

History of US Food Regulation

Food Toxicology

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Learning Objectives

- Understand the historical context of US Food Law
- Discuss public outrage leading to the Meat Inspection Act 1906
- Review the circumstances leading up to the Pure Food and Drug Act 1906
- Review the incidents that catalyzed the Food Drug and Cosmetic Act 1938
- Survey the regulatory history of the Miller Pesticide Amendment and Food Additive and Color Additive Acts
- Examine the Delaney Clause and the later evolution of the Food Quality Protection Act of 1996
- Survey other US food regulatory agencies

Food Law - History

- Early Hebrews and Egyptians had laws governing handling of meat
- Greeks/Romans laws prohibiting watering-down of wine and short measures of grain and oils
- Merchants and apothecary guilds in Middle Ages to prevent adulteration of spices and drugs

Evolution of Food Laws

- Coincided with the industrial revolution
- Loss of control of food supply
- Move from ag environs to urban areas
- More need to transport, store, preserve, process and package
- More use of toxic chemicals
- More regulation needed

Regulatory Problems

- Two major problems
 - Toxic colors and preservatives
 - “Patent” quack medicines
- Medicines contained
 - Opium, morphine, heroin, cocaine w/o restrictions

- Some worthless medicines
 - Colored water as treatment for scurvy

US State Food Laws

- Massachusetts first in 1784
 - {any food sold not wholesome without buyer knowledge punishable by fine, imprisonment, standing in pillory - depending on severity}
- Over 200 state food laws passed in late 1800s

State Food Laws - Problems

- Some states no laws
- Some states lack of enforcement
- Adjoining states with conflicting laws
- Numerous variations in labeling
- National law was needed

Federal Food Law

- Harvey Washington Wiley
- Chemist - Purdue U
- 1883 - Chief, **B**ureau **O**f **C**hemistry, USDA
- Later became Food and Drug Administration

Harvey W. Wiley

- Exposed many different problem products - drugs and food
- Backed by popular journals
 - Colliers Weekly
 - Ladies Home Journal
 - Good Housekeeping
 - Published articles and cartoons
- Expanded BOC staff and capability

Harvey W. Wiley

- “Poison Squads” 1902-1904
- Local college students and BOC
- Took all meals at BOC
- Meals contained additives of concern
- Tested body fluids and looked for clinical toxicity

Poison Squads 1902-1904

- Boric acid / borates

- Salicylic acid / sulfites
- Sulfurous acid / sulfites
- Benzoic acid / benzoates
- Formaldehyde

Upton Sinclair: *The Jungle* - 1906

- Novel about meat processing industry
- Unsanitary conditions and practices for workers
- ‘Yuck’ factor → outrage

The Jungle by Upton Sinclair-1906

“There was never the least attention paid to what was cut up for sausage; there would come all the way back from Europe old sausage that had been rejected, and that was moldy and white - - it would be dosed with borax and glycerine, and dumped into the hoppers, and made over again for home consumption.”

The Jungle by Upton Sinclair-1906

“There would be meat that had tumbled out on the floor, in the dirt and sawdust, where the workers had tramped and spit uncounted billions of consumption germs. There would be meat stored in great piles in rooms; and the water from leaky roofs would drip over it, and thousands of rats would race about on it.”

The Jungle by Upton Sinclair-1906

“It was too dark in these storage places to see well, but a man could run his hand over these piles and sweep off handfuls of the dried dung of rats. These rats were nuisances, and the packers would put poison bread out for them, they would die, and then rats, bread, and meat would go into the hoppers together.”

Federal Meat Inspection Act 1906-1907

- Mandatory inspection of livestock before slaughter
- Mandatory postmortem inspection of every carcass

- Sanitary standards established for slaughterhouses and meat processing plants
- Authorized U.S. Department of Agriculture ongoing monitoring and inspection of slaughter and processing operations.

Pure Food and Drug Act 1906

- First comprehensive federal food law
- Considerable opposition from industry
- Many legal cases pointed out strengths and weakness in law
- Many good things
 - Needed work

Pure Food and Drug Act 1906 - Problems

- Food adulteration still common
- Few purity food standards
 - Food color, water, grass seed, pectin = fruit jam
- Limited analytical techniques
- Weak on food & drug safety
- Burden of proof on FDA/BOC

Elixir of Sulfanilamide, 1937

Raspberry flavored death

"Nobody but Almighty God and I can know what I have been through these past few days. I have been familiar with death in the years since I received my M.D. from Tulane University School of Medicine with the rest of my class of 1911. Covington County has been my home. I have practiced here for years. Any doctor who has practiced more than a quarter of a century has seen his share of death.

"But to realize that six human beings, all of them my patients, one of them my best friend, are dead because they took medicine that I prescribed for them innocently, and to realize that that medicine which I had used for years in such cases suddenly had become a deadly poison in its newest and most modern form, as recommended by a great and reputable pharmaceutical firm in Tennessee: well, that realization has given me such days and nights of mental and spiritual agony as I did not believe a human being could undergo and survive. I have known hours when death for me would be a welcome relief from this agony."

--Letter by Dr. A.S. Calhoun, October 22, 1937

Pure Food and Drug Act 1906 - Problems

- Several attempts to revise Act
- Strenuous industry objection
- 100 deaths from "Elixir Sulfanilamide"; other incidents

- Eventually led to the complete revision of the 1906 Act
- 1938 Food, Drug and Cosmetic Act

Food, Drug & Cosmetic Act 1938

- Included cosmetics, therapeutic devices
- Pre-market safety testing of drugs
- Toxic substances prohibited in foods unless unavoidable or required in processing
- Authority for factory inspections

Food, Drug & Cosmetic Act 1938

- Proof of fraud no longer required to stop false claims
 - Previously only the maker had to believe efficacy
- Safe tolerances were authorized for pesticide residues
- Standards were developed for many foods

Food Adulteration and Misbranding

- Products that are defective, unsafe, filthy or produced under unsanitary conditions
- Statements, designs or pictures that are false or misleading or fail to provide required label information

Problems of Enforcement

- Burden of proof still on FDA
- WWII created extra work
 - New drugs, new chemicals, new processing
- 1949 special committee formed to investigate “chemicals in food”
- Chaired by James T. Delaney, NY

Chemicals in Food Committee

- Developed 3 major amendments
 - Miller Pesticide Amendment 1954
 - Food Additive Amendment 1958
 - Color Additive Amendment 1960
- Shifted burden of proof of safety to industry
- Made unmanageable situation manageable for FDA

Amendments of FDCA

Miller Pesticide Amendment (1954)

- Authorized establishment of tolerances for pesticides on raw food commodities and some processed foods
- Pre-market safety, efficacy testing
- Allows risk vs. benefit evaluation
- FDA enforced tolerances

Food Additives Amendment - 1958

Color Additive Amendment - 1960

- Major changes in FDA approach to food safety of additives
- Mandatory pre-market testing for safety
- Shifted burden of proof of safety to industry
- Emphasized safety under specific conditions of use
- Generally recognized as safe, or *GRAS* substances
- No risk regulation

Amendments to FDCA

Food Additives Amendment 1958 - Color Additives Amendment 1960

- Covered sweeteners, preservatives, animal drug residues, cumulative pesticides, packaging / processing chemicals and colors
- Intentional and non-intentional additives
- Delaney Clause focused on carcinogens

Delaney Clause

- No chemical can be added to food or animal feed that has been shown to be a carcinogen by appropriate tests (animal studies)
- Zero tolerance/zero risk
- Dilemma for cumulative and non-cumulative pesticides
 - Sections 408 and 409

1959 Cranberry Incident

- Aminotriazole residues detected in cranberry products (Delaney Clause)
- Recall of cranberry products during Thanksgiving - Public impact!

Publication of Rachael Carson's "*Silent Spring*"

Publication of “*Silent Spring*”

- Silent Spring” published in 1962
- Written by Rachel Carson, a respected marine biologist (formerly USFWS)
- An expose of the damage to the environment from indiscriminate use of pesticides especially chlorinated pesticides

Impact of “*Silent Spring*”

- A plea for less harmful methods of pest control and a changed attitude toward nature
 - We must abandon the idea of “conquering” nature and seek instead to work with its processes
- Book quickly became a best-seller
 - Chemical and pesticide industry alarmed by book’s success and attacked it
- Congressional hearings, Presidential Scientific Advisory Committee study
- Unreasonable fear of residues?

Impact of “*Silent Spring*”

Key points:

- A technology that seems harmless may have serious long-term effects on the environment
- Actions of humans have become the dominant environmental influence on the health and well-being of the planet
- Birth of environmental movement in America can be traced to the publication of Silent Spring
- (1992) Picked as the “most influential book” published in past 50 years

Template for Challenge

- From the 1960s until the mid-1990s, the Delaney Clause combined with the growing cancer-phobia created problems for regulating chemical residues in food.

Delaney Clause - Problems

- Zero risk legislation - no residues
- Analytical detection of chemicals increased markedly - ppb or lower
- Not sure how to interpret

- One-hit, one-molecule theory of cancer
- No concept of cancer threshold

Delaney Clause - Problems

- Pesticides not food additives on raw products
- Pesticides become food additives if they concentrate in processed foods
- Different regulatory guidelines
 - Section 408 vs 409 of FFDCA

Food Quality Protection Act 1996

- Abolished Delaney Clause for pesticides
- Negligible risk (1 in a million) for carcinogens, *de minimus*
- No residue in edible portion
- 10x safety factor for children
- Risk cup

Federal Food, Drug and Cosmetic Act

- Intended to insure that foods are pure and wholesome, safe to eat and produced under sanitary conditions
- That drugs and medical devices are safe and effective for their intended uses
- That cosmetics are safe and made from appropriate ingredients
- All labeling and packaging is truthful, informative and not deceptive

Federal Food, Drug and Cosmetic Act

- Complicated law
- Product of many forces and legal compromises
- Fundamentals are simple and practical
- Reasonable certainty of no harm inclusive of adulteration and misbranding

Food and Drug Administration History

- 1862 - Division of Chemistry-USDA
- 1883 - Bureau of Chemistry - USDA
- 1927 - Food, Drug and Insecticide Administration - USDA
- 1931 - Food and Drug Administration - USDA

FDA History

- 1940 - FDA transferred to Federal Security Agency which in 1953 became Department of Health, Education and Welfare (DHEW)
- 1979 - DHEW became Department of Health and Human Services - DHHS

FDA History

- 1970 - Center for Food Safety and Applied Nutrition (CFSAN)
 - Responsible for all policy, science and enforcement relating to human food
- Bureau of Veterinary Medicine (1965)
Center for Veterinary Medicine (1984)
 - Impact of animal feed and drugs on human food
 - Evaluation, approval and surveillance of animal drugs, food additives, feed ingredients, and marketed animal devices.

Other Regulatory Agencies - Food

- USDA (Department of Agriculture)
- USEPA (Environmental Protection Agency)
- NIOSH (National Institute for Occupational Safety & Health)
- CPSA (Consumer Product Safety Administration)

US Department of Agriculture

- Food Safety Inspection Service - FSIS
 - Meat, poultry and eggs
- Same philosophy as FDA
- Should combine?

Environmental Protection Agency - 1970

- Intended to streamline and strengthen regulation of pesticides
- Consolidated responsibilities of several agencies into EPA
- Intent to protect health and environment related to air, water and soil pollution with risk - benefit considerations

Environmental Protection Agency

- Federal Insecticide, Fungicide and Rodenticide Act - FIFRA - 1947/1972
- Toxic Substances Control Act - TSCA - 1976

- Resources Conservation and Recovery Act - RCRA - 1976

FIFRA

- Premarket testing of pesticides
 - Efficacy and safety
 - Environmental impact
- Establish testing procedures
 - General and special
- Establish tolerances
- Post-market environmental surveillance monitoring

FIFRA

- Registration of pesticide-producing facilities
- Classification of pesticides (restricted vs. general)
- Banning pesticides
- Risk - benefit evaluation

TSCA

- Intended to bring industrial chemicals under oversight of EPA
- Not to regulate all chemicals, only those that pose unreasonable risk to health and environment
- Prevent reoccurrence of industrial exposures and accidents (asbestos, MeHg, vinyl chloride, PCB)

TSCA

- Pre-manufacture testing of new chemicals or new uses of old chemicals (not pesticides or food additives, ATF)
- Covers manufacture, use, distribution and disposal of any toxic substance
- Risk/benefit analysis

RCRA

- Controls generation, shipping, storage, treatment, record keeping related to hazardous waste
- Identifies hazardous wastes
- Sets guidelines for testing hazardous wastes
- Designs HW storage facilities

Other EPA Programs

- Water Pollution Control Act/Clean Water Act
- Safe Drinking Water Act
- Clean Air Act

National Institute for Occupational Safety and Health - NIOSH

- Health standards in the workplace
- Includes toxic chemicals, stress, noise
- Train personnel, educate workers
- Action is all retrospect
 - Must prove problem exists

Consumer Product Safety Administration

- Any product for use, consumption or enjoyment in a recreational or other manner used in and around personal residences or school
- Protect public from risk/injury from consumer products
- Regulates mostly by labeling

Consumer Product Safety Commission

- Sets standards and evaluates safety of consumer products
 - flammable clothing, childproof lids, household chemicals
- Excludes items covered by other agencies (pesticides, alcohol, drugs)
- Lacks pre-market authority