mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit II of this document.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Enforceable Consent Agreement Solicitation

One, 6-hexamethylene diisocyanate (HDI) is an aliphatic diisocyanate. HDI is used in the manufacture of higher molecular biuret polyisocyanate resins and trimer polyisocyanate resins used in polyurethane paint systems. The production and uses of HDI in polyurethane paint systems results in potential exposures to substantial numbers of workers. The greatest potential for occupational exposures to HDI is in coating application operations, with an estimated 153,000 auto body repair workers having a potential for some exposure to paints containing HDI biuret and trimer. This potential for substantial exposure forms the foundation for the Agency's concern for the potential health risk that may be posed to workers by HDI.

In the **Federal Register** of May 20, 1988 (53 FR 18196), the Interagency Testing Committee (ITC) designated HDI for health effects testing for chronic toxicity, oncogenicity, and reproductive

and developmental effects. EPA responded to the ITC's designation of HDI by issuing a proposed test rule in the Federal Register of May 17, 1989 (54 FR 21240), requiring that HDI be tested for oncogenicity, mutagenicity, reproductive toxicity, developmental toxicity, neurotoxicity, pharmacokinetics, and hydrolysis under section 4 of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2603). The proposed rule contains a chemical profile of HDI, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards and reporting requirements. EPA based its proposal on section 4(a)(1)(B) of TSCA, finding that HDI is produced in substantial quantities and that there is or may be substantial human exposure from its manufacture, processing, and use.

EPA has recently reviewed significant new scientific data developed since publication of the proposed rule in 1989. The new data — which address chronic toxicity, subchronic toxicity, and mutagenicity — significantly affect the final scope of testing needs for this chemical substance. In view of these developments' impact on the scope of needed HDI testing, EPA is considering negotiating an Enforceable Consent Agreement (ECA) as an alternative to finalizing the proposed test rule to acquire the data identified in table 1. In the past, EPA, chemical manufacturers and other interested parties have frequently found that in some circumstances, the ECA process provides a more efficient, more flexible and less resource-intensive means of obtaining needed test data than the rulemaking process.

To be considered for ECA negotiation, testing proposals for HDI should address all data needs identified in table 1. If, after receiving testing proposals, EPA decides to pursue negotiations for HDI, EPA will solicit requests from individuals and others to be designated interested parties to the negotiation. EPA maintains its authority to require testing for HDI under TSCA section 4 and if negotiations do not produce an ECA, EPA intends to proceed with rulemaking to obtain the needed HDI data. EPA is also interested in receiving indications of interest in product stewardship programs as a compliment to the testing effort. Depending on what can be developed, it may be possible to offset some of the testing identified in this notice.

B. Chemical Data Needs

The ITC designated HDI for health effects testing, including chronic toxicity, oncogenicity, and reproductive and developmental effects on May 20. 1988 (53 FR 18196). EPA responded to the ITC's designation of HDI by issuing a proposed test rule in the Federal Register of May 17, 1989 (54 FR 21240), which would require that HDI be tested for oncogenicity, mutagenicity, reproductive toxicity, developmental toxicity, neurotoxicity, pharmacokinetics, and hydrolysis. The proposed rule contained a chemical profile of HDI, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards and reporting requirements. EPA based its proposal on section 4(a)(1)(B) of TSCA, finding that HDI is produced in substantial quantities and that there is or may be substantial human exposure from its manufacture, processing, and use.

EPA has reviewed new significant scientific data developed since publication of the proposed rule in 1989. The new data addressed chronic toxicity and subchronic toxicity which impacts the final scope of testing needs for this chemical substance. EPA believes the testing identified in table 1 is both appropriate and needed for HDI.

ABLE	1	.—Proposed	Testing	and	Test	Standards	For	HDI
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Description of Tests	Species	Exposure Route	Test Dura- tion	Guideline/Notes
Oncogenicity	1 species other than rat.	Inhalation	2 years	40 CFR 798.3300
2 generation reproductive study	1 species	Inhalation	2 generation	40 CFR 798.4700 as proposed for revi- sion (59 FR 42272, August 17, 1994)
Developmental toxicity study	2 species	Inhalation		40 CFR 798.4900 as proposed for revi- sion (59 FR 42272, August 17, 1994)
Acute neurotoxicity	1 species	Inhalation		1991 Neurotoxicity Testing Guidelines
Subchronic neurotoxicity	1 species	Inhalation	90 days	1991 Neurotoxicity Testing Guidelines
Mammalian cells in culture	NA [.]	NA	NA	40 CFR 798.5300
Salmonella typhimurium	NA	NA	NA	40 CFR 798.5265
in vivo cytogenetics	NA	NA	NA	40 CFR 798.5385
Hydrolysis	NA	NA	NA	Holdren, et al.