

public and interested parties. In addition, sections 4, 5, 6, as well as section 21, for example, provide opportunities for public participation in chemical management decisions. Participation must be meaningful, and to be meaningful the public must have access to TSCA non-confidential information.

TSCA was designed in part to address the lack of health, safety, and exposure information government agencies and the public faced in dealing with chemicals. See, H.R. Rep. 94-1341 at 6 (1976), reprinted in Legislative History of the Toxic Substances Control Act, at 414 (1976) ("Present authorities for protecting against and regulating hazardous chemicals are fragmented and inadequate . . . Most significant among the deficiencies are . . . (3) No authority exists for collection of data to determine the totality of human and environmental exposure to chemicals."). TSCA was seen as a way of providing federal agencies and the public with access to health, safety, and exposure data so that the risks of chemical substances could be more fully evaluated and understood. See, Statement of Sen. Hartke, Cong. Rec., March 26, 1976 [S4397- 4432], reprinted in Legislative History of the Toxic Substances Control Act, at 218 (1976) ("[T]he essential element of this legislation is that it has attempted to provide for the individual- not only who works, but for the rest of American society- the right to know what is in store as far as the toxicity of the chemicals is concerned."). Congress envisioned TSCA as a tool for providing the public and others with health, safety, and exposure information about chemical substances.

Finally, TSCA does not limit the use or disclosure of data (except if data are considered confidential) collected under the statute. Congress drafted TSCA in part to provide basic health, safety, and exposure information to other federal agencies, as well as state, local and international governments. TSCA provides several mechanisms--TSCA sections 9, 10, and 12 for example--for sharing health and safety data among various levels of government. These sections again demonstrate TSCA's role as a tool for gathering and disseminating information about chemicals.

B. Comments on Specific Data Elements

1. *Manufacturing information*--a. *Physical form*. EPA requested comment on its proposed requirement that submitters report the physical form of a chemical as it leaves the site of manufacture. Several commenters suggested variations on the specifics of

physical form reporting, but generally agreed with reporting the physical form as the chemical leaves the site of manufacture. For instance, one commenter suggested expanding the types of physical forms that can be reported. EPA has determined that the six categories as proposed (see § 710.52(c)(3)(viii) of the regulatory text) will be adequate for risk screening purposes, and is not adding additional physical form categories at this time. Experience with the same six physical form categories as part of EPA's exposure screening assessment of over 20,000 chemicals in its New Chemicals Program indicates that the categories of physical forms that EPA is using under IURA will be adequate.

Other commenters recommended that EPA allow submitters to report more than one physical form for each reportable substance, because a substance may leave a site in more than one physical form. EPA agrees with this comment and is requiring in this final rule that submitters report all physical forms of a substance when the substance is sent off-site. Reporting on all physical forms in IURA will lead to a better assessment of exposure to a chemical substance. For example, processing a fine, nonagglomerating powder could result in occupational exposure by inhalation of chemical dust. Processing the same chemical as a liquid solution would eliminate, or at least reduce, the inhalation risk (the liquid could become an aerosol and be inhaled, depending on the processing activity). By combining data elements on the physical form of a chemical substance, its production volume, and the fraction directed to each industrial processing or use activity, a screening estimate of the potential exposure associated with manufacturing or processing of a chemical substance can be derived. The resulting exposure assessment will be more representative and less conservative than if the physical form(s) were unknown. For these reasons, EPA is requiring the reporting of all physical forms in which a chemical substance leaves the manufacturing site.

b. *Concentration*. EPA originally proposed to require the reporting of both maximum and average concentrations of each reportable chemical substance at the time the substance is sent off-site. A number of commenters felt that this information would be difficult to report for the following reasons: Chemicals may be used in many product formulations at a given plant site and there may often be no consistent average or maximum concentration of an individual chemical across these formulations; such

information does not reside in any currently available data bases and would need to be generated for IURA reporting (which would be particularly difficult with respect to average concentration information); and average and maximum concentrations may vary in product formulations during different IURA reporting cycles. Commenters suggested that maximum concentration information will be misleading if only a small amount of the reportable chemical substance is made available commercially at that concentration, while the bulk of the total quantity leaving the site has a lower concentration. They also indicated that determining average concentration requires a complicated calculation which falls outside the scope of "reasonably ascertainable" information. Commenters suggested that average concentration can be calculated by product or by the weighted average of each product, and each of the calculations can result in tremendously different answers.

The Agency has determined that average concentration information is not critical for purposes of screening level exposure assessment and has not included this element in this final rule. Screening level review is typically meant, in part, to serve as a method of identifying chemicals that even at their maximum concentration are less likely to present a risk to human health or the environment. Average concentration information cannot be used to make such a determination.

EPA recognizes that the concentration of an IUR reportable chemical may vary from shipment to shipment leaving a submitter's site, or when reacted on-site to produce a different chemical substance. However, maximum concentration is to be reported in wide ranges and not specific numbers, thereby alleviating the need to determine specific concentrations. Additionally, EPA does not intend for submitters to go to great lengths to determine what maximum concentration ranges to select for IUR reporting. Instead, EPA is simply requiring that submitters select a range of concentrations from a list of given ranges. The ranges from which submitters must select are: Less than 1% by weight; 1-30% by weight; 31-60% by weight; 61-90% by weight, and greater than 90% by weight.

One commenter was concerned that EPA did not specify whether it would require submitters to conduct specific chemical testing or statistical analysis in order to report concentration data, or whether submitters should merely estimate concentrations. In addition, the