

standard methods use maximum concentration information to estimate upper limits to exposure estimates. If EPA is aware that a chemical substance is processed or used only as a fraction of a mixture with other chemical substances, exposure estimates may be adjusted downward accordingly. For example, a chemical substance which is a component of a liquid mixture exerts a lower vapor pressure than it would as a pure chemical substance. Because higher vapor pressure is associated with increasing inhalation exposure to a chemical substance, the concentration of a chemical substance in a liquid mixture impacts the exposure assessment.

A chemical may be produced in multiple physical forms and in multiple formulations and products. As described in Unit II.F.5.g., EPA is requiring reporting of each of the physical forms in which a chemical is sent off-site. For the purpose of exposure screening, EPA is requiring only the reporting of the maximum concentration, regardless of the various physical forms in which a chemical may be sent off-site.

EPA had proposed that submitters also report the average concentration of the chemical when leaving the manufacturing site (at 64 FR 46788). EPA is not promulgating this requirement because of the potential difficulty of determining the average concentration. For example, a submitter could produce many formulations containing a particular chemical substance, making a determination of average concentration difficult.

g. *Physical form (§ 710.52(c)(3)(viii) of the regulatory text).* Submitters must report the physical form(s) of the chemical at the time it leaves the site of manufacture or, if the chemical is site-limited, at the time it is reacted on site to produce a different chemical substance. The list of physical forms from which submitters must select is found in § 710.52(c)(3)(viii) of the regulatory text. Further discussion on physical form reporting is found in Unit III.B.1.a.

The physical form of a chemical is an important factor to consider when estimating magnitudes and concentrations of potential exposures. EPA's analyses of TRI and PMN data demonstrated that the physical state of a chemical is a determining factor in predicting the potential for industrial releases of chemicals, and hence, exposures to humans and the environment. The results of the analyses are provided in a technical support document that was developed by EPA in support of this rule ("Inventory Update

Rule (IUR) Amendments Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening," Ref. 14). The physical state, which provides information on volatility and how the chemical is likely to be handled during manufacturing, processing, and use, is an important data element for the purpose of exposure and risk screening.

h. *Percent production volume (§ 710.52(c)(3)(ix) of the regulatory text).* Submitters are required to report the percentage of total production volume (as reported under regulatory text § 710.52(c)(3)(iv)) of the reportable chemical substance that is associated with each physical form reported. Percent production volume estimates will allow the Agency to aggregate, on a case-by-case basis, the production volume of a particular physical form for a given chemical across multiple sites. These determinations will allow EPA to better characterize the risk associated with chemicals that are manufactured in physical forms that typically result in higher exposures, such as volatile liquids or powders, but that are produced in small quantities. These percent production volume estimates will help put the physical form information into context. Estimates must be rounded off to the nearest 10% of production volume.

6. *What new definitions have been added to explain or reworded to clarify the reporting requirements?* EPA has reorganized the definition section of the regulatory text associated with the original Inventory and IUR. There are now three definition sections. The existing § 710.2 contains definitions relevant primarily to the compilation of the original Inventory, although a few of these definitions are also relevant to both IUR and IURA. EPA has recodified these general definitions in § 710.3. Definitions relevant only to IUR, which were originally in § 710.2, are now in § 710.23. Section 710.43 contains definitions relevant only to IURA. This reorganization clarifies the relationships between the definitions and the various rules, and has no substantive effect.

Two existing definitions are being clarified (§ 710.3 of the regulatory text). EPA defines "manufacture" to mean to manufacture, produce, or import for commercial purposes and "manufacture or import" for commercial purposes" to mean to manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, for example, the manufacture or import of any amount of a chemical substance or mixture: (1) For commercial distribution, including for test

marketing, or (2) for use by the manufacturer, including use for product research and development, or as an intermediate.

Certain new definitions are being added to § 710.43 as a result of this final rule.

a. *Known to or reasonably ascertainable by.* TSCA section 8(a)(2) authorizes EPA to require persons to report information that is known to or reasonably ascertainable by the submitter. For the purposes of reporting under IURA, a submitter will report information described in the regulatory text at § 710.52(c)(1), (c)(2), and (c)(3) that is known to or reasonably ascertainable by the submitter. This means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

b. *Readily obtainable information.* TSCA section 8(a)(2) authorizes EPA to require persons to report information that is known to or reasonably ascertainable by the submitter. Under IURA, a submitter will report processing and use information (i.e., the information reported for sites at which the 300,000 lbs. threshold has been met or exceeded) only to the extent that such information is "readily obtainable" by the submitter's management and supervisory employees responsible for manufacturing, processing, distributing, technical services, and marketing of the reportable chemical substance (see regulatory text § 710.43). Extensive file searches are not required. The "readily obtainable" standard for processing and use information requires less effort on the part of the submitter than the "known to or reasonably ascertainable by" standard that applies to all other IUR reporting (see regulatory text § 710.43), while providing sufficiently precise processing and use information for screening level reviews. In addition, the "readily obtainable" standard limits the reporting burden associated with processing and use reporting and is identical to the standard currently in effect under EPA's TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR) (See 40 CFR 712.7). The "readily obtainable" definition is further discussed in Unit III.D.2.

c. *Reasonably likely to be exposed.* For the purposes of reporting under IURA, reasonably likely to be exposed means an exposure to a chemical substance which, under foreseeable conditions of manufacture (including import), processing, distribution in commerce, or use of the chemical substance, is more likely to occur than not to occur. Such exposures would