

iv. *Maximum concentration in commercial and consumer products (§ 710.52(c)(4)(ii)(D) of the regulatory text).* Submitters must report the maximum concentration (measured by weight) of each reportable chemical substance in each commercial and consumer product category. In complying with this requirement, submitters will select from the list of concentration ranges provided in § 710.52(c)(3)(vii) in the regulatory text. Concentration is further discussed in Unit III.B.1.b. As with the other processing and use information that submitters must report, such information will be reported only to the extent that it is readily obtainable by the submitter.

8. *What changes have been made to requirements for making CBI claims?* Submitters are able to claim information submitted to EPA under this amended rule as confidential if they have reason to believe that release of the information would reveal trade secrets or confidential commercial or financial information, as provided by section 14 of TSCA and 40 CFR part 2. Claims of confidentiality must be asserted at the time information is submitted to EPA. EPA's procedures for processing and reviewing confidentiality claims are set forth at 40 CFR part 2, subpart B. EPA strongly encourages submitters to review confidentiality claims carefully to ensure that the information in question falls within the protection of TSCA section 14, and to limit invalid confidentiality claims as much as possible.

Submitters will have an opportunity to make CBI claims for most of the information reported under IURA. To claim information as confidential, a submitter must check the appropriate box and sign the certification statement on the reporting form. If a submitter fails to do so, EPA could release the information to the public without further notice to the submitter. As in the past TSCA Inventory Update collections and the initial TSCA Inventory collection, by signing the certification statement the submitter certifies that its claims of confidentiality are true and correct. Procedures for claiming information submitted electronically (such as a submission on diskette) as CBI will be specified in the instruction manual that will be available each submission period as described in § 710.59 of the regulatory text. CBI should not be submitted by e-mail. A discussion about CBI claims under IURA is provided in this unit.

a. *Upfront substantiation for plant site identity.* Submitters are required to provide upfront substantiation for CBI

claims for plant site identity, in a manner similar to the upfront substantiation of chemical identity under the existing IUR (see 40 CFR 710.38). Under IURA (see § 710.58(d) of the regulatory text), a submitter may assert a claim of confidentiality for a plant site identity if the submitter believes that releasing that identity would reveal trade secrets or confidential commercial or financial information, as provided by TSCA section 14. Submitters in past IUR information collections have claimed in excess of 15% of plant site identities as CBI. While the Agency does not question the occasional need for this claim, it believes that these claims should be limited to only those circumstances in which it is necessary. Further discussion on upfront substantiation is found in Unit III.E.2.

In order to assert a claim of confidentiality for a plant site identity under this amended rule, the submitter must check the appropriate box on the reporting form indicating a confidentiality claim for plant site identity and substantiate the claim in writing by answering certain questions provided in § 710.58(d) of the regulatory text. If a submitter fails to substantiate the plant site CBI claim, EPA could make the information available to the public without further notice to the submitter.

b. *CBI claims for chemical production volume information.* EPA did not change the ability of the submitter to assert a claim of confidentiality for production volume information if the release of that information would reveal trade secrets or confidential commercial or financial information as provided by section 14 of TSCA. However, submitters may now make separate CBI claims for both actual plant site production volume information and a corresponding production volume range. Production volume ranges are similar to those used in the implementation of the original TSCA Inventory collection and can be found at § 710.52(c)(3)(v) of the regulatory text.

In the last four IUR submission periods when EPA sought actual production volume information, approximately 65% of the information was claimed as confidential. In contrast, only 35% of production volume data collected in ranges in the original TSCA inventory collection were claimed as confidential. This difference indicates that submitters may be significantly less likely to make CBI claims for production volume information reported in ranges than for discrete production volume figures. The high proportion of CBI claims in IUR reports has severely

limited EPA's ability to convey production volume information to the public, even in the form of a national aggregate production volume for the chemical. EPA needs to be able to convey production volume information to the public to explain its chemical risk assessment and risk management decisions. Effective communication of this information is vital to EPA's overall mission. EPA has added the ability to claim production volume range information CBI in an effort to address this problem. In some cases, submitters may choose to claim their actual production volume as CBI, while allowing the more general production volume range to be made public.

III. Public Comments

EPA carefully considered the comments it received on the proposed IURA. Major comments are discussed below. Additional comment summaries and more detailed responses are contained in the "Summary of EPA's Responses to Public Comments Submitted in Response to Proposed TSCA Inventory Update Rule Amendments" (Ref. 18).

A. General Comments

1. *How will EPA and others use the new exposure-related data collected under these amendments?* Several commenters expressed the view that EPA has not provided adequate justification supporting the Agency's need for the new IUR data, nor enough specific examples showing how EPA would use the data for its intended purpose.

EPA has an obligation under TSCA to protect human health and the environment from unreasonable risks associated with chemicals under its jurisdiction. In order to evaluate potential chemical risks, EPA has determined that a portion of the chemicals (both inorganic and organic) on the TSCA Inventory currently warrant the collection of manufacturing information, and that a subset of those chemicals (i.e., those produced in annual quantities of 300,000 lbs. or more at a site) currently warrant the collection of supplementary processing and use information. EPA is amending the IUR to provide an accurate and readily available source of basic exposure-related information for approximately 4,000 of the 76,000 substances listed on the TSCA Inventory. The amendments significantly limit industry's reporting burden while providing EPA with information needed to screen for risks to human health and the environment.