FDA U.S. FOOD & DRUG ADMINISTRATION

Update on CFSAN Activities

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IFT 2020 Food Policy Impact Meeting
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FDA's Food Footprint

- Twenty cents of every consumer dollar is spent on FDA-regulated products
- FDA is responsible for the safety of 77% of all food consumed in the United States*
- 93,000+ domestic registered food facilities
- 124,000+ foreign registered food facilities
- 15% of overall food supply is imported (94% of seafood, 53% fresh fruit, 29% fresh vegetables)

* USDA has primary food safety oversight of domestic meat and meat products; domestic poultry and poultry products; frozen, dried, and liquid eggs; and catfish.

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FDA Food Safety Modernization Act (FSMA)

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FSMA

- The FDA Food Safety Modernization Act (FSMA), which became law in 2011, represents the biggest overhaul of our nation's food safety laws in more than 70 years
- Focuses on ***prevention*** rather than response
- Gives FDA new tools in terms of inspection, compliance, response, and oversight of imported foods

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Seven Foundational FSMA Rules

Rule	Date Finalized	Compliance Dates
Preventive Controls for Human Food	Sept. 17, 2015	In effect for all covered businesses
Preventive Controls for Animal Food	Sept. 17, 2015	In effect for all covered businesses
Produce Safety	Nov. 27, 2015	Staggered compliance dates through 2020; for water, 2022-2024
Foreign Supplier Verification Programs	Nov. 27, 2015	In effect for all covered businesses
Accredited Third-Party Certification	Nov. 27, 2015	Portal open for applications
Sanitary Transportation	April 6, 2016	In effect for all covered businesses
Intentional Adulteration	May 27, 2016	Last date is July 2021 for very small businesses; inspections start March 2020

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FSMA Successes

- Major compliance dates have arrived for most rules.
- Draft guidances support industry compliance.
- FDA provides funding for state regulatory programs.
- Thousands in food industry have been through FSMA training.
- Inspections have begun for most, but not all, programs and are continuing on a staggered timeline based on size of business.
- New authorities and programs strengthen import oversight.
- FDA is building strong partnerships with food industry and regulatory counterparts at state, federal and international levels.

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FSMA Inspections

- Human Food: In FY 19, FDA did 4246 inspections in U.S. and 1485 foreign; states did 6793
- Produce Safety
  - On farm rule readiness
  - With NASDA, developing a consistent approach
    - Participating states conducting routine inspections
    - FDA conducting for-cause inspections, including foreign inspections, and surveillance inspections in non-participating states
- Foreign Supplier Verification Program: In FY19, 877 importer inspections

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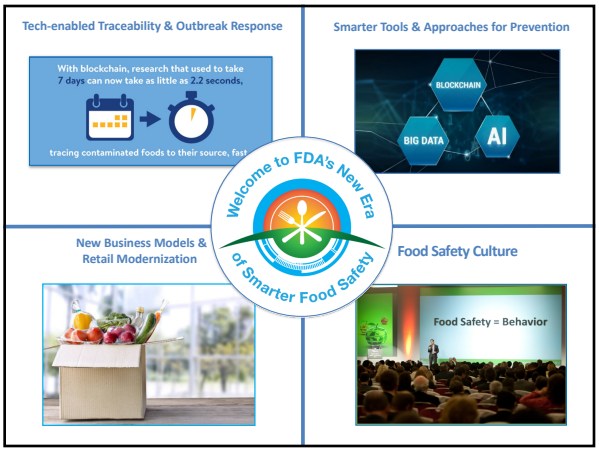

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Outbreak Investigations and Recalls

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Outbreaks/Recalls

- FDA strives for faster and more efficient traceback during outbreaks and processing of recalls in recent years and has made significant inroads on this front
- Increased number of detected outbreaks and subsequent investigations resulting from the success of Whole Genome Sequencing (WGS)
- WGS has made it possible to more easily detect and confirm the source of contaminated human and animal food associated with human and animal illness, and to better identify foodborne outbreaks that previously would have gone undetected

Number of Potential Outbreaks Evaluated by CFSAN Annually				
Year	2015	2016	2017	2018
Potential Outbreaks	67	68	119	114

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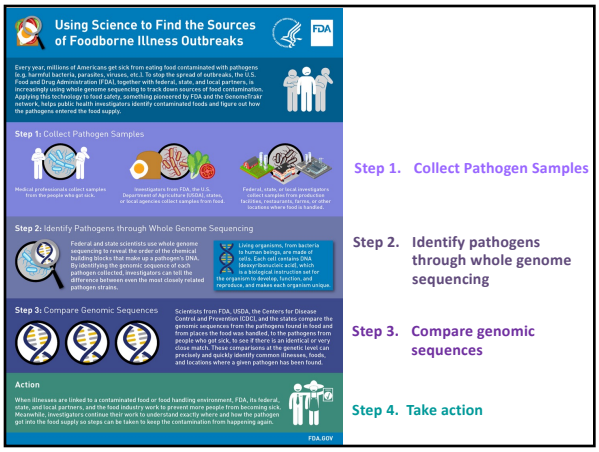

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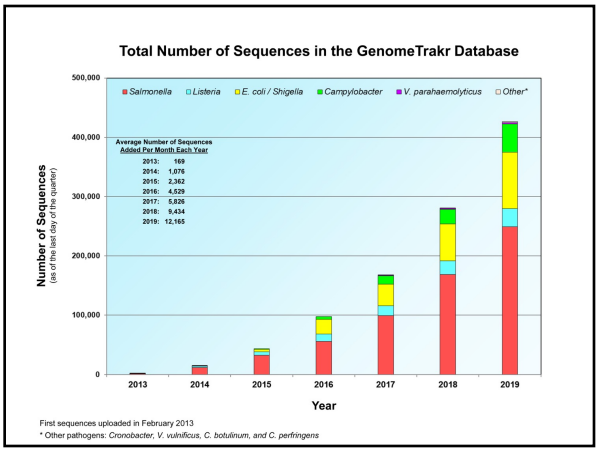

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E. Coli 0157:H7 Outbreaks Linked to Romaine Lettuce

- Outbreaks associated with leafy greens have been an ongoing concern. Between 2009 and 2017, the FDA and the CDC identified 28 foodborne outbreaks of Shiga-toxin producing *E. coli* (STEC) with a confirmed or suspected link to leafy greens in the U.S.
- In 2018, the U.S. experienced two large multistate outbreaks of *E. coli* 0157:H7 infections associated with the consumption of romaine lettuce: one in the spring and the other in the fall.
- In the fall of 2019, FDA was tracking three outbreaks of *E. coli* 0157:H7 infections linked to romaine lettuce. These outbreaks were declared over in January, 2020.

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Outbreaks Related to Romaine – Current Priorities

- Complete investigation from 2019 outbreaks.
- Continue multiyear study in collaboration with Yuma area leafy greens stakeholders to better understand the ecology of human pathogens in the Yuma agricultural region.
- Continue sampling assignment initiated in November 2019 to test romaine lettuce for pathogenic *E. coli* and *Salmonella* spp.
- Continue implementation of the Produce Safety Rule with inspections of small farms beginning this spring.

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Outbreaks Related to Romaine – Current Priorities, cont'd

- Proposed rule on revised agricultural water standards, expected later this year.
- Proposed rule on traceability and high-risk foods, expected later this year.
- Continuous engagement with the leafy greens industry to prevent future outbreaks.

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Nutrition Innovation Strategy

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"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

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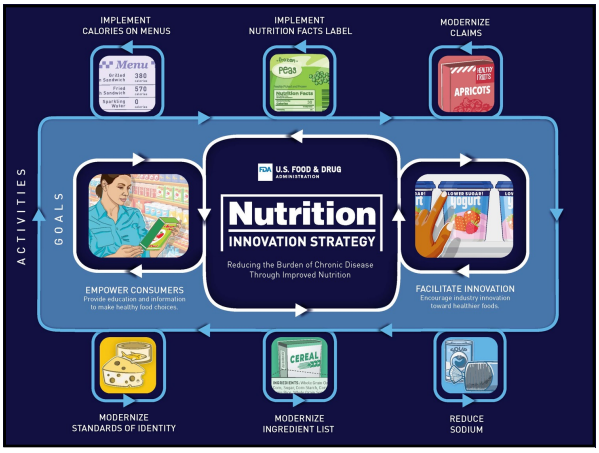

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Updating Use of the Claim "Healthy" in the Labeling of Food

- Notice published 2016, 1000 comments received
- Public meetings in 2017, 2018
  - Themes: Being consistent with the *Dietary Guidelines'* shift towards food-based recommendations versus nutrient-based ones
- Working to publish a proposed rule on use of the claim "healthy" in food labeling
- Considering an FDA-sanctioned "healthy" icon

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Modernizing Standards of Identity, Related Activities Involving Labeling

- September 2019: Held a public meeting on efforts to modernize food standards of identity
- December 2019: Reopened the comment period on use of ultrafiltered milk in certain cheeses
- As a related matter, FDA is examining the issue of labeling of plant-based products using dairy terms in labeling
  - Issued a request for information on the labeling of plant-based products using dairy terms in labeling (September 2018)
  - Reviewing ~13,000 comments
  - FDA is using the comments to inform next steps to provide greater clarity on appropriate labeling to ensure that consumers understand the nature of the products and their nutritional composition

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Implementing the Nutrition Facts Label

- Compliance Date: Jan 1, 2020 for manufacturers with annual food sales at or above $10 million. Jan 1, 2021 for all others
- FDA issued many guidance documents on issues such as dietary fiber, and serving size declarations to help manufacturers comply with the new requirements
- FDA has announced the pending launch of a major educational campaign surrounding the new nutrition information consumers are now seeing in the marketplace

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 240mg	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.

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Consumer Education Campaign

- FDA is working on a consumer nutrition education campaign to raise awareness and understanding of the updated Nutrition Facts label.
- Priority educational topics include:
  - Calories
  - Serving size
  - Percent Daily Value (%DV)
  - Added Sugars, including in the context of the entire label (and the importance of reading the entire label generally)

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Nutrition Education Resources

www.fda.gov/nutritioneducation

Including:

- New Nutrition Facts label materials
- *Read the Label* – Resources for tweens, parents and health educators
- *Science and Our Food Supply* – Free curricula for Middle and High School Teachers
- *Nutrition Facts Label Continuing Medical Education Program* – Resources for healthcare professionals

And more!

For educational materials on the Nutrition Facts label and other nutrition topics and to subscribe to the ***CFSAN News for Educators eNewsletter***

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Sodium Reduction – Overview of FDA Approach

- Draft, voluntary guidance on sodium reduction targets published in 2016
  - Gradual approach
  - Targets for 150 categories of food
  - Applies to food manufacturers, restaurants and food service operations
- Current activities
  - Planning to finalize short-term sodium reduction targets
  - May 2019: Issued draft guidance on the use of an alternative name for potassium chloride in food labeling (food ingredient)

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Additional CFSAN 2020 Priorities

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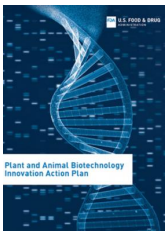
FDA's Plant and Animal Biotechnology Innovation Action Plan

- In FDA's *Plant and Animal Biotechnology Innovation Action Plan* we committed to developing draft guidance regarding the regulation of foods derived from genome edited plant varieties.



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Agricultural Biotechnology Education and Outreach Initiative

- FDA received funds (2017 Consolidated Appropriations Act) to develop an agricultural biotechnology education and outreach initiative.
- FDA is working with USDA and other federal agencies to develop and distribute science-based educational information on the environmental, nutritional, food safety, economic, and humanitarian impacts of agricultural biotechnology.
- Materials will be posted on FDA.GOV in the coming months:

https://www.fda.gov/food/consumers/agricultural-biotechnology-education-and-outreach-initiative

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Innovative Food Products & Ingredients

Product Innovation

- CFSAN scientists review novel emerging products, which can help foster new products and ingredients coming to the market

- Changing consumer behavior is driving industry demand for increased FDA capacity to review petitions for innovative products while continuing to meet consumer expectations for safety oversight:
  - Cell-cultured meat and seafood
  - Other new proteins
  - New ingredients
  - Synthetic foods
  - New packaging solutions

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Per- and Polyfluoroalkyl Substances (PFAS)

FDA's focus is on:

1) Assessing foods for PFAS from environmental contamination
2) Reviewing the limited authorized uses of PFAS in food contact applications

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Per- and Polyfluoroalkyl Substances (PFAS)

- Developed and posted validated analytical method for detection of certain PFAS in foods
- Analyzed produce, meat, dairy and grain products collected as part of FDA's FY 2018 Total Diet Study (released 2019)
- Continuing to support state and local response in assessing the safety of food from specific areas potentially affected by PFAS contamination
- Evaluating the authorized uses of PFAS in food packaging based on new scientific information

https://www.fda.gov/food/chemicals/and-polyfluoroalkyl-substances-pfas

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Additional Priority Initiatives

- Toxic elements in foods
- Allergens including labeling (e.g., sesame)
- Gluten-free labeling of fermented or hydrolyzed foods
- "Natural" labeling
- CBD

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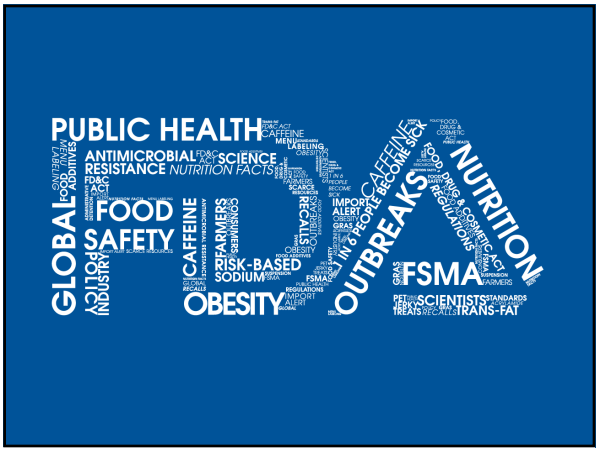

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