

Program (see <http://www.epa.gov/opptintr/chemrtk/volchall.htm>), as well as exposure data through other voluntary programs (e.g., International Council of Chemical Associations (ICCA) data collections and UEIP). Therefore, providing exposure-related information on HPV chemicals via IURA would be duplicative and unnecessary.

The Agency recognizes that a variety of voluntary and regulatory efforts to collect hazard data are underway, such as the voluntary HPV Challenge Program. However, the scope and expected output from the HPV Challenge Program differ markedly from those anticipated under IURA. The HPV Challenge Program centers on providing basic hazard data for HPV chemicals, most of which will also be IURA-reportable chemicals. The IURA focus is on gathering exposure-related information for moderate and high volume chemicals in a wide range of industrial operations, involving multiple sites and covering manufacturing, processing, and use of the chemical substances.

The Agency is unable to limit its IURA information collection efforts to HPV chemicals alone, for several reasons. The Agency could not know definitively which chemicals are HPV substances in any particular IURA reporting cycle as of that reporting year. A chemical substance meets the criteria for an HPV chemical by meeting a one million pound national production volume threshold, based upon the aggregate production volume in the nation (as reported to IUR). Production volumes can vary significantly over a 4-year reporting cycle, and it is not uncommon for chemicals to rise above or fall below the HPV threshold each reporting cycle. For instance, EPA used 1990 IUR reporting to identify approximately 2,800 HPV substances. An additional 500 substances which were not HPV chemicals in 1990 were identified as being HPV via the 1994 IUR production volume data. The IURA collection could be limited to the HPV Challenge Program chemicals (i.e., the baseline set of chemicals for the program, consisting of chemicals that were HPV according to 1990 IUR information). However, that restricts IURA's ability to supply screening level exposure information to only those HPV chemicals. This would severely limit the usefulness of IURA over time, as the universe of chemicals that were HPV in 1990 will not be the same universe of chemicals that are HPV in future years, and would compromise the Agency's broader responsibility for risk screening.

b. *Existing Chemicals Program "low concern" chemicals.* Commenters

recommended that the chemicals previously determined by EPA to be of low concern via the Existing Chemicals Program be exempt from reporting under IURA. However, commenters did not provide sufficient criteria that would clearly distinguish exempted chemicals from others subject to IUR reporting. EPA cannot create exemptions without a clear basis or justification. During the development of these amendments, EPA considered exempting chemicals previously reviewed by the Existing Chemicals Program, but was unable to develop standard criteria for such an exemption (See Ref. 33 and Unit IX.3. of the proposal preamble, at 64 FR 46794). Under the Existing Chemicals Program, no standard criteria were used for determining which chemicals were lower priority, because in the course of the program many different chemicals involve unique risk assessment or risk management issues. For example, many chemicals were analyzed within a specific use, and other uses were not examined. As an alternative to this approach, EPA developed a partial exemption for chemicals which are determined to be of low current interest for purposes of IURA processing and use information reporting, based on considerations described in Unit II.F.1.d., and identified an initial list of chemicals currently covered by the partial exemption (Ref. 5).

c. *Organization for Economic Cooperation and Development (OECD) chemicals.* Commenters recommended that the chemicals for which EPA has a minimum set of hazard and exposure data, such as OECD's SIDS chemicals that have completed the SIDS process, be exempt from reporting under IURA. Commenters also suggested that chemicals in the International Council of Chemical Association (ICCA) screening level data collection programs be included in this exemption.

EPA disagrees that data collection efforts through the OECD and ICCA programs provide sufficient exposure information to replace IURA information. Data collection efforts under the auspices of OECD and ICCA concentrate on the development of hazard assessments and generally provide only a small fraction of the exposure-related data called for under IURA. A goal of the ICCA Program is to process chemical cases through OECD's HPV SIDS Program, which develops hazard information for the program chemicals. As hazard data do not change from year to year, the data collection supports a one-time report. The IURA will provide current exposure-related information for risk

screenings and preliminary assessments. Exposure information, as collected under IURA, will vary from reporting year to reporting year and therefore needs to be collected on a continuing basis. While the OECD HPV SIDS Program does not specifically disallow the collection of exposure information, the program does leave such collection to the discretion of the sponsor country (Ref. 34). Exposure information available via SIDS is therefore generally not specific to U.S. uses and concerns.

d. *Metals.* Various commenters stated that either metals as a group, or specific metals such as zinc and copper, should be granted special consideration for IURA reporting. Several commenters asserted that providing information on maximum concentrations is unnecessary for the metals, because they will generally have close to 100% concentrations when they leave the manufacturing site or whenever they are present in consumer or commercial products. Further, commenters indicate that the only exposure potential for these substances in commercial or consumer products will be dermal (not via other routes such as inhalation or ingestion). Additionally, a commenter stated that workers "in proximity" to or handling solid metal articles should not be considered to be exposed for reporting purposes, because the metal is in a form in which neither inhalation nor dermal exposure will occur. Other commenters believed that any IUR reporting on metals is unnecessary because ample information on metals production and exposure potentials is already available from other sources, such as the USGS, or because specific metals, such as copper and zinc, are beneficial to human health and therefore should be of no exposure concern.

Metals present some unique issues regarding exposure potential, and the information that will be collected under IURA on metals will do much to improve EPA's and others' knowledge about the uses and exposures associated with these chemicals. Not all metal-containing products are pure metal. For example, metal powders used in fine arts, metal pastes used in repairs, and commercial metallic paints contain varying percentages of metals. In addition, although some metals in trace quantities, such as chromium, are essential nutrients to plants and/or animals, in greater exposure concentrations these same metals can be harmful.

Because metals are ubiquitous and can be present in a variety of physical forms, different routes of exposure are possible. Chronic exposure to solutions