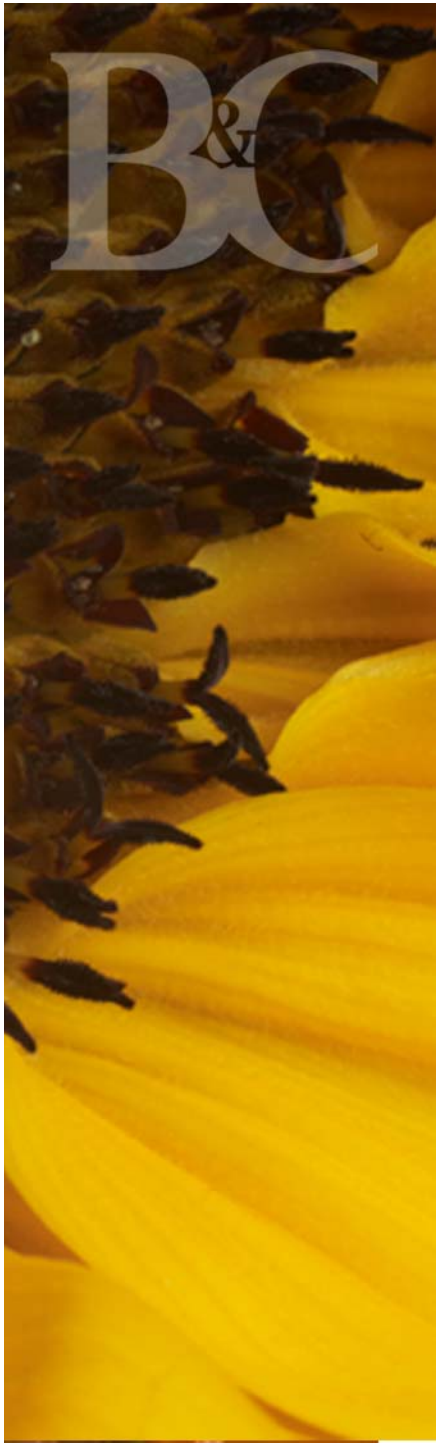

BERGESON & CAMPBELL PC

Society for Chemical Hazard Communication Fall Meeting

Current Status of TSCA Reformed

Arlington, Virginia
September 28, 2016

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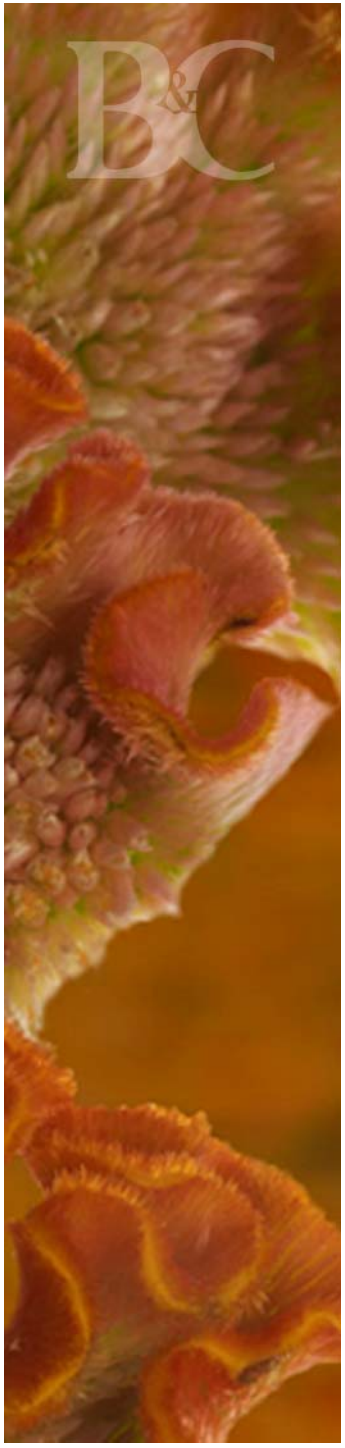
Toxic Substances Control Act (TSCA) Reform Is a Reality

- The U.S. House of Representatives passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act by a vote of 403 to 12 on May 24, 2016
- The U.S. Senate passed the measure by unanimous consent on June 7, 2016
- President Obama signed the measure into law on June 22, 2016



Introduction

- New TSCA changes U.S. federal approach to chemicals management
  - Introduces new concepts and approaches
  - Reflects careful balancing of competing interests
- Centralizing concept is *unreasonable risk*, the evaluation of which:
  - Does not include consideration of cost/benefit factors
  - Focuses on *conditions of use* as determined by the U.S. Environmental Protection Agency (EPA)
  - Includes consideration of *potentially exposed or susceptible subpopulations* identified as relevant by EPA

Overview Focuses on Key Changes

- New chemicals and significant new uses
- Existing chemicals prioritization, risk evaluation, and risk management
- State-federal relationship (preemption)
- Information gathering and confidential business information (CBI)
- Touches on other topics, including, as time allows:
  - Testing, legal aspects, fees, key deadlines

Section 5. New Chemicals and Significant New Uses

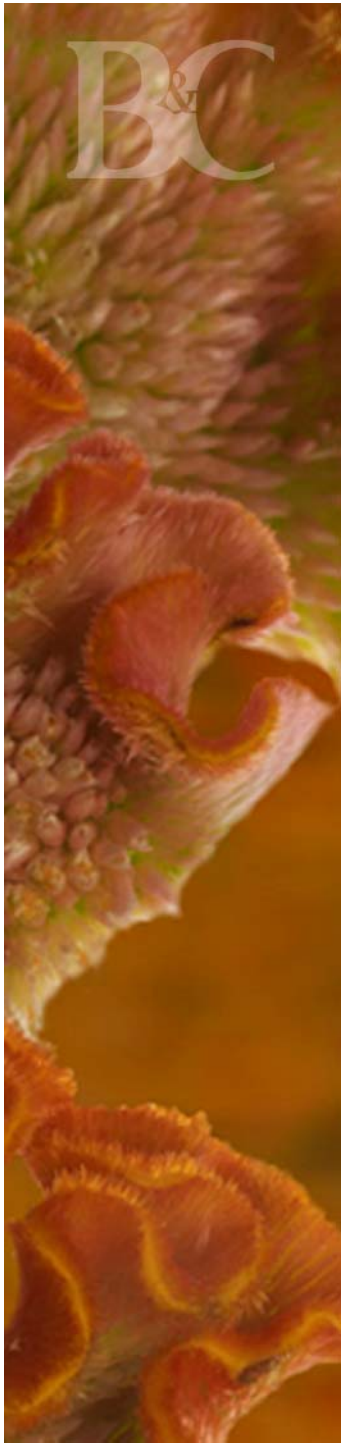
- New TSCA retains much of old TSCA with important changes
  - Requires an EPA affirmative determination on all new chemicals
  - Three alternative determinations:
    1. New chemical *presents* an unreasonable risk
    2. Available information is *insufficient* **or** new chemical *may present* unreasonable risk **or** it has *substantial production and exposure*, or
    3. New chemical *not likely* to present unreasonable risk

Section 5. New Chemicals and Significant New Uses (cont'd)

- EPA required to regulate under 1 and 2
- Limits ability to regulate articles compared to TSCA, but
- Requires EPA also to apply a significant new use rule (SNUR) under 1 and 2 or explain its "why not" reasoning

What Is the Business Impact?

- Longer review time = longer time to market
- EPA will not make affirmative decisions without sufficient information; possible disproportionate impact on evaluating technologies
- EPA finding of insufficient information triggers Section 5(e) Order



Strategy to Manage Change

- Provide EPA with **complete** notification with **sufficien**t information to support an affirmative determination
- Include relevant information on:
  - Hazards
  - Conditions of uses
  - Environmental impacts
  - *Pollution prevention attributes and other benefits --* tell your chemical's story!

Section 6. Prioritization, Risk Evaluation (RE), and Risk Management (RM) of Existing Chemicals

- New TSCA significantly revises old TSCA's approach by adding prioritization and RE steps to process
  - Includes aggressive timelines and specifies minimum number of cases
- **Prioritization** applies risk-based screening process to designate high- versus low-priorities
  - High-priority: *May present* an unreasonable risk because of *a potential hazard* and *a potential exposure*
  - Low-priority: Does not meet this standard
  - Where information is insufficient to support low-priority, default decision is high-priority
  - RE mandatory for high-priority cases

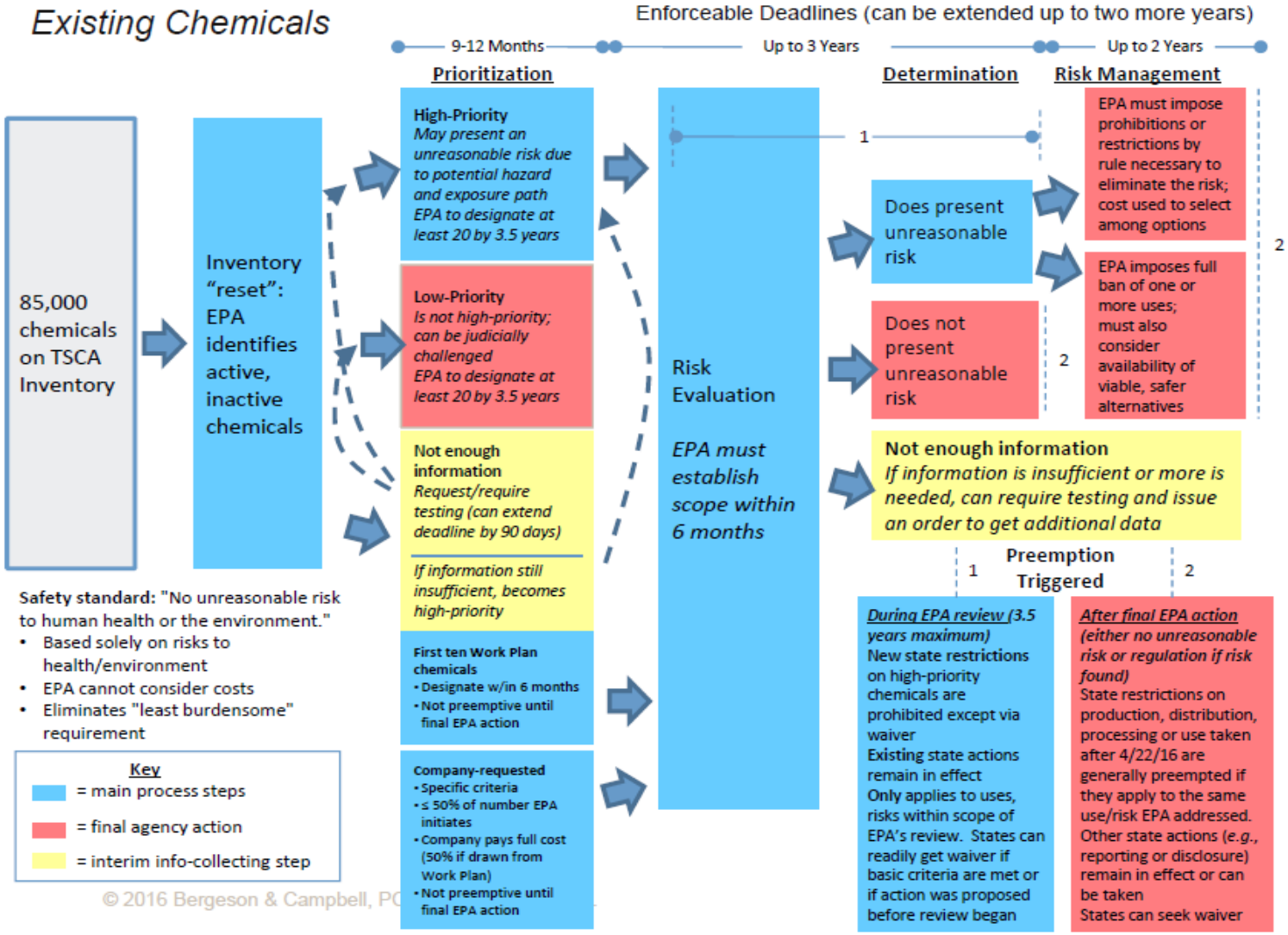
Section 6. Prioritization, Risk Evaluation (RE), and Risk Management (RM) of Existing Chemicals (cont'd)

- **RE** purpose is to determine whether chemical *presents* an unreasonable risk
  - Chemicals found to meet RE standard must proceed to RM
  - Determinations regarding low-priorities and that RE chemicals do not present unreasonable risk are subject to legal challenge

Section 6. Prioritization, Risk Evaluation (RE), and Risk Management (RM) of Existing Chemicals (cont'd)

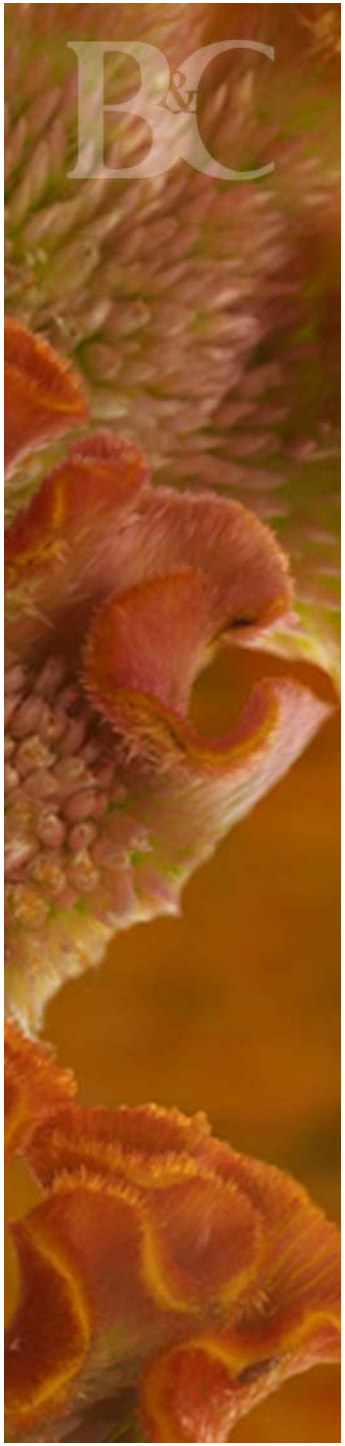
- For chemicals meeting RE standard, EPA is required to take timely RM action
  - To the extent necessary so that
  - The chemical no longer presents an unreasonable risk
- New TSCA deletes old TSCA's "least burdensome" language and simplifies procedural requirements
  - EPA must consider/publish statement on certain cost-benefit aspects
  - When EPA bans one or more uses, must also consider availability of *technically and economically feasible alternatives*
- Allows for RM limitations/exemptions if certain requirements can be met
- Final Section 6 rules and associated REs are subject to judicial review

Environmental Defense Fund -- How the Lautenberg Act Works



What Is the Business Impact?

- Chemicals prioritized as “high-priority” will eventually go through REs
  - Potential findings of unreasonable risk
  - Potential RM actions



Strategy to Manage Change

- Engage in public consultation, review and comment on EPA proposed rulemaking
  - Expected in **December 2017**
- Network within trade groups
- Evaluate prioritization criteria against your chemicals
  - If high-priority is likely, consider if changes could change outcome
    - Alter intended conditions of use?
    - Need to reconsider storage locations?
- If RE likely, consider engagement through organized industry stakeholder group

Section 18. State-Federal Relationship

- Preemption was one of the most debated aspects of TSCA reform
- New TSCA grandfathers:
  - States' actions taken before April 22, 2016
  - Any action taken pursuant to a state law that was in effect on August 31, 2003 (*e.g.,* Prop 65)
- After final EPA action, new TSCA prohibits states from establishing or continuing to enforce statutes, regulations, and related authority that would:
  - Duplicate information requirements under TSCA Sections 4, 5, or 6 actions
  - Prohibit or restrict a chemical after EPA has determined that a chemical does not present an unreasonable risk or issued a final Section 6(a) rule, or
  - Subject a chemical to the same notification of use already established in Section 5 SNUR

Section 18. State-Federal Relationship (cont'd)

- Exceptions: Past and future actions are not preempted when the state action:
  - Is not a restriction/implements a reporting or other information obligation not otherwise required by TSCA or any other federal law
  - Is adopted under the authority of another federal law
  - Under certain circumstances, is adopted under a state law related to water quality, air quality, or waste management
  - Is identical to a requirement prescribed by EPA (with penalties no less stringent than available to EPA)
  - Relates to a low-priority chemical or to a new chemical

Section 18. State-Federal Relationship (cont'd)

- Additional provisions:
  - Waivers: Allows states to seek a waiver from preemption restrictions during or after EPA review

    Preemption prohibits states from imposing new laws once EPA takes certain TSCA actions, such that a waiver granted may remain in effect only until such time as EPA publishes a Section 6(b) risk evaluation, after which:
    - Final preemption applies if EPA finds no unreasonable risk or,
    - If EPA finds unreasonable risk, states can act until the RM action is final
  - Savings: Ensures that preemption does not affect state or federal common law rights and private remedies (*e.g.*, tort actions)

Information Gathering and CBI

Section 8. Reporting and Retention of Information

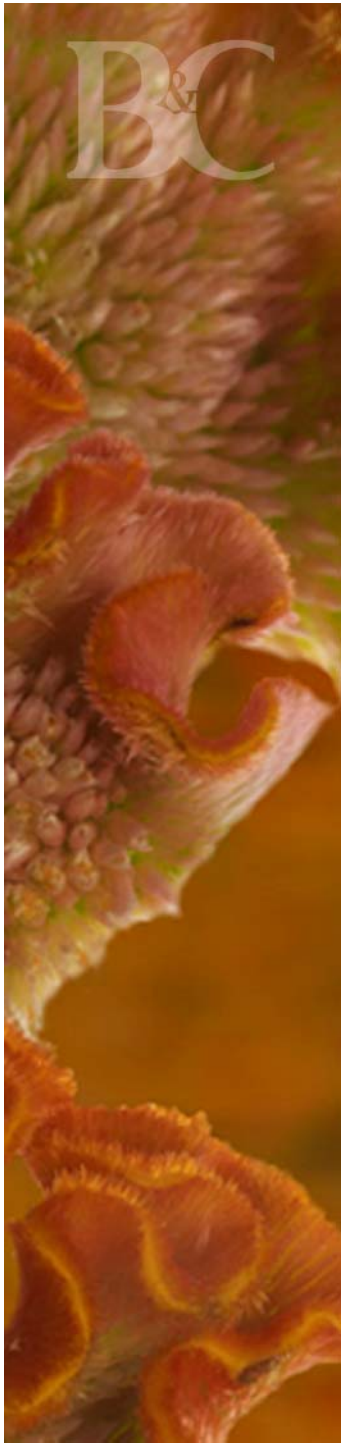
- New TSCA substantially amends approach in TSCA, including:
  - Requires continued use of certain nomenclatures
  - Includes Inventory reset process by June 22, 2017, involving:
    - Reporting rule to obtain information on *active chemicals*
      - Manufactured/imported/processed over previous ten-year period
    - EPA to designate chemicals as *active* or *inactive*
    - Status of *inactive* chemicals can be changed by notice to EPA
    - EPA to review and approve/deny CBI claims made for chemical identity

What Is the Business Impact of Inventory Reset?

- Potential commercial disruption -- albeit short -- if chemicals not listed on active Inventory
  - Inactive chemicals can be moved to active Inventory after submission of activation notification
    - Move from inactive to active prompts EPA action
      - Prompt reviews of CBI claims
      - Potential consideration of priority for Section 6 review

Strategy to Manage Change

- Begin identifying active chemicals NOW
  - Short response time after final rule
  - Reviewing ten years of production, imports, and processing will take longer than 180 days
- 2016 Chemical Data Reporting (CDR) is good start, but:
  - There is no volume threshold triggering reporting chemicals for purposes of the “active” list
  - Remember to include CDR exempt substances
  - CDR = four-year window; reset = ten-year window



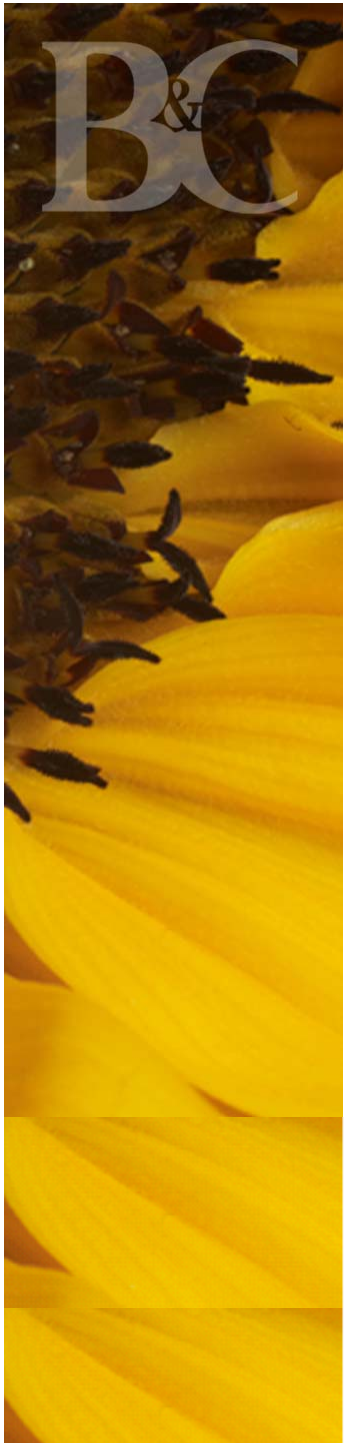
Strategy to Manage Change (cont'd)

- Work with value chain partners to ensure chemicals in supply chain are notified
- Do NOT notify chemicals not currently on the Inventory

Information Gathering and CBI

Section 14. Confidential Information

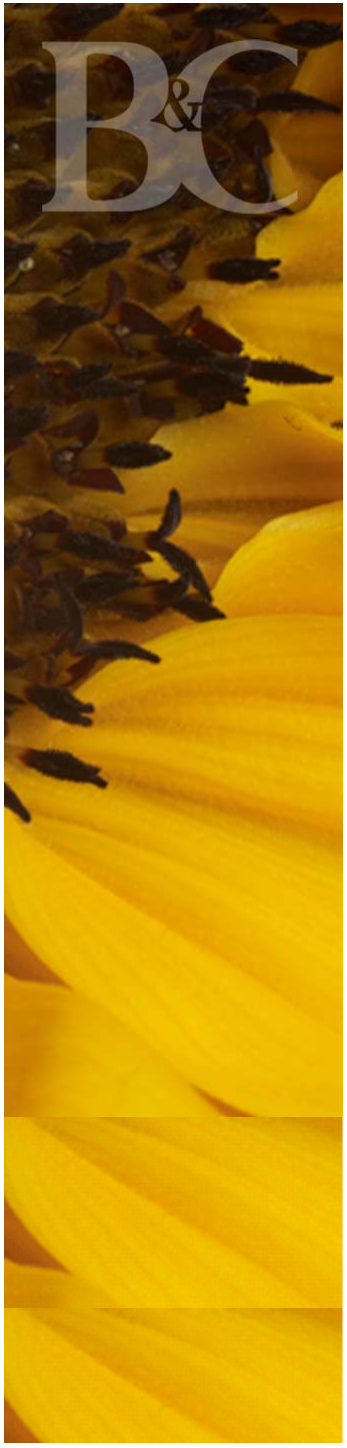
- New TSCA revises and replaces the approach in old TSCA
  - New section considers *information not protected from disclosure,* including information on*:*
    - Banned or phased-out chemicals, with certain limitations
    - Health and safety studies
      - While Lautenberg does not prohibit release of such studies on:
        - Chemicals offered in commerce or
        - Those subject to Section 4 testing or Section 5 notification,
      - It "[d]oes not authorize the disclosure of any information, including formulas (including molecular structures) of a chemical…, that discloses processes used…or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture"
- Among other changes, new TSCA also requires assertion and substantiation of most CBI claims



Other Topics

Section 4. Testing

- Gives EPA new, more flexible authority to require development of needed information
  - Using orders and consent agreements in addition to rules
  - Requires testing needed for prioritization
  - New authority does not require EPA findings
- New section concerns vertebrate animal testing and requires EPA to:
  - Reduce and replace such testing to extent practicable, scientifically justified, and consistent with policies of diminished animal testing
  - Develop and implement strategic plan to promote alternative test methods



Other Topics (cont'd)

Section 19. Judicial Review

- Retains TSCA's *substantial evidence* standard for legal review
  - Also applies to review of orders under Sections 4 and 5 and "no unreasonable risk" determination orders under Section 6
- Deletes certain procedural complexities required in TSCA

Other Topics (cont'd)

Section 26. Administration and Fees

- Expands EPA's authority to collect fees to defray costs subject to certain limitations
  - Applies to manufacturers and processors
- Requires EPA to:
  - Use the best available science
  - Develop needed policies, procedures, and guidance (PP&G)
  - Establish Science Advisory Committee on Chemicals (SACC)

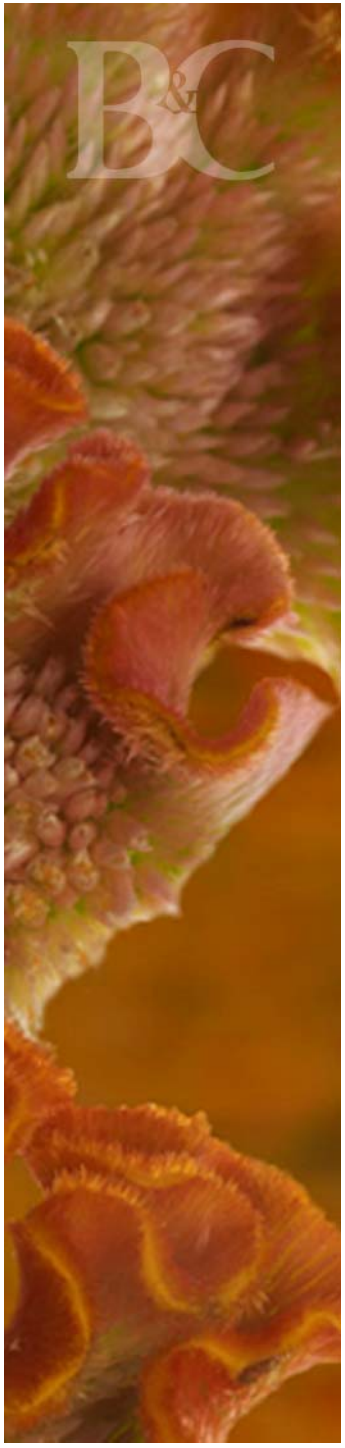
Now What??
Initial Implementation Challenges

- Resources
- Organizational Capacity
- Deadlines and Legislative Mandates
- “Unknowns” -- Unpredictable Events

Now What??
Initial Implementation Challenges (cont'd)

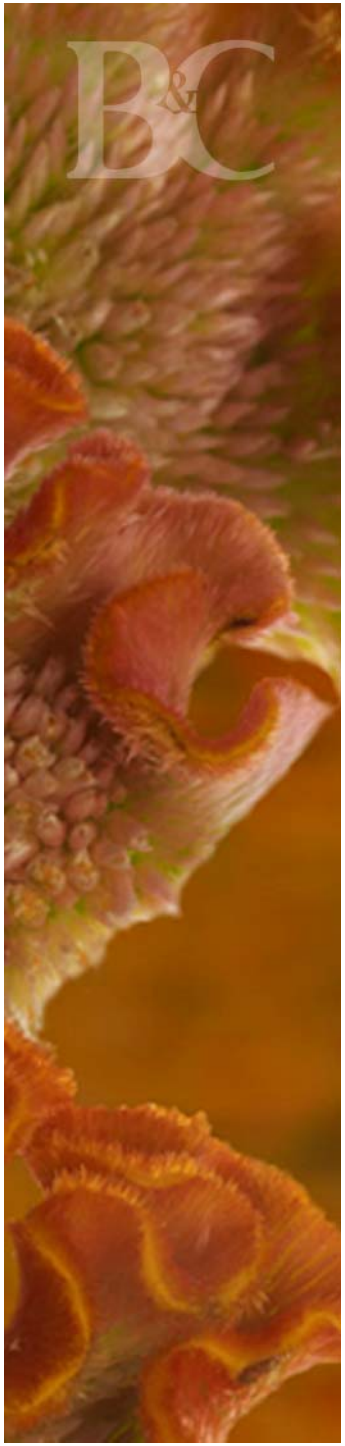
Uncertain/Unpredictable Events

- Lack of exposure information will impact risk assessments
- Number of chemicals that do not fit easily into either the high- or low-priority category will be very large
- Number of manufacturer risk evaluation requests could affect program agenda
- Early litigation and public "demands for action" can disrupt planned implementation path
- How long will any "honeymoon period" last?



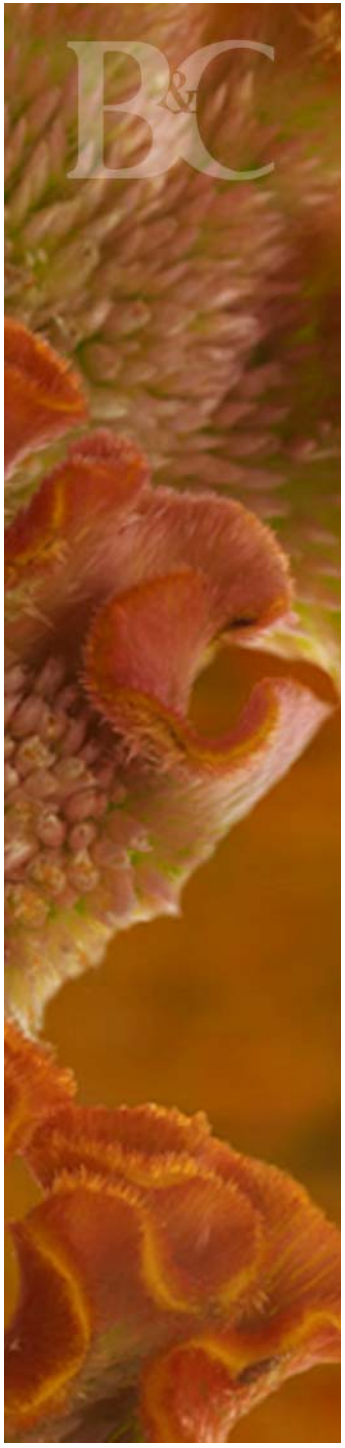
Key Deadlines

- **Six months** after enactment, EPA must submit initial report to Congress concerning its capacity for REs and Section 6 RM rules
- **One year** after enactment, EPA is required to:
  - Issue in final rule establishing prioritization and RE processes
  - Issue Inventory reset reporting rule
  - Establish SACC
  - Develop guidance to assist "interested persons" in developing REs



Key Deadlines (cont'd)

- **Two years** after enactment, EPA is required to develop:
  - Needed PP&Gs
  - Strategic plan for alternative test methods and strategies missing



Key Deadlines (cont'd)

- Other deadlines:
  - Section 5 reviews and determinations completed within 180 days or fees are returned
  - Duration of Section 6 chemical prioritization process is 9-12 months
  - Completion of Section 6 REs: Not later than three years after initiation, extendable for six months
  - Issue in final Section 6 RM actions: Within two years, extendable for two years
  - Section 26 fee authority terminates in ten years unless reauthorized

Key Early Areas to Anticipate and Prepare For

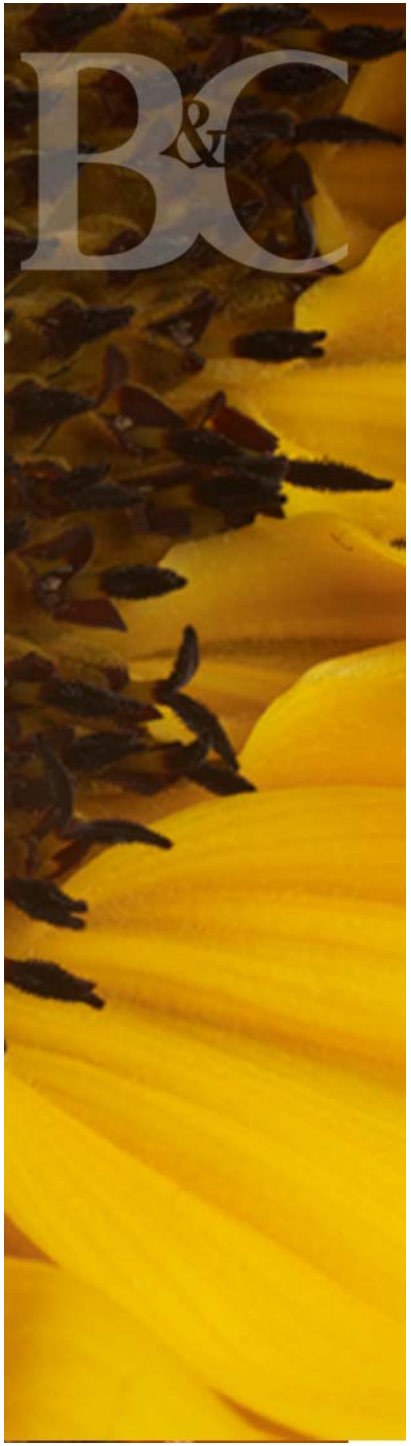
New TSCA does not include an "effective date" section and provisions were effective as of June 22, 2016

Thus:

- The new provisions of Section 5 were effective upon signature
  - Submitters of new chemical notices will need to strengthen their approach to the notification to provide sufficient information to permit a reasoned evaluation
  - They and EPA will also confront need to implement the new requirements for EPA review of/determinations on new chemicals and to take required actions

Key Early Areas to Anticipate and Prepare For (cont'd)

- The new requirements in Sections 4, 5, 6, and 8, among others, will need to be met in promulgating currently proposed regulations (such as certain SNURs)
- New TSCA also makes clear that existing rules, orders, and related actions are not affected and that ongoing risk assessments can be continued



Thank You

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