Risk and Law

From Utilitarian to Precautionary Law:
Protecting Children From Pesticides

Lecture 9
Environmental Politics and Law PLSC 215b/
EVST 255b
February 11, 2010
Professor John Wargo

Risk and Environmental Law

- Fundamental Aspect of Human Logic & Instinct
- Risk? Probability of Damage
- Risk Expression: Qualitative v. Quantitative?
- Standards? Acceptable Magnitude, Distribution, Probability
- Making Choices Balancing: Dangers v Benefits?
Evolution of Law: Reflects Changing Science & Values

- Fraudulent Claims (1906)
- Warning Requirement (1910)
- Balancing Standard (1947 FIFRA)
- Zero Cancer Risk (FFDCA Delaney Amendment 1958)
- De Minimus Risk (1990’s: FDA Interpretation: 10^-6)
- Environmental Risks (FIFRA Amendments 1972)
- Human Health Risks (1996 FQPA)

Last Lecture…

- 6 Billion lbs/year. 1,000 Actives. 20,000 Products
- Licensing System Automatic: Criterion= Risk/Benefit
- Pesticide Imagery: Malaria Legacy,... Sanitation; Health
- DDT Lessons: Persistence, Accumulation, Cancer,
- Waves of Technology: Metals, Chlorine, OP’s, Carb, Pyret
- To Limit or To Ban?
- Substitutes: Prohibit Known Threats, Accept Untested

Persistent Organic Pollutant Treaty 2003 - Entry into Force

Eliminates 16 Persistent Chemicals.

- 11 pesticides--DDT, aldrin, dieldrin, lindane, hexachlorobenzene and heptachlor
- 2 industrial chemicals (hexabromobiphenyl and PCBs) and
- 3 by-products/contaminants--dioxins/furans, hexachlorobenzene and polyaromatic hydrocarbons.

What Does a National Ban Mean in a Global Marketplace?

- 192 NATION STATES RECOGNIZED BY UN
- 115 COUNTRIES SUBMITTED DATA TO UN ON POP’S
  - 47 BAN ALDRIN
  - 47 BAN CHLORDANE
  - 51 BAN DIELEDIN
  - 51 BAN DDT
- 90 NATIONS INCLUDING US AND EU HAVE SIGNED TREATY
**Pure Food and Drug Act of 1906**

January 1906, Upton Sinclair published *The Jungle*

Described filthy slaughtering conditions in the Chicago stockyards.

Pure Food and Drug Act was passed on June 30, 1906.

- The act forbade foreign and interstate commerce in “adulterated” or “fraudulently labeled” food and drugs.
- Products could now be seized and condemned,
- Offending persons could be fined and jailed.
- Fresh, canned or frozen food shipped in interstate commerce must be “pure and wholesome”.

**Insecticide Act 1910**

- Prohibited the sale of fraudulently labeled pesticides, and set standards for their purity.
- Designed to protect farmers from dangerous or impotent pesticides.

**Federal Food Drug and Cosmetic Act 1938**

- FDA authorized to set limits for chemicals in foods
- Tolerances were established for some pesticides
- Color required to be added to pesticides to prevent their being mistaken for flour or sugar.
- **Miller Amendment 1954:**
  - Required tolerances for all pesticides
- **Delaney Amendment 1958:**
  - Zero tolerance for carcinogens in foods
  - Pesticides Defined as Food Additives if Concentrated
  - Raw to Processed Food: Led to Ban of Parent Chem.
  - E.g. apple juice and Alar.

**Federal Food Drug and Cosmetic Act**

Miller Amendment 1954:
- Required tolerances for all pesticides

Delaney Amendment 1958:
- Zero tolerance for carcinogens in foods
- Pesticides Defined as Food Additives if Concentrated
  - Raw to Processed Food: Led to Ban of Parent Chem.
  - E.g. apple juice and Alar.
**FIFRA 1947**

*Federal Insecticide, Fungicide & Rodenticide Act*

- Defined Pesticides as “economic poisons” (benefit/risk balancing)
- Required Product USDA Registration prior to interstate/int’l trade
- Extended Regulation to Herbicides and Rodenticides
- Required Warning Labels to protect users, public, non-target species
- Required Ingredient List other than Inerts
- No authority to remove hazardous chemicals from market

---

**Why Give USDA Authority?**

Remember the Atomic Energy Commission

---

**1964 FIFRA Amendments**

- Rachel Carson’s Silent Spring Published in 1962
- Required Signal Words: Caution, Warning, Hazard
- USDA Secretary Given Authority to Remove Pesticides From Market based upon “imminent hazard to public”

---

**EPA Created in 1970:**

- Given Responsibility to Manage Pesticides
- Consolidated From Other Federal Agencies
- USDA Staff Moved to EPA

**Federal Environmental Pesticide Control Act of 1972**

- Amended FIFRA: New Standard for Registration…
- “No Unreasonable Adverse Effects on Environment”
- General vs. Restricted Use Categories Created
- Intrastate Sales of Pesticides Regulated

---

© Yale University 2012. Most of the lectures and course material within Open Yale Courses are licensed under a Creative Commons Attribution-Noncommercial-Share Alike 3.0 license. Unless explicitly set forth in the applicable Credits section of a lecture, third-party content is not covered under the Creative Commons license. Please consult the Open Yale Courses Terms of Use for limitations and further explanations on the application of the Creative Commons license.
**FIFRA Amendments:**

1975:
- Sec. of Agric. must be notified of pending cancellations
- Consideration of the economic effects of regulations
- Conditional Registration Allowed Absent Full Data

1975:
- Review of Older Pesticides Required
- 1988 Congress mandated a 9 year review deadline
- Costs of Registration Responsibility of Manufacturer

**1995: Fractured Science, Fractured Law**

- EPA, FDA, USDA
- EPA: Registration and Tolerance Setting Responsibility
- FDA: Enforcement of Limits in Domestic & Imported Foods
- USDA: Enforcement in Meat and Poultry, Econ Benefits Assess.
- Different Jurisdictions, Data Sets, Budgets, Political Territories, & Cultural Predispositions to Worry About Different Risks....
- Effect: Confusion and Delay in Implementation
  - Bureaucratic Inertia and Momentum
Food Quality Protection Act of 1996

- General Safety Standard: "Reasonable certainty of no harm"
- Required Finding of Safety: EPA must find limits safe for children.
- Tenfold Additional Safety Factor: when setting allowable levels of exposure.
- Aggregate Risk: The Agency must consider how individuals may be exposed to the same pesticide from food, water, air, lawns and pets and other sources.
- Cumulative Risk: Consider mixtures that are toxic via similar mechanism.
- Pace of Review: EPA Review Complete by 2006
- Strategic Attention to Most Toxic Chemicals. 3 Tiered Review

Historical Pesticide Regulatory Priorities: Why?

- Protect Economy of Farmers
- Food and Crop Uses
- Wildlife Residues
- Soil Contamination
- Drinking Water
- Indoor Environments
- The Susceptible
- Consumer Products
- Occupational Exposures?

Underlying Problems of Law

1. Human Inability to Sense Chemical Risk
2. Lack of Sensitivity to Susceptibility
3. Poor Monitoring of Chemical Release
4. Misunderstanding Persistence and Environmental Fate
5. Misunderstanding Variability in Human Exposure
6. Single Chemical Exposure
7. Incomplete Toxicity Testing
8. Failure of Labeling As Management Strategy
9. Misunderstanding trends in Human Illness:
10. Variance in Human Capacity to Manage Risk

Mixtures

Test common chemical mixtures:

- Diesel exhaust
- Urban smog
- Drinking Water
- Pesticide combinations
- Fragrances
- Plastics
- Pesticides
Targets for Reform

1. Governments
   • Legislative Branch
   • Executive and Administrative (EPA, USDA, FDA, OMB, WH)
   • Judicial
   • Int’l, Nat’l, State, Local… Citizens
2. Media
3. Consumers: Corporations, Universities, Hospitals, Golf Courses
4. Corporations: Where on the Supply Chain?
5. Labor Groups
6. Institutional Risk Bearers: Insurance Companies

Forms of Argument:

Do they differ systematically among stakeholders?

If yes, how and why?

Industry Arguments

1. Emphasize Benefits of Product or Technology
2. Argue that Evidence is Insufficient to Justify Reg: Play the Good Scientist
3. Trivialize Claim of Hazard: Compare it to Natural Hazards
4. Human Experimentation: justify relief from 10X safety factor
5. Exposure: Average nationally, yearly and demographically
6. Label Restrictions: Meet Any Disclosure Requirement in 6 point type
7. Applicator Training and Licensing
8. Registration Is a Property Right: Prohibition Demands Compensation (5th Amend.)
10. If Product is Banned Domestically: Let Us Export
11. Substitutes: Don’t Compare Us; Relative Risk is Uncertain
12. Environmental Surveillance is An Acceptable If We Self Monitor and Report
13. Strategically Regulate Rather Than Ban
14. Comparative Risk: Spend $ on Seat Belts, Drug Control and Suicide Prevention
15. Self Monitoring and Self Modeling of Emissions & Risk

Environmental & Consumer Group Arguments:

1. Shift Burden of Proof to Private Sector: Demonstrate Safety
2. Evidence is Insufficient to Justify Finding Safety (Need 10XSF)
3. Susceptibility: Toxicity: Developmental, Endocrine, Neuro, Immune: Data Are Incomplete….Don’t Wait
4. Exposure: Demand Distributional Analysis by Age Class
5. Mixtures: Common Mechanism Demands Collective Analysis
7. Pace of Review: Keep to Schedule or See you in Court
8. Restricted Use, Label Changes and Ecological Restrictions….
10. Are the most exposed the most susceptible?
11. Oppose Federal Preemption of State and Local Control
**Reform Strategy Summary:**

- a. Labeling Requirements: Ingredients, Warnings, Education
- b. Balancing v. Health Protective Standards
- c. Prior Information vs. Prior Informed Consent
- d. Secrecy: Property Rights to Knowledge of Risk
- e. Certification: Process vs. Product
- f. Defamation Laws: Alar Case
- g. Riskiest First: Strategic Attention to Highest Risk
- h. Safety Factors in Standard Setting: NOEL / 1000?
- i. Burden of Proof: Innovators vs. Public
- j. Protection of the Most Vulnerable
- k. Precaution Policy in the Face of Uncertainty