

either an EPA-designated accession number for confidential substances or a PMN case number.

d. *Confidentiality of production volume range (§ 710.52(c)(3)(v) of the regulatory text).* Submitters must continue to report the specific production volume of the reportable chemical and may claim CBI protection for that production volume.

Additionally, submitters may claim as CBI a pre-determined production volume range corresponding to the reported production volume number. This claim, if needed, would be separate from a CBI claim for the specific production volume.

Submitters of specific CBI production volume data may allow the release of more general range information. EPA expects that roughly 50% of submitters of specific CBI production volume data will allow the public release of volume ranges. This expectation of reduced CBI claims is based on the CBI claim statistics associated with the development of the original TSCA Inventory (See "Inventory Update Rule (IUR) Technical Support Document: Evaluation of Likelihood of Confidential Business Information Claims for Production Volume Information" (Ref. 10)) as well as comments received from industry concerning potential TSCA CBI reforms (Ref. 11). The range option will allow the public greater access to data on chemical production volumes, and the Agency will be better equipped to publicly release more aggregate production volume data relevant to its risk screening and other decisions.

The production volume ranges in the final rule are 25,000 to 300,000 lbs.; 300,000 to 1,000,000 lbs.; 1,000,000 to 10,000,000 lbs.; 10,000,000 to 50,000,000 lbs.; 50,000,000 to 100,000,000 lbs.; 100,000,000 to 500,000,000 lbs.; 500,000,000 to 1,000,000,000 lbs.; and greater than 1,000,000,000 lbs. per year. These ranges are similar to those first used in the development of the original TSCA Inventory, except for one change, i.e., the lowest range starts at the IURA reporting threshold of 25,000 lbs. rather than the 10,000 lb. threshold that was used in the current IUR. EPA additionally made one change to the ranges included in the proposed rule, i.e., the upper end of the first range and the lower end of the second range were raised to 300,000 lbs. from the 100,000 lbs. range limit included in the proposal, resulting in ranges of 25,000 – 300,000 lbs. and 300,000 – 1,000,000 lbs. This change makes the ranges consistent with the second reporting threshold of 300,000 lbs. or more (see § 710.52(c)(4) of the regulatory text), and

provides additional protection for submitters' production volume range CBI claims.

Under the proposed rule's 100,000 lbs. range limit for the lowest production volume range, submitters who did not claim the production volume range as CBI might have inadvertently provided the public with more information than they intended. For instance, for a submitter whose production volume was in the 100,000 to 1,000,000 lbs. range, who did not claim their production volume range CBI, and who did not report any information in Part III of reporting Form U (the industrial processing and use and the commercial and consumer use information), public users of the data would be able to infer that the submitter's production was somewhere between 100,000 to 300,000 lbs. per year – information which the submitter might have considered CBI. To protect against such inadvertent disclosures of CBI, EPA changed the production volume ranges to reflect the second reporting threshold of 300,000 lbs. EPA does not believe that the change significantly affects the utility of the data to the public.

e. *Number of potentially exposed workers (§ 710.52(c)(3)(vi) of the regulatory text).* Submitters must report the range code that corresponds to their estimate of the total number of workers reasonably likely to be exposed to each reportable chemical substance at each plant site. EPA defines "reasonably likely to be exposed" as an exposure to a chemical substance which, under foreseeable conditions of manufacture, processing, distribution in commerce, or use of the chemical substance, is more likely to occur than to not occur. Such exposures would normally include, but not be limited to, exposure during activities such as charging reactor vessels; drumming; bulk loading; cleaning equipment; maintenance operations; materials handling and transfers; and analytical operations. Covered exposures include exposures through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), but exclude accidental or theoretical exposures.

Workers involved in chemical manufacturing, processing, and use are a subpopulation of concern to EPA, the Occupational Safety and Health Administration (OSHA) (Ref. 12), the National Institute of Occupational Safety and Health (NIOSH) (Ref. 13), and other organizations (e.g., labor unions). Workers may often be exposed to chemical substances in higher doses and with greater frequency than the general population, and may therefore

be at potentially greater risk of adverse health effects. The number of workers reasonably likely to be exposed to specific chemical substances is important to EPA and other organizations in developing screening level exposure scenarios. These scenarios are then used to develop priorities for testing, more detailed risk assessment, and risk management.

Under IURA, submitters are required to use ranges rather than specific values for reporting certain data, including the number of workers reasonably likely to be exposed and the number of processing or use sites. The ranges for reporting the estimated number of potentially exposed workers are found in § 710.52(c)(3)(vi) of the regulatory text. In general, reporting these ranges reduces the potential burden to submitters of developing a precise point estimate for the data element. The use of ranges should additionally result in fewer CBI claims than if precise point estimates were provided because ranges tend to reveal less sensitive information than specific estimates while still conveying sufficient information useful to effectively screen chemical risks. Submitters are permitted to claim the reported ranges as confidential if revealing even this general information would disclose information of a sensitive nature.

f. *Maximum concentration (§ 710.52(c)(3)(vii) of the regulatory text).* Submitters must report the maximum concentration, measured by weight, of the reportable chemical substance at the time it leaves the submitter's manufacturing site or, if it is a site-limited chemical, at the time it is reacted on-site to produce a different chemical substance. This information is to be reported regardless of the various physical forms in which the chemical may be sent off-site or reacted on-site. Concentration ranges for use in reporting are found in § 710.52(c)(3)(vii) of the regulatory text.

Concentration is an important variable to consider when estimating the magnitude of potential exposures. Information about the maximum concentration of a chemical substance present at processing and use sites is frequently used in chemical risk screening in the review of PMNs for new chemical substances required by section 5 of TSCA and is used to the extent it is available in screening chemicals on the TSCA Inventory. For example, EPA has developed standard methods to estimate dermal exposures that workers may experience while performing common industrial operations such as sampling and loading chemicals into drums. These