Impact of Science on Development of Global Food Standards

Food & Agricultural Products Center
Oklahoma State University
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Regulatory Issues Overview

Regulators and Regulations
US Regulatory Agencies
US Regulatory Environment
Global Regulatory Considerations
What about Science and RiskBased Regulation?





Key US Food Legislation

Pure Food and Drug Act (1906)

Meat and Poultry Inspection Acts (1907+)

Federal Trade Commission Act (1914)

Food Drug and Cosmetic Act (1938+)

Fair Packaging and Labeling Act (1966)

Bioterrorism Act (2002)

Food Allergen Labeling and Consumer Protection Act (2004)

Food Safety Modernization Act (2011)--prevention



Pure Food and Drug Act

Addressed adulterated food by USDA

- If quality lowered or injuriously affected by mixing or packing the product
 - Did not establish explicit standards
 - Difficult to enforce; No real regulation of food
 - Criminal sanctions; seizure authority

Congress authorized amendments to strengthen the Act



Food Drug and Cosmetic Act Amendments

Amendments- to increase consumer protection, extend coverage of the Act, and enlarge FDA authority over particular products

- 1968 Animal Drug Amendments
- 1976 Vitamin and Minerals Amendment
- 1980 Infant Formula Amendment
- 1986 Interstate Sale of Confections w/Alcohol
- 1990 Nutrition Labeling and Education Act
- 1994 Dietary Supplement Health and Education Act
- 2004 Food Allergen Labeling and Consumer Protection Act



US Food Safety Policy Metamorphisis: Imagine Cement Mix in Your Milk

- Safety Mandate
 — Federal Food Drug and Cosmetic
 Act (recent Food Safety Modernization Act)
- Food Adulteration
 - Intentional- economic
 - Accidental- commingling on processing line
- Food Inspection- Amendments for meat, poultry
- Food Standards- USDA and international
- Food Labeling-FDA, USDA/FSIS and international



Key US Food Regulatory Agencies

USDHHS- Food and Drug Administration
USDA- Food Safety and Inspection Service
US Department of Commerce
Consumer Product Safety Commission
Federal Trade Commission
Environmental Protection Agency



What is the Role of Regulators

Watch dog

Policeman

Rules maker

Enforcer

Regulators do not set policy



Regulatory Imperatives

US Transparency in the Administration (2010)

EFSA Transparency Initiative (2013)

- Increase understanding
- Strengthen scrutiny
- Build confidence
- Open meetings of scientific committees and panel meetings

Generally Recognized as Safe (GRAS) Program



New Issues with Food Ingredients

Generally Recognized as Safe

- Food additives
- Food ingredients
- New technologies

What is GRAS: History of Use and Recognition

- PEW study: Question regulatory imperatives and processes
 - Standard of assessment for food
 - Fundamental to assessment
 — equivalence, substantial equivalence and compositional comparison
 - Who says its safe
 - FDA role



Food Safety Interests

Food Production and Processing

- Canning, freezing
- Food additives and ingredients
- Genetic engineering
- Food Safety
- "Don't fiddle with my food"

FDA: The food industry has responsibility for product safety, nutritional content and claims



Food Technology and Ingredients

- Preservation
- Packaging
- Food Ingredients- Ingredient Technology
- Food Safety
 - Extend shelf life, reduce water availability
 - Anti-microbials- and films, contact surfaces
- Nutritional Attributes
 - Fortification
 - Enrichment
 - Reduced fat
 - Zero trans fat
- Health Benefits of Food Additives and Ingredients



Global Concerns for Food Additives

- Food Additive Function
 - Safety Imperative
 - Technology Opportunities
- Food Additive Benefits
- Consumer Interest
- Food Labels- and Claims
- Interest in Regulatory Oversight



In Food We Trust: Issues of food integrity

US specific information

- Level of trust in the food industry is diminishing
- Food industry responsible for non-communicable disease
- ...and other ailments that plague society!
- Industry support for research and communication is suspect

And so...we (industry) react...

- trans fat reduction

 tropical oils
- high fructose corn syrup
- Sodium
- Sugar
- Gluten
- Allergens- and thresholds



Its All About Consumer Perception

Little is known/understood by consumers

2012 Edelman Trust Barometer

- 25 countries; 30,000 consumers
- 72% swing respondents
- Preferred sources of information
 - Trusters- news, TV, radio, magazines
 - Non-trusters- on-line search engines; 'people like myself'

What they support:

- High quality and services
- Listening to customers
- Treating employees well
- Putting customers first
- Ethical business practices



Communication about food

What they ask



Communication about food

What they ask: What we say



Communication about food

What they ask: What we say

They ask 'what'.. and we reply 'science,' and 'safe'

Role of media- Dr. Ivan Oransky

- Media calls and you always say the same thing
- Social media and blogs
- Expert voices
- People like me



Edelman 2012 Food to Fork Survey

US consumers

55% think US food system is on the wrong track

Three key areas where consumer expectations could increase trust:

- Product portfolio
- Transparency
- Shared value
- >75% want nutrition information that's easy to use
- >70% want to know where the food comes from
- >65% want to know how the food was processed
- >86% believe businesses should place equal weight on societal issues



So what are we choosing to eat

MSI (2012) study of consumers

- >80% adults making effort to eat 'fresh' instead of processed
- **≻60%** avoid food with chemical additives/preservatives
- >52% making changes in food choice for food safety

Technomics (2011): Over 70% think fresh is healthier

- >70%- fresh
- **≻60%-** prepared that day
- **≻50%-** made from scratch; and never frozen



International Trade

Move to considerations about global trade

Consider the 'politics' of food trade



US Labeling Policy Regarding Products of Biotechnology

US food labeling policy for foods derived from modern biotechnology is the same as the policy for packaged foods

Mandatory labeling elements exist

Voluntary labeling information (including claims) must be truthful and not misleading; and must be verifiable

- verification through documentation, certification, analysis
- not misleading either through words used or comparisons made

If a food producer/manufacturer wanted to label foods as to the fact that they were produced using genetic modification, it could do so now under existing FDA labeling policy that includes mandatory and voluntary elements.



Labels Can Get Messy: How Much Information is Enough?

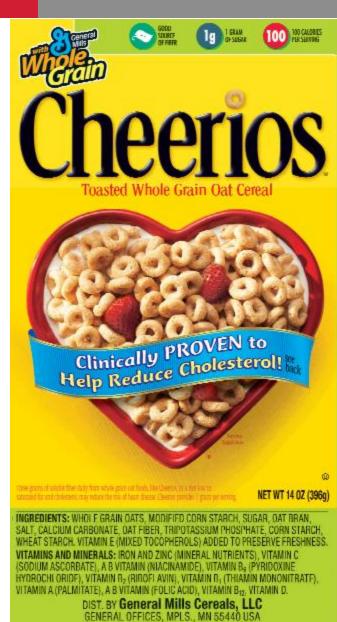




US Requirements for Prepackaged Food Labeling (nonmeat)







© 2007 General Mills

May be mfg. under U.S. Pat. Nos.: 5,433,490; 5,523,109; 7,021,525

Exchange calculations based on the Exchange Lists for Meal Planning, 92003 the American Dietetic

Exchange: 11/2 Starch

Association, the American Diabetes Association.

Nutrition Facts

Serving Size 1 cup (28g)
Children Under 4 - ¾ cup (21g)
Servings Per Container about 14

Servings Per Container about 14 Children Under 4 - about 19

Amount Per Serving Cl	heerios	with ½ cup skim milk	Children Under 4
Calories	100	140	80
Calories from Fat	15	20	10
TASEMON BANGRADAN	% Da	ally Value**	
Total Fat 2g*	3%	3%	1.50
Saturated Fat 0g	0%	3%	00
Trans Fat 0g			00
Polyunsaturated Fa	t 0.5g		00
Monounsaturated F	at 0.5g		.00
Cholesterol 0mg	0%	1%	0mg
Sodium 190mg	8%	10%	140mg
Potassium 170mg	5%	11%	130mg
Total Carbohydrate 20g	7%	9%	15g
Dietary Fiber 3g	11%	11%	20
Soluble Fiber 1g			00
Sugars 1g			10
Other Carbohydrate	16g		120
Protein 3g			29
			% Daily Value
Protein		-	% Daily Value 9%
Protein Vitamin A	10%	15%	
	10%	15% 10%	9%
Vitamin A			9% 10%
Vitarnin A Vitamin C	10%	10%	9% 10% 10%
Vitamin A Vitamin C Calcium	10% 10%	10% 25%	9% 10% 10% 8%
Vitamin A Vitamin C Calcium Iron	10% 10% 45%	10% 25% 45%	9% 10% 10% 8% 50% 6%
Vitamin A Vitamin C Calcium Iron Vitamin D	10% 10% 45% 10%	10% 25% 45% 25%	9% 10% 10% 8% 50% 6% 35%
Vitamin A Vitamin C Calcium Iron Vitamin D Thiamin	10% 10% 45% 10% 25%	10% 25% 45% 25% 30%	9% 10% 10% 8% 50% 6% 35% 35%
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^{*}Amount in cereal. A serving of cereal plus skim milk provides 2g total fat (0.5g saturated fat, 1g monounsaturated fat), less than bring cholesterol, 250mg sodium, 370mg potazsium, 26g total carbohydrate (7g sugars) and 7g protein.

"Percent Daily Values are based on a 2,000 calorie dief. Your daily values may be higher or lower depending on your colone needs: Calories 2,000 2,500

	Caronics	2,000	2,000
Total Fat	Less than	65g	80g
Sai Fai	Less than	20g	25g
Cholesterol	Less than	SDDmg	300mg.
Sodium	Lors than	2,400mg	2,400mg
Polassium		3,500mg	3,500mg
Total Carbohydrate			375g
Dietary Fiber		25g	30g



International Food Regulation

US regulation of imports and exports

Trading partners (NAFTA, MERCOSUR, EU, ASEAN)

Increasing bilateral trade agreements

World Trade Organization (WTO) considerations [www.wto.org]

- Sanitary and Phytosanitary Agreements (SPS)
- Technical Barriers to Trade (TBT)

Codex Alimentarius Commission (FAO and WHO) [www.fao.org; www.who.org;

www.codexalimentarius.org

International Standards Organization (ISO)



Codex Alimentarius Commission-1962

Develop international food standards, codes of practice and guidelines (and the food standard when trade disputes arise under WTO)

- -began as food quality; then to safety; then to trade
- Protect health of consumers and ensure fair practices in the food trade
 - Science-based standards for food trade
- Promote coordination of food standards
- 181 member countries; over 100 international nongovernmental organizations



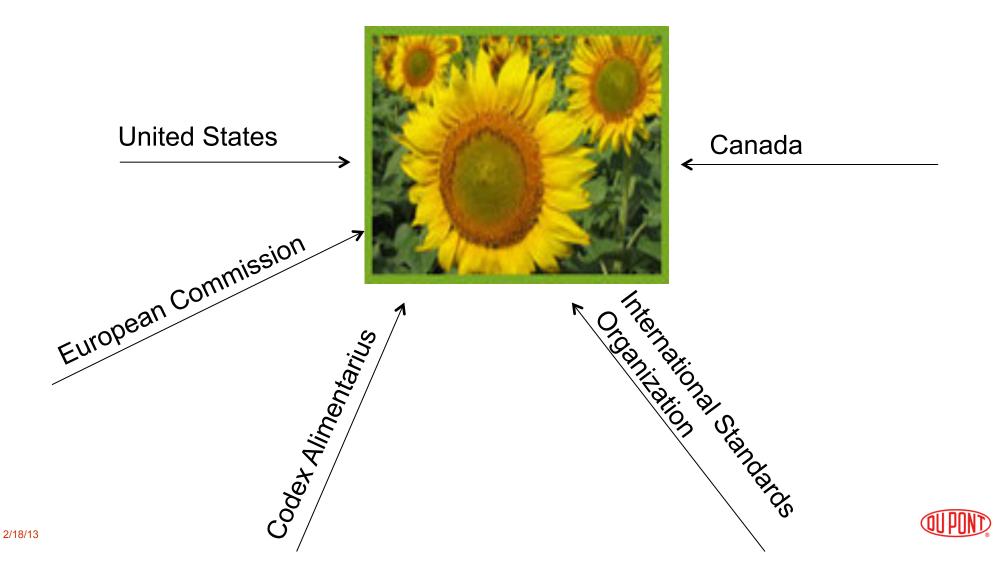
Codex Alimentarius Commission

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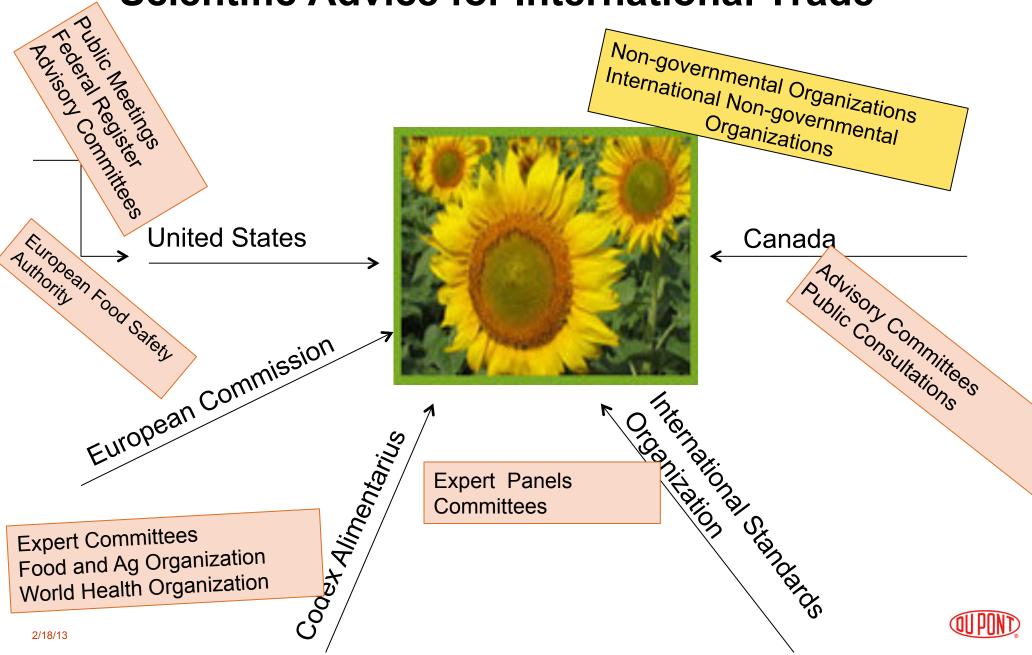
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Scientific Advice for International Trade



Scientific Advice for International Trade



Global Regulatory Issues-Scientific Impact

Ensuring safety of foods within countries

Ensuring safety/inspection equivalence with trading partners

Ensuring safety of imported foods/food ingredients

Minimizing trade barriers

- Sanitary/Phytosanitary
- Technical Barriers

Labeling and tracing requirements between countries



Every Day in the News

Food Safety, Food Safety

Food Nutritional Quality- relative nutrients

Global Food Availability

Non-Congruent Regulatory Systems

Move to 'Natural' and 'Organic' and 'Green'

Environmental overlaps



Thank You

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