

# TSCA Enforcement Under the Biden Administration

February 9, 2022

# Greg Clark



- ◆ Greg Clark advises clients on regulatory and environmental issues, focusing on the Toxic Substances Control Act (TSCA), the Clean Air Act (CAA), state volatile organic compound (VOC) regulations, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA).
- ◆ Greg assists clients needing approval of new chemical substances, genetically modified organisms, and pesticides under TSCA, FIFRA, and similar laws abroad. Clients seek his expert guidance through the Premanufacture Notification (PMN), Low Volume Exemption, Microbial Commercial Activity Notice (MCAN), and TSCA Environmental Release Application (TERA) review processes. He also assists clients by negotiating the terms and conditions of TSCA Section 5(e) consent orders and Significant New Use Rules (SNURs). Additionally, Greg advises companies seeking to market biotechnology-derived products and their production platforms (including bacteria, yeast, algae, and plants) navigate the complex regulatory requirements administered by the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Animal and Plant Health Inspection Service (APHIS).
- ◆ Greg's experience and expertise allows him to advise companies and trade associations on the prioritization, risk evaluation, and risk management of existing chemicals, including chemicals on the 2014 TSCA Work Plan, following the Lautenberg Act amendments to TSCA. Through this work, he develops detailed comments and regularly interacts with EPA staff. He assists companies on periodic reporting under the TSCA Chemical Data Reporting Rule and other agency reporting programs. He also designs, conducts, and coordinates comprehensive internal audits of TSCA compliance for existing operations under EPA's "Audit Policy", as well as under other penalty mitigation policies.
- ◆ Greg has extensive experience representing clients in CAA rulemakings and enforcement matters before administrative agencies, including drafting highly technical comments, filing petitions for reconsideration and judicial review, and meeting with agency staff.
- ◆ Greg has a background in molecular biology and emergency preparedness, offering him a unique foundation from which to advise his clients and assist the firm

# Tom Berger



- ◆ Tom Berger assists clients in bringing forth new products and maintaining the ability to market them in a cost-effective manner using an interdisciplinary approach that combines law and science, with an emphasis on emerging technologies in the industrial chemicals area
- ◆ Tom helps clients navigate the TSCA premanufacture notification (PMN) review process and negotiates the terms and conditions of TSCA section 5(e) orders and significant new use rules (SNUR). He also counsels clients on US Environmental Protection Agency (EPA) enforcement matters and assists companies in preparing for Agency inspections, responding to information requests and subpoenas, and defending enforcement actions. Tom is a recognized leader in designing and conducting extensive voluntary TSCA compliance audits (often as part of corporate mergers and acquisitions) and assisting clients in managing liability under EPA's "Audit Policy" and other available penalty mitigation policies
- ◆ Tom's practice is based on an in-depth understanding of the chemicals, plastics, and electronics industries, with over 25 years of experience counseling clients on the regulation and approval of new and existing chemicals under the Toxic Substances Control Act (TSCA) and TSCA's international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. His technical background allows him to frequently undertake matters that involve polymers, inorganic chemistry, and complex chemistry and chemical nomenclature issues
- ◆ As an active member of the environmental and chemical industries, Tom was heavily involved in efforts to "reform" TSCA and works extensively on all aspects of TSCA, including TSCA Inventory, Inventory "reset," Chemical Data Reporting (CDR), and section 6 "fee" rule issues, as well as confidential business information (CBI), section 8 recordkeeping and reporting, and import/export issues
- ◆ Tom has a chemical engineering background and, prior to joining Keller and Heckman, worked as an engineer for a major international chemical manufacturer

# §11 – Inspection and Subpoena Authority



## ◆ Where

- ◆ Any facility or conveyance in which chemical substances are **manufactured, processed, stored, or held** before or after distribution in commerce

## ◆ When

- ◆ Written notice
- ◆ Reasonableness
- ◆ An agency “can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.”
  - ◆ *U.S. v. Morton Salt Co.*, 338 U.S. 632, 642-43 (1950)

# TSCA Penalties



- ◆ **Civil:** Maximum penalty \$37,500 (2016) → \$ 43,611 (2022 inflation-adjusted)
- ◆ **Criminal:** Maximum penalty \$50,000
  - ◇ And/or imprisonment of up to one year
  - ◇ Knowing and willful violations that place individual in imminent danger of death or serious bodily injury subject to fine of \$250,000, imprisonment not more than 15 years, or both
    - Organizations: also subject to fine of not more than \$1 million
- ◆ No specific statute of limitations, but generally 5 years (*3M v. Browner*)
  - ◇ But some violations are deemed “continuing violations” (*Elementis Chromium*)

# Enforcement Focus Areas – By Section



- ◆ Section **4** – Test Rules and Orders
- ◆ Section **5** – PMNs, SNURs, LVEs
- ◆ Section **6** – Risk Management Rules
- ◆ Section **8** – CDR, Inventory Reset
- ◆ Section **12** – Export Notices
- ◆ Section **13** – Import Certifications

# Key TSCA Enforcement Response Policies



- ◆ *TSCA Section 5 Enforcement Response Policy*
  - ◇ August 5, 1988 (amended June 8, 1989, and July 1, 1993)
- ◆ *Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13*
  - ◇ March 31, 1999
- ◆ *Enforcement Response Policy for TSCA §4 Test Rules*
  - ◇ May 28, 1986
- ◆ **Address gravity-based penalties (“nature”, “circumstance”, “extent”)**

# ERP Penalty Calculation Examples



- ◆ 2020 CDR non-reporting (section 8)
  - ◇ Level 1, Significant, One Day, Per Chemical, Per Site
  - ◇  $\$29,655 * 1 \text{ day} * 5 \text{ substances} * 1 \text{ site} = \text{\textcolor{red}{\$148,275}}$
- ◆ Importing a substance not on the TSCA Inventory (section 5)
  - ◇ Imported 5 times/year for 5 years, 8,000 lbs./import, not further distributed or processed, would have been subject to a 5(e) order
  - ◇ Level 2, Major, 25 days
  - ◇  $\$34,889 * 25 \text{ days} = \text{\textcolor{red}{\$872,225}}$



# Dated ERPs Leave Significant Gaps

- ◆ Section 4 ERP
  - ◇ Test orders (2016)
- ◆ Section 5 ERP
  - ◇ Updated polymer exemption rule (1995)
  - ◇ Majority 5(e) environment for PMNs (“circumstances”)
  - ◇ LVE/LoREX (1995)

# Dated ERPs Leave Significant Gaps



- ◇ Sections 8, 12, and 13 ERP
  - ◇ Inventory Reset (2017)
  - ◇ Mercury export ban (2008, 2016)
- ◇ Section 6 (No ERP)
  - ◇ Risk management rules
  - ◇ Risk evaluation identification

# EPA inspections, information requests



## ◆ On-site inspections

- ◆ Effectively ceased during height of pandemic, but resuming
  - EPA generally sends letter or email in advance
  - December 30, 2021 → EPA rescinds inspection procedure rule to allow flexibility

## ◆ Subpoenas

- ◆ If procedural requirements followed and evidence sought is relevant/material to investigation, court will enforce subpoena unless party proves inquiry unreasonably overbroad or unduly burdensome
  - *e.g.*, Dover, INEOS (2009)
    - Chlorinated paraffin Inventory status

## ◆ Information request letters (IRL)

- ◆ “...in lieu of conducting an inspection or issuing a subpoena”

# Other types of Agency/public actions

## ◆ Citizens' civil actions (§20(a))

- Any person may commence civil action against any person or agency alleged to be in violation of TSCA to restrain violation, or against Administrator to compel Administrator to perform any non-discretionary act/duty
- ◆ Not used until recently – in 2020 Center for Environmental Health (CEH) filed suit alleging 2016 TSCA §8(a) CDR violations by several companies
  - e.g., 3N International
  - Plaintiff compared publicly-available import data to CDR reports
  - Requested relief included - requiring court to order submission of Form Us and companies to conduct CDR compliance audits, and awarding plaintiff attorney and expert witness fees
  - Varying results/impacts...

## ◆ Citizens' petitions (§21) (not enforcement, *per se*)

- Any person can petition EPA to initiate proceeding for issuance, amendment, or repeal of a rule under §4, 6, or 8, or an order under §4, 5(e), or 5(f)

# “No action assurances”

- ◆ EPA has policy (Nov. 16, 1984 memorandum) against “No Action Assurances” (NAA) outside the context of a formal enforcement proceeding
  - ◇ Prior to or after a violation has occurred
- ◆ However, NAA can be used:
  - ◇ In the context of a formal single-company enforcement/settlement (“enforcement discretion”)
  - ◇ To address broader “regulatory” issues, *e.g.*:
    - March 24, 2020 NAA for §6 risk evaluation fee self-identification requirement
      - impurities, byproducts, *etc.*
    - March 8, 2021 NAA extending to 9/4/2021 the 3/9/2021 compliance date for ban on processing/distribution of certain forms of “PIP (3:1)” under §6(h) rule

# EPA “Audit Policy” and enforcement

- ◆ *Incentives for Self-Policing: Discovery, Disclosure, Correction, and Prevention of Violations* (65 Fed. Reg. 19,618 (Apr. 11, 2000))
- ◆ EPA will waive all gravity-based penalties if all nine (9) conditions satisfied
  - ◇ **Policy Condition 4:** Company must discover and disclose violation to EPA prior to: (i) commencement of inspection or investigation (or information request); (ii) notice of a citizen suit; (iii) filing of a complaint by a third party; (iv) reporting of violation to government by “whistleblower”, or (v) imminent discovery of violation by regulatory agency
    - TSCA ERPs contain similar provisions
- ◆ EPA will waive 75% GBP if last 8 conditions of Policy are met
- ◆ EPA retains right to recover any economic benefit from violation

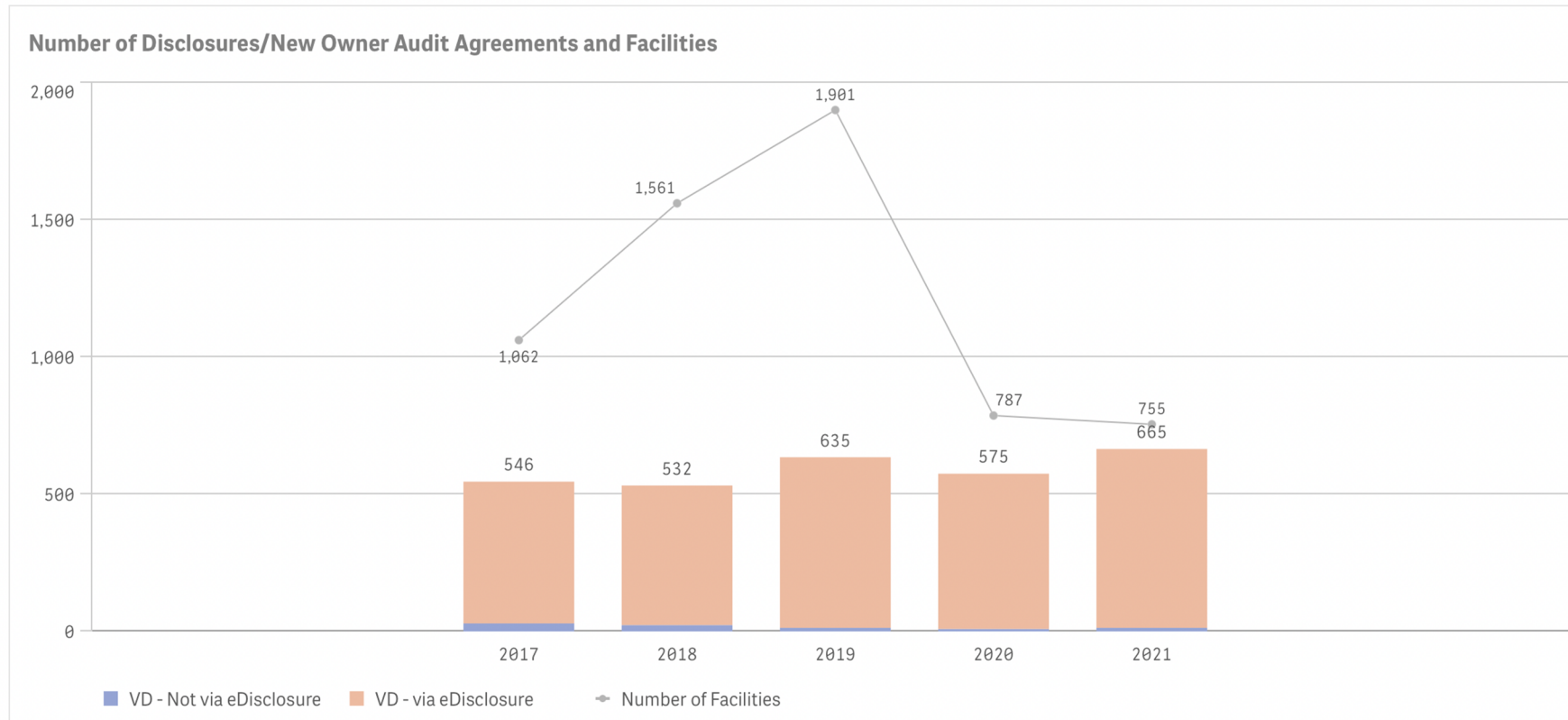
# Audit Policy (cont.)

- ◆ Invoking Audit Policy does not prevent EPA from inspecting or issuing subpoena or IRL
- ◆ **Under Condition 4**, once inspection notice letter, subpoena, or IRL received, too late to use Audit Policy
- ◆ Also note **Condition 7** (“Repeat Violations”)
  - ◇ Specific violation (or closely related violation) cannot have occurred within the past three years at the same facility, or within the past five years as part of a pattern at multiple facilities owned or operated by the same entity
    - “Violation” = violation identified in judicial/administrative order, consent agreement/order, complaint, NOV, conviction or plea agreement, or act/omission for which entity has received penalty mitigation from EPA or State or local agency
  - ◇ EPA sometimes provides written inspection “closeout” report

# Voluntary disclosure trends

## EPA Voluntary Disclosure Programs - Number of Disclosures/New Owner Audit Agreements and Facilities

FY 2017 – FY 2021



1. VD stands for Voluntary Disclosure.

Data Source: Integrated Compliance Information System (ICIS) and eDisclosure System  
Data as of: November 5, 2021 (ICIS) and October 27, 2021 (eDisclosure System)

U.S. Environmental Protection Agency



# Biden EPA priorities (in a nutshell)



- ◆ Climate Change
- ◆ Environmental Justice
- ◆ Critical Water Infrastructure
- ◆ Protecting Communities from Hazardous Waste and Environmental Damage (CERCLA)
- ◆ Addressing Per- and Polyfluoroalkyl Substances (PFAS) Pollution
- ◆ Restoring Capacity to Carry Out Agency's Core Mission
  - ◇ EPA has lost ~1,000 staff over past four years

# FY '20-21 OECA National Program Guidance



## ◆ From 9/21 EPA presentation:

- ◆ 2016 Lautenberg Amendments
- ◆ §4 test orders
- ◆ §5 (§5(e) orders, SNURs, LVEs)
- ◆ §6 rules
- ◆ §8 reporting
- ◆ §13 imports
- ◆ Chemicals of concern, e.g., per- and polyfluoroalkyl substances (PFAS)

*NPG guidance will not be updated until later this year for FY23/24 cycle*

# Other trends/activities

- ◆ Enforcement alert on ski waxes containing PFAS chemicals
  - ◇ <https://www.epa.gov/system/files/documents/2022-01/pfasskiwax.pdf>
    - Swix (\$375,625 penalty + \$1,000,000 SEP)
    - TASR (self-disclosure) (\$12,500 penalty)
- ◆ Increased emphasis on economic benefit recovery, unwillingness to reduce penalty amounts (anecdotal)
  - ◇ Agency often provides “opportunity to show cause” as to why enforcement action should not be brought or otherwise may request factors company believes EPA should consider before issuing complaint, *e.g.*, reliance on compliance assistance, ability to pay penalty, *etc.*

# Recent inspection/information requests

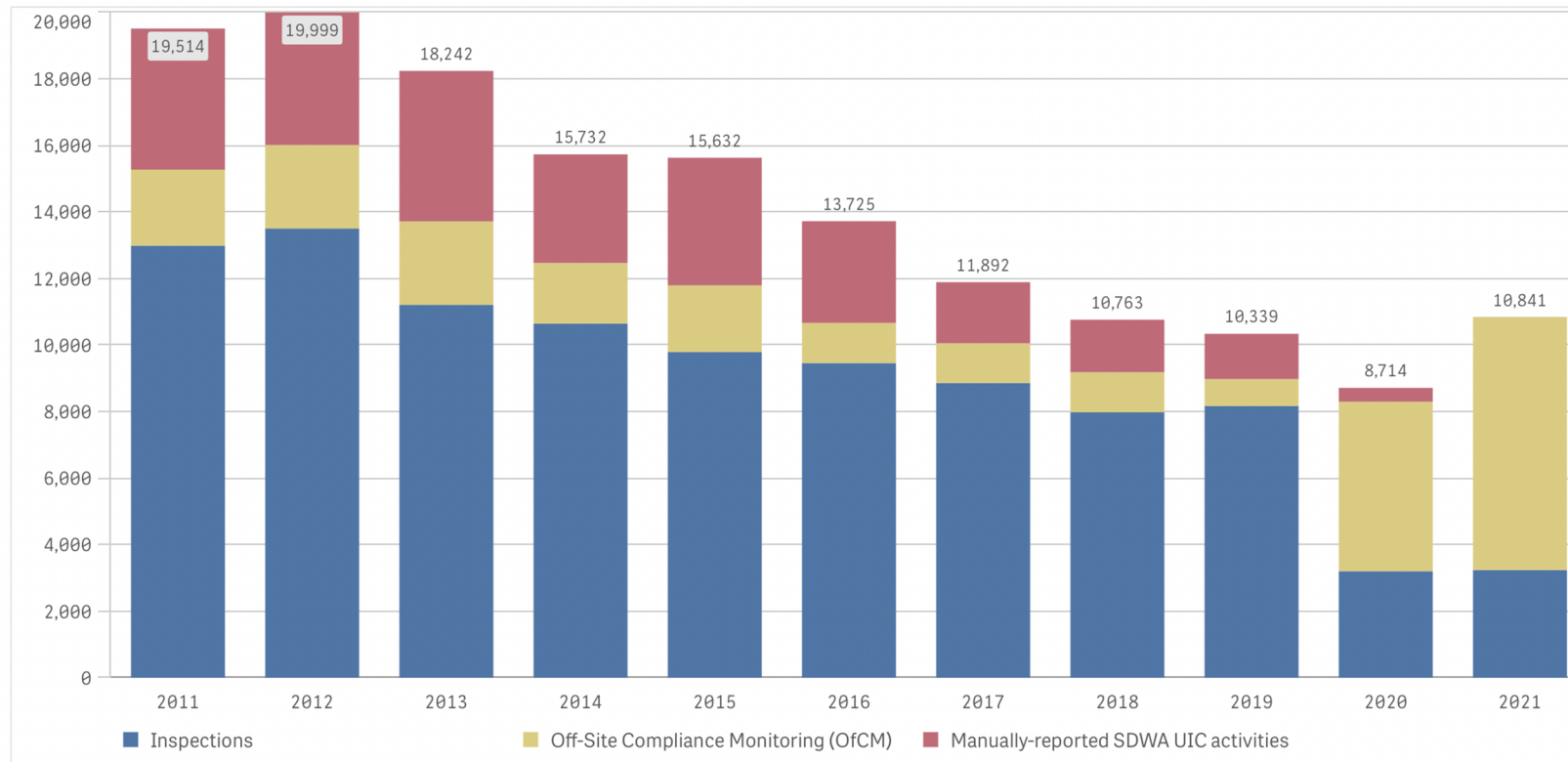


- ◆ Timeframes vary by request and type of information, but most cover activities occurring within past **3** or **5** years (typical default)
- ◆ Process flow diagrams (sometimes “existing”)
- ◆ Lists of substances manufactured, imported, purchased, exported
  - ◇ 2020 **CDR**-focused information (2016-19)
  - ◇ **R&D**-focused information
  - ◇ Lists (sometimes copies) of various TSCA **submissions** made
  - ◇ Frequently request **dates/quantities**
- ◆ Various section 8(c), (d), (e) information
- ◆ Agency may request certain information be submitted (CDX) before inspection, and certain information during inspection

# Inspections, off-site compliance monitoring



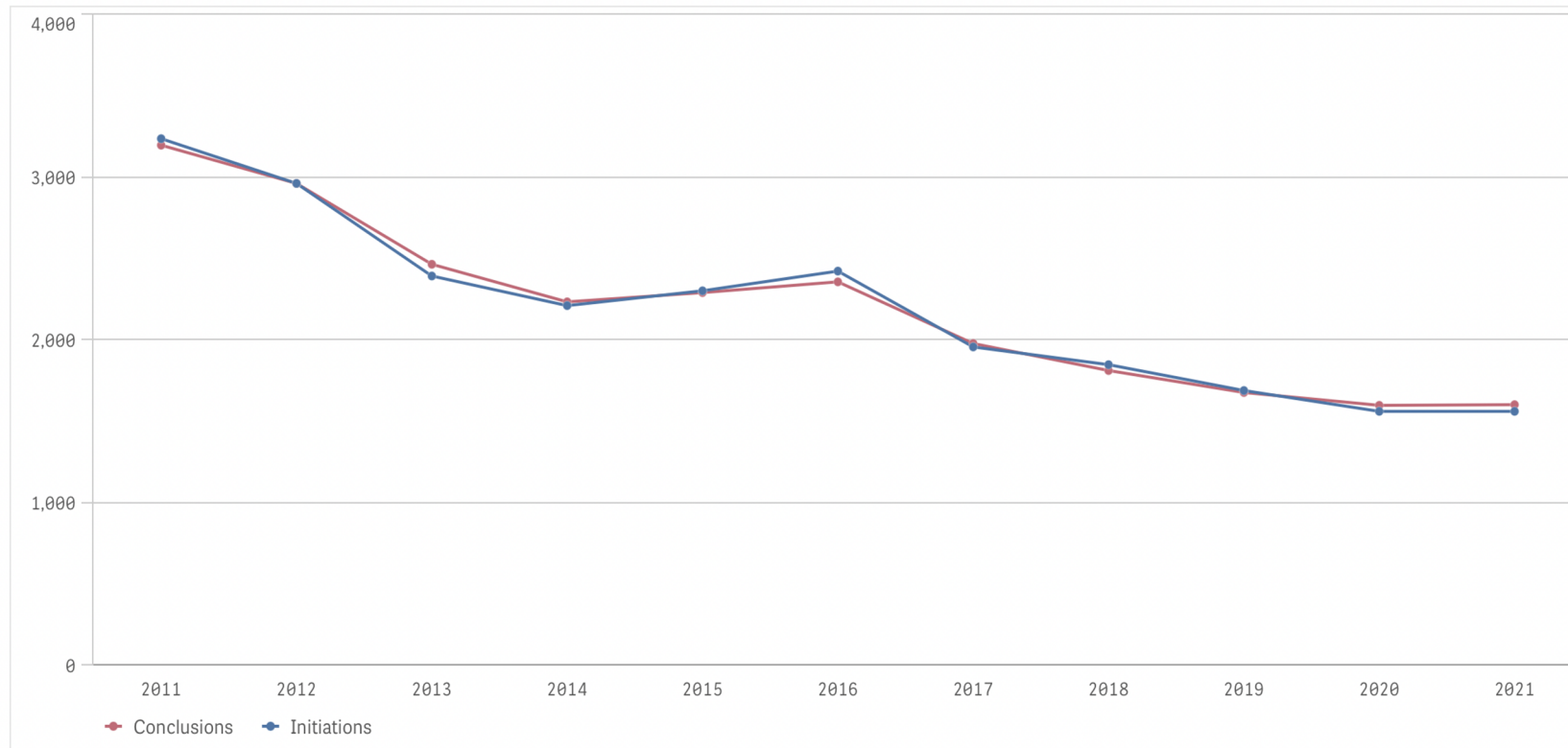
## Federal Compliance Monitoring Activities Conducted by EPA FY 2011 – FY 2021



1. An inspection is a compliance monitoring activity performed on-site at a regulated facility; OfCM activities are not performed on-site. Manually-reported SDWA UIC activities can include both on or off-site activities. Therefore, those UIC activities are listed separately. EPA stopped collecting these data separately in FY 2021.
2. Prior to FY 2020, OECA used a different methodology for deciding which off-site compliance monitoring activities would be reported in its Annual Results and did not collect data on all off-site compliance monitoring activities conducted. The totals for FY 2019 and earlier years reflect the prior methodology. Use caution when comparing FY 2020 and FY 2021 results to prior years.

# Civil enforcement trends

## Total Civil Enforcement Case Initiations and Conclusions FY 2011 – FY 2021



1. Totals include CERCLA Initiations and Conclusions.

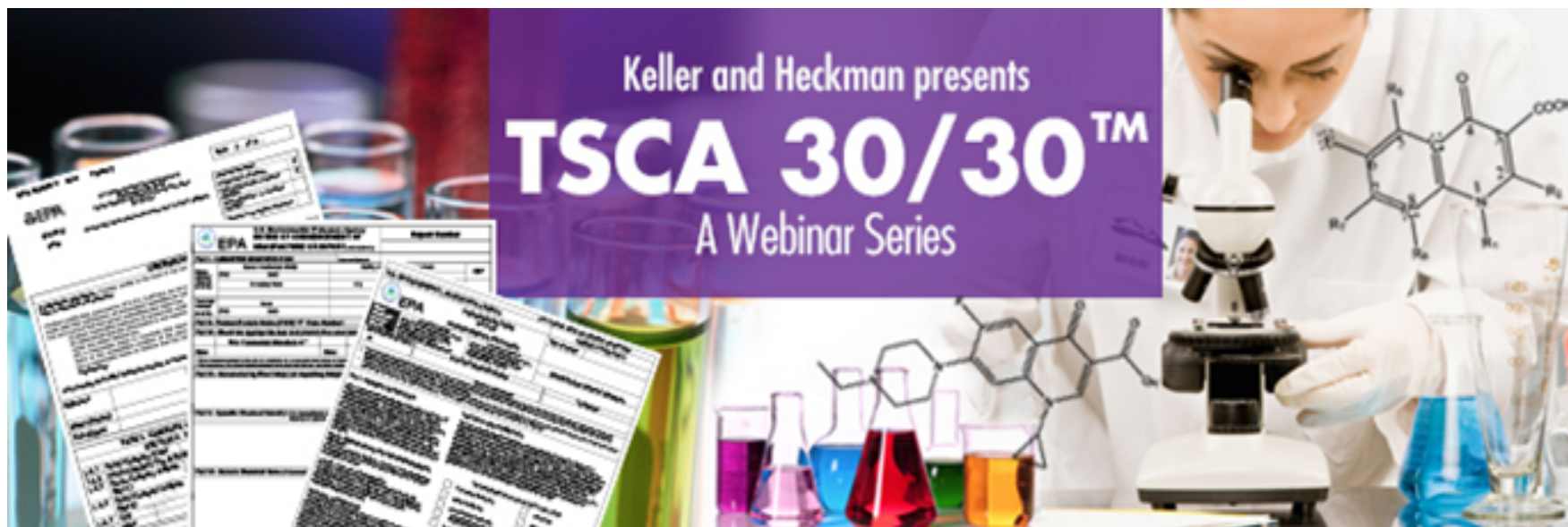
Data Source: Integrated Compliance Information System (ICIS)  
Data as of: December 20, 2021

U.S. Environmental Protection Agency

# So.....

- ◆ Be prepared for an EPA inspection or IRL
  - ◇ Pay particular attention to PFAS and other “focus” chemicals
- ◆ Watch imports
- ◆ Consider TSCA compliance audit
  - ◇ Provides additional flexibility
  - ◇ Can help prevent supply disruption
    - Obtaining authorization to continue manufacture, import, or processing is extremely time/cost intensive and challenging





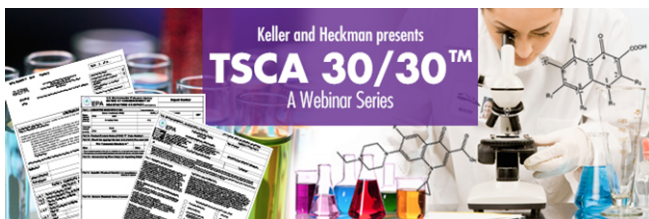
**The Next TSCA 30/30:**  
Wednesday, March 23, 2022

For more information on past and future **TSCA 30/30** programs, please visit **[www.khlaw.com/TSCA3030](http://www.khlaw.com/TSCA3030)**





Please join us at 1:00 PM Eastern U.S.  
Wednesday, Feb 16, 2022  
[www.khlaw.com/OSHA3030](http://www.khlaw.com/OSHA3030)



Please join us at 1:00 PM Eastern U.S.  
Wednesday, March 23, 2022  
[www.khlaw.com/TSCA3030](http://www.khlaw.com/TSCA3030)



Please join us at 1:35 PM Eastern U.S.  
Wednesday, April 13, 2022  
[www.khlaw.com/REACH-3030](http://www.khlaw.com/REACH-3030)

## Tom Berger

Partner  
Washington, DC | Indianapolis,  
IN Satellite Office

202.434.4285

[berger@khlaw.com](mailto:berger@khlaw.com)



## Greg Clark

Partner

Washington, DC

202.434.4302

[clarkg@khlaw.com](mailto:clarkg@khlaw.com)

