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Four Considerations for Companies that Manufacture, Import, or Process Chemicals Subject to Section 4 Test Orders

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GlobalChem 2021, which just wrapped up last month, was as important as ever for the chemical industry with a number of important announcements and excellent panel presentations. I recently had a chance to look back at my GlobalChem presentation from 2019, in which I forecasted how TSCA section 4 data collection would be needed to inform section 6(b) risk evaluations. Since then, the draft and final risk evaluations issued by EPA have predictably resulted in a growing appreciation for the need for high quality data. Attempts to provide data voluntarily have proved challenging. Arguably, section 4 compels EPA to demonstrate that it can and will rely on industry-provided data in its risk evaluations for information developed under this formal framework.

EPA opened the section 4 playbook in earnest on January 15, 2021, when it issued Test Orders for nine of the next twenty high priority chemicals slated for risk evaluation under section 6(b) of TSCA. TSCA §§ 26(h) and (k) require that EPA use the "best available science" and consider "all reasonably available information." EPA defines "reasonably available information" as information it "possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations." 40 C.F.R. § 702.33. Test Orders for the other eleven substances are widely anticipated and these Orders will probably become routine. The information the agency is seeking includes exposure data – arguably the most needed type of data – through these Orders. If your company manufactures, imports or processes a chemical slated for risk evaluation under TSCA, here are four

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considerations to bear in mind:

First, if you manufacture or process a high priority chemical slated for risk evaluation, expect to test. So far, all companies included in the final list of manufacturers for risk evaluation fees are subject to these Test Orders. EPA also is drawing in companies who reported as "processors" for the Toxics Release Inventory (TRI), unless their only processing activity occurs "as an impurity." As EPA states in a helpful instructional video, there is no required method for how EPA identifies the companies who will undertake the testing (40 C.F.R. § 700.45(b)(9)). So, for example, if your company qualifies for one of the exemptions EPA has proposed for collecting section 6 fees, you should understand that EPA has not yet explained if or how those exemptions will apply to Test Order obligations under section 4. For companies that received a study Order, a response is due quickly, with a limited number of available options:

1. Develop the information. Testing deadlines for this option are dependent on the timeframes set forth in the test methods that EPA identifies to strictly guide how the testing is conducted. In this case, companies have to pay their portion of the section 4 administrative fee within 120 days of being invoiced by EPA, as well as the cost of the testing. If there are questions about the required tests, or only a portion of the tests are relevant to your company, further talks with EPA or the test consortium are advised.
2. Submit existing information. If your company is fortunate enough to have relevant data already in hand either alone or as part of a consortium, the existing studies are due on the same day as the response to the Order, after which EPA will determine whether the studies submitted are acceptable. If EPA determines that the studies are unacceptable, the response to the Order must be modified via CDX within 10 calendar days. This option can reduce additional study costs but still requires payment of the section 4 fee.
3. Request an exemption. If the exemption is approved, the exempt company/consortium remains responsible for the fee and has to reimburse those who perform and submit the testing required by the Order. Grounds for asking for an exemption include when other companies are already developing the information.
4. Make a claim that the company is not subject to the Order. This claim can be made, for example, if the company that received the Order does not actually manufacturer or process the chemical. The CDX response requires an explanation of the claim and any supporting documentation. If EPA agrees, fees and reimbursement are avoided since only companies subject to the Order are responsible for payment.
5. Stop Manufacturing / processing the chemical. If your company intends to stop manufacturing the chemical within 90 days of the effective date of the Order, they can notify EPA via CDX in the initial response to the Order. This option also requires payment/reimbursement for the associated fee and costs.

Second, TSCA data compensation provisions help to address but do not completely solve the free rider gap. The required studies can cost thousands or even millions of dollars and the concern here is reliance on these

data by competitors who did not pay for the work, which are referred to as free riders. The data compensation provisions of TSCA only apply to data EPA requires and do not apply if the data are voluntarily submitted. The section 4(c) data compensation provisions of TSCA are located in 40 C.F.R. Part 791. These provisions call for arbitration if cost sharing agreements can't be reached.

Third, TSCA sections 4 and 6 have associated confidentiality considerations that still need to be ironed out. Right now, the only defense against the prospect of free riders (more of an international than domestic concern) is to protect the data. The ability to access data submitted in other countries such as under the EU REACH law is similarly limited for this reason. EPA's willingness or unwillingness – and ability – to maintain as confidential certain aspects of industry-sponsored studies, has led to significant delays in getting needed information into EPA's hands. If the free rider gap can be solved, it would largely solve this problem as well.

Fourth, it is important to gain an early understanding of the information gaps for your high priority chemical to plan and budget to fill those data gaps. EPA generally must "tier" testing and reduce vertebrate testing to the extent practicable. One of my experiences practicing TSCA just out of law school in the mid-1990s was being able to participate in the flurry of enforceable testing agreements that EPA negotiated with industry under Charlie Auer's leadership. I remember taking minutes around large conference tables as Pat Hurd, one of my early mentors, worked with his clients to figure out what tests were important to recommend to EPA, where to place the testing, and how to ensure they were done well. The companies contributed top-flight combinations of business managers and scientists to these discussions. Those activities exemplified the mixture of law and science that still underpins TSCA today. A "roll up the sleeves" approach, informed agency supervision, and the high-quality data that was generated during that brief period was the equivalent of TSCA Camelot.