

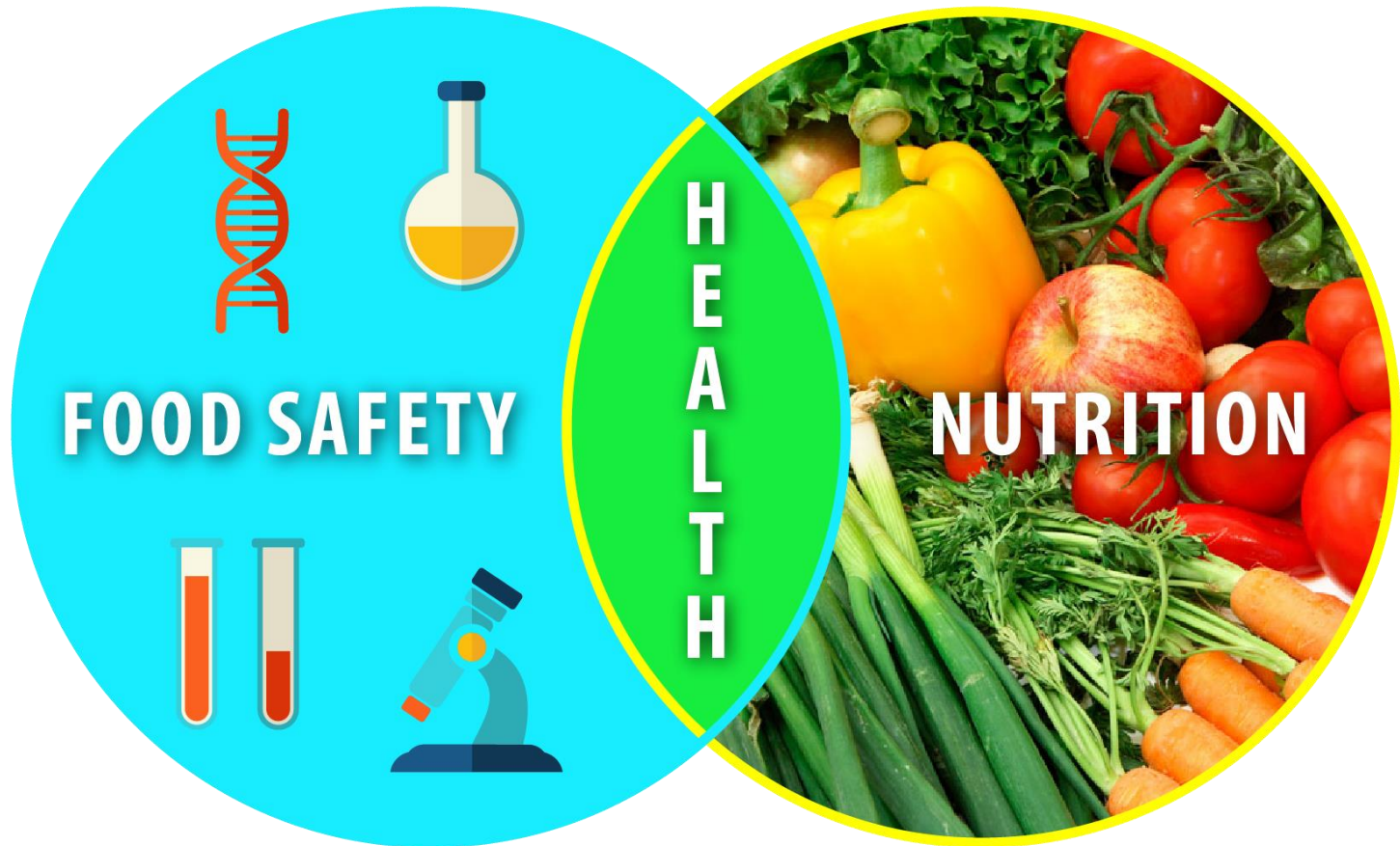
Update

FDA/Center for Food Safety and Applied Nutrition

Comments by
Susan Mayne, Ph.D.

Director
Center for Food Safety and Applied Nutrition
FDLI Annual Conference
May 3, 2018

Food Safety, Nutrition and Health



FDA 2018 Strategic Policy Roadmap

Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap



- **Goal IV** - Strengthen FDA's scientific workforce and its tools for efficient risk management

Strengthen Food Safety – Strengthen the safety of the foods that Americans eat by continuing to fully implement preventive controls and enhancing collaboration with farmers, food producers, and state and local regulators

- Advance adoption of preventive controls
- Ensure water standards and testing methods are practical and effective
- Provide training on produce safety and preventive controls rules
- Expand GenomeTrakr
- Modernize toxicology testing

FSMA Compliance Dates

- First compliance dates:
 - PC Human & modernized CGMPs – September 2016
 - PC Animal CGMPs – September 2016
 - Produce Safety: Sprouts – January 2017
 - Sanitary Transportation – April 2017
 - Foreign Supplier Verification – May 2017
 - PC Animal – September 2017
 - Produce Safety – January 2018
 - Intentional Adulteration – July 2019
- Phased in by size of business

Key Guidance Documents

- **Preventive Controls Human Food**
 - Hazard Analysis and Preventive Controls (chs. 1-5)
 - Use of Heat Treatments as a Process Control (ch. 6)
 - Supplier Controls (ch. 15)
 - “Solely Engaged” Exemption
 - Determining Whether a Measure Offers the Same Level of Public Health Protection
 - Classification of Activities for Farms and Facilities
 - Small Entity Compliance Guides
- **Produce Standards**
 - Sprout Operations
 - Small Entity Compliance Guide

Next Steps for Implementation of Produce Safety Rule

- NPRM (9/13/17) to extend the compliance dates for 2 – 4 years for agricultural water requirements **only** for produce other than sprouts
- Equivalent testing methodologies for agricultural water are posted at <https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm575251.htm>
- FDA is delaying inspections for large farms until Spring 2019





Produce Safety Network

- FDA produce experts in each region of the country
 - Combines staff from the Office of Regulatory Affairs and the Center for Food Safety and Applied Nutrition
- Outreach, education, and technical assistance
- Inspections and outbreak response
- Technical Assistance Network for regulators



Other Food Safety Highlights of 2017

- Published draft guidance on *Listeria* prevention and control in ready-to-eat foods
- Completed and signed a systems recognition arrangement with Australia
- Established SCORE, Strategic Coordinated Oversight of Recall Execution, to promptly address food recalls and get potentially harmful foods off the market as soon as possible to reduce further consumer exposure
- Made publicly available data we received about adverse events related to foods, including conventional foods and dietary supplements, and cosmetics:
<https://www.fda.gov/food/complianceenforcement/ucm494015.htm>

Highlights of 2018 Accomplishments

- Published proposed determination that the European Union's shellfish safety program is equivalent to the U.S. system
- Announced release of the 2017 edition of the FDA Food Code
- Issued guidance to protect consumers against dietary supplements containing dangerously high levels of extremely concentrated or pure caffeine



Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap

Goal 1 – Reduce the burden of addiction crises that are threatening American families

“The FDA is increasingly concerned with the proliferation of products claiming to treat or cure serious diseases like opioid addiction and withdrawal. People who are addicted to opioids should have access to safe and effective treatments and not be victimized by unscrupulous vendors who are trying to capitalize on the opioid epidemic by taking advantage of consumers and selling products with baseless claims. We’ll continue to work with our partners at the FTC to **step up our actions against unapproved products being marketed for the treatment of opioid addiction and withdrawal.**”

Dr. Scott Gottlieb, M.D.
FDA News Release
January 24, 2018

Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap

- **Goal III** - Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease
 - Nutrition Action Plan - Reduce preventable death and disease caused by poor nutrition by ensuring that consumers have access to **accurate, useful information** to make healthy food choices; foster **development of healthier food** options:
 - guidance on menu labeling
 - guidance and outreach on updating Nutrition Facts label
 - better leverage nutrition and diet as ways to reduce morbidity and mortality from disease

Multi-year Nutrition Innovation Strategy

Goals:

- (1) Provide additional ways of communicating nutrition information to consumers so they can be empowered to make informed decisions about their diet; and
- (2) Provide more incentives for food manufacturers to produce products with more healthful attributes

Menu Labeling

- November 7, 2017: FDA released draft guidance that provides flexibility on how covered establishments can provide calorie information in ways that meet various business models
- Consumers can expect to see menu labeling in covered eating establishments by May 7, 2018



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



nd Beans
]- ½ cup

Chili
[260 Cal.] - 1 cup

Plantains
[210 Cal.] - ½ cup

Curried Chicken
and Potatoes
[240 Cal.] - 1 cup

Rice
- ½ cup

HOT!



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



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



PAN

THIN & CRISPY

ORIGINAL

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

Nutrition Facts Labels

- Proposed compliance date
 - Jan 1, 2020 for manufacturers with annual food sales at or above \$10 million. 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 issued guidance (3/1/18) on issues such as fiber, added sugars, and serving size declarations
- FDA will launch a major educational campaign surrounding the new nutrition information consumers will be seeing in the marketplace

Fiber

- Fiber declared on label must have a beneficial physiological effect
- Original Nutrition Facts label was implemented when manufacturers were not adding isolated and synthetic fibers to food to increase the fiber content
- Institute of Medicine recommended that fiber have a physiological benefit
- Definition for declared fiber in Nutrition Facts rule:
 - Fiber that is intact and intrinsic to plants is automatically included in our new fiber definition
 - Isolated or synthetic fiber must demonstrate a beneficial physiological effect to human health (e.g. improved laxation, lower cholesterol levels).



Food Labels: Updating “Healthy”

- Federal Register request for comments (9/28/16); over 1000 comments have been received
- Federal Register notice of availability of guidance for industry, “Use of the Term ‘Healthy’ in the Labeling of Human Food Products” (9/28/16)
- Public meeting – March 9, 2017
 - 224 on site participants and 446 webcast viewers
 - a summary of common themes is available on our website:
<https://www.fda.gov/downloads/Food/NewsEvents/WorkshopsMeetingsConferences/UCM551651.pdf>
- Comment period closed April 26, 2017
- An appropriate definition of *healthy* is important to all stakeholders



Qualified Health Claim: Early Introduction of Peanuts to Certain High-risk Infants may Reduce Risk of Peanut Allergy



Addendum Guidelines for the Prevention of Peanut Allergy in the United States

Report of the NIAID-Sponsored Expert Panel



News & Events

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FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on a new qualified health claim advising that early introduction of peanuts to certain high-risk infants may reduce risk of peanut allergy

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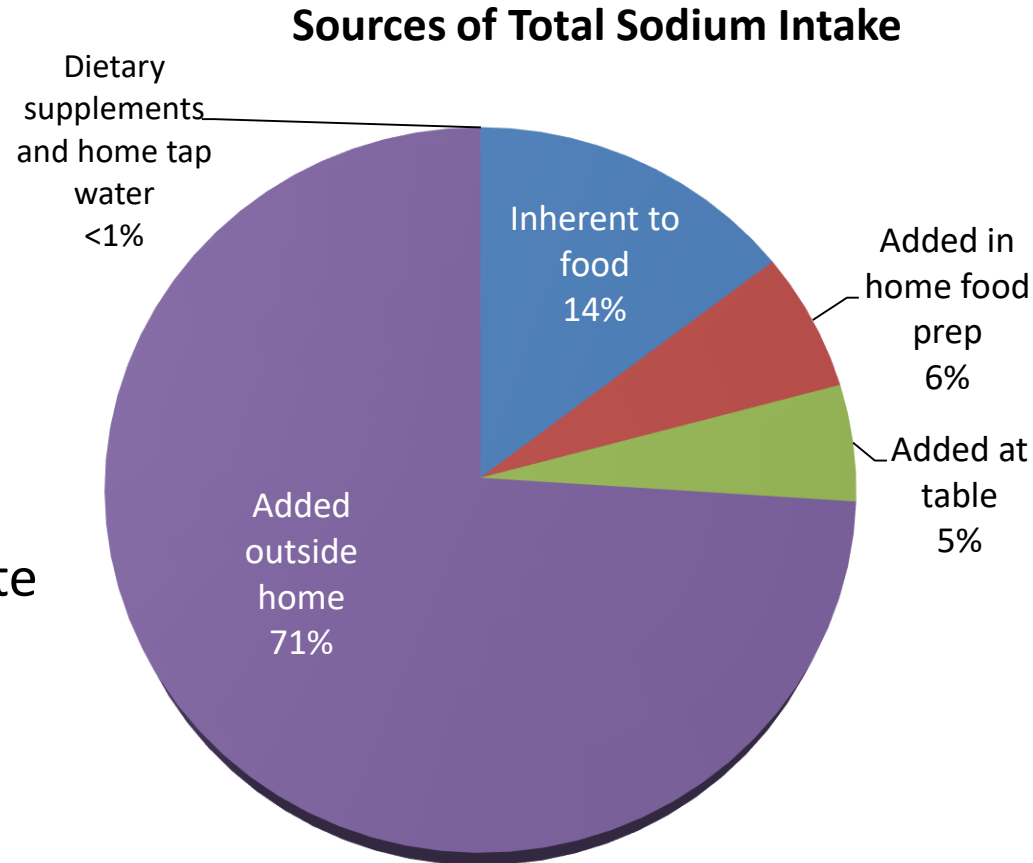


FDA OKs new peanut allergy food labels

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



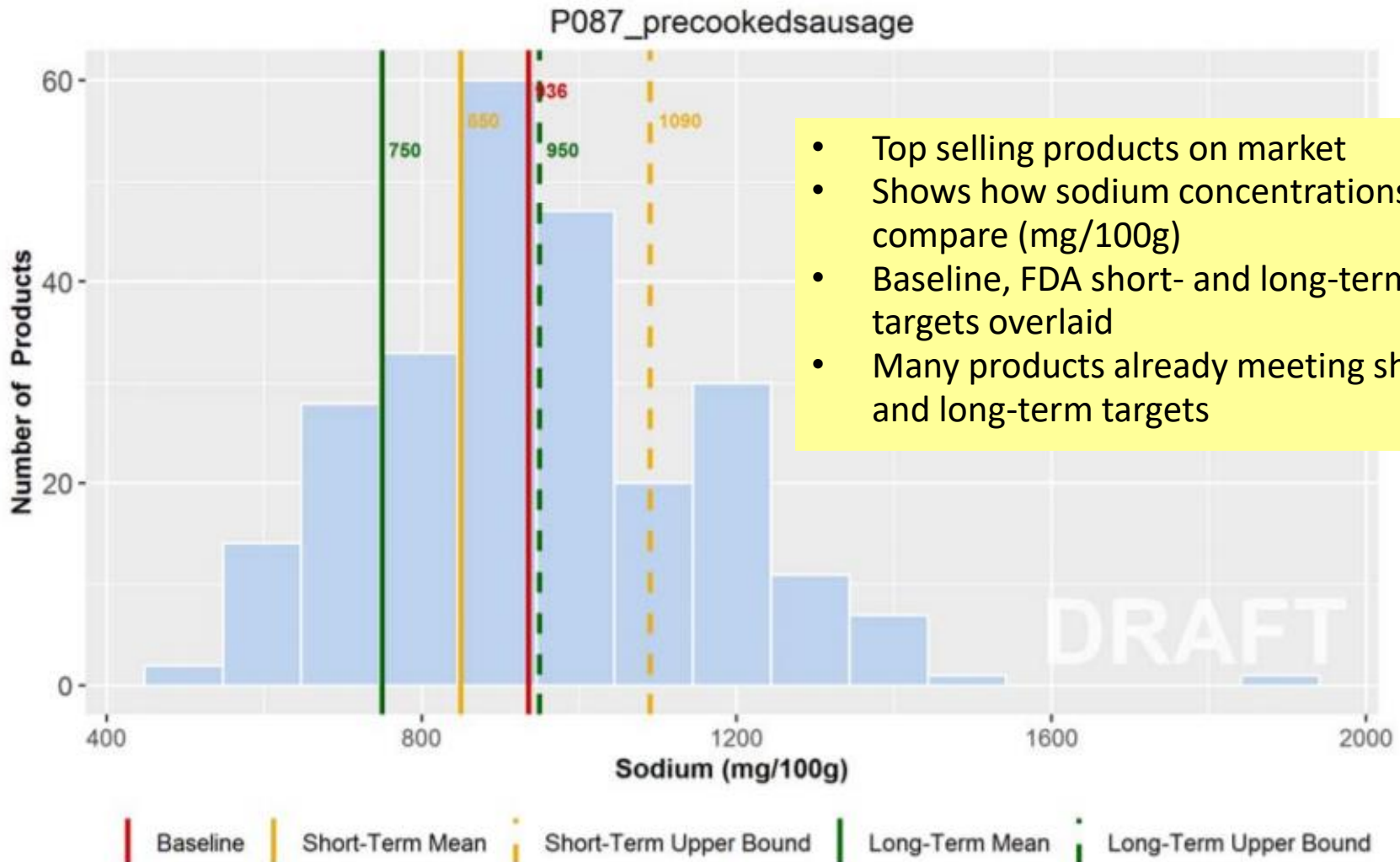
Harnack et al., Circulation 2017

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

Sample Category: Precooked Sausage



Note: Data on the number of products was obtained from Nielsen. Sodium concentration values were calculated from sodium values on nutrition labels obtained from Gladson and Mintel. 24 24

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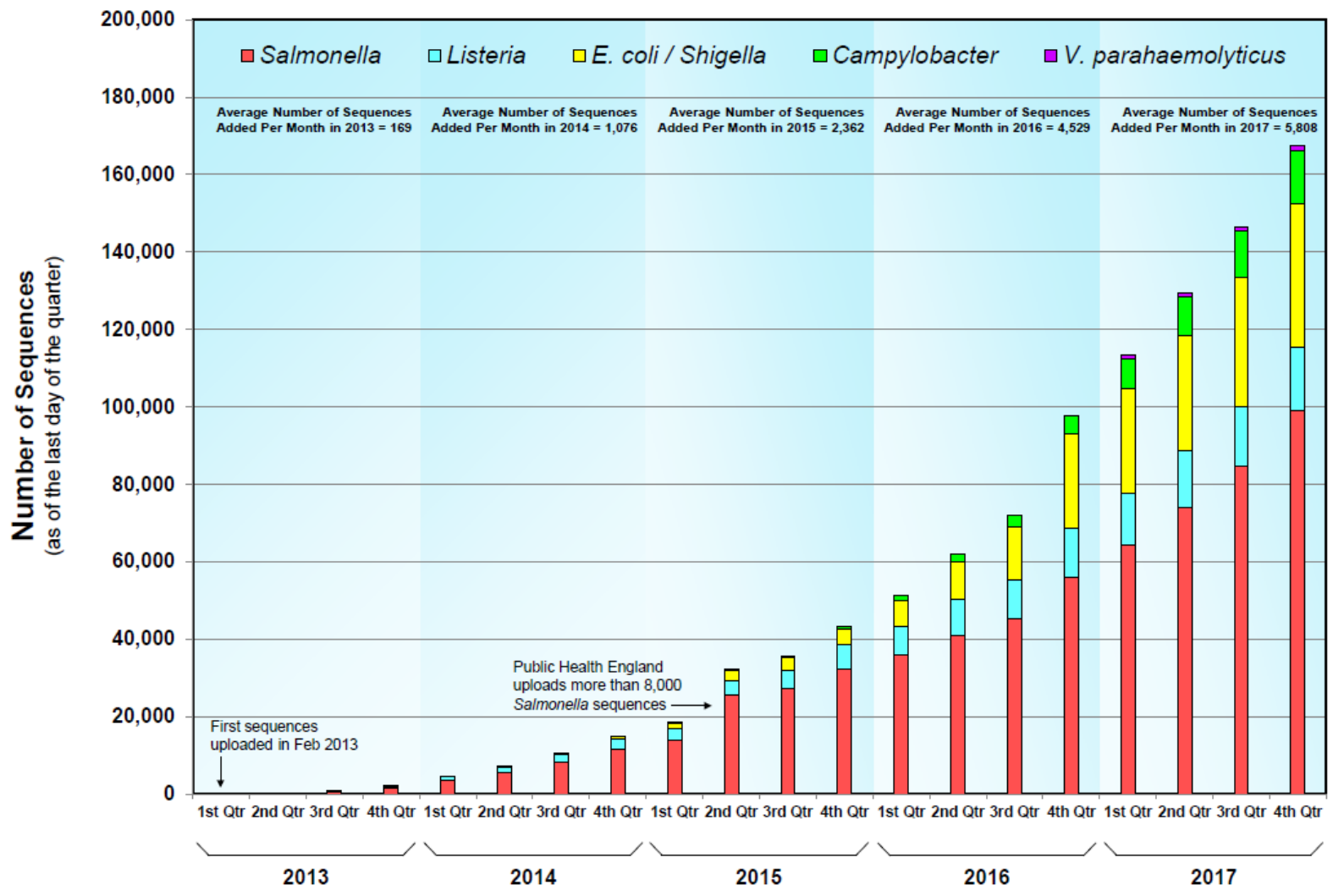
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Using State-of-the-Art Science to Solve Foodborne Outbreaks Quickly

- 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



Total Number of Sequences in the GenomeTrakr Database



nature

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NATURE | NEWS



US regulators test organs-on-chips for food-safety monitoring

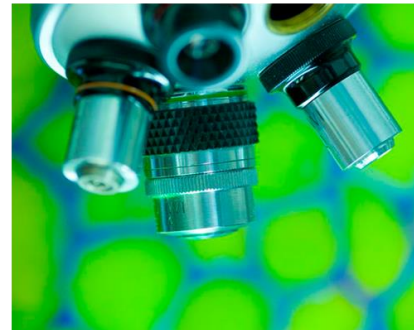
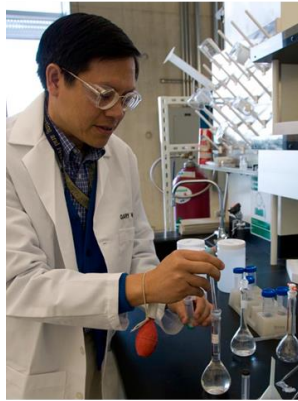
The goal is to compare these engineered livers to animal models, with an eye towards replacing animal testing.

Sara Reardon

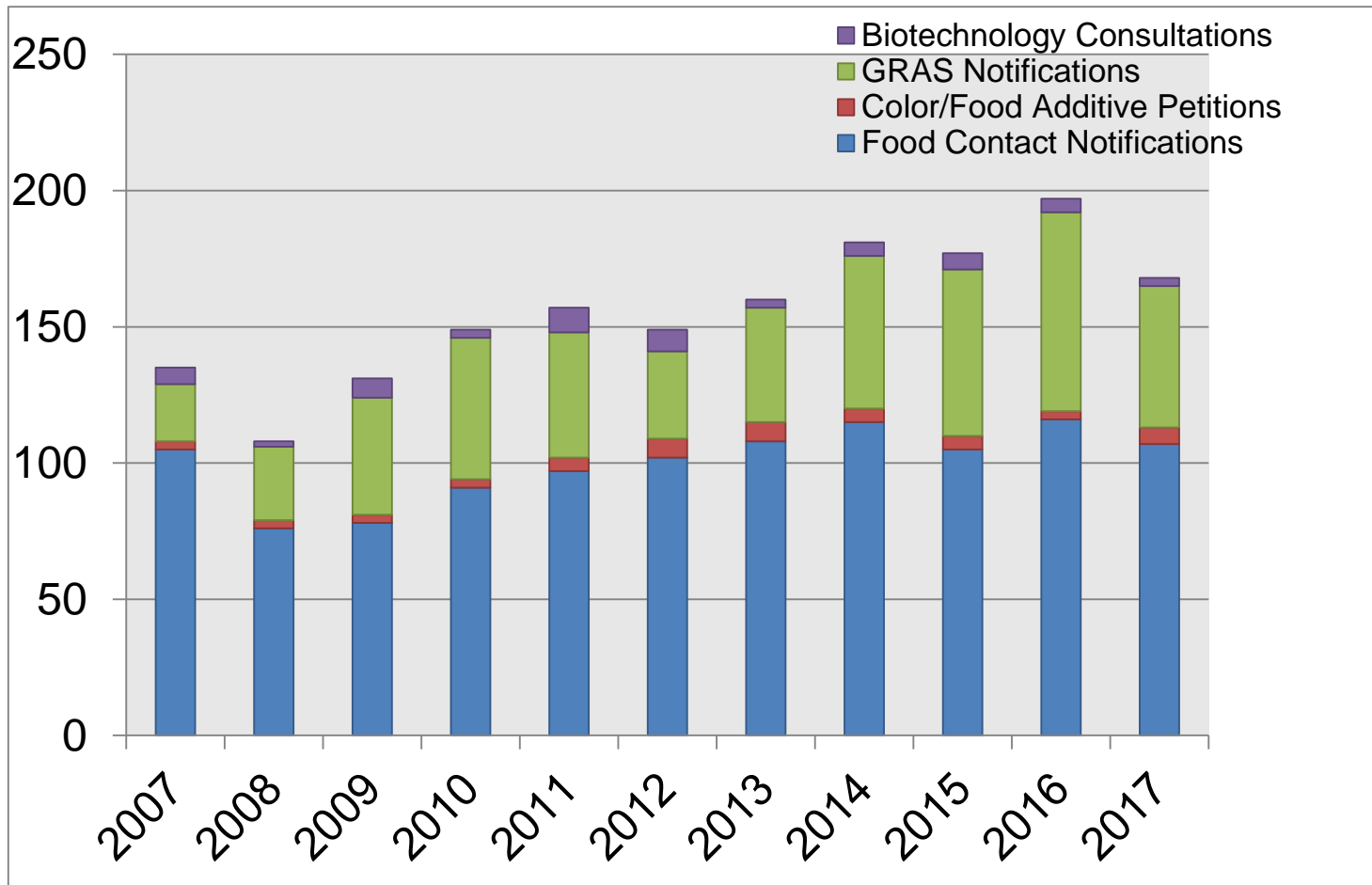
12 April 2017

The US Food and Drug Administration (FDA) has started testing whether livers-on-a-chip — miniature models of human organs engineered to mimic biological functions — can reliably model human reactions to food and food-borne illnesses. The experiments will help the agency to determine whether companies can substitute chip data for animal data when applying for the approval of a new compound, such as a food additive, that could prove toxic. It is the first time that a regulatory agency anywhere in the world has pursued organs-on-chips as an alternative to animal testing.

**Building
Capacity
to Support
Innovation**



Industry Submissions Completed by Fiscal Year



Genome Editing in New Plant Varieties Used for Foods

- January 18, 2017 – FDA published a request for comments seeking scientific evidence and other factual information on specific questions related to genome editing in new plant varieties used as food for humans and/or animals.
 - Comments will help inform FDA’s thinking on human and animal foods derived from new plant varieties produced using genome editing.
 - FDA is reviewing this input to shape next steps.



PUBLIC HEALTH

GLOBAL FOOD LABELING ADDITIVES

ANTIMICROBIAL RESISTANCE

FD&C ACT

FOOD SAFETY

SCIENCE

NUTRITION FACTS

FOOD POLICY

INDUSTRY

CAFFEINE

FARMERS

RISK-BASED

SODIUM

OBESITY

TRANS-FAT
FD&C ACT
CAFFEINE

MENU LABELING

SCIENTISTS

RECALLS

OUTBREAKS

OBESITY

FSMA

REGULATIONS

IMPORT ALERT

1 IN 6 PEOPLE BECOME SICK

OUTBREAKS

CAFFEINE

SCIENTISTS

RECALLS

OUTBREAKS

OBESITY

FSMA

REGULATIONS

IMPORT ALERT

PET TREATS

FOOD, DRUG & COSMETIC ACT

SCIENCE

FOOD SAFETY

REGULATIONS

FOOD ADDITIVES

SCIENTISTS

FSMA

STANDARDS

TRANS-FAT

NUTRITION

FOOD, DRUG & COSMETIC ACT

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