

CFSAN Update

Comments by

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DC IFT Food Policy Impact 2017

February 9, 2017

FDA Food Safety Modernization Act (FSMA)

FSMA Implementation – Accomplishments

Published 7 Final Rules:

- Preventive controls for human and animal food
 - Compliance date for large facilities – 9/19/16
- Produce safety
 - Draft guidance on sprouts - published on 1/23/17
 - FDA is considering how to simplify the agricultural water standards while still protecting public health
- Foreign supplier verification programs
- Accreditation of third-party auditors
- Sanitary Food Transportation
- Intentional Adulteration

FSMA Implementation – Current Initiatives

- Develop Guidance:
 - Preventive Controls, e.g., supply chain, HACCP (chapters 6 – 14)
 - Produce, e.g., general guidance on produce
 - Updated draft guidance on control of *Listeria monocytogenes* (*Lm*) in ready to eat foods – published on 1/17/17
 - Additional draft guidance on *Lm* -- i.e., compliance policy guide, classification of food as ready to eat
- Establish Produce Safety Network
- Establish a unified, modernized approach to import activities

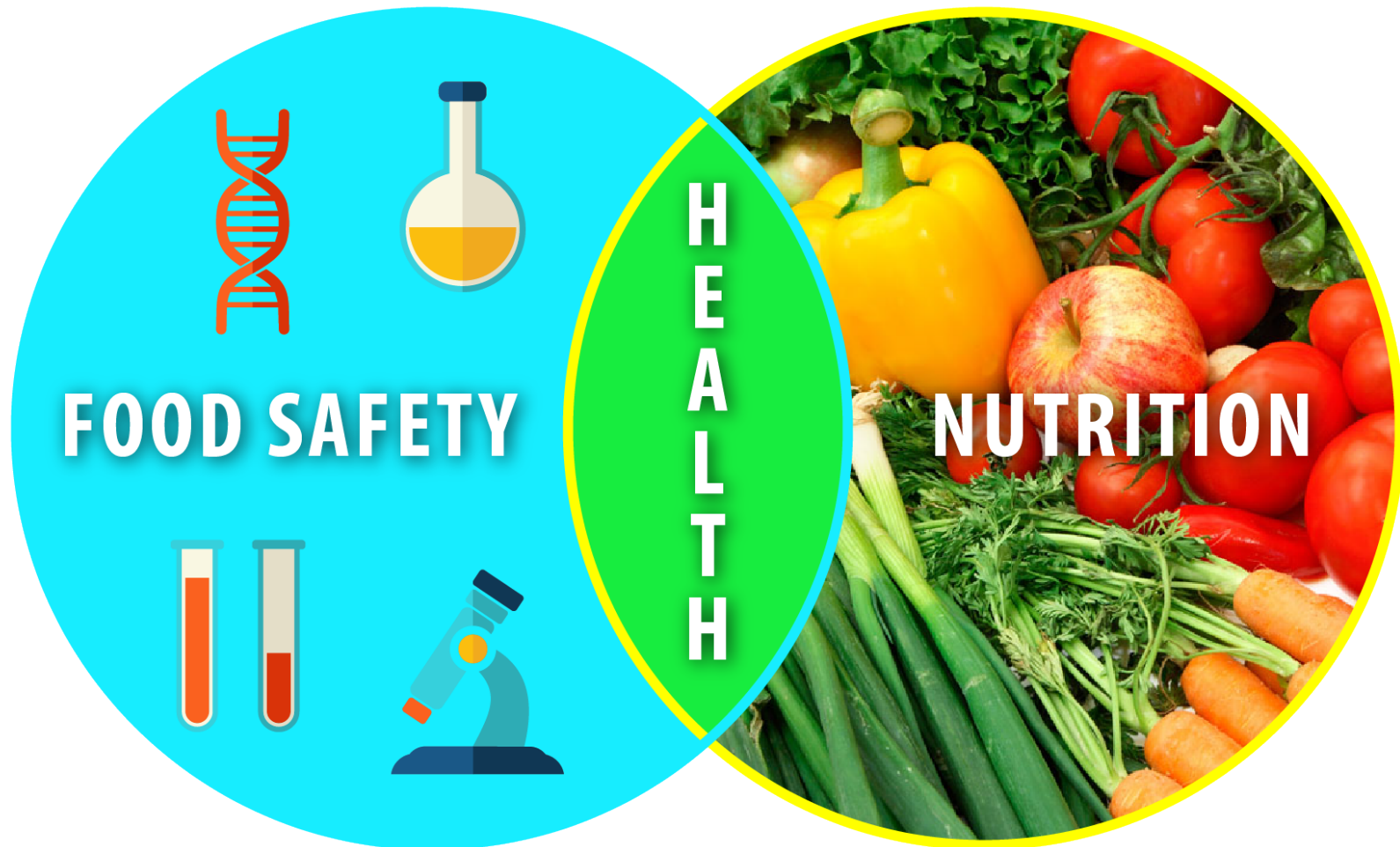
Public Hearing February 14 and 15

- “Partnerships to Ensure the Safety of Imported Foods” Public Hearing Topics:
 - food safety capacity building in other countries
 - employing the “same level of public health protection” requirement
 - enhancing risk-based decision making through consideration of private standards
 - commodity-specific export programs
 - systems recognition agreements
- Opportunity for FDA to receive input from stakeholders as it develops, expands, and refines partnership activities related to imported foods
- The hearing will be held February 14th and 15th in College Park, Maryland



Recent Nutrition Initiatives to Reduce the Risk of Chronic Disease

Food Safety, Nutrition and Health



Updating the Nutrition Facts Label

SIDE-BY-SIDE COMPARISON

Original Label

Nutrition Facts			
Serving Size 2/3 cup (55g)			
Servings Per Container About 8			
Amount Per Serving			
Calories 230		Calories from Fat 72	
		% Daily Value*	
Total Fat	8g	12%	
Saturated Fat	1g	5%	
Trans Fat	0g		
Cholesterol	0mg	0%	
Sodium	160mg	7%	
Total Carbohydrate	37g	12%	
Dietary Fiber	4g	16%	
Sugars	1g		
Protein	3g		
Vitamin A		10%	
Vitamin C		8%	
Calcium		20%	
Iron		45%	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

New Label

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.	

NEW LABEL / WHAT'S DIFFERENT

Servings:
larger,
bolder type

Nutrition Facts	
8 servings per container	
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— Serving sizes updated

— Calories: larger type

— Updated daily values

— Actual amounts declared

— New footnote

New:
added sugars

Change
in nutrients
required

Serving Size Changes

What's considered a single serving has changed in the decades since the original nutrition label was created. So now serving sizes will be more realistic to reflect how much people typically eat at one time.

CURRENT SERVING SIZE



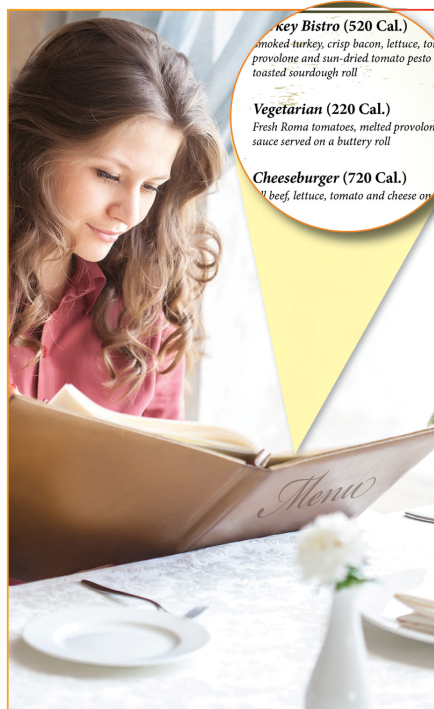
NEW SERVING SIZE



Status/Current Activities

- Draft Guidance and Request for Information (RFI) on Redefining “Healthy”- 9/28/2016
 - Comment period on RFI extended to 4/26/17
 - FDA Public Meeting
 - March 9, 2017; 8:30 am – 5:30 pm
 - Hilton Washington DC/Rockville Hotel
 - 1750 Rockville Pike
 - Rockville, MD 20852
- Draft Guidance and RFI on Fiber – 11/23/16
 - Comment period on both extended to 2/13/17
- Draft Guidance (2) on NFL Updates -1/4/17
- Nutrition Facts Label Education

Menu and Vending Machine Labeling



Menu and Vending Machine Labeling

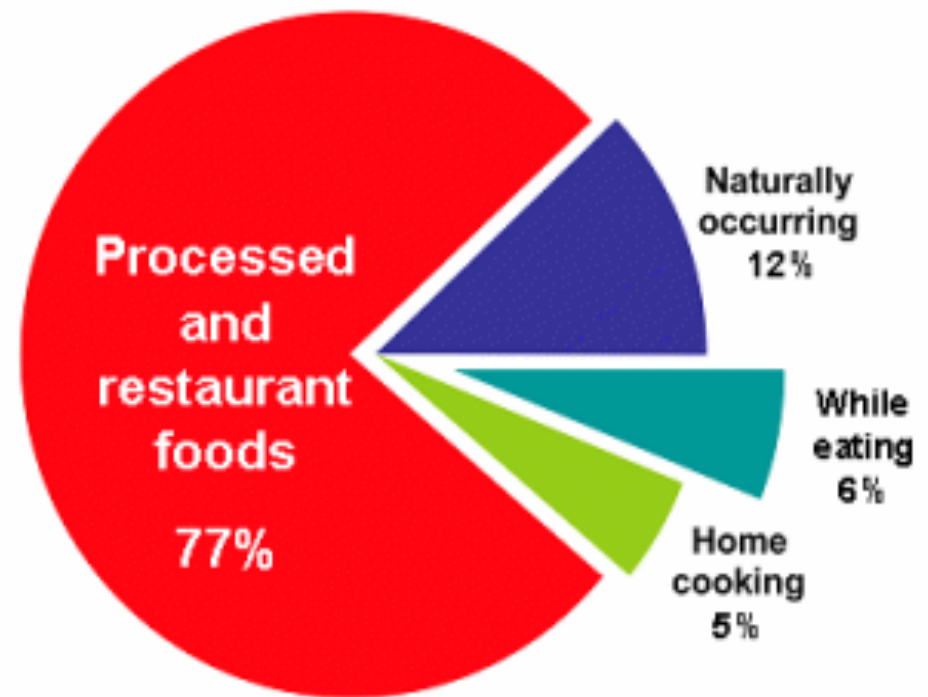
- Section 4205 of the Affordable Care Act
- Applies to restaurants and similar retail food establishments that are part of a chain with 20 or more locations
- Applies to a person who is engaged in the business of owning or operating 20 or more vending machines or who voluntarily register with FDA
- Current activities
 - Rulemaking related to glass front vending machines using front-of-pack calorie disclosure to comply with the vending machine rule

Voluntary Sodium Reduction Targets



Why are Sodium Reduction 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



Mattes and Donnelly, 1991

Overview of FDA Announcement

- Draft, voluntary guidance on sodium reduction targets
 - Gradual approach:
 - Short-term targets (2 years, goal=3,000 mg/day)
 - Long-term targets (10 years, goal=2,300 mg/day)
 - Targets for 150 categories of food that are sales weighted to focus on dominant sellers in each category
 - Applies to food manufacturers, restaurants and food service operations
- Draft targets serve as a basis for continued dialogue
 - Additional data and information will help refine

Status

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



Food Ingredients

Food Ingredients

- Published final rule on food ingredients that may be “generally recognized as safe” (GRAS)
 - reaffirms that a substance, which is GRAS for an intended use, must meet the same safety standard as a food additive: there must be a reasonable certainty of no harm under the intended conditions of its use
 - formalizes voluntary GRAS notification procedure
- Continued work with companies, consumer groups and other stakeholders to improve oversight of ingredients added to food

Status

- Working on additional guidance documents:
 - Best practices for use of GRAS panels and managing conflict of interest
 - What it means to be GRAS

Other Recent Food Safety Updates

- Published a request for comments on gene editing in new plant varieties used for foods (1/19/17)
- Published (updated) advice regarding fish consumption to help consumers make informed choices regarding fish that is healthy and safe to eat (1/19/17)

Advice About Eating Fish

What Pregnant Women & Parents Should Know

Fish and other protein-rich foods have nutrients that can help your child's growth and development.

For women of childbearing age (about 16-49 years old), especially pregnant and breastfeeding women, and for parents and caregivers of young children.

- Eat 2 to 3 servings of fish a week from the "Best Choices" list OR 1 serving from the "Good Choices" list.
- Eat a variety of fish.
- Serve 1 to 2 servings of fish a week to children, starting at age 2.
- If you eat fish caught by family or friends, check for fish advisories. If there is no advisory, eat only one serving and no other fish that week.*

Use this chart!

You can use this chart to help you choose which fish to eat, and how often to eat them, based on their mercury levels. The "Best Choices" have the lowest levels of mercury.

What is a serving?

To find out, use the palm of your hand!



For an adult
4 ounces



For children,
ages 4 to 7
2 ounces

Best Choices EAT 2 TO 3 SERVINGS A WEEK

Anchovy	Herring	Scallop
Atlantic croaker	Lobster, American and spiny	Shad
Atlantic mackerel	Mullet	Shrimp
Black sea bass	Oyster	Skate
Butterfish	Pacific chub mackerel	Smelt
Catfish	Perch, freshwater and ocean	Sole
Clam	Pickrel	Squid
Cod	Plaice	Tilapia
Crab	Pollock	Trout, freshwater
Crawfish	Salmon	Tuna, canned light (includes skipjack)
Flounder	Sardine	Whitefish
Haddock		Whiting
Hake		

OR

Good Choices EAT 1 SERVING A WEEK

Bluefish	Monkfish	Tilefish (Atlantic Ocean)
Buffalofish	Rockfish	Tuna, albacore/white tuna, canned and fresh/frozen
Carp	Sablefish	Tuna, yellowfin
Chilean sea bass/Patagonian toothfish	Sheepshead	Weakfish/seatrout
Grouper	Snapper	White croaker/Pacific croaker
Halibut	Spanish mackerel	
Mahi mahi/dolphinfish	Striped bass (ocean)	

Choices to Avoid HIGHEST MERCURY LEVELS

King mackerel	Shark	Tilefish (Gulf of Mexico)
Marlin	Swordfish	Tuna, bigeye
Orange roughy		

*Some fish caught by family and friends, such as larger carp, catfish, trout and perch, are more likely to have fish advisories due to mercury or other contaminants. State advisories will tell you how often you can safely eat those fish.

www.FDA.gov/fishadvice

www.EPA.gov/fishadvice



Removing Unsafe Products from the Marketplace

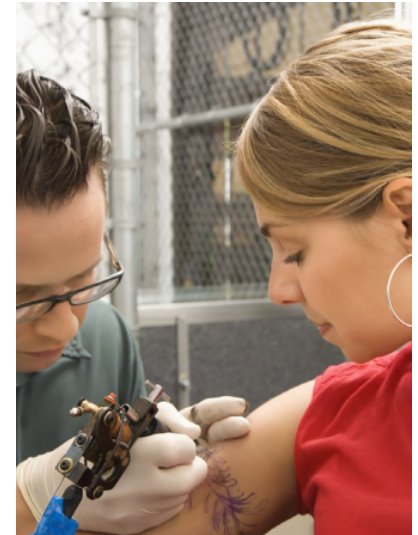
Dietary Supplements

- Newly established Office of Dietary Supplement Programs
- Issued more than 20 warning letters on illegal ingredients, for example:
 - methylsynephrine
 - acacia rigidula
 - picamilion
 - pure powdered caffeine
- Published draft guidance on new dietary ingredients
- Education and outreach to consumers and health professionals
- Research on probiotics



Cosmetics

- WEN Cleansing Conditioners
- Tattoo Ink
- Lead
 - Published draft guidance recommending no more than 10 ppm of lead in lip products and externally applied cosmetics (12/22/16)
- Formaldehyde in hair straightening products



CFSAN Adverse Event Reporting System (CAERS)

- CAERS began in June 2003
 - centralized data from separate systems into a single database
- CAERS captures data on adverse events and product complaints reported about food, dietary supplements and cosmetics
- Purpose: enable post-market surveillance of products to help detect signals of possible safety issues
- Data posted on [FDA.GOV](https://www.fda.gov) as of December 2016



CAERS Modernization

- Automate data entry
- Incorporate standardized dictionaries
- Establish connectivity to other FDA systems
- Enable direct reporting from industry
- Reduce IT & records management costs

Goals of CAERS Modernization

- By September 2017:
 - Improve data quality
 - Increase volume of reports
 - Reduce program costs

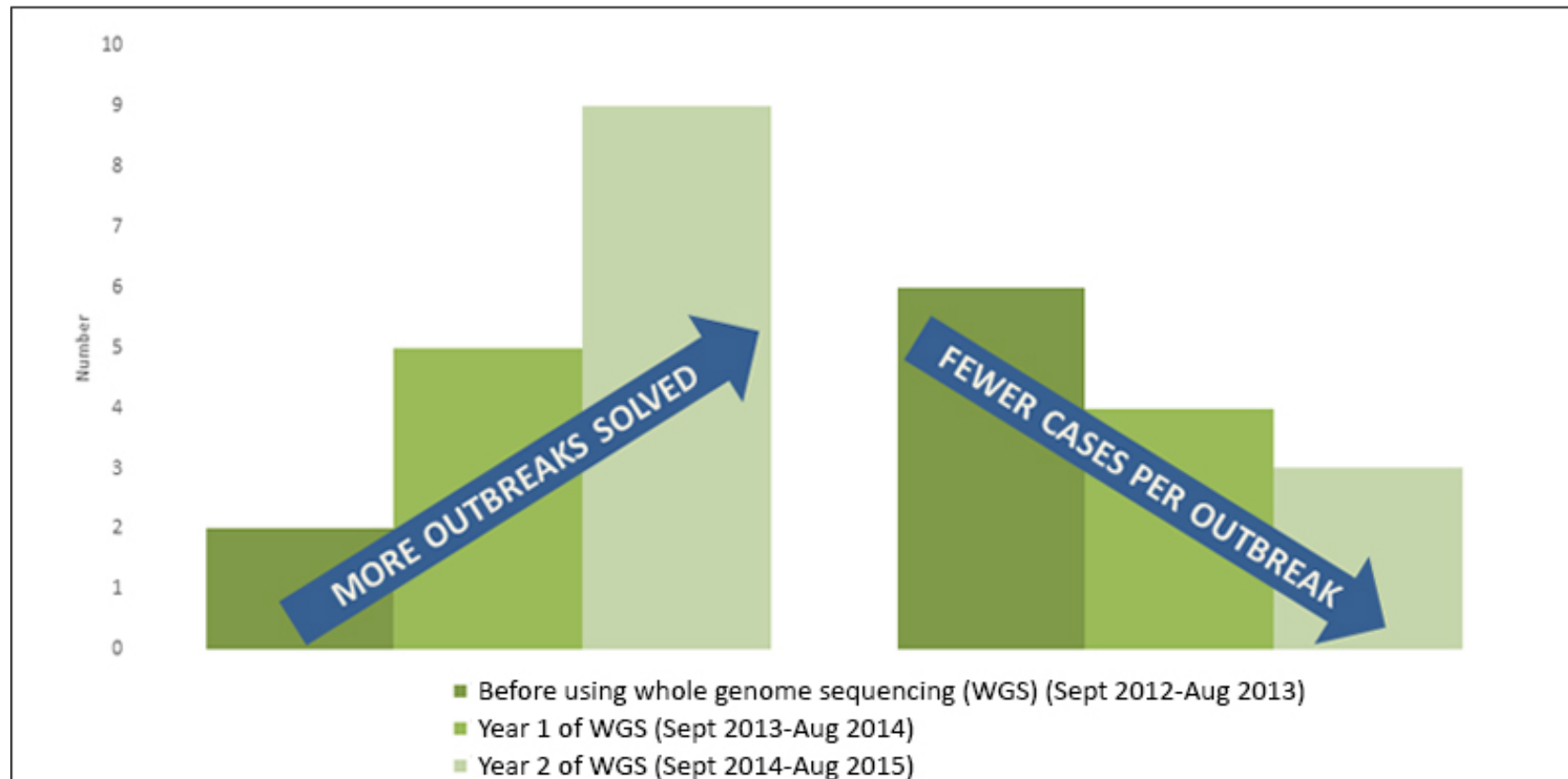
Using Science to Solve Foodborne Outbreaks

Using State-of-the-Art Science to Solve Foodborne Outbreaks Quickly

- Whole genome sequencing helps speed up outbreak investigations
- The faster that public health officials can identify the food or ingredient that caused the illness and where it came from, the faster the harmful ingredient can be removed from the food supply -- and the more illnesses and deaths that can be averted
- Youtube video



Whole Genome Sequencing Prevents *Listeria* Illness



<http://www.cdc.gov/listeria/surveillance/whole-genome-sequencing.html>

The logo for the U.S. Food & Drug Administration (FDA), featuring the letters "FDA" in white on a blue square background.

U.S. FOOD & DRUG
ADMINISTRATION

CENTER FOR FOOD SAFETY & APPLIED NUTRITION