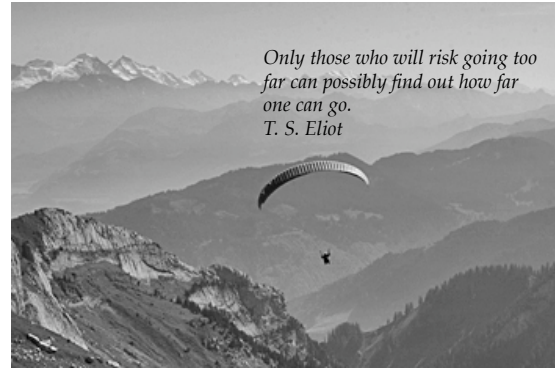


Risk and Law

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 DIELDRIN
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 Concentration
 - Raw to Processed Food: Led to Ban of Parent Chem.
 - E.g. apple juice and Alar.

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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

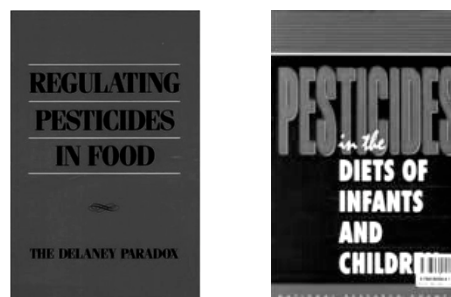
FIFRA Amendments:

1975:

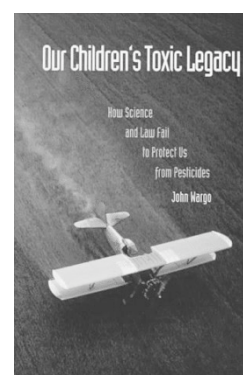
- Sec. of Agric. must be notified of pending cancellations
- Consideration of the economic effects of regulations
- Conditional Registration Allowed Absent Full Data

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



Open Yale courses

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 10 X 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.)
9. Patent Life: Long Lag Time; Existing Stock Provision
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
6. Aggregate Exposure: Air, Water, Foods, Indoor/Outdoor, CP's
7. Pace of Review: Keep to Schedule or See you in Court
8. Restricted Use, Label Changes and Ecological Restrictions....
9. Environmental Testing: EWG—25 million exposed
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