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What Companies Should Know About TSCA Consent Orders

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Following the 2016 changes to the Toxic Substances Control Act, the new chemical notification program is no longer the exclusive domain of the manufacturer. Downstream processors and users of new chemicals are being drawn into premanufacture notification (PMN) reviews due to three of the key changes in the law. The new safety standard language requires the U.S. Environmental Protection Agency to pay closer attention than ever before to the conditions under which a new chemical is used. The EPA also must issue the decision outcomes of new chemical reviews before manufacture can begin. However, the real "game-changer" for new chemicals occurred when Congress changed an "and" to an "or." As a result, the EPA now must regulate new chemicals based on insufficient information in the submission alone. With increasing frequency, we are seeing cases in which the exposure information for the downstream processing and use of new chemicals is often what is lacking.

These changes to the new chemical program went into effect the day the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) was signed into law without any accompanying rulemaking. At that point, the agency made a strategic decision to restart the 90-day review clock on all pending premanufacture notification (PMN) filings. The ripple effects from this decision have been felt for months. The agency spent the better part of this year chipping away the resulting backlog of submissions. To do this, the EPA is relying heavily on its authority to enter into consent orders that bind companies to prescribed behaviors. These orders and the significant new use rules (SNURs) that follow are catching companies off guard as they cascade through the supply chain. They bind the

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companies that make the new chemicals, the companies that formulate with them, the users who incorporate them into products sold to consumers, as well as competitors. This article is designed to inform companies up and down the supply chain about the considerations that go into negotiating consent orders for new chemicals under the TSCA and the requirements that flow from them.

All existing industrial chemicals in U.S. commerce have been compiled over time on an authoritative list called the "TSCA Chemical Substances Inventory," or the "TSCA Inventory" for short. Any chemicals that are not listed on the TSCA Inventory and which do not qualify for an exemption or exclusion are considered new chemicals. New chemicals must pass through the EPA's PMN process, a statutory 90-day process that is extending well beyond that time frame as things stand. The risk determination standard for a new chemical is whether it "presents an unreasonable risk of injury to human health or the environment, without consideration of cost or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use." The EPA regulates a new chemical when this standard is met based on significant exposure or an identified hazard, or when it has insufficient information to make the determination. In these cases, a company is most likely going to receive a consent order from the EPA to review and sign.

If you are a customer and your supplier comes to you with a draft or final EPA consent order, what are your options? It is important to carefully assess the consent order provisions on processing, distribution, use, wastewater treatment, worker protection and disposal as they apply to your operations. Changes that are needed or desirable should be promptly communicated to the supplier. It is common to see consent orders that do not fully capture the customer's operations. A way to try and avoid this result is to share information with the PMN submitter and the EPA earlier in the process in a prenotice consultation meeting or through a supplemental PMN information filing (on a confidential basis if necessary) to the EPA. The EPA will not talk to a customer alone about a consent order or PMN, but discussions with your supplier and the EPA are permitted. In some cases, a customer can sign on as an additional PMN submitter or as a signatory to the consent order. These are just some of the options available for companies to work on the conditions for downstream processes.

The EPA reviews roughly 1,000 new chemicals per year. About 80 percent of those reviewed since the Lautenberg Act passed are the subject of a consent order. In many cases, the decision to sign is influenced by the time a company has before commercial schedules dictate launching the product. These orders are often presented to a company late in the time that the company has allotted to deal with the TSCA's new chemical review process. The conditions in these consent orders should be evaluated for whether they will have a more lasting effect than an extended delay in launching the product, taking contractual obligations into account.

If a company truly believes that the terms of a proposed consent order are unreasonable or will harm business, it is worth taking the time to negotiate. After a consent order is signed, it is difficult to change for several reasons. One option for seeking changes is immediately foreclosed. By its terms, a company that signs one of these orders forfeits the ability to challenge it. The EPA can be asked to amend an order, but the

agency is under no time limit to consider a change request. Examples of when a company might seek changes in a consent order include when the results of animal testing are more favorable than the EPA's original estimate or when a consent order requires the use of a respirator with an assigned protection factor (APF) of 1,000 and subsequent monitoring data support the use of an alternative type of respirator. The ability for manufacturers and downstream companies to seek changes normalizes later, once the EPA issues the terms of a consent order in a more broadly applicable SNUR, which is routinely done. Any company can file a significant new use notice (SNUN) directly with the EPA to propose alternative handling practices or another use. The SNUN filing is similar in timing (90-day review) and information needs to a PMN, with the review's focus on the requested change in use.

Three of the main provisions of an EPA consent order are testing, workplace protection and disposal. Consent orders can impose testing requirements as a condition of manufacturing in a few ways. The EPA can recommend but not require testing. The EPA can require testing before a certain production limit is reached. Or, the EPA can require testing as a condition before manufacturing can occur. Normally test costs are the sole responsibility of the company (or companies) that sign the consent order. The legal responsibility for completing the testing remains with all the parties to the order. Because the EPA reviews test data with a critical eye to identify any reason why the study is not acceptable, it is important to work with the EPA prior to conducting any testing that will be used to support a chemical, and have the agency review and sign off on the test protocol. These consent orders typically require companies to submit the protocol to the EPA in advance of testing for this purpose. It's advisable to consult with the EPA throughout the entire study. To preview of the kind of studies the EPA will have a company run, the agency's "Chemical Categories of Concern" document can be consulted.

The TSCA allows the EPA to regulate workplace exposures. This authority is well established and was reviewed by Congress last year. Congress left the authority largely unchanged except to instruct the EPA to consult with the Occupational Safety and Health Administration "to the extent practicable … prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures." In consent orders, the EPA relies heavily on the elements and hierarchy of controls in OSHA's Hazard Communication Program (HazCom) to implement decisions that a new chemical substance is a hazardous chemical in a company's operations. For example, a consent order will specify information that must appear on labels and safety data sheets. Beyond this, the agency establishes occupational exposure limits for new chemicals and has its own criteria for requiring the use of respiratory protection by workers. APF 1,000 respirators and full body suits are often required by the EPA when a significant potential inhalation hazard is detected. This kind of personal protective equipment (PPE) is highly protective, but creates its own set of challenges to implement in the workplace. A company that thinks that the EPA is being overly precautionary should consider seeking an independent assessment from an industrial hygiene expert and offering it for EPA review before the consent order is signed.

Companies should not hesitate to put forward a detailed rationale for their PPE recommendations in a PMN

for the agency's consideration. Consent orders may require monthly monitoring for workplace exposures to begin as soon as the order is signed. Companies should not sign orders with these provisions without first identifying whether a validated method exists so that it may immediately begin to comply. In practice, companies often need time to develop a method or approach for monitoring, and so this topic is yet another area in need of discussion (and concurrence) with the agency. Reporting monitoring results within a short time frame (e.g., 15 days) also can be part of these orders. In these cases, besides getting agreement on a method, seek an agreement if possible on a workplace exposure limit below which monitoring reports are not required. Worker monitoring information is health and safety data that needs to be maintained per OSHA requirements. Worker privacy needs to be maintained in reporting the information to agencies and to workers.

Disposal restrictions in a TSCA new chemical consent order can direct waste streams to incineration or another specified means outside of a landfill. In addition, a consent order may limit releases of a new chemical to water. This restriction adds another compliance layer to a facility's already permitted wastewater treatment operation. Expect these restrictions to be in the zero to low parts per billion (ppb) range. It is important to confirm that wastewater treatment removal by an associated, permitted wastewater treatment facility (WTF) is counted toward the discharge limit a manufacturer and its downstream customers must achieve. In addition, companies are permitted to ask the EPA to generate a numerical discharge limit alternative to a zero release to water restriction. Again, in these cases, monitoring methods will need to be identified and validated if this kind of provision is in the consent order.

Companies that undertake negotiations with the EPA on TSCA consent orders should be aware where room for negotiation lies. For example, each section of the order is considered "boilerplate" and it is infrequently changed by the EPA (in order, in the EPA's view, to maintain consistency and fairness). The EPA staff have more discretion to decide which standard sections to include in a proposed consent order to begin with, although their inclusion is dictated in large part by the exposure, hazard or information requirement identified in the PMN review. It is important to understand and identify how each section is designed to address a hazard, exposure or insufficient information that is causing the EPA to regulate in the first place. A consent order may be over 100 pages with many sections that span testing, workplace protection, environmental releases, disposal and sustainability. However, any single section of a consent order may be removed or more specifically tailored depending on the extent to which a company can satisfactorily address each concern.

Another consideration to bear in mind is that if the EPA has negotiated one way with a company in the past, it will seek consistent outcomes in subsequent cases. In legal terms, this is called established precedent. In practical terms, the EPA is unlikely to let a company through the gate without testing if it has required others to test similar product. In this way, decisions on accepting terms in consent orders by one company have a cascading effect on them and others also. For example, virtually without exception the outcome in every new chemical notification for solid nanomaterials is a requirement for the company to conduct a 90-day inhalation study as a condition of manufacture. Does the EPA need a 90-day test on every nanomaterial? Probably not. However, only through experience with actual test results can the agency understand whether it is possible to

modify the precedent that has been established through these submissions.

Finally, a signed consent order, as well as a proposed or final SNUR, triggers other regulatory requirements under the TSCA. For example, the chemical substance is subject to export notification under Section 12(b) of the act. The Section 8(a) Chemical Data Reporting (CDR) reporting threshold for regulated chemicals drops significantly — from 25,000 pounds per year down to 2,500 pounds. Also, TSCA consent orders routinely require that the EPA be notified within 30 days following the transfer of a company or product line that includes chemicals subject to consent orders. This is not always on the radar of companies as they close the deal. These add-on requirements were originally established in recognition that a significant exposure or hazard is brought to bear by the new chemical. They were not necessarily designed to capture and regulate chemicals simply due to insufficient information or prescribed uses alone. These provisions were left intact by the Lautenberg Act and their impact is yet to be realized.

Not surprisingly, the EPA is a tough negotiator with safety on its side. Through experience, the areas of a TSCA consent order that lend themselves to information sharing, discussion with the agency and more closely tailored requirements can be learned. Both sides can learn from each other by having substantive and detailed conversations about the technology and the expectations around the language of these orders before they are signed.