Real-world Data to Assess Long-term Impact of FDA Food-Related Regulations and Policies

A SNAPSHOT

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Abstract

The Food and Drug Administration (FDA) has responsibility for ensuring a safe and promoting a wholesome food supply, with mandates in nutrition and food safety.[a] Regulations and policies are foundational elements of these mandates, and the purpose of this initial phase of this project (the Food Evidence Generation Project) was to illustrate the availability of real-world data across the food supply chain to help assess the impact of food safety and nutrition regulations and policies on consumer decision-making and food company action. (This insight can then help inform future FDA action.)

With leadership from an expert working group, interviews were conducted with representatives from 27 companies across the food supply chain (see Appendix A) to understand types of data available within each sector to generate evidence of consumer behavior change or company action in response to FDA action. For nutrition, food retail sales data is compiled to provide nutrition evaluation information; however, there are challenges associated with accessing this data, including the proprietary nature of some data, the cost to purchase data, and potential conflicts in different data sets. Additionally, linkages between retail data and subsequent health outcomes data are not readily available. As compared to food for retail sale, the same level of data capture does not occur in foods prepared away-from-home. This disparity results in significant data gaps and limited ability to determine the impact of nutrition regulations. For food safety, federal agencies capture important data once an outbreak of foodborne illness is identified or a food recall initiated by conducting survey and sampling programs for contaminants and pesticides. More effective capture of food safety data earlier in the food supply chain as well as more strategic analysis of various data sets captured by FDA would support foodborne illness and injury prevention.

In an era of broader transparency all sectors are challenged to elevate the accessibility of data—especially with the nation's health outcomes at stake. The current collection, compilation, curation, and accessibility of food data is insufficient to support robust evidence generation; improvements are needed. Opportunities to generate evidence on the impact of nutrition and food safety regulations include creation of public-private partnerships to compile and curate data within a national infrastructure (with incentives/requirements for companies along the food supply chain to share data across industries and with the FDA); creation of a comprehensive, digitized food data ecosystem including scaled data capture at the expansive list of foodservice outlets; refinement of the regulation development process to further leverage consumer insight data and in-depth analysis of food nutrition and safety data, potentially through public-private partnerships; and leveraging of emerging technologies for data capture and analysis.

a The majority of the food supply is regulated by FDA, which is responsible for dairy, seafood, produce, packaged foods, bottled water, and whole eggs. The USDA regulates meat, poultry, and egg products.

Introduction

Regardless of where food is purchased or consumed, the Food and Drug Administration (FDA) has responsibility for protecting public health by ensuring a safe and wholesome food supply.[b] The agency's nutrition mandate includes ensuring the safety of food ingredients and that those ingredients are used at safe levels, overseeing nutrition labeling of most foods, nutrition education, and promotion of national dietary guidelines through regulation and voluntary guidance documents. The nutrition mandate includes encouraging a healthier food supply, such as with the removal of partially hydrogenated oils from the food supply, and empowering individuals through informative labeling and education as with regulations including Menu Labeling and revisions to the Nutrition Facts label. FDA's food safety mandate includes developing and overseeing the enforcement of food safety regulations, detecting, and responding to outbreaks of foodborne illness or injury, and supporting multiple government layers of food safety activities, food safety research, and outreach to key stakeholders. A rise in global trade has expanded this role to regulation of foreign facilities growing and manufacturing product sold in the United States.

Within the FDA's role of ensuring safe food, it's essential to note that nutrition and food safety are fundamentally interrelated. Access to and availability of adequate amounts of safe and nutritious foods is essential to sustaining life and promoting optimal health. Food that includes hazards like pathogens, heavy metals, foreign materials, or undeclared allergens cannot provide good nutrition. At the same time, ensuring that food does not cause illness involves more than removal of these hazards. Diet-related chronic diseases are at epidemic levels in the United States, with more than 1.5 million Americans dying each year from cardiovascular disease, diabetes, and certain cancers. This results in significant impact on public health and the economy.

Evaluation is an essential piece of the work of the FDA. This process is used to determine if actions taken by the agency, such as through the release of nutrition and food safety regulations and policies, have the intended impact on public health and the nutritional attributes and safety of the food supply. To this end, FDA Commissioner Robert Califf requested that the Reagan-Udall Foundation for the FDA (the Foundation) undertake this project to understand the baseline availability of relevant data and the use of analyses across the food supply chain to help determine the impact of food safety and nutrition regulations and policies on consumer decision-making and food company action. Given the complexity and variety in how consumers can and do procure food through retail and foodservice outlets, no single data stream or analysis can address all foods subject to FDA regulatory oversight; limits in current data availability as well as opportunities to improve data access and availability, in part through technology advances, are addressed.

b The majority of the food supply is regulated by FDA, which is responsible for dairy, seafood, produce, packaged foods, bottled water, and whole eggs. The USDA regulates meat, poultry, and egg products.

Food Industry Overview

In 2022, food spending by U.S. consumers, businesses, and government entities totaled $2.39 trillion. This included food-prepared-at-home spending of $1.05 trillion and food-prepared-away-from-home spending of $1.34 trillion. Spending does not, however, necessarily equate with where the majority of food is eaten; other data show that 82 percent of dinners were prepared at home.[1] As described later in this report, the distinction of at-home versus away-from-home preparation is important when discussing information available for generating evidence.

As depicted in the graphic below, today's consumer can purchase food from an expanding array of locations. Food may be purchased at retail outlets beyond grocery stores, including at drug, convenience, and home improvement stores; farmers' markets; and unattended retail like vending machines. According to Adobe Analytics, online grocery sales totaled $86.8 billion in 2022, and 2023 data from the International Food Information Council shows that 23 percent of consumers shop online for groceries at least once a week.[2] Unattended retail is now a $35 billion dollar industry in the U.S., with a significant amount of food and beverages purchased through these convenience locations.[3]

Foodservice outlets can be differentiated based on consumer dining frequency. High frequency locations include chain restaurants, employee cafeterias, military dining facilities, college and university foodservice, and senior dining sites. Fewer away-from-home meals are eaten in healthcare settings, sports and entertainment venues, non-chain restaurants, retail grocery foodservice, emergency feeding sites, and within the travel industry.

FIGURE A.

*Indicates food buying outlets addressed in this report.

Project Methodology

Two goals of the food evidence generation project were to document data gaps in food safety and nutrition, and based on the data available, to identify opportunities to improve data availability to allow for the creation of real-world evidence[c] focused on the impact of food policy on food supply composition and reformulation and on consumer response and behavior related to policies and safety notices. The impact of food policy on food supply composition and reformulation and consumer behavior are intermediate steps to a final outcome of food policy impact on diet quality and health outcomes. Given the multifactorial nature of health and well-being, including genetics, behavior, environmental and physical influencers, medical care, and social factors as determinants of health, this phase of the project and report focused on data availability and data gaps to allow for the analyses of consumer behavior change and company action in response to new food policies. Future work will consider linkages of nutrition data sets addressed in this report to health outcomes data.

The Foundation used the following methodology to identify real-world data availability related to nutrition, food safety, and consumer and company action:

- Engaged an expert working group with experience in nutrition, food production, food safety, science communications, academia, and the intersection of food and technology.
- Interviewed 27 company representatives across the food supply chain, including ingredient and food manufacturing companies, grocery retailers, convenience and drug stores, nutrition and point-of-sale data syndicators, onsite foodservice management companies, restaurants, military foodservice, industry trade organizations, and consumer insight companies. The expert working group, project consultant, and staff from the Foundation identified potential company representatives to reflect broad viewpoints of the food industry as well as individuals with experience in food safety, regulatory, and government affairs. Interviews were conducted by the Foundation.
- Developed a matrix of data (based on the interviews) on consumer behavior and company action related to nutrition and food safety available across the food supply sectors.
- Identified gaps in current data availability and opportunities to fill these gaps to better understand the impact of FDA nutrition and food safety regulation and guidance on consumer behavior and company actions.

The next three sections of this report explore data related to nutrition, food safety, and consumer insight. In the nutrition and consumer insight sections, food for retail sale is distinguished from food sold through foodservice outlets because of the significant differences in packaging, information availability, and sales data aggregation. Food safety data, by contrast, are more streamlined between these two ways of procuring food, and therefore are discussed in combination. Further, the food-prepared-away-from-home scope within this project is limited to those outlets where consumers most frequently purchase food as indicated [by an asterisk] in Figure A. School foodservice for kindergarten through high school was not considered in this project.

c Real-world evidence (RWE) is strictly defined in the context of drugs and biologics (see 21 U.S. Code § 355g - Utilizing real world evidence). In the context of food and nutrition, real-world evidence loosely refers to data regarding the actual consumption of food by consumers in terms of type of food, volume and rate of food consumption, and any nutritional data related to those foods. These data may be collected from a variety of sources from which evidence about the use of those foods, including risks and benefits, may be derived.

Nutrition Real World Data

Significant nutrition regulatory and policy changes have been made over the past 20 years, including, for example:

- Trans-fat regulatory actions [e.g., requiring the addition of trans fat to the Nutrition Facts panel and revoking the Generally Recognized as Safe (GRAS) status of partially hydrogenated oils (PHOs)],
- Important updates to the Nutrition Facts label requirements, including the requirement to declare added sugars,
- Menu Labeling,
- Requirement for the addition of folic acid to grain products, and
- Voluntary guidance for industry on targets to reduce sodium in processed, packaged, and prepared foods.

Interviews were conducted across the food industry to determine existing data types that would facilitate evaluation of the impact of these types of regulations, specifically related to foods for retail sale and foods purchased away-from-home.

FOOD FOR RETAIL SALE

Nutrition and ingredient information follows a fairly streamlined path for food for retail sale.

1. **Ingredient suppliers** and **food manufacturers** develop ingredient declarations, Nutrition Facts, nutrient content and health claims, and related information based on supplier ingredient information or data available at FoodData Central (USDA database that provides nutrition profiles of foods).
2. **Nutrition data syndicators** capture label information on most foods in the U.S. food supply through a variety of methods, including input of label information into a centralized system by product manufacturers, label scans at the retail shelf, and use of consumers to scan and upload labels to centralized systems.
3. **Attribution companies** purchase data from nutrition data syndicators and use these data to identify nutrient content and health claims from the data. While they capture claims made by food manufacturers, these companies go beyond such information and FDA claim criteria to determine all potential claims a product may meet. Additionally, attributes of food based on consumer interpretation of a healthy lifestyle that are not currently defined by the FDA, such as “plant-based,” may be defined and applied by attribution companies.
4. **Retailers** aspire to provide consistent nutrition messaging within store categories to their shoppers, highlighting products that meet criteria for a specific nutrition or health claim. As food manufacturing companies choose whether or not to make nutrition claims on products, retailers purchase and use attribution company data to assess products that meet a claim. Retailers then create shelf label claims at brick-and-mortar stores and provide health and nutrition filters in online grocery shopping environments. Additionally, retailers may define and apply criteria for their own product attributes, such as “Dietitian Approved.”
5. **Point-of-sale (POS) data aggregators** capture the retail sales data of all packaged foods and some foods sold in bulk (fresh produce, meats, nuts, etc.). This includes food purchased at brick-and-mortar stores, online sales through the store chain directly, or grocery delivery companies like Instacart.

Data sets from nutrition data syndicators, attribution companies, and POS data aggregators is available for purchase by entities such as retailers, researchers, and governmental organizations. When used in combination, these data sets could facilitate assessing the impact of a federal nutrition policy after it is finalized and implemented or at least quantifying changes that occurred after a policy change, although change may have been influenced by other factors. Nutrition, ingredient, and claims data from attribution companies, for individual products as well as food categories, can be tracked over time to assess changes. While controlling, or accounting, for industry formulation changes, this data can be analyzed against POS data to determine if there are sales shifts in products with a specific nutrition attribute, health claim, or ingredient, which can be an indication of consumer behavior change. Differences in consumer behavior between in-store and online shopping can also be assessed.

To illustrate how these data sets might be used to assess change in food company action and consumer behavior, consider trans fat, which was required to be declared on the Nutrition Facts label starting January 1, 2006. Products with partially hydrogenated oils (PHOs), a primary source of trans fat, in the ingredient declaration prior to 2006 could, in theory, be identified in attribution company data; sales of these products could be tracked for this same time period through POS data. The sales of these exact products could then be tracked from 2007 to 2017 to determine if labeling of trans fat impacted market availability and consumer purchase of these products. Additionally, analyzing attribution company data across this time span would identify action by food companies to remove PHO from products. While a direct cause and effect cannot be *definitively* linked to the FDA action in this process, use of these data sets may identify FDA action as a *contributing* factor.

Given the significant dollars spent on food at micro-markets, defined as unstaffed spaces (including vending machines) where individuals can purchase foods and beverages, data sets available in this food purchase stream were also considered. The National Automatic Merchandising Association (NAMA), which represents the convenience service industry, has made a commitment to offering a higher percentage of products in vending machines that meet nutrition criteria. As part of the monitoring process, nutrition data, net weight, UPC codes, and other information on the products sold in vending machines are tracked and maintained in a database. As most vending machines are owned by large foodservice and beverage companies, these companies would need to be willing to share the sales date of items sold in vending to be able to conduct analyses similar to what can be done with foods available for retail sale.

Food for Retail Sale Nutrition Data Accessibility Gaps

In addition to needing to purchase these data, there are challenges that must be considered in exploring what can be assessed as well as the conclusions derived from the data. The challenges are indicated below by category.

PRODUCT FORMULATION

- Slight variation in product formulations and, potentially, label information, may be used for the same product with the same name in different regions of the country.
- A private label product may have similar formulation but be sold under different SKUs in differing brands connected to various retailers. This limits the ability to draw conclusions on the number of unique products that may have been impacted by an FDA regulation or policy.

DATA AVAILABILITY

- Ingredient and food manufacturing companies as well as retailers track label changes to understand shifts in sales and as a resource for consumer contact centers, but these data are often not available quickly nor in an easily accessible format outside individual companies given the variety of systems that are used within the industry to create and store this information.
- Label information on imported, culturally relevant foods may not be available or may not be in standardized format or in English language currently.
- Nutrition data on bulk items (produce, meat, nuts, etc.) is infrequently tracked by nutrition data syndicators and attribute companies due to the complexity in codes used to track this data and the exemption from required nutrition labeling.
- Nutrition data syndicators (including government-managed providers of this data) and attribution companies may store data for as little as three years due to the amount of data captured and the high cost of data storage.
- Some retailers share data only with certain POS data syndicators, some share only certain subsets of their data, such as not sharing private label data, and some do not share any of their sales data. Convenience store sales are only captured if the chain contributes at least one percent of sales in the industry.
- Not all POS data syndicators currently have data sets easily available, such as in an API.
- POS data can be quite expensive.
- While artificial intelligence/machine learning will facilitate analysis of these data sources, high-quality—and comprehensive—data collection is essential.

DATA ACCURACY

- Given the volume of products in the food supply and the potential frequency of label changes by companies (not all of which impact nutrition, ingredients, or claims information on package), real-time accuracy of label information at nutrition data syndicators and attribution companies is not currently possible.
- Some data is modified or rounded in databases. For example, Branded Foods in FoodData Central converts rounded Nutrition Facts data to 100-gram data. This is especially problematic for foods with small serving sizes.
- Not all nutrition data syndicators or attribution companies have quality control processes for data verification or staff with expertise in food and nutrition.
- Many factors other than label changes can impact product sales (price, seasonality, quality, etc.).

DATA COMPLEXITIES

- There are as many as 20 different nutrition data syndicators, each with different processes for capturing label information and varying levels of quality control of the data. Attribute companies will often purchase and use data from several nutrition data syndicators to confirm most recent data is used and to validate against different methods of data capture.
- Definitions of food categories and product types may differ between attribute and POS data syndicators, creating complexity in understanding food company actions and consumer behavior change for a food category.
- Most fresh produce sold in bulk is tracked using PLU codes instead of UPC codes. While three-fourths of the 1,640 PLU codes for conventional produce are consistent across all retailers, 320 of these have some limitations (for example, 20 can be used for apples, as retailers determine apple variety) and 100 can be randomly assigned by each individual retailer. Therefore, sales data for these items has limitations.

Nutrition Evidence Opportunities for Foods for Retail Sale

Despite these data accessibility and usability limitations nuances, processes can be put in place with release of new regulations, policies, and guidelines to understand the long-term intended impact of nutrition regulations and policies. As indicated above, label information is available publicly and through some sources for sale, and retail food and beverage sales data can be purchased through POS data aggregators. The limiting factor is length of time these data are stored, which may be addressed, for example, through public-private partnerships with these entities. While this solution has a relatively long lead time, and involves complexities beyond the few enumerated here, FDA, trade organizations, and/or retailers could establish partnerships with nutrition data syndicators, USDA's FoodData Central, and/or attribution companies to track specific data regarding nutrients, ingredients, and/or claims included in the new regulation for a defined period. At the same time, these organizations would establish partnerships with POS data syndicators for tracking sales shifts in products and/or categories as an indication of consumer behavior change. It is essential at the start of these projects to establish the time frame for which data will need to be kept, stored, and available for analysis. For food sold in vending, partnerships could be formed with the NAMA and the large companies who own and manage the majority of these machines to conduct similar analyses. Moving food labels to a digital format could aid these processes by making information more readily accessible and available for analysis.

FOOD PREPARED AWAY-FROM-HOME

As compared to food for retail sale, nutrition, sales, and consumer insight data on food prepared away-from-home is more complex, making the tracking of the data difficult and not common practice within the foodservice industry. This, in turn, makes it difficult to assess the impact of nutrition policy on foods prepared away-from-home.

Nutrition Data Gaps

Gaps in real-world data are created by multiple models for managing foodservice operations, limited labeling requirements for foodservice products, lack of nutrition and sales data aggregators within this industry, and consumer demand for variety and change from foodservice outlets. These gaps are discussed here.

- **Ingredient labeling.** Current FDA regulations do not require the Nutrition Facts label to be provided on "foods intended for institutional use;" therefore, foodservice companies create standard operating procedures (SOPs) to capture this information from suppliers or use USDA FoodData Central information to create standard nutrition information on menu items. Even if not required to provide this information to consumers, various foodservice establishments, such as healthcare settings, senior dining, corrections, military, and employer cafeterias, create the information to determine alignment with potential consumer dietary needs such as gluten free, allergen free, low sodium, or diabetes friendly. This information is rarely publicly available.
- **Menu Labeling scope.** In May 2018, the Menu Labeling Rule went into effect, requiring certain foodservice establishments to provide consumers with calories and other standard nutrition information on standard items. This applies specifically to retail food establishments with a minimum of 20 outlets operating under the same name and substantially serving the same items. This primarily impacts chain restaurants, coffee shops, and foodservice operations within grocery and convenience stores; the full spectrum of foods prepared away-from-home are not covered by this regulation.
- **Nutrition data availability.** While nutrition information on foods-prepared-away-from-home is publicly available on foods from companies required to comply with the Menu Labeling Rule, it is not in an easily

accessible format. Additionally, there is not yet a service aggregating these data in a standardized format as with foods for retail sale. Some consumer insight companies track restaurant menus as an indication of food trends, but not all menus will provide calorie or nutrition information.

- **Sales data aggregation.** The most readily available data are from chain restaurants and coffee shops. However, this is not representative of the remainder of the foodservice industry, where capturing sales data is more complex. With employer cafeterias, for example, onsite service providers will have nutrition information on menu items, but the employer tracks sales. At colleges and universities as well as military dining, individuals "swipe" a card when entering the location and can select any items within the foodservice offering; sales of individual items are not tracked. Food ingredient procurement records at these locations can be used to track food purchased for menu item preparation, but the accuracy of these data as related to consumer consumption are limited by waste in the preparation process as well as food not eaten by the consumer after it is taken. Additionally, as there is no standard serving size for foods prepared away-from-home as there is with food for retail sale, it is difficult to accurately compare "units" of food sold. No POS data aggregator is capturing sales of food sales data across the foodservice industry.
- **Foodservice operator model.** Foodservice outlets can be self-operated or managed through a third-party "onsite service provider" which limits the availability of real-world data related to nutrition. For example, chain and non-chain restaurants, corrections, military, and grocery foodservice are almost exclusively self-operated. Employer cafeterias, travel industry, and sports and entertainment venues are primarily managed by "onsite providers." Colleges, universities, and health care foodservice are managed under both models. Use of a third-party service provider impacts data capture because the service provider may have nutrition data on menu items, but the sales data is owned by the company that hires the food service provider. These companies consider the sales data proprietary.

Other gaps in real-world data include challenges for restaurants and certain foodservice establishments in managing consistent portion sizes of ingredients and finished menu items and production instructions. With focus on menus that change frequently and have multiple suppliers for the same ingredient, nutritional information is frequently not available or not reliable. Consumer demand for an expanding array of flavors and options as well as locally sourced ingredients add complexity for foodservice establishments to develop and offer nutrition information.

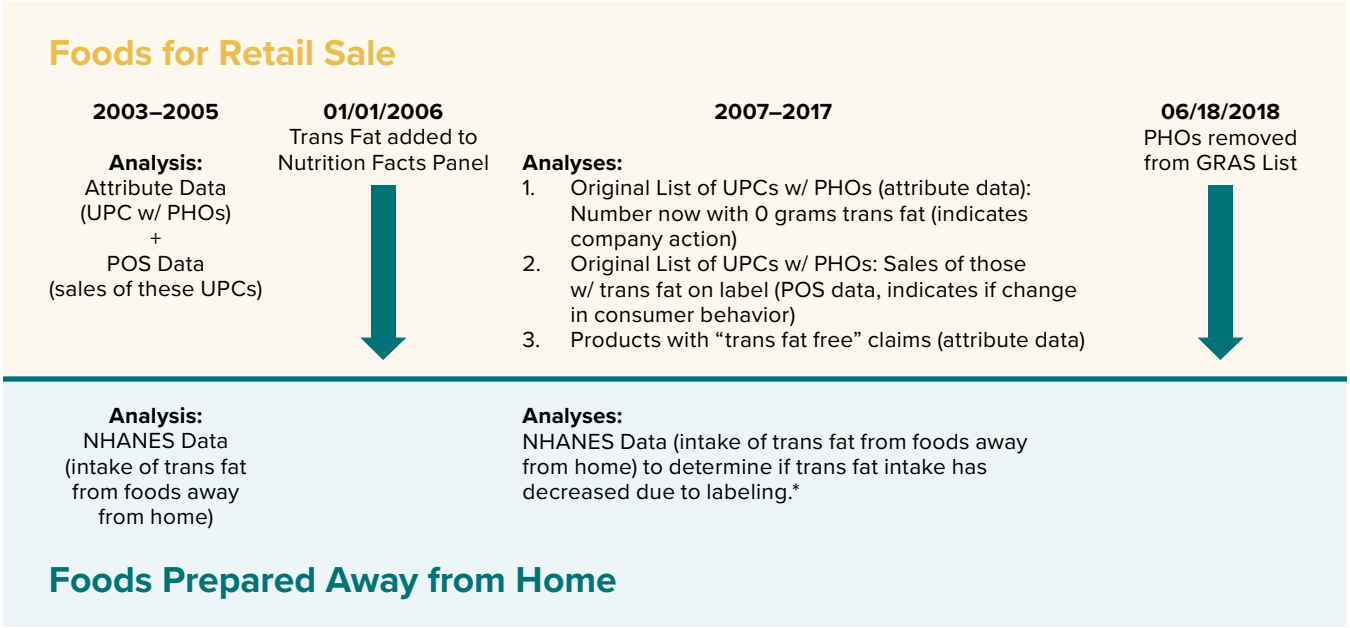
Nutrition Evidence Opportunities for Foods-Away-From-Home

Given the complexities of the foodservice industry, the availability of real-world data to understand company action and consumer behavior in response to regulations and policies is limited. One alternative for the foodservice industry, as well as an additional data analysis option for foods for retail sale, is data from the National Health and Nutrition Examination Survey (NHANES).

NHANES is a program of studies designed to assess the health and nutritional status of adults and children in the United States. NHANES is a major program of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). First conducted in the 1960s, the survey has been considered continuous since 1999. Information captured in the surveys include demographic, socioeconomic, dietary, and health-related questions as well as lab testing and medical, dental, and physiological measurements.

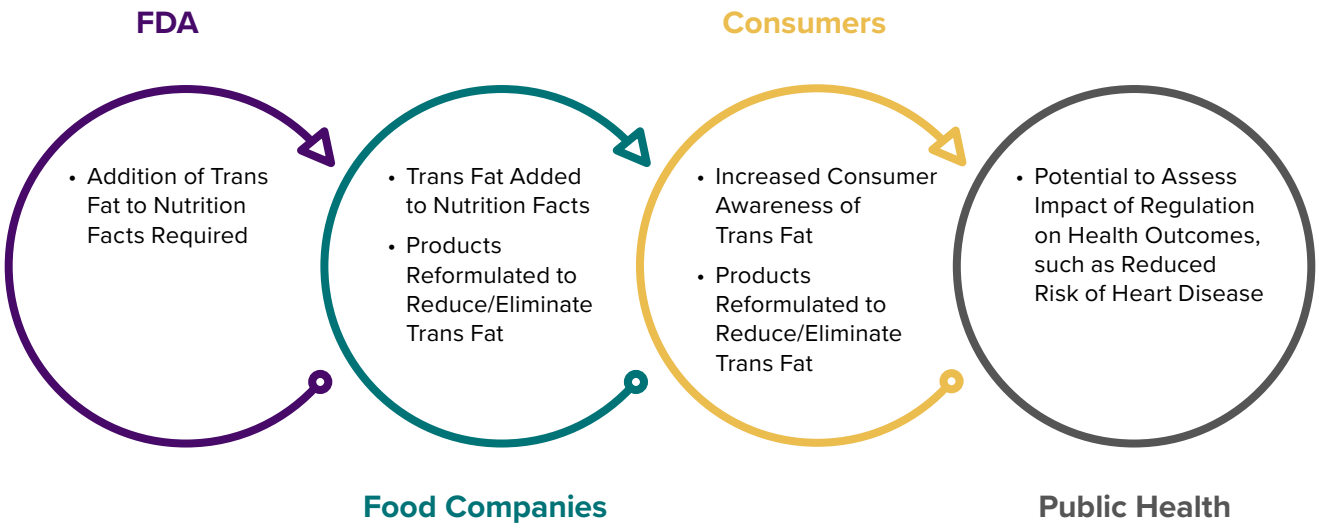
For data assessment for foods-prepared-away-from-home, the dietary recall portion of NHANES includes consumer identification of whether each food item eaten was procured away from home (as well as those prepared at home) and provides some specificity to the type of foodservice establishment. A nutrient analysis

is run on each survey participant's diet recall. NHANES allows tracking changes in nutrient intake specifically from foods eaten away from home over time (as well as for foods prepared at home). With the trans fat regulatory actions mentioned above, for example, the amount of trans fat consumed in food purchased away-from-home prior to 2006, from 2007 to 2017, and after the 2018 revocation of the GRAS status of PHOs, could be assessed using NHANES data and provide an indication of consumer behavior change due to these regulations. The limitation, of course, is the inability to discern, with precision, if the change was due to consumer decision making, due to company action to lower or remove trans-fat from foodservice products, or some other contributing factor. *Whether* a change occurred, however, can be measured.



As NHANES data captures whether a food was prepared at or away from home, this data set can also be used at some level to understand the impact of food policy on consumer behavior change through a broader set of eating environments.

Another data set currently in development is the National Institutes of Health (NIH) Common Fund's *Nutrition for Precision Healt*h, which has a goal of leveraging AI and other technologies to develop algorithms that predict individual responses to food and dietary patterns. With a goal of enrolling 10,000 U.S. individuals, this study examines individual differences observed in response to different diets by studying the interactions between diet, genes, proteins, microbiome, metabolism, and other individual contextual factors. Participant food intake is captured, providing another data set of food consumed when prepared away-from-home or at home. This creates future potential for assessing the impact of food policy on the intermediate goals of consumer behavior change and company action as well as the longer term impact on the ultimate objective of understand food policy impact on diet quality and health outcomes. This creates future potential for assessing the impact of food policy on the intermediate goals of consumer behavior change and company action as well as the longer term impact on the ultimate objective of understand food policy impact on diet quality and health outcomes, as depicted in the example below with trans fat.


FDA
• Addition of Trans Fat to Nutrition Facts Required
Food Companies
• Trans Fat Added to Nutrition Facts
• Products Reformulated to Reduce/Eliminate Trans Fat
Consumers
• Increased Consumer Awareness of Trans Fat
• Products Reformulated to Reduce/Eliminate Trans Fat
Public Health
• Potential to Assess Impact of Regulation on Health Outcomes, such as Reduced Risk of Heart Disease

Food Safety Real World Data

Based on the most common reasons for food recalls and expertise of the Expert Working Group, the scope of "food safety" in this project includes undeclared allergens, pathogens, foreign materials (glass, metal, bone, hard plastic), and levels of vitamins and minerals, heavy metals, or other ingredients (intentional or incidental) that could be acutely toxic or toxic at high levels or with repeat exposure.

Identification of food safety hazards happens at multiple points before and after a food product is introduced into interstate commerce, including on farm, in shipping and packing, in production, at a foodservice or retail outlet, or in a consumer's home. There is a clear distinction in data availability while products are still under the control of the producing company, prior to being available for consumer purchase and/or consumption, versus once food is available to consumers.

DATA PRIOR TO FOOD AVAILABLE FOR PURCHASE/CONSUMPTION

Capture of food safety data from early in the food development process is essential given a goal of prevention of foodborne illness or injury.

- **Company data.** Prior to being available for human purchase and/or consumption, companies may "hold," "reject," or "withdraw" a food ingredient or product based on a potential or confirmed food safety risk. Ingredient, finished product, and raw food product (e.g., produce) companies generally document these actions for procurement and financial purposes as well as part of ongoing assessment of suppliers. These data are not publicly available nor in a format easily accessible when the contamination originated with the producing firm, in part because these companies are not required to file a report in FDA's Reportable Food Registry as the food products have not left control of the company.
- **Industry Association data.** Industry-level organizations, such as the Leafy Greens Marketing Agreement, may establish food safety standards and conduct audits on farms to ensure safe food growing and handling in higher risk food categories. Various data are captured during these audits, but this information is generally not publicly available. If these audits are conducted by federal or state partners, there may be an opportunity for FDA to access this information.
- **FDA data.**
  - FDA houses a Data Dashboard, which is intended to increase transparency and accountability by displaying and allowing analysis of public FDA data via customizable and understandable graphics. Various compliance dashboards on this site provide data that can be helpful in generating real-world evidence related to the impact of food safety regulations. These include, for example:
  - Inspections Compliance Dashboard. FSMA requires inspection of high-risk facilities at least every three years and of non-high-risk facilities every five years. During these visits, inspectors assess facilities and practices related to food safety. Additionally, they have access to a variety of records related to food safety monitoring. Following inspections, findings are evaluated to determine if the facility complies with applicable laws and regulations; the inspection is classified in one of three ways:
    - **No action indicated (NAI)**, which means no objectionable conditions or practices were found during the inspection,
    - **Voluntary action indicated (VAI)**, which means objectionable conditions or practices were found, but the FDA is not prepared to take or recommend any administrative or regulatory action or

- **Official action indicated (OAI)**, which means regulatory and/or administrative actions are recommended.

Since 2009, data on these inspections has been tracked and made publicly available through FDA's Inspections Compliance Dashboard; the data can be sorted to food/cosmetics, includes information on which type of action was indicated following inspections, data on foreign vs. domestic inspections, and the top citations in the inspection reports, such as sanitation, pest control, and/or critical control points. The limitations of these data are that the data combines food with cosmetics and that FDA may contract with states to conduct inspections; data from these state contracted inspections are not included in the data set.

- **Recalls.** This site tracks recalls in biologics, devices, drugs, tobacco, and veterinary in addition to food and cosmetics from 2012 to current day; the dataset is updated weekly and includes only recalls that have been classified. Various reports, such as recalls by year, product type, and classification are provided on the dashboard. While the dataset can be downloaded for further analysis, food and cosmetics are combined as a category and technological or manual separation of food data would be required to further analyze the data.
- **Import Refusals.** These refusals can be tracked by country of origin, import division/district, company name, product category, and reason for refusal, including reasons related to food safety risks.
- **Reportable Food Registry.** Registered Food Facilities that manufacture, process, pack, or hold food for human consumption in the United States are required to report when they detect a hazard where there is a reasonable probability that the use of, or exposure to, a food will cause serious adverse health consequences or death (e.g., circumstances expected to trigger a Class I recall). The registry is designed to help the FDA better protect public health by tracking patterns and targeting inspections.

  Twelve years of data, through September of 2021, can be downloaded, and includes date of report, product type, specific hazard including allergen type if allergen is the hazard, and product country of origin. The limitations of this data set include that it is not downloadable in real time and that the specific company is not named; additionally, farms and restaurants are not registered food facilities and therefore are not required to report within this system.

– **Warning Letters.** When the FDA finds that a manufacturer has significantly violated FDA regulations, the FDA notifies the manufacturer, often in the form of a Warning Letter. The warning letter identifies the violation, such as poor manufacturing practices, undeclared allergens, misbranding, or pathogen presence. This data is publicly available, and includes information on the manufacturer, product, facility, and violation which has been made. There are, however, business-related confidentiality limitations that are considered in the data made publicly available.

DATA ONCE FOOD AVAILABLE FOR PURCHASE/CONSUMPTION

Once a product is available for human consumption, ingredient companies, food companies, and grocery retailers may identify a food safety risk, for example through a review of records or product testing. Product testing is also done by regulators, including as part of routine inspections and targeted sampling assignments. Even if illness is not associated with the finding, these products can be deemed violative, are generally recalled, and therefore provide evidence of system failures.

When a consumer becomes ill through exposure to a foodborne hazard, he/she may take actions that result in the event being reported and investigated, such as:

- Contacting customer service offices of a food company, chain restaurant, or retailer;

- Visiting a healthcare setting such as a doctor's office, urgent care center, hospital, or a healthcare service at a college, university, or military base, or healthcare environment;
- Reporting their illness to a local or state health department; and
- Calling the National Poison Control Hotline.

Local public health agencies may investigate reported illnesses identified through citizen complaints or healthcare reporting to determine if there are clusters of linked cases or an outbreak caused by a common source. Depending on the size of the outbreak, state, territorial, and federal authorities may get involved. Outbreaks may also be discovered by linking data from laboratories; the national PulseNet program coordinated by the Centers for Disease Control and Prevention (CDC) compares the DNA fingerprints of bacteria from patients to find clusters of disease that represent unrecognized outbreaks. Local, state, territorial, and federal investigators from the CDC, FDA, and USDA then work to determine the likely cause of illnesses and take steps to mitigate further illnesses, such as working with companies to recall contaminated or potentially contaminated products.

Federal agencies like the FDA and Centers for Disease Control and Prevention (CDC) track data on food safety incidents and outbreaks as well as recalls by food companies. This data is publicly available in various places, including:

- Centers for Disease Control and Prevention (CDC) National Outbreak Reporting System (NORS): data from reports of foodborne and waterborne disease outbreaks and intestinal disease outbreaks from 1971 to present for waterborne disease outbreaks and 1998 to present for foodborne illness outbreaks. Data are updated annually, but as of this writing only data through 2021 is available.
- CDC List of Multistate Foodborne Outbreak Notices: outbreaks for which CDC led the investigation; data available starting in 2006.
- CDC FoodNet Fast: includes the Foodborne Diseases Active Surveillance Network that shows rates of illness for nine pathogens since 1996 within the FoodNet catchment sites, a subset of states and localities that includes 15% of the U.S. population.
- FDA Investigation of Foodborne Illness Outbreaks: data on outbreaks and adverse event investigations currently being investigated by the FDA's CORE Network.

Additional data sets useful in analysis of the impact of food safety policy on consumer behavior and company action are compliance and enforcement data from these sources:

- FDA Recalls, Market Withdrawals, & Safety Alerts: this site has three years of data and is based on press releases and public notices; after three years, data is archived here by year.
- FDA Data Dashboard: contains data elements from FDA compliance and enforcement data sources, including inspections, recalls, and import refusal. Data can be downloaded and is available in an API.
- FDA Enforcement Reports: information on FDA recalls, including those for food, is available starting in 2012.

Testing of products available in interstate commerce is also conducted through these FDA programs:

- **FDA Food Sampling Assignments.** Periodically, the FDA will sample food products to gather additional data to help identify and address hazards, to identify patterns that may help predict and prevent future product contamination, and to keep contaminated food from reaching the consumer. For example, in 2013 and 2014 FDA conducted a survey to estimate undeclared milk allergen in dark chocolate and in 2018 and

2019 conducted another survey to understand the extent to which dark chocolate bars and chips labeled as "dairy free" contained levels of milk that would be potentially hazardous to consumers with milk allergies. In 2015 and 2016, the FDA conducted sampling of a variety of foods to determine compliance with gluten-free labeling requirements. There have also been several sampling assignments targeting microbial pathogens. The data from these periodic sampling efforts is publicly available.[d]

- **In 2020, FDA launched the Laboratory Flexible Funding Model Cooperative Agreement Program (LFFM)**, which is intended to enhance the capacity and capabilities of state human and animal feed testing laboratories through sample testing in the areas of microbiology, chemistry, and radiochemistry. Key goals of the program are to improve human and animal food testing surveillance programs, accelerate foodborne illness outbreak investigations, and develop methods for early identification of emerging issues, monitoring and evaluation for future sampling initiatives. In Year 2 (July 2021-June 2022), the LFFM Program provided a total of $21.6 million in funding to 55 state laboratories through a cooperative agreement. A portion of that funding is used for human and animal food surveillance and resulted in a total of 20,120 sample analyses (13,862 human food, 6,258 animal food) for a wide range of microbiological and chemical hazards, resulting in 20 recalls of FDA-regulated products. In Year 3, 24,811 human and animal food samples were analyzed through $8.4 million in funding. Data captured in these programs are not currently made publicly available; this data could be valuable in understanding food safety hazards of products available for consumer purchase and consumption.
- **FDA Total Diet Study (TDS)** began in 1961 and today monitors levels of micronutrients, toxic elements, pesticide residues, and other chemicals in food. These data are then used to estimate the average consumption of these nutrients and contaminants by U.S. populations and subpopulations on a daily basis. The longevity of this study allows for the tracking of trends over time as well as intervention and policy to reduce or minimize risks. This data is publicly available as are reports on the data analyses.

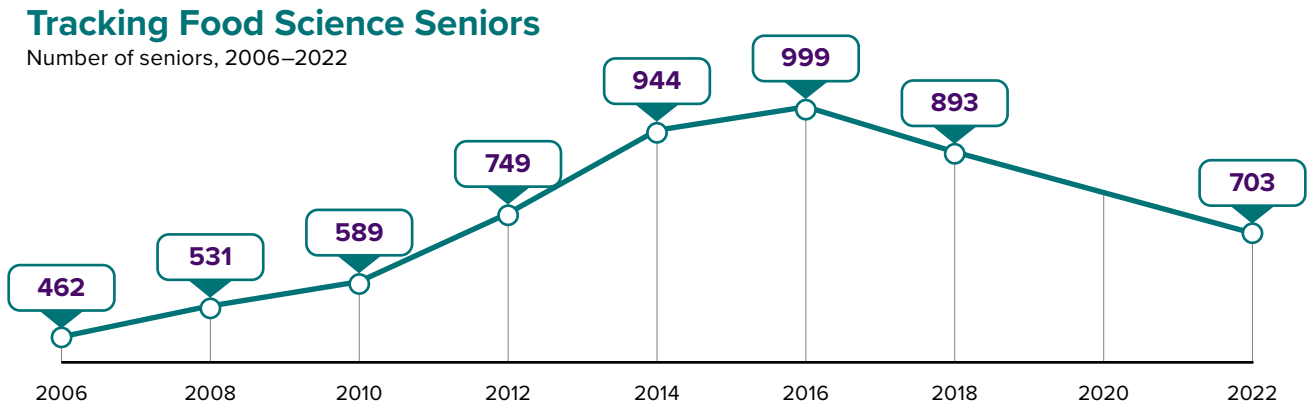
TRAINING DATA

Given human action in all steps of the food supply chain, food safety training is essential for prevention of foodborne illness and injury. Exploring data related to changes in food safety training and education can illuminate industry investment in keeping pace with implementation of preventive food safety activities. Training is available through FDA, third-party vendors, and individual companies and organizations. One example is an FDA partnership with the USDA's National Institute of Food and Agriculture (NIFA) to create the National Food Safety Training, Education, Extension, Outreach, and Technical Assistant Grant Program. Recognizing the need for food safety training for small farm owners and food processors, this program is intended to provide funding so that these critical groups receive training, education, and technical assistance consistent with standards being established under FSMA. The Produce Safety Alliance (PSA) is a collaboration between Cornell University, FDA, and USDA to prepare fresh produce growers to meet the regulatory requirements included in the FSMA/ Produce Safety Rule. Similarly, FDA worked with the institute of Food Safety and Health at the Illinois Institute of Technology to establish the Food Safety Preventive Controls Alliance (FSPCA) which has developed training materials for a breadth of FSMA-related rules. Data tracked in these training programs includes total number of individuals trained, including company tracking by individual employee, pre- and post-training knowledge scores, and survey data indicating change in practices based on the training. This data may or may not be publicly available, depending on the training provider, and most often are not in an easily accessible format.

OPUS International, a food science recruiting firm, tracks the number of seniors graduating with degrees in food science from the leading U.S. programs. Data indicates that the number of graduating seniors in food

d Sampling is, by design, a narrow endeavor and provides only a snapshot of information for portions of the food supply rather than a holistic view.

science has been on the decline since 20164; other data indicates just 32 percent of students pursuing food science degrees are interested in food safety roles.[5] This shortage of trained professionals has potential to impact the current and future ability to fill food safety positions at companies along the food supply chain, which ultimately may impact the full and effective execution of FDA food safety policy.



GAPS IN FOOD SAFETY EVIDENCE OPPORTUNITIES

Data gaps stem from many factors, including:

- **Reliable Baseline Metrics:** To assess the impact of regulations and policies, reliable baseline metrics are essential. For example, the commonly used CDC citation suggesting 48 million Americans get sick from foodborne illness every year is an estimation based on Scallan's 2011 study which used data many years older.[6,7,8] While CDC's NORS data is kept current, only data through 2021 is available for download and detailed analyses. Additionally, only foodborne illness outbreaks, which represent approximately one-tenth the cases of foodborne illness are captured in the system. As another example, while some data is available related to training of food safety staff on farms, in food processing and production companies, and at retailers, the number of those needing training is not currently available.
- **Data privacy:** When food products are still within their control, companies consider data related to withdrawals and product rejections that do not result in a food recall to be proprietary. For example, if a seal on a shipping truck is broken or a perishable product is out of temperature during transport, and the product is rejected for this reason, this information is not required to be reported and is not centrally tracked or publicly available. While this information should be a component of implementation records for companies covered by the Preventive Controls Rule, a mechanism to share these data or centrally track does not exist. Additionally, Food Safety Plans often include flow diagrams, production processes, and other proprietary information, and therefore, companies are only willing to share this data as legally required.
- **Data collection:** FDA does not currently have the infrastructure and resources in place to collect all data available during facility inspections, such as detailed parameters of specific hazard analysis and evaluation. Even if data could be collected, no standardization in monitoring and documentation exists across the food industry, creating complexity in storing, aggregating, and analyzing this information. For example, and as related to lead in cinnamon applesauce, hazard plans for all companies manufacturing the product could be collected and assessed to determine the number of companies that have lead included in their hazard plans, where companies have implemented appropriate controls, and where gaps exist in the industry.

- **Litigation Concern:** There are certain ingredients/compounds which may potentially be harmful to human health with repeat and/or long-term exposure; these compounds are not necessarily required to be named on a product label. Companies may choose not to track the presence of these ingredients/ compounds due to concern about future litigation.
- **Inconsistent practices:** While some companies routinely survey production facilities to identify foreign material or wrong product in wrong package (potential allergen risk), this practice is not consistent across food manufacturing and the data are not easily accessible. Additionally, with acquisition of ingredient or food companies, the new parent company may not have complete information available from the acquired company, other than what may be included in food safety plan implementation records.
- **Expense of Data Sharing:** Broader transparency carries some financial and potentially reputational costs. Industry member interviews revealed willingness to share monitoring and other food safety data with the FDA if there is a clear return in value from such a partnership.
- **Co-manufacturer Use:** Recalls are sometimes announced and publicly tracked by the brand owner, which is not always the same company as the product manufacturer. However, the product manufacturer can initiate a recall of multiple brands of a product or products if the violation occurred at the manufacturing location. This requires communication with the manufacturer and the brands' owners to ensure the public is made aware of the recall and can act accordingly. Co-manufacturer use can create limitations in analyzing food safety hazard and risk by producing company.
- **Resource allocation:** Currently, there is no assessment of company resource allocation to food safety efforts, which could be a valuable data point to understand if resource availability is related to recall numbers. As quality management continues to mature in the food sector (such as the emergency of Western Growers GreenLink described in the next section), these systems should provide an opportunity for greater collection, and use, of data to improve food production.

FOOD SAFETY EVIDENCE OPPORTUNITIES

Opportunities to improve the availability and utility of real-world data to assess the impact of food safety regulations and policies include the following.

ANALYSIS OF EXISTING DATA

- Between the FDA Data Dashboard, warning letters, and the various data sets of recalls, significant opportunity exists for analysis to identify potential refinements to food safety regulations and policies. For example, inspection classification data could be analyzed against recall data to determine if that classification impacts the likelihood of recall. Or reasons for an OAI inspection classification could be analyzed against company recall frequency. Companies that offer services to food companies, such as third-party auditors and law firms, could leverage these data to potentially create new business streams. Researchers, the FDA, and industry trade organizations would likely find meaningful insights from combined analysis.
- Updating the Inspection Compliance Dashboard to include inspections conducted by contracted state inspectors would improve the data available for analysis.
- Trends and changes in NAI, VAI and OAI inspection categorization, and analysis of reasons that firms are cited for regulatory violations can be tracked over time to determine if FDA regulations and guidance are effective. For example, if FDA were to issue enhanced guidance on sanitation management, would there be fewer violations on sanitation-related issues?

- Given the proprietary nature of the rejection, withdrawal and monitoring data captured by companies along the food supply chain (such as environmental monitoring programs, supplier evaluation, age of equipment or facilities, technical qualifications of food safety staff), trade organizations or an established Academic Center of Excellence could study these data, including aggregation and anonymization of the data (recognizing there are analysis and usage limitations of this type of data), across the food industry to provide collective insight to the FDA on food safety issues. A current example of this type of initiative is Western Growers GreenLink™, a digital, secure, and confidential online platform that enables users to share food safety data, analyze their internal food safety data, and learn from aggregated, anonymized data that can help them anticipate, adjust, and better manage food safety strategies.

COMPOUNDS TOXIC AT HIGH LEVELS OR WITH REPEAT EXPOSURE

- While companies interviewed indicate limited tracking of ingredients or compounds (intentional or incidental) that are not required to be labeled that could be toxic at high levels or with repeat exposure, FDA could add surveillance of these compounds to testing done through the Laboratory Flexible Funding Model Cooperative Agreement Program or by creating an FDA Food Sampling Assignment.
- If ingredients and foods which potentially contain these compounds are known, ingredient data captured on foods for retail sale by nutrition syndicator and attribute companies could be used to understand how pervasive the compound is in the food supply by number of UPCs and food categories, and if ingredient use or food promotion changes with release of regulations or policies. Analyzing ingredient data with POS data over time would provide an indication of whether consumers are changing behavior as related to purchase of foods that contain the potentially harmful compound.
- Some retailers and foodservice companies create internal lists of ingredients not allowed for use in products sold in their stores or outlets (so-called “no no” lists). These lists may contain ingredients that are approved or allowed for use by regulators. Sharing these lists with FDA and other regulators could help identify areas for further consideration by regulators.

USE OF TECHNOLOGY

- Explore expanded use of technologies for identification of pathogens and prediction of foodborne illness outbreaks. Examples include sensors that change color based on detection of certain microbial metabolites or that show when a food has been out of temperature control for too long. AI programs could be used to assess past food safety incidents to predict future issues. In the future, machine vision could identify potential pathogens in food sold at retail and food purchased away-from-home.
- Industry trade organizations, third-party audit companies, and/or the FDA could create a centralized system for submission of hazard analyses, which are generally included in Food Safety Plans as a regulatory requirement or to satisfy a private, voluntary audit. During FDA inspections, personnel could scan monitoring records into this centralized system, such as metal detector and x-ray rejection rates, label changeovers, sanitation validation of allergen cleans, frequency of foreign material identification and staff training records. AI technology could then be used to mine these data to assess hazard identification and management procedures.

OTHER OPPORTUNITIES

- FDA has an opportunity to secure monitoring and other food safety data from companies across the food supply chain by creating incentives to sharing this data, such as records that show no potential food safety issues leading to increased length of time between FDA facility inspections. Voluntary participation would require incentives that outweigh the potential risks and costs, such as legal concerns related to regulatory compliance or unwarranted publicity.

- Given a potential gap in trained food safety professionals, food companies and trade organizations could research methods to increase student interest and aptitude in this area, understand incentives that could drive interest, and consider second career or internal cross training for individuals working in related fields to ensure adequate numbers of individuals with the necessary training and background are available to fill food safety positions in companies along the food supply chain. Researchers could partner with companies and agencies conducting training to assess the breadth and impact of their data and relationship to reductions in food recalls.
- The FDA's Food Facility Registration process could be updated to require categorical information on ingredient procurement and types of finished products and volumes as part of the facility's business. This volumetric food flow would allow the FDA to identify supply chain vulnerabilities, better assess facility risk related to inspection frequency and focus, and more effectively investigate foodborne illness outbreaks.

Consumer Insights Data

A final focus of this project was to understand data types that could be monitored to indicate if, when, and how consumers change food purchase or consumption behavior following implementation of a new regulation or policy related to nutrition or food safety. While, as indicated above, product sales of foods with specific attributes or in follow-up to a food recall provide a quantitative measure of consumer behavior, consumer insight data can also be useful. Consumer insight data assess attitudes and motivation behind a behavior and provide an understanding of how an audience thinks and feels. Frequently monitored across the food supply chain and to a lesser degree by the FDA, this data capture and analysis can be related to a specific project, such as consumer interest in plant-based foods or food safety package claims; alternatively, insights can be followed over time to understand ongoing consumer interest and decision-making as related to key topics.

Various types of entities create consumer insight data, including:

- **Consumer insight companies** use standard methodology, including consumer panel data, online surveys, and focus groups to help various types of food companies understand consumer wants, needs, and behaviors. Additionally, quantitative data such as sales of products with specific claims, are used by brands to determine how brands, products, and/or claims are performing in a category, against competitors, and at a specific retailer. Ingredient companies may use qualitative and quantitative data to determine the opportunity to enter a new market. Some consumer insight companies analyze restaurant menus to understand menu offerings, ingredients used, flavors, and preparations. Companies along the food supply chain purchase standard or customized consumer insight reports.
- **Ingredient, food, and larger restaurant companies** may have internal consumer insight teams. At food companies, this work is often related to a specific product category and can include concept testing or data capture after the launch of a new product.
- **Retailers** monitor and analyze consumer data specific to their shoppers, key markets, and stores; these data can be aggregated by household. Types of questions addressed in this data capture include the other products in the cart with a marker product; whether purchases shift to healthier options after exposure to a retail health and well-being promotion or program; and how purchases differ between in-store and e-commerce shopping. Some retailers conduct ongoing surveys of their shoppers related to wants and needs; these may be conducted through QR codes on receipts or loyalty card program communications.
- **Industry Trade Organizations** track consumer insights for the benefit of their membership. The data may be specific to a trending topic, such as ultra-processed foods, or for inclusion in aggregated comments on a proposed regulation, such as the revised “healthy” definition. Additionally, consumer insight studies and surveys may track attitudes and behavior over time; for example, the Food and Health Survey is an annual consumer survey, with a significant number of repeated questions, conducted by the International Food Information Council. If a trade organization is specific to an industry such as retail, surveys and research may address topics specifically useful to this individual sector of the food industry.
- **FDA** has a long history of conducting consumer research in the areas of food safety, nutrition, and diet and health. This research is designed to assess consumers’ awareness, knowledge, understanding, and self-reported behaviors. The survey findings are intended, in part, to help the agency make more informed food policy and decisions which promote public health. As one example, FDA has conducted its national probability surveys, e.g., Food Safety Surveys and Health and Diet Surveys (now the Food Safety and Nutrition Survey), to track trends in consumer knowledge, attitudes, and reported behaviors since the early

1980s to present day. Additionally, the FDA has a survey mechanism designed to get consumer feedback during the height of a foodborne illness outbreak and corresponding food recall. As another example, in 2023, the agency led an experimental study on Front of Package labeling to understand schemes that help consumers, especially those with lower nutrition literacy, easily identify foods that are part of a healthy eating plan.

CONSUMER INSIGHTS DATA GAPS

The primary gap in industry-developed consumer insights data is accessibility. For example, consumer data captured by ingredient, food, and retail companies are considered proprietary. Given tight margins and the competitive nature of these industries, these data are typically not publicly shared. Companies also indicate that because consumer research is often related to a specific product or category, it's not typically in a shareable format, is not stored in one virtual location, and can be managed by different functions within the company (product development vs. marketing, for example). As mentioned previously, not all retailers share sales data with POS data syndicators and sales of food prepared away-from-home are not aggregated, limiting the capabilities to combine food sales data with attitudinal data to draw more complete conclusions as to the impact of food safety and nutrition regulations and policies. While consumer insight companies assess menus for changes in price, menu offerings, flavors and preparations, and ingredients used, only chain restaurants are typically included in their data sets; local restaurants, colleges and universities, senior dining sites, and employee cafeterias are rarely included.

It is essential to note that consumer insight data is most often self-reported data, which does not always reflect actual consumer behavior, including actual food purchase and consumption. Additionally, multiple factors such as taste, price, and product availability can impact consumer intent and behavior, making it difficult to rely solely on consumer insight data to understand the impact of food policy. Rather, this data is only a component of a broader picture.

CONSUMER INSIGHTS OPPORTUNITIES

While cause-and-effect cannot be determined from consumer insight data alone, directional trends can be helpful. The following opportunistic uses of consumer insight data can contribute to an understanding of the impact of FDA regulations and policies on consumer behavior:

- The length of time to propose, gather comments, revise, finalize, and implement regulations coupled with the specificity of regulations allows industry trade organizations and consumer insight companies the opportunity to update ongoing, or create new, surveys to assess consumer attitudes and behaviors on t he topic before a regulatory change is made. After the regulation compliance date has passed, these organizations can address the same area of questioning to determine if attitudes and behaviors have changed due to the regulation. While food companies and the FDA may sometimes conduct new and/or analyze existing consumer research during the regulatory process, a public-private partnership could be developed to ensure the research is unbiased and meets various perspectives.
  - Specific to foods for retail sale and to increase the validation of consumer insight data, this data could then be combined with POS data to determine if consumer purchase behavior matches the attitudes, wants, and needs identified in the consumer insight data.
- As in other areas, creating a systematic and reliable method to blind and aggregate consumer insight data across sectors of the food supply chain would benefit consumers and companies alike, allowing more in-depth understanding of consumer attitudes as well as combination with other data sets for more robust

analysis to create real-world evidence of consumer behavior change and company action. Research on a blinding method of anonymous data collection that eliminated traceback to the original source has been published[13] and creates a starting point for what a process could look like. Availability of blinded, aggregated data would allow for more advanced, expedited analysis through emerging technologies.

Conclusion

Evidence that allows evaluation of the impact of FDA regulations and policies is essential to providing a food supply that is both safe and nutritious. While various types of data exist along the food supply chain, opportunities exist to more effectively capture, analyze, and share data with goals of promoting public health and creating a healthier and safer food supply through impactful food regulations and policies. The data sets, challenges, gaps, and opportunities identified here have application for multiple professions within the food supply chain, including food scientists, nutritionists, food safety professionals, and marketers, along with industry trade organizations and service providers, and government agencies to create a healthier, safer food supply.

Throughout this project's process to identify available data sets, challenges, gaps, and opportunities to improve data availability, the following two key themes emerged:

- **The current collection, compilation, and curation of food data is insufficient to support robust evidence generation.** A comprehensive, fully digitized food ecosystem will improve the situation, but is not immediately on the horizon. In the interim, data holders in the private sector and within government must consider broader data sharing and analysis. A comprehensive food supply chain ecosystem could address many of the current gaps and challenges in accessing data, such as nutrition and sales on food prepared away-from-home, capture more data during food manufacturer facility inspections, including hazard analysis data, and facilitate better traceability for earlier and more rapid investigation of foodborne illness outbreaks. Work remains to determine the data structure and IT architecture of such an ecosystem, ownership, funding, and identification of benefits for the industry to participate. Learnings can be gained through the work of other federal entities, such as the Department of Health and Human Services recent data strategy announcement on making data available, accessible, protected, and usable to improve public health.
- **Public-private partnerships present an opportunity.** Data which would be valuable in understanding the impact of food policy on consumer behavior and company action is often considered proprietary, and public private partnerships present an opportunity for companies to share information in a manner that still protects their proprietary interests but also improves the data ecosystem. Partnerships among the FDA, other government agencies, and companies along the food supply chain have high potential to improve the data available for decision making, development of regulations and policies, and analyses of the impact of food policies. Successful public-private partnerships require mutual trust and benefit, as well as the role of incentives and requirements.

The information documented and opportunities identified in this report reflect a current snapshot of available data. The report is intended to provide the groundwork for researchers, industries, consumer advocates, and regulators as they consider efforts to strengthen data collection, curation, and sharing.

Glossary of Terms

Attribution companies purchase data from nutrition data syndicators and use these data to identify nutrient content and health claims from the data. While they capture claims made by food manufacturers, these companies go beyond claims made on food packages, using FDA claims criteria to determine all potential claims a product may meet. Additionally, lifestyle attributes that are not currently defined by the FDA, such as plant-based, may be defined by attribution companies. A retailer may create their own criteria, such as for "RD Approved" signage; attribution companies run retailer-defined criteria against all foods in their data set to determine which meet the retailer criteria. Examples of attribution companies include the Avery Dennison Corporation (healthyAisles program), Nielsen IQ (Label Insights program), and Sifter™.

FoodData Central provides expanded nutrient profile data on food products. The USDA-administered site offers five distinct data types on food and nutrient profiles:

- **Foundational Foods:** values derived from analyses for food components, including nutrients on a diverse range of foods and ingredients as well as extensive underlying metadata.
- **Food and Nutrient Database for Dietary Supplements 2019–2020:** nutrient and food component values for the foods and beverages reported in What We Eat in America, the dietary intake component of the NHANES.
- **SR Legacy:** comprehensive list of values for food components, including nutrients derived from analyses, imputations, and published literature.
- **Branded Foods:** data from a public-private partnership whose goal is to enhance the open sharing of nutrient data that appear on branded and private label foods and are provided by the food industry.
- **Experimental Foods:** foods produced, acquired, or studied under unique conditions, such as alternative management systems, experimental genotypes, or research/analytical protocols.

FDA Food Safety Modernization Act (FSMA) (FSMA) was enacted by Congress in 2010 and signed into law in 2011. The law required FDA to issue rules affecting many different aspects of food safety, including on-farm produce production, food imports, and the manufacturing and processing of foods. There are nine major rules to implement FSMA, recognizing that safety of the food supply is a shared responsibility across multiple different points in the global supply chain.

FDA Reportable Food Registry is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The Registry helps the FDA better protect the public health by tracking patterns and targeting inspections.

Food Recalls are removals of foods from the market that are in violation of FDA regulations. A food may be recalled because of contamination with disease causing microorganisms, such as bacteria, viruses, or parasites; the presence of foreign objects such as broken glass or fragments of metal or plastic; or failure to list a major allergen in the food, such as peanuts or shellfish, on the product label. Food recalls are usually voluntarily initiated by the manufacturer or distributor of the food. In some situations, the FDA may request or mandate a recall.

National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. NHANES is a major program of the

National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). Starting in the 1960s, the survey has been considered continuous since 1999. Information captured in the surveys include demographic, socioeconomic, dietary, and health-related questions as well as lab testing and medical, dental, and physiological measurements.

Nutrition data syndicators capture all label information, including product name, net weight, nutrition, claims, and ingredient declarations, on most foods in the U.S. food supply (branded and private label) through a variety of methods. This may include input of label information into a centralized system by product manufacturers, label scans at the retail shelf, and use of consumers to scan and upload labels to centralized systems. Examples of nutrition data syndicators include Syndigo, Data Council (IX-One program), and GS1.

Point-of-sale (POS) data aggregators capture the retail sales of all packaged foods and some foods sold in bulk (fresh produce, meats, nuts, etc.). This includes food purchased at brick-and-mortar stores, and online sales through the store chain directly or grocery delivery companies like Instacart. Some retailers share data only with certain POS data syndicators, some share only certain subsets of their data, such as not sharing private label data, and some do not share any of their sales data. Convenience store sales are only captured if the chain contributes at least one percent of sales in the industry. Examples of POS data aggregators include IRI, NielsenIQ, and SPINS. Companies which provide sales data specifically for e-commerce include Stackline and One-Click Retail.

Product Identifier Codes are used to identify food items as they travel through the supply chain. There are two types of codes:

- Price Look Up (PLU): 4–5 digits in length; used on produce items sold by weight or quantity. While three-fourths of the 1,640 PLU codes for conventional produce are consistent across all retailers, 320 of these have some limitations (for example, 20 can be used for apples, retailer determines apple variety) and 100 can be randomly assigned by each individual retailer.
- Universal Product Code (UPC): 12-digit number that sits under a bar code on a product package and is used to identify a specific product in the marketplace. The first 6–10 digits is a company prefix; the next set of digits reference the exact product; the final digit is designed to ensure the bar code scanned correctly during purchase for correct identification of the product.

Stock Keeping Unit (SKU) is a number that retailers assign to products to keep track of stock levels internally. The SKU is typically an eight digit alphanumeric.

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Appendix A: Individuals Interviewed

Thank you to these individuals and others who shared expertise and perspectives for this project.

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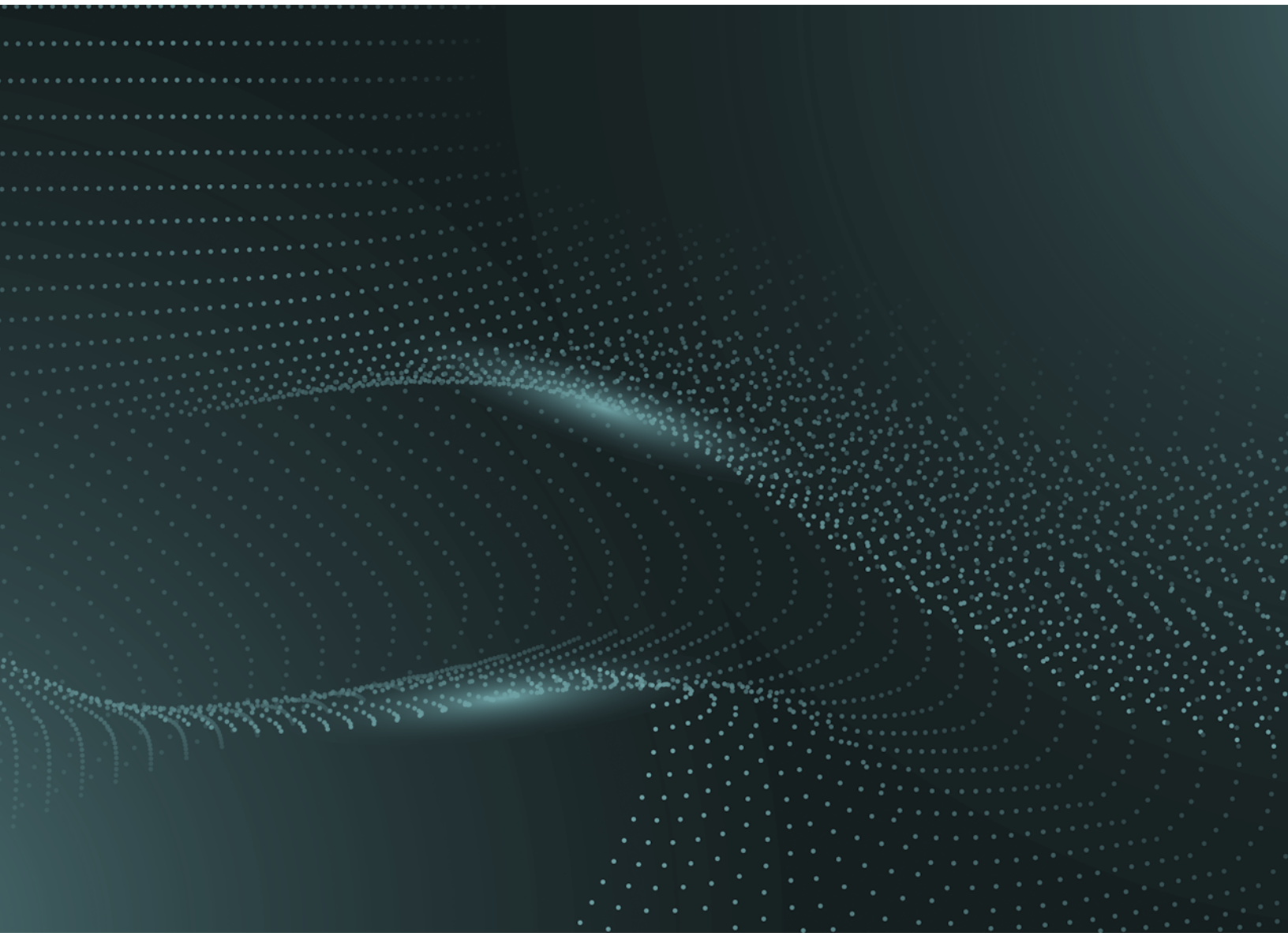

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