



**BERGESON & CAMPBELL PC**

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**Law & Policy of Products Regulation**

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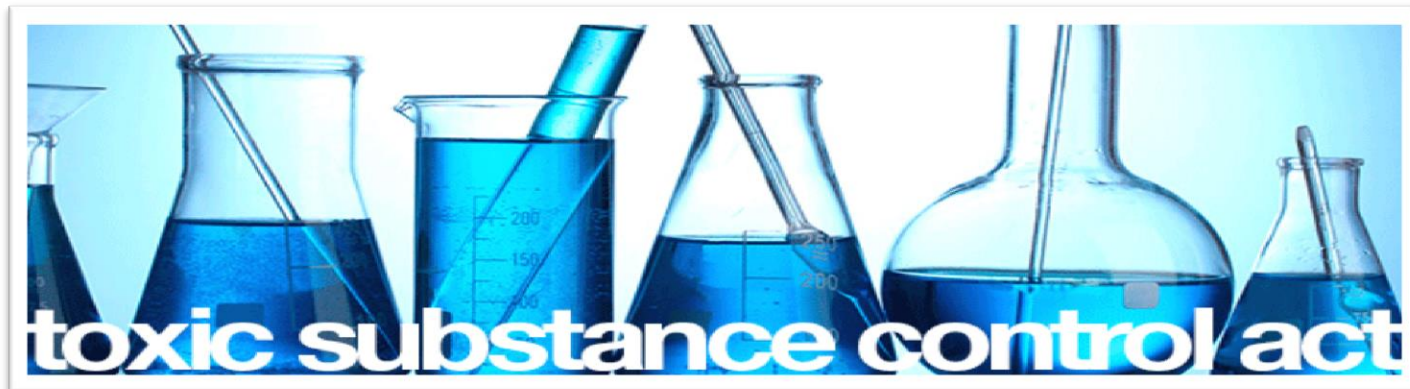
## Key Federal Chemical Use Laws

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

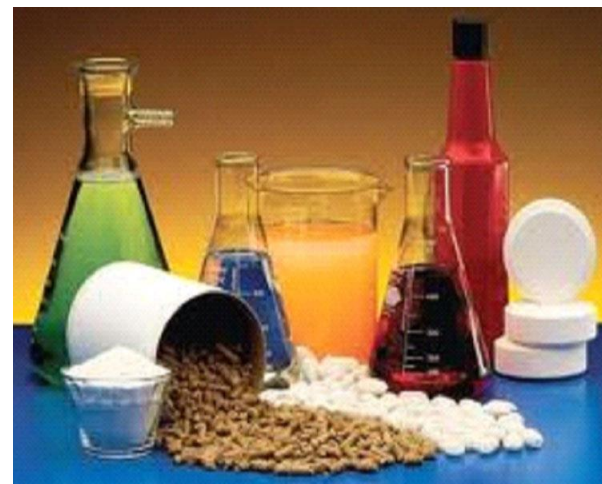


## Other Consumer Product Regulations

- Federal Hazardous Substances Act (FHSA)
- Consumer Product Safety Improvement Act (CPSIA)
- Federal Trade Commission (FTC) Green Guides
- California 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. 114-182)



## 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
- 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 (cont'd)

- 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), 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 (25,000 pounds if subject to certain restrictions)



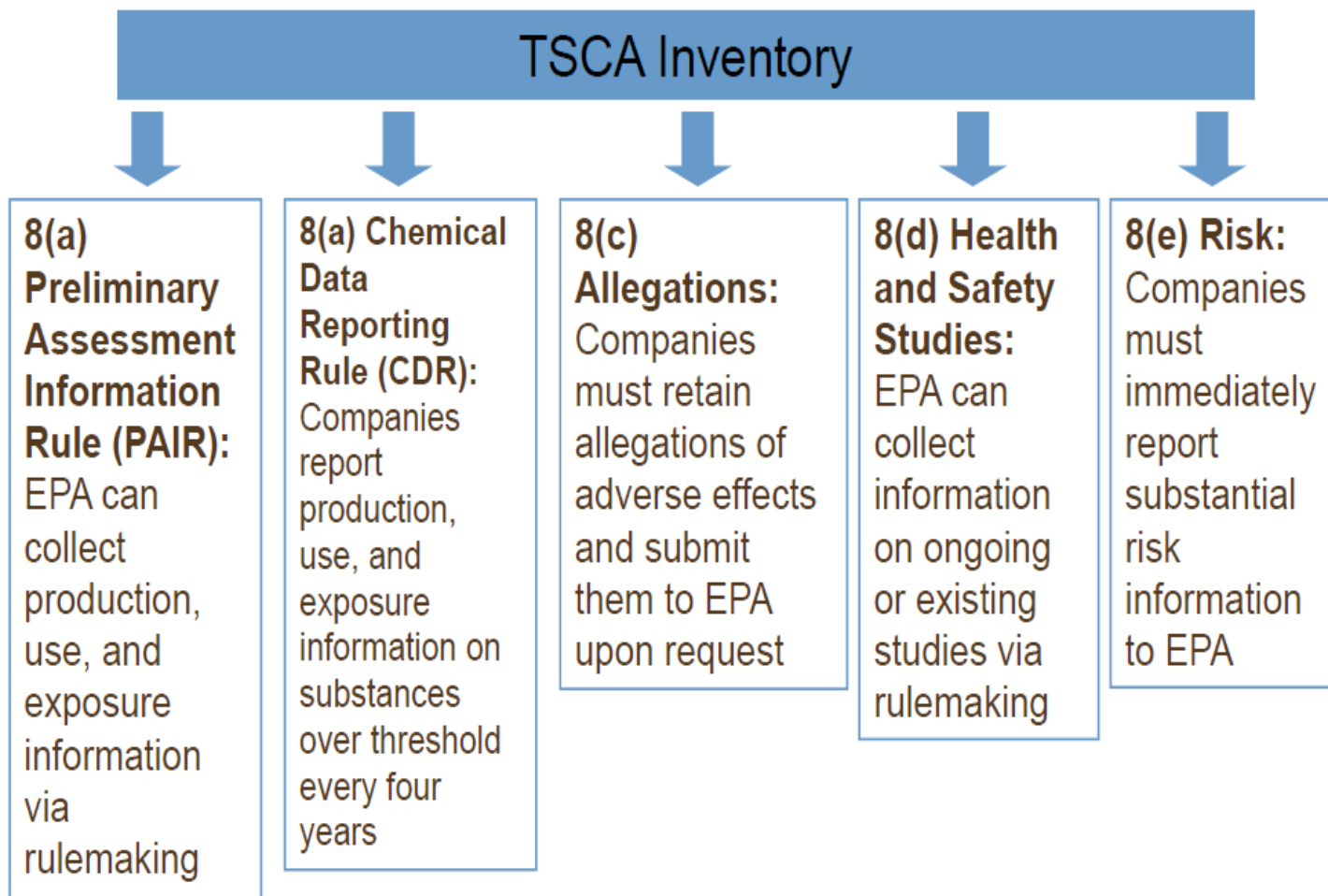


## Section 8 -- Information Gathering (cont'd)

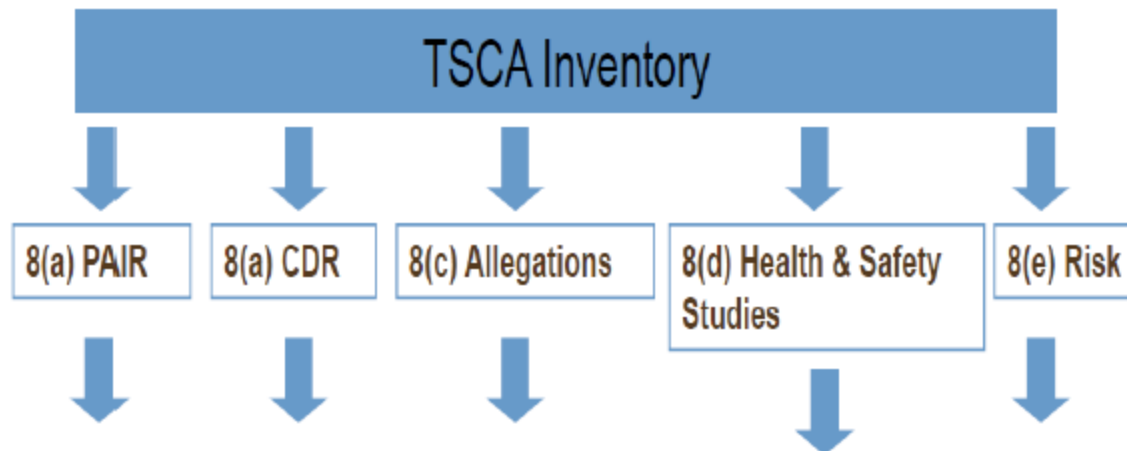
- Requirement that companies immediately notify EPA of substantial risk information
- Requirement that companies record and retain “allegations” of adverse effects and submit them to EPA upon request
- EPA can require companies to submit information on ongoing or existing health and safety studies



# Information Collection on Existing Chemicals



# Testing on Existing Chemicals



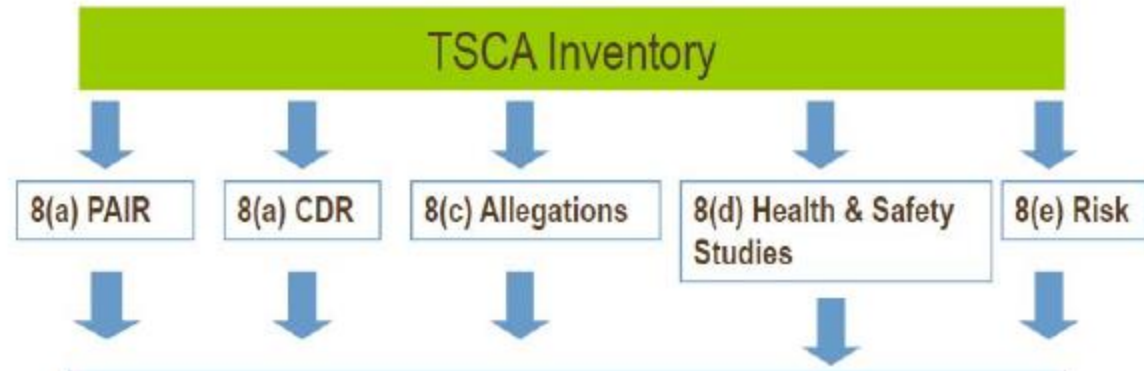
***If available information is not sufficient or raises concerns,*** Section 4 authorizes EPA to issue administrative orders and consent agreements, or to engage in rulemaking to require the development of information

## Testing on Existing Chemicals (cont'd)

- 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 required by June 2017 to establish process for prioritizing chemicals
  - Interim milestone -- proposed rule mid-December 2016

## Specific Requirements -- Existing Chemicals (cont'd)

- Initial Set of Risk Evaluations from Work Plan Chemical Assessments
  - Identify a list of ten TSCA Work Plan chemicals and formally initiate risk evaluations by mid-December 2016
  - Release the scope of each assessment by mid-June 2017

## Specific Requirements -- Existing Chemicals (cont'd)

### ■ 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 (cont'd)

- 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

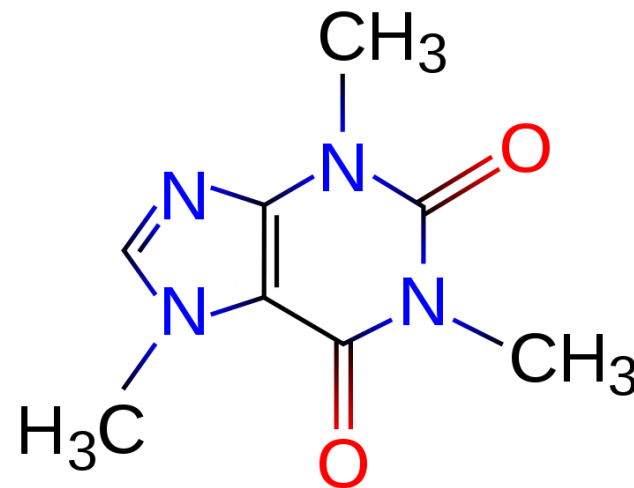
## Specific Requirements -- Existing Chemicals (cont'd)

### ■ 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”

## 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 (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
- *Prior bullets = “old” EPA new chemical review process. Will mandate for affirmative finding impact this review process?*



## 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 (cont'd)

- 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 (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



## 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 (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

## 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



# 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.
- Enter 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.
- Manufacturers do 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 use 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.

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**RESTRICTED USE PESTICIDE**

Use in ground and surface water systems. For retail sale and use only by Certified Applicators or their direct employees and only those persons licensed by the Certified Applicator's certificate.

**BULLET**  
Herbicide by Monsanto

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

Users must read and follow all precautionary statements and instructions for use in order to minimize potential for adverse or unintended pesticide effects.

In case of an emergency involving this product or for user safety information on this product, Call Safety, 24-hour register 1-877-842-4000.

3/2016 WLS 1-877-842-4000

**Complete Directions For Use**  
For use in South and Missouri States of New York

EPA Reg. No. 528-418 2009-1

Read entire label before using this product. Use only according to label instructions.

Read "LIMIT OF LIABILITY AND LIABILITY" before buying or using. If there are not acceptances, return or discontinuance.

THIS IS AN EPA-REGISTERED PESTICIDE. DOES NOT MEAN IT HAS NOT BEEN REGISTERED FOR REFORMULATION. SEE FEDERAL CONTAINER LABEL FOR REFORMULATION INFORMATION.

**LIMIT OF LIABILITY AND LIABILITY**

This Company warrants that this product conforms to the chemical description on the label and is a reasonably fit for the purposes set forth in the Certificate of Labeling for the label (see "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 MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSES OR NON-INFRINGEMENT, IS MADE BY OR FOR THIS COMPANY, AND ANY SUCH WARRANTIES, CONDITIONS, AND WARRANTIES ARE HEREBY DISCLAIMED.

None and all users shall promptly notify this Company of any claims whether based on negligence, strict liability, or other tort theories.

In the event consistent with applicable law, label and all users are responsible for all uses or damage from uses or handling which results from and/or are beyond the control of this Company, including, but not limited to, non-compliance with pesticide label directions set forth in the Directions, unusual weather, weather conditions, which are not within the scope of intended use of the application site and for the time period when the product is applied, or use in weather conditions which violate the application directions set forth in the Directions, application in any manner not explicitly authorized in the Directions, or use in conditions, outside the moisture range specified in the Directions, or the presence of pests other than those set forth in the Directions or in the label or product registration.

This Company does not warrant any product information or packaging from this product except in accordance with this Company's ownership 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 PERSON FOR ANY DAMAGES, INCLUDING CONSEQUENTIAL DAMAGES, SHALL BE LIMITED TO THE PURCHASE PRICE AND THE COST OF LABOR FOR THE REPAIR OR REPLACEMENT OF THE PRODUCT OR SUCH QUANTITY OF SUCH QUANTITY OR FINISH ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW IN NO EVENT SHALL THIS COMPANY OR ANY OTHER PERSON BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES.

None and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be waived by any verbal or written agreement.

**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 humans in some people.

	PPE USE
<b>FOR AERIAL APPLICATION</b>	<ul style="list-style-type: none"> <li>Wear full protective clothing.</li> <li>Wear skin immediately with quantity of water for 15 to 30 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>FOR GROUND APPLICATION</b>	<ul style="list-style-type: none"> <li>Wear protective clothing.</li> <li>If person is not breathing, use P2 or an atmosphere, wear gas and full face when available to reach to mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>

\*For additional information in case of an emergency, call poison, day or night, 1-800-842-4000.

\*From the product container or label within 90 days of use, a poison control center or doctor or going for treatment.

\*This product is certified as a **Bullet™** herbicide. EPA Registration No. 528-418.

**Pesticide Precautionary Statement (PPS)**

Some materials that are chemical related to this product are made of any volatile or material. If you have more options, follow the instructions for labeling in an EPA chemical review or category sensitive that:

**Meets, handles, 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, latex and vinyl.

**or additional, meters and bodies and person cleaning equipment must wear:** chemical-resistant gloves and chemical-resistant suit.

Closed clothing and other absorbent materials that have been drenched or heavily contaminated with this product's contents. Do not wash them. Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no instructions for maintenance, see detergent label under "Keep out of reach PPE" assembly from other laundry.

**Use Safety Precautions/Instructions**

Users must:

- Read/Understand label, including, but not limited to, handling, storage, use, disposal, and disposal.
- 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 before eating, drinking, or using the toilet.

**Equipment Care**

Mixers and loaders, application applicators, or reprocessors of this label, however are required to use a mechanical transfer system. Design by the manufacturer to transfer liquid pesticide in a manner that prevents contact. Do not allow any pesticide to be contacting handlers or other people during the transfer. The closed system must be used in a manner that meets the requirements of section 166 of the Pesticide Protection Standard (PPS) for agricultural pesticides (40 CFR 158.100-100.0).

- **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 (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)



## 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



## Regulatory Framework (cont'd)

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



# Thank You

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