shall require corrective action checking, and the set must be rerun with reports and explanations for the results from both sets.

For 2,3,7,8-HDDs, to demonstrate the requirement of a limit of quantitation of 0.1 ppb at least two analyses of the same isotopically labelled 2,3,7,8-HDD internal calibration standard spiked to a concentration of 0.1 ppb in a product must be quantifiable to within ±10 percent of each other. The limit of quantitation shall be determined by recovery of the internal calibration congeners which have been spiked into the product sample following sampling but before sample cleanup and extraction. The recovery of the internal calibration standard which has run through the entire chemical analysis must be within 70–130 percent of the amount spiked, or documented corrective actions must be taken and the sample set must be rerun.

For 2,3,7,8-HDFs, to demonstrate the requirement of a limit of quantitation of 1.0 ppb, at least two analyses of the same isotopically labelled 2,3,7,8-HDF internal standard spiked to a final concentration of 1.0 ppb in a product must be quantifiable to within ±10 percent of each other. The limit of quantitation shall be determined by recovery of the internal calibration standard congeners which have been spiked into the product following sampling but before sample cleanup and extraction. The recovery of the internal calibration standard which run through the entire chemical analysis must be within ±70–130 percent of the amount spiked or documented corrective actions must be taken and the sample set must be rerun.

Qualitative requirements include (1) response factors for 2,3,7,8-HDDs and HDFs to be measured and (2) instrument hardware and operating conditions (including type and source of column, carrier gas, flow rate operating temperature range, and ion source temperature). For both qualitative and quantitative measurements, the instrument operator should be blind to the nature or source of samples, particularly to duplicates, blanks, and brominated or chlorinated dibenzodioxin/diberzofuran enriched samples.

The limit of detection (LOD) and the limit of quantification, (LOQ) shall be described for each material. Tentative LOD and LOQ definitions are greater than or equal to 3 times background noise (LOD); and greater than or equal to 10 times background noise (LOQ). Details of quantitative calibration procedures for the known and/or expected range of the 2,3,7,8-HDD/HDF levels in actual samples complete this section of the QAP.

Finally, the last section of the QAP must include the results of laboratory participation in round robin analytical programs, the results of performance audits, systems audits, analytical result of performance audit samples, persons responsible for all aspects of sampling, chemical analysis, data analysis, corrective actions, and quality assurance/quality control. This section of the QAP must also include a description of how problems are handled and documented and how corrections in working level notebooks are indicated and explained.

e. Analytical standards

In using HRGC/HRMS to perform the analysis, several possible methods of quantitation were examined, based on analytical standards of 2,3,7,8-HDD/HDF compounds in concentrations similar to the concentration range of interest (0.1 ppb for 2,3,7,8-HDDs and 1.0 ppb for 2,3,7,8-HDFs) found in chemical products to be tested. Analytical standards must be reasonable

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surrogates for 2,3,7,8-HDDs and HDFs with respect to response, retention time, and resolvability from other materials in the extract, and the surrogate standards must not interfere with the response, retention time, and resolvability of the 2,3,7,8-HDDs and HDFs.

Quantitation must be based on internal standards. The use of internal standards can provide continuous monitoring of extraction efficiency and method precision in the analysis of actual product samples, and thus the internal standards may provide information on matrix effects. The best surrogates to use as internal standards are 2,3,7,8-HDDs and HDFs with selected positions having been substituted with the same atoms but having a different isotope (and atomic mass) from native compounds. The isotopes may be deuterium for native hydrogen, carbon-13 or carbon-14 for native carbon, and chlorine-37 for native chlorine. The internal standards labeled with these isotopes have total masses and fragmentation masses which are significantly different from the total masses and fragmentation masses of the native compounds, such that there is no interference with identity and quantitation of the native 2,3,7,8-HDDs and HDFs using mass spectrometry.

External analytical standards have restricted capability to check extraction efficiency at the limit of quantitation. In addition, external standards may not provide adequate information on the true limit of quantitation which is affected by the actual product matrix. Since an external standard is not in a product sample extract, there is no potential interference with 2,3,7,8-HDDs and HDFs in an actual product sample, and the external standards may be native compounds.

A chemical product may be analyzed (1) solely by the use of internal analytical standards, or (2) at least one sample must be analyzed by using an internal standard (to evaluate extraction and matrix interferences), and the other samples may be analyzed using external standards only when response of the external standards is converted to the response observed for internal standards as proven in a valid comparison study.

Since the HDD and HDF compounds of greatest concern are those substituted at the 2,3,7,8 positions, EPA is specifying that these compounds be used as reference standards. Isotopically labelled standards shall be used as internal standards. Native standards may be used as internal standards for the special case using duplicate pairs of samples, as described earlier.

This rule requires quantitation for the following 2,3,7,8-substituted compounds:

| Chlorinated compounds | Brominated compounds |
|---|---|
| 2,3,7,8-TCDD | 2,3,7,8-TBDD |
| 1,2,3,7,8-PeCDD | 1,2,3,7,8-PeBDD |
| 1,2,3,4,7,8-HxCDD | 1,2,3,4,7,8-HxBDD |
| 1,2,3,6,7,8-HxCDD | 1,2,3,6,7,8-HxBDD |
| 1,2,3,7,8,9-HxCDD | 1,2,3,7,8,9-HxBDD |
| 1,2,3,4,6,7,8-HpCDD | 1,2,3,4,6,7,8-HpBDD |
| 2,3,7,8-TCDF | 2,3,7,8-TBDF |
| 1,2,3,7,8-PeCDF | 1,2,3,7,8-PeBDF |
| 2,3,4,7,8-PeCDF | 2,3,4,7,8-PeBDF |
| 1,2,3,4,7,8-HxCDF | 1,2,3,4,7,8-HxBDF |
| 1,2,3,6,7,8-HxCDF | 1,2,3,6,7,8-HxBDF |
| 1,2,3,7,8,9-HxCDF | 1,2,3,7,8,9-HxBDF |
| 2,3,4,6,7,8-HxCDF | 2,3,4,6,7,8-HxBDF |
| 1,2,3,4,6,7,8-HpCDF | 1,2,3,4,6,7,8-HpBDF |
| 1,2,3,4,7,8,9-HpCDF | 1,2,3,4,7,8,9-HpBDF |

EPA realizes that industry may have to develop analytical standards for PHDD/PHDF analysis in order to achieve the analytical accuracy and precision specified in this proposed rule. EPA has identified the following specific congeners as available for use as reference analytical standards:

CURRENTLY AVAILABLE DIBENZODIOXIN AND DIBENZOFURAN STANDARDS

| Unlabeled | Stable isotope labeled |
|---|---|
| **Dibenzodioxins** | |
| Tetrachloro: 2,3,7,8 | 2,3,7,8 ($U^{-13}C^{12}$, 99%)<br>2,3,7,8 ($U^{-37}Cl$, 96%)<br>2,3,7,8 ($U^{-14}C$, 33mCi/mmol) |
| Tetrabromo: 2,3,7,8 | 2,3,7,8 ($U^{-13}C^{12}$, 99%) |
| Pentachloro: 1,2,3,7,8 | 1,2,3,7,8 ($U^{-13}C^{12}$, 99%) |
| Pentabromo: 1,2,3,7,8 | 1,2,3,7,8 ($U^{-13}C^{12}$, 99%) |
| Hexachloro: 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; 1,2,3,7,8,9. | 1,2,3,6,7,8/1,2,3,7,8,9 ($U^{-13}C^{12}$, 99%) |
| Hexabromo: 1,2,3,4,7,8; 1,2,3,6,7,8,/1,2,3,7,8,9. | 1,2,3,6,7,8,/1,2,3,7,8,9 ($U^{-13}C^{12}$, 99%) |
| Heptachloro: 1,2,3,4,6,7,8 | 1,2,3,4,6,7,8 ($U^{-13}C^{12}$, 99%) |
| Heptabromo: 1,2,3,4,6,7,8 | |
| **Dibenzofurans** | |
| Tetracholoro: 2,3,7,8 | 2,3,7,8 ($U^{-13}C^{12}$, 99%) |
| Tetrabromo: 2,3,7,8 | 2,3,7,8 ($U^{-13}C^{12}$, 99%) |
| Pentachloro: 1,2,3,7,8; 2,3,4,7,8. | 1,2,3,7,8 ($U^{-13}C^{12}$, 99%) |
| Pentabromo: 1,2,3,7,8 | 1,2,3,7,8 ($U^{-13}C^{12}$, 99%) |
| Hexachloro: 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; 2,3,4,6,7,8. | 1,2,3,4,7,8 ($U^{-13}C^{12}$, 99%) |
| Hexabromo: 1,2,3,4,7,8 | 1,2,3,4,7,8, ($U^{-13}C^{12}$, 99%) |
| Heptachloro: 1,2,3,4,7,8,9; 1,2,3,4,6,7,8. | 1,2,3,4,6,7,8 ($U^{-13}C^{12}$, 99%) |

### 3. Period for Submission of Test Data

EPA is proposing that manufacturers subject to the testing requirements of this rule submit protocols developed for the analytical methodology within 6 months after promulgation of a final rule, and that test results for the chemicals listed under unit II.A. of this preamble and § 766.20 of this rule be submitted no later than 1 year after EPA review of protocols for analytical methodology. Notification of EPA review of protocols and any comments will be accomplished by a letter to the manufacturer.

These submission dates apply to chemicals in production at the time this proposed rule becomes final. For those chemicals listed for testing which commence or resume production after the effective promulgation date of the final rule, submission dates will be within 6 months after the commencement or resumption of production for submission of test protocols, and within 1 year after EPA review of protocols for the submission of data developed.

The 1-year period for testing may be considerably more time than is needed to perform the actual extraction, cleanup and analysis. However, this amount of time allows an adequate utilization of available facilities without preempting other dioxin analysis work.

EPA requests comment on staging the testing period so that methods and results from testing of chlorinated compounds are received before the methods development and testing of brominated compounds occurs. Since very little testing of brominated compounds has been done, a staged requirement would allow time to work with the method on chlorinated compounds before modifying it for brominated compounds. Staging the testing would also free up additional laboratory capacity.

### 4. Persons Required to Test

EPA has found that there is insufficient data and experience upon which to reasonably determine or predict the effects of the manufacture, processing, distribution in commerce, use and disposal of the chemicals subject to the testing requirements of this rule (see unit I and unit VII 3). Therefore, in accordance with section 4(b)(3)(B) of TSCA, manufacturers and processors are responsible for testing. EPA expects, however, that only manufacturers will be subject to the provisions of this proposed rule, since only manufacturers should be expected to test for contamination in their products.

Persons who manufacture or who intend to manufacture the chemical substances listed under unit II.A of the preamble and § 766.20 of this rule at any time from the effective date of the final test rule to the end of the reimbursement period shall be subject to the testing requirements contained in this proposed rule. The end of the reimbursement period will be 5 years after the last final report on testing required in the final rule has been submitted.

Once this test rule is in effect (44 days after publication in the **Federal Register**), each current manufacturer

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will have 30 days to submit either a letter of intent to perform the testing required or an application for exemption. Each manufacturer who submits a letter of intent to perform the specified testing will be obligated, first, to submit within 6 months of the effective date of the test rule a proposed study plan for that test and, ultimately, to perform testing.

Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790. In the case of the chemical substances listed in proposed § 766.20(a), EPA does not expect to grant exemptions under section 4(c) unless persons who manufacturer or intend to manufacture the chemical substances listed under § 766.20(a) provide information on starting materials, process conditions, and reaction conditions which demonstrate that their substance or mixture is substantially similar to those of another manufacturer subject to this proposed rule. Because of the wide variation in chemical process streams involving different reaction conditions of temperature, pressure, reaction time, types of reaction vessels, and transport equipment, EPA is proposing that each manufacturer individually test the chemical substances which they produce and develop data which will be "process-specific" for their individual product. EPA expects that these data will be unique for each chemical substance and each manufacturer and will ensure that the particular process conditions which influence the production of these chemicals are taken into account.

Chemical analysis methodologies and protocols may be developed by consortia, multilaboratory studies, or round robin studies. These cooperative situations not only may reduce the overall costs, but may so allow for evaluation of the effectiveness of several closely related protocols or operating procedures for the same kinds of products. Even though methodologies are cooperatively developed, however, all participants in the cooperative are still required individually to analyze their own products and report their own results.

It is expected that in all cases subject to this rule, testing will be performed by the manufacturers and that part of the cost of testing will be passed on to the processors through the pricing mechanism, thereby enabling them to share in the costs of testing. However, processors will be called upon to sponsor testing if manufacturers fail to do so, or processors may be required to provide reimbursement directly to those sponsoring this testing. If no manufacturer submits a letter of intent to perform testing within the 30-day period, EPA will publish a notice in the **Federal Register** to notify all processors of the subject chemical. The notice will state that EPA has not received letters of intent to perform testing and that current processors will have 30 days to submit either a letter of intent to perform the test or an exemption application for such testing. Each processor who submits a letter of intent to perform testing will be obligated to submit within 6 months of the publication of the **Federal Register** notice a proposed study plan and, ultimately, to perform testing.

If no manufacturer or processor submits a letter of intent to perform testing, EPA will notify all manufacturers and processors, either by notice in the **Federal Register** or by letter, that all exemption applications will be denied and that within 30 days all manufacturers and processors will be in violation of the rule until a proposed study plan is submitted for required testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790.

*5. Bioanalytical Screening Methods*

EPA recognizes that the analyses required to detect 2,3,7,8-HDDs/HDFs at the extremely low levels specified in this proposed rule are time consuming, laborious, and more costly than normal chemical analyses. In addition, the Agency recognizes that the number of laboratories adequately equipped and staffed with personnel qualified to perform these analyses is limited. Recognizing these limiting factors, EPA considered the possibility of giving manufacturers the option of conducting a less costly general screen to determine whether the full-scale analysis proposed would be necessary. If the manufacturer performed a general screen which showed no 2,3,7,8-HDDs/HDFs to be present at 0.1 ppb, full-scale analysis would not be required. Conversely, if the general screen yielded a positive result, testing to confirm and quantitate the 2,3,7,8-HDD/HDF level would be required. EPA first considered the use of a chemical screen, but found none suitable primarily because of the extremely high rate of false positives that result from product matrix interference.

EPA is continuing to investigate the possibility of using bioanalytical techniques as potential general screening methods in the interest of reducing time and resources for the testing. Bioanalytical techniques currently being examined by EPA include radioimmunoassay (Refs. 1 and 19), an aryl hydrocarbon hydroxylase (AHH) induction assay (Ref. 22), a cytosol receptor assay (Ref. 5), an early life stage (E.L.S.) bioassay (Ref. 15), and an *in vitro* keratinization assay (Refs. 12 and 18). Each of these techniques has afforded an alternative technique for screening for the presence of 2,3,7,8-HDDs/HDFs based on biological/biochemical properties.

The primary advantages of the radioimmunoassay, the AHH and the cytosol receptor assay are relatively low cost and rapidity. The disadvantages of these techniques in general is that they do not necessarily respond to specific isomers of HDDs and HDFs; they respond to other compounds such as halogenated biphenyls, azobenzenes, and nonhalogenated polynuclear aromatic hydrocarbons, and each technique is less sensitive than available mechanical analytical methods.

The *in vitro* keratinization or E.L.S. bioassays more recently have provided additional options and possibly more specificity for determining the presence of 2,3,7,8-HDDs/HDFs (Ref. 16). Both techniques have been demonstrated to give roughly comparable results with HRGC/MS analysis of total PCDDs and PCDFs in a PCB fire soot (Ref. 12, and fly ash from a municipal incinerator (Ref. 15).

It is important to note that each of the bioassay techniques is most sensitive to the presence of 2,3,7,8-TCDD as opposed to other HDDs/HDFs. It is speculated that the relative response to other HDDs and HDFs might be dependent on halogen substitution in the 2,3,7,8 positions and ultimately to the toxic potential of the compound. It is also important to note that the range of compounds evaluated with each of these bioassay techniques is somewhat limited. EPA believes that evaluation of commercial products for the presence of HDDs and HDFs with any of these bioassay techniques could be a valuable screening tool, particularly in terms of time and resources necessary for the chemical preparation and instrumental analyses of these chemicals. EPA is not convinced, however, that these

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bioanalytical techniques are sensitive enough to achieve the level and specificity of detection necessary to quantitate 2,3,7,8-HDDs/HDFs at very low levels. Upon further development of the techniques and resolution of these concerns, EPA may adopt a bioanalytical screening technique in the final rule. Therefore, EPA seeks comments on the applicability and sensitivity of these bioanalytical techniques as potential screening tools for the detection of 2,3,7,8-HDDs/HDFs in commercial products.

V. Economic Analysis and Costs of Testing

**A. Costs of Testing Under Section 4(a)(1)(A)**

Three primary elements comprise the cost of this proposed rule under section 4: (1) Methods development; (2) synthesis of analytical standards; and (3) sample analysis (Ref. 27). At each point in the analysis a wide range of costs can be used depending on the option chosen. In each case, unless noted, a highest cost scenario has been assumed to demonstrate the greatest possible burden which may be incurred by the firms subject to testing.

*1. Methods Development*

Testing for the specified PHDD and PHDF congeners in commercial chemical products will require that methodologies for preparing and testing samples be developed by the manufacturers for each subject chemical. Manufacturers are free to use the most cost effective method of clean up and analysis that they can identify to meet the test requirements, including the QA/QC requirements. For methods development, EPA has assumed that all testing firms will coordinate to share the costs of methods development, estimated to be $250,000. An additional cost of $25,000 per chemical has been added to account for any adaptation of the general method required for a specific chemical matrix.

*2. Synthesis of Analytical Standards*

To conduct the sample analyses, a number of analytical standards that are not currently commercially available will have to be synthesized if they are not commercially available when the rule is promulgated. While the acquisition costs for standards that are commercially available are included in the cost of each sample analysis, the costs for synthesizing and producing the standards that are not available will be a unique cost of this rule. EPA has been able to identify 18 standards that are not now available or in process of becoming available. Estimated cost for synthesizing and manufacturing an adequate amount of native standards ranges from $3,000 to $5,000 depending on the isomeric positions of each. Estimated cost for synthesizing and manufacturing an adequate amount of each isotope-labeled standard is $5,000 to $10,000. In both cases, the higher unit cost was used, and 10 percent of the total cost was increased by a factor of 4 to account for additional difficulties encountered in synthesizing and manufacturing 10 percent of the standards. The total cost for manufacturing 18 standards (10 native and 8 isotope-labeled) is estimated to be $182,000.

*3. Sample Analysis*

EPA has assumed that each sample will be analyzed by the more expensive HR GC/MS, which is estimated to cost from $2,000 to $5,000 per sample. The maximum seven samples required for each chemical to be tested will therefore cost from $14,000 to $35,000. For purposes of this rule, EPA is using the upper bound cost of $35,000. EPA expects that 26 manufacturers will analyze 54 sample sets, for a total cost of $1,890,000. EPA believes that the cost differential for testing chemicals at levels orders of magnitude higher is minimal, and is soliciting additional data on such incremental cost differences.

Of the thirty-four commercial chemicals subject to this proposed test rule, only 14 chemicals are currently commercially manufactured or imported. Twenty-six firms have been identified as manufacturers and/or importers of the 14 chemicals. The total industry cost to carry out the proposed testing for the 14 chemicals currently commercially manufactured, using upper bound estimates, is $2.67 million. The cost for a manufacturer to resume production or import of a listed chemical which is not now in current commercial production is $60,000. This cost consists of $25,000 to adapt the method to the specific chemical and $35,000 for analysis of the seven required samples.

**B. Economic Analysis Under Section 4(a)(1)(A)**

*1. Allocation of Costs*

The distribution of economic impact among the testing firms and among the chemicals subject to testing is dependent on the allocation of jointly shared costs across the firms and chemicals. The impact analysis assumes that each firm will pay for the testing of its own chemicals, but the costs of standards synthesis and methods development will be allocated among firms based on the production volume of each firm's chemicals to be tested. Therefore, firms manufacturing larger quantities of chemicals will assume a greater proportion of the costs. Annualized costs to firms will range from $9,000 to $228,000, with 22 of 26 firms experiencing costs of less than $30,000.

*2. Impact of Test Costs on Firm Revenue*

Allocating total testing costs among the firms identified as current manufacturers and/or importers indicates that the specific costs of the rule per firm are small relative to the total sales of each firm. For 17 of the 26 firms subject to testing, annualized test costs are less than 0.1 percent of annual firm sales. For 8 of the remaining firms, annualized test costs are projected at less than 1 percent of annual sales. For one firm there is a potential for annualized test costs to run as high as 1.3 percent of annual sales.

*3. Costs as a Percentage of Revenues From Chemical*

For 10 of the 26 firms, the cost of the test rule is less than 1 percent of the revenue from the chemicals to be tested. For 5 firms, the cost is greater than 1 percent of annual revenue from the chemicals, but less than 50 percent. The test rule is expected to have little or no impact on the 10 firms; the impact on the 5 firms is expected to be minimal. The test costs imposed on seven chemicals currently manufactured (or imported) by 11 firms may be great enough to alter the market status of each chemical. In some cases, the continued marketability of a chemical may be threatened, while in other cases there may be changes in the firms manufacturing or importing a chemical (generally small volume producers discontinuing production in favor of larger volume producers). The annualized test cost allocated to each of 11 firms is greater than 100 percent of the anticipated annual revenue derived from the sale of the chemicals. Each of these 11 firms manufactures or imports the chemicals in small volumes, and is not likely to continue to produce or import the chemical. However, any lost revenue from small volumes of production will not seriously impact the firms.

*4. Impact of Test Costs on Chemicals*

Seven chemicals have annualized test costs lower than 1 percent of expected revenue, resulting in little impact. Seven chemicals have annualized test costs higher than 1 percent of expected revenue. Of these seven chemicals, three

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should experience minimal impact, two because there are no chemical substitutes which are economically and functionally competitive, and the other because there is the possibility of discontinuing production of multiple grades of the chemical, thus reducing the impact of the rule. The remaining four chemicals may be more severely affected. Three are highly specialized, produced in small volumes, and have functional substitutes. This would indicate that test costs would cause these 3 chemicals to be removed from the market. However, all three are marketed currently at prices higher than their substitutes, indicating there may be some functional advantage leading to continued use at a higher price. If this is the case, these 3 chemicals may or may not be replaced by substitutes. The remaining chemical is imported in very small quantities by seven firms. Its annualized test costs are nearly 500 percent of annual revenue. In addition, functional substitutes are available, leading EPA to believe that none of the seven firms will continue to import this chemical, and the chemical will be displaced from the market.

EPA is requesting submission of additional information during the comment period to enable it to make a more specific assessment of the need for testing in the case of these four chemicals. Information requested is: specific uses for these chemcials, the names and properties of substitutes for these chemicals, process information and reaction conditions under which these chemicals are produced. The chemicals are: tetrabromobisphenol-A diacrylate; tetrabromobisphenol-A bis-ethoxylate; tetrabromobisphenol-A bis-2,3-dibromopropyl ether; 2,3,5,6,-tetrachloro-2,5-cyclohexadiene-1,4-dione.

The four chemicals which are threatened represent a minor portion of total sales for their manufactures/importers. For all but one firm, the lost sales would be less than 0.1 percent of the firm's total annual sales, and for the remaining firm, lost sales would equal 0.2 percent of total sales. For most of the firms manufacturing the four chemicals, the costs of conducting the tests would be greater than the lost revenue from discontinuing their sale.

*5. Economic Consequences of This Rule*

Based on currently available information, EPA has determined that this rule will have negligible economic consequences for any of the chemicals. For most of the chemicals to be tested, costs are extremely low compared to company revenues and revenues from the chemicals. While for other chemicals there may be effects on the marketability of the chemical or the ability of a particular firm to market the chemical at present, all these chemicals appear to be replaceable by functional substitutes, which manufacturers or importers could use if the cost of testing for dioxin and furan contamination is deemed too high. However, it is possible that these chemicals may be irreplaceable for certain specialized uses, (EPA is not currently aware of such uses) and that testing may not be warranted at this time if it is not expected to reveal significant risks. Accordingly, EPA could adopt a different strategy in the final rule for some chemicals, depending on the economic impact of requiring testing for the specific chemicals, the importance of various uses, the number of persons exposed, the levels of the individual chemicals to which persons may be exposed, and the potential for increased use of the chemicals. If EPA determines that testing for certain chemicals is not warranted at the time the final rule is promulgated, EPA may require reporting under the final version of the section 8 rule proposed in this notice to more accurately determine the need for testing these chemicals. EPA will require testing of all chemicals for which additional data is not submitted during the comment period for this rule.

VI. Availability of Facilities

Section 4(b)(1)(C) of TSCA requires that in the development of a test rule the Administrator consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Pursuant to this requirement, EPA conducted a survey of commercial analytic testing laboratories to determine the availability of facilities, equipment, and personnel necessary to perform the tests outlined in this proposed rule (Ref. 27).

A list of 57 laboratories was compiled, consisting of 17 laboratories with current contracts under the EPS's Superfund Contract Laboratory Program, and 40 laboratories from the 1984 Directory of the American Council of Independent Laboratories. Twenty-five laboratories (the 17 EPA contract labs and 8 others chosen at random) were contacted by telephone.

The laboratory capacity survey reviewed the availability of gas chromatography with low-resolution mass spectrometry (LR GC/MS), gas chromatography with high-resolution mass spectrometry (HR GC/MS), and gas chromatography with electron capture detection (GC/ECD). The survey further addressed each laboratory's overall capacity to perform PHDD/PHDF tests of any type.

Of the 25 firms surveyed, 18 reported PHDD/PHDF testing capability. Among the 18 labs, 104 total GC/MS systems were identified, including 8 HR GC/MS systems in 5 facilities and 1 medium resolution system. The total number of GC/ECD systems at the disposal of the survey respondents ranged from 80 to 101. All but one laboratory (with 3 LR GC/MS systems and 1 HR GC/MS system) reported additional capacity available to perform analyses for PHDD/PHDF contaminants in commercial products. Several university laboratories and the in-house research laboratories of some chemical manufacturers will supplement the available supply of HR GC/MS in commercial testing facilities.

Under the guidelines in this rule for selection of chemicals for testing, and sampling and test methodology, it is anticipated that the number of total tests required will be approximately 400 individual sample analyses. The preliminary conclusion of the laboratory capacity survey is that the analysis of these samples will not severely strain the capacity of commercial testing laboratories, supplemented by university and chemical industry research facilities, and the tests required by this rule will not increase the unit price of conducting individual analyses. See the economic analysis (Ref. 27) for a full discussion of laboratory capacity and price of sample analysis.

One testing option discussed in this proposed rule but not incorporated in the laboratory survey is the biological screen for PHDD/PHDF contamination. Because biological screening tests are still under development, the potential capacity available for conducting such tests is unknown. It is assumed, however, that because of the number of laboratories with facilities to conduct various biological analyses and the relatively low start up costs expected, the supply of laboratories to perform biological screens for PHDDs and PHDFs will be available to meet the demand generated by successful development and application of the tests.

**VII. Section 8 Reporting**

Under section 8(a)(1)(A) of TSCA, EPA may require chemical manufacturers to maintain such records and submit such reports as the Agency may reasonably require, which data are to be known to the person making the report or reasonably ascertainable (section 8(a)(2)). Further, section 8(a)(1)(A) exempts small manufacturers

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from recordkeeping and reporting requirements, except where the manufacturer is also subject to a rule proposed or promulgated under section 4 (section 8(a)(3)(A)(ii)). Section 8(a)(2) also notes that to the extent feasible, EPA should not require unnecessary or duplicative reporting.

Small manufacturers are defined as: (1) The parent firm has total annual sales of less than $30 million, and no more than 45,400 kilograms (100,000 pounds) of any one chemical is produced at any one plant site (plant sites which manufacture more than 45,400 kilograms of a chemical product made from a precursor chemical listed under § 766.23 must report on that chemical from that plant site only); or (2) the manufacturer has total annual sales of less than $3 million, regardless of production volume of any chemical at any site. These small manufacturers are not required to report data concerning chemicals made from precursor chemicals under section 8(a) of TSCA. All other data required under section 8(a) must be reported by small manufacturers because it is triggered by a rule under section 4, making the small manufacturer subject both to a rule proposed or promulgated under sections 4 and 8(a).

Under section 8 of TSCA, EPA proposes to require staged reporting by: (1) Manufacturers of chemicals listed in § 766.20; (2) all organic chemical manufacturers; (3) manufacturers (except small manufacturers) of chemicals made from precursor chemicals listed under § 766.23; (4) all manufacturers of tested chemicals reporting a positive test result; and (5) all manufacturers of some uncontaminated chemicals when one manufacturer of a chemical reports contamination. The reporting is staged by a specific trigger from some other action. The first stage is triggered by this rule and occurs 90 days after promulgation of this rule. The second stage is triggered by the reporting of a positive test result, either under section 4, or as a result of test data submitted under section 8(a). The last stage may be triggered by a Notice published in the **Federal Register** by EPA naming those chemicals where at least one manufacturer has reported contamination. A manufacturer always has the option to submit 90 days after promulgation on this rule all data it may be required to submit under section 8 at varous times during the course of this rule.

**A. Use of a form**

To simplify both reporting and tabulation of production volume, process, use, exposure, and disposal data requested under section 8(a), EPA is proposing the use of a form, the Dioxin/Furan Report Form, § 766.30(e)(5), to be filled out for each chemical on which information is being reported under section 8(a). Submission of unpublished health and safety studies will follow procedures set out at 40 CFR Part 716. Submission of allegations of significant adverse reactions will follow procedures set out at 40 CFR Part 717.

**B. Reporting timeframe**

*1. Reporting Triggered by Promulgation of This Rule.*

Ninety days after promulgation of this rule, EPA proposes to require: (a) Manufacturers of chemicals listed under § 766.20 to submit available test data for those chemicals, data which shows contamination (or lack thereof) of the chemical by 2,3,7,8-HDDs/HDFs and which quantifies the level of contamination, along with any protocols showing how samples were taken, cleanup accomplished, and analysis done. This requirement is proposed under section 8(a) of TSCA; (b) Manufacturers of organic chemicals to submit unplublished health and safety studies on dioxins and/or furans. This requirement is proposed under section 8(d) of TSCA; (c) Manufacturers (except small manufacturers) of chemicals made from precursor chemicals listed under § 766.23, to submit information on production volume, process, reaction conditions, use, exposure, and disposal for each chemical product using a precursor chemical in the manufacturing process as a feedstock or intermediate. This requirement is proposed under section 8(a) of TSCA.

*2. Reporting Triggered by a Positive Test Response*

Ninety days after submission of a positive test response to EPA resulting from testing under section 4, or from previous testing submitted under section 8(a) of TSCA, EPA proposes to require manufacturers of contaminated chemicals to: (a) report production volume, process, reaction conditions, use, exposure and disposal data under section 8(a) of TSCA; (b) submit unpublished health and safety studies on the contaminated chemical under section 8(d) of TSCA; and (c) submit allegations of significant adverse reactions to the contaminated chemical and to the dioxin and/or furan contaminants under section 8(c) of TSCA.

*3. Reporting Triggered by a "Federal Register" notice*

Ninety days after EPA publication of a notice in the **Federal Register** listing chemicals for which positive test results from at least one manufacturer have shown contamination by 2,3,7,8-HDDs/HDFs at or above the LOQ, manufacturers of those chemicals which have been shown not to be contaminated are required to submit data on process and reaction conditions for their chemical. This requirement is proposed under section 8(a) of TSCA, and will only be used if EPA needs the process data to determine whether the process can be changed to produce a clean chemical.

**C. Uses of the data**

The kinds of data required under section 8(a) and the reasons for the Agency's request are set forth below. EPA is proposing to collect this information on a form, published under § 766.30(e)(5). Use of a form will facilitate reporting of data for the manufacturer, and processing and comparison of reported data for EPA.

*1. Production and Use Information*

EPA needs use information, including production volume for each use, as detailed as possible, to construct realistic exposure scenarios. EPA needs this information for tested chemicals only after a positive test result has been reported. For chemicals made from precursor chemicals, EPA needs this information to evaluate the potential exposure for any chemical products that may be candidates for future testing. Therefore EPA has requested this information under section 8(a) at two stages—from manufacturers of chemicals made from precursor chemicals 90 days after promulgation of this rule, and from manufacturers of chemicals listed for testing 90 days after a positive test result has been reported.

*2. Process Information*

EPA has requested very detailed reporting of the chemical manufacturing process and process conditions in part II of the form (EPA 7910-51). For chemicals made from precursor chemicals, EPA will examine process conditions and process chemistry to determine whether any of the products are likely to be contaminated, and therefore be candidates for future testing under section 4 of TSCA. For the chemicals listed in § 766.20 and shown to be contaminated EPA will examine process chemistry and process conditions to determine whether a process change will reduce the levels of contamination

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to an acceptable risk level in the final chemical. For "clean" chemicals, where one manufacturer of a given chemical has reported contamination, EPA may compare processes and conditions to ensure that a process is available to produce a clean chemical and that the reports of noncontamination have a basis in process or process conditions. These data have been requested at three stages in the reporting cycle. Data from manufacturers of chemicals made from precursor chemicals have been requested 90 days after promulgation of the rule; data from manufacturers of contaminated chemicals have been requested 90 days after submission of positive test results; data from manufacturers of clean chemicals may be requested 90 days after publication of a notice in the Federal Register naming contaminated chemicals.

A manufacturer may be exempted from submitting process information in section II of the form if this information for the listed chemical and the same process has been provided to the Agency within the last 2 years on "RCRA Section 3007 Questionnaire; Organic Chemical Manufacturing Industry: Halogenated Dioxins, OMB No. 2000–0396."

*3. A Description of Byproducts Resulting From the Manufacture of Listed Chemicals.*

This is any available testing information showing levels of 2,3,7,8-HDDs/HDFs in listed chemicals. This information is designed to give EPA any test data on contamination levels in commercial chemicals as quickly as possible and to exempt manufacturers from the testing requirements under section 4 if the data meet the requirements of this rule. Under this proposed rule, this information must be submitted by manufacturers of listed chemicals 90 days after promulgation of this rule.

*4. Exposure Information*

Manufacturers of both listed chemicals with a positive test result and chemicals made from precursor chemicals would be required to report, by each specific step in the manufacturing process, the maximum number of workers involved in each operation and the maximum duration of time that any one worker will engage in the activity in hours per day and days per year. This information, will enable EPA to calculate occupational exposure to 2,3,7,8-HDDs/HDFs. Manufacturer's of listed chemicals with a positive test result would report this information 90 days after submission of the test result; manufacturers of chemicals made from precursor chemicals would report 90 days after promulgation of this rule.

*5. Disposal Information*

Information to be reported includes the amount of chemical released at each stage of the process that shows an environmental release on the process diagram. A description of control technology used to control or treat the environmental release should be reported, along with the method of disposing of any waste. This information, along with process information requested, assists the Agency in determining the fate of the dioxins and/or furans generated. The fate calculation will be used in determining levels and durations of exposures as a part of the exposure assessment. Some disposal information is avaialble from the Office of Solid Waste (OSW); however, the information does not account for different manufacturing sites. Any manufacturer who has completed and submitted all process data requested on the questionnaire titled "RCRA Section 3007 Questionnaire; Organic Chemicals Manufacturing Industry: Halogenated Dioxins, OMB No. 2000–0396" for both the chemical and the process in question within the past 2 years note that fact in its submission to EPA under section 8(a) and does not have to complete the section of the form on process conditions.

**D. Costs of Reporting**

Reporting costs under section 8 are minimal, and will vary depending on which provision a manufacturer is responding to. The most expensive reporting requirement is for the information needed to complete the Dioxins/Furans Report Form. Completion of this form is expected to cost from $1,607 to $3,214 depending on the complexity of process and use data to be reported. Submission of data from previously conducted tests is expected to cost from $273 to $546 per chemical. Reporting under section 8(c) is expected to cost from $188 to $376 per chemical; and reporting under section 8(d) is expected to cost from $250 to $320 plus $80 for each 15-page report submitted. These costs are not expected to have an impact on any firm's decision to manufacture or import the chemical reported on.

VIII. Compliance and Enforcement

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1)(A) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: "(A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records required by this Act or a rule" issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11(a) applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce. . . ." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with any final rule for chemicals listed under § 766.20. These inspections may be conducted to verify that testing has begun, schedules are being met, and reports accurately reflect the underlying raw data and interpretations and evaluations, and to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility is also derived from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing

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after the deadlines for such submissions. Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

## IX. Rulemaking Record

EPA has established a record for this rulemaking (OPTS-83002). This record includes basic information considered by the Agency in developing this proposal and appropriate **Federal Register** notices. The Agency will supplement the record with additional information as it is received.

This record includes the following kinds of information:

1. **Federal Register** notices pertaining to this rule.
2. Study of availability of test facilities and personnel.
3. Economic analyses.
4. Communications before proposal consisting of written public and intra- or interagency memoranda and comments and summaries of telephone conservations.
5. Reports—published and unpublished factual materials.

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Room E-107, 401 M St., SW., Washington, DC from 8 a.m. to 4 p.m. Monday through Friday, except legal holidays.

## X. References


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(37) Versar, Inc. List of chemicals contaminated or precursors to contamination with incidentially generated polychlorinated and polybrominated dibenzodioxins and dibenzofurans. EPA contract No. 68-02-3968, Task No. 48. 1985.

## XI. Other Regulatory Requirements

### A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. First, the effect on the economy is not expected to exceed the costs of testing 14 chemicals and reporting on those contaminated, plus some additional reporting. The total costs of testing are expected to be $2.67 million. Reporting costs will add an additional $4,100. No significant increases in prices are expected to occur as a result of this rule, as reported in the economic impact analysis. No significant adverse effects are expected on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written, comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

### B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 et seq., Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) Very few small chemical manufacturers and importers will be required to test chemicals and report, and (2) small manufacturers have been exempted from a major reporting requirement.

For this rule the definition of small business is the one used in previous section 8(a) reporting rules, defined at § 766.4(k). For this certification, the total annual sales figure of $4 million was used as the cutoff to denote small chemical manufacturers and importers. Of the firms required to test, 5 qualify as small businesses. These 5 firms do not represent a substantial number of all small chemical manufacturing firms. For these 5 firms, amortized test costs are projected to be less than 1 percent of annual sales, approximately the same precentage experienced by larger manufacturing and importing companies. Only 1 small manufacturer is projected to experience test costs of 1.3 percent of annual sales, approximately 0.3 percent more than other large and small manufacturers.

### C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control numbers 2070-0033 for reporting under section 4, 2070-0004 for submission of health and safety studies under section 8(d), 2070-0017 for submission of allegations of significant adverse reactions under section 8(c), and 2070-0420 for submission of information under section 8(a). Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs: OMB; 726 Jackson Place NW; Washington, DC 20503 marked "Attention: Desk Officer for EPA". The final rule will respond to any OMB or public comments on the information collection requirements.

### List of Subjects in 40 CFR Part 799

Testing, Environmental Protection Agency, Environmental protection, Hazardous material, Chemicals, Recordkeeping and reporting, Health and safety, Significant adverse reactions.

Dated: December 9, 1985.

**John A. Moore,**

*Assistant Administrator for Pesticides and Toxic Substances.*

Therefore, it is proposed that Chapter I of 40 CFR be amended by adding Part 766 to read as follows:

## PART 766—DIBENZODIOXINS/DIBENZOFURANS

### Subpart A—General Provisions

Sec.
766.1 Scope and purpose.
766.2 Applicability.
766.3 Compliance.
766.4 Definitions.
766.5 Submission of information.
766.10 Test standards.
766.11 Testing guidelines.
766.12 Congeners for which quantitation is required.

### Subpart B—Specific Chemical Testing/Reporting Rules

766.20 Chemicals for testing/reporting.
766.23 Reporting on precursor chemicals.
766.25 Analytical test method.
766.27 Method sensitivity.
766.28 Test results.
766.30 Reporting requirements.

Authority: 15 U.S.C. 2061.

### Subpart A—General Provisions

#### §766.1 Scope and purpose.

(a) This Part identifies that chemical substances which are subject to reporting under section 8 of TSCA and testing under section 4 of TSCA, specifies persons required to report and test (manufacturers, including importers, and processors), prescribes the analytical methods required, including the target limits of quantitation and the congeners for which quantitation is required, and provides deadlines for submission of protocols, reports, studies, and test results to EPA. This part also identifies chemicals which are precursors (aids under appropriate process conditions to formation of halogenated dibenzo-p-dioxins (HDDs) and halogenated dibenzofurans (HDFs)), and identifies reporting requirements and persons required to report for chemicals made from these precursor chemicals.

(b) This Part requires manufacturers and processors of chemical substances identified in § 766.20(a) to submit letters of intent to test and protocols for the sampling, sample preparation, extraction and cleanup, and analysis of the chemical substances. Any submissions must be in accordance with the EPA test rule development and exemption procedures contained in Part 790 of this chapter and any modifications to such procedures contained in this Part.

(c) This Part requires manufacturers of chemical substances identified in § 766.20 to: submit any existing test data and protocols to EPA, to submit allegations of significant adverse reactions to HDDs and HDFs, to analyze chemicals for HDDs and HDFs and

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report results. If a test result indicates the presence of contamination of a chemical product by HDDs and/or HDFs, this Part requires additional reporting. In some cases, additional reporting may be required of manufacturers reporting no contamination of a chemical product. This part also requires anyone possessing health and safety studies on HDDs and HDFs to submit such studies.

(d) This Part requires manufacturers of chemical substances produced from chemicals identified as precursors to HDD and HDF formation, listed at § 766.23(a), to report on chemical substances produced from such precursor chemicals.

**§ 766.2 Applicability.**

(a) This Part is applicable to each person who manufactures or intends to manufacture (including import), processes or intends to process, a chemical substance identified in § 766.20(a). This Part is also applicable to each person who manufactures or intends to manufacture (including import) a chemical product from any chemical substance identified in § 766.23(a). The duration for this rule is the period commencing with the effective date of this rule to the end of the reimbursement period defined in §766.24.

(b) Small manufacturers are exempt from reporting production volume, process, use, exposure and disposal data on chemicals made from precursor chemicals listed under § 766.23(a). Manufacturers qualify as small if they meet either of the standards set forth in § 766.4(k).

**§ 766.3 Compliance.**

Any person who fails or refuses to comply with any aspect of this Part is in violation of section 15 of TSCA. Section 15(1) makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) makes it unlawful for any person to fail or refuse to submit information required under this rule. Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Under section 17 of TSCA, the district courts of the United States have jurisdiction to restrain any violation of section 15.

**§ 766.4 Definitions.**

The definitions in section 3 of TSCA and the definitions of §§ 704.3, 716.3, 717.3 and 790.3 also apply to this Part.

(a) Dioxin means any of a family of compounds which has as a nucleus a triple-ring structure consisting of two benzene rings connected through a pair of oxygen atoms.

(b) Dibenzofuran means any of a family of compounds which has as a nucleus a triple-ring structure. Two rings are benzene rings and the third ring, between the benzene rings, is formed by two bridges between the two benzene rings. The bridges are a carbon-carbon bridge and a carbon-oxygen-carbon bridge between respective substitution positions adjacent to the carbon-carbon bridge.

(c) Congener means any one particular member of a class of chemicals. A specific congener is denoted by unique chemical structure, for example 2,3,7,8-tetrachlorodibenzofuran.

(d) Homolog means a group of isomers that have the same degree of halogenation. For example, the homologous class of tetrachlorodibenzo-p-dioxins consists of all dibenzo-p-dioxins containing four chlorine atoms. When the homologous classes discussed in this rule are referred to, the following abbreviations for the prefix denoting the number of halogens are used:

tetra-, T (4 atoms)
penta-, Pe (5 atoms)
hexa-, Hx (6 atoms)
hepta-, Hp (7 atoms)

(e) Polyhalogenated dibenzo-p-dioxin (or PHDD) means any member of a class of dibenzo-p-dioxins containing one to eight chlorine substituents or one to eight bromine substituents. "Polychlorinated dibenzo-p-dioxin" (or PCDD) refers to any member of a class of dibenzo-p-dioxins with one to eight chlorine substitents; "polybrominated dibenzo-p-dioxin" (or PBDD) refers to any member of a class of dibenzo-p-dioxins with one to eight bromine substituents.

(f) Polyhalogenated dibenzofuran (or PHDF) means any member of a class of dibenzofurans containing one to eight chlorine, bromine, or a combination of chlorine and bromine substituents. "Polychlorinated dibenzofuran" refers to any member of a class of dibenzofurans with one to eight chlorine substituents; "polybrominated dibenzofurans" refers to any member of a class of dibenzofurans with one to eight bromine substituents.

(g) Positive test result means: (1) any resolvable gas chromatographic peak for any 2,3,7,8-HDD which equals or exceeds 0.1 part per billion; or (2) any resolvable gas chromatographic peak for any 2,3,7,8-HDF which equals or exceeds 1.0 part per billion.

(h) 2,3,7,8-HDD means any of the dibenzo-p-dioxins totally chlorinated or totally brominated at the following positions: 2,3,7,8; 1,2,3,7,8; 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; and 1,2,3,4,7,8,9.

(i) 2,3,7,8-HDF means any of the dibenzofurans totally chlorinated or totally brominated at the following positions: 2,3,7,8; 1,2,3,7,8; 2,3,4,7,8; 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; 2,3,4,6,7,8; 1,2,3,4,6,7,8; and 1,2,3,4,7,8,9.

(j) Precursor means a chemical which is not contaminated due to the process conditions under which it is manufactured, but because of its molecular structure, under favorable process conditions, may cause or aid the formation of PHDDs and PHDFs in other chemicals in which it is used as a feedstock or intermediate.

(k) Small manufacturer means (1) the parent firm has total annual sales of less than $30 million, and no more than 45,400 kilograms (100,000 pounds) of any one chemical ius produced at any one plant site (plant sites which manufacture more than 45,400 kilograms of a chemical listed under § 766.20(a) or a chemical product made from a chemical listed under § 766.23(a) must report on that chemical from that plant site only); or (2) the manufacturer has total annual sales of less than $3 million, regardless of production volume of any chemical at any site.

(l) Reimbursement period means the period that begins when the data from the last test to be completed under a test rule is submitted to EPA, and ends after an amount of time equal to that required to develop that data or 5 years, whichever is later.

**§ 766.5 Submission of Information.**

All information (including letters of intent, protocols, data, forms, studies and allegations) submitted to EPA under this part must bear the applicable Code of Federal Regulations (CFR) section number (e.g., § 766.30) and must be addressed to: Document Control Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Washington, DC 20460.

**§ 766.10 Test standards.**

Testing required under Subpart B of this part must be performed using the protocols submitted to and reviewed by EPA unless modifications have been submitted and reviewed. All new data, documentation, records, protocols, specimens and reports generated as a result of testing under Subpart B of this part must be fully developed and retained in accordance with Part 792 of this chapter. These items must be made available during an inspection or submitted to EPA upon request by EPA or its authorized representative. Laboratories conducting testing for

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submission to the Agency in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA Good Laboratory Practices (GLPs). These GLPs are published at 40 CFR Part 792. Sponsors must notify the laboratory that the testing is being conducted pursuant to TSCA section 4. Sponsors are also responsible for ensuring that laboratories conducting the testing abide by the TSCA GLP standards. Manufacturers must submit a certification to EPA that the laboratory performing the testing adhered to the TSCA GLPs.

**§ 766.11 Testing guidelines.**

Testing guidelines are contained in a report titled *Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products.* Copies are available from TSCA Assistance Office. (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460 (800-424-9065). Copies are also located in the public reference for this rule (docket no. OPTS-83002) and are available for inspection in the OPTS Reading Rm., E-107, 401 M Street SW., Washington, DC 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

**§ 766.12 Congeners for which quantitation is required.**

Quantitation for any of the following 2,3,7,8-HDD/HDF congeners which may be present in the chemical is required for the chemicals listed under § 766.20(a).

| *Chlorinated Dioxins* | *Brominated Dioxins* |
|---|---|
| 2,3,7,8-TCDD | 2,3,7,8-TBDD |
| 1,2,3,7,8-PeCDD | 1,2,3,7,8-PeBDD |
| 1,2,3,4,7,8-HxCDD | 1,2,3,4,7,8-HxBDD |
| 1,2,3,6,7,8-HxCDD | 1,2,3,6,7,8-HxBDD |
| 1,2,3,7,8,9-HxCDD | 1,2,3,7,8,9-HxBDD |
| 1,2,3,4,6,7,8-HpCDD | 1,2,3,4,6,7,8-HpBDD |

| *Chlorinated Furans* | *Brominated Furans* |
|---|---|
| 2,3,7,8-TCDF | 2,3,7,8-TBDF |
| 1,2,3,7,8-PeCDF | 1,2,3,7,8-PeBDF |
| 2,3,4,7,8-PeCDF | 2,3,4,7,8-PeBDF |
| 1,2,3,4,7,8-HxCDF | 1,2,3,4,7,8-HxBDF |
| 1,2,3,6,7,8-HxCDF | 1,2,3,6,7,8-HxBDF |
| 1,2,3,7,8,9-HxCDF | 1,2,3,7,8,9-HxBDF |
| 2,3,4,6,7,8-HxCDF | 2,3,4,6,7,8-HxBDF |
| 1,2,3,4,6,7,8-HpCDF | 1,2,3,4,6,7,8-HpBDF |
| 1,2,3,4,7,8,9-HpCDF | 1,2,3,4,7,8,9-HpBDF |

## Subpart B—Specific Chemical Testing/Reporting Rules

**§ 766.20 Chemicals for testing/reporting.**

(a) *Identification of chemical substances for testing/reporting.* Chemicals required to be tested for the presence of the congeners of HDDS and HDFs listed under § 766.12 are listed by Chemical Abstracts Service (CAS) Number and Name. The chemicals listed under § 766.20(a)(1) are commercially manufactured and are subject to testing upon promulgation of this rule. Those chemicals listed under § 766.20(a)(2) are subject to testing upon commencement or resumption of commercial manufacture.

(1) *Chemicals commercially manufactured—*

| *CAS Number* and *Chemical Name* | |
|---|---|
| 79-94-7 | Tetrabromobisphenol-A |
| 94-75-7 | 2,4-Dichlorophenoxyacetic acid |
| 94-82-6 | 2,4-Dichlorophenoxybutyric acid |
| 118-75-2 | 2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione |
| 118-79-6 | 2,4,6-Tribromophenol |
| 120-83-2 | 2,4-Dichlorophenol |
| 1163-19-5 | Decabromodiphenyloxide |
| 4162-45-2 | Tetrabromobisphenol-A-bisethoxylate |
| 21850-44-2 | Tetrabromobisphenol-A-bis-2,3-dibromopropyl ether |
| 25327-89-3 | Allyl ether of tetrabromobisphenol-A |
| 32534-81-9 | Pentabromodiphenyloxide |
| 32536-52-0 | Octabromodiphenyloxide |
| 37853-59-1 | 1,2-Bis(tribromophenoxy)-ethane Tetrabromobisphenol-A diacrylate |

(2) *Chemicals not commercially manufactured—*

| *CAS Number* and *Chemical Name* | |
|---|---|
| 79-95-8 | Tetrachlorobisphenol-A |
| 87-10-5 | 3,4,5-Tribromosalicylanilide |
| 87-65-0 | 2,6-Dichlorophenol |
| 95-77-2 | 3,4-Dichlorophenol |
| 95-95-4 | 2,4,5-Trichlorophenol |
| 99-28-5 | 2,6-Dibromo-4-nitrophenol |
| 120-36-5 | 2[2,4-(Dichlorophenoxy)]-propionic acid |
| 320-72-9 | 3,5-Dichlorosalicyclic acid |
| 488-47-1 | Tetrabromocatechol |
| 576-24-9 | 2,3-Dichlorophenol |
| 583-78-8 | 2,5-Dichlorophenol |
| 609-71-9 | Pentabromophenol |
| 615-58-7 | 2,4-Dibromophenol |
| 933-75-5 | 2,3,6-Trichlorophenol |
| 1940-42-7 | 4-Bromo-2,5-dichlorophenol |
| 2577-72-2 | 3,5-Dibromosalicylanilide |
| 3772-94-9 | Pentachlorophenyl laurate |
| 37853-61-5 | Bismethylether of tetrabromobisphenol-A Alkylamine tetrachlorophenate Tetrabromobisphenol-B |

(b) *Persons required to report, submit data and conduct tests.* All persons who manufacture or intend to manufacture or process or intend to process any chemical identified under paragraph (a) of this section from (*insert date 44 days from date of publication of the rule in the* **Federal Register**) to the end of the reimbursement period shall submit the following materials on the stated timetable:

(1) Letters of intent to test by (*insert date 45 days from date of publication of the rule in the* **Federal Register**);

(2) existing test data, with protocols, which show results of testing the chemical product for the existence of and level of any dibenzo-p-dioxins and dibenzofurans by (*insert date 90 days from the date of publication of the rule in the* **Federal Register**);

(3) allegations of significant adverse reactions based on any dibenzo-p-dioxins and/or dibenzofurans by (*insert date 90 days from date of publication of the rule in the* **Federal Register**);

(4) proposed protocols capable of analysis of each congener of HDDs/HDFs listed under § 766.12 at the required Level of Quantitation for the sample collection, clean-up, extraction and analysis of the chemicals listed under § 766.20(a)(1), by (*insert date 180 days from the date of publication of the rule in the* **Federal Register**);

(5) results of conducting the testing, including levels of each 2,3,7,8-HDD and HDF congener present above 0.1 ppb and 1.0 ppb respectively, for each product sample tested; negative results; any deviation from methods and QA submitted and reviewed by EPA; any corrective actions required during sampling and analysis; and actual precision and accuracy established for the samples analyzed, no later than 1 year after receipt of comments on the protocols from EPA;

(6) for chemicals with a positive test result, production volume, process, use, exposure and disposal data on form EPA 7910-51 (one form for each chemical with a positive test result), health and safety studies and allegations of severe adverse reactions based on the tested chemical, no later than 90 days after submission of the positive test result to EPA;

(7) manufacturers of chemicals for which no contamination has been reported may be requested to submit process data (Part II of form EPA 7910-51) if one manufacturer of that chemical reports contamination. Such a request will be made by publication of a notice in the **Federal Register.**

(8) manufacturers of any chemical listed under § 766.12(a)(2) will be required to test that chemical according to the schedule in this rule if that chemical enters commercial manufacture.

(c) Any chemical manufacturer in possession of health and safety studies on any dibenzo-p-dioxin or dibenzofuran must submit those studies not later than (*insert date 90 days from publication of this rule in the* **Federal Register**).

(d) The reporting of test results must follow the procedures set out in Part 790 of this chapter.

(e) The reporting of health and safety studies must follow all procedures set out in Part 716 of this chapter, except

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that studies on dibenzo-p-dioxins and dibenzofurans must be submitted 90 days after publication of this final rule, and studies on chemicals tested under § 766.20(a)(1) must be submitted 90 days after submission of a positive test result.

(f) Submissions of allegations of significant adverse reactions caused by dibenzo-p-dioxins, dibenzofurans, or the tested chemical, must follow procedures set out under Part 717 of this chapter. Allegations of significant adverse reactions caused by dibenzo-p-dioxins and/or dibenzofurans must be submitted by (*insert date 90 days after date of publication of this rule in the* **Federal Register**) and allegations of significant adverse reactions caused by the tested chemical must be submitted no later than 90 days after submission of a positive test result.

(g) Information collection requirements under this rule have been approved by the Office of Management and Budget under control numbers 2070–0033 for reporting under section 4, 2070–0004 for health and safety studies, 2070–0017 for allegations under section 8(c), and 2070–0420 for submission of information under section 8(a).

**§ 766.23 Reporting on precursor chemicals.**

(a) *Identification of precursor chemicals.* Precursor chemicals are produced under conditions that will not yield HDDs and HDFs, but their molecular structure is conducive to HDD/HDF formation under favorable reaction conditions when they are used to produce other chemicals or products. Precursor chemicals are identified by CAS number and name.

| *CAS Number and Chemical Name* | |
|---|---|
| 87–84–3 | Pentabromocyclohexane |
| 89–64–5 | 4-Chloro-2-nitrophenol |
| 92–04–6 | 2-Chloro-4-phenylphenol |
| 94–74–6 | 4-Chloro-o-toloxy acetic acid |
| 94–81–5 | 4-(2-Methyl-4-chlorophenoxy) butyric acid |
| 95–56–7 | o-Bromophenol |
| 95–57–8 | o-Chlorophenol |
| 95–88–5 | 4-Chlororesorcinol |
| 97–50–7 | 5-Chloro-2,4-dimethoxyaniline |
| 99–30–9 | 2,6-Dichloro-4-nitroaniline |
| 615–67–8 | Chlorohydroquinone |
| 827–94–1 | 2,6-Dibromo-4-nitroaniline. |

(b) *Persons required to report.* All persons who manufacture or intend to manufacture chemical products using any of the chemicals listed under § 766.23(a) as feedstocks or intermediates, must report production, process, use, exposure and disposal data on form EPA 7910–51 under § 766.30(e)(5) for each such chemical product. Small manufacturers, defined under §766.4(k) are not required to report under this subpart. A separate form EPA 7910–51 must be submitted for each chemical product reported. All forms must be submitted to EPA no later than (*insert date 90 days from date of publication of this rule in the* **Federal Register**). Information collection requirements under this rule have been approved by the Office of Management and Budget under control number 2070–0420.

**§ 766.25 Analytical test method.**

The analytical method consists of several discrete steps, each fully described or reviewed in the document referred to in § 766.11, Testing Guidelines. Because of the difference in matrices of the chemicals listed for testing, no one method for sample selection, preparation, extraction and cleanup is prescribed. For analysis, High Resolution Gas Chromatography with High Resolution Mass Spectrometry is the method of choice, but other methods may be used if they can be demonstrated to reach the target LOQs.

(a) *Sample selection.* The chemical product to be tested should be sampled so that the specimens collected for analysis are representative of the whole. Guidelines for sample selection are provided in the support document referenced in § 766.11.

(b) *Sample preparation.* The sample must be mechanically homogenized and subsampled as necessary. Subsamples are spiked or reinforced with surrogate compounds or with standard stock solutions, and the surrogates or standards are thoroughly incorporated by mechanical agitation. Guidelines are provided in the document referenced in § 766.11.

(c) *Sample extraction and cleanup.* The spiked samples must be treated to separate the HDDs/HDFs from the sample matrix. Methods are reviewed in the document referenced in § 766.11, but the final method or methods are left to the discretion of the analyst, provided the instrumental response of the surrogates meets the criteria listed in the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins*, appendixes B and C of the document referenced in § 766.11. Cleanup techniques are described in the document referenced under § 766.11. These are chosen at the discretion of the analyst to meet the requirements of the chemical matrix.

(d) *Analysis.* The method of choice is High Resolution Gas Chromatographic/High Resolution Mass Spectrometric Determination, but alternate methods may be used if the manufacturer can demonstrate that the method will reach the target LOQs. Specific operating requirements are found in the document referenced in § 766.11.

**§ 766.27 Method sensitivity.**

(a) *2,3,7,8-Halogenated dibenzo-p-dioxins (HDDs).* The required limit of quantitation is 0.1 ppb for each resolved HRGC peak. For at least one product sample, at least two analyses of the same isotopically labelled HDD internal calibration standards spiked to a final product concentration of 0.1 ppb must be reproducibly extracted, cleaned up, and quantified to within ±10 percent of each other. For each spiked product sample, the signal to noise ratio for the calibration standard peaks after complete extraction and cleanup must be 10:1 or greater. The recovery of the internal calibration standards in the extracted and cleaned up product samples must be within 70–130 percent of the amount spiked.

(b) *2,3,7,8-Halogenated dibenzofurans (HDFs).* The required limit of quantitation is 1.0 ppb for each resolved HRGC peak. For at least one product sample, at least two analyses of the same isotopically labelled HDF internal calibration standards spiked to a final product concentration of 1.0 ppb must be reproducibly extracted, cleaned up, and quantified to within ±10 percent of each other. For each spiked product sample, the signal to noise ratio for the calibration standard peaks after complete extraction and cleanup must be 10:1 or greater. The recovery of the internal calibration standards in the extracted and cleaned up product samples must be within 70–130 percent of the amount spiked.

**§ 766.28 Test results.**

For purposes of reporting test results to EPA, and for further reporting triggered by a positive test result, a positive test result is defined at § 766.4(g).

**§ 766.30 Reporting requirements.**

(a) *Letters of intent.* Manufacturers who currently manufacture any chemical listed under § 766.20(a) are required to submit to EPA a letter which acknowledges their responsibility under this rule to report and test. This letter must be submitted no later than (*insert date 45 days from date of publication of rule in the* **Federal Register**).

(b) *Information required under section 8.* (1) Manufacturers of chemicals listed under § 766.20(a) are required to report, 90 days after publication of this rule in the **Federal Register**, results of all existing test data which show that any chemical listed under § 766.20(a) has been tested for the presence of HDDs

and/or HDFs. EPA will examine the data and notify the manufacturer whether it meets the requirements for testing required under Subpart B of this Part. If testing requirements under Subpart B are met, the manufacturer is exempt from such requirements. The manufacturer is not, however, exempted from requirements of reporting under § 766.30(e) if the test result from his chemical is positive.

(Approved by Office of Management and Budget under the control number 2070-0420)

(2) Any chemical manufacturer in possession of health and safety studies on dibenzo-p-dioxins and/or dibenzofurans is required to submit such studies to EPA no later than 90 days after publication of this rule in the **Federal Register.** Such studies shall be submitted in accordance with procedures set forth in Part 716 of this chapter.

(Approved by the Office of Management and Budget under the control number 2070-0004)

(3) Manufacturers of chemicals listed under § 766.20(a) must submit allegations of significant adverse reactions caused by any HDDs and/or HDFs no later than 90 days after publication of this rule in the **Federal Register.** These allegations shall be submitted in accord with procedures set forth in Part 717 of this chapter.

(Approved by the Office of Management and Budget under the control number 2070-0017)

(4) Manufacturers of chemicals products using any of the chemicals listed under §766.23(a) as feedstocks or intermediates must report production, process, use, exposure and disposal data on form EPA 7910-51 for each such chemical product no later than 90 days after publication of this rule in the **Federal Register.**

(Approved by the Office of Management and Budget under the control number 2070-0420)

(c) *Protocols.* Protocols include all parts of the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins,* as stated in *Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products,* which is referenced in § 766.11. EPA expects to receive specific plans for collection of samples from the process stream, naming the point of collection, the method of collecting the sample, and an estimate of how well the samples will represent the material to be characterized; a description of how control samples (blanks) and HDD/HDF-reinforced control samples, or isotopically labeled compounds (standards) and duplicate samples will be handled; a description of the chemical extraction and clean up procedures to be used; how extraction efficiency and measurement efficiency will be established; and a description of instrument hardware and operating conditions, including type and source of columns, carrier gas and flow rate, operating temperature range, and ion source temperature. These protocols for each chemical product to be tested must be submitted to EPA no later than 6 months after publication of this rule in the **Federal Register.**

(d) *Analytical test results.* All test results must be reported no later than 12 months after receipt of a letter from EPA commenting on protocols submitted. A positive test result is defined at § 766.4(g).

(Approved by the Office of Management and Budget under the control number 2070-0033)

(e) *Information required under section 8.* Submission of a positive test result triggers additional reporting under section 8 of TSCA, all of which must be submitted to EPA no later than 90 days after the date of submission of the positive test result.

(1) A form, EPA 7910-51 under paragraph (e)(5) of this section has been provided for submission of data required under section 8(a) of TSCA. The form is printed under paragraph (e)(5) of this section and copies are available from the TSCA Assistance Office. One form must be submitted for each chemical for which a positive test result has been submitted.

(Approved by the Office of Management and Budget under the control number 2070-0420)

(2) Health and safety studies for chemicals for which a positive test result have been submitted shall be submitted in accord with Part 716 of this chapter, except that the manufacturer has 90 days after submission of a positive test result to submit health and safety studies on the tested chemical.

(Approved by the Office of Management and Budget under the control number 2070-0004)

(3) Allegations of significant adverse reactions to the chemical for which a positive test result has been submitted, shall be submitted in accord with Part 717 of this chapter, except that the manufacturer has 90 days after submission of a positive test result to submit such allegations on the tested chemical.

(Approved by the Office of Management and Budget under the control number 2070-0017)

(4) A positive test result on a chemical from one manufacturer but not from others may require EPA to publish a notice listing chemicals for which a positive result has been received from at least one manufacturer and requiring any manufacturer of that chemical who has not submitted a positive test result to submit the information required in Part II of EPA Form 7910-51 under §766.30(e)(5). Such a notice will be published only if EPA needs additional process data to make a determination of unreasonable risk.

(5) Dioxin/Furan Reporting Form:

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