

FDA's Nutrition Innovation Strategy

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HER/NOPREN Healthy Food Retail Working Group Meeting

December 18, 2018

Agenda



- Background
- Nutrition Innovation Strategy
- Participating in the regulatory process
- Staying in touch with FDA
- Discussion

FDA Food Responsibilities

- 20¢ of every consumer dollar in the US spent on FDA-regulated products
- FDA regulates safety & labeling of 80% of all food consumed in the United States
 - Ensure that consumers are provided with accurate and useful information in food labeling
 - Encourage food product reformulation to create healthier products
- Close collaboration with CDC, NIH, USDA and other federal partners



of food supply
regulated by FDA

Current Eating Patterns in the United States

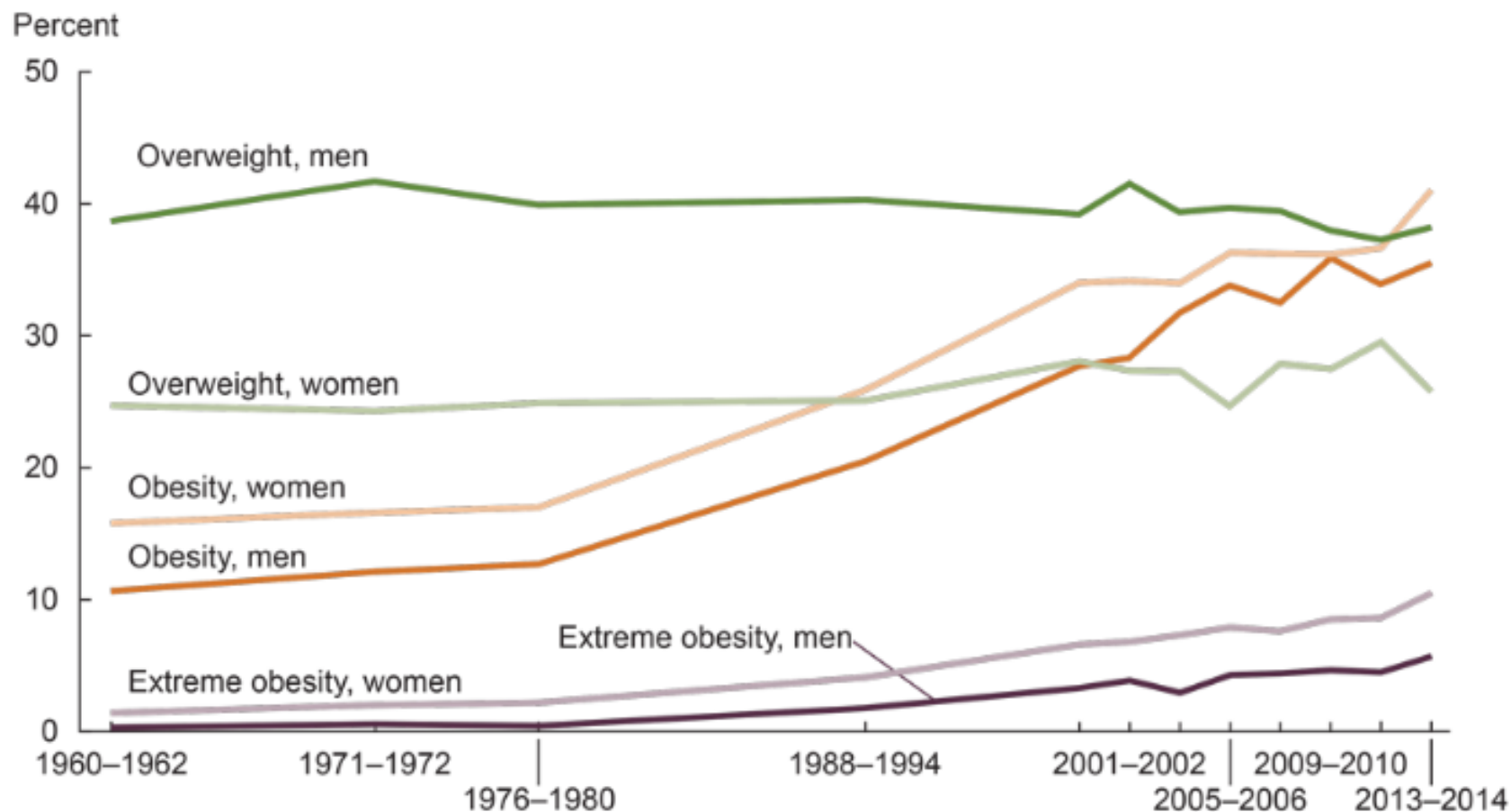
Percent of the U.S. Population Ages 1 Year and Older Who Are Below, At, or Above Each Dietary Goal or Limit



Note: The center (0) line is the goal or limit. For most, those represented by the orange sections of the bars, shifting toward the center line will improve their eating pattern.

Data Source: What We Eat in America, NHANES 2007-2010 for average intakes by age-sex group. Healthy U.S.-Style Food Patterns, which vary based on age, sex, and activity level, for recommended intakes and limits.

Figure. Trends in adult overweight, obesity, and extreme obesity among men and women aged 20–74: United States, 1960–1962 through 2013–2014

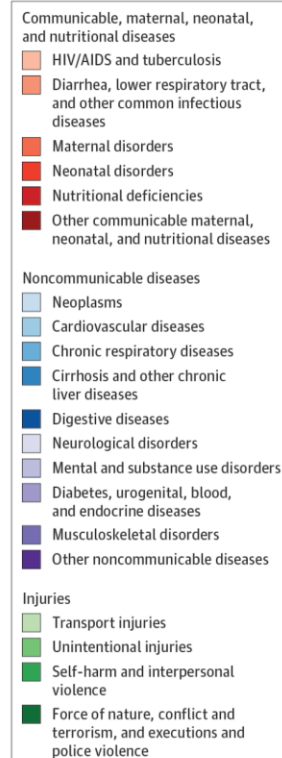
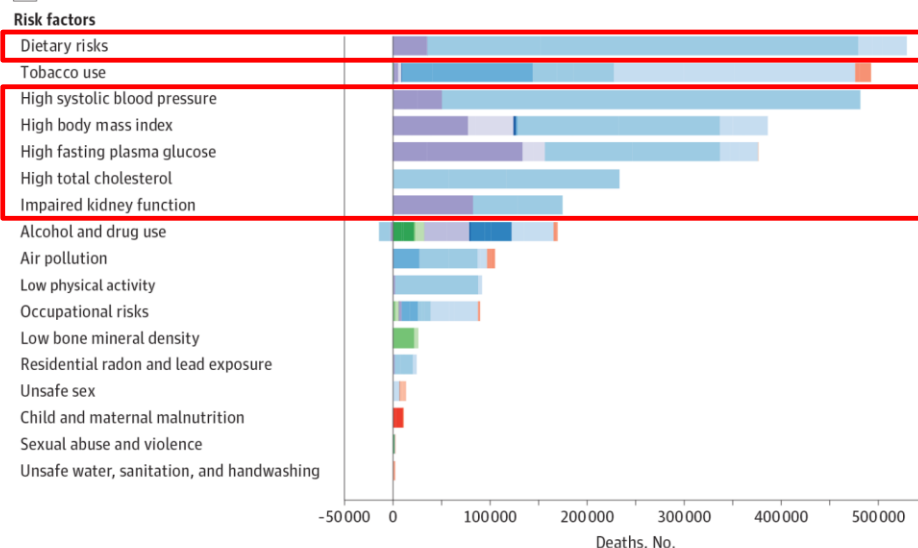


NOTES: Age-adjusted by the direct method to the year 2000 U.S. Census Bureau estimates using age groups 20–39, 40–59, and 60–74. Overweight is body mass index (BMI) of 25 kg/m² or greater but less than 30 kg/m²; obesity is BMI greater than or equal to 30; and extreme obesity is BMI greater than or equal to 40. Pregnant females were excluded from the analysis.

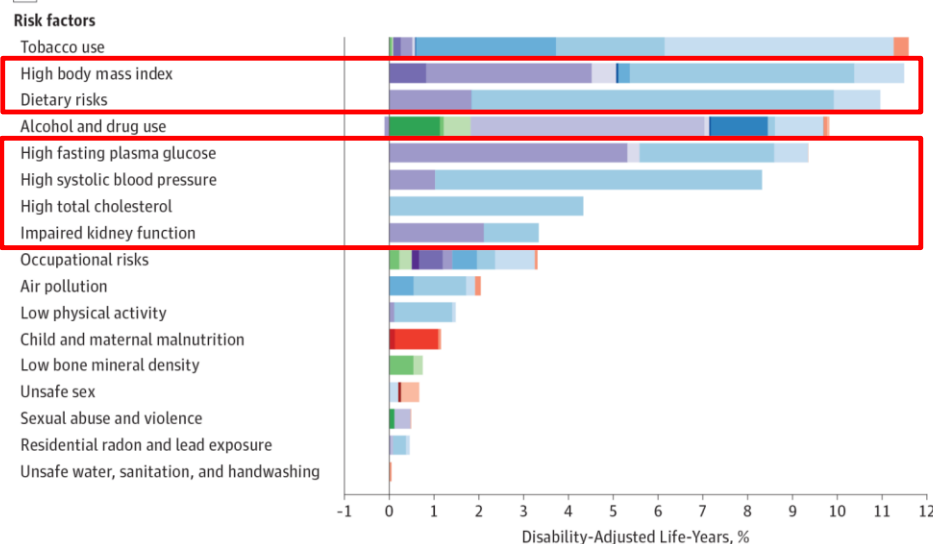
SOURCES: NCHS, National Health Examination Survey and National Health and Nutrition Examination Surveys.

Number of Deaths and Percentage of Disability-Adjusted Life-Years Related to the 17 Leading Risk Factors in the United States, 2016

A Risk factors and related deaths



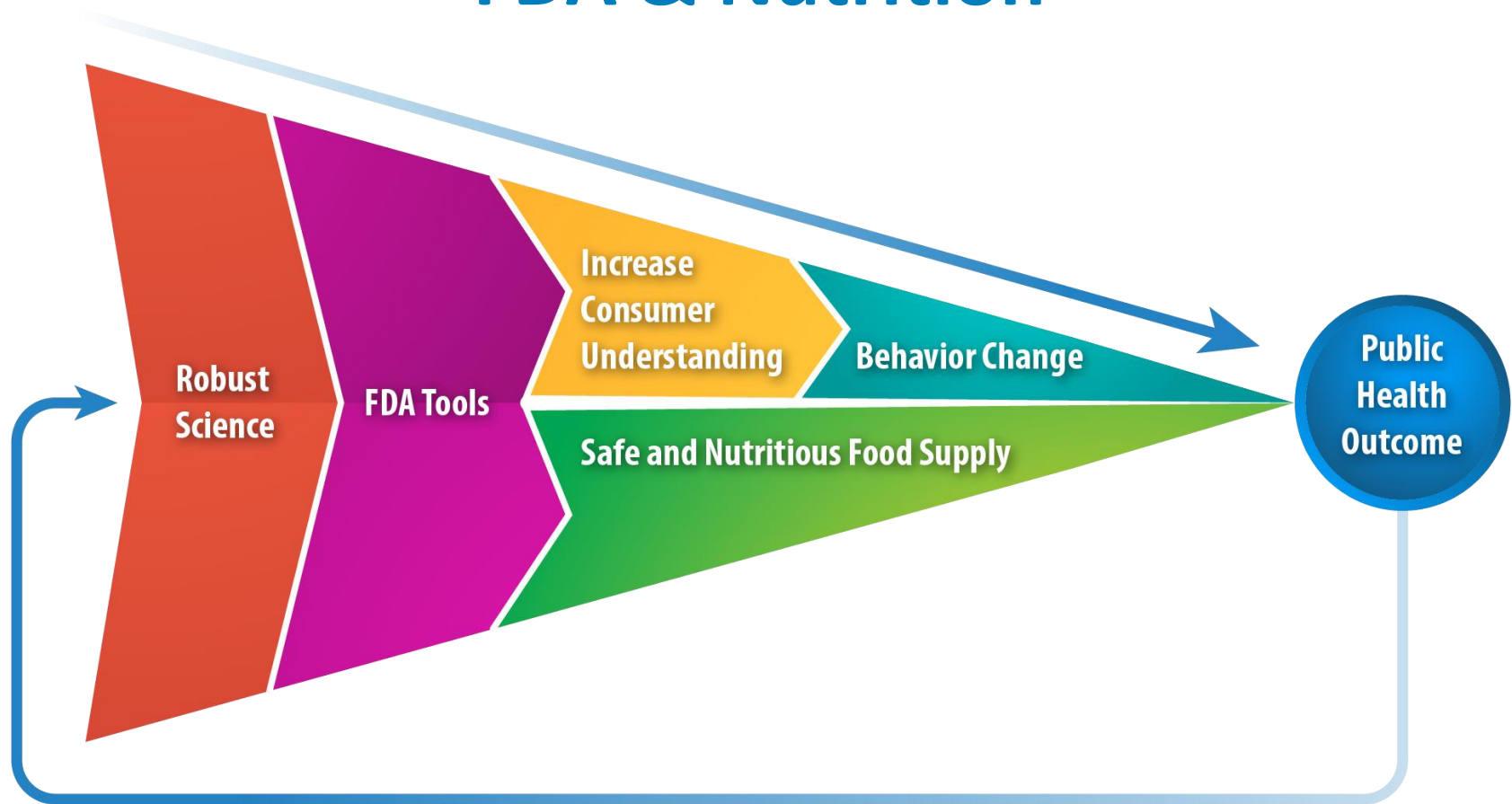
B Risk factors as a percentage of disability-adjusted life-years



Source:

The State of US Health, 1990-2016 Burden of Diseases, Injuries, and Risk Factors Among US States JAMA. 2018;319(14):1444-1472. doi:10.1001/jama.2018.0158

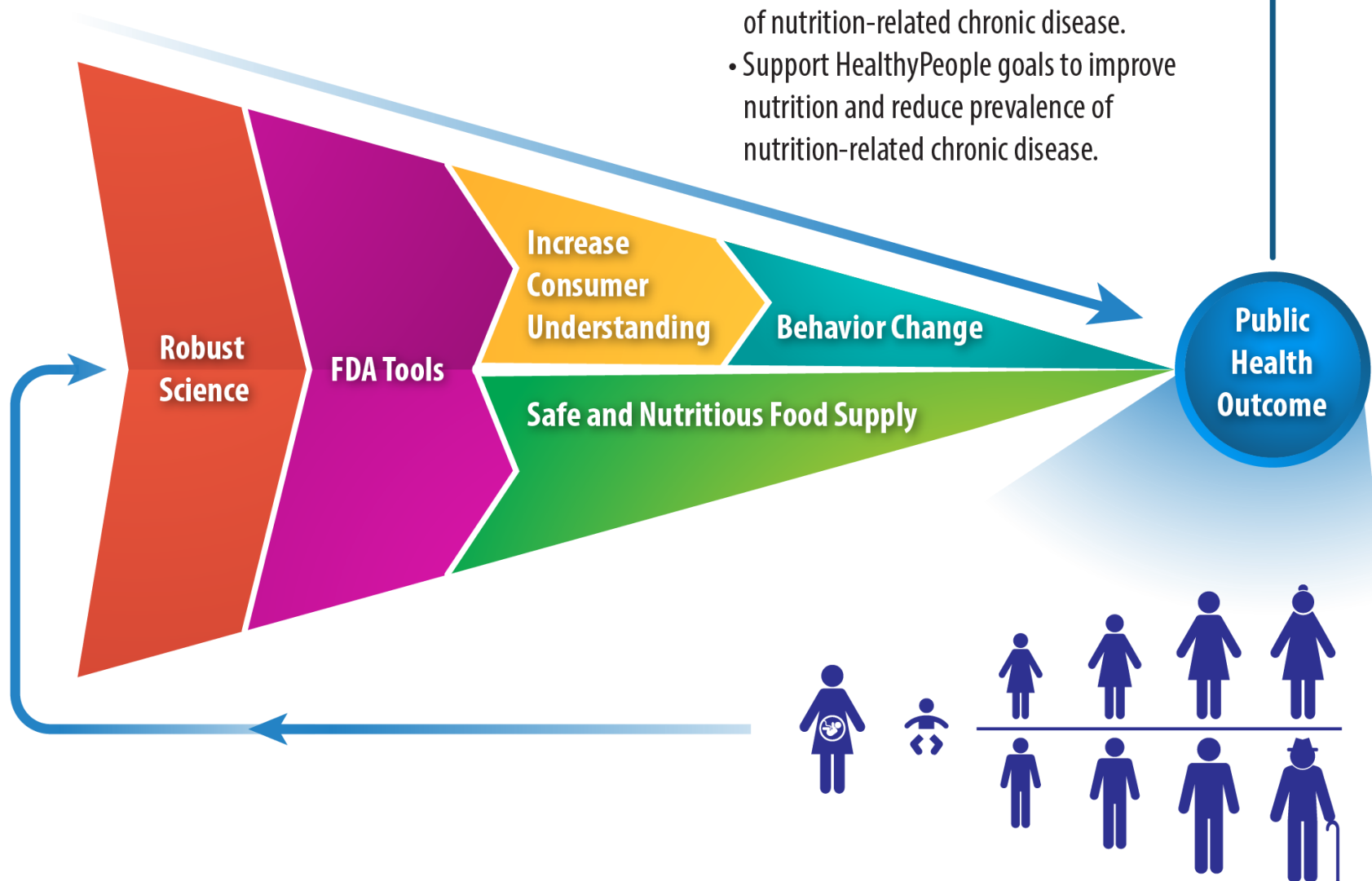
Conceptual Framework FDA & Nutrition





Public Health Outcome

- Reduce risk factors for and the incidence of nutrition-related chronic disease.
- Support HealthyPeople goals to improve nutrition and reduce prevalence of nutrition-related chronic disease.



Nutrition Innovation Strategy



FDA Nutrition Innovation Strategy

“Improvements in diet and nutrition offer us one of our greatest opportunities to have a profound and generational impact on human health....The public health gains of such efforts would almost certainly dwarf any single medical innovation or intervention we could discover.”

Scott Gottlieb, M.D.
National Food Policy Conference
March 29, 2018

FDA's Nutrition Innovation Strategy



Goal: Reduce the burden of chronic disease through improved nutrition

- Empower consumers with information
- Facilitate industry innovation toward healthier foods that consumers are seeking

Key Elements

- Modernizing claims
- Modernizing standards of identity
- Modernizing ingredient labels
- Reducing sodium
- Implementing menu labeling and the updated Nutrition Facts label, including Nutrition Facts label consumer education campaign



Modernizing Claims



- Claims on food and beverage products act as quick signals for consumers about the nutritional benefits of those products, and they can encourage the industry to reformulate products to improve their healthy qualities
- The nutrient content claim “healthy” is one claim that is ready for a change to be more consistent with current science
- Along with updating the definition of the claim “healthy” we are exploring ways to depict “healthy” on the package so consumers can easily find it
- FDA is also interested in exploring claims for products that offer food groups for which American diets typically fall short of recommendations
 - Examples include whole grains, low-fat dairy, fruits and vegetables, and healthy oils

Modernizing Standards of Identity



- Standards of identity establish requirements related to the content and production of certain food products.
- FDA will take a fresh look at existing standards of identity in light of marketing trends and the latest nutritional science.
- The goal is to maintain the basic nature and nutritional integrity of products while allowing industry flexibility for innovation to produce more healthful foods.

Modernizing Ingredient Information

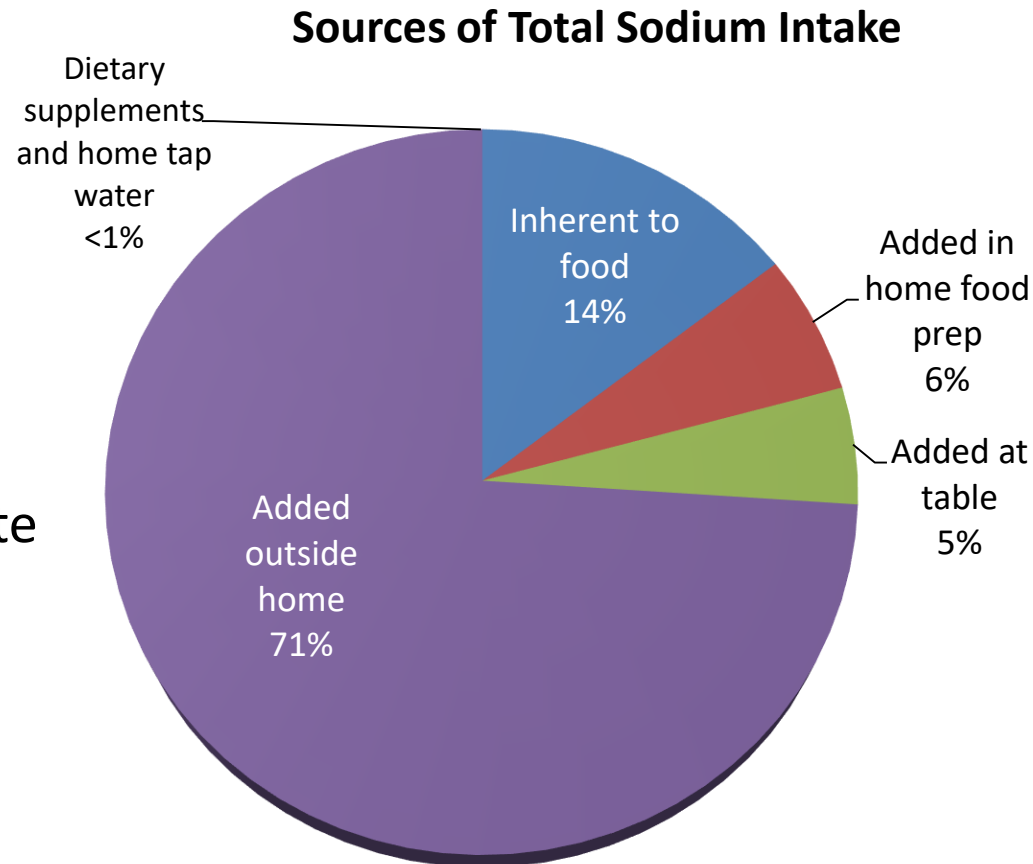


- FDA plans to re-evaluate the ingredient information on food packages to see what changes could make it more consumer-friendly
 - E.g., Making information more readable and understandable by changing font or declaring ingredients by names in common usage
- Combining food claims and making ingredient information on labels easier to decipher can allow consumers to choose healthy diets, while staying within caloric guidelines

Voluntary Sodium Reduction: Why are Targets Needed?



- Most sodium comes from salt added to processed and restaurant foods
- It is difficult to meet recommended sodium intake with current food supply
- Overall sodium content of the food supply remains high, despite industry efforts
- Variability in sodium across similar foods in the food supply shows that reductions are possible



Harnack et al., Circulation 2017

Overview of FDA Approach



- Draft, voluntary guidance on sodium reduction targets
 - Gradual approach
 - Targets for 150 categories of food
 - Applies to food manufacturers, restaurants and food service operations
- Draft targets serve as a basis for continued dialogue

Voluntary Sodium Reduction Targets

- Public comment periods closed on October 17, 2016 (2-year targets) and Dec 2, 2016 (10-year targets)
 - Many comments related to targets and food categories received
- Current activities
 - Reviewing comments; considerations:
 - Feedback regarding certain targets and categories
 - Technical role of sodium in foods



Implementing the Nutrition Facts Label

- May 4, 2018: FDA published a final rule extending compliance date
 - Jan 1, 2020 for manufacturers with annual food sales at or above \$10 million. Jan 1, 2021 for all others
- Many manufacturers have already started using the new labels
 - Additional time helpful for manufacturers using isolated or synthetic fibers
 - Additional time also allows time for USDA to issue its rule on disclosure of genetically engineered ingredients
- FDA has announced the launch of a major educational campaign surrounding the new nutrition information consumers will be seeing in the marketplace
- FDA issued guidances on issues such as dietary fiber, and serving size declarations

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

Implementing the Nutrition Facts Label:

Guidance Documents for Industry



- Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals
- *Draft:* Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics
- The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels
- Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible carbohydrates Submitted as a Citizen Petition
- *Draft:* Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products
- Reference Amounts Customarily Consumed: List of Products for Each Product Category
- Small Entity Compliance Guide for Serving Size Final Rule
- FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels

Labeling Single-Serving Packages



Calories and other nutrients must be declared for the entire package rather than per serving because people typically consume the package in one sitting.

Dual Column Labeling

- Required on packages that can be consumed in one or multiple sittings
- Nutrition information presented per serving and per package
- For packages that contain 200% and up to and including 300% of the RACC (Reference Amount Customarily Consumed)
 - A 3oz (90g) bag of chips would be labeled per serving [1oz (30 g)] and per package [90 g]

Nutrition Facts					
2 servings per container					
Serving size			1 cup (255g)		
	Per serving		Per container		
Calories	220		440		
	% DV*		% DV*		
Total Fat	5g	6%	10g	13%	
Saturated Fat	2g	10%	4g	20%	
Trans Fat	0g		0g		
Cholesterol	15mg	5%	30mg	10%	
Sodium	240mg	10%	480mg	21%	
Total Carb.	35g	13%	70g	25%	
Dietary Fiber	6g	21%	12g	43%	
Total Sugars	7g		14g		
Incl. Added Sugars	4g	8%	8g	16%	
Protein	9g		18g		
Vitamin D	5mcg	25%	10mcg	50%	
Calcium	200mg	15%	400mg	30%	
Iron	1mg	6%	2mg	10%	
Potassium	470mg	10%	940mg	20%	

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Increasing Adoption of Updated Nutrition Facts Label



NFP ADOPTION METRICS

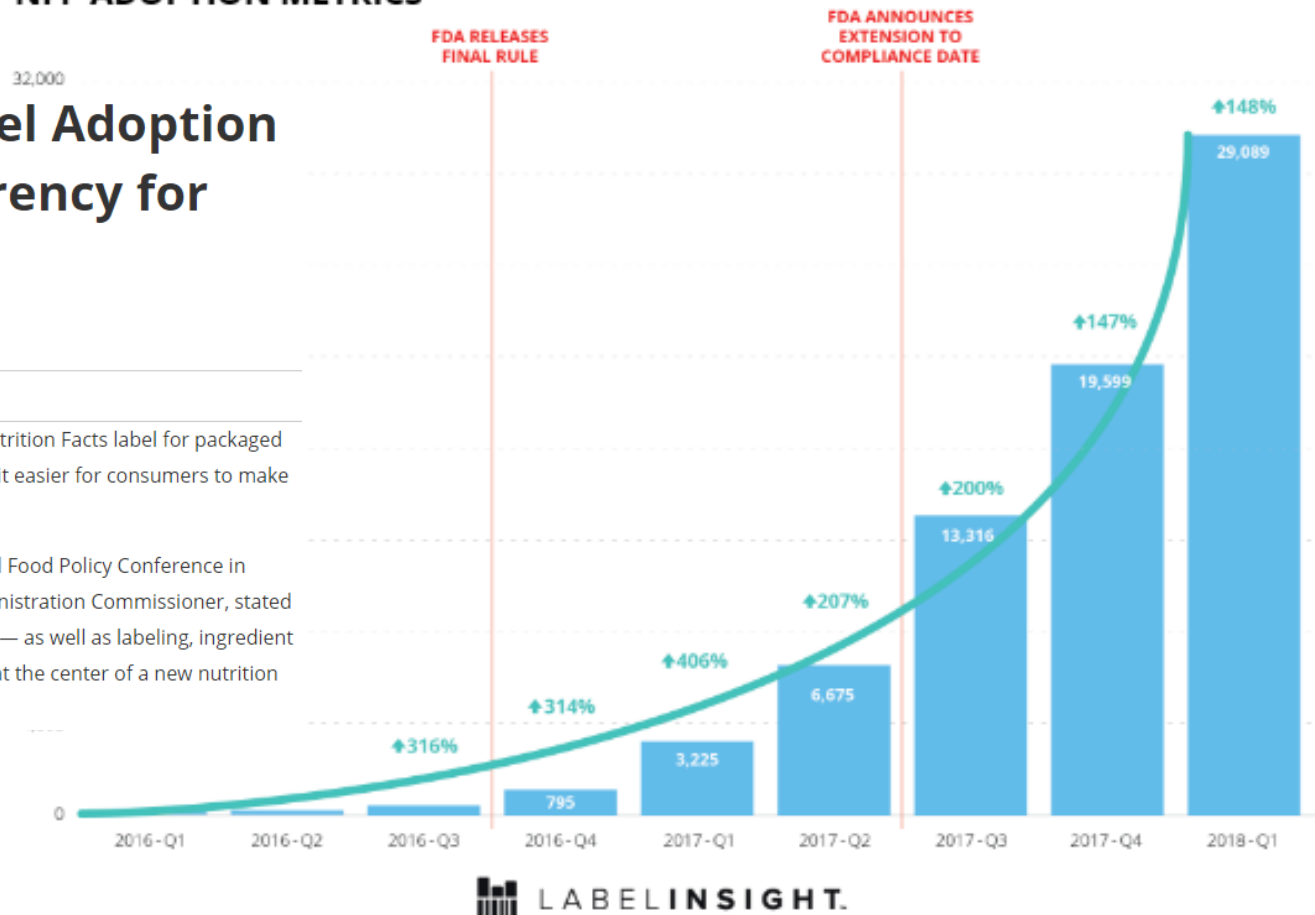
Growing New Label Adoption Provides Transparency for Consumers

Posted by [Megan Sheahan](#) on April 5, 2018

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In May of 2016, the FDA announced the new Nutrition Facts label for packaged foods. The purpose of the new label is to make it easier for consumers to make better informed food and beverage choices.

During a recent [keynote address](#) at the National Food Policy Conference in Washington, D.C., Scott Gottlieb, the Drug Administration Commissioner, stated regulations dealing with consumer information — as well as labeling, ingredient and standard of identification initiatives — are at the center of a new nutrition innovation strategy.



Implementing Menu Labeling

- May 7, 2018: Menu labeling compliance date; FDA released final guidance that provides flexibility on how covered establishments can provide calorie information in ways that meet various business models.
- The new measures, for the first time, create a national and uniform standard for the disclosure of calorie information on menus at chain restaurants and other retail establishments



Menu Labeling: Supplemental Guidance for Industry

*Additional copies are available from:
Office of Nutrition and Food Labeling, HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2373*

<http://www.fda.gov/FoodGuidances>

You may submit written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number [FDA-2011-F-0172] listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

May 2018

CREATE YOUR OWN PIZZA CALORIES ARE LISTED PER SLICE

CHOOSE YOUR SIZE & CRUST

6 SLICES
S

\$9.99

8 SLICES
M

\$11.99

10 SLICES
L

\$13.99

12 SLICES
XL

\$15.99



CHEESE PIZZA

ORIGINAL (200-240 Cal.), THIN & CRISPY (150-190 Cal.), PAN (260-300 Cal.), GLUTEN FREE† (140 Cal.)

†ONLY AVAILABLE IN SMALL

CHOOSE YOUR SAUCE*



TOMATO SAUCE (10 Cal.), SPICY MARINARA (10 Cal.), WHITE GARLIC SAUCE (30-50 CAL.), BBQ (10-20 Cal.)

CHOOSE YOUR TOPPINGS*

S

\$1.00

M

\$1.50

L

\$2.00

XL

\$2.25



MEATS

BACON (45-60 Cal.), BEEF (40-45 Cal.), CHICKEN (15-20 Cal.), HAM (10-15 Cal.), PEPPERONI (25-35 Cal.), SALAMI (25-30 Cal.), ITALIAN SAUSAGE (40-50 Cal.)

VEGGIES

BANANA PEPPERS (0-5 Cal.), GREEN PEPPERS (0 Cal.), JALAPENOS (0-5 Cal.), FRESH MUSHROOMS (5 Cal.), BLACK OLIVES (10-15 Cal.), FRESH ONIONS (0-5 Cal.), PINEAPPLE (10 Cal.), ROASTED RED PEPPERS (0 Cal.), FRESH BABY SPINACH (0 Cal.), TOMATOES (5 Cal.)

2,000 CALORIES A DAY IS USED FOR GENERAL NUTRITION ADVICE, BUT CALORIE NEEDS VARY
ADDITIONAL NUTRITION INFORMATION AVAILABLE UPON REQUEST

*ADDED CALORIES FOR 1 TOPPING PIZZA

Example of declaring calories per slice for a build-your-own pizza using a string format



Example of declaring calories for multiple items on a self-service salad bar or a single sign attached to the sneeze guard



Example of declaring calories for self-service foods on individual signs using gel clings on the sneeze guard

Vending Machine Labeling

- Final Rule issued December 2014:
 - “Food Labeling: Calorie Labeling of Articles of Food in Vending Machines”
 - Compliance date: December 1 2016
- 2018 Proposed Rule:
 - Vending operators may rely on Front of Pack (FOP) labeling to disclose calories on food items in glass front vending machines
 - FDA proposed to amend the type size requirement for FOP calorie disclosures to be at least 150% of the net weight declaration
 - Enforcement discretion until 1/1/2020
 - Glass front vending machines using FOP labeling
 - Gums, mints & rolled candy

The screenshot displays the FDA's official website for Vending Machine Labeling Requirements. The header includes the FDA logo, the text "U.S. FOOD & DRUG ADMINISTRATION", and navigation links for "A to Z Index", "Follow FDA", and "En Español". A search bar is located in the top right corner. Below the header, a navigation menu lists various FDA categories: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled "Food" and includes a breadcrumb trail: Home > Food > Guidance & Regulation > Guidance Documents & Regulatory Information by Topic > Labeling & Nutrition. A sidebar on the left, titled "Labeling & Nutrition", contains links to "Changes to the Nutrition Facts Label", "Topic-Specific Labeling Information", "Menu and Vending Machines Labeling Requirements", and "Small Business Nutrition Labeling Exemption". The main content area features the title "Vending Machine Labeling Requirements" with social media sharing options (Facebook, Twitter, LinkedIn, Pinterest, Email, Print). Below this is a link to "<<< Back to Menu and Vending Machines Labeling Requirements main page". The "Final Rule Information" section states that the "Vending Machine Final Rule: Food Labeling: Calorie Labeling of Articles of Food in Vending Machines" was published in December 2014 and requires operators to register and disclose calorie information. The "2018 Proposed Rule Information" section explains that vending machine operators can rely on front-of-pack labeling to disclose calories, with a proposed amendment to the type size requirement. The "Guidance for Industry" section lists links to draft guidance, small entity compliance guides, and FDA Form 3757, along with contact information for questions. The "Compliance Dates" section specifies that the compliance date is December 1, 2016, for most provisions, except for front-of-pack calorie declarations on food products sold in glass-front vending machines and certain candy products.

Vending Machine Labeling Requirements

<<< Back to Menu and Vending Machines Labeling Requirements main page

Final Rule Information

Vending Machine Final Rule: Food Labeling: Calorie Labeling of Articles of Food in Vending Machines (published December 2014) - Requires operators who own or operate 20 or more vending machines, or who own or operate fewer than 20 vending machines and voluntarily register to be covered by the rule, to disclose calorie information for food sold from vending machines, subject to certain exemptions.

2018 Proposed Rule Information

Vending machine operators may choose to rely on front of pack labeling to disclose calories on food items that consumers can see in glass-front vending machines. On July 12, 2018, FDA published the proposed rule [Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines](#). FDA proposed to amend the current type size requirement for front of pack calorie disclosures on vending machine foods that vending machine operators may rely on to meet the calorie labeling requirements. The proposed rule would allow the vending machine operator to rely on the front-of pack calorie declaration to meet the calorie labeling requirements if the type size of the calorie declaration on the front of pack is at least 150 percent (one and a half times) the type size of the net weight declaration, and the front of the food package can clearly be seen through a glass front vending machine.

Guidance for Industry

- [Draft Guidance: Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry](#)
- [Small Entity Compliance Guide: Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry](#)
- [FDA Form 3757](#) for voluntary registration.
- For questions related to Vending Machine Labeling contact CalorieLabelingVend@fda.hhs.gov.

Compliance Dates

- The compliance date is December 1, 2016 for all provisions of the final rule except for front of pack calorie declarations on food products sold in glass-front vending machines, and calorie declarations for gums, mints and roll candy products sold in glass front vending machines in packages that are too small to bear front-of-package labeling.

For questions related to Vending Machine Labeling: CalorieLabelingVend@fda.hhs.gov.

FDA's Nutrition Innovation Strategy



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- Empower consumers with information
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Key Elements

- Modernizing claims
- Modernizing standards of identity
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FDA's Rulemaking Process

FDA solicits public comment when establishing or modifying how a product is regulated

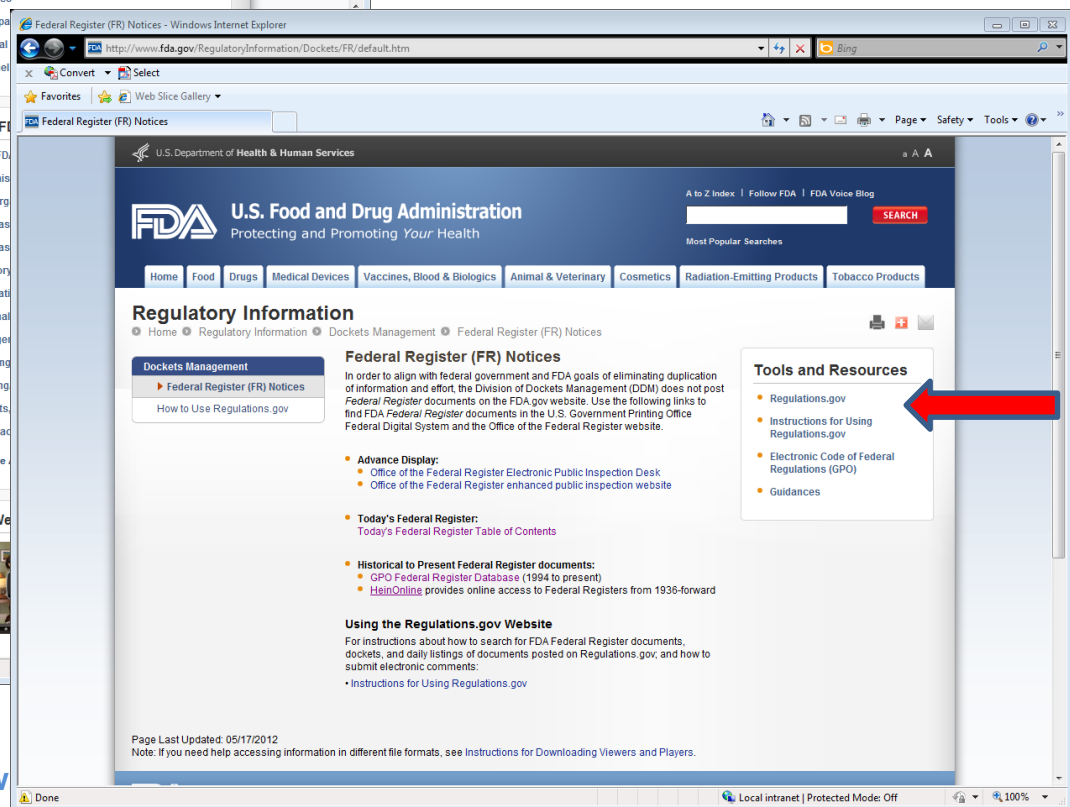
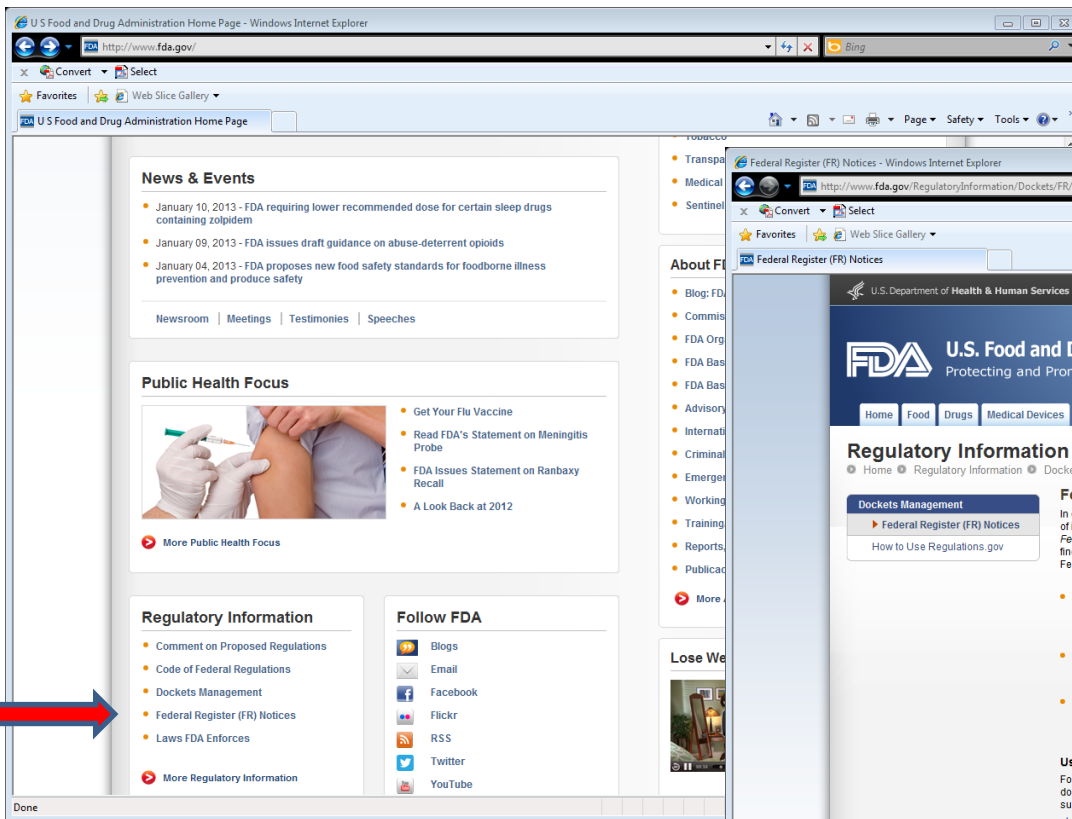
FDA's Rulemaking Process



- FDA requests public comment
- Your participation is needed when FDA:
 - publishes proposed rules (also called regulations, which have the force and effect of law),
 - issues guidance documents (statements of our current thinking on a topic), and
 - conducts public meetings and hearings.

How to Find Federal Register Documents

www.fda.gov or www.regulations.gov



Make a difference. Submit your comments and let your voice be heard.

EXAMPLE



SEARCH for: Rules, Comments, Adjudications or Supporting Documents:

 Healthy public meeting

» Advanced Search

What's Trending

Organic Research, Promotion, and Information Orders: Certified Products

Closing on Apr 19, 2017

Memo opening a comment period for this docket.

Closing on May 15, 2017

Endangered and Threatened Species: Petition for Rulemaking To Establish a Whale Protection Zone for Southern Resident...

Closing on Apr 13, 2017

Federal Motor Vehicle Safety Standards: V2V Communications

Closed on Apr 12, 2017

Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products; Extension of Comment...

Closing on Jul 10, 2017

Comments Due Soon

Today (55)

Next 3 Days (86)

Next 7 Days (180)

Next 15 Days (367)

Next 30 Days (704)

Next 90 Days (1,033)

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Last 90 Days (5,482)

[FAA Section 333](#)

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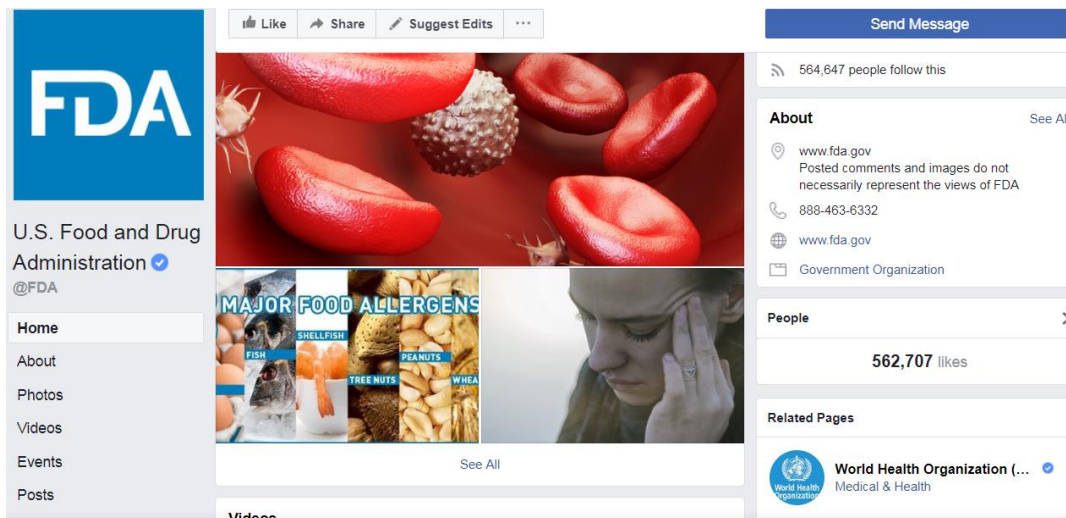


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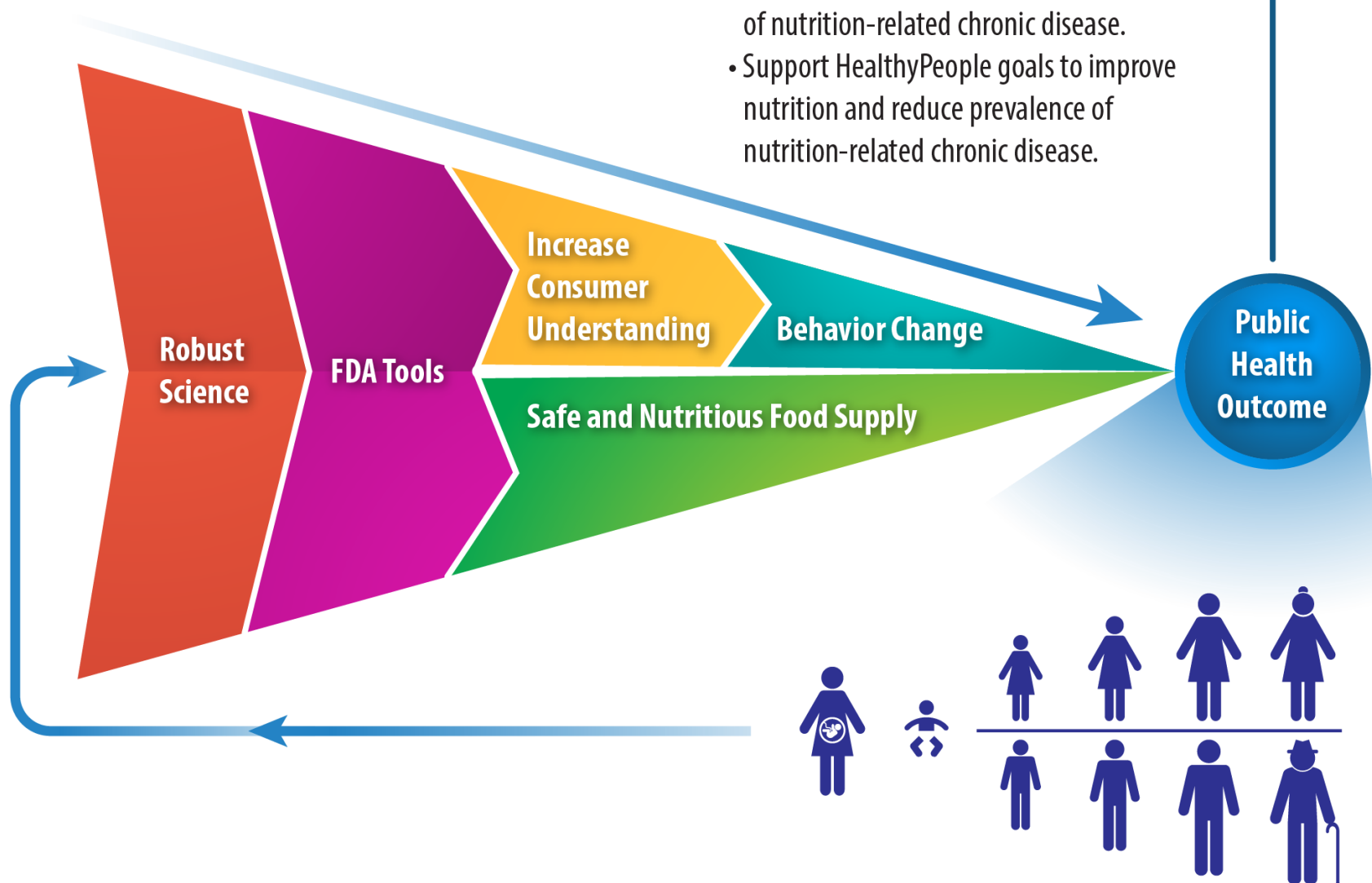
- FDA Constituent Updates

<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/default.htm>



Public Health Outcome

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