

BERGESON & CAMPBELL, P.C.



# **Environmental Law Institute: Summer School 2010**

## **PRODUCTS REGULATION**

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**July 21, 2010**

# 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)
- Both laws rely upon risk-benefit analysis

# Many Chemical-Specific Laws

## ■ Chemical Byproducts Laws

- Clean Air Act (CAA)
  - Criteria and hazardous emissions from manufacturing facilities
  - Greenhouse gas stationary source requirements
  - Regulation of fuels and fuel additives
  - Restrictions on ozone depleting substances
- Clean Water Act (CWA)
- Safe Drinking Water Act (SDWA)

# Many Chemical-Specific Laws (cont'd)

## ■ Chemical Waste and Disposal Laws

- Resource Conservation and Recovery Act (RCRA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

## ■ Workplace Laws

- Occupational Safety and Health Administration (OSHA)
  - Workplace Exposure and Hazard Communication Standards

# Many Chemical-Specific Laws (cont'd)

## ■ Chemical Transportation Laws

- Hazardous Materials Transportation Act (HMTA)

## ■ Other Laws Affecting Chemicals

- Consumer Product Safety Improvement Act (CPSIA)
- Federal Hazardous Substances Act (FHSA)
- Hazardous Substances in Household Products

## ■ Department of Homeland Security

- Homeland Security Appropriations Act of 2007
  - Chemical Facility Anti-Terrorism Standards (CFATS)

# TSCA

# TSCA Definitions -- Chemical Substance, Mixture

- TSCA regulates “chemical substances”
  - Some key exclusions: mixtures, pesticides, food additives, drugs, cosmetics, or devices
  - Dual-use chemicals
- A mixture is any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction
  - Each component of a mixture is considered a chemical substance
  - Mixtures are still subject to certain TSCA requirements

# TSCA Definition -- Persons Subject to TSCA

- Persons subject to TSCA include:
  - Manufacturers and Importers -- TSCA imposes most of its requirements on manufacturers. “Manufacture” is defined in TSCA as meaning “to produce or manufacture in the United States or import into the customs territory of the United States.” This broad definition, therefore, includes importers of chemical substances
  - Processors -- Several TSCA provisions, including TSCA Sections 4, 5, 6, 8, and 12(b), can apply to processors of chemical substances



# TSCA Definition -- TSCA Inventory

## ■ Initial TSCA Inventory (1979)

- Companies informed the U.S. Environmental Protection Agency (EPA) what chemicals were produced at that time
- These substances referred to as “grandfathered chemicals”

## ■ Current TSCA Inventory

- Grandfathered chemicals on initial TSCA Inventory PLUS
- Any new chemical developed and marketed after 1979
  - Subject to EPA New Chemical Review -- Section 5

## Section 5 -- New Chemical Review

- TSCA Section 5 authorizes EPA to review activities associated with the manufacture, processing, use, and disposal of any new chemical substance before it enters the marketplace -- premanufacture notice (PMN) reporting
- TSCA Section 5 also authorizes EPA to regulate existing chemical substances with significant new use rules (SNUR), which are similar to PMNs
- Section 5 does not require specific testing or minimum data to be submitted

# Section 5 -- Process

- Following review of PMN, EPA could
  - Determine more data are needed
    - Company can decide to withdraw PMN or develop data and have PMN re-reviewed
  - Allow the PMN but impose certain restrictions
  - Allow the PMN without any restrictions
  - Not allow the PMN
- If the PMN is allowed, company submits a Notice of Commencement (NOC)
  - At this point, the substance is added to the Inventory; and
  - Is no longer considered a “new” chemical

# TSCA Inventory

- TSCA Inventory -- A list of all chemical substances that can be manufactured or imported in the U.S. for commercial purposes
  - About 85,000 to 90,000 substances listed
  - Not a reflection of chemicals currently in commerce
- TSCA Inventory status determines whether a substance is “new” or “existing”:
  - New Chemical Substance -- Any chemical substance *not* included on the TSCA Inventory
  - Existing Chemical Substance -- Any chemical substance included on the TSCA Inventory

# 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) Inventory Update Rule (IUR):**

Companies report production, use, and exposure information on substances over threshold every five years

**8(c) Allegations:**

Companies must retain allegations of adverse effects and submit them to EPA upon request

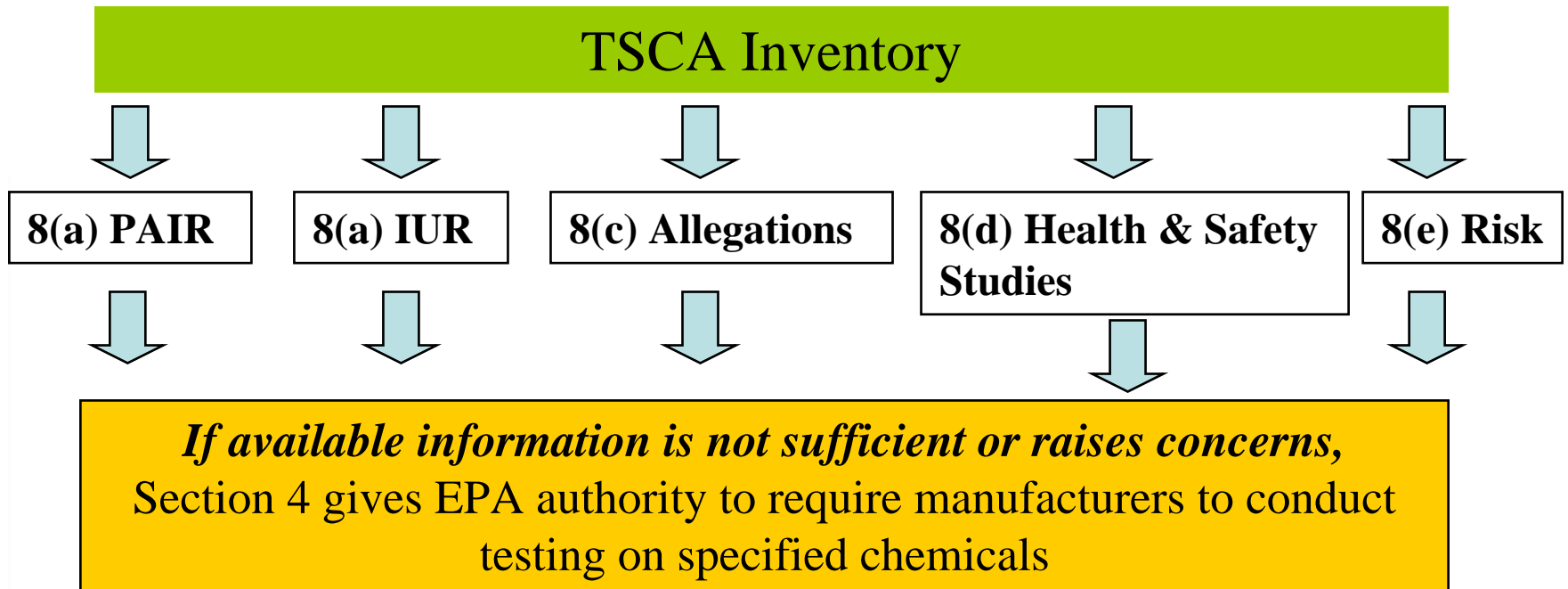
**8(d) Health and Safety Studies:**

EPA can collect information on ongoing or existing studies via rulemaking

**8(e) Risk:**

Companies must immediately report substantial risk information to EPA

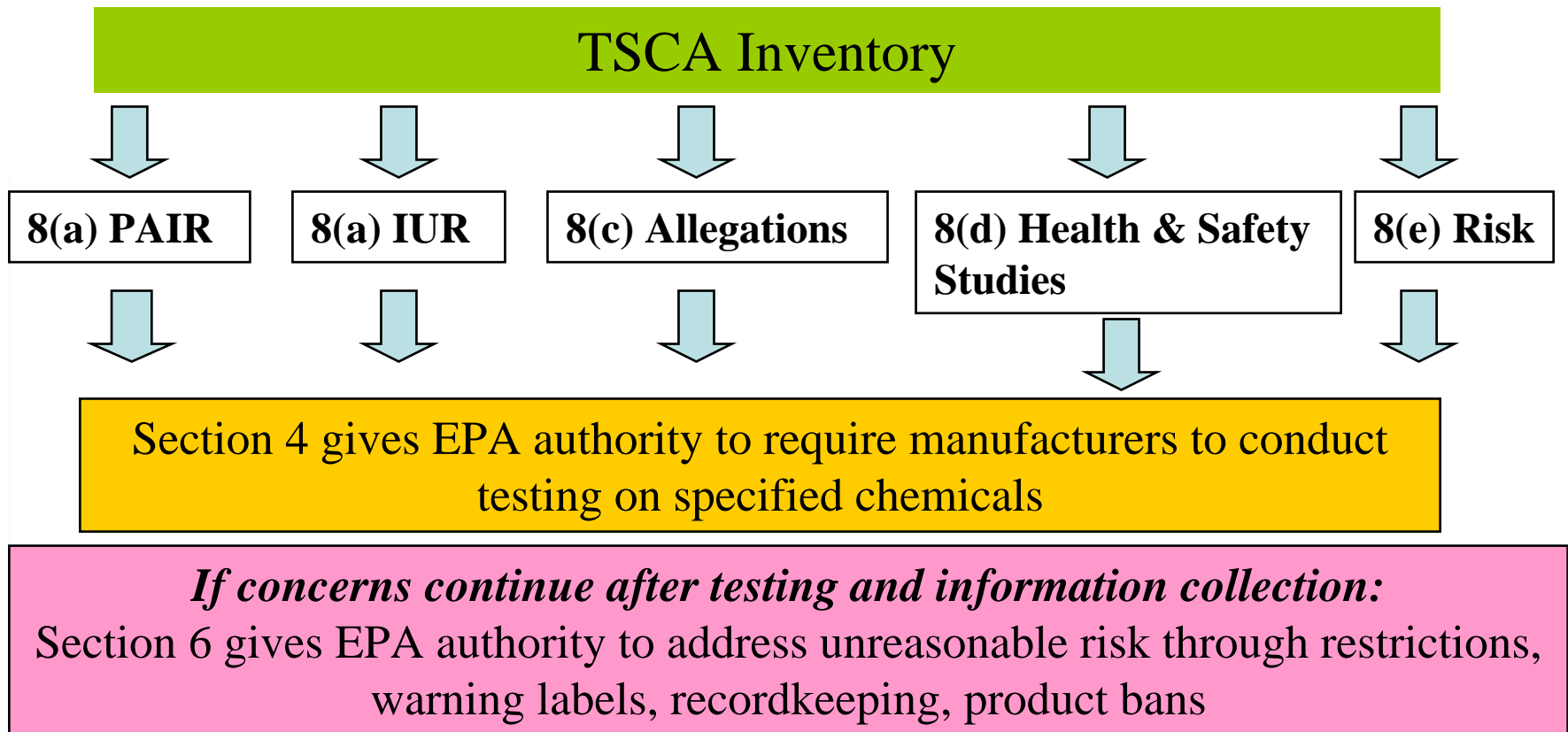
# TSCA -- Testing on Existing Chemicals



# TSCA Section 4 -- Overview

- Section 4 allows EPA to require testing on the health and environmental effects of such substances
- Manufacturers and importers are primarily responsible for testing; processors are subject to testing requirements only in certain circumstances
- About 200 chemicals tested through Section 4 or enforceable consent agreements through Section 4

# TSCA -- Risk Management on Existing Chemicals





# TSCA 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 often flagged as indication that Section 6 does not work

# TSCA -- Criticisms of 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)

OVERALL CRITIQUE: How many of the 85,000 to 90,000 chemicals on the Inventory have been assessed for safety?

# Responding to Criticisms -- Legislative Proposals

- Senate Bill: *Safe Chemicals Act of 2010 (SCA)*
  - Senator Lautenberg
- House Discussion Draft: *Toxic Chemicals Safety Act of 2010 (DD)*
  - Representatives Rush and Waxman
- House Bill: Expected as soon as July 22, with a hearing possibly scheduled for July 29

## Definitions Relating to “*Chemical Substance*” (CS)

- While TSCA definition of CS is largely maintained, important changes are found in both bills
- “CS” explicitly includes any CS in an article
- “*Mixture*” explicitly includes any mixture contained in or formed into an article
- “*New chemical*” CS for which *the* manufacturer or processor has *not* submitted a Section 8(a)(2) declaration

# Other Definitions

- *“Adverse effect”*: Very broadly defined
- *“Aggregate exposure”*: Very broad meaning
  - In addition to “TSCA exposures,” includes exposure to food, food additives, drugs, etc., and to any mixtures of these materials, and
  - All environmental sources include background
- *“Cumulative exposure”*: Sum of aggregate exposure to chemicals “known or suspected to contribute appreciably to risk of same or similar adverse effect”; and mixtures containing such substances
- *“Vulnerable population”*: Population subject to disproportionate exposure to, or to potential for a disproportionate adverse effect from exposure to, a CS or mixture; includes workers and “members of any other appropriate population identified by EPA”

# Recent Regulatory Developments

## ■ Nano Developments

- Section 4 -- EPA is preparing a proposed test rule under which chemical manufacturers would be required to develop data to determine the health effects of certain multi-wall carbon nanotubes (CNT) and nanosized clays and alumina
- Section 5 -- EPA is preparing a proposed TSCA categorical SNUR for nanoscale substances
- Section 8(a) -- EPA is preparing a proposed rule establishing reporting requirements for “certain nanoscale materials.” The rule is likely to include “existing chemical nanoscale materials”

# Recent Regulatory Developments (cont'd)

- TSCA Section 5(a)(4) Chemicals of Concern List
- Chemical Action Plans to Date
  - Bisphenol A (BPA)
  - Phthalates
  - Perfluorinated chemicals (PFC)
  - Penta, octa, and decabromodiphenyl ethers (PBDE) in products
  - Short-chain chlorinated paraffins

# Recent Regulatory Developments (cont'd)

## ■ Chemical Action Plans Being Developed

- Benzidine dyes
- Diisocyanates
- Hexabromocyclododecane (HBCD)
- Nonylphenol and nonylphenol ethoxylates (NP/NPE)
- Siloxanes

## ■ Proposed IUR Reporting Amendments



# 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 Management Division (ITRMD)

# 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 mature pesticide laws -- California, New York, Florida

# 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

# Core Statutory Authority

- FIFRA, 7 U.S.C. §§ 136 *et seq.*
- Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 346a *et seq.*

# 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

# Core Programs

- Register new actives, products, uses
- Establish pesticide residue limits for food and feed
- Reregister/review older actives/products/uses
- Other narrowly-tailored permits/exemptions
- Establish worker protection requirements
- Consultation on endangered species issues

# FIFRA -- Regulatory Framework

- Premarket Approval
- Risk-Based Safety Standard
  - No unreasonable risk (non-food uses)
  - Reasonable certainty of no harm (food uses)
- Risk = Hazard x Exposure
- Burden on registrant to meet safety standard



# FIFRA -- Regulatory Framework (cont'd)

- EPA reviews registrant-submitted data against applicable standard
- Data requirements codified at 40 C.F.R. Part 158, Part 161
  - 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.

L200163-13

**RESTRICTED USE PESTICIDE**

due to 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.



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

Users must read and follow all precautionary statements and instructions for use in order to minimize potential for adverse to reach ground 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) 634-4000.

SHAKE WELL BEFORE USING

**Complete Directions For Use**  
Not for use in Suffolk and Nassau counties of New York.

EPA Reg. No. 524-418 2008-1

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 RESTRICTED 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 those 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 in 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 explicitly set forth in the Directions, moisture conditions outside the moisture range specified in the Directions, or the presence of products other than those set forth in the Directions in or on the soil, crop or treated vegetation.

This Company does not warrant any product reformulated 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 DAMAGE RESULTING FROM THE USE OR

**HANDLING OF THIS PRODUCT (INCLUDING 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	
<b>IF ON SKIN OR CLOTHING</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 to 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF INHALED</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<ul style="list-style-type: none"> <li>• For additional information in case of an emergency, call collect, day or night, (314) 634-4000.</li> <li>• Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</li> <li>• This product is identified as <b>Bullet® herbicide, EPA Registration No. 524-418.</b></li> </ul>	

**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 applications, or impregnation 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 (but not necessarily any vapor) from contacting 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 Act (PRIA))
- 3 months to 24 months review standard, but can be longer

## ■ Existing Actives/Products/Uses

- Review older pesticides against current health standards
- That review typically yields label amendments, use restrictions, or other legal redress (cancellation)

# FIFRA -- Regulatory Framework (cont'd)

- Promote “Safer” or “Reduced-Risk” Pesticides 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

# FIFRA -- Recent Developments

## ■ Increased Transparency/Reduced Confidentiality

- Starting in FY10, EPA risk assessments and proposed decisions for new pesticide active ingredients and certain new uses are published in a public docket for review and comment
- EPA is soliciting comments on mandatory disclosure of inert (other) ingredients

## ■ Nanoscale Ingredients

- OPP regards nanoscale active and inert ingredients as new
- Under imminently-expected new interpretation of FIFRA Section 6(a)(2), presence of nanoscale material in formulation would be reportable

# FIFRA -- Recent Developments (cont'd)

- Misbranding: *Reckitt Benckiser* appellate decision
- EPA Regions will be proposing draft National Pollutant Discharge Elimination System (NPDES) General Permits to cover previously exempt pesticide applications to/over/near U.S. waters
- EPA recently settled a lawsuit concerning its human subjects testing rule to add further protections for pregnant women and children and follow National Academy of Sciences (NAS) scientific and ethical standards



# Thank You

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