Technology and Science-Directed Regulation:

Product-Based vs. Process-Based Regulation

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Goal …

Briefly discuss the underlying approaches for the U.S. “product-based” vs. “process-based” regulation, with focus on GE animals

Overview

- Coordinated Framework for Regulation of Biotechnology (1986)
- “Product” vs. “Process” based regulation

Coordinated Framework for Regulation of Biotechnology (1986)

- Overarching policy document from the Office of Science and Technology Policy (OSTP), across applicable agencies in the US Government (USG)

- Announced the USG policy on regulation of products of biotechnology

- Agencies (e.g., FDA, EPA, USDA, NIH) will seek to operate in an integrated and coordinated fashion

Coordinated Framework

USG role relative to products of biotechnology:

- The risks of GE organisms (animals) not fundamentally different from those posed by non-GE organisms with similar traits (basis for “product-based regulation”)
- Existing laws provide adequate authority
- Regulation should be science based and conducted on a case-by-case basis

FDA Policy Statement, Coordinated Framework

- “FDA Regulation must be based on rational and scientific evaluation of products and not on *a priori* assumptions of certain processes.”

- “ …is conducted in the light of the intended use of the product on a case-by-case basis.”

Regulatory Documents

- Statute
  - Federal Food, Drug, and Cosmetic Act (FD&C Act)
  - National Environmental Policy Act (NEPA)
- Regulations
  - Code of Federal Regulations (CFR; 21 CFR 511, 514)
  - Implements statute; has force of law
- Guidance for Industry (GFI)
  - FDA's current thinking; advice
  - GFI 187
    http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf

FDA regulates articles, not processes

FD&C Act defines drugs as articles intended to

- Diagnose, cure, mitigate, treat, or prevent disease
- Affect the structure or any function of the body of man or other animals

“Products”

- Applies to those regulated articles, the GE animals produced using the regulated article, and products derived from those animals …

- GE animals, regardless of intended use:
  - Enhanced growth/efficiency
  - Disease resistance
  - Meat/milk quality/composition
  - Nutrient utilization
  - Biomedical/industrial uses

In contrast …

- Process-based approaches generally operate from perspective that a given technology presents risks different (e.g., nature, severity) compared to techniques used to produce more “conventional” counterparts

Summary

- FD&C Act, Coordinated Framework as basis for product-based regulation
- FDA & USG – risks of GE vs. non-GE not fundamentally different
- As such, existing statutory/regulatory frameworks provide adequate authority for product-based regulation

Conclusion: USG regulates products of biotechnology, based on “regulatory triggers” in the FD&C Act

Thank you

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