

Texas Department of Agriculture



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Pesticide Laws and Regulations

- Federal
 - Federal Food, Drug, and Cosmetic Act (1939)
 - Federal Insecticide, Fungicide, and Rodenticide Act (**FIFRA**) (1947)
 - Worker Protection Standard (1992)
 - Food Quality Protection Act (**FQPA**) (1996)
- State laws vary

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Gives EPA authority to
 - Require pesticide purchase registration and proper labelling
 - Control of distribution, sale, use
 - Pesticide applicator certification
 - Study pesticide consequences

Federal Food, Drug, and Cosmetic Act (FFDCA)

- Allows EPA to establish tolerances for pesticides in food
- Small fraction of marketed food tested for pesticide residue



Worker Protection Standard

- **Reduce farmworker pesticide illness**
- **Hazard training and communication, decontamination facilities, notification, emergency medical care**

Food Quality Protection Act (FQPA)

- **Health-based standard for pesticides in foods**
- **Requires EPA to review tolerances for pesticide residues in food**
- **Focus on children**
- **Realistic exposure assessment (?)**

EPA Responsibilities

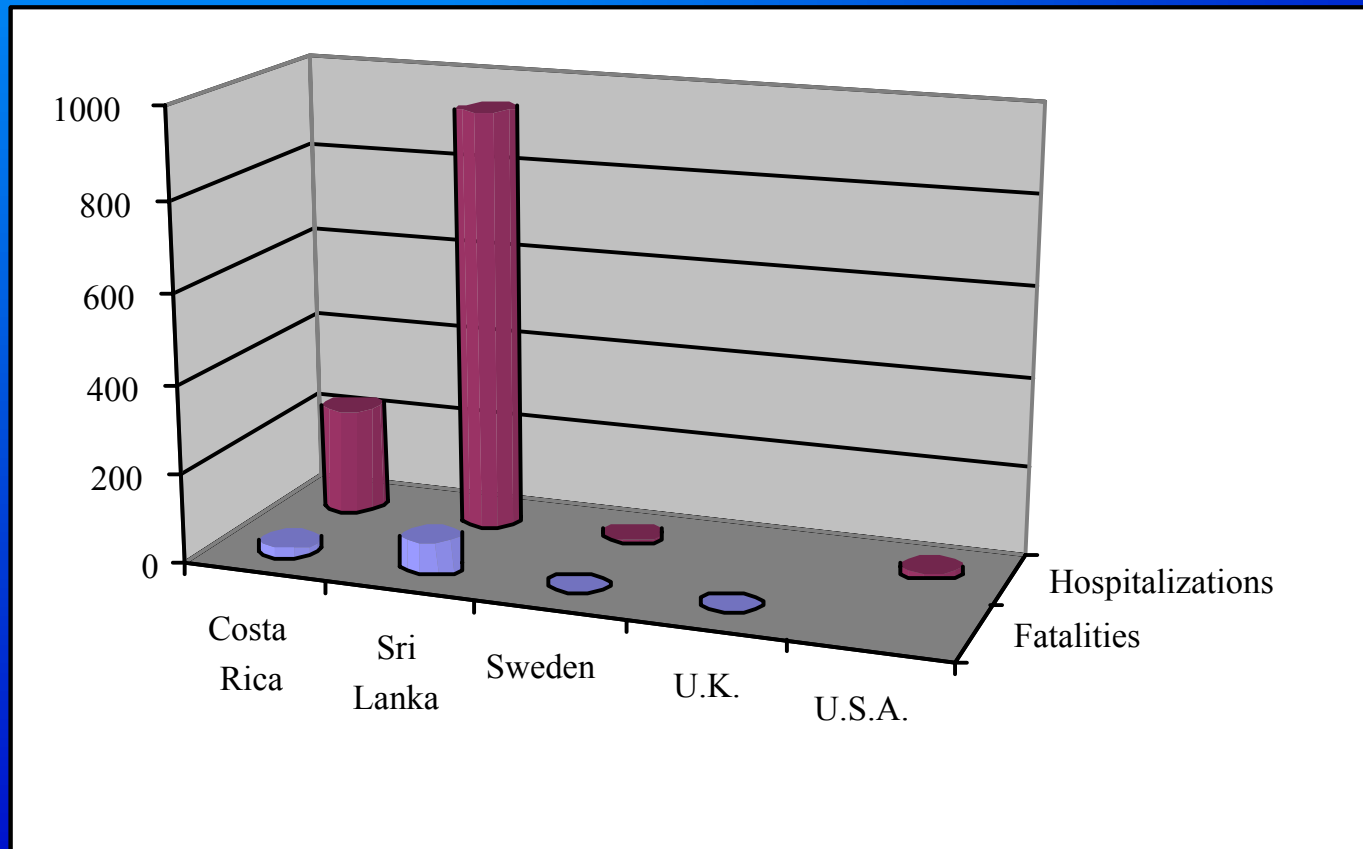
- **Register Pesticides for use in the US**
- **Set Labeling and other Requirements to Prevent “Unreasonable Adverse Effects”**
- **Establish the Maximum Levels of Pesticide Residues (Tolerances) allowed in food**

Enforcement

- **Tolerances are enforced by the FDA and USDA**
- **EPA and States enforce regulations on the sale, labeling and use of pesticides**

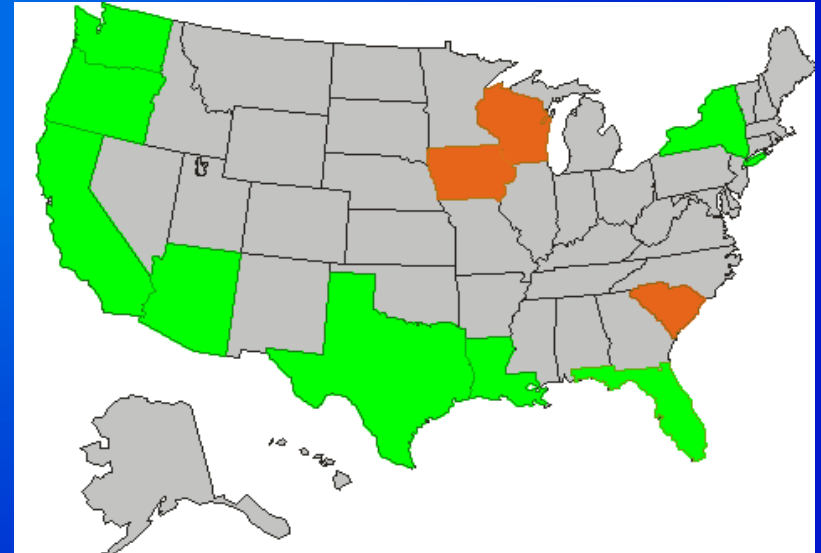
Pesticide Illness Around the World

Annual rates of intentional and unintentional pesticide-related fatalities and hospitalizations in several countries



Surveillance of Pesticide Illness

- States with ongoing surveillance
 - Arizona, California, Florida, Louisiana, New York, Oregon, Texas, Washington
- States with previous pilot or periodic surveillance programs
 - Iowa, South Carolina, Wisconsin



Section 408(b)(4)

International Standards

- Codex MRLs

In issuing a tolerance, EPA must determine whether a Codex maximum residue level have been established. If EPA does not adopt the Codex level, EPA must publish a notice for public comment explaining the reasons for departing from the Codex level. This provision is intended to “avoid unnecessary restraints on international food trade” and to encourage EPA to support international harmonization efforts.

CODEX

- Encourage international harmonization of tolerances
- If EPA different from CODEX, explain why
 - **Notice and Comment**

Section 408(1) Harmonization with Action under Other Laws

- The Administrator must establish tolerances for Section 18 pesticides

EPA must establish tolerances for pesticides granted emergency exemptions under Section 18. The Commerce Committee intends this provision “to resolve a long-standing dilemma regarding legal pesticide residues that, because there were no tolerances or exemptions, could have been considered technically in violation of law.”

FIFRA § 18

Pesticides

- Tolerances required
- Tolerance rules in 1-year

Section 408(n) -- National Uniformity of Tolerances

States and their political subdivisions are preempted from establishing their own regulatory limits unless they are identical to EPA's

BUT:

- ◆ **Prohibition only applies to “qualifying residues” for which there have been a “qualifying Federal determination”**
- ◆ **States can petition EPA for an exemption from preemption for a particular tolerance**
- ◆ **States are not preempted from requiring warnings on food regarding the presence of pesticide residues**

State Training for Maintenance Applicators and Service Technicians

Maintenance applicator is a person who uses or supervises the use of a pesticide not classified as a restricted use pesticide for structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term does not include: a private applicator; individuals who use antimicrobial pesticides; government employees; or individuals who use pesticides not classified for restricted use in or around their homes; boats, sod farms, nurseries, greenhouses; or other non-commercial property.

Optional State Training

- **Exempted:**
 - **Private applicator**
 - **Individuals using antimicrobial pesticides**
 - **Employees of federal, state or local government**
 - **Ready-to-use pesticides**
 - **Individuals who use unrestricted pesticides around their homes or other non-commercial property**

Risk Assessment

- **All about:**
 - **Conservative Assessments**
 - **Conservative Assumptions**
- **Risk = Toxicity X Exposure**

Regulatory Level

- NOAEL
 - “Conservative Assessment”.
 - **Highest** concentration of chemical without an effect in the most sensitive species tested.

Then...

- “Conservative Assumption”
- Adjust NOAEL with 10X safety factor.
 - Why?
 - To account for unlikelihood of sampling the most sensitive individuals from the most sensitive species.
 - Why 10? Because!
 - $(\text{NOAEL}/10) = ???$

Then (again)...

- Another “Conservative Assumption”
 - Humans may be more sensitive than the most sensitive species tested.
 - Do we know this? Usually not.
 - So, add another 10X safety factor.
 - Why 10? Because!
 - (NOAEL/100) = ???????

Then (again, again)...

- Because of FQPA, an additional 10X safety factor is added if:
 - Suspected developmental toxicant.
 - Incomplete toxicity data or exposure assessment.
- Why 10X? Because!
- $(\text{NOAEL}/1000) = \text{????????????????} (\text{RfD})$

RfDc

- **Reference Dose (RfDc)**
 - **The amount of a chemical that an individual can consume everyday for their lifetime without expecting adverse health effects.**

Now, how about exposure assessment?

- Aggregate assessment (FQPA)
 - Diet
 - Food
 - Water
 - Residential
 - Occupational
- Because of uncertainty, assumptions and assessments are “worse-case” scenarios.

OP CRA-Food: 7 Population Groups

	Exposure (mg/kg/day)			
	95 th %	99 th %	99.5 th %	99.9 th %
All infants < 1	0.0001	0.0003	0.0004	0.0009
Children 1-2	0.0002	0.0006	0.0009	0.0018
Children 3-5	0.0002	0.0005	0.0007	0.0015
Children 6-12	0.0001	0.0003	0.0004	0.0009
Age 13-19	0.0001	0.0002	0.0002	0.0005
Adults 20-49	0.0001	0.0002	0.0003	0.0005
Adults 50+	0.0001	0.0002	0.0003	0.0006

Section 18 Example

- Request for use of **diuron** on blue-green algae in catfish ponds in Texas. (Oct. 2003).
 - EPA had previously determined:
 - RfDc = 0.003 mg/kg/day
 - Most exposed population = non-nursing infants.
 - Estimated dietary exposure = 0.00084 mg/kg/day or 28% of RfDc.

So...

- **How does the requested use affect the risk assessment? (Can't exceed 100% of the RfDc!)**
 - **“Conservative Assumptions”**
 - **100% of catfish will contain residues of diuron at maximum levels (tolerance) or 2 ppm.**
 - **Assessment geared to “most sensitive” population (non-nursing infants).**

Exposure Assessment for Sec. 18 use

- Maximum increase in dietary exposure of 0.0000072 mg/kg/day or 0.24% of the RfDc.
 - EPA (Federal) = 0.00084 mg/kg/day (28%)
 - TDA (State) = 0.0000072 mg/kg/day (0.24%)
- Conclusion (?): “...reasonable certainty that no harm will result...”