

further explanation of some of these activities).

#### *D. Why is EPA amending the IUR?*

EPA is amending the IUR for three primary reasons: (1) To tailor the chemical substance reporting requirements to more closely match the Agency's information needs; (2) to obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory; and (3) to improve the utility of the information reported. These amendments will enhance the information collected through the IUR, improve the scope of chemicals covered by the rule, and improve CBI claims, thereby accomplishing these three goals.

These goals are supported by the policy in section 2(b)(1) of TSCA, that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." The data currently available to EPA are generally inadequate for risk screening purposes. TSCA section 8(a)(2) authorizes EPA to require manufacturers and processors of chemical substances to report a wide variety of data, including exposure-related information which will be reported for certain chemical substances under IURA. These amendments remove certain reporting requirements and add others to focus reporting under the IUR on that information which is most needed by EPA and other Federal agencies for screening, assessing, and managing risk. Additionally, the availability of these data will enhance public awareness of basic information about chemical substances.

Any evaluation of potential "risk" is generally based on a combination of hazard information and exposure information. EPA relies on risk screening to indicate which chemical substances pose a potential risk to human health or the environment, and thus warrant a more detailed, resource intensive analysis. The EPA Science Advisory Board's report "Reducing Risk: Setting Priorities and Strategies for Environmental Protection" (Ref. 1) and the National Academy of Public Administration's report "Setting Priorities, Getting Results, A New Direction for EPA" (Ref. 2) recognize that EPA's ability to use risk screening to set priorities and allocate its limited resources has been significantly impeded by a lack of exposure data. The manufacturing, processing, and use of chemicals on the TSCA Inventory result

in a wide array of exposure scenarios. The exposure-related data included in IURA will greatly improve EPA's ability to conduct risk screening to identify chemical substances that could pose an unreasonable risk to human health or to the environment, or that otherwise warrant further investigation.

#### *E. What are EPA's TSCA-Related Chemical Screening and Assessment Activities?*

TSCA authorizes EPA to gather chemical hazard and exposure data, as well as related information such as production volume, to determine whether a chemical may pose an unreasonable risk of injury to human health or the environment. The Agency is able to institute risk management actions when necessary to mitigate or avoid unreasonable risk. Important elements in a successful chemical risk management program include identifying the chemical substances, manufacturing sites, and exposure scenarios of greatest potential concern, and using that information to set priorities for more detailed risk assessment, further research, advisory notices, or other appropriate actions. To help fulfill its TSCA responsibilities, EPA has established the IUR and other regulations to collect information on commercial chemicals.

The TSCA Inventory currently includes more than 76,000 chemical substances. Approximately 8,900 of these chemical substances are non-polymer, organic chemical substances manufactured at at least one site in quantities of 10,000 lbs. or more per year, as reported under the 1998 IUR data collection. EPA estimates that IURA will continue to collect information on approximately 8,900 chemical substances. However, the set of substances that will be reported under IURA will be somewhat different than the set of substances that was reported under the previous IUR collections primarily because of two changes: Raising the basic reporting threshold (see Unit II.F.2.) and adding reporting on the manufacture of inorganic chemical substances (see Unit II.F.1.a.). Data collected under IURA will enable EPA to more effectively conduct initial risk screening on a subset of the chemical substances within its purview, as described in the remaining part of this section and in Unit III.A.1.

EPA conducted tiered risk evaluations of chemical substances even prior to the enactment of TSCA in 1976. A tiered approach allows EPA to sort through many chemicals, focus on those chemical substances of greatest concern,

and take appropriate actions. The Agency is thus able to optimize resources while limiting overall regulatory burdens. The essential steps of the tiered risk evaluation generally include: An initial evaluation (sometimes preceded by a prescreen of candidate chemicals); basic risk management decisions resulting from the initial screening; more detailed risk assessment when appropriate; and resulting risk management actions, such as regulatory or voluntary efforts to reduce risk. Each of these steps is only as effective as the available data inputs—if little data exist to inform the process, each step suffers as a result.

Exposure-related information collected through the IURA will inform the initial risk screening step. Initial risk screening is conducted using readily accessible information from the scientific literature, as well as other data readily available to the Agency, such as those provided by manufacturers and processors. This information set often is incomplete or of insufficient quality to allow the Agency to reach definitive conclusions about the set of chemicals under review, but may be sufficient to decide which chemicals appear to warrant further evaluation, or conversely, appear to be low priority and therefore do not currently warrant further review. These initial reviews are often more qualitative than quantitative. Also, continual updates to these data, such as the recurring reporting of exposure-related data under IURA, will ensure that the most serious concerns will be addressed even as chemical quantities and exposure potentials change between submission periods.

The effectiveness of risk screening, risk assessment, and risk management is dependent upon the quality as well as the availability of both hazard and exposure information. While past approaches to priority setting have emphasized relative chemical hazards and used production volume as a simple surrogate for exposure, EPA must increase its emphasis on the exposure component of risk screening and assessment. EPA no longer believes that reporting under the current IUR is adequate for these purposes. The IURA will provide EPA with data that will more accurately and realistically gauge potential exposures. The exposure-related information reported under IURA will be used in combination with hazard information developed under TSCA section 4 test rules and enforceable consent agreements/orders, through voluntary efforts such as the High Production Volume (HPV) Challenge Program (see [www.epa.gov/opptintr/chemrtk/volchall.htm](http://www.epa.gov/opptintr/chemrtk/volchall.htm)), and