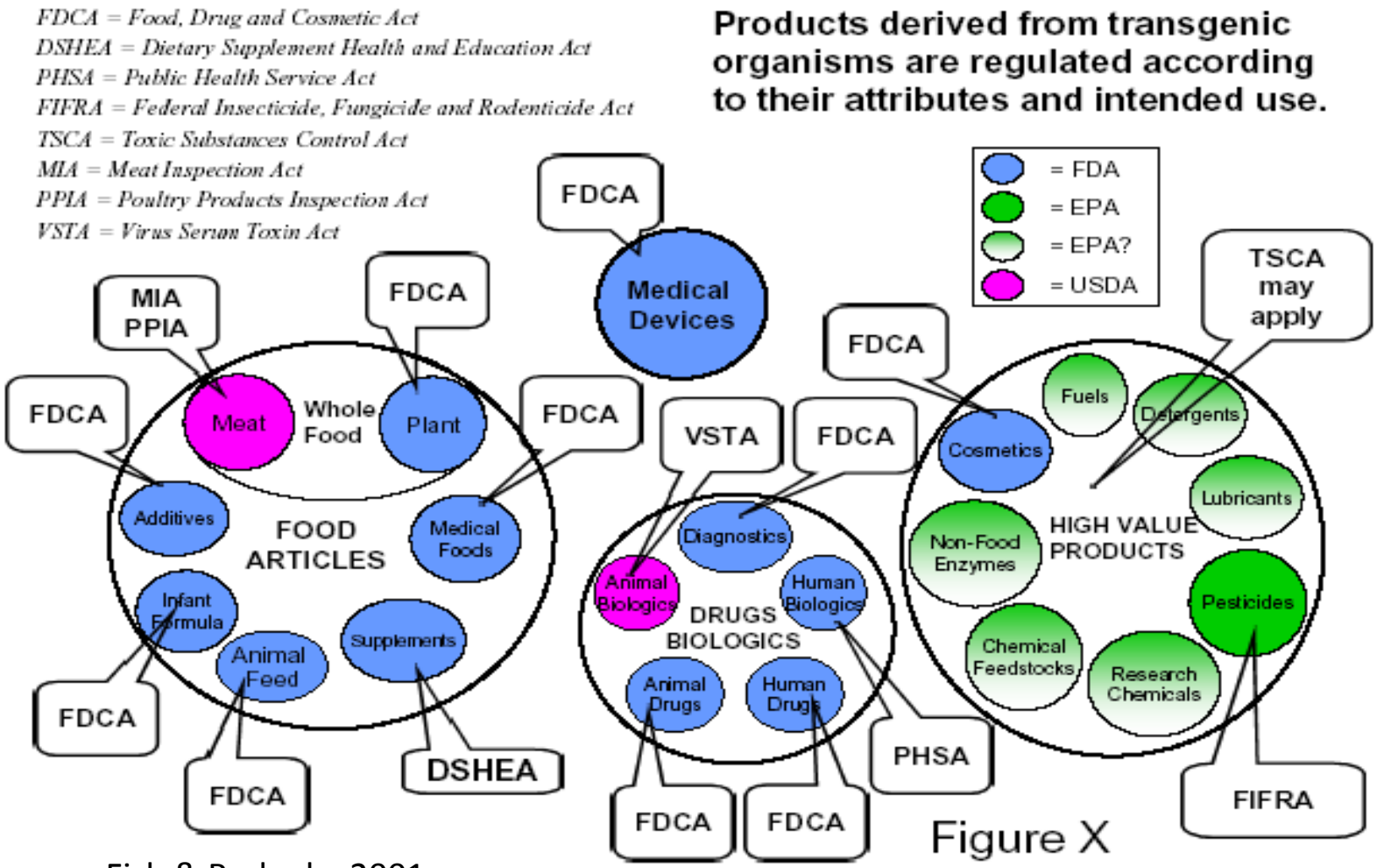
Regulation and Regulatory Gaps in GMO Agriculture

Gregory N. Mandel

Peter J. Liacouras Professor of Law & Associate Dean for Research
Temple University School of Law

TEMPLE UNIVERSITY®
Beasley School of Law

U.S. GMO Regulation



Source: Fish & Rudenko 2001

Coordinated Framework for the Regulation of Biotechnology (1986)

Basic Principles:

- Comprehensive regulatory policy for biotechnology
- Biotechnology process is not inherently risky
- Regulate products, not process
- Existing laws and regulations are adequate
- Address gaps through agency coordination

GMO Agriculture

Types of GMO Agricultural Products	
Food Crops (coybeans, corn, cotton)	Production Crops (industrial chems, pharma.)
Fish (GM salmon)	Livestock Products (therapeutic proteins)
Livestock (GM pigs; hens)	Insect Products (honey, silk)
Artificial Flavor	

Food & Drug Administration (FDA)

- Responsible for food safety for food products except meat and poultry
- GM crops do not require FDA approval prior to commercialization (though often voluntary)
- There is no labeling of GM food
- Asserts authority over GM livestock and fish as "drugs" (based on DNA insert being a "new animal drug")

Environmental Protection Agency (EPA)

- Somewhat limited role concerning GM agriculture
- Regulatory authority primarily based on pesticide use or pesticide residue in food
- Primary authority for GM pest-protected plants, which (unlike other GM crops) require authorization prior to commercialization
- No authority over GM fish, livestock, insects

Department of Agriculture (USDA)

- Regulatory authority is based on protection of American agriculture from GM products
- Crops: Animal and Plant Health Inspection Service (APHIS)--Approval required before growth (generally through notification process)
- Livestock: Food Safety Inspection Service (FSIS)--no products commercialized yet
- Lacks regulatory authority over GM agriculture involving only gene deletion

U.S. GMO Agriculture Regulation

USE	STATUTE	AGENCY
Food and food additives **Meat, poultry, egg products** **Pesticide residues**	**FFDCA** **FMIA, PPIA, EPIA, FFDCA** **FFDCA**	**FDA** **FSIS / CVM** **EPA**
Production of pharmaceuticals **Human drugs** **Human biologics** **Animal drugs** **Animal biologics**	 **FFDCA** **PHS Act, FFDCA** **FFDCA** **AQL, VSTA**	 **FDA** **FDA** **FDA** **APHIS**
Production of pesticidal substances in plants	**FIFRA** **PPA**	**EPA** **APHIS**
Production of plant herbicide-tolerance **Herbicide usage on plants**	**PPA** **FIFRA**	**APHIS** **EPA**
Biocontrol of plants	**PPA** **FIFRA**	**APHIS** **EPA**
Biocontrol of plant pests	**PPA** **FIFRA**	**APHIS** **EPA**
Biomedical research on animals	**AWA** **HREA**	**APHIS** **NIH**

GMO Agriculture Regulation Today

- Coordinated Framework produced a patchwork of regulation that remains the principal policy today
- Regulatory system has functioned relatively well for first generation GM agriculture
- Some regulatory gaps, inconsistencies, redundancies, and agencies regulating outside their areas of expertise
- Significant regulatory challenges for next-generation GM agriculture products