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EPA Proposes
HPV Test Rule For Chemicals

In July, the U.S. Environmental Protection Agency (EPA) published a proposed test rule under Section 4(a)(1)(B) of the Toxic Substances Control Act (TSCA) that would require manufacturers, importers and processors of certain high-production volume (HPV) chemicals to conduct testing. That EPA is renewing its focus on chemical testing, and use of its authority under TSCA Section 4 is noteworthy for the majority of the manufacturing industry.

Chemical Testing

Under TSCA Section 4, EPA can require manufacturers, importers, and in some cases processors of chemical substances to conduct testing of any chemical substance or mixture for which EPA makes certain findings. Under the law, EPA must find that "there are insufficient data and experience upon which the effects of [the] manufacture, distribution in commerce, processing, use or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted," and testing is necessary to develop the data. EPA must also find that the chemical substance or mixture may present "an unreasonable risk" to human health or the environment or that it is produced in substantial quantities that could result in substantial or significant human exposure or environmental release.

While *Manufacturing Today* readers in all cases may not be subject to this TSCA Section 4 test rule or any others, your company may distribute and/or use a chemical substance or mixture included within the scope of this rule, and others like it expected in the future. It is, therefore, important to be mindful of the implications of a TSCA Section 4 test rule, none of which are particularly favorable. In general terms, once EPA has made a TSCA "finding," inferences adverse to the chemical substance and, potentially, to industrial and consumer products made from the chemical substance, may follow. Certainly, if the chemical is used in industrial settings, worker exposure, health and safety implications can be expected to arise. If the chemical substance is a component of consumer products, it is reasonable to assume concerns with potential consumer exposures to the chemical substance will follow. All such concerns are at the expense of the commercial vitality of the chemical substance.

Depending on the nature of the concerns underlying the need for additional data and thus the issuance of the TSCA Section 4 test rule, there are several possibilities. Identified data needs may be relatively specific and finite, and the manufacturers will satisfy them without much fanfare. If more robust data needs are involved, manufacturers may seek to persuade EPA that development of only some data is needed and agree to develop those data, and be excused from other data requirements. In other situations, manufacturers may be unwilling or unable to develop the data EPA believes are necessary, decline to develop the data and decide to withdraw from the market. If others in the value chain decline to step up and develop the data, the chemical substance may simply vanish from the domestic market. Downstream users in all these circumstances had better be prepared for whatever option proves to be the controlling one.

Proposed Rule

According to the notice, EPA has preliminarily determined that each of the 19 chemicals included in the proposed rule is produced in substantial quantities and that there is or may be substantial human exposure to each of them; there are insufficient data to determine reasonably or predict the effects on health or the environment of the manufacture, distribution in commerce, processing, use or disposal of the chemicals, or of any combination of these activities; and the testing program proposed is necessary to develop such data. EPA states that data developed under the proposed rule "will provide critical information about the environmental fate and potential hazards associated with these chemicals which, when combined with information about exposure and uses, will allow the agency and others to evaluate potential health and environmental risks and to take appropriate follow-up action." Persons who export or intend to export any chemical substance included in the final rule would be subject to the export notification requirements in TSCA Section 12(b)(1) and at 40 C.F.R. Part 707, Subpart D.

EPA is proposing to require testing based on its preliminary findings under TSCA Section 4(a)(1)(B)(i) relating to "substantial" production and "substantial human exposure," as well as findings under TSCA Sections 4(a)(1)(B)(ii) and (iii) relating to sufficient data and the need for testing. Tests that would be required include environmental fate (including five tests for physical/chemical properties and biodegradation); ecotoxicity (in fish, Daphnia, and algae); acute toxicity; genetic toxicity (gene mutations and chromosomal aberrations); repeat dose toxicity; and developmental and reproductive toxicity. The proposed rule specifies the tests proposed for each chemical.

According to the proposed rule, EPA intends to use the data obtained to support development of preliminary hazard and risk characterizations for these HPV chemicals as part of the Chemical Assessment and Management Program (ChAMP) process, fulfilling the U.S. commitments under the Security and Prosperity Partnership of North America to set initial priorities for potential future appropriate action, including possible further testing that would produce more definitive hazard information where needed on such chemical substances. EPA states that such additional information is needed by EPA, other federal agencies, the public, industry and others to ensure that adequate hazard and risk assessments can be conducted on these chemical substances. EPA has used data from other test rules to support such activities as the development of water quality criteria, Toxic Release Inventory listings, chemical advisories and input for actions resulting in reduction of workplace exposures. Comments on the proposed rule are due by Oct. 22, 2008.

The proposed testing requirements are not effective until and unless EPA issues a final rule. Based on the effective date of the final rule, which is typically 30 days after the publication of a final rule in the Federal Register, the test sponsor may plan the initiation of any required testing as appropriate to submit the required final report by the deadline indicated as the number of months after the effective date that would be shown in Section 799.5087(j) of the proposed regulatory text. Persons required to comply with the final rule would have to conduct the necessary testing in accordance with the testing and reporting requirements established in the regulatory text of the final rule, and with TSCA Good Laboratory Practice.

Protecting Your Assets

As noted, while relatively few readers may be subject to any forthcoming TSCA Section 4 test rule, many readers may be implicated by virtue of their use of any of the 19 chemical substances. This rule is but one of many that may well be issued in the months and years ahead as a result of intense interest in the safety of existing chemicals used in commerce. To ensure you are fully aware of the implications of such rules, readers are urged to monitor and participate as appropriate in these proceedings and, at the least, assess and plan for the commercial and business consequences of any final test rules. **mt**

Those to Watch

The 19 chemicals included in the proposed rule are listed below.

> CAS No.
> Chemical Name

75-07-0
> Acetaldehyde
78-11-5
> 1,3-Propanediol,2,2-bis[(nitrooxy)methyl]-,dinitrate (ester)
84-65-1
> 9,10-Anthracenedione
89-32-7
> 1H,3H-Benzo[1,2-c:4,5-c']difuran-1,3,5,7-tetrone
110-44-1
> 2,4-Hexadienoic acid, (E,E)-
118-82-1
> Phenol,4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)
119-61-9
> Methanone, diphenyl
144-62-7
> Ethanedioic acid
149-44-0
> Methanesulfinic acid,hydroxy-, monosodium salt
2124-04-1
> Phosphorochloridothioic acid, O,O-diethyl ester
4719-04-4
> 1,3,5-Triazine-1,3,5(2H,4H,6H)-triethanol
6381-77-7
> D-erythro-Hex-2-enonic acid,g-lactone,monosodium salt
31138-65-5
> D-gluco-Heptonic acid, monosodium salt, (2-x.)
66241-11-0
> C.I. Leuco Sulphur Black 1
68187-76-8
> Castor oil, sulfated, sodium salt
68187-84-8
> Castor oil, oxidized
68479-98-1
> Benzenediamine, ar,ar-diethyl-ar-methyl
68527-02-6
> Alkenes, C12-24, chloro
68647-60-9
> Hydrocarbons, C >4

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