

	Foodborne Illness Risk Factor Study	EHS-Net Food Safety Studies	The National Outbreak Reporting System (NORS)	National Environmental Assessment Reporting System (NEARS)
Sponsoring Agency	FDA	CDC	CDC	CDC
Brief Description of Data Collection Activity	- This study collects data on the occurrence of foodborne illness risk factors in various retail and foodservice facility types over time. - This study examines potential correlations between various industry and regulatory operational/policy variables and risk factor control.	These studies collect data that describes retail food preparation and food safety practices (with a focus on environmental antecedents and risk factors associated with foodborne illness) and examines relationships between the retail environment (e.g., establishment and manager characteristics), food preparation, and food safety practices. The studies have focused on the following retail food safety topics: - Differences between outbreak and non-outbreak restaurants - Beef handling practices - Chicken handling practices - Egg handling practices - Leafy greens handling practices - Tomato handling practices - Food cooling practices - Microwave practices - Beef grinding practices - Ill worker practices - Handwashing practices - Kitchen manager certification - Listeria prevention practices - Allergen management - Food worker practices	This is a surveillance system that collects reports of enteric illness outbreaks caused by bacterial, viral, parasitic, chemical, toxin, and unknown agents, as well as waterborne outbreaks of non-enteric illness. The focus is epidemiologic and limited laboratory data from enteric foodborne illness, person to person and animal disease outbreak investigations. These data are reported by the state Epidemiologists and includes state summaries of: - Date and location of outbreak - Primary cases # lab confirmed (% by sex) # Probable cases (% by sex) - Outcomes (by age group) - Incubation period - Signs and symptoms - Etiology information - Food Vehicle info - Pathogen info http://www.cdc.gov/nors/forms.html	This is a surveillance system that collects environmental data from foodborne illness outbreak environmental assessments conducted by environmental health specialists/food safety specialists (EHS/FSS) as part of an outbreak investigation, focusing on retail food service. Data is collected by EHS/FSS and includes data from specific retail and foodservice establishments' foodborne illness outbreak environmental assessments including: - General outbreak information - General information about the food service establishment - Information on policies and practices from a manager interview - Observations of food preparation and the food service establishments - Information on sampling - Data on the implicated or suspected food - Characteristics of specific ingredients and multi-ingredient foods - Processes used for preparation - Contributing factor data https://www.cdc.gov/nceh/ehs/nears/

Matrix Comparing CDC and FDA Data Collection Initiatives

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Purpose	- Assist the FDA with developing retail food safety initiatives and policies focused on the control of foodborne illness risk factors. - Identify retail food work plan priorities and allocate resources to enhance retail food safety nationwide. - Track changes in the occurrence of foodborne illness risk factors in retail and foodservice establishments over time. - Inform recommendations to the retail and foodservice industry and state, local, tribal, and territorial regulatory professionals on reducing the occurrence of foodborne illness risk factors.	- Collect data that will help identify and understand environmental factors associated with foodborne illness. - Translate findings into improved prevention efforts. - Develop training for environmental health specialists. - Strengthen collaboration among epidemiology, laboratory, and environmental health programs.	Support reporting to CDC by local, state, and territorial health departments in the United States of all enteric illness outbreaks transmitted by food, contact with environmental sources, infected persons or animals, or unknown modes of transmission and waterborne illness outbreaks.	Identify factors that can be routinely monitored by food safety programs to prevent or reduce the risk for foodborne outbreaks associated with foodservice establishments. Provide food safety program officials with information to: - Take food safety actions and assess effectiveness, - Support program evaluation, - Develop or modify program policies or regulations based on sound data, - Train environmental health specialists about environmental causes related to foodborne illness outbreaks, and - Help prevent foodborne illness outbreaks associated with restaurants and other food venues (such as banquet facilities, schools, and other institutions).
Objectives	- Identify the foodborne illness risk factors that are least and most occurring during each data collection period. - Determine whether the occurrence of food safety behaviors/practices in a food establishment's is impacted by its' risk categorization and/or	- Describe retail food establishment food preparation and food safety policies and practices. - Determine how retail food establishment and worker characteristics are related to food preparation and food safety policies and practices.	- Better understand the human health impacts of outbreaks. - Understand settings where outbreaks occur. - Evaluate the causes and contributing factors of outbreaks. - Determine major modes of transmission for agents that	- Identify and monitor contributing factors and their environmental antecedents. - Establish a detailed characterization of food vehicles and monitor food vehicle trends. - Establish the basis for hypothesis generation about environmental factors that may contribute to

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	operational characteristics. - Examine whether potential correlations exist between elements within regulatory retail food protection programs and the occurrence of foodborne illness risk factors and food safety behaviors/practices commonly associated with foodborne illness in retail. - Determine the extent to which industry food safety management systems and the presence of certified food protection manager impact the occurrence of foodborne illness risk factors.		cause illness. - Help evaluate the burden of waterborne and enteric illness outbreaks in the United States and its territories. - Develop guidance and recommendations for preventing future outbreaks.	foodborne illness outbreak events. Guide the planning, implementation, and evaluation of food safety programs.
Intended Use of the Data	- Inform agency retail food safety policies and initiatives. - Identify retail food work plan priorities and allocate resources to enhance retail food safety nationwide. - Provide stakeholders with information about changes in the occurrence of foodborne illness risk factors in retail and foodservice establishments over time. - Inform recommendations on best practices and targeted intervention strategies for the	The data will be used by CDC to develop food safety prevention and intervention recommendations for environmental public health programs and the retail food establishment industry.	- To provide information about national outbreak trends. - To learn lessons for preventing future outbreaks.	- To understand how and why foodborne illness outbreaks occur - Identify contributing factors causing foodborne illness outbreaks - Identify environmental antecedents causing foodborne illness outbreaks - Provide science-based information for hypothesis generation about foodborne illness outbreaks - Provide science-based information to inform food safety policy and practice recommendations - Provide data to food safety programs

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	retail and foodservice industry and state, local, and tribal regulators. Track trends in the occurrence of foodborne illness risk factors over time.			about time and resources used in foodborne illness outbreak investigations. Share data with epidemiology and laboratory programs involved in outbreak investigations and use data as part of the larger outbreak investigation that might include any combination of local, state and federal food safety officials depending on the outbreak.
How the Collection Informs the Food Protection Efforts of the Sister Agency	- The Risk Factor Study provides valuable data on food safety practices of concern (i.e. practices that are not performed at an acceptable level by food employees); CDC can use these data to help identify food safety topics for its studies (i.e., topics for which more detailed data are needed, data that can inform the development of prevention and intervention strategies). - Since NEARS does not conduct case control studies to identify what risk factors generally exist in non-outbreak situations, CDC can use data from the FDA Risk Factor Study to identify the current status of risk factor occurrence in retail and foodservice establishments of	- The Risk Factor Study is comprehensive in nature, whereas CDC's studies have focused on specific foods or food safety policies and practices (e.g., handwashing). - The targeted nature of the data received from CDC studies helps FDA develop national strategies, initiatives, guidance, and policy that aim to reduce the occurrence of risk factors that lead to foodborne illness and outbreaks. - Changes in policy may result in changes to the data collected as part of the FDA Risk Factor Study.	- Information reported into NORS helps FDA better understand the human health impacts of outbreaks and the specific setting where outbreaks occur. - Understanding the causes and contributing factors to outbreaks and the major modes of transmission for agents that cause illness helps FDA in developing guidance, recommendations, and policy for preventing future outbreaks. - Information on the burden of foodborne illness outbreaks in the U.S. helps FDA leverage for more resources.	- NEARS collects data on contributing factors and environmental antecedents directly contributing to a specific outbreak in retail and foodservice establishments. - This data helps FDA understand the behaviors and practices that commonly lead to foodborne illness outbreaks at the retail level. Information on environmental antecedents helps FDA understand the reasons why FDA recommended policies and practices are not always followed. - FDA may use contributing factor and environmental antecedent data from NEARS to develop science-based national strategies, initiatives, guidance, and policies aimed at reducing the occurrence of risk factors that lead to foodborne illness and outbreaks.

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	similar type to the outbreak establishments. These data can help CDC and FDA understand if what is seen in outbreak establishments is different from the situations commonly seen in the general population of retail and foodservice establishments.			Provides guidance to FDA on CDC's current terminology and categorization related to foodborne illness risk factors. FDA seeks to report results from its Study on the occurrence of foodborne illness risk factors using terminology and categorization that is consistent with CDC.
Food Chain Sector (Retail, Manufactured Food, Multiple Commodity Areas, Consumers, Farm, Other?)	Retail	Retail	NORS does not focus on a specific food chain sector. Information related to a food chain sector might be collected as part of the outbreak investigation, but it is not specifically reported into NORS unless it is put in a Notes section.	- Currently, NEARS focuses on collecting data in food service establishments and retail food stores. - NEARS can also be used to collect data from other types of food chain sectors if outbreak information is collected.

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Data Collection Type (e.g. study, surveillance system – active or passive, etc.)	Study	Study	Surveillance system (passive)	Surveillance system (passive)
Data Collectors/ Providers	Approximately 25 FDA Retail Food Specialists standardized by FDA Center for Food Safety and Applied Nutrition (CFSAN)	EHS-Net Food Research Sites (current sites: CA, MN, NY State, NY City, RI, TN, Harris County Texas, Southern Nevada Health District)	State Epidemiologists	State and local food safety program officials conducting foodborne illness outbreak environmental assessments
Entities from which the data is collected (restaurants, grocery stores, regulators, epidemiologists, etc.)	Restaurants, Institutional Foodservice, and Retail Food Stores	Restaurants (with the exception of the Listeria study, for which entities were retail delis)	Data is collected from individuals who are sick by state and local epidemiologist. The data in this surveillance system is epidemiologic data. It represents a summary of the state epidemiologic data including total number of ill, pathogen(s) implicated in the outbreak, and where potential exposures happened as determined by the outbreak investigation.	Any retail or foodservice establishment that has been implicated or is suspected of being involved in an outbreak.
Data Collection Method (e.g. field collection (interview or observation), self-reporting (net survey))	Field collection (interviews, observations, record/SOP reviews)	Field collection (interviews, surveys, observations)	Data is reported by state epidemiologists and is a summary of the outbreak investigation epidemiologic and laboratory data	Data is voluntarily reported by environmental health specialist at the local and state levels. Environmental health specialists in food safety programs focus on collecting environmental factor data during foodborne illness outbreak investigations during environmental assessments. The environmental factors identified

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				during these environmental assessment activities include contributing factors and environmental antecedents. These data identify how and why the food became contaminated with pathogens and how and why these pathogens were not eliminated before ingestion. Environmental assessments typically involve: interviews with food service establishment managers to determine characteristics of the establishment and food safety policies and practices; interviews with food preparers to determine their individual food handling practices, hygiene practices, and other circumstances review of records on food source, shipping and handling; observations of food preparation and handling practices and environmental sampling (samples from floors, food preparation equipment, etc.).
Sample Methodology (describe random selection and	Sample is drawn from a geographical information system (GIS) database containing a listing of businesses throughout	The respondent universe is all eligible (eligibility criteria varies for each study) retail food establishments in selected	No sampling is conducted. States are encouraged to report all foodborne illness outbreaks that are	No sampling is conducted. Data on all outbreaks occurring in the jurisdictions of participating food safety

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scope/ representative nature of the establishments included in the data collection)	the U.S. - FDA performs a series of filtering steps to ensure establishments are classified into the appropriate facility type defined by the study and are considered eligible to participate. - Risk categorization is used to help determine eligibility -- To further determine the pool of establishments eligible for selection, establishments that handle only pre-packaged food items or conduct low-risk food preparation activities are excluded. - The data collectors (i.e. Specialists) are located near major metropolitan areas (i.e. population centers) across the contiguous United States. Population centers usually contain a large concentration of state and local regulatory jurisdictions. - Eligible establishments are randomly selected from among all establishments located within a 150-mile radius of each of the Specialists' home locations (zip codes). - Using the 150 mile radius	jurisdictions in the EHS-Net sites. Currently, there are 8 EHS-Net sites (CA, MN, NY, NYC, RI, TN, Harris County TX, Southern Nevada Health District). - For each study, each EHS-Net site selects the jurisdictions in which they will collect data for the study. Based on convenience, the jurisdictions are usually the counties within driving distance of the EHS-Net site office. Each site then sends a list of all establishments in those jurisdictions to the CDC. The CDC then draws a random sample of establishments from those lists for each site. For most studies, each site collects data in 40-50 establishments, totaling to 320-400 establishments per study. - While the number of areas included in EHS-Net is small, they are demographically diverse and provide good geographical coverage of the U.S. (northeast, mid-west, south, and west). The results of the EHS-Net studies can be used to generalize to the population of retail food establishments in the EHS-Net sites. Furthermore, the geographic	investigated.	programs will be reported to NEARS. Thus, we will be utilizing a convenience sample of voluntary participating programs and not obtaining a statistical sample. The data reported through this system are collected primarily from foodborne illness outbreak environmental assessments. Specifically, data collected by regulatory programs during their investigation of foodborne illness outbreaks.

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	sampling zones provides a relatively good cross section of urban and rural areas from which to sample the eligible establishments. It also represents a good mix of small, medium, and large regulatory entities having jurisdiction over the eligible establishments. - For the first restaurant data collection period (2013-2014), the sample was drawn from approximately 62% of all restaurant establishments in the contiguous U.S. 425 fast food restaurant and 396 full service restaurant data collection inspections per facility type yielded sufficient observations to be 95% confident that the compliance percentage is within 5% of the true compliance percentage.	and demographic variability across these sites suggests that CDC may be able to use data collected from these studies to draw conclusions that are likely relevant to establishments in other parts of the U.S.		
Data Collection Tool Used	A single data collection form is used to capture general information about the establishment and regulatory authority; food employees' behaviors and practices related to 19 data items related to personal hygiene and food storage, preparation, and service; the industry food safety	- Interview, observation, and survey forms are part of protocol development for each EHS-Net study. The FDA Food Code recommendations are used as the standard for all EHS-Net studies. - Data are reported electronically to CDC through the Environmental Health Specialists Network Information System (EHSNIS)	- NORS has a specific set of general outbreak classification questions and a specific food section to be completed for any foodborne illness outbreak. Data include: - Primary mode of transmission - Investigation methods	Environmental Assessments are dependent on the specific outbreak investigation and there is not a specific tool that can be used to conduct an environmental assessment during a foodborne illness outbreak. NEARS includes systematic data that should be collected and processed

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	management being employed; and the frequency of food employee hand washing. The most current version of the FDA Food Code is used as a basis for assessing control of each of the data items. The compliance status of the data items is recorded IN Compliance, OUT of Compliance, Not Observed, or Not Applicable, based on marking instructions provided to the data collectors.		• Dates • Primary case data • Incubation data • Signs and symptoms • Secondary cases • Recall and traceback • Reporting agency • Etiology • Samples • Exposure • Food http://www.cdc.gov/nors/pdf/NORS_CDC_5213.pdf	during an outbreak investigation • NEARS includes : - o General Information on the outbreak and the food establishment - o Data from manager interviews - o Data from observations - o Data about the implicated food(s) - o Data from sampling - o Data about contributing factors • NEARS does have a standardized manager interview that represents the minimum information that should be collected to describe current policies and practices in the establishment • Data are reported electronically to CDC through the Environmental Health Specialist Network Information System (EHSNIS).
Resources (Web links, etc.)	http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm2006816.htm	https://www.cdc.gov/nceh/ehs/ehsnet/foodsafety.htm	http://www.cdc.gov/nors/about.html	https://www.cdc.gov/nceh/ehs/nears/

SUMMARY

CDC and FDA have discussed how our respective studies and surveillance systems inform and influence one another. Each of our studies and/or surveillance systems collects unique, but related, information that is vital to informing policy and intervention strategy development to reduce foodborne illness at the retail level. For example:

- CDC uses data from FDA's Risk Factor Study to help identify food safety topics for its studies (i.e. topics for which more detailed data are needed to develop prevention and intervention strategies).
- Since NEARS collects information on outbreak establishments only, CDC uses data from FDA's Risk Factor Study to identify the current status of risk factor occurrence in non-outbreak establishments of similar type to the outbreak establishments. These data help CDC and FDA understand if what is seen in outbreak establishments is different from the situations commonly seen in the general population of retail and foodservice establishments.
- Data collected through NEARS identifies contributing factors of particular concern (e.g., the most common contributing factors; contributing factors that increase over time). FDA then ensures that its data collection focuses on these factors. Conversely, data collected through the FDA Factor Study identifies factors that may need to be focused on in NEARS.

CDC and FDA plan to conduct joint annual reviews of the data collected through our various data collections systems. These reviews will be used to determine if changes are needed to future information collections to ensure the data collected are optimal to meet our collective needs and missions to reduce foodborne illness.

DEFINITIONS

Foodborne Illness Environmental Assessment: The systems-based component of an outbreak investigation that fully describes how the environment contributed to the introduction and/or transmission of agents that cause illness or could cause illness. Environment is everything external to the host, including air, food, water, animals, plants, climate, etc., as well as people and the social and built environments. All aspects of the external environment can be listed as variables that, in relation to transmission, are neutral, conducive, or protective. From this description, contributing factors and environmental antecedents to an outbreak can be determined.

Contributing Factor: A factor that directly or indirectly cause an outbreak or likely caused an outbreak by contributing to contamination and survival of the etiologic agents or suspected agents and possibly supporting their growth or proliferation. A contributing factor can be biological, behavioral, or attitudinal; or an element of the physical or social environment; or the result of policies related to the problem. Contributing factors are what happened to cause a foodborne outbreak. Based on data from previous outbreaks, FDA and CDC have developed a list of contributing factors and have grouped them into three categories:

- Contamination factor - A factor related to how the agent got onto or into the food vehicle. These are associated with contamination of food with foodborne illness pathogens (e.g., a worker with a foodborne illness handles ready-to-eat food bare-handed and contaminates the food with pathogens).
- Proliferation factor - A factor relate to how microbial agents are able to increase in numbers and/or produce toxic products before the vehicle is ingested. These are associated with proliferation of foodborne illness pathogens in food (e.g., cold food is not held at a temperature cold enough to prevent proliferation of pathogens)
- Survival factor- A factor related to processes or steps that should have eliminated or reduced an agent (pathogen) in the food. These are associated with survival of foodborne illness pathogens in food (e.g., raw meat is not cooked to a temperature hot enough to kill the pathogens with which it is contaminated)

Environmental Antecedents: Supporting factor(s) leading to the contamination, survival, or increase of biological or chemical agents in food. They may be related to people, equipment, food process, food type, economics, or other circumstances. In other words, environmental antecedents are the reason why contributing factors occur. Environmental antecedents are sometimes referred to as root causes of outbreaks.

- *Economic* environmental antecedents are those associated with the costs and profit margins of food facilities. For example, poor profit margins may contribute to inadequate staffing, training or equipment maintenance.
- *Equipment* environmental antecedents are those associated with the physical layout and equipment of food facilities. For example, poor equipment maintenance can lead to food being stored and cooked at improper temperatures.
- *Food* environmental antecedents are those associated with the inherent qualities of food, such as, pH levels, texture, and viscosity. For example, the texture of leafy greens makes them difficult to clean; the thickness of some foods may require specialized cooling practices for those foods.
- *People* environmental antecedents are those associated with the individuals working in food facilities and the food safety culture in which they work. Examples of people antecedents include workers' cultural background, gender, education, experience, and food safety attitudes. Examples of food safety culture antecedents include management emphasis on food safety and reinforcement of safe food preparation through reward or punishment systems.
- *Process* environmental antecedents are those associated with the characteristics of the processes used to grow, store, prepare, and cook food. For example, the complexity of the food process (i.e., how many steps are involved in the process) is associated with food safety risk.

Foodborne Illness Risk Factors: The CDC Surveillance Report for 1998 - 2002 identified the most significant contributing factors to foodborne disease outbreaks in which contributing factors were reported during that period. Five of these broad categories of contributing factors directly relate to food

safety concerns in retail and foodservice establishments and are collectively termed by FDA as “foodborne illness risk factors.” The foodborne illness risk factors are:

- Food from Unsafe Sources.
 - Food is not received from safe sources.
- Inadequate Cooking Temperatures.
 - Raw animal foods are not cooked to required temperatures.
 - Cooked foods are not reheated for hot holding to the required temperatures.
- Improper Holding Temperatures.
 - Foods requiring refrigeration are not held at the proper temperature.
 - Foods displayed or stored hot are not held at the proper temperature.
 - Foods are not cooled properly.
 - Refrigerated, ready-to-eat foods are not properly date marked and/or discarded within 7 days of preparation or opening.
- Contaminated Equipment/Protection from Contamination.
 - Food is not protected from cross-contamination during storage, preparation, and display.
 - Food contact surfaces are not properly cleaned and sanitized.
- Poor Personal Hygiene.
 - Employees do not practice proper handwashing.
 - Food employees contact ready-to-eat foods with bare hands.
 - Food employees working when ill.

FDA RISK FACTOR STUDY VS. CDC RESTAURANT FOOD SAFETY STUDIES

Similarities

Both the FDA Risk Factor Study and the CDC Restaurant Food Safety Studies collect standardized data on retail food establishment food safety practices/risk factors. Both agencies’ studies are valuable in that they provide real-world data that identify retail food establishment food safety issues and environmental factors (e.g., establishment and manager characteristics) associated with these issues. These data are critical to foodborne illness prevention and intervention efforts.

Differences

There are some important differences between the design and objectives of the FDA's Risk Factor Study and CDC's Restaurant Food Safety Studies. Specifically:

- The FDA study collects targeted, but limited, data on a wide range of food safety practices/risk factors, while each CDC study collects extensive, detailed data on one specific food safety practice, risk factor, or food.
- The FDA study collects longitudinal data (series of observations more than once in the same study population over a period of time) while the CDC studies are typically only cross-sectional (involves analysis of data collected from a population in one specific point in time).
- The FDA study collects data in a wide range of retail food establishment types, while the CDC studies collect data in restaurants and delis only (as these establishment types account for half of all foodborne illness outbreaks).
- The FDA Study attempts to characterize food safety practices in food establishments across the continental United States and therefore collects data from a geographically diverse sample. CDC studies typically gather data from a smaller geographic location, such as from a single state or a limited number of regulatory jurisdictions.

FDA RISK FACTOR STUDY VS. CDC SURVEILLANCE SYSTEMS

FDA's Risk Factor Study measures the occurrence of practices and behaviors commonly identified as contributing factors to foodborne illness outbreaks in retail and foodservice establishments. The retail and foodservice establishments from which data are collected are selected randomly without consideration of their involvement in a foodborne illness outbreak. The FDA Risk Factor Study provides data on practices and behaviors that occur on a normal, day-to-day basis in a wide range of retail establishment types. The data from this study allow FDA to identify risk factors most in need of intervention efforts, as well as assess trends in the occurrence of risk factors over time. The data collected are representative of real-time conditions in the establishment.

In contrast, NEARS collects data on contributing factors and environmental antecedents directly contributing to a specific outbreak in retail and foodservice establishments. NEARS provides data on practices and behaviors that occur in a foodborne illness outbreak.