

certain chemical were reported for the 1990 IUR as being produced or imported collectively, by manufacturers throughout the United States, then that chemical was identified as an HPV chemical for purposes of the HPV Challenge Program. The 300,000 lbs. IURA threshold captures at least one report for more than 95% of the HPV chemicals reported to the 1990 IUR.

The production volume that defines chemicals as HPV should not be confused with the 300,000 lbs. per year reporting threshold for processing and use data reporting in IURA. The 300,000 lbs. threshold applies to the amount manufactured at a single site and is not an aggregate, industry-wide production number. EPA is implementing the 300,000 lbs. per year reporting threshold for individual IUR submitters because it limits the increase in burden associated with the new IURA processing and use reporting requirements and it limits the number of chemicals for which exposure-related data will be reported to approximately 4,000. This number is consistent with the "several thousand chemicals" suggested by GAO in its 1995 report "EPA Should Focus Its Chemical Use Inventory on Suspected Harmful Substances" (Ref. 36), and ensures that exposure-related data will be reported for almost all HPV chemicals (defined by national aggregate production). Increasing the 300,000 lbs. threshold to one million lbs. would drastically undermine the Agency's collection of processing and use exposure-related data. The higher threshold would reduce the number of chemicals for which this information is submitted and eliminate processing and use data reporting on many of the HPV chemicals. The Agency would be left with very little information with which to conduct the needed screening-level assessments and the resulting prioritization would be less meaningful.

In the proposed IURA, EPA also solicited comments on the possibility of replacing the chemicals identified using the 300,000 lbs. annual production volume threshold (by site) with any of five other groups of chemicals. Those groups include: (1) A set of HPV chemicals that submitters identify as being produced nationwide in amounts of one million lbs. or more; (2) chemicals that are currently subject to testing under TSCA section 4 (i.e., test rules and enforceable consent agreements (ECAs)); (3) chemicals identified for voluntary testing; (4) chemicals designated for testing by the ITC; and (5) chemicals listed in the Agency's Master Testing List (the current edition is available at [http://](http://www.epa.gov/opptintr/chemtest/mtl.htm)

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With respect to the possibility of limiting the collection of processing and use information to HPV chemicals identified by submitters, the Agency asked for comment on: (1) Whether submitters would be able to determine which chemicals have exceeded the nationally aggregated HPV threshold in a given submission period, especially given how frequently chemical production rises above and falls below this threshold from IUR submission period to submission period; (2) what additional burdens such a determination would place on submitters; and (3) whether IURA data would be less useful if processing and use data reporting were limited to HPV chemicals.

Many commenters favored use of the set of HPV chemicals in lieu of the proposed IURA reporting with the 300,000 lbs. threshold, yet none directly responded to the specific Agency questions. Commenters failed to take into account the added burden of aggregating chemical production to determine which substances are HPV chemicals. They also offered no justification for substituting the 300,000 lbs. plant site-specific threshold with a one million lbs. national aggregate threshold, beyond stating that relevant information is being provided already through other programs. Nor did they offer possible solutions to the problem of reliably aggregating production volumes.

EPA does not believe that submitters will be able to effectively aggregate nationwide production volumes. Aggregation is especially difficult in light of continual, market-driven changes in production and many submitters' interest in protecting individual plant site production volume information as CBI. Additionally, for a nationally aggregated one million lbs. threshold to be effective, it must be able to accommodate the frequency with which individual chemicals may rise above or fall below the HPV threshold criteria of a U.S. aggregate production volume of one million lbs. or more per year. For example, 17% of the chemicals which were HPVs according to data submitted under the 1990 IUR were not HPVs according to data submitted under the 1994 IUR.

D. Definitions and Clarification Requests

1. *Is mining considered manufacturing?* Commenters asked whether mining is considered "manufacturing" under TSCA. Under TSCA, the term "manufacture" includes

production or importation of a chemical substance as well as its manufacture (TSCA section 3(7)). Mining, which includes extracting metal ores or minerals from their natural deposits by any means, including secondary recovery of metal ore from reuse or other storage piles, wastes, or rock dumps, or from mill tailings derived from the mining, cleaning, or concentration of metal ores, is production and is considered to be a manufacturing activity under TSCA.

However, chemical substances which are naturally occurring and which, among other things, are unprocessed or processed only by manual, mechanical, or gravitational means (see 40 CFR 710.4(b)(1)) are currently excluded from IUR reporting and will continue to be excluded under IURA (see 40 CFR 710.46(a)(3)). For example, rocks, ores, and minerals are not IURA-reportable to the extent they are manufactured only via the means described in 40 CFR 710.4(b). The § 710.46(a)(3) exclusion is a process-specific exclusion rather than a chemical- or industry-specific one. Therefore, persons who manufacture a substance in a manner other than as specified in § 710.4(b) are required to report under IURA unless they or the substance they manufacture are otherwise excluded. As a result, many mined materials are listed on the TSCA Inventory because at least some of the time they are produced by other than manual, mechanical, or gravitational means.

Section 710.46(a)(3) intentionally exempts from IURA reporting any chemical substance which is isolated or removed from nature, for a commercial purpose, by any means listed in § 710.4(b). It also exempts any other chemical substance derived or separated from the substance originally removed from nature, provided such derivation involved only the means specified in § 710.4(b). For example, when using manual, mechanical, or gravitational processes to separate one or more substances from a naturally-occurring mixture, these isolated component substances are also considered naturally-occurring and excluded from reporting. However, any substance manufactured from a naturally occurring precursor substance via a chemical reaction is not considered naturally occurring and, therefore, not excluded from reporting under § 710.46(a)(3).

2. *What is the difference between "reasonably ascertainable" information and "readily obtainable" information?* A number of commenters raised concerns about the meaning of "readily obtainable" and "reasonably