

Environmental Law Institute Summer School 2012

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)
- Both laws are “risk-benefit” laws

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

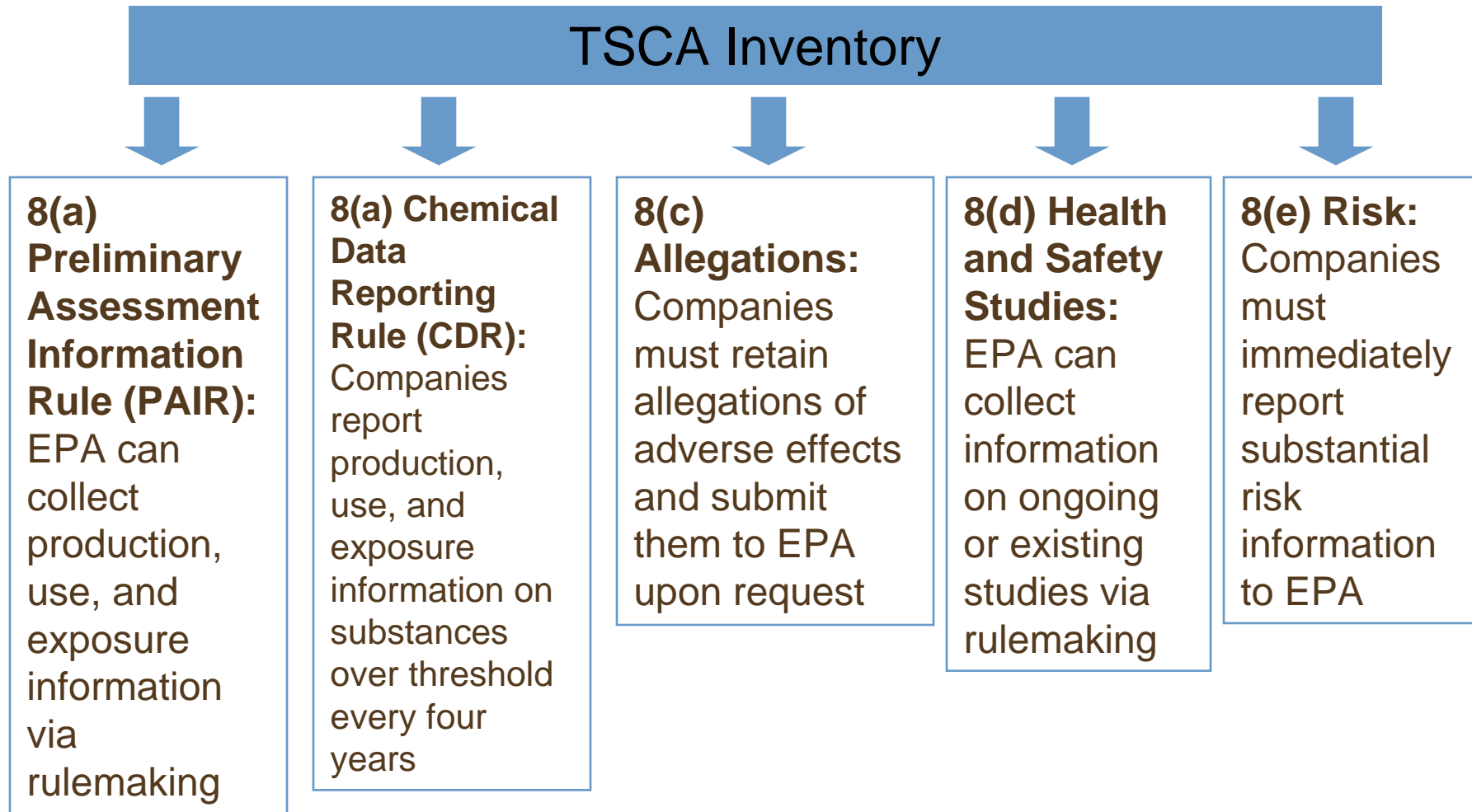
Section 5 -- Process

- 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

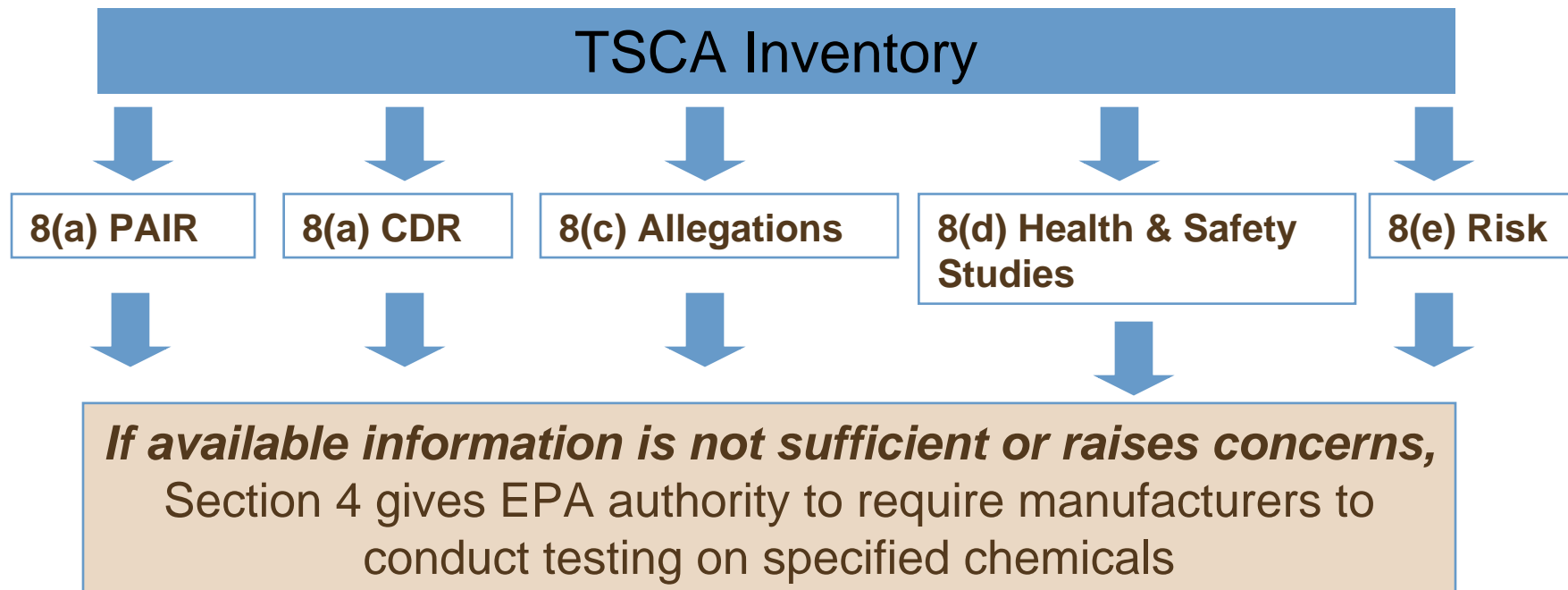
TSCA Inventory

- 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 (likely significantly fewer chemicals)
- 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



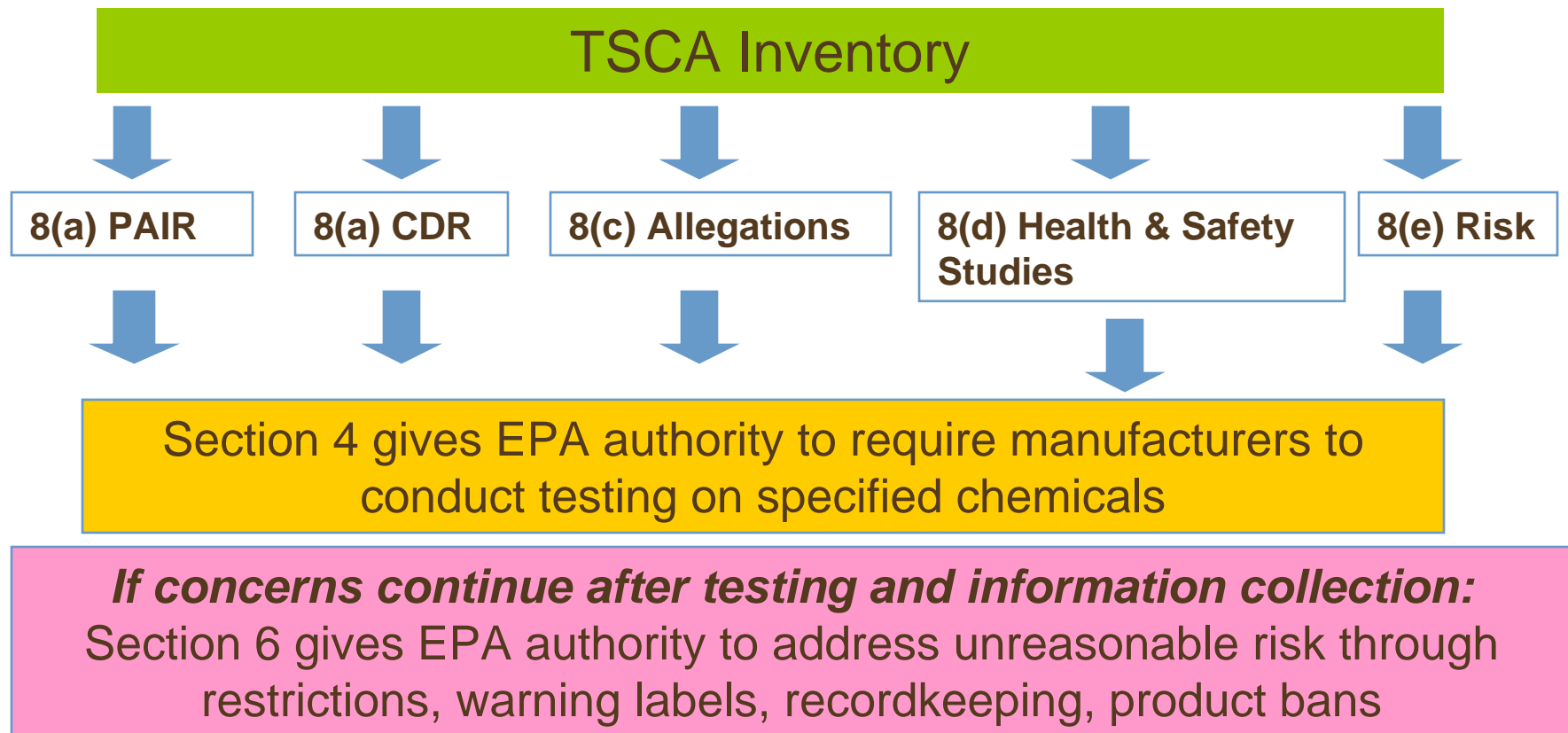
TSCA -- Testing on Existing Chemicals



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 -- 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)

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

■ 2010 --

- Senate Bill: *Safe Chemicals Act of 2010* (S. 3209)
 - Senator Lautenberg (D-NJ)
- House Discussion Draft: *Toxic Chemicals Safety Act of 2010*
 - Representatives Rush (D-IL) and Waxman (D-CA)
- House Bill: *Toxic Chemicals Safety Act* (H.R. 5820)

■ 2011 --

- *Safe Chemicals Act of 2011* (S. 847)
 - Senator Lautenberg (D-NJ)

S. 847 -- Definitions Relating to “*Chemical Substance*” (CS)

- The definition for “chemical substance” would allow the Administrator to determine, notwithstanding molecular identity, that a variant of a CS is a new CS (of key significance to the nano community)
- While the definition for “chemical identity” does not include provisions concerning mixtures, a new Section 26(c)(3) would grant EPA authority to extend authorities and requirements to mixtures if the Administrator determines that “such extension is reasonable and efficient”
- “*New chemical*” CS for which *the* manufacturer or processor has *not* submitted a Section 8(a)(2) declaration

S. 847 -- Other Definitions

- *“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 the same or similar adverse effect”
- *“Vulnerable human 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 continues to develop 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), nanosized clays, alumina, and spray-applied nanomaterials

Recent Regulatory Developments (cont'd)

- Nano Developments (cont'd)
 - Section 5 -- EPA is developing a SNUR for nanoscale materials that would require persons who intend to manufacture, import, or process this/these chemical substance(s) for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity
 - Section 8(a) -- Combined with the proposed SNUR, EPA is developing a proposal to require reporting and recordkeeping under TSCA Section 8(a) for nanoscale materials. This rule has been under review by the Office of Management and Budget (OMB) since November 2010

Recent Regulatory Developments (cont'd)

- TSCA Section 5(a)(4) Chemicals of Concern List
- Chemical Action Plans Issued to Date
 - Phthalates
 - Bisphenol A (BPA)
 - Long-chain perfluorinated chemicals
 - PBDEs in products
 - Short-chain chlorinated paraffins
 - NP/NPE (nonylphenol/nonylphenol ethoxylates)
 - HBCD (hexabromocyclododecane)
 - Benzidine dyes
 - MDI (methylene diphenyl diisocyanate) and related compounds
 - TDI (toluene diisocyanate) and related compounds

Recent Regulatory Developments (cont'd)

- Chemical Action Plans Being Developed
 - Siloxanes
- Identifying Chemicals for Assessment: EPA released a work plan of 83 chemicals for further assessment and identified seven of these chemicals for risk assessment in 2012. EPA intends to use the TSCA Work Plan Chemicals to help focus and direct the activities of the Existing Chemicals Program over the next several years

Recent Regulatory Developments (cont'd)

■ CDR Rule

- EPA promulgated the CDR (previously the Inventory Update Reporting (IUR) rule) to require reporting of manufacturing, processing, and use information for certain TSCA Inventory listed chemical substances. The first CDR reports are due by August 13, 2012

■ CBI

- EPA has been reviewing past claims to treat the identity of chemicals as CBI in health and safety studies submitted to EPA and challenged industry to declassify voluntarily such CBI claims
- EPA is considering establishing regulations relating to CBI claims submitted under TSCA that would require the periodic reassertion and resubstantiation of such claims. Confidentiality claims which are not reasserted and resubstantiated would expire

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 separate state programs that are 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.

1200163-13

RESTRICTED USE PESTICIDE

due to ground and surface water concerns. For retail sale 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 atrazine to reach ground and surface water. In case of an emergency involving this product or for use 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 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 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 PURPOSES 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	
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.
<ul style="list-style-type: none"> For additional information in case of an emergency, call collect, day or night, (314) 634-4000. 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 polyvinylidene, 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 170.246(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 Renewal Act (PRIA2))
- 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

- Registration
 - EPA announced on December 1, 2011, that it conditionally registered a pesticide product containing nanosilver as a new active ingredient. HeiQ AGS-20 is a silver-based antimicrobial pesticide product approved for use as a preservative for textiles
 - This is a momentous regulatory decision and very good news for supporters of nanopesticides
 - The Natural Resources Defense Council (NRDC) has filed a lawsuit objecting to the registration. NRDC contends that EPA should have required HeiQ to produce and submit data before commercializing the product (instead of allowing sales/distribution of product while testing is being conducted)

FIFRA -- Recent Developments (cont'd)

- 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 solicited comments on mandatory disclosure of inert (other) ingredients
- Nanoscale Ingredients
 - In a June 17, 2011, notice, EPA offers two options for obtaining information:
 - FIFRA Section 6(a)(2) or data call-in (DCI) under FIFRA Section 3(c)(2)(B)
 - In the same notice, EPA proposes to classify initially any nanoscale active or inert ingredient as new

FIFRA -- Recent Developments (cont'd)

- Misbranding: *Reckitt Benckiser* decision
- EPA issued a February 2, 2011, proposed rule that would revise its 2006 final rule concerning protections for subjects in human research:
 - Would broaden the applicability of the rules to cover human testing with pesticides submitted to EPA under any regulatory statute it administers
 - Would also disallow participation in third-party pesticide studies by subjects who cannot consent for themselves
 - Would identify specific considerations to be addressed in EPA science and ethics reviews of proposed and completed human research with pesticides, drawn from the recommendations of the National Academy of Sciences (NAS)
 - Although OMB has indicated it completed its review, the final rule is not expected to be released anytime soon

Thank You

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