information being claimed as CBI. The second copy must contain only information not claimed as CBI. The Agency will place the second copy of the submission in a public file. Failure to furnish a second copy of the submission when information is claimed as CBI in the first copy will be considered a presumptive waiver of the claim of confidentiality. The Agency will notify the applicant by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The applicant has 30 days from the date of receipt of notification to submit the required second copy. Failure to submit the second copy will cause the Agency to place the first copy in a public file.

(d) Applicants must substantiate all claims of CBI at the time the applicant asserts the claim, i.e., when the exemption application or supplement is submitted, by responding to the questions in paragraph (e) of this section. Failure to provide substantiation of a claim at the time the applicant submits the application will result in a waiver of the CBI claim, and the information may be disclosed to the public without further notice to the applicant.

(e) Applicants who assert any CBI claims must substantiate all claims by providing detailed responses to the following:

(1) Is this information subject to a patent or patent application in the United States or elsewhere? If so, why is confidentiality necessary?

(2) For what period do you assert a claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

(3) Has the information that you are claiming as confidential been disclosed to persons outside of your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

(4) Briefly describe measures taken by your company to guard against undesired disclosure of the information you are claiming as confidential to others.

(5) Does the information claimed as confidential appear or is it referred to in advertising or promotional materials for the product or the resulting end product, safety data sheets or other similar materials for the product or the resulting end product, professional or trade publications, or any other media available to the public or to your competitors? If you answered yes, indicate where the information appears.

(6) If the Agency disclosed the information you are claiming as confidential to the public, how difficult would it be for the competitor to enter the market for your product? Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes.

(7) Has the Agency, another Federal agency, or a Federal court made any confidentiality determination regarding this information? If so, provide copies of such determinations.

(8) How would your company's competitive position be harmed if the Agency disclosed this information? Why should such harm be considered substantial? Describe the causal relationship between the disclosure and harm.

(9) In light of section 14(b) of TSCA, if you have claimed information from a health and safety study as confidential, do you assert that disclosure of this information would disclose a process used in the manufacturing or processing of a product or information unrelated to the effects of asbestos on human health and the environment? If your answer is yes, explain.

PART 766—DIBENZO-PARA-DIOXINS/DIBENZOFURANS

Subpart A—General Provisions

Sec.

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

SOURCE: 52 FR 21437, June 5, 1987, unless otherwise noted.

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