

§ 766.1

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AUTHORITY: 15 U.S.C. 2603 and 2607.

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Subpart A—General Provisions

§ 766.1 Scope and purpose.

(a) This part identifies requirements for testing under section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603, to ascertain whether certain specified chemical substances may be contaminated with halogenated dibenzodioxins (HDDs)/dibenzofurans (HDFs) as defined in § 766.3, and requirements for reporting under section 8 of TSCA, 15 U.S.C. 2607.

(b) Section 766.35(b) requires manufacturers and processors of chemical substances identified in § 766.25 to submit to EPA:

(1) Any existing test data showing analysis of the chemical substances for concentrations of HDDs/HDFs, applicable protocols, and the results of the analysis for HDDs/HDFs, (2) allegations of significant adverse reactions to HDDs/HDFs, compiled in accordance with part 717 of this chapter, and (3) health and safety studies on the HDDs/HDFs, in accordance with applicable provisions of part 716 of this chapter.

(c) Section 766.35(a) requires manufacturers and, under certain circumstances, processors of chemical substances identified in § 766.25 to submit letters of intent to test and protocols for the analysis of the chemical substances for the presence of HDDs/HDFs. Section 766.20 requires these manufacturers and processors to test their chemical substances for the presence of HDDs/HDFs. Any submissions must be in accordance with the EPA Procedures Governing Testing Consent Agreements and Test Rules contained

in part 790 of this chapter and any modifications to such procedures contained in this part.

(d) Section 766.32 specifies conditions under which persons required to test may request an exclusion or waiver from testing.

(e) Deadlines for submission to EPA of protocols, reports, studies, and test results are specified in part 790, subpart C and § 766.35.

(f) Sections 766.10, 766.12, 766.14, 766.16, and 766.18 prescribe analytical methods required; § 766.27 prescribes target levels of quantitation (LOQ) for each congener for which quantitation is required.

(g) If results of existing tests or tests performed under this part indicate the presence of HDDs/HDFs in the identified chemical substance above the LOQ specified in § 766.27, § 766.35(c) requires the following additional reporting on the specified chemicals: production, process, use, exposure and disposal data under section 8(a) of TSCA; health and safety studies under section 8(d) of TSCA; and reports of allegations of significant adverse reactions under section 8(c) of TSCA. In some cases, additional reporting may be required of manufacturers reporting no contamination of the identified chemical substances under § 766.35(c)(2).

(h) Section 766.38 requires manufacturers of chemical substances produced from chemical substances identified as possible precursors to HDD/HDF formation, to report on chemical substances produced from such precursors.

§ 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 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.