Federal Statutes Addressing Toxics

- FIFRA – pesticides
- FFDCA – food additive and drugs
- OSHA – worker protection
- CWA/CAA – special provisions for toxic chemicals
- EPCRA – reporting requirement
- TSCA - catchall

Should we/do we require testing of all chemicals?

Categories identified as highest concern requiring testing:
- Pesticides (FIFRA)
- Drugs (FFDCA)
When is testing required?

• For pesticides and drugs, testing is required prior to the products being sold or distributed in commerce (i.e., premarket review)
• What about everything else? What if you want to sell a new product (e.g., a non-stick pan coating) that may be very toxic?

No pre-market review for substances that are not pesticides or drugs!

• TSCA does not automatically require testing for pre-market review before a new chemical is put into the marketplace
• TSCA merely has a pre-manufacture notification (PMN), in which the manufacturer must submit any existing data and EPA has 90 days to determine whether to allow sale
Pesticides

What is a pesticide?

FIFRA 136(u)
Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest
"The great expectations for DDT have been realized. During 1946 exhaustive tests have shown that when properly used... DDT is a benefactor of all humanity."

TIME Magazine
June 1947

DDT... FOR CONTROL OF HOUSEHOLD PESTS

Prepared by: USDA, United States Department of Agriculture, Bureau of Entomology and Plant Quarantine, Washington, D.C.
Registration Under FIFRA

FIFRA 136a

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter.
Registration Under FIFRA

FIFRA 136a(5) Approval of Registration

The [EPA] shall register a pesticide if it determines that, when considered with any restrictions imposed under subsection (d)
(A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
(C) it will perform its intended function without unreasonable adverse effects on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT

FIFRA section 136(bb) Unreasonable adverse effects on the environment means:

(1) Any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticides, or
Three Main Approaches to Regulating Risk

- **Pure Risk-Based Statutes**
  - Rarely used
  - Delaney Clause
- **Cost/Benefit Statutes**
  - TSCA
  - FIFRA
- **Feasibility Statutes** (e.g., set MCL as close to MCGL as is feasible)
  - Most Common
  - Parts of CWA, CAA, SDWA & RCRA

Unreasonable Adverse Effects on the Environment

(2) **A human dietary risk** from residues that result form a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21 [FFDCA – “**safety**” standard – i.e., reasonable certainty that no harm will result from aggregate exposure to pesticide residue].
Unreasonable Adverse Effects on the Environment

The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide . . The Administrator shall weigh the risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

FIFRA Labeling

- The “use” of pesticides is regulated through the label
- Each label must contain a statement that says “It is a violation of Federal law to use this product in a manner inconsistent with its labeling.”
Cancellation

- FIFRA section 136d(b) EPA may cancel pesticide if when used in accordance with widespread or generally recognized practice generally causes unreasonable adverse effects on the environment.
- Registrant may request administrative hearing within 30 days.
- EPA may allow existing stocks to continue to be sold.

EPA Pesticide Regulatory Actions

- There are approximately 20,000 EPA-registered pesticide products containing approximately 675 active ingredients.
- Approximately 4.5 million pounds of these active ingredients are used each year.
EPA Pesticide Regulatory Actions

Each year, EPA makes hundreds of significant decisions regarding pesticide registration

For example, in 2003, EPA:

- registered 31 new pesticide active ingredients
- approved the addition of 334 new uses of previously registered active ingredients on over 1,500 different crops
- completed more than 6,500 more minor registration actions
- completed re-registration on 28 previously-registered active ingredients
- processed nearly 500 emergency exemption requests.

Current Problems

- Cholinesterase Inhibiting pesticides (organophosphate & carbamate pesticides) the replaced organochlorine pesticides (e.g., DDT) have low LD50s and are highly acutely toxics to birds and wildlife
2004 Center for Biological Diversity Report

EPA has approved registrations for pesticides that put more than 375 T&E species at risk.

Federal Insecticide, Fungicide and Rodenticide Act

- Based on old “consumer protection” laws
- Focus on “labeling” to warn consumers and users of risks
- Cost/Benefit standard governs regulatory decisions
  - “Unreasonable Adverse Effect on the Environment”
EPA’s Actions Under the ESA

• Consultation on 112 pesticides on one or more of 165 listed species resulting in 1989 Biological Opinion
  – 1,867 TOTAL JEOPARDY FINDINGS
• Consultation on 16 vertebrate control pesticides resulting in 1993 Biological Opinion
  – 189 TOTAL JEOPARDY FINDINGS
• EPA has taken no action to reduce the risks to listed species for any of the 2,056 jeopardy findings made to date!

Relationship between CWA and FIFRA

• Is an NPDES permit required for:
  - Application of pesticides to water to kill aquatic pests?
  - Application to land adjacent to water, where the pesticide drifts into the water?
• Recent case law split
• Recent EPA rule creates exemption