



Questions and Answers About Chemical Testing and Regulations

Are new chemicals screened and evaluated for safety before they enter the market?

Yes. Since the Toxic Substances Control Act (TSCA) became effective in 1977, manufacturers have been required to submit health- and safety-related information to EPA for review prior to bringing any newly developed or imported chemical into the market. In other words, every new chemical that has entered U.S. commerce since 1977 has been reviewed by EPA. This process was designed to ensure that information on the safety of every new chemical is available and has been evaluated.

If EPA has questions or concerns about the risks associated with a particular chemical, the agency can require additional information and/or testing. EPA also has authority to limit or prohibit the manufacture, distribution, or use of a substance if it is found to pose an unreasonable risk.

Since TSCA was implemented, approximately 10 percent of the 36,600 new chemical submission packages (called Premanufacture Notices or PMNs) reviewed by EPA have resulted in various restrictions, additional testing requirements, withdrawn submissions, or denial.

What about chemicals already in commerce when TSCA was passed – are they regulated, too?

Yes. In 1979, EPA established an inventory of chemicals in U.S. commerce. At inception, chemical manufacturers were required to submit information on all chemicals produced, imported, or used for commercial purposes between 1975 and 1979¹. This information enabled EPA to establish an initial “inventory” of approximately 61,000 existing chemicals. Newly developed or imported chemicals are added to the inventory based on the commercialization of PMN submissions.

Under TSCA’s Inventory Update Rule (IUR), every four years, companies must report to EPA updated production and import data for chemicals produced or imported in quantities above a certain threshold. Chemicals produced or imported in lesser quantities remain subject to other TSCA regulations even though updated production volume reporting is not required.

¹ See 45 Fed.Reg. 50544 (July 29, 1980); 47 Fed.Reg. 25767 (June 15, 1982) (TSCA Revised Inventory and 1982 cumulative supplement).

Previously, IUR requirements included reporting on organic chemicals (except polymers) produced or imported in quantities greater than 10,000 pounds per site annually, which typically resulted in reporting on about 9,000 chemicals². In 2002, approximately 1,080 companies compiled and submitted IUR reports.

Recently, EPA promulgated a rule that raised the IUR reporting threshold to 25,000 pounds, but significantly increased the reporting requirements to include use and exposure information (as well as production data), and expanded the scope of reporting to include inorganic chemicals. Companies will begin reporting under the expanded IUR requirements in 2006.

What if EPA needs additional information about a chemical?

IUR reporting is important because it allows EPA to identify and evaluate trends in commercial chemicals. However, TSCA also gives the agency broad authority to require companies to submit additional information. For instance, EPA has virtually unlimited ability to require the submission of basic information on production, uses and exposure, as well as existing data. Furthermore, if EPA finds a gap in the available health and safety information and there is reason to believe a substance may pose a significant risk of adverse health or environmental effects, EPA has the legal authority to require that a manufacturer conduct testing or provide additional information on that substance. The agency may also limit or prohibit the production and use of any chemical that is found to pose an unreasonable risk.

Since TSCA was enacted, EPA has required testing on approximately 200 chemicals, has required that specific information be reported for approximately 1,100 chemicals, and has required submission of health and safety studies for approximately 1,000 chemicals, resulting in more than 50,000 studies covering a broad range of health and ecological endpoints.³ These information collection activities continue; in early 2005 EPA announced plans to conduct “data call ins” for an additional 275 substances.

Additionally, TSCA requires chemical manufacturers and importers to submit to EPA within 30 days any information obtained that reasonably supports the conclusion that a chemical poses a substantial risk of injury to health or the environment. This reporting requirement applies to all chemicals in commerce. Violation of this law renders an individual subject to civil penalties of up to tens of thousands of dollars per day, and knowing and willful violations can lead to criminal penalties, including imprisonment. The agency has received and reviewed more than 15,000 of these notices⁴ covering a wide range of chemical substances and mixtures.

How many chemicals are present in U.S. commerce today?

EPA data indicate that there are currently between 9,000 and 15,000 chemicals in U.S. commerce. Of the more than 80,000⁵ chemical substances listed in the master TSCA inventory, only 9,000 organic chemicals were reported to have been produced or imported in

² EPA’s 2002 IUR Reporting Database (<http://www.epa.gov/oppt/iuold/iur02/index.htm>).

³ Overview: Office of Pollution Prevention and Toxics Programs, December 24, 2003 (Draft)

⁴ Overview: Office of Pollution Prevention and Toxics Programs, December 24, 2003 (Draft)

⁵ Overview: Office of Pollution Prevention and Toxics Programs, December 24, 2003 (Draft, p. 5-6)

annual quantities of 10,000 pounds or more⁶ when the inventory was updated in 2002. However, EPA's Chemical Information and Testing Branch (CITB) estimates that today there could be as many as 6,000 additional chemicals currently in commerce, a figure which presumably includes inorganic chemicals and chemicals produced or imported in quantities less than 10,000 pounds.

Obviously, the TSCA inventory is *not* a list of chemicals in commerce. The inventory contains the 61,000⁷ "existing" chemicals listed in the original inventory when it was established in 1979 and approximately 19,000 "new" chemicals that have been reviewed by EPA and commercialized by manufacturers since that time. It is important to note that many of the chemicals listed in the original inventory are no longer in commercial production and that many of the "new" chemicals reviewed by EPA never actually make it to market or do not remain in commercial production.

How many of these are considered high production volume?

About 2,800 chemicals – approximately 95 percent of the market by volume – are considered high production volume (HPV) substances, which means that they are produced or imported in quantities greater than 1 million pounds per year.

How can the public know for sure that chemicals are being evaluated for safety?

In 1998, the chemical industry, working with EPA, Environmental Defense and others, launched the High Production Volume Challenge Program, an unprecedented, voluntary initiative through which industry has set a goal of making uniform screening information on 2,222 HPV chemicals available to EPA and the public by 2005.

How were chemicals selected for the HPV Challenge Program?

When the HPV Challenge Program was initiated in 1998, EPA developed a list of approximately 2,800 HPV chemicals from the 1990 TSCA Inventory, the most current information available at that time. However, based on its review of these substances, EPA identified roughly 270 chemicals that were no longer produced in HPV quantities, no longer produced at all, or that it otherwise did not consider suitable candidates for screening under the HPV Challenge. The agency exempted these chemicals from the program. Companies have since volunteered to assess and provide to EPA complete screening information on approximately 2,222 HPV chemicals by 2005. The roughly 330 chemicals that were not volunteered for the program may be subject to mandatory testing under one or more TSCA test rules. A complete list of chemicals included in the HPV Challenge can be found at: http://www.epa.gov/chemrtk/hpv_1990.htm

What constitutes "complete screening information" and who makes that determination?

In 1987, the 30 nations of the Organization for Economic Cooperation and Development established a baseline of standard toxicity tests, testing protocols, and information formats to coordinate hazard screening on high production volume chemicals worldwide. These

⁶ Additional information on the 2002 inventory, including a searchable database, is available on EPA's website: <http://www.epa.gov/opptintr/iur/iur02/index.htm>.

⁷ Overview: Office of Pollution Prevention and Toxics Programs, December 24, 2003 (Draft, p. 5-6)

standards, commonly known as “SIDS,” short for Screening Information Data Sets, were developed by U.S. EPA and the international regulatory community with input from industry experts, environmental groups, and others. The SIDS standards define 17 types of information needed to evaluate HPV chemicals.

The HPV Challenge Program has adopted the internationally-agreed SIDS standards. Therefore, information submitted to EPA under the HPV Challenge program must meet SIDS requirements. This means that for each of the 2,222 chemical substances included in the HPV Challenge Program, sponsors must submit 17 types of information, including summarized results in four categories: physical-chemical properties, environmental fate, and potential to induce toxicity in aquatic organisms and humans. Data to be summarized for human toxicity include studies assessing acute toxicity, subchronic toxicity, genotoxicity, and developmental and reproductive toxicity.

Is it true that very few HPV chemicals have even been minimally tested for health and environmental hazards?

No. Between 1997 and 1998, Environmental Defense, EPA and industry each conducted separate but similar studies on the public availability of health and safety information on HPV chemicals. These studies were designed to measure only the amount of information that was publicly available through a limited number of electronically searchable databases. All three evaluations concluded that complete hazard information was not publicly available for a majority of HPV chemicals. However, much of this safety information existed at that time; it simply did not exist in a uniform, electronically searchable format.

Under the HPV Challenge, industry sponsors are reviewing information from a variety of sources, creating robust summaries, writing test plans, and conducting any additional testing needed to meet SIDS standards for 2,222 HPV chemicals.

Why do some people say that chemicals aren't tested?

Oft-cited statistics suggest that only 43% of HPV chemicals have been tested for potential health effects and only 7% have been studied for possible effects on human development. Even EPA has used these numbers as “shorthand” for describing the results of its 1998 HPV information study titled “Chemical Hazard Data Availability Study.” However, these statistics are not an accurate description of the study’s conclusion and are, therefore, misleading. Moreover, the study itself clearly acknowledged that it was a limited review of very specific databases. The EPA study was an important and positive contribution to the development of the HPV Challenge Program. But given its methodology, the study itself did not and could not determine what percentage of HPV chemicals had actually been tested.

What is the status of the HPV Challenge to date?

More than 400 sponsoring manufacturers, acting individually or as members of consortia, have volunteered to provide complete SIDS information for 2,222 HPV Chemicals. This information is provided to EPA in the form of separate “robust summaries” of each study, accompanied by a “test plan” for completing any additional testing needed to fulfill SIDS information requirements. Many of the sponsored chemicals took a “category based” approach, which allows studies from one chemical to be applied to other chemicals with demonstrated similarities. This has resulted in significant saving of test animals, ensuring that new data are generated humanely. According to program sponsors, only 380 additional tests

are needed to complete the SIDS testing required for the first 1,300 chemicals. In fulfillment of their commitment under the HPV Challenge, sponsors have already submitted test plans to provide this information. The robust summaries and test plans for these chemicals are available online at: <http://www.epa.gov/chemrtk/hpvrstp.htm>.

Are SIDS data applicable to children's health?

Absolutely. Each of the 17 types of information collected under the HPV Challenge is important and relevant for evaluating a chemical's potential impact on human health and the environment. Moreover, specific test categories, such as genotoxicity and acute, developmental and reproductive toxicity, are specifically relevant to protecting children's health. To date, EPA has received and posted to its website information on more than 900 reproductive and developmental studies, each of which is most directly relevant to children. For more information, see: <http://www.epa.gov/chemrtk/hpvrstp.htm>.

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