

Hello Chicago Section IFT



Thank you for letting me share some thoughts with you



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THE PARADOX OF FOOD REGULATION

Food Regulation & Policy



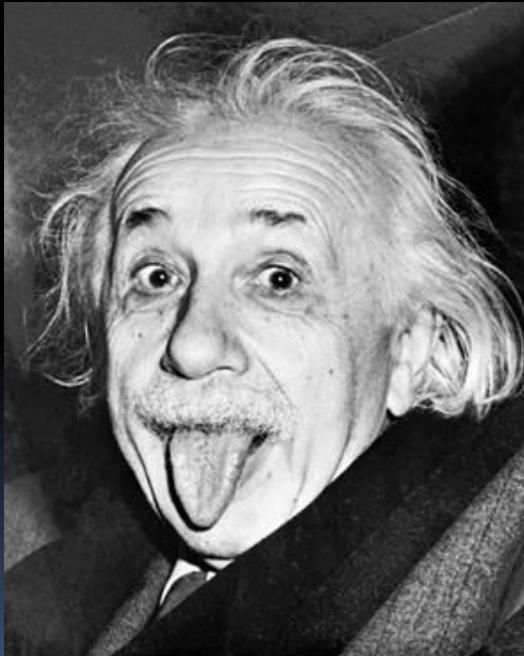
DOES IT WORK?



...Or Should We Take a New Direction?



*We cannot solve our problems with the
same thinking we used when we created
them.*



Albert Einstein

History of Modern Food Regulation

- Foundations of food safety reform in England in 1820 with Frederick Accum – “*A Treatise on Adulterations of Food and Culinary Poisons*”
- First modern food and drug law statutes passed in Parliament in 1860, 1872, and **1875** – **formed basis of Federal Food and Drug Act of 1906**
- In U.S., Prof. Lewis Beck (Rutgers University) published in 1846 – “*Adulterations of Various Substances Used in Medicine and the Arts*”
- Massachusetts created Sanitary Commission – lack of sanitation and adulteration of food and drugs decreased life expectancy by 20-25% from 1810 to 1850

History of Modern Food Regulation

- In 1700's and early 1800's, foods consumed were *local* and states maintained food laws.
- By 1850, food distribution was expanding beyond state borders
- Federal laws started in the Patent Office with the Agriculture Division (\$1000 appropriation) and Chemical Laboratory
- USDA created in 1862 and elevated to cabinet level in 1890 and housed the Bureau of Chemistry (1901) – no statutes; only food-related laws were held by Treasury Department

History of Modern Food Regulation

- Seventh Commissioner of Food and Drug – “Division of Chemistry” was Harvey W. Wiley, MD
- “Poison Squad” – 12 young USDA employees Consumed preservatives: salicylates, sulfites, benzoates, boric acid, and formaldehyde
- 27 yo socialist, Upton Sinclair, wrote *The Jungle*
- 1906 Pure Food & Drug Act and Meat Inspection Act resulted after President Theodore Roosevelt (R) confirmed Sinclair’s findings

History of Modern Food Regulation

- Wiley was idolized by the media and public as a hero – controlled by the Administration and Secretary Agriculture James Wilson
- Upton Sinclair was disappointed:
“I aimed at the public’s heart and by accident I hit it in the stomach.”

History of Modern Food Regulation

- 1906 Federal Food & Drug Act
- FDA created 5 regulations in 32 years



1912 - Mrs. Winslow's Soothing Syrup for teething and colicky babies, unlabeled yet laced with morphine, killed many infants

1920: 374 employees conducted 1407 seizures and 1818 criminal prosecutions – lifting quality and safety of the food supply

History of Modern Food Regulation

- 1938 – Federal Food, Drug, & Cosmetic Act replaced obsolete 1906 Act
 - ✓ Adds cosmetics and medical devices
 - ✓ Adds standards of identity
 - ✓ Adds authorization for factory inspections

History of Modern Food Regulation

- 1954 – pesticide residue limits set
- 1958 – food additives regulated and GRAS established – included the *Delaney Clause* for cancer risk
- 1960 – colors added for cancer risk
- 1973 – low-acid canned foods
- 1973 – Tea Importation Act of 1897 is repealed to eliminate user fees for FDA's testing of all imported tea.
- 1980 – infant formula
- 1990 – NLEA
- 1994 – DSHEA
- 2002 – Bioterrorism Preparedness and Response Act
- 2004 – FALCPA
- 2010 - FSMA

History of Modern Food Regulation

- > 90 statutes enacted from 1939 – 1987
- Every President in the last 40 years issued one or more Executive Orders that directly impacted food regulation
- Meanwhile, in past 20 years, FDA increase 817 employees with loss of \$300 M in inflation
- Budget increases in 2009 (5.7%), 2010 (19%), 2011 (23%)

Health Policy

➤ Nutrition Labeling (NLEA) - 1990

Dr. Sullivan doesn't exaggerate when he says that the supermarket has become "a Tower of Babel," forcing consumers to be "linguists, scientists and mind readers to understand the many labels they see. " The resulting confusion has made it hard to make informed choices.

The Tower of Babel was, "Where God confounded the language of all the Earth". (Genesis 11:5-8)

Health Policy

Nutrition Labeling (NLEA) - 1990

Objective to help consumers make informed choices through the
“**Nutrition Fact Panel**”

- ✓ serving size
- ✓ servings per container
- ✓ nutrient content for standardized set of nutrients
- ✓ consistent format(s) with consistent print size
- ✓ ingredient declarations
- ✓ nutrient claims
- ✓ health claims

Health Policy

US Dietary Guidelines (DG)

- Genesis was the 1977 “McGovern Report” on “*Dietary Goals for the U.S.*” Issued by the Senate Select Committee on Nutrition and Human Needs.
- The *Dietary Guidelines for Americans*, developed jointly by DHHS and USDA, provide recommendations based on current scientific knowledge about how dietary intake can reduce risk for major chronic diseases.
- The *Guidelines* form the basis of Federal food, nutrition education, and information programs.
- First published in 1980, Public Law 101-445, 3 requires publication of the *Dietary Guidelines* at least every 5 years beginning in 1995. This legislation also requires review by the Secretaries of USDA and HHS of all Federal dietary-guidance-related publications for the general public.

2010 Dietary Guidelines:

- Evidence-based
- Highlight plant foods and consider meat a side dish
- Make at least half the plate vegetables & fruits



2010 Dietary Guidelines for Americans

Health of Americans

- 67% are overweight
- 34% are obese – ***double*** the number 30 years ago
- 19% of children are obese – ***triple*** the number 30 years ago

BMI \geq 25 is overweight
BMI \geq 30 is obese

5'6" woman obese at 186 lbs
6' man obese at 221 lbs

Health of Americans

Federal health officials had set a goal a decade ago that no more than 15 percent of people would be obese in 2010.

“We aren’t near that, and we haven’t moved in that direction,” said Dr. Cynthia L. Ogden, an epidemiologist at the National Center for Health Statistics

Good News - Health of Americans

- Obesity rates have reached a plateau.
- Obesity rates constant for men for 5 years
- Obesity rates constant for woman and children for 10 years

*“We may have reached a biological limit
to how obese people can get.”*

Dr. David Ludwig, Children’s Hospital Boston

Health of Americans

International Food Information Council 2011 Sodium Survey (*>1000 people surveyed*)

- 59% say they are “not concerned” about sodium intake
- 70% say they “don’t know how much sodium to consume”
- 56% with high blood pressure don’t know how much sodium they need or consume
- 40% say flavor will suffer with reduced sodium

Health of Americans

Mintel

➤ 49% say they are “doing all they need to achieve a healthy diet”

- 1980 **1 in 7 Americans are obese**
 6 million are diabetic
- 2011 **1 in 3 Americans are obese**
 14 million are diabetic

Carl's Jr. Steakhouse Burger

Angus beef patty smothered in A1 Steak Sauce, Swiss cheese, crumbled Blue cheese, crispy onion strips and standard lettuce, tomatoes, and mayonnaise



Carl's Jr Steakhouse Burger

Angus beef patty smothered in A1 Steak Sauce, Swiss cheese, crumbled Blue cheese, crispy onion strips and standard lettuce, tomatoes, and mayonnaise

Single:

870 calories

450 cals from fat

1640 mg Sodium



Double:

1120 calories

640 cals from fat

1910 mg Sodium

Carl's Jr Introduces “God of Hamburgers” *Hamblor*



Wendy's Dave's Hot 'N Juicy Burger

Buttered buns, apple smoked bacon, crinkle-cut pickles,
extra cheese, and red onions instead of white.
Beef patties still square.



Wendy's Dave's Hot 'N Juicy Burger

Buttered buns, crinkle-cut pickles, extra cheese, and red onions instead of white. Beef patties still square.

¼ lb Burger:

Calories	580
Cals from Fat	297

Sodium	1240 mg
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½ lb Burger:

Calories	810
Cals from Fat	432

Sodium	1580 mg
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¾ lb Burger:

Calories	1060
Cals from Fat	603

Sodium	2070 mg
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Five Guys

Fastest-growing chain in the US – Up 38% last year



Five Guys

Fastest-growing chain in the US – Up 38% last year



Bacon Cheeseburger:

Calories 920

Cals from Fat 560

Sodium 1310 mg

McDonald's Sweet Tea



32 oz Drink

Calories: 280

Sugar: 69 grams

= 17 teaspoons

Carbonated Beverages



32 oz Drink

Calories: 310

Sugar: 83 grams

= 20 teaspoons



32 oz Drink

Calories: 350

Sugar: 94 grams

= 23 teaspoons

Food Safety Policy

- *Listeria monocytogenes* Zero Tolerance
(none found at detectable limit)
 - ✓ Regulation put in place in 1989 as “Interim Final Rule”
 - ✓ Not enough data to establish a safe limit for public health

FSIS Action Plan for Addressing *Listeria monocytogenes*

The Food Safety and Inspection Service (FSIS) has announced its action plan for *addressing Listeria monocytogenes* in response to a nationwide outbreak of listeriosis associated with ready-to-eat meat and poultry products in late 1998 and early 1999 and a spate of recalls related to the pathogen.

The action plan contains both near-term and long-term initiatives.

FSIS has announced three near-term initiatives. First, FSIS is scheduled to publish in the May 26 *Federal Register* a notice advising establishments to reassess their Hazard Analysis and Critical Control Point (HACCP) plans to ensure they are adequately addressing *L. monocytogenes*. Second, FSIS is providing guidance to the industry on practices that have been used successfully by other meat and poultry establishments to prevent the occurrence of *L. monocytogenes* in ready-to-eat products. Third, FSIS is carrying out educational efforts targeted to those individuals who are at an increased risk of developing listeriosis.

FSIS Action Plan for Addressing *Listeria monocytogenes*

FSIS also announced four **long-term** initiatives.

First, FSIS is drafting a protocol to study the post-production growth of *L. monocytogenes* in a wide variety of ready-to-eat products and will ask USDA's Agricultural Research Service to conduct the study.

Second, FSIS is developing an in-depth verification protocol that can be used to evaluate whether plants producing ready-to-eat products have reassessed their HACCP plans to adequately address *L. monocytogenes*.

Third, FSIS is working with the Food and Drug Administration (FDA) to conduct a risk assessment for *L. monocytogenes*.

And fourth, FSIS is developing performance standards for ready-to-eat products that will address the need to control all pathogens, including *L. monocytogenes*, in these products.

May 1999

Food Safety Policy

- *E. coli* O157:H7 Regulations
- 1982 - first associated with ground beef (20 people ill)
- 1992 – major outbreak in Canada
- 1992-93 – Jack-in-the-Box outbreak affecting 700 people, with 4 deaths (children)
- 1994 – *E. coli* O157:H7 declared an adulterant in ground beef
- 1994 – FSIS required safe food handling labels on packages of raw ground beef and poultry (*USDA-FSIS Directive 7235*)

Food Safety Policy

- *E. coli O157:H7* Regulations
- 1994 – Notice 50-94 installed raw beef testing for *E.coli* O157:H7
- 1996 – HACCP mandated for processing controls and prevention
- 1998 – Directive 10,001.1 reinforced raw beef testing for *E.coli* O157:H7
- 1998 – Zero tolerance enforced for visible fecal, ingesta, and milk contaminants at slaughter
- 2004 – Revised Directive 10,001.1 to require testing of raw ground beef for *E.coli* O157:H7
- 2005 - estimated 73,500 illnesses and 60 deaths per year

Brooks JT (2005) *J. Infect. Dis.* 192: 1422-1429

Food Safety Policy

- *E. coli O157:H7 Contamination*
- September 28, 2011 – Tyson announces recall of 131,300 lbs of ground beef, with illness in undisclosed number of individuals

Distribution to: Indiana, Tennessee, North Carolina, South Carolina, Delaware, Florida, Georgia, Maryland, Missouri, New York, New Jersey, Wisconsin

Food Safety Policy

➤ FDA Retail Food Safety Initiative

✓ List of riskiest practices

- Food from unsafe sources
- Poor personal hygiene
- Inadequate cooking
- Improper holding of food (time and temperature control)
- Contaminated food surfaces and equipment

Food Safety Policy

- ✓ **List of riskiest foods**

- Leafy greens (*E.coli*, Norovirus, *Salmonella*)
- Eggs (*S. enteritidis*)
- Fresh tuna (scrombroid toxin)
- Oysters (Norovirus)
- Cheese, unpasteurized, soft, high-moisture (*L. monocytogenes*)

- ✓ **Single biggest contributing factor**

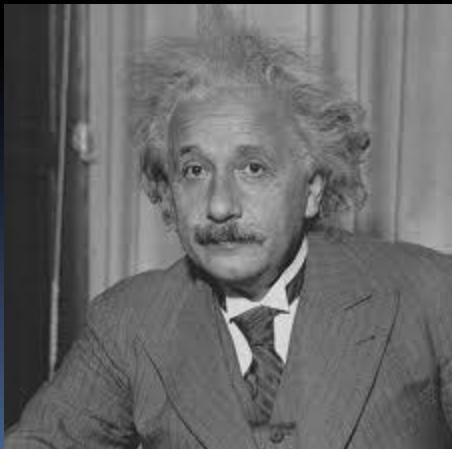
- Unwashed hands from a food handler

Global Society Focuses on the Complex

- Insatiable thirst for more knowledge and better tools

May Be Time to Look for Simple Solutions

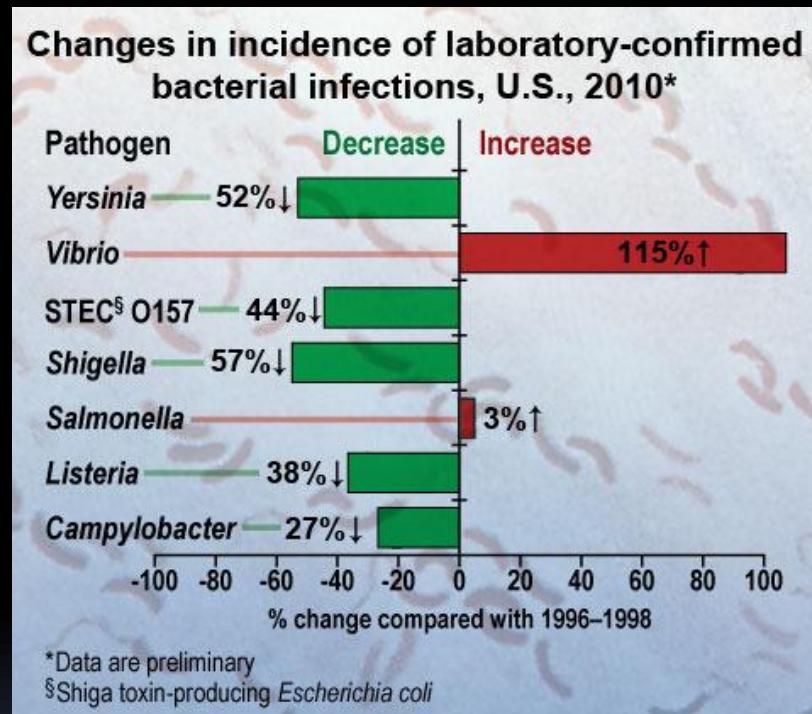
Any intelligent fool can make things bigger and more complex... It takes a touch of genius - and a lot of courage to move in the opposite direction.



Make everything as simple as possible, but not simpler.

In Fact...

- Some foodborne disease appears to be declining
- **48 M get foodborne disease every year**
- **128,000 hospitalized**
- **3000 die**



Food NET, CDC

Food Safety Modernization Act (FSMA) of 2010

- Focus on:
 - Preventive controls
 - Inspection, compliance, and response
 - Enhanced partnerships
 - Import safety

□ **PREVENTION**

□ **New Authorities**

□ **Improved Communications**

FSMA

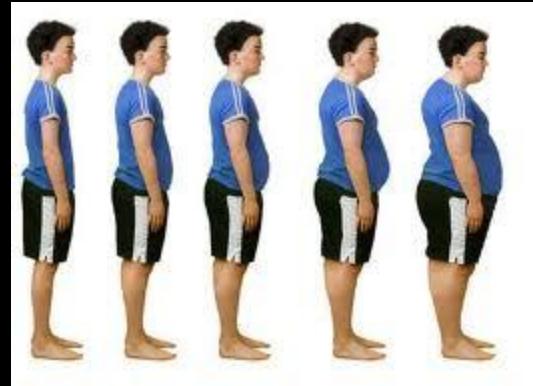
- Further focus on:
 - Training
 - Inspection mandate
 - ❖ risk based
 - ❖ schedule for high risk facility inspections
 - ❖ schedule for all domestic facility inspection
 - ❖ authority to suspend facility registration
 - ❖ authority to detain adulterated or misbranded products
 - Ability to collect fees –
 - ❖ re-inspection
 - ❖ export certificates
 - ❖ 3rd party inspection program administration
 - ❖ Voluntary Qualified Importer Program
 - Ensuring compliance for small and very small facilities

FSMA Progress Report

- Issued administrative detention interim final rule and used 3 times
- Issued imported food prior notice interim final rule
- Guidance to seafood industry on food safety hazards
- Guidance to dietary supplement industry on NDIs
- Convened >350 stakeholder meetings (3 public hearings)
- Established Produce Safety Alliance
- Established Food Safety Preventive Control Alliance
- Meeting food facility inspection requirements and timetable
- Building State-Federal integrated food safety system
- Launched product tracing pilots – product & processed foods

The Answer is Not...

➤ To regulate more.



➤ Or to regulate less.



**Know what it takes to be make safe food
– as a *food industry professional*;
and to be healthy – as an *individual***

Just Do It.

Nike

Never Lose Your Sense of Wonder with the Universe

