Background Discussion Piece:
EPA's TSCA Inventory Reset
(November 25, 2008)

1. TSCA section 8(b) requires EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States." In general, the purpose of this list, called the Toxic Substances Control Act (TSCA) Chemical Substances Inventory ("the TSCA Inventory" or "the Inventory"), is to identify what chemical substances exist in U.S. commerce. Substances not included on the Inventory are considered to be new chemical substances and are subject to the Premanufacture Notification (PMN) requirements set forth in TSCA section 5(a)(1). After PMN review is completed, EPA requires that PMN submitters inform the Agency when non-exempt commercial manufacture (which includes import) of a chemical substance actually begins by submitting a Notice of Commencement of Manufacture or Import (NOC). An NOC is necessary for EPA to add the chemical substance directly to the TSCA Inventory Master File (the TSCA Inventory). The scope of the Inventory under the TSCA Inventory Reporting Regulations is described at 40 CFR 710.4.

2. Approximately 62,000 chemicals were reported when the initial TSCA Inventory was compiled. There are currently almost 84,000 chemicals on the Inventory, with almost 22,000 chemicals added to the Inventory through new chemical review since 1979. In 1986, EPA promulgated the Inventory Update Rule (IUR) requiring companies to update production volume data for certain chemicals on the Inventory. As IUR does not require reporting for all chemicals on the Inventory, it is unclear which chemicals not subject to IUR reporting are in commerce at a given point in time.

3. The TSCA Inventory supports many of EPA's TSCA regulatory functions and, as such, it must be kept current and otherwise accurately identify those substances that are manufactured or processed in the United States. In order to keep the TSCA Inventory current as instructed under TSCA section 8(b), EPA is considering an approach under which persons would be invited to certify -- online via a secure EPA website -- that they have manufactured a chemical listed on the Inventory within a specified timeframe (e.g., as section 8(b) specifies that the Inventory may not include any chemical substance which was not manufactured or processed within three years before the effective of the initial Inventory reporting rules, EPA is considering a three year time period for the Inventory reset process.). This would exclude persons manufacturing or importing chemical substances that are not subject to the TSCA section 5(a) PMN reporting requirements (see 40 CFR 720.22(b)(2) and 40 CFR 720.30) and Microbial Commercial Activity Notification (MCAN) reporting requirements (see 40 CFR 725.110). Under this approach, a "clean" reset Inventory would be developed such that any chemical not on the reset Inventory would be subject to TSCA section 5(a) PMN reporting requirements prior to manufacture. EPA is interested in receiving comments on this approach as well as on the related questions and possible alternatives identified below.

4. Under the clean reset approach, it is envisioned that EPA would publish a notice in the **Federal Register** outlining EPA's interpretation of its duties under TSCA section 8(b) and describe the TSCA Inventory Reset. Through such a notice, EPA would invite the public to test an online TSCA Inventory certification system and to provide comments to the Agency on the proposed TSCA Inventory Reset. Following the comment period, the Agency would finalize its approach to the TSCA Inventory reset, addressing comments as appropriate, and issue a subsequent notice in the **Federal Register** describing the final reset process and initiating the certification process. It is contemplated that the TSCA Inventory reset process would reoccur periodically in the future.

5. The following steps are currently envisioned as part of the clean reset approach:

- EPA would place the current TSCA Inventory online. This would include specific Chemical Abstracts (CA) Index Names and Chemical Abstracts Service Registry Numbers (CASRNs) for non-confidential chemical substance identities. For chemical substances for which the identities have been claimed as confidential, only generic chemical names and TSCA Accession Numbers would be provided online.
- Persons would certify their chemical substances online by checking or flagging the chemical substance(s) they manufactured or imported during the still-to-be-decided specified timeframe and submitting the certification electronically to EPA. As previously stated, this would exclude persons manufacturing chemical substances that are not subject to the TSCA section 5(a) PMN reporting requirements (see 40 CFR 720.22(b)(2) and 40 CFR 720.30) and the MCAN reporting requirements (see 40 CFR 725.110).
- At the close of the certification period, EPA would process the certifications and develop a new, interim reset TSCA Inventory, containing only those chemical substances that have been certified. A public version of the interim reset TSCA Inventory would be made available online, its availability would be announced in the **Federal Register**, and persons would have a time-limited opportunity to make corrections to the interim reset TSCA Inventory.
- Under the clean reset approach, any chemical substances for which a certification was not received would be removed from the TSCA Inventory.
- Subsequently, if a chemical manufacturer or importer intended to manufacture or import a chemical substance that was removed from the TSCA Inventory for non-PMN/MCAN exempt commercial purposes, a TSCA section 5 notice (Premanufacture Notice, Microbial Commercial Activity Notice, or Exemption Notice) would be required, because the chemical substance would be considered "new" under TSCA.

6. EPA would seek to make the reset TSCA Inventory available in time for the next TSCA Inventory Update Rule (IUR) reporting period (reporting to occur June 1 through September 30, 2011, for chemical manufacturing, processing, and use data from the 2010 calendar year). This would help ensure that the timing of reporting for chemicals subject to the IUR is coordinated with an accurate accounting of the chemical

substances currently manufactured for commercial purposes at any production volume. Subsequent periodic TSCA Inventory reset efforts could be timed to occur in conjunction with IUR reporting.

7. It is anticipated that this Inventory Reset may lead to an increase in requests by PMN or Initial Inventory Reporting Form submitters or others for the correct CA Index Names, CASRNs and/or TSCA Accession Numbers regarding the identity of chemicals on the TSCA Inventory. This is especially true if someone is unable to locate their chemicals on the TSCA Inventory or is not the person that originally reported the chemical substance for listing on the TSCA Inventory or provided premanufacture notification followed by a NOC. Some of these inquiries could take the form of Notices of Bona Fide Intent to Manufacture (see reporting provisions found at 40 CFR 720.25 and 40 CFR 725.15).

8. A key benefit of the Inventory Reset is that it would provide EPA and the public with a better understanding of the chemical substances that are actually in commerce in the United States. Another benefit is that it would provide the Agency with the opportunity to review under TSCA section 5 any chemical substances removed from the TSCA Inventory, but for which persons subsequently intended to commence manufacture or import. This would allow EPA to take action (for example, restrict manufacture and/or require the development of certain toxicity data), where appropriate, under TSCA prior to that chemical substance being manufactured or imported for commercial purposes.

9. Through the December 8, 2008 public meeting and the public docket for this activity, the Agency is seeking comment on the benefits and costs associated with all aspects of the TSCA Inventory Reset. In addition to the general approach outlined in this paper, EPA also is inviting public comments **by January 23, 2009** on the following questions and alternative options:

a. An alternative to requiring certification under TSCA section 8(b) to provide the basis for a reset Inventory could be to issue a reporting rule under TSCA section 8(a) to require each subject manufacturer or importer to document to EPA all chemical substances manufactured or imported during an as yet to-be-determined time period. With some exceptions, however, small manufacturers are generally exempt from §8(a) reporting, and it is not clear how many chemical substances are made exclusively by small businesses or how they might be affected by a TSCA Inventory reset. Therefore, EPA would need to determine how best to enable small manufacturers and processors to verify and/or comment on the completeness of an Inventory reset generated based on the results of a TSCA section 8(a) rule.

b. Whether proceeding under TSCA section 8(a) or 8(b), should EPA consider alternatives to the approach of removing chemical substances from the Inventory where there has been no manufacture and subsequently requiring a PMN before manufacture can take place? One alternative to removing those chemical substances no longer being manufactured in or imported into the United States from the TSCA Inventory could be to

issue a TSCA section 5(a)(2) Significant New Use Rule (SNUR) for all or certain of such chemical substances. Under this approach, it is envisioned that manufacture or import for any use would require a Significant New Use Notice (SNUN), unless the activity was exempt under the SNUR regulations at 40 CFR part 721. In addition, the Agency could maintain a list of "active" and "inactive" Inventory chemical substances for purposes of manufacture/import. Note that chemical substances regulated under TSCA section 5(a)(2) would also be subject to TSCA section 12(b) export notification requirements.

c. How should EPA address chemicals that are processed only? TSCA section 8(b) requires EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured *or processed* in the United States." EPA believes that the chemical substances on the TSCA Inventory, which are manufactured in (including imported into) the United States, include all those chemical substances as described in 40 CFR 710.4 that are processed in the United States. In the context of a TSCA Inventory reset, however, there could be instances where a processor is, for example, using existing stock of a chemical substance that is no longer manufactured in or imported into the United States (for non-exempt commercial purposes). As a result, that chemical substance could be removed from the Inventory in the absence of a manufacturer certification even though it was still being processed in the United States. The Agency invites comments on whether this in fact is a realistic scenario or whether there are other scenarios that could raise issues in the absence of processor reporting, and if so, how to address them. For example, certification by processors could be included as part of a TSCA Inventory reset effort. One approach could be to allow processors to report separately, as was done in developing the initial TSCA Inventory in 1978. See 42 FR 64572, December 23, 1977. At that time, persons who only processed or used chemical substances were allowed, but not required, to report during a special second reporting period.

d. As described above, the envisioned process for re-setting the Inventory would involve a step where persons that have manufactured or imported a chemical substance would certify their chemical online by checking or flagging the chemical substance(s) they manufactured or imported during a still-to-be-decided specified timeframe (e.g., within the past 3 years) and submitting the certification electronically to EPA. Are there approaches other than manufacture or import within some limited past time period for which certification could be based that should be considered? For example, should EPA consider allowing certification for purposes of the reset process based on manufacture that is intended to occur within a specific time-limited period in the future?

e. In the event that errors were inadvertently introduced into the final reset TSCA Inventory – for example, a company discovers a chemical substance has been removed from the reset TSCA Inventory that it had intended to certify – should the Agency provide a time-limited process for corrections of errors directly resulting from the certification process under this Inventory Reset? What specific procedures might EPA follow in allowing corrections during a time-limited period to the final reset TSCA Inventory?