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TSCA Reform May Facilitate EPA's Next Generation Enforcement Strategy

Lawmakers, stakeholders, and EPA are advocating for reform to the nation's chemical law, the Toxic Substances Control Act (TSCA). While there may not be agreement as to how the law should be reformed, new legislation could facilitate EPA's enforcement strategy, known as "Next Generation Compliance." Historically, the chemical industry has not been in EPA's crosshairs for compliance with TSCA, unlike other sectors of the regulated universe. However, the confluence of legislation reforming TSCA and the Agency's heightened interest in Next Generation Compliance may foster a more vigorous TSCA enforcement program.

The confluence of TSCA reform and Next Generation Compliance may increase TSCA enforcement.

EPA and the Toxic Substances Control Act of 1976

EPA's authority to regulate chemical substances arises from the Toxic Substances Control Act (TSCA) of 1976. Title I of TSCA, 15 U.S.C. §§ 2601-2629, has not been reauthorized since its enactment. TSCA provides EPA with authority to require reporting, recordkeeping, and testing of chemicals, and to establish restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics, and pesticides. *See* EPA's Summary of the Toxic Substances Control Act, for more background information.

When TSCA was enacted in 1976, it grandfathered approximately 62,000 chemicals, meaning that these chemicals were not subject to pre-manufacture review before being commercially available in the United States. There are currently over 84,000 chemicals on the TSCA Inventory, which is a list of all chemicals in commerce in the United States that EPA is required to maintain under TSCA Section 8(b). According to Jim Jones, the assistant administrator for the Office of Chemical Safety and Pollution Prevention (OCSPP), in the 38 years since TSCA was enacted, EPA has required testing on approximately 200 of the 84,000 TSCA Inventory chemical substances. Testimony of James J. Jones before the Committee on Environment and Public Works and the Subcommittee on Superfund, Toxic and Environmental Health, United States Senate, July 24, 2012

In 2009, EPA initiated an effort to enhance its chemical management program. Later, in 2012, EPA issued the Existing Chemicals Program Strategy, which enunciated a three-pronged approach for its existing chemical management program. The strategy addresses: risk assessment and risk reduction, data collection and screening, and public access to chemical data and information. EPA continues to implement this strategy to date.

While EPA aims to maximize its existing authority under TSCA, it also advocates for legislative reform of TSCA. EPA believes that its statutory mandate to assess

and address the safety of commercial chemicals can only be effectuated through TSCA reform. Towards that end, EPA has prepared a list of Essential Principles for legislation to reform TSCA. EPA identified six essential principles that would give it the mechanisms and authorities to target chemicals of concern and promptly assess and regulate new and existing chemicals.

EPA's FY 2015 budget asks for an increase in funding for TSCA implementation.

EPA's Current Chemical Safety Priority

EPA Administrator Gina McCarthy has articulated a set of themes for EPA: taking action on toxics and chemical safety is one such theme. In particular, McCarthy intends to implement TSCA "to the maximum extent possible in the near term, while providing technical assistance in support of a bipartisan effort to modernize the law." This theme is carried through to EPA's priority goals for FY 2014-2015, as well as the FY 2015 budget.

Goal 4 of EPA's performance plan and budget request is "Ensuring the Safety of Chemicals and Preventing Pollution." EPA has requested \$673 million to "support work to reduce risk and increase the safety of chemicals." See Testimony of EPA Administrator McCarthy Before the House Energy and Commerce Committee This reflects an increase of \$42.5 million over the FY 2014 budget. To implement Goal 4, EPA will: 1) use its available authorities under TSCA to take action to eliminate or reduce identified chemical risks; 2) apply regulatory mechanisms to fill remaining gaps in exposure data, and increase public access to information on TSCA chemicals; and 3) rely on data from all available sources to conduct detailed assessments of priority chemicals to determine whether risk management action is warranted and, if so, what type of action. See EPA's Budget in Brief (at p. 48)

EPA also intends to review and challenge all new TSCA Confidential Business Information (CBI) claims consistent with its FY 2015 Strategic Plan goal of making all health and safety studies regarding chemicals in commerce available to the public. See EPA's Budget in Brief (at p. 49)

TSCA Reform - Access to Information

Both EPA and stakeholder groups agree that access to information is an important component of TSCA reform. There are different permutations that access to information can take: information from industry to the regulator, authority of the regulator to require additional information from chemical companies, and public access to chemical health and safety information. See, e.g., American Chemistry Counsel's 10 Principles for Modernizing TSCA; EPA's Essential Principles for Reform of Chemicals Management Legislation

In the Agency's view, in order to strengthen its chemical management authority, TSCA reform must require manufacturers to provide sufficient hazard, exposure, and use data to support a determination by the Agency that the chemical meets the safety standard. And where manufacturers do not submit sufficient information, EPA requests the "authority and tools" to quickly require testing or obtain information from manufacturers to determine a chemical's safety. EPA's Essential Principles for Reform of Chemicals Management Legislation (Principle No. 2)

EPA also seeks enhanced provisions assuring transparency and public access to information. In particular, EPA would like TSCA reform to include stricter requirements for a manufacturer's claim of CBI. <u>Under Principle No. 5</u>, data relevant to health and safety would not be considered CBI.

Other prominent issues arising in the context of current legislation to reform TSCA include: preemption of state chemical safety laws and prioritization of existing chemicals for risk-based reviews.

Elements of EPA's Next Generation Compliance Strategy

The confluence of TSCA reform and the Agency's recent enforcement strategy — referred to as Next Generation Compliance — may result in more opportunities for TSCA enforcement. EPA has not publicly touted this connection between TSCA reform and Next Generation Compliance. However, in a time of tight budgets and limited resources, EPA's programmatic TSCA reform goal to strengthen access to information dovetails with EPA's enforcement goal to economize on enhanced access to information through its Next Generation strategy.

Indeed, recent TSCA-related rulemakings, such as EPA's Electronic Reporting Under the Toxic Substances Control Act, are already moving in this direction. Under the TSCA reporting rule, which went into effect on March 4, 2014, EPA will only accept the submittal of required data, reports, and other information electronically. The rule applies to reporting requirements under TSCA Section 4 (including test rules and Enforceable Consent Agreements), TSCA Section 5, the Preliminary Analysis Information Rule (PAIR) codified at 40 C.F.R. Part 712 pursuant to TSCA Section 8(a), and TSCA Section 8(d) Health and Safety Data Reporting Rules at 40 C.F.R. Part 716.

According to Cynthia Giles, assistant administrator for the Office of Enforcement and Compliance Assurance (OECA), EPA will be using advances in monitoring and information technology to leverage greater compliance. This is OECA's Next Gen compliance and enforcement strategy.

In OECA's FY 2014 national program manager's guidance, it identified Next Gen as one tool it will use to achieve the office's national enforcement goals. The Next Gen strategy remains in OECA's FY 2015 national program manager's guidance as well. There are five elements of OECA's Next Gen strategy: (1) designing regulations and permits that are easier to implement and that will result in higher compliance and improved environmental outcomes, (2) taking advantage of advanced pollution monitoring; (3) increasing electronic reporting; (4) increasing transparency about pollution and compliance information; and (5) innovative enforcement approaches.

TSCA Reform and Next Gen Present Opportunities for More Vigorous EPA Enforcement

Common examples of EPA's Next Gen strategy involve such programs as the Clean Air Act and Clean Water Act. For instance, advancements in pollution monitoring devices provide EPA and communities with greater access to information regarding pollution from particular sources. EPA has been advancing these fence line devices in its enforcement settlements and rulemakings. Yet, increasing electronic reporting opportunities is a component of the Next Gen strategy — and that is one common goal of TSCA reform.

According to Cynthia Giles - EPA's chief enforcement official -Next Gen will use advances in information technology to leverage greater compliance.

OECA intends to expand transparency by making information from electronic reporting more accessible to the public, with the intention that broader public awareness will foster heightened compliance by the regulated universe. So too, OCSPP intends to enhance public access to information through TSCA reform (Principle No. 5).

There are only a handful of notable cases that EPA has brought under TSCA in the past 12 years. See OECA Civil Cases and Settlements by Statute Since EPA began identifying enforcement priorities in the late 90's, TSCA has never been among the programs that the enforcement office has emphasized as a priority area. With history as prologue, EPA has not identified TSCA as an enforcement priority in the 2014-2016 national enforcement initiatives cycle. While OCSPP has publicly emphasized the importance of chemical safety and risk assessment, OECA has remained silent as to the importance of enforcing chemical safety requirements.

However, with TSCA reform legislation in both chambers, EPA's enforcement office may have the ability to more readily enforce TSCA through its Next Generation approach. For instance, statutory and regulatory requirements that chemical companies submit data regarding a chemical's hazard, exposure, and use could hasten EPA enforcement under the Next Gen framework. And, EPA's goal of making chemical information more accessible to the public could result in the public pressuring EPA to pursue more enforcement actions under TSCA. There is already precedent for this — EPA's largest civil administrative penalty obtained under TSCA (in 2005) was the result of information that EPA first received from the public. Thus, the chemical sector may see increased TSCA enforcement as a result of this confluence of TSCA reform and Next Generation Compliance.

The chemical sector may see increased **TSCA** enforcement as a result of this confluence of TSCA reform and Next Generation enforcement strategies.

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