

and analysis are in the document "Inventory Update Rule (IUR) Amendment Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening" (Ref. 14). Commenters' suggestions on the proposed rule implied that more extensive information about exposures than was included in the proposed rule would be necessary for even a screening level analysis of potential exposure. One commenter stated that there are many other factors that can significantly affect the potential for exposure. These factors include engineering controls and personal protective equipment practices, the nature of the activities in which workers are engaged, and the physicochemical characteristics of the chemical substances. This commenter also stated that the data collected under IURA will provide a limited and potentially inaccurate view of potential exposure. However, as summarized in Unit III.A.1., risk analyses performed by the Agency in general and OPPT in particular are graduated and data-driven. As the initial levels of concern and the quantity and quality of data increase, the need for methodologies used in risk review become more detailed and exacting, and the reviews become more accurate and reliable. Based on its experience screening chemical risks through such programs as the TSCA New Chemicals Program, the Agency believes IURA data will provide information adequate to perform initial screens of chemicals. The Agency also will be better able to prioritize and make basic risk management decisions about those chemicals of greatest concern as indicated by the available data. These better informed decisions will enhance confidence that the most appropriate chemicals are selected for more detailed assessments.

ii. *Accuracy and reliability of the data.* The Agency considered the data accuracy and reliability needed for screening level exposure analyses, and took several steps to ensure IURA data meet those needs. Screening level data need not be absolutely precise, but should be accurate and reliable enough to make usable and defensible technical assessments. The IURA will supply exposure-related information the Agency currently does not have, recognizing that industry has a greater knowledge than EPA about its own operations and the uses of chemicals it manufactures and sells. Without this information, EPA either would not screen these chemicals, would screen them using outdated or anecdotal exposure information, or would rely on

exposure estimates (typically conservative) using modeling data.

Commenters stated that the accuracy and reliability of much of the information reported in Part III of the proposed revised Form U (§ 710.32(c)(4) of the proposed regulatory text, now § 710.52(c)(4)) would be highly questionable because it relates to sites, activities, and products that are not under the direct or indirect control of the reporting company. Industry programs such as the ACC's Responsible Care Program (see <http://www.americanchemistry.com> for more information) require that, as part of the program, member companies work with customers, carriers, suppliers, distributors, and contractors to foster the safe use, transport and disposal of chemicals. The Responsible Care Program, coupled with basic marketing and sales force activities, suggests that many companies are well informed about downstream uses of their chemicals. EPA recognizes that submitters may not always have detailed information about how the chemical(s) they make are used. As a result, submitters will only be required to report this information to the extent it is "readily obtainable" (see Unit II.F.6.b.). In addition, the Agency believes, based on its experience with the New Chemicals Program, the UEIP, stakeholder meetings, discussions with industry about voluntary risk management programs, and industry's various self-regulation initiatives, that most submitters have at least some basic information about downstream uses, such as the information that will be reported under the IURA. These data are believed to be of sufficient reliability for use by the Agency and others for purposes such as screening level risk assessments and prioritization.

EPA also requires much of the IURA information to be submitted in EPA specified ranges. This requirement benefits both the Agency and submitters. First, range reporting is less burdensome for the submitter than calculating specific numeric estimates. Demanding greater data accuracy increases the burdens associated with data collection. Second, information reported in discrete numeric values can indicate a level of accuracy that is not necessarily present. EPA believes that a higher level of confidence in data accuracy can be achieved by specifying ranges.

Commenters suggested that EPA use other methods to obtain processing and use information, such as voluntary data collection programs. However, voluntary industry efforts are not uniformly reliable for collecting data,

and the Agency generally cannot ensure that data submitted under voluntary efforts will be complete and accurate. For example, the UEIP was undertaken by EPA in partnership with industry to collect relatively detailed information on 60 high production volume chemicals. EPA received data for 48 of the 60 UEIP chemicals. Many of the forms received for those 48 chemicals were not completely filled out, and only a subset of manufacturers submitted data. Thus, while the information that EPA received was quite useful, it was insufficiently complete for the purposes to which IURA information will be put. EPA's experience with UEIP is an indicator that exposure data collected under a voluntary effort are likely to be uneven and fall short of meeting EPA's needs.

iii. *Validity of the data.* Another commenter had specific concerns about the validity of the worker exposure data and felt that an auditing program would be necessary to generally ensure an acceptable level of quality for data collected under IURA.

EPA agrees that validated exposure data are the most useful for the full range of Agency risk assessment activities. However, EPA's experience with similar data collection efforts such as TSCA's New Chemicals Program demonstrates that the type of data EPA is collecting under IURA are sufficient for the purpose of screening to prioritize follow-on efforts for risk assessment and management. A rigorous validation process for all IURA exposure-related information would impose significant additional burdens on industry and the Agency that would likely outweigh the benefits accruing to the screening process. As discussed in Unit III.A.1., EPA exposure and risk evaluations are often iterative, with screening level assessments succeeded by more intensive and data rich assessments, as indicated by the screening level assessments and as data become available. The IURA data will be useful to the Agency in evaluating potential exposures and risks, serving as indicators as to what levels and types of exposures from which chemicals need further review.

b. *Will the Agency use the data in a timely manner?* Many commenters questioned whether EPA would be able to make effective and timely use of IURA processing and use information, stating that the large amount of data submitted would overwhelm the Agency. EPA acknowledges that IURA will generate a significant quantity of new data that EPA has not handled under past IUR data collections. However, EPA has carefully designed