

US Government Accountability Office Recommends More Aggressive TSCA Efforts by US EPA

On April 29, 2013 the US Government Accountability Office (GAO) released a report critiquing the US Environmental Protection Agency's (EPA) efforts under the Toxic Substances Control Act (TSCA) and recommending that EPA take more aggressive steps under TSCA to achieve the agency's goal of ensuring the safety of chemicals. The GAO report, "EPA Has Increased Efforts to Assess and Control Chemicals, but Could Strengthen Its Approach," recognized that EPA has made important progress under TSCA since 2009 but concluded that the agency needs to do more to collect needed toxicity and exposure data from chemical manufacturers and processors, as well as more aggressively conduct chemical risk assessments and risk management actions.

The GAO is an independent agency that reviews government programs at the request of Congress and is generally referred to as the "congressional watchdog." The GAO was asked to review EPA's TSCA activities by Senator Barbara Boxer (D-CA), Senator Tom Udall (D-NM) and Senator Frank Lautenberg (D-NJ). All three serve on the US Senate Committee on Environment & Public Works and are involved in congressional efforts to revise TSCA. In particular, Senator Lautenberg has been a long-time proponent of modernizing TSCA and has introduced several bills to amend TSCA over the years, including, most recently, the Safe Chemicals Act of 2013.

The GAO conducted its review from December 2011 through March 2013, and focused on the "new approach" EPA has taken to "managing chemicals within its existing TSCA authorities" since the beginning of the Obama Administration in 2009. The GAO noted that EPA "has made progress" implementing its new approach by increasing efforts to (i) obtain toxicity and exposure data, (ii) assess risks posed by chemicals, (iii) discourage the use of some chemicals and (iv) expand public access to some chemical information. The GAO concluded, however, that "the results of EPA's activities, in most cases, have yet to be realized."

EPA's Efforts to Collect Toxicity and Exposure Data

The GAO complimented EPA's recent efforts to collect chemical toxicity and exposure data, noting that since 2009 EPA has required companies to test 34 chemicals under TSCA section 4 and has announced plans to require testing for another 23 chemicals. This contrasts with the fact that from 1976, when TSCA was enacted, until 2009 EPA promulgated test rules for only 197 chemicals. The GAO reported that, according to EPA, "it can take, on average 3 to 5 years for the agency to promulgate a test rule and an additional 2 to 2 ½ years for the companies to provide the data once EPA has requested them."

While acknowledging EPA's recent efforts, the GAO criticized EPA for not requiring companies to provide to EPA the toxicity and exposure data the companies must submit to the European Chemicals Agency (ECHA) on the chemicals the companies manufacture or process in, or import into, the US. Under the European Union's chemical legislation (called Registration, Evaluation and Authorization of Chemicals (REACH)), companies must submit a range of data to ECHA and receive approval from ECHA to manufacture and market their products in the EU. EPA has signed a "Statement of Intent" with ECHA for cooperation and information-sharing, but the GAO pointed out that EPA has not obtained any data from ECHA that is not already in the public domain or sought a formal agreement with ECHA for more comprehensive data. Moreover, EPA has not issued a rule



under TSCA section 8 requiring companies to submit the ECHA data to EPA.

The GAO also noted that EPA has considered exercising its authority to issue subpoenas under TSCA section 11 to collect toxicity and exposure data. The agency has, however, rarely used this subpoena authority.

The GAO pointed out that EPA "has also not used its authority to obtain exposure-related data from chemical processors" and specifically that EPA "has not issued a rule under section 8 of TSCA to extend its periodic chemical data reporting requirements to chemical processors." EPA instead "has worked on a case-by-case basis with processors and processor associations to ask them to voluntarily submit data."

EPA's Plan to Assess Chemical Risks

The GAO praised EPA's plan, announced in February 2012, to conduct risk assessments on 83 chemicals under its TSCA Work Plan. The GAO criticized EPA, however, for not having more concrete plans for taking risk management actions on chemicals if warranted by the risk assessments. The GAO stated that "[w]hile EPA's effort to initiate TSCA-related risk assessments represents a significant increase in risk assessment activity, it may be years before EPA initiates risk management actions to reduce any chemical risks identified in these assessments."

The GAO expressed concern about EPA's schedule for conducting the risk assessments. The GAO calculated that at the agency's current pace, "it would take EPA at least 10 years to complete risk assessments for the 83 chemicals in the TSCA Work Plan."

The GAO also noted that although EPA "has started or plans to start risk assessments on the 25 chemicals for which it has well-characterized toxicity and exposure data," the agency still must identify and obtain the data it needs to complete risk assessments on the remaining 58 chemicals covered by the Work Plan.

Discouraging the Use of Certain Chemicals

The GAO noted that due in part to an adverse court ruling in 1991 that overturned an EPA rule banning most uses of asbestos, EPA has not sought to significantly limit or ban a chemical under TSCA section 6 in more than 20 years. Instead, EPA has employed other means to limit or discourage the use of certain chemicals.

The GAO found that since 2009 EPA has significantly increased its efforts to discourage the use of certain chemicals by making greater use of Significant New Use Rules (SNURs) under TSCA section 5 and proposing actions that use its TSCA authority in new ways. According to the GAO, EPA "has quadrupled its issuance" of SNURs since 2009: "From 2009 to 2012, EPA issued significant new use rules affecting about 540 chemicals, about 25 percent of all 2,180 chemicals subject to significant new use rules issued by EPA since 1976." Under the SNURs EPA has typically required companies to submit test data when they notify EPA of their intent to manufacture or process the chemicals subject to the SNURs, which, the GAO noted, not only enables EPA to better evaluate any potential risks, but also may discourage companies from pursuing new uses of the chemicals because of the cost and length of such testing.

EPA also has issued SNURs to limit the use of certain chemicals in articles, such as furniture, textiles and electronics. Under its TSCA regulations, EPA has generally exempted chemicals in imported articles from SNURs, but the GAO noted that since 2009 EPA has made greater use of its authority to subject such chemicals to SNURs, which potentially discourages use of some such chemicals.

The GAO observed that EPA has not been able to implement some of its new proposals because of lengthy reviews by the US Office of Management and Budget (OMB). For example, EPA's plan to



exercise its TSCA section 5 authority to create a "chemicals of concern" list has been undergoing OMB review for more than three years, even though OMB is generally supposed to complete its reviews within 90 days. Additionally, it took OMB 422 days to review EPA's proposal to issue a combined SNUR and test rule for certain flame retardants (polybrominated diphenyl ethers (PDBEs)) that are being voluntarily phased out by industry. EPA has not yet finalized the rule.

Expanding Public Access to Chemical Information

The GAO reported that EPA "has made progress in expanding public access to some chemical information." Since 2009, EPA has made 617 formerly confidential chemical identities public, as well as making 783 previously unavailable health and safety studies available to the public. EPA also has issued new policies on confidential business information (CBI) claims for chemical identity in certain health and safety studies and included a new requirement for upfront substantiation for CBI claims related to processing and use information in the 2011 Chemical Data Reporting rule.

GAO's Criticism of EPA's Efforts

While acknowledging EPA's recent efforts, the GAO expressed concern about the adequacy of these actions. The GAO discounted EPA's emphasis on its "Existing Chemicals Program Strategy," which the agency released in 2012. The GAO asserted that EPA's strategy "does not discuss how it will address challenges that might impede its goal of ensuring chemical safety. Specifically ... EPA's strategy does not discuss challenges associated with (1) obtaining toxicity and exposure data; (2) identifying the resources needed to execute EPA's new approach; and (3) banning or limiting the use of chemicals, given the agency's past difficulties with taking such actions." The GAO noted that while EPA has stated that it will take action to limit chemicals where warranted by the agency's risk assessments, "EPA has yet to publicly take steps toward that end and has not articulated, in its strategy or elsewhere, how it would overcome the regulatory challenges its experienced in the past."

The GAO underscored that "many of the challenges that EPA faces are rooted in TSCA's regulatory framework." In several previous reports, the GAO has called on Congress to revise TSCA and has even put TSCA on its list of "high risk" matters needing attention by Congress. The GAO also emphasized, however, that until Congress passes TSCA reform legislation, "EPA can do more to improve its current effort to help bring the agency closer to achieving its goal of ensuring the safety of chemicals."

GAO's Recommendations

Based on its findings, the GAO made three broad recommendations for actions by EPA "to better position EPA to collect chemical toxicity and exposure-related data and to ensure chemical safety under existing TSCA authority." The GAO recommended that EPA:

- Consider promulgating a rule under TSCA section 8, or take action under another section, as appropriate, to require chemical companies to report chemical toxicity and exposurerelated data they have submitted to the European Chemicals Agency.
- Consider promulgating a rule under TSCA section 8, or take action under another section, as appropriate, to require chemical companies to report exposure-related data from processors to EPA.
- To better position EPA to ensure chemical safety under existing TSCA authority, direct the
 appropriate offices to develop strategies for addressing challenges that impede the agency's
 ability to meet its goal of ensuring chemical safety. At a minimum, the strategies should
 address challenges associated with:



- obtaining toxicity and exposure data needed to conduct ongoing and future TSCA Work Plan risk assessments;
- gaining access to toxicity and exposure data provided to the European Chemicals Agency;
- working with processors and processor associations to obtain exposure-related data:
- banning or limiting the use of chemicals under section 6 of TSCA and planned actions for overcoming these challenges – including a description of other actions the agency plans to pursue in lieu of banning or limiting the use of chemicals; and
- identifying the resources needed to conduct risk assessments and implement risk management decisions in order to meet its goal of ensuring chemical safety.

Impact of the GAO Report

Although the GAO's report has no actual effect on either EPA's ongoing TSCA activities or Congressional legislation, it is an important document in the ongoing debate about TSCA and the need for TSCA reform. While recognizing the work that EPA has done since 2009 to exercise its existing authority under TSCA more broadly, the GAO report underscores the argument, made by EPA and others, that TSCA must be "modernized" by Congress to give EPA greater ability to review and, where necessary, take risk management actions on chemicals to "ensure the safety of chemicals."

Moreover, by arguing that EPA can and should do more under the existing TSCA statute, the GAO report provides support for even more aggressive efforts by EPA to collect data on chemicals, take risk management actions to limit or even ban chemicals, and make even more information on chemicals available to the public. Manufacturers, importers and processors of chemicals should pay close attention to whether, and how, EPA follows the GAO's recommendations.

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