

the data collection to facilitate efficient data management and use. Data collected through IURA will be put into a relational data base format, which can be easily searched, compared, and used. The collection of data organized by codes, rather than narrative information presented in an unstructured manner, lends itself to such a data base format. In addition, providing for electronic IURA submissions allows data to be entered into the data base more accurately and expeditiously, resulting in a quick turnaround between the submission of the data to the Agency and the availability of the data for use. The Agency anticipates that approximately 95% of all reports will be submitted electronically or on disks, as opposed to hard copies. This compares with 70% that were submitted on disks in 1998. The IURA will facilitate EPA's information management and the data will be available quickly for the Agency's and others' use.

3. *Why doesn't EPA use other available sources of data or mechanisms to collect the data sought under IURA?* EPA requested comments on specific mechanisms or data sources it could use to obtain needed exposure-related information with greater ease and less burden to industry. Commenters responded with a variety of sources, ranging from current data collection mechanisms within EPA (such as TSCA 8(a) PAIR, UEIP, and cooperative approaches) to public data sources such as the Hazardous Substances Data Bank (HSDB) (HSDB is a toxicology data file on the National Library of Medicine's (NLM) Toxicology Data Network (TOXNET)). In addition, many commenters stated that EPA has not made effective use of the exposure-related data it has collected already under current or prior programs. For example, they stated that data collected under two other TSCA rules - the PAIR and the Comprehensive Assessment Information Rule (CAIR) rules - have not been used effectively to support Agency risk assessment or risk management decisions. Commenters went on further to say that under the voluntary UEIP, EPA was furnished exposure-related data on 60 HPV chemicals (actually only 48), but only two reached the initial risk assessment stage.

The alternate data sources commenters described were generally sources that EPA had already evaluated in its analysis for the proposed rule or with which EPA was otherwise familiar. EPA explored a wide variety of public data sources, as demonstrated in the following: "Inventory Update Rule (IUR) Amendments Technical Support Document: Exposure-Related Data

Useful for Chemical Risk Screening" (Ref. 14), "Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule" (Ref. 26), and "A Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response to CMA" (Ref. 27) (see also Unit V.B.5. of the proposed rule at 64 FR 46780)). For the most part, commenters did not identify new sources or provide additional information to support the assertion that these alternate data sources provide the information that EPA proposed to collect under IURA. After considering the information provided, EPA believes the decision not to use an alternate data source as a replacement for IURA is still sound. The Agency may, however, evaluate an alternate source for individual chemicals as part of its consideration of a particular chemical under the new exemption process established in the final rule.

EPA has spent considerable effort and resources evaluating other data sources that could potentially provide the accurate and up-to-date information that the Agency needs. A primary consideration, as mandated by TSCA, was not to subject industry to unnecessary or duplicative reporting. The exposure information sought under IURA is not currently accessible to EPA. Although some useful exposure-related data exist in some sources, the data are insufficient for the purposes to which IURA data will be put, typically because they are neither timely or detailed enough. Without IURA, EPA has difficulty efficiently screening potential risks posed by approximately 4,000 higher production chemicals on the TSCA Inventory.

Commenters stated that, if EPA were to have specific concerns about information collection for substances or categories of substances, the selective use of TSCA section 8(a) PAIR (40 CFR part 712) reporting would be more cost effective than requiring all manufacturers exceeding a production trigger to report manufacturing, processing, and use information. EPA disagrees with the suggestion that PAIR rules would be an efficient or cost effective way to compile a data base to allow the relatively large-scale risk screening of chemicals on the TSCA Inventory. PAIR is a very useful data collection tool when one or a small group of chemicals is targeted for risk assessment; however, PAIR is limited when collecting information on a large number of chemicals. Additionally, the PAIR rule has fewer, less definitive data elements than IURA, is a one-time collection versus the recurring

collection of IURA, and will not provide data sufficient to meet the goals of IURA. Use of PAIR rather than IURA would force EPA to set risk screening priorities based on hazard and production volume alone, or in response to requests from others. As discussed in the document entitled "A Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response To CMA" (Ref. 27), this approach greatly hinders EPA's ability to make effective and efficient risk management decisions.

EPA plans to continue using existing data sources and information sets. For example, EPA has used data previously collected under PAIR, CAIR, and the UEIP in a variety of ways, such as to support TSCA section 4 test rule analyses, to provide analyses for the Agency's efforts under the OECD SIDS program, and in support of international efforts (Refs. 18 and 27). However, the existing sources are generally best used when conducting a more detailed risk assessment of a specific chemical of concern, rather than preliminary risk screening of a relatively large set of chemicals. The IURA submissions will provide a consistent set of screening level exposure data that will allow EPA to better identify on a relative basis the chemicals of highest priority for further risk evaluation. EPA will use IURA data to identify those specific chemicals which are of potential concern and need follow up assessment. For instance, IURA exposure data integrated with HPV Challenge Program hazard data will provide the input needed to effectively develop risk-based priorities for more detailed assessment of chemicals. Once EPA has determined that a specific chemical (or group of chemicals) has sufficient potential for exposure or risk to warrant further assessment, the Agency will use the other information sources and data gathering tools as appropriate.

4. *Can TSCA information be used for right-to-know purposes?* Some of the commenters stated that TSCA does not authorize EPA to promulgate IURA based in part on EPA's goal of providing "right-to-know" information to the public, non-governmental entities and private organizations. In addition, some commenters noted that OSHA and other agencies have their own authorities to collect information on chemicals.

TSCA contains many of the principles embodied in the right-to-know concept. For instance, TSCA section 14(b) specifically authorizes EPA to disclose health and safety data collected under the statute. TSCA section 14 reflects the legislative determination that certain TSCA data should be available to the