

Perspectives on TSCA Implementation

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- ◆ David Fischer advises clients on environmental, policy, and health and safety matters, with a concentration on the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In addition, he has extensive experience with numerous other statutes including the Clean Air Act (CAA), Clean Water Act (CWA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Safe Drinking Water Act (SDWA), the Emergency Planning and Community Right-to-Know Act (EPCRA), and the Food Quality Protection Act (FQPA).
- ◆ David's clients include domestic and international industrial and specialty chemical manufacturers, and the trade associations which represent them. Having held senior level positions with the U.S. Environmental Protection Agency (EPA) and the American Chemistry Council (ACC), clients look to David for his insight and perspective when navigating the myriad of complex environmental regulations.
- ◆ Prior to joining Keller and Heckman, David was the Deputy Assistant Administrator (DAA) for the Office of Chemical Safety and Pollution Prevention (OCSPP). During his tenure as DAA, he was deeply involved in TSCA implementation, with a particular focus on risk evaluation and risk management of existing chemicals, and all aspects of FIFRA implementation.
- ◆ During his tenure at the American Chemistry Council, David co-managed the Chemical Products and Technology Division (CPTD) where he led the implementation of the Lautenberg Chemical Safety Act.



Agenda

- ◆ OCSPP existing chemical priorities: 1/2019 – 1/2021
- ◆ OPPT reorganization
- ◆ Data gathering under TSCA

OCSPS Existing Chemical Priorities: 1/2019 – 1/2021



- ◆ Finalizing 20 Low Priority Chemicals
- ◆ Issuing final initial 10 risk evaluations
 - ◇ Initiating changes to the development of forthcoming risk evaluations and response to comments documents based on lessons learned
 - ◇ Facilitating the sharing of risk assessment knowledge and approaches within OCSPS and the harmonization of those approaches across OPPT and OPP
 - OPP staff will be co-located with other OCSPS divisions at EPA headquarters
- ◆ Initiating risk management rulemakings for the 10 initial chemicals

OCSPP Existing Chemical Priorities: 1/2019 – 1/2021 (2)



- ◆ Reorganizing OPPT to better align with TSCA
- ◆ Initiating Data Gathering under TSCA:
 - ◆ Section 4 test orders
 - ◆ Section 8(a) and 8(d) rulemakings

Aligning OPPT to Implement TSCA



- ◆ From 2016 – 2019, OPPT organization reflected pre-2016 TSCA
 - ◇ Lack of clear staffing demarcation between existing and new chemicals
 - ◇ Insufficient staff dedicated to existing chemical risk evaluations
 - ◇ Insufficient staff dedicated to data gathering activities activities under TSCA sections 4 and 8

Aligning OPPT to Implement TSCA (2)

- ◆ Realignment of OPPT was a necessary exercise to more efficiently implement TSCA
- ◆ Clear demarcations between new and existing chemicals
 - ◇ Staff are no longer asked to work on both
- ◆ Clear demarcations between risk evaluation and risk management for both new and existing chemicals remain
 - ◇ But there is communication and coordination between the two

Aligning OPPT to Implement TSCA (3)

- ◆ Creation of a “Data Gathering and Analysis Division” within OPPT
 - ◇ Prioritization
 - ◇ Data gathering
 - ◇ Systematic review
- ◆ The five branches in the existing chemicals risk assessment division (ECRAD) focus on risk evaluations
- ◆ Aggressive hiring of scientists including the creation of an OPPT branch at RTP

Data Gathering Under TSCA

- ◆ During peer review of risk evaluations, the SACC frequently highlighted the need for OPPT to fill data needs
- ◆ PV 29 became the first test case of a Section 4 test order for an existing chemical
 - ◇ Required data attainable within the timeframe to complete the risk evaluation
- ◆ But waiting until a risk evaluation is underway to seek data is not sustainable

Data Gathering Under TSCA (2)

- ◆ With the experience gleaned from PV 29, staff focused on the next 20 HP chemicals:
 - ◆ Test orders for 9 of the 20 HP chemicals have been issued
 - ◆ Test orders for the remaining 11 HP chemicals are under development
 - ◆ Even though test orders have been issued earlier in the risk evaluation development process than for PV 29, it will be challenging to timely complete each of the 20 risk evaluations
 - ◆ The likely result is that the risk evaluations will be staggered and finalized at different times

Data Gathering Under TSCA (3)

- ◆ For new data to be developed, reviewed and then integrated into the risk evaluation process, test orders will need to be issued much earlier
 - ◇ The system needs to be “front loaded”
- ◆ Systematic review will need to start earlier in order to identify data needs and to meet TSCA’s “statement of need” requirements
- ◆ But stakeholders need not wait for test orders to be issued
 - ◇ Stakeholders can address data needs voluntarily but should seek input and advice from EPA. And filling those data needs could influence when your chemical is prioritized

Data Gathering Under TSCA (4)

- ◆ Section 4 is not the only means for EPA to acquire data
- ◆ The Interagency Testing Committee, which convened in May 2020, recommended adding 50 chemicals to the Priority Testing List (PTL)
 - ◇ 20 chemicals undergoing risk evaluation (as requested by EPA) and 30 organohalogen flame retardants (as requested by the CPSC)
- ◆ EPA routinely adds substances to the TSCA 8(d) rule when the ITC adds substances to the PTL

Data Gathering Under TSCA (5)

- ◆ EPA has indicated in the Fall 2020 Unified Agenda that it intends to add the 50 chemicals to the TSCA Section 8(d) model Health and Safety Data Reporting rule
 - ◆ Manufacturers would submit to EPA a list and copies of unpublished health and safety studies

Data Gathering Under TSCA (6)

- ◆ EPA also routinely adds substances to the TSCA 8(a) Preliminary Assessment Information Rule (PAIR) when the ITC adds substances to the PTL
 - ◇ As with 8(d) the number of chemicals that can be added in any year is capped at 50
- ◆ Under PAIR, manufacturers would submit a report including production, use, and exposure related information for the newly added chemicals

Data Gathering Under TSCA (7)

- ◆ The Spring 2020 Unified Agenda noted that EPA is developing a section 8 rulemaking to add certain TSCA Work Plan chemicals to chemical specific reporting and recordkeeping rules
 - ◇ EPA intends to collect existing information on hazards and exposures of chemicals from manufacturers and processors
- ◆ Under either Sections 8(a) or 8(d), it is unclear how much information EPA can anticipate receiving. Past experience suggests a modest yield
 - ◇ EPA also created dockets to receive voluntary information submissions on all the work plan chemicals



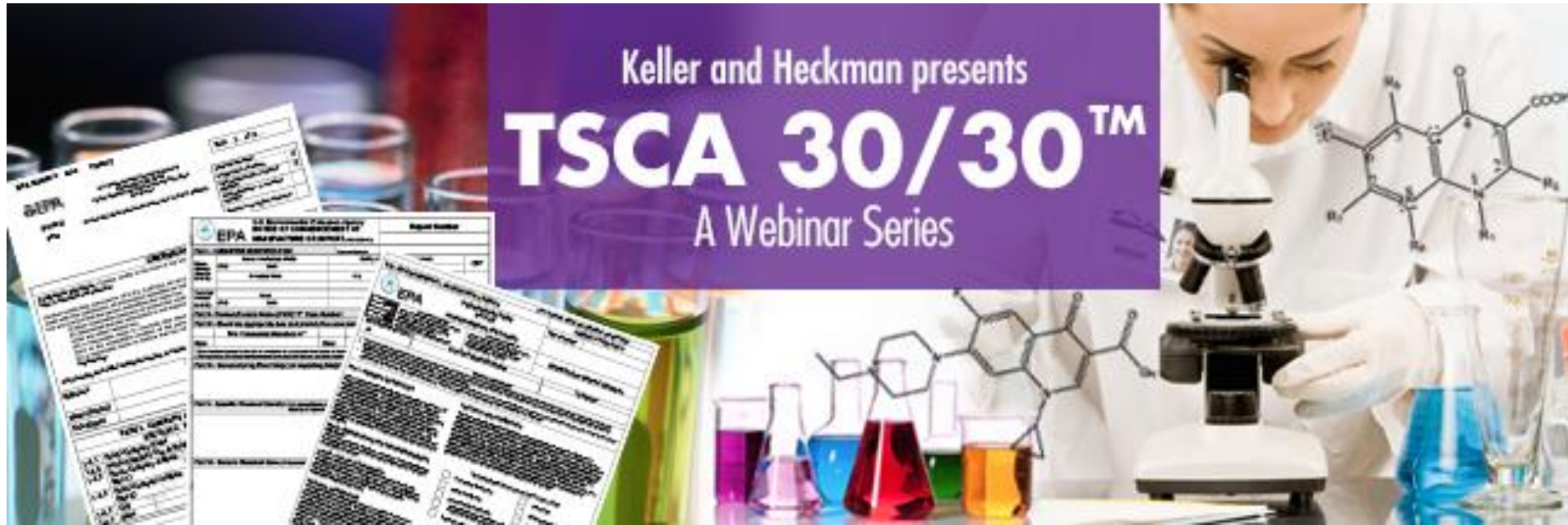
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Thank You

Any Questions?

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