

Board of Scientific Counselors Infectious Diseases

Food Safety Modernization Act Surveillance Working Group

Annual Report to the Secretary, Department of Health and Human Services

2023

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SUMMARY

The Food Safety Modernization Act of 2010 (FSMA), signed into law on January 4, 2011, authorized the Centers for Disease Control and Prevention (CDC) to create a diverse working group of experts and stakeholders to provide routine and ongoing guidance to improve foodborne illness surveillance systems in the United States. Accordingly, in fiscal year (FY) 2012, CDC established a FSMA Surveillance Working Group (FSMA SWG) under the Board of Scientific Counselors Infectious Diseases (BSC ID, formerly the Deputy Director for Infectious Diseases, DDID), a federal advisory committee. FSMA also required this working group to provide an annual report to the Secretary of Health and Human Services with advice and recommendations regarding the improvement of foodborne illness surveillance. This FY 2023 annual report summarizes the FSMA SWG's activities during FY 2023 and the BSC ID's recommendations based on the findings of the FSMA SWG.

The FSMA SWG held one two-day meeting in FY 2023, convening on December 5 and 6, 2022, to review and respond to questions on foodborne illness and outbreak surveillance in the following topic areas:

- Foodborne Disease Surveillance and Data Access Enhancements
- Challenges Solving Outbreaks with Strong Ingredient Collinearity
- Investigations into Frozen Raw Breaded Chicken Products
- Updates to *Cronobacter* Surveillance and Related CDC Activities
- FSMA SWG Future Topics and Directions

Regarding the more general topic area of "Foodborne Disease Surveillance and Data Access Enhancements," SWG discussions focused on the Bacteria, Enterics, Amoeba, and Mycotics (BEAM) Dashboard, PulseNet (PN) Modernization, *Cryptosporidium* Surveillance, and the National Wastewater Surveillance System (NWSS).

The Working Group applauded CDC efforts for greater access to, and timelier, surveillance data and system modernization. Through its discussions, the Working Group highlighted areas for additional research, expanded program capabilities, enhanced communications, and continued resources for these activities.

BSC ID FSMA Surveillance Working Group 2023 Report to HHS Secretary

INTRODUCTION

This report describes the fiscal year (FY) 2023 activities of the Food Safety Modernization Act Surveillance Working Group (FSMA SWG) of the Board of Scientific Counselors Infectious Diseases (BSC ID), a federal advisory committee at the Centers for Disease Control and Prevention (CDC). This Working Group was established in FY 2012 under authorization by the Food Safety Modernization Act of 2010. Membership comprises experts representing local, state, and federal governments; academia; industry; and consumer groups (see Appendix). Due to the COVID pandemic, the FSMA SWG did not meet as regularly as in previous years, and the last annual report was issued for FY 2019.

During FY 2023, the SWG reviewed activities and responded to questions related to foodborne disease surveillance and data access enhancements including the Bacteria, Enterics, Amoeba, and Mycotics (BEAM) Dashboard, PulseNet (PN) Modernization, *Cryptosporidium* Surveillance, and the National Wastewater Surveillance System (NWSS). The Working Group also reviewed and discussed the challenges and opportunities of investigations involving strong ingredient collinearity and frozen raw breaded stuffed chicken products and learned about updates to *Cronobacter* surveillance.

BACKGROUND

Each year, an estimated 48 million people in the United States (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 died from (largely) preventable foodborne diseases.^{1,2} There are also significant costs associated with foodborne illnesses. According to a 2015 study,³ 15 pathogens alone are estimated to cost \$15.5 billion in the United States per year. This includes medical costs (doctor visits and hospitalizations) and productivity loss due to illness and time lost from work as well as premature death. Globally, the World Health Organization (WHO) estimated that, each year, as many as 600 million—or almost 1 in 10 people in the world—fall ill after consuming contaminated food. Of these, an estimated 420,000 people die, including 125,000 children under the age of 5 years.⁴

Public health surveillance is necessary for improving food safety. Timely detection and control of foodborne disease cases and outbreaks can directly reduce their public health impact; identify new food safety hazards; and enable investigators, regulators, and the food industry to learn more about ways to prevent these illnesses.

Foodborne illnesses and outbreaks are reported and investigated at the local and state levels. These investigations help identify and prevent future foodborne illness in local/state jurisdictions and provide essential information for national public health and food safety systems. During nationwide outbreaks, CDC compiles information from local and state agencies and works with them to identify and link outbreak-associated illnesses, leading to identification of contaminated foods using epidemiologic and laboratory data, and control of outbreaks. Outbreak data are collected, analyzed, and shared with many partners. Data from these outbreaks serve as a foundation for action by CDC, regulatory agencies, the food-producing industry, and others interested in improving food safety.

Foodborne disease and outbreak surveillance data aggregated by CDC are essential for many functions, including informing evidence-based policies, effectively assessing public health risk, and developing prevention messages for food safety improvements. These data are relied upon by other government regulatory agencies and analyzed by the media, public health, and consumer organizations that provide food safety advice to consumers and

policymakers. In January 2013, CDC released the first [comprehensive set of estimates](#) of the food categories responsible for foodborne illnesses acquired in the United States from 1998–2008.⁵ As a member of the Interagency Food Safety Analytics Collaboration, CDC, in conjunction with U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA), Food Safety and Inspection Service, provides updated [attribution estimates annually](#) for *Salmonella*, *Escherichia coli* 0157, *Listeria monocytogenes*, and *Campylobacter*. In addition to those annual estimates, CDC reported attribution estimates based on case-control and whole-genome sequencing data for selected pathogens.^{6,7} Building on the 2011 estimates, which showed that about 48 million people (1 in 6) get sick each year from food, these newer estimates—along with annual foodborne illness trend data from the [Foodborne Diseases Active Surveillance Network](#) (FoodNet)—help regulators and industry identify the groups of foods most responsible for foodborne illness. These data also provide a historical baseline of estimates that can be further refined over time as more data and improved analytic methods become available.

Over the years, differences in data collection and reporting among states, along with issues regarding integration among various government agencies, have led to calls for improvements in foodborne illness surveillance systems so they can provide the necessary data to assist government agencies, industry, and other food safety partners in their risk management activities.

CDC and FSMA

The Food Safety Modernization Act of 2010 provided the FDA with new enforcement authority designed to achieve higher rates of compliance with prevention and risk-based food safety standards to better prevent contamination events as well as respond to and contain problems when they occur. Additionally, the law directed FDA to build an integrated national food safety system in partnership with state and local authorities. Recognizing the critical role of foodborne illness surveillance data in informing prevention efforts and CDC's expertise in this area, FSMA also directed CDC to improve governmental coordination and integration, evaluate and improve foodborne illness surveillance systems, and enhance external partner collaboration.

Signed into law on January 4, 2011, FSMA authorized CDC to create a diverse working group of experts and stakeholders to provide routine and ongoing guidance to improve foodborne illness surveillance systems in the United States and to provide advice on the criteria for the designation of five Integrated Food Safety Centers of Excellence (CoEs). In response, this FSMA SWG was created as a working group of the BSC ID.

According to FSMA legislation regarding improvement of foodborne illness surveillance systems, areas for working group discussion and provision of guidance are

- (A) the priority needs of regulatory agencies, the food industry, and consumers for information and analysis on foodborne illness and its causes;
- (B) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;
- (C) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to foodborne illness aggregated, de-identified surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;

- (D) key barriers at Federal, State, and local levels to improving foodborne illness surveillance and the utility of such surveillance for preventing foodborne illness;
- (E) the capabilities needed for establishing automatic electronic searches of surveillance data; and
- (F) specific actions to reduce barriers to improvement, implement the Working Group’s recommendations, and achieve the purposes of this section, with measurable objectives and timelines, and identification of resource and staffing needs.

This annual report to the Secretary, Department of Health and Human Services, (required by FSMA) highlights the FSMA SWG’s activities, observations, and responses in FY 2023 and summarizes priority areas for focus in the coming year. The annual report was discussed and approved by BSC ID.

WORKING GROUP ACTIVITIES—FY 2023

During its eleventh year, the FSMA SWG met once in December 2022 in a hybrid setting with most members present in person. The FSMA SWG considered several recent and ongoing developments in foodborne illness surveillance that are key to maintaining and improving surveillance systems. The December 2022 meeting focused on a review and specific questions for discussion in major topic areas of foodborne disease surveillance and data access enhancements, challenges solving outbreaks with strong ingredient collinearity, and investigations into frozen raw breaded stuffed chicken products. Additionally, updates on important developments related to *Cronobacter* surveillance were provided by CDC. FSMA SWG leadership reported the working group’s activities and findings to the BSC ID at its meetings, also in December 2022, and on November 30, 2023, for discussion and approval of the annual report. These topics and Working Group discussions are summarized below.

I. Foodborne Disease Surveillance and Data Access Enhancements

Open Access Data – BEAM Dashboard

The [BEAM Dashboard](#) is an interactive dashboard that can be used to visualize timely data on pathogens including Shiga-toxin producing *E. coli*, *Shigella*, and *Campylobacter*, along with details about the serotype. BEAM also provides information about antimicrobial resistance and multistate outbreaks. Users can choose which pathogen to examine, and see specimen source, serotypes associated, number of multistate outbreaks, number of isolates by month, and multistate outbreaks associated with each state. The future of BEAM includes adding more pathogens and vehicles while keeping it user friendly to the public.

Discussion Questions:

- What would you like to see on the dashboard (either data or automated analytics) to help galvanize your work and prevention efforts more broadly?
- What connections across federal systems might help public health partners and prevention efforts?
- What are your data needs or examples of challenges that would be assisted with improved data access and data linkages?

Discussion:

- CDC has FoodNet Fast (different source of data but in the same theme) with data publicly available. There should be consideration for integrating these systems, or a means to minimize the user

needing to access multiple dashboards for a similar purpose. CDC indicated that the end goal is to have an all-encompassing dashboard where users can access different data from CDC Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) in one place.

- In addition to FoodNet, there is CDC's National Outbreak Reporting System (NORS) Dashboard. SWG asked how BEAM differs from NORS Dashboard. CDC indicated they are working toward a streamlined approach that integrates other data sources, such as NORS. Currently BEAM shows multistate outbreaks coded by PN versus single-state outbreaks in NORS.
- There was interest in having all food vehicles incorporated. At the time of the meeting, beef, pork and chicken are represented. CDC indicated the goal is to add other vehicles and pathogens, recognizing the need for data standardization and data cleaning.
- States would like to be included in how and when state data is captured. CDC recommended that states contact CDC if their data doesn't match so CDC can improve data cleaning.
- Using an example of a local jurisdiction investigating a *Salmonella* Newport outbreak, discussion involved how the BEAM dashboard would assist them. CDC indicated that users could use the BEAM dashboard to determine if increased *S. Newport* illnesses are happening elsewhere in the U.S., making this more of a nationwide issue. This may provide more collaborative opportunities by enabling investigators to interpret data in real time and reach out to other states and CDC to inform their investigation.
- Consideration for accessing the BEAM Dashboard as a public citizen and the logical interpretation that will tell the public what implications they should draw from the data. Concerns were expressed for knowing what to do with the data in the dashboard and if it was actionable information. CDC is being cautious about providing too much interpretation given the BEAM data is preliminary and data are limited at this time.
- Considerations should be given to more clearly defining the objective of the system and the use cases of the data before more expansion of this system. Other suggestions:
 - Clearly articulate what is intended to be accomplished with this dashboard and its development.
 - Develop design tutorials to help user interpret the data.
 - One suggestion was instead of using a dynamic bar chart—using a static time (temporal) series as its easier to visualize than using dynamic visualizations.
- Overall, there was positive feedback on the BEAM Dashboard. There was interest in integrating other data sources (and from existing Dashboards) into one Dashboard as well as expanding the other pathogens, including reoccurring, emerging, and persisting (REP) enteric bacterial strains, food vehicles, single state outbreak data, and linking to National Center for Biotechnology Information (NCBI) Pathogen Detection system, NLM/NIH.
- Concerns were expressed regarding the public and agencies expecting more data overall as well as more granular data.

Responses:

Based on the above questions, the Working Group highlighted the following:

CDC could:

- explore potential benefits of coupling data with other spatial software and using a geographic scale.
- include states in how and when state data is captured.
- explore using the data to work with partners to elevate efforts around prevention strategies.
- obtain more feedback on the dashboard from external partners.
 - continue evaluating utility and feasibility of dashboards to ensure that outcome is worth effort.

- integrate other data sources from existing dashboards into one, and expand content (see *Discussion*).

PulseNet Modernization

[PulseNet](#) (PN) is a national laboratory system that is used to detect outbreaks occurring. PN is sent samples and analyzes the DNA fingerprints of the bacteria they receive in those samples. This information is used to see if different samples have the same fingerprint, as those are likely to indicate an outbreak. PN has been able to detect outbreaks sooner in order to recall contaminated products. Culture-independent diagnostic tests (CIDTs) have become problematic for disease surveillance. PN is currently undergoing another evolution and preparing for a future version of the PN platform and is exploring ways to better integrate additional surveillance data into the platform.

Discussion Questions:

- Are there any stakeholder groups to get feedback from about the PN Modernized system or questions we need to engage our stakeholders more on?
- For PulseNet 2.0 – any features or outputs from the system that would be of interest more broadly? Views of data that we can share on BEAM?

Discussion:

- IT barriers have been an issue for a long time, and it is key to engage and obtain feedback from states in this area.
- International partners, such as ministries of health and laboratories, who are in the early stages of performing whole genome sequencing (WGS) may need assistance with the transition to PN 2.0.
 - CDC indicated that they have PulseNet International where they provide regular data modernization updates, technical assistance, and explore ways for increased data sharing. Many countries have increased capacity to do sequencing after COVID.
- As PN 2.0 is built, CDC should take into considerations the different capabilities of the variety of laboratories, large and small.
 - CDC indicated that the transition to WGS took six years; it started with a pilot and then expanded. To make that transition, CDC held many trainings and invested in the significant amount of groundwork to make that transition to the new platform easier. During that time of transition and discussion with partners, some key questions were asked about the “cloud” and what it means for state IT specialists, implications with regulations at the state and local levels, and what data will be in the “cloud.” Many lessons were learned during the transition to WGS and with cloud related discussions during SARS-COV-2; however, more work is still needed.
- Clarification was provided by CDC on how PN and BEAM are interrelated. For the PN system, development has been separate as certain data cannot be made publicly available due to concerns with sharing personal identifying information.
- Consideration for working with respiratory infection groups and companies performing culture-independent diagnostic tests (CIDTs) and what they are considering for features and outputs. One aim would be to work together to detect cases that are being lost due to CIDTs.
 - CDC indicated that CIDTs continue to be a major concern for PN and they continue to explore alternatives. Additionally, CDC is looking at ways to build analysis workflow that comes from CIDTs into PN 2.0 so they would be able to integrate that data for cluster detection. For

respiratory infections groups, many of them use BioNumerics, and consequently, have been part of the PN 2.0 transition and CDC internal coordination discussions.

Responses:

Based on the above questions, the Working Group highlighted the following:

CDC could:

- take into considerations the different capabilities of the variety of laboratories, large and small.
- work with respiratory infection groups and companies performing CIDs to learn from each other and, ultimately, to better detect cases that are being lost due to CIDs.
- reassess if the funding is adequate and take into consideration market adjustments for staffing.

***Cryptosporidium* Surveillance**

[Cryptosporidium](#) is a parasite that is typically contracted through consumption of food or water that has been contaminated by the stool of an infected individual. CryptoNet is the CDC-state collaboration to collect laboratory and epidemiologic data in a passive, sentinel surveillance system. Currently, 13 states are participating. With this system, only 1-2% of cases are reported to CDC, indicating that outbreaks associated with nationally distributed food products are not being detected. CryptoNet is currently exploring ways to modernize its data workflows and integrate with existing infrastructure and has engaged in a WGS pilot with state public health laboratories.

Discussion Questions:

- What are the expectations for enhanced cryptosporidiosis surveillance for informing foodborne case and outbreak detection?

Discussion:

- The priority from one SWG member perspective is leafy greens, particularly contamination of irrigation water by animals (e.g., cattle).
- There was discussion surrounding a timeline for expanding beyond three pilots.
- CDC is interested in expanding and providing training beyond the pilots; however, there are challenges and barriers:
 - The method for whole genome sequencing for *Cryptosporidium* is different than for other organisms. *Cryptosporidium* must be isolated from stool, which is labor intensive and expensive.
 - In terms of samples, some states require clinical specimens be submitted, but other states do not. Communication from state and local public health partners is needed for CDC to receive those samples.
 - Initial isolation steps differ from those of bacterial pathogens. CDC is trying to combine processes with PN and CaliciNet upstream and streamline data transmission and pipelines.
 - Resources to expand are very limited.
 - With new tools, CDC may have more flexibility in receiving state data and in a better position to improve disease surveillance.
- Challenges for local jurisdictions were shared, and this highlights the impact of private residence exposure. At the local level, it's difficult to detect illnesses and outbreaks with limitations on testing and typing methods.
- SWG thought widening the pilot would be important given that the current reporting is limited.

- Explore other ways to enter/get data from other systems. Entering data into the CDC System for Enteric Disease Response, Investigation, and Coordination (SEDRIC) is a major task for states.
- SWG expressed interest in learning more about the direction of the pilot and its progress.

Responses:

Based on the above questions, the Working Group highlighted the following:

CDC could:

- widen the pilot and explore ways to make it easier for states to input data and/or ways to obtain data from other systems.

National Wastewater Surveillance System and Potential Foodborne Targets

Wastewater surveillance can detect disease that sheds in the feces of infected individuals. This can allow for asymptomatic infection detection, determination of levels of infection in the community, and can provide data earlier. The [National Wastewater Surveillance System](#) (NWSS) has been implemented widely during the SARS-CoV-2 pandemic to detect levels of the virus. NWSS is being expanded in 2023 and plans to include enteric infections. One of the challenges around using this surveillance system for enteric pathogens is that it does not provide strain information and sampling sites may not be representative.

Discussion Questions:

- Are there other microbial targets that should be considered for inclusion in NWSS testing (PCR based method)?
- Are there other data systems or metadata that NWSS should consider to ensure that wastewater data is able to support food safety goals and investigations?

Discussion:

- SWG is interested in *Salmonella* and *E. coli*, however, the current system has methods that are PCR based and would not provide strain information to aid in detecting illnesses and outbreaks. Discussion revolved around criteria to select the next pathogens, such as if the assay will be informative; SWG was interested in a more strain specific assay.
- From the geospatial aspect and considering norovirus, particularly at retail level, it would be helpful if there were some metric that shows that there is an increase in norovirus and having some proactive aspect to it to notify schools, and other potentially affected groups or venues.
- Discussion around the possibility of detecting animal diseases or outbreaks of *Salmonella* in animals (e.g., backyard poultry).
- Several equity-related considerations were conveyed. Observations included that most sampling sites are in the Midwest and Northeast, apparent lack of geographic diversity, and extent of coverage of urban versus rural areas. Concerns were expressed about utility/wastewater infrastructure and equity of underserved populations.
- Industry (e.g., food processing facilities) has their own wastewater facilities; these are not captured by NWSS.
 - In a discussion about wastewater data and the sewer shed, some SWG members expressed interest in the discharge water from industrial facilities that feed into wastewater systems.

Considerations should include identifying the benefit for industry, practical use of the data, and any regulatory implications for the firm.

Responses:

Based on the above questions, the Working Group highlighted the following:

CDC could:

- work towards a more strain-specific assay to support food safety goals and investigations.
- better define the criteria used to add or modify targets (pathogens).
- consider adding geospatial aspects, particularly for norovirus, and including a notification alert.
- examine health equity aspects in future NWSS sampling strategies.

II. Challenges Solving Outbreaks with Strong Ingredient Collinearity

There are several methods currently in place to identify a contaminated ingredient in multistate outbreaks where multiple ingredients are implicated, also known as ingredient collinearity. In addition to leveraging tracebacks, product market share, and product testing data, new epidemiologic approaches to collinearity are needed to identify foodborne outbreak vehicles. A recent outbreak of Shiga toxin-producing *E. coli* (STEC) O157 within a single distribution chain failed to identify a contaminated ingredient, emphasizing the need for modernized tracebacks and improved epidemiological methods. Other approaches for responding to collinear outbreaks shift the focus from ingredients predictive modeling that focuses on sources and sampling products of potential concern.

Discussion Questions:

- What are the most effective epidemiologic tools to implicate an ingredient when strong collinearity exists (e.g., restaurant-based ingredient-level case-control studies; comparing case meal items to sales data)
- How much emphasis should be put on epidemiologic tools to identify an ingredient versus traceback or product testing in these situations?
- Are there additional traceback methods or approaches that could rapidly and efficiently narrow down the potential list of ingredients (e.g., probabilistic tracebacks, use of “control” tracebacks)

Discussion:

- Important to keep in mind the big picture. Some public health partners based on the size and complexity of their staff may not consistently understand the breadth of what state investigators mean when they ask the local public officials to conduct an investigation at a restaurant, nor might they have the capability for this level of analysis (e.g., environmental, contributing factors, sampling). The right skill set is needed to perform local investigations.
- The most successful data collection at a single point retail location is when the epidemiologist joins an environmental health professional in the investigation. This is key from a foundational level. Additionally, CDC’s National Environmental Assessment Reporting (NEARS) forms might be revised to ask key questions that aren’t currently asked.
- Focusing too much on the ingredient may result in missing the signal. For example, many producers are conducting internal testing and may have positives; if that product is distributed

and then there's testing further in the supply chain you may lose visibility into the geographical implications. An additional layer of complexity is the distribution chain. There should be more thought about testing further down the supply chain close to the source and how the process works.

- There was support for using predictive models. If there was more vocal support from stakeholders, it would help with the shift in approach that is needed.
 - With respect to reoccurring, emerging, and persisting strains, there has been success in identifying suspect foods. This type of approach might be incorporated into a model. Focus should be on firms and products with a history of contamination events.
 - Using predictive models may lead to identifying suspect places/sources and for sampling products of potential concern.
 - There is a need for modernizing tracebacks while also moving epidemiological methods forward and integrating environmental health partners.
 - There are a lot of opportunities for the future, specifically as it relates to produce, but there needs to be a cultural shift towards more preventive approaches. Traceback is one of those areas. Connections through the entire chain are missing and systems are not sophisticated enough.
- There was support for using predictive models. Efforts should be explored to develop a predictive model of testing high-risk foods at high-risk times and move surveillance back toward the likely source. Multiple partners, such as states and relevant associations, should be involved in development. Potential resources might be needed at the states and local level to conduct this work for both development and implementation; increased sampling and testing would likely result.
- There should be more emphasis on local investigations.
 - Local jurisdictions should be performing environmental health assessments and using a risk-based approach. It was suggested to return to the basics and train staff at local, state, and tribal levels to obtain a better picture for the epidemiologists.
 - More local jurisdictions should be sampling/testing more often.
- While it may not happen often, there should be consideration for intentional contamination. Establishing and maintaining partnerships with law enforcement authorities is critical for investigations.

Responses:

Based on the above questions, the Working Group highlighted the following:

CDC could:

- place more emphasis on local investigations with a return to the basics in training resulting in a better picture for the epidemiologists.
- move epidemiological methods forward and integrate environmental health partners.
- develop predictive models in concert with various partners recognizing resources would likely be needed at multiple levels.
- support a cultural shift towards more preventive approaches.

III. Investigations into Raw Frozen Breaded Stuffed Chicken Products

It is estimated that chicken is responsible for more salmonellosis than any other food category. Furthermore, data suggests that stuffed products cause the most outbreaks that have a confirmed source. A 2015 investigation in Minnesota found 35% of raw frozen breaded stuffed chicken products sampled from production yielded *Salmonella*. "Further processed" chicken products make up the majority of chicken product sales and are often undercooked, but consumer-based interventions have not been sufficient to prevent illnesses. In 2022, USDA's Food Safety Inspection Service announced plans to declare *Salmonella* an adulterant in raw breaded stuffed chicken products with the intent of decreasing foodborne cases of salmonellosis.

The below questions were used to generate discussion among the SWG and obtain their perspectives and suggestions.

If the adulteration ruling is implemented, how might CDC support assessing the impact?

SWG responses:

- Discussion revolved around needing to improve and/or increase data collection from investigation.
- Collecting data that demonstrates a link to a product and the associated regulated operation and to human illnesses provides support to the regulatory agencies, in collaboration with CDC, to assess impacts.
- More data would be available if more food history questionnaires were completed.
 - This is particularly an issue with hospitals/medical centers not performing full assessment questionnaires with foodborne illness. If CDC can emphasize that to the hospitals, it would be beneficial.
 - CDC shared with the SWG that hospitals may not have staff to conduct interviews for foodborne illness. Public health officials in the local and state level are key to collecting food histories but may also be understaffed and lack adequate resources.
 - Another potential missing data source is homeless shelters.

How might CDC estimate the number of illnesses caused by raw frozen stuffed chicken products?

SWG responses:

- Product information: Sales information, survey of products to assess contamination levels
- Generate related estimates: % undercooked, % that cause illness, fraction of chicken illnesses due to these products.
- Consumer practices: Repeat questions on Population Surveys

Should CDC obtain more information about raw frozen breaded stuffed chicken products?

There was general support that CDC should obtain more information. Below were suggestions:

- How often consumed, number sold annually, how many companies make them, volume per company

Should CDC obtain information about other frozen chicken products---nuggets, pot pies?

There was general support that CDC should obtain more information. Below were suggestions:

- % of product sold that is not ready-to-eat. If substantial, collect annual volume sold to consumers, to restaurants.

How can health departments (in addition to Minnesota) help to detect and investigate clusters of illnesses possibly due to particular chicken products?

See “General discussion” below.

Should CDC obtain more information on the “processed” category (main type of chicken sold)?

There was general support that CDC should obtain more information. Below were suggestions:

- Amount or % sold at retail (versus to fast-food chains, for frozen chicken products, canned soup, pet food)
- % comminuted versus mechanically separated (25% performance standard versus no standard)
- % sold at retail that is not ready-to-eat

General discussion:

- Considerations were discussed regarding the appliances, such as oven, toaster oven, microwave, used in the home for cooking these types of products.
 - CDC performed a study to see what appliances people used to prepare frozen chicken products – 54% reported using an appliance other than, or in addition to, a conventional oven.
 - In a recently investigated outbreak, the cooking instructions would undercook the product by several minutes. It was suggested that how industry is testing the cooking, and what they’re using, would be an area to explore.
 - Though CDC is not the likely organization to collect data on the appliances consumers use to “cook” these products, this is an area for further exploration.
- Presentation by CDC and SWG discussions highlighted that some products have more of an information and research gap, and some products are riskier, such as this one.
- With respect to the presentation, consider collecting data on who is buying these products. This would aid the SWG in providing suggestions.
- It was suggested to explore if there is a behavior issue with these products and hand washing when handling them.
 - Discussion around multi-factorial problem beyond cooking behavior – when the level of *Salmonella* becomes very high, other protections may make little difference, such as proper cooking, hand washing.
- One company established a microwave center of excellence to see how different foods are cooked. An important component of this issue is considering the role of industry and interventions they can take.
- This issue should also be examined from a health equity standpoint – who’s eating this product? Is it the vulnerable, low-income population, and if so, who is protecting them. Many of these products have skin to make them moist – all the ingredients should be explored. Inexpensive protein sources should be safe.
- Regulatory agencies may be facing challenges with limited available science for many of these issues.
- Industry, such as retailers, may have information that could help CDC, such as percentage of raw products sold versus fully cooked products, or if they are chicken parts or mechanically separated chicken.
- When considering epidemiologic tools, it’s important to look at the value of Centers of Excellence (CoEs) - what they do and what they teach. Additionally, it’s important to integrate environmental health and epidemiology. Based on the geographic focus of cases of raw frozen breaded chicken products and that these products are not unique to that area, public health infrastructure and training needs to be improved. Additional input included:
 - Need to engage industry.
 - Important to emphasize surveillance systems in trainings – public health is losing staff; important to train the next generation.

- CoEs could have a role in better training of the workforce and help with analytic projects in priority areas.
- There seems to be an opportunity in the area of family food science and education of children so they know from an early age how to read labels, how to cook food, etc. In addition, there was discussion as to whether CoEs have a consumer education component to them.
- Regulatory agency representatives provided their perspective and expressed interest in receiving feedback. There was interest in learning of ways to gauge if regulatory efforts are working and indicators of progress.

Responses:

Based on the general discussion, the Working Group highlighted the following:

CDC could:

- support more research.
- expand and increase data collection from investigations.
- engage industry in multiple aspects of the issue.
- engage Centers of Excellence for enhanced training of public health officials, assisting with priority projects, and potentially having a role in consumer education.
- explore opportunities to further childhood and family food science education.
- evaluate more frozen chicken products.
- factor in considerations from a health equity standpoint.
- increase awareness of the food safety risk with increased data availability.

IV. CDC Update: *Cronobacter* Surveillance and Related CDC Activities

CDC provided technical background regarding *Cronobacter sakazakii* (or “*Cronobacter*”) and an investigational summary related to recent efforts to develop a *Cronobacter* case definition and better understand incidence of the disease. *Cronobacter* is a bacterium that is found naturally in the environment and can live in dry foods, like powdered infant formula, powdered milk, herbal teas, and starches. It has also been found in contaminated feeding items like breast pump equipment. *Cronobacter* infections are often very serious for babies who are younger than 2 months or were born prematurely.

On February 10, 2022, CDC was notified of the Food and Drug Administration’s (FDA’s) investigation of consumer complaints of infant illness potentially related to products from a major infant formula manufacturer. CDC received reports of four *Cronobacter* cases in infants with exposure to powdered infant formula that were later found to be part of FDA’s ongoing investigation. WGS showed that bacteria from two available patient samples were not closely related to each other nor to environmental samples obtained from a major infant formula manufacturer’s facility, and an outbreak was not declared.

At the time of the December 2022 FSMA SWG meeting, *Cronobacter* was reportable in Minnesota and Michigan but was not a nationally notifiable disease. The Council of State and Territorial Epidemiologists (CSTE) was collaborating with CDC through a working group convened to discuss surveillance and reporting.

The SWG’s discussion included the following:

- Exposure to powdered infant formula as a risk factor is not very meaningful to an investigation given it is a main source of nutrition for infants unless a product lot, or bacterial strain, can be pinpointed.

- States need to be involved with confirmed cases and need specimens/isolates for investigations to be valuable. Exposure information alone is not enough.
- *Cronobacter* should become a reportable disease with understanding that more specificity and narrowing of scope might be needed.

In June 2023, CSTE members approved a position statement recommending making invasive *Cronobacter* infection in infants nationally notifiable. CDC has been preparing for this recommendation to be implemented in 2024 by enhancing surveillance and laboratory efforts and through collaboration with CSTE, FDA, and the Association of Public Health Laboratories partners.

RESOURCES

The Working Group recognized that supplemental funding resources were specifically provided for the COVID pandemic. The funds are being eliminated when surveillance tools, such as wastewater testing, provided valued and timely data. Current impacts of the pandemic on public health partners at the state and local levels are significant, with reduced staffing and turnover often resulting in a loss of institutional knowledge. Issues addressed in this report emphasize the need for continued resources for these activities. As CIDTs and other technologies continue to rapidly evolve, public health and regulatory agencies will face substantially increased costs in responding to the transition. Data management and translation of increasingly large amounts of new types of data into formats that are meaningful to outbreak investigators and regulators will require increased investment in laboratory and informatics infrastructure. Additional research will be needed to guide the food industry, public health and regulatory agencies in using increasingly sensitive and detailed data to find and eliminate threats at various levels in the food chain.

NEXT STEPS

There was considerable discussion of the value of SWG activities and observations since its inception over 10 years ago. The SWG explored areas of the legislation for additional focus and potential future topics. Based on the discussion, examples of potential future topics include:

- Cooperation with international partners and harmonization of methodologies with WGS/PulseNet International
- Continued dialogue and updates on data modernization efforts (e.g., BEAM Dashboard, PN); attribution and reoccurring, emerging, and persisting strains and potential for predictive models
- Revisiting mechanisms and breaking down barriers for data sharing among all partners
- CIDTs and impact on surveillance; progress with metagenomics
- Climate-related impacts on foodborne illness: shellfish and vibriosis, produce contamination, changes in wildlife patterns
- Issues surrounding surveillance and response of shellfish-related outbreaks domestically and working with international partners
- Reduction of *Listeria* positives in industry not correlating with reductions in illness rates
- Updates on *Cronobacter* surveillance
- The role of food workers in disease transmission and paid sick leave as a policy
- Scientific data for foodborne illness related to home kitchens, ghost kitchens, micro-enterprise

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APPENDIX: FSMA SURVEILLANCE WORKING GROUP MEMBERS

Meeting held in December 2022

***Chair:** Virginia Caine, MD—Director and Chief Medical Officer, Marion County Public Health Department

*Lauren Meyers, PhD—Cooley Centennial Professor, Departments of Integrative Biology and Statistics & Data Sciences, The University of Texas, Austin, Texas

*James LeDuc, PhD, MSPH—Adjunct Professor, Department of Microbiology and Immunology, University of Texas Medical Branch, Galveston

Stic Harris, DVM, MPH—Food and Drug Administration (Susan Lance, FDA Liaison to CDC, presenting FDA)

Denise R. Eblen, PhD—United States Department of Agriculture, Food Safety and Inspection Service

Jennifer Trodden—National Association of State Departments of Agriculture

Denise M. Toney, PhD, HCLD (ABB)—Association of Public Health Laboratories (not present at meeting)

Michele DiMaggio, REHS—National Environmental Health Association

Carlota Medus, PhD, MPH—Council of State and Territorial Epidemiologists

Ernest M. Julian, PhD—Association of Food and Drug Officials

Clifford Mitchell, MS, MD, MPH—Association of State and Territorial Health Officials

Douglas Dyer, MS, RS—National Association of County and City Health Officials

Sarah Sorscher, JD, MPH—Center for Science in the Public Interest

Kyle Kinner—The Pew Charitable Trusts

Natalie Dyenson, MPH—Dole Food Company, Inc.

Michael J. Roberson, MS, CFS, CP-FS—Publix Super Markets, Inc.

Rosalind Zils—8th Avenue Food and Provisions

Jeffrey B. Bender, DVM, MS—University of Minnesota

Francisco Diez-Gonzalez, PhD—University of Georgia

Janet Baseman, PhD, MPH—University of Washington

*BSC Representative Member