



**BERGESON & CAMPBELL PC**

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Lynn L. Bergeson  
Bergeson & Campbell, P.C.  
Washington, D.C.  
[www.lawbc.com](http://www.lawbc.com)

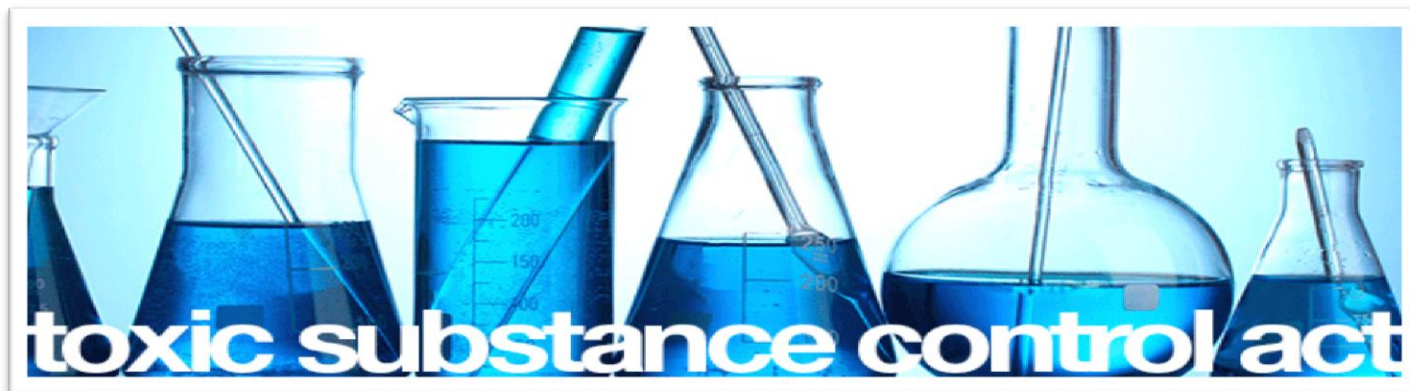
# Key Federal Chemical Use Laws

- Toxic Substances Control Act (TSCA)
  - Regulation of industrial chemicals
  
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Regulation of pesticides (agricultural chemicals, biocides)

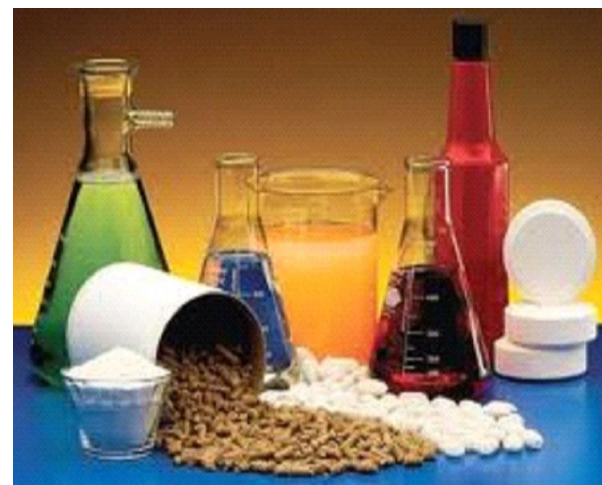


## Other Consumer Product Regulations

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



# TSCA



## Overview

- Passed in 1976 following several years of debate and revisions
- Almost four decades passed without substantive amendment
- Frank R. Lautenberg Chemical Safety for the 21st Century Act enacted on June 22, 2016 (P.L. No. 114-182)



## Overview

- 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
- New TSCA dramatically changes how industrial chemicals are introduced and regulated in the U.S.



## Purposes



- To encourage or require industry to develop **adequate information** on the human health and environmental effects of chemicals
- To **regulate chemicals** and mixtures that may present unreasonable risk of injury to health or the environment under intended conditions of use, and to take action against imminent hazards
- **No regulation should unduly impede** or create unnecessary economic barriers to technological innovation

## Key Sections of TSCA

- Section 4 -- Chemical Testing
- Section 5 -- New Chemicals
- Section 6 -- Regulation of Hazardous Chemical Substances
- 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



## 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)

## Major Changes Over Current Law

- Mandatory duty on the U.S. Environmental Protection Agency (EPA) to evaluate existing chemicals with clear and enforceable deadlines
  - *Old TSCA -- No duty to review; no deadlines for action*
- Chemicals assessed against a risk-based safety standard with no consideration of nonrisk factors
  - *Old TSCA -- Risk-benefit balancing standard*
- Unreasonable risks identified in the risk evaluation must be eliminated
  - *Old TSCA -- Significant risks might not be addressed due to cost/benefit balancing and no mandate to act*
- Expanded authority to compel development of chemical information when needed by order, rule, or consent agreement
  - *Old TSCA -- Required lengthy rulemaking*



## Major Changes Over Current Law

- Requires EPA to make an affirmative determination on new chemicals before entry into the marketplace
  - *Old TSCA -- New chemicals enter the market in the absence of EPA action*
- Requires substantiation of certain confidential business information (CBI) claims
  - *Old TSCA -- No statutory substantiation requirements for CBI claims*
- New funding source (up to \$25 million total in annual user fees plus costs for manufacturer-requested risk evaluations), to be supplemented by Congressional appropriations
  - *Old TSCA -- Cap on individual user fees at \$2,500, and limited fee collection authority*

## 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 (2,500 pounds if subject to certain restrictions)

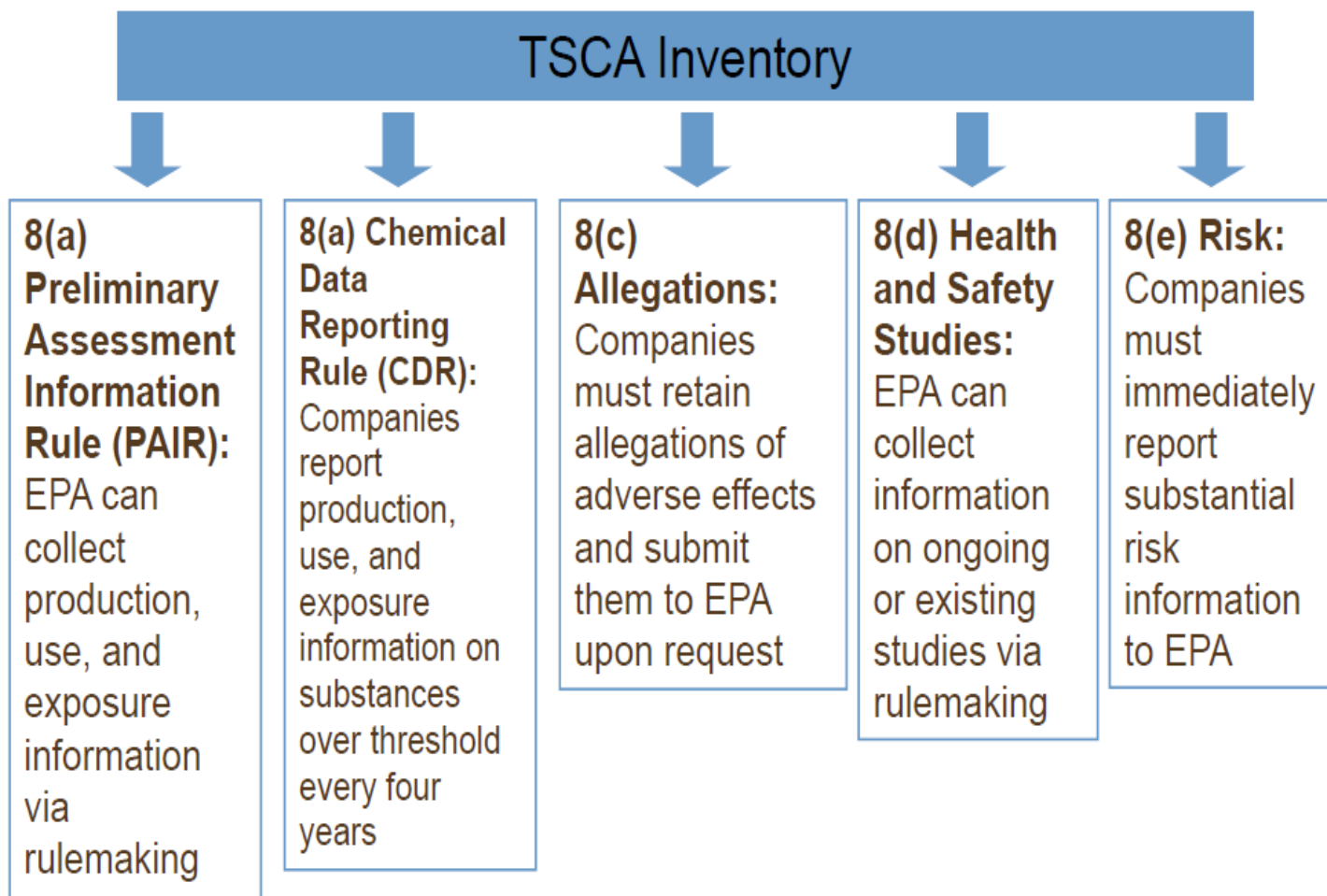


## Section 8 -- Information Gathering

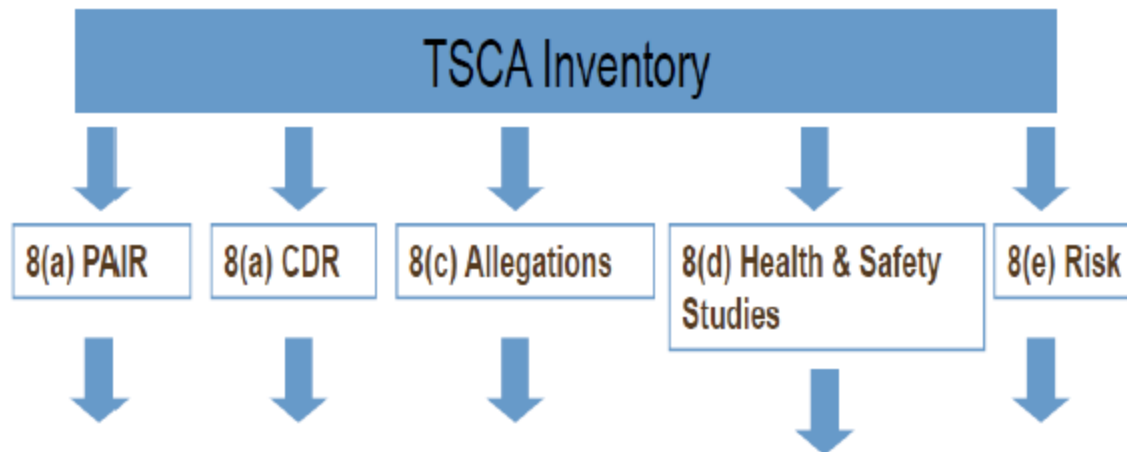
- Requirement that companies immediately notify EPA of substantial risk information
- Requirement that companies record and retain “allegations” of adverse effects and submit them to EPA upon request
- EPA can require companies to submit information on ongoing or existing health and safety studies



# Information Collection on Existing Chemicals



# Testing on Existing Chemicals



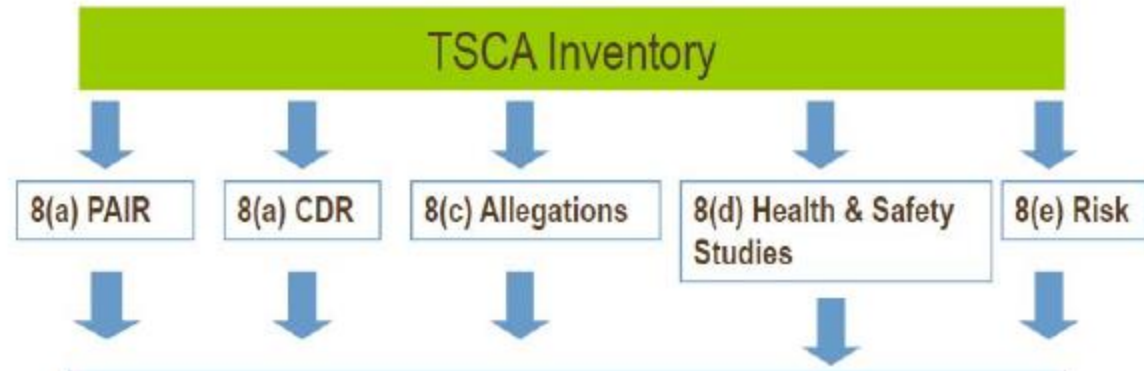
***If available information is not sufficient or raises concerns,*** Section 4 authorizes EPA to issue administrative orders and consent agreements, or to engage in rulemaking to require the development of information

## Testing on Existing Chemicals

- New TSCA expands EPA authority to require development of information
  - Authorizes administrative orders and consent agreements in addition to rulemaking
  - Permits EPA to require testing needed for prioritization
  - New authority does not require EPA findings
  - May not be used to establish “a minimum information requirement of broader applicability”
- New Section 4(h) 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, within two years of enactment, and implement a strategic plan to promote alternative test methods



# Risk Management on Existing Chemicals



Section 4 authorizes EPA to issue administrative orders and consent agreements, or to engage in rulemakings

***If concerns continue after testing and information collection:*** Section 6 authorizes EPA to address unreasonable risk through restrictions, warning labels, recordkeeping, and product bans

## Specific Requirements -- Existing Chemicals

- New TSCA -- Prioritizing Chemicals for Assessment
  - Establish a risk-based process to identify “high” and “low” priority substances
  - High-priority -- The chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including to susceptible subpopulations
  - Low-priority -- The chemical use does not meet the standard for high-priority
- Procedural rule issued on June 22, 2017, establishes a process for prioritizing chemicals

## Specific Requirements -- Existing Chemicals

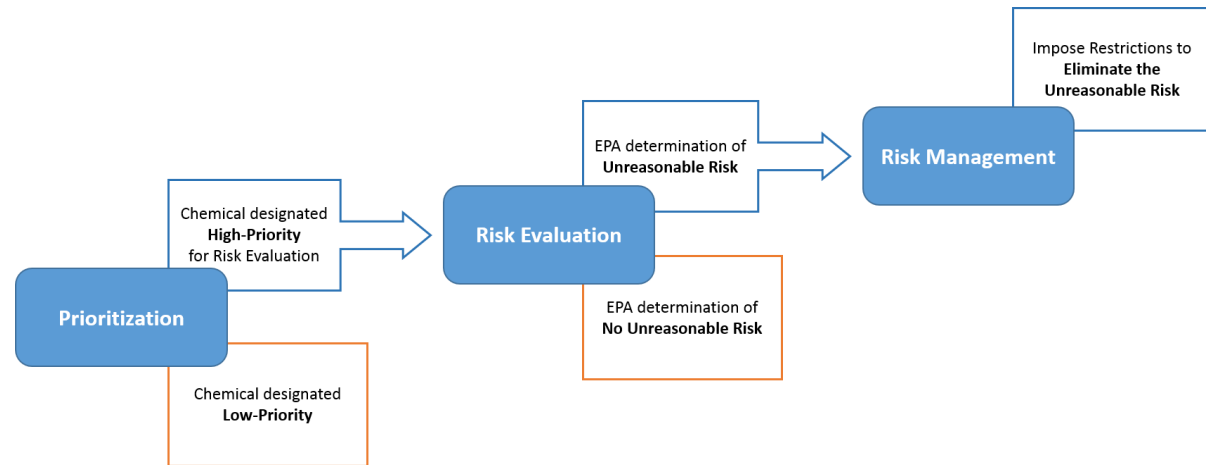
- Initial Set of Risk Evaluations from Work Plan Chemical Assessments
  - EPA identified a list of ten TSCA Work Plan chemicals and formally initiated risk evaluations last December
  - Scope of each assessment released on June 22, 2017

## Specific Requirements -- Existing Chemicals

- Risk-Based Safety Standard
  - Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an “unreasonable risk”
  - The risk determination is to be made without consideration of costs or other nonrisk factors
  - Risks to susceptible and highly exposed populations must be considered
- EPA must take risk management action to address unreasonable risks
  - Costs and availability of alternatives to be considered when selecting among risk management options
  - Exemption process for critical uses
  - Risk management actions must be promulgated within two years of completing risk evaluation, with extension of up to two additional years

# Specific Requirements -- Existing Chemicals

- EPA issued Final Risk Evaluation Process Rule on June 22, 2017



## Specific Requirements -- Existing Chemicals

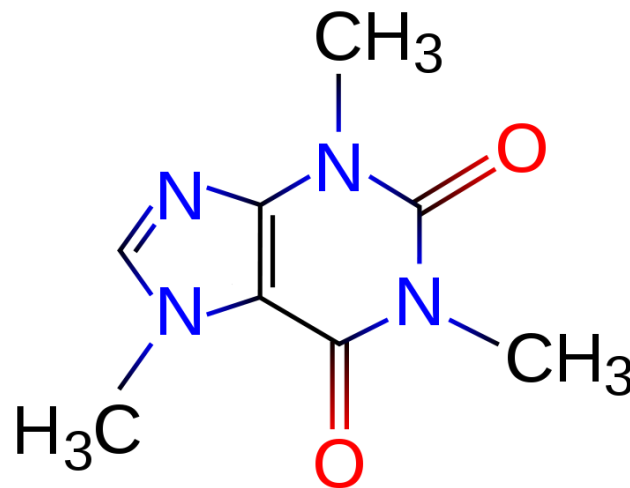
- Persistent, Bioaccumulative, and Toxic Chemicals (PBT)
  - The new law establishes fast-track process to address certain PBT chemicals already on TSCA Work Plan
  - No risk evaluation; only a use and exposure assessment
  - Rules to reduce exposure to the extent practicable must be proposed within three years of enactment and issued in final 18 months later, unless a manufacturer requests a risk evaluation by September 22, 2016
  - Additional requirements encourage prioritization of PBTs in overall risk evaluation process

## Specific Requirements -- Existing Chemicals

- TSCA Inventory
  - Requires industry to report on the chemicals they manufactured or processed in previous ten years to determine if chemicals are currently “active” in the marketplace
  - The chemicals on the TSCA Inventory will not change
  - Chemicals will be designated as “active” or “inactive”
  - Only “active” chemicals may be prioritized
  - No premanufacture notification (PMN) required to move from “inactive” to “active”
- Final Inventory Notification rule issued on June 22, 2017

## Section 5 -- New Chemical Review

- Company submits PMN
  - 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



- Evaluates health effects, environmental effects, environmental fate
- Establishes health and environmental hazard potential
- EPA develops Exposure/Release Profile
- EPA holds Focus Meeting -- drop or full review
- *Prior bullets = “old” EPA new chemical review process. Mandate for affirmative finding has adjusted process and outcomes*

## New Chemicals/Significant New Uses

- Retains certain basic requirements for new chemicals (NC) and significant new uses (SNU)
  - 90-day review period, extensions permitted
- Requires EPA determination on all notices
- Three alternative determinations:
  1. NC/SNU *presents* an unreasonable risk
  2. Available information is *insufficient* **or** NC/SNU *may present* unreasonable risk **or** NC/SNU chemical has *substantial production and exposure*, or
  3. NC/SNU *not likely* to present unreasonable risk

## New Chemicals/Significant New Uses

- EPA required to regulate under 1 and 2
- EPA has limited ability to regulate articles/category of articles compared to prior TSCA, but
- Requires EPA also to apply a SNU rule (SNUR) under 1 and 2 or “make public” a statement explaining its findings
- Under 3, the submitter can begin to commercialize immediately, and EPA will later publish in the *Federal Register* a notice that the chemical is most likely to pose an unreasonable risk



# 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

- 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



## 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





## 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



## Regulatory Framework



- 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

## Regulatory Framework

- 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



# Regulatory Framework

**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 restrictions for use of this product that are not included herein.
- Manufacturer does not guarantee the completeness or accuracy of this specimen label. The information listed in this label may differ from the information found on the product label. You must have the EPA approved labeling only you at the time of use and must read and follow all label directions.
- You should not have any use of a similar product with 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**  
Use in ground and surface water systems. For use in tanks and on-site only by Certified Applicators or persons under their direct supervision and only for those uses authorized by the Certified Applicator's certificate.

**BULLET**  
Herbicide for Emergents

Selective herbicide for pre-emergence weed control in corn (off-label) and green sugarcane (label).

Always read and follow all precautionary statements and instructions for use in order to minimize potential for adverse or undesirable effects. In case of an emergency involving this product or for more safety information on this product, call Chemagro, a division of Bayer CropScience, at 1-800-333-3333.

**Complete Directions For Use**  
For use in Florida and Missouri, based on New York.

EPA Reg. No. 524-418

**CAUTION!**  
Hazardous to Humans and Domestic Animals  
Keep out of reach of children.

**PRECAUTIONARY STATEMENTS**  
Hazardous 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 in some people.

FIRST AID	
<b>IF ON SKIN:</b>	• Wash off contaminated clothing.
<b>IF ON CLOTHING:</b>	• Remove and immediately wash away if water for 15 to 30 minutes. • Call a poison control center or doctor for treatment advice.
<b>IF SWALLOWED:</b>	• Show poison control card. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

• If you need additional information in case of an emergency, call toll-free, day or night, 1-800-888-4444.

• From the product container or label within 90 days of purchase, call toll-free, day or night, 1-800-888-4444.

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

**Pesticide Protection Agreement (PPA)**  
Some materials that are chemical related to this product are made of any water-soluble material. If you have more options, follow the instructions for cleanup for cleanup for an EPA chemical-related cleanup solution.

**Mixers, loaders, applicators and other handlers must wear:** long-sleeved shirt and long pants; chemical-resistant gloves made of any material of material such as nitrile, neoprene, polyethylene, butyl rubber, or vinyl.

**Use in addition, remove and protect and protect cleaning equipment must wear:** chemical-resistant gloves and chemical-resistant boots.

Do not use clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not wash them. Follow manufacturer's instructions for cleaning/maintaining PPE. If they are not cleanable, they must be replaced and disposed of according to applicable regulations.

**Washable PPE (recommended)**  
Clean PPE:  
• Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.  
• Remove clothing immediately if you get sprayed. Wash thoroughly and put on clean clothing.  
• Remove PPE immediately after handling the product. Wash the outside of gloves before removing. As soon as possible, wash before eating, drinking, using tobacco, or using the toilet.

**Equipment Clean-Up**  
Mixers and loaders, applicators and other handlers, at reapplication of this label, follow the requirements for use a mechanical transfer system. Design by the manufacturer to transfer liquid pesticide in a manner that prevents leakage. Do not reuse any or parts of the transfer system in other parts during the transfer. The closed system must be used in a manner that meets the requirements for use the Active Protection Standard (APS) for agricultural pesticides (40 CFR 171.101-101.101).

- **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)**

# Regulatory Framework

## ■ 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)

## Regulatory Framework

- 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



## Enforcement Framework

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



## Thank You

Lynn L. Bergeson  
Bergeson & Campbell, P.C.  
2200 Pennsylvania Avenue, N.W.  
Suite 100W  
Washington, D.C. 20037  
[lbergeson@lawbc.com](mailto:lbergeson@lawbc.com)  
[www.lawbc.com](http://www.lawbc.com)  
<http://www.tscablog.com/>  
<http://pesticideblog.lawbc.com>

The Acta Group  
2200 Pennsylvania Avenue, N.W.  
Suite 100W  
Washington, D.C. 20037  
[lbergeson@actagroup.com](mailto:lbergeson@actagroup.com)  
[www.actagroup.com](http://www.actagroup.com)