

## EPA's Process for Assessing and Controlling Toxic Chemicals Remains on GAO's High-Risk List



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The U.S. Government Accountability Office (GAO) released on March 6, 2019, a report entitled [High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas](#). GAO's high-risk program identifies government operations with vulnerabilities to fraud, waste, abuse, and mismanagement, or in need of transformation to address economy, efficiency, or effectiveness challenges. GAO's report describes the status of high-risk areas and outlines actions necessary to assure further progress. GAO states that in the two years since its last high-risk report, three areas, including "Transforming EPA's Process for Assessing and Controlling Toxic Chemicals," have regressed in their ratings against GAO's criteria for removal from the High-Risk List. GAO notes that since adding this area to its High-Risk List in 2009, it has made 12 recommendations to the U.S. Environmental Protection Agency (EPA) related to the Integrated Risk Information System (IRIS) Program and the Toxic Substances Control Act (TSCA). According to GAO, while EPA

has taken steps to manage chemicals that pose risks to human health and the environment, leadership and implementation challenges remain.

## **IRIS Program**

GAO evaluated EPA's IRIS Program on five criteria to assess progress in addressing high-risk areas: (1) leadership commitment; (2) agency capacity; (3) an action plan; (4) monitoring efforts; and (5) demonstrated progress. GAO states that, since its 2017 high-risk report, four criteria remain unchanged. The rating for leadership commitment declined to partially met, however. Below is a summary of GAO's findings.

### ***Leadership Commitment: Partially Met***

In 2017, GAO reported that the then EPA Administrator demonstrated leadership commitment to the IRIS Program by identifying action on toxics and chemical safety as one of her top seven priorities for the agency -- priorities that included the IRIS Program. Current EPA leadership has not made a similar statement, however. For the past two years, EPA's budget justification for human health risk assessment work was reduced to about \$22 million from its fiscal year 2017 budget of \$40.5 million, contributing to a lower rating than GAO gave in 2017. GAO notes that Congress did not support these reductions. Specifically, according to the joint explanatory statements accompanying the Consolidated Appropriations Act, 2018, and the Consolidated Appropriations Act, 2019, Congress agreed to continue providing funding at fiscal year 2017 enacted levels.

GAO states that "EPA leadership's long-term accountability for actions has been limited, as demonstrated by four IRIS assessments that were in the later stages of development on the 2015 Multi-Year agenda but have not been released, or included on the December 2018 list of assessments." According to GAO, EPA provided no information on the status of these assessments or whether it plans to discontinue working on them or restart them at another time. GAO notes that, as it previously reported, an overarching factor that affects EPA's ability to complete IRIS assessments in a timely manner is that once a delay occurs, work that has been completed can become outdated, necessitating rework throughout some or all of the assessment process. Thus, it remains to be seen when these assessments can be expected to move to the next step in the IRIS process or be completed.

### ***Capacity: Partially Met***

As reported in our March 6, 2019, memorandum, "[GAO Reviews EPA's IRIS Assessment Efforts and Implementation of TSCA Reforms](#)," GAO's March 2019 report on chemical assessments indicates that the IRIS Program has made progress in addressing some challenges to its assessment process, including adopting project management principles and new software; streamlining the peer review process; implementing systematic review; and making changes to the frequency and type of communication, among others. GAO states that it will continue to monitor EPA's efforts and assess the progress the agency is making. GAO's previous work has shown that decision makers in the U.S. and around the world rely on information from IRIS assessments. Because of this key role, GAO states that it is "concerned that

without adequate funding, untimely implementation of IRIS assessments could have profound impacts on chemical risk management activities.”

### ***Action Plan: Partially Met***

As GAO reported in its 2017 high-risk report, EPA had not evaluated the demand for IRIS toxicity assessments with input from users both inside and outside EPA. EPA issued an IRIS Multi-Year Agenda in December 2015. According to EPA, the purpose of the 2015 agenda was to: (1) identify IRIS assessments currently under way and their status; (2) prioritize IRIS assessments that will be initiated over the next few years; and (3) evaluate assessment needs and develop an updated process for existing IRIS values. In December 2018, EPA issued the IRIS Program Outlook, but it was missing some key information. The Outlook identifies assessments currently under way and lists the next anticipated step in the IRIS process. According to GAO, the Outlook fails to list the projected date for most of the assessments and includes no information regarding assessment prioritization, however, including how these assessments will meet program and regional office needs. Moreover, GAO notes that it recommended in May 2013 that EPA should develop an Action Plan or strategy, among other things, to address the needs of EPA program offices and regions when IRIS toxicity assessments are not available; EPA is still working to do so.

### ***Monitoring: Met***

In January 2018, the IRIS Program produced a report to Congress that offered an overview of progress, and it took part in a National Academies of Sciences (NAS) review of the Program in February 2018. The resulting NAS report provided a supportive assessment of ongoing transformations aimed at ensuring data quality, new systematic approaches for data analysis and expanded stakeholder engagement efforts, and increasing efficiency of assessments. According to the report, NAS reviewers were impressed with the changes instituted in the IRIS Program since 2014, including substantive reforms by new IRIS Program leadership, such as the development, implementation, and use of systematic review methods to conduct IRIS assessments. According to GAO, for EPA to sustain the rating for the monitoring criterion, it will need to provide clear milestones and metrics for its action plan and monitor progress toward them.

### ***Demonstrated Progress: Partially Met***

EPA provided a list of chemicals in the December 2018 IRIS Program Outlook. According to GAO, it is not clear what data and priorities EPA used to establish its current priorities, however, or when it will assign time frames and future resources to ensure sustained performance. For example, according to the 2015 IRIS Multi-Year Agenda, the formaldehyde assessment was being revised to incorporate elements of systematic review and was to be released for public comment and external peer review. The December 2018 IRIS Program Outlook does not list the formaldehyde assessment, however, and provides no explanation of why the assessment was not included. GAO notes that the IRIS Program issued an assessment of hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) in August 2018, although the assessment took almost two decades.

## **What Remains to Be Done**

Since GAO added the IRIS Program to its High-Risk List in 2009, it has made nine recommendations related to the IRIS segment of this high-risk issue. As of mid-February 2019, six recommendations remain open. According to GAO, EPA will need to implement these recommendations, along with meeting the high-risk criteria discussed above, to make progress. GAO recommends that EPA:

- Assess the feasibility and appropriateness of the established time frames for each step in the IRIS assessment process, including whether different time frames should be established for different types of IRIS assessments;
- Publish IRIS agendas on which chemicals EPA is actively assessing and when it plans to start assessments of the other listed chemicals to demonstrate progress; and
- Develop a strategy to address the needs of EPA Program Offices and regions when IRIS toxicity assessments are not available.

GAO notes that its March 2019 chemical assessments report provides information on what remains to be done to address challenges (e.g., producing assessments) in the IRIS Program.

## **Congressional Actions Needed**

GAO states that “EPA and Congress should continue to ensure that the resources dedicated to IRIS are sufficient to implement it and to maintain a viable database of chemical assessments.”

## **TSCA**

GAO evaluated TSCA on the same five criteria to assess progress in addressing high-risk areas for IRIS. GAO states that, since its 2017 high-risk report, ratings for capacity, monitoring, and demonstrated progress progressed to partially met. The rating for leadership commitment remains unchanged at met and for action plan at partially met.

### **Leadership Commitment: Met**

In January 2019, then Acting Administrator Andrew Wheeler indicated his commitment to fulfill EPA’s obligations under TSCA. According to GAO, Wheeler stated that EPA had, among other things, released guidance and policy on confidential business information, a strategy to reduce animal testing, and the final mercury reporting rule. In addition, EPA's First Year Implementation Plan identified actions taken to meet the deadlines in the new law, such as: (1) identifying the initial ten work plan chemicals to be assessed under TSCA; (2) establishing a process and criteria for identifying high-priority chemicals for risk evaluation under TSCA; and (3) issuing a rule that establishes EPA’s process for evaluating risks from high-priority chemicals under TSCA.

GAO states that, as of December 2018, EPA had implemented two of GAO's recommendations made in 2013 regarding TSCA. As GAO elaborated in its March 2019 chemical assessments report, EPA has encountered some challenges in implementing the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) -- the law that recently amended TSCA, and as of mid-February 2019, several lawsuits were pending. GAO states that how EPA addresses issues such as its capacity to implement the program, collect appropriate fees, and demonstrate progress will be key to continuing to meet the leadership criterion in the future.

### ***Capacity: Partially Met***

The Lautenberg Act provides EPA with greater authority to address chemical risks, but in turn increases both EPA's responsibility for regulating chemicals and its workload. EPA recently issued a rule to collect fees from certain companies to defray a portion of TSCA implementation costs but, according to GAO, it is unclear whether the fees collected will be sufficient to support relevant parts of the program. GAO states that, according to EPA, the agency will be tracking its costs and will use that information to adjust future fees, if appropriate. As required by law, EPA will evaluate and readjust, if necessary, the fees every three years.

### ***Action Plan: Partially Met***

EPA's strategic plan discusses general approaches for meeting TSCA's statutory requirements and mandatory deadlines. EPA issued a First Year Implementation Plan in June 2016 noting that this document is intended to be a roadmap of major activities EPA will focus on during the initial year of implementation. GAO states that as of mid-February 2019, the plan had not been updated, although EPA had indicated that the plan would be further developed over time.

### ***Monitoring: Partially Met***

According to GAO, the Lautenberg Act provided EPA with significant new authorities to regulate chemicals, but EPA's full implementation will take many years. EPA has partially met the criterion for monitoring because it is too soon to determine whether EPA's approach to managing chemicals within the new TSCA authorities will position the agency to achieve its goal of ensuring the safety of chemicals. GAO states that it will continue to monitor TSCA as the agency implements this important legislation.

### ***Demonstrated Progress: Partially Met***

As described in GAO's March 2019 chemical assessments report, EPA has responded to many of the new provisions in the Lautenberg Act. For example, EPA has issued rules governing the prioritization and conduct of chemical assessments under TSCA. In addition, EPA informed GAO of efforts to engage its offices in a variety of ways to obtain information necessary to conduct risk evaluations and to leverage the expertise and experience of experts within the agency. GAO notes that EPA did not provide documentation that these activities have occurred, however. Moreover, GAO

states that EPA “has additional Lautenberg Act requirements to address in the years ahead.”

## ***What Remains to Be Done***

Since GAO added TSCA implementation to its High-Risk List in 2009, it has made three recommendations related to this high-risk issue. EPA will need to implement one open recommendation, along with meeting the high-risk criteria discussed above, to make progress. GAO states that, as noted in several criteria above, EPA needs to maintain leadership commitment and ensure that it has the resources and plans in place to facilitate progress. For example, for the demonstrated progress criterion, EPA will need to respond to provisions in the Lautenberg Act, such as having 20 ongoing risk evaluations by **December 2019** and making findings on the safety of all new chemicals. In addition, GAO’s March 2019 chemical assessments report discusses what remains to be done to address challenges (e.g., process improvements) in implementing the Lautenberg Act.

## ***Congressional Actions Needed***

GAO states that EPA and Congress should consider ensuring that the resources dedicated to TSCA activities are sufficient to implement TSCA reform activities.

## ***Commentary***

The latest GAO high-risk report is generally consistent with its prior recommendations concerning actions needed to improve performance under the IRIS Program and TSCA implementation. It is notable that GAO identifies EPA as having regressed from “met” to “partially met” regarding EPA’s leadership commitment to the IRIS Program. As discussed above, the factors contributing to this downgrading include the lack of a restatement of commitment to the IRIS Program by current EPA leadership, an almost 50 percent decline in EPA’s budget request for IRIS, and inadequate recent reporting by EPA on the status of IRIS assessments and on the changes made. We agree that greater openness and transparency regarding EPA’s current thinking and approach would be welcome. At the same time, we question the extent to which the need to meet the legal requirements for chemical assessments under TSCA is affecting EPA’s leadership views on resourcing and prioritizing IRIS assessments. While we agree that IRIS assessments are of value to many stakeholders, domestically and internationally, and that the assessments can be a critical input to meeting statutory requirements by other EPA offices, EPA is not legally required to produce IRIS assessments *per se*. This situation thus differs significantly from that under new TSCA where EPA is under considerable pressure to meet statutory deadlines for risk evaluations; we wonder about the extent to which this reality is influencing the thinking of EPA leadership. We encourage EPA to be clearer about its plans and to explain its thinking regarding the best way to balance and meet its assessment priorities and statutory obligations.

Regarding TSCA implementation, GAO notes that one of its 2013 recommendations remains “open.” This recommendation (Recommendation # 3 from the March 2013 GAO report [GAO-13-249](#)) is as follows:

To better position EPA to collect chemical toxicity and exposure-related data and ensure chemical safety under existing TSCA authority, while balancing its workload, and to better position EPA to ensure chemical safety under existing TSCA authority, the Administrator of EPA should 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: (1) obtaining toxicity and exposure data needed to conduct ongoing and future TSCA Work Plan risk assessments, (2) gaining access to toxicity and exposure data provided to the European Chemicals Agency, (3) working with processors and processor associations to obtain exposure-related data, (4) 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 (5) identifying the resources needed to conduct risk assessments and implement risk management decisions in order to meet its goal of ensuring chemical safety.

While we agree this is an important and unmet recommendation, it appears to pertain almost exclusively to action under TSCA Section 6 in assessing and regulating existing chemicals. We noted the brief mention in the 2019 High-List Risk report of the Section 5 new chemicals program but wondered why it was limited to the “what remains to be done” section at page 208. While TSCA Section 6 implementation is a work in progress, EPA has had to implement and meet the new chemical requirements under new TSCA Section 5 for almost three years now. As readers of our writings are aware, we have identified many issues and concerns with EPA’s implementation efforts on new chemicals that, among other things, initially led to a significant slowing in the new chemicals innovation pipeline in America. We recognize EPA’s commitment to accelerate the pace of new chemical review and applaud its efforts. It would seem, however, that some greater GAO focus in this area is warranted.

We also note the absence of any mention in the recent GAO reports of TSCA Section 4, the testing provision that under new TSCA included new but as yet untried legal authority to require testing by order, in addition to rulemaking. It is our view that EPA cannot meet its broader obligations under new TSCA in the absence of an appropriately robust program to obtain the toxicity and exposure information needed to inform EPA’s scientific and assessment judgments on TSCA chemicals. While GAO has in the past focused on EPA’s limited efforts in implementing Section 4 under old TSCA, we are puzzled by GAO’s current silence in this regard.

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