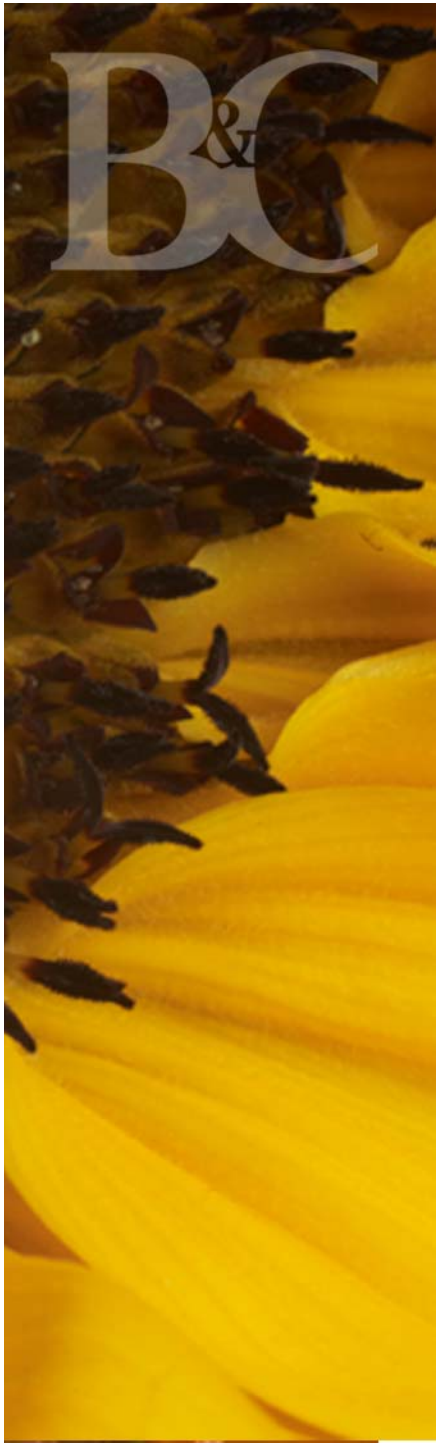

BERGESON & CAMPBELL PC

Environmental Law Institute Summer School 2014

Law & Policy of Products Regulation

Washington, D.C.
July 9, 2015

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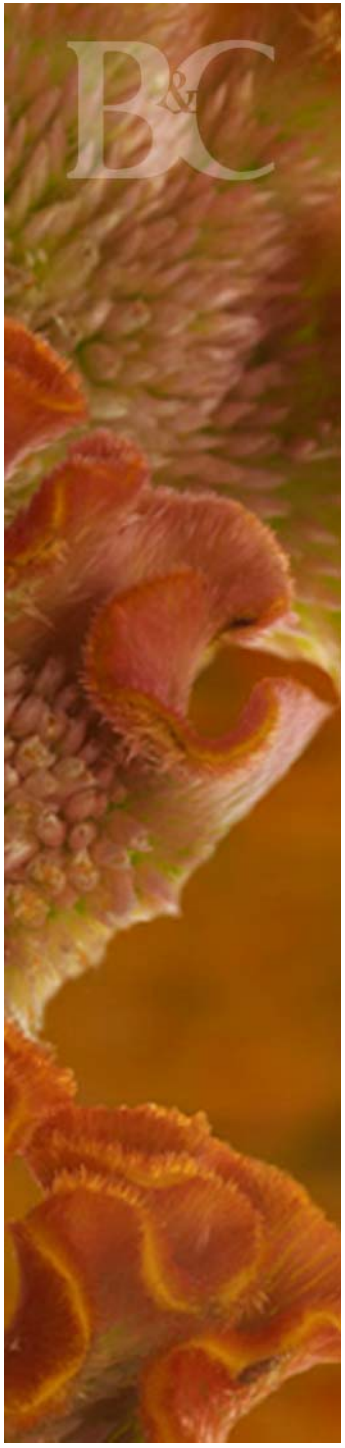
Key Federal Chemical Use Laws

- Toxic Substances Control Act (TSCA)
  - Regulation of industrial chemicals

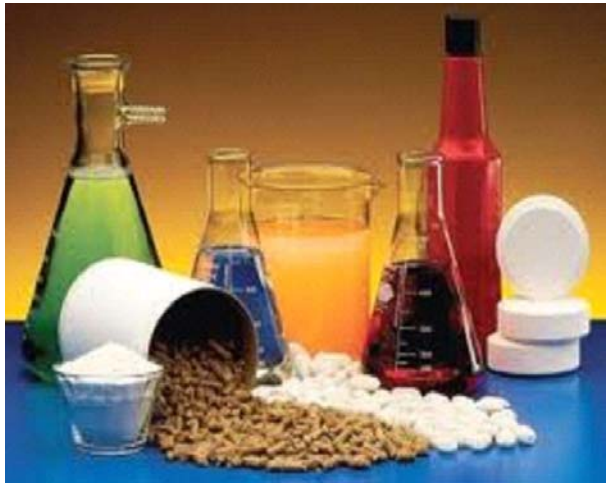
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Regulation of pesticides (agricultural chemicals, biocides)



Other Consumer Product Regulations

- Federal Hazardous Substances Act (FHSA)
- Consumer Product Safety Improvement Act (CPSIA)
- Federal Trade Commission (FTC) Green Guides
- California Safe Consumer Products Regulations (SCPR)
- State Consumer Protection Laws

TSCA



Overview

- Passed in 1976 following several years of debate and revisions
- Notable incidents involving chemicals
  - Council on Environmental Quality (CEQ) 1971 Report on Toxic Substances
    - Lack of data on chemicals in commerce
    - Lack of government oversight

Overview (cont'd)

- TSCA provides a chemical safety net
- TSCA is one of several statutes that regulate chemicals
- TSCA's unique focus is on industrial chemicals in commerce

TSCA Purposes

- To encourage or require industry to develop adequate data on the human health and environmental effects of chemicals
- To regulate chemicals that may pose unreasonable risk of injury to health or the environment and to take action against imminent hazards
- No regulation should unnecessarily impede technological innovation

TSCA Definitions

- "Chemical substance" covers industrial chemicals and excludes pesticides, food additives, drugs, cosmetics, and preparations



- Regulates both manufacturers and processors (including importers)
- Distinguishes "new" from "existing" substances
  - A new chemical substance is "any chemical substance which is not included in the chemical substance list compiled and published under [TSCA Section 8(b)]"
  - TSCA Inventory is a list of all chemical substances in commerce prior to 1979 and those that have been commercialized since (about 86,000 chemicals)

Key TSCA Components

- Allows the U.S. Environmental Protection Agency (EPA) to regulate chemical substances in a broad way from bans to labeling
- Authorizes EPA to require industry to test existing and new substances
- Authorizes EPA to exercise regulatory control over the introduction of new chemicals at premarket stage
- Contains broad recordkeeping and reporting requirements

Key Sections of TSCA

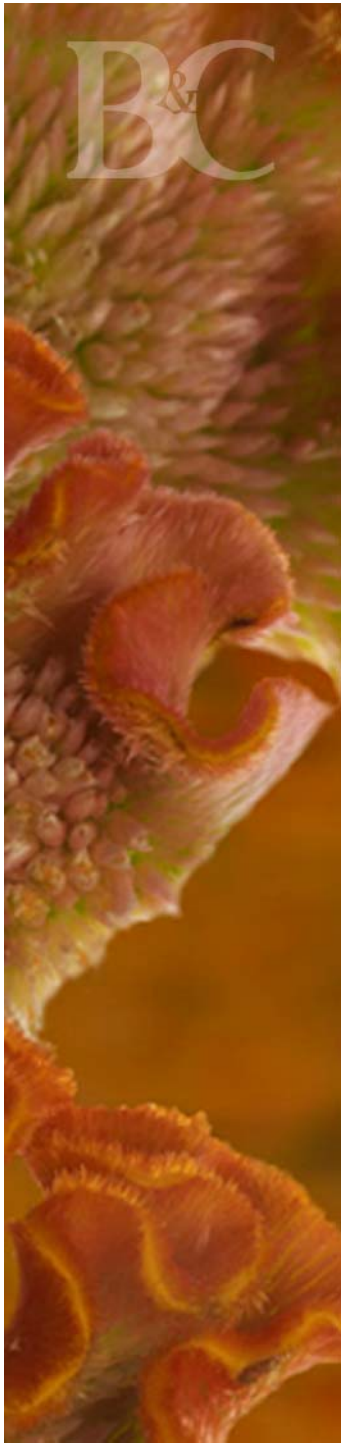
- Section 4 -- Chemical Testing
- Section 5 -- New Chemicals
- Section 6 -- Regulation of Hazardous Chemical Substances
- Section 7 -- Imminent Hazards
- Section 8 -- Reporting and Retention of Information
- Section 9 -- Relationship to Other Laws
- Section 14 -- Disclosure of Data
- Section 26 -- Ability to Regulate Categories of Chemicals

Section 8 -- Information Gathering

- Authorizes EPA to require chemical manufacturers and processors to maintain records and report data to EPA -- established through rulemaking (small manufacturers exempt)
  - Chemical identity, use categories, health and environmental information, people exposed
  - Chemical Data Reporting (CDR) rule -- Requires manufacturers of non-polymeric chemicals over 25,000 pounds listed on Inventory every four years to report current data on production use, exposure, and related information (25,000 pounds if subject to certain restrictions)

Section 8 -- Information Gathering (cont'd)

- Requirement that companies immediately notify EPA of substantial risk information
- EPA can require companies to record, retain, and report "allegations" of adverse effects and submit them to EPA upon request
- EPA can require companies to submit information on ongoing or existing health and safety studies

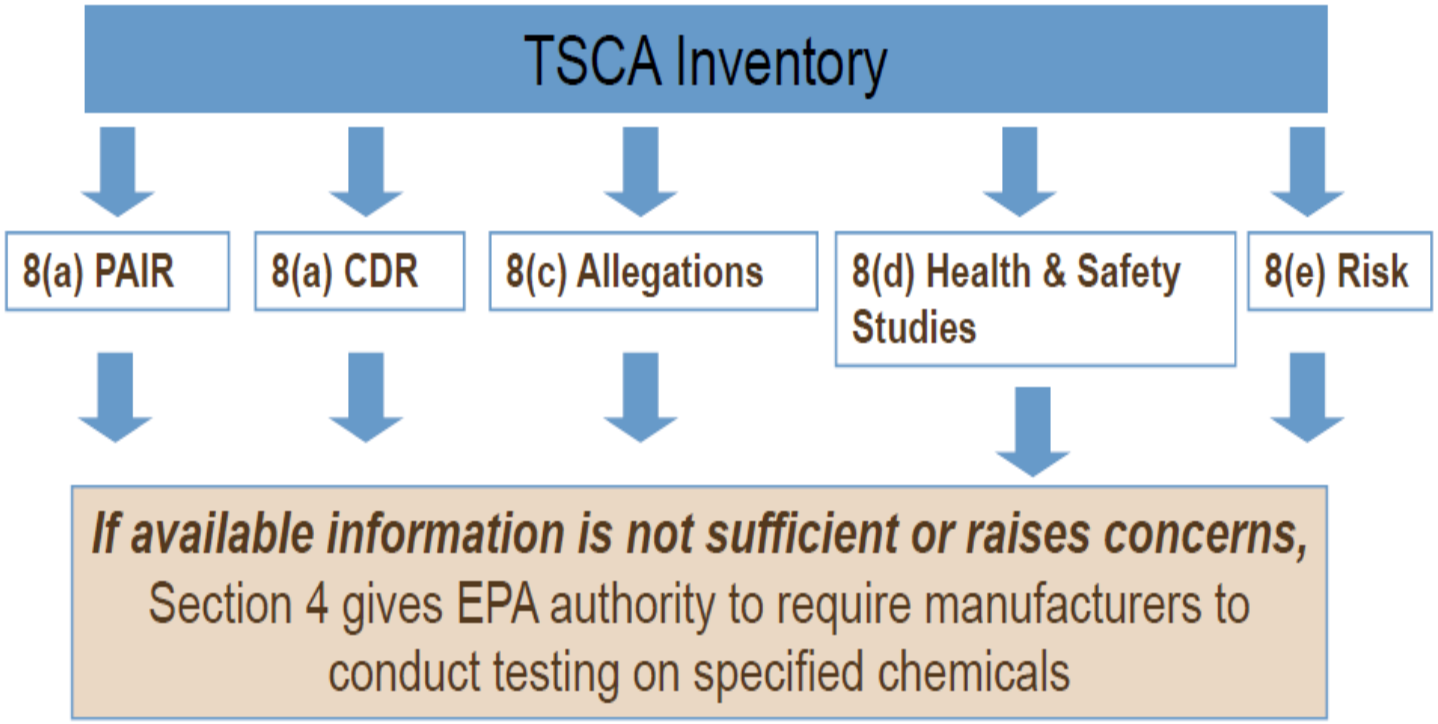


TSCA -- Information Collection on Existing Chemicals

TSCA Inventory

- **8(a) Preliminary Assessment Information Rule (PAIR):** EPA can collect production, use, and exposure information via rulemaking
- **8(a) Chemical Data Reporting Rule (CDR):** Companies report production, use, and exposure information on substances over threshold every four years
- **8(c) Allegations:** Companies must retain allegations of adverse effects and submit them to EPA upon request
- **8(d) Health and Safety Studies:** EPA can collect information on ongoing or existing studies via rulemaking
- **8(e) Risk:** Companies must immediately report substantial risk information to EPA

TSCA -- Testing on Existing Chemicals



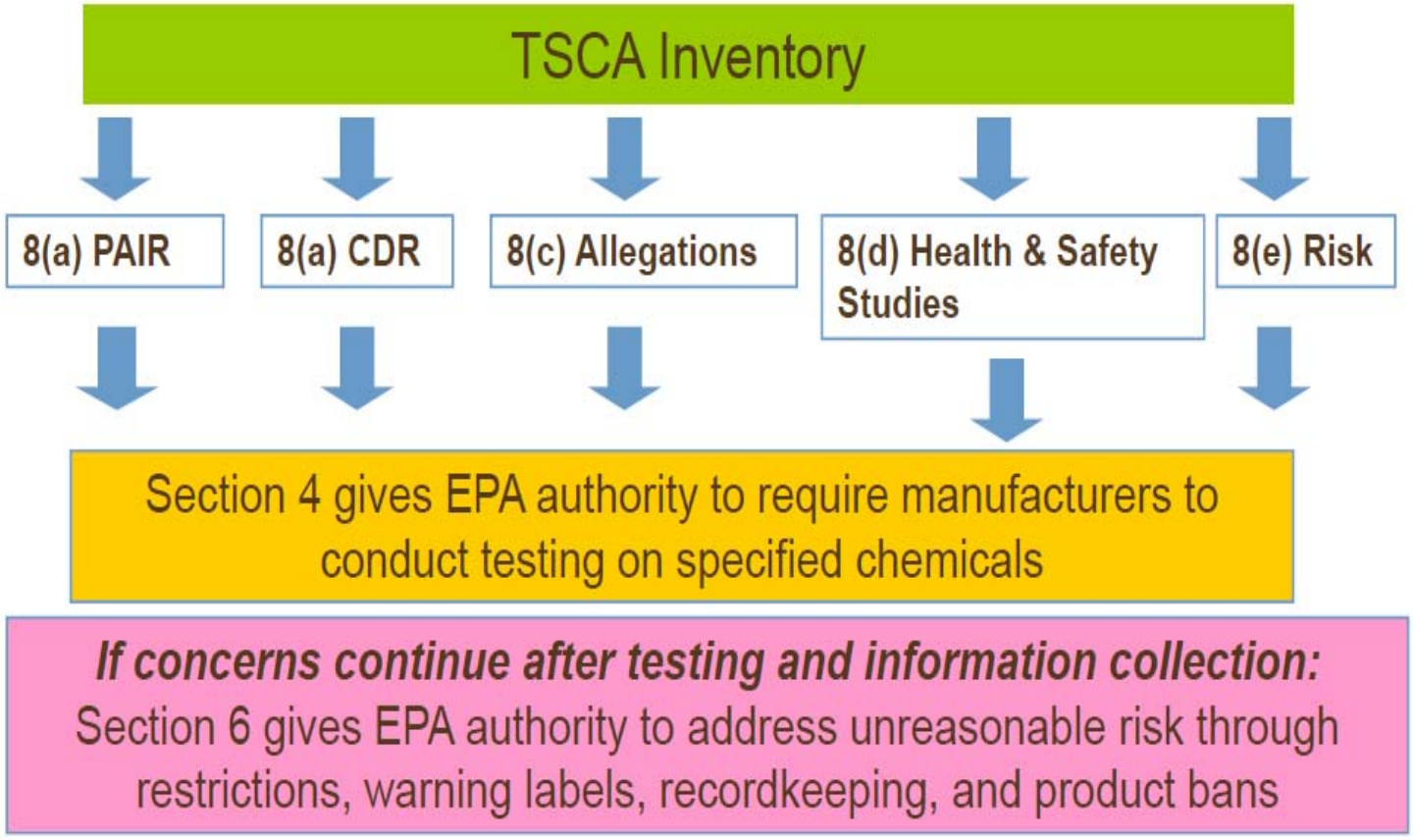
Section 4 -- Chemical Testing

- Authorizes EPA Administrator to require testing of a chemical substance or mixture, new or existing, if:
  - The chemical or mixture "may present an unreasonable risk" (hazard/risk finding) or
  - The chemical will be produced in substantial quantities and either may enter the environment in substantial quantities or lead to significant human exposure (exposure finding) **and**
  - Inadequate data exist for use in risk assessment
- Testing is necessary to develop the needed data

Section 4 -- Chemical Testing (cont'd)

- All rules undergo economic analysis and are subject to public notice and comment; costs are shared among companies subject to the rule
- Must adhere to published test guidelines
- Interagency Testing Committee identifies TSCA chemicals to add to Priority Testing List; rule issued within one year
- EPA often uses Enforceable Consent Agreements

TSCA -- Risk Management on Existing Chemicals



Section 6 -- Overview

- Specific list of risk management options identified in Section 6
  - Includes labeling, recordkeeping, use restrictions, bans
- Only five substances have been restricted under Section 6
  - Thousands of substances with restrictions in place from Section 5 review

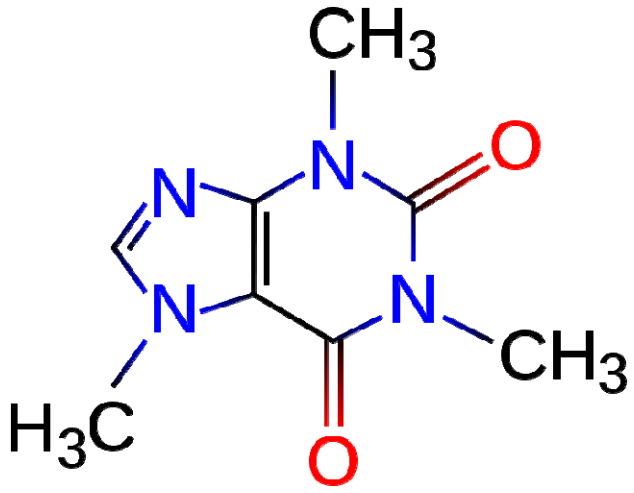
- Asbestos court decision (*Corrosion Proof Fittings*) often flagged as proof that Section 6 does not work

Section 6 -- Risk Management of Existing Substances

- EPA must demonstrate that one or more activities involving a substance or mixture presents or will present an unreasonable risk
- EPA must evaluate health and environmental effects, exposure, benefits of the substance, availability of substitutes, and economic effects (must choose least burdensome form of regulation and balance costs and benefits)
- In actions from prohibitions to risk communications and use of consent orders and preliminary notices, EPA must demonstrate that one or more activities involving a substance or mixture presents or will present an unreasonable risk

Section 5 -- New Chemical Review

- Company submits PMN (premanufacture notice)
  - Chemical identity information
  - Production volume
  - Intended categories of use
  - Description of byproducts
  - Molecular formula
  - Available information



- EPA conducts initial review
- EPA develops hazard profile
  - Structure Activity Team (SAT) uses analogs

Section 5 -- New Chemical Review (cont'd)

- Evaluates health effects, environmental effects, environmental fate
- Establishes health and environmental hazard potential

- EPA develops Exposure/Release Profile
- EPA holds Focus Meeting -- final decision
- More testing is needed for EPA to make a decision
  - Company can produce data or withdraw PMN

Section 5 -- New Chemical Review (cont'd)

- PMN allowed after additional data provided by company
- PMN allowed, but with use restrictions
- PMN allowed without restrictions
- PMN not allowed

- Company submits NOC (Notice of Commencement)
  - New chemical added to the Inventory

Outcomes of New Chemicals Review

- No action
- Voluntary withdrawal
- Section 5(e) order to prohibit or limit activities associated with the chemical if: there are insufficient data to evaluate effects and it may present an unreasonable risk; or it is or will be produced in substantial quantities or result in substantial exposure

Outcomes of New Chemicals Review (cont'd)

- Usually use consent orders that include: exposure mitigation, testing, labeling and hazard communication, and recordkeeping
- Section 5(e) order limiting the substance if substance presents or will present an unreasonable risk

Significant New Use Rules (SNUR)

- Section 5(e) order only binding on original PMN submitter
- SNUR mimics consent order and extends to other companies that wish to manufacture the PMN substance
- Can also use to capture new uses of substances that may result in an unreasonable risk (notice and comment procedure)
- Can also be used for existing chemicals when discontinued production (polybrominated diphenyl ethers (PBDE)), discontinued use, increased volume production, or new uses Section 5(e) order only binding on original PMN submitter
- SNUR mimics consent order and extends to other companies that wish to manufacture chemical substance
- Can also use to capture new uses of substances that may result in an unreasonable risk (notice and comment procedure)

Significant New Use Rules (SNUR) (cont'd)

- Anyone who wishes to manufacture or import a chemical subject to a SNUR must submit a Significant New Use Notification (SNUN) to EPA 90 days prior
- SNUNs are functionally identical to PMNs

Concerns with Current TSCA System

- No requirement for data generation on new chemicals under Section 5
- No minimum data set required for existing chemicals
- Too few chemicals tested under Section 4
- Too few chemicals regulated under Section 6
- Too easy to claim confidential business information (CBI)
- These concerns have fueled calls for TSCA reform

FIFRA

FIFRA

- Who Implements the Program?
  - EPA
    - Office of Pesticide Programs (OPP)
      - Antimicrobials Division (AD)
      - Biological and Economic Analysis Division (BEAD)
      - Biopesticides and Pollution Prevention Division (BPPD)
      - Environmental Fate and Effects Division (EFED)
      - Field and External Affairs Division (FEAD)
      - Health Effects Division (HED)
      - Information Technology and Resources

FIFRA (cont'd)

  - Pesticide Re-Evaluation Division (PRD)
  - Registration Division (RD)

- Where a state has a federally-approved pesticide program, the state is the primary enforcement authority

- Several states have developed separate state programs that are quite mature and pose formidable market entry challenges -- California, New York, Florida

California Environmental Protection Agency
dpr Department of Pesticide Regulation

DEPARTMENT OF ENVIRONMENTAL CONSERVATION • NEW YORK STATE •

FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES EST. 1868

FIFRA -- What Is a Pesticide?

- Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pests
- A substance is considered to be intended for a pesticidal purpose requiring registration if the person who distributes or sells the substance claims, states, or implies that the substance can or should be used as a pesticide

Regulatory Scope

- Active Ingredients
  - Ingredients that prevent, destroy, repel, or mitigate pests
  - Plant regulators, defoliants, desiccants, and nitrogen stabilizers
- Inert Ingredients
  - "Other ingredients" in pesticide formulations
- Pesticide Types
  - Conventional pesticides
  - Minimum-risk pesticides
  - Biopesticides
  - Antimicrobials
  - Treated articles

FIFRA -- Regulatory Framework

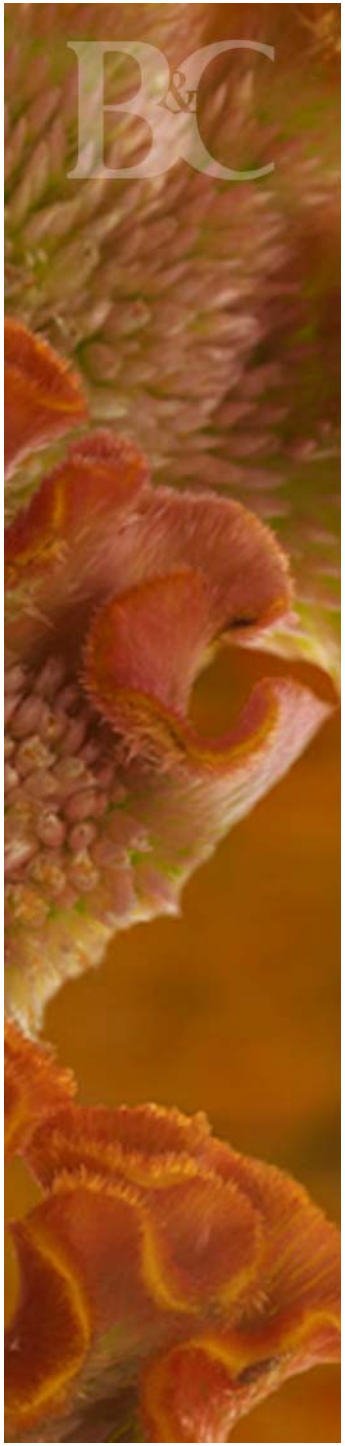
- Premarket Approval
- Risk-Based Safety Standard
  - No unreasonable risk (non-food uses)
  - Reasonable certainty of no harm (food uses)
- Burden on registrant to meet safety standard
- Unlike TSCA, FIFRA is “use” specific, not “chemical” specific

FIFRA -- Regulatory Framework (cont'd)

- EPA reviews registrant-submitted data against applicable standard
- Data requirements codified at 40 C.F.R. Part 158
  - Battery of testing requirements
  - EPA has authority to require additional data
  - EPA discretion to waive data requirement
- Data development can cost millions and take years before an application can be submitted to EPA

FIFRA -- Regulatory Framework (cont'd)

- Protections for trade secrets and CBI
- EPA has adopted a narrow interpretation of protected information; enhanced transparency
- Compensation provisions for third-party use of proprietary data



FIFRA -- Regulatory Framework (cont'd)

ATTENTION:

This specimen label is provided for general information only.

- This pesticide product may not yet be available or approved for sale or use in your area.
- It is your responsibility to follow all Federal, state and local laws and regulations regarding the use of pesticides.
- Before using any pesticide, be sure the intended use is approved in your state or locality.
- Your state or locality may require additional precautions and instructions for use of this product that are not included here.
- Monsanto does not guarantee the completeness or accuracy of this specimen label. The information found in this label may differ from the information found on the product label. You must have the EPA approved labeling with you at the time of use and must read and follow all label directions.
- You should not base any use of a similar product on the precautions, instructions for use or other information you find here.
- Always follow the precautions and instructions for use on the label of the pesticide you are using.

RESTRICTED USE PESTICIDE

For ground and surface water concerns. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

BULLET

Herbicide by Monsanto

Selective herbicide for preemergence weed control in corn (all hybrids) and grain sorghum (milo).

Users must read and follow all precautionary statements and instructions for use in order to minimize potential for abrasion to roadground and surface water.

In case of an emergency involving this product or for user safety information on this product, Call Collect, day or night (314) 694-4000.

SEE INSIDE BEFORE USING

Complete Directions For Use

Not for use in Suffolk and Nassau counties of New York.

EPA Reg. No. 524-418 3308-1

Read the entire label before using this product.

Use only according to label instructions.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

THIS IS AN END-USE PRODUCT. MONSANTO DOES NOT INTEND AND HAS NOT REGISTERED THIS PRODUCT FOR REFORMULATION. SEE INDIVIDUAL CONTAINER LABEL FOR REPACKAGING LIMITATIONS.

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes set forth in the Complete Directions for Use label booklet ("Directions") when used in accordance with these Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims, whether based on contract, negligence, strict liability, other tort or otherwise.

To the extent consistent with applicable law, buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, incompatibility with products other than those set forth in the Directions, unusual weather, weather conditions which are outside the range considered normal at the application site and for the time period when the product is applied, as well as weather conditions which are outside the application ranges set forth in the Directions, application in any manner not expressly set forth in the Directions, mixed use conditions outside the mixture ranges specified in the Directions, or the presence of products other than those set forth in the Directions in or on the soil, or prior treated vegetation.

This Company does not warrant any product, either installed or repackaged from this product except in accordance with this Company's stewardship requirements and with express written permission from this Company.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT OR ON CLOSING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

CAUTION!

Harmful if absorbed through skin or inhaled. Avoid contact with eyes, skin or clothing. Avoid breathing spray mist. This product may cause skin sensitization reactions in some people.

FIRST AID	
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

• For additional information in case of an emergency, call collect, day or night, (314) 694-4000.

• Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

• This product is identified as Bullet™ herbicide, EPA Registration No. 524-418.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are made of any waterproof material. If you want more options, follow the instructions for category A on an EPA chemical-resistant category selection chart.

Mixers, loaders, applicators and other handlers must wear: long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material such as polyethylene or polyvinylchloride, socks and shoes.

In addition, mixers and loaders and persons cleaning equipment must wear: chemical-resistant gloves and chemical-resistant apron.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Engineering Controls

Mixers and loaders supporting aerial applicators, or impregnators of dry bulk fertilizer are required to use a mechanical transfer system designed by the manufacturer to transfer liquid pesticide in a manner that prevents the liquid that has come solely into contact with handlers or other people during the transfer. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)].

- Mandatory Label Requirements
  - Ingredients
  - Approved claims
  - Use directions
  - Warning statements
  - Registrant information
- Use inconsistent with label prohibited
- Labeling covers all written materials (and then some)

FIFRA -- Regulatory Framework (cont'd)

- New Actives/Products/Uses
  - Review timeframes established by statute (Pesticide Registration Improvement Extension Act (PRIA 3))
  - Four months to 24 months review standard, but can be longer
- Existing Actives/Products/Uses
  - Review older pesticides against current health standards
  - This review typically yields label amendments, use restrictions, or other legal redress (cancellation)

FIFRA -- Regulatory Framework (cont'd)

- Promote "Safer" or "Reduced-Risk" Pesticide Alternatives
  - Reduced fees
  - Expedited reviews
  - Dedicated resources

- Various Programs to Register Reduced-Risk Pesticides
  - Minimum-risk pesticides
  - Reduced-risk conventional pesticides
  - Biopesticides

FIFRA -- Regulatory Framework (cont'd)

- **Restrict** Future Sale of Products
- Stop-Sale Orders
- Civil Penalties
- Criminal Penalties

Thank You

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