

BIO/FOR 430/530: Biotechnologies: Agriculture, Food & Resources Issues

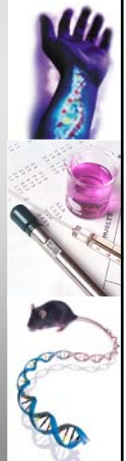
Ethics in Toxicology &
the Precautionary
Principle

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Key Concepts

- Be able to discuss examples of historical violations of human rights for biomedical testing & laws that were influenced by these lessons.
- Be familiar with the precautionary principle and the detailed example of how this principle interfaces with PBDEs.



Nuremberg



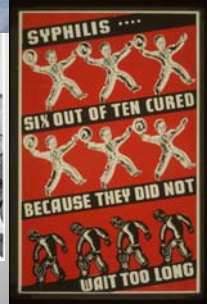
Nuremberg Code

In 1947, judges delivered their verdict against Karl Brandt and several other Nazis convicted of illegal medical experiments. Out of this trial came the Nuremberg Code, a set of research ethics and principles for human experimentation.

The principles include (in part):

- voluntary consent of the human subject is essential
- experiments should yield fruitful results good for society
- experiments should avoid all unnecessary physical and mental suffering
- during the experiment, the subject can end their involvement at any point, for any reason

Tuskegee Airmen



Belmont Report

Issued in 1979, this report focused on boundaries in human research, basic ethical principles and applications, in part due to the Tuskegee tragedy.



Respect for Persons: individuals should be treated as autonomous; people with diminished autonomy are entitled to protection (What are examples?)

Beneficence: do not harm subjects and maximize possible benefits, while minimizing possible risks

Justice: fairness in distribution of benefits or bearing costs

National Research Act

In 1974, the National Research Act was signed into law. This law created a commission to protect human subjects used in biomedical and behavioral research

The National Research Act considers:

- boundaries between biomedical & behavioral research
- risk-benefit assessment to determine appropriateness of research involving human subjects
- appropriate guidelines for human subject selection
- nature and definition of informed consent

Declaration of Helsinki

Originally adopted in 1964, the World Medical Association developed ethical principles for the medical community regarding human experimentation. This is not a legally binding document, but is considered the cornerstone of human research ethics.

In a 1975 revision, the concept of oversight by independent committees spawned the system of Institutional Review Boards (IRB) in U.S. university and medical systems. The regulations that govern IRBs are known as the "Common Rule."

Ethics in Toxicology

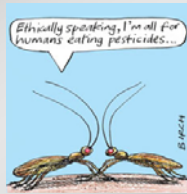
Conduct work objectively and with integrity.

Give due consideration to the ethical, legal, social and policy implications of their research & communications.

Be a thoughtful advocate for human, animal & environmental health.

Recognize a duty to communicate information concerning health, safety, and toxicity in a timely and responsible manner, with due regard for the significance and credibility of the available data.

Society of Toxicology, modified



Precautionary Principle

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken, even if some cause and effect relationships are not fully established scientifically.”

Wingspread Conference, 1998.

A Small Dose of Toxicology, modified

Precautionary Principle components

- Taking preventive action in the face of uncertainty
- Shifting the burden of proof/responsibility to the proponents of an activity
- Exploring a wide range of alternatives to possibly harmful actions
- Increasing public participation in decision making

Wingspread Conference, 1998.

A Small Dose of Toxicology, modified

Example of Precautionary Principle

Changes in purchase policy to less toxic cleaners & paints

Integrated pest management

Banning/phase out chemicals in consumer products

Approach to decision making

Government Policy

Example: Multnomah County, OR Resolution, 2004

A Small Dose of Toxicology, modified

Polybrominated Diphenyl Ethers (PBDEs)

Fire kills more than 3,000/year
 Injures more than 20,000
 \$11 billion in damage
 Flame retardants
 Used in many consumer products



A Small Dose of Toxicology, modified

PBDE Use

Millions of lbs used/year (2001)

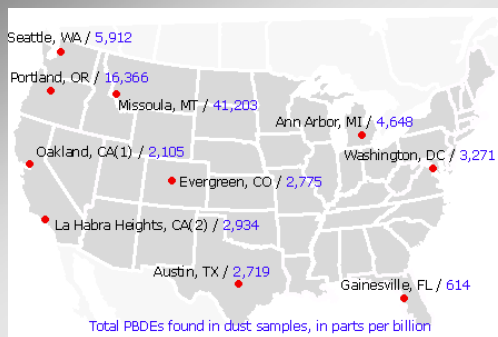
PBDEs	Americas	Europe	Asia
Deca-	53.9	16.7	50.6
Octa-	3.3	1.3	3.3
Penta-	15.6	0.33	0.33
Total –	72.8	18.4	54.2

Total world-wide 148.3 M lbs/yr

Data from BSEF (2001)

A Small Dose of Toxicology, modified

PBDEs in House Dust (ppb)



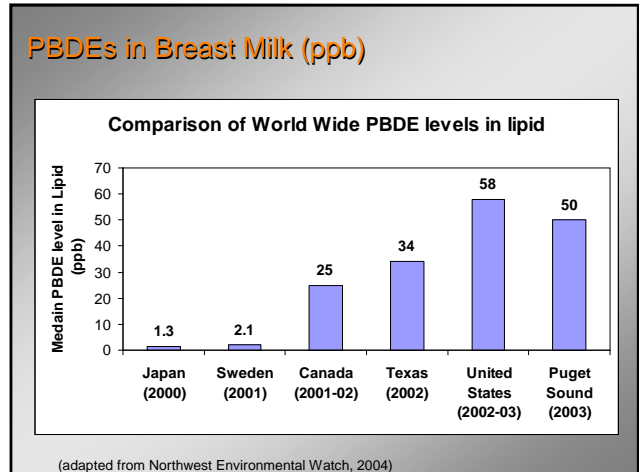
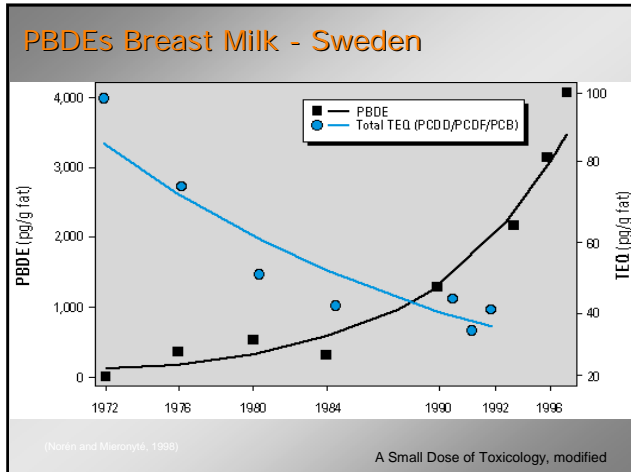
From EWG - Toxic Fire Retardants Contaminate American Homes - <http://www.ewg.org/reports/inthedust/summary.php>

Bioavailability & occurrence of PBDEs

Detected in animal tissue
 -salmon, killer whales, raptors
 -human breast milk and blood

Found in the environment
 -sewage sludge
 -house dust





Toxicology of PBDEs

Similar to PCBs (Polychlorinated biphenyls)
 PBT (Persistent Bioaccumulative Toxicant)
 No human data
 Animals studies indicate

- Effects thyroid hormone levels
- Neurobehavioral toxicity
 - Effects development - alters Behavior
 - Impairs memory and learning
- Delays sexual development

A Small Dose of Toxicology, modified

PBDEs and uncertainty

PBDEs migrate out of products
 Detected in the environment & animal tissue
 Detected in house dust & mother's breast milk
 PCBs and PBDEs share similar structure
 PBDEs may have health effects at low doses
 Deca- can break down and is metabolized

PBDE Regulation

By the end of 2004, the U.S. EPA and a U.S. chemical manufacturer, agreed to phase out Penta and Octa-PBDE formulations. The penta and octa formulations are most likely to bioaccumulate. Deca-PBDE will continue to be manufactured in the U.S., especially in consumer electronics (80% of the chemical's commercial use).

The European Union has banned Penta and Octa-PBDE as well. A Deca-PBDE phase-out will be implemented. This approach to PBDEs is influenced by REACH.

Europe & Precautionary Principle

REACH -- Registration, Evaluation and Authorization of Chemicals

The two most important aims are: 1) to improve protection of human health and the environment from the hazards of chemicals and 2) to enhance the competitiveness of the EU chemicals industry.

REACH is a Precautionary approach that seeks to reduce uncertainty in our knowledge of chemical effects and behavior.

Key Concepts

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- Why are ethical principles so important in the field of toxicology?
- If you were a regulator, how would you apply the precautionary principle to PBDEs.
- What role do benefits have when considering regulation under the precautionary principle framework?