



Global Trends Impacting Food and Medical Products

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Outline

- Constant challenges
- Managing change on multiple fronts
- Approaches to managing risks
- Messages to stakeholders





Today's Challenges

- Complex supply chains
- Consumer drivers
- Emerging threats
- Improving epidemiology
- Influence of media and litigation
- Drive toward lowering health care costs
- New regulations
- Inconsistent standards globally



Major Drivers

- Intersection of food, nutrition and health
- The reality of economics
 - Feeding people
 - Health care costs
 - Food production
- Developing safe products that meet all the needs at a reasonable cost



Political Drivers

- Need to drive down health care costs
 - Obesity
 - Chronic disease
- Incentives for preventive health strategy
 - Weight control
 - Foods associated with lowering the risk of cancer and diabetes
- Penalties for selling food that is perceived to increase health risk
 - Soda tax
 - Sugar tax

The Reality of Producing Food Today

- Narrow margins
- Drive to minimize procurement costs
- Risk of going out of business if there is a food safety problem
- Risk of going out of business if consumers decide they don't like you
- Dealing with consumer demands
 - High quality
 - Low price
 - Innovative products with global ingredients
 - Zero risk

Global Landscape

- Increasing focus on food
 - Safety
 - Sustainability
 - Environmental impact
 - Trends – organic, local etc.
 - Nutrition
 - GMO
- Health care changes
 - Increasing complexity
 - Economic realities
 - Greater focus on prevention
 - Increasing recognition of the role of diet in health care





Building a Strategy

- Taking advantage of the global opportunities in food
 - Being a leader in the global market place
 - Leveraging leadership to grow new business globally
- Being aware of the trends, pitfalls and drivers
- Building the infrastructure to address change
 - Gathering information
 - Interpreting and responding to information
- Staying informed and thus out in front
- Responsible progression



Points to Keep in Mind

- Who are the players
- What are the drivers
 - Global economics and acquisitions
- What is changing
 - Governments, regulators, & regulations
 - Consumers
 - Science
 - Health care
- Impact of perceptions – good and bad

The Players

➤ Consumers

- Have to understand the attitudes of the local market
 - Irradiation in the US vs. GMO in the EU
 - EU worries over food safety – BSE
 - Push against processed foods – move to simple foods
 - Push towards local foods
 - Organic food movement

➤ Social media

- Food safety
- Nutrition and health

➤ Mainstream media

- Power to influence before, during and after a crisis





The Players

- ▶ Law Makers

- ▶ US Congress

- ▶ Regulators

- ▶ Varying structures – Depts. of Health vs. Agriculture

- ▶ US structure vs. China vs. the EU

- ▶ Determine who drives the power base

- ▶ What is the process used

- ▶ Mechanism of jurisdiction local/state/federal

- ▶ Regulatory process-legislation vs. regulation



Global Organizations

➤ Standards

- Codex Alimentarius
- International Organization of Standards (ISO)
- Global Food Safety Initiative (GFSI)
- European Food Safety Authority (EFSA)

➤ Health

- World Health Organization (WHO)

➤ Regulatory interactions

- “Quadrilateral Meetings” – USA, Canada, AUS, NZ
- European Commission

Government Oversight

- Every country has different priorities
 - Economics
 - Politics
 - Import/export
 - US is inwardly focused
 - Little emphasis on exports
 - China is outwardly focused
 - Huge economic drivers for food export
 - Economic adulteration
- Understand the regulations in your market and the markets to which you export



Government Oversight

- Legislators and regulators set domestic rules
 - Impact on how food is grown, manufactured, retailed
 - Import rules – EU vs. the US vs. Japan
- Approaches to nutrition messages
 - Front of packing labeling
 - Health claims
 - Dietary supplements
- Approaches to food safety issues
 - Melamine in wheat gluten/dairy
 - BPA
 - GMO



Changing Science

- Previously unrecognized risks associated with foods (peanut butter, cookie dough)
- Greater capacity to link food with illness
 - Acute illness linked to microbes
 - Chronic illness linked to chemicals
- Ability to measure lower levels of chemicals
- Impacts of antioxidants etc. on disease prevention and treatment
- Health claims



Emerging Threats

- New pathogens
 - E. coli O104 – Europe 2011
 - Over 4000 cases
 - 900 case of kidney failure (HUS)
 - Over 50 deaths
- Antibiotic resistance
 - Salmonella
 - Campylobacter



Know your Market

➤ China

- Growing middle class demanding higher standards
- More testing of food
- Greater concern around residues (heavy metals, pesticides)
- Top down legislative process
- But bottom up food safety control
- Use of the “ultimate” punishment for transgressors

➤ India

- Move toward greater safety and processing
- Cumbersome regulatory process
- Expanding infrastructure
- Big opportunity but difficult regulatory environment



Food Regulatory Change Focused on Health

- Health claims
- Medical devices for weight loss
- Dietary supplements
- Regulate away “junk food”

Regulating Junk Food In NYC

Bloomberg's ban on big sodas is unconstitutional: appeals court

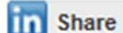
BY JOSEPH AX

NEW YORK | Tue Jul 30, 2013 6:58pm EDT

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Regulating Junk Food In NYC



Dr. Mary Bassett ♥ Become a fan
Health Commissioner for New York City



Let's Put a Cap on Big Soda

Posted: 06/05/2014 5:53 pm EDT | Updated: 06/05/2014 5:59 pm EDT



This week, New York City and the beverage industry squared off in the state's highest court over the proposed portion cap on soda and other sugary beverages.



Regulating Junk Food In NYC

The New York Times

New York City Soda Fight, in Court, Tests Agency's Power

By MICHAEL M. GRYNBAUM JUNE 4, 2014

ALBANY — New York City's battle over sugary drinks is entering its endgame. But much more than soda is at stake.

A plan to limit the sale of large, high-calorie beverages, championed by former Mayor Michael R. Bloomberg as a novel way to fight obesity, went before the State Court of Appeals here on Wednesday, the city's final recourse after a lower court judge struck down the proposal last year.

Regulating Junk Food In California



California lawmakers reject sugary drink warnings

AP 9:29 p.m. EDT June 17, 2014



(Photo: Rich Pedroncelli, AP)

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SACRAMENTO, Calif. (AP) — A bill that would have made California the first state in the nation to require warning labels on sodas and other sugary drinks was effectively killed on Tuesday.

SB1000 by Sen. Bill Monning, D-Carmel, failed on a 7-8 vote as his fellow Democratic lawmakers doubted whether a label would change consumer behavior. It needed 10 votes to pass.



Regulating Junk Food – Mexico Tax

THE WALL STREET JOURNAL.  BUSINESS

BUSINESS

Junk Food Feels the Heat in Latin America

Governments Enact Taxes, Restrict Sales as Obesity Rates Rise

By AMY GUTHRIE

Dec. 27, 2013 4:22 p.m. ET

MEXICO CITY—From a Mexican tax on sugary drinks to legislation banning Happy Meal toys in Chile and Peru, Latin America is becoming a laboratory for public policies meant to steer consumers away from processed food.

tag

Regulating Junk Food in Schools

LATIN AMERICAN
Gerald Tribune

Mexico Regulates Junk Food in Schools

MEXICO CITY – A new law regulates sales of junk food in elementary schools in Mexico, where about 30 percent of children and 70 percent of adults are overweight.

The law, which took effect on Monday, does not ban sales of junk food in schools, but it requires private and public schools to control servings of all foods that are high in fat and sugar.

The measure also requires food companies to offer smaller portions of their products.



Food Safety Modernization Act

Signed into law on January 4, 2011

Most sweeping overhaul of the
food safety system since 1938



Food Safety Modernization Act

Enhanced
Partnerships

Prevention

Increased Inspections
Enhanced Response

Import Safety

Apply Domestic Standards to Imported Foods





FDA Implementation Activities

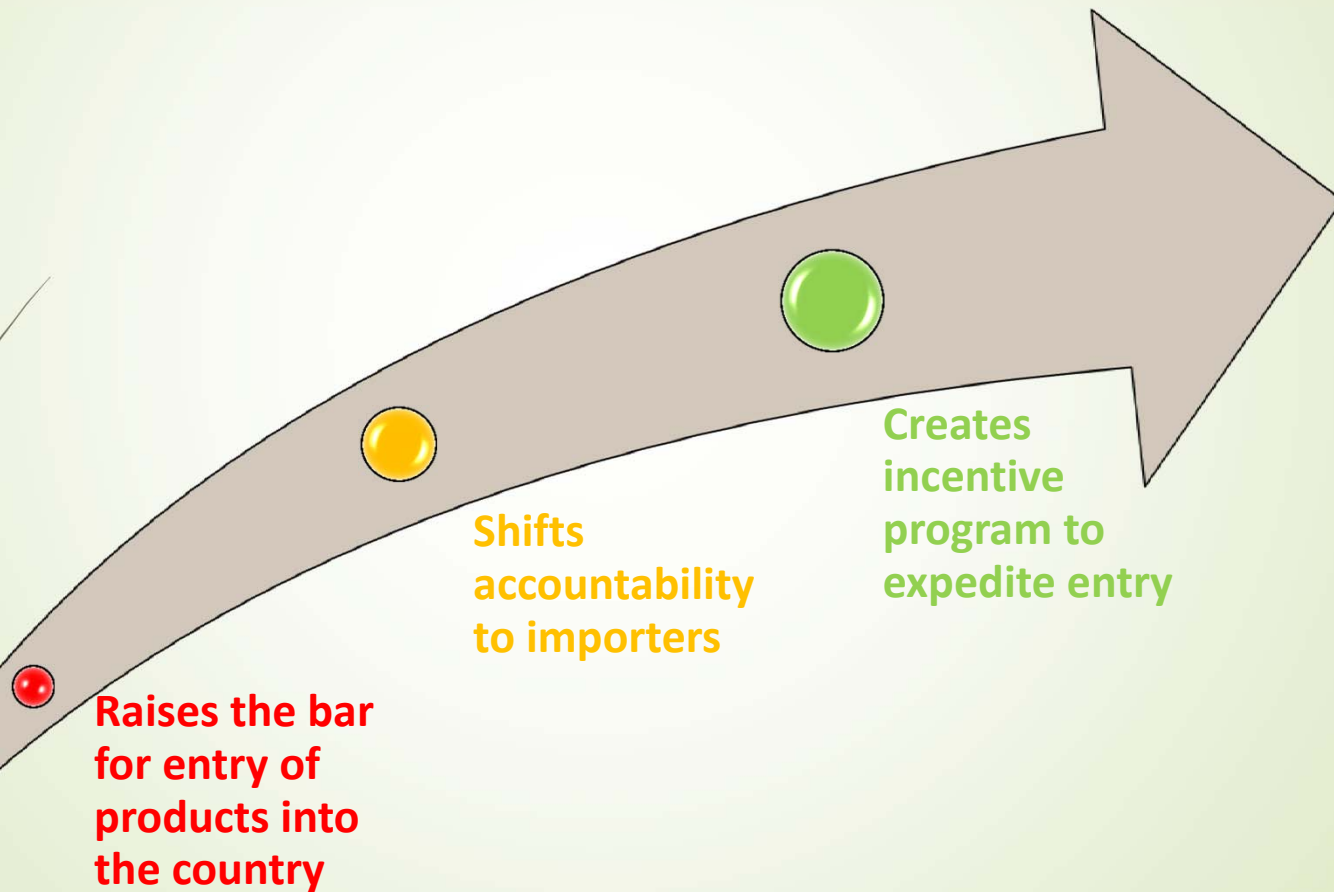
- Inspection of records
- Mandatory recall
- Authority to require import certificates
- Suspension of registration
- Expanded administrative detention



The Seven Pillars of Prevention

- Preventive controls for human food
- Preventive controls for animal food
- Produce
- Foreign supplier verification
- Third party auditor
- Food Defense
- Sanitary Transport

Stricter Import Requirements





Approach

- Managing Risk in a cost conscious environment
 - Operational Risk
 - Regulatory Risk
 - Reputational Risk



Managing Operational Risk

- Supply chain risk evaluation
 - Assess risk of incoming products and suppliers and develop management strategy
- Internal operations
 - Design and implement comprehensive food safety systems
 - Sanitation and environmental monitoring testing plans and data analysis
 - Process Controls
 - Traceability
- Consumer / Customer complaint handling
- Food defense vulnerability assessments and food defense plans
- Crisis and recall preparedness



Managing Reputational Risk

- Track social media trends for your brand/company
- Learn what consumers are saying about you
- Assist you in staying better informed of the changing food safety & social media risks
- Develop key messages and programs to inform your consumers
- Adding credibility to your food safety systems
- Identify avenues to create good relations with regulators



Managing Regulatory Risk

- Understand the Impact of FSMA and FSIS regulatory changes
- How to respond to regulatory issues (e.g., 483, Import alert, FSA, NOIE)
- Dealing with a recall
 - Assessing the risk using a Health Hazard Evaluation
 - Interacting with Local, State or Federal regulators
 - Developing appropriate messages to customers, the public and the media
 - Logistics
 - Product tracking
 - Speed

Our Biggest Challenges

- Complacency
- Ignorance
- Arrogance





Where Do We Need To Go

- Accept that we will always have risk with food
- Develop a culture of reward based on continuous improvement
- Establish tools to better understand long term chronic exposures
- Focus on technology to save cost and reduce risk
- Be risk focused to leverage limited resources



Messages For Today

Messages to:

Industry

Regulators

Congress

Consumers





Message To Industry

- Focus on your food safety culture
 - Food safety vs. procurement
- Understand where your risk is
 - Internally
 - Supply chain
- Don't let compliance be the driver to food safety
- Establish good relations with regulators
- Recognize that you are never done



Message To Regulators

- Reward good industry behavior
- Focus on the harmonizing regulatory systems
 - Local
 - State
 - Federal
- Stop internal competitiveness
- Listen to and leverage industry expertise
- Be approachable
- Be educators first and regulators second



Message To Congress

- Learn about the food industry
- Simplify statutes
- Drive new laws based on risk
- Support studies to understand long term risks
- Create the single food safety agency
- Take the politics out of food safety



Message To Consumers

- Take responsibility for things you can control
- Be open minded to technology
- Be a positive influence on industry good practices through buying habits



Looking Forward

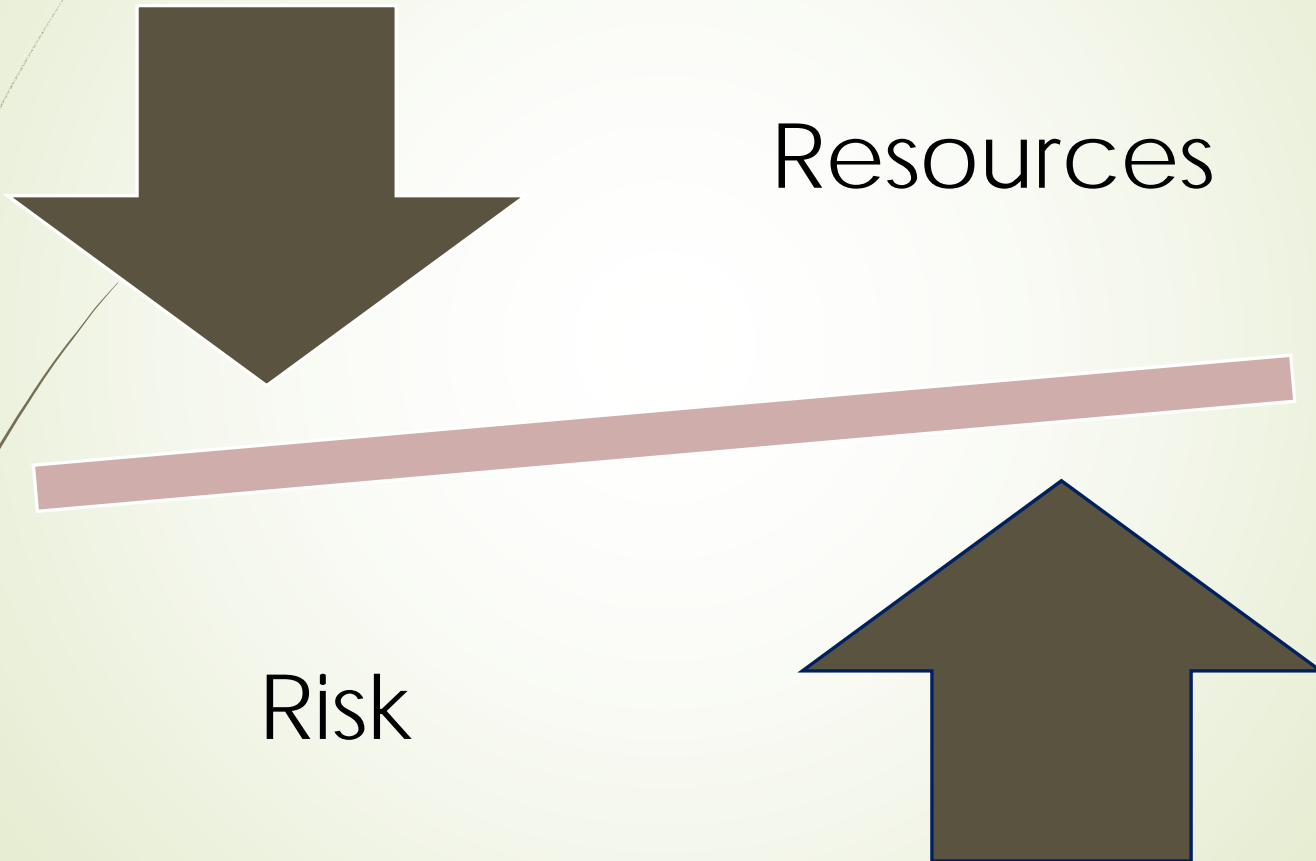
- Recalls may become more frequent and larger
- Consumers and lawyers will continue to push food companies and chase deep pockets
- New risks will emerge that we don't fully understand
 - Chemicals
- Supply chains will become more complex and risky
- Regulations will continue to tighten
- Health economics will have a great influence on food



Summary

- Global food supply needs global regulatory harmonization
- Challenge of feeding the planet and controlling obesity
- We all have a role in controlling food safety
- Stay informed of the rapidly changing landscape

The Balancing Act





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