Risk Factor Study Approaches Fact Sheet

What is a Risk Factor Study

A risk factor study is a process used to measure the effectiveness of a jurisdiction's retail food program in enhancing food safety and public health within their community. The collection of data is used to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors that are most reported to the Centers for Disease Control and Prevention (CDC) as contributing factors to foodborne illness outbreaks within the retail food segment of the industry. The purpose of collecting this data is to determine food safety practices and employee behaviors that are in most need of priority attention during each data collection period as well as the measurement of trends of improvement or regression in foodborne illness risk factor occurrence over time.

The Value of a Risk Factor Study

- Identify essential food safety program public health performance measurements
- Assess strengths and gaps in the design, structure, and delivery of program services
- Establish program priorities and intervention strategies focused on reducing the occurrence of foodborne illness risk factors
- Create a mechanism that justifies program resources and allocates them to program areas that will provide the most significant public health benefits
- Determine food safety practices and employee behaviors that are in most need of priority attention during each data collection period
- Measure trends of improvement or regression in foodborne illness risk factor occurrence over time

How to conduct a Risk Factor Study

Using the criteria contained in Standard 9 of the FDA Voluntary National Retail Food Regulatory Program Standards, there are two basic methods for collecting data for a risk factor study. A health agency may conduct a separate collection of data, or they may base their study on their inspectional data. Before making that decision, the jurisdiction's leadership should consider the quality of the data and how it will impact the program's strategic direction and operational priorities.

Using inspectional data means that the agency bases their study on the information from their routine inspections. This may save staff time in that a separate inspection is not needed to collect data. This method may, however, present quality assurance challenges due to a lack of a standardized study approach and data review processes. Performing a separate data collection involves developing a study that is separate from routine inspectional data. A separate data collection form may be used, and staff will need to conduct inspections, outside of their routine work, solely for the purpose of collecting data. This method takes more time up front but results in consistency in data collection and a higher quality of data analysis.

Determine Industry Segments

To meet the criteria in Standard 9, a jurisdiction must collect data on all establishments that fall under four industry segments for which they have regulatory oversight. The four industry segments with corresponding facility types are:

- Health Care, which includes hospitals and long-term care facilities.
- Schools, K-12.
- Restaurants, which includes fast food and full-service restaurants.
- Retail Food Stores – Which include deli, seafood, and produce departments.

A jurisdiction has the option of developing their own facility types within each of these industry segments or they can develop additional industry segments. The only requirement is that a minimum of these four industry segments are used and all establishments under regulatory authority of the jurisdiction are assigned to a category. Be aware that using too many industry categories may result in smaller study sample sizes making it harder to collect a sufficient number of observations needed in each category to determine statistically significant findings.

Determine Schedule

Your first data collection will be your baseline. A single data collection can be used to measure the occurrence of risk factors. You will compare the results of subsequent data collections to your baseline to measure trends over time. No single point in time can be used to derive improvement or regression trends on observations of out of compliance foodborne illness risk factors. A minimum of three data collection periods are needed to assess trends over time. You do not have to collect data on everything at once. Standard 9 gives jurisdictions five years to complete a study.

A risk factor study need only be completed once every five years. The data collections for the various facility types can be conducted in different years. Scheduling data collections for facility types in different years can alleviate some of the demand for staff resources.

Determine sample size and statistical significance.

To understand sample size, we need talk about confidence levels, margins of error, and population size.

Confidence levels express how sure you are that your sample accurately reflects what is occurring within your target population. Another way to look at the confidence level is that it measures your tolerance for being wrong. If you want a low chance of being wrong, you need a higher confidence interval.

Margin of error is how close you want your data results to be from the real value. The closer you want to be, the smaller the margin of error.

Population size affects the number of samples needed to obtain the desired confidence level within the determined margin of error.

For example, to obtain the number of observations needed to make a statistically significant analysis of the data in the FDA Risk Factor Study, the FDA CFSAN Biostatistics Branch has determined that approximately 400 data collection inspections of each industry segment are needed. This sample size provides sufficient observations to be 95% confident that compliance percentages derived from the data collections are within 5% margin of error. This level of statistical accuracy is not required in standard 9. Your jurisdiction may not need to achieve this level. It is sufficient to achieve a 90% confidence level of +/- 10%. Thus, you may be able to use a smaller sample size depending on your goals and resources.

Some tools to help determine sample size and confidence levels:

https://www.surveymonkey.com/mp/sample-size-calculator/
http://www.raosoft.com/samplesize.html
https://www.checkmarket.com/sample-size-calculator/

Random Sample
After you determine the sample size needed to obtain your desired statistical significance, you will need to get your random sample. You will need to make separate inventory lists for each industry segment. Use a random number generator to pull a list of numbers. Take the list of numbers and start matching them to the establishment list. You should pull a backup list for each industry segment. This will be needed if you are unable to collect data at an establishment on the main list.

Random number generators are available from a variety of web site. An example of a random number generator can be access at: www.randomizer.org

Use the proper data collection or inspection forms

The jurisdiction's data collection form must include data items pertaining to each of the following Center for Disease Control and Prevention (CDC) contributing factors to foodborne illness:

- Food from unapproved sources
- Improper holding/time and temperature
- Inadequate cooking
- Poor personal hygiene
- Contamination equipment/protection from contamination

Your data collection form must use the In (In Compliance)/Out (Out of Compliance)/NO (Not Observed)/NA (Not Applicable) marking options. Failure to include the NO and NA marking options will heavily skew the data towards the "In" compliance status. The risk factor study findings should be based on actual observations of food safety practices and employee behaviors.

Conduct the field work and collect and enter Risk Factor Study data
You will need to consider who will collect the data. It is recommended that you use experienced inspection staff. Consider developing marking instructions and specialized training to help staff perform their data collections in a consistent manner.

The FDA has developed a Risk Factor Study Database that can be used to store your data in a secure place. The database has the capability to help with data analysis and develop reports in conformance with the Standard 9 criteria.

Analyzing and reporting the Risk Factor Study data

The Standard 9 criteria requires an analysis of the data collected and a written report on the outcomes and conclusions. A narrative is not necessary, but information supporting the jurisdiction's ability to identify the risk factors most in need of attention for each of the regulated facility types must be documented.The description of the requirements for Standard 9 specifies that one of the intents of a risk factor study and report is to measure trends and to determine whether there has been a net change over time in the occurrence of foodborne illness risk factors in a jurisdiction.

A risk factor study database has been created and is accessible to all SLTT jurisdiction on the FoodShield web-based platform. The FoodShield Risk Factory Study database provide jurisdictions with a system to store, maintain and track the data from their own studies using a secure web site. Jurisdictions can obtain and complete a request form to set up their own secure data base site from the following FoodShield link: https://www.retailfoodriskfactorstudy.net/register.pdf

Helpful Links

Risk Factor Study Website
This site has the FDA data collection form, protocol, and marking instructions. It also has past reports and info on the current FDA study: https://www.fda.gov/food/retail-food-protection/retail-food-risk-factor-study

Retail Food Risk Factor Studies Database and Registration.
https://www.retailfoodriskfactorstudy.net/

FDA Retail Food Specialists
Your FDA Retail Food Specialist is here to help. https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/directory-fda-retail-food-specialists

The information contained in this publication is intended only as a guide for regulatory agencies to begin their own discovery of the process of completing a Risk Factor Study in their jurisdiction.

The Association of Food and Drug Officials is the international leader and trusted resource for building consensus and promoting uniformity on public health and consumer protection issues related to the regulation of foods, drugs, devices, cosmetics and consumer products.

The Association of Food and Drug Officials (AFDO)
www.AFDO.org
155 W. Market Street, 3rd floor
York, PA 17401
717.757.2888
afdo@afdo.org