

Kathleen M. Roberts  
Bergeson & Campbell, P. C.  
www.lawbc.com

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# NACD and EPA: Relief, Reform, and Rhetoric

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# **Will Recent Regulatory Reform Rhetoric Provide Relief?**

- As far as the U.S. Environmental Protection Agency (EPA) goes -- probably not
  - A renewed attention by Congress on the Toxic Substances Control Act (TSCA) and other EPA programs
  - Likelihood of any significant movement by Congress in foreseeable future is slim to none
  - Therefore, EPA management/Obama Administration have focused their attention to address perceived deficiencies on their own
  - Such EPA actions will result in increased industry burden, not relief

# **Adjust the View -- How You See Yourself Versus How EPA Sees You**

- You may not see yourself as a chemical manufacturer or hazardous chemical operator, but if EPA does, you better know the rules

# Consequences and Impacts

- Even if you play by the rules, your company will spend:
  - Time and resources in learning applicable regulations
  - Time and resources in monitoring regulations
  - Time and resources in internal training/communications
- But if you choose not to play by the rules, your company could have:
  - Lost business opportunities due to delays in getting materials to market
  - Angry customers that are impacted by held up shipments
  - Penalties for non-compliance
    - \$37,500 per day for each violation
    - Putting it into perspective
    - Missed reports for two chemicals  
six months ago -- \$13,500,000+



# TSCA

- Originally passed in 1976
- Applies to the manufacturers, processors, importers, distributors, users, and disposers of chemical substances or mixtures
- Who might be considered chemical manufacturer? processor? distributor?

# TSCA Obligations for Chemical Distributors

- **Distributors** engage in storage, warehouse, distribution, and/or repackaging of materials without any change to chemical components
- Although many of the provisions and rulemakings in TSCA focus on chemical manufacturers, distributors are impacted

# TSCA Obligations for Chemical Distributors (cont'd)

- Distributors are obligated to report under or adhere to:
  - Section 8(c) -- Must maintain a “central file” of records of allegations of significant adverse health or environmental reactions and provide to EPA upon rulemaking
  - Section 8(d) -- Upon rulemaking, submit copies or lists of unpublished health and safety studies on specified chemical substances and mixtures
  - Section 8(e) -- Report substantial risk information to EPA “immediately”
  - Section 6 -- If EPA has issued risk management requirements under Section 6, distributors would be required to adhere to those requirements

# TSCA Obligations for Chemical Distributors (cont'd)

- Section 7 -- Distributors would be required to adhere to relief actions to address imminent risks of serious or widespread injury
- Section 14 -- If distributors are submitting information to EPA, they would be eligible to claim certain information as confidential
  - Recent EPA actions, however, have made making confidential business information (CBI) claims more burdensome
- Section 11 -- Distributors are subject to inspections
- Section 16 -- Distributors are subject to TSCA penalties
  - Penalties can be up to \$37,500 per day or up to one year in prison

# TSCA Obligations for Chemical Distributors (cont'd)

- Distributors may be asked to provide information for reporting under:
  - TSCA Section 8(a), Inventory Update Rule (IUR) -- Distributors are not required to submit reports under the IUR, but some chemical suppliers may ask distributors to provide information on downstream sites, workers, and uses
  - Section 12 -- If a chemical distributor is exporting chemicals subject to certain TSCA rules or orders, it must notify EPA in writing

# TSCA Obligations and Chemical Processors

- **Processors** engage in blending, formulation, or other activities in which chemical components are mixed together but DO NOT result in chemical reactions
- In addition to the TSCA obligations set forth for distributors, processors are subject to:
  - Section 4 -- If EPA specifies, processors can be subject to completing health and environmental effects testing on certain chemicals
  - Section 5 -- A processor of existing chemicals must provide notice to EPA of any use of a substance that EPA has determined is a “significant new use.” The determination of a “significant new use” is made via a rulemaking known as a SNUR (Significant New Use Rule)

# TSCA Obligations and Chemical Manufacturers

- In TSCA, manufacture includes importation, so importers must comply with all requirements applicable to manufacturers
- Definition of importer
  - Per IUR -- Any unit that controls an import transaction
  - Per U.S. Customs Regulations -- Party liable for the payment of duties
  - Per 40 C.F.R. § 704.3 -- Any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the United States, and includes:
    - The person primarily liable for the payment of any duties on the merchandise, or
    - An authorized agent acting on his behalf (as defined in 19 C.F.R. § 1.11 )

# TSCA Obligations and Chemical Manufacturers (cont'd)

- Importer also includes, as appropriate:
  - The consignee
  - The importer of record
  - The actual owner if an actual owner's declaration and superseding bond have been filed in accordance with 19 C.F.R. § 141.20
  - The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 C.F.R. part 144
- For TSCA purposes, the importer/party required to comply with TSCA regulations must be a U.S. entity

# TSCA Obligations and Chemical Manufacturers (cont'd)

- All of the items included for distributors and processors, and:
  - Section 4 -- Developing Test Data
  - Section 5 -- New Chemicals
  - Section 8(a) -- Preliminary Assessment Information Rule
  - Section 8(a) -- Chemical Data Reporting (CDR) (previously known as IUR)
  - Section 13 -- Imports. At point of entry, importers must certify that:
    - Chemical substances, mixtures, and articles being imported comply with applicable rules and orders under TSCA and are not offered for entry in violation of TSCA (**positive certification**); or
    - Chemical substances, mixtures, and articles being imported are not subject to TSCA (**negative certification**)

# Regulatory Reform and TSCA

- EPA Administrator Jackson announced numerous actions intended to enhance EPA's chemical management program, including:
  - Risk management actions
    - Focused actions on nanoscale materials, lead, mercury, formaldehyde, PCBs, and glymes
  - Development of chemical action plans for chemicals of concern
    - Intends to use all available tools under TSCA, including Section 6 provisions to label, restrict, or ban
    - About ten action plans currently posted on EPA's website

# Regulatory Reform and TSCA (cont'd)

- Increased transparency
  - More scrutiny on CBI claims
  - EPA declassified identities of more than 150 chemicals in 104 studies that were previously claimed as confidential
  - EPA has stated that it will deny CBI claims for chemical identities in health and safety studies filed, except in certain circumstances
- Requirements for additional information to understand chemical risks
  - Required testing under Section 4 on certain high production volume chemicals
  - Changes in required reporting of production, processing, and use information

# Chemical Data Reporting (CDR)

- Previously known as the Inventory Update Reporting rulemaking
- Amendments to IUR proposed in August 2010
- Rulemaking at the Office of Management and Budget from January to July 2011
- Final rulemaking published in *Federal Register* on August 16, 2011

# CDR -- Background on Previous Requirements

- Reporting of production information for substances manufactured or imported over 25,000 pounds per year
- Additional reporting of exposure and use information for substances manufactured over 300,000 pounds per year, including downstream sites; users; and industrial, commercial, and/or consumer use categories
- If manufacturers do not have such information, they indicate “not readily obtainable”
- No requirement to survey downstream users
- Reporting to occur every five years

# CDR -- The Good, The Bad, and The Ugly

## ■ The Good

- EPA did not lower reporting threshold
  - still at 25,000 pounds per site
- EPA opted to delay required reporting of production volumes for years in between reporting years until 2016 reporting cycle (for years 2012 and beyond)
- EPA decided to phase in lower reporting threshold for processing and use information
  - Process and use reporting for chemicals at 100,000 pounds per site in 2011
  - Process and use reporting for chemicals at 25,000 pounds per site in 2016

## CDR -- The Good (cont'd)

- EPA chose to specify a reporting threshold for chemicals subject to certain TSCA rules
  - Proposed rule had no *de minimis* level; final rule included 2,500 pounds per site reporting threshold.
- EPA opted to delay reporting on the 2,500 reporting threshold for certain chemicals until 2016

# CDR -- The Bad

- Upfront substantiation of CBI claims for processing and use reporting
- “Known to or reasonably ascertainable” standard for processing and use information
- Reporting on number of commercial workers that might potentially be exposed to reported chemicals

# CDR -- The Ugly

- Reduced reporting time for 2012
- Required use of e-CDRweb, EPA's electronic reporting tool, to submit all CDR information through the Internet
- 2011 as Principal Reporting Year

# CDR -- Who Is Required to Report?

- **Manufacturers and importers, that meet reporting threshold, to include:**
  - **Distribution centers that serve portable manufacturing units**
    - **Examples of “portable manufacturing units” are building or road projects that use tanks to produce calcium hydroxide slurry in construction and agricultural facilities that make ammonium hydroxide for land use**
  - **Contract or toll manufacturers must ensure their manufacturing data are reported under the CDR**

# CDR Reporting in 2012

- Determination of whether reporting is needed will be production volumes in 2011
  - Reporting threshold will be 25,000 pounds per site
- Threshold for process and use information will be 100,000 pounds per site
- Also report production and/or import volume for 2010
- Report to be submitted to EPA by June 30, 2012

# CDR Reporting in 2016

- Determination of whether reporting is needed will be production volumes from 2012 through 2015
  - Reporting threshold will be 25,000 pounds per site
  - If threshold is exceeded in any of those years, reporting is required in 2016
- Threshold for process and use information will be 25,000 pounds per site
  - Process and use information will be reported for principal reporting year only (*e.g.*, 2015) -- regardless of what year's production triggered CDR reporting

# CDR Reporting in 2016 (cont'd)

- Also report production and/or import volume for 2012, 2013, 2014, and 2015
  - Even if some of these years did not exceed reporting threshold
- Report to be submitted to EPA by September 30, 2016

# Regulatory Reform and Risk Management Plan (RMP)

- Who is covered by the RMP Regulations?
  - According to March 2009 EPA guidance, owners and operators of stationary sources that handle more than a threshold quantity of a listed substance must implement a risk management program and submit an RMP for all covered substances
- So, if you are below the threshold quantity, you are not covered by RMP -- right?

# Regulatory Reform and Risk Management Plan (RMP) (cont'd)

- **WRONG!!** If your facility uses any type of extremely hazardous substances (EHS), you are obligated to comply with Clean Air Act Section 112(r)(1) and the General Duty Clause
- How can I tell if I have EHSs?
  - Not limited to the list of regulated substances in Section 112(r)
  - Not defined in Section 112(r)
  - May or may not be listed or otherwise identified by government agencies
  - EPA suggested criteria -- short term exposures associated with releases to air cause death, injury, or property damage due to toxicity, reactivity, flammability, volatility, or corrosivity

# **Regulatory Reform and Risk Management Plan (RMP) (cont'd)**

- **General Duty Clause reflects view that owners/operators have responsibility to:**
  - Know the hazards of chemicals on site
  - Understand impacts of possible releases of chemicals
  - Maintain a safe facility to prevent accidents
  - Minimize potential impact if release does occur

# Regulatory Reform and Risk Management Plan (RMP) (cont'd)

- From NACD Responsible Distribution Guiding Principles:
  - *To make health, safety, security, and environmental considerations a priority in our planning for all existing and new operations, products, processes, and facilities*
  - *To inform emergency response officials, employees, customers, and the public of manufacturer's information on chemical-related health or environmental hazards, and the manufacturer's recommendations on protective measures*
- Facilities have had to comply with the General Duty Clause since November 1990

# Regulatory Reform and Emergency Planning and Community Response Act

- Changes to Emergency and Hazardous Chemical Inventory Forms in August 8, 2011, *Federal Register*
  - Tier I and Tier II
- New data elements to make forms more useful to agencies and to better inform the public

# **EPA Proposal for Tier I and Tier II Forms**

- Facility identification to include phone number, latitude, longitude and number of employees
- Parent company name
- Owner/operator of facility
- Facility emergency coordinator
- Contact information for person responsible for Tier I and Tier II forms
- Indication as to whether facility is subject to Emergency Planning under Emergency Planning and Community Right-to-Know Act (EPCRA) Section 302
- Narrower range for maximum amount and average daily amount

# EPA Proposal for Tier II Forms

- Reporting on chemical information/mixtures to include:
  - Whether mixture contains an EHS
  - Physical and health hazards of mixture
  - Amount present onsite
  - Type of storage
  - Storage locations
- Storage types
- Storage conditions

# Regulatory Reform and Endocrine Disruptor Screening Program (EDSP)

## ■ EDSP History

- June 2007: Draft of specific chemicals subject to testing
  - 73 pesticides and inert ingredients
- April 2009: First final list of chemicals subject to testing requirements
  - 67 pesticides and inert ingredients
- November 17, 2010: List of 134 chemicals
  - Expands beyond pesticides

# Regulatory Reform and Endocrine Disruptor Screening Program (EDSP) (cont'd)

- Questions on what any newly developed results mean and if they obviate previous conclusions from more advanced tests (*e.g.*, the multi-generation reproductive toxicity tests)
- EPA needs to define how any test results from Tier 1 will be related to a determination that Tier 2 is needed
- Petition requesting EPA to develop explanation on how Tier 2 decisions will be made
  - Test orders for chemicals to conduct Tier 1 screening
    - Eleven assays to determine potential for a chemical to interact with estrogen, androgen, and thyroid hormone systems
  - If interaction shown, additional Tier 2 testing may be required
- Public comments on petition are due by October 11, 2011

# New EDSP Materials Online

## ■ Resources for Test Order Recipients

- Assay information
- Test order response and status tracking
- How to submit information in response to an EDSP test order/data call-in
- Chemicals for screening
- See <http://www.epa.gov/endo/pubs/toresources/index.htm>

# New EDSP Materials Online (cont'd)

## ■ Standard Evaluation Procedures (SEP)

- Guidance for the review and evaluation of data submitted in response to test orders for EDSP Tier 1 battery
- Consistent evaluations of major scientific topics
- Provide interpretive scientific and policy guidance where appropriate
- SEPs for aromatase and steroidogenesis assays at <http://www.epa.gov/endo/pubs/toresources/seps.htm>

# New EDSP Materials Online (cont'd)

## ■ Study Profile Templates

- Describe layout and scope of information that should be contained within a study profile
- Guide for the preparation of study documents
- Templates for the aromatase and steroidogenesis assays at [http://www.epa.gov/pesticides/regulating/studyprofile\\_templates/studyprofile\\_templatelist.htm#series-890](http://www.epa.gov/pesticides/regulating/studyprofile_templates/studyprofile_templatelist.htm#series-890)

## ■ Technical Questions/Answers about the Assays

- Available at <http://www.epa.gov/endo/pubs/toresources/faqs.htm>

# EDSP Future Prospects

- EPA expected to be aggressive in its utilization of this authority
- Programmatic details unclear (data cost sharing, how results will be interpreted)
- Regulatory implications unclear (when might EPA regulate or otherwise act to mitigate exposure based on EDSP results)
- Can EPA meet its goal of communicating clearly what results do and do not mean?
- Bergeson & Campbell, P.C.'s December 20, 2010, Endocrine Disruptor Webinar available online at <http://www.lawbc.com/tsca/webinars/20101220/>

# **Endocrine-Disrupting Chemicals Exposure Elimination Act of 2011**

- Representative Jim Moran (D-VA) and Senator John Kerry (D-MA)
- Research activities with National Toxicology Program (NTP) and its Board of Scientific Counselors
  - Panel to NTP Director on research and issues relating to the identification, classification, or evaluation of potential endocrine disruptors
- Director of National Institute of Environmental Health Sciences (NIEHS) would conduct a research program designed to develop information for federal agencies to understand the chemical disruption of the endocrine system and how to reduce such exposure

# **Endocrine-Disrupting Chemicals Exposure Elimination Act of 2011 (cont'd)**

- If the Director of NIEHS makes a finding that a chemical is a high level of concern as a disruptor, it would be unlawful to use the chemical in a manner affecting interstate commerce unless the pathway to human exposure is mitigated
  - The NIEHS Director could move to “ban” up to ten endocrine disruptor chemicals per year

Questions?

# Thank You

Kathleen M. Roberts  
BERGESON & CAMPBELL, P.C.  
1203 Nineteenth Street, N.W.  
Suite 300  
Washington, D.C. 20036  
[kroberts@lawbc.com](mailto:kroberts@lawbc.com)  
[www.lawbc.com](http://www.lawbc.com)