

and concentrations and physical forms of the chemical. EPA uses these exposure-related data to generate screening level risk assessments for regulatory decision-making under TSCA section 5.

The manufacturer of a new chemical provided the following information in a recent PMN submission: An estimated import volume; chemical uses and the percentages of the import volume devoted to each use (non-cosmetic applications as a component of a fragrance formulation used in household products such as detergents, cleaners, soaps, room fresheners, etc.); number of sites and workers; and consumer product information (weight percent in products). EPA used this information in combination with technical references and other data to estimate the number of manufacturers of household products who may use the new substance. Releases of the new substance as a result of the fragrance formulation process and from manufacturers of the household products were estimated, resulting in estimated environmental concentrations of the new substance due to its release and estimated general population exposures to the new substance. EPA also used the information on processing and use in combination with modeling techniques to estimate the number of workers and consumers who may be exposed to the new substance and their estimated exposures to the new substance. These exposure-related estimates, when combined with information on the estimated hazards of the new substance, indicated that the estimated risks to potentially-exposed workers, the general population, consumers, and aquatic species were all below levels of concern. Therefore, the Agency could determine that no further regulation under TSCA section 5 was needed for this new substance. In contrast, without this information, EPA would have had to rely on generic assumptions for approximating potential exposures. These types of assumptions are intended to be conservative in nature and therefore often result in higher than likely exposure estimates.

Information from the IURA may also be used in efforts to identify single chemicals to support potential exposure prevention activities. For example, EPA recently learned that certain imports of zinc sulfate were contaminated with cadmium. Using the IURA processing and use data on inorganic substances, EPA could have quickly identified importers of zinc sulfate and segments of industry or the general population that might use the chemical. EPA then

could have targeted warnings of the potential for exposure to cadmium more effectively, thereby preventing exposures to the groups likely to be the most highly exposed.

Other Federal agencies have also long recognized the need for and importance of exposure data. OSHA, NIOSH, and CPSC have written letters supporting EPA's and their own need for exposure data (Refs. 12, 13, 21, 22, and 23). In May 2000, the Government Accounting Office (GAO) stated that "Various federal agencies have collected such human exposure data for a number of purposes; historically, these collection efforts have been limited to selected chemicals, subpopulations, and time periods" (Ref. 24).

Other government agencies, industry, public interest groups, and the public in general will be able to access and use the non-CBI portion of IURA information. The IURA exposure-related data will be important to users beyond those who accessed the existing IUR in the past solely for production volume information. The Natural Resources Defense Council (NRDC), for example, has expressed interest in using IURA information (Ref. 25). In another case, persons interested in reviewing the HPV Challenge Program screening level hazard data (see <http://www.epa.gov/opptintr/chemrtk/volchall.htm>) will be able to use the non-CBI exposure-related IURA data to put the hazard data into context. Risks identified via evaluation of these screening level hazard and exposure data then can be addressed.

Although EPA can envision a wide variety of uses for the new IURA exposure-related information as described in this section, the Agency anticipates that even more opportunities exist for use of this information, as is true for the basic production data reported under the current IUR.

#### *2. What is the practical utility of the new exposure-related data?*

Commenters have questioned whether the data collected as a part of this rulemaking will have "practical utility." Practical utility is defined in the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3502(11)) to mean "the ability of an Agency to use information, particularly the capability to process such information in a timely and useful fashion." The OMB regulatory definition of "practical utility" at 5 CFR part 1320.3(l) addresses not only the theoretical or potential usefulness of information to an Agency, but also its actual usefulness, taking into account its accuracy, validity, adequacy, and reliability, the Agency's ability to process the information in a useful and timely fashion, and whether the Agency

demonstrates actual timely use of the data by the Agency's own functions. The following discussion addresses commenters' concerns in two parts: First, the accuracy, validity, adequacy, and reliability of the data; and second, the timely use of the data by EPA.

a. *How has the Agency ensured that the data will be accurate, valid, adequate, and reliable?* Commenters asserted that the data EPA proposed to collect through IURA would not be adequate for the purposes stated by EPA, and would not be accurate, valid, or reliable. Commenters stated that the information collected through IURA would be of limited accuracy and would be inferior to data the Agency has collected in other programs.

Commenters also stated that the information would be so uncertain that it would not be useful to predict chemical risk, and that there are so many other factors that affect exposure, such as engineering controls, that the data would provide a limited and potentially inaccurate view of potential exposure. Additionally, commenters asserted that they do not know how their chemicals are used downstream of the manufacturing site, therefore if they were required to report such information, the resulting data would be unreliable.

EPA considered the types of information needed for screening level exposure and risk assessments and believes the information that will be collected through IURA will have the necessary level of accuracy, validity, adequacy, and reliability for such assessments. EPA agrees that there are many ways to increase the accuracy, validity, and reliability of the data. However, in developing IURA and considering various alternatives, EPA relied on experience from programs such as TSCA's PMN program and the UEIP data collection, and maintained a balance between data needs for exposure screening and priority setting and the burden associated with providing the information. If the Agency had required very precise, specific reporting, submitter burden would have increased beyond that which is appropriate for a screening level data collection. EPA also agrees that there are many factors that can affect exposure potential; however, the data provided by the submitters will provide baseline information sufficient for an initial screen of exposure potential.

i. *Adequacy of the data.* Before proposing the IURA, EPA analyzed various exposure data collections and assessments to determine the data elements needed for a screening level exposure assessment. This discussion