US Food & Nutrition Policies: The Actors, Structures & Instruments

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“Food and nutrition policies are like sausage. You don't want to see how they are made.”
Translating Science into Policy

Data collection → Interpretation → Scientific Consensus

Societal priorities
Resource allocation
Opportunity Costs
Changing cultural norms
Special interests
Politics
Greed

Translation of science to food and nutrition policy
Outline

What is the historical context for US food and nutrition policies and regulations?
- 1906, 1938 Food Laws
- Standard of Identity

What are policy instruments used to ensure that the foods we eat are safe, sanitary, wholesome, and properly labeled?
- FDA
- Food Labels and Health Claims

What is the basis for US Dietary Guidelines, and how are these used?
- DRIs
- What’s new in the 2005 Dietary Guidelines?
- Critique of MyPyramid.gov
- Healthy Eating Index
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Historical Context for Existing U.S. Food and Nutrition Laws

Pre-1900’s

US was “dumping” ground

States exercised principal control over domestically produced & distributed foods & drugs

Federal authority limited to imports

Adulteration & misbranding of foods & drugs rampant
  e.g. arsenic in vinegar; sulfuric acid in pickles, woodchips in bread, alum and clay in wheat flour

Bold and unsubstantiated health claims
  e.g. foods marketed as cures for cancer, prevention against baldness, restoration of vitality
Selling false hopes with vigor!

Cartoon from Life Magazine, April 29, 1909

http://www.cfsan.fda.gov/~lrd/history2.html
Context for the passage of the first consumer protection law in 1906

- Competition from new and cheaper food & drugs (e.g. glucose, oleomargarine, alum baking powder, lard)
- Creation of national markets and growing inter-state commerce.
- Scientific advances that increased the complexity of many products
- Transportation advances
- Publication of “the Jungle” by Upton Sinclair
- Nat’l politicians interested to extend regulatory mandate and budgets
- Growing urbanization
- Harvey Washington Wiley’s poison squads
- Muckraking press
Modern Era of the Food & Drug Administration (FDA)

1906 Pure Food and Drug Act:

Prohibited the manufacturing and interstate shipment of adulterated and misbranded foods and drugs

Backed by the statutory authority of the Bureau of Chemistry of the US Dept of Agriculture (USDA), the predecessor of the FDA.
“Salad Bouquet” - vinegar
“Peanut Spread” with hardly any peanuts
“Bred Spred” with a tiny bit of fruit and lots of pectin masquerading as “jam”

http://www.fda.gov/oc/history/slideshow/Slide_492.html

“Chicken Delicacies” which reveals white meat but is mostly dark meat hidden behind the label

http://www.fda.gov/oc/history/slideshow/Slide_156.html
5 brands of malted milk

http://www.fda.gov/oc/history/slideshow/Slide_135.html

Identical ingredients, but different processes used (dry vs. wet mix) which affects consistency.
Tomato paste with only 14% tomato solids

Maple Syrup with only 1.7% maple syrup

http://www.fda.gov/oc/history/slideshow/Slide_174.html
http://www.fda.gov/oc/history/slideshow/Slide_141.html

**Same package size, different package weight**
1938 Federal Food, Drug and Cosmetics Act

Replaced the 1906 act

Together with subsequent amendments, it remains the statutory framework under which FDA operates today.

Authorized creation of “standards of identity”

Required labeling of every processed and packaged food product to contain the name of the food, net weight, ingredients (of certain products), and name and address of manufacturer and distributor.

Provided specific authority for factory inspections.
1938-1980’s

Classic cases outright frauds decreased

Modern food technology blurred line between unlawful adulteration & lawful use of functional additives.

Numerous amendments to 1938 Act that dealt with food coloring, quality of container for canned food, details about factory inspections that the FDA could conduct, safety limits for pesticide residues on raw agricultural commodities, safety of food additives, packaging and infant formula content
Standards of Identity

Purpose: ensure that products sold on the particular name have characteristics expected by consumers.

- Prescribe minimum amount of certain ingredients; maximum fat, water or filler contents; and methods of processing, cooking and preparation
- Permit optional safe and suitable ingredients
- Identify expected or characterizing ingredients

Foods that do not conform to these standards may be sold under other non-standardized names (e.g. “fruit topping”)

Codified in the Code of Federal Regulations (CFR)

280 food standards (FDA); 80 meat and poultry products (USDA)
“Breakfast sausage" is sausage prepared with fresh and/or frozen meat; or fresh and/or frozen meat and meat byproducts, and may contain mechanically separated (Species) in accordance with Sec. 319.6, and may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used. Binders or extenders may be added as provided in Sec. 319.140 of this part.
Value of Existing Food Standards

Protect consumers from fraud

Insure products meet consumers nutritional expectations

Insure level playing field for industry

In absence of federal food standards, states may enact their own

Provide basis for negotiations related to int’l harmonization of standards

Without nat’l standards, int’l bodies may “impose” standards unfriendly to American consumer or food industry
Is there a need to modernize food standards?

Current standards might….

Impede technological innovation in food industry

Prevent food industry from producing products that have lower amounts of fat, saturated fat, cholesterol, sodium

Unlevel playing field with non-standardized products (with new ingredients designed to enhance taste, shelf life, etc.)
Food Identity Crisis?

*The battle to change the recipe of ice cream!*

Petition by the International Ice Cream Association to remove a limitation on the use of whey, a milk derived protein, in the recipe for ice cream.

Whey is cheaper than milk, and aids in freezing & whipping ingredients together and preventing ice crystals.

Opposed by Nat’l Milk Producers Federation, which has a stake in how much of its product goes into ice cream.

Raises the issue of how new food technology, processes and nutritional demands from consumers for low-fat and low-calorie foods are driving the development of new products that don’t fall into old categories.
When is frozen “pizza with meat” not pizza with meat?

**Petition to FDA:** National Frozen Pizza Institute (NFPI) petition to remove the current standard of identity for “pizza with meat” and “pizza with sausage”

**Rationale:** Current standards are restricting the development of new products; and consumer’s concept of “pizza” are broader than the current prescription. Standard does NOT apply to restaurants, only to federally inspected frozen pizza industry.

**Stakeholder:** American Frozen Food Institute has 530 member companies, is responsible for ~90% of frozen pizza sold in the USA, valued at >$60 billion (& almost all of the $2.5 b frozen pizza industry)
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  FDA
  National Labeling and Education Act

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Food and Drug Administration (FDA)

Sees that…

Foods we eat are safe, sanitary, wholesome & honestly labeled (& protected against bio-terrorism)
Cosmetics won’t hurt us
Medicines & medical devices are safe & effective
Radiation-emitting products won’t hurt us

10,000 person agency under Dept of Hlth & Human Services

$1.6 billion budget (~$6/person/year)
Regulates 25¢ of every $1(>$1 trillion); 75% spent on food
1,100 investigators; Cover 95,000 FDA regulated businesses

Collects 80,000 domestic & imported product samples for examination by its 2,100 scientists in 40 laboratories
FDA’s Center for Food Safety & Applied Nutrition (CFSAN)

Responsible for 80% of all food consumed in US (everything except meat, poultry & eggs-regulated by USDA)

- $240 billion worth of cornucopia
- 50,000 food manufacturers, processors & warehouses (excl. restaurants, supermarkets, groceries which are regulated by state & local gov’t)
FDA Regulatory Powers

Encourage voluntary correction

Recall product from market

Force company legally to stop selling a product & have items already produced seized & destroyed

Seek criminal penalties
A Notice From The Food and Drug Administration to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products About the Safety of Food Affected by Hurricane Katrina

Certain foods exposed to these [flood] waters and perishable foods that are not adequately refrigerated are adulterated and should not enter the human food supply.....Crops; fresh fruits and vegetables; food requiring refrigeration and freezing; food in screw-top, crimped-cap and similar containers; Food Packed in Plastic, Paper, Cardboard, Cloth, and Similar Containers.
1990: The Nutrition Labeling and Education Act (NLEA)
Context

Prior to NLEA, foods that made health claims were drugs & required to file a new drug application prior to marketing

1980’s food companies bypassed drug approval process

FDA exercised its enforcement discretion

Market was soon overrun with false and misleading health claims: 1989 Business Week Cover Story: *Can Cornflakes Cure Cancer?*

Consumer, public health and medical community concerned over relationship between diet and disease, but hindered to act on concern due to inadequate and inconsistent information on the food labels

Opposition from food industry—costs, fat content, sales
1990 Nutrition Labeling and Education Act (NLEA)
Amendment to 1938 Federal Food, Drug & Cosmetic Act

Goal: "bring a sense of order to the understanding of terms used when describing characterizations of food products."

Empowers FDA to
- Mandatory and uniform format & content of food labels
- Evaluate scientific basis for health claims—"significant scientific agreement"
- Set comprehensive standards for nutrition claims like "Low Fat," "Low Cholesterol," "Light," and "Healthy."
% Daily Values are based on a 2000 calorie/day diet.
Uniform label

Lists per serving quantity of 14 mandatory items

Standard serving sizes

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**Nutrition Facts**

<table>
<thead>
<tr>
<th>Amount Per Serving</th>
<th>Calories 250</th>
<th>Calories from Fat 110</th>
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<tbody>
<tr>
<td>% Daily Value*</td>
<td>18%</td>
<td>15%</td>
</tr>
<tr>
<td>Total Fat</td>
<td>12g</td>
<td>18%</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>3g</td>
<td>15%</td>
</tr>
<tr>
<td>Trans Fat</td>
<td>3g</td>
<td>5%</td>
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<tr>
<td>Cholesterol</td>
<td>30mg</td>
<td>10%</td>
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<tr>
<td>Sodium</td>
<td>470mg</td>
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<tr>
<td>Total Carbohydrate</td>
<td>31g</td>
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<tr>
<td>Dietary Fiber</td>
<td>0g</td>
<td>0%</td>
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<tr>
<td>Sugars</td>
<td>5g</td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td>5g</td>
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</tr>
</tbody>
</table>

**Quick Guide to % DV**

- 5% or less is Low
- 20% or more is High

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* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.

<table>
<thead>
<tr>
<th>Calories:</th>
<th>2,000</th>
<th>2,500</th>
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<tbody>
<tr>
<td>Total Fat</td>
<td>Less than</td>
<td>65g</td>
</tr>
<tr>
<td>Sat Fat</td>
<td>Less than</td>
<td>20g</td>
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<tr>
<td>Cholesterol</td>
<td>Less than</td>
<td>300mg</td>
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<tr>
<td>Sodium</td>
<td>Less than</td>
<td>2,400mg</td>
</tr>
<tr>
<td>Total Carbohydrate</td>
<td>300g</td>
<td>375g</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>25g</td>
<td>30g</td>
</tr>
</tbody>
</table>

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FDA’s Definition of “Low”:

- **low-fat**: 3 g or less per serving
- **low-saturated fat**: 1 g or less per serving
- **low-sodium**: 140 mg or less per serving
- **very low sodium**: 35 mg or less per serving
- **low-cholesterol**: 20 mg or less and 2 g or less of saturated fat per serving
- **low-calorie**: 40 calories or less per serving.
Trans Fat

- Made during hydrogenation
- ↑ shelf life & flavor stability
- Associated with ↑ LDL (“bad cholesterol”) & ↓ HDL (“good” cholesterol, which are linked to CHD

Timeline: 12 yrs from petition to implementation

- 1994-Cntr for Science in the Public Interest (CSPI) filed petition
- 1999-FDA issued proposed rule
- 2000-Comments period re-opened 3 times
- 2006-All food manufacturers must list trans fat on label
Enhancing Food Labels

Recommendations of FDA Obesity Working Group:

- Increase font size for calorie content
- Add total caloric content on food label of an entire food package if it is likely to be consumed in one sitting.
- Have %DV appear right next to calorie content
- Revise serving size
- Restaurant labeling of meals (rather than single products)
- Develop labeling statement that would inform consumer how much exercise would be necessary to burn the calories in the food package.
Health Claims

Health Claims are an extremely powerful marketing tool

Presently only US and Japan have established regulatory frameworks for the approval of health claims.

Food industry say FDA’s health claim policy is too restrictive and is envious of makers of dietary supplements that operate under looser regulations.

12 claims currently authorized:

1. Calcium and osteoporosis; (2) Fats and cancer; (3) Saturated fat and cholesterol and coronary heart disease; (4) Fiber-containing grain products, fruits, veggies & cancer; (5) Fiber-containing grain products, fruits, veggies & heart disease; (6) Sodium & Hypertension; (7) Fruits & veggies, with good sources of substances such as antioxidant vitamins, and cancer; (8) Folic acid and neural tube birth defects; (9) Dietary sugar alcohol and dental caries; (10) Soy protein and coronary heart disease; (11) Plant sterols and coronary heart disease; (12) Dietary soluble fiber and heart disease (new)
Should FDA’s powers to regulate health claims be relaxed?

Current criteria: “Significant Scientific Agreement”

Proposed: New standard defined as “the weight of scientific evidence”

- “Significant Scientific Agreement”
- Substantial but inconclusive evidence
- Evidence that is limited but inconclusive
- Little scientific evidence

E.g. “Supportive but not conclusive evidence shows that eating 1.2 ounces per day of walnuts as part of a diet of low unsaturated fat and cholesterol may reduce the risk of heart disease”
Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [name of food] provides [x] grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat and cholesterol content.]
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Dietary Guidelines

“It’s good. No, it’s bad. No, it’s good, really. I think.”

For more than 100 years Uncle Sam has scolded us to eat right!

“unless care is exercised in selecting food, a diet may result which is one-sided or badly balanced – that is, one in which either protein or fuel ingredients (carbohydrate & fat) are provided in excess “…..“the evils of overeating may not be felt at once, but sooner or later they’re sure to appear – perhaps an excessive amount of fatty tissue, perhaps a general debility, perhaps an actual disease”.

USDA
Relationship of Food, Nutrition & Health

Sanitation - role of contamination & illness
Germ Theory

<1900

Deficiency - role of inadequate intake & illness
Vitamin Theory

1910

Excess: Diet linked with non-communicable diseases
Diet & Chronic Disease

1950

Health & well-being

1980 1990 2002

New roles for nutrients in disease

RDAs

DRIs

Dietary Guidelines

Adapted from http://medocs.ucdavis.edu/imdbcm/419/Syllabus/04/Lec5-Functional.ppt
History of Dietary Guidelines

1894-1st USDA dietary recommendations (Atwater)
1916-US Food Guide (5 food groups)
1930’s-Food plans at 4 cost levels
1940’s-National Nutrition Council of Defense issued first set of RDAs for calories and 9 essential nutrients
1970’s-shift from obtaining adequate nutrition to avoiding excess of certain food components
1977-Dietary Goals for the United States
1979-Healthy People: The Surgeon General’s Report on Health Promotion & Disease
   Led to development of Food Guide and Food Pyramid (1992)
First USDA Food Guide, 1916

Five Food Groups:
1. Milk and meat
2. Cereals
3. Vegetables and Fruits
4. Fats and Fatty Foods
5. Sugars and sugary foods
RDAs

- 1941 Food and Nutrition Board (FNB) estab within the Nat’l Academy of Sciences.
- Role: Advise gov’t on issues relating to food & nutr’l status of the U.S. population.
- Developed guidelines on the amounts of nutrients to meet nutr’l needs & prevent disease due to nutrient deficiencies.
**Recommended Dietary Allowance (RDA)**

- Based on amount of nutrient needed to prevent deficiency for healthy people.
- Established on the basis of available scientific evidence to meet the known nutritional needs of practically all healthy persons in US.
- Levels are set to cover individual variation and provide a margin of safety above the minimal requirement.

**Roles of RDAs:**
- Set nutritional goals & evaluate dietary intake.
- As a basis of allotment & standard of nutritional quality.
- As a basis for food labeling standards & education.
- Guide food fortification.
Recommended Dietary Allowances

<table>
<thead>
<tr>
<th>1941</th>
<th>1989</th>
</tr>
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<tbody>
<tr>
<td>- Energy</td>
<td>- Energy</td>
</tr>
<tr>
<td>- Protein</td>
<td>- Protein</td>
</tr>
<tr>
<td>- 2 minerals (Ca, Fe)</td>
<td>- 7 minerals (Ca, Fe, P, Mg, Zn, I, Se)</td>
</tr>
<tr>
<td>- 6 vitamins (A, C, D, thiamin, riboflavin, niacin)</td>
<td>- 11 vitamins (A, C, D, thiamin, riboflavin, niacin, E, K, B, B₁₂, Folate)</td>
</tr>
<tr>
<td>- Safe and adequate daily dietary intakes (biotin, pantothenate, Cu, Mn, F, Cr, Mo)</td>
<td></td>
</tr>
</tbody>
</table>
Dietary Reference Intakes (DRIs)

Shift from preventing deficiency to decreasing risk of chronic disease through nutrition (includes levels that may decrease risk of CVD, osteoporosis & diet-related cancers)

Describe a distribution of requirements

How determined?

**Estimated Average Requirement (EAR)**-nutrient intake value that is estimated to meet nutrient req. in 50% on individuals

**Recommended Dietary Allowance (RDA)**-daily dietary intake level sufficient to meet nutrient requirements of nearly all individuals (EAR+2SD)

**Adequate Intake (AI)**-no EAR; approximates nutrient intake observed for healthy people

**Tolerable Upper Intake Level (TU)**-highest level on nutrient intake considered unlikely to pose any adverse health risk
Use of DRIs

- Used by health professionals to develop educational materials
- Used to assess the adequacy of dietary patterns
- Used by policy-makers for the development of science-based policies on food, nutrition, health & disease prevention—e.g. Dietary Guidelines
Dietary Guidelines

- Cornerstone of federal nutrition policy and education
- Allow government to speak with one voice to the public when presenting advice about proper dietary habits for healthy Americans
- Influence the direction of government nutrition programs, including research, labeling, and nutrition promotion.
- Federal nutrition assistance programs such as USDA's School Meal and Food Stamp Programs, and the WIC Program (Supplemental Food Program for Women, Infants and Children)
- Approved jointly by Secretaries of Health and Human Services and of Agriculture
Process for Development of Dietary Guidelines & Food Pyramid

Dietary Guidelines (DGs) for Americans:
- 5 year review mandated by Congress
- Review performed by panel of experts
- Changes must be evidence-based
- Final report issued by Sec’tys of HHS & USDA

Food Pyramid
- Educational tool developed by USDA
- Must be consistent with DGs
- Goal is to translate nutrient recommendations into kinds & amounts of food to eat daily
What’s New?

Emphasis on balancing energy intake with energy expenditure (calories in=calories out)

Paradigm change: Look at activity level, and select food pattern closest to your energy expenditure level

   12 different patterns—1000 kcal/day to 3200 kcal/day

Emphasizes food patterns rich in nutrient levels for which intake is low in adult American diet (Vit A, Vit C, Vit D, Calcium, Manganese & Fiber)

Increase servings of fruits and vegetables (2 fruit, 2.5 veggies for 2000 kcal diet)

Increased serving of milk from 2 to 3 to reach potassium recommendation (dairy foods one of the best potassium sources in addition to fruits and vegetables)

Specific amount of whole grains (3 oz) or ~1/2 of recommended 5-10 daily servings of grains, depending on calorie need.

Portions focus on cups or ounces rather than servings
What are the critiques saying?

No reference to body size.

Guidelines do not specify what foods to avoid or cut back on (e.g. whole milk, refined carbs, sugar beverages, trans fat)

Too much of the burden falls on the consumer’s personal responsibility (e.g. to distinguish between whole vs. refined grains, identify low-fat foods, etc).

Food Pyramid viewed more as a marketing tool of the food industry than an educational tool for consumers

The Pyramid’s web-based tools mean less access for low-income individuals.
“Eat less”

At the root of much controversy over nutrition advice

Directly conflicts with food industry demands that people eat more of their products

“Eat less beef” → “Eat less saturated fat”

“Eat less sugar” → “Choose a diet moderate in sugar”
What’s at Stake?

Dairy Council: Launched $50m “3-a-Day Dairy” marketing blitz

Potato farmers hope to regain the “spud’s” former glory (which took a hit during the low-carb craze) with higher recommendation of vegetable intake

Large segment of food industry trying to recover from low carb trend, and believes it has found the answer in whole grains.
Ancel & Margaret Key’s 1959 Dietary Guidelines for prevention of CHD

Do not get fat, if you are fat, reduce.

Resist saturated fats, the fats in beef, pork, lamb, sausage, margarine, solid shortenings, fats in dairy products.

Prefer vegetable oils to solid fats, but keep total fats under 30% of your diet calories.

Favor fresh vegetables, fruits and non-fat milk products.

Avoid heavy use of salt and refined sugar

Good diets do not depend on drugs or fancy preparations

Get plenty of exercise and outdoor recreation.

Be sensible about cigarettes, alcohol, excitement, business strain

See your doctor regularly, and do not worry.

Evaluating how well Americans conform to recommended dietary patterns
Healthy Eating Index

a measure of how well American diets conform to recommended healthy eating patterns

10 components

Score: Per component: 0-10; Total Score: 0-100

Rating: >80=“Good”; 51-80=“Needs Improvement”; <51=“Poor”
Distribution of Individuals by HEI, 1990, n=3400

Mean HEI=63.9

So, how is policy made?

Societal priorities
Resource allocation
Opportunity Costs
Changing cultural norms
Special interests
Politics
Greed

And hopefully informed by SCIENCE and scientists who are willing to be engaged in the policy process!