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Congress Reforms Toxic Substances Control Act

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The federal Toxic Substances Control Act (TSCA), passed 40 years ago, regulates the safety of chemicals used in manufacturing. A substantial revision, called The Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Act"), went into effect on June 22, 2016. It had received support from majorities of both parties in Congress and from a wide variety of interest groups, including the National Association of Manufacturers and the Environmental Defense Fund. The Act is likely to have significant impact on the industrial use and consumption of chemicals that present toxic risks.

Unlike the 1976 law, which was designed to address risks posed by chemicals newly introduced to the marketplace, the 2016 Act requires the federal Environmental Protection Agency (EPA) to evaluate the safety of currently used chemicals as well, thousands of which have been in use for decades. The new law also changes the standards to be used in evaluating the risks of chemicals, and it establishes new procedures to be used in evaluating both new and existing substances. This summary will present some of the material changes to the TSCA.

Existing Chemicals: Prioritization

The first step in analyzing the risks of chemicals already in use will be to set priorities for assessment. By June 22, 2017, EPA must promulgate a rule to establish the processes and criteria for identifying high-priority and low-priority chemicals among those now in use. In determining priority, EPA must consider the hazard and route of exposure of the chemical and whether certain populations, such as children or the elderly, might be significantly exposed to or susceptible to the chemical. A chemical that does not meet the standard for high priority would be considered low priority. EPA plans to have a proposed prioritization rule by mid-December 2016, with the final rule in force by mid-June 2017.

Existing Chemicals: Risk Evaluation

Once EPA places a chemical in the "high priority" category, it must evaluate the risk that the chemical presents. Unlike the 1976 TSCA, the new Act makes clear that cost and other non-risk factors are not to be considered in risk evaluations. EPA is to consider the likely frequency, duration, and intensity of exposures to chemicals in commerce, based upon their use. EPA will first consider chemicals that are known to cause cancer, that have high acute or chronic toxicity, or that persist or bio-accumulate in the environment.

In 2014, EPA published a "Work Plan List" of approximately 90 existing chemicals that it believed were most likely to require evaluation. Under the new Act, by mid-December of this year, EPA must designate as high priority, 10 chemicals from the Work Plan List and must formally initiate risk evaluations of them. EPA must have at least 20 risk evaluations underway by 2020. For each risk evaluation that is completed, EPA must designate a new high-priority chemical to be evaluated. By 2020, EPA must also designate at least 20 chemicals as low priority.

For each chemical designated as high priority, the risk evaluation is to be completed within three years after the date it was initiated. EPA can extend the deadline for a risk evaluation by at most six months.

EPA is thus under a very aggressive timetable to begin evaluating existing chemicals. Under the old TSCA, there was neither a duty to review existing chemicals, nor a deadline for EPA action.

Existing Chemicals: Risk Management

If EPA's risk evaluation shows that a chemical poses an unreasonable risk, it must issue a risk management rule. Such a rule could, for example, require a mere labeling change, a phase-out, or an outright ban of a particular chemical. In developing a risk management rule, EPA must consider the effects of the chemical on human health and the environment, the chemical's benefits for various uses, the economic consequences of the regulation, and the cost and availability of alternative chemicals. Economic consequences could include the rule's effect on the national economy and on small businesses.

A risk management rule for an existing chemical must be proposed by EPA within one year of completing its risk assessment of that chemical, and EPA must publish a final rule no more than a year later (extendable in the aggregate for two additional years).

Existing Chemicals: Manufacturer-Requested Assessment

Under the Act, a manufacturer can request that EPA evaluate specific chemicals. These requests are to be granted at the administrator's discretion and will not count toward the 20 risk evaluations that EPA must have underway by 2020. Of the ongoing risk evaluations that are initiated by EPA, it can accept additional evaluation requests from manufacturers as long as they are not less than 25% (if sufficient manufacturer requests are made) and not more than 50% of the number of evaluations initiated by EPA. For example, if EPA is evaluating 20 high priority chemicals, there could be an additional 5–10 industry-petitioned evaluations proceeding in parallel. The manufacturer must pay 100% of the cost of the evaluation unless the chemical is already on the Work Plan List, in which case the manufacturer must pay 50% of the cost.

Existing Chemicals: TSCA Inventory

The TSCA Inventory, first published in 1979, lists the chemicals that are manufactured or processed (including imports) in the US. Process means the preparation for distribution in commerce, of a chemical substance or mixture that has been manufactured, in which (1) the form or physical state of the chemical substance or mixture may be either preserved or changed, and (2) the chemical substance or mixture may be standalone or part of a mixture or article. The TSCA Inventory lists approximately 83,000 chemicals. Removing from the TSCA Inventory, the many chemicals that are no longer in active use is an objective of the new Act's reforms.

EPA must have in place by June 22, 2017, a final rule that requires manufacturers and may require processors to notify EPA within 180 days after the final rule is published, of all chemicals they manufactured or processed in the previous 10-year period. Such chemicals will then be designated by EPA as active and will be prioritized. All other chemicals will be designated by EPA as inactive.

New Chemicals

Newly introduced chemicals have been subject to EPA review since the 1976 TSCA, which required a manufacturer of a new chemical or a user of a chemical not on the TSCA Inventory of existing chemicals to submit to EPA a notification 90 days before its intended use or intent to manufacture. If EPA failed to act within 90 days after receipt of the notification, the manufacturer or user was free to manufacture the chemical or use the chemical in its manufacturing process.

Under the new Act, a manufacturer or processor must notify EPA at least 90 days before a new chemical is manufactured or processed or before a significant new use of an existing chemical occurs. Within 90 days of that notification (a period that can be extended for an additional 90 days if EPA deems it necessary), EPA must issue a finding on the safety of the new chemical or significant new use. If the new chemical or significant new use presents an unreasonable risk to human health or the environment, EPA needs to take regulatory action to eliminate the risk. If EPA instead determines that the chemical or new use is not likely to present an unreasonable risk, then it will publish its findings and the manufacture and use in commerce can begin. If EPA finds that in the absence of sufficient information, (1) the new chemical may pose an unreasonable risk, (2) there is insufficient information to allow a reasonable evaluation, or (3) the new chemical is made in substantial quantities and may be anticipated to enter the environment in substantial quantities or to pose significant human exposure, then EPA will take regulatory action to address the potential concerns, including requiring additional testing or use restrictions on the chemical.

EPA has indicated that for new chemical or use notifications that were pending before June 22, 2016, the Act effectively resets the 90-day clock for reviews that are underway.

Ongoing Risk Management Rule-making

For chemical uses with completed risk assessments showing unreasonable risk that were completed before June 22, 2016, EPA is going to propose and issue final rules consistent with the risk assessment. EPA intends to issue rules regarding trichloroethylene (TCE) use in spot cleaning and aerosol degreasing, TCE use in vapor degreasing, and methylene chloride and N-methylpyrrolidone use in paint removers.

Testing Authority

Under the new Act, the EPA has authority to obtain toxicity information as well as exposure and other information through regulations, consent agreements, and orders. In contrast, under the 1976 TSCA, EPA could acquire such information only after required lengthy rule-making and a demonstration by EPA of potential risk.

Confidential Business Information

Under the 1976 TSCA, companies that wanted chemical identity, formulas, and other specific information to be considered confidential business information (CBI) and thereby protect it from being publicly disclosed, had merely to request that the information be kept confidential and did not have to substantiate their CBI claim. Under the new Act, CBI claims for the identity of chemicals have to be substantiated and EPA is required to review and either approve or deny all CBI claims. In addition, under the Act, all CBI claims sunset after 10 years unless reasserted by the company. When they are reasserted, they will need to be re-substantiated. EPA must both review all new CBI claims and retrospectively review past CBI claims to determine whether the claims were adequately substantiated. EPA is also granted authority to share CBI with state and tribal governments.

Funding

The new Act grants EPA authority to establish user fees under which chemical manufacturers and processors would contribute to the cost incurred to assess and regulate their chemicals or use. It allows EPA to collect fees from manufacturers or processors who (1) are required to submit test data, (2) submit a notification of intent to manufacture a new chemical or new use of a chemical, (3) manufacture or process a chemical substance that is subject to a risk evaluation, or (4) request EPA to conduct a risk evaluation on an existing chemical. The fees collected would go not to the U. S. Treasury but to a dedicated fund for EPA's use in carrying out specific tasks under the Act. EPA can set fee amounts to defray 25% of the program implementation cost, subject to an annual cap of $25 million. EPA plans on publishing a proposed rule regarding fees by mid-December 2016, with a final rule by mid-June 2017.

State–Federal Relationship and Preemption

To fill gaps left by the 1976 TSCA, many states crafted their own chemical regulations. This has resulted in a patchwork of state regulatory structures that created industry concerns and made doing business in the US inefficient. Those concerns will likely continue under the new Act. Under the Act, states continue to have authority to act on any chemical not acted on by the EPA. In addition, even if the EPA does act, any state laws or regulations in effect before April 22, 2016 that address specific chemicals, are grandfathered and remain in force. States are also allowed to regulate chemicals under their air, water, or waste statutes. In addition, states can take actions on chemicals identified as low priority by EPA. If a state has an identical regulation to the EPA regulation, it may co-enforce the regulation and independently assess penalties for violations of the state requirements. However, the aggregate fine between the state and EPA can't exceed the statutory limit under the Act. A state's requirements for reporting, monitoring, and other information obligations are also not preempted.

There are cases, however, where a state is preempted under the new Act. One is where EPA's risk evaluation indicates that a chemical is safe. In addition, if EPA takes final action, through rulemaking or otherwise, to address a chemical's risks, the state provisions are preempted. A new state action is "paused" during EPA's risk evaluation of high-priority chemicals. However, states can obtain a waiver from EPA for a pause preemption, so that states can impose restrictions on such chemicals during risk management rulemaking after the risk evaluation, or if EPA misses the deadline to complete the risk evaluation. Once EPA regulates the chemical through rulemaking, the state law is again preempted.

What Lewis Rice Clients Should Be Doing

For many years, U.S. companies have reduced their reliance on toxic chemicals. Existing regulatory schemes governing the disposal of hazardous waste, limiting air emissions, and controlling discharges to waterways have created strong incentives for businesses to find non-toxic or less toxic substitutes for chemicals that were used for many years.

The new Act, by reforming TSCA to include evaluation of existing chemicals that have been in the marketplace for many decades, is likely to accelerate that trend. Some chemicals are likely to be eliminated or restricted. In anticipation of possible adverse action, clients should continue to look for cost-effective, non-toxic substitutes for toxic chemicals they use.

Manufacturers and processors should consider the following actions:

- Establish systems to track orders for new chemicals you have not previously used, or new uses you plan to make of existing chemicals, to determine whether EPA notification is required.
- Make sure you have the information available to provide EPA with the names of all chemicals you manufactured or processed within the last 10 years. You will have only 180 days to provide this information after the final rule is published, which will be January 22, 2017 if not before.
- Review your product lines and the chemicals used within the products, to determine which are likely to become high-priority targets for EPA risk evaluations.
- Determine whether EPA's Work Plan Inventory includes any chemicals used in your product, as these are likely targets for restriction and you would do well to contemplate possible substitutes. If EPA commences a risk evaluation on a chemical that a business uses, customers and users of that business's product may become concerned and look for alternative products before the risk assessment has been completed.
- Under the 1976 TSCA, there had been little regulatory action restricting the use of chemicals, and downstream users would often just check the TSCA Inventory to verify that the chemicals they buy are on the list. That is likely to change, considering the increase in EPA regulatory action restricting chemicals and their uses under the new Act. Manufacturers, processors, and downstream users of a chemical that is undergoing a risk evaluation should follow the evaluation closely and should participate in any applicable rulemaking, especially risk management rulemaking, because it can affect the use of the chemical.
- Businesses submitting confidentiality claims should be prepared to substantiate them, whether they are new or previously asserted.
- Finally, businesses should continue to pay attention to new or proposed state chemical regulatory legislation and regulations because chemicals that are not determined to be safe by EPA or are not regulated by EPA can continue to be regulated by the states.

This consensus legislation contains provisions intended to protect the interests of commercial users of toxic chemicals, including small businesses. How it is implemented—and whether user interests will be respected, consistent with the agreed need to reduce toxic exposures—will be crucial. Any business with a particular need for one or more of the likely-targeted chemicals would do well to monitor the review process, either independently or through industry groups or trade associations.

Our Experience

- Legal issues regarding dioxin, asbestos, PCBs, lead and other heavy metals, and pentachlorophenol
- Claims for personal injury including cancer, cognitive and attention deficits, immune diseases, and a wide variety of other illnesses
- Claims for property damage, site remediation, and medical monitoring
- CERCLA, RCRA, the Clean Water Act, and the Clean Air Act
- Air, water, and hazardous waste permits for manufacturing, trucking, and service industry clients
- Criminal environmental investigations, in which we represent individuals and companies involved as targets, subjects, or witnesses

Our clients also regularly utilize our environmental services in connection with real estate acquisitions and other types of corporate transactions. In addition, we counsel our financial institution clients regarding potential environmental liabilities associated with their lending activities.

Case Studies

Toxic Tort Team Secures Dismissal of DuPont in Asbestos Case for Lack of General Personal Jurisdiction in Missouri

Lewis Rice attorneys Jeremy P. Brummond, Edward T. Pivin, Corey M. Schaecher, and David A. Weder secured an order dismissing E. I. du Pont de Nemours and Company ("DuPont") for lack of general jurisdiction in an asbestos case pending in the 22nd Circuit Court for the City of St. Louis, Missouri, despite DuPont's ongoing business contact with the state. (*Smith v. Union Carbide Corp., et al.*, Cause No. 1422-CC000457.) The decision is a significant development for personal jurisdiction jurisprudence in Missouri, following the U.S. Supreme Court's decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014) that was issued in January 2014.

Daimler AG v. Bauman

In *Daimler AG v. Bauman*, the U.S. Supreme Court refocused the doctrine of general jurisdiction to its intended scope and held that Daimler AG, a German car manufacturer with "multiple California-based facilities," was not subject to general personal jurisdiction in that state because California was neither its state of incorporation nor principal place of business. (134 S. Ct. 746, 752 (2014).) The *Daimler* court held that there were two "paradigm bases" on which courts may rely in exercising general, all-purpose personal jurisdiction over a foreign corporation: (1) state of incorporation and (2) principal place of business. Exceptional cases aside, it is only in these forums that a corporation is truly "at home" and constitutionally subject to general personal jurisdiction.

The exemplar "exceptional case" cited by the *Daimler* court presented a scenario where a corporation temporarily relocated its headquarters to a new jurisdiction and did not focus on the quantity or quality of the contacts as a potential "exception." (*See Perkins v. Benguet Consolidated Mining, Co.,* 342 U.S. 437 (1952).) In fact, the *Daimler* court went further to explain that "the exercise of general jurisdiction in every State in which a corporation engages in a substantial, continuous, and systematic course of business" would be "unacceptably grasping." *Id.* at 761.

Smith v. DuPont, et al.

In *Smith v. DuPont*, Cause No. 1422-CC000457 (22nd Judicial Circuit, St. Louis City, State of Missouri), DuPont was named as one of approximately 70 defendants in a claim filed by Oklahoma resident David F. Smith in the City of St. Louis on February 26, 2014. Plaintiff pursued premises liability claims against DuPont, related to his work and alleged exposure to asbestos at a DuPont facility in Oklahoma and admitted that his DuPont-related claims did not arise out of any purported contacts with Missouri (eliminating any grounds for the exercise of specific jurisdiction under Missouri's long-arm statute). In a well-reasoned order following *Daimler*, the Court (Hon. Robert A. Dierker) held that because DuPont was neither incorporated nor headquartered in Missouri, the court could not exercise personal jurisdiction over DuPont in Missouri.

Judge Dierker also agreed that the Missouri contacts of DuPont's wholly-owned subsidiary, Solae, Inc. – which is headquartered in St. Louis – were insufficient to infer personal jurisdiction over the parent company DuPont. Judge Dierker also disagreed with Plaintiff's arguments and held that the mere facts that DuPont is registered to do business and maintains a registered agent in for service of process in Missouri did not mean that DuPont consented to the exercise of general jurisdiction of Missouri Courts.

A copy of the order can be found by clicking the link under "Resources" below.

Lewis Rice has many attorneys with significant experience in toxic tort cases, including cases like the *Smith* case involving alleged asbestos exposure. For more information, please contact a lawyer from Lewis Rice's Toxic Tort and Environmental Law Practice Group.