

EXISTING CHEMICALS PROGRAM: Strategy

| *Overview*

The TSCA inventory of chemicals in commerce now exceeds 84,000 chemicals. Periodic TSCA chemical data reporting indicates that there are approximately 7,000 chemicals currently produced at volumes of 25,000 pounds or greater. Under TSCA, EPA is charged with the responsibility of assessing the safety of these commercial chemicals and to act upon those chemicals if there are significant risks to human health or the environment. A sustained and predictable approach is needed to effectively carry out this responsibility.

EPA believes that this significant and long-term challenge can best be met via legislative reform of TSCA to improve EPA's chemical management authorities¹. Until reform is achieved, however, EPA's responsibility to create a sustained and effective existing chemicals program must be carried out under current authorities. This strategy summarizes EPA's approach in 2012 and beyond, pending legislative reform.

Given the vast number of chemicals; the high cost to EPA of performing comprehensive risk assessments, and, if appropriate, risk management; and the Agency's responsibility to protect human health and the environment, EPA has developed the following multi-pronged approach for the Agency's existing chemicals management program:

- 1) Risk assessment and risk reduction
- 2) Data collection and screening
- 3) Public access to chemical data and information

In summary, the Agency will perform risk assessments and, if appropriate, risk management for those chemicals with well-characterized hazard concerns and which present the possibility of significant exposure. These are likely to be a relatively small number of chemicals, compared to the size of the universe of commercial chemicals. While risk assessments are being conducted for this small group of chemicals, EPA will be developing an approach to screen the thousands of other compounds to determine which ones warrant further attention, which could include comprehensive risk assessments, or additional data development, addressing either hazard or exposure. Many chemicals will likely be judged as being of lower concern. Finally, EPA will work toward making chemical information available. In particular, the Agency will work to ensure that hazard and exposure data are available to the public in a manner that is most useful to those in the public who will be using the information. Taking this approach to address multiple aspects of the chemicals management challenge simultaneously should allow the Agency to be more comprehensive in its efforts, despite the large number of high production chemicals.

¹ <http://www.epa.gov/oppt/existingchemicals/pubs/principles.html>

| Risk Assessment and Risk Reduction

At present, there are thousands of chemicals that have yet to be screened and assessed. There are, however, a number of chemicals for which there are well-characterized hazard concerns and which present the possibility of significant exposure. It is important that EPA identify and assess these chemicals, even as the Agency works to collect data and to screen the many other chemicals in commerce for future assessment.

In 2011, EPA sought stakeholder input on the criteria for identifying such chemicals for the risk assessment/risk reduction component of EPA's work plan. The Agency heard general agreement with the proposal to identify chemicals for assessment with well-characterized concerns for human health or environmental toxicity, which are persistent and bioaccumulative, are used in consumer or children's products, have dispersive uses, or have been detected in human or environmental biomonitoring. EPA also received stakeholder input on the use of a number of well-known, well-documented sources proposed to inform that process.²

EPA has used these criteria to identify a work plan of 83 chemicals for review. From this work plan list, EPA has identified an initial set of chemicals for which EPA has begun risk assessments in 2012. The Agency will complete some and initiate additional new assessments each succeeding year. The chemical assessments may also include evaluation of alternatives. If an assessment indicates significant risk, EPA will evaluate and pursue appropriate risk reduction actions. If an assessment indicates no significant risk, EPA will conclude its current work on that chemical. Over time, additional chemicals will be added to the work plan as more data are developed and more chemicals screened.

In 2012, the Agency will also continue to carry out work identified for chemicals in Action Plans, under other statutory requirements such as those for formaldehyde in pressed wood products, and other priority issues as they arise.

| Data Collection and Screening

For the thousands of chemicals for which toxicity or exposure data are less adequate to inform assessments, EPA must acquire and review data to support further screening and determine whether these chemicals are candidates for risk assessment and reduction, or whether they are of lower priority. Although, given current authorities and funding, it will take a number of years to work through the initial work plan of chemicals for assessment, EPA must begin now to build the pipeline of future assessment chemicals, as well as to identify chemicals of lower concern.

In 2011, EPA completed final amendments to the Chemical Data Reporting rule for the reporting of production and use information under that rule which will occur in 2012. The 2012 reporting will provide the first update on chemicals in commerce above the 25,000 pound threshold since 2006, and will provide use and exposure information on an expanded subset of chemicals. As information is being reported in 2012, EPA intends to engage with stakeholders to discuss how the CDR data might be used

² <http://www.epa.gov/oppt/existingchemicals/pubs/chempridiscguide.html>

to aid the screening of chemicals to refine data needs and identify candidate chemicals for risk assessment and reduction. EPA plans to begin releasing data from the CDR within months of the end of the reporting period and to conduct and release further analysis of the data by early 2013.

Also in 2011, the Agency finalized several test rules for high production volume chemicals and proposed the fourth and final test rule in that series. In the proposed test rule, EPA solicited comment on future testing approaches by asking, for example: whether production volume should continue to drive testing requirements or whether other exposure or hazard factors should be included; whether the Screening Information Data Set remains the best testing approach; and how computational toxicology should be incorporated into the testing program. In 2012, EPA plans to engage stakeholders in discussion about the future approach to the testing program, and will continue to work on how best to utilize a range of data sources, with particular focus on data collected by other national governments and by states, also engaging stakeholders in these issues.

The Agency's approach to screening chemicals has involved a resource-intensive process to review in vivo data, as well as making estimates of exposure, to determine which chemicals warrant further review and attention. After screening, the Agency may decide a more comprehensive risk assessment is appropriate. In 2012 and 2013, the Agency will explore the use of computational techniques as a potentially faster means to screen thousands of chemicals far more quickly and efficiently.

While the pace of this work will depend on funding levels, the work in 2012 will put the Agency in a position to begin work in 2013 to identify chemicals for additional data collection and analysis and to begin the creation of a pipeline of candidate chemicals for future risk assessment and reduction.

| Public Access to Chemical Data and Information

An important underpinning of a credible chemicals program is EPA's ability to make health and safety information available to the public, to the extent allowed by law. Since 2009, EPA has undertaken a number of specific efforts to increase the public's ability to access EPA's chemical information, e.g., the new Chemical Data Access Tool, free on-line access to the complete (non-confidential) TSCA Inventory, and including critical chemical information in Data.Gov. As part of a sustainable and predictable chemicals program, the Agency will continue to improve the accessibility and usability of its chemical data, including hazard and exposure information. This information will support the work of the Agency as well as informing other decision makers in the public and private sector.

Since 2009, EPA has made a priority the clearing of a large backlog of unchallenged CBI claims in health and safety studies, so that only justified CBI is withheld from the public. Industry has acknowledged that excessive claims of confidentiality have been made over the years of TSCA implementation, as EPA failed to require justification for such claims. In addition, outdated program systems have limited the ready accessibility of data to both Agency staff and the public. The Agency has also begun to digitize the TSCA data holdings and to create search tools that improve access.

In 2012, EPA will continue to work to address unsupported claims of confidentiality for chemicals in commerce, and to digitize and make public additional health and safety data from the TSCA data

holdings. The Agency will seek stakeholder input on tools and approaches for improving the accessibility and usefulness of these data for private and public sector decision-making.