

## Environmental Protection Agency

## § 766.3

### § 766.2 Applicability and duration of this part.

(a) *Chemical substances subject to testing.* (1) This part is applicable to each person who, at any time during the duration of this part, manufactures (and/or imports), or processes, a chemical substance identified under § 766.25.

(2) The duration of this part for any testing requirement for any chemical substance is the period commencing with the effective date of this part to the end of the reimbursement period, as defined in § 766.3, for each chemical substance. All reporting requirements for any chemical substance listed under § 766.25 shall be in effect for the same period as the testing requirement.

(b) *Precursor chemical substances.* (1) This part is applicable to each person who manufactures (and/or imports) a chemical substance from any precursor chemical substance identified in § 766.38.

(2) The requirement for precursor reporting under § 766.38 shall be in effect until three years after the effective date of this part.

(3) Small manufacturers are exempt from reporting process and reaction condition data on chemical substances made from precursor chemical substances listed under § 766.38.

### § 766.3 Definitions.

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

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

*Dibenzofuran* 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 bridges between the benzene rings. The bridges are a carbon-carbon bridge and a carbon-oxygen-carbon bridge at both substitution positions.

*Dibenzo-p-dioxin* or *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.

*Guidelines* means the Midwest Research Institute (MRI) publication *Guidelines for the Determination of Polyhalogenated Dioxins and Dibenzofurans in Commercial Products*, EPA contract No. 68-02-3938; MRI Project No. 8201-A(41), 1985.

*HDD* or *2,3,7,8-HDD* means any of the dibenzo-p-dioxins totally chlorinated or totally brominated at the following positions on the molecular structure: 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.

*HDF* or *2,3,7,8-HDF* means any of the dibenzofurans totally chlorinated or totally brominated at the following positions on the molecular structure: 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.

*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 part 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)

*HRGC* means high resolution gas chromatography.

*HRMS* means high resolution mass spectrometry.

*Level of quantitation* or *LOQ* means the lowest concentration at which HDDs/HDFs can be reproducibly measured in a specific chemical substance within specified confidence limits, as described in this part.

*Polybrominated dibenzofurans* refers to any member of a class of dibenzofurans with two to eight bromine substituents.

*Polybrominated dibenzo-p-dioxin* or *PBDD* means to any member of a class of dibenzo-p-dioxins with two to eight bromine substituents.

*Polychlorinated dibenzofuran* means any member of a class of dibenzofurans with two to eight chlorine substituents.

*Polychlorinated dibenzo-p-dioxin* or *PCDD* means any member of a class of

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dibenzo-p-dioxins with two to eight chlorine substituents.

*Polyhalogenated dibenzofuran* or *PHDF* means any member of a class of dibenzofurans containing two to eight chlorine, bromine, or a combination of chlorine and bromine substituents.

*Polyhalogenated dibenzo-p-dioxin* or *PHDD* means any member of a class of dibenzo-p-dioxins containing two to eight chlorine substituents or two to eight bromine substituents.

*Positive test result* means: (1) Any resolvable gas chromatographic peak for any 2,3,7,8-HDD or HDF which exceeds the LOQ listed under §766.27 for that congener, or (2) exceeds LOQs approved by EPA under §766.28.

*Precursor* means a chemical substance which is not contaminated due to the process conditions under which it is manufactured, but because of its molecular structure, and under favorable process conditions, it may cause or aid the formation of HDDs/HDFs in other chemicals in which it is used as a feedstock or intermediate.

*QA* means quality assurance.

*QC* means quality control.

*Reimbursement period* means the period that begins when the data from the last test to be completed under this part for a specific chemical substance listed in §766.25 is submitted to EPA, and ends after an amount of time equal to that which had been required to develop that data or 5 years, whichever is later.

*TSCA* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

## §766.5 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 part. 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.

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## §766.7 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., §766.20) and must be addressed to: Document Control Office, (7407), Information Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: Dioxin/Furan Report.

[52 FR 21437, June 5, 1987, as amended at 60 FR 31922, June 19, 1995]

## §766.10 Test standards.

Testing required under subpart B of this part must be performed using the protocols submitted to and reviewed by the EPA expert panel established under §766.28. 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 submission to EPA in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA Good Laboratory Practices (GLPs) published in part 792 of this chapter. 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. At the time test data are submitted, manufacturers must submit a certification to EPA that the laboratory performing the testing adhered to the TSCA GLPs.

## §766.12 Testing guidelines.

Analytical test methods must be developed using methods equivalent to those described or reviewed in *Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products*. Copies are available from the Director, Environmental Assistance Division