Part I: Benefits & Utility

Why Use Pesticides???
- Non-pesticide technologies are ready, "off-the-shelf" technologies
- IPM means less pesticide use

Complexity of Agroecosystems
Public health pests

Definitions: ‘Fertilizer’
- Macro & trace nutrients added to soil (sometimes plant foliage) to maximize crop production/quality
- Not regulated by EPA with regards to labeling, application rates, applicator licensing
  - Federal regulation intercedes when environmental hazard arises
    - For example, water pollution
- Regulated by states
  - Labeling to protect against adulteration
  - Heavy metal content (Canada and Washington State)

Definitions: ‘Pesticide’
- Defined by law, Federal Insecticide, Fungicide, & Rodenticide Act (FIFRA, 1947)
- Any substance or mixture intended for preventing, destroying, repelling, or mitigating any pest
  - Exempted: microbes living on or in humans
  - Includes: whatever the EPA administrator rules to be a pest
- Includes plant growth regulators, defoliants, pheromones, desiccants, disinfectants

Have You Used a Pesticide Recently???

Natural vs. Agroecosystems

Natural Ecosystems
- Diversity rich
- Plant nutrients stored & recycled
- Infrequent perturbations
- Dominated by native species
- Good natural control

Agroecosystems
- Diversity poor
- Plant nutrients depleted
- Frequent perturbations
- Invaded by exotic species
- Poor natural control
**Agroecosystems Demand Management**

- Easier for one species to become dominant
- Nutrients are continually removed by annual harvesting
- Pest can be native or imported
  - pests are opportunists
  - consider presence or absence of mortality factors as limiting or enhancing factor

Conflict among economic value of crop, its susceptibility to damage from pests, and removal of nutrients demands management of both the pest and the crop.

**Historical Role of Pesticides**

- **1000 BC**: Sulfur used as fumigant
- **100 BC**: Hellebore (lily containing alkaloids) for control of rodents & insects
- **70 AD**: Report of Greek use of gall of green lizard for protection against caterpillars & rot!!!!!
- **900 AD**: Chinese use arsenic
- **1690 AD**: Tobacco extracts
- **1787**: Soap mentioned as insecticide; turpentine emulsion as repellant
- **1800 AD**: Persian louse powder (pyrethrum); sprays of lime and sulfur; whale oil for scales
- **1848 AD**: Rothenone
- **1867 AD**: Paris Green (aceto-meta-arsenite of copper for Colorado potato beetle; mosquitoes)
- **1892 AD**: Lead arsenate for gypsy moth; dinitrophenols

**More People, Less Acres More Production/Acre**

<table>
<thead>
<tr>
<th>Year</th>
<th>1910</th>
<th>2000</th>
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<tbody>
<tr>
<td>Total Principal Crops (acres)</td>
<td>306,299,000</td>
<td>307,839,000</td>
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<tr>
<td>Potatoes (acres)</td>
<td>3,644,000</td>
<td>1,352,000</td>
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<tr>
<td>Potato Yield Per Acre (cwt)</td>
<td>56</td>
<td>382</td>
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</table>

National Agricultural Statistics Service

**Significant Increase in Yield Associated with Fertilizer & Insecticide Use**

*Hayes 1991*

**Effect of Weeds on the Production of Corn and Soybeans**

*Hayes 1991*
### Estimated Effects of Reduction in Pesticide Use

**Vegetables**
- Fresh
- Processed

**Fruit**
- Fresh
- Processed

% Yield Reduction
- 50% reduction
- Zero use

Knutson et al. 1993

### Public Health Benefits

- **Anopheline mosquitoes/month from capturing stations**
- **Malaria cases/1000 inhabitants**

DDT Spraying Post 1945—Latina Province, Italy

Hayes 1991

### Pest Management Tools

- Cultural practices
- Mechanical control
- Plant resistance
- Parasitoids & Predators
- **Pesticides**

### Advantages of Pesticides

- Many times they are the only practical or available technology
- Rapid action
  - can be used in an emergency
  - Biodegradable (modern pesticides)
- Wide range of properties, uses, and methods of application
  - Broad spectrum to selective

### Farming Costs & Returns

- Market Value
- Total Production Expenses
- Labor
- Fertilizer
- Pesticides

USDA Database

### Advantages of Pesticides

- Economic return-cost ratio favorable
  - $4 - $29 returned per $1 spent
  - However,
    - Ratio goes down when
      - Price of crop decreases but pesticide cost is fixed;
      - A product is used and pest populations are not at a level that will cause economic damage
      - Development costs for a new product are high
**Are We On a Treadmill?**

- Costs of Research & Development are extremely high
  - $70 million
  - It may take 15 years to recover a positive cash flow

Is pesticide use rising significantly?

<table>
<thead>
<tr>
<th></th>
<th>1991</th>
<th>2003</th>
<th>Change</th>
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<tbody>
<tr>
<td><strong>Corn</strong></td>
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<td>Acres Planted $x 10^{6}$</td>
<td>76.2</td>
<td>72.7</td>
<td>-3.51</td>
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<tr>
<td>Herbicides-% Area Applied</td>
<td>94</td>
<td>95</td>
<td>1</td>
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<td>Pounds $x 10^{6}$</td>
<td>210.5</td>
<td>149.0</td>
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<td>Insecticides-% Area Applied</td>
<td>30</td>
<td>29</td>
<td>-1</td>
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<tr>
<td>Pounds $x 10^{6}$</td>
<td>23.3</td>
<td>7.47</td>
<td>-15.83</td>
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<table>
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<tr>
<td><strong>US Potato Pesticide Use</strong></td>
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<td>Potatoes</td>
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<td></td>
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<td>Acres Planted $x 10^{6}$</td>
<td>1.2</td>
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<td>Herbicides-% Area Applied</td>
<td>79</td>
<td>91</td>
<td>12</td>
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<td>Pounds $x 10^{6}$</td>
<td>2.2</td>
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<td>Insecticides-% Area Applied</td>
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<td>Pounds $x 10^{6}$</td>
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<td>1.67</td>
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<td>Fungicides-% Area Applied</td>
<td>69</td>
<td>91</td>
<td>22</td>
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<td>Pounds $x 10^{6}$</td>
<td>2.7</td>
<td>7.5</td>
<td>5.1</td>
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<td>Other-% Area Applied</td>
<td>45</td>
<td>47</td>
<td>2</td>
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<td>Pounds $x 10^{6}$</td>
<td>29</td>
<td>75.4</td>
<td>46.4</td>
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<tr>
<td><strong>US Apple Pesticide Use</strong></td>
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<tr>
<td>Apple</td>
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<tr>
<td>Acres Planted $x 10^{6}$</td>
<td>0.35</td>
<td>0.31</td>
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<tr>
<td>Herbicides-% Area Applied</td>
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<td>0</td>
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<tr>
<td>Pounds $x 10^{6}$</td>
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<td>0.39</td>
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<td>Insecticides-% Area Applied</td>
<td>99</td>
<td>94</td>
<td>-5</td>
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<tr>
<td>Pounds $x 10^{6}$</td>
<td>12.7</td>
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<td>-3.4</td>
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<tr>
<td>Fungicides-% Area Applied</td>
<td>83</td>
<td>90</td>
<td>2</td>
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<td>Pounds $x 10^{6}$</td>
<td>4.7</td>
<td>4.9</td>
<td>0.2</td>
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**What Pesticide Use Statistics Can Tell Us**

- Trends in use of particular products
- Adoption of new products
- Trends in outbreaks of certain pests

**What Pesticide Use Statistics Cannot Tell Us**

- Nothing about hazard nor risk
- Nothing about implementation of IPM nor sustainable agricultural systems

**The Down Side of Pesticides**

- Worker exposure & poisoning
- Pest resistance
- Reduction of natural enemies
- Potential for adverse environmental health effects
- Potential for human health effects
Reconciliation
- Integrated Control Concept
- Integrated Pest Management
- Ecologically Based Pest Management
- Sustainable Agriculture

Pesticide Regulation
In the Beginning
- Pure Food & Drug Act (1906)
- Insecticide Act (1910)
- Prohibit Misbranding and Adulteration
- Health Protection
- Ensure Efficacious Product
- The adulteration standard placed the laws in conflict!!

Early Evolution of Pesticide Laws
- Pure Food & Drug Act (1906)
- Insecticide Act (1910)
- Federal Food, Drug & Cosmetic Act (FFDCA '38)
- Federal Insecticide Fungicide & Rodenticide Act (FIFRA '47)
- Residue Tolerances
- FDA
- Registration, Labeling
- USDA
- Safety Testing Not Mandatory!!

Putting Some Teeth into FFDCA
- Pure Food & Drug Act (1906)
- Federal Food, Drug & Cosmetic Act (FFDCA 1938)
- Miller Amendment (1954)
- Food Additives Act Delaney Amendment (1958)
- Residue Tolerances

New & Improved FFDCA
Tolerance before registration
- Manufacturer petitions for tolerance
  - Name & chemical composition
  - Application procedures
  - Safety data
  - Residue tests
  - Method for removing excess residue
  - Proposed tolerance
- Manufacturer obtains certificate of usefulness from USDA or exemption
- Food sold with residues above tolerance considered adulterated

New & Improved FFDCA
No Carcinogens
- Raw agricultural commodity vs. processed food
- If concentration of residues in processed food above raw ag. commodity
  - Then must obtain tolerance specifically for processed food
- If chemical caused cancer in lab rats, then no processed food allowed tolerance
  - Paradoxically, A-OK for raw commodity if benefits outweighed risk
Silent Spring Drives Environmental Concern

- Mrak Commission Report, 1969
  - Study of effects of pesticides on environment
- Pesticide regulation responsibilities removed from USDA to newly created EPA (1970)
- FEPCA (Federal Environmental Pesticide Control Act, 1972)
  - Manufacturer must demonstrate that a product could be used without "unreasonable adverse effects on the environment."

FEPCA

- Regrant had to show that a pesticide could perform its intended function without unreasonable adverse effects on the environment
  - Use in violation of product label becomes a crime
- Classification of Pesticides
  - Restricted Use
    - Pesticide could cause unreasonable adverse effects to environment or applicator if additional regulatory restrictions were not imposed
    - Must be certified to buy
      - Initiated training and certification programs by the states
    - General Use (no license required; available to public)

Shared Responsibilities But EPA In Charge

- FFDCA Amended (1954, 1958)
- FIFRA (1947)
- FEPCA (1972)
- Food Residues Monitoring (FDA)
- Eggs, Meat Residues (USDA)

Re-Registration

- FIFRA had historically intended that all products be reviewed periodically, i.e., re-registered
- FEPCA reiterated this goal (within four yr)
- Many amendments to FIFRA to extend the initial deadline under FEPCA
  - By 1988, 600 active ingredients required re-registration
  - Amended FIFRA in 1988 to new 1997 deadline

Re-Registration Rationale

- Only products registered prior to 1984 required re-assessment and re-registration
  - Perceived need to require newer tests under more modern testing and safety standards
  - Need for implementation of GLPs (Good Laboratory Practices Standards)
    - Systematic data tracking and auditing
    - Requires documentation of standard operating procedures, protocols, in-progress inspections, data & report audits

Re-Registration

- EPA updates and examines database to prioritize information needs
- Companies submit new information and/or conducts new studies to fill data gaps
- EPA can cancel product or require change in label language
  - Note that the product label is the law!!!
The Pesticide Label
It's the Law
- All registered active ingredients formulated into commercial products
  - All individual products must be registered, but registration not given until label developed and approved
- The label is the governing law
  - Identification of active ingredient and contents
  - Legal uses (crops, maybe specific pests)
  - Rates of application; application methods
  - Personal protective equipment
  - Restrictions on use (no drift; no application near water; sometimes region-restricted)
  - Directions for disposal

Paradox of Delaney Amendment
- No residues of animal carcinogens (zero tolerance) in processed food, but OK in raw food
  - EPA maneuvered around by using de minimis standard
    - 1 in 1,000,000 risk of additional cancer ok
- Advocacy groups sue to have Delaney strictly enforced
- Industry Concerns over implementation plans for Delaney Amendment following Federal court ruling for strict implementation
  - If processed commodity affected by Delaney, then so would be raw commodity

New Concerns About Pesticide Regulation
- Where are the children????
  - Pesticides in the Diets of Infants and Children
    - 1993 National Academy of Sciences report
    - Questioned adequacy of regulations to protect children
    - Never concluded that pesticides were unsafe or harming children

Birth of the Food Quality Protection Act (1996)
- Industry wanted Delaney Amendment repealed
- Advocacy groups wanted children protected and many pesticides scrutinized under a risk only perspective

Mandate of the FQPA
- Tolerances will be “safe,” i.e., “a reasonable certainty that no harm will result from aggregate exposure”
- All tolerances will be reassessed by 2006

Basis for the Tolerance
- Tolerances (legal limits for residues) had been based on dietary exposure
  - Represented a residue level somewhat above highest levels expected in field trials
  - Sum total of all tolerances for all registered uses adjusted for food consumption and body weight could not exceed Reference Dose (RfD)
    - Initial screening uses the Theoretical Maximum Residue Contribution (TMRC) concept (all residues at the tolerance level)
Determination of the Reference Dose (RfD = mg residue/kg body weight/day)
- The dose at which there is a reasonable certainty of no harm for either a single (acute) or daily lifetime (chronic) exposure
- Rat & dog toxicity tests used to determine a dose causing no effect
  • No observable effect level (NOEL)
  • NOAEL divided by a safety factor of 100 = RfD

Factors To Consider
- Infants & Children
- Threshold vs. Non-threshold Effect
- Endocrine Disruption
- Aggregate Exposure Assessment
- Cumulative Exposure Assessment

Aggregate Exposure
All exposures are aggregated together. The risk cup represents the maximum exposure.

The Shrinking RfD
- If enhanced susceptibility of children;
- If endocrine disruptor;
- If non-threshold,……
- THEN
  - Apply extra safety factor &
  - reduce the RfD

The Changing Size of the Risk Cup

Child Sensitivity--
A Double Whammy for the Risk Cup
- If fetal and newborn rats are more sensitive at a given dose than adult rats, then up to an extra 10-fold safety factor may be applied to the RfD
- The RfD divided by this FQPA Safety Factor is called the
  - Population Adjusted Dose (PAD)
Is It Safe Enough???

\[
\text{NOAEL} \quad 100 = \text{Reference Dose (RfD)}
\]

\[
\text{RfD} \quad 10 = \text{Population Adjusted Dose (PAD)}
\]

Overflowing FQPA Risk Cup

- What determines the size of the cup?
- How is the cup filled?
- If the cup overflows, EPA freaks, but is that really hazardous?

Secrets of the FQPA

- As written, the FQPA deals with consumer protection
  - Nothing is stated about worker and ecological protection
  - Risk based assessment
- However, the process of tolerance reassessment places all hazards on the table (by virtue of FEPCA!!!)
  - EPA issues a RED (Re-registration Eligibility Decision document)

Registration Eligibility Decision Documents (REDs)

- EPA’s analyses leading to a determination of eligibility for registration
- Input from
  - HED (Health Effects Division)
  - EFED (Ecological Fate & Effects Division)
- Chapters are typical risk assessment process
  - Hazard & Dose-Response Assessment
  - Dietary, Drinking Water, Residential & Worker Exposure
  - Nontarget Organism Exposure
  - Risk Characterization

The Cat Is Out of the Bag

- In late 1999, the NRDC (Natural Resources Defense Council) and several other environmental advocacy groups sued EPA claiming failure to properly implement the FQPA
  - The main issue was failure to consider cumulative exposure
- Consent Decree signed Spring, 2001
  - Provisions to ensure cumulative exposure assessment and publication of determinations
  - Provisions to include worker exposure and ecological effects

Caveats of Pesticide Risk Assessment

- The assessment of risk to consumers is now guided by the mandates of the FQPA
  - No benefits consideration (with one exception)
- The assessment of risk to workers and the environment is pretty much the same as before the FQPA
  - But, benefits of pesticide use can be considered
U.S. Pesticide Law 101

FIFRA (1947)  FIFRA (1947)
FFDCA (1938)  FFDCA (1938)
FEPCA (1972)  FEPCA (1972)
Risk Assessment  Risk Assessment
Labeling  Labeling
Tolerance ("MRL")  Tolerance ("MRL")
Registration  Registration


Consequences of the FQPA

- More transparency in EPA risk assessment policies and decision making
- Blazing new trails in risk assessment methodology
- OP insecticide uses being curtailed and even cancelled in urban sectors
- Label changes to protect workers; less often the environment
- Tolerance reductions