

# EU and U.S. Food Regulatory Systems Compared: Is There Hope for Harmonization?

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# Introduction

- The food marketplace has become increasingly global
- Historically, food has been regulated differently in the United States than throughout the European Union
- With the emergence of private standards in the EU – and continuing trade competition and disputes – the short term promises more complexity and conflict
- As food companies become even more global – and consumers on both sides of the Atlantic focus on diet and health – objectives of international regulation become compatible
- Regulators and industry have shared incentives to adopt and implement harmonized schemes

# The U.S. Regulatory System

- Food is primarily regulated by two federal agencies and 50 states
- FDA has jurisdiction over all food
- USDA has jurisdiction over products containing more than “small amounts” of meat and poultry
- Although state regulation may be preempted by federal law, states have some autonomy and concurrent jurisdiction
- The differences in statutory authority and regulatory philosophy of the federal and state agencies with jurisdiction sometimes results in inconsistent regulation
  - even within U.S. borders

# FDA Regulatory Focus

- FDA regulates all food/feed except meat and poultry
- Deriving its authority from the Federal Food, Drug, and Cosmetic Act
  - Goal is to prevent distribution of adulterated or misbranded food
- FDA's focus is on food safety and proper labeling to ensure that consumers are not misled as to product composition or attributes
- Imported products must comply with regulations applicable to products produced domestically

# USDA Regulatory Focus

- USDA's Food Safety and Inspection Service administers Federal Meat Inspection Act and Poultry Products Inspection Act
  - "Continuous inspection," prior approval of labels, enforcement mechanism
  - Prohibits production, processing, and introduction into interstate commerce of adulterated or misbranded meat or poultry
- Focus is on food safety and labeling to prevent consumers from being misled
- Inspection systems of countries seeking to export to U.S. (and plants) must be approved by USDA
- Imported products must comply with the same requirements applicable to domestic products

# The Federal Trade Commission, the States, and Industry Self- Regulation

- The Federal Trade Commission regulates food advertising and challenges ads that are false or deceptive
- State Attorneys General can be quite aggressive in challenging misleading promotional materials under state consumer protection laws
- Industry monitors competitor labeling and advertising and often seeks challenge and resolution through the National Advertising Division of the Council of Better Business Bureaus

# Prevailing Legal Standards

- Products must be “safe”
  - “a reasonable certainty of no harm”
- Labeling may not be “false or misleading”
  - Historically, to the “incredulous” and “unthinking” consumer
  - Current trend, to the “reasonable” consumer
- Focus of regulation on safety and labeling
- USDA approach: must be satisfied that product is not adulterated or misbranded
  - Continuous inspection
  - Prior approval
- FDA approach: products must comply with the law
  - Random inspection
  - Enforcement in the marketplace

# Recent Initiatives

- Increased focus on relationship between diet and health
  - Health and nutrient content claims
  - MyPyramid/Dietary Guidelines
  - Calories
- FDA and USDA considering modernizing food standards of identity
  - Key to product innovation
- Food safety focus on sanitation
  - FDA updating Good Manufacturing Practices
- Some of the same issues are “hot topics” in EU – approached from a different perspective



# History of EU Food Regulatory System

- Originated with EC Treaty (1957)
- After World War II
- Goals:
  - Ensure availability of supply
  - Increase productivity
  - Stabilize markets
  - Reasonable prices
  - Fair standard of living for farmers

# EU Single Market Programme

- Adopted in 1992
- Goal:
  - free movement of goods (including food products)
  - again primarily economic driving force

# Evolution of EU System

Food chain has changed dramatically, particularly since early 1990s:

- Rise in trade across national borders
- Increasingly complex food processing and distribution network
- Emergence of new scientific techniques

# EU Regulatory Approach

However:

- Regulatory policy did not develop at same speed
- Food safety crises show weaknesses in system, and:

EU Member States have had to comply with prohibitions on restrictions on trade in goods, except where justified on grounds of *“the protection of health and life of humans, animals or plants”* (principle enshrined in EC Treaty)

# European Food Safety Authority

- In order to restore Consumer Confidence
  - European Food Safety Authority (EFSA)
    - European Parliament and Council Regulation 178/2002
  - Consumer dialogue
  - Review food safety legislation

# Principles of EU Food Law

- Protection of Health
- Protection of Consumer Interests
  - Informed choice
  - No misleading information
- Risk Analysis
  - Risk Assessment and Management
- Precautionary Principle
  - Permits provisional measures to be taken pending further scientific assessment

# Requirements of EU Food Law

- Food/Feed Safety requirements
- Responsibilities on food/feed business operators
- Traceability

# Internal Challenges for the EU

- EFSA: internal (EU) focus *vs.* “external” pressure
- EU Enlargement
- Focus of Common Agricultural Policy



# External Challenges

- WTO (and other) international obligations and bilateral agreements
  - Is no longer just about “traditional” matters (tariff quotas; tariffs)
  - Market access increasingly determined by domestic regulations and other “behind the border” issues
- Need for improved regulatory framework and scientific cooperation, not only between EU and U.S., but also:
  - Between EU Member States & European Commission/ EFSA
  - At international level, including developing countries (WTO, Codex, Cartagena Protocol, OECD, OIE, G8, IPPC, *etc.*)

# Effects of Globalization on Food Trade

- Erosion of distinction between domestic and international concerns
- Increased economic integration – more opportunities for conflict
- Tension between
  - civil society and governments
  - developed and developing countries

# International Implications

- EU food crises/issues take on an international character
  - BSE
  - FMD
  - Biotech
  - *Lysteria*
  - Dioxin
  - Acrylamide
- EU standard-setting from “farm to table” has an international impact
  - Traceability
  - Labeling
  - Precautionary principle

# EU and U.S. Perception of Each Others Systems

- U.S. thinks EU system is
  - Parochial
  - Protectionist
  - Precautionary
  - Political
- EU thinks U.S. system is
  - Protectionist and political
  - Presumptuous
    - Works fine for U.S. but EU requires different framework
  - Not the only manner by which to regulate
    - Food is cultural in EU
    - Different risk perception

# In Reality

- Objectives of U.S. and EU food law are the same
  - Food safety and meaningful labeling
- Fundamental differences are cultural and historical
- The difference with the most significant real-world impact is the perception of risk
- As a result
  - Continuing cause for conflict
  - Hope for harmonization

# EU and U.S. Systems Compared

Perception of Risk is key to understanding different regulatory approaches

- Beef hormones
- Biotech
- BSE
- Traceability

However, there is also room for convergence/harmonization

- Bioterrorism
- Health Claims
- Obesity and Health

# The Future

- Increased communication between EU-U.S. regulators and stakeholders
  - before proposals are published
  - to assess outside border ramifications
- More active cooperation through international forums
  - in particular Codex
- Convergence on risk assessment between EU and U.S. should be the goal
  - Science should drive regulatory policy
  - it is the least political approach

# Summary

- Historically, regulation of food by U.S. and EU has been different – at least in effect
- But the differences are notwithstanding compatible objectives
- The differences are cultural and political, but also/largely the result of risk perception
- Although continued conflict is likely, marketplace globalization and common concerns offer hope for harmonization