

Biotechnology - The Big Picture

Tobi Jones, Ph.D.

California Department of Pesticide Regulation

Biotechnology: The Early Days

- Early 1970's: Emergence of recombinant DNA technology
- 1978: NIH guidelines prohibit environmental release of rDNA organisms without approval
- 1983: UC Berkeley field test of Ice Minus approved
- 1983-1987: Lawsuits/environmental analysis delay field test
- 1983-1984: Congressional hearings on government preparedness

Coordinated Framework for the Regulation of Biotechnology

- 1984: White House appoints committee under Office of Science and Technology Policy
- Framework published in 1986
- Outlines agency roles, responsibilities
- Framework still used today by federal agencies

Coordinated Framework Principles

- Techniques of biotechnology are not inherently risky
- Regulate products, not process
- Use existing laws
- National Academy of Sciences agreed on risk issues

Federal Regulatory Oversight - USDA

- Jurisdiction: Plant pests, plants, veterinary biologics
- Laws: Federal Plant Pest Act
- Activity: Permits or notification, non-regulated status determination

Federal Regulatory Oversight – FDA

- Jurisdiction: Food, feed, food additives, veterinary drugs, human drugs, medical devices
- Laws: Federal Food Drug and Cosmetic Act
- Activity: Novel foods policy; consultation; food additive petition; labeling as needed

Federal Regulatory Oversight - EPA

- Jurisdiction: Microbial and plant pesticides, new uses of existing pesticides, novel microorganisms
- Laws: Federal Insecticide Fungicide, and Rodenticide Act; Federal Food, Drug and Cosmetic Act; Toxic Substances Control Act
- Activity: Registration or exemption (FIFRA); tolerance/exemption (FFDCA); reporting/exemption/field tests (TSCA)

Plant Pesticides

- EPA proposed rules in 1994
- Covers *genes and gene products* to protect plants against pests
- Plants are not subject of regulation
- Definition is broad; proposed rule contains FIFRA 25(b) exemptions

Herbicide Tolerant Plants

- EPA regulating the herbicide, not the plant
- Not subject to plant pesticide rule
- May require new tolerances, label